



A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study

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Declaration

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A handwritten signature in black ink, appearing to read 'Leo Rall', is written over a horizontal line.

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List of Abbreviations

ACSM	American College of Sports Medicine	FER	Forced expiratory ratio
ADLs	Activities of daily living	FEV₁/FVC	The ratio of FEV ₁ to FVC
AIS	Adolescent idiopathic scoliosis	FEV₁ (L.s⁻¹)	Forced Expiratory Volume in one second
ATR	Angle of trunk rotation	FIF	Forced inspiratory flow
BMR kcal	Basal metabolic rate	FIV₁	Forced inspired volume
BMI	Body mass index	FIVC	Forced inspiratory vital capacity
CDCS	Clinical data collection sheet	FVC	Forced Vital Capacity in litres
CHI	Children's Health Ireland	GLI	Global Lung Initiative
cm	Centimetres	H	Kruskal-Wallis H statistic
CNS	Central nervous system	HEP	Home exercise programme
COM	Centre of mass	HHD	Hand-held dynamometry
COP	Centre of Pressure	HR	Heart rate
CON	Control	HSE	Health Service Executive
CPET	Cardiopulmonary exercise testing	I²	I-squared statistic
CO₂	Carbon dioxide	ICC	Intraclass correlation coefficient
C90area	The area of the 90% confidence ellipse	INT	Intervention
DH	Dominant hand	ISWT	Incremental Shuttle Walk Test
DPIA	Data protection impact assessment	kg	Kilograms
F	ANOVA F value	mBESS	Modified Balance Error Scoring System

MEF	Maximum expired flow	PIF	Peak inspiratory flow rate
MEP	Maximal expiratory pressure	PIL	Participant Information Leaflet
MeSH	Medical Subject Headings	PNF	Proprioceptive Neuromuscular Facilitation
MET	Metabolic equivalent	PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
MIP	Maximal inspiratory pressure	PSSE	Physiotherapeutic scoliosis specific exercises
MVC	Maximal voluntary contraction	SOSORT	Society of Scoliosis Orthopaedic and Rehabilitation Treatment
N₂	Nitrogen	QOL	Quality of life
N	Newton's	r	Pearsons Correlation coefficient
n	Number	R²	Coefficient of determination
NDH	non-dominant hand	RAB	Rotational angular breathing
NSCA	National Strength & Conditioning Association	RCT	Randomised control trials
O₂	Oxygen	RER	Respiratory exchange ratio
P	Probability	RHR	Resting heart rate
PA	Physical activity	RME	Respiratory muscle exercise
PARQ	Physical Activity Readiness Questionnaire	RPE	Rate of perceived exertion
PEF	Peak Expiratory Flow in (L.s ⁻¹)	SBP	Systolic blood pressure
PFM	Percentage fat mass	SEAS	Scientific Exercise Approach to Scoliosis
PFT	Pulmonary function test	SLWS	Single-leg wall squats
PI	Prospective intervention		

SMD	Standardised mean difference	VO₂	Oxygen consumption
SRS-22r	Scoliosis-specific health-related quality of life outcome questionnaire	VO₂max	Maximum oxygen consumption
SD	Standard deviation	W	Workload
TLC	Total lung capacity	WMD	Weighted mean difference
VCO₂	Volume of carbon dioxide production	$\bar{x}$	mean
		6MWT	6-minute walk test
		95% CI	95% confidence interval

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Publications from this PhD

Peer reviewed publications

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Conference presentations

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Summary

Adolescent Idiopathic Scoliosis (AIS) is a spinal deformity affecting 2–3% of adolescents, particularly females. The condition involves a three-dimensional spinal curvature that arises around the time of puberty in adolescents with no prior health issues. The primary aim of all treatment protocols for patients with AIS is to prevent the progression of the curvature in the adolescent years. In the public healthcare system, current treatment protocols for patients with AIS are guided by the severity of spinal curvature and involve observation of those with mild curves, bracing for those with moderate curves, and surgical intervention for those with severe curves. In addition, physiotherapeutic scoliosis-specific exercise programmes, which target spinal curve reduction in patients with mild and moderate AIS, are available in the private health sector.

Despite the availability of treatment protocols, significant gaps remain in the literature regarding the extent of functional, cardiorespiratory, and quality of life (QOL) impairments experienced by children and adolescents across the spectrum of mild, moderate, and severe AIS. Existing treatment approaches overlook broader physiological, functional and psychological outcomes. In addition, there is limited evidence of the effectiveness of physiotherapeutic scoliosis-specific exercise (PSSE) programmes, such as Schroth, in addressing these impairments in individuals with mild to moderate AIS. Similarly, it remains unclear whether an individualised, targeted, physiotherapy-led intervention could effectively address residual deficits in post-operative AIS patients.

The aims of this thesis were fourfold. First, to establish if exercise rehabilitation improves pulmonary function in children with AIS. Second, to determine if patients with AIS had impairments in muscle strength, power, endurance, exercise capacity, pulmonary function, balance and quality of life, when compared to healthy peers. Third, to compare the care of patients with mild or moderate AIS in the public healthcare pathway with those in the private pathway that included a PSSE programme. Fourth, to investigate whether a targeted, physiotherapy-led intervention can effectively address post-operative impairments in individuals with AIS following surgical correction.

To address these objectives, four studies were conducted: a systematic review and meta-analysis (Study 1), a cross-sectional cohort study (Study 2), a prospective cluster design observational study (Study 3) and a prospective interventional cohort study (Study 4).

Study 1 (Chapter 2), a systematic review and meta-analysis, established that exercise-based therapies appear to lead to significant improvements in pulmonary function in individuals with AIS. Study 2 (Chapter 4) established that adolescents with AIS exhibit a range of clinically significant functional, pulmonary, cardiovascular and QOL impairments when compared to age-matched healthy controls. This study also found that the prevalence and severity of several impairments appear to be associated with the severity of spinal curvature. Findings from Study 3 (Chapter 5) indicated that while the Schroth programme shows therapeutic potential, it is not sufficient as a stand-alone intervention. Lastly, Study 4 (Chapter 6) a targeted physiotherapy-led intervention effectively addressed most functional impairments in post-operative AIS patients. However, notable deficits in pulmonary function, exercise capacity and QOL still remained when compared to healthy peers.

In conclusion, the findings of this thesis demonstrate that children and adolescents with mild, moderate, and severe AIS experience significant functional, cardiovascular, and QOL impairments that are not adequately addressed within current healthcare pathways. There is a clear need for the implementation of a standardised baseline clinical assessment to identify these impairments in a systematic fashion. The results of these assessments would facilitate the development of effective, individualised rehabilitation programmes. The inclusion of a supervised aerobic element in these individualised interventions should be considered and may address the remaining pulmonary and cardiovascular impairments. Furthermore, the involvement of a mental health professional from the point of diagnosis is recommended to address the lower QOL experienced by this population.

Chapter 1: Introduction

1.1: General introduction to scoliosis

Scoliosis, referred to as a lateral deviation of the spine, is a complex three-dimensional spinal deformity with a lateral curvature of at least 10° in the coronal plane and restricted spinal rotation from fixed vertebrae (Romano et al., 2012, Negrini et al., 2018). Curvatures can be seen at any level of the spine, and the location of the vertebrae involved will define whether it is referred to as thoracic, thoracolumbar or lumbar scoliosis (Rolton et al., 2014). The disorder can result in musculoskeletal deformity, pain, impaired pulmonary function, and long-term physiological problems (Kotwicki et al., 2013). It can be classified as structural or non-structural scoliosis. Structural scoliosis comprises any functional or pathological change that results in the development of a rigid lateral curvature, and includes idiopathic, congenital, traumatic, infectious and rheumatic deformities of the spine (Rolton et al., 2014, Castner et al., 2019). It may also include deformities from neural and lung disease (Rolton et al., 2014, Castner et al., 2019). Non-structural scoliosis refers to spinal deformities relating to posture, tumours or herniation of the spine, hip deformities or significant leg length discrepancy (Rolton et al., 2014). In addition, scoliosis is also associated with a number of diseases and syndromes including spina bifida, cerebral palsy, spinal muscular atrophy, Prader Willi syndrome and Charcot-Marie-tooth-disease. Individuals with scoliosis and a co-morbidity may require different treatment pathways to those individuals who are diagnosed with scoliosis alone (Kouwenhoven and Castelein, 2008).

The aetiology and pathogenesis remain unknown for the majority of those who present with structural scoliosis, and it has therefore been defined as ‘idiopathic’ scoliosis. Idiopathic scoliosis accounts for approximately 80% of diagnosed scoliotic deformities (Negrini et al., 2012). Idiopathic scoliosis is further sub-divided into three distinct groups: ‘infantile’, children under 4 years of age, ‘juvenile’, children between the ages of 4 and 9 and ‘adolescent’, children from 10 years of age up to skeletal maturity. The latter group, called adolescent idiopathic scoliosis (AIS) is the most common, and represents approximately 85% of children and adolescents diagnosed with idiopathic scoliosis (Asher and Burton, 2006).

1.2: Adolescent idiopathic scoliosis

Adolescent Idiopathic Scoliosis is the most frequent spinal deformity in growing adolescents (Bettany-Saltikov et al., 2013). AIS, in some adolescents, is a progressive deformity of the spine that originates around the commencement of puberty in healthy children (Reamy and Slakey, 2001, Negrini et al., 2012). The disorder is 8-10 times more common in females than males (Reamy and Slakey, 2001, Dunn et al., 2018). It is estimated that 2 to 3% of the adolescent population are affected by this condition (Kotwicki et al., 2013, Fadzan and Bettany-Saltikov, 2017). To date extensive research has investigated possible causes of this disorder without success (Kouwenhoven and Castelein, 2008, Peng et al., 2020, Marya et al., 2022).

There is considerable heterogeneity in the pattern of the development of AIS. For some adolescents, the continued growth of the abnormal curvature ceases and requires no clinical intervention. For others, the angle of deformity continues to increase, and they will require treatment. The spinal deformity can develop curvatures that create an asymmetric upper-body alignment. The curvature can be a single deformity in the thoracic or lumbar region, or in some cases children can develop compensatory secondary curves. These secondary curves are not normally structural and generally fail to progress past a Cobb angle of 25° (measurement used in radiology to assess the severity of spinal curvature) (Malfair et al., 2010).

No published data is available in the public domain for the total number of those diagnosed with or treated for AIS annually in the Republic of Ireland. It is estimated that there are more than 2,000 adolescents diagnosed with AIS annually in the Republic of Ireland (P. Kiely & R McManus, personal communication June 25, 2021). The current public clinical sites that treat patients with AIS include Children's Health Ireland (CHI) and the National Orthopaedic Hospital Cappagh. The CHI includes Crumlin Hospital, Temple Street and Tallaght Hospital. Private hospitals providing this service include Beacon Hospital and Blackrock Clinic. In the public hospitals, 214 patients had spinal fusion surgery in 2023, with 145 patients awaiting surgery. (CHI@hselive, www.childrenshealthireland.ie/news/scoliosis-updates). CHI reported 513 spinal surgeries performed in the year ending 31st December 2024, a significant increase on previous years with 230 patients remaining on the waiting list. However, the report did not provide a breakdown of the specific types of spinal surgeries conducted. In the first four months of 2025, CHI recorded the completion of 174 spinal surgeries, while the waiting list remains at 230 paediatric and adolescent patients. As with the previous report no detailed

breakdown of the procedures performed was made available (CHI@hse.ie, www.childrenshealthireland.ie/news/scoliosis-updates). No data is available on the number of surgeries performed on patients with severe AIS or the number of those on the waiting list for spinal surgery in the Beacon Hospital or Blackrock Clinic, however most of these are CHI patients referred on for private treatment. It is estimated that 10% of children and adolescents diagnosed annually with AIS in the Republic of Ireland, will require surgery (P. Kiely, personal communication April 27, 2021).

1.3: Pathophysiology and aetiology of AIS

The exact aetiology of adolescent idiopathic scoliosis is unknown. A number of factors may influence scoliosis development including, neuromuscular factors, primary muscle disorders (Lowe et al., 2004), elastic fibre system defect (Hadley-Miller et al., 1994), disorganised skeletal growth (Smit, 2020), genetics and intrinsic biomechanical factors (Schlösser et al., 2015, Kikanloo et al., 2019, Peng et al., 2020, Marya et al., 2022).

The theory behind a primary muscle disorder as a possible cause of AIS is based on a study by Lowe et al. (2004) who examined calmodulin protein levels in children with spinal curve progression greater than 10°. Calmodulin is a calcium binding protein that has a role in skeletal muscle development. This study found an imbalance in levels of calmodulin in the paraspinal muscles of adolescents with AIS.

Elastic fibres are extracellular matrix macromolecules that assist in the elasticity and strength of connective tissues in the body. Elastic fibres system defect has been linked to a number of skeletal and connective tissue disorders including, Williams-Beuren syndrome and Marfan syndrome (Milewicz et al., 2000).

The human spinal structure is unique. No other mammals, other than humans, are affected by scoliosis (Schlösser et al., 2015, Hamad et al., 2017). Disorganised skeletal growth and mechanical modulation of skeletal bone have been put forward as a possible aetiology for AIS (Tanabe et al., 2017). A study by Castelein et al. (2005) argued that the spinal column is prone to rotational deformity and its unique design may play a role in the development of idiopathic scoliosis. Other studies reported abnormalities in the structure or content of the vertebrae with significantly lower bone volume in the spinous processes and lower bone mineral density in patients with AIS (Tanabe et al., 2017, Wang et al., 2017a). The mechanical modulation theory speculates that growth dysplasia causes a Hueter-Volkman effect on the spine, potentially leading to idiopathic scoliosis (Hung et al., 2005). The

Hueter-Volkman law asserts that increased mechanical compressive forces retard skeletal growth (Mehlman et al., 1997).

Genetic causes have been strongly postulated by some authors (Kesling and Reinker, 1997, Simony et al., 2016). Studies have shown hereditary links and a much higher incidence rate in twins and first-degree relatives (Hamad et al., 2017). Despite numerous studies and investigations into the aetiology and pathogenesis of idiopathic scoliosis, the disorder remains idiopathic and may be a multifactorial condition (Hamad et al., 2017). A quote by White (1990) encapsulates the complexity surrounding the idiopathic nature of scoliosis, “The normal spine in a growing person has a precise, precarious, delicate mechanical balance. Asymmetrical changes in primary structures, support structures, growth centres, the position of the spine and related neural or muscular components can result in the development of scoliosis”.

1.4: The diagnosis of AIS

Adolescent idiopathic scoliosis is initially diagnosed from a physical examination using standardised assessment tools such as the Adam’s Forward Bend Test. The Adam’s test can assist in detecting potential spinal curvature and prompting further investigation. It is a simple test that can be used in doctor’s surgeries, physiotherapy clinics, clinical sites, schools or homes (Cote et al., 1998). The test requires the child or adolescent to bend forward at the waist until the spine is roughly parallel with the floor, legs and feet together, straight arms and hands together (a diver’s stance). The tester needs to see the spine and examines the person’s spinal column from a posterior-anterior and lateral viewpoint looking for asymmetries (Figure 1.1). The initial indication for scoliosis is the formation of a rib hump, which is a visible asymmetry between left and right sides of the rib cage (Figure 1.1). In thoracic curves, the test has a sensitivity of greater than 92% for curves with a Cobb angle more than 20° (Kuznia et al., 2020). The Adam’s Test has a lower reliability for lumbar scoliosis of 73% (Goldberg et al., 1995, Simpson and Gemmell, 2006).

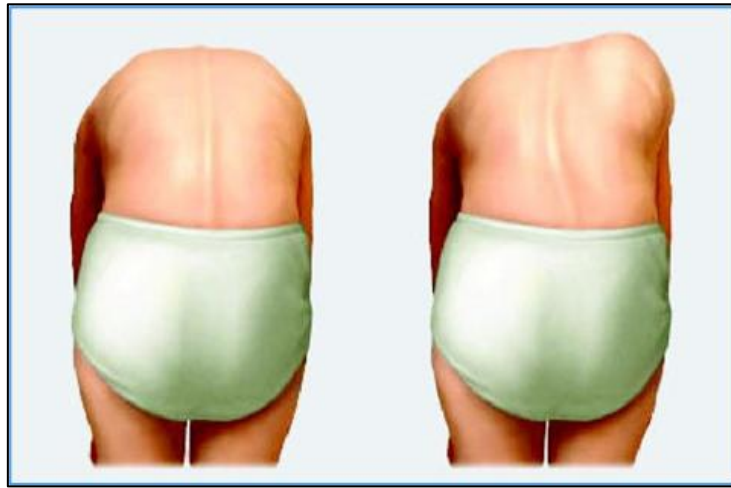


Figure 1.1: Adam's forward bend test

Source: The NLM Style Guide for Authors (2007)

In cases where abnormal spinal curvature is suspected, the Adam's test is normally combined with a Scoliometer measurement. This simple hand-held instrument gives an estimate of the angle of trunk rotation (ATR). An angle of 5° to 7° on the Scoliometer indicates potential scoliosis of 15° to 20° (Figure 1.2). A Scoliometer has a sensitivity of circa. 83% (Kuznia et al., 2020), however a high BMI reduces the sensitivity (Kuznia et al., 2020). It is recommended that Scoliometer readings of 5° to 7° should be seen as a threshold for a radiography referral, which is the gold standard in determining the degree of scoliosis present (Dunn et al., 2018, Grossman et al., 2018).



Figure 1.2: Scoliometer measurement

Source: Izatt et al. (2012)

Radiographic evidence identifies the extent of the lateral curvature, the degree of vertebral rotation, the skeletal maturation of the child or adolescent, and the level of spinal flexibility

(Horne et al., 2014). The magnitude and severity of the spinal curves are identified using the Cobb-Lippmann angle measurement. The Cobb angle radiographic measurement of coronal spinal movement is named after its pioneer, Dr Robert Cobb (Botterbush et al., 2023). This measurement calculates the angle between the superior surface of the most proximal displaced vertebrae and the inferior surface of the most distally displaced vertebrae (called the terminal vertebrae). Digital lines are calculated based on the angles of the terminal vertebrae and the overall angle of displacement calculated is called the Cobb angle (Figure 1.3). Digital Cobb angle measurements have been established as a reliable method of establishing curve displacement (Langensiepen et al., 2013). The assessment and measurement of Cobb angles in scoliosis is subject to several limitations, including inter- and intra-observer variability (typically ranging from 3–5°) when interpreting radiographs, as well as considerable inconsistency among observers in identifying the terminal or ‘end’ vertebra (Lechner et al., 2017).

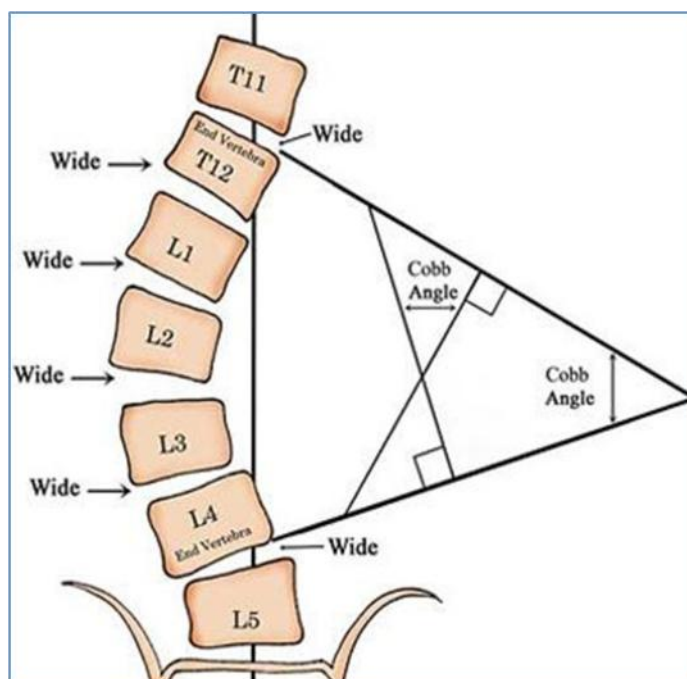


Figure 1.3: Cobb method of angle measurement

Source: Safari et al. (2019)

1.5: Classification

The severity of AIS is typically based on Cobb angle ranges and has been defined as ‘mild’ from 10° to 25°, ‘moderate’ from 26° to 45° and ‘severe’ >45° (Romano et al., 2012, Negrini et al., 2018). These are important ‘cut-off’ points as a person’s treatment prescription is normally based on the Cobb angle. Given the nature of AIS, which is a 3-dimensional

deformity of the spine in the coronal, sagittal and axial planes, a classification system to guide treatment options is a key component of the management of those with AIS. As the curve progresses, the body of the apex vertebrae (vertebrae that has curved the greatest distance from the midline) rotates in a convex direction and the spinous process in a concave direction. The most commonly used method to determine this vertebral rotation is the Nash & Moe grading (Nash and Moe, 1969) (Figure 1.4). Using radiography, this system grades the movement of the convex pedicle on a vertebra into six segments. Each grade corresponds with the movement of the pedicle from neutral to grade four, where grade 4 is a rotation of the convex pedicle past the mid-point line (Kim et al., 2010).

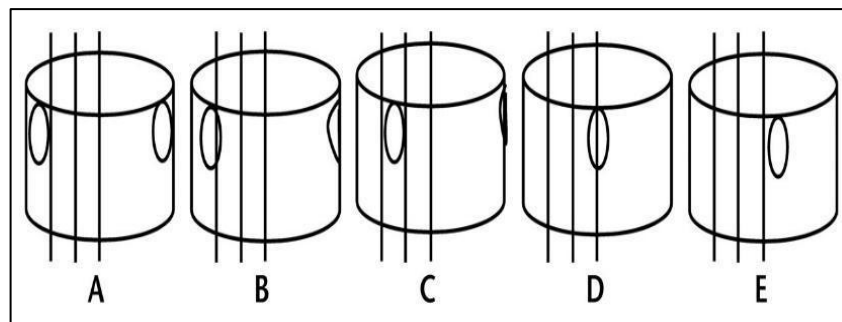


Figure 1.4: Vertebral rotation: The Nash-Moe method

Source : Kim et al. (2010)

Several classification systems exist for scoliosis. These classification systems take into account curve types and the structure of each curve and are important tools in the treatment of those with AIS. The King classification and the King – Moe classification (Ovadia, 2013) were the most widely used classification systems until they were superseded by the Lenke classification system (Lenke et al., 2001, Hoashi et al., 2013). The Lenke classification system overcame some of the shortcomings of previous classification methods notably by addressing all types of curves and accounting for both the coronal and sagittal curve displacement. The Lenke system assesses the individual's spine in two dimensions, coronal and sagittal, based on posterior-anterior, lateral and side bending radiographs. It classifies scoliosis into six curve types (Figure 1.5). It has demonstrated good inter- and intra- observer reliability (Hamad et al., 2017). The major limitation of the Lenke classification method is that it does not incorporate vertebral rotation, a weakness that may well be addressed in evolving 3-D classifications (Balne et al., 2020).

Type	Curve	Proximal thoracic	Main thoracic	Thoracolumbar /lumbar
1	Main thoracic	Not structural	Structural*	Not structural
2	Double thoracic	Structural	Structural*	Not structural
3	Double major	Not structural	Structural*	Structural
4	Triple major	Structural	Structural*	Structural
5	Thoracolumbar/lumbar	Not structural	Not structural	Structural*
6	Thoracolumbar/lumbar-main thoracic	Not structural	Structural	Structural*
Modifiers				
Lumbar spine modifier	CSVL to lumbar apex		Thoracic sagittal profile	
A	CSVL between pedicles		- (below normal)	< 10°
B	CSVL touches apical bodies		N (normal)	10°-40°
C	CSVL completely medial		+ (above normal)	> 40°

*Major curve; CSVL = center sacral vertical line.

Figure 1.5: Lenke's criteria for curve classification

Source: Slattery and Verma, (2018)

1.6: Curve progression

Curve progression is vital in determining treatment decisions for children and adolescents with a spinal deformity (Reem et al., 2009). In many cases, curve progression stops at the end of puberty when a person reaches skeletal maturity (Ohashi et al., 2018). The identification of skeletal maturity is therefore a key element in deciding on curve management. There are a number of ways to estimate skeletal maturity including the evaluation of the epiphyses of the distal radius or the distal ulna, the small bones of the hand and iliac apophysis (Beatty et al., 2022). The most common approach in the estimation of skeletal maturity in scoliosis management is the establishment of the level of ossification of the iliac apophysis, also known as the Risser sign (Hacquebord and Leopold, 2012). The iliac apophysis is the final site of ossification in skeletal maturation (Risser, 2010). When this apophysis is no longer detectible on a radiograph, the adolescent has reached skeletal maturity. Risser (2010) graded the levels of iliac apophysis ossification from 1 to 5 with each grade from 1 to 4 representing approximately 25% progression to complete ossification (Figure 1.6). A low Risser grade suggests that considerable skeletal growth has yet to occur and is associated with a higher risk of curve progression in AIS (Lonstein, 1994, Taft and Francis, 2003). Risser grade 5 indicates full skeletal maturity. It is important to note that the timing and progression of Risser grading can vary between sexes as puberty typically starts earlier in girls.

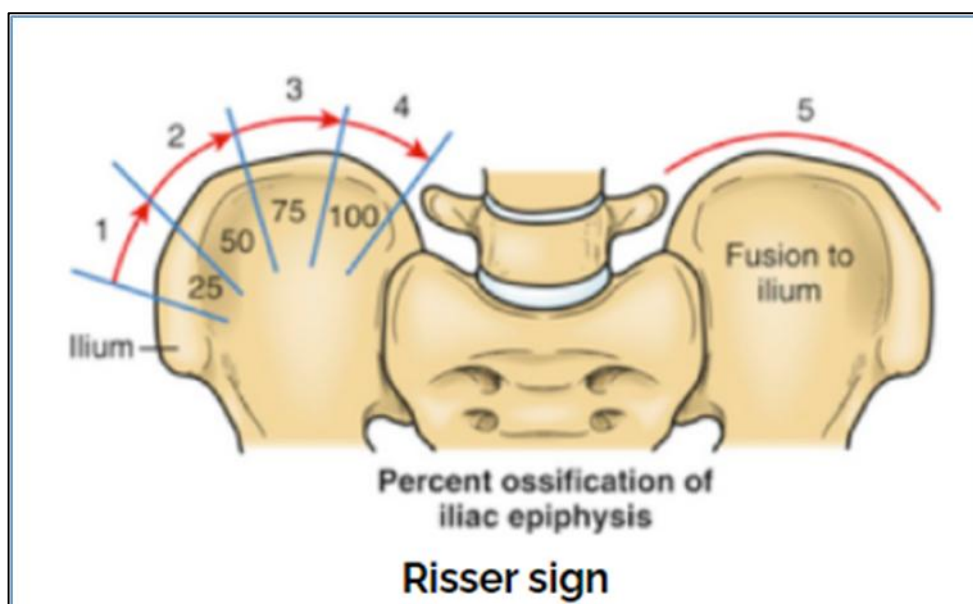


Figure 1.6: Skeletal maturity, The Risser index

Source: Risser, (2010)

1.7: Screening programmes

Most cases involving adolescents with AIS are initially queried for diagnosis by caregivers and/or their general medical practitioner. In Ireland, USA, United Kingdom, Canada, Australia and most of Europe there are currently no formal scoliosis screening programmes for children and adolescents (Grossman et al., 2018, Glavaš et al., 2023b). The arguments for screening are based on early detection and treatment before skeletal maturity. The arguments against screening programmes are founded on the benefits of screening versus the potential harms (Deurloo and Verkerk, 2015, Dunn et al., 2018, Grossman et al., 2018). The majority of adolescents with mild structural curvatures of the spine do not progress to severe curves (Horne et al., 2014). Screening programmes could lead to needless medical referrals, unnecessary exposure to radiography in low-risk cases, and increased stress and psychological trauma to young individuals who may never develop progressive scoliosis (Deurloo and Verkerk, 2015).

1.8: The impact of scoliosis on psychological and social wellbeing

Research indicates that AIS may lead to enduring psychological issues (Kotwicki et al., 2013, Mitsiaki et al., 2022). Individuals with AIS commonly display signs of depression and anxiety (Gallant et al., 2018, Tomczak and Rogalski, 2024), along with experiences of social isolation (D'Agata et al., 2017). Given that females are 8-10 times more likely to develop scoliosis than males (Lonstein, 2003) and that curve development takes place at the onset of

puberty, this can result in negative self-image (Tarrant et al., 2014a, Tarrant et al., 2018). A health-related quality of life longitudinal study (Danielsson et al., 2006) found that patients with AIS had significantly higher pain scores, reduced physical function and poorer general health than healthy controls. A recent study by Wang et al. (2021) found higher levels of mental health disorders and negative self-image in patients with AIS treated with bracing when compared to those treated without bracing. Fernandes et al. (2019) examined the effects of surgery on the mental health in patients with AIS. Their findings, based on pre- and post-operative interviews, suggest surgery had a significant positive effect on body image; however, mental health scores did not significantly improve. Pyatakova et al. (2019) conducted a literature review on the psychological dimensions of AIS treatments, identifying AIS as a contributing factor to various psychological issues such as stress, anxiety, body image concerns, low self-esteem, and reduced communication skills. The review noted rising rates of mental health disorders within this population, involving depression and suicidal ideation. There is no formal protocol in the Irish healthcare system to address the impact of idiopathic scoliosis on child or adolescent mental health. The current system relies on ad-hoc referrals from the medical teams.

1.9: Treatment approaches

The primary aim of all treatment protocols for patients with AIS is to prevent the progression of the curvature in the adolescent years (Weinstein et al., 2008). Treatment can be conservative or surgical, with the decision frequently linked to the severity of the curve. The definition of adolescent idiopathic scoliosis is lateral curves greater than 10° (Negrini et al., 2018). Consequently, adolescents who present with a spinal curvature less than 10° are considered normal. The current treatment protocols for patients with AIS are based on the classification of curve severity using the Cobb angle (Romano et al., 2012, Negrini et al 2018). For those with mild AIS, their management consists of observation and annual re-testing. Bracing is considered as a treatment for those with moderate spinal deformities, a Cobb angle between 26° and 45° . For patients with a Cobb angle that has progressed to greater than 45° , surgical intervention to fuse the spine is the preferred option. Consideration is given to risk factors for curve progression, including the child or adolescent's maturation stage, curve patterns and Cobb angle at initial diagnosis (Horne et al., 2014). In addition, gender is considered important, as female curve progression has been shown to accelerate at a greater rate than male curves in patients with AIS (Horne et al., 2014). The impact on health is also a major issue that must be factored in, including on-going pain levels, and

pulmonary and cardiovascular complications (Asher and Burton, 2006, Bettany-Saltikov et al., 2013).

In Ireland and most of the western world there are currently three treatment protocols for children and adolescents with mild, moderate and severe AIS. Observation of curve progression and bracing are the predominant strategies for those with a mild or moderate scoliosis. There is a higher emphasis on surgery as the ultimate treatment option in cases of severe curve progression. The SOSORT (Society of Scoliosis Orthopaedic and Rehabilitation Treatment) guidelines on idiopathic scoliosis during growth (Negrini et al., 2018) included multiple studies supporting the use of conservative treatments to reduce curve progression in patients with AIS. A recent systematic review found that the inclusion of physiotherapeutic scoliosis-specific exercises (PSSE) as a treatment for AIS was superior to conventional treatment (Ma et al., 2023). However, in the context of the Irish healthcare system, conservative interventions such as PSSE are not currently provided within the public health care system. As a result, families seeking access to these treatments need to attend specialist private physiotherapy clinics

1.10: Conservative treatment

The 2016 International Society of Scoliosis Orthopaedic and Rehabilitation treatment (SOSORT) guidelines outline the goals of conservative treatment for individuals with idiopathic scoliosis (Negrini et al., 2018). The main objectives of treatment are to reduce the progression of the curve at puberty, to prevent or treat respiratory dysfunction, to prevent or treat spinal pain syndromes, and to improve aesthetics via postural correction (Negrini et al., 2012, Negrini et al., 2018).

Conservative treatment for patients with AIS includes observation, bracing and PSSE programmes. In Ireland, the public healthcare system provides observation and bracing only. The private healthcare system can provide PSSE programmes. Observation for those with mild AIS in Ireland (Adam's forward bend test and radiography) is generally carried out in clinical sites on an annual basis unless the child or adolescent has shown signs of rapid progression, in which case testing is carried out on a more regular basis.

Rigo et al. (2006) defined the use of bracing as 'the application of external supports to the trunk'. Braces are usually rigid and are applied with the aim of achieving maximum correction of the abnormal curvature. There are numerous bracing models available both in a hard-shell and soft-shell format. The standard brace used in Irish hospitals is the 3D Rigo

Chêneau-type brace (Figure 1.7). In patients with AIS, brace treatment normally commences when the spinal curvature exceeds 25° or in cases where the curvature has a progressive diagnosis (Negrini et al., 2012). Most braces are worn for up to 23 hours a day for a number of years until bone growth ceases which is approximately 16 years of age for girls and 18 years of age for boys (Katz and Durrani, 2001). This intensive treatment over several years has been associated with significant challenges related to patient compliance and mental health in adolescents with idiopathic scoliosis (Schlenzka and Yrjönen, 2013, Mitsiaki et al., 2022).

The efficacy of bracing for scoliosis has been investigated and researchers have produced conflicting results (Coillard et al., 2007, Aulisa et al., 2015, Zaborowska-Sapeta et al., 2011). An early review by Maruyama et al. (2011) was unable to reach a conclusion on the effectiveness of bracing in patients with AIS because of the poor quality of the studies. A Cochrane review (Negrini et al., 2015) concluded that there was low-quality evidence to support brace treatment in preventing curve progression in patients with AIS. Both reviews recommended the need for further high-quality studies on the efficacy of bracing in patients with AIS. More recent systematic reviews have provided strong evidence supporting the efficacy of bracing as a treatment option for adolescents with AIS (Costa et al., 2021, Tang et al., 2024). Costa et al. (2021) reported that bracing is particularly effective during the early stages of skeletal maturity (Risser 0–2 and 0–3), while Tang et al. (2024) emphasised that maintaining high daily compliance throughout the treatment period is critical for achieving curve regression.

Brace technology is continually developing. The 3D Rigo Chêneau-type brace, incorporating the latest 3D technology is currently used in both private and public hospitals. This brace, using sensors, is designed to correct the spine in a three-dimensional alignment (Figure 1.7). Each brace is specifically designed and fitted based on the patient's curve diagnosis (P.J. Kiely & N. McGowan, personal communication May 11, 2025).

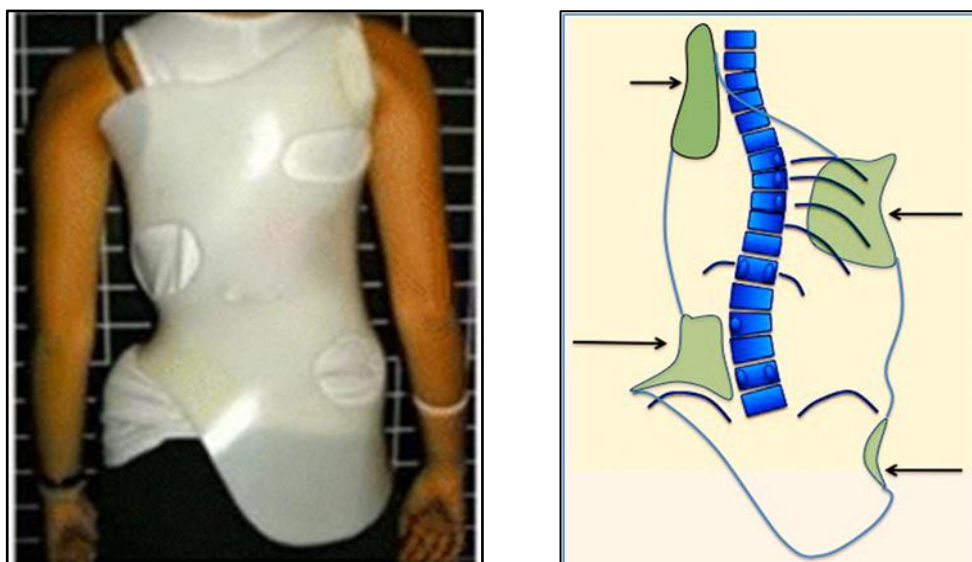


Figure 1.7 : 3D Rigo Chêneau-type brace

Source: Rigo and Jelačić, (2017)

Conservative treatments such as PSSE can also be used in conjunction with bracing to treat patients with AIS (Karavidas and Tzatzaliaris, 2022). The term PSSE is an umbrella term for different exercise-based programmes used in the conservative treatment of scoliosis. A narrative review by Berdishevsky et al. (2016) identified seven major schools of conservative treatment approaches for patients with scoliosis. The major schools are the Lyon (France), Schroth (Germany), Scientific Exercise Approach to Scoliosis (SEAS) (Italy), the Barcelona Scoliosis (modified Schroth, Spain), Dobomed (Poland), Side Shift approach (UK), and the Functional Individual Therapy of Scoliosis (Poland). All these PSSE schools support the values laid down by SOSORT. Each school provides its own unique, evidence-based treatment programme. However, the aims of the different scoliosis schools are similar; they treat scoliosis as a 3-dimensional deformity requiring the realignment of shoulders, spine, thoracic cage and pelvis. All treatment approaches target the core principles of breathing, corrective posture, spinal mobilisations and flexibility.

PSSE programmes have been used as a conservative method of reducing Cobb angle and improving physical function in individuals with mild to moderate AIS for many years in Europe (Romano et al., 2012, Negrini et al., 2018). The SOSORT guidelines 2011 and 2016 for the orthopaedic and rehabilitation treatment of those with idiopathic scoliosis during growth have supported the use of PSSE programmes as an intervention for managing curve progression in patients with AIS (Negrini et al., 2012, Negrini et al., 2018). Additionally, it has been reported that a 6-month PSSE programme resulted in improvement in quality of

life and back muscle endurance in adolescents with AIS (Schreiber et al., 2015). Recent studies suggest that PSSE programmes may have a positive effect on patient outcomes (Kwan et al., 2017, Laita et al., 2018, You et al., 2024). PSSE programmes are not currently available as a treatment option in the public healthcare system in the Republic of Ireland. They are only available through a limited number of private chartered physiotherapy clinics.

1.11: Surgery

There are three major circumstances where the choice of surgery as a treatment option is considered; firstly, when the spinal curvature exceeds 45°. Secondly, when all other treatments have failed to halt or reduce the curvature. Thirdly, when the curve progression causes cardiovascular, pulmonary or increased pain symptoms (Westrick and Ward, 2011, Bettany-Saltikov et al., 2013).

The primary goal of spinal fusion surgery in patients with severe AIS is to stop curve progression and correct abnormality in trunk posture (Kotwicki et al., 2013). There is a range of different surgical procedures including anterior, posterior surgery or in some cases a combined approach (Al-Mohrej et al., 2020). Posterior spinal fusion with instrumentation is the most common approach with estimates of 75% of fusion surgery using this method (Al-Mohrej et al., 2020). The process involves fixing rods to the spine using anchors (usually pedicle screws) attached to pedicles of the vertebrae (Figure 1.8). The type of surgery and the extent of spinal fixation is dependent on size, location and alignment of the patient's spinal curvature.

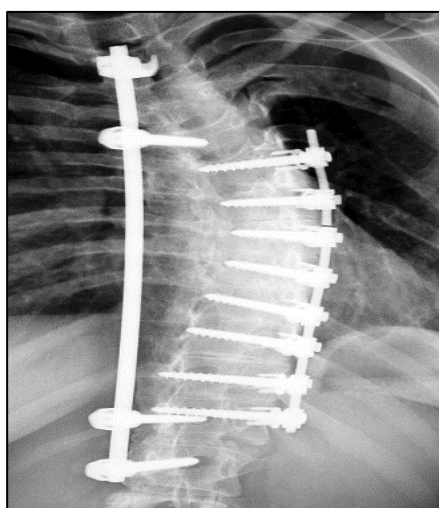


Figure 1.8: Spinal fusion

Source: Weiss and Goodall, (2008)

Surgery is an invasive option; the lengthy procedure can range between 4 and 8 hours. According to Westrick and Ward, (2011), surgery provides the best option for halting curve progression with little follow up required. However, all forms of surgery, including spinal surgery have significant risk factors associated with the procedure. It is estimated that between 6-29% of AIS surgical patients will require further surgery at some stage in the future (Asher and Burton, 2006). Weiss & Goodall, (2008) estimated the short-term risk from a spinal fusion surgery to be circa 5% with long-term risks potentially higher. Lykissas et al. (2013) carried out a meta-analysis with a 15-year follow-up. This study found revision surgery was required in 7.2% of cases primarily for pseudarthrosis, infections, neurological complications or broken instrumentation. In certain cases, complications related to spinal implants may arise, including pedicle screw misplacement, loosening or breakage, as well as implant migration or structural damage. Koshimizu et al. (2024) found the overall incidence of implant-related complications was 4.6%. Despite improvements in surgical approaches, complication rates from spinal fusion in patients with AIS have also been reported in 5-23% of cases (Al-Mohrej et al., 2020).

1.12: A summary review of the rationale for this body of work

It is widely acknowledged that Adolescent Idiopathic Scoliosis can detrimentally impact pulmonary function (Negrini et al., 2012, Negrini et al., 2018). Respiratory problems among patients with AIS are multifaceted and encompass irregular ventilation patterns, predominantly restrictive in nature.

Various factors could affect exercise capacity in patients with AIS, including diminished spinal mobility and weakened respiratory muscles (Weinstein et al., 2003). Research to date suggests that severe AIS can lead to limitations in cardiorespiratory function and exercise capacity among this population (Czaprowski et al., 2012, Sperandio et al., 2014). Patients with moderate AIS may also have restricted exercise capacity (Barrios et al., 2005). There is currently limited research into the effects of mild and moderate AIS on exercise capacity.

Several studies have examined balance and postural deficits in this population. A 2015 Cochrane review examining changes in posture and trunk balance, post-surgery, was unable to identify any studies suitable for inclusion (Bettany-Saltikov et al., 2015). Differences in published research on postural analysis in adolescents with AIS may be due to the varied curve types, Cobb angles, location of the curvature, thoracic or lumbar, used in these studies (Schimmel et al., 2015).

The impact of AIS on quality of life is complex (Schreiber et al., 2015, Bettany-Saltikov et al., 2016, Hannink et al., 2023, Newman et al., 2023). The relatively unknown effects of spinal fusion surgery on anatomical, musculoskeletal and systemic systems compounds this complexity over time.

Internationally, there are a growing number of clinicians and researchers advocating the conservative management of scoliosis, including PSSE rehabilitation programmes (Schreiber et al., 2015, Kwan et al., 2017, Laita et al., 2018, Negrini et al., 2018, Negrini et al., 2019). The efficacy of PSSE programmes as treatment options is still unclear (Thompson et al., 2019). There is evidence to indicate improvements in patients with AIS post-PSSE intervention, however the quality of the studies included in recent reviews is low (Thompson et al., 2019). The evidence for the effectiveness of PSSE on mild and moderate AIS is varied. A number of studies reported benefits from PSSE (Moramarco et al., 2016, Weiss et al., 2016, Langensiepen et al., 2017, Negrini et al., 2019). There were some limitations in these studies notably the exclusion of patients with AIS using a brace (Negrini et al., 2018), and no control groups (Moramarco et al., 2016, Langensiepen et al., 2017).

Very few studies have examined the musculoskeletal (strength, endurance and power) impairments present in post-operative adolescents with AIS after the surgical recovery period. A prospective study by Tarrant et al. (2014b) documented that the majority (88.5%) of post-operative patients with AIS involved in their study returned to unrestrictive physical activity by the 12th month. Danielsson et al. (2006) reported that lumbar range of motion and muscle endurance significantly decreased when compared to controls in a 20-year longitudinal study. A study by Rafferty et al. (2020) found significant musculoskeletal deficits in post-operative adolescents with AIS 12 months post-surgery when compared to a control group of anthropometrically matched participants.

To the author's knowledge, this study is the first to evaluate and identify specific impairments across a broad set of variables in adolescents with severe AIS, both before and after surgery, and to introduce a physiotherapy-led, targeted rehabilitation programme designed to address these deficits. Research is therefore warranted to establish if cardiorespiratory, pulmonary, musculoskeletal, balance and quality of life impairments, measured with objective validated tests, continue to exist post-surgery. The subject matter of this thesis is novel, timely and in the public domain. The healthcare needs of adolescents with scoliosis have been previously identified (Negrini et al., 2018) but have not been adequately met in the past.

The relevance of this research is threefold. Firstly, to establish a standardised assessment to identify impairments in children and adolescents with AIS. Secondly, to compare current public healthcare treatment of patients with mild and moderate AIS against a private healthcare pathway which involves a PSSE (Schroth) programme. It may highlight that existing public healthcare pathways are substandard in comparison to private conservative treatment of patients with mild and moderate AIS. Thirdly, if it can be demonstrated that a post-surgical targeted physiotherapy-led intervention programme can address post-operative impairments in patients with severe AIS, it may focus attention on the need to incorporate a post-operative rehabilitation programme into the healthcare pathway for this population.

1.13: Aims and Objectives

There are clear gaps in the literature in relation to the degree of impairments experienced by children and adolescents with mild, moderate and severe AIS. There are also clear gaps in the literature regarding the potential benefits of a physiotherapy-led targeted intervention programme for post-operative patients with severe AIS. Finally, an evaluation of private PSSE treatment programmes and public healthcare provision for children and adolescents with mild to moderate AIS is both timely and of public interest.

The primary objective of this thesis was to carry out a detailed investigation into the impact of scoliotic curve severity on muscle strength, endurance and power, pulmonary function, exercise capacity, balance and quality of life in patients with AIS, and to assess the effect of targeted rehabilitation interventions. To accomplish these objectives, four studies were completed with specific aims as stated below:

1. To review the existing literature examining exercise rehabilitation as a means of improving pulmonary function in patients with AIS. To achieve this aim, a systematic review and meta-analysis was carried out (Chapter 2).
2. To determine if patients with AIS had impairments in muscle strength, power, endurance, exercise capacity, pulmonary function, balance and quality of life, when compared to an age, gender and anthropometrically matched sample of the general population. A secondary aim for this study was to assess if the magnitude of identified impairments in muscle, exercise capacity, pulmonary function, balance, and quality of life, were associated with the degree of spinal curvature (Chapter 4).

3. To compare the care of patients with mild or moderate AIS in the public healthcare pathway with those in the private pathway that included a PSSE programme (Chapter 5).
4. To assess the efficacy of a targeted physiotherapy-led rehabilitation programme on post-operative patients with AIS. The secondary aim of study 4 was to establish the impact of spinal fusion surgery on any impairments identified in outcome measures assessed pre-operatively (Chapter 6).

Table 1.1: Study Titles

Study 1 (Chapter 2)	Does exercise therapy improve pulmonary function in patients with adolescent idiopathic scoliosis? A Systematic Review and Meta-analysis.
Study 2 (Chapter 4)	An assessment of strength, endurance and power, exercise capacity, pulmonary function, balance, and quality of life in patients with AIS when compared to healthy controls.
Study 3 (Chapter 5)	Public vs. Private treatment of patients with mild and moderate AIS: A cluster design study.
Study 4 (Chapter 6)	An evaluation of the effects of a targeted physiotherapy-led post-operative exercise intervention on patients with severe AIS.

Chapter 2: Does exercise therapy improve pulmonary function in patients with adolescent idiopathic scoliosis? A Systematic Review and Meta-analysis.

2.1: Introduction

Adolescent Idiopathic Scoliosis is the most common form of scoliosis, accounting for 80% of diagnosed cases (Lorente et al., 2017, Negrini et al., 2018). While prevalence rates vary depending on geographic latitude (Grivas et al., 2006), the most frequently reported prevalence is 2–3% of the general population (Negrini et al., 2018) with females having a disproportionately greater risk of developing the condition (Wong et al., 2005).

Curve severity in AIS can result in structural deformities to the thoracic cage that impair pulmonary function. In patients with moderate and severe scoliosis, a negative linear correlation has been established between the magnitude of the curve and forced vital capacity (FVC) (Tsiligiannis and Grivas, 2012). This impairment is most notably observed as a reduction in total lung capacity (TLC), measured either directly via dilution techniques or indirectly via FVC. However, it has also been noted that the severity of pulmonary impairments cannot be inferred from the angle of scoliosis alone (Kearon et al., 1993b). Regardless of the cause or severity, any impaired pulmonary function is likely to negatively impact on exercise tolerance, reduce participation in physical activity and impair quality of life. Tsiligiannis and Grivas (2012) highlighted that exercise capacity is decreased even in patients with mild scoliosis and exercise dyspnoea may be one of the first clinical manifestations in AIS.

Negrini et al. (2011) argued that AIS curve severity beyond 30° is linked to pulmonary impairments. Further studies have supported this view (Negrini et al., 2018, Kempen et al., 2022). These impairments included restrictive ventilation patterns, weakened respiratory muscles, restricted respiratory muscle function and uneven chest wall movement with localized changes (Lisboa et al., 1985, Kearon et al., 1993b, Leong et al., 1999, Kotani et al., 2002, Kotani et al., 2004, Martinez-Liorens et al., 2010). Potential causes included reduced spinal flexibility, vertebral rotation, and rigidity of the thoracic cage (Kim et al., 2005).

The current treatment options for patients with AIS are conservative management for patients with mild and moderate AIS, and spinal fusion surgery for those with severe AIS. The objectives of conservative management are to halt curve progression, prevent or treat pulmonary dysfunction and/or spinal pain, and correct posture (Negrini et al., 2018).

Conservative management of patients with AIS typically involves a general/generic exercise programme or a physiotherapeutic scoliosis-specific exercise programme (PSSE) and/or spinal bracing. The four PSSE programmes most widely used are: 1) Schroth (Lehnert-Schroth, 1992); 2) Scientific Exercise Approach to Scoliosis (SEAS) (Romano et al., 2015); 3) Dobosiewicz (DoboMed) technique (a modification of Schroth) (Dobosiewicz et al., 2008), and 4) Side shift programme (Berdishevsky et al., 2016). While these programmes are widely used in clinical settings, their efficacy is still widely debated.

Systematic reviews investigating conservative interventions in AIS tend to be broad in nature, focusing primarily on Cobb angle and angle of trunk rotation (ATR). Plaszewski and Bettany-Saltikov (2014) carried out an overview of systematic reviews for non-surgical interventions. They included 21 published systematic reviews from 1980 to 2014. Of these studies, 16 were of low quality, 3 were of moderate quality and 2 Cochrane reviews were classified as ‘high methodological quality’. Of the two high quality reviews, only one had ‘pulmonary function’ as a primary outcome measure and this review was specific to bracing (Negrini et al., 2010). Of the three moderate-quality studies, one was a mixed population study including participants with other paediatric disorders (Posadzki et al., 2013) and the remaining reviews (Lenssinck et al., 2005, Negrini et al., 2008) did not include pulmonary function as an outcome measure. More recent systematic reviews examining efficacy of PSSE have produced contradictory findings regarding its effect on spinal curvature and pulmonary function. Park et al. (2018) reviewed 15 studies and concluded that PSSE had a moderate effect on Cobb Angle ($d=0.65$) and ATR ($d=0.53$) but negligible effect on pulmonary function ($d=0.13$). A more recent overview of systematic reviews and meta-analyses concluded that the strength of evidence to support PSSE for improving either Cobb Angle or ATR was in general, weak (Li et al., 2021). This review did not include pulmonary function as an outcome measure.

Little is known about the efficacy of general exercise programmes or PSSE on pulmonary function. No previous systematic review has focused on this topic and no meta-analysis has been performed on the cumulative pulmonary function data of all relevant studies. Park et al. (2018) reported a moderate effect of PSSE on vital capacity ($d=0.62$), but this effect was synthesized from only three studies. Considering the clinical objectives of PSSE include prevention and treatment of pulmonary dysfunction (Negrini et al., 2018) and the fact that many programmes incorporate specific pulmonary exercises (Lehnert-Schroth, 1992, Dobosiewicz et al., 2002), a more detailed understanding of the effect of exercise therapies on pulmonary function in patients with AIS is required.

Despite significant evidence that progressive spinal curvature is strongly linked to negative pulmonary function in AIS, no previous review has established whether conservative interventions can improve pulmonary function in this population. The purpose of this review was therefore to determine whether current evidence supports exercise-based therapy as a means of improving pulmonary function in patients with AIS.

2.2: Materials and Methods

2.2.1. Search Strategy

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (PLOS Medicine; 2009). A systematic search was carried out in July 2020 using four electronic databases, (CINAHL, Embase, Medline and Web of Science) to identify relevant studies. Following publication of the original findings and in order to update the review, a subsequent search was conducted in October 2025 using the same search strategy. The search strategy was designed in consultation with the medical Librarian and consisted of the following key search terms, 'Idiopathic scoliosis' OR 'scoliosis therapy' OR 'therapy' OR 'rehabilitation Or Schroth OR Scoliosis Specific Exercises OR SSE'. 'Respiratory function' OR 'pulmonary and airway function analyser' OR 'lung function test' OR 'respiratory tract parameters'. 'Forced vital capacity' OR 'vital capacity' OR 'forced expiratory volume' OR 'absolute pulmonary function' OR 'total lung capacity' OR 'absolute PFT' OR FVC OR FEV OR TLC.

A search Medical Subject Headings (MeSH) was specifically designed for each database (Table 2.1). Filters were used to restrict the search to specific dates (Search 1: January 1980 - July 2020; and Search 2: August 2020 – September 2025), English language studies and human studies. Authors were contacted by e-mail where data were incomplete. Manual searches using bibliographies of key reviews and included studies were also conducted for potentially eligible studies.

Table 2.1. MeSH terms

EMBASE	
1.	'idiopathic scoliosis' /exp OR 'scoliosis therapy'/exp
2.	(scoliosis NEAR/3 (therapy OR rehabilitation OR Schroth OR Scoliosis Specific Exercises OR SSE)): ti,ab
3.	#1 OR #2
4.	'respiratory function'/exp OR 'pulmonary and airway function analyser'/exp OR 'lung function test'/exp OR 'respiratory tract parameters'/exp
5.	((Respiratory OR pulmonary OR lung) NEAR/1 function*): ti,ab
6.	((Lung OR pulmonary OR respiratory OR ventilation) NEAR/3 test*): ti,ab
7.	('forced vital capacity' OR 'vital capacity' OR 'forced expiratory volume' OR 'absolute pulmonary function' OR 'total lung capacity' OR 'absolute PFT' OR FVC OR FEV OR TLC): ti,ab
8.	#4 OR #5 OR #6 OR #7
9.	#3 AND #8
Medline	
1.	Exp Scoliosis/
2.	(scoliosis adj3 (therapy OR rehabilitation OR Schroth OR Scoliosis Specific Exercises OR SSE)).ti,ab.
3.	or/1-2
4.	exp Respiratory Function Tests/
5.	((Respiratory OR pulmonary OR lung) adj1 function*).ti,ab.
6.	((Lung OR pulmonary OR respiratory OR ventilation) adj3 test*).ti,ab.
7.	(forced vital capacity OR vital capacity OR forced expiratory volume OR absolute pulmonary function OR total lung capacity OR absolute PFT OR FVC OR FEV OR TLC).ti,ab.
8.	or/4-7
9.	and/3,8
CINAHL	
1.	(MH "Scoliosis+")

2. TI (scoliosis N3 (therapy OR rehabilitation OR Schroth OR Scoliosis Specific Exercises OR SSE)) OR AB (scoliosis N3 (therapy OR rehabilitation Or Schroth OR Scoliosis Specific Exercises OR SSE))
3. S1 OR S2
4. (MH "Respiratory Function Tests+")
5. TI ((Respiratory OR pulmonary OR lung) N1 function*) OR AB ((Respiratory OR pulmonary OR lung) N1 function*)
6. TI ((Lung OR pulmonary OR respiratory OR ventilation) N3 test*) OR AB ((Lung OR pulmonary OR respiratory OR ventilation) N3 test*)
7. TI ("forced vital capacity" OR "vital capacity" OR "forced expiratory volume" OR "absolute pulmonary function" OR "total lung capacity" OR "absolute PFT" OR FVC OR FEV OR TLC) OR AB ("forced vital capacity" OR "vital capacity" OR "forced expiratory volume" OR "absolute pulmonary function" OR "total lung capacity" OR "absolute PFT" OR FVC OR FEV OR TLC)
8. S4 OR S5 OR S6 OR S7
9. S3 AND S8

Web of Science

TS = ((scoliosis NEAR/3 (therapy OR rehabilitation OR Schroth OR Scoliosis Specific Exercises OR SSE)) AND (((Respiratory OR pulmonary OR lung) NEAR/1 function*) OR ((Lung OR pulmonary OR respiratory OR ventilation) NEAR/3 test*) OR ("forced vital capacity" OR "vital capacity" OR "forced expiratory volume" OR "absolute pulmonary function" OR "total lung capacity" OR "absolute PFT" OR FVC OR FEV OR TLC

2.2.2. Inclusion and Exclusion Criteria

Studies which satisfied the following criteria were included in the systematic review; (1) Study participants had a clinical diagnosis of AIS. (2) An exercise-based intervention was performed with at least one of the following pulmonary function outcome variables measured pre- and post-intervention; forced expired volume in 1 second (FEV₁ or FEV₁%), forced vital capacity (FVC or FVC%), vital capacity (VC or VC%), peak expiratory flow rate (PEF), total lung capacity (TLC), maximum expired flow (MEF), forced inspired volume (FIV₁) forced inspiratory vital capacity (FIVC), peak inspiratory flow rate (PIF), forced inspiratory flow (FIF), maximal inspiratory pressure (MIP) or maximal expiratory pressure (MEP). (3) The study design was a randomised control trial, case-control intervention, or interventional cohort design. Case reports, editorials and literature reviews were excluded. Studies needed a minimum statistical analysis of sample means, standard deviation, and sample size for inclusion. Studies that included AIS participants with cardiorespiratory comorbidities were excluded. Studies not in the English language and those that were carried out prior to 1980 were also excluded.

2.2.3. Data Extraction

Studies identified by searches were imported into a reference manager (EndNote Version X9, Philadelphia, PA) and transferred to Covidence, an online platform that streamlines the production of systematic and other research reviews (www.covidence.org). Following pilot screening to establish inter-rater reliability (Cohen's Kappa = 80%), initial screening of titles and abstracts was conducted by three reviewers (TR, NF, SD). Full-text review was also carried out independently (TR and SD) with any disputes deliberated with a third reviewer (NF) until agreement was reached. Details of the randomised control trials (RCT) (Table 2.2) and prospective intervention (PI) studies (Table 2.3) were recorded in Excel. The extracted information included the author, publication year, country, study design, type of intervention, its duration and frequency, pulmonary function outcome measures, and participant details such as gender, age, and Cobb angle. The key findings from each study were also recorded.

2.2.4. Quality Assessment

Each study was appraised using a modified Downs and Black Checklist (Downs SH, 1998) that evaluates methodological strengths and weaknesses of randomised and non-randomised studies based on: (1) Reporting, (2) Internal validity (Bias), (3) Internal validity

(Confounding), (4) External validity and (5) Power. Based on previously published descriptors (Hooper et al., 2008), studies were graded for quality as follows: excellent (26-28); good (20-25); fair (15-19); and poor (≤ 14). Two independent reviewers conducted the quality assessment (TR and NF). Inter-rater disagreements were discussed until a consensus was reached.

2.2.5. Data Analysis

Statistical analysis was conducted using Review Manager (The Cochrane Collaboration, 2020). For the purposes of analysing global effects, papers were allocated to one of two subgroups depending on study design. For RCTs, standardised mean difference (SMD) between pre- and post-intervention pulmonary function data was calculated. SMD and 95% confidence interval (CI) were subsequently compared between control and intervention groups to establish intervention effects. For PI studies, pre- and post-intervention pulmonary function data were compared using random effects meta-analyses. Weighted mean difference (WMD) with a 95% CI were calculated and intervention effect (Z) estimated. The I^2 statistic was used to establish the extent of heterogeneity. I^2 values of 25%, 50%, and 75% broadly representing low, moderate, and high heterogeneity (Higgins et al., 2003). The focus of this review was on the most relevant pulmonary function tests that are carried out, namely FVC, VC and FEV₁ (Graham et al., 2019). Summary findings from each meta-analysis were represented by forest plots.

Table 2.2. Patient and Intervention Characteristics of Randomised Control Trials

Author (year)	Country	Patient Characteristics			Intervention Characteristics			
		Age (year)	Gender (F/M)	Curve	Type	Duration (week)	Measures	Findings
Athanasopoulos <i>et al</i> , 1999	Greece	INT: 13.5 (0.2) CON: 13.6 (0.2)	INT: 20/0 CON: 20/0	Mild	INT: 4 x 30 min.wk ⁻¹ cycle ergometer training (bouts lasting 5-15 min), intensity 80-100% of load @ HR 170 beats.min ⁻¹ (adjusted every 2 week). Bracing, except during training sessions. CON: Bracing	8	FVC VC FEV ₁ FEV ₁ /FVC%	INT: Increased FVC (P< 0.01), FEV ₁ /FVC (P< 0.05). CON: Decreased VC and FVC (P< 0.01)
Gao <i>et al</i> , 2019	China	INT: 12.2 (1.4) CON: 12.4 (1.3)	INT: 18/5 CON: 18/4	Moderate	INT: 6 x 15 min.wk ⁻¹ home-based PSSE and 1 x 40min.wk ⁻¹ supervised PSSE. Bracing, except during training sessions. CON: Bracing for 23 hr.day ⁻¹	26	FVC FEV ₁ FEV ₁ /FVC%	INT: Increased FEV ₁ , FVC (P< 0.001), FEV ₁ /FVC% (P<0.01) CON: Decreased FEV ₁ (P< 0.05), FVC (P< 0.01), FEV ₁ /FVC% (P<0.14)
Wei <i>et al</i> , 2015	China	INT: 9.1 (0.4) CON: 8.9 (0.6)	INT: 40/18 CON: 39/10	Moderate	INT: 2 x 40 min.day ⁻¹ home-based “Daoyin” exercises. Traditional “Tuina” manipulation 2 x 20-25 min. wk ⁻¹ . “Acupotomology” facial release 1 x session. wk ⁻¹ for 10 treatments. CON: Bracing for 22 hr.day ⁻¹ + breathing exercises.	52	VC FEV ₁ FEV ₁ /FVC%	INT: Increased VC, FEV ₁ /FVC%, (P< 0.05) CON: Decrease in VC (P<0.05)
Kim and Park 2017	Republic of Korea	INT: 17.75 (4.71) CON: 15.57 (2.70)	INT: 6/2 CON: 4/3	Mild and moderate	INT: 3 x 60 min.wk ⁻¹ Schroth + RME; 5 mins warm-up, 10 min RME, 40 min Schroth, 5 mins cool down. CON: 3 x 60 wk ⁻¹ Schroth + cycling; 5 min warm-up, 10 min cycle ergometer, 40 min Schroth, 5 min cool down.	8	FVC FEV ₁ FEV ₁ /FVC% PEF	INT: Increases in all PFTs post-intervention when compared to baseline (P<0.05). Increased PEF only when compared to CON: (P<0.05)
Kumar <i>et al</i> , 2017	India	INT: 12.17 (1.72) CON: 11.56 (1.46)	INT: 7/11 CON: 8/10	Mild	INT: Control protocol plus task-orientated exercise programme. CON: Spinal extension, strengthening, active self-correction, and breathing exercises.	52	FVC FEV ₁ FEV ₁ /FVC%	Pre-intervention: No differences comparing INT to CON. Post-intervention: increased FVC (P< 0.001), FEV ₁ (P< 0.01), VC (P< 0.01) comparing INT to CON.

Xavier <i>et al</i> , 2020	Brazil	INT: 16 (2) CON: 16 (2)	INT: 18/2 CON: 19/1	Severe	INT: 3 x 60min.wk ⁻¹ supervised aerobic and resistance training. 10 min warm-up, 30 min treadmill running @ 60-80% HRmax, 10 min resistance exercises at 60% of 1RM, 10min cool down. CON: 10 min warm-up, 40min treadmill running @ 60-80% HRmax, 10min cool down.	12	FVC FEV ₁ FEV ₁ /FVC% PEF	INT: Increased FEV ₁ , FEV ₁ /FVC% (P<0.05). For FVC results unclear; may indicate INT more favourable than CON.
Dimitrijevic <i>et al</i> , 2025	Serbia	INT: 14.1(1.02) CON: 13.4 (1.63)	INT: 12/5 CON: 12/5	Moderate	INT: Supervised Schroth programme, 3 x 90 min.wk ⁻¹ CON: Home-based unsupervised Schroth programme, 3 x 90 min.wk ⁻¹	8	FVC VC FEV ₁ FEV ₁ /FVC%	INT: Increased FEV ₁ , FVC and VC (P< 0.000), CON: No significant changes in PFT variables
Kumar, 2024	India	INT: 12.1(1.74) CON: 12.5 (1.44)	INT: 7/11 CON: 8/10	Mild	INT: Home-based Schroth rotational angular breathing, 2 x 25/30 min.daily and, scoliosis correction exercises 2 x 25/30 min.daily. CON: Usual care	52	FVC VC FEV ₁	INT: Significant increases post intervention in FVC (P< 0.001), VC (P< 0.002) and FEV ₁ (P<0.01) when compared to CON.
Liu <i>et al</i> , 2023	China	INT: 13.2 (2.6) CON: 13.5 (2.3)	INT: 15/5 CON: 17/3	Severe	INT: Supervised Schroth programme, 4 x 60 min.wk ⁻¹ CON: Supervised aerobic exercise programme, 4 x 60 min.wk ⁻¹	12	FVC FVC pred% FEV ₁ FEV ₁ pred% FEV ₁ /FVC%	Significant increases post intervention in all PFTs for both groups (P<0.05). FEV ₁ /FVC% was significantly higher in INT group (P<0.05). No significant differences between groups, post intervention for remaining PFTs.
Ogonowska-Slodownik <i>et al</i> , 2021	Poland	INT: 14.2 (1.4) CON: 14.1 (1.5)	INT: 9/4 CON: 7/4	Mild and moderate	INT: Spinal corrective exercises, 40 min, general strengthening 30 min and aquatic breathing programme 40 min with 30 min rests between each exercise modality 5 x 110 min.wk ⁻¹ CON: Spinal corrective exercises, 40 min, general strengthening 30 min and corrective swimming 40 min with 30 min rests between each exercise modality 5 x 110 min.wk ⁻¹	3	FVC FVC pred% FEV ₁ FEV ₁ pred%	INT: Significant increase in FEV ₁ pred% post-intervention when compared to baseline (P<0.05). CON: Significant decrease in FEV ₁ pred% and FEV ₁ post-intervention when compared to baseline (P<0.05).

CON, Control; **INT**, Intervention; **n**, number of participants; **NS**, not specified; **HR**, Heart rate; **VC**, Vital capacity; **FVC**, Forced vital capacity; **FEV₁**, Forced expiratory volume; **PEF**, Peak expiratory flow; **RME**, Respiratory muscle exercise; **PFT**, Pulmonary function test.

Table 2.3. Patient and Intervention Characteristics of Prospective Intervention Studies

Author (year)	Country	Patient Characteristics			Intervention Characteristics			
		Age (year)	Gender (F/M)	Curve	Type	Duration (week)	Measures	Findings
dos Santos Alves <i>et al</i> , 2006	Brazil	13.9 (NS)	31/3	Severe	3 x 60 min.wk ⁻¹ aerobic exercise on treadmill or cycle ergometer. 10 min warm-up, 40 min @ 60-80% of HRmax; 10 min cool down & stretch.	16	FVC, FEV ₁ FEV ₁ /FVC% PEF	Improvements in FVC (P< 0.000), FEV ₁ (P< 0.009) & VC (P< 0.001), PEF (P<0.001). No change in FEV ₁ /FVC% (P=0.338)
Amaricai <i>et al</i> , 2019	Romania	13.1 (2.8)	24/16	Mild and moderate	3 x sessions. wk ⁻¹ .Sessions included stretching concave side, strengthening convex side, core stability & breathing exercises. Additional bracing 20 hr.day ⁻¹ for moderate participants.	12	FVC, FEV ₁ FEV ₁ /FVC% PEF	Improvements in all PFT measures (P<0.001).
Borysov and Borysov, 2012	Ukraine	13.7 (NS)	32/2	Moderate	1-week modified Schroth programme. 2 days of 3 x 90 mins.day ⁻¹ progressed to 5 days of 2 x 60 mins.day ⁻¹ .	1	VC	Improvement in VC (P<0.05)
Fabian 2010a	Poland	14.8 (0.8)	30/0	NS	Dobosiewicz Technique. Frequency (NS), time (NS).	4-5	FVC FEV ₁ FEV ₁ /FVC PEF	Improvements in all PFT measures. (P<0.001)
Fabian 2010b	Poland	13.4 (2.2)	30/0	NS	150 mins.day ⁻¹ supervised exercises + “additional procedures”. Dobosiewicz Technique. Asymmetric respiratory exercises.	4-5	FVC, VC, FEV ₁ /FVC%, PEF	Improvements in all PFT measures VC (P< 0.001); FVC (P< 0.01) PEF (P < 0.001). No change in FEV ₁ /FVC% (P<0.001)
Kim and Hwangbo, 2016	Republic of Korea	22.6 (1.8)	5/0	Severe	3 x 60 min.wk ⁻¹ Schroth programme. 10min preparation, 5 min stretching, 40 min main exercises, 5 min cool down	12	VC	Improvement in VC (P<0.05)
Moramarco <i>et al</i> , 2016	USA	13.9 (NS)	33/3	Mild, moderate and severe	5-7 consecutive days of 3-4h.day ⁻¹ (20h total). Modified Schroth programme (Schroth Best Practice). Spinal corrective exercises, spinal mobilisation, ADLs.	1	FVC, FEV ₁	Improvements in all PFT measures (P<0.001).
Otman <i>et al</i> , 2005	Turkey	14.2 (1.7)	38/12	Moderate	5 x 240 min.day ⁻¹ for 6 weeks supervised Schroth Programme, followed by 5 x 240 min.day ⁻¹ for 46 weeks unsupervised HEP.	52	VC	Improvement in VC (P<0.01)
Weiss 1991	Germany	NS	813 (NS)	Moderate and severe	6-8h.day ⁻¹ Schroth Programme. Supervised corrective spinal exercises, spine symmetry + breathing exercises.	4-6	VC	Improvement in VC (P<0.001)

NS, not specified; **HR**, Heart rate; **PFT**, Pulmonary function test; **VC**, Vital Capacity; **FVC**, Forced vital capacity; **FEV₁**, Forced expiratory volume; **PEF**, Peak expiratory flow; **ADL**, Activities of daily living; **HEP**, Home exercise programme.

2.3: Results

2.3.1. Search Results

The initial search of four databases yielded 1,835 studies before the removal of 544 duplicates (Figure 2.1). The subsequent search conducted in October 2025 yielded a further 94 studies before the removal of 29 duplicates. Overall, forty-nine studies were selected for full text reads based on abstracts and title. Of the 49 studies, 30 papers were excluded after full text reads (Figure 2.1). Eleven studies (n=11) were not based on conservative interventions. Other papers were not in the English language (n=9), pre-1980 (n=2), not based on an AIS population (n=2) did not include statistical analysis (n=1), wrong study design (n=3), retracted (n=1), and different outcome measures (n=1). Nineteen papers met the study criteria and were included in this systematic review. Ten papers were RCTs and the remaining nine were PI studies (Tables 2.2 and 2.3, respectively). Two papers were omitted from the meta-analysis due to inappropriate presentation of data (Wei et al., 2015) and lack of reporting of standard deviation (Weiss, 1991).

Three RCTs were conducted in a hospital setting (Wei et al., 2015, Gao et al., 2019, Xavier et al., 2020), six in a university setting (Athanasopoulos et al., 1999, Kim and Park, 2017, Kumar et al., 2017, Liu et al., 2023, Kumar, 2024, Dimitrijevic et al., 2025) and one study was carried out in a rehabilitation centre (Ogonowska-Slodownik et al., 2021). Five PI studies were carried out in a hospital setting (Weiss, 1991, Fabian, 2010a, Fabian, 2010b, dos Santos Alves et al., 2006, Amaricai et al., 2020), three in universities (Otman et al., 2005, Borysov and Borysov, 2012, Kim and Hwangbo, 2016) and one in a specialist scoliosis rehabilitation clinic (Moramarco et al., 2016). All studies measured FVC (L) or VC (L) (Figure 2.2 and Figure 2.3) while five RCTs (Figure 2.2) and four PIs (Figure 2.3) measured FEV₁.

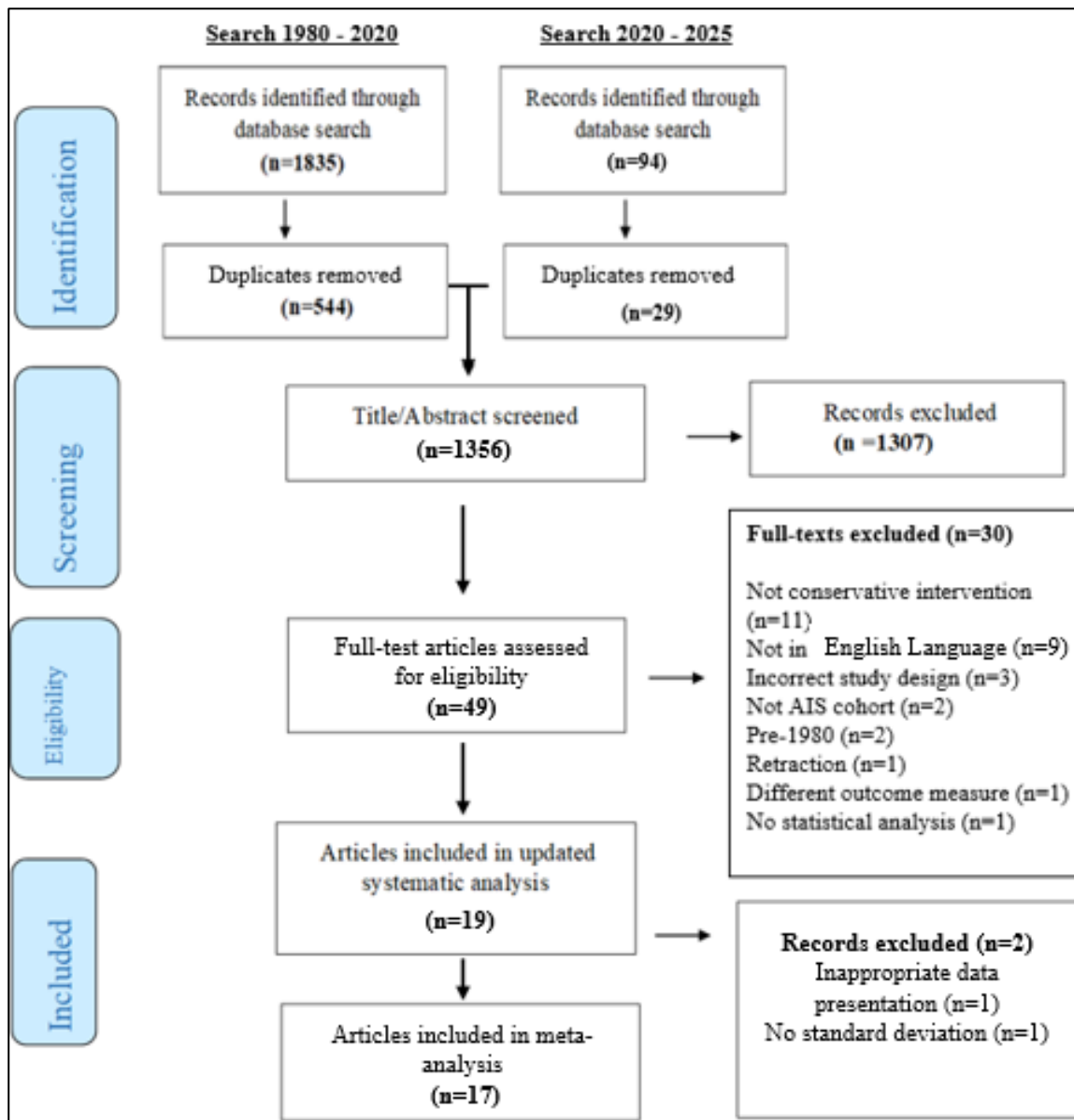


Figure 2.1: PRISMA flow diagram including the search conducted in July 2020 and the subsequent search conducted in October 2025.

2.3.2. Methodological quality assessment

Output from the modified Downs and Black quality appraisal is presented in Table 2.4. The RCTs were classified as ‘good’ (n=3), ‘fair’ (n=6) and ‘poor’ (n=1). Five PI studies were classified as ‘fair’, and the remaining four studies had a rating of ‘poor’. In general, studies scored well on external validity but were of moderate quality in terms of internal validity and selection bias. In addition, only nine studies justified their sample size (Table 2.4).

Table 2.4. Modified Downs and Black Risk of Bias Assessment (Hooper et al., 2008)

Author (year)	Reporting (/11)	External Validity (/3)	Internal Validity (/7)	Selection Bias (/6)	Power (/1)	Total (/28)
dos Santos Alves <i>et al.</i> (2006)	4	3	4	3	1	15
Amaricai <i>et al.</i> (2019)	8	3	5	2	1	19
Athanasopoulos <i>et al.</i> (1999)	6	3	3	4	0	16
Borysov and Borysov (2012)	6	3	2	3	1	15
Fabian (2010a)	6	3	4	2	0	15
Fabian (2010b)	5	2	3	1	0	11
Gao <i>et al.</i> (2019)	7	3	6	5	0	21
Wei <i>et al.</i> (2015)	7	3	3	4	1	18
Kim and Hwangbo (2016)	4	2	4	1	0	11
Kim and Park (2017)	5	3	4	3	0	15
Kumar <i>et al.</i> (2017)	6	3	5	5	0	19
Moramarco <i>et al.</i> (2016)	4	3	3	3	1	14
Otman <i>et al.</i> (2005)	6	2	3	2	1	14
Weiss (1991)	7	3	5	3	1	19
Xavier <i>et al.</i> (2020)	10	3	7	4	0	24
Dimitrijevic <i>et al.</i> (2025)	9	1	6	3	1	20
Kumar (2024)	3	1	3	1	1	9
Liu <i>et al.</i> (2023)	6	1	4	3	0	14
Ogonowska-Slodownik <i>et al.</i> (2021)	6	2	5	3	0	16

Total Score: Excellent, 26-28; Good, 20-25; Fair 15-19; Poor ≤ 14 .

2.3.3. Participant characteristics

The total sample population was 1,488 (RCT $n=2416$; PI $n=1072$). The majority of participants were female (RCT 77%; PI 86%). One study did not specify participant gender (Weiss, 1991). The mean age of participants was 14 ± 3 years. One study did not provide the mean age of the participants (Weiss, 1991).

The Lenke classification for AIS spinal curves identifies 6 different curve types (Lenke *et al.*, 2001). This review included two studies of participants with single thoracic curves (Xavier *et al.*, 2020, Athanasopoulos *et al.*, 1999), and seven studies with a mixed curve type including thoracic curves, lumbar curves and double curves (Otman *et al.*, 2005, dos Santos Alves *et al.*, 2006, Fabian, 2010a, Fabian, 2010b, Borysov and Borysov, 2012, Moramarco *et al.*, 2016, Liu *et al.*, 2023). The remaining ten studies did not identify the curve type of

participants (Weiss, 1991, Wei et al., 2015, Kim and Hwangbo, 2016, Kim and Park, 2017, Kumar et al., 2017, Gao et al., 2019, Amaricai et al., 2020, Liu et al., 2023, Kumar, 2024, Dimitrijevic et al., 2025).

Ten studies included participants with mild or moderate scoliosis (Athanasopoulos et al., 1999, Otman et al., 2005, Borysov and Borysov, 2012, Wei et al., 2015, Kim and Park, 2017, Kumar et al., 2017, Gao et al., 2019, Amaricai et al., 2020, Ogonowska-Słodownik et al., 2021, Kumar, 2024). Another RCT focused solely on those with moderate AIS (Dimitrijevic et al., 2025). Two studies (Weiss, 1991, Moramarco et al., 2016) included participants with a spectrum of AIS severity; mild, moderate and severe. Four studies only included participants classified as severe AIS (dos Santos Alves, et al., 2006, Kim and Hwangbo, 2016, Xavier, et al., 2020, Liu, et al., 2023). Two studies (Fabian, 2010a, Fabian, 2010b) did not specify the curve severity of the participants in their study.

2.3.4. Types of Intervention

The types of intervention used in the included studies can be divided into two broad categories: (i) aerobic-based exercise programmes (n=3) (Athanasopoulos et al., 1999, dos Santos Alves et al., 2006, Xavier et al., 2020) and (ii) PSSE programmes designed to strengthen and straighten the spine and improve posture and breathing (n=16). A number of studies had additional components such as supplementary ergonomic exercises for the intervention group (Kumar et al., 2017), Chinese traditional medicine and manual manipulation techniques (Wei et al., 2015), lower limb strengthening, or low resistance exercises (Xavier et al., 2020) in their interventions. Ogonowska-Słodownik et al. (2021) incorporated aquatic breathing exercises into their intervention.

Two studies using aerobic-based exercise programmes (Athanasopoulos et al., 1999, dos Santos Alves et al., 2006,) had durations of 8 and 16 weeks, respectively. A study using concurrent aerobic and resistance training had a duration of 12 weeks (Xavier et al., 2020). The duration of the PSSE interventions ranged from 1 week (Borysov and Borysov, 2012, Moramarco et al., 2016) to 52 weeks (Otman et al., 2005, Wei et al., 2015, Kumar, 2024, Kumar et al., 2017). Ogonowska-Słodownik et al. (2021) aquatic breathing exercises programme had a duration of 3 weeks. Two studies included a combination of supervised training and home exercises, with the programmes lasting 26 and 52 weeks, respectively (Gao et al., 2019, Otman et al., 2005).

2.3.5. Effectiveness of Exercise on Pulmonary Function

A fixed effects meta-analysis was conducted on nine RCTs and indicated a positive effect of exercise-based interventions on lung volume (FVC and VC) in patients with AIS (SMD = 0.34, 95% CI 0.44 to 0.24, $I^2 = 55\%$, $P = 0.00001$) (Figure 2.2). The I^2 score of 65% suggests moderate heterogeneity between studies. The results of a random effects meta-analysis on the PIs (n=8) showed a positive effect of an exercise-based intervention (MD=0.27, 95% CI 0.37 to 0.17, $I^2=10\%$, $P=0.00001$) on FVC and VC (Figure 2.3).

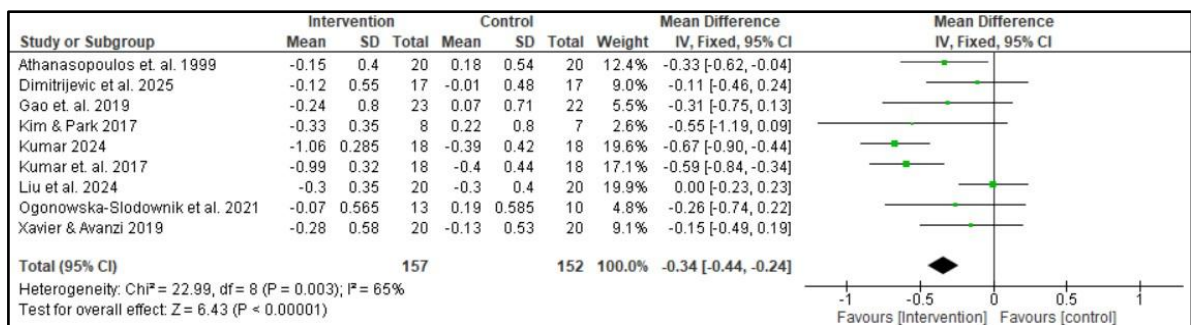


Figure 2.2. Forest plot depicting the cumulative effect of an exercise intervention on FVC and VC in randomised control trials (RCT).

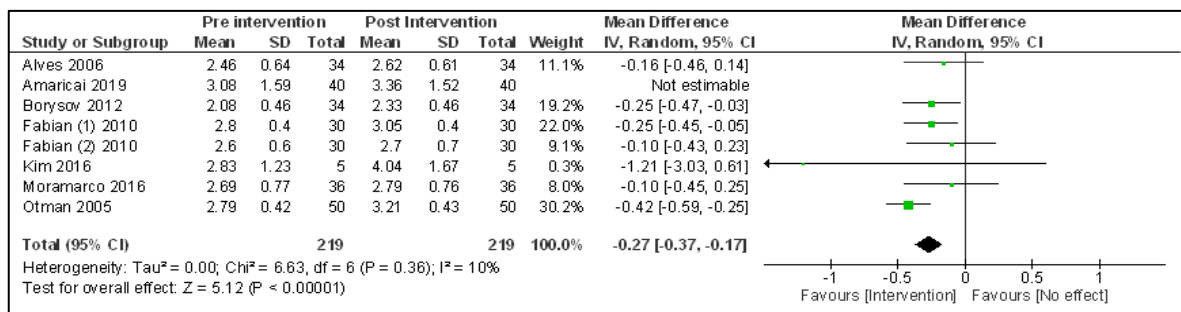


Figure 2.3. Forest plot depicting the cumulative effect of an exercise intervention on FVC and VC in prospective interventions (PI).

Results of a fixed-effects meta-analysis for the RCT studies in relation to FEV_1 (n=9) also indicated a positive effect of exercise-based interventions (SMD= 0.91, 95% CI 1.01 to 0.81, $I^2=98\%$, $P = 0.00001$) (Figure 2.4). The findings for a random effects meta-analysis of FEV_1 within PIs (n=4) indicated a positive significant outcome favouring an exercise-based intervention (MD= 0.19, 95% CI 0.34 to 0.05, $I^2=0\%$, $P = 0.00001$) (Figure 2.5).

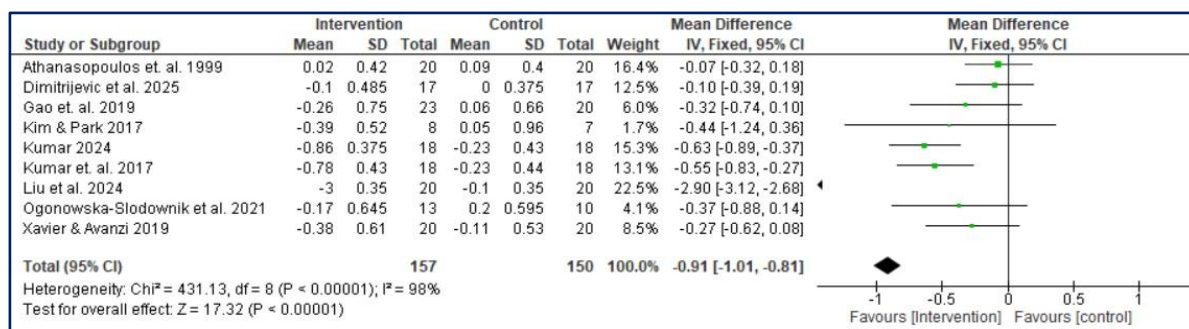


Figure 2.4. Forest plot depicting the cumulative effect of an exercise intervention on FEV₁ in randomised control trials (RCT).

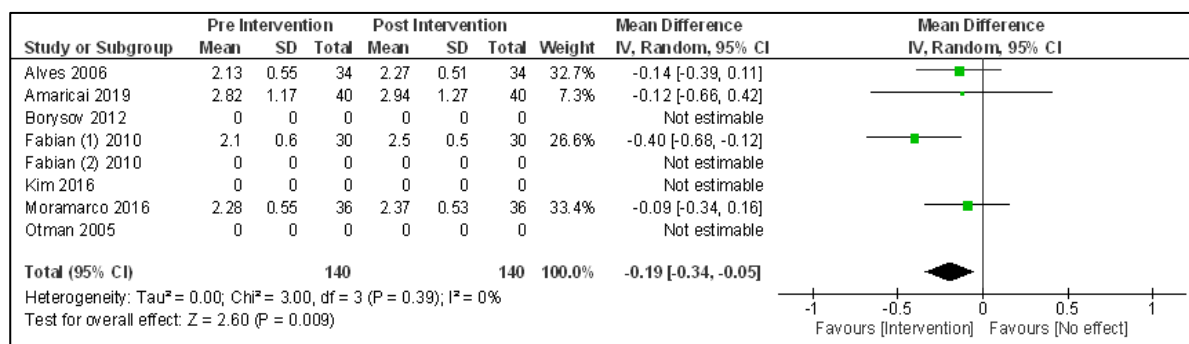


Figure 2.5. Forest plot depicting the cumulative effect of an exercise intervention on FEV₁ in prospective interventions (PI).

2.4: Discussion

The main finding of this review is that exercise-based therapies appear to significantly improve pulmonary function in patients with AIS. Intervention duration varied greatly between studies, but improvements did not appear related to the duration of the programme, with significant improvements in VC reported after as little as one week (Borysov and Borysov, 2012). The quality of included papers was generally fair (12/19), with higher quality reporting in the RCT studies.

2.4.1: *Pulmonary Function*

Testing of the pulmonary system is particularly important in individuals with AIS, given that thoracic spinal curvatures can lead to pulmonary impairments (Tsiligiannis and Grivas, 2012). In patients with moderate to severe AIS, a negative linear correlation has been established between curve severity and FVC (Tsiligiannis and Grivas, 2012). However, in the absence of other underlying disorders, mild to moderate scoliosis produces very few respiratory signs or symptoms (Tsiligiannis and Grivas, 2012), despite patients with even mild AIS having impaired FEV₁ and FVC compared to age-matched controls (Abdelaal et al., 2018).

Individuals with impaired FVC may be entirely asymptomatic unless they are undertaking vigorous physical activity and therefore may go unnoticed without a pulmonary function test (PFT) being conducted. An undiagnosed impairment in FVC could potentially act as a barrier to participation in physical activity for patients with AIS. A recent observational study reported lower physical activity rates in patients with AIS, irrespective of curve severity, compared to healthy age-matched controls (Chopra et al., 2020). Considering the importance of physical activity for the health and development of adolescents (Kumar et al., 2015, Mohankumar and Yie, 2016) any impairments in pulmonary function should be quickly identified and acted upon even in patients with mild AIS. The results from this review suggest that the implementation of an exercise-based programme could significantly improve FVC and FEV₁ in adolescents with AIS.

2.4.2: *Types of Exercise Intervention*

The studies identified in this review were broadly categorised into two types of exercise intervention: aerobic exercise and PSSE programmes. Studies using aerobic exercise reported significant improvements in FVC and VC (Athanasopoulos et al., 1999, dos Santos Alves et al., 2006, Xavier et al., 2020). Aerobic fitness has been shown to be positively

correlated with improvements in FVC, VC and FEV₁ in children regardless of height, weight or gender (Hancox and Rasmussen, 2018). Previous studies have shown improvements in FEV₁ from high intensity exercise programmes (Rawashdeh and Alnawaiseh, 2018).

PSSE programmes are frequently used in the management of spinal curve progression in scoliosis (Berdishevsky et al., 2016, Negrini et al., 2018). Despite the methodological variability, all 16 studies in this review that included a PSSE intervention reported significant improvements in FVC or VC. A number of studies postulated that improvement in pulmonary function following a PSSE was related to addressing the abnormal breathing patterns that occur in patients with scoliosis because of reduced chest expansion and restricted rib mobility (Borysov and Borysov, 2012, Moramarco et al., 2016). Weiss (1991) proposed the concept of abnormal chest cage mechanics leading to dysfunctional breathing. Interestingly, Xavier et al., (2020) who included resistance exercises in their intervention group, found that severe AIS participants had better outcomes when aerobic exercises were combined with anaerobic workouts. Similar findings have also been found in other non-AIS based cohorts (Khosravi et al, 2013).

2.4.3: Duration of Intervention

The intervention duration does not seem to be a factor in improvements in post-intervention PFTs. The most significant improvements in FVC and VC were reported in a 16-week intervention (dos Santos Alves et al., 2006) and one with a 52-week intervention (Athanasopoulos et al., 1999). Similarly, PIs with the most significant results were studies with a 4–5-week intervention (Fabian, 2010a), a 4–6-week intervention (Weiss, 1991), and a 52-week intervention (Otman et al., 2005). Results from studies comparing absolute pulmonary data, over longer time-periods would need to be viewed with caution. Individual's lung volumes progressively increase from birth until pulmonary maturity is reached at approximately 20 years of age (Barroso et al., 2018). The pattern of development is linear with age and height until adolescence is reached, at approximately 10 years for females and 12 years for males (Neve et al., 2002). In adolescence, a number of other factors have been shown to influence lung capacity such as, height, weight, gender and racial background (Neve et al., 2002, Barroso et al., 2018). A direct comparison between absolute pulmonary function tests before and after an intervention takes no account of the factors affecting lung growth and may overstate the respiratory improvements of an intervention (Neve et al., 2002). The potential for error when using absolute data increases as the duration of the intervention increases. Since stature and arm span are independent predictors of

pulmonary function (Golshan et al., 2007), it is suggested normalising PFT data to arm span might provide a more accurate estimate of any changes brought about by longer-term interventions (Graham et al., 2019).

2.4.4: Recently Identified Papers

The evidence from these recent studies supports the original review that exercise-based interventions (particularly PSSE), are effective in improving pulmonary function in adolescents with AIS. Three studies reported significant post-intervention increases in FEV₁ compared to baseline (Ogonowska-Słodownik et al., 2021, Liu et al., 2023, Dimitrijevic et al., 2025), with Kumar (2024) demonstrating improvements relative to the controls. Similarly, two studies identified gains in FVC post-intervention compared to baseline (Liu et al., 2023, Dimitrijevic et al., 2025), and one also showed superiority over controls (Kumar, 2024). Of particular importance, Liu et al. (2023) reported improvements in predicted values (FVC pred% and FEV₁ pred%), indicating potential clinical relevance beyond short-term functional outcomes. In addition, this study observed equivalent improvements in both Schroth and aerobic exercise groups, indicating that pulmonary benefits may result from structured exercise more broadly, rather than scoliosis-specific approaches alone. This supports the findings in previous research (Athanasopoulos et al., 1999, dos Santos Alves et al., 2006, Xavier et al., 2020) reported in the original review for this thesis.

The results from Kumar (2024) should be treated with caution. The duration of their study was 52 weeks. As already discussed, the potential for error when using absolute data increases as the duration of the intervention increases (Neve et al., 2002).

2.4.5: Study limitations

A number of factors limit this review. Firstly, studies included a combination of RCTs and PIs with participants who had varying curve severity ranging from mild to severe AIS. Caution is therefore required when interpreting conclusions presented. Secondly, only six studies reported results in predicted values. Predicted pulmonary values are recommended for use in pulmonary analysis and take into account child and adolescent development over time. In particular, it is recommended that FEV₁ is reported as a percentage of predicted or as a z-score when performing test-retest comparisons, to avoid

gender or height bias (Graham et al., 2019). Thirdly, the majority of the more recently identified studies included small sample sizes and short follow-up periods (Ogonowska-

Ślodek et al., 2021, Liu et al., 2023, Dimitrijevic et al., 2025). Finally, the review focused on primary pulmonary function test results, FVC, VC and FEV₁ as key variables that highlight pulmonary capacity in individuals with scoliosis, although several studies carried out a number of other PFT's not quantitatively evaluated in this review.

2.5: Conclusion

This is the first systematic review to assess the impact of exercise-based interventions on pulmonary function in patients with AIS. The meta-analysis demonstrated that exercise-based treatments, including aerobic exercise and PSSE, have a positive effect on lung volumes (FVC and VC) and FEV₁ in individuals with AIS. To validate and strengthen these findings, future clinical trials with larger sample sizes, standardised pulmonary function measurements, and clearly defined curve severity classifications are needed.

Chapter 3: Methodology

This chapter describes the ethics approval process, participants, recruitment, the justification for each outcome measures selected and the assessment procedure.

3.1: Ethical approval

Ethical approval for the research described in Chapters 4, 5 and 6 was obtained between June and September 2019 from the following sites: (i) Children's Health Ireland, Crumlin Hospital, Dublin (GEN/735/19), (ii) Beacon Hospital, Dublin (BEA0134), (iii) Blackrock Clinic, Dublin and (iv) Trinity College Dublin Faculty of Health Sciences Research Ethics committee (190611) (Appendix 1.1 -1.4). Because of the age range (12-21 years) and the different levels of severity of scoliosis (mild, moderate, and severe) in the participants, each ethics application included 12 different versions of the Participant Information Leaflet (PIL) and 12 different versions of the consent/assent forms. Each PIL was specifically written for a given age group as follows; 12-14 years; 15-16 years and 17-21 years. All PILs and consent/assent forms were prepared based on the Flesch-Kincaid, age-appropriate readability scale to reflect the different age groups (Kincaid, 1975). A copy of each PIL and consent form are included for reference purposes (Appendix 2.1- 2.12 and 3.1 - 3.6 respectively). In addition, each ethics application included a mandatory data protection impact assessment (DPIA) (Appendix 4).

3.2: Recruitment and Consent

The recruitment process for participants with AIS is outlined in Figure 3.1. Participants with AIS were recruited on an ongoing basis from the principal surgical sites, Children's Health Ireland (CHI) Crumlin, Beacon Hospital and Blackrock Clinic through a poster campaign (Appendix 5). Control participants were recruited from the general adolescent population in Dublin secondary schools and colleges, including Trinity College Dublin, Portmarnock Community school, Ardscoil Ris, Griffith Avenue, Ardscoil La Salle, Raheny and Manor House school, Raheny also through a poster campaign (Appendix 6). The recruitment process for control participants mirrored that used for the AIS participants (Figure 3.1).

Potential participants and their guardians (if appropriate) were invited to contact the principal investigator (TR) via the email address or telephone number listed on the poster. The principal investigator forwarded age-appropriate participant information leaflets (PIL)

to participants and guardians (if required). A 7-day reflective period was provided after which the principal investigator contacted the potential participants and their guardians (if required) to address any queries and to confirm if they were interested in taking part in the study. If participants were interested, an assessment appointment was made.

Written informed consent was sought from all participants. Those under 16 years of age were required to complete an age-appropriate assent form and additional written consent from their parents or guardians to participate in the study was required. On the day of assessment, the investigator reviewed the consent and assent forms (if required) with potential participants and fully explained the purpose of the assessment including the benefits and risks to the participant and guardian (if applicable). If they agreed to proceed, the consent and assent forms were signed by the participants and countersigned by the investigator. Participants were subsequently screened for study inclusion.

3.2.1: COVID-19 and HSE cyber-attack

Recruitment was seriously disrupted due to the COVID-19 pandemic lockdown, in March 2020. Surgical procedures on patients with AIS and weekly AIS clinics were cancelled in all participating hospitals until early 2022. Additionally, the laboratory facilities at Trinity College Dublin, where the assessments were planned to take place, were also closed during this period. The resumption of normal day-to-day operations at the clinical sites was further delayed by a cyber-attack on the HSE computer system in May 2021. As a result, most HSE services were closed for four months, leading to significant backlogs in patient appointments and causing additional challenges in recruiting participants for the studies.

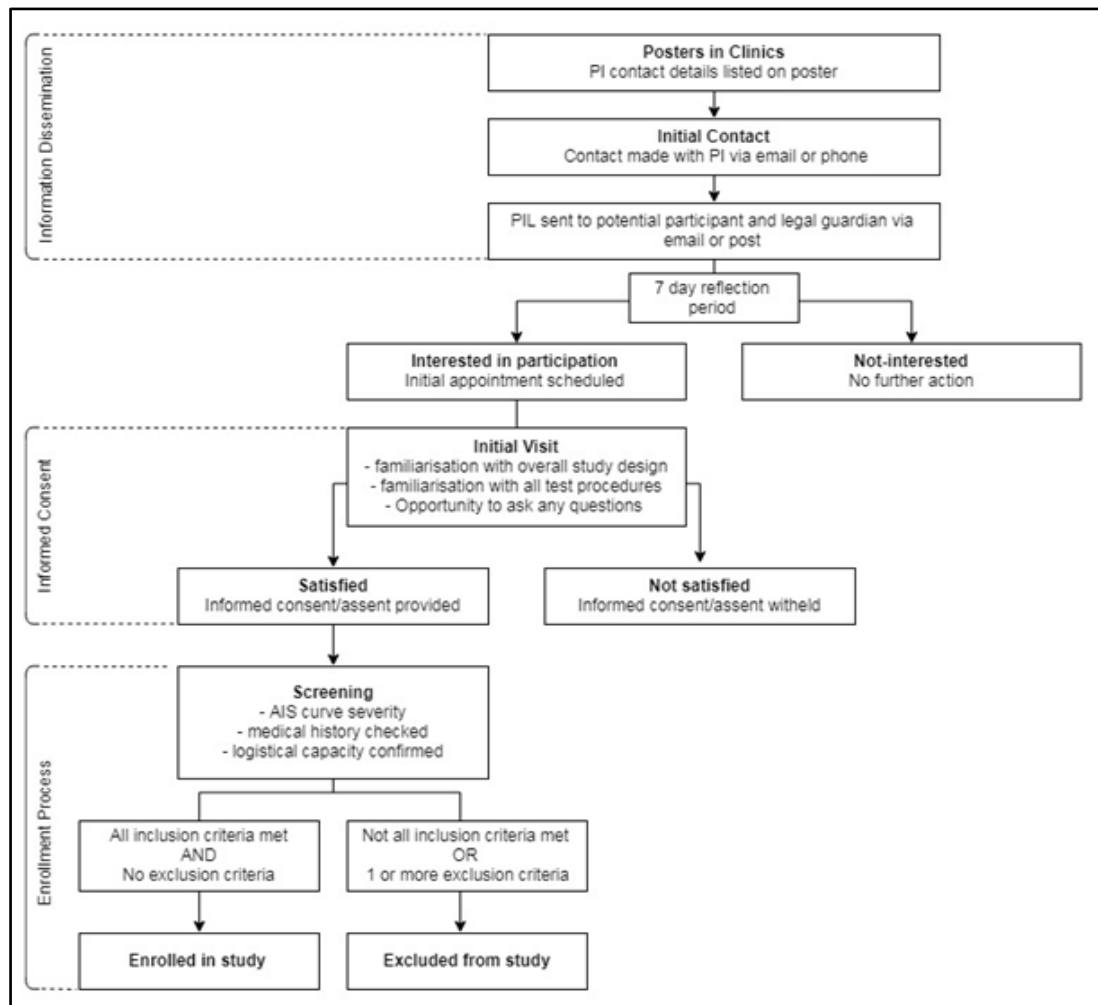


Figure 3.1: AIS participant recruitment process

3.3: Participant screening

Upon obtaining consent, each participant was screened prior to inclusion in any of the studies. All participants meeting the inclusion criteria were included in the cross-sectional study described in Chapter 4. Participants with mild or moderate AIS were also included in the PSSE intervention study outlined in Chapter 5. Participants with severe AIS took part in the post-operative intervention study described in Chapter 6. For AIS participants, confirmation from their medical team was required to verify the diagnosis and determine their current spinal Cobb angles. For patients with a severe AIS diagnosis, confirmation was also required from the hospital surgical team that the prospective participant was listed for imminent surgery (within 3 months).

On the day of the first assessment, each participant (AIS and controls) was required to complete a Physical Activity Readiness Questionnaire (PARQ – Appendix 7) (Warburton et al., 2021) and an American College of Sports Medicine (ACSM) health status questionnaire

(Liguri, 2021). In the event of a 'yes' response to a question on the PARQ, or a health issue raised in the ACSM questionnaire, the participant was asked to seek guidance from their doctor before being allowed to participate in the study. One participant was referred to their doctor and was subsequently excluded from the study.

3.3.1: Inclusion criteria for research participants

A full list of the inclusion criteria for each study cohort is listed below:

All Participants

1. No illness, musculoskeletal injury, balance problems or reported neurological condition that would restrict exercise or testing.
2. Ability to cooperate, take, and follow instructions in English.
3. Age 12-21 inclusive.

Participants with mild or moderate AIS

1. A clinical diagnosis of mild or moderate AIS.
2. Be able to attend two assessments in the Trinity Centre for Health Sciences, St. James's Hospital, Dublin.
3. Confirmation from the Scoliosis clinics that potential participants had not completed or commenced a physiotherapeutic scoliosis-specific exercise intervention (PSSE).
4. Be capable of completing a 4-month PSSE intervention if assigned to the intervention group.

Participants with severe AIS

1. A clinical diagnosis of severe AIS.
2. Scheduled for spinal fusion surgery within 3 months of the initial assessment date.
3. Be able to attend three assessments at the Trinity Centre for Health Sciences, St. James's Hospital Dublin.
4. Be able to attend a bi-weekly in-person supervised rehabilitation session and be able to complete a home exercise programme (HEP) over the duration of the 3-month programme.

Control participants

1. Must not have a scoliosis diagnosis.
2. Be able to attend one assessment at the Trinity Centre for Health Sciences, St. James's Hospital Dublin.

3.3.2. Exclusion criteria

Potential participants were excluded if they had any illness, musculoskeletal injury, balance problems, or reported neurological condition that would restrict exercise or testing. A full list of exclusion criteria is outlined below:

1. History of a cardiac event (such as an acute cardiac event, unstable chest pain, irregular heartbeat, cardiac infection).
2. An existing acute or chronic respiratory condition.
3. An existing acute or chronic neurological condition
4. Known blood pressure abnormalities (e.g., hypertension/hypotension).
5. Fitted electronic device (e.g., pacemaker).
6. Individuals who take part in sport at an elite level.
7. Pregnant or a breastfeeding mother.
8. Advised on medical grounds not to exercise.
9. Under the age of 12 or over the age of 21.
10. Individuals who had previously engaged in or recently commenced a PSSE programme.
11. Incomplete or unsatisfactory medical screening prior to testing.

3.4: Assessment protocol

Appointments were scheduled to accommodate the availability of participants and their families. All assessments took place in the exercise laboratory in the Trinity Centre for Health Sciences, St. James's Hospital Dublin 8. The exercise laboratory, where testing occurred, was a quiet environment free of interruptions or distractions throughout the testing period. Access to the laboratory was restricted during assessments.

A standardised one hour and 35-minute assessment protocol was used to evaluate muscle strength, endurance, and power, exercise capacity, pulmonary function, balance, and quality of life (Figure 3.2). The assessment protocol applied to all participants across all three prospective studies (Chapters 4, 5 and 6).

Before testing, participants were provided with a detailed explanation of the assessment process, including its potential benefits and risks. The procedures were thoroughly described, and all equipment used in the tests was demonstrated. Participants were also given the opportunity to familiarise themselves with each test and the associated equipment. The

Adam's forward bend test was performed on the control participants before taking part in the assessment to ensure they did not have a scoliosis. Upon completion of the assessment, a Physical Activity Health and Fitness Report was made available to all participants upon request (Appendix 8).

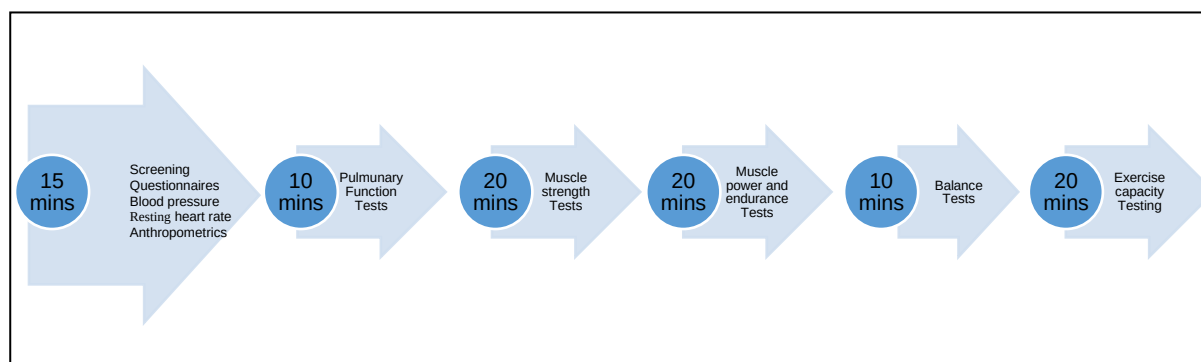


Figure 3.2: Timeline for assessment procedure

3.4.1: Development of the assessment protocol

The assessment protocol was developed and tested prior to the commencement of the data collection. Several trial tests took place in the exercise laboratory to establish the timing and running order of the tests. Feedback was provided by two independent observers (NF and SD) to facilitate amendments to the assessment protocol aimed at increasing the efficiency of the process and maximising participant effort and comfort. The principal investigator, an experienced Chartered Physiotherapist, was familiar with the assessment protocols and test equipment from clinical practice. A clinical data collection sheet (CDCS) was designed to record and collate information and data collected in each assessment (Appendix 9).

3.5: Outcome measures

Detailed descriptions of all study outcome measures are provided in the following sections.

3.5.1: Questionnaires: Weekly activity levels and Quality of life

As part of each assessment, participants were required to complete a physical activity questionnaire (IPAQ) (Craig et al., 2003) and scoliosis-specific health-related quality of life outcome questionnaire, (SRS-22r) (Asher et al., 2003).

The IPAQ is a self-reported questionnaire created to assess physical activity (PA) intensity and sedentary time in populations. The short form consists of 7 items. These items include engagement in vigorous activities, moderate activities, and walking over the past 7 days,

along with the time dedicated to each of these activities on one of those days (if applicable). Additionally, time spent sitting on a typical weekday is recorded (Appendix 10). Calculations are based on MET-minutes per week and sitting time in minutes. Its reliability and validity have been well established (Craig et al., 2003). The IPAQ questionnaire was completed to facilitate a comparison of physical activity levels between AIS participants and healthy controls.

The SRS-22r is an internationally validated questionnaire used to assess health-related quality of life in young people with AIS. The questionnaire evaluates five key parameters: pain perception, function, mental health, self-image, and treatment satisfaction. The questionnaire comprises 25 items, each offering 5 possible responses. Participants select the response that best reflects their mindset. Scoring is based on the Likert scale, each question is scored on a scale from “1” (worst) to “5” (best). The questionnaire generates a composite mean score for each domain at the conclusion, ranging from “1” (indicating very poor quality of life) to “5” (indicating excellent quality of life) (Appendix 11).

Carreon et al. (2010) have previously examined MCID in a range of sub-domains within a large cohort of patients with AIS (n=887). They reported MCIDs for sub-domains including pain (MCID=0.2), activity (0.08) and self-image (0.98), however no published MCID for mental health could be found. These published MCID were used as criteria were used to determine “clinically meaningful” changes in these SRS22-R sub-domains.

3.5.2: Anthropometric assessment

Barefoot height (cm) was measured using a Seca 213 portable height stand (Seca, Hamburg, Germany) with the participant's heels, buttocks and upper back touching the stadiometer and their head positioned in the Frankfurt plane (Sebo et al., 2017) (Figure 3.3). The participant was requested to take a deep inhalation of breath through the nostrils to lung capacity. At maximum inhalation, a precise height measurement was taken to the nearest 0.01m. Results were recorded in the participant's CDCS.



Figure 3.3: Seca 213 portable height stand (Seca products)

Body mass, body mass index (kg.m^2), percentage body fat, percentage fat mass (PFM), muscle mass (kg), fat-free mass (kg), bone mass (kg) and estimated basal metabolic rate (BMR kcal) were assessed using a Tanita Body Composition Analyser to the nearest 0.10kg (Kabiri et al., 2015). Participants were requested to remove their shoes, socks, wrist and finger jewellery, stand on the body composition analyser and follow the prompts (Figure 3.4). Participant's gender, height (nearest 0.01mm) and date of birth were entered into the Tanita analyser and whole body, and segmental fat measurements were selected. Prior to each assessment, the Tanita Analyser was calibrated and pre-set to -0.5kg to account for the participant's clothing (shorts/T-shirt). Results were recorded in the participant's CDCS.



Figure 3.4: Tanita Body Composition Analyser

Source: (<https://tanita.com>)

Lower limb length measurements in centimetres were recorded using a standardised measuring tape. The measurements were taken from the anterior superior iliac spine to the

medial malleolus on both limbs with the participant in a supine position on the plinth (Figure 3.5).



Figure 3.5: Lower limb measurement

Source: Picot et al., (2021)

3.5.3: Blood pressure and resting heart rate measurements

According to the European guidelines for systolic and diastolic blood pressure in children and adolescents, normal blood pressure in individuals under 15 years of age is defined as values below the 90th blood pressure percentile (Lurbe et al., 2016). Among female adolescents with a mean age of 14 years, this corresponds to a systolic blood pressure of less than 122–125 mmHg across the 50th to 95th percentiles of height. The corresponding normal diastolic blood pressure for the same height percentiles is classified as 78–80 mmHg. Normal resting heart rate has been defined as 60 -100 (beats.min⁻¹) for adolescents between ages of 13 -18 years of age (Rabbia et al., 2002). Normal resting heart rate has been defined as 60 - 100 (beats.min⁻¹) for adolescents between ages of 13 -18 years of age (Rabbia et al., 2002).

Blood pressure and resting heart rate were measured using an Omron M6 automatic blood pressure monitor (Omron Healthcare Europe, The Netherlands) in accordance with the protocols described by Muntner et al. (2019) (Figure 3.6). Readings of systolic and diastolic blood pressures and resting heart rate are displayed on a digital panel on the Omron M6. This device has an accuracy of ± 3 mmHg in terms of pressure and $\pm 5\%$ in terms of pulse readings (Topouchian et al., 2014). Participants were seated prior to the test for a minimum of 5 minutes, in a chair with back support with both feet on the floor. Participants were instructed to keep their legs uncrossed and to rest both arms at heart level. The participant's

left arm was positioned and supported on a table. The appropriate-sized blood pressure cuff was attached evenly and firmly around the exposed left arm, approximately 2 cm (two fingerbreadths) above the elbow with the tubing connected to the sensor unit placed at the centre of the arm facing the palm of the hand. During each measurement, participants were asked to remain relaxed and still and to breathe normally. Every participant was given the same instruction prior to the commencement of the measurements 'No talking or movement during cuff inflation'.

Two measurements were taken one minute apart. In cases where the systolic blood pressure (SBP) differed by more than 5 mmHg, a further set of measurements were obtained after an additional 1-minute rest. If participants' SBP consistently recorded a reading in excess of 140 mmHg, the assessment was terminated (Flynn et al., 2017). The participant and their guardian (if applicable) were informed of the high blood pressure readings and advised to report this finding to their general practitioner. A follow-up letter, to the participant's general practitioner was sent by the principal investigator outlining the findings of the blood pressure assessment (permission granted by participants in consent forms). The mean of the two sets of measurements was recorded in the participant's CDCS in mmHg (Muntner et al., 2019).



Figure 3.6: Omron M6 automatic blood pressure monitor

3.5.4: Pulmonary function testing

Pulmonary function tests were performed using a hand-held MicroLab Spirometer (MicroMedical, Surrey, UK) (Figure 3.7). The MicroLab is a portable battery-operated hand-held microcomputer unit incorporating a digital volume transducer. A disposable antibacterial cardboard filter was attached to the volume transducer for each pulmonary function test. The disposable filter was replaced with a new filter for each participant. A nose clip was used during each test to prevent nasal inspiration or expiration. The procedure was explained and demonstrated in full for each participant prior to the commencement of the test.

Before the pulmonary function test commenced, participants' gender, date of birth, height and weight were entered into the MicroLab Spirometer. The pulmonary function test requires participants, in standing, to inhale maximally, place their mouth tightly around the mouthpiece and explosively and maximally exhale. The participants were encouraged to continue forcing air out until all air was expelled from their lungs. Standardised verbal encouragement was given to each participant 'Keep going, keep breathing' to ensure maximal exhalation was achieved. Coughing during the first second of exhalation (for FEV₁), glottis closure, abrupt termination or accidental blocking of the mouthpiece rendered that attempt void and required the test to be repeated. Three acceptable tests were required with repeatability within 0.150L or 10% of highest value; whichever was greater (Culver et al., 2017). One minute of normal breathing was allowed between tests for participants to recover normal pulmonary function.

Data were collected for the following variables: (i) Forced Vital Capacity (FVC) in litres (L), (ii) Forced Expiratory Volume in one second (FEV₁) (L.s⁻¹), (iii) Forced expiratory ratio (FER), the ratio of FEV₁ to FVC, (iv) Peak Expiratory Flow (PEF) in litres per second (L.s⁻¹). The highest acceptable result for each variable was recorded in the participant's CDCS to two decimal places (Culver et al., 2017). Additionally, the percentage predicted pulmonary outcomes for FEV₁ and FVC (the difference between the actual outcomes and the predicted outcomes) were calculated using the Global Lung Function calculator (Quanjer et al., 2012, Stanojevic et al., 2013).

AIS can result in structural deformities to the thoracic cage that impair pulmonary function leading to restrictive lung function. The Global Lung Initiative (GLI) endorsed by the European Respiratory Society, serves as the standard for spirometry analysis in the Irish healthcare system. Implemented in Europe since 2012, the GLI is recognised as the gold

standard for evaluating pulmonary function. The GLI is based on complex formulae that calculate predicted pulmonary outcomes based on each individual's ethnic background, age, gender, height, and weight. Actual spirometry results are then compared to the expected predicted outcomes. The current benchmark for indications of pathology in children and adolescents is less than 80% of predicted values (Barreiro et al, 2004). Results were generated for each participant's percentage predicted FEV₁ (L.s⁻¹), FVC (litres) and FEV₁/FVC ratio.

Normative values for pulmonary function outcomes (FVC and FEV₁) in adolescents are influenced by sex, height, and age; therefore, a single reference value is insufficient. Predicted values derived from reference equations that account for these variables is used in the Irish healthcare system to identify pulmonary deficits. Lower percentage FVC outcomes are indicative of a restrictive ventilatory impairment (Hall et al., 2021).

Consensus from the European and American Thoracic Societies established a minimum clinically important difference (MCID) in FEV₁ of 100mL for patients with underlying pulmonary disease (Pellegrino et al., 2005, Crim et al., 2021). However, an evaluation of test-retest reliability in two large cohorts (n=421 and n=427) of COPD patients determined that the 95% limits of agreement were 370 and 422mL, respectively (Crim et al., 2021). Changes in FEV₁ that lie within these 95% LOA boundaries would therefore be “technically indistinguishable from the background noise or measurement error” (Donohue, 2005). A reference criterion of 400mL was therefore used to determine “clinically meaningful” changes in FEV₁ within this thesis.

In terms of absolute FVC, reference criteria for MCID are unavailable due to the relationship and association between lung volume and patient anthropometrics, age and gender. However, Kafaja et al. (2018) used an anchoring method to establish MCID in relative FVC (percentage predicted FVC) within a large cohort of scleroderma patients (n=300). These authors used the Transition Dyspnea Index to establish that the mean change in %FVC was 4.4% for patients who reported their symptoms as “much better” at a 12-month follow-up. The MCID for %FVC was therefore set at 4.4% within this thesis.



Figure 3.7: MicroLab Spirometer

3.5.5: Exercise capacity testing

According to the American Heart Association medical statement (Washington et al., 1994), maximal exercise capacity testing is suitable for paediatric and adolescent populations. Previous studies in exercise testing on participants with AIS have used a wide variety of different maximal and submaximal protocols. These protocols included the use of treadmills (Barrios et al., 2005, Lorente et al., 2017,), cycle ergometers (Czaprowski et al., 2012) and field tests (dos Santos Alves and Avanzi, 2009, Abdelaal et al., 2018). Hebestreit et al. (2015), recommend the Godfrey protocol with gas exchange measurements as the most suitable protocol for paediatrics and adolescents with lung conditions (Godfrey, 1971). Cycle ergometers are widely used in studies on paediatric populations (Takken et al., 2017). Considering the age profile of the participants in the studies of this thesis, the range of spinal curvatures, and the prevalence of potential lung conditions, the Godfrey protocol using a cycle ergometer was deemed to be the most appropriate method for assessing maximal exercise capacity. A Cosmed Ergometer stationary bike was used for all exercise capacity testing. Prior to conducting the Godfrey protocol, the seating position and handlebars on the cycle ergometer were adjusted to each participant's height and leg length. A straight leg in a seated position with the heel on the distal pedal was used to estimate the correct seat height (Figure 3.8a and 3.8b).

In the Godfrey protocol, the initial workload and incremental work rate is increased in a stepped pattern based on each participant's barefoot height (Godfrey, 1971) Participants with a height of less than 120cm commenced with a workload of 10W and increased by 10W.min⁻¹. Participants whose height ranged between 120 -150cm commenced with a workload of 15W and increased by 15W.min⁻¹. Participants whose height was greater than

150cm commenced with a workload of 20W and increased by 20W.min⁻¹. All participants completed the test until volitional exhaustion.

Once appropriately fitted on the cycle ergometer, resting data were recorded during a 3-minute familiarisation period. In addition, the participant was familiarised with the Borg rate of perceived exertion (RPE) scale (Appendix 12). All participants were instructed to maintain a cycle cadence between 55 and 60 (available on-screen to participants) throughout the test, not to talk and to try not to cough or sneeze during testing as it may affect gas collection results (unless test termination is required).



Figure 3.8: The Quark CPET (a) and COSMED Ergoline cycle ergometer (b).

Source: (www.cosmed.com)

Heart rate (HR) and VO₂ (Oxygen Consumption) were measured continuously throughout the test. The average HR and VO₂ from the last 15 seconds of each one-minute interval completed by the participant were recorded in their CDCS (Hebestreit et al., 2015). At the end of each minute, the participant was asked to rate their perceived exertion on the RPE scale, and this was also recorded in their CDCS. Standardized encouragement was given during the final 15 seconds of each minute ("Keep going, you are doing well"). Additional continuous encouragement was provided if the participant's rate of perceived exertion (RPE) reached 7 or their cadence dropped below 55. When the participant ended the test, a "MARK" was placed on the digital data to indicate the termination of the test.

The plateau of VO_2 despite an increase in workload is regarded as the best evidence for maximal effort (Takken et al., 2017), and this criterion was used in the studies of this thesis. In the event that a participant's VO_2 did not plateau during the test, maximal effort was assumed if one of the following criteria was met:

- Cadence at 55 is not maintained for a period of 20 seconds, despite verbal encouragement.
- A participant reaches $185 \text{ beats} \cdot \text{min}^{-1}$ or a HR at or above predicted maximal HR for adolescents (Gelbart, 2017).
- A recorded respiratory exchange ratio (RER) equal to or greater than 1.05 (Hebestreit et al., 2015).
- A rating of 9 or 10 on the Borg 10-point scale (ATS/ACCP, 2003).

If, during the exercise testing, any of the following criteria (Fletcher et al., 2013) were identified by the investigator, the test was terminated:

- Suspicion of a myocardial infarction or acute myocardial infarction (heart attack)
- Onset of moderate-to-severe angina (chest pain)
- Abnormally high HR response to initial exercise workload ($\geq 180 \text{ beats} \cdot \text{min}^{-1}$)
- Failure of HR to rise with increased workload
- Signs of poor perfusion (circulation or blood flow), including pallor (pale appearance to the skin), cyanosis (bluish discoloration), or cold and clammy skin
- Severe or unusual shortness of breath
- CNS (central nervous system) symptoms including ataxia (failure of muscular coordination), vertigo (illusion of dizzying movement), visual problems, or confusion.

Prediction models developed by Blanchard et al. (2018) were used to estimate cardiopulmonary fitness in children and adolescents. These equations, derived from a healthy paediatric population, provide predicted values for key cardiopulmonary exercise testing (CPET) parameters, including $\text{VO}_{2\text{max}}$. Z-scores were calculated using Blanchard's equations to quantify the deviation of an individual's results from population norms, adjusted for age, sex, body mass, height, BMI, and Tanner stage (A classification system used to assess maturation through 5 stages of development (Emmanuel and Bokor, 2022)). A deficit in a participant score was deemed to exist where a Z score of -2 or greater was recorded.

Maximal aerobic capacity ($\text{VO}_{2\text{max}}$) is recognised as the gold standard for the assessment of exercise capacity (Hebestreit et al., 2015, Takken et al., 2017). The terms $\text{VO}_{2\text{max}}$ and

VO₂peak are interchangeable in paediatrics (Takken et. al. 2017). The Quark CPET is a valid and reliable tool for the assessment of metabolic factors during maximal graded exercise testing (Nieman et al., 2013). Gas exchange variables and heart rate were measured throughout exercise capacity testing, using a Quark B² (Cosmed, Rome, Italy) breath-by-breath pulmonary gas exchange analyser. The Quark CPET is an advanced metabolic cart designed for gas exchange analysis VO₂, and Volume of carbon dioxide production (VCO₂) during both exercise and resting protocols.

Before each test, the COSMED Quark CPET was calibrated for O₂ and CO₂ using room air and a standardized α -certified gas mixture (15% O₂, 5% CO₂, and the balance nitrogen - N₂). The protocol described by Fleming (2012) was used in this thesis. This protocol involved calibration of the volume transducer using a 3L gas calibration syringe (Cosmed, Rome, Italy). The sampling line was plugged in to the sampling socket on the front of the CPET unit, and calibrated using the system software (Quark B2, Version 2.0, Cosmed, Rome, Italy). Gas analysers were calibrated twice prior to testing using room air and the certified gas mixture. Volume calibration was conducted using a 3-litre calibration syringe connected to the flowmeter. The syringe piston was moved in and out for 5 inspiratory and 5 expiratory strokes before the first measurements appeared on the calibration screen. An additional 10 repetitions were carried out, and the percentage errors were shown before the new calibration factors were saved. This process was repeated until the average percentage error was less than 0.5%.

Upon completion of calibration, each participant's details were entered into the COSMED programme (OMNIA) using their unique allocated code number. Details included gender, date of birth, height, weight and test programme selection. Participants were fitted with a heart rate monitor (Polar H10, Polar Electro, Inc), with conducting gel applied, and a gas exchange mask which was attached to the flow meter and gas sampling line, allowing gas exchange data to be continuously recorded by The Quark CPET. Proper mask fitting was essential to ensure total pulmonary volume was captured accurately on each breath. On completion of the exercise capacity test, all data including VO₂max (mL.kg⁻¹. min⁻¹), maximal heart rate (beats.min⁻¹) and maximal workload (W) were exported to an Excel file and transferred to the research laptop for subsequent data analysis. These outcome variables were also recorded in the participant's CDCS.

3.5.6: Muscle strength

Strength has been defined as ‘the peak force (in Newton’s, N) or torque (in newton-metres, Nm) developed during a maximal voluntary contraction (MVC) under a given set of conditions’ (Sale, 1991). The ability to provide consistent and reliable results from muscle function tests is dependent on the establishment of ‘demonstrated reliability and validity’ in the muscle testing process (Feiring et al., 1990). Measurement of skeletal muscle function needs to be consistent, and error-free and needs to measure the variable that has been selected for measurement (Drouin et al., 2004).

3.5.6.1: Hand-held Dynamometer

Isokinetic dynamometry is considered the 'gold standard' for the measurement of muscle strength (van der Woude et al, 2022). Hand-held dynamometry (HHD) is also considered a validated method of strength measurement (Stark et al., 2011).



Figure 3.9: Lafayette manual muscle tester

For the purposes of this thesis, muscle strength was assessed using hand-held dynamometry (Figure 3.9). The reliability and validity of using a hand-held dynamometer to measure muscle strength, have been established in numerous studies. A systematic review by Stark et al., (2011) found HHD to be a 'reliable and valid instrument' to measure muscle strength when compared to isokinetic dynamometry. A more recent systematic review and meta-analysis (Chamorro et al., 2017) examined the absolute reliability (by how much the results of repeated measures vary) and concurrent validity (how well HHD compares to the 'gold standard' of Isokinetic dynamometry) of HHDs. This review concluded that there was a high

correlation between HHD and isokinetic testing for hip muscles and a moderate correlation for knee and ankle muscles. Romero-Franco et al. (2017) found excellent validity (ICC > 0.90), and high intra, and inter-tester reliability (ICC > 0.75) for lower limb muscle test comparisons between HHD and isokinetic dynamometry. These results supported the findings of Mentiplay et al. (2015), who found moderate to excellent concurrent validity in lower limb strength testing and good to excellent intra-rater and inter-rater reliability with scores of $ICC \geq 0.75$ for both these measures. Studies focusing on upper limb strength have also validated the HHD as a reliable tool to establish muscle force (McLaine et al., 2016), high intra-rater reliability McLaine et al. (2016), ICC: 0.87-0.99; Donatelli et al., (2000), ICC: 0.79-0.96; Balogun et al. (1998), ICC: 0.75-0.96). Cools et al. (2014) also found the intra-rater reliability across several test protocols to be good to excellent (ICC: 0.85-0.99). The validity and intra and inter-tester reliability of HHD have also been established in paediatric and adolescent populations (Eek et al., 2006, Hebert et al., 2011, Daloia et al., 2018). The experience of the tester is also an important factor. Hand-held dynamometry is a reliable assessment method when performed by an experienced tester (Kolber and Cleland, 2005).

3.5.6.2: Muscle testing protocol

A calibrated Lafayette manual muscle tester (Model 001165, Lafayette Instrumentation, New York, USA) was used to measure muscle strength in the studies described in Chapters 4, 5 and 6 of this thesis. Two types of assessments can be performed using a hand-held dynamometer; a 'break' test or a 'make' test. In a 'break' test, the examiner applies pressure to the participant's limb until the participant's maximum muscular strength is exceeded and the joint gives way. In a 'make' test, the examiner holds the dynamometer steady while the participant pushes with their greatest force against it (Stratford and Balsor, 1994). A 'make' test was used for all muscle tests in this thesis (Mentiplay et.al., 2015).

There is no consensus on how many HHD tests should be carried out on each muscle, or muscle group, or which result should be used for statistical analysis. Nor is there a consensus on the optimum length of the rest period between tests. Rest periods ranged between 10 seconds to 60 seconds (Cools et al., 2014, Hébert et al., 2015). A 30-second break between tests was the most widely used rest period (Couppe et al., 2014, Keep et al., 2016, Daloia et al., 2018). Previous research in this area has recorded the mean of either two or three tests or the maximum result achieved (Hebert et al., 2011, Couppe et al., 2014, Daloia et al., 2018). The mean of three maximal test scores with a 30-second rest between tests was used throughout this thesis.

Mentiplay et al. (2015), stated that there is no universal consensus on participant test positioning for HHD muscle strength tests. They recommended that the positioning of participants should favour the tester, a proposal supported by Beshay et al. (2017). Bohannon (2019) recommends reduced muscle gravity and a tester who has sufficient strength to hold the HHD in its correct position for the duration of a test correlates best with 'gold standard' scores from isokinetic dynamometry. This view supports earlier opinions of tester strength (Wikholm and Bohannon, 1991, Celik et al., 2012). Standardisation of participant positioning and stabilisation of the muscle group to be tested increases the reliability of results (Vermeulen et al., 2005). A study by Eek et al. (2006) shows a strong correlation between HHD test results in different test positions (supine, prone and sitting) with the same participant. The results indicated excellent intra-rater reliability across all three test positions.

The protocol described by Mentiplay et al. (2015) and Thorborg et al. (2010) was used for lower limb muscle testing in the studies of this thesis and is described in detail below. A submaximal test was carried out prior to each muscle test, in order to familiarise the participant with each test procedure.

Hip flexion strength was assessed in a sitting position (Mentiplay et al., 2015). Participants were seated and hips and knees were flexed at 90°. The dynamometer was placed on the anterior aspect of the thigh, proximal to the knee joint and participants were asked to flex their hip against resistance (Figure 3.10a). Hip extensor strength was assessed with the participant lying prone with hips and knees extended. The dynamometer was placed on the posterior aspect of the distal hamstrings proximal to the posterior knee joint and the participant was asked to extend their hip against resistance (Figure 3.10b). The prone position for hip extension has proven validity and reliability (Eek et al., 2006, Thorborg et al., 2010, Herbert et al., 2011, Mentiplay et al., 2015).



Figure 3.10: Hip flexor (a) and hip extensor strength (b) test positions

Hip abduction and adduction were assessed in a supine position (Eek et al., 2006, Herbert et al., 2011). To test hip abduction, the participant had knees extended. The dynamometer was placed on the lateral aspect of the fibula, proximal to the ankle joint (Figure 3.11a). Participants were asked to maintain their foot in a vertical position and abduct their hip against resistance. Hip adductors were also assessed with the participant in supine with knees extended. The dynamometer was placed on the medial aspect of the distal tibia, proximal to the ankle joint (Figure 3.11b). Participants were asked to maintain their foot in a vertical position and adduct their hip against resistance. For all lower limb muscle group strength testing, participants were asked to stabilise their position by holding the edges of the plinth during the test.

Thoborg et al. (2010) established intra-operator reliability for hip strength measures using a hand-held dynamometer. The test-retest measurement variation for hip abduction, hip internal/external rotation, and hip flexion was below 5%. The test-retest measurement variation for hip adduction and hip extension were 6% and 8%, respectively. These criteria were used to report “clinically meaningful” changes in these measures.

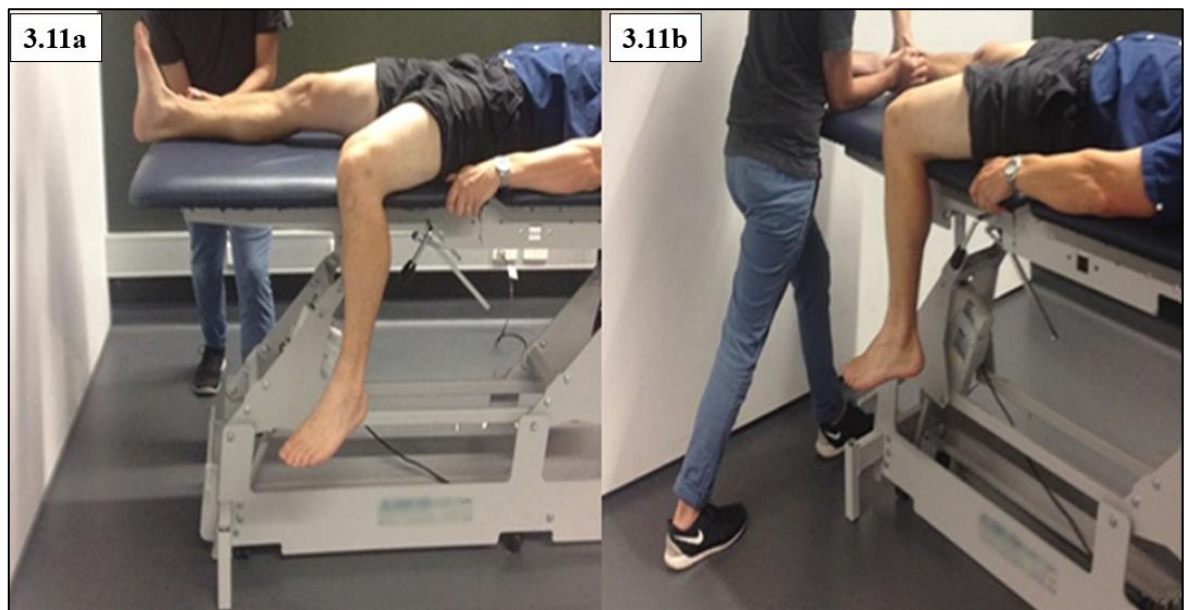


Figure 3.11: Hip abductor (a) and hip adductor (b) strength test positions

Upper trapezius muscles were assessed with the participant in sitting as described by Michener et al. (2005). The dynamometer was placed over the superior scapula and the participant was asked to elevate the scapula against resistance (Figure 3.12a). The lower trapezius muscles were tested with the participant in prone with the shoulder placed at 145° abduction, external rotation of the humerus, arm straight with thumb facing upwards. The dynamometer was placed on the styloid process of the ulna and the participant was asked to flex their shoulder against resistance (Donatelli et al., 2000). Participants were instructed to ‘keep your elbow straight, thumb pointing upwards, now lift your arm’ (Figure 3.12b).

Michiner et al. (2005) established the minimal detectable change (MDC90) for upper (3.3kg) and lower trapezius (2.6kg) strength using a hand-held dynamometer. These criteria were used to report “clinically meaningful” changes in these measures.



Figure 3.12: Upper trapezius (a) and lower trapezius (b) strength test positions

The latissimus dorsi muscle was tested in sitting. The elbow was in 90° of flexion and the shoulder in 30° of extension using a standard baseline 12-1000 goniometer (Baseline Evaluation Instruments, White Plains, NY, USA) (Figure 3.13). The dynamometer was placed on the posterior aspect of the upper arm, just proximal to the elbow. The participant was asked to extend the shoulder against resistance (Celik et al., 2012). Celik et al. (2012) evaluated the intra-operator reliability of this latissimus dorsi strength testing procedure. The test was deemed to have excellent reliability with ICCs above 0.91. The reported mean difference between test 1 and test 2 of 1kg was used to report “clinically meaningful” changes in this measure.



Figure 3.13: Latissimus Dorsi strength test position

3.5.6.3: Identifying muscle weakness

Normative mean data established by Hébert et al. (2015) was used to identify deficits in hip abduction and extensor strength. The median (50th percentile) score for the healthy control group, collected in Chapter 4 (Study 2), was used as a benchmark for the remaining muscles and muscle groups. In addition to the muscle and muscle group assessments described above each participant was assessment for left/right asymmetry in muscle strength. According to Knapik et al. (1983), asymmetry in muscle strength greater than 15% between left and right sides in athletes may increase the risk of injury. A literature review by Orchard et al. (2005) indicates a reference value of less than 10% disparity between left and right-sided muscles as a marker for return to play in sports. Any muscle or muscle group strength disparity between left and right sides, greater than 10% was identified as a deficit in the studies of this thesis.

3.5.6.4: Lumbar strength

Back muscle strength was measured using a Takei back-D dynamometer (Model T.K.K.5402, Takei, Tokyo, Japan) (Figure 3.14b). The reliability and validity of using a

Takei back-D dynamometer for assessing back muscle strength have been established (Coldwells et al., 1994).

Each participant was instructed to stand upright on the base of the dynamometer with feet shoulder-width apart and with arms in a neutral position. Participants were instructed to grasp the handle with both hands with palms facing toward the body. Participants' knees were flexed to 110° (measured with a standard Baseline 30cm 12-1000 goniometer). The investigator adjusted the chain attaching the handle to the dynamometer until there was no slack in the system (Figure 3.14a).

Participants were instructed to maintain an upright head position, straight thoracic spine and look straight ahead. Participants were instructed to extend their torso against resistance and pull steadily with maximal strength against resistance (with no stop–start movements), while keeping their feet flat on the base of the dynamometer. A digital screen recorded their efforts in kg. Encouragement was given for each attempt ('pull, pull, pull'). Warm-up consisted of two submaximal efforts. Three maximal tests were recorded with a one-minute rest in between efforts. The maximum score achieved to the nearest 0.5kg was recorded in the participant's CDCS.

To the author's knowledge, no normative data for the lumbar strength Back D test exists for children and adolescents. Recent systematic reviews by Brady et al. (2020) and Grgic et al. (2022) did not include non-athletic children or adolescents in the studies selected. For the purposes of this thesis, the median (50th percentile) score identified from the healthy control group in Chapter 4 (Study 2) was used as the cut-off point for identifying a deficit for this test throughout this thesis. Hannibal et al. (2006) established the test-retest reliability of the lumbar strength test in a cohort of 72 adolescents. Their root mean square error (RMSE) of 4.92kg for males and 3.25kg for females were used as the criteria for reporting "clinically meaningful" changes.

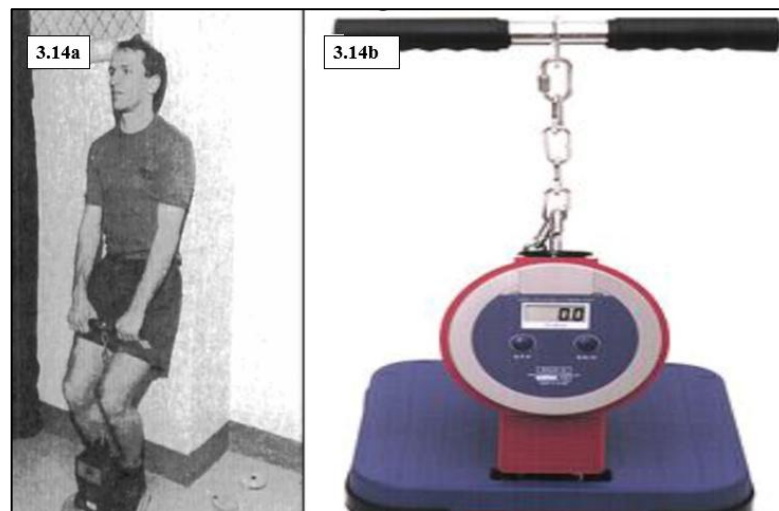


Figure 3.14: Leg back dynamometer testing

Source: Coldwells et al. (1994) (a) and Takei back-D dynamometer (b).

3.5.6.5: Grip strength

Grip strength was measured using a Takei digital grip strength dynamometer (Model TKK 5401, Takei, Tokyo, Japan) (Figure 3.15). The reliability and validity of the TKK handgrip dynamometer have been established (Cadenas-Sanchez et al., 2016). Artero et al. (2011) carried out a systematic review in children and adolescents and found the TKK handgrip dynamometer to be a reliable method of muscle testing with ICC coefficients ranging from 0.96 to 0.98, and no significant differences at $P > 0.05$. These studies supported an earlier systematic review which found the TKK handgrip dynamometer to be a reliable method of assessing upper limb strength in 12–16-year-olds (Castro-Pinero et al., 2010).

In accordance with the procedure described by Cadenas-Sanchez et al. (2016) the grip size of the Takei dynamometer was adjusted for each participant in the studies of this thesis to 90° flexion between the proximal and inter-phalangeal joint. Each participant was standing with their feet hip-width apart, toes pointing forward, knees comfortable but not bent, shoulders back, chest up, head level with eyes straight ahead and arms at side, elbows in full extension and with the palm of the hand facing medially. With the dynamometer set at zero, the participants were instructed to grasp the dynamometer between their fingers and the palm at the base of the thumb in line with the forearm at thigh level not touching the body. The participants were reminded that neither the hand nor the dynamometer should touch the body or any other object during the test. The participants were encouraged to squeeze the dynamometer with maximal strength ('squeeze, squeeze, squeeze, try harder'). Warm-up consisted of two bilateral sub-maximal attempts prior to testing. Three assessments were conducted for alternating left and right hands, with a 30-second rest between each hand

assessment. The dynamometer was reset to zero after each attempt. The maximum score achieved to the nearest 0.5kg was recorded in the participant's CDCS. Normative mean data established by Tomkinson et al. (2018) was used to establish deficits in hand grip strength.



Figure 3.15: Takei digital grip strength dynamometer

3.5.7: Muscle endurance

Upper limb endurance was measured using the push-up test (Liguri, 2021) (Figure 3.16). A standard gym mat and a 2cm foam block was used for this assessment. Female participants used the modified knee push-up test, on their knees, lower legs contacting the mat, ankles plantar flexed, back straight, hands shoulder-width apart, head up, with the knees as the pivot point. Male participants used the standard push-up test, hands pointing forward and positioned under the shoulder, back straight, head up, with toes as the pivot point.

Participants started in a 'down' position, raising their body to straight elbows and then lowering their chin to the foam block without the body touching the ground. Participants were required to always maintain a straight back. Participants were encouraged ('keep going, another one') to perform as many full-range push-ups/modified push-ups as possible without pausing until failure. The test was stopped when a participant failed to complete a push-up, their body touched the mat, or they were unable to maintain their back in a straight position. The total number of push-ups achieved was recorded in the participant's CDCS.

Hoffman (2006) established normative values for male/female push-ups to failure across the age ranges. This is the criterion used by National Strength & Conditioning Association (NSCA) the leading strength & conditioning association in the USA. The 50th percentile

(median) was used as the cut-off point. Participants in the studies of this thesis who scored below the 50th percentile for age and gender were classified as having an upper limb endurance deficit.



Figure 3.16: Modified push-up test

Lower limb muscle endurance was measured using a bilateral one-legged wall-squat test (Mackenzie, 2005). Participants were requested to stand comfortably with feet shoulder-width apart, with their spine and pelvis against a smooth vertical wall and hands on hips (no wall support with arms or hands). Participants were instructed to slide their spine and pelvis down the wall until achieving a position where both knees and hips formed a 90° angle, as measured with a goniometer (Figure 3.17). The test commenced when the participant was in position and the investigator said 'go' and the participant lifted one foot off the ground. The test was stopped when the participant could not maintain the correct position, the raised leg was supported by the stable leg, or the raised foot is returned to the ground. Encouragement was given throughout the test ('keep going, keep going'). An iPhone stopwatch was used to record the time achieved. A rest period of 1 minute was given prior to testing the opposite leg. Times achieved for left and right lower limbs were recorded in the participant's CDCS in (s). To the author's knowledge, no normative data exists for single-leg wall squats (SLWS) in the child and adolescent population. Lubans et al. (2011) included the SLWS during strength testing of 68 adolescents and used the average time achieved between the left and right side as their main outcome measure of lower limb muscle endurance. In Chapter 6 (Study 4) the median (50th percentile) score for the healthy control group was used as the cut-off point for this test. Participants who scored below the 50th percentile for age and gender were classified as having a lower limb endurance deficit.

Lubans et al. (2011) established the test-retest reliability of both the Wall Squat Test and push-up test in a cohort of 68 adolescents. The reported standard error of the measurement (SEM) for the Wall Squat Test was 12.3s while the SEM for the push-up test was 1 repetition

(Lubans et al., 2011). These criteria were used to report “clinically meaningful” changes in upper and lower limb muscular endurance.



Figure 3.17: Single leg wall-squat test

3.5.8: Balance

Balance and postural control are the ability to keep the centre of mass (COM) within the base of support with minimal sway (Cho et al., 2014). Balance was assessed using the modified Balance Error Scoring System (mBESS). This test is frequently used by researchers and clinicians to assess balance (Bell et al., 2011, Ozinga et al., 2018). The BESS includes three stances: double-leg stance (hands on hips with feet together), single-leg stance (standing on the nondominant leg with hands on hips), and tandem stance with the nondominant foot placed behind the dominant foot in a heel-to-toe position. The stances are performed on a hard and a soft surface. The mBESS assesses double-leg, single-leg, and tandem stance on a firm surface only (with eyes open and eyes closed). A systematic review of the BESS test found it to be reliable and valid for balance testing in children and adolescents (Bell et al., 2011). It has moderate test-retest reliability ($ICC=0.70$), as well as good content, construct, and criterion validity. Sheehan et al. (2011) established good intra-rater ($ICC=0.83$) and inter-rater ($ICC=0.85$) reliability for mBESS outcome measures.

Participants' static balance was further assessed during the mBESS, by measuring deviations in Centre of Pressure (COP) using calibrated 80x60 cm balance platform (HUR Labs, Tampere, Finland) (Figure 3.17). Data from four force sensors positioned at the corners of the balance platform were used to determine the X and Y vertical coordinates of participants'

centre of pressure (COP). This information was recorded and analysed on a Dell Inspiron laptop (Dell, Texas, USA) using HURLabs iBalance software (iBalance Premium Ver 2.4, HURLabs, Tampere, Finland).

Two static balance variables were calculated from the recorded COP data: mean sway velocity and C90 area. Mean sway velocity ($\text{mm}\cdot\text{s}^{-1}$) represents the total distance travelled by the COP divided by the time duration of the test and was determined by dividing the total trace length by the test duration (20 seconds) (Lee et al., 2021). The trace length on the posturogram was calculated by summing the straight-line segments connecting successive COP points, which were separated by 5ms (200 Hz). The C90area (mm^2) is the area of the 90% confidence ellipse. Both mean sway velocity and C90area were calculated within the HUR balance software using the following 2 equations:

$$\text{C90area (mm}^2\text{)} = 4.605 * \pi * \sum [C_{xx} * C_{yy} - (C_{xy})^2]^{0.5},$$

$$\text{where } C_{xx} = \sum (x_i - x_m)^2 / (n-1), C_{yy} = \sum (y_i - y_m)^2 / (n-1) \text{ and } C_{xy} = \sum (x_i - x_m) * (y_i - y_m) / (n-1)$$

$$\text{Mean Sway Velocity (mm}\cdot\text{s}^{-1}\text{)} = \sum d / t, \text{ where } d = [(x_i - x_j)^2 + (y_i - y_j)^2]^{0.5} \text{ and } t = \text{time}$$

Before each test, the HUR balance platform was connected to a laptop specifically set up with HUR balance software. Participants' unique coded details were inputted together with gender, height, weight, and date of birth. The platform was positioned consistently for each test in the exercise laboratory, using permanent floor markers to ensure precision. In addition, a marker was set at eye level for each participant, on the wall facing the balance platform. For each static test, participants were asked to take the appropriate position on the balance platform. A timer commenced with a 5-second countdown and a buzzer signalled the start of the test. The duration for each test was 20 seconds. For eyes-open tests, participants were instructed to focus on the wall marker set in front of the balance platform. For the eyes-closed tests participants were instructed to close their eyes once they had assumed the correct testing position at the end of the 5-second countdown. One trial was carried out in each test position.

For the bilateral stance, participants were asked to stand on the balance platform (HUR) in their bare feet, heels and foot position aligned to the set HUR board markers (Figure 3.18a). For the single-leg stance, standing on the non-dominant leg, the dominant leg was placed and held at 30° hip flexion and 40°-50° knee flexion (Figure 3.18b). For the tandem stance, the participants were instructed to stand with the non-dominant foot behind the dominant, in a heel-to-toe position, without letting their feet touch (Figure 3.18c). For each test, the foot

positions were clearly marked on the HUR platform. For all tests, participants were required to keep their hands on their hips.

When a participant's balance tests were completed the C90 area (mm^2) and sway velocity (mm.s^{-1}) data were exported in an Excel file from the HUR balance laptop to the encrypted research laptop specific to this thesis, for data analysis. In addition, the HUR balance software automatically compares the participant's data to its own normative data set and identifies deficits in the participants (<https://www.hur.fi/en/product/2001-balance-trainer>). The HUR balance system categorises participants into one of three groups: (1) no balance issues, (2) medium balance risk and (3) high balance risk.

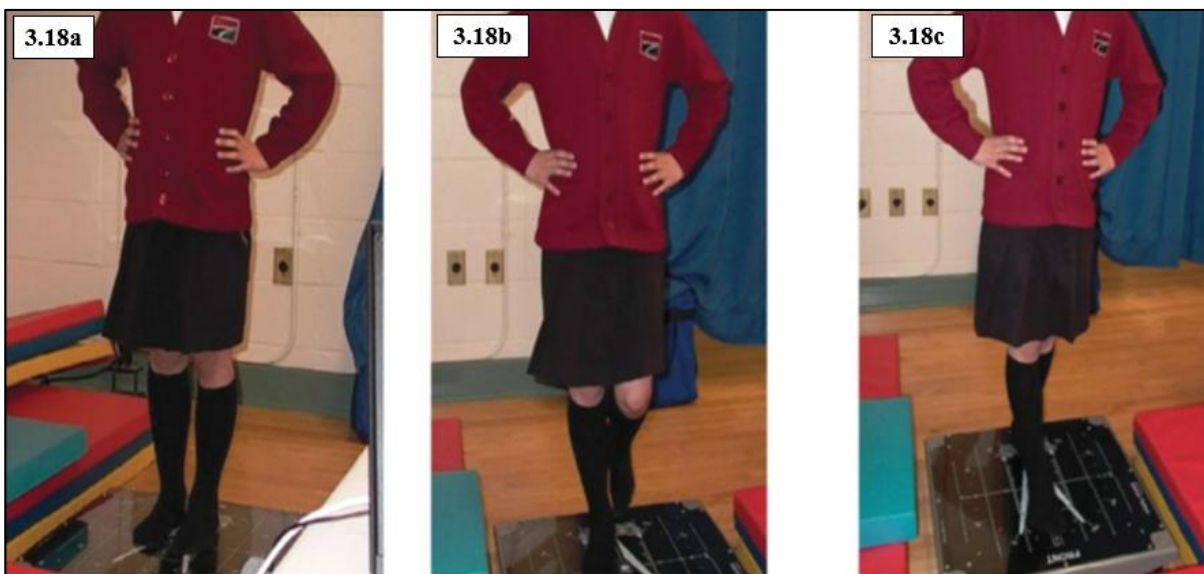


Figure 3.18: Testing on a HUR balance platform during mBESS stages including bilateral stance (a), single stance (b) and tandem stance (c)

Source: Sheehan et al. (2011)

3.5.9: Lower limb power

Lower limb power was evaluated using a countermovement vertical jump conducted on a HUR force plate. The vertical countermovement jump is a recognised and validated technique for assessing the force and power of the lower limbs (Markovic et al., 2004, Slinde et al., 2008). The force plate is considered the 'gold standard' for measuring vertical jump height (Buckthorpe et al., 2012). The outcome measures assessed were maximal jump height (cm), maximum power (W), maximum force (N) and max force/ body weight (N/kg). Force was calculated based on the participant's body mass and the velocity determined from the jump height. Jump height was derived from flight time (time between participant lift-off and

landing on the force plate, and the mean and peak velocities during the vertical jump were used to calculate vertical jump power (Wang, 2017b).

The protocol described by Focke et al. (2013) was used in this thesis (Figure 3.19). Before each test, the HUR platform was calibrated and connected to a laptop specifically set up with HUR force plate software. Participants' unique code was entered in addition to gender, height, weight, and age. The investigator demonstrated the countermovement jump technique, which involved arms akimbo and a squat to 90° (or as far as comfortable), and the participant was encouraged to take a practice jump. The participant then performed three jumps with countermovement with 1 minute's rest in between each jump. The investigator commenced a countdown from eight and the participant performed the jump on the instruction 'go'. Standardised encouragement was given to each participant for each jump 'jump higher'. The participant needed to land upright on the force plate for the jump to be valid. Additional steps or stumbles were not allowed. In the event of an error, the jump was retaken after 1 minute's rest. At the conclusion of the test, the participant's outcome measures were downloaded into an Excel document and exported to the encrypted research laptop specific to this thesis, for data analysis. Outcome measures include maximal jump height (cm), maximum power (W), maximum force (N) and max force/ body weight (N/kg). The best score of the three jumps was selected for analytical purposes.

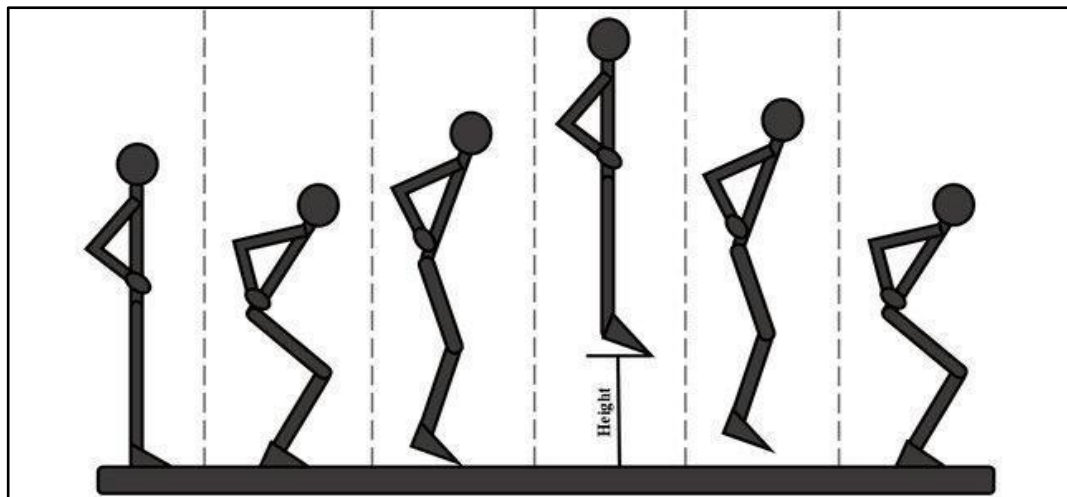


Figure 3.19: Lower limb power assessment on force platform.

Source: Vanegas et al. (2021)

3.5.10: Upper limb power

Upper limb power was assessed using a seated medicine ball throw. This test is a recognised and valid method to assess upper limb power (Clemons et al., 2010). The assessment is

regarded as easy to administer and has direct specificity to upper limb functional power movement (Clemons et al., 2010)

The protocol described by Clemons et al. (2010) was used in this thesis (Figure 3.20). The equipment required was a 45° incline bench, medicine balls 6kg (female) and 9kg (male), chalk and measuring tape. Prior to the test, a measuring tape was fixed to the floor directly below the participant's sternum and extended adjacent to the gym mats directly in line with the flight of the ball. A supervised 3-minute warm-up was conducted, consisting of dynamic shoulder flexion, extension, abduction exercises and modified wall push-ups. The investigator demonstrated the test, including the correct body position and the placement of the ball on the sternum. The participant was seated, feet flat on the ground, ball against chest, hands on both sides of the ball. Participants were permitted three submaximal ball throws to familiarise themselves with the technique. The ball was then marked with chalk to identify where it landed on the mat. Participants propelled the ball with maximum effort at a 45° angle with no counter-arm movement or trunk flexion. There was a 1-minute rest between each attempt. Standardised encouragement was given to each participant 'push, push'. The distance between the participants sternum to the nearest point on ball impact (chalk mark on the gym mat nearest to the participant) was measured using the floor tape. The maximum distance achieved after 3 attempts to the nearest centimetre was recorded in the participant's CDCS.



Figure 3.20: Seated medicine ball throw

3.6: Data collection, screening, protection, and storage

3.6.1: Data collection

Data collected during each assessment was recorded on Clinical Data Collection Sheets (CDCS) (Appendix 9). Additional data were also collected on the questionnaires, International Physical Activity Questionnaire (IPAQ), and the Scoliosis Research Society version 22r questionnaire (SRS-22r).

All participant data recorded on the CDCS forms, and the completed questionnaires were transferred to a password-protected master Excel document. Digital data from exercise capacity testing, HUR balance tests, and force plate tests were downloaded immediately after the assessments were completed and uploaded to a password-protected laptop file. Digital data were subsequently transcribed into the master Excel document for analytical purposes. The data were analysed in Excel in group format. In Chapter 6, (Study 4) data were also analysed for individual participants. Only necessary data were collected and analysed and no reference to individuals was made at any stage in the process.

3.6.2: Data screening

Before analysis commenced, the Excel document containing the data for each test was screened for any anomalies. All individual data entries in the Excel file were rechecked against the original CDCS documents by a third party to ensure accuracy. When screening was complete, the Excel data, in its coded form, was transferred into GraphPad Prism (version 10.0.0 for Windows) for statistical analysis. Results were processed in aggregate form, with no reference to participants' details at any stage of the process.

3.6.3: Data storage and protection

All hardcopy records (CDCS and questionnaires) were stored securely in compliance with ethical requirements. A separate document (key code) contained the names of participants, and the unique codes allocated to participants. This document was retained in hard copy in a locked cabinet in a secure room in the Trinity Centre, St James's Hospital. Only the principal investigator had access to this document. No other documents, files or information relating to the project was stored with the key codes. A data protection impact assessment (DPIA) was completed and approved by the TCD Data Protection Officer and the ethics committees from the clinical sites.

Chapter 4: An assessment of strength, endurance and power, exercise capacity, pulmonary function, balance, and quality of life in patients with AIS when compared to healthy controls.

4.1: Introduction

The primary focus of research on Adolescent Idiopathic Scoliosis to date has been on Cobb angle development over time and the changes in the angle of trunk rotation (ATR) (Burger et al., 2019, Thompson et al., 2019, Fan et al., 2020, Khaledi et al., 2022, Schreiber et al., 2023). Patients with AIS are monitored to establish the extent of curve progression and trunk rotation. As a result, the focus in the existing treatment pathways for patients with AIS in Ireland is primarily on maintaining the normal curvature of the spine. Deficits in muscle strength (Martínez-Llorens et al., 2010, Rafferty et al., 2020), balance (Dufvenberg et al., 2018), cardiorespiratory function (Sperandio et al., 2014) and quality of life (QOL) (Gallant et al., 2018, Wang et al., 2021) have been identified in patients with AIS. These deficits are not assessed or monitored during clinical visits. Although some sequelae have been identified in pulmonary function (Negrini et al., 2018, Kempen et al., 2022), they are not routinely monitored during clinical visits. In addition, the relationships between curve severity in AIS, its progression, and the resultant sequelae have not been established.

A potential concern is the lack of a standardised assessment process within the current treatment pathway to identify potential musculoskeletal, cardiorespiratory, balance, or quality-of-life impairments that may be present throughout the spectrum of AIS, including post-surgical review.

4.1.1: Pulmonary function

There is general agreement that AIS can have a negative effect on pulmonary function (Negrini et al., 2012, Negrini et al., 2018). Pulmonary impairments in the AIS population are complex and include abnormal ventilation patterns, mainly restrictive, (Martínez-Llorens et al., 2010), impaired function of respiratory muscles (Lisboa et al, 1985, Weiss & Maier-Hennes 2008), restriction and asymmetric motion of the chest wall, with localised alterations (Kotani, 2002). Furthermore, abnormal patterns of ventilation during exercise have also been identified (Estenne et al., 1998, Leong et al., 1999). The possible causes of these impairments are outlined in the SOSORT 2016 guidelines (Negrini et al., 2011) and include reduced side flexion, vertebral rotation, and thoracic cage stiffness (Kafer, 1975, Takahashi et al., 2007, Weiss and Goodall, 2008, Anwer et al., 2015).

The relationship between curve progression in AIS and its manifestation as a pulmonary impairment is still uncertain and inconclusive (Kempen et al., 2022). Weinstein et al. (1981) proposed that curves over 70° could lead to pulmonary impairments in patients with AIS, and subsequently Loinstein, (1994), Newton, (2005), and Danielsson, (2013) established that curves over 50° could do so. However, more recent studies have presented evidence of pulmonary impairment in patients with curves exceeding 30° (Negrini et al., 2012, Sperandio et al., 2015). Other studies have contended that pulmonary dysfunction is an unusual occurrence in patients with mild or moderate AIS (Barrios et al., 2005, dos Santos Alves et al., 2006).

A recent systematic review and meta-analysis examining the effects of curve progression on untreated AIS argued that pulmonary impairments might commence earlier in the curve spectrum than previously thought (Kempen et al., 2022). This study established an inverse relationship between thoracic Cobb angle and lung function. The authors contended that curve progression in AIS might be linked to restrictive lung disease. Given the ongoing debate about curve progression and pulmonary impairments, one of the aims of the current study was to establish at what stage of spinal curve progression (mild, moderate or severe) were pulmonary impairments identified.

4.1.2: Exercise capacity

Exercise capacity has been defined as ‘the maximum amount of physical exertion that a person can sustain’ (Goldstein et al., 1990). The gold standard for measuring exercise capacity is maximum oxygen uptake (VO₂max) which measures the body’s ability to transport oxygen to the musculoskeletal system. In patients with scoliosis, several potential factors could influence exercise capacity such as decreased spinal movement and weakened respiratory muscles (Weinstein, 2003). In addition, individual motivation (Shneerson, 1980) and an individual’s fitness level can also contribute to the outcome (Kesten et al., 1991).

Previous studies have indicated that patients with severe AIS have restrictions in exercise capacity (Chong et al., 1981, Barrios et al., 2005, Czaprowski et al., 2012, Sperandio et al., 2014). Controversy surrounds the effect mild and moderate AIS has on exercise capacity. There is some evidence that moderate AIS can restrict exercise capacity. Barrios et al., (2005) found significantly reduced VO₂max and reduced workload in patients with moderate AIS. Czaprowski et al. (2012) supported the results from Barrios et al. (2005) for those with moderate AIS but found no significant deficit in exercise capacity in patients with mild AIS. Abdelaal et al. (2018) on the other hand, identified reduced exercise capacity in patients with

mild AIS. It is worth noting that some differences in methodology exist between the above studies. Barrios et al., (2005) used a maximal VO₂max test on moderate AIS participants using a cycle ergometer. Czaprowski et al. (2012) included both mild and moderate AIS participants and used a submaximal VO₂max test on a cycle ergometer. Abdelaal et al. (2018) only included participants with mild AIS and used distance in a 6-minute walk test (6MWT) as a key outcome measure for exercise capacity. These differences in approach may have influenced the outcomes reached in each of these studies.

There is currently limited research into the effects of mild and moderate AIS on exercise capacity. This study aims to enhance our understanding of how spinal curvature influences exercise capacity across the spectrum of mild, moderate, and severe AIS.

4.1.3: Muscle strength, endurance, and power

Very few studies have focused on peripheral muscle strength, endurance, and power in patients with AIS. Research has primarily focussed on the effectiveness of PSSE (Ramadhani et al., 2022, Seleviciene et al., 2022, Ma et al., 2023, Schreiber et al., 2023,). The principal focus of physiotherapeutic rehabilitation programmes, and consequently recent research, has been on Cobb angle stabilisation or reduction. The main emphasis in PSSE programmes is the targeting of core stabilisation, and paraspinal and abdominal muscle strength (Berdishevsky et al., 2016).

At a physiological level, Sahgal et al. (1983) observed alterations in fibre size and the distribution of muscle fibres in paraspinal muscles on both the concave and convex sides of the apex of the spinal curve in patients with scoliosis. Muscle fibre atrophy was identified exclusively on the concave side. Paz et al. (2015) also examined morphological and morphometric changes in the deep back muscles and the intercostal muscles of the thorax in patients with severe AIS. This study found fibre atrophy on the concave side of the scoliosis curve in both intercostal and paraspinal, supporting the view that AIS has a negative systemic effect on paraspinal muscle structures.

A small number of studies have examined the effects of AIS on peripheral muscle strength. Martinez-Llorens et al. (2010) compared 60 adolescents with non-surgical AIS who had Cobb angles over 40° with 25 normal adolescents and found deficits in handgrip and knee extensor strength. Hassan and Mohammad (2015) assessed hip abductor and adductor muscle strength in 44 adolescents with moderate to severe AIS compared to a healthy control group. This study found significant hip abductor muscle weakness in the AIS group. A more

recent study found significant upper and lower limb muscle weaknesses in post-operative patients with AIS (Rafferty et al., 2020).

Danielsson et al. (2006) reported lumbar muscle endurance significantly decreased in both a post-operative cohort of participants with AIS and a group of participants with moderate AIS when compared to healthy controls in a 20-year longitudinal study. The majority of participants in the studies to date on strength and endurance were diagnosed with moderate to severe AIS. Very few participants with mild AIS were included. Notably, research examining the effects of spinal curve progression on muscle endurance or power remains absent from the current literature.

4.1.4: Balance

Currently, there is no consensus on whether patients with AIS have similar balance when compared to the normal population. Several studies report no differences in patients with AIS compared to healthy controls (Schimmel et al., 2015, Le Berre et al., 2017). Other studies have argued that patients with AIS have poorer balance compared to a healthy population (de Santiago et al., 2013, Dufvenberg et al., 2018, Larni et al., 2023). The latter study contends that the key reasons for reduced balance in the AIS population are consequential to either sensory-motor processing or biomechanical abnormalities (de Santiago et al., 2013). Biomechanical shortcomings have been linked to spinal deformity and deviations from the centre of gravity, muscle asymmetry, and muscle dysfunction. (de Santiago et al., 2013). The hypothesis behind sensory-motor processing negatively affecting balance in those with AIS is based on the theory that motor responses from the central nervous system are compromised (Le Berre et al., 2017, Wilczynski et al., 2023). There is currently no agreement as to whether static balance and postural sway abnormalities exist in the AIS population and if these abnormalities exist when they appear in the AIS curve spectrum.

4.1.5: Quality of life

There is well-documented evidence that long-term psychological problems can develop in patients with AIS (Kotwicki et al., 2013). Patients with AIS exhibit higher levels of depression, anxiety (Gallant et al., 2018), and social isolation (D'Agata et al., 2017). A literature review by Pyatakova et al. (2019) considered AIS to be a risk factor for a range of psychological manifestations including stress, anxiety, body image, low self-esteem, and poor communication skills. This review highlighted higher levels of mental disorders in the AIS population including depression and suicidal ideation. An earlier health-related quality

of life (QOL) longitudinal study by Danielsson et al. (2001) found that patients with AIS had significantly higher pain perception scores, reduced physical function, and poorer general health than healthy controls. Furthermore, Mitsiaki et al. (2022) supported previous literature on the subject and concluded that AIS was a risk factor for mental health disorders.

Wang et al. (2021) found higher levels of mental health disorders and negative self-image in patients with AIS treated with bracing compared to those treated without bracing. Fernandes et al. (2019) examined the effects of surgery on the mental health of patients with AIS. Their findings, based on pre-and post-operative interviews, suggest surgery had a significant positive effect on body image; however, mental health scores did not significantly improve.

It is important to consider that females are 8-10 times more likely to develop scoliosis than males (Lonstein, 2003). Curve development predominately takes place at the onset of puberty, which can result in low body mass and negative self-image (Tarrant et al., 2016, Tarrant et al., 2014a). No study to date has compared mental health, body image, and pain perception across the spinal curve spectrum, in patients with AIS.

To date research examining the relationship between curve severity in patients with AIS and their associated muscle strength, endurance and power, exercise capacity, pulmonary function, balance, and QOL is limited. Therefore, the primary aim of this study was to examine the impact of curve severity in AIS on muscle strength, endurance and power, exercise capacity, pulmonary function, balance, and QOL when compared to a healthy cohort. A secondary aim was to establish if a relationship exists between the degree of spinal curvature and any of the outcome measures noted above.

4.2: Methodology

4.2.1: Study design

A cross-sectional cohort study design was used in this study. All participants, including patients with AIS and healthy controls, were assessed on one occasion using the assessment procedure outlined in Section 3.5. Ethics approval was obtained for this study between June and September 2019 (see Section 3.1 for full description). Based on an expected effect size of $f=0.635$ for differences in predicted FVC between patients with AIS and healthy controls (Saraiva et al., 2018), a P-value of 0.05, and a statistical power of 85%, the required sample size was estimated at $n=33$. A total of 49 participants were recruited for this study.

The control group was recruited from a non-athletic population and met the inclusion and exclusion criteria set out in sections 3.3.1 and 3.3.2.

4.2.2: Recruitment

A full description of the recruitment and consent process is outlined in Section 3.2. Data collection started at the beginning of March 2020. Recruitment for this study faced significant disruption due to the COVID-19 pandemic and the cyber-attack on the HSE (Section 3.2.1).

4.2.3: Participant screening

Screening for inclusion into the study is described in detail in Section 3.3. The inclusion criteria for control, mild and moderate and severe AIS cohorts are described in Section 3.3.1, while study exclusion criteria are described in Section 3.3.2

4.2.4: Assessment and outcome measures

Assessments were conducted at the exercise laboratory located in Trinity Centre for Health Sciences, St. James's Hospital, Dublin. A summary of the assessment protocol is outlined in detail in Section 3.4. A detailed description of the outcome variables assessed, and equipment used is provided in Section 3.5.

4.2.5: Data collection and processing

Data collection and processing is described in detailed in Section 3.6.

4.2.6: Data analysis

Due to the lower-than-expected number of participants recruited consequential to the COVID-19 pandemic and the HSE cyber-attack, data for the mild and moderate AIS participants were combined for statistical analysis. Statistical analysis was conducted using the statistical software package, GraphPad Prism (GraphPad Prism version 10.0.0 for

Windows). Data collated in Excel from the assessments were copied in columnar form into separate outcome variable files in GraphPad Prism.

The Kolmogorov Smirnov test (Eadie et al., 1971, Wayne, 1990) was used to establish if data sets were normally distributed. Group results are presented as mean ($\bar{x}$) $\pm$ standard deviation (SD). Statistical testing to compare the three groups (mild and moderate AIS, severe AIS, and healthy controls) was undertaken using a one-way ANOVA for normally distributed data. Tukey's multiple pairwise comparisons test was used when results from the one-way ANOVA were identified as statistically significant ($P < 0.05$). The F-ratio was calculated to establish the source of variation (between group variance to within group variance). For data that was found to be not normally distributed the Kruskal-Wallis test was applied (non-parametric) for continuous data and categorical data. Dunn's post-hoc pairwise comparison was calculated when a result was found to be statistically significant ($P < 0.05$). A H-statistic was also calculated for non-parametric data to determine if the medians of the group's outcomes were different.

A Pearson's correlation coefficient was used to measure the strength and direction of the relationship between thoracic and lumbar spinal curve and Cobb angle for any outcome measure that was found to have a significant difference in the one-way ANOVA tests. For non-parametric data, Spearman's correlation coefficients were used. In all cases the strength of correlations was defined as follows: 0 - 0.10 (Negligible); 0.10 - 0.39 (Weak); 0.40 - 0.69 (Moderate); 0.70 - 0.89 (Strong); 0.90 - 1.00 (Very strong) (Schober et al., 2018). A simple regression analysis was used to establish if a predictive relationship existed between the outcome variables with significant ANOVA results and the severity of the lumbar and thoracic curves.

4.3: Results

4.3.1: Demographic and anthropometric measurements

Fifty-three participants were initially recruited for this study. Three were deemed ineligible due to their participation in elite-level sports. A further participant was also removed from the study following a diagnosis of Prader-Willi syndrome. Forty-nine participants completed the study (n=39 female; n=10 male). Sixteen participants were diagnosed with severe AIS, 15 participants had mild or moderate AIS, and 18 healthy control adolescents also participated. All participants except one individual (Asian) were Caucasian. The mean (SD) age, height, body mass, and BMI for the control, mild/moderate AIS, and severe AIS groups are presented in Table 4.1. There was no statistically significant difference identified between the groups for any of these variables ($P = 0.05$).

Table 4.1. Demographics and anthropometrics by group

Outcome Measures	Control (n=18) mean $\pm$ SD	Mild and moderate AIS (n=15) mean $\pm$ SD	Severe AIS (n=16) mean $\pm$ SD	Overall Effect (F, P)
Biological sex (F/M)	n=14/4	n=11/4	n=14/2	
Age (years)	15.9 $\pm$ 2.1	14.5 $\pm$ 2.2	14.8 $\pm$ 1.0	F=2.97 P=0.067
Height (cm)	165.7 $\pm$ 10.3	164.3 $\pm$ 6.5	163.5 $\pm$ 6.6	F=0.32 P=0.730
Mass (kg)	54.8 $\pm$ 12.8	52.8 $\pm$ 9.6	54.2 $\pm$ 10.2	F=0.14 P=0.143
Body Mass Index (kg/m ²)	20.0 $\pm$ 3.2	19.4 $\pm$ 2.8	20.4 $\pm$ 3.7	F=0.39 P=0.681
Thoracic curve (°)	-	19.1 $\pm$ 13.2	59.7 $\pm$ 10.3	-
Lumbar curve (°)	-	16.1 $\pm$ 14.9	44.7 $\pm$ 24.6	-

4.3.2: Blood Pressure Measurements

An analysis of mean diastolic blood pressure (mmHg) demonstrated significant inter-group differences (Table 4.2). Multiple pairwise comparison showed that the severe AIS group had a significantly higher diastolic blood pressure when compared to controls (74 ± 5 vs. 68 ± 7 , $P=0.021$) (Table 4.2). Diastolic blood pressure (mmHg) was also significantly correlated with increasing thoracic spinal curvature ($r=0.47$) (Figure 4.1). There were no

significant differences in mean systolic blood pressure (mmHg) between groups (Table 4.2). Additionally, no significant differences were identified in the mean resting heart rate (beats.min⁻¹) (MRHR), although a trend toward increasing MRHR with increasing curve severity was apparent.

Table 4.2. Blood pressure and resting heart rate measurements by group and AIS severity

Outcome Measures	Control (n=18) mean $\pm$ SD	Mild and moderate AIS (n=15) mean $\pm$ SD	Severe AIS (n=16) mean $\pm$ SD	Overall Effect (F, P)
Mean systolic blood pressure (mmHg)	109 $\pm$ 9	108 $\pm$ 11	107 $\pm$ 10	F=0.32 P=0.723
Mean diastolic blood pressure (mmHg)	68 $\pm$ 7	69 $\pm$ 6	74 $\pm$ 5*	F=4.19 P=0.021
Mean resting heart rate (beats.min ⁻¹)	68 $\pm$ 14	73 $\pm$ 11	78 $\pm$ 13	F=2.46 P=0.097

Asterisk (*) infers a significant pairwise difference between the control and severe AIS group * P<0.05).

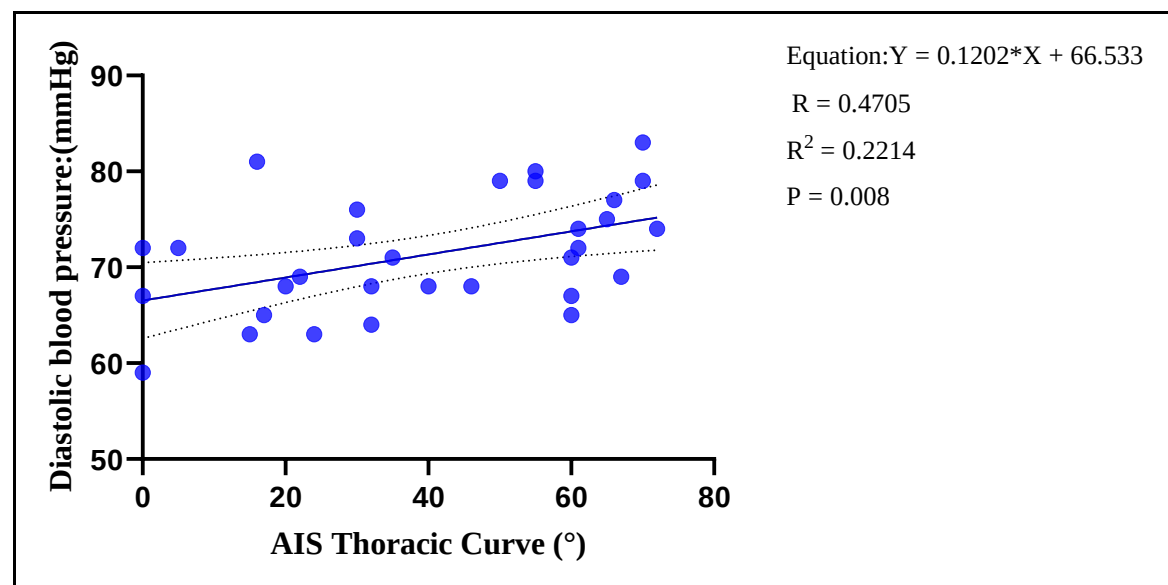


Figure 4.1: Regression of thoracic curvature and diastolic blood pressure.

4.3.3: Pulmonary function

Statistically significant differences in pulmonary function were identified between the control group and both AIS groups for FEV₁ (3.27 $\pm$ 0.63 vs. 2.73 $\pm$ 0.44, and 2.76 $\pm$ 0.49, P=0.007) and multiple pairwise comparison analyses indicated a significantly lower FEV₁

in the mild and moderate AIS group ($P=0.015$) and the severe AIS group ($P=0.020$) when compared to the control group. No significant differences were found between AIS groups for FEV_1 (Table 4.3). Regression analysis indicated no relationship between thoracic or lumbar Cobb Angle and FEV_1 .

Statistically significant differences were also identified between the control group and both AIS groups for FVC (3.74 ± 0.89 vs. 3.05 ± 0.49 , 3.07 ± 0.52 , $P=0.006$). Multiple pairwise comparison analyses highlighted a significant difference with lower FVC in both the mild/moderate ($P=0.013$) and severe ($P=0.016$) when compared to the control group. No significant differences were found between the AIS groups. Analysis of FEV_1/FVC ratio and PEF results indicated no material differences in mean outcomes between the three groups.

Normative values for pulmonary function outcomes (FVC and FEV_1) in adolescents are influenced by sex, height, and age; therefore, a single reference value is insufficient. Predicted values derived from reference equations that account for these variables is used in the Irish healthcare system to identify pulmonary deficits. Lower percentage FVC outcomes are indicative of a restrictive ventilatory impairment (Hall et al., 2021).

In this study, percentage predicted FEV_1 and FVC values indicated significant differences between the control group and both the mild/moderate and severe AIS groups (FEV_1 , $96.3 \pm 13.1\%$ vs. $84.8 \pm 9.6\%$ and $85.2 \pm 14.6\%$, $P=0.017$), (FVC, $96.30 \pm 15.2\%$ vs. $82.8 \pm 9.3\%$, and $84.6 \pm 15.9\%$, $P=0.014$). Multiple pairwise comparisons revealed that both the mild/moderate AIS group ($P=0.024$) and the severe AIS group ($P=0.027$) had significantly lower percentage predicted FEV_1 compared to the control group, with no significant differences observed between the two AIS groups (Table 4.3). Similarly, multiple analyses indicated that the mild/moderate AIS group ($P=0.020$) and the severe AIS group ($P=0.049$) had significantly lower percentage predicted FVC compared to the control group, again with no significant differences between the AIS groups. Analysis of the percentage predicted FEV_1/FVC ratio showed no significant differences in mean outcomes among the three groups ($P=0.929$).

Table 4.3. Pulmonary function by group and AIS severity

Outcome Measures	Control (n=18) mean $\pm$ SD	Mild and moderate AIS (n=15) mean $\pm$ SD	Severe AIS (n=16) mean $\pm$ SD	Overall Effect (F, P)
FEV ₁ (l.sec ⁻¹)	3.27 $\pm$ 0.63	2.73 $\pm$ 0.44 ⁺⁺	2.76 $\pm$ 0.49 ^{**}	F=5.56 P=0.007
FVC (litres)	3.74 $\pm$ 0.89	3.05 $\pm$ 0.49 ⁺⁺	3.07 $\pm$ 0.52 ^{**}	F=5.84 P=0.006
FEV ₁ /FVC (ratio)	89.5 $\pm$ 8.82	88.9 $\pm$ 5.84	89.6 $\pm$ 6.62	F=0.04 P=0.966
PEF (litres)	410 $\pm$ 96.70	338 $\pm$ 81.40	379 $\pm$ 114	F=2.25 P=0.051
Percentage predicted				
FEV ₁ (%)	96.3 $\pm$ 13.1	84.8 $\pm$ 9.6 ⁺	85.2 $\pm$ 14.6 [*]	F=4.47 P=0.017
FVC (%)	96.30 $\pm$ 15.2	82.8 $\pm$ 9.3 ⁺	84.6 $\pm$ 15.9 [*]	F=4.73 P=0.014

(**FEV₁**) forced expiratory volume in 1 second; (**FVC**) forced vital capacity, (**PEF**) peak expiratory flow. Asterisks infer a significant pairwise difference between the control and severe AIS group (** P<0.01, * P<0.05). The plus sign infers a significant difference between the control and mild and moderate AIS group (**P<0.01, +P<0.05).

4.3.4: Exercise capacity

All participants undertook a VO₂max test on a cycle ergometer. Analysis of the results shows a statistically significant difference was observed between the mild/moderate AIS group and the severe AIS group (46.80 $\pm$ 12.70 vs. 36.70 $\pm$ 8.48, P=0.039), with the severe AIS group demonstrating a significantly lower VO₂max. No significant difference in VO₂max was found between the control group and both AIS groups (mild and moderate or severe) (Table 4.4). A significant difference in peak workload was also identified between the control group and the severe AIS group, with the severe AIS group exhibiting a significantly lower output (157 $\pm$ 40.10 vs. 126 $\pm$ 29.00, P=0.040), (Table 4.4). A moderate inverse relationship was also observed between VO₂max (mL·kg⁻¹·min⁻¹) and thoracic curve severity, as well as between peak workload (W) and thoracic curvature (Figures 4.2 and 4.3, respectively). No meaningful differences were found between the groups for predicted maximum heart rate, VO₂max, and peak workload.

Table 4.4. VO₂max, peak workload, and maximum heart rate, by group and AIS severity

Outcome Measures	Control (n=18) mean ± SD	Mild and moderate AIS (n=15) mean ± SD	Severe AIS (n=16) mean ± SD	Overall Effect (F, P)	R
VO ₂ max (mL.kg ⁻¹ .min ⁻¹)	41.90 ± 10.40	46.80 ± 12.70 ⁺	36.70 ± 8.48	F=3.48 P=0.039	-0.48
Max heart rate (beats. min ⁻¹)	175 ± 12.60	181 ± 11.10	175 ± 16.10	F=1.05 P=0.359	-
Peak workload (W)	157 ± 40.10*	147 ± 30.90	126 ± 29.00	F=3.47 P=0.040	-0.36
Percentage predicted outcomes (%)					
VO ₂ max (%)	104.3 ± 25.22	108.2 ± 16.94	93.91 ± 17.14	F=2.05 P=0.147	-
Max heart rate (%)	90.91 ± 6.45	93.91 ± 6.12	90.18 ± 8.45	F=1.21 P=0.31	-
Peak workload (%)	89.32 ± 20.79	82.77 ± 14.03	73.87 ± 17.20	F=3.21 P=0.066	-

(VO₂max) maximal oxygen consumption; (predicted outcomes) difference between the actual value and the predicted value. **Asterisk (*)** infers significant inter-group differences between control and severe AIS groups (* P<0.05). Dollar symbols (\$) infer a significant difference between mild and moderate and severe AIS groups (§ P<0.05).

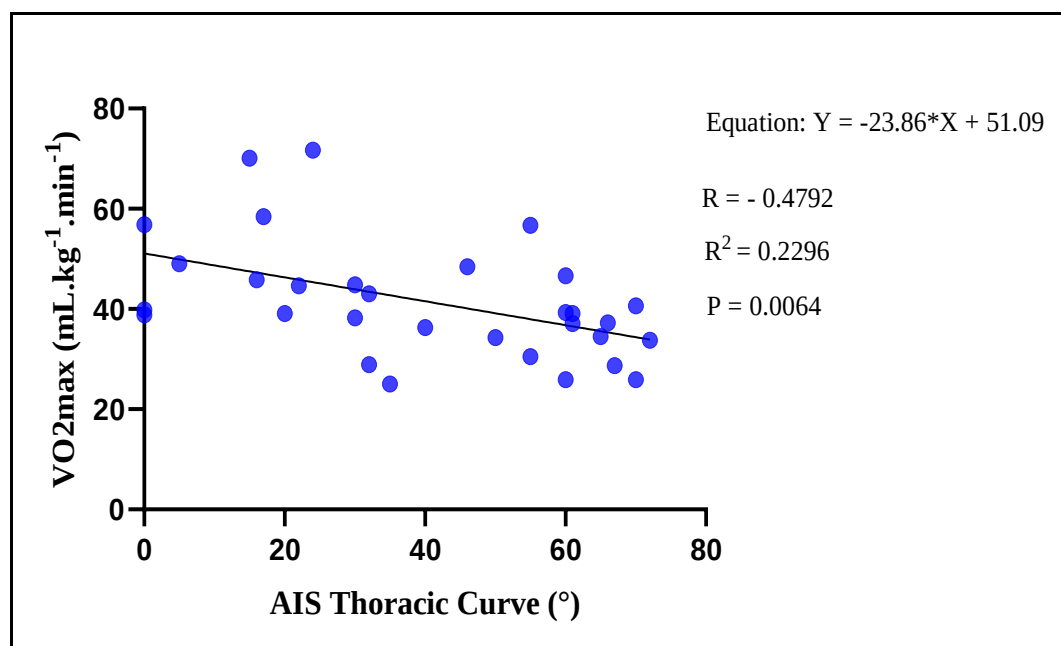


Figure 4.2: Regression of thoracic curvature and VO₂max

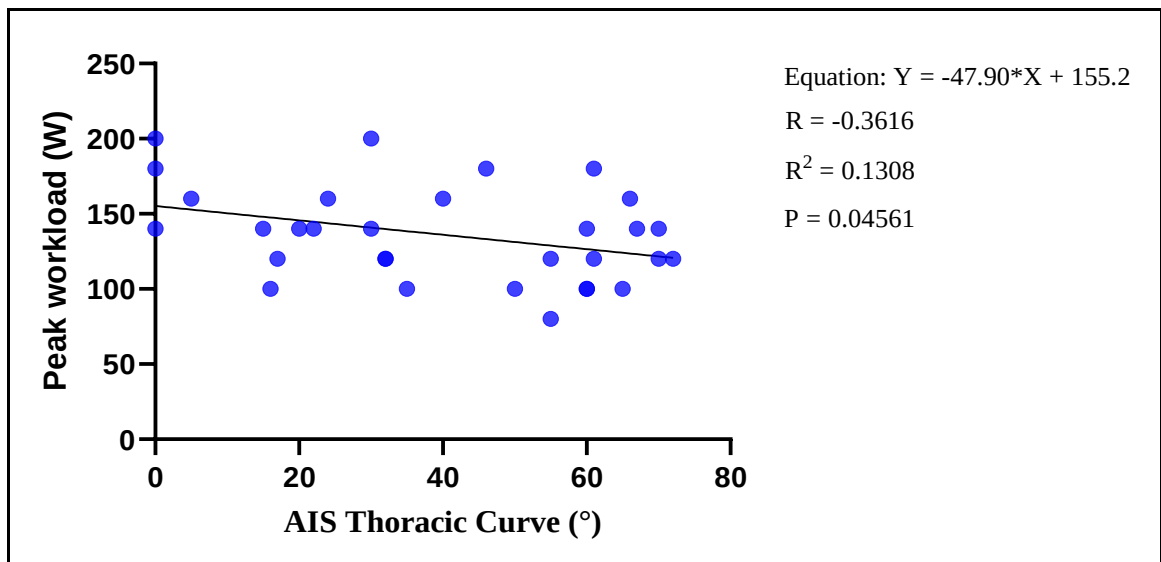


Figure 4.3: Regression of thoracic curvature and peak workload.

Secondary analysis was carried out to examine the relationship between exercise capacity and pulmonary function (Figure 4.4 and 4.5) and exercise capacity and self-reported activity levels (Figure 4.7). A weak association was identified between exercise capacity and FVC (L) and exercise capacity and vigorous activity (mins) (Figure 4.6). A moderate relationship was also identified between exercise capacity and weekly physical activity (Figure 4.7).

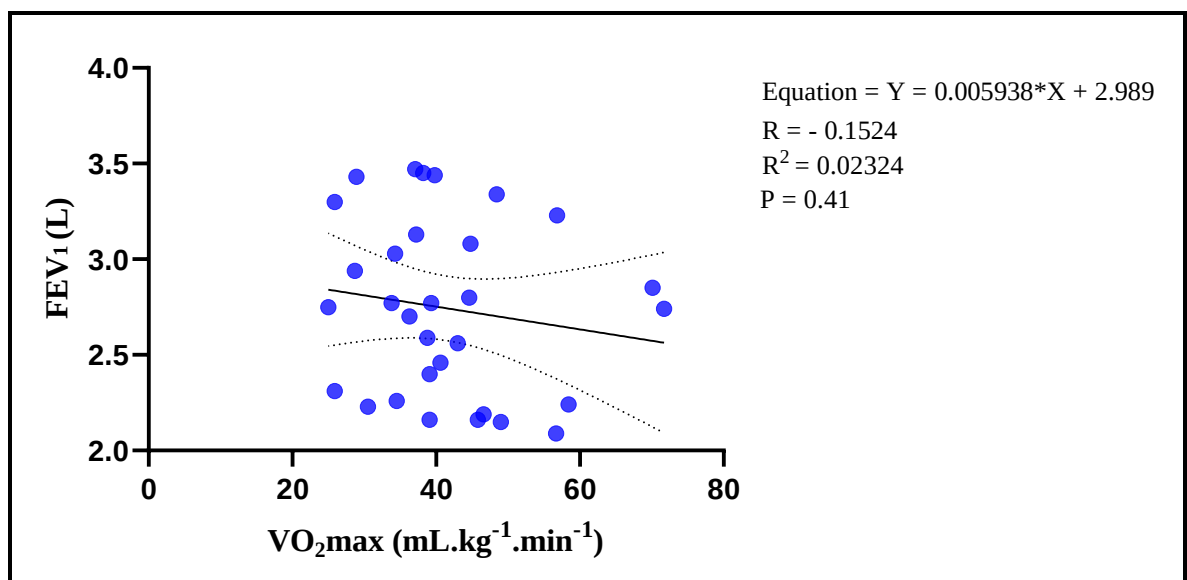


Figure 4.4: Regression of FEV₁ and VO₂max

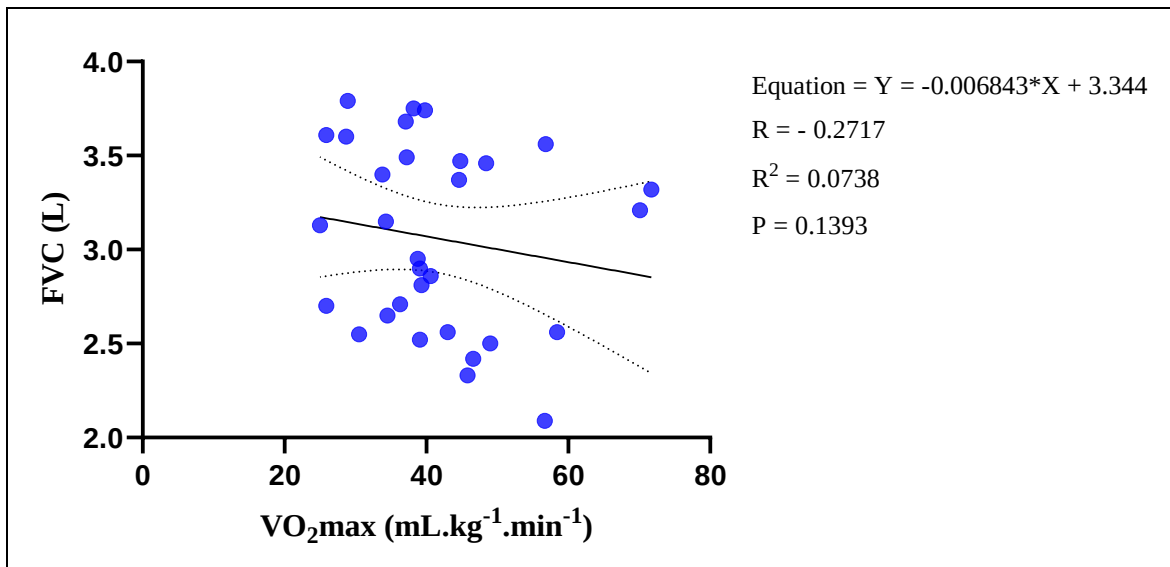


Figure 4.5: Regression of FVC and VO₂max.

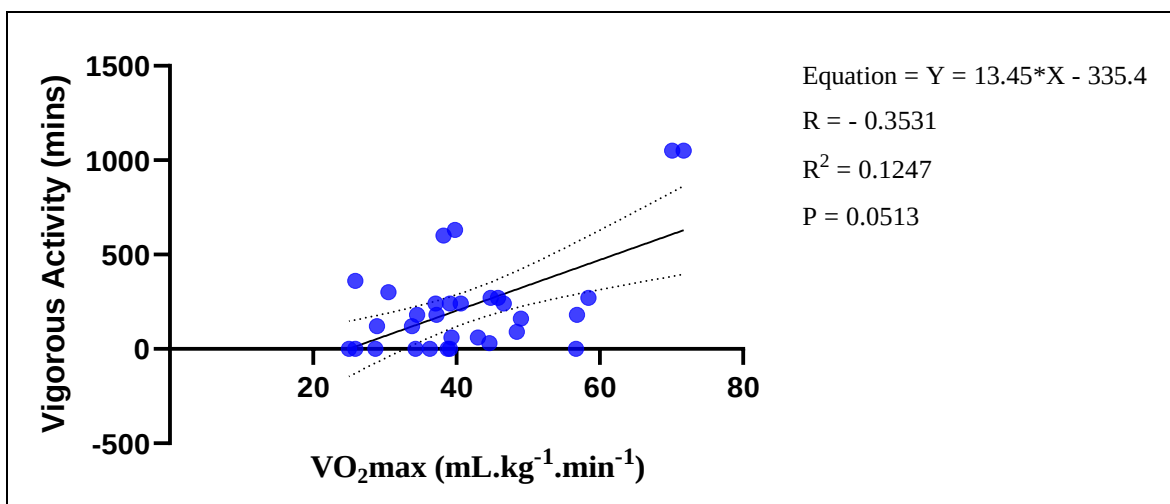


Figure 4.6: Regression Vigorous activity and VO₂max.

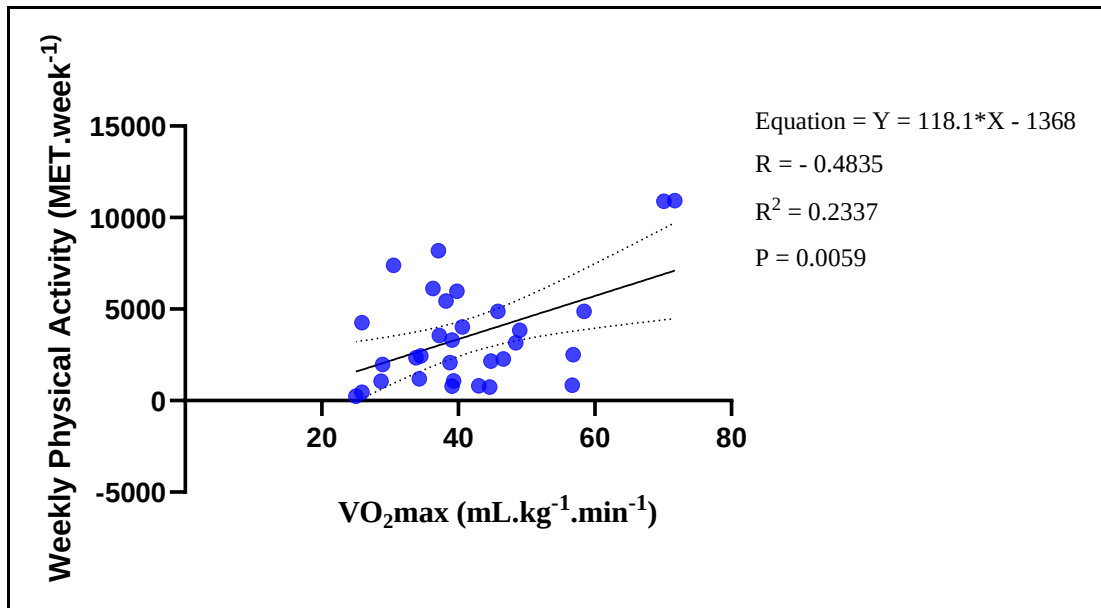


Figure 4.7: Regression of weekly physical activity and VO₂max.

4.3.5: Grip strength

Grip strength tests are a broad measure of upper limb strength. No statistically significant differences were observed in grip strength between the 3 groups. While not significant, the mean outcomes indicate poorer grip strength in both AIS groups (Table 4.5).

4.3.6: Lumbar strength

A statistically significant inter-group difference was found for lumbar strength ($P=0.018$). A multiple pairwise comparison analysis identified significantly lower lumbar strength in the severe AIS group when compared to the control group (87.1 ± 14 vs. 71.2 ± 15.3 , $P=0.016$). No differences were identified between the control group and the mild/moderate group or between the two AIS groups. While not statistically significant, the mean outcomes indicate poorer lumbar strength in both AIS groups when compared to healthy controls (Table 4.5)

Table 4.5. Grip strength and lumbar strength by group and AIS severity

Outcome Measures	Control (n=18) mean $\pm$ SD	Mild and moderate AIS (n=15) mean $\pm$ SD	Severe AIS (n=16) mean $\pm$ SD	Overall Effect (F, H & P)
Lumbar Strength (kg)	87.1 $\pm$ 14	76.4 $\pm$ 19.0	71.2 $\pm$ 15.3*	F=4.37 P=0.018
Hand Grip Strength (DH) (kg)	27.6 $\pm$ 6.4	24.5 $\pm$ 6.0	22.8 $\pm$ 5.6	H=5.81 P=0.055
Hand Grip Strength (NDH) (kg)	25.3 $\pm$ 5.8	23.2 $\pm$ 5.9	22.3 $\pm$ 4.9	F=1.35 P=0.270

DH dominant hand; NDH non-dominant hand. Asterisk infers significant inter-group difference between the control and severe AIS group (* P<0.05)) (F = 4.3.7).

4.3.7: Muscle strength

Strength of key muscle groups associated with the pelvis and spine was assessed. Overall analysis revealed significant differences between groups for the left hip flexors (P=0.001) and left hip extensors (P=0.034). Multiple pairwise comparisons showed that the severe AIS group had significantly weaker left hip flexors (20.9 $\pm$ 4.8 vs. 16.4 $\pm$ 3.7, P=0.012) and left hip extensors (19.5 $\pm$ 6.5 vs. 14.5 $\pm$ 5.6, P=0.048) compared to the control group. No other significant differences were identified, although a trend toward decreased muscle strength with increasing curve severity was observed (Table 4.6).

Table 4.6. Muscle strength by group and AIS severity

Outcome Measures Left (L), Right (R)	Control (n=18) mean $\pm$ SD	Mild and moderate AIS (n=15) mean $\pm$ SD	Severe AIS (n=16) mean $\pm$ SD	Overall Effect (F, H & P)
Hip flexor (R) (kg)	19.7 $\pm$ 5.2	16.5 $\pm$ 4.3	16.2 $\pm$ 3.8	F=3.12 P=0.054
Hip flexor (L) (kg)	20.9 $\pm$ 4.8	17.3 $\pm$ 4.4	16.4 $\pm$ 3.7**	F=5.14 P=0.001
Hip extensor (R) (kg)	18.3 $\pm$ 6.7	15.2 $\pm$ 5.7	14.1 $\pm$ 4.2	F=2.54 P=0.090
Hip extensor (L) (kg)	19.5 $\pm$ 6.5	15.0 $\pm$ 6.6	14.5 $\pm$ 5.6*	F=3.65 P=0.034
Hip abductor (R) (kg)	6.9 $\pm$ 2.2	6.1 $\pm$ 2.3	6.1 $\pm$ 1.4	H=1.57 P=0.456
Hip abductor (L) (kg)	7.9 $\pm$ 1.8	6.8 $\pm$ 2.2	6.9 $\pm$ 1.4	F=1.81 P=0.175
Hip adductor (R) (kg)	8.0 $\pm$ 2.6	7.3 $\pm$ 2.5	7.0 $\pm$ 1.3	F=1.05 P=0.358
Hip adductor (L) (kg)	7.8 $\pm$ 2.7	7.0 $\pm$ 2.0	6.5 $\pm$ 1.7	F=1.43 P=0.249
Trapezius lower (R) (kg)	4.5 $\pm$ 1.5	4.0 $\pm$ 1.4	3.8 $\pm$ 1.3	F=1.23 P=0.305
Trapezius lower (L) (kg)	4.2 $\pm$ 1.4	3.6 $\pm$ 1.4	3.2 $\pm$ 1.1	F=2.13 P=0.130
Trapezius upper (R) (kg)	18.1 $\pm$ 6.4	18.0 $\pm$ 5.9	15.9 $\pm$ 3.6	H=1.28 P=0.527
Trapezius upper (L) (kg)	18.3 $\pm$ 6.6	17.0 $\pm$ 5.1	16.1 $\pm$ 3.8	F=0.75 P=0.499
Latissimus dorsi (R) (kg)	13.4 $\pm$ 4.5	12.4 $\pm$ 3.6	11.2 $\pm$ 3.4	H=2.88 P=0.238
Latissimus dorsi (L) (kg)	12.9 $\pm$ 4.0	10.9 $\pm$ 2.4	10.8 $\pm$ 2.6	F=2.34 P=0.109

Asterisk infers a significant pairwise difference between the control and severe AIS group (** P<0.01, * P<0.05).

4.3.8: Upper and lower limb endurance

A standardised modified push-up to-failure test was used to estimate upper limb muscle endurance. Analysis indicated a significant overall effect (15 ± 8 vs 7 ± 7 and 5 ± 6 , $P=0.000$). Multiple pairwise comparisons found significant differences between the control group and both AIS groups (mild/moderate, $P=0.003$; severe, $P=0.000$). In both cases, the AIS groups had significantly weaker upper limb endurance. No significant differences were found between the mild/moderate and severe AIS groups for upper limb endurance (Table 4.7).

A standardised bilateral one-leg wall squat test was used to assess lower limb muscle endurance. A significant overall effect was found for both left-sided (18.7 ± 18.4 vs. 8.5 ± 10.0 and 6.7 ± 7.7 s, $P=0.023$) and right sided (22.2 ± 21 vs. 16.8 ± 5.0 and 8.7 ± 9.6 s, $P=0.003$) wall squats. Further analysis showed that right-sided squat endurance was significantly lower in both the mild/moderate AIS group ($P=0.004$) and the severe AIS group ($P=0.025$) compared to the control group. A moderate association was observed between lumbar curve severity and right-sided squat performance, suggesting that greater lumbar curvature is linked to increased endurance in the right lower limb. The left-sided squat, the severe AIS group also demonstrated significantly lower endurance compared to the control group ($P=0.029$). No significant differences in lower limb endurance were found between the AIS groups (Table 4.7).

Table 4.7. Upper and lower limb endurance by group and AIS severity

Outcome Measures	Control (n=18) mean $\pm$ SD	Mild and moderate AIS (n=15) mean $\pm$ SD	Severe AIS (n=16) mean $\pm$ SD	Overall Effect (F, P)	Correlation
Upper Limb Endurance (reps)					
Push-ups (reps)	15 ± 8	7 ± 7	$5 \pm 6^{***}$	F=10.67 P=0.000	-
Lower Limb Endurance (sec)					
Single-leg wall squats (R)	22.2 ± 21.1	$6.8 \pm 5.0^{***}$	$8.7 \pm 9.6^{**}$	F =,6.63 P=0.003	0.48
Single-leg wall squats (L)	18.7 ± 18.4	8.5 ± 10.0	$6.7 \pm 7.7^*$	F=4.12 P=0.023	-

Asterisks infer significant inter-group differences, between control and both AIS groups. ** infers $P < 0.01$, *** infers $P < 0.001$. Asterisk infers significant inter-group difference between the control and severe AIS group only (* $P < 0.05$). (R) = right side squat, (L) = left side squat.

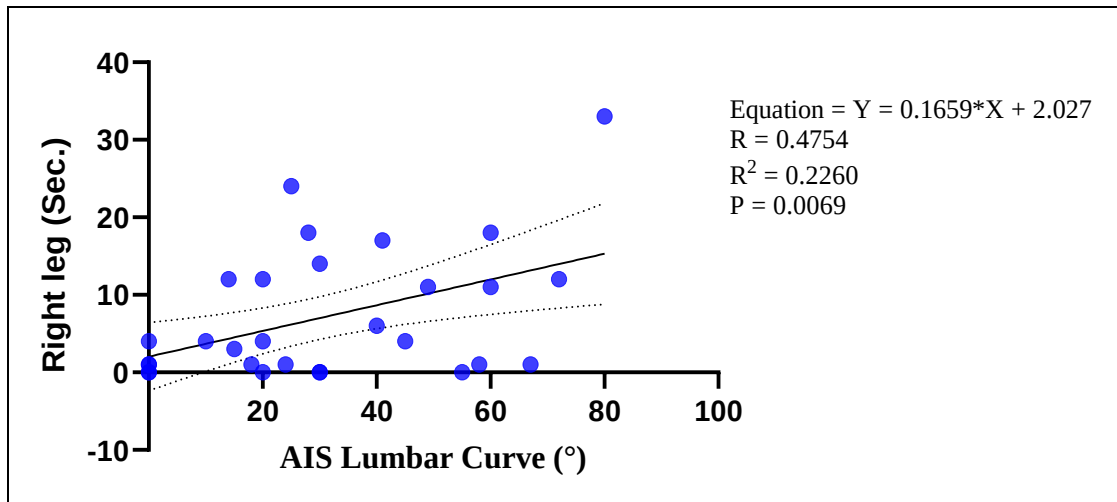


Figure 4.8: Regression of lumbar curvature and right-sided single-leg wall squat.

4.3.9: Upper and lower limb power

Upper limb power was assessed using a standardised medicine ball throw. Lower limb power was measured using a digital HUR force plate. No overall statistically significant differences were identified between the three groups for either upper limb power or lower limb power. There was a trend in recorded scores for lower limb power jump height (cm), with the control group attaining the highest mean height and the severe AIS group recording the lowest mean height. This trend was also evident in the maximum power output. (Table 4.8).

Table 4.8. Upper and lower limb power by group and AIS severity

Outcome Measures	Control (n=18) mean $\pm$ SD	Mild and moderate AIS (n=15) mean $\pm$ SD	Severe AIS (n=16) mean $\pm$ SD	Overall Effect (F, H & P)
Upper Limb Power (cm)				
Medicine Ball Putt (cm)	194 $\pm$ 42.2	183 $\pm$ 37.1	187 $\pm$ 33.8	F=,0.34 P=0.071
Lower Limb Power				
Jump Height (cm)	27.5 $\pm$ 7.8	24.6 $\pm$ 6.7	21.4 $\pm$ 4.5	H=5.97 P=0.050
Maximum Power (watts)	1798 $\pm$ 6.5	1565 $\pm$ 480	1471 $\pm$ 247	H=2.53 P=0.282
Maximum Force (N)	903 $\pm$ 267	835 $\pm$ 199	860 $\pm$ 202	F=0.390 P=0.682
Max Force/ Body Weight (N/kg)	22.8 $\pm$ 2.8	23.1 $\pm$ 2.9	22.8 $\pm$ 2.9	F=0.080 P=0.919

4.3.10: Balance

Balance was evaluated using a HUR Balance platform across a range of validated tests for both centre of pressure (C90 Area [mm²]) and sway velocity (mean sway velocity [mm/s]) (Bell et al., 2011; Sheehan et al., 2011). Statistically significant results were identified for single leg stance eyes open for centre of pressure tests (P=0.026) and sway velocity (P=0.046). Further analysis indicated that the mild/moderate AIS group had significantly poorer C90 Area (906 $\pm$ 484 vs. 2773 $\pm$ 3426 mm², P=0.030) and greater postural sway (32.8 $\pm$ 11.6 vs. 42.3 $\pm$ 16.0 mm/s, P=0.043) than the control group. Sway velocity was also greater in the severe AIS group when compared to the control group for double leg stance with eyes closed (13.4 $\pm$ 5.5 vs. 18.3 $\pm$ 7.1 mm/s, P=0.027). All other balance score comparisons were non-significant (Table 4.9).

Table 4.9. Balance by group and AIS severity

Outcome Measures	Control (n=18) mean $\pm$ SD	Mild and moderate AIS (n=15) mean $\pm$ SD	Severe AIS (n=16) mean $\pm$ SD	Overall Effect (F, H & P)
Balance: C90 Area [mm²]				
Double Leg Stance: eyes open	317 $\pm$ 208	408 $\pm$ 186	279 $\pm$ 115	F=2.08 P=0.136
Single Leg Stance: eyes open	906 $\pm$ 484	2773 $\pm$ 3426*	2559 $\pm$ 4544	H=7.29 P=0.026
Tandem Stance: eyes open	1576 $\pm$ 3311	641 $\pm$ 861	1568 $\pm$ 3502	H=0.24 P=0.888
Double Leg Stance: eyes closed	538 $\pm$ 551	493 $\pm$ 373	619 $\pm$ 751	H=1.74 P=0.419
Single Leg Stance: eyes closed	6348 $\pm$ 3829	9764 $\pm$ 15719	10269 $\pm$ 7478	F=2.24 P=0.121
Tandem Stance: eyes closed	5528 $\pm$ 6153	7349 $\pm$ 7568	9674 $\pm$ 11737	H=2.48 P=0.289
Balance: Mean sway velocity [mm/s]				
Double Leg Stance: eyes open	10.4 $\pm$ 3.4	12.7 $\pm$ 3.7	11.5 $\pm$ 3.4	F=1.85 P=0.169
Single Leg Stance: eyes open	32.8 $\pm$ 11.6	42.3 $\pm$ 16.0*	41.6 $\pm$ 26.2	H=6.15 P=0.046
Tandem Stance: eyes open	30.2 $\pm$ 22.1	29.2 $\pm$ 10.3	34.9 $\pm$ 34.8	H=0.87 P=0.648
Double Leg Stance: eyes closed	13.4 $\pm$ 5.5	17.2 $\pm$ 6.2	18.3 $\pm$ 7.1*	H=7.20 P=0.027
Single Leg Stance: eyes closed	88.9 $\pm$ 27.2	117.0 $\pm$ 50.2	105.0 $\pm$ 45.7	F=1.88 P=0.165
Tandem Stance: eyes closed	70.7 $\pm$ 36.2	93.3 $\pm$ 50.2	107.0 $\pm$ 81.1	H=3.33 P=0.190

Asterisk infers significant pairwise difference between the control and mild and moderate AIS groups, Single leg stance, eyes open and closed (* P<0.05). Significant pairwise difference between control and severe AIS groups; Double leg stance: eyes closed (* P<0.05)

4.3.11: Quality of life

Quality of life was assessed using the validated Scoliosis Research Society questionnaire, SRS-22r (Asher et al., 2003). The results inferred statistically significant differences between groups across all four parameters: pain perception, function, mental health, and self-image ($P=0.0001$) (Table 4.10).

Table 4.10. Quality of life by group and AIS severity

Outcome Measure (SRS-22r)	Control (n=18) mean $\pm$ SD	Mild and moderate AIS (n=15) mean $\pm$ SD	Severe AIS (n=16) mean $\pm$ SD	Overall Effect (H & P)	R
Pain	4.8 $\pm$ 0.3	4.5 $\pm$ 0.3 ⁺⁺⁺	3.5 $\pm$ 0.9 ^{***}	H=69.26 P=0.0001	-0.56 (T) -0.36 (L)
Function	4.9 $\pm$ 0.2	4.8 $\pm$ 0.2 ⁺⁺⁺	4.2 $\pm$ 0.4 ^{***}	H=44.72 P=0.0001	-0.61 (T)
Mental health	4.3 $\pm$ 0.5	4.0 $\pm$ 0.6 ⁺⁺⁺	3.4 $\pm$ 0.9 ^{***}	H=26.19 P=0.0001	-0.25 (T) -0.35 (L)
Self-Image	4.6 $\pm$ 0.5	4.0 $\pm$ 0.6 ⁺⁺⁺	2.6 $\pm$ 0.8 ^{***}	H=94.39 P=0.0001	-0.74 (T) - 0.59 (L)

(SRS-22r) Scoliosis Research Society 22r Questionnaire. Asterisk infers significant inter-group differences, between control and both AIS groups. ^{***} infers $P < 0.0001$. (T) = Thoracic spine, (L) = Lumbar spine.

4.3.12: Pain

A detailed analysis of pain perception outcomes revealed significantly higher pain scores in both the mild/moderate AIS group ($P=0.006$) and the severe AIS group ($P=0.000$) compared to the control group. Additionally, significant differences in pain perception were observed between the mild/moderate AIS group and the severe AIS group ($P=0.000$), with the severe AIS group reporting higher pain scores. A weak inverse association was also identified between the severity of thoracic and lumbar curvature and pain perception, suggesting that greater curve severity is linked to increased pain. (Figures 4.9 and 4.10)

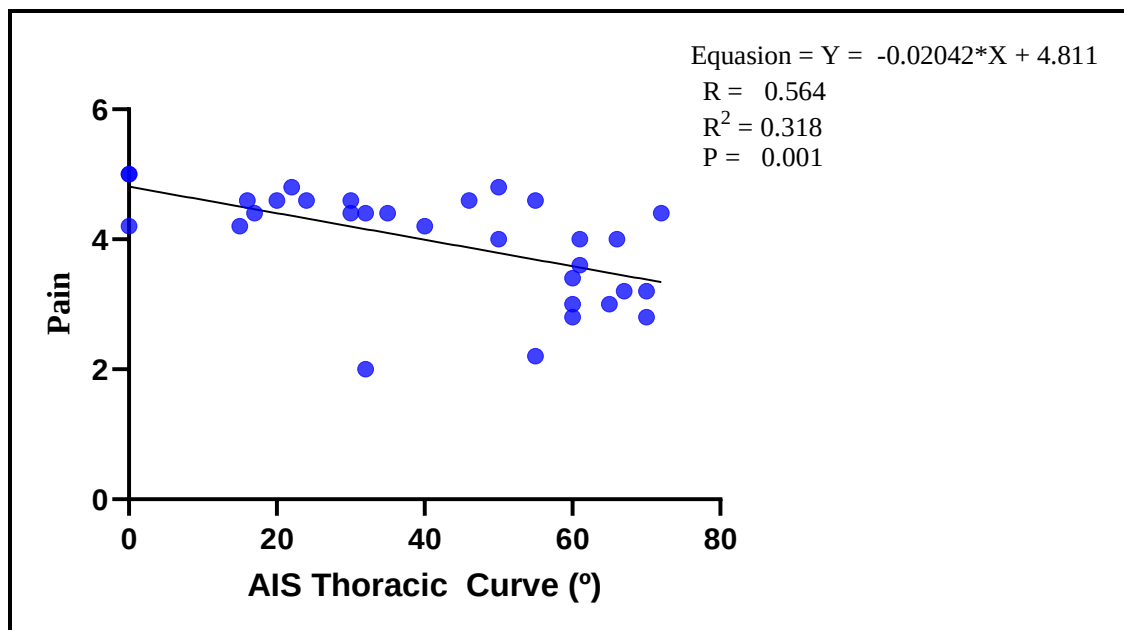


Figure 4.9: Regression of thoracic curvature and pain (SRS-22r)

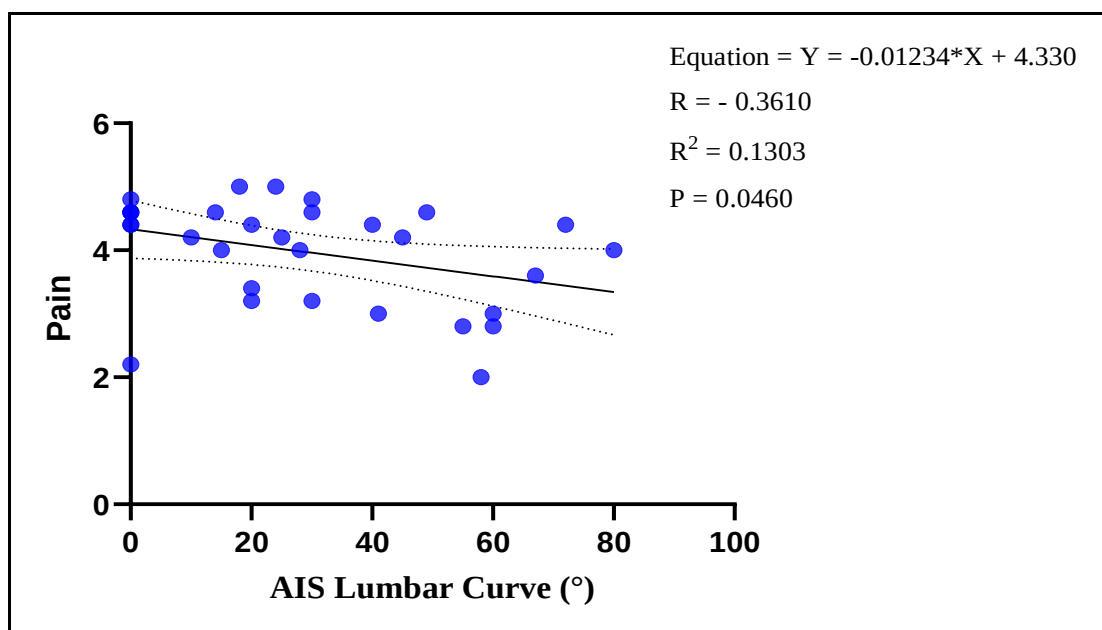


Figure 4.10: Regression of Lumbar curvature and pain (SRS-22r)

4.3.13: Self-image

Analysis of self-image outcomes indicated that the severe AIS group had significantly poorer self-image compared to both the mild/moderate AIS group and the control group (4.6 ± 0.8 vs. 4.0 ± 1.1 vs. 2.6 ± 1.3 , $P=0.0001$), (Table 4.10). The mild/moderate AIS group also demonstrated poorer self-image compared to the control group. Additionally, a strong inverse relationship was identified between the severity of thoracic spinal curvature and self-image, while a moderate inverse relationship was observed between the severity of lumbar curvature and self-image (Figures 4.11 and 4.12).

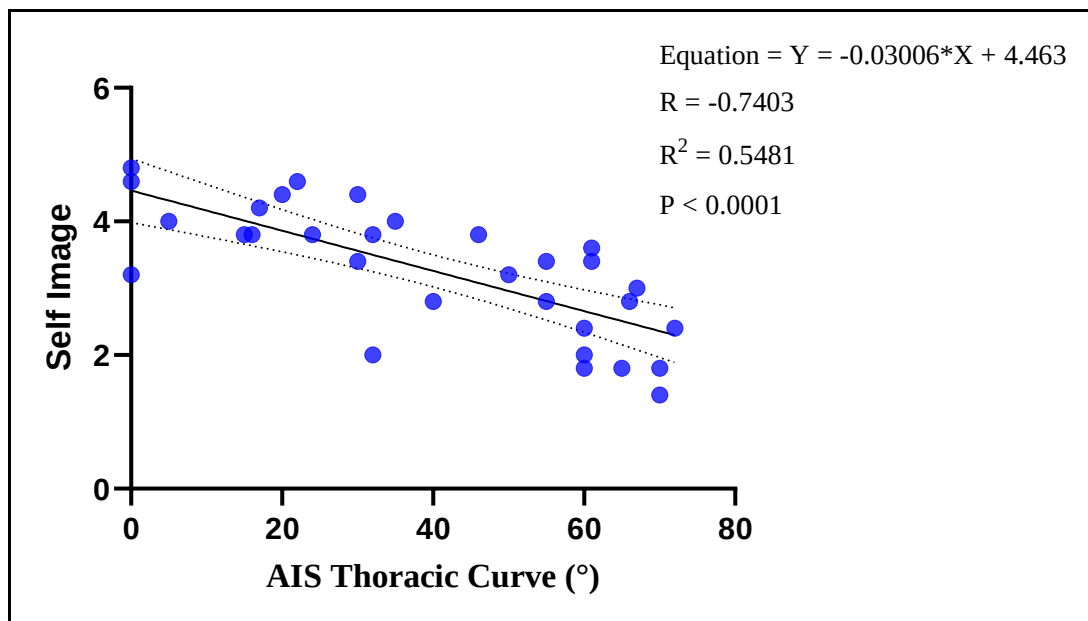


Figure 4.11: Regression of thoracic curvature and self-image (SRS-22r)

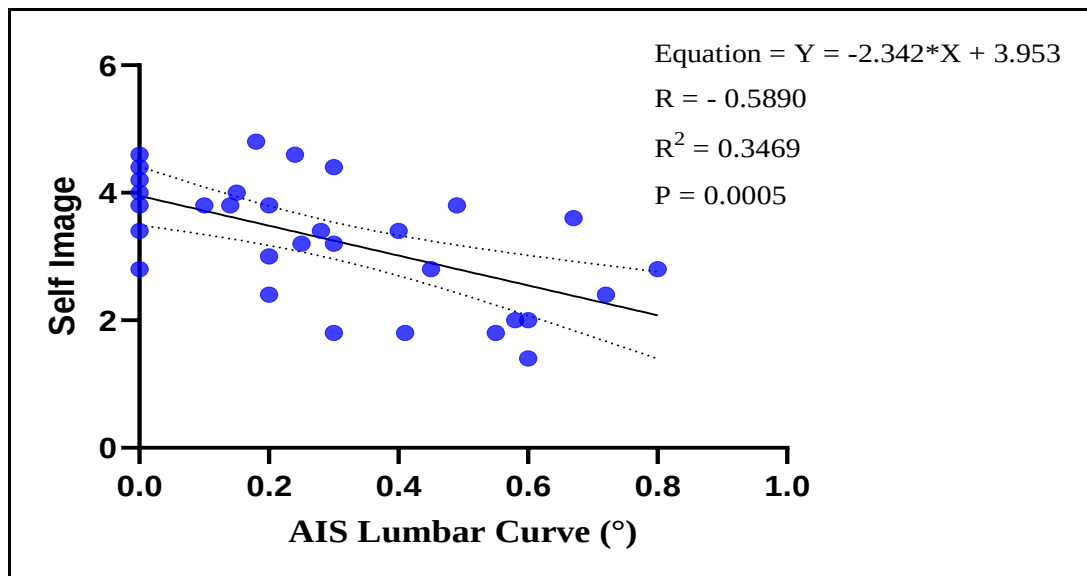


Figure 4.12: Regression of Lumbar curvature and self-image (SRS-22r)

4.3.14: Function

Multiple pairwise comparison analyses of functional outcomes revealed significant differences between the control group and the severe AIS group and between the mild/moderate AIS group and the severe AIS group (4.9 ± 0.4 vs. 4.8 ± 0.6 and 4.2 ± 1.0 , $P=0.000$). The severe AIS group demonstrated lower function scores compared to both the control group and the mild/moderate AIS group. No significant differences were observed between the control group and the mild/moderate AIS group. Additionally, a moderate inverse relationship was identified between the severity of thoracic spinal curvature and reduced functional outcomes (Figure 4.13).

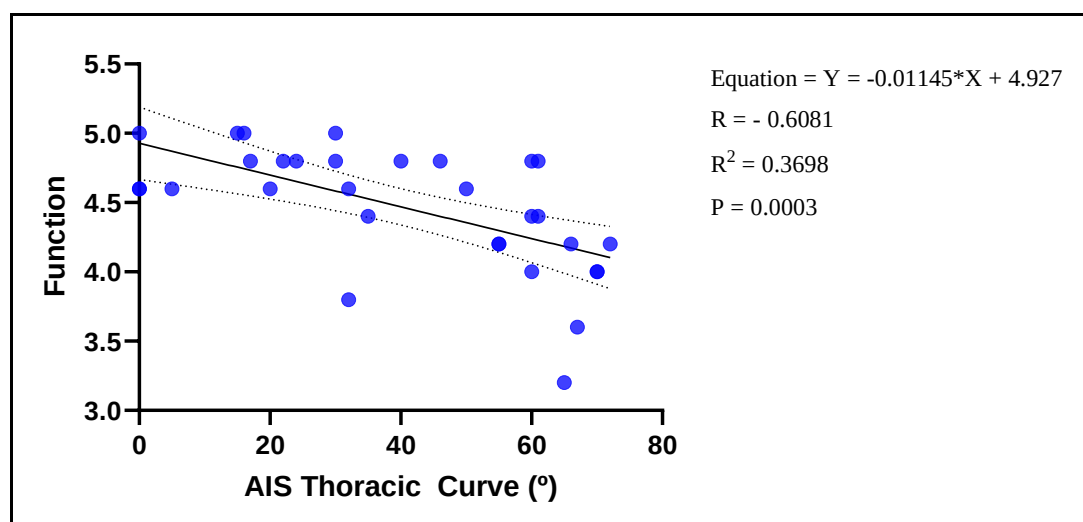


Figure 4.13: Regression of thoracic curvature and function (SRS-22r).

4.3.15: Mental health

A significant difference in mental health outcomes was observed between the control group and the severe AIS group, as well as between the mild/moderate AIS group and the severe AIS group (4.2 ± 0.8 vs 4.0 ± 0.8 and 3.4 ± 1.1 , $P=0.000$). The severe AIS group reported poorer mental health compared to both the control and mild/moderate AIS groups. No significant differences were found between the control group and the mild/moderate AIS group. Additionally, a weak inverse association was identified between declining mental health and the severity of thoracic and lumbar spinal curvature (Figures 4.14 and 4.15). The results above indicate that spinal curvature is associated with increased levels of pain, and a deterioration of self-image, function, and mental health (Table 4.10).

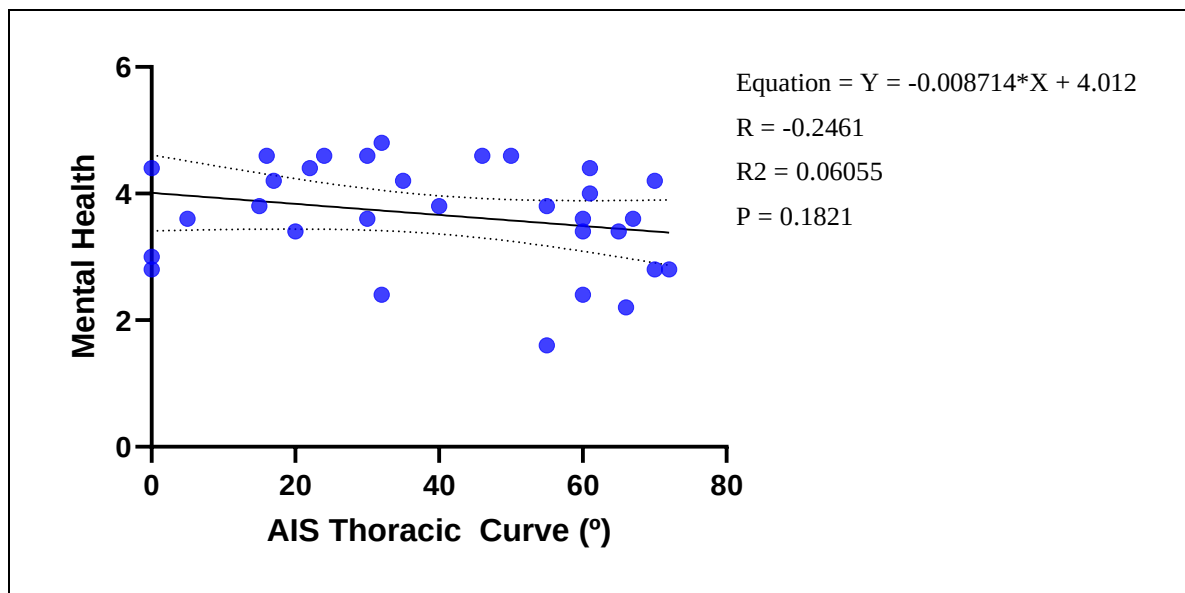


Figure 4.14: Regression of Thoracic curvature and mental health (SRS-22r)

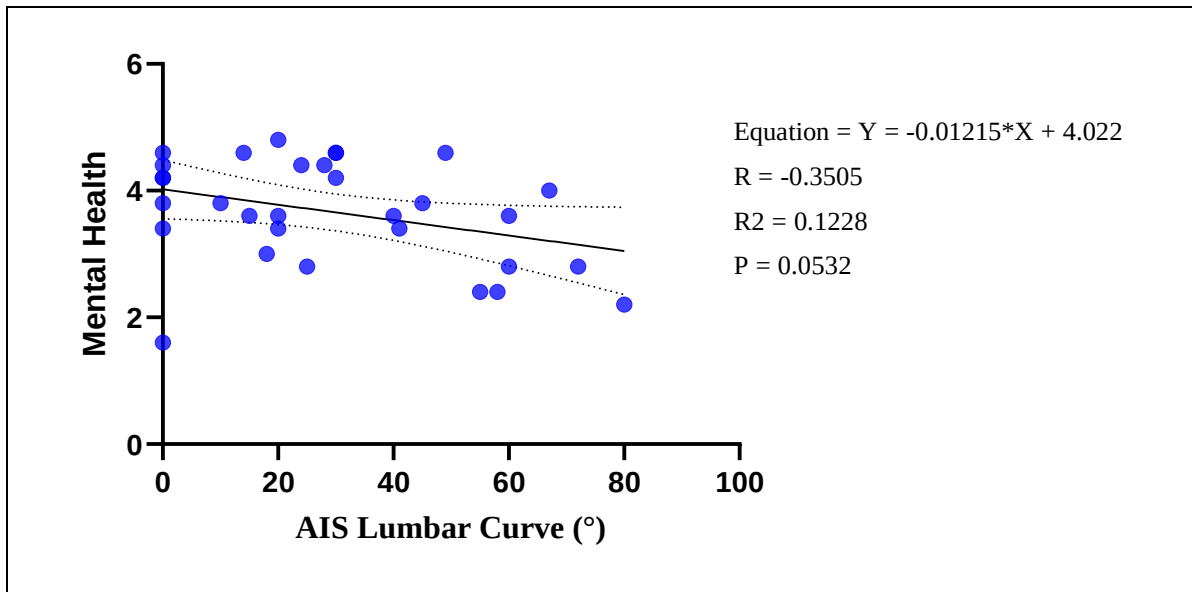


Figure 4.15: Regression of Lumbar curvature and mental health (SRS-22r)

4.3.16: Physical activity and sedentary behaviour

Weekly activity levels were determined by participant completion of the validated International Physical Activity Questionnaire (IPAQ) (Craig et al., 2003). No significant differences were identified in weekly metabolic equivalent (MET) output across the three groups (Table 4.11). However, a statistically significant overall difference was observed in weekly minutes spent sitting ($P=0.005$). Further multiple analysis revealed that both the mild/moderate AIS group ($P= 0.018$) and the severe AIS group ($P=0.001$) spent significantly more time inactive compared to the control group (245 ± 158 vs. 390 ± 119 and 399 ± 155 , $P=0.005$). These findings suggest that while overall activity levels in adolescents with AIS are broadly comparable to those of their non-AIS peers, they tend to spend more time engaged in sedentary behaviour.

Table 4.11. Physical activity and sedentary behaviour by group and AIS severity

Outcome Measures (IPAQ)	Control (n=18) mean $\pm$ SD	Mild and moderate AIS (n=15) mean $\pm$ SD	Severe AIS (n=16) mean $\pm$ SD	Overall Effect (F, P)
Sitting mins per week	245 $\pm$ 158	390 $\pm$ 119*	399 $\pm$ 155**	F=0.793 P=0.005
MET output Total per week	3772 $\pm$ 2370	4152 $\pm$ 3397	2971 $\pm$ 2212	F=0.208 P=0.459

(IPAQ) International Physical Activity Questionnaire. Asterisk (*) infers significant inter-group difference, between control and both AIS groups. ** infers $P < 0.01$

Results: Main findings

1. Patients with AIS when compared to a sample of the normal population have:
 - Poorer pulmonary function and exercise capacity.
 - Weaker muscle strength and muscle endurance.
 - Poorer balance.
 - Higher pain levels, and poorer mental health, lower self-image and reduced function.
2. Patients with severe AIS have poorer exercise capacity than those with mild/moderate AIS.
3. Impairments in exercise capacity, higher diastolic blood pressure, higher levels of pain, and poorer self-image and function appear to be associated with spinal curve severity.

4.4: Discussion

The main findings from this study are threefold; firstly, patients with AIS appear to have significant impairments in exercise capacity, pulmonary function, muscle strength and endurance, balance, and quality of life when compared to an anthropometrically matched sample from the general population. Secondly, impairments may occur earlier in the curve spectrum, particularly in pulmonary function, muscle endurance, balance and quality of life. Thirdly, there appears to be an association between curve severity and the onset and development of impairments in exercise capacity, diastolic blood pressure, pain perception, self-image, and function.

4.4.1: Blood pressure and resting heart rate

The current study identified an association between thoracic curvature and diastolic blood pressure (Figure 4.1). This finding supports previous literature concerning diastolic dysfunction and spinal deformity (Li, 2015, Quintero Santofimio et al., 2023). Quintero Santofimio et al. (2023) found that abnormal curvature of the spine could increase the mechanical constraint on the heart, leading to an increase in right atrial and ventricular pressure.

4.4.2: Pulmonary function

There is a long-standing debate on what impact spinal curvature has on pulmonary function in patients with AIS (Kempen et al. 2022). Early research suggested that pulmonary function is only significantly affected when thoracic curvature exceeds 70° (Weinstein et al., 1981). However, subsequent studies revised this threshold to 50° (Loinstein, 1994, Newton, 2005, Danielsson, 2013). Supporting this view, Tsiligiannis and Grivas (2012) also concluded that mild (curves 10° to 25°) to moderate (curves 26° to 45°) scoliosis has minimal or no impact on pulmonary function. In contrast to previous findings, results from the current study suggest that pulmonary function impairments may already be present in individuals with mild and moderate AIS. This aligns with the proposal by Negrini et al. (2018) who suggested that pulmonary impairments can develop in patients with moderate AIS. Furthermore, a recent systematic review and meta-analysis examining the effects of untreated AIS on pulmonary function supports the view that pulmonary impairments can manifest earlier during the progression of spinal curvature (Kempen et al., 2022). This review concluded that pulmonary function in patients with AIS decreases by approximately 1% for every 2.6° to 2.9° of curve progression. Furthermore, the authors argue that

pulmonary impairments begin to manifest from a curvature angle of 20°. The current study supports Kempen et al. (2022) in relation to the development of pulmonary impairments earlier in the progression of spinal curvature. However, in contrast to their findings, no significant association was found between curve severity and pulmonary function. In the Kempen et al. (2022) study the majority of the 8,723 patients reviewed were pre-operative individuals with Cobb angles exceeding 50°, a factor that may have influenced the study outcomes. It is important to note however, that pulmonary impairments cannot be determined solely based on the Cobb angle (Kearon et al., 1993), as factors such as curve location, and the degree of spinal rotation also play a significant role in influencing pulmonary function.

An important finding in the current study was that the percentage predicted FEV₁ and FVC outcomes for mild/ moderate and severe AIS groups were significantly lower than the control group. The results for FVC for both AIS groups placed the cohorts close to the diagnostic threshold for classification of restrictive pulmonary disease (Hall et al., 2021, Agustí et al., 2023). Reduced pulmonary function in patients with AIS may hinder participation in physical activities, including sports and may lead to a more sedentary lifestyle. This argument is supported by the findings of the present study, which demonstrated that both the mild/moderate AIS group and the severe AIS group exhibited significantly higher levels of inactivity compared to the healthy controls. The findings of this study support the view that early pulmonary intervention is required in patients with AIS (Athanasopoulos et al., 1999, Xavier et al., 2020).

4.4.3: Exercise capacity

Exercise capacity was significantly lower in the severe AIS group when compared to the mild/moderate AIS group ($P= 0.039$). In addition, a moderate inverse relationship between aerobic capacity and spinal curvature was observed (Table 4.4). Very few studies have assessed the impact of AIS on exercise capacity. Saraiva et al. (2018) and Sperandio et al. (2014) using the Incremental Shuttle Walk Test (ISWT), found reduced functional exercise capacity and reduced pulmonary function in moderate and severe AIS participants when compared to a healthy control group. Both authors speculated that reduced functional exercise capacity in AIS participants may be linked to reduced pulmonary function.

The current study, in line with a small number of other studies, assessed exercise capacity using standardised ramped protocols. In contrast to the current study, Shen et al. (2016)

found no association between curve severity and exercise capacity. However, most participants in their study were classified as severe AIS. Consistent with the findings from the current study, Kearon et al. (1993a), Barrios et al. (2005), and Czaprowski et al. (2012) found lower VO_2max in AIS participants when compared to healthy controls. The predominant argument for reduced exercise capacity was restrictive ventilatory function in the AIS population (Kearon et al., 1993a, Barrios et al., 2005, Sperandio et al., 2014, Shen et al., 2016). These studies, however, differed as to the reasons behind the reduction in ventilatory function. Sperandio et al. (2014) and Barrios et al. (2005) proposed that physical deconditioning may be an important element in reduced exercise capacity in adolescents with mild and moderate AIS, whereas Shen et al. (2016) proposed that pulmonary gas exchange worsened as thoracic curvature increased in severe AIS. Unfortunately, none of these studies documented the current activity levels of the AIS participants, making it impossible to establish any association between muscular and/or cardiovascular deconditioning and exercise capacity.

A moderate and statistically significant relationship was identified between exercise capacity and weekly physical activity (Figure 4.7), which is logical since increased weekly physical activity is linked to higher fitness levels (Kesten et al., 1991). However, when weekly physical activity was compared across the three groups, no significant differences were observed. Weekly physical activity levels were self-reported however and may have included an element of recall bias.

4.4.4: Muscle strength

The current study identified significantly reduced strength in the left hip flexors, left hip extensors, and lumbar musculature in the severe AIS group compared to the healthy control group. A small number of studies have examined muscle strength in patients with AIS (Martinez-Llorens et al., 2010, Hassan and Mohammad, 2015, Yildirim et al., 2022). The current study supports the results of Hassan and Mohammad (2015) who found significant muscle weaknesses in the hip opposing the direction of the primary thoracic spinal curve (concave side of the spinal curve).

The current study found no statistically significant differences in handgrip strength across groups. In contrast to the findings of the current study, Martinez-Llorens et al. (2010) identified significantly lower grip strength in patients with severe AIS when compared to healthy controls. Yildirim et al. (2022) also reported no differences in handgrip strength

between patients with mild and moderate AIS after a core stabilisation intervention. However, their study did not include a healthy control group as a comparison. It is worth noting that while the current study did not identify any statistically significant differences in grip strength, there was a clear trend toward reduced grip strength with increasing spinal curvature severity (Table 4.5), indicating a possible association.

Various theories have been proposed to explain muscle weakness in patients with AIS. An early study by Kearon et al. (1993a) hypothesised that muscle weakness in AIS may be attributed to both muscle deconditioning and systemic effects of scoliosis. Martínez-Llorens et al. (2010) speculated that muscle weakness may be more closely related to the systemic impact of the disorder rather than to disuse or deconditioning. Additionally, pelvic obliquity, a common feature in AIS, has been identified as a potential contributor to reduced hip muscle strength on the concave side (Banno et al., 2020). In addition to factors raised above, Hopf et al. (1998) argued that neuromuscular imbalances may also play a contributing role in the pathophysiology

The underlying factors contributing to the reduced lumbar strength observed in the severe AIS cohort in the present study remain unclear. It may be associated with pelvic obliquity, neuromuscular imbalance or a systemic effect. An early study by Sahgal et al. (1983) analysed paraspinal and gluteus maximus muscle biopsies from both sides of the Cobb angle apex (the vertebra positioned farthest laterally from the body's midline) in patients with severe AIS. Their study identified reductions in fibre size, internal nuclei, and fibre splitting, along with type II fibre atrophy in the muscles on the concave side of the spinal curve. Supporting this perspective, Paz et al. (2015), through muscle biopsy analysis in patients with severe AIS, identified fibre atrophy in the paraspinal and intercostal muscles on both sides of the spinal curve, with more pronounced atrophy on the concave side.

The current study shows a clear pattern of declining strength as curve severity increases. Despite limitations in directly comparing findings across studies due to variations in methodology and participant characteristics, there is a consistent body of evidence indicating that trunk, lumbar and lower limb muscle asymmetries and weaknesses are common features in individuals with AIS.

4.4.5: Muscle endurance

This is the first study to the author's knowledge to examine peripheral upper and lower limb muscle endurance in patients with AIS. Overall, the results inferred that patients with

mild/ moderate and severe AIS have poorer upper and lower limb muscle endurance than the healthy controls.

Lower limb muscle endurance was assessed using single leg wall squats. The right-side squat was noticeably weaker when compared to the left side. Pelvic obliquity with predominately right-sided thoracic curves can lead to a higher right-sided sacral angle (Banno et al., 2020). This may have influenced the results of lower limb endurance for both AIS groups. Interestingly, a moderate association was identified between increased spinal curves and a greater ability to maintain the squat. This may be related to the fact that most patients with severe thoracic curves develop a compensatory lumbar curve (Lenke et al., 2001).

The current study found poor feasibility for the upper limb endurance (push-ups) and lower limb endurance (single leg wall squat) tests. The participants with AIS struggled to complete the tests primarily because of bilateral height differences in shoulders and hips. Pelvic obliquity, a common feature in AIS is also linked to shoulder imbalance (Banno et al., 2020). Shoulders at different heights and spinal curvature affecting hip height may have been contributory factors in the outcomes for the upper limb endurance test for the AIS groups.

4.4.6: Balance

Most outcomes from the balance tests were not significantly different between groups. This may be linked to the ceiling effect of some of the tests and the small sample size. Patients with mild/moderate and severe AIS exhibited poorer balance than healthy controls in certain conditions of the mBESS protocol, notably in conditions with lower base of support and lack of visual inputs. This was evidenced by greater C90 areas and higher sway velocity (Table 4.9). Balance impairments have been associated with scoliosis (O'Beirne, 1989). Gauchard et al. (2001) concluded that curve type could affect the size of the balance impairment. Double curvature, lumbar and thoracic, appear to offset each other and have the smallest bearing on balance while single lumbar curvature results in the greatest balance impairment (Gauchard et al., 2001). The results of the present study are consistent with Gauchard et al. (2001), where the majority of severe AIS participants (14 out of 16) with compensatory curves demonstrated minimal balance impairments. In relation to the mild/moderate AIS group, the current study is consistent with a recent study by Larni et al.

(2023) who found poorer balance and greater sway velocity in participants with mild and moderate AIS when compared to a healthy control group.

Reduced vision has been implicated in balance dysfunction associated with AIS (Simoneau et al., 2006, Simoneau et al., 2009, de Santiago et al., 2013). The current study found greater sway velocity in the severe AIS group when vision was restricted. These results are consistent with de Santiago et al. (2013), who also observed decreased balance in AIS participants when vision was restricted. Findings from the current study imply that patients with AIS depend more on visual cues for balance compared to their healthy counterparts.

4.4.7: Quality of life

The negative impact of AIS on the quality of life in children and adolescents is well recognised (Kotwicki et al., 2013, Tarrant et al., 2016, D'Agata et al., 2017, Gallant et al., 2018, Pyatakova et al., 2019, An et al., 2023). However, only two studies were identified that included a healthy control group (Watanabe et al., 2005, Auerbach et al., 2014). Auerbach et al. (2014) concluded that patients with severe AIS had poorer self-image than healthy controls. Watanabe et al. (2005) found poorer pain perception and self-image in a combined group of patients with mild, moderate and severe AIS when compared to healthy controls. The authors suggested that there was a tendency for poorer scores in those who had severe AIS.

The current study supports research to date on the negative impact of AIS on pain (An et al., 2023), mental health (Pyatakova et al., 2019), body image (Gallant et al., 2018) and function (Tarrant et al., 2016). The current study is also the first study to examine the relationship between spinal curvature and QOL domains (pain, self-image, function, mental health, and treatment satisfaction). The results from this analysis highlighted a strong association between curve severity and self-reported pain, mental health, self-image and function (Table 4.10). The current study found that participants with severe AIS had higher pain perception, poorer function, mental health, and self-image than both the healthy control group and the mild/moderate group and furthermore, the mild/moderate AIS group reported higher pain levels and poorer self-image than the healthy controls. These results indicate that poorer QOL commences early in the development of spinal curvature and deteriorates with increasing curvature of the spine. The development of AIS occurs at a 'fragile period of adolescence' (Kotwicki et al., 2013) at an age when adolescents are susceptible to poorer mental health issues and negative self-image. The results of this study

are significant and clearly highlight the need for an early intervention to reduce curve progression. It is also recommended that mental health services be introduced when AIS is diagnosed.

4.4.8: How “normal” was the control cohort?

The healthy control cohort from the current study were recruited from secondary schools in the greater Dublin area. To evaluate if their physiological and anthropometric characteristics could be considered “normal”, a selection of characteristics were compared against larger published population data. In terms of pulmonary function, the control group can be considered normal for both FEV1 and FVC, since their mean percentage predicted values (based on relative age, gender, and anthropometrics) fell within 4% of their respective normative data sets (Hall et al., 2017). Both mean systolic (109mmHg) and diastolic (68mmHg) blood pressure for the control group fell within half a standard deviation of large population (n=24,390) healthy adolescent data collected from 8 European countries (Systolic: 106 ± 16 mmHg; Diastolic 64 ± 10 mmHg) (Lurbe et al., 2025).

Since the majority (14 out of 18) of the control cohort were female with a mean age of 16yr, handgrip strength data were compared against normative data from Bohannon et al. (2017)

In that study, a large sample of 16-year-old females (n=99) had handgrip strength of 28.2 ± 5.4 kg on their dominant side and 26.4 ± 5.4 kg on their non-dominant side. This closely matches the control data in the current study (27.6 ± 6.4 kg on the dominant side; 25.3 ± 5.8 kg on the non-dominant side). Similarly, the mean VO_2max of 41.9 ± 10.4 mL.kg⁻¹.min⁻¹ recorded in our control cohort closely matches data published from a larger cohort of 16-year-old females (40.7 ± 4.0 mL.kg⁻¹.min⁻¹) from American High Schools (Nagle et al., 1977). Based on this comparison of global measures of cardiovascular, pulmonary and musculoskeletal health, the control cohort appear “normal” relative to the overall adolescent population.

4.4.9: Study limitations

Several limitations need to be considered. Due to the COVID-19 pandemic, the slow return of scoliosis clinics, and the HSE cyber-attack, the number of participants recruited for this study was lower than expected. A larger cohort of participants was anticipated and would have been desirable. Because of the lower participant numbers, the mild and moderate AIS groups were merged. Future studies should consider whether differences in the variables addressed in this study exist between patients with mild AIS and those with moderate AIS.

The results for muscle strength in the current study show a clear trend of weaker muscle groups across the AIS spectrum when compared to the control group (upper body, lumbar, spinal muscles, and pelvic musculature). The sample size for this study may have influenced the overall results. A study with a larger number of participants is necessary to determine if the trend of weaker upper body, lumbar, spinal muscles, and pelvic musculature across the curve spectrum is indeed significant in patients with AIS.

The SRS-22r (Scoliosis Research Society-22 revised) is among the most widely used patient-reported outcome measures (PROMs) for assessing health-related quality of life in individuals with spinal deformity, particularly scoliosis (Mannion et al., 2018). The Scoliosis Research Society also recognises it as the standard tool used in most of its clinical and research studies. Despite its wide use, several important limitations of the questionnaire have been highlighted in the literature.

The content validity of the SRS-22r may not fully reflect the experiences of adolescents with idiopathic scoliosis. A qualitative study by (Alamrani et al., 2023) found that adolescents described several physical, social, and emotional challenges, including stiffness, shoulder or hip asymmetry, problems sitting for long periods, and body image concerns, which were not well represented in the SRS-22r questionnaire.

A second limitation of the SRS-22r is the presence of ceiling effects and reduced sensitivity in adolescents with milder idiopathic scoliosis (AIS). Several studies, including (Alamrani et al., 2021), have reported noticeable ceiling effects, particularly in the self-image domain. The SRS-22r may have a limited ability to detect subtle differences in patients with mild or moderate scoliosis, or in those who are generally well functioning.

Another potential limitation is that parts of the questionnaire may not clearly measure what they're supposed to. A recent psychometric evaluation of SRS-22r found that the link between several questions and their intended domain was weak (e.g., items in the self-image and mental health domains) (Oeffinger et al., 2024). In addition, certain questions may not be worded appropriately for children or teenagers. The mental health domain of SRS-22r incorporates questions originally derived from the generic SF-36 survey which was originally designed for adults. Because of this, some questions may be less relevant or phrased less appropriately for younger adolescents (10-18 yrs) with AIS (Alamrani et al, 2021). Additionally, a retrospective study focusing on pre-operative patients with AIS found a weak correlation between the mental health and self-image domains and spine

asymmetry in adolescents with AIS (Cheshire et al., 2017). The authors argue that the SRS-22r questionnaire provides very little insight into the measurable aspects of spinal deformity that surgeons can directly modify.

Despite its acknowledged limitations, the SRS-22r remains the most frequently used and currently the most appropriate instrument for assessing health-related quality of life in individuals with scoliosis. Its widespread implementation, extensive validation across different languages and cultural contexts, and its comparability with existing research make it a valuable tool in both clinical and research applications.

4.5: Conclusion

In conclusion, patients with AIS have lower pulmonary function and poorer exercise capacity than the normal population. Muscle strength and endurance declines with curve severity. The control group were strongest while patients with mild/moderate AIS were stronger than those with severe AIS. Abnormal balance in those with AIS, irrespective of classification (mild/moderate, severe) was not as prevalent as reported in previous studies. Balance declined as curvature increased but not significantly in most outcomes. The AIS population had a significantly decreased quality of life across the curve spectrum. The current study found a deterioration in self-image, function, and mental health and rising levels of pain perception with increasing Cobb angle. Findings from this study suggest that a standardised assessment protocol should be introduced and applied at all spinal curve reviews. Early identification of specific physical dysfunction in AIS patients may enable timely and targeted intervention early in the diagnostic process. In addition, there is a strong argument for the introduction of a mental health service at the early stages of an AIS diagnosis.

Chapter 5: Public vs. Private treatment of patients with mild and moderate AIS: A cluster design study.

5.1: Introduction

In some European countries, notably Germany and Poland (Froehlich et al., 2023) a greater emphasis is placed on the use of physiotherapeutic scoliosis-specific exercises (PSSE) in addition to bracing for the management of patients with mild and moderate AIS (Negrini et al., 2018). PSSE interventions are not currently available as a treatment option in the public healthcare system in Ireland. There are a small number of private physiotherapy clinics providing Schroth programmes as a treatment option for those who can afford private care.

5.1.1: Physiotherapeutic Scoliosis Specific Exercises (PSSE)

PSSE is a generic term for conservative exercise programme used to treat patients with AIS. The International Society on Scoliosis Orthopaedic and Rehabilitation Treatment (SOSORT) recommends the use of PSSE interventions to reduce curve progression in those with AIS (Negrini et al., 2018,). The primary aims of PSSE are to reduce the Cobb angle and the angle of trunk rotation (ATR). The SOSORT guidelines for physical exercises and rehabilitation in AIS recommend that PSSE should consist of three-dimensional spinal correction, stabilisation of posture, training in activities of daily living (ADLs) and patient education. PSSE programmes therefore focus on corrective body posture, mobilisation, and strength and flexibility of the spine (Negrini et al., 2018). Among the seven major PSSE programmes described in detail in Chapter 1, Section 1.10, the Schroth programme is the most widely used for patients with AIS (Seleviciene et al., 2022).

The Schroth method is a specialised and well-established conservative treatment approach for scoliosis (Seleviciene et al., 2022). Schroth programmes are individualised according to the needs of the patient, the curve pattern, and the treatment stage (Negrini et al., 2018). The intervention focuses on correcting body posture, enhancing spinal mobility, and improving spinal strength and flexibility particularly targeting the concave side of the spinal curve as well as addressing pelvic alignment (see Figures 5.1 - 5.5). The intervention is designed to reduce spinal flexion and rotation while improving the alignment and orientation of the spinal vertebrae (Schreiber et al., 2019). Schroth exercises are designed around breathing cycles and isometric spinal corrections (Negrini et al., 2018, Berdishevsky et al., 2016). Central to the Schroth method is spinal autocorrection, which

refers to the patient's capacity to actively realign the spine in three dimensions to diminish spinal deformity (Fusco et al., 2011). In addition, Schroth programmes aim to provide patients with the tools to implement Schroth methods into their activities of daily living such as correctly sitting, standing, breathing, lifting and carrying (Negrini et al., 2018).

5.1.2: Cobb angle and ATR

Based on the SOSORT recommendations, research to date has primarily concentrated on the impact of PSSE on reducing Cobb angle and ATR (Weinstein et al., 2008, Romano et al., 2012, Berdishevsky et al., 2016, Negrini et al., 2018). There has been a general consensus that PSSE has a positive impact on Cobb angle in patients with AIS (Burger et al., 2019, Day et al., 2019, Seleviciene et al., 2022, Ma et al., 2023). Ma et al. (2023) separated the studies included in their review into sub-groups (mild, moderate and severe AIS) and found PSSE was a more effective treatment in patients with mild curves compared to those with moderate or severe AIS. However, in contrast to the earlier systematic reviews a more recent Cochrane review concluded that not enough evidence exists to support the argument that PSSE reduces Cobb angle or ATR in patients with mild, moderate or severe AIS (Romano et al., 2024).

5.1.3: Quality of life

Several systematic reviews have also assessed the effects of PSSE on quality of life (QOL). Anwer et al. (2015) and Burger et al. (2019) found overall improvements in QOL in patients with AIS after a PSSE intervention. Anwer et al. (2015) included six studies in a review, only three of which could be included in their meta-analysis. Burger et al. (2019) incorporated two studies in their review. One study (Kuru et al., 2016) was common to both reviews. In both reviews, a meta-analysis demonstrated a significant improvement in pooled QOL results. Similarly, Ceballos-Laita et al. (2023), using pooled results, reported significant improvements in QOL, but the results were based on only three studies. Seleviciene et al. (2022) included seven randomised control trials in their review evaluating the impact of a Schroth programme on QOL in patients with mild, moderate and severe AIS. The authors concluded that there was a lack of high-quality evidence to evaluate the effectiveness of PSSE interventions on QOL in children and adolescents with AIS.

5.1.4: Pulmonary function

There is limited knowledge regarding the effectiveness of PSSE on pulmonary function. Early studies of pulmonary function in patients with AIS identified impaired function of respiratory muscles and restrictions and asymmetric motion of the chest wall (Martínez-Llorens et al., 2010, Leong et al., 1999, Lisboa, 1985, Kotani, 2002). A number of studies have indicated that a PSSE programme may have a positive impact on pulmonary function in patients with AIS (Moramarco et al., 2016, Kim and Park, 2017, Amaricai et al., 2020, Liu et al., 2023, Rafferty et al., 2023). Amaricai et al. (2020) reported that, despite undergoing PSSE rehabilitation, and showing significant improvements in pulmonary function, patients with AIS continued to exhibit reduced pulmonary capacity when compared to a healthy control group.

A study by Kim and Park (2017) found a Schroth intervention and a respiratory muscle training intervention combined (intervention group) was more effective than a Schroth intervention alone. A more recent systematic review and meta-analysis concluded that both PSSE and aerobic interventions had a positive effect on pulmonary function in patients with AIS (Rafferty et al., 2023). This review advises caution concerning a direct comparison of absolute pulmonary function test results before and after an intervention. Such an approach fails to consider factors that can affect lung growth, potentially overstating the pulmonary improvements attributable to an intervention. The current study aims to evaluate whether a Schroth programme yields significant improvements in key pulmonary function tests when compared to a comparable cohort of adolescents with mild to moderate AIS receiving public health care.

5.1.5: Balance

A small number of studies have assessed the effects of a PSSE intervention on balance and postural sway in patients with AIS (Aktan and Erdoganoglu, 2021, Akyurek et al., 2022, Radwan et al., 2022). A literature review by Kastrinis et al. (2023) identified seven studies that evaluated conservative interventions on balance and postural sway in patients with AIS. Of the seven studies, three specifically assessed a Schroth intervention (Aktan and Erdoganoglu, 2021, Akyurek et al., 2022, Radwan et al., 2022). Only one of these studies (Radwan et al., 2022) used a validated balance platform to conduct the tests. In contrast to the current study, Radwan et al. (2022) evaluated balance stability using a double-leg stance on a moving platform. The studies conducted by Aktan and Erdoganoglu (2021) and Akyurek et al. (2022) primarily focused on assessing changes in the ATR, rather than static

balance and sway velocity. The secondary objectives of these studies included an examination of the effects of a Schroth intervention on dynamic balance (Aktan and Erdoganoglu, 2021) and the impact of Proprioceptive Neuromuscular Facilitation (PNF) on spinal joint reposition sense (Akyurek et al., 2022). Kastrinis et al. (2023) concluded that the Schroth method may contribute to improvements in certain aspects of postural control. They recommended that future studies should consider ‘different spinal curve patterns and severity’.

Chapter 4 (Study 2) of this thesis established that mild/moderate AIS participants had significantly poorer centre of pressure scores and greater postural sway when compared to a healthy control group. There is currently a lack of high-quality research on the impact of the Schroth programme on balance in patients with AIS. Accordingly, a key objective of the present study was to determine whether a Schroth programme can improve static balance and postural sway among individuals with mild to moderate AIS.

5.1.6: Exercise capacity, muscle strength, endurance and power

There is evidence that mild and moderate AIS can restrict exercise capacity (Barrios et al., 2005, Czaprowski et al., 2012, Abdelaal et al., 2018). To the author’s knowledge, no studies have been published evaluating the impact of a PSSE intervention on exercise capacity in patients with AIS.

There are a small number of studies that have identified muscle impairments in adolescents with AIS (Martínez-Llorens et al., 2010, Hassan and Mohammad, 2015, Becker et al., 2023). A systematic review and meta-analysis by Park et al. (2018) reported significant effect sizes for Schroth-based interventions on both back extensor strength (1.17) and trunk flexor strength (1.69). The review included evidence from four studies evaluating the effects of Schroth exercises on back extensor strength and two studies assessing their impact on trunk flexor strength in individuals with adolescent idiopathic scoliosis (AIS). To the author’s knowledge no studies have been conducted examining the efficacy of a PSSE intervention on upper and lower limb muscle strength, endurance, and power in those with mild and moderate AIS.

5.1.7: Aims and Objectives

The primary aim of this study was to evaluate the efficacy of a Schroth programme in participants with mild and moderate AIS. The specific objective was to examine the effects of a Schroth programme on participants recruited from private healthcare (PRI group), on

muscle strength, power, endurance, exercise capacity, pulmonary function, balance, and QOL when compared to a group of patients with mild and moderate AIS receiving ‘usual care’ in public healthcare (PUB group). The null hypothesis was there would be no difference in the outcomes between the two groups after a 4-month Schroth intervention.

5.2: Methodology

5.2.1: Study design

A prospective cluster design observational study was employed. This study was a comparison between two different populations (Public vs Private healthcare), receiving different treatments, in different settings by different therapists. Participants clinically diagnosed with mild or moderate AIS were recruited for the study. Participants recruited from private scoliosis clinics and private hospitals (Blackrock and Beacon hospitals) participated in a 4-month Schroth programme (PRI group), by attending a total of 6 treatment sessions and completing an ongoing home exercise programme (HEP) at a frequency of 5 sessions per week. Participants recruited from CHI (PUB group) received standard public hospital care, which consisted of observation, including radiographic assessment, Cobb angle measurement, and bracing when clinically indicated (i.e., usual care). Every participant was assessed at baseline (commencement of their treatment) and again after 4 months. Ethical approval was obtained for this study between June and September 2019 (see Chapter 3, Section 3.1 for a full description).

The mean (SD) changes in pulmonary function (FVC) observed by Americali et al. (2018) in a cohort of patients undergoing Schroth treatment, was used to determine the expected effect size for this study. Based on the resultant effect size of $f=0.091$, a P-value of 0.05 and a statistical power of 85%, the required sample size was estimated at $n=192$.

5.2.2: Recruitment and consent

Patients recently diagnosed with mild or moderate AIS at Children’s Health Ireland were recruited on a continuous basis into the PUB group via a poster campaign. In parallel, patients with recent, comparable diagnoses of AIS, referred from private hospitals or private scoliosis clinics prior to commencing a Schroth exercise programme, were recruited in the PRI group. A full description of the recruitment, consent process, and recruitment challenges are outlined in Chapter 3, Section 3.2.

5.2.3: Participant Screening

Screening for inclusion into this study is described in detail in Chapter 3 Section 3.3. Study inclusion criteria for those with mild and moderate AIS are described in Section 3.3.1, while study exclusion criteria are described in Section 3.3.2.

5.2.4: Assessment and outcome measures

Assessments were conducted in the exercise laboratory located in the Trinity Centre for Health Sciences, St. James's Hospital, Dublin. The assessment protocol is set out in detail in Chapter 3, Section 3.4. A detailed description of the outcome variables assessed, and equipment used is also provided in Chapter 3, Section 3.5.

5.2.5: The Schroth programme (PRI) group

Participants in the PRI group were required to complete a 4-month Schroth programme. Each participant attended the clinic for a weekly 90-minute treatment session for the first 3 weeks, and a 60-minute treatment session for each of the subsequent 3 months. In total, each participant therefore attended the clinic for 6 x one-to-one treatment sessions over the 4-month period. In addition, they were expected to complete a 30-minute home exercise programme (HEP), 5 times each week.

The initial 90-minute session comprised a comprehensive spinal assessment and the development of an individualised treatment plan. Each treatment plan was reviewed and discussed with the participant and their caregivers, in order to ensure comprehension and “buy-in” from all involved. A digital HEP was then provided to the participant and their caregiver, which included a detailed description of all movements and the prescribed sequence, duration, number of sets and repetitions required. Each treatment session began with a review of the participant's progress to date, including updates on their experiences with the HEP. The remainder of each treatment session focused on teaching and emphasising these specific movements and providing feedback to the patients and their caregivers. The Schroth programme was administered by two certified Schroth physiotherapists (NMG and RE) with extensive training and experience in the Schroth method.

While the intervention was tailored, the examples provided below offer a general overview of the intervention process. Treatment sessions commenced with ‘breath’ training. AIS has been shown to weaken respiratory muscles and impair cardiorespiratory function (Lonstein, 1994). Rotational angular breathing (RAB) is an essential component of the Schroth

method. Spinal rotation during breathing targets the rib cage and surrounding soft tissues, particularly the concave side of the thoracic, to improve the muscular structures of the thoracic wall and increase respiratory capacity (Kim and Hwangbo, 2016). Each individualised programme was tailored to the participant's unique spinal curvature pattern and the severity of their scoliosis, ensuring that treatments targeted their specific postural and functional needs.

Following the initial emphasis on RAB, the Schroth programme shifts its focus to spinal alignment and postural correction. The postural positions outlined below illustrate key components of this phase of treatment. The first four sample exercises (Figures 5.1 to 5.4) are classified as 'unloading' with props in the desired position to support the spine. The props maintain a constant pressure to specific locations on the spine and torso to maintain correct spinal positioning. The fifth example (Figure 5.5) demonstrates the translation of body position from the 'unloading' phase to the 'loading' phase where the participant holds the spine in the correct position without the support of props. This exercise teaches the adolescent the ability to maintain correct body posture without support. The exercise is initially worked on in sitting and progresses to standing. Each position is held isometrically for a minimum of three minutes up to a maximum of 5 minutes.

A typical 60-minute treatment session included RAB for 10 minutes, followed by 2 sets x 3–5-minute repetitions of supine lying with props (Figure 5.1), side-lying (Figure 5.2), prone kneeling (Figure 5.3), semi-hangs (Figure 5.4) and integration sit and stand (Figure 5.5). The level of difficulty for each participant was based on the individual's curve location, severity, and their progress to date. The HEP was reviewed and adjusted if required at the end of each treatment session. Activities of daily living including dining, grooming, transfers, and seated positioning (such as in school settings) were integrated into the intervention to gradually help participants incorporate corrective spinal alignment into their everyday routines. Functional items like counter-tops, tables, and chairs were utilised as tools to support and reinforce proper postural habits during everyday tasks. Full length mirrors were recommended for the HEP to allow the participant to observe their body position when carrying out their exercises.



Figure 5.1: Spine elongation and curve countertraction
Source: Berdishevsky et. al., (2016)



Figure 5.2: Unloading lumbar curves and major thoracic curves



Figure 5.3: Active thoracic mobilisation

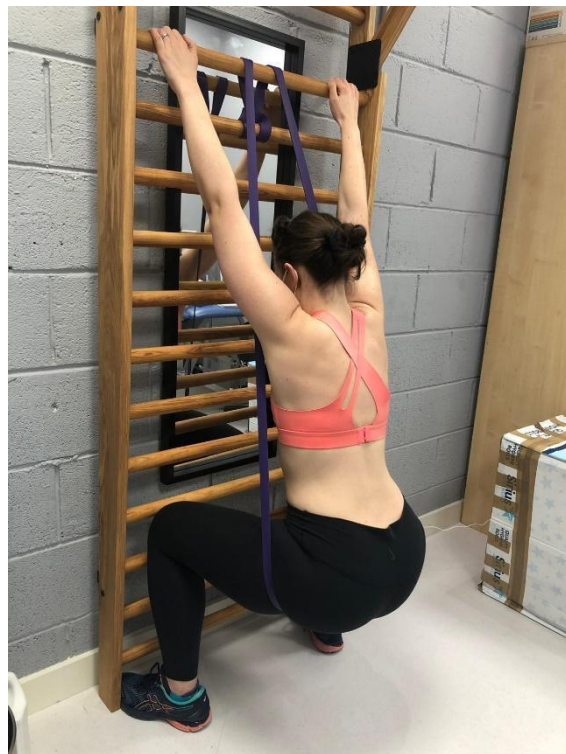


Figure 5.4: Lateral, dorsal and caudal pelvic correction



Figure 5.5: Spinal flexibility, loading and unloading integration sitting and standing.

Source: Berdishevsky et. al., (2016)

5.2.6: Public healthcare (PUB) group

The participants in the PUB group received 'usual care' which consisted of observation, including radiographic assessment Cobb angle measurement, and bracing when clinically indicated. Usual care assessments are normally carried out on an annual basis, as described in Section 1.10. No PUB participant had their treatment (observation or bracing) changed nor undertook any Schroth or PSSE treatment during the study period.

5.2.7: Compliance with the Schroth programme

Attendance at clinical treatment sessions were recorded by the Schroth physiotherapist in the clinic's patient files. Compliance with the HEP was monitored and recorded in all cases by the participants caregiver. Caregivers were asked to maintain a record of the participant's home exercise programme (HEP) compliance. At each subsequent treatment session, they were requested to report the participant's level of compliance using a Likert scale with the following categories: Regular (80–100%), Often (60–80%), Sometimes (40–60%), A little of the time (20–40%), and Rarely (<20%). Caregivers were also asked to report any issues that may have arisen (sickness, difficulty with specific exercises etc.). HEP compliance was recorded in the clinical notes by the physiotherapist. Upon completion of the four-month programme, the clinic staff provided the investigator with a written summary for each participant stating their attendance at treatment sessions and their adherence to the home exercise programme (HEP).

5.2.8: Data collection, processing and analysis

Data collection and processing is described in detailed in Chapter 3, Section 3.6. Before analysis took place, the master Excel document was screened for any errors. Additionally, all individual Excel data entries were crosschecked against the original CDCS documents by a third party to ensure accuracy. All hardcopy records (CDCS and questionnaires) were securely stored in accordance with ethical and data storage requirements.

Statistical analysis was conducted using the statistical software package, GraphPad Prism (GraphPad Prism version 10.0.0 for Windows). Data collated in Excel were copied in columnar form into separate variable files in the GraphPad Prism software. The mean results for blood pressure and muscle strength were calculated in Excel before data transfer. Results were processed in a group format, with no reference to individual participants' details at any stage of the process.

The Kolmogorov-Smirnov test (Eadie et al., 1971, Wayne, 1990) was used to determine if the data sets followed a normal distribution. Group results were presented as mean ($\bar{x}$) and standard deviation (SD). An unpaired t-test was conducted at baseline to assess if there were any significant differences in age, height, body mass, BMI, and thoracic or lumbar curves between the PRI group and the PUB group.

A two-way mixed factorial ANOVA (examining time and group effects) was conducted to assess the impact of two independent variables, time and intervention on the outcome measures assessed. (Blood pressure, resting heart rate, pulmonary function, exercise capacity, grip strength, lumbar strength, upper and lower limb strength, upper and lower limb endurance and power, balance, quality of life, physical activity, and sedentary behaviour). When a significant effect ($P < 0.05$) in either time, intervention or interaction effect was identified, post-hoc testing (Bonferroni) was performed to quantify where the differences lay. For each variable, the mean and standard deviation (SD), simple main effects, P value, and F-score are reported.

5.3: Results

5.3.1: Demographic and Anthropometric Measurements

Sixteen participants were recruited for this study. One participant was deemed ineligible following a diagnosis of Prader-Willi syndrome. The remaining 15 participants formed two groups, eight participants took part in a 4-month Schroth programme, and the remaining seven participants received ‘usual care’ from CHI. All participants were Caucasian, eleven of the participants were female, and four were male. Seven participants had double curves (PRI/PUB; 4/3), five had thoracic-only curves (PRI/PUB; 3/2) and three participants had lumbar-only curves (PRI/PUB; 1/2). Three participants in the PUB group (n=3) and two of the participants in the PRI group (n=2) were braced prior to commencement of the study. There were no statistically significant differences identified between groups for any of the variables tested ($P < 0.05$) (Table 5.1).

Participant attendance in the PRI group was 76% for clinical treatment sessions. No dropouts were reported for the PRI group. HEP compliance was recorded as ‘Regular’ (80-100%) for all participants.

Table 5.1. Anthropometric characteristics

	PRI Group (n=8)		PUB Group (n=7)		
Biological sex (F/M)	6/2		5/2		
Braced (n)	2		3		
Thoracic curve (n)	3		2		
Lumbar curve (n)	1		2		
Double curve (n)	4		3		
	Mean	SD	Mean	SD	P
Age (years)	13.50	1.64	15.50	2.61	0.09
Mass (kg)	51.10	9.70	54.70	9.80	0.48
Height (cm)	165	8	163	5	0.63
BMI (kg/m ²)	18.40	2.06	20.50	3.18	0.16
Thoracic curve (°)	21	12	17	16	0.54
Lumbar curve (°)	14	14	19	16	0.50

5.3.2: Blood pressure and resting heart rate

There were no statistically significant time, group or interaction effects observed for systolic blood pressure (mmHg), diastolic blood pressure (mmHg) or resting heart rate (beats.min⁻¹) (Table 5.2).

Table 5.2. Blood pressure and resting heart rate

PRI Group (n=8)			PUB Group (n=7)		Fixed effects (type III)	P	F
Mean	SD	Mean	SD				
Systolic blood pressure (mmHg)							
Pre	106	13	109	6	Time	0.742	0.11
Post	105	10	108	14	Group	0.632	0.24
					Time by group	0.945	0.00
Diastolic blood pressure (mmHg)							
Pre	68	6	69	5	Time	0.815	0.06
Post	67	5	68	9	Group	0.777	0.08
					Time by group	0.986	0.00
Resting heart rate (beats.min ⁻¹)							
Pre	73	11	72	10	Time	0.290	1.22
Post	76	10	73	5	Group	0.716	0.14
					Time by group	0.523	0.43

5.3.3: Pulmonary function

A significant overall time effect was found for FEV₁ (P=0.034). Post-hoc testing revealed no significant pre-post differences in either the PRI (P=0.227) or the PUB group (P= 0.245). No significant overall time, group or interaction effects were observed for any of the remaining pulmonary variables (FVC, FEV₁/FVC, PEF, and predicted FEV₁) (Table 5.3).

Table 5.3. Pulmonary function

PRI Group (n=8)			PUB Group (n=7)		Fixed effects (type III)	P	F
	Mean	SD	Mean	SD			
FEV ₁ (L.sec ⁻¹)							
Pre	2.73	0.42	2.73	0.49	Time	0.034	5.60
Post	2.88	0.59	2.89	0.49	Group	0.995	3.70
					Time by group	0.962	0.00
FVC (L)							
Pre	3.05	0.50	3.09	0.53	Time	0.243	1.50
Post	3.19	0.60	3.12	0.59	Group	0.974	0.00
					Time by group	0.436	0.65
FEV ₁ /FVC (ratio)							
Pre	90.00	5.07	88.29	6.02	Time	0.196	1.86
Post	90.38	4.53	92.71	5.59	Group	0.884	0.02
					Time by group	0.270	1.33
PEF (L)							
Pre	367	90	358.00	74	Time	0.376	0.84
Post	377	70	366.14	47	Group	0.792	0.07
					Time by group	0.905	0.02
Predicted FEV ₁ (%)							
Pre	85	1	85	1	Time	0.393	0.78
Post	86	0	87	1	Group	0.981	0.00
					time by group	0.678	0.18
Predicted FVC (%)							
Pre	83	1	84	1	Time	0.534	0.41
Post	82	1	83	1	Group	0.812	0.06
					Time by group	0.746	0.12

(**FEV₁**) forced expiratory volume in 1 second; (**FVC**) forced vital capacity, (**PEF**) peak expiratory flow.

5.3.4: Exercise capacity

All participants undertook a VO₂max test on a cycle ergometer. There were no significant group, time or interaction effects for VO₂max, HRmax, peak workload or predicted VO₂max (Z-score) (Table 5.4).

Table 5.4: VO₂max, HRmax, peak workload, and predicted VO₂max

PRI Group (n=8)			PUB Group (n=7)		Fixed effects (type III)	P	F
Mean	SD	Mean	SD				
VO ₂ max (mL.kg ⁻¹ .min ⁻¹)							
Pre	49.8	15.9	43.3	7.4	Time	0.239	1.52
Post	44.4	11.9	38.9	6.6	Group	0.189	1.92
					Time by group	0.893	0.02
HRmax (beats. min ⁻¹)							
Pre	179	12	182	11	Time	0.123	2.72
Post	176	17	175	14	Group	0.889	0.02
					Time by group	0.539	0.40
Peak workload (W)							
Pre	143	41	151	16	Time	0.764	0.09
Post	150	57	137	29	Group	0.911	0.01
					Time by group	0.342	0.97
Predicted Z scoresVO ₂ max							
Pre	0.6	1.4	0.6	0.9	Time	0.586	0.31
Post	0.4	2.2	0.1	0.9	Group	0.807	0.06
					Time by group	0.733	0.12

(VO₂max) maximal oxygen consumption; (Predicted Z score) difference between the measured value and the predicted value.

5.3.5: Lumbar strength and grip strength

A significant overall interaction effect (P=0.013) and time effect (P=0.032) were identified for lumbar strength. Post-hoc testing indicated that the PRI group demonstrated a significant improvement in lumbar strength (75±22 vs. 93±34kg; P=0.002), while no significant changes were observed in the PUB group. This improvement in lumbar strength within the PRI group was deemed not only statistically significant but also “clinically meaningful” as it exceeded the previously published technical error for this measurement (Hannibal et al., 2006). In contrast, no significant overall time, group or interaction effects were identified for grip strength measures (Table 5.5).

Table 5.5. Lumbar strength and grip strength

PRI Group (n=8)			PUB Group (n=7)		Fixed effects (type III)	P	F
Mean	SD	Mean	SD				
Lumbar Strength (kg)							
Pre	75	22	79	16	Time	0.032	5.76
Post	93**	34	77	21	Group	0.625	0.25
					Time by group	0.013	8.25
Hand Grip- dominant (kg)							
Pre	25	7	24	5	Time	0.136	2.53
Post	27	9	25	5	Group	0.625	0.25
					Time by group	0.403	0.75
Hand Grip-non-dominant (kg)							
Pre	23	7	24	5	Time	0.224	1.63
Post	24	9	24	5	Group	0.950	0.00
					Time by group	0.543	0.39

Asterisk infers a significant difference between pre- and post-assessments within either the PRI or PUB group (** P<0.01).

5.3.6: Upper and lower limb strength

The strength of key muscle groups was assessed, and the results are presented in Tables 5.6.1 and 5.6.2. A significant overall time effect was observed for right hip extensor strength. Post-hoc testing indicated a significant increase in right hip extensor strength within both the PRI group (P=0.024) and the PUB group (P=0.004). The left hip extensors also showed a significant overall time effect, and post-hoc testing indicated a significant and clinically meaningful (>8%) increase in hip extensor strength within the PUB group only (P=0.005). No significant time, group or interaction effects were noted for hip flexor strength.

A significant overall time effect was observed for left hip abductor strength. Post-hoc analysis revealed a significant and clinically meaningful (>5%) increase in left hip abductor strength within the PRI group only (P=0.030). No significant group or interaction effects were identified for right hip abductor strength. A significant overall time effect was also found for both left (P=0.008) and right hip adduction strength (P=0.018). Additionally, an interaction effect (P=0.007) was observed for left hip adductor strength. For both left (P=0.001) and right (P=0.007) hips, post-hoc analysis indicated a significant increase in the

PRI group only. These increases in hip adductor strength within the PRI group were deemed clinically meaningful as they exceeded the 6% threshold established by Thoborg et al. (2010).

A significant overall group effect was observed for right lower trapezius strength. The right lower trapezius was significantly stronger in the PRI group at both timepoint 1 ($P=0.017$) and timepoint 2 ($P=0.044$), compared to the PUB group. Additionally, a significant overall time effect was observed for left lower trapezius strength. Post-hoc analysis identified a significant time effect for the PUB group only ($P=0.030$), however this change was not deemed “clinically meaningful” as it did not exceed the previously reported 2.6kg technical error of the measurement (Michener et al., 2005). No significant interaction effect was identified for left or right upper trapezius. Finally, a significant overall time effect was identified for left latissimus dorsi strength. Post-hoc analysis revealed that left latissimus dorsi strength significantly increased across time in the PRI group only ($P=0.049$). No significant overall time, group or interaction effects were observed for latissimus dorsi (right).

Table 5.6.1. Muscle strength - Lower limb

PRI Group (n=8)			PUB Group (n=7)		Fixed effects (type III)	P	F
Kg	Mean	SD	Mean	SD			
Hip flexor Right							
Pre	17.7	4.9	15.2	3.4	Time	0.055	4.43
Post	18.0	3.7	17.1	1.6	Group	0.366	0.88
					Time by group	0.148	2.36
Hip flexor Left							
Pre	18.4	5.0	16.0	3.4	Time	0.240	1.52
Post	18.7	5.6	17.7	2.2	Group	0.432	0.66
					Time by group	0.407	0.74
Hip extensor Right							
Pre	17.3	6.3	12.7	4.0	Time	0.000	23.17
Post	20.3*	6.5	16.9**	2.4	Group	0.143	2.43
					Time by group	0.418	0.70
Hip extensor Left							
Pre	17.6	8.0	12.1	3.0	Time	0.001	17.91
Post	20.7	7.3	18.0**	2.1	Group	0.174	2.07
					Time by group	0.213	1.72
Hip abductor Right							
Pre	6.4	2.3	5.7	2.5	Time	0.208	1.76
Post	7.8	2.0	5.5	1.4	Group	0.149	2.35
					Time by group	0.095	3.25
Hip abductor Left							
Pre	7.3	2.0	6.1	2.4	Time	0.021	6.90
Post	8.6*	2.5	6.6	2.5	Group	0.184	1.97
					Time by group	0.216	1.69
Hip adductor Right							
Pre	7.9	3.1	6.6	1.6	Time	0.018	7.35
Post	9.5**	3.1	6.8	2.0	Group	0.153	2.31
					Time by group	0.053	4.55
Hip adductor Left							
Pre	7.6	2.2	6.23	1.7	Time	0.006	10.83
Post	9.3**	2.6	6.26	1.7	Group	0.056	4.40
					Time by group	0.007	10.27

Asterisk infers significant difference between pre-and post-assessments within either the PRI or PUB groups (* P<0.05, ** P<0.001).

Table 5.6.2. Muscle strength – Upper limb

PRI Group (n=8)			PUB Group (n=7)		Fixed effects (type III)	P	F
Kg	Mean	SD	Mean	SD			
Trapezius lower (R)							
Pre	4.8 ^{\$}	1.5	3.1	0.5	Time	0.081	3.58
Post	5.1 ^{\$}	1.4	3.6	0.8	Group	0.015	7.82
					Time by group	0.533	0.41
Trapezius lower (L)							
Pre	4.4	1.4	2.8	0.8	Time	0.014	8.17
Post	4.8	1.8	3.7*	1.1	Group	0.070	3.90
					Time by group	0.265	1.36
Trapezius upper (R)							
Pre	19.8	6.8	15.9	4.2	Time	0.113	2.89
Post	21.3	4.8	17.5	2.0	Group	0.122	2.74
					Time by group	0.916	0.01
Trapezius upper (L)							
Pre	18.7	5.5	15.2	4.3	Time	0.010	8.97
Post	21.9	4.2	18.7	3.7	Group	0.122	2.74
					Time by group	0.909	0.01
Latissimus dorsi (R)							
Pre	13.1	4.3	11.5	2.5	Time	0.219	1.67
Post	13.6	4.0	12.5	3.0	Group	0.470	0.55
					Time by group	0.641	0.23
Latissimus dorsi (L)							
Pre	11.6	2.9	10.1	1.3	Time	0.009	9.39
Post	13.7*	3.3	11.7	2.3	Group	0.183	1.98
					Time by group	0.695	0.16

Asterisk infers significant difference between pre- and post-assessments within either the PRI or PUB groups (* P<0.05). Dollar symbols (\$) infer significant difference between groups (P<0.05).

5.3.7: Upper and lower limb endurance

A significant overall interaction time and group effect was identified for upper limb endurance, as measured by a push-up test. Subsequent post-hoc tests identified no significant time effect within either group or a significant group effect within either time-point. Although not statistically significant, the PUB group demonstrated a noticeable mean decline in upper limb endurance over time, whereas the PRI group showed an improvement over time. Lower limb endurance, assessed through a timed single-leg squat, showed no

significant interaction, time, or group effects. Although not statistically significant, the PUB group demonstrated a trend towards decline in mean right-sided single-leg squat performance over time, whereas the PRI group showed an increase in their mean score (Table 5.7).

Table 5.7. Upper and lower limb endurance

PRI Group (n=8)		PUB Group (n=7)		Fixed effects (type III)	P	F
Mean	SD	Mean	SD			
Push-ups (n)						
Pre	4	6	10	8	Time	0.658
Post	7	10	5	7	Group	0.21
				Time by Group	0.603	0.28
					0.010	9.08
Single-leg wall squats (R) (secs)						
Pre	10	11	7	10	Time	0.990
Post	14	16	3	2	Group	0.00
				Time by Group	0.188	1.93
					0.251	1.44
Single-leg wall squats (L) (secs)						
Pre	4	4	7	9	Time	0.176
Post	9	10	10	11	Group	1.94
				Time by Group	0.538	0.39
					0.761	0.09

5.3.8: Upper and Lower Limb Power

No significant group, time or interaction effects were identified for either upper limb power or lower limb power (Table 5.8.).

Table 5.8. Upper and lower limb power

PRI Group (n=8)			PUB Group (n=7)		Fixed effects (type III)	P	F
Mean	SD		Mean	SD			
Medicine Ball Throw (cm)							
Pre	176	39.3	191	35.3	Time	0.400	0.76
Post	181	33.1	196	26.4	Group	0.383	0.81
					Time by group	0.916	0.01
Jump Height (cm)							
Pre	25.3	7.7	23.9	5.9	Time	0.886	0.02
Post	26.4	6.5	22.4	5.6	Group	0.419	0.70
					Time by group	0.305	1.14
Maximum Power (W)							
Pre	1552	560	1580	414	Time	0.431	0.66
Post	1747	543	1526	334	Group	0.684	0.17
					Time by group	0.177	2.04
Maximum Force (N)							
Pre	828	213.6	843	197.2	Time	0.463	0.57
Post	880	192.8	844	160.3	Group	0.912	0.01
					Time by group	0.482	0.53
Max Force/ Body Weight (N/kg)							
Pre	23.8	3.1	22.4	2.6	Time	0.443	0.63
Post	23.1	2.6	22.0	2.8	Group	0.338	0.99
					time by group	0.875	0.03

5.3.9: Balance and sway velocity

No significant overall effects were identified for C90 area [mm²] (Table 5.9.1). However, a significant overall group effect was observed for mean sway velocity during both double-

leg stance with eyes closed and single-leg stance with eyes closed (Table 5.9.2). For both double-leg stance with eyes closed ($P<0.05$) and single-leg stance with eyes closed ($P<0.05$), the PRI group exhibited greater sway velocity compared to the PUB group before the intervention began. Post-hoc testing revealed no significant differences between the groups for either test following the intervention.

Table 5.9.1. Balance - C90 Area

PRI Group (n=8)			PUB Group (n=7)		Fixed effects (type III)	P	F
Mean		SD	Mean		SD		
C90 Area [mm²]							
Double leg stance: eyes open							
Pre	402	222	409	152	Time	0.445	0.62
Post	347	152	601	489	Group	0.285	1.24
					Time by group	0.184	1.97
Single leg stance: eyes open							
Pre	2161	1653	3473	4809	Time	0.076	3.42
Post	1270	962	957	226	Group	0.592	0.29
					Time by group	0.386	0.78
Tandem stance: eyes open							
Pre	742	405	997	852	Time	0.450	0.61
Post	1617	2073	703	243	Group	0.504	0.47
					Time by group	0.142	2.44
Double leg stance: eyes closed							
Pre	671	424	290	156	Time	0.511	0.46
Post	545	341	558	549	Group	0.310	1.12
					Time by group	0.084	3.51
Single leg stance: eyes closed							
Pre	12068	6000	7130	4377	Time	0.878	0.02
Post	11237	7893	8663	5561	Group	0.108	2.77
					Time by group	0.605	0.27
Tandem stance: eyes closed							
Pre	9449	9260	4949	4583	Time	0.433	0.63
Post	6617	5619	4203	2308	Group	0.136	2.37
					Time by group	0.646	0.22

Table 5.9.2. Balance - Sway Velocity

PRI Group (n=8)			PUB Group (n=7)		Fixed effects (type III)	P	F
Mean	SD		Mean	SD			
Mean sway velocity [mm/s]							
Double leg stance: eyes open							
Pre	13.4	3.7	11.9	3.9	Time	0.687	0.17
Post	13.6	4.0	12.6	5.0	Group	0.515	0.45
					Time by group	0.844	0.04
Single leg stance: eyes open							
Pre	43.3	8.6	41.2	22.5	Time	0.200	1.82
Post	40.4	10.4	33.2	6.0	Group	0.416	0.71
					Time by group	0.541	0.39
Tandem stance: eyes open							
Pre	30.3	10.6	27.9	10.6	Time	0.289	1.22
Post	38.8	19.2	26.2	5.8	Group	0.222	1.65
					Time by group	0.120	2.77
Double leg stance: eyes closed							
Pre	20.2 ^{\$}	7.0	13.9	3.0	Time	0.580	0.32
Post	18.3	5.5	14.2	3.8	Group	0.040	5.21
					Time by group	0.453	0.60
Single leg stance: eyes closed							
Pre	138.0 ^{\$}	50.3	92.4	40.5	Time	0.987	0.00
Post	128.4	41.6	102.5	39.4	Group	0.048	4.76
					Time by group	0.533	0.41
Tandem stance: eyes closed							
Pre	107.2	46.0	77.4	53.5	Time	0.412	0.72
Post	92.4	54.2	66.5	20.6	Group	0.153	2.31
					Time by group	0.900	0.02

Dollar symbols (\$) infers significant difference between groups (P<0.05).

5.3.10: Quality of life

A significant but not “clinically meaningful” (Carreon et al., 2010) overall time effect was found for pain perception, with both groups displaying poorer pain scores at time-point 2 (P=0.043). However, post-hoc testing did not identify a time effect in either the PUB or PRI group. An overall group effect was observed for mental health. Post-hoc analysis

revealed that the PUB group had poorer mental health than the PRI group at the initial assessment ($P=0.007$). No significant overall effects were identified for the self-image, function or treatment satisfaction domains. (Table 5.10).

Table 5.10. Quality of life

PRI Group (n=8)			PUB Group (n=7)		Fixed effects (type III)	P	F
Mean		SD	Mean		SD		
Pain Perception							
Pre	4.50	0.24	4.49	0.36	Time	0.043	4.24
Post	4.25	0.93	4.40	0.81	Group	0.665	0.19
					Time by group	0.317	1.02
Function							
Pre	4.80	0.61	4.71	0.57	Time	0.560	0.34
Post	4.68	0.69	4.77	0.60	Group	0.968	0.00
					Time by group	0.120	2.48
Mental Health							
Pre	4.80 ^s	0.21	3.74	0.70	Time	0.704	0.15
Post	4.05	0.75	3.89	0.87	Group	0.016	6.01
					Time by group	0.092	2.92
Self-image							
Pre	3.93	0.35	4.03	0.75	Time	0.586	0.30
Post	3.95	1.05	4.14	0.77	Group	0.437	0.61
					Time by group	0.586	0.30
Treatment satisfaction							
Pre	4.19	1.11	4.43	0.65	Time	0.262	1.31
Post	3.94	1.06	4.14	1.03	Group	0.424	0.66
					Time by group	0.940	0.01

SRS-22r Scoliosis Research Society 22r Questionnaire. Dollar symbol (\$) infers a significant difference between groups ($P<0.05$). Based on Likert scoring 0-5 where 5 is the best possible outcome.

5.3.11: Physical activity and sedentary behaviour

No significant time or group effects were identified for either weekly physical activity or time spent sitting (Table 5.11).

Table 5.11. Physical activity and sedentary behaviour

PRI Group (n=8)			PUB Group (n=7)		Fixed effects (type III)	P	F
Mean		SD	Mean		SD		
MET output (mins/wk) ¹⁾							
Pre	5093	4121	3076	2140	Time	0.067	4.00
Post	3672	2277	2455	974	Group	0.234	1.56
					Time by group	0.447	0.61
Sitting time (mins/wk) ¹⁾							
Pre	394	150	386	84	Time	0.211	1.73
Post	359	151	313	141	Group	0.644	0.22
					Time by group	0.652	0.21

Results: Main findings

- Patients with mild and moderate AIS who received a 4-month Schroth programme had significant improvements in the following outcome variables:
 - Lumbar strength
 - Left hip abduction, and bilateral adduction strength
 - Left latissimus dorsi strength
- The Schroth programme had no significant effect on the following outcome variables:
 - Blood pressure and resting heart rate.
 - Pulmonary function, FEV₁ (l.sec⁻¹), FVC (litres), FEV₁ /FVC (%), PEF (L.min⁻¹), % predicted FEV₁, and % predicted FVC.
 - VO₂max (mL.kg⁻¹.min⁻¹), peak workload (W), max heart rate (beats.min⁻¹),
 - Most pelvic muscle and upper limb muscle groups tested on the dominant side.
 - Grip strength, upper and lower limb endurance, upper and lower limb power, balance and postural sway, sedentary time or physical activity levels

5.4: Discussion

The aim of the current study was to compare the effectiveness of a Schroth programme in comparison to ‘usual care’ for individuals with mild and moderate adolescent idiopathic scoliosis (AIS). Specifically, the study assessed the impact of a public healthcare and private healthcare intervention on impairments identified in Chapter 4, Study 2. The key findings indicate that a 4-month Schroth programme significantly improved lumbar strength and strength in certain other muscle groups, most notably left and right hip adductors, left hip abductors and left latissimus dorsi (Table 5.5 and 5.6.1).

However, the Schroth programme did not have a significant effect on several other outcome measures. No differences were observed between the PUB and PRI groups for blood pressure, resting heart rate, or pulmonary function. Similarly, no intervention effect was found for exercise capacity indicators such as VO_2max , maximum heart rate, or maximal workload. Additionally, there were no significant differences in the muscle strength of bilateral hip flexors, right hip abductors, bilateral upper trapezius or right latissimus dorsi. Also, no differences were identified between the groups for grip strength, muscle endurance, muscle power, balance, postural sway, or across any of the quality-of-life domains. Weekly physical activity levels and sedentary behaviour also remained unchanged between groups following the 4-month intervention.

Attendance for both Schroth therapy sessions and adherence to the HEP programme was reported to be high among participants. This high level of engagement is not unexpected, as families of children and adolescents with AIS are often highly motivated and committed to managing the condition. Given the chronic nature of AIS and the potential long-term effects, caregivers and patients are typically proactive in seeking out and adhering to conservative treatment options such as the Schroth method.

5.4.1: Curve progression

Although curve progression is regarded as the primary clinical outcome of interest in Schroth-based scoliosis interventions, it was not included as an outcome in the present study. The specific aim of Study 3 was to evaluate the effects of a 4-month Schroth programme on functional and quality-of-life outcomes including muscle strength, power, endurance, exercise capacity, pulmonary function, balance, and health-related quality of life in patients with mild and moderate AIS receiving private healthcare (PRI group), compared to ‘usual care’ public healthcare (PUB group).

This focus reflects a functional and patient-centred perspective, emphasising improvements in physical capacity and overall well-being. Curve progression typically requires longer-term monitoring, often spanning months to years, to capture clinically meaningful changes in spinal alignment. Given the short 4-month intervention period and the observational study design, assessing curve progression was unlikely to yield reliable or meaningful results. Furthermore, from an ethical viewpoint, the need for additional exposure to X-ray that was unlikely to yield any meaningful results was also avoided. Therefore, the study was designed to test the null hypothesis that no differences would be observed between the PRI and PUB groups in the selected functional and quality-of-life outcomes. The focus of the research in this study was on measurable short-term effects of the Schroth intervention rather than long-term anatomical changes in the spine.

5.4.2: Muscle strength and endurance

The findings of the current study suggest that a Schroth programme may be effective in enhancing muscle strength in the lumbar region, as well as in certain hip and thoracic muscle groups, when compared to a PUB group receiving ‘usual care’. Previous studies have demonstrated that Schroth interventions, which focus on spinal mobilisation and strengthening particularly on the concave side of the spinal curve can be effective in improving strength in the lumbar and pelvic musculature (Schreiber et al., 2015, Park et al., 2018). The finding of the current study supports the role of targeted, curve-specific exercises in addressing some muscle imbalances associated with AIS. While the current study identified significant improvements after a 4-months, both Schreiber et al. (2015) and a systematic review by Park et al. (2018) found the greatest effects occurred after a six-month PSSE programme.

Although muscle strength normally increases during adolescence as part of natural growth (De Ste Croix, 2007), the extent to which this influenced strength measures in the current study has could not be fully determined. However, the significant improvements in certain measures which were not observed in the PUB cohort, suggests that PSSE did contribute to increased strength within specific muscle groups. In addition, the strength gains were region-specific, notably in muscles directly targeted by the Schroth corrective postures and stabilisation exercises rather than generalised across all muscle groups. However, the extent to which natural growth and maturation may have contributed to the results could not be fully determined in the absence of longitudinal tracking of a healthy control cohort of age-matched adolescents.

To the author's knowledge, no study to date has investigated the effects of a Schroth programme on upper and lower limb muscle endurance in adolescents with AIS. Existing research on muscle endurance in this population has primarily focused on the endurance of the paraspinal musculature with mixed results (Schreiber et al., 2015, Khaledi et al., 2024). Results from the current study suggest that participation in a Schroth programme does not significantly improve upper or lower limb muscle endurance. The PRI group demonstrated a trend towards a significant improvement in upper limb endurance and due to the small sample size, it is possible this observation is a false negative.

Notably, both the PUB and the PRI groups had poor baseline upper and lower limb endurance, with all participants falling below the 20th percentile for their age and gender based on normative data (Miller, 2012, Arnot and Gaines, 1984). Both groups remained in the lower percentile for their age and gender, when re-assessed.

Muscle endurance, the ability to maintain workload at submaximal levels, is closely linked to an individual's pulmonary and cardiovascular capacity (Yang et al., 2022, Allaire et al., 2004). Neither group demonstrated significant improvements in exercise capacity or pulmonary function over the course of the intervention period. The lack of improvement in exercise capacity and pulmonary function may have been a contributing factor to the limited improvements in muscular endurance observed in the current study. Previous studies have shown the positive effects of aerobic exercise on pulmonary function in AIS (dos Santos Alves et al., 2006, Athanasopoulos et al., 1999, Xavier et al., 2020). However, the Schroth programme does not include aerobic components in its programme and therefore may not provide the necessary stimulus for a cardiovascular training adaptation.

5.4.3: Pulmonary function

AIS is associated with pulmonary limitations linked to the biomechanical constraints of the rib cage (Negrini et al., 2012). The thoracic cage plays a crucial role in pulmonary exhalation (Leong et al., 1999). When thoracic cage mechanics are compromised, pulmonary outcomes tend to be poorer than expected. Chapter 2, Study 1 of this thesis identified a limited number of studies that evaluated the impact of a conservative intervention on pulmonary function in patients with mild and moderate AIS. Randomised control trials that included mild and moderate AIS participants all found significant improvements in pulmonary function post-intervention (Kumar et al., 2017, Kim and Park 2017, Wei et al., 2015, Athanasopoulos et al., 1999, Gao et al., 2019, Xavier et al., 2020).

Three of these studies (Kim and Park, 2017, Kumar et al., 2017, Gao et al., 2019) were PSSE-based and two were aerobic programmes (Athanasopoulos et al., 1999, Xavier et al., 2020). The duration of the three PSSE studies was two months, six months and one year respectively. Unfortunately, these studies did not account for the potential participants' growth and development during the course of the studies, and this may have influenced the outcomes. Longer intervention periods should be interpreted with caution, as lung volumes progressively increase from birth until pulmonary maturity is reached, which occurs at around 20 years of age (Barroso et al., 2018).

In contrast to the above studies, the current study did not observe any improvements in pulmonary function following a Schroth programme. Several potential factors may explain this outcome. While the Schroth method focuses on spinal mobilisation, rib cage mechanics, and breathing techniques, it does not incorporate an aerobic component that previous studies have suggested may contribute to improved pulmonary function in patients with AIS (Athanasopoulos et al, 1999, dos Santos Alves et al., 2006, Xavier et al., 2020). Additionally, differences in curve location, the severity of the spinal deformity, and the impact of bracing may have influenced the varying results across studies. Notably, the current study controlled for age, gender, anthropometric development, and predicted pulmonary function values, key variables that were not accounted for in earlier research, potentially contributing to the discrepancy in findings.

5.4.4: Balance

Very few studies have examined the impact of a Schroth programme on balance and postural sway in patients with mild and moderate AIS. Previous research has illustrated that progressive curvature of the spine can result in asymmetrical loading and abnormal centre of pressure resulting in postural sway disturbances (Gauchard et al., 2001, Şahin et al., 2019). Results from the current study suggest that a Schroth programme has no significant effect on balance. In contrast to the current study, Radwan et al. (2022) found a significant reduction in postural sway ($P < 0.001$) in a group of adolescents with mild and moderate AIS on completion of a 3-month Schroth intervention when compared to a control group of healthy adolescents. Radwan et al. (2022) focused on dynamic balance and performed testing on a controlled unstable surface (Biodex Balance System) whereas the current study assessed static balance under a range of different conditions (double leg stance, single leg

stance, tandem stance, eyes open and closed). This may have accounted for differences in the outcomes. A recent systematic review concluded that PSSE interventions had a beneficial effect on both balance and postural sway in patients with AIS (Kastrinis et al., 2022). Of the 7 randomised control studies included, only 2 studies examined the effects of a Schroth intervention alone and only one of these studies included postural sway (Radwan et al., 2022). The other studies in the review combined Schroth treatments with other treatment modalities. The authors recognised that intervention durations and exercise dosage varied across the included studies. In addition, curve type was not taken into consideration (Kastrinis et al., 2022).

Research has shown that the type of spinal curve can influence the magnitude of balance deficits (Gauchard et al., 2001). Dual curvature, involving both lumbar and thoracic regions, appears to mitigate each other's effects and has a minimal impact on balance, whereas a single lumbar curvature leads to the most significant balance impairment (Gauchard et al., 2001). and the small number of participants included in the current study may have influenced the results. In the current study, no significant improvements in balance were observed when compared to a cohort of patients with mild and moderate AIS receiving usual care. It should be noted that Schroth programmes do not incorporate a specific balance training component within their treatment programmes. Any improvement in balance may instead occur indirectly as a result of improvements in spinal curvature (Kastrinis et al., 2023). The impact of AIS on balance is complex and several factors may have influenced the findings of this study, including the small sample size ($n = 8/7$), the variability in curve types and the duration of the intervention.

5.4.5: Quality of Life

The effectiveness of PSSE interventions on quality-of-life parameters in patients with mild to moderate AIS remains unclear (Anwer et al., 2015, Burger et al., 2019). Only a few studies have investigated the impact of a PSSE intervention on quality of life (QOL) in adolescents with mild and moderate AIS. Studies by Monticone et al. (2014), Noh et al. (2014) and Schreiber et al., (2015), reported a significant improvement in some quality-of-life parameters. While Kuru et al. (2016) reported a Schroth intervention had no effect on QOL in adolescents with mild, moderate and severe AIS. In contrast to the above studies, a six-month randomised control trial (RCT) involving participants with moderate AIS (Dufvenberg et al., 2025), reported statistically significant declines in three domains:

increased pain ($p = 0.03$), reduced self-image ($p = 0.01$), and poorer mental health ($p = 0.02$).

Schreiber et al. (2015) supports the current study, indicating no significant reduction in pain after a 3-month Schroth intervention. However, Schreiber et al. (2015) does report a significant reduction in pain perception in the intervention group after 6 months. Pain is the only domain intrinsically linked to the skeletal structures. It is plausible to consider that an improvement in Cobb angle or ATR along with increased thoracic and lumbar strength in patients with mild and moderate AIS could positively alter their pain perception. The findings of the current study support Schreiber et al. (2015) who reported no improvements in function or self-image following a three-month intervention. In contrast, Noh et al. (2014) found a significant improvement in self-image in a group of adolescents with mild and moderate AIS after a 4-month PSSE intervention when compared to a group receiving a conventional exercise programme. Interestingly both groups in Noh et al. (2014) had a significant reduction in Cobb angle. No changes in the other QOL parameters were reported by Noh et al. (2014). In contrast to the current study, Monticone et al. (2014) reported a positive effect of a PSSE intervention across all QOL parameters. However, this study only included participants with mild AIS and had a significantly different duration when compared to the current and other studies. The mean duration of Monticone et al.'s study in 2014 was 42.76 ± 9.09 months, as each participant remained in the rehabilitation programme until reaching skeletal maturity. The duration of the Schreiber et al. (2015) and Noh et al. (2014) studies were broadly in line with the current study.

Based on the limited available evidence, the effects of PSSE programme, including Schroth programmes, on QOL in patients with mild and moderate AIS remain inconclusive, particularly regarding mental health. Investigations into the impact of AIS on QOL are inherently complex and may be confounded by factors such as reliance on self-reported measures and the influence of bracing in some cases (Wang et al., 2021).

Chapter 4, Study 2 of this thesis identified that adolescents with AIS reported significantly lower QOL compared to their healthy peers. The current study found no significant improvements in QOL following participation in a Schroth programme. These findings suggest that Schroth-based programmes alone may not adequately address the psychosocial challenges experienced by this population. Given the limited impact on QOL outcomes, the

integration of mental health support into the treatment pathway, beginning at the point of AIS diagnosis, should be considered to ensure a more comprehensive approach to care.

5.4.6: Limitations

This study was designed as an observational cluster study comparing the management of patients with mild and moderate AIS within two distinct healthcare settings: the public healthcare pathway and the private healthcare pathway, under the care of a single spinal consultant. While this design allowed for the pragmatic comparison of real-world clinical practices, several limitations should be acknowledged. As an observational study, participants were not randomly assigned to groups. The allocation to public or private healthcare pathways was determined by patient choice, referral source, or socioeconomic factors, which may have introduced selection bias. Consequently, observed differences in outcomes may be partially attributed to underlying differences in patient characteristics rather than solely to the Schroth programme or the healthcare setting.

The use of a cluster design where participants within each healthcare pathway were treated as distinct clusters may have led to intra-cluster correlation (ICC). Patients within the same cluster are likely to share contextual factors such as access to resources, clinician expertise, or follow-up frequency.

All participants were managed under the supervision of one spinal consultant. While this ensured consistency in diagnostic and clinical decision-making, it also limits the external validity of the findings. The consultant's clinical approach and referral practices may not reflect wider practice variations across other clinicians or institutions.

The “usual care” pathway in the public healthcare system is not fully standardised and may vary between patients according to factors such as waiting times, availability of local resources, and access to physiotherapy services. This variability introduces heterogeneity which may complicate direct comparisons between groups and may dilute the observed effects of the PSSE programme.

This study was underpowered due to a substantially smaller sample size than originally projected. The shortfall arose from major external factors including the COVID-19 pandemic and the HSE cyber-attack which seriously disrupted both public and private AIS clinics and significantly curtailed recruitment opportunities. Due to the limited number of participants, data from mild and moderate AIS groups were merged for analysis. These limitations in sample sizing likely increased the risk of a Type II error.

A 4-month follow-up period was relatively short and may not have allowed sufficient time to significantly influence some of the outcomes. As AIS is a progressive condition influenced by growth and maturation, a longer intervention period would have strengthened the conclusions.

Self-reported adherence to the HEP in the Schroth programme and patient reported quality-of-life measures may have been subject to response bias. While this study provides valuable insights into the comparative effectiveness of PSSE within real-world healthcare contexts, its observational and clustered nature limits the establishment of a cause-and-effect relationship. Future research employing randomised controlled designs, multi-consultant settings, and standardised objective outcome assessment would strengthen the evidence base for integrating PSSE into the public healthcare models for AIS.

5.5: Conclusion

An important finding of this study is a PSSE intervention, in this case a Schroth programme, strengthens upper spinal, lumbar, and pelvic musculature, particularly on the concave side of the spinal curve, in patients with mild and moderate AIS. However, a Schroth programme does not significantly improve pulmonary function, exercise capacity, upper and lower limb muscular endurance, muscle strength (in most muscle groups), balance, or quality of life. It is important to acknowledge that Schroth programmes are primarily designed to reduce Cobb angle and angle of trunk rotation (ATR). Therefore, any observed improvements in secondary outcomes such as pulmonary function, muscular performance, balance, or QOL may be incidental benefits resulting from curve correction. It is also important to acknowledge that Study 3 had a short duration of 4-months, and this may have influenced the outcomes. Park et al. (2018) reported that six-month intervention programmes produced greater effects than shorter durations, with the most substantial improvements observed in programmes extending beyond 12 months. Based on the findings of this study and accepting the limitations addressed above, several recommendations are proposed to enhance the treatment approach for patients with mild to moderate AIS receiving PSSE treatment

- At the point of diagnosis, a comprehensive and standardised assessment should be conducted to identify potential impairments in pulmonary function, exercise capacity, muscle strength and endurance, balance, and quality of life, in addition to traditional clinical measures such as Cobb angle and angle of trunk rotation (ATR).

- PSSE intervention programmes, should be modified to incorporate targeted rehabilitation strategies to address any specific impairments identified during the initial assessment.

Finally, the integration of mental health support at the early stages of diagnosis should be considered to address the psychosocial challenges often experienced by adolescents with AIS, and to promote a more holistic model of care.

Chapter 6: An evaluation of the effects of a targeted physiotherapy-led post-operative exercise intervention on patients with severe AIS.

6.1: Introduction

For some patients with AIS, surgical intervention to fuse the spine is the preferred treatment option (Negrini et al., 2018). There are three major circumstances where surgery is considered. Firstly, when the spinal curvature exceeds 40° (Negrini et al., 2018). Secondly, when all other treatments including bracing and physiotherapy have failed to halt or reduce the curvature. Thirdly, when the curve progression causes cardiovascular, pulmonary, or increased pain symptoms (Bettany-Saltikov et al., 2013). In the Irish healthcare system, the current treatment protocol for post-operative patients with AIS without complications from surgery, typically involves inpatient care for approximately six days. During this time, the focus of patient care is on wound management, reduction of swelling, inflammation, and management of muscle contractures. In addition, the Physiotherapist ensures that the child or adolescent can safely perform transfers (bed/chairs/stairs) and has regained independent mobility. Following hospital discharge, after circa 6 days, the patient receives a single post-surgical appointment at an outpatient clinic approximately 3 months post-spinal fusion surgery. If no complications have developed over this period, the patient is discharged from care. In some cases, implant-related complications such as pedicle screw misplacement, loosening, or breakage, and implant migration or damage can occur (Koshimizu et al., 2024). A multi-centre study found implant related complications in 5.2% of patients with AIS who had a spinal fusion (Coe et al., 2006). In cases with implant complications, further surgery is required.

There are no formal assessment processes in place in the Irish healthcare system to establish if any post-operative impairments are evident in this population. Referral for private physiotherapy or other hospital services is on an ad-hoc basis and is reactive to complications in the post-operative review, rather than part of a proactive healthcare pathway. The accepted practice in the western world, including Irish hospitals, is to consider this population as returned to ‘normal function’ 12-months post-operatively (<https://ssr.org.uk/scoliosis-treatment/ais-surgery>.www.srs.org/Patients/Diagnosis-And-Treatment/surgery).

6.1.1: Post-operative management

The current post-operative management for patients with AIS is founded on a study by Rubery & Bradford (2002) and a subsequent survey by Lehman et al. (2015). Rubery & Bradford (2002) conducted a questionnaire-based survey among members of the Scoliosis Research Society, receiving responses from 316 members (45% response rate). The survey aimed to ascertain current practices regarding post-surgical recommendations for returning to physical activity. The recommendations included advocating for a return to non-contact exercise or sport between 6- and 12-months post-surgery and permitting contact sports after 12 months. Thirteen percent of respondents recommended abstaining from contact sports entirely. Lehman et al. (2015) supported the earlier work of Rubery & Bradford (2002). Their survey concluded that, based on a survey of spinal surgeons, running was permissible 3 months post-surgery. Non-contact and contact exercises could commence at 6 months, and collision sports could be entered into after 12 months. The survey was completed by members of the Spinal Deformity Study Group of which all 23 members (100%) completed the survey. One of the survey questions addressed post-operative rehabilitation, ‘Do you recommend formal post-operative physical therapy?’. Eighteen out of the 23 surgeons who took part in the survey (78%) did not recommend physiotherapy post-operatively. This suggests that those surveyed either did not believe musculoskeletal, pulmonary, exercise capacity or balance impairments were present in post-operative AIS patients or did not consider physiotherapy beneficial for post-operative patients who presented with impairments. Tarrant et al. (2014b) conducted a survey of post-operative patients with AIS in Children’s Health Ireland (CHI) and concluded that post-operative AIS patients could return to unrestricted physical activity after 12 months. The study involved 77 post-operative AIS patients who were interviewed by telephone every two months for one year to assess physical activity levels. Findings from this self-reported survey revealed that 88% of participants had resumed full physical activity by 12 months post-surgery. Tarrant et al. (2014b) acknowledged that a formal position statement on return to sporting activity was lacking and that guidelines to date were based on expert opinion only and these opinions have been shown to vary. There is a clear lack of objective scientific evidence to address when post-operative adolescents with AIS should return to full physical activity.

The original guidelines (Rubery & Bradford, 2002) are approximately 23 years old, and the Irish healthcare system, as well as most healthcare systems in the western world, continue

to adhere to them. Considering the weak evidence supporting these guidelines, more objective and robust research is needed to enhance post-operative care pathways for patients with AIS.

6.1.2: *Physiotherapy intervention*

There are currently no specialist spinal physiotherapists appointed in the CHI to rehabilitate post-operative patients with AIS. The role of physiotherapy in CHI Ireland is focused on immediate post-surgical care and preparing the patient for discharge. There is growing evidence of decreased functional capacity in adolescents who have undergone spinal fusion surgery for AIS (Asher & Burton, 2006, Martínez-Llorens et al., 2010, Rafferty et al., 2020). A limited number of longitudinal studies have also found that surgically treated patients with AIS have reduced function and increased pain when compared to healthy controls (Asher & Burton, 2006, Danielsson et al., 2006). A recent study by Rafferty et al. (2020) supported the earlier findings. This study found significant musculoskeletal and functional impairments in one-year post-operative adolescents when compared to an anthropometrically matched control group.

There are divergent views on why musculoskeletal impairments remain in post-operative AIS adolescents. Martínez-Llorens et al. (2010) proposed that muscle weakness (in AIS) was related to the systemic effects of the condition such as hormonal and inflammatory mechanisms. Barrios et al. (2005) speculated that muscle deconditioning may occur from reduced function and limited physical activity.

Post-operative physiotherapy may have a role to play in the rehabilitation of patients with AIS. Only a limited number of studies have investigated post-operative rehabilitation in this cohort. Cetinkaya et al. (2025) included participants aged 15–20 years up to 2 years post-surgery in an eight-week remote general rehabilitation programme. This research highlighted post-intervention improvements in trunk endurance and flexibility and pain reduction. Walters et al. (2025) conducted a feasibility study comparing a post-operative, physiotherapy-led general rehabilitation programme with usual care, delivered over 12 outpatient sessions across six months. Their research focussed on methodological outcomes such as the safety and feasibility of delivering a post-operative rehabilitation programme. No previous study has evaluated the potential benefits of a targeted physiotherapy-led intervention on the impairments identified in post-operative patients with AIS.

6.1.3: Aims and Objectives

The primary aim of this study was to evaluate the efficacy of a post-operative physiotherapy-led intervention on patients with AIS. The objectives were (i) to compare post-intervention outcome measures with impairments identified pre-operatively; (ii) to compare post-intervention outcome measures with post-operative data and (iii) to compare the post-intervention outcome measures with those of a healthy control group. The null hypothesis proposed that a post-operative targeted physiotherapy-led intervention would not significantly improve any impairments identified either before or after surgery in participants with severe AIS. Furthermore, it was expected that significant impairments would persist post intervention when compared to outcomes observed in a healthy control group.

6.2: Methodology

6.2.1: Study design

A prospective interventional cohort study design was conducted. Participants clinically diagnosed with severe AIS and scheduled for surgery within three months were recruited. All participants underwent 3 standardised assessments over the course of this study. The 1st assessment took place three months prior to surgery. The 2nd assessment took place three months post-surgery. The final assessment was conducted within one month following the completion of the post-operative, physiotherapy-led intervention. The 12-week intervention targeted impairments identified in outcome measures collected during the 2nd assessment. The impairments identified for each participant guided the selection of rehabilitation exercises tailored to their specific needs. Ethical approval was obtained for this study between June and September 2019 (Section 3.1).

The mean (SD) changes in total SRS-22 score observed by Pellegrino et al. (2012) in a cohort of patients with severe AIS who underwent spinal fusion surgery, was used to determine expected effect size for this study. Based on the resultant effect size of $f=0.353$, a P-value of 0.05 and a statistical power of 85%, the required sample size was estimated at $n=12$.

6.2.2: Recruitment and consent

Patients diagnosed with severe AIS were recruited from scoliosis clinics in CHI Crumlin, Blackrock Clinic, and the Beacon Hospital through a poster campaign (Appendix 5). A

full description of the recruitment, consent process and recruitment challenges are outlined in Section 3.2.

6.2.3: Participant screening

Screening for inclusion into the study is described in detail in Section 3.3. Study inclusion criteria for those with severe AIS are described in Section 3.3.1, while study exclusion criteria are described in Section 3.3.2.

6.2.4: Assessment and outcome measures

All assessments were conducted at the exercise laboratory located in Trinity Centre for Health Sciences, St. James's Hospital, Dublin. A summary of the assessment protocol is outlined in detail in Section 3.4. A detailed description of each outcome variable assessed, and equipment used is provided in Section 3.5.

6.2.5: Targeted physiotherapy-led intervention

The development of a post-operative targeted physiotherapy-led intervention involved a comprehensive review of the literature published on exercise rehabilitation in scoliosis (Berdishevsky et al., 2016, Moramarco et al., 2016, Langensiepen et al., 2017, Rafferty et al., 2023). The investigator, a chartered physiotherapist and strength and conditioning (S&C) coach, designed the rehabilitation protocol after extensive consultations with clinicians, academics, advanced-practice chartered physiotherapists with special training in the treatment of AIS and a qualified S&C coach. A formal feasibility study was not conducted due to the COVID-19 pandemic. However, the targeted rehabilitation programme was implemented by experienced clinicians with extensive expertise in addressing identified impairments in patients with AIS.

Participants were deemed eligible to take part in the 12-week intervention after receiving approval from their medical team, which was granted following a medical review conducted three months after surgery. Before commencing the intervention, each participant was required to undergo a further assessment (Sections 3.4 and 3.5). Based on the data collected during this assessment, the investigator generated a personalised report for each participant identifying any impairments and highlighted their strengths and weaknesses. Each participant's report was sent to the rehabilitation team before the first consultation session. The personalised reports formed the basis for designing each participant's 12-week intervention programme. The criteria for establishing whether an impairment existed in an outcome variable are explained below in section 6.2.6.

6.2.6: Criteria for identifying impairments in outcome variables

6.2.6.1: Pulmonary function, Forced Expiratory Volume in 1 second (FEV₁) and Forced Vital Capacity (FVC)

The Global Lung Initiative (GLI) (Quanjer et al., 2012), recognised by the European Respiratory Society, is the standard protocol for spirometry testing. The GLI was developed to provide standardised, internationally accepted reference values for pulmonary function tests, accounting for variations in lung function due to factors such as age, sex, and ethnicity. This approach helps minimise inconsistencies that may arise from reliance on differing national or local reference standards. Scores below 80% of the predicted value in children and adolescents are indicative of a potential pathology (Barreiro and Perillo, 2004). For the purposes of this study, pulmonary scores below 80% were treated as impairments.

6.2.6.2: Exercise capacity

Exercise capacity was defined as VO₂max. The measured VO₂max was compared against reference normative data published by Blanchard et al. (2018) as outlined in Section 3.5.5.3. Based on each participant's age, gender, height and weight a Z-score was calculated. An impairment was deemed to exist when a Z-score of -2 or greater was recorded between a participant's measured VO₂max score and their reference VO₂max as estimated by Blanchard et al. (2018).

6.2.6.3: Upper and lower limb muscle strength

To identify the existence of a lower limb strength impairment, participants' results were compared to normative data for lower limb muscle groups published by Herbert et al. (2015). A participant was considered to have an impairment if their score fell below the 50th percentile. The 50th percentile (median) represents the average for a specific population group. Scores falling below this threshold are indicative of potential impairments (Miller, 2012, Landi et al., 2020). Upper limb muscle groups (trapezius and latissimus dorsi) were compared to outcomes from the healthy control group (Chapter 4; Study 2), as there are no normative data for these tests. An impairment was deemed to exist if a participant's score was below the 50th percentile. Orchard et al. (2005) proposed that a side-to-side asymmetry of less than 10% should be used as a marker for safe return to play sports. The current study also identified any muscle imbalance of 10% or greater between the left and right sides as a strength impairment.

6.2.6.4: Grip strength

Participants' handgrip strength data were compared to normative data published by Tomkinson et al. (2018) for European children and adolescents. An impairment was defined as a score below the 50th percentile or an inter-limb difference of 10% or greater, in line with criteria proposed by Orchard et al. (2005).

6.2.6.5: Lumber strength

Lumbar strength was assessed using the Back D Test (Coldwells et al., 1994). No normative data was identified for non-athletic children and adolescents. Therefore, the control data from Chapter 4, Study 2 of this thesis was used as a benchmark for this test. An impairment was deemed to exist if a participants' score fell below the 50th percentile.

6.2.6.6: Upper limb endurance

Hoffman (2006) established normative values for male and female push-ups to failure across various age groups. These values are used as the benchmark by the National Strength & Conditioning Association (NSCA), the leading strength and conditioning organisation in the USA. For this study, the 50th percentile was used as the benchmark. Participants who scored below this threshold for their age and gender were classified as having an upper limb endurance impairment.

6.2.6.7: Lower limb endurance

No normative data for the Single Leg Wall Squat (SLWS) to 90° for children and adolescents were identified. Therefore, control data from Chapter 4, Study 2 was used as the benchmark for this test. An impairment was deemed to exist if a participant's score fell below the 50th percentile.

6.2.6.8: Upper limb power

Normative data for children and adolescents do not exist for the Seated Medicine Ball Throw (Biggar et al., 2021). Data from healthy controls in Chapter 4, Study 2 was used as a standard for measuring upper limb power. An impairment was deemed to exist if a participant's score fell below the 50th percentile.

6.2.6.9: Lower limb power

Focke et al. (2013) established normative data for children and adolescents on the Countermovement Jump Test using a force plate. Participants whose scores fell below the

mean score for their age and gender in jump height were identified as having a lower limb power deficit.

6.2.6.10: Balance, C90 area [mm²] and mean sway velocity

Participants' C90 area [mm²] and mean sway velocity were assessed using a modified Balance Error Scoring System (mBESS) test on a HUR balance platform (hursolutions.com). The test includes three stances: double-leg stance (hands on hips with feet together), single-leg stance (standing on the nondominant leg with hands on hips), and tandem stance with the nondominant foot placed behind the dominant foot in a heel-to-toe position, eyes open and closed. Balance deficits were identified using HUR software which compares individual performance to a comprehensive normative dataset.

6.2.6.11: QOL, activity and sedentary levels

At each assessment point pre-operative, post-operative, and post-intervention, participants completed the International Physical Activity Questionnaire (IPAQ) (Craig et al., 2003) and the Scoliosis Research Society-22r (SRS-22r) questionnaire, a scoliosis-specific measure of health-related quality of life (Asher et al., 2003). Statistically significant differences ($P < 0.05$) in questionnaire scores across time points were interpreted as either significant improvements or deteriorations in specific QOL domains, activity and sedentary levels. Additionally, the previously established minimal clinically important difference (MCID) values are 0.2 for pain, 0.8 for function, and 0.098 for self-image, reflecting the standard error of measurement associated with a meaningful improvement (Carreon et al., 2010). No MCID values have been calculated for the mental health domain.

6.2.7: Post-operative intervention

The post-operative intervention consisted of two components: (i) an in-person supervised rehabilitation session every 2nd week over the course of 12 weeks, with an advanced-practice chartered physiotherapist and (ii) a home exercise programme (HEP). The supervised in-person sessions took place in one of two private physiotherapy clinics. Each one-hour clinical session began with a review of the participant's HEP from the previous week. This was followed by a 10-minute warm-up, including active range of motion exercises for both upper and lower limbs. Targeted interventions were then delivered to address specific impairments identified. Strength and endurance deficits were managed through tailored resistance programmes. For strength-related impairments, participants performed weighted or TheraBand exercises in four sets of six repetitions, using a

resistance level that allowed completion of the set with proper form. For endurance-related impairments, two sets of 15–18 repetitions were completed, incorporating rest breaks as needed. Balance training included single-leg stance and tandem stance exercises, each held for 20 seconds on both flat and uneven surfaces. Sessions concluded with guided breathing exercises. The aerobic component of the intervention was incorporated into the weekly HEP. Based on guidelines from the American College of Sports Medicine (ACSM) and the American Heart Association, participants were also instructed to engage in 30-minutes of steady-paced walking five days per week.

After each supervised session, the participant was provided with a HEP to follow until the next appointment. The HEP was completed three times per week, each session lasting approximately 30 minutes. The HEP was individualised based on each participants identified impairments. A sample of HEP exercises are set out in Appendix 13. The rehabilitation team consisted of two advanced-practice chartered physiotherapists who specialise in child and adolescent scoliosis and a paediatric and adolescent S&C coach. The investigator was blinded to the content of the supervised intervention and HEP.

6.2.8: Compliance with the HEP and the intervention programme

Attendance at clinical treatment sessions was documented by the physiotherapist in the clinic's patient records. To ensure compliance with the HEP, a "gatekeeper" was designated for each participant during the initial appointment. In all cases, this role was assumed by a parent, whose responsibility was to ensure that the HEP was completed 3 times a week. The S&C coach arranged a weekly online meeting with each participant and their gatekeeper to review the previous week's progress. Following the meeting, the S&C coach recorded the previous weeks HEP compliance on an Excel sheet. The S&C coach also identified and recorded any specific rehabilitation exercises the participant found easy or those that they found difficult, and any concerns they had regarding the programme. This information was provided to the relevant physiotherapist who could make amendments to improve the participant's programme based on the feedback from the S&C coach. Relevant strategies to maximise adherence to the programme, such as motivational interviewing (Bischof et al., 2021) and SMART goal setting (Wade, 2009) were used, in addition to the weekly online reviews between participants and the S&C coach.

Participant compliance with the HEP and related comments was recorded and updated weekly in an Excel spreadsheet by the S&C coach, following the online meetings. This

documentation was provided to the investigator when all participants had completed the intervention programme. In addition to weekly updates, monthly online meetings were conducted between the two physiotherapists involved in the study and the S&C coach to review participant progress and modify the intervention content as needed to maximise outcomes. The attendance record was provided to the investigator on conclusion of the intervention programme.

6.2.9: Data collection and processing

Data collection and processing is described in Section 3.6.

6.2.10: Data analysis

Prior to analysis, the master Excel document was screened for any anomalies. In addition, all individual Excel data entries were rechecked for errors with the original clinical data collection sheets (CDCS) documents by a third party to ensure the Excel data were correct. Screened Excel data were transferred into GraphPad Prism for statistical analysis purposes in its coded form. Results were processed in a group format; no reference was made to any personal details of participants at any stage in the process.

Statistical analysis was subsequently conducted using the statistical software package, GraphPad Prism (GraphPad Prism version 10.0.0 for Windows). Data collated in Excel were copied in columnar form into separate variable files in the GraphPad Prism software. The mean results for blood pressure and muscle strength were calculated in Excel before data transfer. Results were processed in a group format, with no reference to participants' details at any stage of the process. The Kolmogorov-Smirnov test (Eadie, 1971, Wayne, 1990) and visual inspection of normal Q-Q plots was used to determine if the data sets followed a normal distribution. Group results were presented as mean ($\bar{x}$) and standard deviation (SD).

Hypothesis testing was undertaken using repeated measures ANOVA across the three time-points: pre-operative, post-operative and post-physiotherapy-led intervention programme. Tukey's multiple comparisons test was calculated when a result was found to be significantly different ($P < 0.05$). Cohen's d (Cohen, 1988) was computed for each outcome measure to assess effect size. Additionally, the unpaired Student's T test was used to compare the post-intervention data with the healthy control group. For non-parametric data, the Friedman test was used to compare data across the three time-points and the Mann

Whitney U test was used to compare post-intervention data with the healthy control group. results were found to be significantly different if ($P < 0.05$).

6.3: Results

Sixteen participants, diagnosed with severe AIS, who formed part of the severe AIS cohort in Chapter 4 and had a surgical intervention to fuse the spine, were recruited for this study. One participant, who was assessed pre-operatively and post-operatively, was withdrawn from the study prior to the rehabilitation programme due to complications that required a surgical revision.

The remaining 15 participants completed a targeted physiotherapy-led intervention. All participants were Caucasian, 13 of the participants were female, and two participants were male. The mean thoracic and lumbar curves prior to surgery were $60 \pm 10^\circ$ and $45 \pm 25^\circ$ respectively. The mean age on completion of the 3-month intervention programme was 15.7 ± 1.1 years and mean BMI was $20.7 \pm 3.9 \text{ kg.m}^{-2}$. Descriptive statistics (mean and standard deviation) and overall effects for pre-operative, post-operative and post-intervention outcomes are presented in Tables 6.1 to 6.9. Participant attendance at the in-person supervised rehabilitation session was 100% with no dropouts reported. Compliance with the HEP was 89%. Post-intervention outcomes were also compared to the outcomes recorded for the healthy control group (Chapter 4, Study 2) and are presented in Table 6.10.

6.3.1: Resting cardiovascular measures

There were no significant differences in mean resting heart rate (beats.min^{-1}) across the three time-points. There was a significant overall effect for systolic blood pressure (mmHg) ($P = 0.037$) and for diastolic blood pressure (mmHg) ($P = 0.046$). Post-hoc tests indicated mean systolic blood pressure (mmHg) was significantly lower post-operatively when compared to pre-operative results ($P = 0.016$) (Table 6.1).

Table 6.1. Blood pressure and resting heart rate

Outcome variable	Pre-Op (n=16)	Post-Op (n=16)	Post-Intervention (n=15)	Overall Effect
Systolic Blood Pressure (mmHg)	107 ± 10	$102 \pm 8^*$	103 ± 11	$F=4.01, P=0.037$
Diastolic Blood Pressure (mmHg)	74 ± 5	71 ± 5	69 ± 8	$F=3.60, P=0.046$
Resting Heart Rate (beats.min^{-1})	78 ± 13	79 ± 10	76 ± 9	$F=0.58, P=0.490$

Asterisks (*) infers a significant difference ($P < 0.05$) between pre-op and post-op results

6.3.2: Pulmonary function

All participants received a standardised spirometry test at each of the three time-points. Significant overall effects were found for FEV₁ (L.sec⁻¹) (P= 0.037) and FVC (L) (P= 0.008). Post-hoc analyses revealed a positive time effect post-intervention for FEV₁ (L.sec⁻¹) (P= 0.038) and FVC (L) (P= 0.001) when compared to post-operative results. A significant overall effect was also found for percentage predicted FVC (P= 0.000), post-hoc testing identified a significant reduction in percentage predicted FVC post-surgery (P= 0.003) and a significant increase post-intervention (P= 0.002). A significant overall effect was identified for FEV₁ /FVC (%) (P= 0.001). Post-hoc analysis identified a significant increase in both pre-operative FEV₁ /FVC (%), (P= 0.003) intervention FEV₁/FVC (%), (P= 0.035). Percentage Predicted FEV₁/FVC showed a significant overall effect (P= 0.020). Post-hoc analysis identified a significant increase in percentage predicted FEV₁/FVC post-operatively (P= 0.009) (Table 6.2).

Table 6.2. Pulmonary function

Outcome variable	Pre-Op (n=16)	Post-Op (n=16)	Post-Intervention (n=15)	Overall Effect
FEV ₁ (L.sec ⁻¹)	2.76 ± 0.5	2.72 ± 0.6	2.87 ± 0.5 ^{\$}	F=3.81, P= 0.037
FVC (litres)	3.07 ± 0.5	2.90 ± 0.7	3.12 ± 0.6 ^{\$}	F=6.09, P= 0.008
FEV ₁ /FVC (%)	90 ± 6	95 ± 4 ^{**}	94 ± 3 [#]	F=9.45, P= 0.001
PEF (L.min ⁻¹)	357 ± 71	364 ± 74	379 ± 72	F=3.25, P=0.065
% Predicted FEV ₁	85 ± 15	76 ± 24	84 ± 16	F=3.74, P=0.059
% Predicted FVC	85 ± 16	75 ± 17 [*]	81 ± 17 ^{\$}	F=12.14, P= 0.000
% Predicted FEV ₁ /FVC	101 ± 8	106 ± 6 ^{**}	104 ± 5	F=4.72, P= 0.020

Asterisks (*) infers a significant difference (P<0.05) between pre-op and post-op results. **Hash symbols (#)** infers a significant difference (P<0.05) between pre-op and post-intervention results. **Dollar symbols (\$)** infer a significant difference (P<0.05) between post-op and post-intervention results.

6.3.3: Exercise capacity

Participants undertook a standardised VO₂max test on a cycle ergometer pre-operatively, post-operatively and post-intervention. No significant effects were observed across the three time-points for maximum heart rate (beats.min⁻¹), peak workload (W) or VO₂max (mL.kg⁻¹.min⁻¹). (Table 6.3).

Table 6.3. VO₂max, peak workload, maximum heart rate

Outcome variable	Pre-Op (n=16)	Post-Op (n=16)	Post-Intervention (n=15)	Overall Effect
VO ₂ max (mL.kg ⁻¹ .min ⁻¹)	36.7 ± 8.5	32.8 ± 7.8	39.3 ± 8.1	F=3.50, P=0.052
Peak workload (W)	126 ± 29	120 ± 18	129 ± 29	F=2.02, P=0.153
Max heart rate (beats.min ⁻¹)	175 ± 16	172 ± 16	180 ± 14	F=1.96, P=0.159

6.3.4: Lumbar and hand grip strength

A significant overall effect was found for lumbar strength. Post-hoc testing identified post-operative lumbar strength significantly weakened when compared to pre-operative results (P= 0.012). In addition, post-hoc analysis also identified a significant improvement in lumbar strength, post-intervention when compared to post-operative results (P= 0.002). No significant overall effect was identified for handgrip strength (Table 6.4).

Table 6.4. Lumbar strength and grip strength

Outcome variable	Pre-Op (n=16)	Post-Op (n=16)	Post-Intervention (n=15)	Overall Effect
Lumbar strength (kg)	71.16 ± 15.3	55.94 ± 16.0*	76.33 ± 22.9 ^{\$}	F=10.11, P=0.001
Grip strength - (D) (kg)	22.81 ± 5.6	22.63 ± 4.1	23.93 ± 3.3	F= 3.19, P=0.076
Grip strength - (non-D) (kg)	22.25 ± 4.9	22.19 ± 4.1	22.67 ± 3.2	F= 1.51, P=0.242

Asterisks (*) infers a significant difference (P<0.05) between pre-op and post-op results. **Dollar symbols (\$)** infer a significant difference (P<0.05) between post-op and post-intervention results. D = Dominant hand, Non-D – Non dominant hand.

6.3.5: Upper and lower limb strength

A significant overall effect was found for all tests with the exception of right-side hip flexors. Post-hoc testing identified significant positive effects of the targeted intervention when compared to post-operative results in the following muscle groups left hip flexors (P= 0.004), left/right hip extensors (P<0.001; P<0.001), hip abductors (P<0.001; P= 0.002) and adductors (P<0.001; P<0.001). Additionally, post-hoc analyses also identified significant strength increases in lower trapezius muscles bilaterally (left/right) post-intervention (P= 0.003; P= 0.03), right sided lower trapezius (P = 0.04) and left and right sided latissimus dorsi (P= 0.02; P= 0.000).

Post-hoc analysis also highlighted significant increases in strength post-intervention when compared to pre-operative outcomes for (left/right) hip extensors (P = 0.002; P= 0.006),

abductors (P = 0.023; P = 0.002), adductors (P = 0.03; P = 0.03), left lower trapezius (P = 0.045) and upper trapezius (P = 0.006; P = 0.01) (Table 6.5).

Table 6.5. Muscle strength

Outcome variable	Pre-Op (n=16)	Post-Op (n=16)	Post-Intervention (n=15)	Overall Effect
Hip flexion (R) (kg)	16.15 ± 3.81	15.32 ± 3.6	17.65 ± 2.7	F=3.12, P=0.073
Hip flexion (L) (kg)	16.42 ± 3.7	15.28 ± 3.9	18.41 ± 3.5 ^{\$}	F=4.56, P= 0.037
Hip extension (R) (kg)	14.13 ± 4.2	14.86 ± 4.2	18.98 ± 3.4 ^{\$\$\$ #}	F=9.66, P= 0.003
Hip extension (L) (kg)	14.50 ± 4.6	15.35 ± 5.1	19.46 ± 4.6 ^{\$\$\$ ##}	F=13.58, P= 0.000
Hip abduction (R) (kg)	6.12 ± 1.3	6.56 ± 1.6	8.19 ± 1.8 ^{\$} ^{##}	F=14.41, P= 0.000
Hip abduction (L) (kg)	6.90 ± 1.4	6.40 ± 1.9	8.33 ± 1.9 ^{\$\$\$ #}	F=15.04, P= 0.000
Hip adduction (R) (kg)	6.95 ± 1.3	6.94 ± 1.8	8.43 ± 2.0 ^{\$\$\$ #}	F=8.76, P= 0.006
Hip adduction (L) (kg)	6.50 ± 1.7	6.57 ± 1.5	8.47 ± 1.9 ^{\$\$\$ #}	F=7.94, P= 0.008
Trapezius lower (R) (kg)	3.79 ± 1.3	3.48 ± 1.4	4.51 ± 1.6 ^{\$}	F=3.67, P= 0.039
Trapezius lower (L) (kg)	3.24 ± 1.1	3.11 ± 1.0	4.51 ± 1.7 ^{\$} [#]	F=7.79, P= 0.003
Trapezius upper (R) (kg)	15.89 ± 3.6	17.25 ± 4.4	20.17 ± 3.3 ^{\$\$\$ ##}	F=7.34 P= 0.003
Trapezius upper (L) (kg)	16.11 ± 3.8	17.57 ± 5.2	20.82 ± 3.2 ^{##}	F=7.53, P= 0.003
Latissimus dorsi (R) (kg)	11.20 ± 3.4	10.17 ± 2.5	12.65 ± 2.5 ^{\$\$\$}	F=9.32, P= 0.005
Latissimus dorsi (L) (kg)	10.83 ± 2.6	10.09 ± 2.6	12.08 ± 2.7 ^{\$}	F=3.68, P= 0.048

Hash symbols (#) (P<0.05), **(##)** (P< 0.01) and **(###)** (P< 0.001), infers a significant difference between pre-op and post-intervention results. **Dollar symbols (\$)** (P<0.05), **((\$))** (P<0.01) and **(\$\$\$)** (<0.001) infers a significant difference between post-op and post-intervention results.

6.3.6: Upper and lower limb endurance

A significant overall effect was found for upper limb endurance. Post-hoc testing identified a significant positive improvement in upper limb endurance post-intervention when compared to post-operative results (P = 0.002). A significant overall effect was also found for lower limb endurance. Post-hoc analysis identified significant improvements in SLWS (L) post-intervention when compared to post-operative results (P= 0.030). No statistically significant effects were identified for SLWS (R) (Table 6.6).

Table 6.6. Upper and lower limb endurance

Outcome variable	Pre-Op (n=16)	Post-Op (n=16)	Post- Intervention (n=15)	Overall Effect
Upper limb endurance				
Push up (n) (i)	2 (0 - 7)	0 (0 - 1.)	4. (1 -11) ^{\$\$}	F=16.58, P=0.000
Lower limb endurance (sec)	-			
SLWS (right)	6.69 ± 7.7	5.56 ± 10.5	10.47 ± 13.1	F= 1.46, P=0.251
SLWS (left)	8.69 ± 9.5	5.63 ± 8.8	16.40 ± 16.2 ^{\$}	F=4.89, P=0.024

(i) Denotes non-parametric results, median and interquartile. **Dollar symbols (\$)** (P<0.05), **(\$\$)** (P<**0.01**) infers a significant difference between post-op results and post-intervention results.

6.3.7: Upper and lower limb power

Upper limb power was assessed using a seated medicine ball throw. Lower limb power was measured using a HUR force plate platform. No significant overall effect time was found for upper limb power. A significant overall effect was found for lower limb Maximum Power (P = 0.016), Maximum Force (N) (P= 0.04) and the ratio Maximum Force/Body Weight (N/kg) (P = 0.003). Post-hoc testing identified a significant decline in Maximum Power post-operatively when compared to pre-operative results (P = 0.039). The ratio of Maximum Force/Body Weight (N/kg) showed a significant post-intervention decline, when compared to pre-operative results (P = 0.007) (Table 6.7). Post-hoc analysis identified no significant effects for Maximum Force (N).

Table 6.7. Upper and lower limb power

Outcome variable	Pre-Op (n=16)	Post-Op (n=16)	Post- Intervention (n=15)	Overall Effect
Upper limb power				
Seated Medicine Ball throw (cm)	186.60 ± 33.8	175.60 ± 21.6	190.70 ± 18.5	F=2.88, P=0.100
Lower limb power				
Jump Height (cm)	21.40 ± 4.5	19.49 ± 5.6	20.91 ± 5.0	F=1.06, P=0.357
Maximum Power (Watts)	1471.00 ± 247.5	1299.00 ± 180.5*	1391.00 ± 166.2	F=5.52, P=0.016
Maximum Force (N)	860.40 ± 201.5	765.60 ± 147.6	774.20 ± 106.1	F=4.28, P=0.040
Max Force/ Body Weight (N/kg)	22.79 ± 2.9	20.99 ± 1.7*	20.28 ± 1.5#	F=8.14, P=0.003

Asterisks (*) (P<0.05) infers a significant difference between pre-op and post-op results. **Hash symbols (#)** (P<**0.05**) infers a significant difference between pre-op and post-intervention results.

6.3.8: Balance

No significant overall effects were identified for C90 area [mm²] or mean sway velocity [mm/s] (Table 6.8).

Table 6.8. Balance

Outcome variable	Pre-Op (n=16)	Post-Op (n=16)	Post- Intervention (n=15)	Overall Effect
C90 Area[mm^2]				
DLS: eyes open	282.60 ± 118.6	431.80 ± 330.5	415.90 ± 350.3	F=2.57, P=0.095
SLS: eyes open (Fi)	1143 (758 - 1454)	916.40 (748.1 - 1271)	1317 (637.7 - 1963)	F=1.73, P=0.420
TS: eyes open (Fi)	655.2 (396.8 - 850.2)	775.1 (522.9 - 1885)	650 (455.5 - 1199)	F=0.93, P=0.627
DLS: eyes closed (Fi)	395.4 (282.6 - 672.1)	361.8 (211.8 - 685.4)	374.7 (227.7 - 470.7)	F=1.26, P=0.285
SLS: eyes closed (Fi)	7773 (4365 - 12923)	7457 (4246 - 15231)	5230 (2857 - 11248)	F=1.73, P=0.420
TS: eyes closed (Fi)	3464 (1380- 13781)	2450 (1959- 6095)	4010 (2110- 13848)	F=0.53, P=0.766
Mean sway velocity [mm/s]				
DLS: eyes open	11.62 ± 3.5	13.14 ± 4.7	13.17 ± 3.6	F=1.80, P=0.065
SLS: eyes open (Fi)	34.65 (27.72 - 40)	30.89 (27.35 - 33.89)	32.67 (25.57 - 47.78)	F ⁱ =0.13, P=0.936
TS: eyes open (Fi)	24.97 (22.54 - 29.18)	30.91 (24.46 - 40.11)	29.64 (24.95 - 35.77)	F ⁱ =2.53, P=0.282
DLS: eyes closed	18.55 ± 7.2	15.89 ± 5.0	15.90 ± 4.3	F=1.72, P=0.101
SLS: eyes closed (Fi)	93.3 (67.28 - 135.9)	100.1 (78.74 - 116)	88.71 (67 - 113)	F ⁱ =0.93, P=0.627
TS: eyes closed (Fi)	85.85 (51.46 - 131.89)	59.8 (52.08 - 81.75)	75.23 (43.01 - 147.6)	F ⁱ =0.93, P=0.627

Parentheses denote non-parametric results, median and interquartile range. F= Friedman statistic.

6.3.9: Quality of life

Significant overall effects were identified in all four SRS-22r sub-domains: pain, self-image, mental health and function (see Table 6.9). Post-hoc analysis revealed a significant and clinically meaningful improvement in pain perception post-intervention when compared to pre-operative (P<0.01) and post-operative scores (P<0.05). Post-hoc analysis also identified significant improvements in mental health post-intervention when compared to both the pre-operative and post-operative results (P<0.05). Significant and clinically meaningful improvements were also observed in participants' self-image post-surgery

($P<0.01$) and post-intervention ($P<0.01$) when compared to pre-operative results. No significant improvements were noted for the function domain, however (Table 6.9).

Physical activity and sedentary behaviour were self-assessed using the validated International Physical Activity Questionnaire (IPAQ). No significant overall interactions were identified for either physical activity or sedentary behaviour (Table 6.9).

Table 6.9. Quality of life, physical activity and sedentary time

Outcome variable	Pre-Op (n=15)	Post-Op (n=15)	Post-Intervention (n=15)	Overall Effect
Quality of life: SRS-22r				
Pain	3.47 (0.89)	3.55 (0.63)	4.13 (0.80) ^{## \$}	F=11.88, P=0.003
Function	4.16 (0.43)	3.92 (0.64)	4.35 (0.44)	F=6.36, P=0.041
Mental health	3.32 (0.93)	3.32 (0.83)	3.64 (0.80) ^{* \$}	F=7.05, P=0.029
Self-Image	2.53 (0.73)	3.91 (0.88)	3.96 (0.78) ^{** ##}	F=19.75, P<0.001
Physical activity: IPAQ				
Sedentary Time (mins. wk ⁻¹)	399.4 ± 155.2	435 ± 128.7	432 ± 106.9	F=0.44, P=0.646
Physical Activity (MET.wk ⁻¹)	2971 ± 2212	2396 ± 2055	2806 ± 1918	F=1.35, P=0.275

Mean (SD) data for SRS22 Asterisks infer significant difference between pre-op and post-op results (* $P<0.05$; ** $P<0.01$; *** $P<0.001$). Hash symbols infer a significant difference between pre-op and post-intervention results (# $P<0.05$; ## $P<0.01$; ### $P<0.001$). Dollar symbols infer a significant difference between post-op and post-intervention results (\$ $P<0.05$; \$\$ $P<0.01$; \$\$\$ $P<0.001$).

6.3.10: Comparison of differences in post-intervention results between the severe AIS group and the control group in Study 2 (Chapter 4)

Post-intervention results for the severe AIS group showed increases in strength across most pelvic and spinal muscle groups, as well as improvements in lumbar strength and lower limb endurance. These results were not significantly different from those observed in the control group in Chapter 4, Study 2. However, significant differences remained between the severe AIS group post-intervention and the healthy control group for most pulmonary function tests, exercise capacity, upper limb endurance, and all four quality of life domains (Table 6.10).

Table 6.10. Comparison of post-intervention group with the control group

Outcome variable	Mean $\pm$ SD Control	Mean $\pm$ SD AIS	P
Pulmonary function			
FEV ₁ (L.sec ⁻¹)	3.26 $\pm$ 0.6	2.87 $\pm$ 0.6	=0.065
FVC (litres)	3.74 $\pm$ 0.9	3.12 $\pm$ 0.6	= 0.029*
% Predicted FEV ₁	0.97 $\pm$ 0.1	0.84 $\pm$ 0.2	= 0.016*
% Predicted FVC	0.96 $\pm$ 0.2	0.81 $\pm$ 0.2	= 0.009**
Cardiorespiratory Function			
VO ₂ max (mL.kg-1.min-1)	41.86 $\pm$ 10.36	39.26 $\pm$ 8.143	=0.437
Peak workload (watts)	156.70 $\pm$ 40.2	129.30 $\pm$ 29.2	= 0.036*
Lumbar strength	87.14 $\pm$ 14.1	76.33 $\pm$ 22.9	=0.107
Lower limb Strength:			
Hip flexion (Left)	20.89 $\pm$ 4.8	18.41 $\pm$ 3.6	=0.108
Hip extension (Left)	19.50 $\pm$ 6.5	19.46 $\pm$ 4.6	=0.982
Upper limb endurance			
Modified push up (n)	15.11 $\pm$ 7.7	8.07 $\pm$ 11.3	= 0.042*
Lower limb endurance			
One leg wall squat (Right)	22.17 $\pm$ 21.1	10.47 $\pm$ 12.3	=0.073
One leg wall squat (Left)	18.72 $\pm$ 18.4	16.40 $\pm$ 16.2	=0.716
Balance: Mean sway velocity			
Double leg stance (eyes open)	13.36 $\pm$ 5.5	15.9 $\pm$ 4.3	=0.155
Quality of Life: (MW)			
Pain	5.00 $\pm$ 5.5	4.00 $\pm$ 5.4	< 0.001***
Function	5.00 $\pm$ 5.5	5.00 $\pm$ 5.4	< 0.001***
Mental health	4.00 $\pm$ 5.4	4.00 $\pm$ 4.3	< 0.001***
Self –image	5.00 $\pm$ 5.4	4.00 $\pm$ 5.3	< 0.001***

((MW) Quality of life non-parametric tests; Mann-Whitney; median and interquartile range. Asterisk * (P<0.05.), ** (P < 0.01) *** (P < 0.0001), infers significant inter-group difference, between control and AIS group.

Results: Main findings

1. Post-operative patients with AIS who received a targeted physiotherapy-led rehabilitation programme had significant improvements in the following outcome variables:
 - QOL domains, pain, mental health, when compared to both pre-operative and post operative scores. Function when compared to post operative results and self-image when compared to pre-operative results.
 - Upper and lower limb strength when compared to both pre-operative and post operative results
 - Lumbar strength when compared to post -operative results.
 - Upper limb endurance and lower limb endurance on the non-dominant side when compared to post operative results.
 - Pulmonary function tests, $FEV_1(l.sec^{-1})$, FVC (litres), and % predicted FVC when compared to post-operative results and $FEV_1 / FVC (\%)$ when compared to pre-operative results.
2. The intervention had no significant effect on the following outcome variables:
 - Pre-operative pulmonary outcomes, $FEV_1 (l.sec^{-1})$, FVC (litres), PEF ($L.min^{-1}$), % predicted FEV_1 , % predicted FVC and post-operative PEF ($L.min^{-1}$).
 - $VO_2max (mL.kg^{-1}.min^{-1})$, Peak workload (W), Max heart rate ($beats.min^{-1}$), Grip strength, Lower limb endurance on the dominant side, Postural balance and postural sway, Sedentary time or physical activity levels when compared to both pre-operative and post-operative results.

6.4: Discussion

The main findings from this study indicate that a targeted physiotherapy-led intervention significantly improved quality of life, lumbar strength, upper and lower-limb strength, upper limb and lower limb endurance (non-dominant side). Pulmonary function also improved when compared to post-operative results.

The results also suggest that the physiotherapy-led intervention had no material effect on most vascular measurements, pre-operative pulmonary function outcomes, exercise capacity, max workload, VO_2max , grip strength, lower limb endurance (dominant side) and balance. In addition, no differences in self-reported weekly sedentary time or physical activity levels were recorded across the three timelines (pre-operative, post-operative and post-intervention).

Recent studies by Çetinkaya et al. (2025) and Walters et al. (2025) represent important contributions to the existing literature but differ substantially from the scope and methodological content of the current study. The findings of Cetinkaya et al. (2025) are consistent with the current study in demonstrating improvements in QOL following intervention. However, the current study additionally identified significantly lower QOL in participants compared with a healthy control group, a comparison that was not included in Cetinkaya et al. (2025). Additionally, Cetinkaya et al. (2025) did not evaluate the same comprehensive set of outcome measures as the current study, preventing direct comparison of results. Walters et al. (2025) primarily focused on methodological outcomes, including recruitment, response, and adherence rates, rather than specific patient or participation outcomes. While the SRS-22r was used as a primary outcome measure, no objective physical assessments were conducted. As such, direct comparisons with the current study are limited.

6.4.1: *Pulmonary function and exercise capacity*

The results of the current study found significant differences in some pulmonary function tests when the post-intervention AIS group were compared with the healthy control group (Chapter 4, Study 2). Specifically, post-intervention values for FVC, % predicted FEV_1 , and % predicted FVC remained significantly lower in the AIS group. This supports the evidence to date which suggests that severe AIS has a negative impact on pulmonary function (Jeans et al., 2017, Negrini et al., 2018, Kempen et al., 2022).

The current study also found that key pulmonary outcomes FEV₁, FVC, and % predicted FVC showed significant improvements following the intervention when compared to post-operative outcomes. However, pulmonary function tests post-intervention was comparable to the pre-operative results, indicating pulmonary function had broadly returned to pre-operative levels post-intervention. These results are in contrast to previous studies that found pulmonary function may initially decline for up to 2 years post-operatively before returning to pre-operative levels (Lee et al., 2016). An earlier study by Shneerson (1980) carried out pre- and post-operative pulmonary tests (peak flow, FEV₁ and FVC) prior to surgery and again 17 to 23 months post-surgery. No significant improvement over time was identified. The authors concluded that spinal fusion produced anatomical improvement but no significant physiological improvement. Rafferty et al. (2020) also found significantly reduced pulmonary function in one-year post-operative adolescents with AIS when compared to an anthropometrically matched control group. In contrast to the current study, previous research referred to above (Shneerson, 1980, Lee et al., 2016) were follow-up studies and did not incorporate a targeted intervention, a key distinction in study design that may account for differences in outcomes.

Chapter 2, Study 1 found that exercise-based treatments improved key pulmonary outcomes in children and adolescents with AIS. Other studies have found significantly improved PFTs when an intervention includes aerobic exercise (Athanasopoulos et al., 1999, dos Santos Alves et al., 2006, Xavier et al., 2020). Findings from the current study support the premise that incorporating an aerobic component into a post-operative rehabilitation programme may enhance pulmonary function in post-operative patients with severe AIS. Several studies have established that aerobic exercise can lead to significant improvements in FVC and VC in healthy children and adolescents (Hancox and Rasmussen, 2018). High-intensity exercise programmes have also been linked to improvements in FEV₁, further supporting the role of aerobic training in promoting respiratory function (Rawashdeh and Alnawaiseh, 2018)

Post-operative measurements for exercise capacity (VO₂max, max heart rate and max workload) showed a mean decline when compared to the pre-operative results. Following the intervention these outcome variables were comparable with those observed pre-operatively. Furthermore, no significant differences in VO₂max were observed post-intervention when compared to healthy controls; however, maximum workload remained significantly lower than that of the healthy controls (Chapter 4, Study 2). These results

support Jeans et al. (2017) who found VO₂max outcomes for post-operative patients with AIS comparable with healthy controls three months and two years post-spinal fusion. The authors concluded that patients with AIS compensated for reduced tidal volume with increased rate of breathing. They also speculated that activity levels rather than curve severity may have the greatest impact on exercise capacity. The current study shows a mean decline in exercise capacity post-operatively and a return to pre-operative levels post-intervention. This pattern suggests that the changes in exercise capacity outcomes across the three time-points were more likely associated with post-operative recovery rather than a significant improvement in cardiorespiratory function as a result of the intervention. It is important to note that the aerobic component of the physiotherapy-led intervention, which consisted of brisk walks on five days a week, was self-administered and self-reported, and this may have influenced the overall results.

6.4.2: Muscle strength

Several papers have highlighted musculoskeletal impairments in post-operative patients with AIS (Hopf et al., 1998, Danielsson et al., 2006, Rafferty et al., 2020). However, no research was found that specifically investigated the effectiveness of a rehabilitation intervention addressing musculoskeletal issues in post-operative adolescents with severe AIS. The current study demonstrated that a targeted intervention can effectively address muscle strength impairments in post-operative adolescents with AIS.

Hopf et al. (1998) examined the effects of structural changes to the spine and how these changes might affect muscle, fascia and other skeletal structures. The results of Hopf et al. (1998) suggest that AIS can influence muscle activation and result in asymmetrical muscle activity in hip abductor and adductor muscle groups. Danielsson et al. (2006) conducted a 20-year longitudinal study and found that lumbar range of motion and muscle endurance noticeably decreased in post-operative adults with AIS in comparison to a control group. Rafferty et al. (2020) confirmed these findings identifying significant musculoskeletal weaknesses in post-operative adolescents with AIS 12 months post-surgery, when compared to a healthy control group. The existing evidence suggests that post-operative patients exhibit musculoskeletal impairments, which are not adequately addressed within the current healthcare system.

In patients with AIS, a temporary decrease in lumbar strength following corrective spinal surgery is well documented (Temby et al., 2021). This decline is mainly attributed to

surgical trauma, muscle dissection, post-operative immobilisation, and pain-related inhibition of trunk musculature. In the current study, as expected, lumbar strength significantly decreased in the immediate post-operative phase. However, following the targeted physiotherapy-led rehabilitation programme, lumbar strength returned to pre-operative levels, with mean values demonstrating an upward trend.

The improvements observed may reflect both neuromuscular reactivation and functional adaptation resulting from the rehabilitation programme's emphasis on trunk control, core strengthening, and postural re-education. Importantly, these results indicate that while surgery primarily corrects structural deformity and alignment, it may not, in isolation, restore muscle function. A 20-year longitudinal study by Danielsson (2006) found lumbar spine muscle endurance was significantly decreased when compared with healthy controls. A targeted rehabilitation should therefore be considered for optimising post-operative recovery and overall physical performance (Temby et al., 2021). The current intervention programme led to significant improvements in the majority of muscle groups treated, which may enable post-operative AIS patients to engage in physical and sporting activities which were previously inaccessible to them. Numerous studies have highlighted the physical and mental health benefits of sports participation in children and adolescents (Eime et al., 2013, Malm et al., 2019, Song and Shi, 2023).

6.4.3: Muscle endurance and power

Post-intervention results showed significant improvements in upper limb endurance and left-sided lower limb endurance when compared to post-operative results. Although no significant improvement was noted for right-sided lower limb endurance, the post-intervention mean scores were noticeably higher than pre- and post-operative results indicating a positive trend. One explanation for the findings in the current study is that surgical correction of the spinal curve results in the correction of pelvic obliquity (Banno et al., 2021). Pelvic obliquity creates an asymmetry in pelvic alignment. In the majority of cases, this leads to a lower positioning of the right side of the pelvis. Spinal surgery can correct the pelvic alignment making the single leg squats easier to perform. A further explanation is that muscle endurance is closely associated with an individual's pulmonary and cardiovascular capacity (Allaire et al., 2004, Yang et al., 2022). The physiotherapy-led rehabilitation programme resulted in significant improvements in lung function, which also may have contributed to the improvements in muscle endurance.

No previous studies examining muscle power in patients with AIS were located. Study 2, Chapter 4 of this thesis found no significant difference in upper or lower limb power in the pre-operative AIS group compared to healthy controls. Although not statistically significant, there was a clear trend in the power results suggesting that healthy controls were more powerful than adolescents with severe AIS post-rehabilitation. The findings of the current study may be related to general muscle deconditioning in the AIS group, or due to the small sample size recruited for this study. A larger study with a greater number of participants is required to establish if upper and lower limb power deficits exist in post-operative patients with AIS.

6.4.4: Balance

The current study found no significant differences in postural balance or postural sway in patients with AIS when the results from preoperative, post-operative and post-rehabilitation time-points were compared. In addition, no differences were observed when post-operative AIS postural balance or postural sway were compared to healthy controls. These results support the earlier findings of Schimmel et al. (2015) who compared pre- and post-operative postural balance in 26 patients with AIS and 18 healthy controls. They found no significant difference in postural balance between the two groups. The authors recognised several potential limitations, including the absence of anthropometric data matching the groups at the onset and the inclusion of a broad range of spinal curve progressions, which could have influenced the outcomes.

In contrast to the results of the current study, de Santiago et al. (2013) investigated how vision and base of support affect balance during quiet standing in individuals with AIS, both before and after surgery. Their findings indicated that patients with AIS displayed greater postural sway compared to healthy controls, regardless of whether eyes were open or closed before and after surgery. Notably, the degree of sway increased when visual input was removed, highlighting a greater reliance on vision for balance in the AIS population compared to healthy controls. de Abreu et al. (2012) identified a significant difference ($P < 0.01$) in quiet standing before surgery and up to three months post-surgery when compared to a healthy control group. An interesting feature of this paper was that balance results three months post-operatively were significantly poorer than before surgery. The authors acknowledged that no record was taken of physical activity for either group in the post-surgical period prior to testing and this may have influenced the results. In addition, the authors speculated that the recovery from a significant invasive procedure may also

have contributed to the increased postural sway post-operatively. Li et al. (2019) also found greater postural sway in a cohort of AIS patients who had spinal surgery two years previously compared to a control group. The authors speculated that positive adaptations to the fused spine might take place over a longer period. The consensus is that post-surgical patients with AIS have greater postural sway than healthy controls (de Abreu et al., 2012, de Santiago et al., 2013, Li et al., 2019).

The current study found no significant differences between pre- and post-operative balance and postural sway outcomes. However, the Double Leg Stance Test (eyes open) had increased mean postural sway post-operatively and post-rehabilitation when compared to their pre-surgical results. The overall effects for this test were trending towards a significant difference ($P = 0.06$). The limited numbers recruited in the current study and study duration may have influenced the balance results. Several theories have been proposed to explain the cause of deficits in postural sway in post-operative patients with AIS including biomechanical abnormalities, sensory-motor processing (de Santiago et al. 2013) and under-developed proprioceptive pathways (Schimmel et al. 2015). Further suitably powered longitudinal studies are needed to establish the underlying cause of balance impairments.

6.4.5: Quality of life

The current study found significant positive outcomes post-intervention, for pain, mental health and in particular self-image when compared to pre-operative outcomes. Surgery also had a significant positive impact on self-image, but no significant improvement was noted for pain, mental health or function. Additionally, post-intervention functional outcomes significantly surpassed post-operative results, which would be expected given the recovery period required after major surgery. Function levels did not significantly increase post-intervention when compared to function levels prior to surgery.

Very few studies have analysed the impact spinal surgery has on QOL in patients with AIS. An early longitudinal study by Danielsson et al. (2001) found adolescents who had spinal fusion surgery for AIS had greater pain scores, lower physical function, and poorer overall health when compared to a control group 20 years post-surgery. Spinal surgical procedures have considerably advanced since the early 2000's and these results may not be as relevant today. Fernandes et al. (2019) carried out pre- and post-operative interviews on QOL with adolescents with severe AIS. Their findings indicated that surgery had a meaningful effect

on body image a marginal impact on mental health and made no significant difference in pain or function results. The authors support the arguments made by (Andersen et al., 2010) that timing of surgery is critical to mental health and self-image in patients with severe AIS. Andersen et al. (2010) found significant improvements in QOL outcomes when surgical procedures were carried out before the age of 16.

While the current study shows that the intervention led to improvements in the QOL of patients with AIS when compared to their pre-operative levels, a key question remained, were the post-intervention QOL outcomes for pain, mental health, self-image and function comparable to those of healthy adolescents? When the QOL outcomes post-intervention were compared with a healthy control group (Chapter 4, Study 2), the healthy group demonstrated significantly stronger results across all QOL domains, self-image, mental health, pain, and function. These findings suggest that the physiotherapy-led intervention had a meaningful positive effect on pre-surgical QOL in children and adolescents with severe AIS. However, there still remains a considerable difference in all QOL parameters when compared to the normal adolescent population. It is clear that there is a negative psychological burden associated with an AIS diagnosis which impacts QOL from an early stage.

6.4.6: Limitations

The author acknowledges the need to consider several limitations. Firstly, the absence of a control group limits the ability to draw definitive causal inferences regarding the effects of surgery and rehabilitation, as improvements observed may, in part, reflect natural temporal recovery or other external factors. Secondly, factors such as the COVID-19 pandemic, the closure of scoliosis clinics, and the HSE cyber-attack significantly affected participant recruitment. However, based on previously published effect sizes (Pellegrino et al., 2012), our a-priori sample sizing (n=12) suggests the study was adequately powered.

The duration of the targeted physiotherapy-led intervention was 12 weeks. A longer programme may have generated additional positive effects. However, as the first intervention of its kind there were no previous studies on which the duration of the post-operative intervention could be based. The 12-week intervention period was selected based on the widely accepted understanding that measurable improvements in strength, endurance, and cardiorespiratory function generally occur following 8 to 12 weeks of consistent training (Farrell and Turgeon, 2021, Schoenfeld et al., 2021, Spiering et al.,

2023) . Future studies should evaluate different durations of post-operative interventions to establish the optimum duration. Finally, although compliance with the HEP was monitored, the HEP was unsupervised and self-reported on a weekly basis. Future studies should include a fully supervised rehabilitation programme.

6.5: Conclusion

The current study differs from previous research in several important respects. It is the first study to incorporate pre- and post-operative assessments across a broad range of outcome domains in patients with severe AIS. The study also implements a targeted rehabilitation programme tailored specifically to the needs of each participant and evaluates the impact of the intervention on both the physical and psychosocial outcomes. By addressing several methodological and conceptual limitations of earlier studies, this work contributes to our understanding of post-operative impairments and the potential role of structured rehabilitation in the management of patients with AIS.

This study was suitably powered and provides valuable preliminary evidence supporting the feasibility and potential benefits of a physiotherapy-led, targeted rehabilitation programme for post-surgical AIS patients. The findings indicate meaningful improvements in pulmonary function, core muscle strength, endurance, lower-limb power, and health-related quality of life. However, the lack of a control group restricts our interpretation of the results, as general improvements due to growth and maturation cannot be ruled out. Larger randomised controlled trials are required to confirm these preliminary trends and establish definitive efficacy.

The study also underscores the importance of a detailed, standardised baseline clinical assessment as the foundation for developing effective, individualised rehabilitation programmes. Furthermore, given the well-documented psychosocial challenges experienced by patients with AIS, integrating a qualified mental health practitioner within the rehabilitation team from the early stages of treatment is strongly recommended.

To further advance understanding of post-operative recovery in patients with AIS and quality-of-life outcomes, future research should consider a longitudinal design with extended follow-up. These studies would help determine the durability of physical and psychosocial improvements and clarify the mechanisms through which targeted rehabilitation contributes to long-term wellbeing in patients with AIS.

Chapter 7: Discussion

7.1: Introduction

Adolescent Idiopathic Scoliosis (AIS) is a prevalent spinal deformity affecting 2–3% of adolescents, particularly females. It is defined by a three-dimensional spinal curvature that emerges around puberty in otherwise healthy individuals. Despite substantial research, its precise cause remains unknown. Current treatment strategies, including observation, bracing, and surgery are largely guided by radiological measures such as the Cobb angle. However, these approaches often neglect the broader physiological and functional impairments that may arise in patients with AIS.

7.2: Summary of findings

The primary findings of this thesis are fourfold. Firstly, there are impairments in pulmonary function, exercise capacity, muscle strength and endurance, balance, and QOL in patients with AIS, identified in Study 2, Chapter 4. The prevalence and magnitude of some of these impairments were associated with the severity of the spinal curvature. Secondly, a Schroth programme (Study 3, Chapter 5) strengthens the upper spinal, lumbar, and pelvic musculature, particularly on the concave side of the spinal curve, in patients with mild to moderate AIS. However, it does not improve pulmonary function, exercise capacity, muscular endurance, balance, or QOL. Thirdly, a targeted physiotherapy-led intervention (Study 4, Chapter 6) significantly improved some pulmonary function outcomes, pelvic and spinal muscle strength, muscle endurance, power and QOL in post-operative patients with severe AIS. The intervention did not produce significant changes in % predicted FEV₁, exercise capacity, lower limb endurance on the dominant side, balance, physical activity levels, or sedentary time. Additionally, although the intervention led to significant improvements, notable impairments in pulmonary function, upper limb endurance, and all domains of QOL persisted when post-intervention outcomes were compared to those of a healthy control group. Finally, a systematic review and meta-analysis (Study 1, Chapter 2) found that exercise-based therapy leads to significant improvements in pulmonary function among patients with AIS.

7.3: Clinical context and current gaps in AIS management

An estimated 2,000 children are diagnosed with Adolescent Idiopathic Scoliosis (AIS) annually in Ireland (Kiely, May 2023 personal communication). Currently, the average waiting time for an initial scoliosis assessment is approximately 12 months (O’Keeffe, personal communication, June 8th, 2025). As of April 2025, the Spinal Surgery Management Unit reported that 230 patients are awaiting spinal fusion surgery, with current wait times ranging between 4 to 6 months. The significant improvement in surgical scheduling in recent years has been attributed to the outsourcing of procedures to private hospitals in Ireland, the UK, and the USA. The decision to outsource surgeries and reduce waiting times is clearly a direct result of political and media pressure over the past 3 years. However, the majority of patients (approximately 1,800) are diagnosed with mild to moderate AIS and are therefore not surgical candidates but are instead placed under observation with annual reviews or prescribed bracing. An additional option, available only to families with sufficient financial means, is to access private physiotherapeutic scoliosis-specific exercise (PSSE) programmes, with Schroth being the most widely used. While such programmes have shown potential in improving strength in specific muscle groups, they remain inaccessible within the public healthcare system. In Children’s Health Ireland (CHI) hospitals at Crumlin and Temple Street, where most patients with AIS are managed, there is currently no dedicated spinal physiotherapist assigned to the spinal wards (O’Keeffe, personal communication June 8th, 2025). This is an example of the systemic gap in resources when the public health system is compared to private health services. It clearly underscores the urgent need for a comprehensive and accessible rehabilitation strategy for all patients with AIS.

This thesis has highlighted that an AIS diagnosis demands timely and targeted attention. Extended delays between diagnosis and skeletal maturity can lead not only to a worsening spinal curvature but also to the development of musculoskeletal, pulmonary, and cardiovascular impairments, as well as reductions in QOL.

The findings from Study 2 (Chapter 4) challenge the current clinical assumptions and practices in the management of patients with AIS. AIS protocols in Ireland are based on the assumption that patients with mild and moderate AIS have no functional impairments and that patients with severe AIS return to ‘normal’ function 12 months post-operatively (Rubery and Bradford, 2002). Consequently, no rehabilitation programmes are available to

patients at any stage of the curve spectrum. Study 2 highlighted a gap in the current health care treatment model that warrants attention. The functional impairments identified in Study 2 were evident in patients across all curve severities, indicating that these impairments emerge earlier in curve development than previously assumed.

A particularly important finding in this thesis was that both the mild/moderate and severe AIS groups exhibited significantly lower pulmonary function compared to healthy controls. These results are consistent with Kempen et al. (2022), who established an inverse relationship between thoracic Cobb angle and lung function. In individuals with AIS, reduced pulmonary function may be associated with lower levels of physical activity (Jagger et al., 2020). When these respiratory deficits are combined with muscle strength and endurance impairments, as well as the psychosocial challenges linked to body image, adolescents may experience limitations in participating in school or community sports. These limitations can contribute to a sedentary lifestyle, which in turn leads to increased health risks and social isolation (Pyatakova et al., 2019, Tomczak and Rogalski, 2024, Xu et al., 2024)

Despite demonstrating a number of positive outcomes, neither of the intervention studies (Study 3 and Study 4) were able to fully alleviate the deficits in pulmonary function and exercise capacity observed in the study participants. The Schroth-based intervention described in Study 3 (Chapter 5) did not result in significant improvements in pulmonary function, exercise capacity, or muscle endurance. This may be due to the absence of an aerobic component in the intervention protocol. Previous research supports the association between pulmonary function and exercise capacity (Sperandio et al., 2014, Shen et al., 2016) as well as between pulmonary function and peripheral muscle endurance (Yang et al., 2022).

Study 4 (Chapter 6), a novel, targeted physiotherapy-led intervention programme resulted in improvements in some aspects of pulmonary function and cardiovascular fitness. Nevertheless, despite these gains, participants, post intervention, continued to show significant deficits in pulmonary function and exercise capacity compared to healthy controls. One potential reason for this persistence was the lack of a supervised aerobic training component. While aerobic activity was encouraged, it was self-reported and unsupervised, in contrast to the hands-on guidance for other elements of the programme. This may have limited the potential cardiorespiratory and endurance-related benefits.

Study 1 (Chapter 2), a systematic review and meta-analysis has shown the positive impact of exercise-based interventions on pulmonary function in patients with AIS. The results from Study 3 (Chapter 5) do not support the findings of the review, whereas the results from Study (Chapter 6) are in agreement with it. Therefore, the findings from this thesis reinforce the argument that an exercise intervention as a core component of post-operative management for those with severe AIS is beneficial, but there was little evidence to support its use for patients with mild or moderate AIS.

In this thesis, a strong association was identified between curve severity and QOL. Both the mild/moderate and severe AIS groups reported significantly poorer QOL scores compared to healthy controls. Additionally, patients with severe AIS showed significantly lower scores in the domains of pain, self-image, and mental health compared to those with milder curves. These findings indicate that QOL deterioration begins early in the progression of scoliosis and worsens as the spinal curvature becomes more severe. Poor QOL in adolescents with AIS can contribute to long-term psychological distress, and social withdrawal (Tomczak & Rogalski, 2024, Xu et al., 2024).

Study 3 did not demonstrate improvements in QOL for patients undertaking conservative management (PRI) when compared to a cohort receiving 'usual care' (PUB). The influence of bracing may have negatively impacted on these results. Both the PRI and PUB groups included participants who were braced, and bracing has been previously shown to negatively impact QOL, particularly in terms of self-image, activity limitations, and social isolation (Piantoni et al., 2018, Wang et al., 2021). These psychosocial burdens underscore the importance of holistic care models that integrate psychological and emotional support.

Another finding of particular concern was that following a post-operative physiotherapy-led targeted intervention, QOL scores remained significantly lower than those of healthy controls. An important factor to consider is that adolescents with AIS live with spinal deformity and its psychosocial impact over extended periods, and their long-term experiences, often culminating in surgery, may contribute to a negative perception of their overall well-being (Gallant et al., 2018, Chen et al., 2024). Research has shown that reduction in pulmonary function and exercise capacity can also have detrimental effects on activity levels, leading to potential mental health issues (Xu et al., 2024). Previous research has demonstrated that lower levels of physical activity in individuals with AIS are negatively associated with quality of life (Glavaš et al., 2023a). It is interesting to note that

no significant improvements in activity levels or reductions in sedentary time were observed in either of the two studies carried out as part of this thesis. This may also have contributed to the persistent QOL deficits observed.

The multifactorial and complex nature of QOL outcomes, particularly in response to scoliosis-specific exercises such as the Schroth programme, has been acknowledged in prior research (D'Agata et al., 2017, Gallant et al., 2018). Conflicting findings across studies (Monticone et al., 2014, Anwer et al., 2015, Schreiber et al., 2015, Burger et al., 2019, Liu et al., 2025, Ren et al., 2025) highlight important differences in trial design, outcome selection, intervention dose, and measurement that may limit cross-study comparability. Zhu et al. (2025) meta-analysis suggests that PSSE programmes can improve patient-reported outcomes, including self-image and overall QOL. However, they contend that the overall evidence remains limited by moderate study quality and ongoing variation between studies, which reduces confidence in the findings. Similarly, Schreiber et al. (2023) conducted a systematic review examining the methodologies used in Schroth trials. Their review also found that methodological rigour was generally suboptimal, limiting the reliability of findings, and that overall reporting quality across studies was poor. These findings were in keeping with those of Chapter 2 where the majority of the studies were judged to be 'fair'. The findings from these studies highlight the need for more robust, standardised approaches to measuring and enhancing QOL in this population.

This thesis demonstrates that adolescents with AIS may continue to experience significant impairments in pulmonary function, exercise capacity, and quality of life after a targeted 3-month intervention. While targeted post-operative physiotherapy interventions appear promising in improving physical outcomes, their effectiveness may be enhanced by incorporating supervised aerobic training and early mental health support to address the complex needs of individuals with AIS. There remains a need to explore rehabilitation programmes that are comprehensive, equitable, and introduced early within both conservative and surgical care pathways to support patients' physical and emotional well-being. Given the ongoing challenges in mental health, self-image, and overall well-being, this thesis highlights the potential value of integrating early mental health support within rehabilitation models for AIS.

The importance of intervention duration in achieving meaningful clinical outcomes in AIS has been highlighted. The duration of Schroth programmes varies worldwide from `1 week

(Borysov and Borysov, 2012) to 4-years (Seleviciene et al., 2022). A meta-analysis by Park et al. (2018) found that a six-month programme was more effective than a shorter one, with the most significant improvements being associated with interventions lasting longer than 12 months. A recent randomised controlled trial by Kyrkousis et al. (2024) demonstrated that longer intervention durations were associated with superior outcomes, proposing a ‘linear dose–response relationship’ between intervention length and treatment efficacy. The 4-month duration of the Schroth programme in this thesis was informed by previous studies using Schroth programmes, but also by the established guidelines for strength, endurance and aerobic training (Alver, 2017, Schoenfeld et al., 2021). It is widely recognised that due to adaptations in muscle fibres, significant improvements in muscle strength, endurance, and power (Clark, 2016, Greenlee et al., 2017, Spiering et al., 2023), cardiorespiratory output (Farrell and Turgeon, 2021, Renaud et al., 2010) and balance (Martínez-Amat et al., 2013, Yilmaz et al., 2024) typically emerge following a consistent training period of 2 to 3 months.

A final consideration relates to the potential benefits of a prehabilitation programme, a strategy currently implemented in some Irish hospitals for adult surgical candidates. Shakya and Poudel (2022) contended that a patient's overall outcome after surgery is influenced not only by the quality of the surgical procedure but also by their pre-operative conditioning and post-operative care. Prehabilitation refers to actively getting patients ready for surgery using strategies like exercise, improved nutrition, psychological support, or a mix of these approaches (McIsaac et al., 2025). Prehabilitation has been found to have a positive impact on post-operative outcomes in adults undergoing spinal surgery (Gränicher et al., 2025, Gohel et al., 2025). Punnoose et al. (2023) reported high-certainty evidence for prehabilitation in reducing back pain, and moderate-certainty evidence in improving QOL after spinal surgery. Exercise based prehabilitation has also been shown to improve post-operative outcomes and reduce complications in children undergoing a range of surgical procedures (Noronha et al., 2022). Prehabilitation is currently not available for surgical AIS patients in Ireland. Given the evidence supporting prehabilitation and considering the range of functional impairments and reduced quality of life observed in children and adolescents with severe AIS, the potential value of developing a targeted prehabilitation programme in the public healthcare system should be considered.

7.4: Proposed model for guidelines in the treatment of AIS

Building on the findings from Studies 1 through 4, I have considered ways in which care for adolescents with AIS could be more effectively structured and delivered. I propose a more integrated and functional approach to AIS management. In my view, an improved care pathway should include four key components. First, a standardised assessment protocol should be established to comprehensively capture baseline outcomes across key domains such as muscle strength, endurance and power, pulmonary function, exercise capacity, balance, and quality of life. Second, these baseline data should be compared against normative values that account for individual differences in age, gender, and ethnicity, ensuring that results are interpreted meaningfully. Third, clinician training is essential to maintain consistency and accuracy in assessment and interpretation. Finally, the pathway should include tailored rehabilitation programmes that address each patient's specific functional impairments. This proposed model of care would enable the monitoring of progress and inform ongoing rehabilitation needs. This model of care is a shift away from the traditional, curve-centric approach toward one that prioritises function, impairment, and overall well-being. Early identification and personalised rehabilitation could help mitigate long-term physical and psychological consequences of AIS, while also addressing disparities in access to care across the public and private healthcare systems.

7.5: Limitations and Future Directions

While this research has made a significant contribution to understanding and improving rehabilitation approaches for patients with AIS, several limitations have been acknowledged in the relevant chapters of this thesis. These limitations referred to in the chapters (sections 4.4.9, 5.4.6, and 6.4.6) provide valuable guidance for the design and focus of future studies. Despite these limitations, the findings from this thesis provide meaningful guidance for future research, highlighting the need for larger, multi-site trials with standardised, interventions, objective outcome measures, and longer-term follow-up to evaluate sustained functional and psychosocial benefits in rehabilitation for patients with AIS.

7.6: Conclusions

This thesis has provided evidence that patients diagnosed with AIS present with a range of clinically significant impairments when compared to their healthy peers. Importantly, these

impairments appear to emerge earlier in the curve progression than previously understood, reinforcing the urgent need for early identification and intervention. A key outcome of this thesis is the case it makes for the adoption of a standardised clinical assessment protocol and the potential of early rehabilitation for all individuals diagnosed with AIS. Such a strategy would enable the timely identification of modifiable impairments, potentially altering the trajectory of disorder progression and improving long-term outcomes.

This research presents what is believed to be the first Irish-based evaluation of a Schroth programme for private patients with mild to moderate AIS, compared to a group of patients receiving ‘usual care’ in the public health care system. The findings suggest that while the Schroth programme has merit, it may not be comprehensive enough as a stand-alone treatment. It is therefore recommended that PSSE programmes, like Schroth, be supplemented with additional components that address identified deficits. Clinicians administering PSSE should also be aware of the need to correctly assess and treat specific functional impairments, along with Cobb angle and ATR management.

A particularly novel aspect of this thesis is the implementation and evaluation of an individualised, post-operative rehabilitation programme for patients following spinal fusion surgery (Study 4, Chapter 6). To the author's knowledge, this is the first study of its kind to target a rehabilitation programme based on identified impairments pre- and post-surgery. The programme, which was based on outcomes from a standardised assessment protocol and the findings of a post-operative assessment, yielded significant improvements across a range of clinical measures. These results highlight the potential for personalised rehabilitation in the recovery process and underscore the value of thorough post-operative assessment in guiding a targeted intervention.

Finally, the author hopes that the dissemination of the findings of this thesis will contribute meaningfully to health policy discussions and decision-making regarding the future care pathways for patients with AIS. By advocating for early assessment, personalised intervention, and multidisciplinary support, this research aspires to improve the standard of care and long-term outcomes for this vulnerable population.

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Appendices

Appendix 1.1: Ethics approval CHI



St. Anne's Sexual Health (SSE) at Crumlin, D12 NS12, Dublin 12
Children's Health Ireland (CHI) at Crumlin, D12 NS12, Ireland
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ETHICS (MEDICAL RESEARCH) COMMITTEE OFFICE

Tel: +353 (0)1 409 6307/6243

Mr Tony Rafferty
Discipline of Physiotherapy
Trinity Centre for Health Sciences
St James's Hospital
Dublin 8

17th July 2019

REC Reference: GFN/735/19

The National Adolescent Idiopathic Scoliosis Physical Wellbeing Study

Principal Investigators: Mr. Pat Kiely, Mr. Tony Rafferty.

Dear Mr Rafferty

Further to our previous correspondence dated 25th June 2019 in relation to the above.

At a meeting which took place on, 16th July 2019, the Ethics (Medical Research) Committee reviewed and approved all the requested revised documentation was subsequently submitted.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Claire Rice'.

Claire Rice
Secretary
Ethics (Medical Research) Committee

CC: Mr. Patrick Kiely, Consultant Orthopaedic Surgeon, Children's Health Ireland (CHI) at Crumlin, Dublin 12 NS12.

Appendix 1.2: Ethics approval Beacon Hospital.



Sandyford - Dublin 18 - D18 AK68

TEL +353 1 293 6600 www.beaconhospital.ie

Mr Tony Rafferty
Discipline of Physiotherapy,
Trinity Centre for Health Sciences,
St. James's Hospital,
Dublin 8.

Date: 15th October 2019

Study Title: A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study.

Reference Number: BFA0134

Dear Mr Rafferty,

The Beacon Hospital Research Ethics Committee (BHREC) reviewed your application in relation to the above titled study received on the 18th July 2019 at their meeting on the 9th September 2019.

Following on from received and approved amended documentation, I am pleased to inform you that the BHREC has given **Full Approval** for your study to proceed.

The submission has been reviewed from an ethical perspective only. It is the responsibility of the PI/sponsor/data controller to ensure and monitor compliance with any relevant data protection legislation in the country where the study is due to take place and/or with any local policy in the site where the study is being conducted. The application was reviewed by the Beacon Hospital Data Protection Officer.

The documents submitted, reviewed and approved are listed as follows:

Updated ethics app form multi site study 18.9.19 V2

1. Appendix Ethics References V2

2. Appendix 2 Questionnaires V2

- ACSM-Health-Status-Form v2
- IPAQ V2
- Physical-activity-readiness-questionnaire PAR-Q V2
- Srs-22r v2

3&4 Appendix PILs revised V2

- 1 Parental Information Leaflet – controls (BH) V2
- 2 Parental Information Leaflet – Severe surgical AIS (BH) V2
- 3 Parental Information Leaflet – mild & moderate AIS (BH) V2
- 4 Participant Information Leaflet – Controls 16+ (BH) V2
- 5 Participant Information Leaflet – Severe surgical AIS 16+ (BH) V2
- 6 Participant Information Leaflet – mild & moderate AIS 16+ (BH) V2
- 7 Participant Information Leaflet – Controls 14 - 16 (BH) V2
- 8 Participant Information Leaflet – Severe surgical AIS 14 - 16 (BH) V2
- 9 Participant Information Leaflet – Mild & Moderate AIS 14 - 16 (BH) V2
- 10 Participant Information Leaflet – Controls Age 12 - 14 (BH) V2

Directors: Mr Colin Delaney (Chairman), Mr Michael Cullen (CEO), Mr Dermot Hayes, Mr Niall Dwyer, Ms Maureen Lynott, Prof. Mark Redmond, Mr Brian Cowen
Registered Office: Beacon Court, Sandyford, Dublin 18
Registration No: 462475

Appendix 1.3: Ethics approval Blackrock Clinic.



Blackrock Clinic

Rock Road, Blackrock
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Blackrock Clinic Ethics Committee

12/02/2020

PROJECT TITLE: A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study

CHIEF INVESTIGATOR: Mr Pat Kiely

ADDITIONAL INVESTIGATOR: Mr Tony Rafferty

Dear Tony,

I hereby confirm that the Blackrock Clinic Ethics Committee has reviewed your application.

As discussed at the meeting with you, given candidates for this study are identified in the consultant's (Mr Pat Kiely) private rooms and managed externally with no Blackrock data being accessed or used, it is not a matter for the ethics committee here in Blackrock Clinic.

However, should participants in the study be subsequently referred for surgery in Blackrock Clinic, we would ask that you notify us.

We wish you all the very best.

Yours sincerely,

PROFESSOR MARK LAHER
CHAIRPERSON, ETHICS COMMITTEE

Blackrock Clinic Limited
Registered in Ireland No. 45213
Registered Office
at Upper Drumcondra Road, Dublin 9
Tel: 01 206 4374

Executive Director
R. Butler
C. Duffy
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Dr Flynn
J. Conboy
R. Conboy (Chairman)
J. O'Donoghue
J. Sheehan (Vice-Chair)

J. Sheehan (Vice-Chair)
J. Sheehan (Vice-Chair)
R. Sheehan
R. Sheehan

D. Sheehan

Accredited by Joint Commission International

Appendix 1.4: Ethics approval Trinity College Dublin.



Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

Appendix 1.4: Ethics approval Trinity College Dublin

Tony Rafferty
Discipline of Physiotherapy,
Trinity Centre for Health Sciences,
St. James's Hospital,
James's Street,
Dublin 8.
15th July 2019

Ref: 190611

Title of Study: A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study

Dear Tony,

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in June 2019.
We are pleased to inform you that the above project has ethical approval to proceed.

As a researcher you must ensure that you comply with other relevant regulations, including DATA PROTECTION and HEALTH AND SAFETY.

Yours sincerely,

Prof. Brian O'Connell
Chairperson
Faculty Research Ethics Committee

Appendix 2.1: Parental information leaflet Severe AIS – Surgical.



Parental Information Leaflet

Study: A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study.

Your child is invited to take part in a clinical research study. Before you decide whether you wish her/him to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP. Take time to ask questions, do not feel rushed and do not feel under pressure to make a quick decision. You should clearly understand the risks and benefits of your child/adolescent taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

Why is this study being done?

This study will focus on adolescents diagnosed with Adolescent Idiopathic Scoliosis (AIS). There is very little research into musculoskeletal strength, power, endurance and balance in adolescents diagnosed with AIS. Recent research has indicated that weaknesses may exist. Previous studies have also indicated that adolescents with severe AIS have a lower lung function when compared to the general population. Some studies indicate that adolescents with AIS have a lower cardiorespiratory capacity (the ability of your heart and lungs to supply oxygen to your muscles

during physical activity). This study hopes to add to the knowledge in this area and may provide an approach to address some or all of any issues identified over the course of the project. These studies will inform us if adolescents with severe AIS have any musculoskeletal or cardiorespiratory weaknesses and whether an individualised physiotherapy led exercise programme can address any weakness identified.

Aim of current study

The aims of the current study are fourfold: Adolescents diagnosed with severe AIS will be included in studies 1, 3 and 4 below.

Study 1. To assess and compare muscle strength, power, and endurance, balance, cardiorespiratory function and quality of life between adolescents who are diagnosed with severe AIS and awaiting surgery with adolescents diagnosed with mild and moderate AIS and similar aged adolescents from the general population who do not have scoliosis.

Study 2. To assess the effects of a 4-month scoliosis specific exercise programme (Schroth), on adolescents diagnosed with mild and moderate AIS on their muscle strength, power, and endurance, balance, cardiorespiratory function and quality of life, when compared to adolescents diagnosed with mild and moderate AIS who have received standard care and adolescents who do not have AIS.

Study 3. To examine the effect of spinal fusion surgery on musculoskeletal, cardiorespiratory and pulmonary function and quality of life by re-assessing severe AIS participants 3 months after surgery.

Study 4. To examine the effects of a targeted 12-week physiotherapy led exercise programme incorporating a 12-week home exercise programme on adolescents who have undergone spinal fusion surgery.

We will be enrolling adolescents diagnosed with AIS who have consented to surgery and are listed for spinal fusion. If you would like your child to take part in this study, please take time to read this document carefully.

Who is doing the research?

The lead investigator is Tony Rafferty a CORU registered Chartered Physiotherapist with specialist training in sports and exercise medicine and a Strength and Conditioning specialist in Trinity College Dublin. The Co-lead investigator is Mr Pat Kiely Consultant Orthopaedic surgeon Beacon Hospital, Sandyford Dublin 18. This study is a multi-site study and will include participants from Children's Health Ireland, Beacon Hospital and Blackrock Clinic.

The investigators do not or will not receive any payment to recruit patients into this study. We hope to provide important information that may contribute to achieving better patient outcomes for AIS patients in the future.

Who can take part in the study?

To be involved in this study, your child must:

1. Be 12 - 21 years of age.
2. Have a diagnosis of severe Adolescent Idiopathic Scoliosis
3. Be approved for spinal fusion surgery within the next 3 months.
4. Have no illness or musculoskeletal injury, reported neurological, or balance problems that would restrict exercise.
5. Be able to cooperate, take, and follow instructions in English
6. Have written consent from you as legal guardians if they are under the age of 16 years.
7. Have the ability to attend three, 2-hour physical assessments, in the Trinity Centre for Health Sciences, James's Hospital Dublin 8.
8. Be willing and able to attend a targeted physiotherapy led rehabilitation session every 2-weeks for a period of 12 weeks.
9. Agree to take part in a home exercise programme run in conjunction with the supervised rehabilitation programme.

Your child cannot take part in this study if:

1. They have a history of a heart condition (such as acute cardiac event, unstable chest pain, irregular heartbeat, and cardiac infection).
2. They have an existing acute or chronic lung condition.
3. They have an existing acute or chronic neurological condition.
4. They have a known blood pressure abnormality (e.g. hypertension/hypotension).
5. They are fitted with an electronic device (e.g. pacemaker).
6. They play sport at elite level.
7. They are pregnant or are a breastfeeding mother.
8. They have been advised by your medical team not to exercise or have a life threatening illness.
9. They answer "yes" to any one question on the PAR-Q, which would contraindicate exercise testing. This is a standard physical activity readiness questionnaire, which they will complete before exercise testing begins.
10. They have incomplete or dissatisfactory medical screening prior to testing.
11. They are under the age of 12 or over the age of 21.

What does this study involve?

The study involves attending Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8, on 3 occasions for physical assessments over the course of the programme and taking part in a targeted physiotherapy-led exercise programme and a home exercise programme.

All participants will be invited to attend the Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8 for an initial assessment. Parents are welcome to attend; a family member will be required to attend if the participant is under the age of 16. Participants will be assessed again; three months after surgery; and again, at the end of rehabilitation programme. Each assessment will take approximately 2 hours. Assessments will be scheduled to suit the participant.

What does the assessment involve?

Upon arrival, participants will complete short questionnaires about fitness, exercise, quality of life, function and physical activity. When these are completed, standing height and weight will be measured along with heart rate and resting blood pressure. The amount of fat, water and muscle in your child's body will be estimated using a Tanita body composition analyser (pictured, right) that analyses details of body weight, body mass index (BMI), percentage body fat, muscle mass and fat free mass. This machine is non-invasive and will not cause any pain. You child will be asked to remove your shoes and socks and stand on the body composition analyser.



Cardiorespiratory fitness test: Bike Ergometer

Before exercising, participants will complete a short questionnaire (the Physical Activity Readiness Questionnaire, or PAR-Q). The results of this questionnaire will indicate if they are safe to carry out an exercise test. Participants will be familiarised with how the test will work and shown the equipment to be used in this study: a gas analysis system with a facemask and heart rate monitor (pictured, right).

For this test, participants will be fitted with a heart rate monitor and a gas exchange mask and asked to sit on the cycle ergometer for 3 minutes. Resting measurements taken in this period. The test will follow the Godfrey protocol. Each minute of cycling is harder than the previous one.

The participant will keep cycling for as long as they can. Heart rate monitored throughout the test.

You or your child can end the test at any point, if they feel any pain or discomfort, if they feel dizzy, too breathless, or if they feel faint or too fatigued. The researcher will be monitoring for unexpected changes in blood pressure and heart rate, and will end the test if these occur, or if there are any technical difficulties with the equipment used. At the end of the test, there will be a 5-minute cool-down phase, at a slow pace.



Lung function: Lung function tests using a hand-held Micro Plus Spirometer.

We will assess how well the participants lungs work by measuring the volume and effort of breathing using a Micro Plus spirometer (pictured below). This is a non-invasive portable battery-operated hand-held microcomputer unit. An antibacterial filter will be attached for each lung test. A nose clip is used during each test to prevent nasal breathing.



The test will require the participant to stand upright, place their mouth tightly around the mouthpiece and breathe in fully prior to a breathing out fully. They will be encouraged to continue forcing air out until your lungs are empty. Any coughing or accidental blocking of the mouthpiece will render that attempt void and will need to be repeated. The test will be repeated until two satisfactory results are achieved. One minute of normal breathing will be allowed between tests to recover normal lung function.

Muscle testing

Musculoskeletal Strength: Upper limb strength will be measured using a Takei digital grip strength dynamometer. Back muscle strength will be measured using a Takei back-D dynamometer. A calibrated Lafayette manual muscle tester will be used to measure lower limb muscle strength (pictured below).



Takei digital grip



Takei back-D dynamometer



Lafayette manual tester

Muscle Endurance: Upper limb muscle endurance will be measured using a modified push-up test and lower limb muscle endurance testing will be measured using a wall squat test.

Muscle Power: A digital force plate will measure your lower limb power, and a medicine ball will be used to measure upper limb power.



Force plate



Medicine ball throw



modified push up

Balance

A HUR balance platform will assess your balance. The participant will be asked to perform simple balance exercises on the platform (pictured below).



Quality of Life

Quality of life will be assessed using a standardised questionnaire SRS-22rr.

What does the targeted exercise rehabilitation programme involve?

A Chartered Physiotherapist will supervise the bi-weekly exercise programme over 12 weeks. The physiotherapist will be provided with a specific rehabilitation programme for each participant based on the results of the physical assessments. The proposed programme will be based on calisthenics, designed using individual body weight; no free weights or weight machines will be used. Each session will include a warmup and warm down period. All exercises will be demonstrated to the participant prior to commencement. The physiotherapist will also provide assistance/ modification of exercises to any participant who has difficulty executing the technique. Exercises will be set in a circuit and will include a variety and combination of exercises targeting each individual participant's needs. Exercises will be varied to reduce post exercise stiffness. All exercises selected will be appropriate to the age group and levels of muscular and aerobic fitness. The in-person session will be private and last approximately 45 minutes.

The 12-week home exercise programme will be a non-supervised, participant specific, rehabilitation programme, remotely monitored on a weekly basis via zoom call and pre-agreed with each participant. Each participant will maintain an electronic rehabilitation log of physical activity. With agreed access by the lead investigator, weekly maintenance of the rehabilitation log is expected.

Are there any benefits to taking part in this study?

Full analysis of fitness levels and body composition measurements will be provided to each participant on completion of the physical assessments in the form of an individual health report. These reports can be beneficial to understanding your child's fitness levels, their strengths and

weaknesses and how they compare to the general population. This information can be used to guide personal exercise plans going forward.

Participating in this study may also benefit adolescents with scoliosis. If we find that differences exist between groups that have scoliosis and those that do not, it will allow us to investigate ways these differences can be overcome. Participation in the supervised exercise programme and the home exercise programme may greatly benefit your child's overall health, fitness, and quality of life. If we find individual weaknesses in relation to a participant's muscle strength, endurance, power or balance, lung capacity or cardiovascular fitness this programme may address some of these findings.

Are there any risks involved in taking part in this study?

Risks associated with exercise testing are rare, especially when participants have been cleared for exercise and have no medical history that increases risk during exercise. However, there exists the possibility of pain, abnormal blood pressure, fainting, irregular heart rhythm, and joint or muscle injury or cramp. These events are unlikely, and every effort will be made to minimise any risks by evaluating individual participant's health before testing, and by careful monitoring during and after testing and exercise. If the participant experiences any of the above, the test will be stopped immediately, if symptoms do not subside, they will be seen by a doctor and if necessary, brought to A&E in St. James's Hospital. Your child's doctor will also be informed.

Confidentiality and Data Protection

What data will be collected?

Personal data to be collected in this study will include your child's gender, age, relevant medical history from their medical records, body composition, musculoskeletal, lung and aerobic fitness levels and their view on their quality of life. Only personal data, which is relevant for the purpose of this study, will be collected and used (this is called "data minimisation").

Who has access to the collected data?

The Lead Investigator will have access to the data. The research team will have access to pseudonymised data for analytical purposes. Both have undergone training in data protection law and practice, prior to starting this research.

How will my child's data be stored and protected?

Your child's identity will remain confidential. All details and results will be coded with a numerical ID to maintain confidentiality (this is called "pseudonymisation"). Data will be coded, rather than being kept completely anonymous, to allow for comparison of results from one testing day to the

next. Names and personal details will not be published and will not be disclosed to anyone. All information relating to your child in hard-copy form will be stored in a locked filing cabinet within a secure office only accessible by the Lead Investigator and information and records in electronic form will be stored on a password-protected PC at the Trinity Centre for Health Sciences in St. James's Hospital. Study information and results will be retained by Trinity College for 5 years in keeping with good research practice standards and data protection legislation. It will be destroyed after this time (electronic data will be erased, and hard copy forms will be shredded).

How will data be used, now and in the future?

The information collected in this study will be grouped together and analysed. Overall findings from this study may be published in international peer reviewed journals and may be shared at research conferences. The results of the study may be used for comparative purposes in other studies of a similar nature. However, participant's data will remain coded and personal identifiers will never be published or disclosed to anyone. Participant's data will only be used for comparative purposes in studies that have Research Ethics Committee approval. The data controllers and researchers in this project are bound by our Professional Code of Conduct to maintain confidentiality regarding all data gained during this research.

Is there any risk with processing and storing personal data? What will happen if there is a data breach?

Considering that sensitive personal data relating to participants health is involved, in the unlikely event of a data breach (i.e. data being mislaid, lost or stolen), you will be notified as soon as possible, and it will be reported immediately to the Data Protection Commissioner. However, data collected will be pseudonymised and the key to your child's identity will be secured separately. There is a low risk of a data breach.

What are your Childs rights under GDPR?

They have the right to:

- Access their data
- Rectify or correct any mistakes with their data
- Have their data erased or deleted
- Data portability (moving data from one controller to another)
- Object to or stop the processing or profiling of your data
- Lodge a complaint to the Data Protection Commissioner (contact: +353 57 8684800 or +353 (0)761 104 800; <https://dataprotection.ie/en/contact>).

What is the lawful basis to using a participant's personal data?

Data will be processed under the lawful basis of Article 6(1) (e) and 9(2) (i) of the EU General Data Protection Act 2016. If you have any queries regarding your child's data, or the General Data Protection Rules (GDPR), you can contact the research team (details at end of document) or the Data Protection Officer of Trinity College Dublin, by email: dataprotection@tcd.ie.

Insurance

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your child's rights.

Voluntary Participation

Participation in this study is voluntary, and you will be asked to sign a consent form, before your child takes part, after you have read this document and have had the study procedures, risks and benefits explained to you. Your child does not have to take part in this study, and you or your child may withdraw participation at any time, even if the study has already started. You do not have to give a reason for not taking part in or for leaving the study.

If you or your child decide not to participate, or if you or your child withdraw participation, your child will not be penalised and will not give up any benefits, which your child had before entering the study. You should not feel in any way obliged to take part in this study. If you do not give consent, or withdraw your consent, no attempt will be made to access your child's data, and **no** application will be made by the research team for a consent exemption to the Health Research Consent Declaration Committee.

If you wish to seek more information about this research study, or if you wish to opt-out, please contact the lead investigator on the details provided below.

Stopping the Study

You understand that the research team may stop your child's participation in the study at any time without your consent.

Permission

The Research Ethics Committee of Children's Health Ireland, Crumlin, Beacon Hospital, Sandyford Dublin 18, and Blackrock clinic has approved this research. There is no known personal connection between members of the research team and these ethics committees.

Future Contact

After completion of the study, the researchers may contact you again in relation to your study results, if you express that you would like to receive feedback on them.

How can your child prepare for the assessments?

If you consent for your child to take part in this study, the following points explain how they should prepare for their physical assessments.

- Please fast from midnight on the night before your assessment days. Please limit your liquid intake while fasting: you may drink water, but refrain from caffeine drinks, energy drinks, and alcohol. Fasting ensures more accurate results in body composition analysis. A snack and drink will be provided to you after each assessment.
- Please wear clothing and footwear suitable for exercise
- Bring a towel, shower gel, and change of clothes if you wish to shower after testing.
- Please try to drive, arrange a lift or use public transport to get to the testing venue and avoid walking or cycling on the days of your visit. Results of your fitness test will be more accurate. Please refrain from strenuous physical activity for 24-hours prior to each assessment.
- We request that you continue your normal physical activity regime for the duration of the study, and not to increase the training intensity or frequency.

Further information

You can obtain more information or answers to your questions about the study, your child's participation in the study, and you and your child's rights, from **Tony Rafferty, the lead investigator who can be contacted on 0873986551 or emailed at raffertt@tcd.ie**. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

Lead Investigator: Tony Rafferty, Discipline of Physiotherapy, School of Medicine, Trinity College Dublin: Contact: Tel 087 3986551, E-mail raffertt@tcd.ie

Lead Co-Investigator: Patrick Kiely, Consultant Orthopedic Surgeon, Beacon Hospital, Sandyford Dublin 18.

Research Supervisors & Co-Investigators: Dr Sara Dockrell & Dr Neil Fleming: Contact: Tel (01) 8962121, E-mail: sara.dockrell@tcd.ie; neil.fleming@tcd.ie

Data Controller: Trinity College Dublin.

Data Protection Officer: Data Protection, Trinity College Dublin

Contact: E-mail: dataprotection@tcd.ie

Appendix 2.2: Parental information leaflet – Mild and Moderate AIS.



Parental Information Leaflet

Study: A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study.

Your child is invited to take part in a clinical research study. Before you decide whether you wish her/him to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP. Take time to ask questions, do not feel rushed and do not feel under pressure to make a quick decision. You should clearly understand the risks and benefits of your child/adolescent taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

Why is this study being done?

This study will focus on adolescents diagnosed with Adolescent Idiopathic Scoliosis (AIS). There is very little research into musculoskeletal strength, power, endurance and balance in adolescents diagnosed with AIS. Recent research has indicated that weaknesses may exist. Previous studies have also indicated that adolescents with severe AIS have a lower lung function when compared to general population. Some studies indicate that adolescents with AIS have a lower cardiorespiratory capacity (the ability of your heart and lungs to supply oxygen to your muscles during physical activity). This study hopes to add to the knowledge in this area and may provide an approach to address some or all of the issues identified over the course of the project. This study will also inform us if adolescents with AIS have any musculoskeletal or cardiorespiratory

weaknesses and whether a physiotherapy led exercise programme can address any weakness identified.

Aim of current study

The aims of the current study are fourfold: Individuals diagnosed with mild and moderate scoliosis will be included in studies 1 & 2 below.

Study 1. To assess and compare muscle strength, power, and endurance, balance, cardiorespiratory function and quality of life between adolescents who are diagnosed with severe AIS and awaiting surgery with adolescents diagnosed with mild and moderate AIS and similar aged adolescents from the general population who do not have scoliosis.

Study 2. To assess the effects of a 4-month scoliosis specific exercise programme (Schroth), on adolescents diagnosed with mild and moderate AIS on their muscle strength, power, and endurance, balance, cardiorespiratory function and quality of life, when compared to adolescents diagnosed with mild and moderate AIS who have received the current health care pathway and adolescents who do not have AIS.

Study 3. To examine the effect of spinal fusion surgery on musculoskeletal, cardiorespiratory and pulmonary function and quality of life by re-assessing severe AIS participants 3 months after surgery.

Study 4. To examine the effects of a targeted 12-week physiotherapy led exercise programme incorporating a 12-week home exercise programme on adolescents who have undergone spinal fusion surgery.

We will be recruiting adolescents diagnosed with mild and moderate AIS. If you would like your child to take part in this important study, please take time to read this document carefully.

Who is doing the research?

The lead investigator is Tony Rafferty a CORU registered Chartered Physiotherapist with specialist training in sports and exercise medicine and a Strength and Conditioning specialist in Trinity College Dublin. The Co-lead investigator is Mr Pat Kiely Consultant Orthopaedic surgeon in Beacon Hospital, Sandyford Dublin 18. This study is a multi-site study and will include participants from Children's Health Ireland, Beacon Hospital and Blackrock Clinic.

The investigators do not or will not receive any payment to recruit patients into this study. We hope to provide important information that may contribute to achieving better patient outcomes for AIS patients in the future.

Who can take part in the study?

To be involved in this study, your child must:

1. Have a diagnosis of mild or moderate Adolescent Idiopathic Scoliosis
2. Have no illness or musculoskeletal injury, reported neurological, or balance problems that would restrict exercise.
3. Be able to cooperate, take, and follow instructions in English
4. Have written consent from you as legal guardians if they are under the age of 16 years.
5. Have the ability to attend two, 2-hour physical assessments sessions in the Trinity Centre for Health Sciences, James's Hospital Dublin 8.

Your child cannot take part in this study if:

1. They have a history of a heart condition (such as acute cardiac event, unstable chest pain, irregular heartbeat, and cardiac infection).
2. They have an existing acute or chronic lung condition.
3. They have an existing acute or chronic neurological condition.
4. They have a known blood pressure abnormality (e.g. hypertension/hypotension).
5. They are fitted with an electronic device (e.g. pacemaker).
6. They play sport at elite level.
7. They are pregnant or are a breastfeeding mother.
8. They have been advised by your medical team not to exercise or you have a life threatening illness.
9. They answer "yes" to any one question on the PAR-Q, which would contraindicate exercise testing. This is a standard physical activity readiness questionnaire, which you will complete before exercise testing begins.
10. They have incomplete or dissatisfactory medical screening prior to testing.
11. They are under the age of 12 or over the age of 21.

What does this study involve?

Participants will be invited to attend the Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8, for a physical assessment on 2 occasions. Parents are welcome to attend; a family member will be required to attend if the participant is under the age of 16. The assessment will take approximately 2 hours. Assessments will be scheduled to suit the participant.

What does the assessment involve?

Upon arrival, participants will complete short questionnaires about fitness, exercise, quality of life, function and physical activity. When these are completed, standing height and weight will be measured along with heart rate and resting blood pressure. The amount of fat, water and muscle in your child's body will be estimated using a Tanita body composition analyser (pictured, right) that analyses details of body weight, body mass index (BMI), percentage body fat, muscle mass and fat free mass. This machine is non-invasive and will not cause any pain. You child will be asked to remove your shoes and socks and stand on the body composition analyser.



Cardiorespiratory fitness test: Bike Ergometer

Before exercising, participants will complete a short questionnaire (the Physical Activity Readiness Questionnaire, or PAR-Q). The results of this questionnaire will indicate if they are safe to carry out an exercise test. Participants will be familiarised with how the test will work and shown the equipment to be used in this study: a gas analysis system with a facemask and heart rate monitor (pictured, right).

For this test, participants will be fitted with a heart rate monitor and a gas exchange mask and asked to sit on the cycle ergometer for 3 minutes. Resting measurements taken in this period. The test will follow the Godfrey protocol. Each minute of cycling is harder than the previous one. The participant will keep cycling for as long as they can. Heart rate monitored throughout the test.



You or your child can end the test at any point, if they feel any pain or discomfort, if they feel dizzy, too breathless, or if they feel faint or too fatigued. The researcher will be monitoring for unexpected changes in blood pressure and heart rate, and will end the test if these occur, or if there are any technical difficulties with the equipment used. At the end of the test, there will be a 5-minute cool-down phase, at a slow pace.

Lung function: Lung function tests using a hand-held Micro Plus Spirometer.

We will assess how well the participants lungs work by measuring the volume and effort of breathing using a Micro Plus spirometer (pictured below). This is a non-invasive portable battery-operated hand-held microcomputer unit. An antibacterial filter will be attached for each lung test. A nose clip is used during each test to prevent nasal breathing.



The test will require the participant to stand upright, place their mouth tightly around the mouthpiece and breathe in fully prior to breathing out fully. They will be encouraged to continue forcing air out until your lungs are empty. Any coughing or accidental blocking of the mouthpiece will render that attempt void and will need to be repeated. The test will be repeated until two satisfactory results are achieved. One minute of normal breathing will be allowed between tests to recover normal lung function.

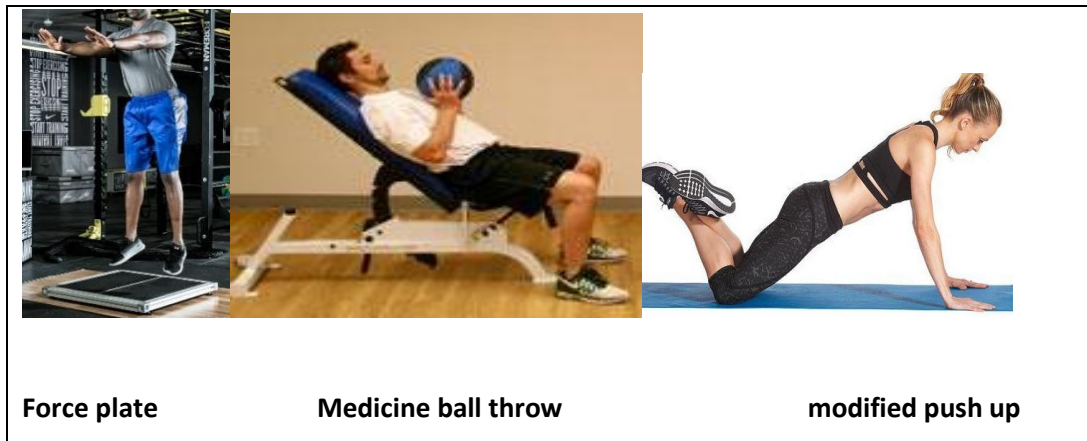
Muscle testing

Musculoskeletal Strength: Upper limb strength will be measured using a Takei digital grip strength dynamometer. Back muscle strength will be measured using a Takei back-D dynamometer. A calibrated Lafayette manual muscle tester will be used to measure lower limb muscle strength (pictured below).



Muscle endurance: Upper limb muscle endurance will be measured using a modified push-up test and lower limb muscle endurance testing will be measured by a wall squat test.

Muscle Power: A digital force plate will measure your lower limb power, and a medicine ball will be used to measure upper limb power.



Balance

A HUR balance platform will assess your balance. The participant will be asked to perform simple balance exercises on the platform (pictured below).



Quality of Life

Quality of life will be assessed using a standardised questionnaire SRS-22r.

Are there any benefits to taking part in this study?

Full analysis of fitness levels and body composition measurements will be provided to each participant on completion of the physical assessments in the form of an individual health report. These reports can be beneficial to understanding your child's fitness levels, their strengths and weaknesses and how they compare to the general population. This information can be used by your clinicians in rehabilitation plans going forward.

Participating in this study may also benefit adolescents with scoliosis. If we find that differences exist between groups that have scoliosis and those that do not, it will allow us to investigate ways these differences can be overcome. Participation in the supervised exercise programme and the home exercise programme may greatly benefit your child's overall health, fitness, and quality of life. If we find individual weaknesses in relation to a participant's muscle strength, endurance, power or balance, lung capacity or cardiovascular fitness this programme may address some of these findings.

Are there any risks involved in taking part in this study?

Risks associated with exercise testing are rare, especially when participants have been cleared for exercise and have no medical history that increases risk during exercise. However, there exists the possibility of pain, abnormal blood pressure, fainting, irregular heart rhythm, and joint or muscle injury or cramp. These events are unlikely, and every effort will be made to minimise any risks by evaluating individual participant's health before testing, and by careful monitoring during and after testing and exercise. If the participant experiences any of the above, the test will be stopped immediately, if symptoms do not subside, they will be seen by a doctor and if necessary, brought to A&E in St. James's Hospital. Your child's doctor will also be informed.

Confidentiality and Data Protection

What data will be collected?

Personal data to be collected in this study will include your child's gender, age, relevant medical history from your child's medical records, body composition, musculoskeletal, lung and aerobic fitness levels and their view on their quality of life. Only personal data, which is relevant for the purpose of this study, will be collected and used (this is called "data minimisation").

Who has access to the collected data?

The lead Investigator will have access to the data. The research team will have access to pseudonymised data for analytical purposes. Both have undergone training in data protection law and practice, prior to starting this research.

How will my child's data be stored and protected?

Your child's identity will remain confidential. All details and results will be coded with a numerical ID to maintain confidentiality (this is called "pseudonymisation"). Data will be coded, rather than being kept completely anonymous, to allow for comparison of results from one testing day to the next. Names and personal details will not be published and will not be disclosed to anyone. All information relating to you in hard-copy form will be stored in a locked filing cabinet within a

secure office only accessible by the lead Investigator and information and records in electronic form will be stored on a password-protected PC at the Trinity Centre for Health Sciences in St James's Hospital. Study information and results will be retained by Trinity College for 7 years in keeping with good research practice standards and data protection legislation. It will be destroyed after this time (electronic data will be erased, and hard copy forms will be shredded).

How will data be used, now and in the future?

The information collected in this study will be grouped together and analysed. Overall findings from this study may be published in international peer reviewed journals and may be shared at research conferences. The results of the study may be used for comparative purposes in other studies of a similar nature. However, participant's data will remain coded and personal identifiers will never be published or disclosed to anyone. Participant's data will only be used for comparative purposes in studies that have Research Ethics Committee approval. The data controllers and researchers in this project are bound by our Professional Code of Conduct to maintain confidentiality regarding all data gained during this research.

Is there any risk with processing and storing personal data? What will happen if there is a data breach?

Considering that sensitive personal data relating to participants health is involved, in the unlikely event of a data breach (i.e. data being mislaid, lost or stolen), you will be notified as soon as possible, and it will be reported immediately to the Data Protection Commissioner. However, data collected will be pseudonymised and the key to your child's identity will be secured separately. There is a low risk of a data breach.

What are your Child's rights under GDPR?

They have the right to:

- Access their data
- Rectify or correct any mistakes with their data
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What is the lawful basis to using a participant's personal data?

Data will be processed under the lawful basis of Article 6(1) (e) and 9(2) (i) of the EU General Data Protection Act 2016. If you have any queries regarding your child's data, or the General Data

Protection Rules (GDPR), you can contact the research team (details at end of document) or the Data Protection Officer of Trinity College Dublin, by email: dataprotection@tcd.ie .

Insurance

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your child's rights.

Voluntary Participation

Participation in this study is voluntary, and you will be asked to sign a consent form, before your child takes part, after you have read this document and have had the study procedures, risks and benefits explained to you. Your child does not have to take part in this study, and you or your child may withdraw participation at any time, even if the study has already started. You do not have to give a reason for not taking part in or for leaving the study.

If you or your child decides not to participate, or if you or your child withdraw participation, your child will not be penalised and will not give up any benefits, which your child had before entering the study. You should not feel in any way obliged to take part in this study. If you do not give consent, or withdraw your consent, no attempt will be made to access your child's data, and **no** application will be made by the research team for a consent exemption to the Health Research Consent Declaration Committee.

If you wish to seek more information about this research study, or if you wish to opt-out, please contact the lead investigator on the details provided below.

Stopping the Study

You understand that the research team may stop your child's participation in the study at any time without your consent.

Permission

The Research Ethics Committee in Beacon Hospital, Sandyford Dublin 18, has approved this research. There is no known personal connection between members of the research team and this ethics committee.

Future Contact

After completion of the study, the researchers may contact you again in relation to your study results, if you express that you would like to receive feedback on them.

How can your child prepare for the assessments?

If you consent for your child to take part in this study, the following points explain how they should prepare for their physical assessments.

- Please fast from midnight on the night before your assessment days. Please limit your liquid intake while fasting you may drink water, but refrain from caffeine drinks, energy drinks, and alcohol. Fasting ensures more accurate results in body composition analysis. A snack and drink will be provided to you after each assessment.
- Please wear clothing and footwear suitable for exercise
- Bring a towel, shower gel, and change of clothes if you wish to shower after testing.
- Please try to drive, arrange a lift or use public transport to get to the testing venue and avoid walking or cycling on the days of your visit. Results of your fitness test will be more accurate. Please refrain from strenuous physical activity for 24-hours prior to each assessment.
- We request that you continue your normal physical activity regime for the duration of the study, and not to increase the training intensity or frequency.

Further information

You can obtain more information or answers to your questions about the study, your child's participation in the study, and you and your child's rights, from **Tony Rafferty, the lead investigator who can be contacted on 0873986551 or emailed at raffertt@tcd.ie**. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

Lead Investigator: Tony Rafferty, Discipline of Physiotherapy, School of Medicine, Trinity College Dublin: Contact: Tel 087 3986551, E-mail raffertt@tcd.ie

Lead Co-Investigator: Patrick Kiely, Consultant Orthopedic Surgeon, Beacon Hospital, Sandyford Dublin 18.

Research Supervisors & Co-Investigators: Dr Sara Dockrell & Dr Neil Fleming: Contact: Tel (01) 8962121, E-mail: sara.dockrell@tcd.ie; neil.fleming@tcd.ie

Data Controller: Trinity College Dublin.

Data Protection Officer: Data Protection, Trinity College Dublin: Contact: E-mail: dataprotection@tcd.ie

Appendix 2.3: Parental information Leaflet – Controls.



Parental Information Leaflet

Study: A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study.

Your child is invited to take part in a clinical research study as part of the control group. The control group consists of healthy adolescents **who do not have a scoliosis**. This will allow us to compare those who have Adolescent Idiopathic Scoliosis (AIS) with those who do not have AIS (controls).

Before you decide whether you wish her/him to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP. Take time to ask questions, do not feel rushed and do not feel under pressure to make a quick decision. You should clearly understand the risks and benefits of your child/adolescent taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

Why is this study being done?

This study will focus on adolescents diagnosed with Adolescent Idiopathic Scoliosis (AIS). There is very little research into musculoskeletal strength, and balance in adolescents diagnosed with AIS. Recent research has indicated that weaknesses may exist. Also, adolescents with severe AIS have a lower lung function and cardiorespiratory capacity (the ability of your heart and lungs to supply

oxygen to your muscles during physical activity) when compared to the general population. This study hopes to add to the knowledge in this area and may provide an approach to address some or all of any weaknesses that are identified.

Aim of current study

The aim of the current study is fourfold:

Study 1. To assess and compare muscle strength, power, and endurance, balance, cardiorespiratory function and quality of life between AIS adolescents who are diagnosed with severe AIS and awaiting surgery with adolescents diagnosed with mild and moderate AIS and similar aged adolescents from the general population who do not have scoliosis.

Study 2. To assess the effects of a 4-month scoliosis specific exercise programme (Schroth), on adolescents diagnosed with mild and moderate AIS on their muscle strength, power, and endurance, balance, cardiorespiratory function and quality of life, when compared to adolescents diagnosed with mild and moderate AIS who have received standard care and adolescents who do not have AIS.

Study 3. To examine the effect of spinal fusion surgery on musculoskeletal, cardiorespiratory and pulmonary function and quality of life by re-assessing severe AIS participants 3 months after surgery.

Study 4. To examine the effects of a targeted 12-week physiotherapy led exercise programme incorporating a 12-week home exercise programme on adolescents who have undergone spinal fusion surgery.

If you would like your child to take part in this study, please take time to read this document carefully.

Who is doing the research?

The lead investigator is Tony Rafferty a CORU registered Chartered Physiotherapist with specialist training in sports and exercise medicine and a Strength and Conditioning specialist in Trinity College Dublin. The Co-lead investigator is Mr Pat Kiely Consultant Orthopaedic surgeon in Beacon Hospital, Sandyford Dublin 18. This study is a multi-site study and will include participants from Children's Health Ireland, Beacon Hospital and Blackrock Clinic.

The investigators do not or will not receive any payment to recruit patients into this study. We hope to provide important information that may contribute to achieving better patient outcomes for AIS patients in the future.

Who can take part in the study?

To be involved in this study, your child must:

1. Be 12 - 21 years of age.
2. Not have a diagnosis of Adolescent Idiopathic Scoliosis
3. Have no illness or musculoskeletal injury, reported neurological, or balance problems that would restrict exercise.
4. Be able to cooperate, take, and follow instructions in English
5. Have written consent from you as legal guardians if they are under the age of 16 years.
6. Have the ability to attend a 2-hour physical assessment in the Trinity Centre for Health Sciences, James's Hospital Dublin 8.

Your child cannot take part in this study if:

1. They have, or a history of, a heart condition (such as acute cardiac event, unstable chest pain, irregular heartbeat, and cardiac infection)
2. They have an existing acute or chronic lung condition.
3. They have an existing acute or chronic neurological condition.
4. They have a known blood pressure abnormality (e.g. hypertension/hypotension).
5. They are fitted with an electronic device (e.g. pacemaker).
6. They play sport at elite level.
7. They are pregnant or are a breastfeeding mother.
8. They have been advised by your medical team not to exercise, or you have a life threatening illness.
9. They answer "yes" to any one question on the PAR-Q, which would contraindicate exercise testing. This is a standard physical activity readiness questionnaire, which you will complete before exercise testing begins.
10. They have incomplete or dissatisfactory medical screening prior to testing.
11. They are under the age of 12 or over the age of 21.

What does this study involve?

The following section sets out what is involved in the physical assessment. Participants will be invited to attend the Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8, for a physical assessment. Parents are welcome to attend; a family member will be required to attend

if the participant is under the age of 16. The assessment will take approximately 2 hours. The assessment will be arranged to suit you and your child.

What does the assessment involve?

Upon arrival, participants will complete short questionnaires about fitness, exercise, quality of life, function and physical activity. When these are completed, standing height and weight will be measured along with heart rate and resting blood pressure. The amount of fat, water and muscle in your child's body will be estimated using a Tanita body composition analyser (pictured, right) that analyses details of body weight, body mass index (BMI), percentage body fat, muscle mass and fat free mass. This machine is non-invasive and will not cause any pain. You child will be asked to remove your shoes and socks and stand on the body composition analyser.



Cardiorespiratory fitness test: Bike Ergometer

Before exercising, participants will complete a short questionnaire (the Physical Activity Readiness Questionnaire, or PAR-Q). The results of this questionnaire will indicate if they are safe to carry out an exercise test. Participants will be familiarised with how the test will work and shown the equipment to be used in this study: a gas analysis system with a facemask and heart rate monitor (pictured, right).

For this test, participants will be fitted with a heart rate monitor and a gas exchange mask and asked to sit on the cycle ergometer for 3 minutes. Resting measurements taken in this period. The test will follow the Godfrey protocol. Each minute of cycling is harder than the previous one. The participant will keep cycling for as long as they can. Heart rate monitored throughout the test.



You or your child can end the test at any point, if they feel any pain or discomfort, if they feel dizzy, too breathless, or if they feel faint or too fatigued. The researcher will be monitoring for unexpected changes in blood pressure and heart rate, and will end the test if these occur, or if there are any technical difficulties with the equipment used. At the end of the test, there will be a 5-minute cool-down phase, at a slow pace.

Lung function: Lung function tests using a hand-held Micro Plus Spirometer.

We will assess how well the participants lungs work by measuring the volume and effort of breathing using a Micro Plus spirometer (pictured below). This is a non-invasive portable battery-operated hand-held microcomputer unit. An antibacterial filter will be attached for each lung test. A nose clip is used during each test to prevent nasal breathing.



The test will require the participant to stand upright, place their mouth tightly around the mouthpiece and breathe in fully prior to breathing out fully. They will be encouraged to continue forcing air out until your lungs are empty. Any coughing or accidental blocking of the mouthpiece will render that attempt void and will need to be repeated. The test will be repeated until two satisfactory results are achieved. One minute of normal breathing will be allowed between tests to recover normal lung function.

Muscle testing

Musculoskeletal Strength: Upper limb strength will be measured using a Takei digital grip strength dynamometer. Back muscle strength will be measured using a Takei back-D dynamometer. A calibrated Lafayette manual muscle tester will be used to measure lower limb muscle strength (pictured below).



Takei digital grip



Takei back-D dynamometer



Lafayette manual tester

Muscle Endurance: Upper limb muscle endurance will be measured using a modified push-up test and lower limb muscle endurance testing will be measured using a wall squat test.

Muscle Power: A digital force plate will measure your lower limb power, and a medicine ball will be used to measure upper limb power.



Balance

A HUR balance platform will assess your balance. The participant will be asked to perform simple balance exercises on the platform (pictured below).



Quality of Life

Quality of life will be assessed using a standardised questionnaire SRS-22r.

Are there any benefits to taking part in this study?

Full analysis of fitness levels and body composition measurements will be available to each participant on completion of the physical assessment in the form of an individual health report. These reports can be beneficial to the understanding of your child's fitness levels, strengths and weaknesses and how they compare to the fitness levels of the general population. The information can be used to guide progression of your own exercise regime.

Participating in this study may also benefit adolescents with scoliosis. If we find that differences exist between groups that have scoliosis and those that do not, it will allow us to investigate ways these differences can be addressed.

Are there any risks involved in taking part in this study?

Risks associated with exercise testing are rare, especially when participants have been cleared for exercise and have no medical history that increases risk during exercise. However, there exists the possibility of pain, abnormal blood pressure, fainting, irregular heart rhythm, and joint or muscle injury or cramp. These events are unlikely, and every effort will be made to minimise any risks by evaluating individual participant's health before testing, and by careful monitoring during and after testing and exercise. If the participant experiences any of the above, the test will be stopped immediately, if symptoms do not subside, they will be seen by a doctor and if necessary, brought to A&E in St. James's Hospital. Your child's doctor will also be informed.

Confidentiality and Data Protection

What data will be collected?

Personal data to be collected in this study will include your child's gender, age, relevant medical history, body composition, musculoskeletal, lung and aerobic fitness levels and your view on the quality of your life. Only personal data, which is relevant for the purpose of this study, will be collected and used (this is called "data minimisation").

Who has access to the collected data?

The Lead Investigator will have access to the data. The research team will have access to pseudonymised data for analytical purposes. Both have undergone training in data protection law and practice, prior to starting this research.

How will my child's data be stored and protected?

Your child's identity will remain confidential. All details and results will be coded with a numerical ID to maintain confidentiality (this is called "pseudonymisation"). Data will be coded, rather than being kept completely anonymous, to allow for comparison of results from one testing day to the next. Names and personal details will not be published and will not be disclosed to anyone. All information relating to you in hard-copy form will be stored in a locked filing cabinet within a secure office only accessible by the Lead Investigator and information and records in electronic form will be stored on a password-protected PC at the Trinity Centre for Health Sciences in James Hospital. Study information and results will be retained by Trinity College for 5 years in keeping with good research practice standards and data protection legislation. It will be destroyed after this time (electronic data will be erased, and hard copy forms will be shredded).

How will data be used, now and in the future?

The information collected in this study will be grouped together and analysed. Overall findings from this study may be published in international peer reviewed journals and may be shared at research conferences. The results of the study may be used for comparative purposes in other studies of a similar nature. However, participant's data will remain coded and personal identifiers will never be published or disclosed to anyone. Participant's data will only be used for comparative purposes in studies that have Research Ethics Committee approval. The data controllers and researchers in this project are bound by our Professional Code of Conduct to maintain confidentiality regarding all data gained during this research.

Is there any risk with processing and storing personal data? What will happen if there is a data breach?

Considering that sensitive personal data relating to participants health is involved, in the unlikely event of a data breach (i.e. data being mislaid, lost or stolen), you will be notified as soon as possible, and it will be reported immediately to the Data Protection Commissioner. However, data collected will be pseudonymised and the key to your child's identity will be secured separately. There is a low risk of a data breach.

What are your Childs rights under GDPR?

They have the right to:

- Access their data
- Rectify or correct any mistakes with their data
- Have their data erased or deleted
- Data portability (moving data from one controller to another)

- Object to or stop the processing or profiling of your data
- Lodge a complaint to the Data Protection Commissioner (contact: +353 57 8684800 or +353 (0)761 104 800; <https://dataprotection.ie/en/contact>).

What is the lawful basis to using a participant's personal data?

Data will be processed under the lawful basis of Article 6(1) (e) and 9(2) (i) of the EU General Data Protection Act 2016. If you have any queries regarding your child's data, or the General Data Protection Rules (GDPR), you can contact the research team (details at end of document) or the Data Protection Officer of Trinity College Dublin, by email: dataprotection@tcd.ie.

Insurance

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your child's rights.

Voluntary Participation

Participation in this study is voluntary, before your child takes part, you will be asked to sign a consent form after you have read this document and have had the study procedures, risks and benefits explained to you. Your child does not have to take part in this study, and you or your child may withdraw participation at any time, even if the study has already started. You do not have to give a reason for not taking part in or for leaving the study.

If you or your child decide not to participate, or if you or your child withdraw participation, your child will not be penalised, and they will not give up any benefits which your child had before entering the study. You should not feel in any way obliged to take part in this study. If you do not give consent, or withdraw your consent, no attempt will be made to access your child's data, and **no** application will be made by the research team for a consent exemption to the Health Research Consent Declaration Committee.

If you wish to seek more information about this research study, or if you wish to opt-out, please contact the lead investigator on the details provided below.

Stopping the Study

You understand that the research team may stop your child's participation in the study at any time without your consent.

Permission

The Research Ethics Committee of Beacon Hospital, Sandyford Dublin 18, has approved this research. There is no known personal connection between members of the research team and this ethics committee.

Future Contact

After completion of the study, the researchers may contact you again in relation to your study results, if you express that you would like to receive feedback on them.

How can your child prepare for the assessments?

If you consent for your child to take part in this study, the following points explain how they should prepare for their physical assessments.

- Please fast from midnight on the night before your assessment days. Please limit your liquid intake while fasting you may drink water, but refrain from caffeine drinks, energy drinks, and alcohol. Fasting ensures more accurate results in body composition analysis. A snack and drink will be provided to you after each assessment.
- Please wear clothing and footwear suitable for exercise
- Bring a towel, shower gel, and change of clothes if you wish to shower after testing.
- Please try to drive, arrange a lift or use public transport to get to the testing venue and avoid walking or cycling on the days of your visit. Results of your fitness test will be more accurate. Please refrain from strenuous physical activity for 24-hours prior to each assessment.
- We request that you continue your normal physical activity regime for the duration of the study, and not to increase the training intensity or frequency.

Further information

You can obtain more information or answers to your questions about the study, your child's participation in the study, and you and your child's rights, from **Tony Rafferty, the lead investigator who can be contacted on 0873986551 or emailed at raffertt@tcd.ie**. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

Lead Investigator: Tony Rafferty, Discipline of Physiotherapy, School of Medicine, Trinity College Dublin: Contact: Tel 087 3986551, E-mail raffertt@tcd.ie

Lead Co-Investigator: Patrick Kiely, Consultant Orthopaedic Surgeon, Beacon Hospital, Sandyford Dublin 18.

Research Supervisors & Co-Investigators: Dr Sara Dockrell & Dr Neil Fleming. Contact: Tel (01) 8962121, E-mail: sara.dockrell@tcd.ie; neil.fleming@tcd.ie

Data Controller: Trinity College Dublin. **Data Protection Officer:** Data Protection, Trinity College Dublin. Contact: E-mail: dataprotection@tcd.ie

Appendix 2.4: Participant Information leaflet –Severe surgical AIS age 16+.



Participant Information Leaflet

A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study.

Introduction

This study will focus on adolescents diagnosed with Adolescent Idiopathic Scoliosis (AIS). There is very little research into musculoskeletal strength, power and endurance in adolescents diagnosed with AIS. Recent research has indicated that weaknesses may exist. Previous studies have also indicated that adolescents with severe AIS have a lower lung function. Some studies indicate that adolescents with AIS have a lower cardiorespiratory capacity (the ability of your heart and lungs to supply oxygen to your muscles during physical activity). This study hopes to add to the knowledge in this area and may provide an approach to address some or all of the issues identified over the course of the project.

Aim of current study

The aims of the current study are fourfold: adolescents diagnosed with severe AIS will be included in studies 1, 3 and 4 below.

Study 1. To assess and compare muscle strength, power, and endurance, balance, cardiorespiratory function and quality of life between three groups. AIS adolescents who are diagnosed with severe AIS and awaiting surgery, adolescents diagnosed with mild and moderate AIS and, similar aged adolescents from the general population who do not have scoliosis.

Study 2. To assess the effects of a 4-month scoliosis specific exercise programme (Schroth), on adolescents diagnosed with mild and moderate AIS on their muscle strength, power, and endurance, balance, cardiorespiratory function and quality of life, when compared to adolescents diagnosed with mild and moderate AIS who have received standard care and adolescents who do not have AIS.

Study 3. To examine the effect of spinal fusion surgery on musculoskeletal, cardiorespiratory and pulmonary function and quality of life by re-assessing severe AIS participants 3 months after surgery.

Study 4. To examine the effects of a 12-week physiotherapy led exercise programme incorporating a 12-week home exercise programme on adolescents who have undergone spinal fusion surgery.

The studies above will inform us if adolescents with severe AIS have any musculoskeletal or cardiorespiratory weaknesses and whether an individualised physiotherapy led exercise programme can address any weakness identified.

We will be recruiting adolescents diagnosed with AIS who have consented to surgery and are listed for spinal fusion. If you would like to take part in this study, please take time to read this document carefully. You should understand the risks and benefits of taking part in the study, so that you can make a decision that is right for you. This is known as “Informed Consent”.

Who is doing the research?

The lead investigator is Tony Rafferty a CORU registered Chartered Physiotherapist with specialist training in sports and exercise medicine and a Strength and Conditioning specialist in Trinity College Dublin. The Co-lead investigator is Mr Pat Kiely Consultant Orthopaedic surgeon in Beacon Hospital, Sandyford Dublin 18. This study is a multi-site study and will include participants from Children’s Health Ireland, Beacon Hospital and Blackrock Clinic.

The investigators do not or will not receive any payment to recruit patients into this study. We hope to provide important information that may contribute to achieving better patient outcomes for AIS patients in the future.

Who can take part in the study?

To be involved in this study, you must:

1. Be 12 - 21 years of age.
2. Have a diagnosis of severe Adolescent Idiopathic Scoliosis
3. Be approved for spinal fusion surgery within the next 3 months.
4. Have no illness or musculoskeletal injury, reported neurological, or balance problems that would restrict exercise.
5. Be able to cooperate, take, and follow instructions in English
6. Have written consent from your parents or legal guardians if you are under the age of 16 years.
7. Have the ability to attend three, 2-hour physical assessments, in the Trinity Centre for Health Sciences, St. James's Hospital, Dublin.
8. Be willing and able to attend a targeted physiotherapy led rehabilitation session every 2-weeks for a period of 12 weeks.
9. Agree to take part in a home exercise run in conjunction with the supervised rehabilitation programme.

You cannot take part in this study if:

1. You have a history of a heart condition (such as acute cardiac event, unstable chest pain, irregular heartbeat, and cardiac infection).
2. You have an existing acute or chronic lung condition.
3. You have an existing acute or chronic neurological condition.
4. You have a known blood pressure abnormality (e.g. hypertension/hypotension).
5. You are fitted with an electronic device (e.g. pacemaker).
6. You play sport at elite level.
7. You are pregnant or are a breastfeeding mother.
8. You have been advised by your medical team not to exercise, or you have a life threatening illness.
9. You answer "yes" to any one question on the PAR-Q, which would contraindicate exercise testing. This is a standard physical activity readiness questionnaire, which you will complete before exercise testing begins.
10. You have incomplete or dissatisfactory medical screening prior to testing.
11. You are under the age of 12 or over the age of 21

What does this study involve?

The study involves attending Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8, on 3 occasions for physical assessments over the course of the programme and taking part in a targeted physiotherapy-led exercise programme and a home exercise programme.

All participants will be invited to attend the Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8 for an initial assessment. Parents are welcome to attend; a family member will be required to attend if the participant is under the age of 16. Participants will be assessed again, three months after surgery; and again, at the end of rehabilitation programme (12-weeks). Each assessment will take approximately 2 hours. Assessments will be scheduled to suit the participant.

What does the assessment involve?

Upon arrival, participants will complete short questionnaires about fitness, exercise, quality of life, function and physical activity. When these are completed, your standing height and weight will be measured along with your heart rate and resting blood pressure. The amount of fat, water and muscle in your body will be estimated using a Tanita body composition analyser (pictured, right) that analyses details of body weight, body mass index (BMI), percentage body fat, muscle mass and fat free mass. This machine is non-invasive and pain-free. You will be asked to remove your shoes and socks and stand on the body composition analyser.



Cardiorespiratory fitness test: Bike Ergometer

Before exercising, participants will complete a short questionnaire (the Physical Activity Readiness Questionnaire, or PAR-Q). The results of this questionnaire will indicate if they are safe to carry out an exercise test. Participants will be familiarised with how the test will work and shown the equipment to be used in this study: a gas analysis system with a facemask and heart rate monitor (pictured, right).

For this test, participants will be fitted with a heart rate monitor and a gas exchange mask and asked to sit on the cycle ergometer for 3 minutes. Resting measurements taken in this period. The test will follow the Godfrey protocol. Each minute of cycling is harder than the previous one. The participant will keep cycling for as long as they can. Heart rate monitored throughout the test.



You can end the test at any point, if you feel any pain or discomfort, if you feel dizzy, too breathless, or if you feel faint or too fatigued. The researcher will be monitoring for unexpected changes in blood pressure and heart rate, and will end the test if these occur, or if there are any technical difficulties with the equipment used. At the end of the test, there will be a 5-minute cool-down phase, at a slow pace.

Lung function: Lung function tests using a hand-held Micro Plus Spirometer.

We will assess how well your lungs work by measuring the volume and effort of breathing using a Micro Plus spirometer (pictured below). This is a non-invasive portable battery-operated hand-held microcomputer unit. An antibacterial filter will be attached for each lung test. A nose clip is used during each test to prevent breathing through your nose.



The test will require you to stand upright, place your mouth tightly around the mouthpiece and breathe in fully prior to breathing out fully. You will be encouraged to continue forcing air out until your lungs are empty. Any coughing or accidental blocking of the mouthpiece will render that attempt void and will need to be repeated. The test will be repeated until two satisfactory results are achieved. One minute of normal breathing will be allowed between tests for you to recover normal lung function.

Muscle testing

Musculoskeletal Strength: Upper limb strength will be measured using a Takei digital grip strength dynamometer. Back muscle strength will be measured using a Takei back-D dynamometer. A calibrated Lafayette manual muscle tester will be used to measure lower limb muscle strength (pictured below).



Takei digital grip



Takei back-D dynamometer



Lafayette manual tester

Muscle Endurance: Upper limb muscle endurance will be measured using a modified push-up test and lower limb muscle endurance testing will be measured using a wall squat test.

Muscle Power: A digital force plate will measure your lower limb power, and a medicine ball will be used to measure upper limb power.



Force plate



Medicine ball throw



modified push up

Balance

A HUR balance platform will assess your balance. You will be asked to perform simple balance exercises on the platform (pictured below).



Quality of Life

Quality of life will be assessed using a standardised questionnaire SRS-22r.

What does the targeted exercise rehabilitation programme involve?

A Chartered Physiotherapist will supervise the bi-weekly exercise programme over 12 weeks. The physiotherapist will be provided with a specific rehabilitation programme for each participant based on the results of the physical assessments. The proposed programme will be based on calisthenics, designed using individual body weight; no free weights or weight machines will be used. Each session will include a warmup and warm down period. All exercises will be demonstrated to the participant prior to commencement. The physiotherapist will also provide assistance/ modification of exercises to any participant who has difficulty executing the technique. Exercises will be set in a circuit and will include a variety and combination of exercises targeting each individual participant's needs. Exercises will be varied to reduce post exercise stiffness. All exercises selected will be appropriate to the age group and levels of muscular and aerobic fitness. The in-person session will be private and last approximately 45 minutes.

The 12-week home exercise programme will be a non-supervised, participant specific, rehabilitation programme, remotely monitored on a weekly basis via zoom call and pre-agreed

with each participant. Each participant will maintain an electronic rehabilitation log of physical activity. With agreed access by the lead investigator, weekly maintenance of the rehabilitation log is expected.

Are there any benefits to taking part in this study?

Full analysis of fitness levels and body composition measurements will be provided to each participant on completion of the physical assessments in the form of an individual health report. These reports can be beneficial to understanding your own fitness level, your strengths and weaknesses and how you compare to the general population. This information can be used to guide your own exercise plans going forward.

Participating in this study may also benefit adolescents with scoliosis. If we find that differences exist between groups that have scoliosis and those that do not, it will allow us to investigate ways these differences can be overcome. Participation in the supervised exercise programme and the home exercise programme may greatly benefit your overall health, fitness, and quality of life. If we find you have individual weaknesses in relation to your muscle strength, endurance, power or balance, your lung capacity or cardiovascular fitness this programme may address some of these findings.

Are there any risks involved in taking part in this study?

Risks associated with exercise testing are rare, especially when you have been cleared for exercise and have no medical history that increases your risk during exercise. However, there exists the possibility of pain, abnormal blood pressure, fainting, irregular heart rhythm, and joint or muscle injury or cramp. These events are unlikely and every effort will be made to minimise any risks by evaluating individual participant's health before testing, and by careful monitoring during and after testing and exercise. If you experience any of the above, the test will be stopped immediately, if symptoms do not subside, you will be seen by a doctor and if necessary, brought to A&E in St. James's Hospital. Your doctor will also be informed.

Do I need my parents' consent to take part in this study?

If you are under the age of 16, you will need your parent's written informed consent to participate in this study.

Confidentiality and Data Protection

What data will be collected?

Personal data to be collected in this study will include your gender, age, relevant medical history from your medical records, body composition, musculoskeletal, lung and aerobic fitness levels and your view on the quality of your life. Only personal data, which is relevant for the purpose of this study, will be collected and used (this is called “data minimisation”).

Who has access to the collected data?

The Lead Investigator will have access to the data. The research team will have access to pseudonymised data for analytical purposes. Both have undergone training in data protection law and practice, prior to starting this research.

How will my data be stored and protected?

Your identity will remain confidential. All of your details and results will be coded with a numerical ID to maintain your confidentiality (this is called “pseudonymisation”). Your data will be coded, rather than being kept completely anonymous, to allow for comparison of your results from one testing day to the next. Your name and personal details will not be published and will not be disclosed to anyone. All information relating to you in hard-copy form will be stored in a locked filing cabinet within a secure office only accessible by the Lead Investigator and information and records in electronic form will be stored on a password-protected PC at the Trinity Centre for Health Sciences in St. James’s Hospital. Your study information and results will be retained Trinity College for 5 years in keeping with good research practice standards and data protection legislation. It will be destroyed after this time (electronic data will be erased, and hard copy forms will be shredded).

How will my data be used, now and in the future?

The information collected in this study will be grouped together and analysed. Overall findings from this study may be published in international peer reviewed journals and may be shared at research conferences. The results of the study may be used for comparative purposes in other studies of a similar nature. However, your data will remain coded, and your personal identifiers will never be published or disclosed to anyone. Your data will only be used for comparative purposes in studies that have Research Ethics Committee approval. Your rights under GDPR and what will happen in the event of a data breach will apply for use of your data in future studies.

The data controllers and researchers in this project are bound by our Professional Code of Conduct to maintain confidentiality regarding all data gained during this research.

Is there any risk with processing and storing my data? What will happen if there is a data breach?

Considering that sensitive personal data relating to your health is involved, in the unlikely event of a data breach (i.e. data being mislaid, lost or stolen), you will be notified as soon as possible, and it will be reported immediately to the Data Protection Commissioner. However, your data will be collected as pseudonymised data and the key to your identity will be secured separately. There is a low risk of a data breach.

What are my rights under GDPR?

You have the right to:

- Access your data
- Rectify or correct any mistakes with your data
- Have your data erased or deleted
- Data portability (moving your data from one controller to another)
- Object to or stop the processing or profiling of your data
- Lodge a complaint to the Data Protection Commissioner (contact: +353 57 8684800 or +353 (0)761 104 800; <https://dataprotection.ie/en/contact>).

What is the lawful basis to using my personal data?

Your data will be processed under the lawful basis of Article 6(1) (e) and 9(2) (i) of the EU General Data Protection Act 2016. If you have any queries regarding your data, or the General Data Protection Rules (GDPR), you can contact the research team (details at end of document) or the Data Protection Officer of Trinity College Dublin, by email: dataprotection@tcd.ie .

Insurance

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation

Participation in this study is voluntary, and you will be asked to sign a consent form before taking part, after you have read this document and have had the study procedures, risks and benefits explained to you. You do not have to take part in this study, and you may withdraw participation

at any time, even if the study has already started. You do not have to give a reason for not taking part in or for leaving the study.

If you decide not to participate, or if you withdraw participation, you will not be penalised and will not give up any benefits, which you had before entering the study. You should not feel in any way obliged to take part in this study. If you do not give consent, or withdraw your consent, no attempt will be made to access your data, and **no** application will be made by the research team for a consent exemption to the Health Research Consent Declaration Committee.

If you wish to seek more information about this research study, or if you wish to opt-out, please contact the lead investigator on the details provided below.

Stopping the Study

You understand that the research team may stop your participation in the study at any time without your consent.

Permission

The Research Ethics Committee in Beacon Hospital, Sandyford Dublin 18, has approved this research. There is no known personal connection between members of the research team and this ethics committee.

Future Contact

After completion of the study, the researchers may contact you again in relation to your study results, if you express that you would like to receive feedback on them.

How can I prepare for the assessments?

If you consent to taking part in this study, the following points explain how to prepare for your testing day.

- Please fast from midnight on the night before your assessment days. Please limit your liquid intake while fasting you may drink water, but refrain from caffeine drinks, energy drinks, and alcohol. Fasting ensures more accurate results in body composition analysis. A snack and drink will be provided to you after each assessment.
- Please wear clothing and footwear suitable for exercise
- Bring a towel, shower gel, and change of clothes if you wish to shower after testing.
- Please try to drive, arrange a lift or use public transport to get to the testing venue and avoid walking or cycling on the days of your visit. Results of your fitness test will be more

accurate. Please refrain from strenuous physical activity for 24-hours prior to each assessment.

- We request that you continue your normal physical activity regime for the duration of the study, and not to increase the training intensity or frequency.

Further information

You can obtain more information or answers to your questions about the study, your participation in the study, and your rights, from **Tony Rafferty, the lead investigator who can be contacted on 0873986551 or emailed at raffertt@tcd.ie.** If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

Lead Investigator: Tony Rafferty, Discipline of Physiotherapy, School of Medicine, Trinity College Dublin: Contact: Tel 087 3986551, E-mail raffertt@tcd.ie

Lead Co-Investigator: Patrick Kiely, Consultant Orthopaedic Surgeon, Beacon Hospital, Sandyford Dublin 18.

Research Supervisors & Co Investigators: Dr Sara Dockrell & Dr Neil Fleming: Contact: Tel (01) 8962121, E-mail: sara.dockrell@tcd.ie; neil.fleming@tcd.ie

Data Controller: Trinity College Dublin.

Data Protection Officer: Data Protection, Trinity College Dublin

Contact: E-mail: dataprotection@tcd.ie

Appendix 2.5: Participant Information leaflet –Mild and Moderate AIS age 16+.



Participant Information Leaflet

A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study.

Introduction

This study will focus on adolescents diagnosed with Adolescent Idiopathic Scoliosis (AIS). There is very little research into musculoskeletal strength, power and endurance in adolescents diagnosed with AIS. Recent research has indicated that weaknesses may exist. Previous studies have also indicated that adolescents with severe AIS have a lower lung function. Some studies indicate that adolescents with AIS have a lower cardiorespiratory capacity (The ability of your heart and lungs to supply oxygen to your muscles during physical activity). This study hopes to add to the knowledge in this area and may provide an approach to address some or all of any issues identified over the course of the project. This study will also inform us if adolescents with AIS have any musculoskeletal or cardiorespiratory weaknesses and whether a physiotherapy led exercise programme can address any weakness identified.

Aims of current study

The aims of the current study are fourfold: Individuals diagnosed with mild and moderate scoliosis will be needed for studies 1 & 2 below.

Study 1. To assess and compare muscle strength, power, and endurance, balance, cardiorespiratory function and quality of life between AIS adolescents who are diagnosed with severe AIS and awaiting surgery with adolescents diagnosed with mild and moderate AIS and similar aged adolescents from the general population who do not have scoliosis.

Study 2. To assess the effects of a 4- month scoliosis specific exercise programme (Schroth), on adolescents diagnosed with mild and moderate AIS. We will test muscle strength, power, and endurance, balance, cardiorespiratory function and quality of life and compare the results to adolescents diagnosed with mild and moderate AIS who have received standard health care and adolescents who do not have AIS.

Study 3. To examine the effect of spinal fusion surgery on musculoskeletal, cardiorespiratory and pulmonary function and quality of life by re-assessing severe AIS participants 3 months after surgery.

Study 4. To examine the effects of a targeted 12-week physiotherapy led exercise programme and a 12-week home exercise programme on adolescents who have undergone spinal fusion surgery.

We will be recruiting adolescents who have been diagnosed with mild or moderate AIS. Please take time to read this document carefully. You should understand the risks and benefits of taking part in the study, so that you can make a decision that is right for you. This is known as “Informed Consent”.

Who is doing the research?

The lead investigator is Tony Rafferty a CORU registered Chartered Physiotherapist with specialist training in sports and exercise medicine and a Strength and Conditioning specialist in Trinity College Dublin. The Co-lead investigator is Mr Pat Kiely Consultant Orthopaedic surgeon in Beacon Hospital, Sandyford Dublin 18. This study is a multi-site study and will include participants from Children’s Health Ireland, Beacon Hospital and Blackrock Clinic.

The investigators do not or will not receive any payment to recruit patients into this study. We hope to provide important information that may contribute to achieving better patient outcomes for AIS patients in the future.

Who can take part in the study?

To be involved in this study, you must:

1. Be 12 - 21 years of age.
2. Have a diagnosis of mild or moderate Adolescent Idiopathic Scoliosis
3. Have no illness or musculoskeletal injury, reported neurological, or balance problems that would restrict exercise.
4. Be able to cooperate, take, and follow instructions in English
5. Have written consent from your parents or legal guardians if you are under the age of 16 years.
6. Have the ability to attend two, 2-hour physical assessments in the Trinity Centre for Health Sciences, James's Hospital Dublin 8.

You cannot take part in this study if:

1. You have a history of a heart condition (such as acute cardiac event, unstable chest pain, irregular heartbeat, and cardiac infection).
2. You have an existing acute or chronic lung condition.
3. You have an existing acute or chronic neurological condition.
4. You have a known blood pressure abnormality (e.g. hypertension/hypotension).
5. You are fitted with an electronic device (e.g. pacemaker).
6. You play sport at elite level.
7. You are pregnant or are a breastfeeding mother.
8. You have been advised by your medical team not to exercise or you have a life threatening illness.
9. You answer "yes" to any one question on the PAR-Q, which would contraindicate exercise testing. This is a standard physical activity readiness questionnaire, which you will complete before exercise testing begins.
10. You have incomplete or dissatisfactory medical screening prior to testing.
11. You are under the age of 12 or over the age of 21.

What does this study involve?

Participants will be invited to attend the Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8, for a physical assessment on 2 occasions. Parents are welcome to attend; a family

member will be required to attend if the participant is under the age of 16. The assessment will take approximately 2 hours. Assessments will be scheduled to suit the participant.

What does the assessment involve?

Upon arrival, you will complete short questionnaires about fitness, exercise, quality of life, function and physical activity. When these are completed, your standing height and weight will be measured along with your heart rate and resting blood pressure. The amount of fat, water and muscle in your body will be estimated using a Tanita body composition analyser (pictured, right) that analyses details of body weight, body mass index (BMI), percentage body fat, muscle mass and fat free mass. This machine is non-invasive and will not cause you any pain. You will be asked to remove your shoes and socks and stand on the body composition analyser.



Cardiorespiratory fitness test: Bike Ergometer

Before exercising, participants will complete a short questionnaire (the Physical Activity Readiness Questionnaire, or PAR-Q). The results of this questionnaire will indicate if they are safe to carry out an exercise test. Participants will be familiarised with how the test will work and shown the equipment to be used in this study: a gas analysis system with a facemask and heart rate monitor (pictured, right).

For this test, participants will be fitted with a heart rate monitor and a gas exchange mask and asked to sit on the cycle ergometer for 3 minutes. Resting measurements taken in this period. The test will follow the Godfrey protocol. Each minute of cycling is harder than the previous one. The participant will keep cycling for as long as they can. Heart rate monitored throughout the test.

You can end the test at any point, if you feel any pain or discomfort, if you feel dizzy, too breathless, or if you feel faint or too fatigued. The researcher will be monitoring for unexpected changes in blood pressure and heart rate, and will end the test if these occur, or if there are any technical difficulties with the equipment used. At the end of the test, there will be a 5-minute cool-down phase, at a slow pace.



Lung function: Lung function tests using a hand-held Micro Plus Spirometer.

We will assess how well your lungs work by measuring the volume and effort of breathing using a Micro Plus spirometer (pictured below). This is a non-invasive portable battery-operated hand-held microcomputer unit. An antibacterial filter will be attached for each lung test. A nose clip is used during each test to prevent nasal breathing.



The test will require you to stand upright, place your mouth tightly around the mouthpiece and breathe in fully prior to breathing out fully. You will be encouraged to continue forcing air out until your lungs are empty. Any coughing or accidental blocking of the mouthpiece will render that attempt void and will need to be repeated. The test will be repeated until two satisfactory results are achieved. One minute of normal breathing will be allowed between tests for you to recover normal lung function.

Muscle testing

Musculoskeletal Strength: Upper limb strength will be measured using a Takei digital grip strength dynamometer. Back muscle strength will be measured using a Takei back-D dynamometer. A calibrated Lafayette manual muscle tester will be used to measure lower limb muscle strength (pictured below).



Takei digital grip



Takei back-D dynamometer



Lafayette manual tester

Muscle endurance: Upper limb muscle endurance will be measured using a modified push-up test and lower limb muscle endurance testing will be measured by a wall squat test.

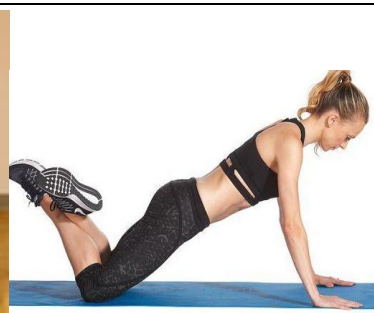
Muscle Power: A digital force plate will measure your lower limb power, and a medicine ball will be used to measure upper limb power.



Force plate



Medicine ball throw



modified push up

Balance

A HUR balance platform will assess your balance. You will be asked to perform simple balance exercises on the platform (pictured below).



Quality of Life

Quality of life will be assessed using a standardised questionnaire SRS22r.

Are there any benefits to taking part in this study?

Full analysis of fitness levels and body composition measurements will be provided to each participant on completion of the physical assessment in the form of a individual health report. These reports can be beneficial to understanding your own fitness level your strengths and weaknesses and how you compare to the general population. This information can be used to guide your own exercise plans going forward.

Participating in this study may also benefit adolescents with scoliosis. If we find that differences exist between groups that have scoliosis and those that do not, it will allow us to investigate ways these differences can be overcome.

Are there any risks involved in taking part in this study?

Risks associated with exercise testing are rare, especially when you have been cleared for exercise and have no medical history that increases your risk during exercise. However, there exists the possibility of pain, abnormal blood pressure, fainting, irregular heart rhythm, and joint or muscle injury or cramp. These events are unlikely, and every effort will be made to minimise any risks by evaluating individual participant's health before testing, and by careful monitoring during and after testing and exercise. If you experience any of the above, the test will be stopped

immediately, if symptoms do not subside, you will be seen by a doctor and if necessary, brought to A&E in St. James's Hospital. Your doctor will also be informed.

Do I need my parents' consent to take part in this study?

If you are under the age of 16, you will need your parent's written informed consent to participate in this study.

Confidentiality and Data Protection

What data will be collected?

Personal data to be collected in this study will include your gender, age, relevant medical history from your medical records, body composition, musculoskeletal, lung and aerobic fitness levels and your view on the quality of your life. Only personal data, which is relevant for the purpose of this study, will be collected and used (this is called "data minimisation").

Who has access to the collected data?

The Lead Investigator will have access to the data. The research team will have access to pseudonymised data for analytical purposes. Both have undergone training in data protection law and practice, prior to starting this research.

How will my data be stored and protected?

Your identity will remain confidential. All of your details and results will be coded with a numerical ID to maintain your confidentiality (this is called "pseudonymisation"). Your data will be coded, rather than being kept completely anonymous, to allow for comparison of your results from one testing day to the next. Your name and personal details will not be published and will not be disclosed to anyone. All information relating to you in hard-copy form will be stored in a locked filing cabinet within a secure office only accessible by the Lead Investigator and information and records in electronic form will be stored on a password-protected PC at the Trinity Centre for Health Sciences in St. James's Hospital. Your study information and results will be retained in Trinity College for 5 years in keeping with good research practice standards and data protection legislation. It will be destroyed after this time (electronic data will be erased, and hard copy forms will be shredded).

How will my data be used, now and in the future?

The information collected in this study will be grouped together and analysed. Overall findings from this study may be published in international peer reviewed journals and may be shared at research conferences. The results of the study may be used for comparative purposes in other

studies of a similar nature. However, your data will remain coded, and your personal identifiers will never be published or disclosed to anyone. Your data will only be used for comparative purposes in studies that have Research Ethics Committee approval. Your rights under GDPR and what will happen in the event of a data breach will apply for use of data in future studies. The data controllers and researchers in this project are bound by our Professional Code of Conduct to maintain confidentiality regarding all data gained during this research.

Is there any risk with processing and storing my data? What will happen if there is a data breach?

Considering that sensitive personal data relating to your health is involved, in the unlikely event of a data breach (i.e. data being mislaid, lost or stolen), you will be notified as soon as possible, and it will be reported immediately to the Data Protection Commissioner. However, your data will be collected as pseudonymised data and the key to your identity will be secured separately. There is a low risk of a data breach.

What are my rights under GDPR?

You have the right to:

- Access your data
- Rectify or correct any mistakes with your data
- Have your data erased or deleted
- Data portability (moving your data from one controller to another)
- Object to or stop the processing or profiling of your data
- Lodge a complaint to the Data Protection Commissioner (contact: +353 57 8684800 or +353 (0)761 104 800; <https://dataprotection.ie/en/contact>).

What is the lawful basis to using my personal data?

Your data will be processed under the lawful basis of Article 6(1) (e) and 9(2) (i) of the EU General Data Protection Act 2016.

If you have any queries regarding your data, or the General Data Protection Rules (GDPR), you can contact the research team (details at end of document) or the Data Protection Officer of Trinity College Dublin, by email: dataprotection@tcd.ie .

Insurance

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation

Participation in this study is voluntary, and you will be asked to sign a consent form before taking part, after you have read this document and have had the study procedures, risks and benefits explained to you. You do not have to take part in this study, and you may withdraw participation at any time, even if the study has already started. You do not have to give a reason for not taking part in or for leaving the study.

If you decide not to participate, or if you withdraw participation, you will not be penalised and will not give up any benefits, which you had before entering the study. You should not feel in any way obliged to take part in this study. If you do not give consent, or withdraw your consent, no attempt will be made to access your data, and **no** application will be made by the research team for a consent exemption to the Health Research Consent Declaration Committee. If you wish to seek more information about this research study, or if you wish to opt-out, please contact the lead investigator on the details provided below.

Stopping the Study

You understand that the research team may stop your participation in the study at any time without your consent.

Permission

The Research Ethics Committee in Beacon Hospital, Sandyford Dublin 18, has approved this research. There is no known personal connection between members of the research team and this ethics committee.

Future Contact

After completion of the study, the researchers may contact you again in relation to your study results, if you express that you would like to receive feedback on them.

How can I prepare for the assessments?

If you consent to taking part in this study, the following points explain how to prepare for your testing day.

- Please fast from midnight on the night before your assessment days. Please limit your liquid intake while fasting you may drink water, but refrain from caffeine drinks, energy drinks, and alcohol. Fasting ensures a more accurate result in body composition analysis. A snack and drink will be provided to you after each assessment.
- Please wear clothing and footwear suitable for exercise
- Bring a towel, shower gel, and change of clothes if you wish to shower after testing.

- Please try to drive, arrange a lift or use public transport to get to the testing venue and avoid walking or cycling on the days of your visit. Results of your fitness test will be more accurate. Please refrain from strenuous physical activity for 24-hours prior to each assessment.
- We request that you continue your normal physical activity regime for the duration of the study, and not to increase the training intensity or frequency.

Further information

You can obtain more information or answers to your questions about the study, your participation in the study, and your rights, from **Tony Rafferty, the lead investigator who can be contacted on 0873986551 or emailed at raffertt@tcd.ie**. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

Lead Investigator: Tony Rafferty, Discipline of Physiotherapy, School of Medicine, Trinity College Dublin: Contact: Tel 087 3986551, E-mail raffertt@tcd.ie

Lead Co-Investigator: Patrick Kiely, Consultant Orthopaedic Surgeon, Beacon Hospital, Sandyford Dublin 18.

Research Supervisors & Co-Investigators: Dr Sara Dockrell & Dr Neil Fleming: Contact: Tel (01) 8962121, E-mail: sara.dockrell@tcd.ie; neil.fleming@tcd.ie

Data Controller: Trinity College Dublin.

Data Protection Officer: Data Protection, Trinity College Dublin:
Contact: E-mail: dataprotection@tcd.ie

Appendix 2.6: Participant Information leaflet –Controls age 16+.



Blackrock Clinic



Trinity College Dublin

Coláiste na Tríonóide, Baile Átha Cliath

The University of Dublin

Participant Information Leaflet

A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study.

Introduction

You are invited to take part in a clinical research study as part of the control group. The control group consists of healthy adolescents **who do not have a scoliosis**. This will allow us to compare those who have Adolescent Idiopathic Scoliosis (AIS) with those who do not have AIS (controls).

Before you decide whether you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP. Take time to ask questions, do not feel rushed and do not feel under pressure to make a quick decision. You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

Why is this study being done?

This study will focus on adolescents diagnosed with Adolescent Idiopathic Scoliosis (AIS). There is very little research into musculoskeletal strength, and balance in adolescents diagnosed with AIS. Recent research has indicated that weaknesses may exist. Also, adolescents with severe AIS have a lower lung function and cardiorespiratory capacity (the ability of your heart and lungs to supply

oxygen to your muscles during physical activity) when compared to the general population. This study hopes to add to the knowledge in this area and may provide an approach to address some or all of any weaknesses that are identified.

Aim of current study

The aims of the current study are:

Study 1. To assess and compare muscle strength, balance, fitness and quality of life between healthy adolescents and those with AIS.

Study 2. To assess the effects of a 4-month scoliosis specific exercise rehabilitation programme in those with mild and moderate AIS.

Study 3. To examine the effect of spinal fusion surgery on muscle strength, balance, fitness and quality of life by re-assessing severe AIS participants 3 months after surgery.

Study 4. To examine the effects of a 12-week physiotherapy exercise programme in conjunction with a 12-week home exercise programme on adolescents who have undergone spinal fusion surgery.

Who is doing the research?

The lead investigator for this study is Tony Rafferty. Tony is a CORU registered Chartered Physiotherapist. He specialises in sports and exercise medicine at Trinity College Dublin. The Co-lead investigator is Mr. Patrick Kiely. Pat is a surgeon in Beacon Hospital, Sandyford Dublin 18. . He works with children who have scoliosis. This study will include children and adolescents from Children's Health Ireland, Crumlin, Beacon Hospital and Blackrock Clinic.

Who can take part in the study?

To be involved in this study, you must:

1. Be 12 - 21 years of age.
2. Do not have Adolescent Idiopathic Scoliosis.
3. Have no illness or injury.
4. Have no neurological or balance problems that would restrict exercise.
5. Be able to cooperate, take, and follow instructions in English.
6. Have written consent from your parents or legal guardians if you are under the age of 16 years.
7. Be able to attend a 2-hour physical assessment in the Trinity Centre for Health Sciences, James's Hospital Dublin 8

You cannot take part in this study if:

1. You have a history of a heart condition (such as acute cardiac event, unstable chest pain, irregular heartbeat, and cardiac infection).
2. You have an existing acute or chronic lung condition.
3. You have an existing acute or chronic neurological condition.
4. You have abnormal blood pressure.
5. You are fitted with an electronic device (e.g. pacemaker).
6. You play sport at elite level.
7. You are pregnant or are a breastfeeding mother.
8. You have been advised by your doctor not to exercise.
9. You answer “yes” to any one question on the PAR-Q questionnaire. This is a standard physical activity readiness questionnaire, which you will complete before beginning the study.
10. You have incomplete or dissatisfactory medical screening prior to testing.
11. You are under the age of 12 or over the age of 21.

What does this study involve?

You will be invited to attend the Trinity Centre for Health Sciences, St. James’s Hospital, Dublin 8, for a physical assessment. Your parents are welcome to attend. A family member will be required to attend if you are under the age of 16. The visit will take approximately 2 hours and will be scheduled to suit you.

What does the assessment involve?

Upon arrival, you will complete short questionnaire about fitness, physical activity and quality of life. When these are completed your standing height and weight will then be measured. Your resting heart rate and blood pressure will also be measured. We will estimate the amount of fat, water and muscle in your body using a Tanita body composition analyser (pictured, right). This machine is non-invasive and will not cause you any pain.



You will be asked to remove your shoes and socks and stand on the body composition analyser.

Cardiorespiratory fitness test: Bike Ergometer

Before exercising, participants will complete a short questionnaire (the Physical Activity Readiness Questionnaire, or PAR-Q). The results of this questionnaire will indicate if they are safe to carry out an exercise test. Participants will be familiarised with how the test will work and shown the equipment to be used in this study: a gas analysis system with a facemask and heart rate monitor (pictured, right).

For this test, participants will be fitted with a heart rate monitor and a gas exchange mask and asked to sit on the cycle ergometer for 3 minutes. Resting measurements taken in this period. The test will follow the Godfrey protocol. Each minute of cycling is harder than the previous one. The participant will keep cycling for as long as they can. Heart rate monitored throughout the test.

You can end the test at any point, if you feel any pain or discomfort, if you feel dizzy, too breathless, or if you feel faint or too fatigued. The researcher will be monitoring for unexpected changes in blood pressure and heart rate, and will end the test if these occur, or if there are any technical difficulties with the equipment used. At the end of the test, there will be a 5-minute cool-down phase, at a slow pace.



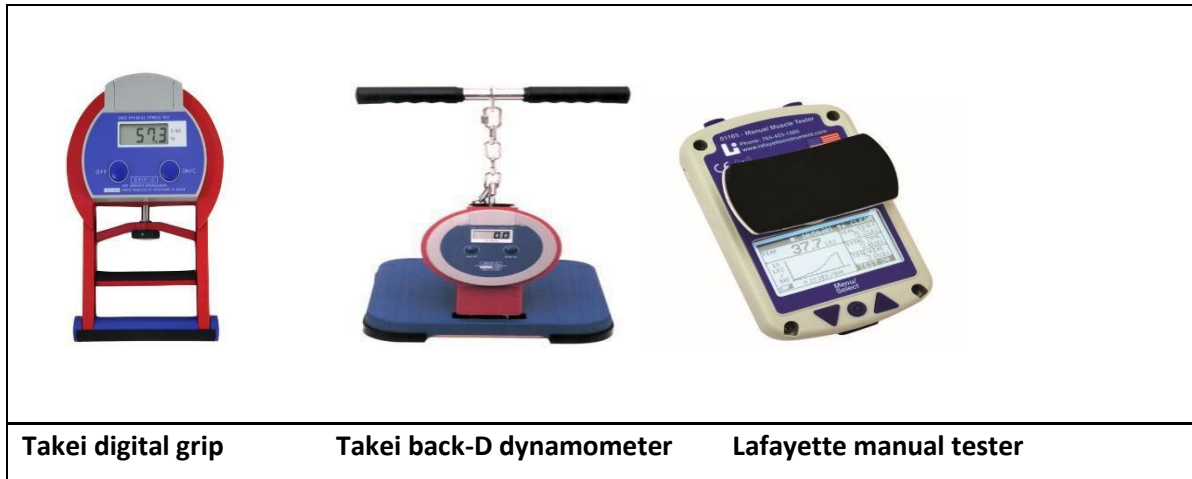
Lung function test.

We will assess how well your lungs work by measuring the volume and effort of breathing using a Micro Plus spirometer (pictured below). This is a portable battery-operated hand-held microcomputer unit. An antibacterial filter will be attached for each lung test. A nose clip is used during each test to prevent nasal breathing. The test will require you to stand upright, place your mouth tightly around the mouthpiece and breathe in fully prior to a breathing out fully. You will be encouraged to continue forcing air out until your lungs are empty. Any coughing or accidental blocking of the mouthpiece will render that attempt void and will need to be repeated. The test will be repeated until two satisfactory results are achieved. One minute of normal breathing will be allowed between tests for you to recover normal lung function.



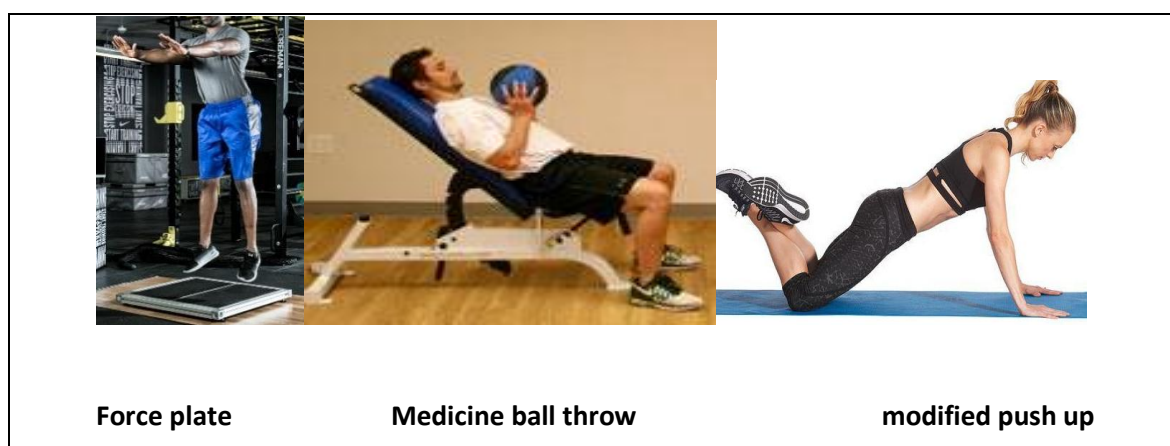
Muscle testing

Muscle Strength: Upper limb strength will be measured using a Takei digital grip strength dynamometer. Back muscle strength will be measured using a Takei back-D dynamometer. A calibrated Lafayette manual muscle tester will be used to measure lower limb muscle strength (pictured below).



Muscle endurance: Upper limb muscle endurance will be measured using a modified push-up test and lower limb muscle endurance testing will be measured by a wall squat test.

Muscle Power: A digital force plate will measure your lower limb power, and a medicine ball will be used to measure upper limb power.



Balance

A HUR balance platform will assess your balance. You will perform simple balance exercises on this platform (pictured below).



Quality of Life

You will complete a questionnaire designed for scoliosis patients.

Are there any benefits to taking part in this study?

Yes. When you complete the tests you will receive an individual health report which details your fitness levels and body composition. This report will help to understanding your own fitness level, your strengths and weaknesses. This report can be used to guide your own personal exercise plans. Participating in this study may also benefit adolescents with scoliosis. If we find that differences exist between groups that have scoliosis and those that do not, it will allow us to investigate ways these differences can be addressed.

Are there any risks involved in taking part in this study?

Adverse reactions to exercise testing are rare, especially when you have no medical history that increases your risk. However, you may feel some pain and discomfort. It is also possible that you could experience abnormal blood pressure, fainting, irregular heart rhythm, and a muscle cramping. These events are unlikely, and every effort will be made to minimise any risk to you. We will check your health before testing and carefully monitor you during and after each test. If you experience any of the above, the test will be stopped immediately. If symptoms do not

disappear, you will be seen by a doctor and if necessary, brought to A&E in St. James's Hospital. Your doctor will also be informed.

Do I need my parents' consent to take part in this study?

If you are under the age of 16, you will need your parent's written informed consent to participate in this study.

Confidentiality and Data Protection

What data will be collected?

Personal data will be collected during this study. This will include your gender, age, medical history, body composition, strength, lung function and fitness levels. We will also collect data on the quality of your life using a questionnaire. We need this information to compare people with AIS those that have no scoliosis. Only data which is relevant to the study will be collected and used (this process is called "data minimisation").

Who has access to the collected data?

The research team will have access to your data. All members of the team have undergone training in data protection law and practice, before starting this project.

How will my data be stored and protected?

Your identity will remain confidential. All of your details and results will be coded with a numerical ID (this is called "pseudonymisation"). The file with your name and code will be protected with a password. Only the Leads Investigator will have access to this password. Your name and personal details will not be published and will not be disclosed to anyone. All information relating written on paper form will be stored in a locked filing cabinet within a secure office. Only the Leads Investigator will have access to this. All data will be transferred to electronic file. This file will be stored on a password-protected PC at the Trinity Centre for Health Sciences in St James's Hospital. Your study information and results will be kept for 5 years in Trinity College it will then be destroyed. Electronic data will be erased, and all paper copy forms will be shredded.

How will my data be used, now and in the future?

The information collected in this study will be grouped together and analysed. Results from this study may be published in international journals. They may also be shared at research conferences or used to compare other similar studies. However, your data will remain coded, and your personal details will never be published or disclosed to anyone. Your data will only be used for comparative purposes in studies that have Research Ethics Committee approval. Your rights under

GDPR will apply for use of data in future studies. The data controllers and researchers in this project are bound by a Code of Conduct to maintain confidentiality at all times.

Is there any risk with processing and storing my data? What will happen if there is a data breach?

A data breach occurs when data is mislaid, laid or stolen. As all data will be collected at one location, there is a low risk of a data breach in this study. However, in the unlikely event of a data breach you will be notified as soon as possible. The breach will be immediately reported to the Data Protection Commissioner. Your data will be collected as pseudonymised data and the key to your identity will be secured separately. So in the event of a data breach, it will not be possible for anyone to link the data to you.

What are my rights under GDPR?

You have the right to:

- Access your data
- Rectify or correct any mistakes with your data
- Have your data erased or deleted
- Data portability (moving your data from one controller to another)
- Object to or stop the processing or profiling of your data
- Lodge a complaint to the Data Protection Commissioner (contact: +353 57 8684800 or +353 (0)761 104 800; <https://dataprotection.ie/en/contact>).

What is the lawful basis to using my personal data?

Your data will be processed under the lawful basis of Article 6(1) (e) and 9(2) (i) of the EU General Data Protection Act 2016. If you have any queries regarding your data, or the General Data Protection Rules (GDPR), you can contact the research team (details at end of document) or the Data Protection Officer of Trinity College Dublin, by email: dataprotection@tcd.ie .

Insurance

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation

Participation in this study is voluntary. After you have read this document you will have the study procedures, risks and benefits explained to you. You will then have a chance to ask any questions you have. If you are happy with everything, you will be asked to sign a consent form before taking part. You do not have to take part in this study, and you may withdraw participation at any time,

even if the study has already started. You do not have to give a reason for not taking part in or for leaving the study.

If you decide not to participate, or if you withdraw participation, you will not give up any benefits which you had before entering the study. You should not feel in any way obliged to take part in this study. If you do not give consent, or withdraw your consent, no attempt will be made to access your data, and **no** application will be made by the research team for a consent exemption to the Health Research Consent Declaration Committee.

If you wish to seek more information about this research study, or if you wish to opt-out, please contact the leads investigator on the details provided below.

Stopping the Study

You understand that the research team may stop your participation in the study at any time without your consent.

Permission

The Research Ethics Committee of Beacon Hospital, Sandyford Dublin 18 , has approved this research. There is no known personal connection between members of the research team and this ethics committee.

How can I prepare for the assessments?

If you consent to taking part in this study, the following points explain how to prepare for your testing day.

- Please fast from midnight on the night before your assessment days. You may drink water, but refrain from caffeine drinks, energy drinks, and alcohol. Fasting ensures more accurate results for body composition analysis. A snack and drink will be provided to you after each assessment.
- Please wear clothing and footwear suitable for exercise.
- Bring a towel, shower gel, and change of clothes if you wish to shower after testing.
- Please arrange a lift or use public transport to get to the testing venue. Please avoid walking or cycling on the days of your visit. The results of your fitness test will be more accurate.
- Please refrain from strenuous physical activity for 24-hours prior to each assessment.
- Please continue your normal physical activity regime during the study. Do not to increase the training intensity or frequency.

Further information

You can obtain more information or answers to your questions about the study, your participation in the study, and your rights, from **Tony Rafferty, the leads investigator who can be contacted on 0873986551 or emailed at raffertt@tcd.ie**. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

Lead Investigator: Tony Rafferty, Discipline of Physiotherapy, School of Medicine, Trinity College Dublin: Contact: Tel 087 3986551, E-mail raffertt@tcd.ie

Lead Co-Investigator: Patrick Kiely, Consultant Orthopaedic Surgeon in Beacon Hospital, Sandyford Dublin 18.

Research Supervisors: Dr Sara Dockrell& Dr Neil Fleming: Contact: Tel (01) 8962121, E-mail: sara.dockrell@tcd.ie; neil.fleming@tcd.ie

Data Controller: Trinity College Dublin.

Data Protection Officer: Data Protection, Trinity College Dublin

Contact: E-mail: dataprotection@tcd.ie

Appendix 2.7: Participant Information leaflet –Severe AIS age 14-16.



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Participant Information Leaflet

A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study.

Introduction

This study will focus on those diagnosed with Adolescent Idiopathic Scoliosis (AIS). There is little research into musculoskeletal strength, power and endurance in this group. Recent research has indicated that weaknesses exist. Previous studies have also indicated that adolescents with AIS have lower lung function and fitness levels. This study hopes to add to the knowledge in this area. It may provide an approach to address some of the issues identified during project.

Aim of current study

The aims of the current study are:

Study 1. To assess and compare muscle strength, balance, fitness and quality of life between healthy adolescents and those with AIS.

Study 2. To assess the effects of a 4-month scoliosis specific exercise rehabilitation programme in those with mild and moderate AIS.

Study 3. To examine the effect of spinal fusion surgery on muscle strength, balance, fitness and quality of life by re-assessing severe AIS participants 3 months after surgery.

Study 4. To examine the effects of a 12-week physiotherapy exercise programme along with a 12-week home exercise programme on adolescents who have undergone spinal fusion surgery.

We will also be recruiting adolescents who do not have AIS. We will compare adolescents with AIS to a healthy group of adolescents. If you have been diagnosed with severe AIS and scheduled for surgery within the next 3-months and would like to take part in this study, please take time to read this document carefully. Before agreeing to participate you should understand the risks and benefits of taking part in the study. This is known as “Informed Consent”.

Who is doing the research?

The lead investigator for this study is Tony Rafferty. Tony is a CORU registered Chartered Physiotherapist. He specialises in sports and exercise medicine at Trinity College Dublin. The Co-lead investigator is Mr. Patrick Kiely. Pat is a surgeon in Beacon Hospital, Sandyford Dublin 18. He works with children who have scoliosis. This study will include children and adolescents from Children’s Health Ireland, Crumlin, Beacon Hospital and Blackrock Clinic.

Who can take part in the study?

To be involved in this study, you must:

1. Be 12 - 21 years of age.
2. Have a diagnosis of severe Adolescent Idiopathic Scoliosis
3. Be approved for spinal fusion surgery within the next 3 months.
4. Have no illness or musculoskeletal injury.
5. Have no neurological, or balance problems that would restrict exercise.
6. Be able to cooperate, take, and follow instructions in English
7. Have written consent from your parents or legal guardians if you are under the age of 16 years.

8. Have the ability to attend three, 2-hour physical assessments, in the Trinity Centre for Health Sciences, St. James's Hospital, Dublin.
9. Be willing and able to attend a targeted physiotherapy led rehabilitation session every 2-weeks for a period of 12 weeks and take part in a home exercise programme.

You cannot take part in this study if:

1. You have a history of a heart condition (such as acute cardiac event, unstable chest pain, irregular heartbeat, and cardiac infection).
2. You have an existing acute or chronic lung condition.
3. You have an existing acute or chronic neurological condition.
4. You have abnormal blood pressure.
5. You are fitted with an electronic device (e.g. pacemaker).
6. You play sport at elite level.
7. You are pregnant or are a breastfeeding mother.
8. You have been advised by your doctor not to exercise.
9. You answer "yes" to any one question on the PAR-Q. This is a standard physical activity readiness questionnaire, which you will complete before exercise testing begins.
10. You have incomplete or dissatisfactory medical screening prior to testing.
11. You are under the age of 12 or over the age of 21.

What does this study involve?

You will attend Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8, 3 times for physical assessments over the course of the programme. You will take part in a physiotherapy-led exercise programme and a home exercise programme.

You will be invited to attend the Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8 for an initial assessment. Parents are welcome to attend. A family member will be required to attend if you are under the age of 16. You will be assessed again, three months after surgery and at the end of rehabilitation programme (12-weeks). Each physical assessment will take approximately 2 hours. Assessments will be scheduled to suit you.

What does the assessment involve?

Upon arrival, you will complete short questionnaire about fitness, physical activity and quality of life. When these are completed your standing height and weight will then be measured. Your resting heart rate and blood pressure will also be measured. We will estimate the amount of fat, water and muscle in your body using a Tanita body composition analyser (pictured, right). This

machine is non-invasive and will not cause you any pain. You will be asked to remove your shoes and socks and stand on the body composition analyser.



Cardiorespiratory fitness test: Bike Ergometer

Before exercising, participants will complete a short questionnaire (the Physical Activity Readiness Questionnaire, or PAR-Q). The results of this questionnaire will indicate if they are safe to carry out an exercise test. Participants will be familiarised with how the test will work and shown the equipment to be used in this study: a gas analysis system with a facemask and heart rate monitor (pictured, right).

For this test, participants will be fitted with a heart rate monitor and a gas exchange mask and asked to sit on the cycle ergometer for 3 minutes. Resting measurements taken in this period. The test will follow the Godfrey protocol. Each minute of cycling is harder than the previous one. The participant will keep cycling for as long as they can. Heart rate monitored throughout the test.



You can end the test at any point, if you feel any pain or discomfort, if you feel dizzy, too breathless, or if you feel faint or too fatigued. The researcher will be monitoring for unexpected changes in blood pressure and heart rate, and will end the test if these occur, or if there are any technical difficulties with the equipment used. At the end of the test, there will be a 5-minute cool-down phase, at a slow pace.

Lung function test.

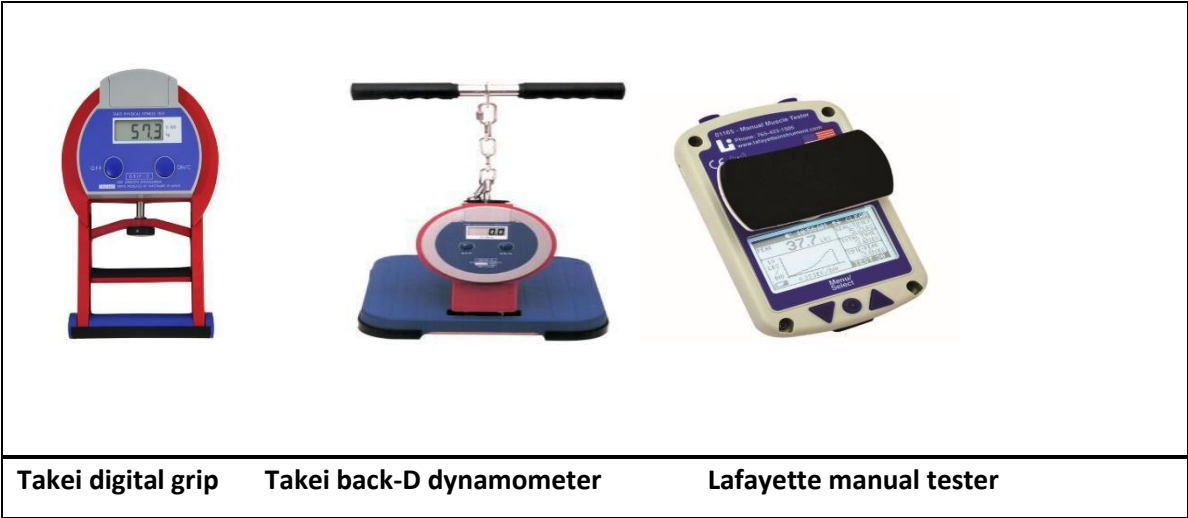
We will assess how well your lungs work by measuring the volume and effort of breathing using a Micro Plus spirometer (pictured below). This is a portable battery-operated hand-held microcomputer unit. An antibacterial filter will be attached for each lung test. A nose clip is used during each test to prevent nasal breathing. The test will require you to stand upright, place your mouth tightly around the mouthpiece and breathe in fully prior to a breathing out fully. You will be encouraged to continue forcing air out until your lungs are empty. Any coughing or accidental blocking of the mouthpiece will render that attempt void and will need to be repeated. The test

will be repeated until two satisfactory results are achieved. One minute of normal breathing will be allowed between tests for you to recover normal lung function.



Muscle testing

Muscle Strength: Upper limb strength will be measured using a Takei digital grip strength dynamometer. Back muscle strength will be measured using a Takei back-D dynamometer. A calibrated Lafayette manual muscle tester will be used to measure lower limb muscle strength (pictured below).



Muscle Endurance: Upper limb muscle endurance will be measured using a modified push-up test and lower limb muscle endurance testing will be measured using a wall squat test.

Muscle Power: A digital force plate will measure your lower limb power, and a medicine ball will be used to measure upper limb power.



Balance

A HUR balance platform will assess your balance. You will perform simple balance exercises on this platform (pictured below).



Quality of Life

You will complete a questionnaire designed for scoliosis patients.

What does the targeted exercise rehabilitation programme involve?

A Chartered Physiotherapist will supervise the bi-weekly exercise programme over 12 weeks. The physiotherapist will be provided with a specific rehabilitation programme for each participant based on the results of the physical assessments. The proposed programme will be based on

calisthenics, designed using individual body weight; no free weights or weight machines will be used. Each session will include a warmup and warm down period. All exercises will be demonstrated to the participant prior to commencement. The physiotherapist will also provide assistance/ modification of exercises to any participant who has difficulty executing the technique. Exercises will be set in a circuit and will include a variety and combination of exercises targeting each individual participant's needs. Exercises will be varied to reduce post exercise stiffness. All exercises selected will be appropriate to the age group and levels of muscular and aerobic fitness. The in-person session will be private and last approximately 45 minutes.

The 12-week home exercise programme will be a non-supervised, participant specific, rehabilitation programme, remotely monitored on a weekly basis via zoom call and pre-agreed with each participant. Each participant will maintain an electronic rehabilitation log of physical activity. With agreed access by the lead investigator, weekly maintenance of the rehabilitation log is expected.

Are there any benefits to taking part in this study?

Yes. When you complete the tests you will receive an individual health report which details your fitness levels and body composition. This report will help to understanding your own fitness level, your strengths and weaknesses. This report can be used to guide your own personal exercise plans. Participating in this study may also benefit adolescents with scoliosis. If we find that differences exist between groups that have scoliosis and those that do not, it will allow us to investigate ways these differences can be addressed.

Are there any risks involved in taking part in this study?

Adverse reactions to exercise testing are rare, especially when you have no medical history that increases your risk. However, you may feel some pain and discomfort. It is also possible that you could experience abnormal blood pressure, fainting, irregular heart rhythm, and a muscle cramping. These events are unlikely, and every effort will be made to minimise any risk to you. We will check your health before testing and carefully monitor you during and after each test. If you experience any of the above, the test will be stopped immediately. If symptoms do not disappear, you will be seen by a doctor and if necessary, brought to A&E in St. James's Hospital. Your doctor will also be informed.

Do I need my parents' consent to take part in this study?

If you are under the age of 16, you will need your parent's written informed consent to participate in this study.

Confidentiality and Data Protection

What data will be collected?

Personal data will be collected during this study. This will include your gender, age, medical history, body composition, strength, lung function and fitness levels. We will also collect data on the quality of your life using a questionnaire. We need this information to compare people with AIS those that have no scoliosis. Only data which is relevant to the study will be collected and used (this process is called "data minimisation").

Who has access to the collected data?

The research team will have access to your data. All members of the team have undergone training in data protection law and practice, before starting this project.

How will my data be stored and protected?

Your identity will remain confidential. All of your details and results will be coded with a numerical ID (this is called "pseudonymisation"). The file with your name and code will be protected with a password. Only the Lead Investigator will have access to this password. Your name and personal details will not be published and will not be disclosed to anyone. All information relating written on paper form will be stored in a locked filing cabinet within a secure office. Only the Lead Investigator will have access to this. All data will be transferred to electronic file. This file will be stored on a password-protected PC at the Trinity Centre for Health Sciences in St James's Hospital. Your study information and results will be kept in Trinity College for 5 years. It will then be destroyed. Electronic data will be erased, and all paper copy forms will be shredded.

How will my data be used, now and in the future?

The information collected in this study will be grouped together and analysed. Results from this study may be published in international journals. They may also be shared at research conferences or used to compare other similar studies. However, your data will remain coded and your personal details will never be published or disclosed to anyone. Your data will only be used for comparative purposes in studies that have Research Ethics Committee approval. Your rights under GDPR will apply for use of data in future studies. The data controllers and researchers in this project are bound by a Code of Conduct to maintain confidentiality at all times.

Is there any risk with processing and storing my data? What will happen if there is a data breach?

A data breach occurs when data is mislaid, laid or stolen. As all data will be collected at one location, there is a low risk of a data breach in this study. However, in the unlikely event of a data breach you will be notified as soon as possible. The breach will be immediately reported to the Data Protection Commissioner. Your data will be collected as pseudonymised data and the key to your identity will be secured separately. So, in the event of a data breach, it will not be possible for anyone to link the data to you.

What are my rights under GDPR?

You have the right to:

- Access your data
- Rectify or correct any mistakes with your data
- Have your data erased or deleted
- Data portability (moving your data from one controller to another)
- Object to or stop the processing or profiling of your data
- Lodge a complaint to the Data Protection Commissioner (contact: +353 57 8684800 or +353 (0)761 104 800; <https://dataprotection.ie/en/contact>).

What is the lawful basis to using my personal data?

Your data will be processed under the lawful basis of Article 6(1) (e) and 9(2) (i) of the EU General Data Protection Act 2016. If you have any queries regarding your data, or the General Data Protection Rules (GDPR), you can contact the research team (details at end of document) or the Data Protection Officer of Trinity College Dublin, by email: dataprotection@tcd.ie .

Insurance

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation

Participation in this study is voluntary. After you have read this document you will have the study procedures, risks and benefits explained to you. You will then have a chance to ask any questions you have. If you are happy with everything, you will be asked to sign a consent form before taking part. You do not have to take part in this study and you may withdraw participation at any time,

even if the study has already started. You do not have to give a reason for not taking part in or for leaving the study.

If you decide not to participate, or if you withdraw participation, you will not give up any benefits which you had before entering the study. You should not feel in any way obliged to take part in this study. If you do not give consent, or withdraw your consent, no attempt will be made to access your data, and **no** application will be made by the research team for a consent exemption to the Health Research Consent Declaration Committee.

If you wish to seek more information about this research study, or if you wish to opt-out, please contact the lead investigator on the details provided below.

Stopping the Study

You understand that the research team may stop your participation in the study at any time without your consent.

Permission

The Research Ethics Committee in Beacon Hospital, Sandyford Dublin 18, has approved this research. There is no known personal connection between members of the research team and this ethics committee.

How can I prepare for the assessments?

If you consent to taking part in this study, the following points explain how to prepare for your testing day.

- Please fast from midnight on the night before your assessment days. You may drink water, but refrain from caffeine drinks, energy drinks, and alcohol. Fasting ensures more accurate results for body composition analysis. A snack and drink will be provided to you after each assessment.
- Please wear clothing and footwear suitable for exercise.
- Bring a towel, shower gel, and change of clothes if you wish to shower after testing.
- Please arrange a lift or use public transport to get to the testing venue. Please avoid walking or cycling on the days of your visit. The results of your fitness test will be more accurate.
- Please refrain from strenuous physical activity for 24-hours prior to each assessment.
- Please continue your normal physical activity regime during the study. Do not to increase the training intensity or frequency.

Further information

You can obtain more information or answers to your questions about the study, your participation in the study, and your rights, from **Tony Rafferty, the main investigator who can be contacted on 0873986551 or emailed at raffertt@tcd.ie**. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

Lead Investigator: Tony Rafferty, Discipline of Physiotherapy, School of Medicine, Trinity College Dublin: Contact: Tel 087 3986551, E-mail raffertt@tcd.ie

Lead Co-Investigator: Patrick Kiely, Consultant Orthopaedic Surgeon, Beacon Hospital, Sandyford Dublin 18.

Research Supervisors & Co-Investigators: Dr Sara Dockrell & Dr Neil Fleming: Contact: Tel (01) 8962121, E-mail: sara.dockrell@tcd.ie; neil.fleming@tcd.ie

Data Controller: Trinity College Dublin.

Data Protection Officer: Data Protection, Trinity College Dublin

Contact: E-mail: dataprotection@tcd.ie

Appendix 2.8: Participant Information leaflet –Mild and Moderate AIS age 14-16.



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Participant Information Leaflet

A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study.

Introduction

This study will focus on those diagnosed with Adolescent Idiopathic Scoliosis (AIS). There is little research into musculoskeletal strength, power and endurance in this group. Recent research has indicated that weaknesses exist. Previous studies have also indicated that adolescents with AIS also have lower lung function and fitness levels. This study hopes to add to the knowledge in this area. It may provide an approach to address some of the issues identified during project.

Aim of current study

The aims of the current study are:

Study 1. To assess and compare muscle strength, balance, fitness and quality of life between healthy adolescents and those with AIS.

Study 2. To assess the effects of a 4-month scoliosis specific exercise rehabilitation programme in those with mild and moderate AIS. We will test muscle strength, power, and endurance, balance, cardiorespiratory function and quality of life. Results will be compared to adolescents diagnosed with mild and moderate AIS who have received standard hospital care and adolescents who do not have AIS.

Study 3. To examine the effect of spinal fusion surgery on muscle strength, balance, fitness and quality of life by re-assessing severe AIS participants 3 months after surgery.

Study 4. To examine the effects of a 12-week physiotherapy exercise programme and a 12-week home exercise programme on adolescents who have undergone spinal fusion surgery.

We will also be recruiting adolescents who do not have AIS. We will compare adolescents with AIS to a healthy group of adolescents. If you have been diagnosed with mild or moderate AIS and would like to take part in this study, please take time to read this document carefully. Before agreeing to participate you should understand the risks and benefits of taking part in the study. This is known as “Informed Consent”.

Who is doing the research?

The lead investigator for this study is Tony Rafferty. Tony is a CORU registered Chartered Physiotherapist. He specialises in sports and exercise medicine at Trinity College Dublin. The Co-lead investigator is Mr. Patrick Kiely. Pat is a surgeon in Beacon Hospital, Sandyford Dublin 18. He works with children who have scoliosis. This study will include children and adolescents from Children’s Health Ireland, Crumlin, Beacon Hospital and Blackrock Clinic.

Who can take part in the study?

To be involved in this study, you must:

1. Be 12 - 21 years of age.
2. Have a diagnosis of mild or moderate Adolescent Idiopathic Scoliosis
3. Have no illness or musculoskeletal injury, reported neurological, or balance problems that would restrict exercise.
4. Be able to cooperate, take, and follow instructions in English

5. Have written consent from your parents or legal guardians.
6. Have the ability to attend two, 2-hour physical assessments in the Trinity Centre for Health Sciences, James's Hospital Dublin 8.

You cannot take part in this study if:

1. You have a history of a heart condition (such as acute cardiac event, unstable chest pain, irregular heartbeat, and cardiac infection).
2. You have an existing acute or chronic lung condition.
3. You have an existing acute or chronic neurological condition.
4. You have abnormal blood pressure.
5. You are fitted with an electronic device (e.g. pacemaker).
6. You play sport at elite level.
7. You are pregnant or are a breastfeeding mother.
8. You have been advised by your doctor not to exercise.
9. You answer "yes" to any one question on the PAR-Q. This is a standard physical activity readiness questionnaire, which you will complete before exercise testing begins.
10. You have incomplete or dissatisfactory medical screening prior to testing.
11. You are under the age of 12 or over the age of 21.

What does this study involve?

You will be invited to attend the Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8, for a physical assessment on 2 occasions. You will need to bring a parent or legal guardian with you. The assessment will take approximately 2 hours. Assessments will be scheduled to suit you.

What does the assessment involve?

Upon arrival, you will complete short questionnaire about fitness, physical activity and quality of life. When these are completed your standing height and weight will then be measured. Your resting heart rate and blood pressure will also be measured. We will estimate the amount of fat, water and muscle in your body using a Tanita body composition analyser (pictured, right). This machine is non-invasive and will not cause you any pain. You will be asked to remove your shoes and socks and stand on the body composition analyser.



Cardiorespiratory fitness test: Bike Ergometer

Before exercising, participants will complete a short questionnaire (the Physical Activity Readiness Questionnaire, or PAR-Q). The results of this questionnaire will indicate if they are safe to carry out an exercise test. Participants will be familiarised with how the test will work and shown the equipment to be used in this study: a gas analysis system with a facemask and heart rate monitor (pictured, right).

For this test, participants will be fitted with a heart rate monitor and a gas exchange mask and asked to sit on the cycle ergometer for 3 minutes. Resting measurements taken in this period. The test will follow the Godfrey protocol. Each minute of cycling is harder than the previous one. The participant will keep cycling for as long as they can. Heart rate monitored throughout the test.

You can end the test at any point, if you feel any pain or discomfort, if you feel dizzy, too breathless, or if you feel faint or too fatigued. The researcher will be monitoring for unexpected changes in blood pressure and heart rate, and will end the test if these occur, or if there are any technical difficulties with the equipment used. At the end of the test, there will be a 5-minute cool-down phase, at a slow pace.



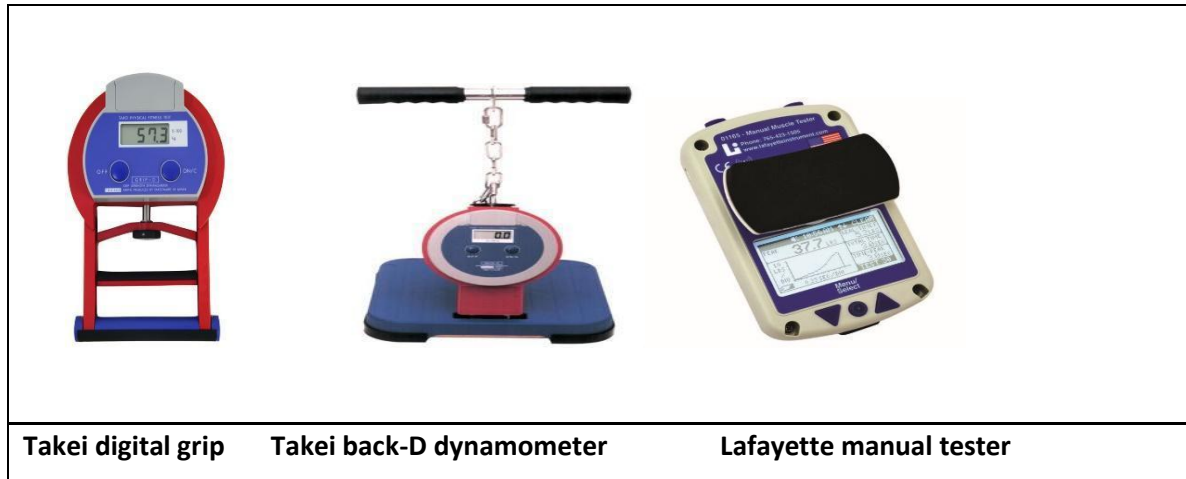
Lung function test.

We will assess how well your lungs work by measuring the volume and effort of breathing using a Micro Plus spirometer (pictured below). This is a portable battery-operated hand-held microcomputer unit. An antibacterial filter will be attached for each lung test. A nose clip is used during each test to prevent nasal breathing. The test will require you to stand upright, place your mouth tightly around the mouthpiece and breathe in fully prior to a breathing out fully. You will be encouraged to continue forcing air out until your lungs are empty. Any coughing or accidental blocking of the mouthpiece will render that attempt void and will need to be repeated. The test will be repeated until two satisfactory results are achieved. One minute of normal breathing will be allowed between tests for you to recover normal lung function.



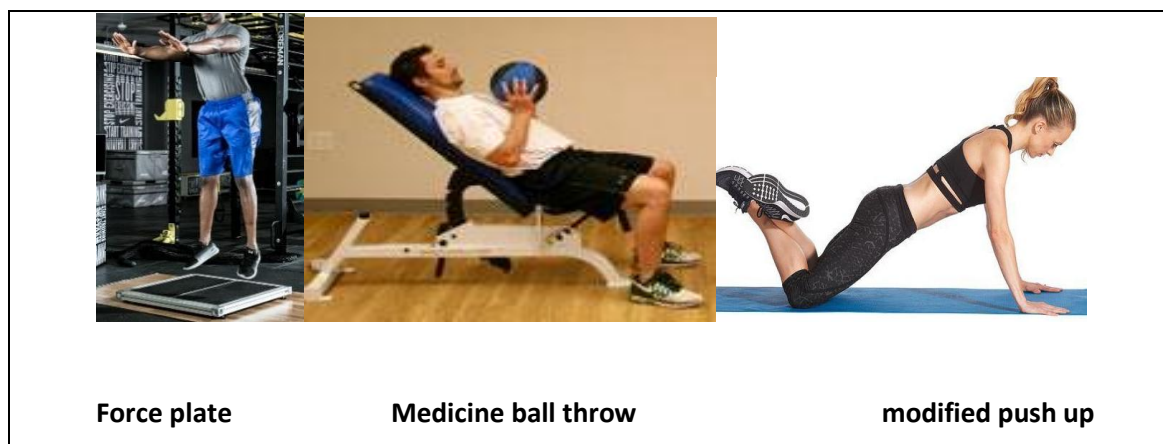
Muscle testing

Muscle Strength: Upper limb strength will be measured using a Takei digital grip strength dynamometer. Back muscle strength will be measured using a Takei back-D dynamometer. A calibrated Lafayette manual muscle tester will be used to measure lower limb muscle strength (pictured below).



Muscle endurance: Upper limb muscle endurance will be measured using a modified push-up test and lower limb muscle endurance testing will be measured by a wall squat test.

Muscle Power: A digital force plate will measure your lower limb power, and a medicine ball will be used to measure upper limb power.



Balance

A HUR balance platform will assess your balance. You will perform simple balance exercises on this platform (pictured below).



Quality of Life

You will complete a questionnaire designed for scoliosis patients.

Are there any benefits to taking part in this study?

Yes. When you complete the tests you will receive an individual health report which details your fitness levels and body composition. This report will help to understanding your own fitness level, your strengths and weaknesses. This report can be used to guide your own personal exercise plans. Participating in this study may also benefit adolescents with scoliosis. If we find that differences exist between groups that have scoliosis and those that do not, it will allow us to investigate ways these differences can be addressed.

Are there any risks involved in taking part in this study?

Adverse reactions to exercise testing are rare, especially when you have no medical history that increases your risk. However, you may feel some pain and discomfort. It is also possible that you could experience abnormal blood pressure, fainting, irregular heart rhythm, and a muscle cramping. These events are unlikely and every effort will be made to minimise any risk to you. We will check your health before testing and carefully monitor you during and after each test. If you experience any of the above, the test will be stopped immediately. If symptoms do not disappear, you will be seen by a doctor and if necessary, brought to A&E in St. James's Hospital. Your doctor will also be informed.

Do I need my parents' consent to take part in this study?

If you are under the age of 16, you will need your parent's written informed consent to participate in this study.

Confidentiality and Data Protection

What data will be collected?

Personal data will be collected during this study. This will include your gender, age, medical history, body composition, strength, lung function and fitness levels. We will also collect data on the quality of your life using a questionnaire. We need this information to compare people with AIS those that have no scoliosis. Only data which is relevant to the study will be collected and used (this process is called "data minimisation").

Who has access to the collected data?

The research team will have access to your data. All members of the team have undergone training in data protection law and practice, before starting this project.

How will my data be stored and protected?

Your identity will remain confidential. All of your details and results will be coded with a numerical ID (this is called "pseudonymisation"). The file with your name and code will be protected with a password. Only the Lead Investigator will have access to this password. Your name and personal details will not be published and will not be disclosed to anyone. All information relating written on paper form will be stored in a locked filing cabinet within a secure office. Only the Lead Investigator will have access to this. All data will be transferred to electronic file. This file will be stored on a password-protected PC at the Trinity Centre for Health Sciences in St James's Hospital. Your study information and results will be kept in Trinity College for 5 years. It will then be destroyed. Electronic data will be erased, and all paper copy forms will be shredded.

How will my data be used, now and in the future?

The information collected in this study will be grouped together and analysed. Results from this study may be published in international journals. They may also be shared at research conferences or used to compare other similar studies. However, your data will remain coded and your personal details will never be published or disclosed to anyone. Your data will only be used for comparative purposes in studies that have Research Ethics Committee approval. Your rights under GDPR will apply for use of data in future studies. The data controllers and researchers in this project are bound by a Code of Conduct to maintain confidentiality at all times.

Is there any risk with processing and storing my data? What will happen if there is a data breach?

A data breach occurs when data is mislaid, laid or stolen. As all data will be collected at one location, there is a low risk of a data breach in this study. However, in the unlikely event of a data breach you will be notified as soon as possible. The breach will be immediately reported to the Data Protection Commissioner. Your data will be collected as pseudonymised data and the key to your identity will be secured separately. So in the event of a data breach, it will not be possible for anyone to link the data to you.

What are my rights under GDPR?

You have the right to:

- Access your data
- Rectify or correct any mistakes with your data
- Have your data erased or deleted
- Data portability (moving your data from one controller to another)
- Object to or stop the processing or profiling of your data
- Lodge a complaint to the Data Protection Commissioner (contact: +353 57 8684800 or +353 (0)761 104 800; <https://dataprotection.ie/en/contact>).

What is the lawful basis to using my personal data?

Your data will be processed under the lawful basis of Article 6(1) (e) and 9(2) (i) of the EU General Data Protection Act 2016. If you have any queries regarding your data, or the General Data Protection Rules (GDPR), you can contact the research team (details at end of document) or the Data Protection Officer of Trinity College Dublin, by email: dataprotection@tcd.ie .

Insurance

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation

Participation in this study is voluntary. After you have read this document you will have the study procedures, risks and benefits explained to you. You will then have a chance to ask any questions you have. If you are happy with everything, you will be asked to sign a consent form before taking part. You do not have to take part in this study and you may withdraw participation at any time, even if the study has already started. You do not have to give a reason for not taking part in or for leaving the study.

If you decide not to participate, or if you withdraw participation, you will not give up any benefits which you had before entering the study. You should not feel in any way obliged to take part in this study. If you do not give consent, or withdraw your consent, no attempt will be made to access your data, and **no** application will be made by the research team for a consent exemption to the Health Research Consent Declaration Committee.

If you wish to seek more information about this research study, or if you wish to opt-out, please contact the lead investigator on the details provided below.

Stopping the Study

You understand that the research team may stop your participation in the study at any time without your consent.

Permission

The Research Ethics Committee of Beacon Hospital, Sandyford Dublin 18, has approved this research. There is no known personal connection between members of the research team and this ethics committee.

How can I prepare for the assessments?

If you consent to taking part in this study, the following points explain how to prepare for your testing day.

- Please fast from midnight on the night before your assessment days. You may drink water, but refrain from caffeine drinks, energy drinks, and alcohol. Fasting ensures more accurate results for body composition analysis. A snack and drink will be provided to you after each assessment.
- Please wear clothing and footwear suitable for exercise.
- Bring a towel, shower gel, and change of clothes if you wish to shower after testing.
- Please arrange a lift or use public transport to get to the testing venue. Please avoid walking or cycling on the days of your visit. The results of your fitness test will be more accurate.
- Please refrain from strenuous physical activity for 24-hours prior to each assessment.
- Please continue your normal physical activity regime during the study. Do not to increase the training intensity or frequency.

Further information

You can obtain more information or answers to your questions about the study, your participation in the study, and your rights, from **Tony Rafferty, the main investigator who can be contacted on 0873986551 or emailed at raffertt@tcd.ie**. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

Lead Investigator: Tony Rafferty, Discipline of Physiotherapy, School of Medicine, Trinity College Dublin: Contact: Tel 087 3986551, E-mail raffertt@tcd.ie

Lead Co-Investigator: Patrick Kiely, Consultant Orthopaedic Surgeon, Beacon Hospital, Sandyford Dublin 18.

Research Supervisors & Co-Investigators: Dr Sara Dockrell & Dr Neil Fleming: Contact: Tel (01) 8962121, E-mail: sara.dockrell@tcd.ie; neil.fleming@tcd.ie

Data Controller: Trinity College Dublin.

Data Protection Officer: Data Protection, Trinity College Dublin

Contact: E-mail: dataprotection@tcd.ie

Appendix 2.9: Participant Information leaflet –Controls age 14-16.



Participant Information Leaflet

A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study.

Introduction

You are invited to take part in a clinical research study as part of the control group. The control group consists of healthy adolescents **who do not have a scoliosis**. This will allow us to compare those who have Adolescent Idiopathic Scoliosis (AIS) with those who do not have AIS (controls).

Before you decide whether you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP. Take time to ask questions, do not feel rushed and do not feel under pressure to make a quick decision. You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

Why is this study being done?

This study will focus on adolescents diagnosed with Adolescent Idiopathic Scoliosis (AIS). There is very little research into musculoskeletal strength, and balance in adolescents diagnosed with AIS. Recent research has indicated that weaknesses may exist. Also, adolescents with severe AIS have a lower lung function and cardiorespiratory capacity (the ability of your heart and lungs to supply

oxygen to your muscles during physical activity) when compared to the general population. This study hopes to add to the knowledge in this area and may provide an approach to address some or all of any weaknesses that are identified.

Aim of current study

The aims of the current study are:

Study 1. To assess and compare muscle strength, balance, fitness and quality of life between healthy adolescents and those with AIS.

Study 2. To assess the effects of a 4-month scoliosis specific exercise rehabilitation programme in those with mild and moderate AIS.

Study 3. To examine the effect of spinal fusion surgery on muscle strength, balance, fitness and quality of life by re-assessing severe AIS participants 3 months after surgery.

Study 4. To examine the effects of a 12-week physiotherapy exercise programme including a 12-week home exercise programme on adolescents who have undergone spinal fusion surgery.

Who is doing the research?

The lead investigator for this study is Tony Rafferty. Tony is a CORU registered Chartered Physiotherapist. He specialises in sports and exercise medicine at Trinity College Dublin. The Co-lead investigator is Mr. Patrick Kiely. Pat is a surgeon in Beacon Hospital, Sandyford Dublin 18. He works with children who have scoliosis. This study will include children and adolescents from Children's Health Ireland, Beacon Hospital and Blackrock Clinic.

Who can take part in the study?

1. To be involved in this study, you must:
2. Be 12 - 21 years of age.
3. Not have Adolescent Idiopathic Scoliosis.
4. Have no illness or injury.
5. Have no neurological or balance problems that would restrict exercise.
6. Be able to cooperate, take, and follow instructions in English.
7. Have written consent from your parents or legal guardians if you are under the age of 16 years.
8. Be able to attend a 2-hour physical assessment in the Trinity Centre for Health Sciences, James's Hospital Dublin 8.

You cannot take part in this study if:

1. . You have a history of a heart condition (such as acute cardiac event, unstable chest pain, irregular heartbeat, and cardiac infection).
2. You have an existing acute or chronic lung condition.
3. You have an existing acute or chronic neurological condition.
4. You have abnormal blood pressure.
5. You are fitted with an electronic device (e.g. pacemaker).
6. You play sport at elite level.
7. You are pregnant or are a breastfeeding mother.
8. You have been advised by your doctor not to exercise.
9. You answer “yes” to any one question on the PAR-Q questionnaire. This is a standard physical activity readiness questionnaire, which you will complete before beginning the study.
10. You have incomplete or dissatisfactory medical screening prior to testing.
11. You are under the age of 12 or over the age of 21.

What does this study involve?

You will be invited to attend the Trinity Centre for Health Sciences, St. James’s Hospital, Dublin 8, for a physical assessment. Your parents are welcome to attend. A family member will be required to attend if you are under the age of 16. The visit will take approximately 2 hours and will be scheduled to suit you.

What does the assessment involve?

Upon arrival, you will complete short questionnaire about fitness, physical activity and quality of life. When these are completed your standing height and weight will then be measured. Your resting heart rate and blood pressure will also be measured. We will estimate the amount of fat, water and muscle in your body using a Tanita body composition analyser (pictured, right). This machine is non-invasive and will not cause you any pain. You will be asked to remove your shoes and socks and stand on the body composition analyser.



Cardiorespiratory fitness test: Bike Ergometer

Before exercising, you will complete a short questionnaire (the Physical Activity Readiness Questionnaire, or PAR-Q). The results of this questionnaire will indicate if they are safe to carry out an exercise test. you will be familiarised with how the test will work and shown the equipment to be used in this study: a gas analysis system with a facemask and heart rate monitor (pictured, right).

For this test, participants will be fitted with a heart rate monitor and a gas exchange mask and asked to sit on the cycle ergometer for 3 minutes. Resting measurements taken in this period. The test will follow the Godfrey protocol. Each minute of cycling is harder than the previous one. You will keep cycling for as long as they can. Heart rate monitored throughout the test.

You can end the test at any point, if you feel any pain or discomfort, if you feel dizzy, too breathless, or if you feel faint or too fatigued. The researcher will be monitoring for unexpected changes in blood pressure and heart rate, and will end the test if these occur, or if there are any technical difficulties with the equipment used. At the end of the test, there will be a 5-minute cool-down phase, at a slow pace.



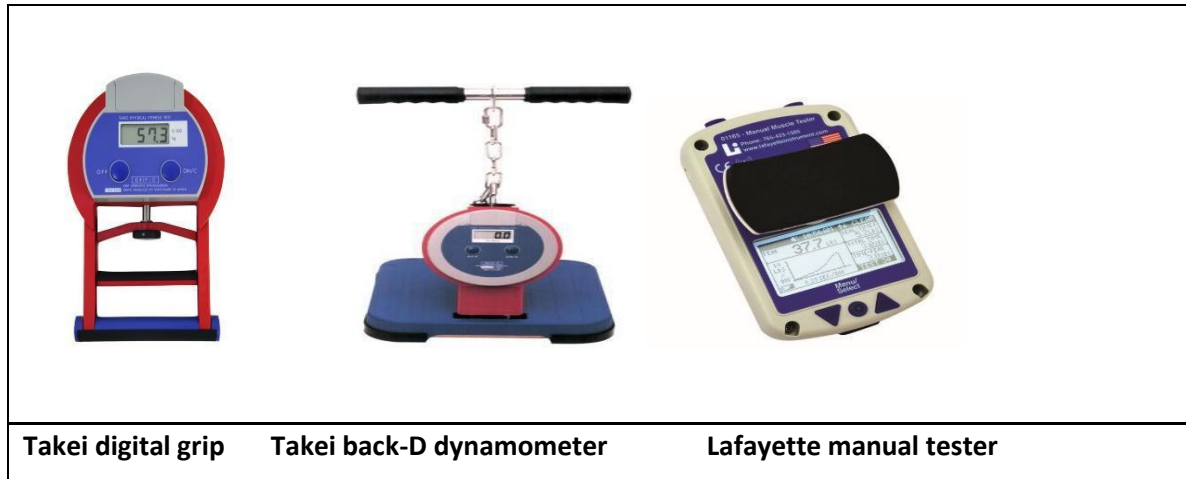
Lung function test.

We will assess how well your lungs work by measuring the volume and effort of breathing using a Micro Plus spirometer (pictured below). This is a portable battery-operated hand-held microcomputer unit. An antibacterial filter will be attached for each lung test. A nose clip is used during each test to prevent nasal breathing. The test will require you to stand upright, place your mouth tightly around the mouthpiece and breathe in fully prior to a breathing out fully. You will be encouraged to continue forcing air out until your lungs are empty. Any coughing or accidental blocking of the mouthpiece will render that attempt void and will need to be repeated. The test will be repeated until two satisfactory results are achieved. One minute of normal breathing will be allowed between tests for you to recover normal lung function.



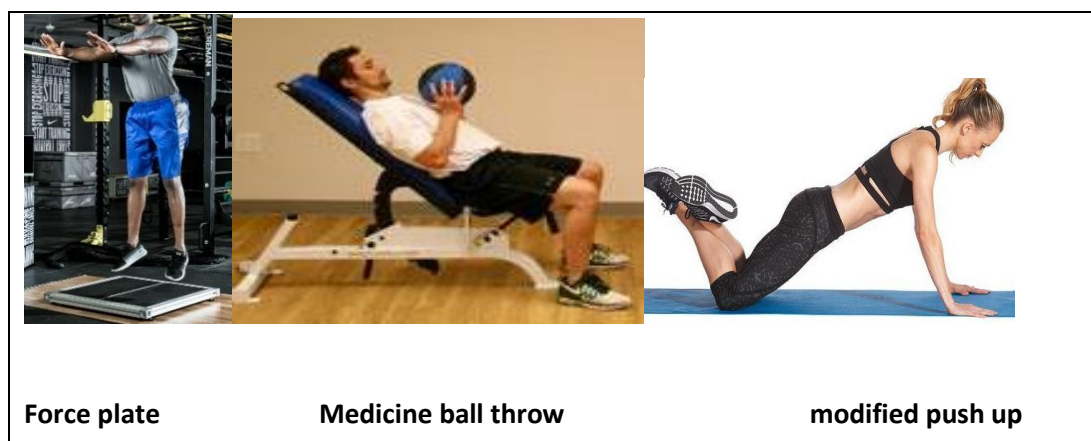
Muscle testing

Muscle Strength: Upper limb strength will be measured using a Takei digital grip strength dynamometer. Back muscle strength will be measured using a Takei back-D dynamometer. A calibrated Lafayette manual muscle tester will be used to measure lower limb muscle strength (pictured below).



Muscle endurance: Upper limb muscle endurance will be measured using a modified push-up test and lower limb muscle endurance testing will be measured by a wall squat test.

Muscle Power: A digital force plate will measure your lower limb power, and a medicine ball will be used to measure upper limb power.



Balance

A HUR balance platform will assess your balance. You will perform simple balance exercises on this platform (pictured below).



Quality of Life

You will complete a questionnaire designed for scoliosis patients.

Are there any benefits to taking part in this study?

Yes. When you complete the tests you will receive an individual health report which details your fitness levels and body composition. This report will help to understanding your own fitness level, your strengths and weaknesses. This report can be used to guide your own personal exercise plans. Participating in this study may also benefit adolescents with scoliosis. If we find that differences exist between groups that have scoliosis and those that do not, it will allow us to investigate ways these differences can be addressed.

Are there any risks involved in taking part in this study?

Adverse reactions to exercise testing are rare, especially when you have no medical history that increases your risk. However, you may feel some pain and discomfort. It is also possible that you could experience abnormal blood pressure, fainting, irregular heart rhythm, and a muscle cramping. These events are unlikely and every effort will be made to minimise any risk to you. We will check your health before testing and carefully monitor you during and after each test. If you experience any of the above, the test will be stopped immediately. If symptoms do not disappear, you will be seen by a doctor and if necessary, brought to A&E in St. James's Hospital. Your doctor will also be informed.

Do I need my parents' consent to take part in this study?

If you are under the age of 16, you will need your parent's written informed consent to participate in this study.

Confidentiality and Data Protection

What data will be collected?

Personal data will be collected during this study. This will include your gender, age, medical history, body composition, strength, lung function and fitness levels. We will also collect data on the quality of your life using a questionnaire. We need this information to compare people with AIS those that have no scoliosis. Only data which is relevant to the study will be collected and used (this process is called "data minimisation").

Who has access to the collected data?

The research team will have access to your data. All members of the team have undergone training in data protection law and practice, before starting this project.

How will my data be stored and protected?

Your identity will remain confidential. All of your details and results will be coded with a numerical ID (this is called "pseudonymisation"). The file with your name and code will be protected with a password. Only the Leads Investigator will have access to this password. Your name and personal details will not be published and will not be disclosed to anyone. All information relating written on paper form will be stored in a locked filing cabinet within a secure office. Only the Leads Investigator will have access to this. All data will be transferred to electronic file. This file will be stored on a password-protected PC at the Trinity Centre for Health Sciences in St James's Hospital. Your study information and results will be kept for 5 years in Trinity College it will then be destroyed. Electronic data will be erased, and all paper copy forms will be shredded.

How will my data be used, now and in the future?

The information collected in this study will be grouped together and analysed. Results from this study may be published in international journals. They may also be shared at research conferences or used to compare other similar studies. However, your data will remain coded and your personal details will never be published or disclosed to anyone. Your data will only be used for comparative purposes in studies that have Research Ethics Committee approval. Your rights under GDPR will apply for use of data in future studies. The data controllers and researchers in this project are bound by a Code of Conduct to maintain confidentiality at all times.

Is there any risk with processing and storing my data? What will happen if there is a data breach?

A data breach occurs when data is mislaid, laid or stolen. As all data will be collected at one location, there is a low risk of a data breach in this study. However, in the unlikely event of a data breach you will be notified as soon as possible. The breach will be immediately reported to the Data Protection Commissioner. Your data will be collected as pseudonymised data and the key to your identity will be secured separately. So, in the event of a data breach, it will not be possible for anyone to link the data to you.

What are my rights under GDPR?

You have the right to:

- Access your data
- Rectify or correct any mistakes with your data
- Have your data erased or deleted
- Data portability (moving your data from one controller to another)
- Object to or stop the processing or profiling of your data
- Lodge a complaint to the Data Protection Commissioner (contact: +353 57 8684800 or +353 (0)761 104 800; <https://dataprotection.ie/en/contact>).

What is the lawful basis to using my personal data?

Your data will be processed under the lawful basis of Article 6(1) (e) and 9(2) (i) of the EU General Data Protection Act 2016. If you have any queries regarding your data, or the General Data Protection Rules (GDPR), you can contact the research team (details at end of document) or the Data Protection Officer of Trinity College Dublin, by email: dataprotection@tcd.ie .

Insurance

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation

Participation in this study is voluntary. After you have read this document you will have the study procedures, risks and benefits explained to you. You will then have a chance to ask any questions you have. If you are happy with everything, you will be asked to sign a consent form before taking part. You do not have to take part in this study and you may withdraw participation at any time, even if the study has already started. You do not have to give a reason for not taking part in or for leaving the study.

If you decide not to participate, or if you withdraw participation, you will not give up any benefits which you had before entering the study. You should not feel in any way obliged to take part in this study. If you do not give consent, or withdraw your consent, no attempt will be made to access your data, and **no** application will be made by the research team for a consent exemption to the Health Research Consent Declaration Committee.

If you wish to seek more information about this research study, or if you wish to opt-out, please contact the leads investigator on the details provided below.

Stopping the Study

You understand that the research team may stop your participation in the study at any time without your consent.

Permission

The Research Ethics Committee of Beacon Hospital, Sandyford Dublin 18 , has approved this research. There is no known personal connection between members of the research team and this ethics committee.

How can I prepare for the assessments?

If you consent to taking part in this study, the following points explain how to prepare for your testing day.

- Please fast from midnight on the night before your assessment days. You may drink water, but refrain from caffeine drinks, energy drinks, and alcohol. Fasting ensures more accurate results for body composition analysis. A snack and drink will be provided to you after each assessment.
- Please wear clothing and footwear suitable for exercise.
- Bring a towel, shower gel, and change of clothes if you wish to shower after testing.
- Please arrange a lift or use public transport to get to the testing venue. Please avoid walking or cycling on the days of your visit. The results of your fitness test will be more accurate.
- Please refrain from strenuous physical activity for 24-hours prior to each assessment.
- Please continue your normal physical activity regime during the study. Do not to increase the training intensity or frequency.

Further information

You can obtain more information or answers to your questions about the study, your participation in the study, and your rights, from **Tony Rafferty, the leads investigator who can be contacted on 0873986551 or emailed at raffertt@tcd.ie**. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

Lead Investigator: Tony Rafferty, Discipline of Physiotherapy, School of Medicine, Trinity College Dublin: Contact: Tel 087 3986551, E-mail raffertt@tcd.ie

Lead Co-Investigator: Patrick Kiely, Consultant Orthopaedic Surgeon in Beacon Hospital, Sandyford Dublin 18.

Research Supervisors: Dr Sara Dockrell& Dr Neil Fleming: Contact: Tel (01) 8962121, E-mail: sara.dockrell@tcd.ie; neil.fleming@tcd.ie

Data Controller: Trinity College Dublin.

Data Protection Officer: Data Protection, Trinity College Dublin

Contact: E-mail: dataprotection@tcd.ie

Appendix 2.10: Participant Information leaflet – Severe AIS age 12-14.



Beacon Hospital



Blackrock Clinic



Trinity College Dublin

Coláiste na Tríonóide, Baile Átha Cliath

The University of Dublin

Participant Information Leaflet

A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study.

Introduction

This study is about Adolescent Idiopathic Scoliosis (AIS). There is little research into muscle strength in scoliosis. Recent research says adolescents with scoliosis may have weaker muscles. Previous studies have also show that adolescents with AIS also have lower lung function and fitness levels. This study hopes to add to the knowledge in this area. It may help us find a way to improve adolescents with AIS.

Aim of current study

The aims of the current study are:

Study 1. To assess and compare muscle strength, balance, fitness and quality of life between healthy adolescents and those with AIS.

Study 2. To assess the effects of a 4-month scoliosis specific exercise rehabilitation programme in those with mild and moderate AIS.

Study 3. To examine the effect of spinal fusion surgery on muscle strength, balance, fitness and quality of life by re-assessing severe AIS participants 3 months after surgery.

Study 4. To examine the effects of a 12-week physiotherapy exercise programme and a 12-week home exercise programme on adolescents who have undergone spinal fusion surgery.

We will also be recruiting adolescents who do not have AIS. We will compare adolescents with AIS to a healthy group of adolescents. If you have a diagnosis of severe AIS and are scheduled for surgery and would like to take part in this study, please take time to read this document carefully. Before agreeing to participate you should understand the risks and benefits of taking part in the study. This is known as “Informed Consent”.

Who is doing the research?

The lead investigator for this study is Tony Rafferty. Tony is a CORU registered Chartered Physiotherapist. He specialises in sports and exercise medicine at Trinity College Dublin. The Co-lead investigator is Mr. Patrick Kiely. Pat is a surgeon in Beacon Hospital, Sandyford Dublin 18. He works with children who have scoliosis. This study will include children and adolescents from Children’s Health Ireland, Crumlin, Beacon Hospital and Blackrock Clinic.

Who can take part in the study?

To be involved in this study, you must:

1. Be 12 - 21 years of age.
2. Have a diagnosis of severe Adolescent Idiopathic Scoliosis
3. Be approved for spinal fusion surgery within the next 3 months.
4. Have no illness or muscle injury.
5. Have no neurological, or balance problems that would stop you exercising.
6. Be able to cooperate, take, and follow instructions in English
7. Have written consent from your parents or legal guardians if you are under the age of 16 years.
8. Be able to attend three, 2-hour physical assessments in the Trinity Centre for Health Sciences, St. James’s Hospital, Dublin.
9. Be willing and able to attend a targeted physiotherapy led rehabilitation session every 2-weeks for a period of 12 weeks and take part in a home exercise programme.

You cannot take part in this study if:

1. You have a history of a heart condition (such as acute cardiac event, unstable chest pain, irregular heartbeat, and cardiac infection).
2. You have an existing acute or chronic lung condition.
3. You have an existing acute or chronic neurological condition.
4. You have abnormal blood pressure.
5. You are fitted with an electronic device (e.g. pacemaker).
6. You play sport at elite level.
7. You are pregnant or are a breastfeeding mother.
8. You have been advised by your doctor not to exercise.
9. You answer “yes” to any one question on the PAR-Q. This is a standard physical activity readiness questionnaire, which you will complete before exercise testing begins.
10. You have incomplete or dissatisfactory medical screening prior to testing.
11. You are under the age of 12 or over the age of 21.

What does this study involve?

You will attend Trinity Centre for Health Sciences, St. James’s Hospital, Dublin 8, 3 times for physical assessments. You will also take part in a targeted physiotherapy-led exercise programme including a home exercise programme.

You will be invited to attend the Trinity Centre for Health Sciences, St. James’s Hospital, Dublin 8 for an initial assessment. A parent or legal guardian will need to attend these assessments with you. You will be assessed again three months after surgery and at the end of rehabilitation programme (12-weeks) Each physical assessment will take approximately 2 hours. Assessments will be arranged to suit you.

What does the assessment involve?

Upon arrival, you will complete short questionnaire about fitness, physical activity and quality of life. When these are completed your standing height and weight will be measured. Your resting heart rate and blood pressure will also be measured. We will estimate the amount of fat, water and muscle in your body using a Tanita body composition analyser (pictured, right). This machine

is non-invasive and will not cause you any pain. You will be asked to remove your shoes and socks and stand on the body composition analyser.



Cardiorespiratory fitness test: Bike Ergometer

Before exercising, participants will complete a short questionnaire (the Physical Activity Readiness Questionnaire, or PAR-Q). The results of this questionnaire will indicate if they are safe to carry out an exercise test. Participants will be familiarised with how the test will work and shown the equipment to be used in this study: a gas analysis system with a facemask and heart rate monitor (pictured, right).

For this test, participants will be fitted with a heart rate monitor and a gas exchange mask and asked to sit on the cycle ergometer for 3 minutes. Resting measurements taken in this period. The test will follow the Godfrey protocol. Each minute of cycling is harder than the previous one. The participant will keep cycling for as long as they can. Heart rate monitored throughout the test.



You can end the test at any point, if you feel any pain or discomfort, if you feel dizzy, too breathless, or if they feel faint or too fatigued. The researcher will be monitoring for unexpected changes in blood pressure and heart rate, and will end the test if these occur, or if there are any technical difficulties with the equipment used. At the end of the test, there will be a 5-minute cool-down phase, at a slow pace.

Lung function test.

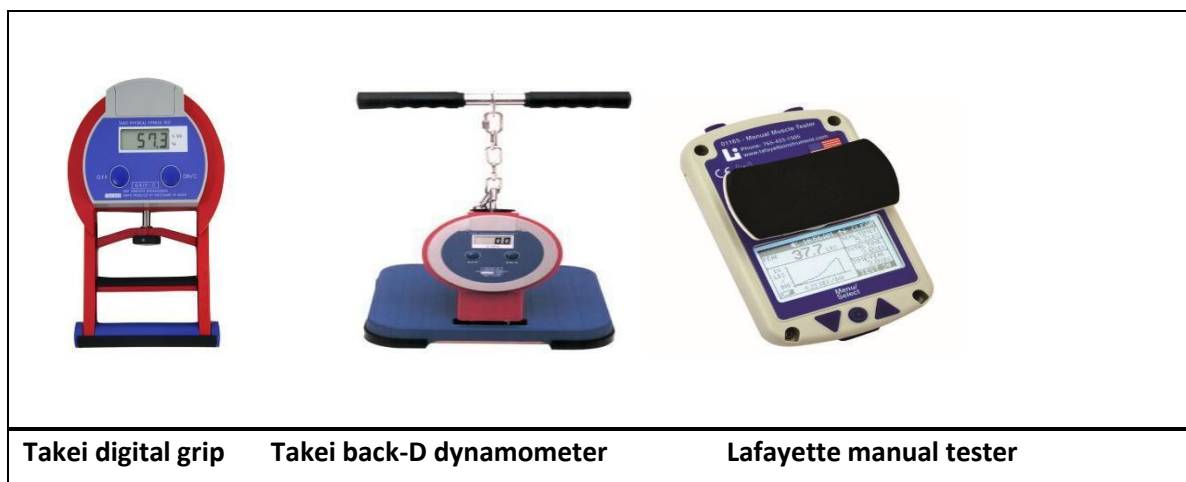
We will assess how well your lungs work by measuring the volume and effort of breathing using a Micro Plus spirometer (pictured below). This is a portable battery-operated hand-held microcomputer unit. An antibacterial filter will be attached for each lung test. A nose clip is used during each test to prevent nasal breathing. The test will require you to stand upright, place your mouth tightly around the mouthpiece and breathe in fully prior to a breathing out fully. You will be encouraged to continue forcing air out until your lungs are empty. Any coughing or accidental

blocking of the mouthpiece will render that attempt void and will need to be repeated. The test will be repeated until two satisfactory results are achieved. One minute of normal breathing will be allowed between tests for you to recover normal lung function.



Muscle testing

Muscle Strength: Muscles in your upper body will be measured using the devices in the picture below. Your back muscle strength will be measured using a Takei back-D dynamometer. A manual muscle tester will be used to measure muscles in your lower body (pictured below).



Takei digital grip

Takei back-D dynamometer

Lafayette manual tester

Muscle Endurance: Upper limb muscle endurance will be measured using a modified push-up test and lower limb muscle endurance testing will be measured using a wall squat test.

Muscle Power: A digital force plate will measure your lower limb power, and a medicine ball will be used to measure upper limb power.



Balance

A HUR balance platform will assess your balance. You will perform simple balance exercises on this platform (pictured below).



Quality of Life

You will complete a questionnaire for scoliosis patients.

What does the targeted exercise rehabilitation programme involve?

A Chartered Physiotherapist will supervise the bi-weekly exercise programme over 12 weeks. The physiotherapist will be provided with a specific rehabilitation programme for each participant based on the results of the physical assessments. The proposed programme will be based on

calisthenics, designed using individual body weight; no free weights or weight machines will be used. Each session will include a warmup and warm down period. All exercises will be demonstrated to the participant prior to commencement. The physiotherapist will also provide assistance/ modification of exercises to any participant who has difficulty executing the technique. Exercises will be set in a circuit and will include a variety and combination of exercises targeting each individual participant's needs. Exercises will be varied to reduce post exercise stiffness. All exercises selected will be appropriate to the age group and levels of muscular and aerobic fitness. The in-person session will be private and last approximately 45 minutes.

The 12-week home exercise programme will be a non-supervised, participant specific, rehabilitation programme, remotely monitored on a weekly basis via zoom call and pre-agreed with each participant. Each participant will maintain an electronic rehabilitation log of physical activity. With agreed access by the lead investigator, weekly maintenance of the rehabilitation log is expected.

Are there any benefits to taking part in this study?

Yes. When you complete the tests you will receive an individual health report which details your fitness levels and body composition. This report will help to understanding your own fitness level, your strengths and weaknesses. This report can be used to guide your own personal exercise plans. Participating in this study may also benefit adolescents with scoliosis. If we find that differences exist between groups that have scoliosis and those that do not, it will allow us to investigate ways these differences can be addressed.

Are there any risks involved in taking part in this study?

A bad response to exercise testing is rare, especially when you have no medical history that increases your risk. However, you may feel some pain and discomfort. It is also possible that you could experience abnormal blood pressure, fainting, irregular heart rhythm, and a muscle cramping. These events are unlikely and every effort will be made to minimise any risk to you. We will check your health before testing and carefully monitor you during and after each test. If you experience any of the above, the test will be stopped immediately. If symptoms do not disappear, you will be seen by a doctor and if necessary, brought to A&E in St. James's Hospital. Your doctor will also be informed.

Do I need my parents' consent to take part in this study?

If you are under the age of 16, you will need your parent's written informed consent to take part.

Confidentiality and Data Protection

What information will be collected?

Personal information will be collected during this study. This will include your gender, age, medical history, body composition, strength, lung function and fitness levels. We will also collect information on the quality of your life using a questionnaire. We need this information to compare people with AIS with those that have no scoliosis. Only information which is important to the study will be collected and used (this process is called “data minimisation”).

Who has access to the collected information?

The research team will have access to your data. All members of the team have undergone training in data protection law and practice, before starting this project.

How will my information be stored and protected?

Your identity will remain confidential. All of your details and results will be coded with a numerical ID (this is called “pseudonymisation”). The file with your name and code will be protected with a password. Only the Lead Investigator will have access to this password. Your name and personal details will not be published and will not be disclosed to anyone. All information relating written on paper form will be stored in a locked filing cabinet within a secure office. Only the Lead Investigator will have access to this. All information will be transferred to electronic file. This file will be stored on a password-protected PC at the Trinity Centre for Health Sciences in St James’s Hospital. Your study information and results will be kept in Trinity College for 5 years. It will then be destroyed. Electronic data will be erased, and all paper copy forms will be shredded.

How will my information be used, now and in the future?

The information collected in this study will be grouped together with a lot of other similar information. Results from this study may be published in international magazines. They may also be shared at research conferences or used to compare other similar studies. However, your information will remain coded, and your personal details will never be published or disclosed to anyone. Your information will only be used for comparative purposes in studies that have Research Ethics Committee approval. Your rights under GDPR will apply for use of information in future studies. All the people involved in this project are required to keep your information safe.

Is there any risk with processing and storing my data? What will happen if there is a data breach?

A data breach occurs when your information is lost or stolen. As all data will be collected at one location, there is a low risk of a data breach in this study. However, in the unlikely event of a data

breach you will be notified as soon as possible. The breach will be immediately reported to the Data Protection Commissioner. Your data will be collected as pseudonymised data and the key to your identity will be secured separately. So in the event of a data breach, it will not be possible for anyone to link the data to you.

What are my rights under GDPR?

You have the right to:

- Access your information
- You can change any mistakes in your data
- Have your information deleted
- Data portability (moving your data from one controller to another)
- Object to or stop the processing or profiling of your data
- Lodge a complaint to the Data Protection Commissioner (contact: +353 57 8684800 or +353 (0)761 104 800; <https://dataprotection.ie/en/contact>).

What is the lawful basis to using my personal information?

Your information will be processed under the lawful basis of Article 6(1) (e) and 9(2) (i) of the EU General Data Protection Act 2016. If you have any questions about your information, or the General Data Protection Rules (GDPR), you can contact the research team (details at end of document) or the Data Protection Officer of Trinity College Dublin, by email: dataprotection@tcd.ie.

Insurance

This study is covered by insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation

Participation in this study is voluntary. After you have read this document you will have the study procedures, risks and benefits explained to you. You will then have a chance to ask any questions you have. If you are happy with everything, you will be asked to sign a consent form before taking part. You do not have to take part in this study and you may stop at any stage. Even if the study has already started. You do not have to give a reason for not taking part in or for leaving the study. If you decide not to participate, or if you withdraw participation, you will not give up any benefits which you had before entering the study. You do not have to take part in the study if you do not want to. If you do not give consent, or withdraw your consent, no attempt will be made to access your data, and **no** application will be made by the research team for a consent exemption to the Health Research Consent Declaration Committee.

If you would like more information or if you decide to stop taking part. Contact Tony Rafferty on the details below.

Stopping the Study

The research team may stop your participation in the study at any time without your consent.

Permission

This project has been approved by Beacon Hospital, Sandyford Dublin 18, The people involved in this project are not involved with the hospital approval.

How can I prepare for the assessments?

If you consent to taking part in this study, the following points explain how to prepare for your testing day.

- Please fast from midnight on the night before your assessment days. You may drink water, but refrain from caffeine drinks, energy drinks, and alcohol. Fasting ensures more accurate results for body composition analysis. A snack and drink will be provided to you after each assessment.
- Please wear clothing and footwear suitable for exercise.
- Bring a towel, shower gel, and change of clothes if you wish to shower after testing.
- Please arrange a lift or use public transport to get to the testing venue. Please avoid walking or cycling on the days of your visit. The results of your fitness test will be more accurate.
- Please refrain from strenuous physical activity for 24-hours prior to each assessment.
- Please continue with your normal sports or exercise during the study. Do not do any extra sports or exercise.

-

Further information

You can obtain more information or answers to your questions about the study, your participation in the study, and your rights, from **Tony Rafferty, the main investigator who can be contacted on 0873986551 or emailed at raffertt@tcd.ie**. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

Lead Investigator: Tony Rafferty, Discipline of Physiotherapy, School of Medicine, Trinity College Dublin: Contact: Tel 087 3986551, E-mail raffertt@tcd.ie

Lead Co-Investigator: Patrick Kiely, Consultant Orthopaedic Surgeon, Beacon Hospital, Sandyford Dublin 18.

Research Supervisors & Co-Investigators: Dr Sara Dockrell & Dr Neil Fleming: Contact: Tel (01) 8962121, E-mail: sara.dockrell@tcd.ie; neil.fleming@tcd.ie

Data Controller: Trinity College Dublin.

Data Protection Officer: Data Protection, Trinity College Dublin

Contact: E-mail: dataprotection@tcd.ie

Appendix 2.11: Participant Information leaflet – Mild and Moderate AIS age 12-14.



Participant Information Leaflet

A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study.

Introduction

This study is about Adolescent Idiopathic Scoliosis (AIS). There is little research into muscle strength in scoliosis. Recent research says adolescents with scoliosis may have weaker muscles. Previous studies have also show that adolescents with AIS also have lower lung function and fitness levels. This study hopes to add to the knowledge in this area. It may help us find a way to improve adolescents with AIS.

Aim of current study

The aims of the current study are:

Study 1. To assess and compare muscle strength, balance, fitness and quality of life between healthy adolescents and those with AIS.

Study 2. To assess the effects of a 4-month scoliosis specific exercise rehabilitation programme in those with mild and moderate AIS when compared to adolescents diagnosed with mild and moderate AIS who have received standard hospital care and adolescents who do not have AIS.

Study 3. To examine the effect of spinal fusion surgery on muscle strength, balance, fitness and quality of life by re-assessing severe AIS participants 3 months after surgery.

Study 4. To examine the effects of a 12-week physiotherapy exercise programme and a 12-week home exercise programme on adolescents who have undergone spinal fusion surgery.

We will also be recruiting adolescents who do not have AIS. We will compare adolescents with AIS to a healthy group of adolescents. If you have a recent diagnosis of mild or moderate AIS and would like to take part in this study, please take time to read this document carefully. Before agreeing to participate you should understand the risks and benefits of taking part in the study. This is known as “Informed Consent”.

Who is doing the research?

The lead investigator for this study is Tony Rafferty. Tony is a CORU registered Chartered Physiotherapist. He specialises in sports and exercise medicine at Trinity College Dublin. The Co-lead investigator is Mr. Patrick Kiely. Pat is a surgeon Beacon Hospital, Sandyford Dublin 18. He works with children who have scoliosis. This study will include children and adolescents from Children’s Health Ireland, Beacon Hospital and Blackrock Clinic.

Who can take part in the study?

To be involved in this study, you must:

1. Be 12 - 21 years of age.
2. Have a diagnosis of mild or moderate Adolescent Idiopathic Scoliosis
3. Have no illness or musculoskeletal injury, reported neurological, or balance problems that would restrict exercise.
4. Be able to cooperate, take, and follow instructions in English
5. Have written consent from your parents or legal guardians.
6. Have the ability to attend two, 2-hour physical assessments in the Trinity Centre for Health Sciences, James’s Hospital Dublin 8.

You cannot take part in this study if:

1. You have a history of a heart condition (such as acute cardiac event, unstable chest pain, irregular heartbeat, and cardiac infection).
2. You have an existing acute or chronic lung condition.
3. You have an existing acute or chronic neurological condition.
4. You have abnormal blood pressure.
5. You are fitted with an electronic device (e.g. pacemaker).

6. You play sport at elite level.
7. You are pregnant or are a breastfeeding mother.
8. You have been advised by your Doctor not to exercise.
9. You answer “yes” to any one question on the PAR-Q. This is a standard physical activity readiness questionnaire, which you will complete before exercise testing begins.
10. You have incomplete or dissatisfactory medical screening prior to testing.
11. You are under the age of 12 or over the age of 21.

What does this study involve?

You will be invited to attend the Trinity Centre for Health Sciences, St. James’s Hospital, Dublin 8, for a physical assessment on 2 occasions. You will need to bring a parent or legal guardian with you. The assessment will take approximately 2 hours. Assessments will be scheduled to suit you.

What does the assessment involve?

Upon arrival, you will complete short questionnaire about fitness, physical activity and quality of life. When these are completed your standing height and weight will then be measured. Your resting heart rate and blood pressure will also be measured. We will estimate the amount of fat, water and muscle in your body using a Tanita body composition analyser (pictured, right). This machine is non-invasive and will not cause you any pain. You will be asked to remove your shoes and socks and stand on the body composition analyser.



Cardiorespiratory fitness test: Bike Ergometer

Before exercising, you will complete a short questionnaire (the Physical Activity Readiness Questionnaire, or PAR-Q). The results of this questionnaire will indicate if they are safe to carry out an exercise test. you will be familiarised with how the test will work and shown the equipment to be used in this study: a gas analysis system with a facemask and heart rate monitor (pictured, right).

For this test, participants will be fitted with a heart rate monitor and a gas exchange mask and asked to sit on the cycle ergometer for 3 minutes. Resting measurements taken in this period. The test will follow the Godfrey protocol. Each minute of cycling is harder than the previous one.

The participant will keep cycling for as long as they can. Heart rate monitored throughout the test.

You can end the test at any point, if you feel any pain or discomfort, if you feel dizzy, too breathless, or if you feel faint or too tired. The researcher will be monitoring for unexpected changes in blood pressure and heart rate, and will end the test if these occur, or if there are any technical difficulties with the equipment used. At the end of the test, there will be a 5-minute cool-down phase, at a slow pace.



Lung function test.

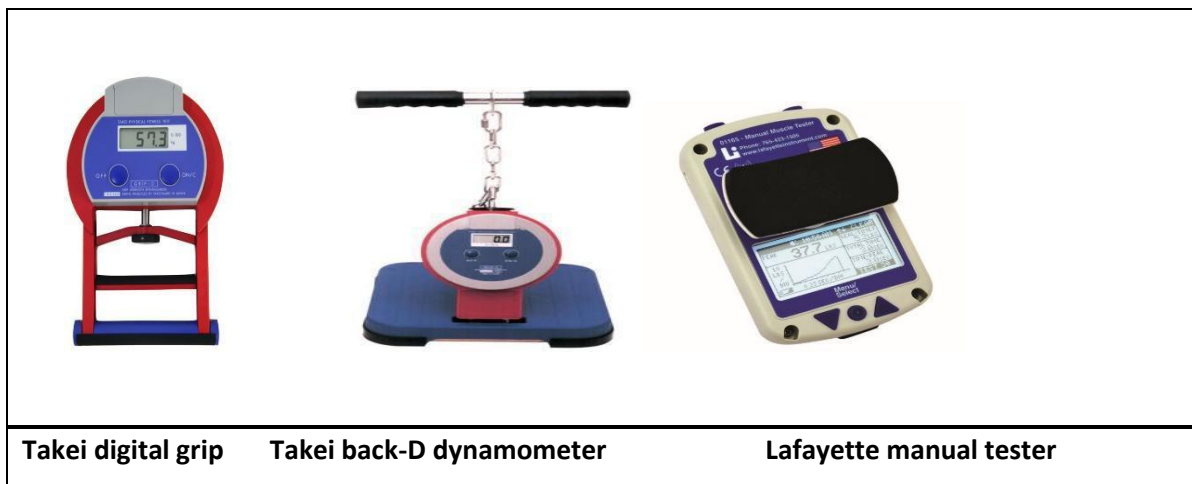
We will assess how well your lungs work by measuring the volume and effort of breathing using a Micro Plus spirometer (pictured below). This is a portable battery-operated hand-held microcomputer unit. An antibacterial filter will be attached for each lung test. A nose clip is used during each test to prevent nasal breathing. The test will require you to stand upright, place your mouth tightly around the mouthpiece and breathe in fully prior to a breathing out fully. You will be encouraged to continue forcing air out



until your lungs are empty. Any coughing or accidental blocking of the mouthpiece will render that attempt void and will need to be repeated. The test will be repeated until two satisfactory results are achieved. One minute of normal breathing will be allowed between tests for you to recover normal lung function.

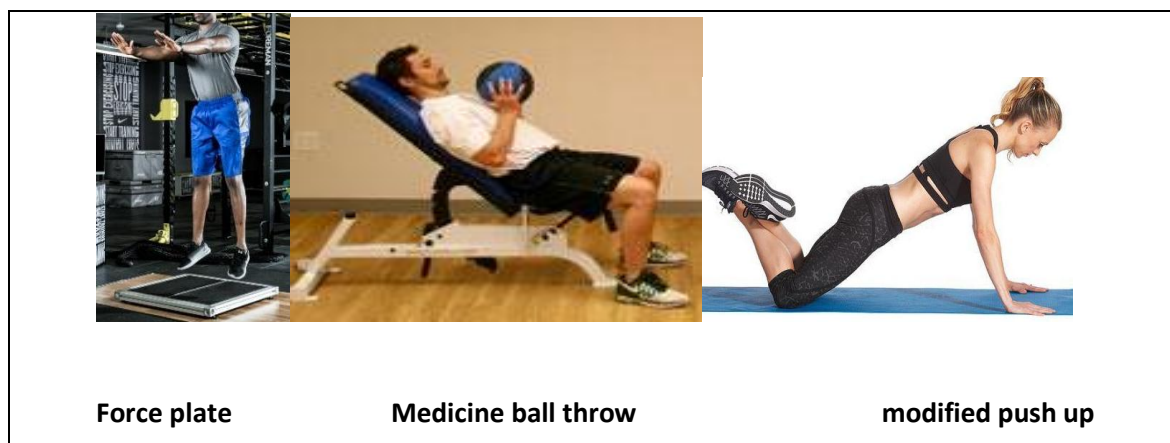
Muscle testing

Muscle Strength: Muscles in your upper body will be measured using the devices in the picture below. Your back muscle strength will be measured using a Takei back-D dynamometer. A manual muscle tester will be used to measure muscles in your lower body (pictured below).



Muscle endurance: Upper limb muscle endurance will be measured using a modified push-up test and lower limb muscle endurance testing will be measured by a wall squat test.

Muscle Power: A digital force plate will measure your lower limb power, and a medicine ball will be used to measure upper limb power.



Balance

A HUR balance platform will assess your balance. You will perform simple balance exercises on this platform (pictured below).



Quality of Life

You will complete a questionnaire for people with scoliosis.

Are there any benefits to taking part in this study?

Yes. When you complete the tests you will receive an individual health report which details your fitness levels and body composition. This report will help to understanding your own fitness level, your strengths and weaknesses. This report can be used to guide your own personal exercise plans. Participating in this study may also benefit adolescents with scoliosis. If we find that differences exist between groups that have scoliosis and those that do not, it will allow us to investigate ways these differences can be addressed.

Are there any risks involved in taking part in this study?

A bad response to exercise testing is rare, especially when you have no medical history that increases your risk. However, you may feel some pain and discomfort. It is also possible that you could experience abnormal blood pressure, fainting, irregular heart rhythm, and a muscle cramping. These events are unlikely, and every effort will be made to minimise any risk to you. We will check your health before testing and carefully monitor you during and after each test. If you experience any of the above, the test will be stopped immediately. If symptoms do not disappear, you will be seen by a doctor and if necessary, brought to A&E in St. James's Hospital. Your doctor will also be informed.

Do I need my parents' consent to take part in this study?

If you are under the age of 16, you will need your parent's written informed consent to take part.

Confidentiality and Data Protection

What information will be collected?

Personal information will be collected during this study. This will include your gender, age, medical history, body composition, strength, lung function and fitness levels. We will also collect information on the quality of your life using a questionnaire. We need this information to compare people with AIS with those that have no scoliosis. Only information which is important to the study will be collected and used (this process is called “data minimisation”).

Who has access to the collected information?

The research team will have access to your data. All members of the team have undergone training in data protection law and practice, before starting this project.

How will my information be stored and protected?

Your identity will remain confidential. All of your details and results will be coded with a numerical ID (this is called “pseudonymisation”). The file with your name and code will be protected with a password. Only the Lead Investigator will have access to this password. Your name and personal details will not be published and will not be disclosed to anyone. All information relating written on paper form will be stored in a locked filing cabinet within a secure office. Only the Lead Investigator will have access to this. All information will be transferred to electronic file. This file will be stored on a password-protected PC at the Trinity Centre for Health Sciences in St James’s Hospital. Your study information and results will be kept in Trinity College for 5 years. It will then be destroyed. Electronic data will be erased, and all paper copy forms will be shredded.

How will my information be used, now and in the future?

The information collected in this study will be grouped together with a lot of other similar information. Results from this study may be published in international magazines. They may also be shared at research conferences or used to compare other similar studies. However, your information will remain coded and your personal details will never be published or disclosed to anyone. Your information will only be used for comparative purposes in studies that have Research Ethics Committee approval. Your rights under GDPR will apply for use of information in future studies. All the people involved in this project are required to keep your information safe.

Is there any risk with processing and storing my data? What will happen if there is a data breach?

A data breach occurs when your information is lost or stolen. As all data will be collected at one location, there is a low risk of a data breach in this study. However, in the unlikely event of a data breach you will be notified as soon as possible. The breach will be immediately reported to the Data Protection Commissioner. Your data will be collected as pseudonymised data and the key to your identity will be secured separately. So in the event of a data breach, it will not be possible for anyone to link the data to you.

What are my rights under GDPR?

You have the right to:

- Access your information
- You can change any mistakes in your data
- Have your information deleted
- Data portability (moving your data from one controller to another)
- Object to or stop the processing or profiling of your data
- Lodge a complaint to the Data Protection Commissioner (contact: +353 57 8684800 or +353 (0)761 104 800; <https://dataprotection.ie/en/contact>).

What is the lawful basis to using my personal information?

Your information will be processed under the lawful basis of Article 6(1) (e) and 9(2) (i) of the EU General Data Protection Act 2016. If you have any questions about your information, or the General Data Protection Rules (GDPR), you can contact the research team (details at end of document) or the Data Protection Officer of Trinity College Dublin, by email: dataprotection@tcd.ie .

Insurance

This study is covered by insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation

Participation in this study is voluntary. After you have read this document you will have the study procedures, risks and benefits explained to you. You will then have a chance to ask any questions you have. If you are happy with everything, you will be asked to sign a consent form before taking part. You do not have to take part in this study and you may stop at any stage. Even if the study has already started. You do not have to give a reason for not taking part in or for leaving the study.

If you decide not to participate, or if you withdraw participation, you will not give up any benefits which you had before entering the study. You do not have to take part in the study if you do not want to. If you do not give consent, or withdraw your consent, no attempt will be made to access your data, and **no** application will be made by the research team for a consent exemption to the Health Research Consent Declaration Committee.

If you would like more information or if you decide to stop taking part. Contact Tony Rafferty on the details below.

Stopping the Study

The research team may stop your participation in the study at any time without your consent.

Permission

This project has been approved by Beacon Hospital, Sandyford Dublin 18. The people involved in this project are not involved with the hospital approval.

How can I prepare for the assessments?

If you consent to taking part in this study, the following points explain how to prepare for your testing day.

- Please fast from midnight on the night before your assessment days. You may drink water, but refrain from caffeine drinks, energy drinks, and alcohol. Fasting ensures more accurate results for body composition analysis. A snack and drink will be provided to you after each assessment.
- Please wear clothing and footwear suitable for exercise.
- Bring a towel, shower gel, and change of clothes if you wish to shower after testing.
- Please arrange a lift or use public transport to get to the testing venue. Please avoid walking or cycling on the days of your visit. The results of your fitness test will be more accurate.
- Please refrain from strenuous physical activity for 24-hours prior to each assessment.
- Please continue with your normal sports or exercise during the study. Do not do any extra sports or exercise.

Further information

You can obtain more information or answers to your questions about the study, your participation in the study, and your rights, from **Tony Rafferty, the main investigator who can be contacted on 0873986551 or emailed at raffertt@tcd.ie**. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

Lead Investigator: Tony Rafferty, Discipline of Physiotherapy, School of Medicine, Trinity College Dublin: Contact: Tel 087 3986551, E-mail raffertt@tcd.ie

Lead Co- Investigator: Patrick Kiely, Consultant Orthopaedic Surgeon, Beacon Hospital, Sandyford Dublin 18.

Research Supervisors & Co-Investigators: Dr Sara Dockrell& Dr Neil Fleming: Contact: Tel (01) 8962121, E-mail: sara.dockrell@tcd.ie; neil.fleming@tcd.ie

Data Controller: Trinity College Dublin.

Data Protection Officer: Data Protection, Trinity College Dublin

Contact: E-mail: dataprotection@tcd.ie

Appendix 2.12: Participant Information leaflet – Controls age 12-14.



Participant Information Leaflet

A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study.

Introduction

You are invited to take part in a clinical research study as part of the control group. The control group consists of healthy children and teenagers **who do not have a scoliosis**. This will allow us to compare those who have Adolescent Idiopathic Scoliosis (AIS) with those who do not have AIS (controls).

Before you decide whether you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP. Take time to ask questions, do not feel rushed and do not feel under pressure to make a quick decision. You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

Why is this study being done?

Some studies have suggested that children and teenagers with severe AIS have weaker lungs and are not as strong or as fit as children or teenagers who do not have AIS. This study hopes to find ways to address any weaknesses we find in children and teenagers with AIS.

Aim of current study

The aims of the current study are:

Study 1. To assess and compare muscle strength, balance, fitness and quality of life between healthy adolescents and those with AIS.

Study 2. To assess the effects of a 4-month scoliosis specific exercise rehabilitation programme in those with mild and moderate AIS.

Study 3. To examine the effect of spinal fusion surgery on muscle strength, balance, fitness and quality of life by re-assessing severe AIS participants 3 months after surgery.

Study 4. To examine the effects of a 12-week physiotherapy exercise programme along with a 12-week home exercise programme on adolescents who have undergone spinal fusion surgery.

Who is doing the research?

The lead investigator for this study is Tony Rafferty. Tony is a CORU registered Chartered Physiotherapist. He specialises in sports and exercise medicine at Trinity College Dublin. The Co-lead investigator is Mr. Patrick Kiely. Pat is a surgeon in Beacon Hospital, Sandyford Dublin 18. He works with children who have scoliosis. This study will include children and adolescents from Children's Health Ireland, Beacon Hospital and Blackrock Clinic.

Who can take part in the study?

To be involved in this study, you must:

1. Be 12 - 21 years of age.
2. Not have Adolescent Idiopathic Scoliosis.
3. Have no illness or injury.
4. Have no neurological or balance problems that would restrict exercise.
5. Be able to cooperate, take, and follow instructions in English.
6. Have written consent from your parents or legal guardians.
7. Be able to attend a 2-hour physical assessment in the Trinity Centre for Health Sciences, James's Hospital Dublin 8.

You cannot take part in this study if:

1. You have a history of a heart condition (such as acute cardiac event, unstable chest pain, irregular heartbeat, and cardiac infection).
2. You have an existing acute or chronic lung condition.
3. You have an existing acute or chronic neurological condition.

4. You have abnormal blood pressure.
5. You are fitted with an electronic device (e.g. pacemaker).
6. You play sport at elite level.
7. You are pregnant or are a breastfeeding mother.
8. You have been advised by your doctor not to exercise.
9. You answer “yes” to any one question on the PAR-Q. This is a standard physical activity readiness questionnaire, which you will complete before exercise testing begins.
10. You have incomplete or dissatisfactory medical screening prior to testing.
11. You are under the age of 12 or over the age of 21.

What does this study involve?

You will be invited to attend the Trinity Centre for Health Sciences, St. James’s Hospital, Dublin 8, or the Human Performance Laboratory, Watts building in the Anatomy Department in Trinity College Dublin 2, for a physical assessment. A parent or legal guardian will be required to attend with you. The visit will take approximately 2 hours and will be scheduled to suit you.

What does the assessment involve?

Upon arrival, you will complete short questionnaire about fitness, physical activity and quality of life. When these are complete your standing height and weight will be measured. Your resting heart rate and blood pressure will also be measured. We will estimate the amount of fat, water and muscle in your body using a Tanita body composition analyser (pictured, right). This machine is non-invasive and will not cause you any pain. You will be asked to remove your shoes and socks and stand on the body composition analyser.



Cardiorespiratory fitness test: Bike Ergometer

Before exercising, you will complete a short questionnaire (the Physical Activity Readiness Questionnaire, or PAR-Q). The results of this questionnaire will indicate if they are safe to carry out an exercise test. You will be familiarised with how the test will work and shown the equipment to be used in this study: a gas analysis system with a facemask and heart rate monitor (pictured, right).

For this test, participants will be fitted with a heart rate monitor and a gas exchange mask and asked to sit on the cycle ergometer for 3 minutes. Resting measurements taken in this period. The test will follow the Godfrey protocol. Each minute of cycling is harder than the previous one. you will keep cycling for as long as they can. Heart rate monitored throughout the test.



You can end the test at any point, if you feel any pain or discomfort, if you feel dizzy, too breathless, or if you feel faint or too fatigued. The researcher will be monitoring for unexpected changes in blood pressure and heart rate, and will end the test if these occur, or if there are any technical difficulties with the equipment used. At the end of the test, there will be a 5-minute cool-down phase, at a slow pace.

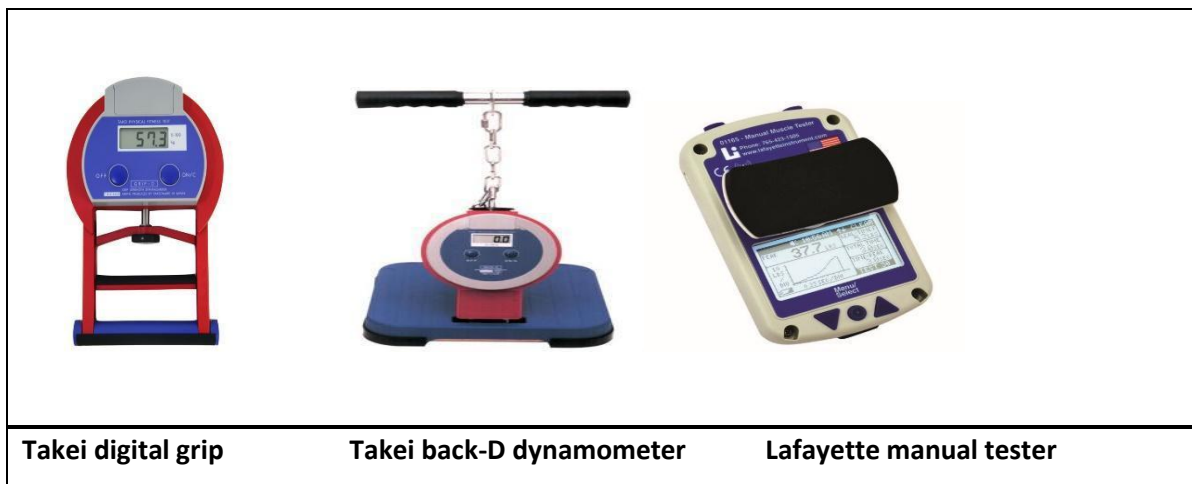
Lung function test.

We will assess how well your lungs work by measuring the volume and effort of breathing using a Micro Plus spirometer (pictured below). This is a portable battery-operated hand-held microcomputer unit. An antibacterial filter will be attached for each lung test. A nose clip is used during each test to prevent nasal breathing. The test will require you to stand upright, place your mouth tightly around the mouthpiece and breathe in fully prior to a breathing out fully. You will be encouraged to continue forcing air out until your lungs are empty. Any coughing or accidental blocking of the mouthpiece will render that attempt void and will need to be repeated. The test will be repeated until two satisfactory results are achieved. One minute of normal breathing will be allowed between tests for you to recover normal lung function.



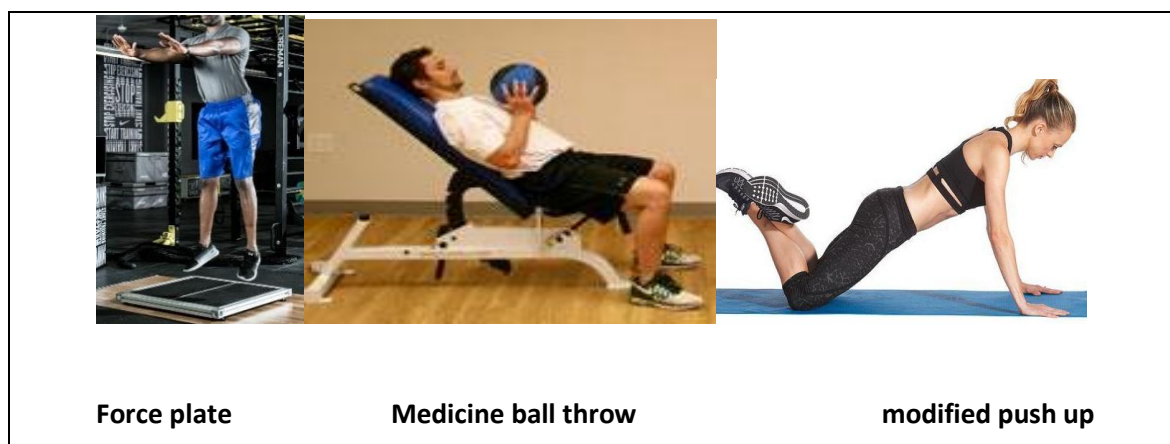
Muscle testing

Muscle Strength: Muscles in your upper body will be measured using the equipment in the picture below. Your back muscle strength will be measured using a Takei back-D dynamometer. A manual muscle tester will be used to measure muscles in your lower body (pictured below).



Muscle endurance: Upper limb muscle endurance will be measured using a modified push-up test and lower limb muscle endurance testing will be measured by a wall squat test.

Muscle Power: A digital force plate will measure your lower limb power, and a medicine ball will be used to measure upper limb power.



Balance

A HUR balance platform will assess your balance. You will perform simple balance exercises on this platform (pictured below).



Quality of Life

You will complete a short questionnaire.

Are there any benefits to taking part in this study?

Yes. When you complete the tests you will receive an individual health report which details your fitness levels and body composition. This report will help to understanding your own fitness level, your strengths and weaknesses. This report can be used to guide your own personal exercise plans. Participating in this study may also benefit adolescents with scoliosis. If we find that differences exist between groups that have scoliosis and those that do not, it will allow us to investigate ways these differences can be addressed.

Are there any risks involved in taking part in this study?

A bad response to exercise testing is rare, especially when you have no medical history that increases your risk. However, you may feel some pain and discomfort. It is also possible that you could experience abnormal blood pressure, fainting, irregular heart rhythm, and a muscle cramping. These events are unlikely and every effort will be made to minimise any risk to you. We will check your health before testing and carefully monitor you during and after each test. If you experience any of the above, the test will be stopped immediately. If symptoms do not disappear, you will be seen by a doctor and if necessary, brought to A&E in St. James's Hospital. Your doctor will also be informed.

Do I need my parents' consent to take part in this study?

If you are under the age of 16, you will need your parent's written informed consent to take part.

Confidentiality and Data Protection

What information will be collected?

Personal information will be collected during this study. This will include your gender, age, medical history, body composition, strength, lung function and fitness levels. We will also collect information on the quality of your life using a questionnaire. We need this information to compare people with AIS with those that have no scoliosis. Only information which is important to the study will be collected and used (this process is called “data minimisation”).

Who has access to the collected information?

The research team will have access to your data. All members of the team have undergone training in data protection law and practice, before starting this project.

How will my information be stored and protected?

Your identity will remain confidential. All of your details and results will be coded with a numerical ID (this is called “pseudonymisation”). The file with your name and code will be protected with a password. Only the Lead Investigator will have access to this password. Your name and personal details will not be published and will not be disclosed to anyone. All information relating written on paper form will be stored in a locked filing cabinet within a secure office. Only the Lead Investigator will have access to this. All information will be transferred to electronic file. This file will be stored on a password-protected PC at the Trinity Centre for Health Sciences in St James’s Hospital. Your study information and results will be kept Trinity College for 5 years. It will then be destroyed. Electronic data will be erased, and all paper copy forms will be shredded.

How will my information be used, now and in the future?

The information collected in this study will be grouped together with a lot of other similar information. Results from this study may be published in international magazines. They may also be shared at research conferences or used to compare other similar studies. However, your information will remain coded and your personal details will never be published or disclosed to anyone. Your information will only be used for comparative purposes in studies that have Research Ethics Committee approval. Your rights under GDPR will apply for use of information in future studies. All the people involved in this project are required to keep your information safe.

Is there any risk with processing and storing my data? What will happen if there is a data breach?

A data breach occurs when your information is lost or stolen. As all data will be collected at one location, there is a low risk of a data breach in this study. However, in the unlikely event of a data

breach you will be notified as soon as possible. The breach will be immediately reported to the Data Protection Commissioner. Your data will be collected as pseudonymised data and the key to your identity will be secured separately. So in the event of a data breach, it will not be possible for anyone to link the data to you.

What are my rights under GDPR?

You have the right to:

- Access your information
- You can change any mistakes in your data
- Have your information deleted
- Data portability (moving your data from one controller to another)
- Object to or stop the processing or profiling of your data
- Lodge a complaint to the Data Protection Commissioner (contact: +353 57 8684800 or +353 (0)761 104 800; <https://dataprotection.ie/en/contact>).

What is the lawful basis to using my personal information?

Your information will be processed under the lawful basis of Article 6(1) (e) and 9(2) (i) of the EU General Data Protection Act 2016. If you have any questions about your information, or the General Data Protection Rules (GDPR), you can contact the research team (details at end of document) or the Data Protection Officer of Trinity College Dublin, by email: dataprotection@tcd.ie.

Insurance

This study is covered by insurance. Nothing in this document restricts or curtails your rights.

Voluntary Participation

Participation in this study is voluntary. After you have read this document you will have the study procedures, risks and benefits explained to you. You will then have a chance to ask any questions you have. If you are happy with everything, you will be asked to sign a consent form before taking part. You do not have to take part in this study and you may stop at any stage. Even if the study has already started. You do not have to give a reason for not taking part in or for leaving the study. If you decide not to participate, or if you withdraw participation, you will not give up any benefits which you had before entering the study. You do not have to take part in the study if you do not want to. If you do not give consent, or withdraw your consent, no attempt will be made to access your data, and **no** application will be made by the research team for a consent exemption to the Health Research Consent Declaration Committee.

If you would like more information or if you decide to stop taking part. Contact Tony Rafferty on the details below.

Stopping the Study

The research team may stop your participation in the study at any time without your consent.

Permission

This project has been approved by Beacon Hospital, Sandyford Dublin 18. The people involved in this project are not involved with the hospital approval.

How can I prepare for the assessments?

If you consent to taking part in this study, the following points explain how to prepare for your testing day.

- Please fast from midnight on the night before your assessment days. You may drink water, but refrain from caffeine drinks, energy drinks, and alcohol. Fasting ensures more accurate results for body composition analysis. A snack and drink will be provided to you after each assessment.
- Please wear clothing and footwear suitable for exercise.
- Bring a towel, shower gel, and change of clothes if you wish to shower after testing.
- Please arrange a lift or use public transport to get to the testing venue. Please avoid walking or cycling on the days of your visit. The results of your fitness test will be more accurate.
- Please refrain from strenuous physical activity for 24-hours prior to each assessment.
- Please continue with your normal sports or exercise during the study. Do not do any extra sports or exercise.

Further information

You can obtain more information or answers to your questions about the study, your participation in the study, and your rights, from **Tony Rafferty, the main investigator who can be contacted on 0873986551 or emailed at raffertt@tcd.ie**. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

Lead Investigator: Tony Rafferty, Discipline of Physiotherapy, School of Medicine, Trinity College Dublin: Contact: Tel 087 3986551, E-mail raffertt@tcd.ie

Lead Co-Investigator: Patrick Kiely, Consultant Orthopaedic Surgeon, Beacon Hospital, Sandyford Dublin 18.

Research Supervisors & Co-Investigators: Dr Sara Dockrell & Dr Neil Fleming: Contact: Tel (01) 8962121, E-mail: sara.dockrell@tcd.ie; neil.fleming@tcd.ie

Data Controller: Trinity College Dublin.

Data Protection Officer: Data Protection, Trinity College Dublin, Contact: E-mail: dataprotection@tcd.ie

Appendix 3.1: Consent form - AIS participants age 16+.



Participant Consent Form

Explicit, informed, voluntary consent to partake in the research study.

Study Title: A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study

Lead Investigator: Mr. Tony Rafferty: Trinity College Dublin.

Co-lead Investigator: Mr. Pat Kiely: Beacon Hospital, Sandyford Dublin 18.

Academic Supervisors & Co-Investigators: Dr Sara Dockrell & Dr Neil Fleming: Trinity College Dublin

Study Information

Please read the participation information leaflet in full and clarify any concerns or queries with Tony Rafferty lead investigator before consenting to take part in this study.

Will my identity be known?

All data collected will be coded with numerical ID to maintain participant confidentiality. Data will be stored in a secure office and on a password protected computer for 5 years after the study is finished in accordance with good research standard guidelines and data protection legislation. It will be destroyed after this period of time by the relevant personnel. The information will not be used for any other purpose other than this research study without your permission. Participation is entirely voluntary, and you may withdraw your consent at any stage over the course of your involvement in this study.

Statement of Participant's Consent

Explicit, informed, voluntary consent to partake in the research study.

Please tick each item to give your consent.

I confirm that I have read and fully understood the relevant Participation Information Leaflet provided to me.	YES •	NO •	Initials
I understand I will be asked to undertake research which collects data about my gender, age and relevant medical history, as well as the assessment of body composition, my cardiorespiratory, lung and musculoskeletal function and my quality of life. I have been assured that information about me will be kept private and confidential.	YES •	NO •	Initials
I am aware of the benefits and risks of this research study. I understand the risks that have been explained to me.	YES •	NO •	Initials
I have had the opportunity to discuss the study and ask questions about the study, and I have received satisfactory answers to all my questions.	YES •	NO •	Initials
I have received enough information about this study and understand what is involved if I agree to participate.	YES •	NO •	Initials

I understand that I am free to withdraw from the study at any time without giving a reason and I understand that withdrawing from the study will not affect my future medical care.	YES •	NO •	Initials
I agree to be contacted by researchers as part of this study.	YES •	NO •	Initials
I give permission for Co- lead investigator to look at my medical records to get necessary information. I have been assured that information about me will coded and kept private and confidential.	YES •	NO •	Initials

***You are now entering a separate part of this consent form, relating to data protection* Explicit, informed, voluntary consent regarding data protection and storage.**

I understand that all of my data will be pseudonymised and minimised for this study The words 'pseudonymisation' and minimisation' have been explained to me.	YES •	NO •	Initials
I understand my name or other personal identifiers will not be disclosed to anybody and my personal data will be kept strictly confidential.	YES •	NO •	Initials
I understand the lead investigator will be processing my data and that Trinity College is in control of my data.	YES •	NO •	Initials
I understand that my data will be used for study analysis, and may be published in peer reviewed journals, in presentations, and may be disseminated at conferences but my data will remain confidential and none of my personal identifiers will be disclosed in these circumstances.	YES •	NO •	Initials

I understand how my data will be stored (pseudonymised and minimised in secure locations) and that it will be stored for a total of 5 years and will then be destroyed by the study investigators.	YES •	NO •	Initials
I have been made aware of my rights under the General Data Protection Regulations and contact details of the Data Protection Officer and Data Commissioner have been provided to me in the Participant Information Leaflet.	YES •	NO •	Initials
I have read and understood the personal data protection section of the Participant Information Leaflet.	YES •	NO •	Initials
I have had the opportunity to discuss data protection in this study and I have received satisfactory answers to all my questions.	YES •	NO •	Initials
I understand that I am free to withdraw from the study at any time without giving a reason with no consequence and my personal data will not be used and will be destroyed.	YES •	NO •	Initials
I freely and voluntarily consent to allow the researcher's use of my information (personal data) as part of this study as outlined in the information leaflet.	YES •	NO •	Initials

I understand that my data collected from the research study, may be used for comparative purposes in similar studies to this one.	YES •	NO •	Initials
I have read and understood the use of personal data in future studies section of the Participant Information Leaflet. I understand that my data will remain coded and personal identifiers will never be published or disclosed to anyone in the future and that all my data will be destroyed by Trinity College after 5 years.	YES •	NO •	Initials

I understand that I am free to withdraw my consent to use my personal data in future studies at any time without giving a reason, with no consequence, and my personal data will not be used and will be destroyed.	YES •	NO •	Initials
I freely and voluntarily consent for my data to be stored for comparative purposes in similar studies which is unrelated to the current study without further consent being required but only if the research is approved by a Research Ethics Committee.	YES •	NO •	Initials

Participant's Name (BLOCK CAPITALS)	
Participant's Signature	
Date	

To be completed by the **Researcher**:

I have fully explained the purpose and nature (including benefits and risks) of this study to the participant in a way that he could understand. I have invited the participant to ask questions on any aspect of the study.	YES •	NO •	Initials
I have fully explained the purpose and nature of data protection and the nature of storage and future use of personal data in this study to the participant in a way that he could understand. I have invited the participant to ask questions on any aspect of the study.	YES •	NO •	Initials

I confirm that I have given a copy of the information leaflet and consent form to the participant.	YES •	NO •	Initials

Researcher's Name (BLOCK CAPITALS)	
Researcher's Title and Qualifications	
Researcher's Signature	
Date	

Participant Consent Form: to contact General Practitioner in case of adverse finding or outcome

I, _____ (*participant's name in BLOCK CAPITALS*),
agree that if an unusual finding occurs during the pre-screening and/or the exercise
testing of this research study, the research team may contact my General Practitioner
to inform them of the findings.

The contact information of my General Practitioner is:

G.P. NAME:

G.P. ADDRESS:

G.P. CONTACT NUMBER:

Participant's Name:

Participant's Signature:

Date: _____

Appendix 3.2: Consent form - Control participants age 16+.



Participant Consent Form

Explicit, informed, voluntary consent to partake in the research study.

Study Title: A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study

Lead Investigator: Mr. Tony Rafferty: Trinity College Dublin.

Co-lead Investigator: Mr. Pat Kiely: Beacon Hospital, Sandyford Dublin 18.

Academic Supervisors & Co-Investigators: Dr Sara Dockrell & Dr Neil Fleming: Trinity College Dublin

Study Information

Please read the participation information leaflet in full and clarify any concerns or queries with the Tony Rafferty lead investigator before consenting to take part in this study.

Will my identity be known?

All data collected will be coded with numerical ID to maintain participant confidentiality. Data will be stored in a secure office and on a password protected computer for 5 years after the study is finished in accordance with good research standard guidelines and data protection legislation. It will be destroyed after this period of time by the relevant personnel. The information will not be used for any other purpose other than this research study without your permission. Participation is entirely voluntary, and you may withdraw your consent at any stage over the course of your involvement in this study.

Statement of Participant's Consent

Explicit, informed, voluntary consent to partake in the research study.

Please tick each item to give your consent.

I confirm that I have read and fully understood the relevant Participation Information Leaflet provided to me.	YES •	NO •	Initials
I understand I will be asked to undertake research which collects data about my gender, age and relevant medical history, as well as the assessment of body composition, my cardiorespiratory, lung and musculoskeletal function and my quality of life. I have been assured that information about me will be kept private and confidential.	YES •	NO •	Initials
I am aware of the benefits and risks of this research study. I understand the risks that have been explained to me.	YES •	NO •	Initials
I have had the opportunity to discuss the study and ask questions about the study, and I have received satisfactory answers to all my questions.	YES •	NO •	Initials
I have received enough information about this study and understand what is involved if I agree to participate.	YES •	NO •	Initials

I understand that I am free to withdraw from the study at any time without giving a reason and I understand that withdrawing from the study will not affect my future medical care.	YES •	NO •	Initials
I agree to be contacted by researchers as part of this study.	YES •	NO •	Initials

***You are now entering a separate part of this consent form, relating to data protection* Explicit, informed, voluntary consent regarding data protection and storage.**

I understand that all of my data will be pseudonymised and minimised for this study The words 'pseudonymisation' and 'minimisation' have been explained to me.	YES •	NO •	Initials
I understand my name or other personal identifiers will not be disclosed to anybody and my personal data will be kept strictly confidential.	YES •	NO •	Initials
I understand the lead investigator will be processing my data and that Trinity College is in control of my data.	YES •	NO •	Initials
I understand that my data will be used for study analysis, and may be published in peer reviewed journals, in presentations, and may be disseminated at conferences but my data will remain confidential and none of my personal identifiers will be disclosed in these circumstances.	YES •	NO •	Initials
I understand how my data will be stored (pseudonymised and minimised in secure locations) and that it will be stored for a total of 5 years and will then be destroyed by the study investigators.	YES •	NO •	Initials
I have been made aware of my rights under the General Data Protection Regulations, and contact details of the Data	YES •	NO •	Initials

Protection Officer and Data Commissioner have been provided to me in the Participant Information Leaflet.			
I have read and understood the personal data protection section of the Participant Information Leaflet.	YES •	NO •	Initials
I have had the opportunity to discuss data protection in this study and I have received satisfactory answers to all my questions.	YES •	NO •	Initials
I understand that I am free to withdraw from the study at any time without giving a reason with no consequence and my personal data will not be used and will be destroyed.	YES •	NO •	Initials
I freely and voluntarily consent to allow the researcher's use of my information (personal data) as part of this study as outlined in the information leaflet.	YES •	NO •	Initials

I understand that my data collected from the research study, may be used for comparative purposes in similar studies to this one.	YES •	NO •	Initials
I have read and understood the use of personal data in future studies section of the Participant Information Leaflet (dated 25 th January 2019). I understand that my data will remain coded and personal identifiers will never be published or disclosed to anyone in the future and that all my data will be destroyed by Trinity College after 5 years.	YES •	NO •	Initials
I understand that I am free to withdraw my consent to use my personal data in future studies at any time without giving a reason, with no consequence, and my personal data will not be used and will be destroyed.	YES •	NO •	Initials

I freely and voluntarily consent for my data to be stored for comparative purposes in similar studies which is unrelated to the current study without further consent being required but only if the research is approved by a Research Ethics Committee.	YES •	NO •	Initials

Participant's Name (BLOCK CAPITALS)	
Participant's Signature	
Date	

To be completed by the **Researcher**:

I have fully explained the purpose and nature (including benefits and risks) of this study to the participant in a way that he could understand. I have invited the participant to ask questions on any aspect of the study.	YES •	NO •	Initials
I have fully explained the purpose and nature of data protection and the nature of storage and future use of personal data in this study to the participant in a way that he could understand. I have invited the participant to ask questions on any aspect of the study.	YES •	NO •	Initials

I confirm that I have given a copy of the information leaflet and consent form to the participant.	YES •	NO •	Initials

Researcher's Name (BLOCK CAPITALS)	
Researcher's Title and Qualifications	
Researcher's Signature	
Date	

Participant Consent Form: to contact General Practitioner in case of adverse finding or outcome

I, _____ (*participant's name in BLOCK CAPITALS*),
agree that if an unusual finding occurs during the pre-screening and/or the exercise
testing of this research study, the research team may contact my General Practitioner
to inform them of the findings.

The contact information of my General Practitioner is:

G.P. NAME:

G.P. ADDRESS:

G.P. CONTACT NUMBER:

Participant's Name:

Participants Signature:

Date: _____

Appendix 3.3: Parental consent – AIS.



Beacon Hospital



Blackrock Clinic



Children's Health Ireland
at Crumlin



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Parental Consent Form

Explicit, informed, voluntary consent to partake in the research study.

Study Title: The National Adolescent Idiopathic Scoliosis Physical Wellbeing Study

Lead Investigator: Mr. Tony Rafferty: Trinity College Dublin.

Co-lead Investigator: Mr. Pat Kiely: Our lady's Beacon Hospital, Sandyford Dublin 18.

Academic Supervisors & Co-Investigators: Dr Sara Dockrell & Dr Neil Fleming: Trinity College Dublin

Study Information

Please read the participation information leaflet in full and clarify any concerns or queries with Tony Rafferty the lead investigator before consenting to take part in this study.

Will my child's identity be known?

All data collected will be coded with numerical ID to maintain participant confidentiality. Data will be stored in a secure office and on a password protected computer for 5 years

after the study is finished in accordance with good research standard guidelines and data protection legislation. It will be destroyed after this period of time by the relevant personnel. The information will not be used for any other purpose other than this research study without your permission. Participation is entirely voluntary, and you may withdraw your consent at any stage over the course of your involvement in this study.

Statement of Parental Consent

Explicit, informed, voluntary consent to partake in the research study.

Please tick each item to give your consent.

I confirm that I have read and fully understood the relevant Participation Information Leaflet provided to me.	YES •	NO •	Initials
I understand my child will be asked to undertake research which collects data about their gender, age and relevant medical history, as well as the assessment of body composition, cardiorespiratory, lung and musculoskeletal function and quality of life. I have been assured that information about my child will be kept private and confidential.	YES •	NO •	Initials
I am aware of the benefits and risks of this research study. I understand the risks that have been explained to me.	YES •	NO •	Initials
I have had the opportunity to discuss the study and ask questions about the study, and I have received satisfactory answers to all my questions.	YES •	NO •	Initials
I have received enough information about this study and understand what is involved if I agree to allow my child participate.	YES •	NO •	Initials
I understand that I am free to withdraw my child from the study at any time without giving a reason and I understand that withdrawing from the study will not affect future medical care.	YES •	NO •	Initials

I agree to be contacted by researchers as part of this study.	YES •	NO •	Initials
I give permission for the Co- lead investigator to look at my child's medical records to get necessary information. I have been assured that information about my child will be coded and kept private and confidential.	YES •	NO •	Initials

***You are now entering a separate part of this consent form, relating to data protection* Explicit, informed, voluntary consent regarding data protection and storage.**

I understand that all of my child's data will be pseudonymised and minimised for this study The words 'pseudonymisation' and 'minimisation' have been explained to me.	YES •	NO •	Initials
I understand my child's name or other personal identifiers will not be disclosed to anybody and my child's personal data will be kept strictly confidential.	YES •	NO •	Initials
I understand the lead investigator will be processing my child's data and that Trinity College is in control of my child's data.	YES •	NO •	Initials
I understand that my child's data will be used for study analysis, and may be published in peer reviewed journals, in presentations, and may be disseminated at conferences but my child's data will remain confidential and none of my personal identifiers will be disclosed in these circumstances.	YES •	NO •	Initials
I understand how my child's data will be stored (pseudonymised and minimised in secure locations) and that it will be stored for a total of 5 years and will then be destroyed by the study investigators.	YES •	NO •	Initials
I have been made aware of my child's rights under the General Data Protection Regulations and contact details of the Data	YES •	NO •	Initials

Protection Officer and Data Commissioner have been provided to me in the Parental Information Leaflet.			
I have read and understood the personal data protection section of the Parental Information Leaflet.	YES •	NO •	Initials
I have had the opportunity to discuss data protection in this study and I have received satisfactory answers to all my questions.	YES •	NO •	Initials
I understand that I am free to withdraw my child from the study at any time without giving a reason with no consequence and my child's personal data will not be used and will be destroyed.	YES •	NO •	Initials
I freely and voluntarily consent to allow the researcher's use of my child's information (personal data) as part of this study as outlined in the parental information leaflet.	YES •	NO •	Initials

I understand that my child's data collected from the research study, may be used for comparative purposes in similar studies to this one.	YES •	NO •	Initials
I have read and understood the use of personal data in future studies section of the Participant Information Leaflet. I understand that my child's data will remain coded and personal identifiers will never be published or disclosed to anyone in the future and that all my child's data will be destroyed by Trinity College after 5 years.	YES •	NO •	Initials
I understand that I am free to withdraw my consent to use my child's personal data in future studies at any time without giving a reason, with no consequence, and my child's personal data will not be used and will be destroyed.	YES •	NO •	Initials

I freely and voluntarily consent for my child's data to be stored for comparative purposes in similar studies which is unrelated to the current study without further consent being required but only if the research is approved by a Research Ethics Committee.	YES •	NO •	Initials

Participant's Name (BLOCK CAPITALS)	
Legal guardians Name (BLOCK CAPITALS)	
Legal guardians Signature	
Date	

To be completed by the **Researcher**:

I have fully explained the purpose and nature (including benefits and risks) of this study to the participant's legal guardian(s) in a way that could be understood. I have invited the participant's legal guardian(s) to ask questions on any aspect of the study.	YES •	NO •	
I have fully explained the purpose and nature of data protection and the nature of storage and future use of personal data in this study to the participants legal guardian(s) in a way they could be understood. I have invited the participant's legal guardian(s) to ask questions on any aspect of the study.	YES •	NO •	

I confirm that I have given a copy of the parental information leaflet and consent form to the participants legal guardian(s).	YES •	NO •

Researcher's Name (BLOCK CAPITALS)	
Researcher's Title and Qualifications	
Researcher's Signature	
Date	

**Parental Consent Form: to contact General Practitioner in case
of adverse finding or outcome**

I, _____ (*Legal guardian name in BLOCK CAPITALS*),
agree that if an unusual finding occurs during the pre-screening and/or the exercise
testing of this research study, the research team may contact my child's General
Practitioner to inform them of the findings.

The contact information of my General Practitioner is:

G.P. NAME:

G.P. ADDRESS:

G.P. CONTACT NUMBER:

Name: _____

Signature: _____

Date: _____

Appendix 3.4: Parental consent – Controls.



Parental Consent Form

Explicit, informed, voluntary consent to partake in the research study.

Study Title: A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study

Lead Investigator: Mr. Tony Rafferty: Trinity College Dublin.

Co-lead Investigator: Mr. Pat Kiely: Beacon Hospital, Sandyford Dublin 18.

Academic Supervisors & Co-Investigators: Dr Sara Dockrell & Dr Neil Fleming: Trinity College Dublin

Study Information

Please read the participation information leaflet in full and clarify any concerns or queries with Tony Rafferty the Lead investigator before consenting to take part in this study.

Will my child's identity be known?

All data collected will be coded with numerical ID to maintain participant confidentiality. Data will be stored in a secure office and on a password protected computer for 5 years after the study is finished in accordance with good research standard guidelines and data protection legislation. It will be destroyed after this period of time by the relevant personnel. The information will not be used for any other purpose other than this research study without your permission. Participation is entirely voluntary, and you may withdraw your consent at any stage over the course of your involvement in this study.

Statement of Parental Consent

Explicit, informed, voluntary consent to partake in the research study.

Please tick each item to give your consent.

I confirm that I have read and fully understood the relevant Participation Information Leaflet provided to me.	YES •	NO •	Initials
I understand my child will be asked to undertake research which collects data about their gender, age and relevant medical history, as well as the assessment of body composition, cardiorespiratory, lung and musculoskeletal function and quality of life. I have been assured that information about my child will be kept private and confidential.	YES •	NO •	Initials
I am aware of the benefits and risks of this research study. I understand the risks that have been explained to me.	YES •	NO •	Initials
I have had the opportunity to discuss the study and ask questions about the study, and I have received satisfactory answers to all my questions.	YES •	NO •	Initials
I have received enough information about this study and understand what is involved if I agree to allow my child to participate.	YES •	NO •	Initials

I understand that I am free to withdraw my child from the study at any time without giving a reason and I understand that withdrawing from the study will not affect future medical care.	YES •	NO •	Initials
I agree to be contacted by researchers as part of this study.	YES •	NO •	Initials

***You are now entering a separate part of this consent form, relating to data protection* Explicit, informed, voluntary consent regarding data protection and storage.**

I understand that all of my child's data will be pseudonymised and minimised for this study The words 'pseudonymisation' and 'minimisation' have been explained to me.	YES •	NO •	Initials
I understand my child's name or other personal identifiers will not be disclosed to anybody and my child's personal data will be kept strictly confidential.	YES •	NO •	Initials
I understand the lead investigator will be processing my child's data and that Trinity College is in control of my child's data.	YES •	NO •	Initials
I understand that my child's data will be used for study analysis, and may be published in peer reviewed journals, in presentations, and may be disseminated at conferences but my child's data will remain confidential and none of my personal identifiers will be disclosed in these circumstances.	YES •	NO •	Initials
I understand how my child's data will be stored (pseudonymised and minimised in secure locations) and that it will be stored for a total of 5 years and will then be destroyed by the study investigators.	YES •	NO •	Initials
I have been made aware of my child's rights under the General Data Protection Regulations, and contact details of the Data	YES •	NO •	Initials

Protection Officer and Data Commissioner have been provided to me in the Parental Information Leaflet.			
I have read and understood the personal data protection section of the Parental Information Leaflet.	YES •	NO •	Initials
I have had the opportunity to discuss data protection in this study and I have received satisfactory answers to all my questions.	YES •	NO •	Initials
I understand that I am free to withdraw my child from the study at any time without giving a reason with no consequence and my child's personal data will not be used and will be destroyed.	YES •	NO •	Initials
I freely and voluntarily consent to allow the researcher's use of my child's information (personal data) as part of this study as outlined in the parental information leaflet.	YES •	NO •	Initials

I understand that my child's data collected from the research study, may be used for comparative purposes in similar studies to this one.	YES •	NO •	Initials
I have read and understood the use of personal data in future studies section of the Participant Information Leaflet. I understand that my child's data will remain coded and personal identifiers will never be published or disclosed to anyone in the future and that all my child's data will be destroyed by Trinity College after 5 years.	YES •	NO •	Initials
I understand that I am free to withdraw my consent to use my child's personal data in future studies at any time without giving a reason, with no consequence, and my child's personal data will not be used and will be destroyed.	YES •	NO •	Initials

I freely and voluntarily consent for my child's data to be stored for comparative purposes in similar studies which is unrelated to the current study without further consent being required but only if the research is approved by a Research Ethics Committee.	YES •	NO •	Initials

Participant's Name (BLOCK CAPITALS)	
Legal guardians Name (BLOCK CAPITALS)	
Legal guardians Signature	
Date	

To be completed by the **Researcher**:

I have fully explained the purpose and nature (including benefits and risks) of this study to the participant's legal guardian(s) in a way that could be understood. I have invited the participant's legal guardian(s) to ask questions on any aspect of the study.	YES •	NO •	Initials
I have fully explained the purpose and nature of data protection and the nature of storage and future use of personal data in this study to the participants legal guardian(s) in a way they could be understood. I have invited the participant's legal guardian(s) to ask questions on any aspect of the study.	YES •	NO •	Initials

I confirm that I have given a copy of the parental information leaflet and consent form to the participants legal guardian(s).	YES •	NO •	Initials

Researcher's Name (BLOCK CAPITALS)	
Researcher's Title and Qualifications	
Researcher's Signature	
Date	

Parental Consent Form: to contact General Practitioner in case of adverse finding or outcome

I, _____ (*Legal guardian name in BLOCK CAPITALS*),
agree that if an unusual finding occurs during the pre-screening and/or the exercise
testing of this research study, the research team may contact my child's General
Practitioner to inform them of the findings.

The contact information of my General Practitioner is:

G.P. NAME:

G.P. ADDRESS:

G.P. CONTACT NUMBER:

Name: _____

Signature: _____

Date: _____

Appendix 3.5: Assent form 14 -16-year-old.



Assent Form (14-16 year olds)

Study Title: A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study

Lead Investigator: Mr. Tony Rafferty: Trinity College Dublin.

Co-lead Investigator: Mr. Pat Kiely: Beacon Hospital, Sandyford Dublin 18.

Academic Supervisors & Co-Investigators: Dr Sara Dockrell & Dr Neil Fleming: Trinity College Dublin

INFORMATION ABOUT THIS STUDY:

A copy of the participants information leaflet has been provided to you and your legal guardian. Please read this participation information leaflet. If you have any questions, please ask Tony Rafferty the lead investigator. It is important you fully understand the study before agreeing to take part.

We are inviting you to participate in this study because you meet the criteria for inclusion. The results of this study may be new and valuable. They could help improve the health and wellbeing of adolescents with idiopathic scoliosis.

Statement of Participant's Assent

Explicit, informed, voluntary assent to partake in the research study.

Please tick each item to give your assent (your agreement with it)

I confirm that I have read and fully understood the relevant Participation Information Leaflet provided to me.	YES •	NO •	Initials
I understand I will be asked to undertake research, which collects data about my gender, age and relevant medical history. Information on my body composition, heart, lung and muscle function and my quality of life will also be collected. I have been assured that information about me will be kept coded and private and confidential.	YES •	NO •	Initials
I am aware of the benefits and risks of this research study. I understand the risks that have been explained to me.	YES •	NO •	Initials
I have had the opportunity to discuss the study and ask questions about the study. I have received satisfactory answers to all my questions.	YES •	NO •	Initials
I have received enough information about this study. I understand what is involved if I agree to participate.	YES •	NO •	Initials
I understand that I am free to withdraw from the study at any time without giving a reason. I understand that withdrawing from the study will not affect my future medical care.	YES •	NO •	Initials
I agree to be contacted by researchers as part of this study.	YES •	NO •	Initials

***You are now entering a separate part of this assent form, relating to data protection* Explicit, informed, voluntary assent regarding data protection and storage.**

I understand that all of my data will be pseudonymised and minimised for this study The words 'pseudonymisation' and 'minimisation' have been explained to me.	YES •	NO •	Initials
I understand my name or other personal identifiers will not be disclosed to anybody and my personal data will be kept strictly confidential.	YES •	NO •	Initials
I understand the lead investigator will be processing my data and that Trinity College is in control of my data.	YES •	NO •	Initials
I understand that my data will be used for study analysis. The results may be published in peer reviewed journals, in presentations, and may be disseminated at conferences. My data will remain confidential and none of my personal identifiers will be disclosed in any of these circumstances.	YES •	NO •	Initials
I understand how my data will be stored. I understand that it will be stored for a total of 5 years and will then be destroyed by the study investigators.	YES •	NO •	Initials
I have been made aware of my rights under the General Data Protection Regulations and contact details of the Data Protection Officer and Data Commissioner have been provided to me in the Participant Information Leaflet.	YES •	NO •	Initials
I have read and understood the personal data protection section of the Participant Information Leaflet.	YES •	NO •	Initials
I have had the opportunity to discuss data protection in this study. I have received satisfactory answers to all my questions.	YES •	NO •	Initials
I understand that I am free to withdraw from the study at any time without giving a reason. If I withdraw, my personal data will not be used and will be destroyed.	YES •	NO •	Initials

I freely and voluntarily consent to allow the researcher's use of my information (personal data) as part of this study as outlined in the information leaflet.	YES •	NO •	Initials

I understand that my data collected from the research study, may be used for comparative purposes in similar studies to this one.	YES •	NO •	Initials
I have read and understood the use of personal data in future studies section of the Participant Information Leaflet. I understand that my data will remain coded and personal identifiers will never be published or disclosed to anyone in the future and that all my data will be destroyed by Trinity College after 5 years.	YES •	NO •	Initials
I understand that I am free to withdraw my assent to use my personal data in future studies at any time without giving a reason. In this case, my personal data will not be used and will be destroyed.	YES •	NO •	Initials
I freely and voluntarily consent for my data to be stored for comparative purposes to similar studies which are unrelated to the current study without further assent being required but only if the research is approved by a Research Ethics Committee.	YES •	NO •	Initials

Participant's Name (BLOCK CAPITALS)	
Participant's Signature	
Date	
Legal Guardians Name (BLOCK CAPITALS)	
Legal guardians Signature	

To be completed by the **Researcher**:

I have fully explained the purpose and nature (including benefits and risks) of this study to the participant in a way that he could understand. I have invited the participant to ask questions on any aspect of the study.	YES •	NO •
I have fully explained the purpose and nature of data protection and the nature of storage and future use of personal data in this study to the participant in a way that he could understand. I have invited the participant to ask questions on any aspect of the study.	YES •	NO •

I confirm that I have given a copy of the Participant Information Leaflet and Consent Form to the participant.	YES •	NO •

Researcher's Name (BLOCK CAPITALS)	
Researcher's Title and Qualifications	
Researcher's Signature	
Date	

Appendix 3.6: Assent form 12 - 14-year-old.



Assent Form (12-14 year olds)

Study Title: A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study

Lead Investigator: Mr. Tony Rafferty: Trinity College Dublin.

Co-lead Investigator: Mr. Pat Kiely: Beacon Hospital, Sandyford Dublin 18.

Academic Supervisors & Co-Investigators: Dr Sara Dockrell & Dr Neil Fleming: Trinity College Dublin

INFORMATION ABOUT THIS STUDY:

An information leaflet has been provided to you and your legal guardian. Please read this carefully. If you have any questions, please ask the Tony Rafferty the main investigator. It is important you fully understand the study before agreeing to take part.

You are invited to take part because you meet the criteria for inclusion. The results of this study may be new and valuable. They could help improve the health and wellbeing of adolescents with idiopathic scoliosis.

Statement of Participant's Assent

Explicit, informed, voluntary assent to partake in the research study.

Please tick each item to give your assent (your agreement with it)

I confirm that I have read and fully understood the Information Leaflet given to me.	YES •	NO •	Initials
I understand that information about my will be collected in this study. I have been told that information about me will be kept private and confidential.	YES •	NO •	Initials
I am aware of the benefits and risks of this research study. I understand the risks that have been explained to me.	YES •	NO •	Initials
I have had the opportunity to discuss the study and ask questions about the study. I have received satisfactory answers to all my questions.	YES •	NO •	Initials
I have received enough information about this study. I understand what is involved if I agree to participate.	YES •	NO •	Initials
I understand that I am free to withdraw from the study at any time without giving a reason. I understand that withdrawing from the study will not affect my future medical care.	YES •	NO •	Initials
I agree to be contacted by researchers as part of this study.	YES •	NO •	Initials

***You are now entering a separate part of this assent form, relating to data protection* Explicit, informed, voluntary assent regarding data protection and storage.**

I understand that all of my information will be pseudonymised and minimised for this study. The words 'pseudonymisation' and 'minimisation' have been explained to me.	YES •	NO •	Initials
I understand my personal information will be kept strictly confidential.	YES •	NO •	Initials
I understand the lead investigator will be processing my information and that Trinity College is in control of my data.	YES •	NO •	Initials
I understand that my personal information will be used in the study. The results may be published in journals and presentations and conferences. Nothing that identifies me will be disclosed in any of these circumstances.	YES •	NO •	Initials
I understand how my data will be stored. I understand that it will be stored for a total of 5 years and will then be destroyed by the study investigators.	YES •	NO •	Initials
I have been told of my rights under the General Data Protection Regulations. I have been given contact details of the Data Protection Officer and Data Commissioner.	YES •	NO •	Initials
I have read and understood the personal data protection section of the Participant Information Leaflet.	YES •	NO •	Initials
I have had the opportunity to discuss data protection in this study. I have received satisfactory answers to all my questions.	YES •	NO •	Initials
I understand that I am free to withdraw from the study at any time without giving a reason. If I withdraw, my personal data will not be used and will be destroyed.	YES •	NO •	Initials

I agree (consent) to allow the researcher's use of my information (personal data) as part of this study. As outlined in the information leaflet.	YES •	NO •	Initials

I understand that my data may be used to compare with similar studies to this one.	YES •	NO •	Initials

I have read and understood the use of personal data in future studies section of the Participant Information Leaflet. I understand that my data will remain coded and personal identifiers will never be published or disclosed to anyone in the future and that all my data will be destroyed by Trinity College after 5 years.	YES •	NO •	Initials

I understand that I am free to withdraw my assent to use my personal data in future studies at any time without giving a reason. In this case, my personal data will not be used and will be destroyed.	YES •	NO •	Initials

I agree (consent) for my data to be stored for comparative purposes to similar studies without further assent being required. But only if the research is approved by a Research Ethics Committee.	YES •	NO •	Initials

Participant's Name (BLOCK CAPITALS)	
Participant's Signature	
Date	
Legal Guardians Name (BLOCK CAPITALS)	
Legal guardians Signature	

To be completed by the **Researcher**:

Project Title: A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study			
I have fully explained the purpose and nature (including benefits and risks) of this study to the participant in a way that he could understand. I have invited the participant to ask questions on any aspect of the study.	YES •	NO •	Initial s
I have fully explained the purpose and nature of data protection and the nature of storage and future use of personal data in this study to the participant in a way that he could understand. I have invited the participant to ask questions on any aspect of the study.	YES •	NO •	Initial s
I confirm that I have given a copy of the Participant Information Leaflet and Consent Form to the participant.	YES •	NO •	Initial s
Researcher's Name (BLOCK CAPITALS)			
Researcher's Title and Qualifications			
Researcher's Signature			
Date			

Appendix 4: Data Protection Impact Assessment.

Completed By:	Tony Rafferty	Date:	Sept 2019
Phone No:	0873986551	Department	Discipline of Physiotherapy;
Email:	raffertt@tcd.ie	:	Department of Medicine

DPIA complete by:	
Data Protection committee member:	Click or tap here to enter text.
IT manager:	Click or tap here to enter text.
Project Manager/CRA:	Click or tap here to enter text.
Principal Investigator:	Tony Rafferty

Section 1: Background Information

Is a Data Protection Impact Assessment required? All Research Applications Require A DPIA	
Will the project/ change be collecting, using or disclosing personal health and/or employee information?	☒ Yes ☐ No
What is the objective of the project/ change?	
Click or tap here to enter text. This project will involve 4 studies designed to assess the effects of clinical interventions aimed at halting or reversing curve progression in mild, moderate and severe AIS patients. A standard two hour battery of tests which will test, musculoskeletal and cardiorespiratory function and quality of life will be used across all studies.	
What are the potential privacy impacts of this project? How will this change impact upon the data subject?	
<i>Example it could be that specific information is being held that hasn't previously or that the level of information is increasing</i> Only data related specifically to the aims and objectives of the study will be collected. Information in relation to a participant's physical assessment and exercise intervention (if relevant) will be collected together with relevant medical history from medical charts.	

New information in relation to each individuals maximal isometric force, muscular power and endurance, joint range of motion, balance, lung function, VO ₂ max, body composition and quality of life and pain will be collected
What is the source the data?
Click or tap here to enter text. Existing data from patient's medical charts will be provided by medical team in pseudonymised form. Data will be collected from physical assessments at pre-determined time points in the study. Data will also be collected from rehabilitation programme and from validated questionnaires completed by the participants.
Where is the data being stored?
Click or tap here to enter text. Collected data will be completely confidential. No individual other than the lead investigator will have access to the data. In addition, all data collected will be pseudonymised and retained in its coded form. Data processing and statistical analysis will only be carried out on group data sets and not individual data entries. All data collected, including electronic data stored on a password protected laptop will be stored in a secure locked cabinet, in a secure office in the Trinity Centre for Health Sciences, St. James's Hospital, Dublin 8. Only the lead investigator will have access to the data. All data will be backed up on a double encrypted external hard drive on a weekly basis to protect against technical issues and the unlikely event that the laptop used on this project is stolen. The external hard-drive will be secured in a separate locked press in a separate office. Only the lead investigator will have access to the keys to this press.

Section 2: Data Involved

Data that relates to:	Yes	N/A	Justification
An individual & their personal characteristics	☒	☐	Click or tap here to enter text.
Children or other vulnerable groups?	☒	☐	Click or tap here to enter text.
Physical, mental health or condition	☒	☐	Click or tap here to enter text.
Sex life	☐	☒	Click or tap here to enter text.
Family	☐	☒	Click or tap here to enter text.
Lifestyle and their social circumstances	☒	☐	Click or tap here to enter text.

Employment and career history information	☐	☒	Click or tap here to enter text.
Financial affairs of the individual	☐	☒	Click or tap here to enter text.
Religion or other beliefs	☐	☒	Click or tap here to enter text.
Membership of a trade union	☐	☒	Click or tap here to enter text.
Criminal proceedings, outcomes and sentences	☐	☒	Click or tap here to enter text.
Offenses committed or alleged to be committed	☐	☒	Click or tap here to enter text.
Education and any professional training of the individual	☐	☒	Click or tap here to enter text.

Section 3: Assessment

Legal Compliance	Response	Required action
Is there legal basis for processing the information?	☒ Yes ☐ No ☐ n/a	With full participant consent/assent and legal guardian consent where appropriate.
Will the project interfere with the 'right to privacy'?	☐ Yes ☒ No ☐ n/a	Click or tap here to enter text.
Have the social need & aims of the project been identified?	☒ Yes ☐ No ☐ n/a	Click or tap here to enter text.
Are individuals informed about what is happening with their information?	☒ Yes ☐ No ☐ n/a	Click or tap here to enter text.
Will the project obtain & record consent? What information will be provided?	☒ Yes ☐ No ☐ n/a	Click or tap here to enter text.
Are there procedures in place if consent is withheld or given but later withdrawn?	☒ Yes ☐ No ☐ n/a	Click or tap here to enter text.

Purpose		
Does the project involve the use of existing personal data for new purposes?	☒ Yes ☐ No ☐ n/a	Click or tap here to enter text.
Are potential new purposes likely to be identified as the scope of the project expands?	☐ Yes ☒ No ☐ n/a	The data will be collected only for the purposes of this study as described. All data will address the objectives of the study and only data that is going to be used will be collected.

Adequacy		
Is the information you are using likely to be of good enough quality for the purposes it is used for?	☒ Yes ☐ No ☐ n/a	Click or tap here to enter text.
Are you able to amend information when necessary to ensure it is up to date?	☒ Yes ☐ No ☐ n/a	Given the nature of the study, information will be collected on an ongoing basis from the participants and therefore will be up-to-date. Additionally, any errors identified during data cleaning can be rectified.
Are there procedures in place to ensure that the personal information obtained from individuals or other organisations is accurate?	☒ Yes ☐ No ☐ n/a	The information will only be collected by the researchers who are trained and professional and associated with the project. All information collected will be entered

		at source and immediately onto a previously developed clinical data sheet. During the process of data management, any errors identified during data cleaning can be rectified. No data will be obtained from other individuals or organisations.
Are there procedures in place for retention of the information? How will they be implemented?	☒ Yes ☐ No ☐ n/a	Data will be held for 5 years post completion of the study. Data will be destroyed securely following this 5-year period in line with Trinity College Dublin's Record Storage, Retention and Archiving Policy.
Are there any exceptional circumstances for retaining certain data for longer than the normal period?	☐ Yes ☒ No ☐ n/a	Click or tap here to enter text.
Are there procedures in place to anonymise & destroy information after it is no longer necessary?	☒ Yes ☐ No ☐ n/a	Click or tap here to enter text.
Right of the Individual		
Are there procedures in place for actioning requests from individuals (or someone acting on their behalf) for access to their personal information once held?	☒ Yes ☐ No ☐ n/a	Click or tap here to enter text.
Are there procedures in place to ensure that all staff with access to the information have adequate information governance training?	☒ Yes ☐ No ☐ n/a	Click or tap here to enter text.
If you are using an electronic system to process the information, have security measures been put in place?	☒ Yes ☐ No ☐ n/a	Click or tap here to enter text.

Are there procedures in place for to provided, collated & use the information gathered?	☒ Yes ☐ No ☐ n/a	Click or tap here to enter text.
Are there security measures in place to transfer identifiable information?	☒ Yes ☐ No ☐ n/a	Click or tap here to enter text.
Will individual's personal information be disclosed internally /externally in identifiable form and if so to who, how & why?	☐ Yes ☒ No ☐ n/a	Click or tap here to enter text.
Will personal data be transferred to a country outside of the European Economic Area? If yes, how will you safeguard?	☐ Yes ☒ No ☐ n/a	Click or tap here to enter text.

Section 4: Issues identified and risk analysis

Multiply the ratings for each risk in the area of likelihood, severity to get the overall risk number:

Identify & Assess the risks: **Please refer to hospital risk matrix**				
No.	Describe source of risk & nature of potential impact on individuals.	Likelihood	Severity	Overall Risk
1	Hacking of computers where project data is stored	1		
2	Clinical data sheets lost or stolen	1		
3	The sharing and merging of datasets can allow organisations to collect a much wider set of information than individuals might expect.	3		
4	If a retention period is not established information might be used for longer than necessary	1	1	1
5	Data collection and confidentiality	1	1	1

MATRIX SCORING	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Extreme (5)
Almost Certain (5)	5	10	15	20	25
Likely (4)	4	8	12	16	20
Possible (3)	3	6	9	12	15
Unlikely (2)	2	4	6	8	10
Rare/Remote (1)	1	2	3	4	5

Identify additional measures you could take to reduce or eliminate risks identified as medium or high risk:		
Risk no.	Options to reduce/ eliminate risk	Measure Approved
1	All computers storing data are password protected. The external hard drive and remotely accessible computer are also encrypted and locked in an office (on Trinity's campus). Access is restricted to designated staff only. All data will be pseudonymised	☒ Yes ☐ No ☐ n/a
2	All data entries on clinical data sheets are pseudonymised coded entries only	☒ Yes ☐ No ☐ n/a
3	Each participant will be allocated a unique code number. Only the code number will be entered on the CDS and questionnaires. Data will be transferred into a relevant statistical package for statistical analysis purposes in its coded form. Results will be processed in group format, not individually. Participant's individual results will never be shared with 3 rd parties. Data sharing protocol is clearly set out in participant information leaflets and consent forms.	☒ Yes ☐ No ☐ n/a
4	Data will be held for 5 years post completion of the study. Data will be destroyed securely following this 5-year period in line with Trinity College Dublin's Record Storage, Retention and Archiving Policy.	☒ Yes ☐ No ☐ n/a
5	Data collection from medical charts will be carried out by participant's medical team and will be pseudonymised before data entry. Data collected over the course of the study will be collated by lead investigator, Chartered physiotherapist. All investigators are bound by common law duty of confidentiality. Data analysis will only include grouped data no individual participants outcomes will be identified.	☒ Yes ☐ No ☐ n/a

How are outcomes integrate into the project plan?	
Outcomes to eliminate risk	Integration
Secure storage of hardcopy & electronic data	Storage and protection of data is clearly set out in participant's information leaflets and consent forms. The data storage and protection procedures have been approved by the TCD ethics committee.
Data collected will be pseudonymised and study analysis will be in group sets not individual data.	The data pseudonymised process and data analysis has been approved by the TCD ethics committee and clearly set out in

	patient information and consent documents
Each participant will be allocated unique code number.	.Data collected will be recorded on Clinical Data Sheets (CDS) (appendix 9) and in questionnaires (IPAQ, ACSM medical history questionnaire and SRS22r). Each participant will be allocated a unique code number. Only the code number will be entered on the CDS and questionnaires. Data will be transferred into a relevant statistical package for statistical analysis purposes in its coded form. Results will be processed in group format, not individually. Only necessary data will be collected and analysed and no reference to individuals will be made at any stage in the process. The CDS documents are included in ethics application for approval.
Data storage will be in line with Trinity College's data storage protocol	In line with accepted practice.
Only the lead investigators will collect data	Lead investigator is a trained health professional and registered with CORU. Personal data will not be shared with other individuals or organisations. Only pseudonymised data will be shared with the research team for discussion and evaluation of findings.

Section 5: Sign Off

Sign Off:		
Sign off by data protection committee:	☐ Yes ☐ No	Click or tap here to enter text.
Sign off by DPO:	☐ Yes ☐ No ☐ n/a	Click or tap here to enter text.

Appendix 5: Recruitment Poster – AIS.

**Have you been diagnosed with mild, moderate, or severe
Adolescent Idiopathic Scoliosis?
We would like to hear from you!**

The National Adolescent Idiopathic Scoliosis Physical Wellbeing Study

WHAT IS THE RESEARCH ABOUT?

We want to find out, is there a difference in muscle function, balance, heart & lung function and quality of life between adolescents with severe, moderate or mild adolescent idiopathic scoliosis (AIS) and adolescents who do not have scoliosis.

WHO CAN TAKE PART?

- ✓ If you have a mild, moderate or severe diagnosis for adolescent idiopathic scoliosis.
- ✓ You are between the ages of 12 and 21 and have your parent's consent if this is required.
- ✓ You have no medical reason that stops you from exercising.

WHAT DOES IT INVOLVE?

Mild, Moderate and Severe AIS: A comprehensive physical assessment and questionnaire.

Severe AIS: A 12-week physiotherapy led exercise programme and a 12-week home exercise programme for those who have had surgery.

WHAT WE OFFER

- ❖ Full individual health report of your fitness levels and body composition measurements will be provided to **everyone** on completion of the physical assessment.
- ❖ An individualised 12-week physiotherapy - led exercise programme and a 12-week home exercise programme for those who have had surgery.

INTERESTED IN PARTICIPATING?

For more information, please contact **Tony Rafferty**, Discipline of
Physiotherapy, School of Medicine,
Trinity College Dublin

Contact: Tel **087 3986551**, E-mail raffertt@tcd.ie



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Appendix 6: Recruitment Poster – Controls.

If you do not have scoliosis, we would like to hear from you!

A National Adolescent Idiopathic Scoliosis Physical Wellbeing Study

WHAT IS THE RESEARCH ABOUT?

We want to find out if there a difference in muscle function, balance, heart & lung function and quality of life between adolescents with adolescent idiopathic scoliosis (AIS) and adolescents who do not have scoliosis.

WHO CAN TAKE PART?

- ✓ If you do not have scoliosis.
- ✓ You are between the ages of 12 and 21 and have your parent's consent if this is required.
- ✓ You have no medical reason that stops you from exercising.



WHAT DOES IT INVOLVE?

Comprehensive physical assessment (2 hours) and questionnaire completion.

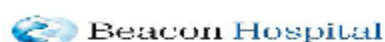
WHAT WE OFFER

Full analysis of fitness levels and body composition measurements will be provided to each participant on completion of the physical assessment in the form of an individualised health report.

INTERESTED IN PARTICIPATING?

For more information please contact **Tony Rafferty**, Department of Physiotherapy, School of Medicine, Trinity College Dublin:

Contact: Tel **087 3986551**, E-mail raffertt@tcd.ie



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Appendix 7: Physical Activity Readiness Questionnaire (PAR-Q).



Fidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Physical Activity Readiness Questionnaire (PAR-Q)

Name: _____

Date: _____ DOB: _____ Age: _____

Home Phone: _____ Work Phone: _____

Regular exercise is associated with many health benefits, yet any change of activity may increase the risk of injury. Completion of this questionnaire is a first step when planning to increase the amount of physical activity in your life.

Please read each question carefully and answer every question honestly: (Tick the appropriate answer)

1. Do you have a heart condition and should only do physical activity recommended by a physician?	☐ Y	☐ N
2. When you do physical activity, do you feel pain in your chest?	☐ Y	☐ N
3. When you were not doing physical activity, have you had chest pain in the past month?	☐ Y	☐ N
4. Do you ever lose consciousness or do you lose your balance because of dizziness?	☐ Y	☐ N
5. Do you have a joint or bone problem that may be made worse by a change in your physical activity?	☐ Y	☐ N
6. Is a physician currently prescribing medications for your blood pressure or heart condition?	☐ Y	☐ N
7. Are you pregnant?	☐ Y	☐ N
8. Do you know of any other reason you should not exercise or increase your physical activity?	☐ Y	☐ N

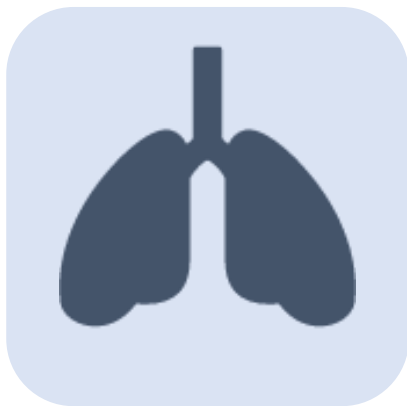
If you answered yes to any of the above questions, talk with your doctor BEFORE you become physically active. Tell your doctor of your intention to exercise and which questions you answered 'yes' to. If at any stage your health changes, resulting in a 'yes' answer to any of the above questions, please seek guidance from a GP.

Participant's Signature: _____ Date: _____

version 2.0 Sept 2019



Appendix 8: Physical Activity, Health and Fitness Report.



Physical Activity

Health & Fitness Report

Participant ID:

C005

Dear

Thank you for your recent participation in the study. The research team has analysed your data and compiled your results. As well as reporting your individual results, **the normal reference ranges for the general population are also indicated in a table to the right of your result.**

These are specific to your age and gender. You can find where your results fall within these ranges to establish your health status for each component of the assessment.

Being more physically active can greatly improve overall health. Regular daily physical activity (30 minutes or more) can reduce the risk of heart disease, high blood pressure, diabetes and can improve levels of mood and fatigue.

If you have further queries about these results, please feel free to consult with your

Age:

Height (cm):

Weight (kg):



Blood Pressure

Ideal average blood pressure, (also known sometimes as BP), is typically around 120/80. The first number, always the higher number, is the pressure in the blood vessels when the heart is beating and the lower number is the pressure in-between beats, when the heart is relaxed. High blood pressure is generally accepted as being **persistently** over 140/90 according to medical guidelines. High blood

Your result

**Blood
Pressure**



Low	<90/60
Normal	120/80
Increased	140/90 +



Body Composition

Body fat is vital to daily body function. However, it is not the amount you weigh but your percentage body fat that potentially influences your health. Weight alone does not distinguish between fat and lean body tissue (muscle and bone). If you start exercising and don't appear to be losing weight you may in fact be reducing your body fat and replacing it with newly developed muscle mass, which is denser and heavier than fat.

Excessive body fat can increase your risk of developing serious health problems such as high blood pressure, high cholesterol, heart disease, diabetes and cancer. Maintaining a healthy body fat percentage can reduce your risk and help prevent the onset of these conditions. Too little body fat can also be unhealthy. Women's bodies

BMI

Your Result

BMI (kg/m^2)



Underweight	< 18.5
Normal	18.5 - 24.9
Overweight	25.0 - 29.9
Obese	30 +



Pulmonary Function

Body fat %

Body fat is vital to daily body functions. It cushions joints, protects organs, helps regulate body temperature, and stores vitamins. However, serious health risks are associated with both too much, and too little body fat. By design, women's bodies require a higher percentage of body fat to be healthy.

Your Result:

Reference Range (%)

Athletic	5-10
Good	11-14
Acceptable	15-20
Obese	>24

Other Body Composition values

Fat free mass: kg

Skeletal muscle mass: kg

Bone mass: kg

Fat mass: kg

BMR: kcal



Cardiorespiratory Fitness

Cardiorespiratory fitness refers to the ability of your body to supply oxygen to your muscles and how efficiently your muscles use that oxygen during physical activity. Both the circulatory and respiratory systems work together during this process. Your predicted $\text{VO}_{2\text{max}}$ value reflects the maximum capacity of your body to transport and use oxygen during physical activity.

A high level of cardiorespiratory fitness allows continuous physical activity without a decline in performance and allows for rapid recovery following a fatiguing activity. There are many benefits of cardiorespiratory fitness. It can reduce the risk of heart disease, lung cancer, type 2 diabetes, stroke, and other diseases.

Your Predicted $\text{VO}_{2\text{max}}$:

$\text{ml.kg}^{-1}.\text{min}^{-1}$

1

Reference Range ($\text{ml.kg}^{-1}.\text{min}^{-1}$)

Age (yr)	Very poor	Poor	Below average	Average	Above average	Good	Excellent
18-25	<30	30-36	37-41	42-46	47-51	52-60	>60
26-35	<30	30-34	35-39	40-42	43-48	49-56	>56
36-45	<26	26-30	31-34	35-38	39-42	43-51	>51
46-55	<25	25-28	29-31	32-35	36-38	39-45	>45
56-65	<22	22-25	26-29	30-31	32-35	36-41	>41
65+	<20	20-21	22-25	26-28	29-32	33-37	>37



Physical Activity

Adults need **at least 150 minutes of *moderate-intensity* aerobic exercise** (e.g. brisk walking, riding a bike, pushing a lawn mower) **or 75 minutes of *vigorous-intensity* aerobic activity** (e.g. jogging or running, swimming lengths, or running) every week. Activities can be broken down into smaller chunks of time, as long as the activity is at least 10 minutes long.

Physical activity is a major modifiable risk factor for heart disease, stroke, type 2 diabetes and certain cancers. It is also associated with mental health and obesity. If you haven't been very active lately, increase your activity levels gradually.

Weekly Physical Activity Recommendations

(Minimum 150 min moderate or
75 min vigorous physical activity)

Your activity

Appendix 9: Clinical Data Collection Sheet.

Test Number: 1 ☐ 2 ☐ 3 ☐ 4 ☐ Reported Curvature

type and degree.

Dominant Hand L/R

Participant ID _____8

A National Adolescent Idiopathic Scoliosis Wellbeing Study

1: RECRUITMENT, CONSENT & QUESTIONNAIRES

Study group codes

Control = C

Mild = MI

Mild Schroth= MIS

Moderate = MO

Moderate Schroth = MOS

Severe = S

PU – HSE

PR - Private

Code: _____/_____

Date of birth	
Written consent obtained	
Participant information provided and explained	
Satisfactory PAR –Q	
Completed IPAQ, ACSM questionnaires	
Completed SRS-22r questionnaire	
Smoker – nonsmoker	
Ex-smoker years	

Clinical assessment date:

□□.□□.□□

2: VASCULAR MEASUREMENTS

Number of blood pressure measurements :(**mm Hg**):

Test **Systolic** **Diastolic BP** **Mean BP** **(Rest HR (Beats.min⁻¹)):**

1. □□□ □□□ □□□ □□□

2. □□□ □□□ □□□ □□□

3. □□□ □□□ □□□ □□□

3: ANTHROPOMETRICS

3.1) Gender:

Male ☐ Female ☐

3.2) Ethnicity (enter appropriate number):

☐

White

Irish 1 Irish traveller 2 any other white background 3

Black or Black Irish 4 African 5 Any other black background 6

Asian or Asian Irish 7 Chinese 8 Any other Asian background 9

Other, including mixed background 10

Baseline Measures

Component	Measurement
Height (cm)	
Weight (kg)	
BMI	
Body fat %	
Fat Mass (kg)	
FFM (kg)	
Muscle Mass (kg)	
Bone Mass (kg)	
BMR (kcal)	

4: PULMONARY FUNCTION 7

Measurement	FEV ₁	FVC	FVC/FEV %	PEF
1				
2				
3				

Number of measurements:

☐

Lower limb measurement : (cm)	<i>Right</i>	
	<i>Left</i>	

5 & 6: STRENGTH

Supine –Right side HHD		
Hip abduction	1	3
Hip adduction	1	3
Supine –Left side HHD		
Hip abduction	1	2 3
Hip adduction	1	2 3
Prone Right side HHD		
Trapezius lower (140°)	1	2 3
Hip extensors	1	2 3
Prone Left side HHD		
Trapezius lower (140°)	1	2 3
Hip extensors	1	2 3

395

Sitting

Hip flexion	<i>Right</i>	1 2 3
Hip flexion	<i>Left</i>	1 2 3
Trapezius Upper	<i>Right</i>	1 2 3
Trapezius Upper	<i>Left</i>	1 2 3
Latissimus Dorsi	<i>Right</i>	1 2 3
Latissimus Dorsi	<i>Left</i>	1 2 3

Standing

Upper limb measurement :(cm)	<i>Right</i>	
	<i>Left</i>	

Lumbar flexion (Schober's)

HHD Squeeze test (kg) to nearest 0.5kg

Right	1 2 3
Left	1 2 3

Back D

Lumbar spine	1 2 3

7: UPPER LIMB ENDURANCE

Modified 'Push-up' – completed repetitions

8 : LOWER LIMB ENDURANCE

One leg 'Wall squats' (s)

Right

Left

9: UPPER LIMB POWER

Medicine ball put

Distance (cm's)

1

2

3

10: BALANCE TESTING

1. Double leg stance
2. Single leg stance (eyes closed)
- 3.
4. Tandem Stance

11: LOWER LIMB POWER

Vertical jump HUR

SECTION 12: CARDIORESPIRATORY TESTING

Estimated HR_{max}

Estimated HR _{max} $HR_{max} = 208 - (0.7 \times \text{age})$	
VO ₂ Max (mL.kg ⁻¹ .min ⁻¹)	
Max Heart Rate (beats.min ⁻¹)	
Finishing Time (s)	

Perceived exertion scale

Stage	Duration (minutes)	HR	RPE	Observations / Notes
1	1			
2	1			
3	1			
4	1			
5	1			
6	1			
7	1			
8	1			
9	1			
10	1			
11	1			
12	1			
12	1			
14	1			
15	1			
16	1			

Termination due to:

Cool Down (5 minutes active rest)		Observations
Min	HR	
1		
2		
3		
4		
5		



International Physical Activity Questionnaire - Short Form

OVERVIEW

- This measure assesses the types of intensity of physical activity and sitting time that people do as part of their daily lives are considered to estimate total physical

activity in MET-min/week and time spent sitting.

SUBSCALES

- None
- Sample items from the scale:

» During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling?



STEPPING UP THEME(S) & OUTCOME(S)

- Health & Wellness
- » Youth are physically healthy



TARGET POPULATION

- Youth 15 years of age and older



LENGTH & HOW IT IS MEASURED

- 7 items
- Open-ended questions surrounding individuals' last 7-

day recall of physical activity

- Self-report, paper-pencil version or orally
- Available in: English and many other languages



DEVELOPER

- International Physical Activity Questionnaire, 1998



GOOD TO KNOW

- Used by the Ontario Trillium Foundation
- [Click here for Guidelines for Data Processing and Analysis of the International Physical Activity Questionnaire \(IPAQ\) - Short Form](#)



LEARN MORE

- International Physical Activity Questionnaire. (2016). Home. Retrieved from <https://sites.google.com/site/theipaq/>

- C.L. Craig, A. Marshall, M. Sjostrom, A. Bauman,

M. Booth, B. Ainsworth, *et al.* International Physical Activity Questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc*, 35 (2003), pp. 1381–1395

- Lee, P.H., Macfarlane, D.J., Lam, T.H., Stewart, S.M. (2011). *Validity of the international physical activity questionnaire short form (IPAQ-SF): A systematic review.* *International Journal of Behavioral Nutrition and Physical Activity*. 8:115.
- van Poppel MNM, Chinapaw MJM, Mokkink LB, van Mechelen W, Terwee CB: Physical activity questionnaires for adults: A systematic review of measurement properties. *Sports Medicine*. 2010, 40: 565-600. 10.2165/11531930-000000000-



PSYCHOMETRICS

- Reliability

Test-retest reliability indicated good stability High reliability ($\alpha < .80$)

- Validity

Predictive validity

Concurrent validity

Convergent validity

Criterion validity

Discriminant

validity

SHORT LAST 7 DAYS SELF-ADMINISTERED FORMAT

FOR USE WITH YOUNG AND MIDDLE-AGED ADULTS (15-69 years)

The International Physical Activity Questionnaires (IPAQ) comprises a set of 4 questionnaires. Long (5 activity domains asked independently) and short (4 generic items) versions for use by either telephone or self-administered methods are available. The purpose of the questionnaires is to provide common instruments that can be used to obtain internationally comparable data on health-related physical activity.

Background on IPAQ

The development of an international measure for physical activity commenced in Geneva in 1998 and was followed by extensive reliability and validity testing undertaken across 12 countries (14 sites) during 2000. The final results suggest that these measures have acceptable measurement properties for use in many settings and in different languages, and are suitable for national population-based prevalence studies of participation in physical activity.

Using IPAQ

Use of the IPAQ instruments for monitoring and research purposes is encouraged. It is recommended that no changes be made to the order or wording of the questions as this will affect the psychometric properties of the instruments.

Translation from English and Cultural Adaptation

Translation from English is supported to facilitate worldwide use of IPAQ. Information on the availability of IPAQ in different languages can be obtained at www.ipaq.ki.se. If a new translation is undertaken we highly recommend using the prescribed back translation methods available on the IPAQ website. If possible please consider making your translated version of IPAQ available to others by contributing it to the IPAQ website. Further details on translation and cultural adaptation can be downloaded from the website.

Further Developments of IPAQ

International collaboration on IPAQ is on-going and an ***International Physical Activity Prevalence Study*** is in progress. For further information see the IPAQ website.

More Information

More detailed information on the IPAQ process and the research methods used in the development of IPAQ instruments is available at www.ipaq.ki.se and Booth, M.L. (2000). *Assessment of Physical Activity: An International Perspective*. Research Quarterly for Exercise and Sport, 71 (2): s114-20. Other scientific publications and presentations on the use of IPAQ are summarized on the website.

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**.

Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ **days per week**

☐

No vigorous physical activities → **Skip to question 3**

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐

Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**.

Moderate activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **days per week**

No ☐ moderate physical activities

Skip ➡ question 5

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐

Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

☐

No walking → **Skip to question 7**

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐

Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ hours per day

_____ minutes per day

☐

Don't know/Not sure

This is the end of the questionnaire, thank you for participating.

Appendix 11: Scoliosis Research Society (SRS) -22r Patient Questionnaire.

1

SRS-22r Patient Questionnaire

Patient Name: _____ Date of Birth: _____

First MI Last Mo Day Yr

Today's Date: _____ Age: _____ + _____

Mo Day Yr Yrs Mo

Medical Record #: _____

INSTRUCTIONS: We are carefully evaluating the condition of your back and it is **IMPORTANT THAT YOU ANSWER EACH OF THESE QUESTIONS YOURSELF.** Please **CIRCLE THE ONE BEST ANSWER TO EACH QUESTION.**

1. Which one of the following best describes the amount of pain you have experienced during the past 6 months?

None

Mild

Moderate

Moderate to severe

Severe

2. Which one of the following best describes the amount of pain you have experienced over the last month?

None

Mild

Moderate

Moderate to severe

Severe

3. During the past 6 months have you been a very nervous person?

None of the time

A little of the time

Some of the time

Most of the time

All of the time

4. If you had to spend the rest of your life with your back shape as it is right now, how would you feel about it?

Very happy

Somewhat happy

Neither happy nor unhappy

Somewhat unhappy

Very unhappy

5. What is your current level of activity?

Bedridden

Primarily no activity

Light labor and light sports

Moderate labor and moderate sports

Full activities without restriction

6. How do you look in clothes?

Very good

Good

Fair

Bad

Very bad

7. In the past 6 months have you felt so down in the dumps that nothing could cheer you up?

Very often

Often

Sometimes

Rarely

Never

8. Do you experience back pain when at rest?

Very often

Often

Sometimes

Rarely

Never

9. What is your current level of work/school activity?

100% normal

75% normal

50% normal

25% normal

0% normal

10. Which of the following best describes the appearance of your trunk; defined as the human body except for the head and extremities?

Very good

Good

Fair

Poor

Very Poor

11. Which one of the following best describes your pain medication use for back pain?

None

Non-narcotics weekly or less (e.g., aspirin, Tylenol, Ibuprofen)

Non-narcotics daily

Narcotics weekly or less (e.g. Tylenol III, Lorcet, Percocet)

Narcotics daily

12. Does your back limit your ability to do things around the house?

Never

Rarely

Sometimes

Often

Very Often

13. Have you felt calm and peaceful during the past 6 months?

All of the time

Most of the time

Some of the time

A little of the time

None of the time

14. Do you feel that your back condition affects your personal relationships?

None

Slightly

Mildly

Moderately

Severely

15. Are you and/or your family experiencing financial difficulties because of your back?

Severely

Moderately

Mildly

Slightly

None

16. In the past 6 months have you felt down hearted and blue?

Never

Rarely

Sometimes

Often

Very often

17. In the last 3 months have you taken any days off of work, including household work, or school because of back pain?

0 days

1 day

2 days

3 days

4 or more days

18. Does your back condition limit your going out with friends/family?

Never

Rarely

Sometimes

Often

Very often

19. Do you feel attractive with your current back condition?

Yes, very

Yes, somewhat

Neither attractive nor unattractive

No, not very much

No, not at all

20. Have you been a happy person during the past 6 months?

None of the time

A little of the
time

Some of the time

Most of the time

All of the time

21. Are you satisfied with the results of your back management?

Very satisfied

Satisfied

Neither satisfied nor unsatisfied

Unsatisfied

Very unsatisfied

22. Would you have the same management again if you had the same condition?

Definitely yes

Probably yes

Not sure

Probably not

Definitely not

Thank you for completing this questionnaire. Please comment if you wish.

END

Appendix 12: Borg RPE Scale.

1 - 10 Borg Rating of Perceived Exertion Scale	
0	Rest
1	Really Easy
2	Easy
3	Moderate
4	Sort of Hard
5	Hard
6	
7	Really Hard
8	
9	Really, Really, Hard
10	Maximal: Just like my hardest race

Appendix 13: Home exercise programme (HEP) Study 4 -example.

Arms & Chest program

3 Sets / 12 Reps



1. 4 point kneeling scapula protraction in - side to side rock

Kneel down with your hands under your shoulders and knees under your hips. Your head should be in a neutral position looking down at the floor between your hands. Perform a small press up, bending your elbows and dropping your chest towards the floor.

Feel your shoulder blades move closer together. Straighten your elbows to push yourself back up. Feel your shoulder blades move apart a little.

Keeping your back straight, drive the heels of your hands into the floor so that you feel your shoulder blades spread apart as far as they can around the sides of your rib cage. Your back should not arch as you do this.

Tighten your abdominal muscles and gently tuck your chin in so that your spine is in alignment.

Holding this position, rock your body from one side to the other.

Ensure you do not lose the control of your shoulder blades as you do this.

3 Sets / 12 Reps



2. Pilates hip twist level 2

Lie on your back.

Bend your legs, keeping your knees and feet parallel and at hip width apart with your arms by your sides.

EXHALE: rotate in your hip and slowly open one leg outwards with your knee reaching toward the mat.

INHALE: bring your knee back in line with your hip.

Repeat with the opposite leg.

Keep your knee at a consistent angle and in line with your opposite knee as you rotate in your hip joint. Maintain a stable pelvis and use your adductors to bring the knee back to the starting position.

3 Sets / 12 Reps



3. Pilates single leg stretch level 1 * no head lift

Lie on your back with your legs in the Table Top position (hips and knees bent at 90 degrees) with a hand on each knee and your head and shoulders raised off the mat. Ensure your abdominal muscles are pulled in towards your spine.

EXHALE: extend one leg upwards to 90 degrees off the mat, shift your hands onto your bent knee.

INHALE: switch legs.

EXHALE: stretch the other leg up to the ceiling.

INHALE: switch legs and maintain your body in a stable position.

Continue switching legs smoothly and ensure your abdominals are pulled in at all times and that you maintain a stable body position.



4. Pilates single leg lift

Lie on your back in a neutral spine position.

Bend your legs, keeping your knees and feet parallel and at hip width apart with your arms by your sides.

EXHALE: lift your leg off the mat with the bent knee at a 90 degree angle and your foot Plantar flexed (pointed).

INHALE: lower your leg down and tap the floor with your toe. Perform the desired number of the repetitions and change legs.

Keep the pelvis stable as you raise and lower your leg, hinging at the hip joint. Maintain your leg bent at a constant angle of 90 degrees.

3 Sets / 15 Reps



5. Sciatic nerve mobilisation in supine - ankle plantarflexion/dorsiflexion

Lie on your back with your legs straight and a hip's width apart.

Bring your affected leg in towards your chest and interlace your fingers behind your thigh. With your arms straight, allow your leg to rest in the grasp of your hands. Your hip should be around 90 degrees.

Holding this position, slowly straighten your knee until you feel a pull down the back of your leg.

Keep your toes pointed.

Bring your lower leg back down a little to ease off the tension, then pull your foot towards you.

Straighten your knee a little while simultaneously pointing your toes, then bend your knee to bring your lower leg back down to the starting position.

Continue this movement at a steady pace.

3 Sets / 12 Reps / 1 s hold

**6. 4 point kneeling - UL raise (elevated)**

Start on your hands and knees, with your hands under your shoulders, and knees under your hips.

Keep your back straight and your hips in a neutral position. Lift one arm up and keep your elbow straight.

Ensure your body and hips do not move throughout this movement.

Lower the arm and repeat

3 Sets / 12 Reps / 1 s hold



7. 4 point kneeling - knee hovers

Start on your hands and knees with your hands under your shoulders and knees under your hips.

Find your neutral spine ensuring your head is also in the neutral position with your gaze between your hands.

With your arm straight but not locked, push the heels of your hands into the floor so that your shoulder blades flatten against your back.

Keeping this neutral position with your spine and shoulder blades, tuck your toes under and lift your knees from the floor.

Your knees should only rise around 1 centimetre. Hold this position.

You should feel the muscles in your tummy tighten.

Check that your back remains straight and your shoulder blades remain in contact with your back.

This now turns into 2 exercises

1. Prep 'hover' for 15 sec hold X 3

2. From the prep hold - do a walk back plank step back one foot at a time into plank then step back in to knee hover

Repeat X 35-40seconds

3 Sets / 12 Reps



8. 4 point kneeling - LL extension (elevated)

Start on your hands and knees with your hands under your shoulders and knees under your hips.

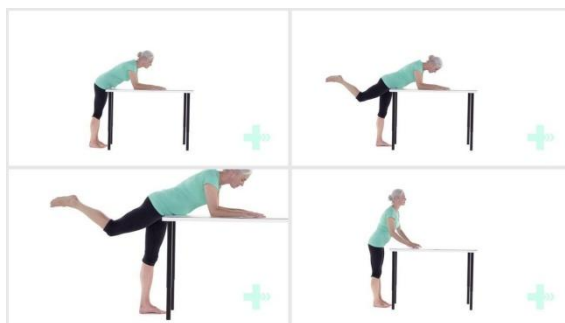
Find your neutral position with your spine and head.

Push the heels of your hands into the floor so that your shoulder blades flatten against your back.

Tighten your abdominal muscles to help stabilise your trunk as you slowly straighten one leg out behind you. Lift your leg from the floor until you have a straight line from the back of your head to the heel of your foot. Do not allow your hips to rotate with this movement. Control the movement as you bring your leg back in to the starting position. Ensure your back and neck remain in the neutral position throughout, with your shoulder blades controlled.

3 Sets / 12

Reps / 1 s hold



9. Prone (over table) hip extension

Stand up straight and lie your body over a high table. Make sure your body is well supported.

Bend your knee on your affected leg, then push your foot directly up towards the ceiling.

Tighten your buttock muscles as you do this.

Control the movement as you lower your leg back down and then repeat.

Straight leg - be respectful of the end range GLUTE ON focus

3 Sets / 12 Reps



10.3 moves: Modified PushUp, shoulder tap and renegade rows

Start on your hands and knees and walk your hands forwards until you have a straight line from your shoulders to your knees.

Keeping your body straight, slowly bend your elbows, bringing your chest towards the floor, then push back up to the start position.

3 exercises here

1. Elbows in by side - press ups - reps for 35-40 sec
2. Shoulder taps 40seconds
3. renegades with weights 3-4kg 40sec

3 Sets / 12 Reps / 1 s hold



11. High plank

Kneel down on a mat with your hands under your shoulders and knees under your hips.

Straighten one leg and then the other leg back behind you.

There should be a straight line from the back of your head through your back, the back of your legs to your heels.

Push your hands into the floor so that your shoulder blades fix onto your back. Hold this position.

Ensure your hips do not push up into the air. Remember to breathe.

3 Sets / 12 Reps / 1 s hold / 0.1kg weight



12. Plank one arm row

Get in to a press up position.

Keeping a straight line from your head to your feet, lift the arm up and down, moving your elbow towards the ceiling.

There will be a slight rotation in your torso.

We did this round the house in combo with leg lifts Option to add light weights as you get better

3 Sets / 12 Reps / 0.1kg weight



13. Plank with one arm weighted row

Get in to a press up position with a weight in one hand.

Keeping a straight line from your head to your feet and lift the weight up and down, moving your elbow towards the ceiling.

There will be a slight rotation in your torso.

3 Sets / 12 Reps / 1 s hold



14. Plank - knee to chest

Lie on your front with your toes on the floor.

Place your hands on the floor by your shoulders and push yourself up, lifting your torso and knees.

Hold a neutral line from the back of your head to your heels, driving your hands into the floor so that your shoulder blades flatten on your back.

Maintaining this control, bring one knee in towards your chest. Move this leg back to the starting position and repeat.

Keep your buttocks squeezed and your hips level throughout this movement.

1 set of mountain climbers

1 set of spider climbers - aiming for knee to outside of elbow

3 Sets / 12 Reps

**15. Plank (high) with alternate leg lift**

Kneel down on a mat with your hands under your shoulders and knees under your hips.

Straighten one leg and then the other leg back behind you.

There should be a straight line from the back of your head through your back, the back of your legs to your heels.

Drive your hands into the floor so that your shoulder blades flatten on your back. Maintaining this control, lift one leg up from the floor.

Keep your leg straight as you lower it back down, and repeat with the other leg. Ensure you keep your abdominal and buttock muscles activated throughout.

Do not allow your hips to rotate.

We did this around the house - paired with renegade rows or arm lifts

3 Sets / 12 Reps

**16. Four point inner range press up (narrow)**

Start on your hands and knees.

Walk your hands forwards until you form a straight line from your shoulders to your knees.

Lift your knees off the floor, so that you are supporting your bodyweight through your hands and toes.

Keeping your body straight, slowly bend your elbows, lowering your chest until your bent knees touch the floor.

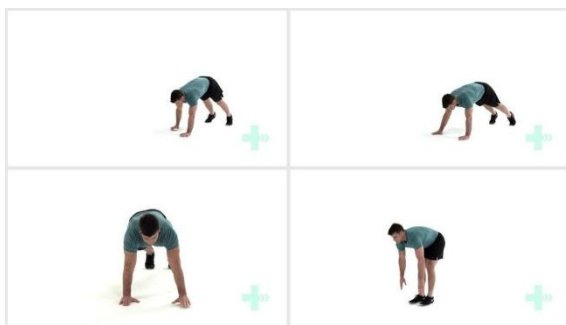
Your elbows should remain close beside your body.

Pause briefly, and then return to the start position by extending your arms out straight, ensuring you do not lock your elbows at the top of the movement.

Pause briefly, and then repeat.

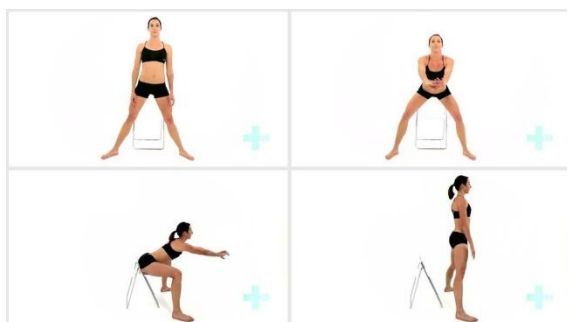
3 Sets / 12 Reps

17. Handwalks



Stand with your legs straight and your body bent over with your hands on the ground in front of you. Keeping your legs straight and stomach tight, walk your hands forward to a push up position. Still keeping your legs straight, walk your feet back up to your hands. When a stretch is felt, walk your hands back out to a push-up position. Continue to complete the set.

3 Sets / 12
Reps



18. Box squat with chair

Put the chair behind you and take a very wide step. Push your hips back behind you, as you try and sit down into the chair. Counterbalance this by leaning your chest forwards, keeping your back straight. Elevate your heels when you're sitting down. Stand up, ensuring your knees travel forwards over your toes the whole time.

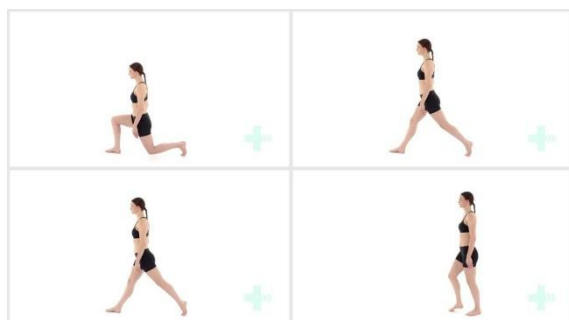
3 Sets / 12 Reps



19. Wall squats with stability ball

Hold a stability ball against a wall, placed in the small of your back. Lean firmly back against the ball. Walk your feet forwards, keeping your toes pointing ahead and your legs at hips-width apart. Squat down, dropping your hips towards the floor and bending your knees until they reach 90 degrees. Stand up straight, driving the movement with your buttock muscles. Make sure your body remains straight and knees travel directly forwards over your toes throughout this exercise.

3 Sets / 12 Reps

**20. Split squat (full depth)**

Stand up straight and take one large step forward.

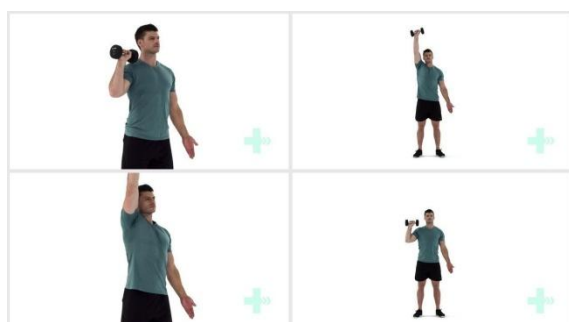
Maintaining your balance, bend your knees, aiming to achieve a right angle at your hips and knees.

Ensure your front knee does not drop inwards.

Tighten your thigh and buttock muscles to straighten back up again.

Repeat.

3 Sets / 12 Reps / 2kg weight

**21. Overhead press - standing, single arm with dumbbell**

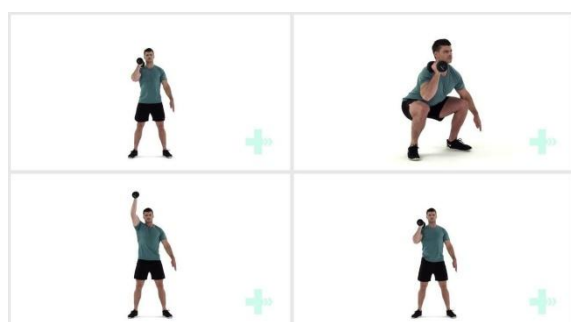
Stand with your feet shoulder width apart, holding a dumbbell at your shoulder in one hand.

Contract your glutes and keep your stomach tight.

Press the weight overhead ensuring your arm is fully locked out. Lower the dumbbell back down to your shoulder.

Continue the set on one side before repeating with the opposite arm.

3 Sets / 12 Reps / 3kg weight

**22. Squat to press - single arm with dumbbell**

Stand with your feet shoulder width apart, holding a dumbbell at one shoulder with your elbow pointed down.

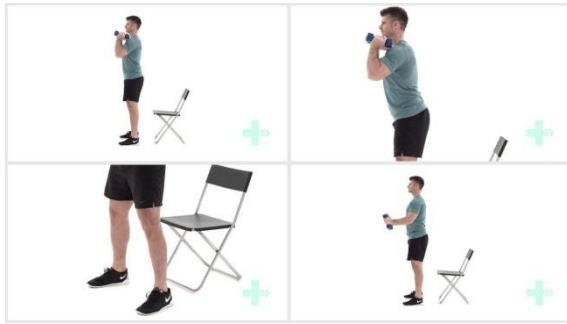
Initiate the movement by flexing at the hips, knees and ankles until your thighs are parallel to the ground.

Your back must remain straight and upright throughout the movement with your head up and gaze forward.

Keep your knees inline with your toes and do not allow your heels to rise off the ground.

Stand by pushing through your hips and press the dumbbell overhead

3 Sets / 12 Reps / 6kg weight



23. Box squat with chair - weights

Put a chair behind you and take a very wide step to the side. Hold some weights on your shoulders.

Push your hips back behind you, as you try and sit down into the chair. Counterbalance this by leaning your chest forwards, keeping your back straight. Stand up, ensuring your knees travel forwards over your toes the whole time.

Complete with 10kg Weighted Vest

Appendix 14 The TIDieR Checklist

Information to include when describing an intervention and the location of the information	Item	Where located **
Item number		
Primary paper (page or appendix number)		Other † (details)
BRIEF NAME		Chapter 5
1.	To evaluate efficacy of a Schroth intervention on impairments identified in Study 2.	_____
WHY		
2.	The null hypothesis is there will be no difference in the treatment outcomes when a Schroth programme compared to 'usual care'. Describe any rationale, theory, or goal of the elements essential to the intervention.	Section 5.1.7. _____
WHAT		
3.	To assess the efficacy of Schroth in addressing impairments identified in Chapter 4. And to compare the outcomes of a Schroth programme with outcomes in 'usual care' management. Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Appendix 13 HEP examples Provide information on where the materials can be accessed (e.g. online appendix, URL).	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_____
		Chapter 5
Section 5.2.6.		