Physical activity level and barriers to physical activity among an adult type 1 diabetes population

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Declaration

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Summary

Methods: There were 2 phases of this research.

Phase 1 took place in two parts: (a) Using an observational cross-sectional design, physical activity (PA) was measured objectively over 7 days in 72 participants (34 males) using accelerometry (ActiGraph). Subjectively-reported PA levels were captured using the International Physical Activity Questionnaire (IPAQ). PA data from the accelerometer was compared to subjectively reported PA data from the IPAQ. The Interclass correlation coefficient (ICC) was used to test the reliability between both measures. Barriers to PA were measured using the BAPAD-1 [Barriers to Physical Activity in Diabetes (Type 1)] scale. Anthropometrical (Weight, height, BMI, waist and hip circumference, % body fat and fat mess), biochemical (lipid and renal profile, urine albumin and urine albumin: creatinine ratio) and clinical parameters [glucometer downloads for the week wearing the accelerometer (i.e. average blood glucose, blood glucose standard deviation and number of hypoglycaemic episodes) and blood pressure] were recorded. Multiple linear regression models were applied to assess how PA influenced HbA1c and cardiovascular risk factors. (b) All participants attending an adult type 1 diabetes clinic over a 4 month period were asked to complete the IPAQ and the BAPAD-1 scale. Anthropometric (weight, height, BMI), biochemical (lipid and renal profile, urine albumin and urine albumin: creatinine ratio) and clinical data (blood pressure) were extracted retrospectively from data sources and participant records within the hospital.

Phase 2: Three focus groups were conducted with a total of 25 participants with type 1 diabetes. Mean age was 38 (SD 11.1) years and mean HbA1c of 7.4 (SD 1.4) %. Dictaphones were used and focus groups were transcribed verbatim. Qualitative analysis of the focus group data was performed using Interpretative Phenomological Analysis. Analysis was performed manually by the researcher (Mary Finn). Information was coded according to key themes and emerging categories and a coding frame was developed with superordinate and subordinate themes. Key phrases from the focus group individuals were used to illustrate emerging themes.

Major Findings: Phase 1 (a) Mean age (± SD) was 40.9 (± 12.9) years, diabetes duration was 18 (± 11.6) years and HbA1c was 8.0 (± 1.3) %. Twenty-three (32%) participants exercised to PA recommendations as measured by accelerometry, compared to 69 (97%) participants reporting meeting the recommendations as per the IPAQ. Those meeting PA recommendations, as measured by accelerometry, had a significantly lower HbA1c (7.7 ± 1.1 % vs 8.4 ± 1.2 %; p = 0.001), BMI [24.5 (22.3, 27) kg/m^2 vs 27 (23.4, 31.1) kg/m^2; p = 0.032], waist circumference [80.9 (76.4, 87.5) cms vs 88.6 (80.4, 100) cms; p = 0.006] and fat mass [19.0 (11.7, 21.5) kg vs 22.1 (17.3, 33.8) kg; p = 0.032]. Participants also had a significantly greater number of hypoglycaemic events [5 (3, 8.5) vs 2 (1, 4); p = 0.004].

A significant difference in the reported time spent in moderate-intensity physical activity as per the IPAQ and moderate-intensity physical activity measured by the ActiGraph was found (187 ± 184.6 vs 31.9 ± 21.5 mins/ day). Reported time spent in vigorous-intensity physical activity and time spent sedentary significantly correlated with time spent in vigorous-intensity physical activity and time spent sedentary from the actigraph monitor. However, using the ICC, there was only significant agreement in sedentary time between both measures ($p = 0.032$).

Fear of hypoglycaemia was identified as the strongest barrier to PA (3.4 ± 2.0). The other main barriers to PA included low fitness levels (2.9 ± 1.9), weather (2.8 ± 1.9) and loss of control over diabetes (2.7 ± 1.9). There was no association between BAPAD-1 score and PA level measured by the accelerometer or diabetes control as measured by HbA1c. As percentage body fat and fat mass increased there was a significant increase in BAPAD-1 score ($p = 0.004$ and $p = 0.026$ respectively).

(b) 151 participants completed the IPAQ and 168 participants completed the BAPAD-1 scale. Median age was 35 (23.5, 49.7) years and diabetes duration was 13.9 (6.8, 21.4) years. The IPAQ captured 95% (n = 143) of participants as meeting the PA guidelines. The mean BAPAD-1 score was 2.4 ± 1.1. The highest barrier scores were fear of hypoglycaemia (3.3 ± 1.9), followed by low fitness level (2.8 ± 1.9); weather (2.8 ± 1.9) and loss of control over your diabetes (2.7 ± 1.9). Glycaemic control, as measured by HbA1c, was positively correlated with BAPAD-1 score ($p = 0.047$).

<u>Phase 2:</u> From the themes that emerged there appear to be many frustrations and issues with currently available apps. Previously used apps were found to be burdensome, time consuming, complicated, and the data they received back to be overwhelming. Suggestions that will aid in the design of a type 1 diabetes and exercise app included tailoring advice to the individuals based on their individual profile and data entry, advice in the form of suggestions rather than specific figures, and making the app uncomplicated and user friendly.

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Abstract

Adherence to physical activity recommendations and barriers to physical activity among Irish adults with type 1 diabetes

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Context: Information on physical activity (PA) levels and its association with glycaemic control and cardiovascular disease (CVD) risk is lacking among Irish adults with T1DM.

Aims: (1) PA levels were assessed in this population using objective (accelerometry) and subjective [International Physical Activity Questionnaire (IPAQ)] PA measures and the relationship between PA, glycated haemoglobin (HbA1c) and CVD risk factors was evaluated. (2) Objective and subjective measures of PA were compared to determine the reliability of a subjective measure of PA. (3) Barriers to PA were identified using the Barriers to Physical Activity in Diabetes (Type 1) scale (BAPAD-1 scale). (4) Qualitative research was used to explore the attitudes, needs and expectations of an mHealth app for the management of type 1 diabetes and exercise

Methods: (a) Using an observational cross-sectional design, PA was measured objectively over 7 days in 72 participants (34 males) using accelerometry (ActiGraph), and subjectively using the IPAQ long form. Participants also completed the BAPAD-1 scale. Anthropometrical, biochemical and clinical parameters were recorded. Multiple linear regression models were applied to assess how PA influenced HbA1c and cardiovascular risk factors. (b) An additional 186 participants completed one or both of the questionnaires (IPAQ and BAPAD-1 scale). Anthropometric, biochemical and clinical data was extracted retrospectively from data sources and participant records within the hospital. (c) Three focus groups were conducted with a total of 25 participants with T1DM [mean age was 38 (SD 11.1) years and mean HbA1c was 7.4 % (SD 1.4)]. Dictaphones were used and focus groups were transcribed verbatim. Qualitative analysis of the focus group data was performed using Interpretative Phenomological Analysis.

Results: (a) Mean age (±SD) was 40.9 (±12.9) years, diabetes duration was 18 (±11.6) years and HbA1c was 8.0 (±1.3) %. Twenty-three (32%) participants exercised to PA recommendations as measured by accelerometry, compared to 69 (97%) participants reporting meeting the recommendations as per the IPAQ. Those meeting recommendations (accelerometry) had a lower HbA1c (p=0.001), BMI (p=0.032), waist circumference (p=0.006) and fat mass (p=0.032) and a greater number of hypoglycaemic events (p=0.004). Fear of hypoglycaemia was the strongest barrier to PA (3.4 ± 2.0). Other barriers included low fitness levels, weather and loss of control over diabetes. (b) 151 participants completed the IPAQ and 168 participants completed the BAPAD-1 scale. Median age was 35 (23.5, 49.7) years and diabetes duration was 13.9 (6.8, 21.4) years. The IPAQ captured 143 (95%) participants as meeting the PA guidelines. The highest barrier score was fear of hypoglycaemia (3.3 ± 1.9), followed by low fitness level (2.8 ± 1.9); weather (2.8 ± 1.9) and loss of control over your diabetes (2.7 ± 1.9). Glycaemic control, as measured by HbA1c, was positively correlated with BAPAD-1 score (p=0.047). (c) From the themes that emerged there appear to be many frustrations and issues with currently available apps. Previously used apps were found to be burdensome, time consuming, complicated, and the data they received back to be overwhelming. Suggestions that will aid in the design of a T1DM and exercise app included tailoring advice to the individuals based on their individual profile and data entry, advice in the form of suggestions rather than specific figures, and making the app uncomplicated and user friendly.

Conclusion: The majority of participants fail to meet PA recommendations, however those that do have healthier cardiovascular risk factor profiles. Participants likely overestimate their PA level using a subjective measure. Several barriers to PA were identified. Participants with T1DM require support and education to safely improve activity levels. Involving individuals with T1DM early in the design of a T1DM and exercise app could help support those looking to commence or increase exercise.

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1. Chapter 1: Introduction

1.1. Overview

Individuals with type 2 diabetes are at higher risk of developing cardiovascular disease (CVD) and to die of CVD-related complications when compared to the general population (Norhammar, Malmberg et al. 2004). Physical activity is associated with a decreased risk of mortality and CVD in participants with type 2 diabetes (Sigal, Kenny et al. 2006; Warburton, Nicol et al. 2006). Among those with type 2 diabetes physical activity prevents CVD through improvements in glycaemic control, blood lipids, blood pressure, insulin sensitivity and endothelial function (Stewart 2002). The Look AHEAD study however found that an intensive lifestyle intervention that promoted weight loss through decreased calorie intake and increased physical activity did not reduce the rate of cardiovascular events among overweight and obese adults with type 2 diabetes. The authors speculated several possible reasons for this, including the increased use of statins in the control group; the study lacking sufficient power; and insufficient weight loss in order to reduce the risk of CVD.

Individuals with type 1 diabetes are also at increased risk of cardiovascular morbidity and mortality with clinical manifestation beginning 15-20 years after the onset of diabetes (Andersen, Christiansen et al. 1983; Jacobs, Sena et al. 1991). However, the benefits of physical activity among those with type 1 diabetes is less clear, with many studies showing mixed results (Chimen, Kennedy et al. 2012). Aerobic training has been shown to improve cardiorespiratory function, decrease insulin resistance, and improve lipid levels and endothelial function (Chimen, Kennedy et al. 2012). However, the results of studies on exercise and glycaemic control are conflicting (Kennedy, Nirantharakumar et al. 2013). Physical activity is associated with risks in type 1 diabetes, as due to the complexity of physiologically regulating exogenous insulin during exercise, physical activity can often result in episodes of hypoglycaemia or hyperglycaemia shortly following and even long after finishing exercise (MacDonald 1987). Therefore, further evidence is needed to clarify whether the risks associated with physical activity in type 1 diabetes outweigh the benefits, particularly in terms of glycaemic control.

Several barriers to exercise in type 1 diabetes exist, including fear of hypoglycaemia, lack of time, work pressure, environmental conditions etc. (Brazeau, Rabasa-Lhoret et al. 2008). These barriers, along with the lack of evidence for the beneficial effect of exercise on long term glycaemic control, likely contribute to the poor physical activity levels among those with type 1 diabetes (Yardley, Hay et al. 2014). To date efforts to increase physical activity among this population have largely been unsuccessful. Therefore, exploring new and more novel interventions looking to address the issue of physical inactivity is desirable.

1.2. Incidence of overweight / obesity and CVD risk factors among the type 1 diabetes population

While adiposity in the past was not considered a characteristic of type 1 diabetes, the prevalence of overweight (22.1%) and obesity (12.6%) in youth with type 1 diabetes (age 3-19 years) has increased (Liu, Lawrence et al. 2010). Among youth with type 1 diabetes the prevalence of overweight was higher than among those without diabetes [22.1% vs. 16.1% ($P < 0.05$)]. However, the prevalence of obesity among youth with type 1 diabetes was not higher than nondiabetic youth. Among adults (≥18 to <80 years) with type 1 diabetes the majority did not have a healthy bodyweight (Bohn, Herbst et al. 2015). This cross-sectional multicentre study consisting of 18,028 participants with type 1 diabetes showed that about 60% of individuals were overweight or obese (45.5% were overweight and 14.5% were obese). Among 589 adults in the United States with Type 1 diabetes (mean age 29 years), the prevalence of overweight and obesity were 28.6% and 3.4%, respectively. Participants were first seen in 1986-1988, and biennially thereafter for 18 years. After 18 years' follow-up, the prevalence of overweight increased by 47% (from 28.6% to 42%) while the prevalence of obesity increased sevenfold (from 3.4% to 22.7%), highlighting the dramatic weight gain that occurs in individuals with Type 1 diabetes (Conway, Miller et al. 2010). Thus it would appear that currently overweight and obesity levels among adults with type 1 diabetes are not that dissimilar to the general population. The National Adult Nutrition Survey outline levels of overweight and obesity in Ireland (Alliance 2011) and reports that among 18-64 year olds, 39% percent of the population were in the normal weight range. However, a total of 24% were obese (men 26%, women 21%) and 37% were overweight (men 44%, women 31%). Overweight and obesity leads to an increased risk of cardiovascular disease (CVD) due to dyslipidemia, hyperinsulinemia, and hypertension. Therefore, this already high risk population are at further increased risk of CVD due to high rates of overweight and obesity. Persons with Type 1 diabetes exhibit a greater than three-fold higher risk of acute CVD compared to their non-diabetic counterparts, resulting in a 7 year reduction in life expectancy (Liese, Ma et al. 2013). Cardiovascular risk factors include abdominal obesity, albuminuria, blood glucose control, blood pressure and lipid levels (HLD, LDL and triglycerides), along with unmodifiable factors including age, gender and family history. Among adults with type 1 diabetes, 62% had dyslipidaemia, 20% had microalbuminuria and 40% had hypertension, placing these individuals at increased risk of developing CVD (Bohn, Herbst et al. 2015).

1.3. Impact of physical activity on CVD risk in type 1 diabetes

In the literature, results showing the effect of physical activity on CVD risk factors among those with type 1 diabetes are mixed. In a systematic review and meta-analysis, data for cardiovascular risk factors (LDL, HDL, VLDL, TG, TC, Apo-A, Apo-B) were not consistently available for all studies. Where they were available no effect of exercise was observed (Yardley, Hay et al. 2014). On the other hand, Tielemans et al. showed that physical activity had a borderline inverse association with both all-cause mortality (both sexes) and incident CVD (women only) among those with type 1 diabetes (Tielemans, Soedamah-Muthu et al. 2013).

1.3.1. Physical activity level and glycaemic control

A literature review by Chimen at al. (2012) demonstrated that physical activity improves insulin requirements but shows a limited effect on glycaemic control as measured by HbA1c (Chimen, Kennedy et al. 2012). These studies have predominantly involved adolescents or young adults.

Also this literature review included non-randomized trials, and studies of interventions that combined diet and exercise training (Yardley, Hay et al. 2014). A more recent systematic review and meta-analysis of exercise interventions (regular exercise training performed at least twice weekly for a minimum of eight weeks) in adults with type 1 diabetes (mean age 10.5-35.5 years) found a significant reduction in HbA1c (mean difference -0.78%) in the exercise group compared with controls receiving standard care in four out of six randomized controlled trials (280 participants – 191 assigned to exercise training; 89 assigned to control) (Yardley, Hay et al. 2014). It must be noted that of the 191 participants in this review, 148 participants were from a single study looking at adolescents with type 1 diabetes (mean age 14.6 ± 2.3 years) (Salem, AboElAsrar et al. 2010). In this study participants who took part in a 6 month supervised programme had significant reductions in HbA1c. The greater reduction was noted in participants who performed regular exercise three times per week (8.9 ± 1.6 to 7.8 ± 1 %) compared to those who performed once weekly exercise sessions (8.9 ± 1.4 to 8.1 ± 1.1 %). A meta-analysis looked at the effects of different forms of exercise (chronic exercise [or training]) on chronic glycaemic control among individuals with type 1 diabetes. This showed that aerobic training is a favourable tool for decreasing chronic glycaemic control, whereas mixed, high-intensity and resistance exercise did not significantly improve chronic glycaemic control (Tonoli, Heyman et al. 2012). In this meta-analysis 12 studies were used to estimate the effect size of aerobic training on chronic glycaemic control among a total population of 171 adults, adolescents and children with type 1 diabetes. Overall the effect size was small but significant (Effect size -0.23; 95% CI -0.44, -0.02). A recent cross-sectional multicenter study of 18,028 adult participants (18 to <80 years) with Type 1 diabetes showed that participants who were categorized as being physically active (exercising more than two times per week) had a significantly lower HbA1c than those not physically active (7.84% versus 8.2%; $p < 0.0001$) (Bohn, Herbst et al. 2015). The benefits of physically activity on HbA1c has also been seen among children and young people with type 1 diabetes with a systematic review and meta-analysis showing a reduction in HbA1c by about 0.3% (Quirk, Blake et al. 2014).

On the other hand a slight worsening of blood glucose control was found in one study where six females (aged 25 to 45 years) with type 1 diabetes (diabetes duration at least five years) took part in five months of non-supervised exercise training (20 mins daily bicycle exercise) and were compared to non-exercised controls (Wallberg-Henriksson, Gunnarsson et al. 1986). Also among adolescents no improvement in glycaemic control was seen after 12 weeks of exercise training. In this study nine adolescents with type 1 diabetes performed 45 mins of exercise three times weekly for 12 weeks and were compared to age matched non exercise controls with diabetes. Despite an increase in insulin , HbA1c remained unchanged at 12 ± 1 % (Landt, Campaigne et al. 1985). It must be noted that both of these studies included very small numbers.

1.3.2. Physical activity level and Insulin sensitivity / requirements

It has previously been demonstrated that physical activity is associated with reduced insulin requirements, with the reduction ranging from 6% to greater than 15% (Chimen, Kennedy et al. 2012). During a one week sports camp, where physical activity increased six fold, insulin dose was decreased by almost 20% in order to avoid severe hypoglycaemic episodes (Lehmann, Kaplan et al. 1997). In a systematic review and meta-analysis of exercise interventions among adults with type 1 diabetes, insulin requirements were reported in two out of the six randomised controlled trials, with one showing a significant reduction in insulin dosage in the exercise group of participants with a HbA1c >8.5% while the other trial showed no difference in participants with a HbA1c <8.5% compared with standard care (Yardley, Hay et al. 2014). A significant inverse association was seen between insulin dosage and physical activity in a large cross-sectional study of 18,028 participants with type 1 diabetes (Bohn, Herbst et al. 2015). It is likely that much of this reduction in insulin with increasing physical activity seen in the literature is necessary for hypoglycaemia avoidance (Chimen, Kennedy et al. 2012).

Regular exercise could improve insulin sensitivity through several mechanisms, including changes in body composition, muscle mass and capillary density (Lehmann, Kaplan et al.

1997). A significant increase in physical activity among subjects with type 1 diabetes engaged in a three month regular exercise programme consisting of endurance activities (long-distance running, hiking, and biking) led to a significant increase in insulin sensitivity as assessed by a 30% lower steady state plasma glucose (SSPG), with a comparable decrease in steady state plasma insulin (Lehmann, Kaplan et al. 1997). A significant negative correlation was seen between the decrease in SSPG and the increase in physical activity, meaning that those most active had the greatest improvement in insulin sensitivity (Lehmann, Kaplan et al. 1997). The significant reduction in body weight and waist-to-hip ratio, and increase in lean muscle mass, likely contributed to this increased insulin sensitivity (Lehmann, Kaplan et al. 1997).

1.3.3. Physical activity level and body composition

An inverse association between physical activity and BMI ($p < 0.0001$) was seen in a cross-sectional study among 18,028 adults with type 1 diabetes (Bohn, Herbst et al. 2015). In this study, the prevalence of obesity was highest among the inactive participants, irrespective of age or sex ($p = 0.0001$). During a six month exercise program the group that performed more frequent exercise (attended the exercise sessions three times per week) had a more significant reduction in BMI ($p = 0.001$) compared to those who only attended the exercise session once weekly ($p = 0.05$) (Salem, AboElAsrar et al. 2010). A significant increase in physical activity ($p < 0.001$) during a three month exercise program among well controlled individuals with type 1 diabetes ($n = 20$) resulted in a significant reduction in body weight ($p = 0.003$), percentage body fat ($p < 0.001$) and waist-to-hip ratio ($p < 0.001$) (Lehmann, Kaplan et al. 1997). Finally, a cross-sectional study among 75 adults with type 1 diabetes found that those with an active lifestyle [defined by a recommended threshold of physical activity level ≥ 1.7 ratio total/resting energy expenditure)] when compared to a more sedentary lifestyle (physical activity level ≤ 1.7) was associated with a significantly lower BMI, waist circumference, percentage total fat mass and percentage truncal fat mass (Brazeau, Leroux et al. 2012). However, not all studies found an improvement in body composition with increased physical activity. In a randomized trial consisting of a 12-16 weeks supervised aerobic exercise program 56 adult males with type

1 diabetes found no significant changes in BMI or percentage body fat (Laaksonen, Atalay et al. 2000).

1.3.4. Physical activity level, lipid profile, blood pressure and albuminuria

In a cross sectional study of 18,028 participants with type 1 diabetes an inverse relationship was found between physical activity and dyslipidaemia ($p < 0.001$), hypertension ($p = 0.0150$) and microalbuminuria ($p < 0.001$) (Bohn, Herbst et al. 2015). In this study an inverse association between diastolic blood pressure and physical activity was found ($p = 0.0377$), whereas systolic blood pressure was not associated with physical activity. Another cross-sectional study among 75 adults with type 1 diabetes who wore a motion sensor for one week to measure physical activity found no association between physical activity and blood lipid profile and blood pressure (Brazeau, Leroux et al. 2012). One possibility for this finding alluded to by the authors was the use of aggressive pharmacological treatment of these risk factors among the type 1 diabetes population.

Studies involving exercise interventions ranging from three to six months found mixed results in terms of the benefits of physical activity on blood pressure and lipid profile. Systolic and diastolic blood pressure remained unchanged during a six month exercise intervention where adults with type 1 diabetes participated in an exercise session three times per week, however, frequent exercise improved dyslipidaemia (significant decrease in LDL-c, TG, and cholesterol and significant increase in HDL-c) in this study (Salem, AboElAsrar et al. 2010). A study involving a three month unsupervised exercise intervention where individuals were asked to exercise at least three times per week found a significant decrease in systolic and diastolic blood pressure and a significant decrease in LDL-c and increase in HDL and HDL3-c subfraction, while triglycerides remained unchanged (Lehmann, Kaplan et al. 1997). Finally a 12- to 16- week aerobic exercise program among young adult men with type 1 diabetes ($n = 56$) randomized to either training or control found that favourable changes in HDL, LDL and triglyceride levels were significantly greater in the training group compared to the controls (Laaksonen, Atalay et al. 2000).

1.4. Physical Activity Recommendations

A recent Position statement from the American Diabetes Association on Physical activity / exercise and diabetes state that most adults with diabetes (type 1 and type 2 diabetes) should engage in 150 minutes or more per week of moderate-to-vigorous-intensity physical activity, spread over at least three days per week, with no more than two consecutive days without activity (Colberg, Sigal et al. 2016). The same recommendation was made for those with type 1 diabetes in a recent consensus statement on exercise management in type 1 diabetes (Riddell, Gallen et al. 2017). Aerobic activity bouts should ideally last at least 10 min, with the goal of approximately 30 min per day, or more, most days of the week (Colberg, Sigal et al. 2016). Two to three resistance exercise sessions per week on non-consecutive days is also recommended for those with type 1 and type 2 diabetes (Colberg, Sigal et al. 2016; Riddell, Gallen et al. 2017). These exercise recommendations are the same as the recommendations for the general population as per the position stand from the American College of Sports Medicine (Garber, Blissmer et al. 2011). For younger and more physically fit individuals with diabetes for a shorter duration, vigorous intensity or interval training (for a minimum of 75 mins per week) may be sufficient (Colberg, Sigal et al. 2016). Finally for older adults with diabetes flexibility and balance training (i.e. yoga, tai chi) are recommended two to three times per week in order to increase flexibility, balance and muscle strength (Colberg, Sigal et al. 2016).

1.5. Current levels of physical activity among adults with type 1 diabetes

Despite these recommendations it appears from the available evidence that the majority of those with type 1 diabetes fail to meet the recommended physical activity guidelines and are less physically active than their non-diabetic counterparts (Brazeau, Rabasa-Lhoret et al, 2008; Komatsu, Gabbey et al. 2005; Lobelo, Liese et al. 2010). Among the available observational research physical activity is measured using both objective and subjective measures.

1.5.1. *Objective versus subjective measure of physical activity*

There are many tools available for the measurement of physical active and these can generally be broken into subjective and objective measures. The majority of studies use subjective measures of physical activity, which include self-reported or interview based methods of recalling physical activity over a certain time frame (i.e. self-reported or telephone questionnaires) (Pober, Staudenmayer et al. 2006). Due to the difficulty with subjects having to recall their physical activity as well as the desire to conform to social norms these tools are subject to biases (Pober, Staudenmayer et al. 2006). Among children and adolescents with type 1 and type 2 diabetes a review of the literature showed that approximately half the studies included used questionnaires (either self-reported by the participants or their parents) and the majority of these questionnaires were validated tools (unable to determine in 4 studies if the tools used were validated) (Liese, Ma et al. 2013). This authors of this review highlight the need to exercise caution when reviewing the literature, as self-reported physical activity is likely to be overestimated by individuals.

The International Physical Activity Questionnaire (IPAQ) is one of the most widely used physical activity questionnaires and was developed for assessing population levels of health-related physical activity (Dyrstad, Hansen et al. 2014). In 1998 a consensus group was set up and the objective of the group was to develop a self-reported measure of physical activity suitable for assessing population levels of physical activity across countries. The initial pilot testing occurred between 1998 and 1999. There are two versions available, the IPAQ-short form and the IPAQ-long form. The reliability and validity of both versions was carried out in 14 centers in 12 countries during 2000. The IPAQ questionnaires produced repeatable data (Spearman's ρ clustered around 0.8). Criterion validity had a median ρ of about 0.3, which was comparable to most other self-reported validation studies. It was concluded that the IPAQ has acceptable measurement properties for monitoring population levels of physical activity among adults (18 to 65 years old) in diverse settings (Craig, Marshall et al. 2003). Also the IPAQ-long form is ideal for research purposes as well as for providing more detail on the different domains of physical activity (Craig, Marshall et al. 2003). Both versions cover four domains of physical activity: work-related, housework/gardening, transportation and leisure-time activity, and the long version also includes a question on total time spent sitting per week (Hagströmer, Oja et al. 2006). The validity of the IPAQ-long form was also assessed by comparing its results to data from a physical activity logbook and an accelerometer (Manufacturing Technologies Inc. Actigraph model) (Hagströmer, Oja et al. 2006) and results indicated that the IPAQ had acceptable properties for assessing physical activity (different domains and intensities and total physical activity) among healthy adults.

Objective measures of physical activity provide a more accurate estimate and accelerometry is one such method. (Liese, Ma et al. 2013). Accelerometers are activity monitors that measure position and motion (Liese, Ma et al. 2013). Other objective measures include heart rate monitoring, exercise/ fitness testing and pedometers / step counters (Liese, Ma et al. 2013). Accelerometry can be employed at a reasonable cost and provides detailed information about duration and intensity of physical activity (Pober, Staudenmayer et al. 2006).

1.5.2. Physical activity levels

Much of the available observational evidence on physical activity levels in type 1 diabetes has been performed in children and adolescents. A review of the epidemiologic literature suggests that a large proportion of children and adolescents with diabetes do not engage in sufficient amounts and intensities of physical activity to meet current recommendations of 60 mins of moderate/ vigorous-intensity physical activity per day and that a large proportion of children and adolescents with diabetes watch excessive amounts of TV (ranging between 110 and 140 min/day) (Liese, Ma et al. 2013). Physical activity questionnaires overestimated those meeting recommendations in this review with one study using the 3DPAR questionnaire suggesting that 81-82% of youth with type 1 diabetes achieved the recommended 60 mins per day of moderate-to-vigorous physical activity (Lobelo, Liese et al. 2010). Comparing this to accelerometer data from the US National NHANES study which found that only 11% of boys and 4% of girls aged 12-19 years achieved the recommended amount of physical activity, serves to highlight the issue of over-reporting with use of questionnaires (Troiano, Berrigan et al. 2008). Young people with Type 1 diabetes report less time spent in physical activity than their peers without diabetes (Komatsu, Gabbay et al. 2005). However, a study using the ActiGraph accelerometer among young people aged between 8 to 16 years (60 participants with type 1 diabetes and 37 participants without diabetes) found no difference in terms of physical activity between both groups, with those with diabetes undertaking 27.6 (±21.4) mins per day of moderate-to-vigorous-intensity physical activity, a lot less the recommended 60 mins per day on most days of the week (Cuenca-García, Jago et al. 2012).

Among adults with type 1 diabetes a large cross sectional study demonstrated that 63% of participants included were not physically active (Bohn, Herbst et al. 2015). Individuals in this study self-reported their physical activity levels. Less than 20% of individuals in this study do aerobic exercise more than twice per week and about 60% do no structured exercise at all. Using the Minnesota Leisure Time Physical Activity Questionnaire 130 adult participants with type 1 diabetes reported an average of 169.9 ± 212.1 mins per week of moderate-intensity physical activity and 120.6 ± 184.2 mins per week of intense physical activity (Carral, Gutiérrez et al. 2013). 23% of participants performed no intense physical activity and 38% performed no moderate activities in the previous month. In comparison, using accelerometry (motion sensor) to measure physical activity among adults with type 1 diabetes (mean age 43.5 ± 10.5 years), 43% of women and 55% of men met the recommended threshold of physical activity level (PAL) of ≥ 1.7 (Brazeau, Leroux et al. 2012). Another study also using a motion sensor among adults (age 43.5 ± 10.4 years) with type 1 diabetes showed that close to 60% reached an adequate PAL that could be considered an active lifestyle (Brazeau, Mircescu et al. 2012). Both these studies were done among a Canadian population. This accelerometer data is very different to data from those without diabetes in the U.S. NHANES 2003-2004 sample of adults which found that less than 5% of adults met the recommendation of 30 mins or more of at least moderate-intensity activity on five or more days per week (Troiano, Berrigan et al. 2008). The Actigraph accelerometer was used in this study. The differences are likely related to the different methods used to measure physical activity and the cut-offs used to define those considered physically active.

Finally, local data from the 2014 HANA Survey looks at physical activity levels (questionnaire) among the general population (1082 individuals living in the Tallaght area) (Darker, Whiston et al.). Only 15.7% (n = 53/337) of respondents reported meeting the guidelines of engaging in moderate physical activity five or more days of the week, which is also far lower than the accelerometer data found among those with type 1 diabetes.

From reviewing this literature it would appear that the results on physical activity levels are very different across studies, most likely due to the several different self-reported questionnaires or accelerometers that have been used to assess physical activity levels. Therefore, when choosing a questionnaire it is of upmost importance to choose a reliable and validated tool. Also an accelerometer must be extensively studies for its reliability and validity.

1.6. Barriers to physical activity

The 11-item Barriers to Physical Activity in Type 1 Diabetes (BAPAD-1) scale was developed by Dubé et al (Dubé, Valois et al. 2006). 74 participants with type 1 diabetes completed the questionnaire. Cronbach alpha coefficient was 0.85 and the correlation between the test-retest scores was 0.84, both indicating adequate reliability of the barriers scale. Overall the BAPAD-1 scale showed excellent psychometric qualities to adequately evaluate barriers to regular physical activity among those with type 1 diabetes (Dubé, Valois et al. 2006). Using the scale participants rate the 11 barriers to physical activity on a scale from 1 to 7 (whether the item would keep them from engaging in regular physical activity over the next 6 months, with 1 being extremely unlikely to 7 being extremely likely) (Brazeau, Rabasa-Lhoret et al. 2008).

To date public health messages to increase physical activity to meet recommendations among the general population and those with diabetes have largely been unsuccessful. Therefore, identifying perceived barriers to physical activity and addressing these in order to increase physical activity levels is extremely important. Several barriers to exercise in type 1 diabetes have been identified including concerns over loss of control of their diabetes and low fitness levels. However, one of the main barriers to physical activity that has been identified in children, adolescents (Liese, Ma et al. 2013) and adults (Brazeau, Rabasa-Lhoret et al. 2008) with type

1 diabetes is fear of hypoglycaemia. Physical activity can predispose to hypoglycaemia and is in fact one of the most frequent and feared acute complication of physical activity among those with type 1 diabetes and as a result participants may be apprehensive and reluctant to participate in physical activity (Kemmer 1992).

Exercise associated changes in glycaemia (mainly due to hypoglycaemia) may be dangerous and difficult to control, decreasing the benefits of exercise (Tamborlane 2007). There are many factors which complicate glycaemic management during exercise, including the type, intensity and duration of activity, along with differing insulin regimens and food intake for exercise (Colberg, Sigal et al. 2016). It can be extremely challenging for individuals to balance all of these factors in an effort to improve glycaemic control around exercise (Colberg, Sigal et al. 2016). Very often it’s through trial and error and several attempts by the individual that they come up with their own strategy to avoid hypoglycaemia and hyperglycaemia. However, this is difficult and requires a lot of motivation and effort on the individual’s part, therefore reducing adherence to exercise programs that would result in health benefits (Perkins and Riddell 2006) and discouraging those wishing to partake in some form of exercise (Brazeau, Rabasa-Lhoret et al. 2008). The NICE guidelines recommend that those choosing to integrate increased physical activity into a healthier lifestyle are provided with information about nutritional intake and appropriate adjustments of insulin dosage for exercise and post-exercise periods, and the next 24 hours (Excellence 2004). Despite this guideline a large proportion of participants with type 1 diabetes report a lack of practical advice on effective strategies for preventing exercise-induced hypoglycemia, and many feel largely uninformed about insulin administration and carbohydrate intake around exercise (Brazeau, Rabasa-Lhoret et al. 2008). This often discourages individuals to partake in exercise (Brazeau, Rabasa-Lhoret et al. 2008). Therefore, it is essential that programs aiming to increase physical activity among those with type 1 diabetes incorporate diabetes-specific strategies to prevent hypoglycaemia (Brazeau, Rabasa-Lhoret et al. 2008).

Qualitative research has also been done assessing barriers to physical activity among adults (Lascar, Kennedy et al. 2014) and young adults (Ryninks, Sutton et al. 2015). Focus groups with 12 young adults (age 11-16 years) with type 1 diabetes were used to assess attitudes to exercise (Ryninks, Sutton et al. 2015). Young people were aware of the benefits of physical activity and did not report risk of hypoglycaemia as a major concern. However, they felt that the lack of understanding among school staff (including PE teachers) and their peers without diabetes held them back. This finding highlighted the need for education among school staff in order to provide adequate supports to those with type 1 diabetes wishing to exercise. Another qualitative study using semi-structured interviews with long standing adult type 1 diabetic participants showed that many of the barriers to exercise are the same as that of the non-diabetic population (lack of time and work related factors; lack of motivation; access to facilities; weather; embarrassment and body image), with the only difference being the requirement for education around the effect of exercise on diabetes control (Lascar, Kennedy et al. 2014). Also they preferred support to be given on a one to one basis rather than group settings.

Education in this area can be resource intensive and challenging for the health care professional. Unfortunately, busy clinics leave health care professionals with very little time to provide one to one education in this complex area. This leaves individuals vulnerable and without sufficient education and knowledge to manage exercise without exposure to significant blood glucose variability.

1.7. Role of technology / mobile health applications to help educate and change behaviours among individuals with type 1 diabetes

We must develop a more effective way to educate and inform our patents in this complex area within available resources/staffing. The use of technology such as smartphone applications is one way to do this and future technology should strive to assist those with type 1 diabetes who wish to become or remain physically active (Colberg, Sigal et al. 2016).

The increased prevalence of mobile phone use makes them a powerful tool for providing individualized healthcare in a convenient and efficient way to our participants. Smartphones have the potential to be used to manage disease using mobile health (mHealth) applications (‘apps’) (Hoppe, Cade et al. 2016). mHealth has broadly been defined as medical or public health practice supported by mobile devices (Heerden, Tomlinson et al. 2012) and can be used to enhance chronic disease care beyond the traditional outpatient physician-participant encounter (Eng and Lee 2013). Apps can be used to change participant behaviours in health-related areas such as diet and exercise and also to improve adherence to prescribed treatment regimens (Becker, Miron-Shatz et al. 2014). Close to one in five individuals with a smartphone have downloaded a health app (Fox and Duggan 2012). In a review of diabetes medical apps (n = 100) in the iPhone store the majority of apps (33%) focused on health tracking (blood sugars, carbohydrates, insulin doses) with the majority requiring the user to manually enter the health data into the app. The remainder of the diabetes apps were teaching / training apps (22%), food reference databases (8%), social blogs / forums (5%) and physician directed apps (8%) (Eng and Lee 2013). Within dietetic practice, smartphone health apps were used in participant care by 62% of respondents (Chen, Lieffers et al. 2017). This study showed that their use within participant care was primarily as information resources, followed by participant self-monitoring, and as an extra support for participants (Chen, Lieffers et al. 2017).

Users of mHealth technologies and health apps perceive them to be effective in promoting healthy eating and exercise among the general population (Wang, Egelandsdal et al. 2016). Among those with type 1 diabetes benefits of mHealth apps have also been seen. Use of a smartphone application called *Glucose Buddy* (by SkyHealth) combined with a weekly text-message feedback from a certified diabetes educator significantly improved glycaemic control compared to usual care among adults with type 1 diabetes (mean 9.08 ± 1.18 % at baseline to 7.8 ± 0.75 % at 9-month follow-up (Kirwan, Vandelanotte et al. 2013). A meta-analysis looking at the effect of mobile phone interventions (use of short messaging service with or without internet to provide support for self-monitoring blood glucose, continuous education, and reinforcement of diet, exercise and medication adjustment) among those with both type 1 and type 2 diabetes showed significant improvement in diabetes self-management and glycaemic control (by a mean of 0.5 % over a median of six months follow-up duration) (Liang, Wang et al. 2011). This evidence was much stronger for those with type 2 diabetes than those with type 1 diabetes.

When it comes to the use of technology to promote physical activity most of the available evidence has been among those with type 2 diabetes. A systematic review on the effectiveness of technology-based interventions (mobile phones and text messages, websites, CD-ROMS, and computer based learning) showed their effectiveness at increasing physical activity among those with type 2 diabetes with all studies showing an increase in physical activity (9 out of 15 showing a significant increase) (Connelly, Kirk et al. 2013).

Finally, insulin dose calculators, intended to recommend an appropriate insulin dose, are a popular feature in medical apps. A small number of these apps extended the basic meal bolus calculation to incorporate additional adjustments for exercise (Huckvale, Adomaviciute et al. 2015). According to the US Food and Drug Administration a mobile health app is deemed a medical device if it is intended to diagnose, treat, cure or prevent a disease (Food and Administration 2013). If this is the case it would need FDA approval before it is released into the market. A systematic assessment of available rapid / short acting insulin dose calculators revealed many issues, most importantly that the majority of these apps contributed to incorrect or inappropriate insulin dose recommendations, thus putting individuals at risk (Huckvale, Adomaviciute et al. 2015). This highlights the importance of clinical input during the design of these medical apps in order to avoid such errors.

1.8. Concerns / risks associated with mobile health apps

Although evidence shows that mHealth apps benefit people suffering from chronic disease, there are also problems associated with them (Hoppe, Cade et al. 2016). These problems include lack of evidence of clinic effectiveness, lack of integration into the health care system and potential threats to safety (Eng and Lee 2013). The effectiveness of an app should be scientifically proven before being recommended to participants by health professionals (Hoppe, Cade et al. 2016). Despite the large quantity of apps that are available on the market, few have been formally evaluated for effectiveness (Eng and Lee 2013). One issue highlighted by a small number of studies is that many app developers have little or no formal medical training and do not involve clinicians in the development process and may therefore be unaware of participant safety issues raised by inappropriate app content or functioning (Lewis and Wyatt 2014). This issue was highlighted in the many concerns around the available insulin dose calculators and thus the potential risk they could cause individuals (Huckvale, Adomaviciute et al. 2015). Another concern is the threat to privacy and security of information transmitted through mobile apps as system developers, app companies, advertisers etc. can access a wealth of personal consumer information from the phone (Eng and Lee 2013). As recommended by the Federal Trade Commission (FTC), developers in the mobile industry must give consumer disclosures as to what data is being collected and how it is being used (Commission 2013). However, there is no current enforcement of these regulations and therefore few apps have these disclosures (Eng and Lee 2013).

Lastly, a huge concern is the availability of many medical devices that do not meet FDA criteria and approval. In a review of rapid / short acting insulin dose calculators which are deemed medical apps as per the FDA, none of the apps met the FDA criteria for formal regulation and review (due to their high probability of causing harm). Worryingly, however these apps remained available in app stores (Hoppe, Cade et al. 2016). Therefore, these apps should not be recommended by health professionals without testing their accuracy.

1.9. Use of Focus groups to assess the attitudes, needs and expectations of mobile health apps

Focus groups are proficient at collecting in-depth data (Barbour 1999). They have the ability to study the ways in which participants actively manage their conditions, develop strategies for dealing with their illness, and share information with each other (Barbour 1999).

Including consumers in the design process (user-centered design) is extremely important as this allows development of an mHealth app in response to the user's needs (Fonda, Kedziora et al. 2010). Previous studies have used consumers in usability tests or focus groups of complete or nearly complete products (Fonda, Kedziora et al. 2010; Cafazzo, Casselman et al. 2012). This entails the interactive involvement of the end user in the design process by eliciting formal feedback on prototype versions of the intervention and formative usability testing of the system (Cafazzo, Casselman et al. 2012). Involving the end user early in the process holds the potential for an overall improved outcome (Årsand and Demiris 2008). Insight into factors that affect a participant's self-efficacy (belief in being in control over their disease) can be ascertained through focus groups and are important considerations in the design phase (Årsand and Demiris 2008).

Focus groups were used to create a prototype personal health application for diabetes self-management (Fonda, Kedziora et al. 2010). In the 90 minute focus groups individuals with diabetes reported wanting actionable, understandable, and timely information from a tool that was not necessarily reliant on the health care provider for input (Fonda, Kedziora et al. 2010). They reported receiving guidance from their providers during consults but becoming confused between visits (Fonda, Kedziora et al. 2010). Smart phone technology could overcome this by providing easy, quick access to necessary information / advice when access to health care providers is limited.

A user-centered design was employed among adolescents with type 1 diabetes to design an mHealth app to improve diabetes self-management (Cafazzo, Casselman et al. 2012). Thematic analysis of interviews and focus groups led to the design of the mobile app *Bant* (Apple Inc, Cupertino, CA, USA). Some of the themes that emerged were the need for fast, discrete transactions, the need for simple data display and decision-support prompts. This app was then piloted among a small group of adolescents and showed that frequency of blood glucose measurements increased by 50%. Satisfaction was high and 88% reported that they would continue to use the app (Cafazzo, Casselman et al. 2012).

A few studies have looked at the motivators and barriers to continued engagement in the use of mobile health apps (Fukuoka, Kamitani et al. 2011). Qualitative analysis of focus groups made up of non-diabetic sedentary individuals revealed the following would support continued use and help motivate participants: real time peer or professional social support; tailoring the content, frequency and timing of messages and providing real time feedback based on individuals needs and preferences; motivators such as realistic goal setting with self-monitoring tools; and a mobile virtual community. Also emerging from the focus groups was potential barriers to continued use of such apps, including fear of failing to meet goals or expectations of others as well as diminished motivation over time (Fukuoka, Kamitani et al. 2011). Focus groups consisting of non-diabetic young adults revealed their experiences and attitude to smartphone apps used to support a healthy lifestyle (Dennison, Morrison et al. 2013). Some important challenges / barriers that emerged included: lack of commitment to an app and transient engagement; features that were burdensome and effortful would negatively impact its use; and potential to trigger negative emotions as a result of receiving too many prompts or messages or becoming demotivated as a result of not achieving ones goals (Dennison, Morrison et al. 2013). These are important considerations for developers looking to design such apps.

1.10. Qualitative research: Interpretative Phenomenological Analysis (IPA)

IPA is an approach to qualitative analysis with the aim being to generate a detailed understanding of how individuals make sense of their experiences (event or object) under investigation (Pietkiewicz and Smith 2014). IPA has been used among young people with type 1 diabetes to assess their attitudes to exercise (Ryninks, Sutton et al. 2015) and to explore and describe their perceptions of living with type 1 diabetes (Samson 2006). IPA recognises the strong influence of personal, cultural, societal and familial perspectives (Krueger and Casey 2010) which are important influential factors among the type 1 diabetes population. Using IPA allows the researcher to generate important themes from the analysis and demonstrate them with individual narratives (Pietkiewicz and Smith 2014).

1.11. Hypothesis to be tested

1.11.1. Phase 1

Irish adults with type 1 diabetes are not meeting physical activity recommendations as measured by accelerometry and self-reported questionnaires. This insufficient physical activity level is leading to poorer glycaemic control and increased CVD risk factors (increased LDL and triglyceride levels and decreased HDL levels; higher blood pressure; increased BMI, waist circumference and body fat levels). There are many barriers to physical activity and individuals with the most barriers are the most inactive. Hypoglycaemia is one of the main barriers to physical activity.

1.11.2. Phase 2

This is the first study to include focus groups to explore the individual needs and expectations of a mobile phone app designed to help individuals with type 1 diabetes exercise with less variability in blood glucose, and thus more safely. Information from the focus groups should provide an in-depth understanding of the attitudes and needs for an exercise and type 1 diabetes mobile app. Understanding the user's needs and expectations is the first step towards designing an effective tool. The information from the focus groups will be used in the future design of a bespoke app. The actual design and delivery of this app is outside the scope of this thesis.

1.12. Aims

Given the above information the aims of this thesis were as follows:

1.12.1. Phase 1 (a & b)

To our knowledge there is currently no Irish data on the level of physical activity and sedentary behaviour among our adult type 1 diabetes population and the impact this is having on glycaemic control and CVD risk factors. Therefore, the aims of this phase of the study were:

(1) Determine current physical activity levels using an objective physical activity measure (accelerometry – ActiGraph) among an Irish adult type 1 diabetes population and determine whether the level of physical activity is impacting on glycaemic control, weight, BP, lipid profile and micro and macro vascular complications.

(2) Assess whether the physical activity levels of Irish adult type 1 diabetes population are meeting physical activity recommendations proposed by the American College of Sports Medicine and the American Diabetes Association of 150mins / week of moderate-intensity physical activity.

(3) Compare objective versus subjective (validated International physical activity questionnaire [IPAQ]) physical activity measures to determine the accuracy of a subjective measure of physical activity used among this population.

(4) Identify the barriers to physical activity in this Irish population using the BAPAD-1 scale (Barriers to Physical Activity in Type 1 Diabetes).

1.12.2. Phase 2

(1) Use focus groups to gain an insight into individual's experiences and attitudes of using mobile health apps

(2) Use focus groups to explore the use of smartphone technology to help educate and guide individuals on better blood glucose management around exercise by gaining knowledge of their needs and expectations for a mobile application designed for this purpose.

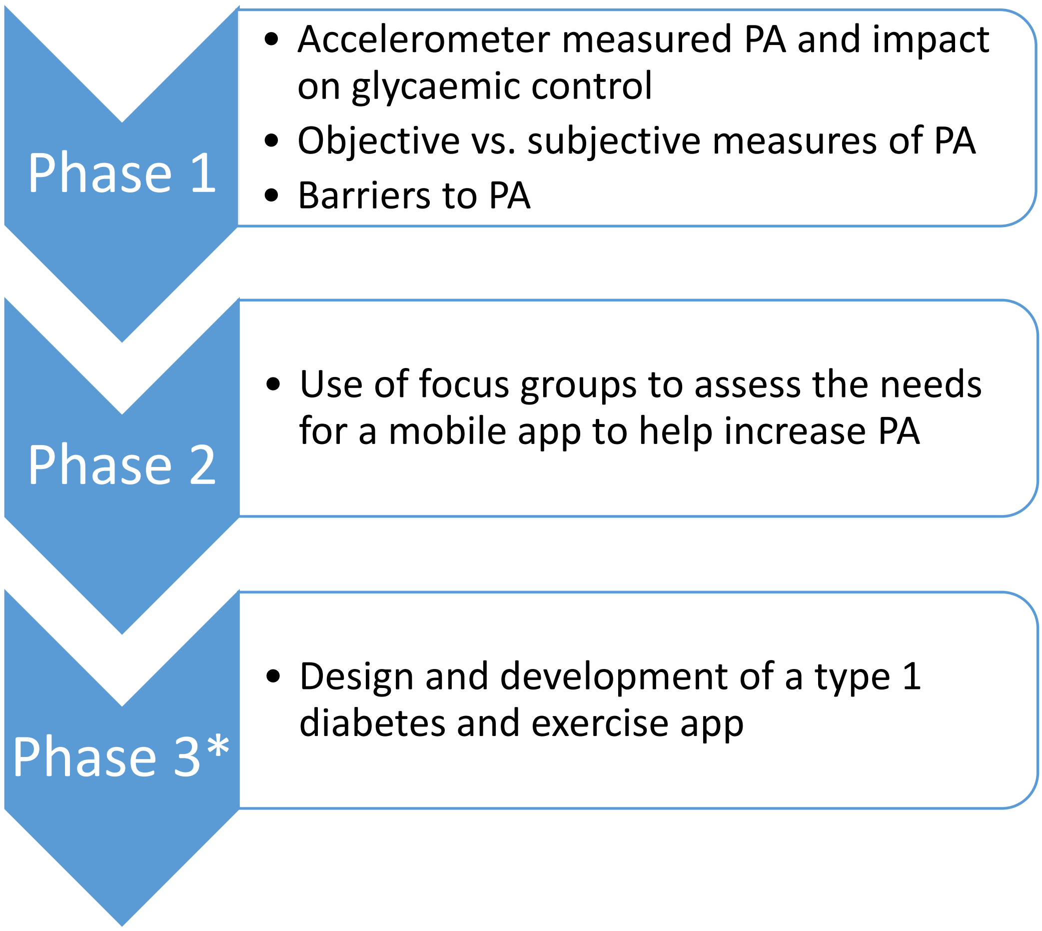

Figure 1-1 Phases of research project. PA = Physical activity. CVD = Cardiovascular disease.

** Phase 3 is outside the scope of this research masters. This project will cover phase 1 and phase 2.*

2. Chapter 2: Study Design, Methods and Participants

Phase 1 (a)

2.1. Study design and participants

This project was designed as an observational cross-sectional study.

Inclusion criteria included:

- Having a diagnosis of Type 1 diabetes for greater than 1 year
- On multiple daily injections (MDI) of rapid and long acting insulin or on Insulin pump therapy
- Aged ≥ 18 years

Exclusion criteria included:

- Participants with major diabetes complications or other chronic conditions meaning they were unable to ambulate without any limitations:
    - significant cardiovascular pathologies (e.g. coronary artery disease, heart failure etc.).
    - severe peripheral or autonomic neuropathy
    - severe retinopathy, blindness or severe visual impairment (proliferative retinopathy)
    - uncontrolled or poorly controlled epilepsy or asthma
    - pregnant
    - physical disability
    - learning disorder / psychiatric illness (e.g. severe depression)

The Tallaght Hospital / St. James's Hospital Joint Research Ethics Committee approved the study protocol and all participants provided written informed consent prior to participation in the study (Appendix II).

72 participants attending the diabetes day centre in Tallaght Hospital met the inclusion criteria and participated in the study. Recruitment took place in two ways:

(1) All previous individuals who undertook the Accu-Check Structured education programme (Berger) (approximately 150 participants) were emailed with details of the research (Participant Information leaflet – Appendix I) and invited to take part. Of these 42 participants agreed to take part and were seen either at their dietetics outpatient clinic or at their next type 1 medical clinic appointment

(2) 30 participants were randomly recruited at a weekly Type 1 diabetes outpatient clinic over a three month period (approximately two to three participants at each clinic out of an average of 30 participants attending the clinic). A participant clinic list was printed prior to clinic and participants were randomly selected from this list using the computer random number generated list in excel. All those selected that were eligible for inclusion were approached at their clinic visit and asked to take part in the study. Participants were given a participant information leaflet (Appendix I). If they refused the next participant was chosen from the computer generated list.

As this was a pilot study a sample size power analysis calculation was not done. However, reviewing the epidemiologic literature looking at the health benefits of physical activity among those with type 1 diabetes, four studies used accelerometers as the objective measure of physical activity and the sample size was small in all studies. One study did not use controls and the sample size was 30 participants. The remaining three had 26 to 35 participants and 30 to 49 controls (Liese, Ma et al. 2013). This possibly highlights the difficulty in recruiting individuals to wear an accelerometer for a one week duration. With this in mind we aimed for a sample size of 80 participants to allow for a dropout rate of 10%.

2.2. Data Collection Methods

2.2.1. Physical activity assessment (Objective measure):

The ActiGraph accelerometer (wGT3X-BT) was chosen to measure physical activity in this study. The ActiGraph monitors (ActiGraph, Pensacola, FL, USA) are the most widely used and studied monitors, and have shown favourable reliability compared to other monitor brands (Welk, Schaben et al. 2004). Participants wore the ActiGraph accelerometer (wGT3X-BT) for 7 days during waking hours. The participants were advised to make no changes to their normal physical activity level and to wear it during a typical week (i.e not if on holidays or travelling with work etc). Participants were asked to remove it only for sleeping and bathing and were given a stamped addressed padded envelope to post back the accelerometer the morning after they remove it. Participants recorded the time they put the accelerometer on and off (for shower / sleeping / swimming) and any activity they did when not wearing the monitor (e.g. swimming) or it they forgot to put the monitor on. Participants were given an ActiGraph frequently asked question (FAQ) sheet (Appendix III) in case any issues arose during the week and also contact details for the researcher (Mary Finn) if they had any issues or queries. Participants received a telephone call or email at the end of the week to remind them to post back the accelerometer (and food diary).

All information was downloaded from the ActiGraph monitor as soon as it was returned. To correctly classify wear and non-wear time intervals we chose an automated algorithm to detect and eliminate the non-wear time intervals, during which no activity is detected (Choi, Liu et al. 2011). With the Choi technique the minimum bout length is set to ≥90 minutes consecutive zeros with a spike tolerance set to 2 minutes.

Counts per minute is a measure of total physical activity and this was expressed as the total number of registered counts for all valid days divided by wearing time (Dyrstad, Hansen et al. 2014). To identify physical activity at the different intensities (light, moderate and vigorous-intensity physical activity), count thresholds corresponding to the energy cost of the given intensity were applied to the data set. The Troiano (2008) cut points were used to define physical activity at different intensities (Troiano, Berrigan et al. 2008). Sedentary time was identified as activity time of <100 counts per minute (cpm) (corresponds to sitting, reclining or lying down) (Dyrstad, Hansen et al. 2014). Low intensity physical activity was defined as between 100 – 2019 cpm. Time in moderate intensity was defined as between 2020– 5998 cpm and vigorous intensity was ≥5998 cpm. Time spent in each intensity of activity was determined by summing minutes in a day where the count met the criterion for that intensity.

Finally the adherence to physical activity recommendations was examined by estimating the proportion of the cohort that meets the published physical activity guidelines to accumulate at least 150 minutes per week of moderate-to-vigorous-intensity activity in at least 10 minute bouts (Colberg, Sigal et al. 2016). Freedson Adult (1998) cutpoints were used to detect “activity bouts” which detects moderate-to-vigorous bouts of activity of 10 minute duration (allows a drop time or non-compliant time of 2 minutes) (Freedson, Melanson et al. 1998). This was used to estimate the adherence to physical activity guidelines.

2.2.2. Physical activity assessment (Subjective measure):

All participants wearing the ActiGraph were asked to complete the International Physical Activity Questionnaire (IPAQ) (Appendix IV). This self-reported physical activity questionnaire is the English language version of the long self-administered version of the IPAQ. It captures physical activity over the previous 7 days and addresses physical activity performed in at least 10 minute bouts. The long form of IPAQ asks in detail about time spent walking and at moderate and vigorous-intensity physical activity; and covers four domains of physical activity: leisure time activity, domestic and gardening, work-related and transport-related activity. One of the most unique aspects of the IPAQ over other physical activity questionnaires is that it also includes questions about time spent sitting as an indicator of sedentary behaviour. Sitting time also includes lying down to watch television and is expressed in minutes per day.

The IPAQ research committee has developed guidelines for data cleaning and processing (Committee 2005). These guidelines include:

- If ‘don’t know’ or ‘refused’ or data is missing for time or days that case is removed from analysis.
- All cases in which the sum of total walking, moderate and vigorous time variables is greater than 960 minutes (16 hours) should be excluded from the analysis. This assumes that on average an individual spends eight hours per day sleeping.
- Only values of ten or more minutes of activity should be included in the calculation of summary scores.

After cleaning the data for missing and out-of-range values as per these guidelines the data was summed from each physical activity domain to estimate the total time spent walking and in moderate and vigorous-intensity activities as well as time spent sitting. In order to get a total of all moderate-intensity physical activity the IPAQ guidelines recommend to sum total walking and total moderate-intensity activity (Committee 2005).

Adherence to physical activity recommendations was examined using the IPAQ data. Those categorized as moderate or high activity as per IPAQ were classified as being sufficiently active according to physical activity guidelines (as above). Physical activity data from the accelerometer was compared with the IPAQ data to assess the reliability of the self-reported physical activity questionnaire. The following were compared from both physical activity measures:

- Sitting / sedentary time

- Moderate-intensity physical activity (included total walking from the IPAQ data)
- Vigorous-intensity physical activity
- Total moderate and vigorous-intensity physical activity in ten minute bouts

2.2.3. Barriers to physical activity:

All participants wearing the Actigraph were also asked to complete the BAPAD-1 scale (Barriers to Physical Activity in Diabetes [Type 1] Scale) (Appendix V). This was used to identify the barriers to physical activity. Using this 11-item BAPAD-1 scale participants rate barriers to physical activity on a scale of 1 to 7 (whether the item would keep them from practising regular physical activity over the next 6 months: 1, extremely unlikely, and 7, extremely likely).

Associations between the BAPAD total score and physical activity level, HbA1c and number of hypoglycaemic events were explored.

2.2.4. Glycaemic control:

Their most recent HbA1c (not exceeding two months prior to their participation in the research) was recorded from Diamond (diabetes database). If a recent HbA1c was not available participants were sent for repeat bloods which were taken by a phlebotomist. On the same week they wore the accelerometer, the 72 participants were asked to use the Freestyle Optium Neo (Abbott) to record all of their blood glucose readings. Participants either downloaded the week's data themselves and emailed or posted it back with their accelerometer and food diary, or if participants were unable to do the download themselves this was done by the researcher (Mary Finn). If participants refused to use the Optium Neo (n=6) they were told to continue to use the meter they currently had and where possible data was downloaded after 1 week.

The relationship between physical activity levels and glycaemic control as measured by HbA1c was assessed. All relationships between information obtained from the glucometer (Average blood glucose reading; blood glucose standard deviation; number of blood glucose readings; number of hypoglycaemic events) and physical activity levels were explored. Hypoglycaemia was defined as a BG of <4 mmol/l.

2.2.5. CVD risk factors:

Participant's most recent lipid profile, renal profile, urine albumin and urine albumin: creatinine ratio (not exceeding two months from their participation in the research) were recorded from the hospital's Diamond diabetes database. If recent results were not available participants had repeat bloods taken by a phlebotomist.

For those participants recruited at the type 1 diabetes outpatient clinic blood pressure was measured by the nurse after checking in for their appointment. For previous Berger participants not recruited at clinic the most recent blood pressure was recorded from diamond (not exceeding two months from their participation in the research). If no blood pressure result was available in the last two months it was measured by the researcher (Mary Finn). All blood pressure recordings were taken with the Dinamap PRO 300 blood pressure monitor. The systolic and diastolic blood pressure was recorded in mmhg. The presence of diabetic retinopathy and nephropathy were recorded from the hospital's Diamond diabetes database.

The relationship between physical activity level and incidence of blood pressure, hyperlipidaemia; diabetes retinopathy and nephropathy were examined.

2.2.6. Anthropometry and body composition:

The participant's height was measured using a stadiometer, a device for measuring height that consists of a vertical ruler with a sliding horizontal rod to rest on the top of the head and the participant is without shoes. Height was recorded to the nearest half centimetre.

The weight and body mass index (BMI) was measured using the bio-electrical impedance analyser (BIA) (Tanita body composition analyser BC-420MA, Tanita Ltd, GB) where the participants height is entered manually and the weight and BMI is electronically calculated when the participant stands barefoot on the BIA machine. The weight was recorded in kilograms (kgs) and the BMI in kilograms per metre squared (kg/m^2). The BMI cut off points adopted were those established by the WHO in 2003 (Organization 2003) and are as follows:

<u>Classification BMI (kg/m^2)</u>

Underweight < 18.5 kg/m^2

Healthy weight 18.5 - 24.9 kg/m^2

Overweight 25.0 - 29.9 kg/m^2

Obese ≥ 30.0 kg/m^2

Waist circumference was measured using a flexible, non-stretchable tape measure. Measurement was taken at the mid-point between the iliac crest and top of the ribcage. The measurement is made at normal respiration and recorded to the nearest half centimetre. Hip circumference was taken at the widest part of the buttocks. The cut off points used for waist circumference were those established by Lean et al (Lean, Han et al. 1995) according to cardiovascular risk level: waist circumference (WC) ≥80cms for women and ≥94cms for men equates to an increased cardiovascular risk and advice should be to gain no further weight; a WC ≥88cms for men and ≥102cms for men equates to very high cardiovascular risk and they should be advised to reduce their weight.

The association between physical activity level and weight, BMI, waist circumference, hip circumference and body composition (% body fat and fat mass) were examined.

2.2.7. Food diary & Insulin dosage:

Participants were asked to keep a 7 day food diary that recorded all food, beverages, insulin boluses and basal insulin throughout the day. Participants were instructed and given written information on how to record information on portion sizes and insulin boluses. Using this data the relationship between physical activity and total energy, carbohydrate, fat and protein intake was assessed. Also the association between physical activity and insulin amounts (basal and bolus); and number of insulin boluses was examined. Food diaries were analysed using Nutritics (Version 4.2) for total energy, carbohydrate; fat, protein and micronutrients.

Phase 1 (b)

2.3. Study design and participants

A separate cross sectional observational study (excluding participants from phase 1 (a)) was done looking at physical activity (reported) and barriers to physical activity among a larger sample of participants with type 1 diabetes attending a type 1 diabetes outpatient clinic. All individuals attending a weekly type 1 diabetes outpatient clinic over a four month period were asked to complete two questionnaires (IPAQ and BAPAD-1 scale). Questionnaires were distributed by the secretarial staff on check in for their appointment and collected from participants prior to leaving the clinic. 187 participants (out of 270 participants) completed the questionnaires. All participants completing the questionnaires signed a consent form to allow this information to be used as part of the research project and for us to access their health information from the diamond database or their medical notes.

As this was a pilot study a sample size power analysis calculation was not done. However using a review of the epidemiologic literature looking at the health benefits of physical activity among those with type 1 diabetes 21 different studies used a range of physical activity questionnaires and there was a wide range of sample sizes (Liese, Ma et al. 2013). 15 studies used a sample size in the range of 30 to 407 participants (average was 152 participants). 4 of the 21 studies used very large numbers in the range of 723 to 23,251 participants. (Liese, Ma et al. 2013). With this in mind we aimed for a sample size of approximately 200 participants to allow for a dropout rate of 10%.

2.4. Data collection methods

2.4.1. Physical activity assessment

The validated International physical activity questionnaire (IPAQ) form was used to assess reported physical activity. This questionnaire and its scoring has been described previously (2.2.2. Physical activity assessment).

2.4.2. Barriers to physical activity

Participants were also asked to complete the Barriers to Physical Activity questionnaire (BAPAD-1 scale). This questionnaire and its scoring has been described previously (2.2.3. Barriers to physical activity).

2.4.3. Anthropometry, biochemistry and clinical data

All anthropometric, biochemical and clinical data needed was collected retrospectively following collection of participant's questionnaires and consent forms. All data was collected from existing participant records and data sources within the hospital. The main researcher and assistant researcher extracted the data from the two electronic data sources; the Diamond diabetes database, which is a fully integrated patient and clinic management system and the Key iSoft patient management database. Once extracted the data was put in to an excel file available to the main researcher. Missing data was taken from the participants' medical file where necessary.

Data extracted included:

- Anthropometry (weight, height, BMI)
- Biochemistry results (HbA1c, lipid profile, renal profile, urine albumin, and urine albumin:creatinine)
- Systolic and diastolic blood pressure
- Incidence of diabetic retinopathy and hypertension requiring hypertensive medication.
- Diabetes duration, type of insulin therapy (multiple daily injections / insulin pump therapy) and whether the participant was a smoker.

2.5. Statistical Methods (Phase 1 a & b)

Analysis was performed using IBM SPSS Statistics 24. Continuous variables were inspected for normality and subsequently means or medians were tested within two groups using Student's T test or Mann-Whitney U test. For more than two groups, analysis of variance was used. The descriptive analysis of qualitative variables was performed by calculating frequencies and percentages, and from quantitative variables the mean, standard deviation (SD), median and IQR were determined. For correlation of non-normally distributed values, Spearman's rho correlations are given. Correlations were discussed as weak (r=.10 to .29), moderate (r=.30 to .49), or strong (r=.50 to 1.0) (Pallant J 2007).

Multiple linear regression models were built to assess how the total time spent in Freedson bouts, the total moderate-vigorous-intensity physical activity, and the adherence to the 150-minute physical activity recommendation influenced HbA1c (%), BMI, waist circumference (cm), fat mass (kg), and triglycerides. Gender and age were included as explanatory variables. The included variables were evaluated for normality using Q-Q plots and for multicollinearity with a correlation matrix.

Spearman's correlation coefficient, ρ (rho) was used to assess associations between the two methods used to measure physical activity (subjective and objective measures). The intraclass correlation coefficient (ICC) were also used to test the reliability between the two methods.

A p value of less than 0.05 was regarded as statistically significant in all analysis.

2.6. Ethics (Phase 1 a, b)

The Tallaght Hospital / St. James's Hospital Joint Research Ethics Committee approved the study protocol and all participants provided written informed consent prior to participation in the study (Appendix II).

Phase 2

2.7. Study design

Qualitative research was employed in this study in order to achieve an in-depth understanding of the phenomenon being studied (Patton 1990). The qualitative approach of Interpretative Phenomological Analysis (IPA) was chosen. Focus groups were identified as the most appropriate way to explore the needs and opinions of those with type 1 diabetes. A total of 3 focus groups were held in the diabetes day centre in Tallaght Hospital. The researcher (Mary Finn, Research Dietitian) facilitated all three focus groups.

2.8. Focus group recruitment

The employment of inclusion and exclusion criteria, and ensuring these criteria are very specific, assured that our sample population was homogenous (Robinson 2014). IPA is explicit that homogenous samples work best in conjunction with its philosophical foundations and analytical processes (Smith, Flowers et al. 2009), therefore employment of inclusion and exclusion criteria was critical in this IPA study. To ensure an homogenous group we chose physical homogeneity as the parameter (all participants must have type 1 diabetes) (Robinson 2014) and also employed the following inclusion criteria: having a diagnosis of Type 1 diabetes for greater than 6 months; on multiple daily injections (MDI) of rapid and long acting insulin or on Insulin pump therapy; aged ≥ 18 years; own a smartphone; and be able to speak and read

English. Participants were excluded if they did not fully understand the explanation of the study and were thus unable to provide informed consent: language difficulties, intellectual difficulties or experiencing active psychotic episode.

The following steps were taken to recruit participants:

- Advertisement on two separate social media sites (‘Sporty Diabetics Type1’s Facebook page’ and ‘DFI Type 1 support group Facebook page’).
- Flyers posted to all previous Berger participants attending Tallaght Hospital
- Flyers distributed to possible interested candidates at type 1 diabetes clinics in Tallaght Hospital.
- Flyers sent to other diabetes departments within Dublin and surrounding areas for display in waiting areas or to distribute to interested individuals.

Full appreciation to each participants account of the phenomenon being studies is the main concern with IPA and as a result samples in IPA studies are generally small (Pietkiewicz and Smith 2014). Six to eight participants is often seen as appropriate for an IPA study as this sample gives an opportunity to examine similarities and differences between individuals (Turpin, Barley et al. 1997). Taking this phemonological approach into consideration in this study six to ten participants per focus group were chosen. To allow for non-attenders, participants were over recruited by 10-25% (Rabiee 2004). Our smaller sample prevented the researcher being overburdened with too much data, while allowing a detailed and time consuming case-by-case analysis (Pietkiewicz and Smith 2014).

As this study is guided by a phenomenological approach (described above) we used a purposive sampling strategy to select participants for inclusion (Lee, Saunders et al. 2005). ‘Purposive’ sampling is very often employed in qualitative research (Cafazzo, Casselman et al. 2012; Lascar, Kennedy et al. 2014; Darker, Sweeney et al. 2016). Purposive sampling strategies are designed to enhance understandings of selected individuals or groups experience(s) (Devers and Frankel 2000). To accomplish this it’s important to select “information rich” cases, that is individuals that provide the greatest insight into the research question (Devers and Frankel 2000). Therefore, we chose individuals with type 1 diabetes that were smart phone users (+/- experience using smartphone applications). We also chose a mixed gender purposive sampling that ensured both male and female representation. To ensure this we aimed for an approximate 50/50 split between genders in each focus group. This was to avoid female bias as females are more likely to put themselves forward for qualitative research and show a higher tendency towards self-disclosure (Dindia and Allen 1992). We also aimed to ensure that our purposive sample was reflective of the overall type 1 diabetes population attending our service. To do this we chose a wide age range (≥ 18 years), and a mix of individuals on insulin pump therapy and MDI among all groups.

Prior to attending the focus groups volunteers were screened by telephone or email and assessed for eligibility (as per inclusion/exclusion criteria) by the main researcher (Mary Finn). We recruited suitable participants on a first come basis until we have sufficient numbers in each group.

A total of three focus groups were conducted. 34 participants with type 1 diabetes were recruited. 5 participants cancelled in the one to two days prior to the focus group (main reason stated was work commitments) and 4 participants did not attend on the evening. Therefore a total of 25 participants took part in the focus groups (n=8 FG1; n=7 FG2; n=10 FG3).

2.9. Focus group procedures

All participants were emailed a participant information leaflet (Appendix VI) prior to attending the focus group outlining the aim of the study, what participation entails, and how anonymity will be protected. Participants were given an opportunity to raise any questions prior to the focus group starting.

A facilitator’s guide (including focus group questions) was drafted prior to the focus groups (Appendix VII). Input was sought from an Endocrinologist and an individual with type 1 diabetes working in the area of app development. This was then piloted among 3 individuals with type 1 diabetes and changes made thereafter prior to use in the focus groups. All questions used were open ended and intended to elicit a range of thoughts on the topic. Some questions included prompts if the initial question was insufficient to elicit a satisfactory response (Smith 2007). The focus groups began with more general questions and moved to more specific questions as the interview went on (Smith 2007).

On arrival and while waiting for the focus group to begin participants were asked to complete a short demographic form (Appendix VIII) to gather information around focus group participants. Also before starting the focus group and following the introduction all individuals completed written informed consent prior to partaking in the focus group (Appendix IX). The consent form was read by the facilitator to ensure thorough understanding among the group. The sessions began with brief introductions to promote comfort and sharing of ideas within the group.

Depending on the participant's ability, 2 hours seems to be close to the maximum length a session should last (Årsand and Demiris 2008). We chose a duration of 60 minutes with an additional 15-20 minutes to allow for completing of demographic and consent form and for the discussion to run over slightly. The average duration of the focus groups was approximately 75minutes.

Audiotapes and transcripts were used in this study due to the complexity of the subject and difficulty capturing all information through field notes (Devers and Frankel 2000). Field notes were made by the researcher after each focus group. Focus groups were transcribed verbatim following each group (using a company called Essential Secretarial Solutions based in Cavan, Ireland) and all participants' identifiable details were removed and pseudonyms inserted. The main researcher (Mary Finn) listened to tapes and checked transcripts for accuracy. All audio sound files were then deleted.

2.10. Ethics

The Tallaght Hospital / St. James's Hospital Joint Research Ethics Committee approved the study. The flyer used for recruitment (Appendix X), along with the participant information leaflet

(Appendix VI) and consent form (Appendix IX) was written up and sent to the Tallaght Hospital ethics committee for approval.

2.11. Data analysis

Data was analysed using IPA which allows a detailed understanding of how individuals make sense of their experiences (event or object) under investigation (Pietkiewicz and Smith 2014). IPA has been used among young people with type 1 diabetes to assess their attitudes to exercise (Ryninks, Sutton et al. 2015) and to explore and describe their perceptions of living with type 1 diabetes (Samson 2006). IPA recognises the strong influence of personal, cultural, societal and familial perspectives (Krueger and Casey 2010) which are important influential factors among our population. Using IPA allows the researcher to generate important themes from the analysis and demonstrate them with individual narratives (Pietkiewicz and Smith 2014). Focus group transcripts were analysed manually by the researcher (Mary Finn) for recurrent themes by questions and then overall. Information was coded according to key themes and emerging categories and a coding frame was developed with superordinate and subordinate themes. Triangulation was conducted by a researcher separate to data collection (Lucy Whiston, Adelaide PhD Candidate/Irish Research Council Scholar, School of Medicine, TCD). This involved the external researched taking one third of the transcripts and applying the coding frame to the transcripts. Key phrases from focus group individuals were used to illustrate emerging themes. Finally the COREQ criteria were applied when reporting this qualitative research (Tong, Sainsbury et al. 2007).

3. Chapter 3: Adherence to physical activity recommendations and impact on glycaemic control and CVD risk

3.1. Abstract

Context: Information on physical activity (PA) levels and its association with glycaemic control and cardiovascular disease (CVD) risk is lacking among Irish adults with T1DM.

Aims: We assessed PA levels among Irish adults with type 1 diabetes and evaluated the relationship between PA, glycated haemoglobin (HbA1c) and cardiovascular risk factors.

Methods: Using an observational cross-sectional design, PA was measured objectively over 7 days in 72 participants (34 males) using accelerometry (ActiGraph). Anthropometrical, biochemical and clinical parameters were recorded. Multiple linear regression models were applied to assess how PA influenced HbA1c and cardiovascular risk factors.

Results: Mean age (± SD) was 40.9 (±12.9) years, diabetes duration was 18 (±11.6) years and HbA1c was 8.0 (±1.3) %. Median BMI was 25.9 (23.2 – 30.3) kg/m^2 with 57% of the participants being overweight or obese (29% overweight and 28% obese). Most of the time was spent sedentary (8.4 ± 1.6 h/day) or in light activity (4.4 ± 1.5 h/day), with a mean of 33.9 ± 22.2 min/day in moderate-to-vigorous-intensity activity. However only 8.6 (2.3 – 23.3) min/day was spent in moderate- to vigorous-intensity activity in at least 10 minute bouts. Twenty-three (32%) of participants exercised to PA recommendations. Those meeting PA recommendations had a significantly lower HbA1c (7.7 ± 1.1 % vs 8.4 ± 1.2 %; p = 0.001), BMI [24.5 (22.3, 27) kg/m^2 vs 27 (23.4, 31.1) kg/m^2; p = 0.032], waist circumference [80.9 (76.4, 87.5) cms vs 88.6 (80.4, 100) cms; p = 0.006] and fat mass [19.0 (11.7, 21.5) kg vs 22.1 (17.3, 33.8) kg; p = 0.032]. Participants also had a significantly greater number of hypoglycaemic events [5 (3, 8.5) vs 2 (1, 4); p = 0.004] over the 7 days.

Conclusion: The majority of participants fail to meet PA recommendations; however those that do have healthier cardiovascular risk factor profiles. Meeting PA guidelines and time spent in moderate-to-vigorous-intensity PA were associated with a more adverse CVD risk profile.

3.2. Introduction

Overweight and obesity leads to an increased risk of cardiovascular disease (CVD) due to dyslipidemia, hyperinsulinemia, and hypertension. Among adults with type 1 diabetes the majority were overweight or obese (45.5% overweight and 14.5% obese) (Bohn, Herbst et al. 2015). Persons with Type 1 diabetes exhibit a greater than three-fold higher risk of acute CVD compared to their non-diabetic counterparts, resulting in a mean reduction in life expectancy of 7 years (Liese, Ma et al. 2013).

Regular exercise has been shown to have many benefits among those with type 1 diabetes. Among adults with type 1 diabetes, those physically active had lower HbA1c, lipid levels, blood pressure and BMI (Bohn, Herbst et al. 2015). A systematic review and meta-analysis of exercise interventions (regular exercise training performed at least twice weekly for a minimum of 8 weeks) in adults with type 1 diabetes (mean age 10.5-35.5 years) found a significant reduction in HbA1c (mean difference -0.78%) in the exercise group compared with controls receiving standard care in four out of six randomized controlled trials (280 participants – 191 assigned to exercise training; 89 assigned to control) (Yardley, Hay et al. 2014). Physical activity has also been shown to improve insulin requirements among those with type 1 diabetes (Chimen. Kennedy et al, 2012). Tielemans at al (2013) showed that physical activity had a borderline inverse association with both all-cause mortality (both sexes) (HR 0.66, 95% CI 0.42, 1.03) and incident CVD (women only) (HR 0.66, 95% CI 0.40, 1.08) among those with type 1 diabetes (Tielemans, Soedamah-Muthu et al. 2013).

Based on the many benefits of physical activity a recent position statement from the American Diabetes Association (ADA) on physical activity / exercise and diabetes state that most adults with diabetes should engage in 150 minutes or more of moderate-to-vigorous-intensity activity, spread over at least 3 days/ week, with no more than 2 consecutive days without activity (Colberg, Sigal et al. 2016). Aerobic activity bouts should ideally last at least 10 min, with the goal of approximately 30 min per day, or more, most days of the week (Colberg, Sigal et al. 2016).

Despite these guidelines it appears from the available evidence that the majority of those with type 1 diabetes fail to meet the recommended physical activity guidelines and are less physically active than their non-diabetic counterparts (Brazeau, Rabasa-Lhoret et al, 2008, Komatsu, Gabbey et al. 2005; Lobelo, Liese et al. 2010). The majority of studies use subjective measures of physical activity (self-reported or telephone questionnaires) which are often wrought with a variety of biases (e.g. inaccurate memory, social desirability) (Pober, Staudenmayer et al. 2006). Objective measures of physical activity, such as accelerometry, provide a more accurate estimate and are both clinically feasible and cost effective (Pober, Staudenmayer et al. 2006).

Among 18,028 adults with type 1 diabetes a cross sectional study demonstrated that 63% of participants included were not physically active (Bohn, Herbst et al. 2015). Among 406 adults with diabetes (19% with type 1 and 81% with type 1 diabetes) physical activity was undertaken by 34% of individuals (Thomas, Alder et al. 2004). Both these studies used self-reported physical activity measures. Using accelerometry (motion sensor) to measure physical activity among 75 adults with type 1 diabetes (Mean age 43.5 ± 10.5yrs), 43% of women and 55% of men met the recommended threshold of physical activity level of ≥ 1.7 (Those meeting the physical activity recommendations were defined as a physical activity level ≥ 1.7) (Brazeau, Leroux et al. 2012). Also using a motion sensor among 77 adults (age 43.5 ± 10.4) with type 1 diabetes close to 60% reached an adequate PAL that could be considered an active lifestyle (Brazeau, Mircescu et al. 2012). Both these studies were based in Canada.

A recent systematic review and meta-analysis of exercise interventions (regular exercise training performed at least twice weekly for a minimum of eight weeks) in adults with type 1 diabetes (mean age 10.5-35.5 years) found a significant reduction in HbA1c (mean difference -0.78%) in the exercise group compared with controls receiving standard care in four out of six randomized controlled trials (Yardley, Hay et al. 2014). Benefits of physical activity were also seen in a cross sectional study of 18,028 adults with type 1 diabetes, where those most physically active had better HbA1c concentrations, a more favourable BMI, less hypertension and dyslipidaemia and also fewer diabetes related complications than those less habitually active (Bohn, Herbst et al. 2015).

To our knowledge no data exists on the level of physical activity among an Irish adult type 1 diabetes population. With this in mind we assessed physical activity levels and adherence to physical activity guidelines in this population and evaluated the relationship between physical activity, glycated haemoglobin (HbA1c) and cardiovascular risk factors (BMI, waist circumference, lipid profile and blood pressure).

3.3. Aims

Information on physical activity levels and its association with glycaemic control and cardiovascular disease risk is lacking among Irish adults with T1DM. This study aimed to:

1. Determine current physical activity levels using accelerometry (ActiGraph) among an Irish adult type 1 diabetes population.

2. Examine whether the level of physical activity is impacting on glycaemic control and CVD risk factors.

3. Assess whether these physical activity levels are meeting physical activity recommendations proposed by the American College of Sports Medicine and the American Diabetes Association of 150mins / week of moderate intensity exercise (Garber, Blissmer et al. 2011; Colberg, Sigal et al. 2016).

4. Correlate levels of physical activity with CVD risk factors.

3.4. Participants and methods

3.4.1. Participants

This study was designed as an observational cross-sectional study. Inclusion and exclusion criteria and details on how recruitment took place can be found in Chapter 2 (2.1 Study design and participants). In total 72 participants attending the diabetes day centre in Tallaght Hospital met the inclusion criteria and participated in the study.

3.4.2. Measurements

3.4.2.1. Physical activity assessment

Participants wore the Actigraph accelerometer (wGT3X-BT) on the right hip on an elasticized belt for 7 days and were asked to remove it only for sleeping and swimming/ bathing. Participants recorded the time they put the accelerometer on and off (for shower / sleeping / swimming) and any activity they did when not wearing the monitor (e.g. swimming) or if they forgot to put the monitor on. All information was downloaded from the Actigraph monitor as soon as it was returned. Participants with at least 4 days of at least 10 hours or more of monitor wear were included in the analysis. Refer to Chapter 2 (2.2.1. Physical activity assessment: objective measure) for details on classifying wear and non-wear time and cutpoints used to define different intensities of physical activity and "activity bouts" (used to determine adherence to physical activity recommendations).

3.4.2.2. Clinical and biochemical measures

See Chapter 2 (2.2.4. Glycaemic control and 2.2.5. CVD risk factors) for information on clinical and biochemical measures.

3.4.2.3. Anthropometry and body composition

Height was recorded to the nearest half centimetre using a stadiometer. The weight (kgs) and body mass index (BMI) (kg/m^2) was measured using the bio-electrical impedance analyser (BIA) (Tanita body composition analyser BC-420MA) where the participants height was entered manually and the weight and BMI is electronically calculated when the participants stands barefoot on the BIA machine. Waist and hip circumference were measured using a flexible, non-stretchable tape measure. See Chapter 2 (2.2.6. Anthropometry and body composition) for further details.

3.4.2.4. Food intake & Insulin dosage

Participants were asked to keep a 7 day food diary and also record insulin boluses and basal insulin in this diary. Food diaries were analysed using Nutritics (Version 4.2) for total energy, carbohydrate; fat, protein and micronutrients. See Chapter 2 (2.2.7. Food diary and insulin dosage) for further details.

3.5. Data analysis

Analysis was performed using IBM SPSS Statistics 24. Continuous variables were inspected for normality and subsequently means or medians were tested within two groups using Student's T test or Mann-Whitney U test. ANOVA was used to compare more than two groups. The descriptive analysis of qualitative variables was performed by calculating frequencies and percentages, and from quantitative variables the mean, standard deviation (SD), median and IQR were determined. Spearman's rho correlations were used to examine correlation between non-normally distributed values.

Multiple linear regression models were built to assess how the total time spent in Freedson bouts, the total moderate-vigorous physical activity, and the adherence to the 150-minute physical activity recommendation influenced HbA1c (%), BMI (kg/m^2), waist circumference (cm), fat mass (kg), and triglycerides (mmol/l). Gender and age were included as explanatory variables. The included variables were evaluated for normality using Q-Q plots and for multicollinearity with a correlation matrix.

A p value of less than 0.05 was regarded as statistically significant in all analysis.

3.6. Results

3.6.1. Participants characteristics

Seventy two adults (34 males) with type 1 diabetes agreed to participate in the study. Anthropometric and clinical characteristics of those participating in the study are presented in Table 3-1.

The median age of the study participants was 40 (31 – 48.8) years and mean diabetes duration was 18 ± 11.6 years. Median BMI was 25.9 (23.2 – 30.3) kg/m^2 with 57% (n=41) of the participants being overweight and obese [29% overweight (n=21) and 28% obese (n=20)]. Mean HbA1c was 8.0 ± 1.3%. The majority (61%) of participants were on multiple daily injections. 72% (n=52) had completed the Accu-Check (Berger) Structured Education programme.

Physical activity level, measures of glycaemic control and nutrient intake were compared using various participant characteristics (Received structured education, insulin treatment and frequency of BG testing). There was no significant difference in HbA1c among those who had completed the structured education programme (7.9 ± 1.3%) and those who had not (8.4 ± 1.1%). Also no difference was observed in BG variability, number of hypoglycaemic events, total insulin, total time in Freedson bouts (moderate-to-vigorous activity in at least 10 min bouts) or total time in moderate-to-vigorous physical activity (total MVPA) among those who had completed structured education and those who had not. There were no differences in HbA1c, BG variability, total insulin, number of hypoglycaemic events, physical activity level and average BAPAD-1 score between participants on an insulin pump (n=28) versus those on MDI (n=44). Finally we examined differences in those who tested BG more frequently (≥4 tests per day) compared to those who tested less often (<4 tests per day). There was no difference in HbA1c or physical activity level between the two groups. However the group meeting the physical activity guidelines (n=23) tended to test more frequently with 17 (74%) testing ≥4 times per day. Those testing less frequently had a greater intake of energy, carbohydrate, protein and fat but only protein intake reached significance.

Participants characteristics	Total sample (n=72)
Age (years)	40 (31, 48.8)
Diabetes duration (years)	17.96 (11.6)
Treatment	
— MDI n (%)	44 (61)
— Insulin pump n (%)	28 (39)
Smoking habit n (%)	15 (21)
Completed Structured education n (%)	52 (72)
BMI	25.9 (23.2, 30.3)
— Overweight, n (%) (BMI = 25.0-29.9kg/m^2)	21 (29)
— Obese, n (%) (BMI >30kg/m^2)	20 (28)
Waist Circumference (cms)	85.8 (78.3, 95.6)
Hip Circumference (cms)	99.5 (95.7, 108.4)
% body fat	28.5 (22.6, 34.4)
Fat mass (kg)	19.8 (16.7, 27.5)
HbA1c (%) / (mmol/mol)	8.0 (1.3) / 64.5 (14.3)
Total Cholesterol (mmol/l)	4.6 (0.8)
LDL (mmol/l)	2.4 (0.8)
HDL (mmol/l)	1.7 (0.4)
Triglycerides (mmol/l)	0.9 (0.7, 1.2)
HTN requiring treatment n (%)	17 (24)
Retinopathy n (%)	27 (38)
Total insulin (units)	43.7 (32.7, 59.4)
— basal	22.9 (16.7, 30.6)
— bolus	21.7 (15.5, 27.57)
Number of boluses per day	3.3 (3, 4.1)
Blood glucose variability (mmol/l)	3.9 (1.3)
Average tests per day	5.0 (3.6, 6.7)
Total number of hypoglycaemic episodes	3.0 (1.0, 5.8)
Energy intake (kcal/day)	1778 (432.9)
Carbohydrate intake (g/day)	199.9 (47)
Protein intake (g/day)	84.6 (26.6)
Fat intake (g/day)	68.7 (22.2)

Table 3-1 Characteristics of Participants wearing the accelerometer. Values are expressed as mean (SD) or median (25th - 75th percentile) or number (n) (%). Abbreviations: BMI, body mass index; HbA1c, glycated haemoglobin; LDL, low density lipoprotein; HDL, high density lipoprotein; HTN, hypertension

See Table 3-1 for information on nutrient intake. % energy from carbohydrate, protein and fat was 47%, 27% and 22% respectively. There was a significant increase in bolus insulin as carbohydrate intake increased (p = 0.01). Nutrient intake did not correlate with any level of physical activity or sedentary behaviour.

3.6.2. Physical activity duration

The descriptive data for the accelerometer are shown in Table 3-2. The Actigraph monitor was worn for a median 7 days (7, 8). 50 participants wore the actigraph for 7 days; 16 for 8 days; 3 for 9 days and 3 for 6 days. Over the day most of the time was spent sedentary (8.4 ± 1.6 h/day) or in light activity (4.4 ± 1.5 h/day), with a mean of 33.9 ± 22.2 min/day in moderate-to-vigorous-intensity activity (all minutes spent at moderate-to-vigorous-intensity PA). However, time spent in moderate-to-vigorous-intensity PA in at least 10 minute bouts was only 60.5 (IQR=16.5-168.3) min/ week (includes only moderate-to-vigorous-intensity PA of ≥10-min duration). During waking hours percentage of time spent in sedentary, light, moderate and vigorous physical activity was 63.2 (10.8) %; 32.6 (10.4) %; 3.4 (2, 5.7) % and 0.02 (0, 0.31) % respectively.

Actigraph Variable	n=72	Male	Female
Total Time in Freedson Bouts (min)	60.5 (16.5, 168.3)	52 (23.2, 242.0)	69 (7.5, 157.3)
Daily Average of Freedson Bouts (min/day)	8.6 (2.3, 23.4)	–	–
Average Time per Freedson Bout (min)	15.3 (11.1, 19.3)	16.6 (11.8, 18.6)	14.4 (7.5, 20.0)
Total Time in Sedentary Bouts (hours)	38.9 (13.2)	38.3 (15)	39.6 (11.6)
Daily Average of Sedentary Bouts (hours)	5.4 (1.8)	5.5 (2.1)	5.4 (1.6)
Average Length of Sedentary Bouts (min)	22.4 (20.2, 25)	–	–
Sedentary (h/day)	8.4 (1.6)	8.3 (1.8)	8.4 (1.3)
Light (h/day)	4.4 (1.5)	4.6 (1.6)	4.1 (1.5)
Moderate (min/day)	31.9 (21.5)	37.0 (22.4)	27.3 (19.8)
Vigorous (min/day)	0.14 (0, 2.4)	–	–
Total MVPA (min/day)	33.9 (22.2)	38.9 (11.3)	29.3 (20.9)
% in Sedentary	63.2 (10.8)	61.2 (11.9)	65 (9.4)
% in Light	32.6 (10.4)	33.9 (11.3)	31.4 (9.5)
% in Moderate	3.4 (2, 5.7)	3.9 (2.6, 5.9)	2.9 (1.5, 5.4)
% in Vigorous	0.02 (0, 0.31)	0.03 (0.0, 0.3)	0.0 (0.0, 0.3)
Steps per day	7,994 (3,536)	8,813 (3,782)	7,261 (3,177)

Table 3-2 Descriptive data from the activity monitor for total group and male/ female. Values are expressed as mean (SD) / median (25th - 75th percentile). Abbreviations: Total MVPA, total moderate-vigorous physical activity

3.6.3. Adherence to physical activity recommendations

One of the aims of this study was to establish adherence to physical activity guidelines. Adherence to physical activity guidelines was defined as accumulating ≥150 min per week of moderate-to-vigorous-intensity physical activity. It must be kept in mind that although the majority of our participants wore the Actigraph for 7 days (81%), 3 participants wore it for 6 days and the remaining wore it for 8-9 days. In order to explore the benefits of achieving physical activity guidelines the group were divided into 2 categories: ≥ 150 minutes of moderate-to-vigorous-intensity physical activity or <150 minutes of moderate-to-vigorous-intensity physical activity per week.

Only 23 (32%) participants met the exercise recommendations. Off the remaining 49 (68%) participants the majority were well below the recommendation, with many achieving little or no time in moderate-to-vigorous activity in at least 10 minute bouts [(0 min (n=11); 0 - 30 min (n = 12); 30 - 60 min (n = 13); 60 - 100 min (n= 7); 100 – 149 min (n = 6)] (Figure 3-1). Therefore 36 (50%) participants undertook less than 60 min per week of health related physical activity.

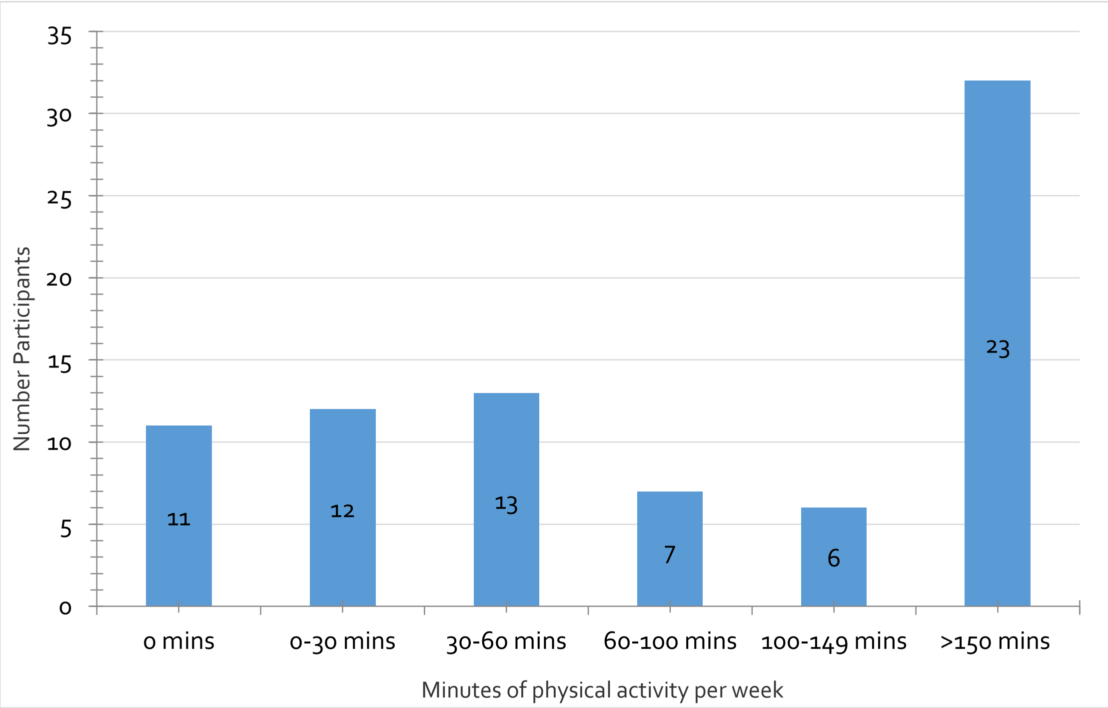

Figure 3-1 This figure shows the number of participants achieving the physical activity recommendations of >150mins/wk (n=23/72) and the number of participants achieving <150mins/wk (n=49/72)

Average daily step counts was 7,911 ± 3,536 per day. This is less than the recommended 10,000 steps per day, which was only achieved by 18 (25%) participants (Figure 3-2).

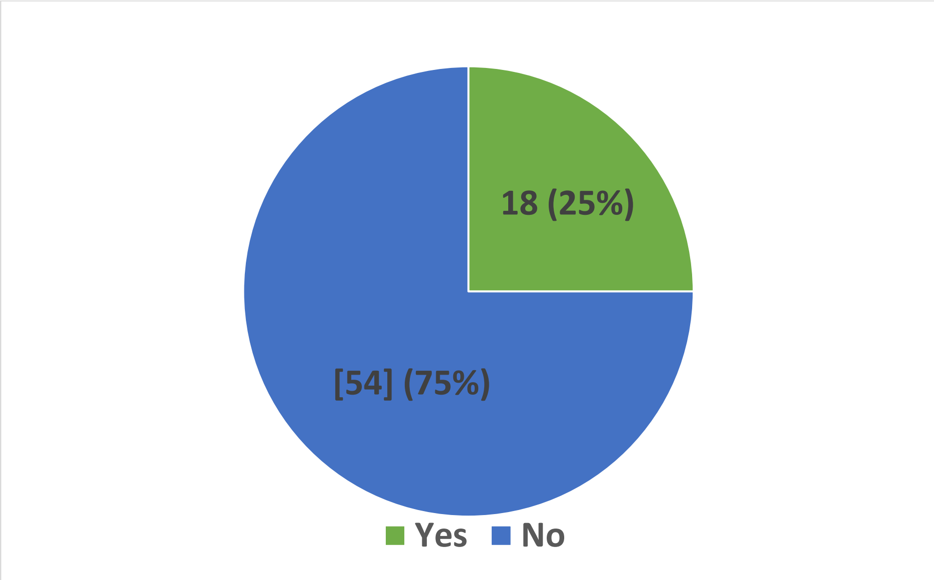

Figure 3-2 Percentage of participants meeting daily step recommendations

3.6.4. Benefits of achieving physical activity recommendations

We examined differences in glycaemic control and CVD risk factors among those meeting exercise recommendations and those not (Table 3-3). Interestingly, of the 20 people that were obese (BMI ≥30kg/m^2), 18 were classified as physically inactive (<150 minutes of moderate-to-vigorous-intensity physical activity per week). Those meeting physical activity recommendations had a significantly lower weight [72.3 (64.4, 78.6) kg vs 79.2 (66.6, 95.4) kg; p = 0.023] and BMI [24.5 (22.3, 27) kg/m^2 vs 27 (23.4, 31.1) kg/m^2; p = 0.032]. Participants also had a significantly lower waist circumference [80.9 (76.4, 87.5) cms vs 88.6 (80.4, 100) cms; p = 0.006] and hip circumference [96.5 (72.7, 101.3) cms vs 100.4 (96.6, 111.6) cms; p = 0.005], as well as a significantly lower fat mass [19.0 (11.7, 21.5) kg vs 22.1 (17.3, 33.8) kg; p = 0.032]. HbA1c was significantly lower in those meeting physical activity guidelines (7.7 ± 1.1 % vs 8.4 ± 1.2 %; p = 0.001), as was blood glucose average (7.9 ± 1.6 mmol/l vs 9.5 ± 2.2 mmol/l; p = 0.006) and individual blood glucose variability (3.5 ± 1.2 mmol/l vs 4.1 ± 1.3 mmol/l; p = 0.05). Finally, those meeting physical activity recommendations had a significantly greater number of hypoglycaemic events [5 (3, 8.5) vs 2 (1, 4); p = 0.004] during the week they wore the accelerometer. Hypoglycaemia was defined as a BG of <4 mmol/l.

Figure 3-3 displays the differences in HbA1c, waist circumference and number of hypoglycaemic episodes among those meeting and not meeting physical activity guidelines.

Variable	> 150 mins (n=23)	<150 mins (n=49)	p value
Total time Freedson bouts (min/day)	262 (169, 362)	33 (10, 68.5)	0.0001***
Daily average of sedentary time (h/day)	8.6 (1.3)	8.3 (1.7)	0.345
Male / Female (%)	16.7 / 15.3	30.6 / 37.5	0.564
Age (years)	33 (29, 45)	41 (32.5, 52)	0.118
Diabetes duration (years)	14.9 (11.0)	19.4 (11.7)	0.132
HbA1c (%)	7.7 (1.1)	8.4 (1.2)	0.001***
Total insulin (units)	39.7 (32.3, 56.3)	47.1 (37, 59.5)	0.23
BG average (mmol/l)	7.9 (1.6)	9.5 (2.2)	0.006**
BG variability (mmol/l)	3.5 (1.2)	4.1 (1.3)	0.05*
Number of hypoglycaemic episodes	5 (3, 8.5)	2 (1, 4)	0.004**
Total cholesterol (mmol/l)	4.5 (0.56)	4.6 (0.87)	0.43
LDL cholesterol (mmol/l)	2.3 (0.58)	2.5 (0.81)	0.4327
HDL cholesterol (mmol/l)	1.8 (0.42)	1.6 (0.44)	0.18
Triglycerides (mmol/l)	0.76 (0.63, 0.95)	0.99 (0.64, 1.26)	0.06
Systolic blood pressure (mmHg)	136.5 (16.9)	136.4 (13.5)	0.986
Diastolic blood pressure (mmHg)	75 (66, 88)	75 (68, 82)	0.858
Weight (kg)	72.3 (64.4, 78.6)	79.2 (66.6, 95.4)	0.023*
BMI (kg/m2)	24.5 (22.3, 27)	27 (23.4, 31.1)	0.032*
Waist Circumference (cms)	80.9 (76.4, 87.5)	88.6 (80.4, 100)	0.006**
Hip Circumference (cms)	96.5 (72.9, 101.3)	100.4 (96.6, 111.6)	0.005**
% body fat	27.5 (16.4, 30.5)	29.1 (23.5, 41.3)	0.122
Fat mass (kg)	19 (11.7, 21.5)	22.1 (17.3, 33.8)	0.032*

*Table 3-3 Differences in those adhering to physical activity guidelines. Values are expressed as mean (SD), median (25th - 75th percentile) or percentage. * p < 0.05, ** p < 0.01, *** p < 0.001. Abbreviations: HbA1c, glycated haemoglobin; BG, blood glucose; LDL, low density lipoprotein; HDL, high density lipoprotein; BMI, body mass index*

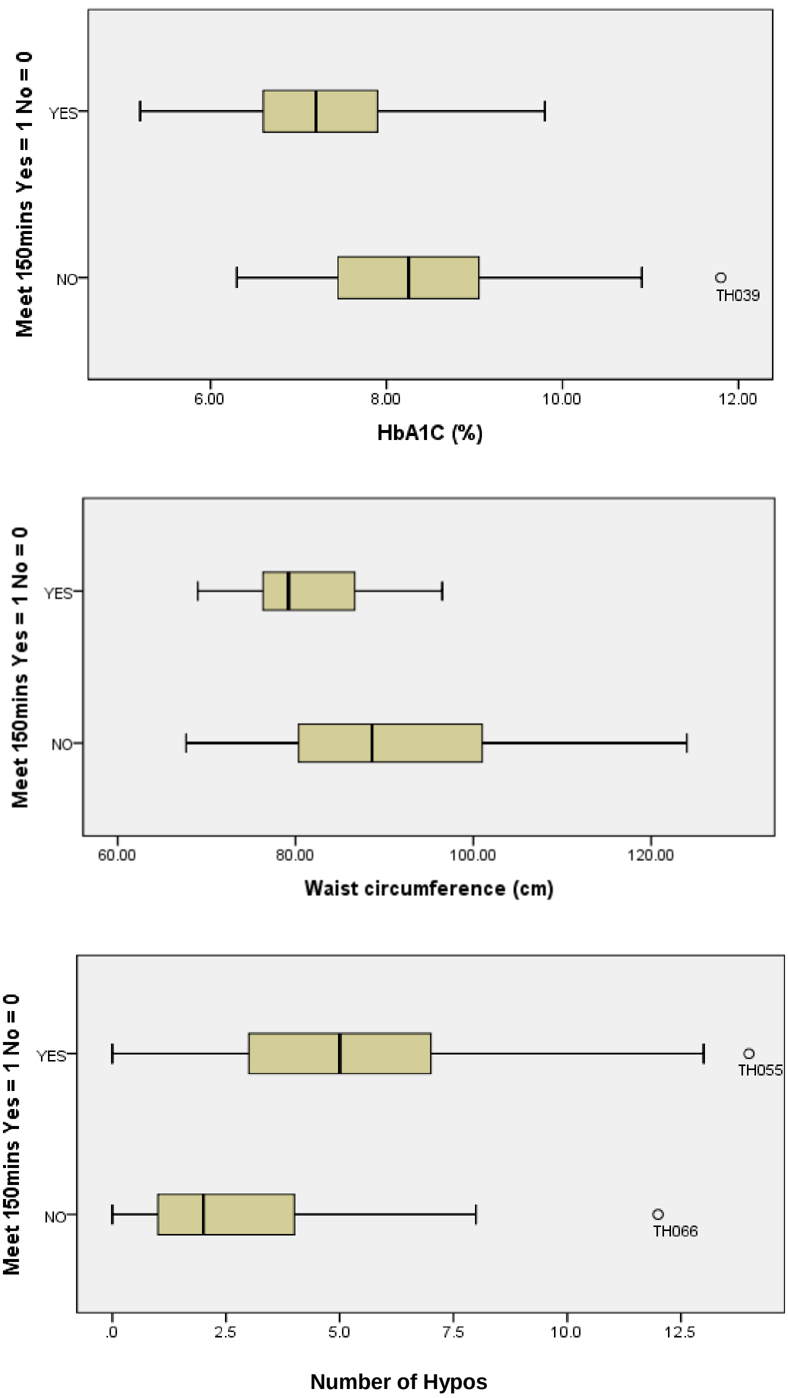

Figure 3-3 Differences in HbA1c, Waist Circumference and number of hypoglycaemic events among those adhering to physical activity guidelines

When we compared those meeting the recommended daily steps per day (10,000 steps per day) versus those not meeting the recommendation, the only significant difference found was % body fat, with those meeting the recommended steps having a significantly lower % body fat (median 28.7 versus 22.4kg, p=0.018).

3.6.5. Correlations between physical activity and CVD risk

Several correlations were observed between glycaemic control and anthropometric measures as level of physical activity (time in moderate-to-vigorous-intensity physical activity in 10 min bouts or ‘Freedson bouts’) increased (Table 3-4). As time in moderate-to-vigorous-intensity activity in at least 10 min bouts increased there was a significant decrease in BMI (r= -0.273; p=0.02), waist circumference (r= -0.355; p=0.002) (Figure 3-5), % body fat (r= -0.231; p=0.05), and fat mass (r= -0.263; p=0.026) and a significant decrease in HbA1c (r= -0.265; p= 0.026) (Figure 3-4). The correlation between HbA1c and total MVPA remained significant when controlled for diet, age, diabetes duration and number of hypoglycaemic episodes. Triglyceride level significantly decreased with increasing time in moderate to vigorous intensity activity in at least 10 min bouts (r= -0.254; p = 0.035). Finally, there was a significant increase in hypoglycaemic events as moderate-to-vigorous-intensity activity in at least 10 min bouts increased (r=0.27; p = 0.026). Most of these correlations were weak, with the exception of waist circumference, where the strength of the association was moderate.

Correlations were also examined between glycaemic control and anthropometric measures as total moderate vigorous physical activity (Total MVPA) increased (Table 3-4). As total MVPA increased there was a significant decrease in waist circumference (r= -0.288; p=0.015), hip circumference (r= -0.234; p = 0.05), % body fat (r= -0.321; p=0.006), fat mass (r= -0.291; p = 0.013) and triglycerides (r= -0.32; p = 0.007). There was a significant increase in the number of hypoglycaemic events (r= 0.358; p=0.003) as total MVPA increased. Borderline significance was seen between total MVPA and HbA1c (r= -0.227; p=0.059). Again most of these correlations were weak, with the exception of % body fat and number of hypoglycaemic events, where the strength of the association was moderate.

Finally there were no associations between sedentary time and any anthropometric or biochemical markers.

	Total MVPA		Freedson bouts	
Variable	**r**	**p**	**r**	**P**
Age	-0.294	0.012*	-0.229	0.53
Diabetes duration	-0.153	0.198	-0.076	0.524
BMI	-0.208	0.079	-0.273	0.02*
Waist Circumference	-0.288	0.015*	-0.355	0.002**
Hip Circumference	-0.234	0.05*	-0.293	0.013*
% body fat	-0.321	0.006**	-0.231	0.050*
Fat mass	-0.291	0.013*	-0.263	0.026*
Fat free mass	0.057	0.635	-0.072	0.55
HbA1c	-0.227	0.059	-0.265	0.026*
BG average	-0.099	0.422	-0.253	0.037*
BG Variability	-0.016	0.9	-0.228	0.074
Number hypos	0.358	0.003**	0.27	0.026*
Total insulin	-0.032	0.795	-0.126	0.308
Basal insulin	-0.097	0.424	-0.122	0.316
Bolus insulin	0.031	0.805	-0.099	0.428
Total cholesterol	-0.054	0.661	-0.084	0.494
LDL cholesterol	-0.039	0.754	-0.114	0.356
HDL cholesterol	0.179	0.148	0.196	0.111
Triglycerides	-0.32	0.007**	-0.254	0.035*
Systolic blood pressure	-0.026	0.83	-0.104	0.397
Diastolic blood pressure	0.056	0.647	-0.065	0.595
Sedentary	-0.169	0.156	0.048	0.687

*Table 3-4 Correlations with total MVPA and total time in freedson bouts. TMVA: Total moderate & vigorous physical activity. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$. Abbreviations: BMI, body mass index; HbA1c, glycated haemoglobin; BG, blood glucose; Number hypos, number hypoglycaemic episodes; LDL, low density lipoprotein; HDL, high density lipoprotein*

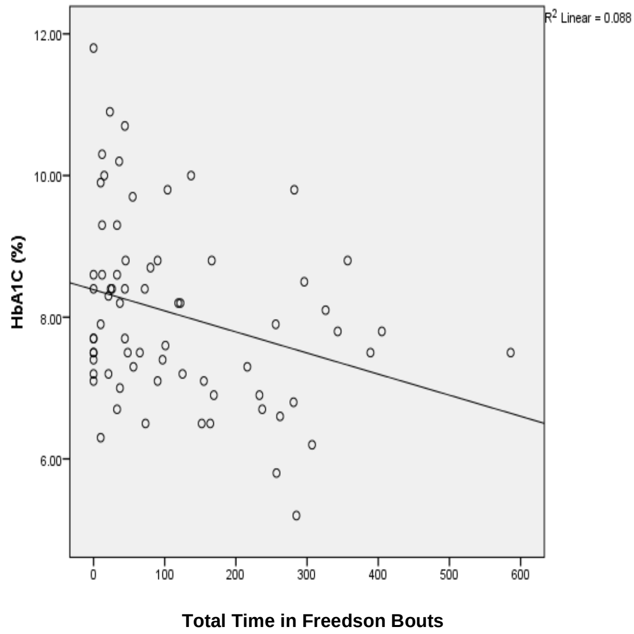

Figure 3-4 Relationship between HbA1c and total time in Freedson bouts (moderate-to-vigorous-intensity physical activity in 10 min bouts)

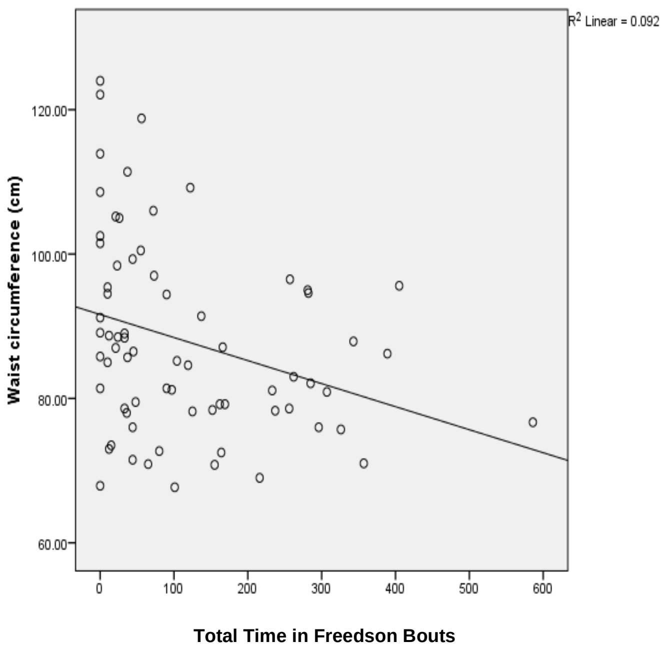

Figure 3-5 Relationship between waist circumference and total time in Freedson bouts (moderate-to-vigorous-intensity physical activity in 10 min bouts)

3.6.6. Multiple regression analysis

Multiple linear regression models were built to assess how the level of physical activity (expressed as the total moderate-vigorous physical activity, time spent in Freedson bouts and the adherence to the physical activity recommendation) influenced HbA1c (%), BMI (kg/m^2), waist circumference (cm), fat mass (kg), and triglycerides (mmol/l). Table 3-5 shows the results for both the unadjusted and adjusted models (adjusted for gender and age). Only the adjusted models are discussed here.

Results show that meeting physical activity guidelines was the strongest predictor of HbA1c, explaining 15% of the variability (R^2 = 0.15, p=0.003). This association was moderate. Total time spent in moderate- to vigorous physical activity, freedson bouts and meeting physical activity recommendations explained 27.5% (R^2 = 0.275, p=<0.001), 25.3% (R^2 = 0.253, p=<0.001) and 25.1% (R^2 = 0.251, p=<0.001) respectively of the variance in fat mass. Total time spent in moderate-to-vigorous physical activity and meeting physical activity recommendations were independent predictors of waist circumference explaining 13.4% (R^2 = 0.134, p=0.005) and 13% (R^2 = 0.130, p=0.006) of the variability respectively. Total time spent in moderate-to-vigorous physical activity explained 7.8% (R^2 = 0.078, p=0.041) of the variability in triglycerides.

	Independent variables											
	Total MVPA				**Freedson bouts**				**Meeting recommendations**			
Dependant variables	**P**	**R^2**	**P†**	**R^2†**	**P**	**R^2**	**P†**	**R^2†**	**P**	**R^2**	**P†**	**R^2†**
HbA1c	0.059	0.051	0.099	0.049	0.013	0.088	0.030	0.086	0.001	0.148	0.003	0.150
BMI	0.019	0.063	0.086	0.052	0.030	0.066	0.093	0.049	0.018	0.077	0.057	0.065
fat mass (kg)	<0.001	0.168	<0.001	0.275	0.004	0.112	<0.001	0.253	0.009	0.094	<0.001	0.251
Waist Circumference	0.007	0.100	0.005	0.134	0.010	0.092	0.010	0.118	0.005	0.109	0.006	0.130
Triglyceride	0.014	0.087	0.041	0.078	0.065	0.05	0.218	0.022	0.071	0.048	0.253	0.017

Table 3-5 Associations of physical activity with CVD risk factors & glycaemic control. †Adjusted for age and gender Abbreviations: Total MVPA, Total moderate-to-vigorous-intensity physical activity; Freedson bouts, Total moderate-to-vigorous-intensity physical activity in 10 minute bouts; Meeting recommendations, ≥150mins moderate-to-vigorous physical activity per week; HbA1c, glycated haemoglobin; BMI, body mass index

3.7. Discussion

The results of this study highlight the issue of physical inactivity among those with type 1 diabetes with most of the time spent sedentary (8.4 ± 1.6 h/day) or in light activity (4.4 ± 1.5 h/day), and only 8.6 (2.3 – 23.3) min/day spent in moderate-to-vigorous-intensity activity in at least 10 minute bouts. Only twenty-three (32%) participants exercised to physical activity recommendations. Those meeting physical activity recommendations had a significantly lower HbA1c (p=0.001), BMI (p=0.032), waist circumference (p=0.006) and fat mass (p=0.032). Participants also had a significantly greater number of hypoglycaemic events (p = 0.004).

Results highlight that having an active lifestyle (those meeting physical activity recommendations) is associated with better glycaemic control and a better body composition (significantly lower BMI, waist and hip circumference, percentage body fat and fat mass). The differences between the groups had important clinical significance with those not meeting the recommendations having a HbA1c well above clinical targets (8.4% vs 7.7%) and being significantly overweight (27kg/m^2 vs 24.5kg/m^2). Also the waist circumference for female participants (85.8±15.3cms) places them at increased cardiovascular risk (a waist circumference ≥80cms for women equates to an increased cardiovascular risk). Consistent with these findings, a similar cross-sectional study by Brazeau et al (Brazeau, Leroux et al. 2012) found that those meeting physical activity recommendations measured by a motion sensor (SenseWear Pro 3 Armband) had a lower BMI, fat mass index, percentage of fat mass and waist circumference. However, unlike our findings which found a significant relationship with physical activity level and HbA1c, they did not see any associations between physical activity and parameters of diabetes control. Also no other associations were observed between physical activity and insulin dose which was comparable to our findings. Thus observational studies have shown associations with exercise and glycaemic control and anthropometric variables. Therefore, there is considerable potential for exercise interventions to improve glycaemic control and anthropometric markers. Exercise training and its benefits in type 1 diabetes have been explored in systematic reviews (Chimen, Kennedy et al. 2012; Kennedy, Nirantharakumar et al. 2013). Kennedy et al (2013) did not detect a benefit in glycaemic control, however, sub analysis suggested that exercise may have a glycaemic benefit in the young and when undertaken for longer periods. Similarly, Chimen et al (2013) showed that physical activity did not demonstrate an improvement in glycaemic control, however a reduction in CVD risk factors, improvement in physical fitness and strength and a reduction in insulin requirements were seen. A more recent systematic review and meta-analysis among adults with type 1 diabetes included only longer term (> 8 weeks training) randomized controlled trials (RCT's) (Yardley, Hay et al. 2014). Only four RCT's were identified and a significant absolute reduction in HbA1c, significant improvements in fitness and reduction in the required insulin dose were found. The results from this meta-analysis should be interpreted with caution as 75% of the participants included in the analysis were from one single study which showed very positive findings.

An exploration on whether physical activity level (light or moderate-to-vigorous-intensity physical activity) or time spent sedentary is the better predictor of metabolic dysfunction among those with type 1 diabetes was conducted in this study. Significant inverse associations between time spent in moderate-to-vigorous-intensity physical activity in at least 10 min bouts (total freedson bouts) and HbA1c, BMI, waist and hip circumference, fat mass and triglycerides were found. These associations were moderate, apart from BMI and waist circumference which had weak associations. Total freedson bouts was the strongest predictor of HbA1c, while total time spent in moderate-to vigorous-intensity physical activity was the strongest predictor of waist circumference, fat mass and triglycerides, regardless of age and sex. Among 11,029 Australian adults (mean age 53.4 years) with type 2 diabetes sedentary time had a stronger influence on waist circumference than moderate-to-vigorous-intensity activity (Healy, Wijndaele et al. 2008). In comparison, the results of this study found no associations with both sedentary time or light-intensity physical activity and anthropometric or biochemical markers. In fact, those meeting physical activity recommendations engaged in slightly more sedentary time.

To the authors knowledge this is the first available Irish data on the levels of physical activity and the adherence to physical activity recommendations among Irish adults with type 1 diabetes. Despite the many benefits of physical activity found here many individuals with type 1 diabetes are very sedentary. Accelerometer data showed that the majority of waking hours (>90%) were spent either sedentary or in light-intensity physical activity. Only a small amount of time was spent in moderate-to-vigorous-intensity physical activity (3.4%). Other studies among adults with type 1 diabetes which have used accelerometry, have used Sensewear

Armbands (motion sensor), which do not give detailed assessment of time spent sedentary and at different physical activity intensities, making the results difficult to compare to our findings (Brazeau, Leroux et al. 2012; Brazeau, Mircescu et al. 2012). There is much available literature among type 2 diabetes. In one study using the Actigraph accelerometer among Australian adults (age range 30-87 years) with diabetes they found that the majority of time was spent sedentary (57%) or in light-intensity activity (39%) with only 4% of time in moderate-to vigorous-intensity activity (Healy, Wijndaele et al. 2008). This was similar to our findings.

In the cohort studied here adherence to physical activity recommendations was poor with only a small percentage (32%) of our sample meeting the physical activity recommendations. In fact 50% of the group undertook less than 60 minutes per week of health-enhancing physical activity which is well below the recommendation. Our results were lower than that reported in other studies using accelerometry among adults to measure physical activity level. Brazeau et al (Brazeau, Leroux et al. 2012) defined a physical activity level (PAL) of ≥ 1.7 as meeting the recommended threshold defining an active lifestyle. Using an accelerometer (motion sensor) to measure physical activity level they found that among adults with type 1 diabetes (Mean age 43.5 +/-10.5yrs), 43% of women and 55% of men met the physical activity recommendations. Another study using a motion sensor among adults (48% women; mean age 43.5+/- 10.4) with type 1 diabetes showed that 60% reached an adequate PAL that could be considered an active lifestyle (Brazeau, Mircescu et al. 2012). The authors speculated that the study population here may not be representative of the general population with type 1 diabetes as those who declined to participate had higher BMIs, poorer blood glucose control and perceptions of health status, as well as less knowledge of insulin pharmacokinetics. To compare the results here to that of the general population that were living in a similar catchment area we looked at the 2014 HANA Survey (Darker, Whiston et al.). This looks at physical activity levels (using questionnaires) among 1082 individuals living in the Tallaght area. Only 15.7% (n=53/337) of respondents reported meeting the guidelines of engaging in moderate physical activity 5 or more days of the week. This a far lower than our findings, which is interesting given that questionnaires can overestimate physical activity practice by up to 60% (Mahabir, Baer et al. 2006).

With poor physical activity levels among our participants it was not so surprising to find that a large percentage (57%) of the participants in this study were overweight (n=21; 29%) and obese (n=20; 28%). Of the 20 obese participants, 18 were defined as being physically inactive or not meeting physical activity guidelines. To the authors knowledge there is no Irish data on the level of overweight and obesity among adults with type 1 diabetes. Among 13,612 participants on the Swedish National diabetes register in 2004 37.2% were overweight and 10.5% were obese (Eeg-Olofsson, Cederholm et al. 2007). Conway et al (Conway, Miller et al. 2010) found that among 589 adults in the United States with Type 1 diabetes (mean age 29 years), the prevalence of overweight and obesity increased from 28.6% to 42% and 3.4% to 22.7% respectively after 18 years' follow-up.

Finally, the findings from this study showed a significantly greater number of hypoglycaemic episodes among those meeting physical activity recommendations, and also a significant positive association between total time spent in moderate-to-vigorous- intensity physical activity and number of hypoglycaemic episodes. In a review of the literature Chimen at al (2012) reported that the majority of studies did not record the frequency of hypoglycaemic events and among those that did two showed no increase and one study showed a minimal increase in hypoglycaemic events (Chimen, Kennedy et al. 2012). Thus they concluded that hypoglycaemia is not a significant factor and is a concern that can be managed using simple approached to insulin and carbohydrate adjustment (Chimen, Kennedy et al. 2012). However from the literature the majority of individuals report a lack of practical advice for preventing hypoglycemia after exercise, and many feel largely uninformed about insulin administration and carbohydrate intake around exercise (Brazeau, Rabasa-Lhoret et al. 2008).

3.8. Strengths and limitations

This was a pilot study and thus a sample size power calculation was not done. Therefore the cohort studied may have been too small to detect statistical significance in all areas. The participants in this study volunteered to take part in the study, therefore this may have introduced bias by including those more motivated and omitting more sedentary individuals who may have been less willing to take part. Also 39% of participants were on insulin pump therapy which is greater than the proportion of patients on insulin pump therapy in general. This would possibly indicate a more selected and motivated study population. Food diaries were used as part of this study as they are a practical and cost effective method of collecting information on nutrient intake. However, they are subject to bias, including under and over-reporting.

A major strength to the study is the use of an objective measure of physical activity which is far more reliable than objective measures such as questionnaires. Also the study population had a wide age range (20-67 years), diabetes duration (1 to 46 years) and mixed gender (47% male). Therefore the sample was representative of the general adult population with type 1 diabetes.

3.9. Conclusion

On average the majority of waking hours (96%) were spent in sedentary or light-intensity activity with only a small percentage (32%) meeting the recommendations for physical activity. Interestingly no associations were seen between sedentary or light-intensity physical activity and metabolic dysfunction. The greatest predictor of metabolic risk was actually time spent in moderate-to vigorous-intensity physical activity (both total and in 10 min bouts) which was negatively correlated with many markers of metabolic risk. This has important clinical and public health implications as it highlights the importance of promoting regular participation in moderate-to-vigorous-intensity physical activity. It would appear that even those who sit for a large percentage of the day (e.g. office workers etc.) attain the benefits of meeting at least 150 minutes of moderate-to-vigorous-intensity physical activity per week. Also those currently undertaking only light-intensity physical activity should be encouraged to increase the intensity to at least moderate in order to achieve the health benefits of physical activity.

There was an increase in hypoglycaemic episodes as moderate-to-vigorous-intensity physical activity increased. More education is needed to help guide individuals around insulin adjustment and / or carbohydrate replacement to help reduce the incidence of exercise induced hypoglycaemia.

4. Chapter 4: The International Physical Activity Questionnaire (IPAQ): a comparison of subjective versus objective measured physical activity

4.1. Abstract

Context: The International Physical Activity Questionnaire (IPAQ) is a tool used to measure health related physical activity (PA) in population based research. It is one of the most widely used PA questionnaires.

Aims: (a) To compare objective (ActiGraph accelerometer) versus subjective (validated IPAQ - long form) PA measures to determine the accuracy and reliability of a subjective measure of PA. **(b)** Use a subjective PA measure (IPAQ) to provide information on levels of PA and sedentary behaviour among a larger type 1 diabetes population.

Materials and methods: (a) 72 participants (34 males) with type 1 diabetes wore an accelerometer (ActiGraph wGT3X-BT) for 1 week and also completed the IPAQ long form. Anthropometrical, biochemical and clinical parameters were recorded. **(b)** All participants attending an adult type 1 diabetes outpatient clinic over a 4 month period were asked to complete the IPAQ long form. Anthropometric, biochemical and clinical data was extracted retrospectively from data sources and participant records within the hospital.

Results: (a) 97% (n=69) reported meeting the PA guidelines (≥ 150 minutes per week of moderate-to-vigorous-intensity PA) as per the IPAQ compared to only 32% (n=23) of individuals as per the ActiGraph accelerometer. A significant difference in the reported time spent in moderate-intensity activity as per the IPAQ and moderate-intensity activity measured by the ActiGraph was found (187 ± 184.6 vs 31.9 ± 21.5 mins/ day). Reported time spent in vigorous-intensity activity and time spent sedentary significantly correlated with time spent in vigorous-intensity activity and time spent sedentary from the actigraph monitor. However, there was only significant agreement in sedentary time between both measures (p=0.032). **(b)** 151 participants [median age 35 (23.5, 49.7) years and diabetes duration 13.9 (6.8, 21.4) years] completed the IPAQ. The IPAQ captured 95% (n=143) of participants as meeting the PA guidelines.

Conclusion: It is likely that individuals overestimate the amount of moderate and vigorous-intensity PA and underestimate sedentary time using the IPAQ. Aside from time spent sedentary there was poor agreement between both measures, therefore this PA questionnaire should be used with caution when identifying PA levels among this population.

4.2. Introduction

Physical activity can be measured using subjective (self-reported or telephone questionnaires, diaries etc.) or objective measures (motion sensors, heart rate monitors etc.). The majority of studies use subjective measures of physical activity as they are practical, can be administered at a low cost and low participant burden and can be used to assess physical activity levels of populations (Prince, Adamo et al. 2008). However these measures are subject to a variety of biases, primarily due to inaccuracy of the subjects' reporting of their physical activity or due to their desire to conform to social norms (Pober, Staudenmayer et al. 2006). Therefore we must exercise caution when reviewing the literature using self-reported measures as physical activity is likely to be overestimated (Liese, Ma et al. 2013). The International Physical Activity Questionnaire (IPAQ) is one example of a subjective measure of physical activity. It is the most widely used physical activity questionnaire and was developed to assess population levels of physical activity across countries (Dyrstad, Hansen et al. 2014). There is a long and short version of this tool and their reliability and validity has been tested among the general population (Craig, Marshall et al. 2003; Hagströmer, Oja et al. 2006).

Objective measures of physical activity include accelerometry. Accelerometry provides a more accurate measure of physical activity as they are not reliant on individual's recall of physical activity (Liese, Ma et al. 2013). They are activity monitors that measure position and motion (Liese, Ma et al. 2013). Accelerometry provides information about duration and intensity of physical activity and can generally be employed at a reasonable cost (Pober, Staudenmayer et al. 2006).

A cross-sectional study compared measures of physical activity from the IPAQ-long and an activity monitor (MTI Actigraph) (Hagströmer, Oja et al. 2006) among adult Swedish men and women without diabetes (n=46). Results showed that reported time spent in vigorous-intensity physical activity correlated significantly with time spent in vigorous-intensity physical activity from the MTI activity monitor. This correlation was however moderate. The correlation between self-reported time in moderate-intensity physical activity and time spent sitting with time spent in moderate-intensity physical activity and time spent sitting recorded by the activity monitor were not significant.

The IPAQ can be used to examine the percentage of the population meeting physical activity guidelines (≥ 150 minutes per week of moderate- to-vigorous-intensity physical activity). Using the IPAQ - long form Booth et al. (2003) reported 89% of adults among the general population met the physical activity guidelines (Booth, Ainsworth et al. 2003). Dyrstad, Hansen et al. (2014) found that 22% of participants met the physical activity guidelines as determined by the accelerometer, compared to 86% captured by the IPAQ – short form.

The aims of this part pf the study was:

(1) To compare physical activity and sedentary time recorded from the long version of the IPAQ to accelerometer measured physical activity and sedentary time among adults with type 1 diabetes.

(2) To examine the reliability of the IPAQ-long form when used among this population.

(3) Assess physical activity levels subjectively using a large type 1 diabetes population.

4.3. Participants and methods

4.3.1. Participants

(a) An observational cross-sectional study was used to compare physical activity measures from the long self-administered version of the IPAQ (Appendix IV) to physical activity measured by the ActiGraph accelerometer. 72 participants attending the diabetes day centre in Tallaght Hospital met the inclusion criteria (having a diagnosis of Type 1 diabetes for greater than 1 year; on multiple daily injections [MDI] of rapid and long acting insulin or on Insulin pump therapy; and aged ≥ 18 years) and participated in the study.

(b) All participants attending a weekly type 1 diabetes outpatient clinic over a 4 month period were asked to complete the IPAQ. 151 participants (excluding the 72 participants above) completed the physical activity questionnaire, but did not wear an accelerometer. The inclusion criteria was the same as that above. All participants completing the questionnaire signed a consent form to allow this information to be used as part of the research project and for us to access their health information from the diamond database or their medical notes.

4.3.2. Measurements

4.3.2.1. Subjective PA measurement

All 72 participants that wore the accelerometer were also asked to complete the IPAQ. An additional 151 participants attending a weekly type 1 diabetes outpatient clinic completed the IPAQ. The IPAQ self-reported physical activity questionnaire is the English language version of the long self-administered version of the IPAQ. Information on the IPAQ, including information on data cleaning and the IPAQ scoring protocol can be found in Chapter 2 (2.2.2 Physical Activity Assessment: Subjective measure). Adherence to physical activity recommendations will be examined using the IPAQ data. Those categorized as moderate or high level of physical activity as per the IPAQ were classified as being sufficiently active according to physical activity guidelines.

4.3.2.2. Objective PA measurement

72 participants wore the ActiGraph accelerometer (wGT3X-BT) for 7 consecutive days during waking hours. Participants recorded the time they put the accelerometer on and off (for shower / sleeping / swimming) and any activity they did when not wearing monitor (e.g. swimming) or it they forgot to put the monitor on. All information was downloaded from the ActiGraph monitor as soon as it was returned. Refer to Chapter 2 (2.2.1 Physical activity assessment: Objective measure) for further details on the ActiGraph accelerometer, classifying wear and non-wear time and cutpoints used to define different intensities of physical activity and “activity bouts” (used to determine adherence to physical activity guidelines).

4.3.2.3. Comparing subjective versus objective measures of physical activity

Data from the Actigraph accelerometer (72 participants) was compared to reported data from the IPAQ. The following were compared:

- Sitting / sedentary time
- Moderate-intensity activity (including and excluding walking)
- Vigorous-intensity activity
- Moderate-to-vigorous-intensity activity in 10 minute bouts
- Percentage of the sample meeting physical activity recommendations

4.3.2.4. Anthropometric and biochemical measures

(a) As previously described anthropometric measures (weight, height, BMI, body composition, waist and hip circumference) were measured according to standard procedures (See Chapter 2; 2.2.6. Anthropometry and body composition). Biochemical and clinic measures included HbA1c, renal and lipid profile, urine albumin and urine albumin: creatinine ratio, blood pressure, and presence of diabetic retinopathy and nephropathy were recorded from the hospital's Diamond diabetes database (Chapter 2; 2.2.5. CVD risk factors).

(b) Participant's most recent anthropometry, biochemistry and clinical data were taken retrospectively, following collection of the questionnaires, from the hospital's Diamond diabetes database. Any missing data was searched for using alternate sources (participants' medical notes and hospital's KEY iSoft database). For further information refer to Chapter 2 (2.4.3. Anthropometry, biochemistry and clinical data).

4.4. Statistics

Analysis was performed using IBM SPSS Statistics 24. Continuous variables were inspected for normality of distribution prior to analysis using the Kolmogorov-Smirnov test. Descriptive statistics were calculated for study variables and displayed as mean (SD) or median (25th - 75th percentile).

Spearman's correlation coefficient, ρ (rho) was used to assess associations between the two methods used to measure physical activity (subjective and objective measures). The intraclass correlation coefficient (ICC) was also used to test the reliability between the two measures of physical activity. The ICC provides a measure of the agreement between the two measures so that they report the same values and are comparable ways of measuring physical activity. A p value of less than 0.05 was regarded as statistically significant in all analysis.

4.5. Results

The characteristics of the participants wearing the accelerometer and completing the IPAQ are presented in Table 4-1.

Participants characteristics	Total sample (n=72)
Age (years)	40 (31, 48.8)
Diabetes duration (years)	17.96 (11.6)
Treatment	
– Multiple daily injections n (%)	44 (61)
– Insulin pump n (%)	28 (39)
Smoking habit n (%)	15 (21)
Completed Structured education n (%)	52 (72)
BMI	25.9 (23.2, 30.3)
– Overweight, n (%) (BMI = 25.0-29.9kg/m^2)	21 (29)
– Obese, n (%) (BMI >30kg/m^2)	20 (28)
Waist Circumference (cms)	85.8 (78.3, 95.6)
Hip Circumference (cms)	99.5 (95.7, 108.4)
% body fat	28.5 (22.6, 34.4)
Fat mass (kg)	19.8 (16.7, 27.5)
HbA1c (%) / (mmol/mol)	8.0 (1.3) / 64.5 (14.3)
Total Cholesterol (mmol/l)	4.6 (0.8)
LDL (mmol/l)	2.4 (0.8)
HDL (mmol/l)	1.7 (0.4)
Triglcerides (mmol/l)	0.9 (0.7, 1.2)
Hypertension requiring treatment n (%)	17 (24)
Retinopathy n (%)	27 (38)

Table 4-1 Characteristics of group wearing accelerometer and completing IPAQ for total sample (n=72). Values are expressed as mean (SD) or median (25th - 75th percentile) or number (n) (%).Abbreviations: BMI, body mass index; HbA1c, glycated haemoglobin; LDL, low density lipoprotein; HDL, high density lipoprotein

Following data cleaning and examination of the IPAQ data for outliers, the IPAQ data for one participant was excluded from the analysis as the sum of walking, moderate and vigorous physical activity exceeded 960 minutes (16 hours). This left valid IPAQ data for 71 participants. Table 4-2 shows the results obtained from the IPAQ.

IPAQ Variables	Total sample (n = 71)
Sitting (hr/day)	6.2 (2.3)
Walking (min/day)	47.1 (17.1, 122.9)
Moderate (excluding walking) (min/day)	60 (17.1, 120)
Moderate (including walking) (min/day)	125.7 (64.3, 244.3)
Vigorous (min/day)	8.6 (0, 45)
Total activity time* (min/day)	158.6 (82.1, 247.3)

*Table 4-2 Descriptive data from IPAQ for total sample (n=71). Values are expressed as mean (SD) / median (25th - 75th percentile). Abbreviations: IPAQ, International Physical Activity Questionnaire; *Total activity time (min/day) = Walking + moderate + Vigorous*

Table 4-3 shows the difference between the IPAQ and accelerometer data. According to the ActiGraph data, during waking hours, the majority of the time was spent sedentary (8.4 ± 1.6 hr/day) or in light activity (4.4 ± 1.5 hr/day), with a mean of 31.9 ± 21.5 min/day in moderate-intensity activity and 2.0 ± 3.9 min/day in vigorous-intensity activity. Comparing this to the IPAQ data, participants reported a significantly greater amount of moderate-intensity physical activity than that captured by the ActiGraph [187.0 (184.6) min/day vs 31.9 (21.5) min/day]. Even when walking is excluded from the moderate-intensity IPAQ data it remains significantly greater than the accelerometer measured moderate-intensity data [89.7 (21.5) vs 31.9 (21.5) min/day)]. Participant's also report less sedentary time (25% less) (6.1 ± 2.4 hr/day vs 8.4 ± 1.6 hr/day) and higher levels of vigorous-intensity physical activity (98% higher) (35 ± 64.2 min/day vs 2.0 ± 3.9 min/day) when compared with the accelerometer data. As the IPAQ captures activity in at least ten minute bouts it is important to compare this to ActiGraph data captured in ten minute bouts. Doing this showed that time spent in moderate-to-vigorous-intensity activity in at least 10 minute bouts as measured by the ActiGraph was significantly less than reported time in moderate-to-vigorous-intensity activity captured by the IPAQ (222.0 ± 209.5 min/day vs 16.1 ± 17.7 min/day).

23 (32%) participants met the physical activity guidelines as per the ActiGraph. However using the IPAQ 69 (97%) participants reported meeting the recommended ≥150 min per week of moderate-to-vigorous-intensity activity. The 2 participants that did not meet the

recommendations as per the IPAQ were correctly captured by the ActiGraph as not meeting the recommendations.

A more detailed analysis was performed in order to understand the relationship between the IPAQ and the accelerometer data. Firstly the correlation between the two measures of physical activity (Spearmans Rho) was assessed and secondly the agreement of the two methods using the Interclass correlation coefficient (ICC) was examined (Table 4-3). The correlation between reported time in vigorous-intensity physical activity by the IPAQ and time spent in vigorous activity recorded by the Actigraph was significant (r= 0.326; p = 0.006), although the strength of this relationship was moderate. Also reported sitting / sedentary time and sitting / sedentary time recorded by the Actigraph was significantly correlated, however the strength of the relationship was weak (r = 0.267; p = 0.023). Using the ICC, there was only significant agreement between sitting / sedentary time between both measures and again the strength of this agreement was weak (r = 0.218; p=0.032).

IPAQ Variable	IPAQ	ActiGraph	Correlation	p value	Correlation^{ICC}	p value
	n=71	n=72				
Sitting / sedentary (h/day)	6.1 (2.4)	8.4 (1.6)	0.267^{s}	0.023	0.218	0.032
Moderate (excluding walking) (min/ day)	89.7 (21.5)	31.9 (21.5)	-0.015^{s}	0.904	-0.002	0.508
Moderate (including walking) (min/day)	187.0 (184.6)	31.9 (21.5)	0.126^{s}	0.294	0.004	0.486
Vigorous (min/ day)	35.0 (64.2)	2.0 (3.9)	0.326^{s}	0.006	0.001	0.497
Moderate and Vigorous (min/day)*	222.0 (209.5)	33.9 (22.2)	0.144^{s}	0.232	0.009	0.471
Total MVPA in 10 min bouts (min/day)*	222.0 (209.5)	16.1 (17.7)	-0.001^{s}	0.991	-0.014	0.546

*Table 4-3 Correlation coefficients and agreement between the IPAQ and Actigraph measures. Data are presented as mean (SD), s = Spearman's rho, Correlation^{ICC} = ICC. Abbreviations: IPAQ, International Physical Activity Questionnaire; MVPA, moderate-to-vigorous physical activity; *The IPAQ includes walking as part of moderate physical activity*

(b) 187 participants completed the IPAQ and signed the consent form. This was a 69% response rate. 1 participant was removed as he had type 2 diabetes which left 186 participants. Table 4-4 shows the main clinical characteristics of the group (n=186). Their median age was 35 (23.5, 49.7) years and median diabetes duration was 13.9 (6.8, 21.4) years. Median BMI was 25.7 (23.3, 28.3) kg/m^2 with 59% of the participants being overweight and obese [43%

overweight (n=74) and 16% obese (n=27) respectively]. Median HbA1c was 8.2% (7.5, 9.0). The majority were on multiple daily injections (78%). There was no significant difference in HbA1c between those on an insulin pump versus those on MDI.

Participants characteristics	**Total sample n=186**	**Male n=114**	**Female n=72**
Age (years)	35 (23.5, 49.7)	38.8 (23.9, 50.5)	31.7 (22.9, 47.7)
Currently in employment (%)	66	38	28
Smoking habit (%)	16	12	4
Diabetes duration (years)	13.9 (6.8, 21.4)	13.5 (6.5, 20.7)	16.8 (7.8, 26.8)
HbA1c (%)	8.2 (7.5, 9.0)	8.2 (7.5, 9.0)	8.2 (7.5, 9.1)
Diabetes Treatment (%)	-	-	-
Multiple daily injections	78	12	10
Insulin pump	22	49	28
Total insulin (IU/day)	48 (34.1, 61.8)	49 (37, 65)	48 (30, 59.5)
Basal insulin (IU/day)	24 (16, 34)	25 (16.8, 34)	22 (15, 33.5)
Bolus insulin (IU/day)	27.2 (15.7)	28 (17.6, 36.3)	22 (15, 33.5)
Weight (kg)	76 (67.2, 86.7)	79.4 (70.8, 91.6)	71.8 (63.3, 79.8)
BMI (kg/m2) (%)	25.7 (23.3, 28.3)	25.3 (23.2, 27.6)	26.9 (23.7, 29.6)
Normal weight: BMI 18.5-24.9kg/m^2	41	29	12
Overweight: BMI = 25.0-29.9kg/m^2	43	26	17
Obese: BMI >30kg/m2	16	8	8
Total Cholesterol (mmol/l)	4.3 (3.8, 4.9)	4.2 (3.7, 4.8)	4.6 (4, 5.2)
LDL (mmol/l)	2.2 (1.8, 2.8)	2.2 (1.8, 2.8)	2.3 (1.7, 2.9)
HDL (mmol/l)	1.5 (1.3, 1.9)	1.4 (1.2, 1.7)	1.7 (1.5, 2.1)
Triglycerides (mmol/l)	0.9 (0.7, 1.2)	0.9 (0.7, 1.3)	0.9 (0.7, 1.2)
Systolic blood pressure (mmHg)	134 (123, 142)	136 (123, 145)	132 (123, 140)
Diastolic blood pressure (mmHg)	73 (68, 81)	74.5 (68, 83)	71.5 (68, 78)
Hypertension requiring treatment (%)	29	22	7
Diabetic Retinopathy (%)	27	19	8
Microalbuminuria	7.1 (4.1, 17.4)	7.9 (4.3, 22.6)	6.5 (3.7, 11.2)
Microalbumin:creatinine	0.7 (0.4, 1.8)	0.7 (0.4, 1.8)	0.8 (0.5, 1.7)

Table 4-4 Characteristics of group completing questionnaires. Mean / median for continuous data and number (%) for categorical data. Abbreviations: HbA1c, glycated haemoglobin; BMI, body mass index; LDL, low density lipoprotein; HDL, high density lipoprotein

During the IPAQ data cleaning 21 participants reported >16 hours or 960 minutes per day of total activity (walking + moderate + vigorous) in the IPAQ. Therefore this IPAQ data was excluded from the database as they were considered outliers. This assumes that an individual spends on average 8 hours per day sleeping. Among these outliers the number of reported hours ranged from 16.4 – 33.6 hours. The majority of outliers were male (n=16; 76%) with an average age of 37.2 years (range 20-52 years). An additional 14 participants (8 male and 6 female; age 42.3 (range 21 – 70) had an incomplete IPAQ [100% incomplete (n=7); 90% incomplete (n = 5); 75% incomplete (n = 2)]. This left a total of 151 participants with valid IPAQ data.

Table 4-5 shows the results obtained from the IPAQ. Participants spent a median of 5.6 (3.8, 8) hours per day sitting or sedentary. The majority of reported activity was either walking or moderate-intensity physical activity with a median of 3.4 (1.2, 6.6) hours per day spent active (total of walking and moderate-to-vigorous-intensity activity). The IPAQ captured 95% (n=143) of participants as meeting the recommended ≥150 min per week of moderate-to-vigorous-intensity physical activity (walking is included in moderate intensity physical activity as per the IPAQ scoring guidelines).

IPAQ Variables	Total sample (n=151)
Sitting (hr/day)	5.6 (3.8, 8)
Walking (min/day)	51.4 (17.1, 171.4)
Moderate (min/day)	68.5 (17.1, 210)
Vigorous (min/day)	8.6 (0, 54.3)
Total activity time* (min/day)	202.9 (82.1, 394.3)
Total activity time* (hr/day)	3.4 (1.3, 6.6)

*Table 4-5 Descriptive data from the IPAQ (n=151). Abbreviations: IPAQ, International Physical Activity Questionnaire; *Total activity time = Walking + moderate + Vigorous*

4.6. Discussion

The primary aim of the study was to assess the agreement between the two measures of physical activity. Using the ICC only sitting / sedentary time showed a significant agreement.

There was poor agreement between both physical activity measures in terms of moderate and vigorous-intensity activity. Among the group wearing the accelerometer, the majority of participants reported meeting the recommended physical activity guidelines (97%; n=69) as per the IPAQ, which was far greater than the actual number of participants meeting the guidelines as measured using the ActiGraph (37%). Similarly 95% (n=143) reported meeting the physical activity guidelines using the IPAQ among the larger type 1 diabetes cohort. It is likely that participants over-reported moderate and vigorous-intensity physical activity and under-reported sitting / sedentary time.

The agreement between the two measures in terms of sitting / sedentary time, although significant, was weak ($r = 0.267$). Participants in this study likely under-reported sedentary time as reported sitting / sedentary time was a lot lower in the IPAQ (6.2 ± 2.3 hr/day) compared to that measured by the ActiGraph (8.4 ± 1.6 hr/day). Similar low levels of sitting / sedentary were found among our larger sample [5.6 (3.8, 8) hr/day]. However we must also take into consideration that the ActiGraph sedentary time (<100 cpm) includes sitting, standing (does not differentiate between sitting and standing) and lying down to watch television whereas the IPAQ only asks about time spent sitting / lying and not standing (Dyrstad, Hansen et al. 2014). Therefore this could also explain some of the discrepancy between the reported lower estimation of sitting / sedentary time in this study using the IPAQ compared to that measured by the accelerometer. The results of this study are consistent with the results of Dyrstad, Hansen et al. (2014) which used the short version of the IPAQ and compared it to accelerometer (ActiGraph) measured physical activity. They also found that the highest correlation between the IPAQ and accelerometer items was total sitting / sedentary time (Dyrstad, Hansen et al. 2014). They too found that mean self-reported sitting time was 2.19 hours/day lower compared with accelerometer data. However the reported sitting / sedentary time was 7.0 hours per day which is a lot higher than that reported in out study. In contrast, another study which used the long version of the IPAQ and compared it to data from the MTI Actigraph did not find a significant correlation between self-reported time spent sitting and the amount of sitting time recorded by the MTI activity monitor ($\rho = 0.17$) (Hagströmer, Oja et al.

2006). Interestingly the authors in this study found that self-reported time spent sitting (52.0 ± 16.1 hr/wk) was greater than sitting time recorded by the activity monitor (50.4 ± 9.1 hr/wk). The lower levels of sitting / sedentary time reported in this study, compared to other studies, is again likely due to underreporting of sitting / sedentary time among our sample.

There was no significant agreement found in this study between both measures for moderate and vigorous-intensity physical activity. There was a significant correlation between reported and measured vigorous-intensity physical activity found in our study but the strength of this correlation was moderate ($r = 0.326$). There was a higher amount of reported vigorous-intensity physical activity as per the IPAQ than that measured by the accelerometer (35 ± 64.2 min/day vs 2.0 ± 3.9 min/day). Drystad et al (2014) also found similar results with a significantly higher self-reported vigorous-intensity activity compared to that measured by the accelerometer (16 min/day vs 2.7 min/day). Results from Hagströmer, Oja et al (2006) also showed a significant correlation ($\rho = 0.71$; $p < 0.001$) between the reported time spent in vigorous-intensity physical activity (2.3 ± 4.4 hr/week) and the time spent in vigorous-intensity physical activity from the MTI activity monitor (1.7 ± 1.1 hr/week). Again the self-reported vigorous intensity activity was higher than that measured by the accelerometer. Possible reasons explaining the differences in our study and that of others (Drystad, Hansen et al. 2014; Hagströmer, Oja et al. 2006) could be that activities that are done at higher intensities are easier to remember due to their association with the feeling of exhaustion, they tend to be more structured and therefore easier to recall, and if the warm up and cool down are included the time at this intensity could be overestimated.

Finally in this study a large discrepancy was found between reported moderate-intensity physical activity using the IPAQ versus that measured by the ActiGraph, where self-reported moderate-intensity physical activity was far greater than accelerometer measured moderate-intensity physical activity. In contrast, other studies however have found lower amounts of reported moderate-intensity physical activity compared to that measured by the ActiGraph (Dyrstad, Hansen et al. 2014; Hagströmer, Oja et al. 2006). Possible reasons for the discrepancies in the results presented here could be the different cutpoints used for defining moderate-intensity physical activity (refer to chapter 2.2.1 Physical activity assessment). A cutpoint of 2020 counts per minute (cpm) was used in this study to define moderate intensity physical activity. Dyrstad, Hansen et al. (2014) used a cutpoint of 760cpm and they report that using 2020 cpm and not 760 cpm as the cutpoint for moderate-intensity physical activity would have excluded 77min of physical activity from their accelerometer data (Dyrstad, Hansen et al. 2014). Other possible explanations is that the reporting overestimate could also be a result of individuals misclassifying sedentary or light-intensity activity as moderate-intensity or an overestimation of the activity duration by individuals. Hagströmer, Oja et al. (2006) used a similar cutpoint to us of 1952 cpm to define moderate-intensity and yet reported moderate-intensity physical activity (5.1±6.9 hours/wk) is far lower than that measured by the activity monitor (9.1±2.7 hours/wk). They put this finding down to poor recall by the participants using the reported measure as these activities are accumulated throughout the day and the number and diversity of these activities is enormous. Participants in their study performed far greater amounts of moderate-intensity activity (78 min/day) than in our study (32 min/day) when measured by accelerometry. This Scandinavian population are likely far more active than our population. Therefore it may have been more difficult for them to recall all moderate-intensity activity undertaken.

A limitation of the accelerometer is that some moderate or vigorous-intensity activities like strength training or cycling may not be recorded by the activity monitor which can only provide information about acceleration in the vertical plane (Drystad, Hansen et al. 2014). This must be taken into consideration when comparing physical activity levels from both measures as perhaps some of the discrepancy between the moderate and vigorous-intensity activity found here could be a result of the accelerometer not capturing all forms of physical activity. However, even when taking this limitation into consideration it would still appear that participants are over reporting their level of moderate and vigorous-intensity activity when we look at the percentage of those meeting the physical activity recommendations. Findings in this study showed that 97% (95% among the larger sample) were captured by the IPAQ as meeting physical activity guidelines which was far greater than the 32% meeting the guidelines as measured by the ActiGraph. When comparing this to other studies Booth et al. (2003), also using the IPAQ-long form, reported 89% of adults among the general population meet 150 minutes per week of at least moderate to vigorous physical activity (Booth, Ainsworth et al. 2003). Dyrstad, Hansen et al. (2014) (IPAQ-short form) found that 22% of participants met the physical activity guidelines as determined by the accelerometer, compared to 67% captured by the IPAQ. Dyrstad, Hansen et al. (2014) report that the sensitivity of the IPAQ in capturing those who were categorized as insufficiently inactive by the accelerometer was only 39%. Therefore it's clear, from our study and that of others, that the IPAQ's ability to capture inactive individuals is limited. Overestimation of self-reported physical activity is common (Liese, Ma et al. 2013) and may be caused by social desirability response bias (Aadahl and JØrgensen 2003). Other issues include the fact that self-reported physical activity is dependent on the physical fitness of the individuals, therefore lower fitness levels may lead to over-reporting of moderate and vigorous-intensity physical activity (Dyrstad, Hansen et al. 2014).

4.7. Strengths and limitations

Accelerometers do have limitations and depending on the setting can either under or over report activity levels in comparison to 'gold standard' methods such as doubly-labelled water or indirect calorimetry. However, neither of the latter two methods are suitable for measuring physical activity in the free-living setting, and therefore accelerometry is the best available measure. However we must keep in mind their limitations, including their inability to capture all activities, which could result in an underestimate of physical activity levels during activities like bicycling, skating and strength training. Therefore, this may have resulted, to some degree, in the discrepancy we observed between subjectively reported physical activity and accelerometer measured physical activity. Also the accelerometer cut points used has a significant influence when comparing both measures and when comparing results to other similar research. Finally, our questionnaire data may not always represent the same week as that while wearing the accelerometer. However, as this was the case for only a small number of individuals (n=4), and because both measures serve to provide a snapshot of habitual physical activity levels, all data was included in the analysis. It was felt by the author that this would not provoke valuable comparative data.

Strengths of the study included the fact that the IPAQ was compared to an objective measure of physical activity (accelerometry), which has been suggested as one of the best criterion instruments when validating self-reported measures of physical activity (Hagströmer, Oja et al. 2006). Also another strength was the large number that accurately completed the IPAQ among our smaller sample (all accurately completed aside from one questionnaire). Also among our larger sample there was a 69% response rate. However 19% of the questionnaires were incomplete or not completed correctly. The long form has been reported as being “too boring and repetitive” and too long (Booth, Ainsworth et al. 2003) which could explain some of the incomplete / incorrectly completed forms.

4.8. Conclusion

There were large discrepancies between self-reported and accelerometer measured moderate and vigorous-intensity physical activity. Better agreement was observed between reported and measured sedentary time, although participants likely under-reported sedentary time using the IPAQ. Limitations of the accelerometer when measuring moderate and vigorous-intensity activity must be acknowledged. However it would appear that individuals over-report the amount of moderate and vigorous-intensity physical activity using the IPAQ as 97% (95% among the larger sample) of the participants were captured as meeting the physical activity recommendations compared to only 32% meeting the recommendations as measured by the ActiGraph. Therefore, the IPAQ long form should be used with caution among this population due to the likelihood that individuals over-report the amount of moderate and vigorous-intensity physical activity and under-report the amount of time spent sedentary. Using the IPAQ alone to measure physical activity will result in an over-reporting of physically active individuals. The fact that individuals believe they are doing a lot more physical activity than they are actually doing is a great concern and must be addressed in order to tackle the issue of physical inactivity among this population.

5. Chapter 5: Barriers to Physical Activity in Adults with Type 1 Diabetes

5.1. Abstract

Context: One determinant of physical activity (PA) is perceived barriers and these can be assessed using a diabetes-specific barriers measure called the BAPAD-1 [Barriers to Physical Activity in Diabetes (Type 1)] scale.

Aims: Identify the barriers to PA among Irish adults with type 1 diabetes using the BAPAD-1 scale. Examine factors associated with these barriers (including physical activity level and diabetes control).

Materials and methods: (a) 72 participants with type 1 diabetes wore an accelerometer (ActiGraph) for 7 consecutive days to determine their PA level. Participants also completed the BAPAD-1 scale. Anthropometric, biochemical and clinical parameters were recorded. **(b)** All participants attending an adult type 1 diabetes clinic over a 4 month period were asked to complete the BAPAD-1 (Barriers to Physical Activity in Diabetes [Type 1]) Scale. Anthropometric, biochemical and clinical data was extracted retrospectively from data sources and participant records within the hospital.

Results: (a) Fear of hypoglycaemia was identified as the strongest barrier to PA (3.4 ± 2.0). The other main barriers to PA included low fitness levels (2.9 ± 1.9), weather (2.8 ± 1.9) and loss of control over diabetes (2.7 ± 1.9). There was no association between BAPAD-1 score and PA level measured by the accelerometer or diabetes control as measured by HbA1c. As percentage body fat and fat mass increased there was a significant increase in BAPAD-1 score ($p = 0.004$ and $p = 0.026$ respectively). **(b)** 168 participants [median age 35 (23.5, 49.7) years and diabetes duration 13.9 (6.8, 21.4) years] completed the BAPAD-1 scale. The mean BAPAD-1 score was 2.4 ± 1.1. The highest barrier scores were fear of hypoglycaemia (3.3 ± 1.9); low fitness level (2.8 ± 1.9); weather (2.8 ± 1.9) and loss of control over your diabetes (2.7 ± 1.9). Glycaemic control, as measured by HbA1c, was positively correlated with BAPAD-1 score ($p=0.047$).

Conclusion: These barriers to PA must be taken into consideration when planning future interventions looking to address physical inactivity. For example PA interventions must include education and strategies to prevent exercise induced hypoglycaemia, which has been identified as the main barrier to PA.

5.2. Introduction

Participation in regular physical activity has been shown to have multiple health benefits among those with type 1 diabetes, including improved cardiovascular fitness, insulin sensitivity, muscle strength and reduced cardiovascular disease risk factors (Chimen, Kennedy et al. 2012; Yardley, Hay et al. 2014). Physical activity recommendations state that adults with diabetes should engage in 150 minutes or more per week of moderate-to-vigorous-intensity physical activity (Colberg, Sigal et al. 2016). Despite these recommendations approximately 60% of participants with type 1 diabetes do no structured exercise at all and only 20% undertake exercise more than twice per week (Bohn, Herbst et al. 2015). Therefore it would appear that public health messages to increase physical activity have largely been unsuccessful. One way to address this major public-health concern is to begin to understand the major determinants of physical activity such as barriers, motivators and perceptions of self-efficacy (Sherwood and Jeffery 2000). Perceived barriers is one determinant of physical activity and addressing these in an effort to increase physical activity levels is imperative.

Perceived barriers to physical activity have been evaluated using either interviews (Lascar, Kennedy et al. 2014; Ryninks, Sutton et al. 2015) or questionnaires (Brazeau, Rabasa-Lhoret et al. 2008; Brazeau, Mircescu et al. 2012). The advantages of questionnaires over interviews is that they are inexpensive, reliable as they avoid interviewer bias, and also they allow the collection of information from larger groups of individuals (Brazeau, Mircescu et al. 2012). The BAPAD-1 scale is one such questionnaire that has been used in the literature to help identify barriers towards physical activity among those with type 1 diabetes and thus contribute to the development and guide for future interventions to promote physical activity among these individuals (Dubé, Valois et al. 2006). The 11-item BAPAD-1 scale (Appendix v) has been developed and validated and shows excellent psychometric qualities to adequately evaluate barriers to regular physical activity among this population (Dubé, Valois et al. 2006). The reliability and predictive validity of the tool has been assessed among 77 adults (48% female) with type 1 diabetes (Brazeau, Mircescu et al. 2012). Assessing predictive validity was done by objectively measuring physical activity practice and comparing this to the perceived level of barriers to physical activity (BAPAD-1 score). Despite the low level of perceived barriers found in this study, significant associations were found between the BAPAD-1 score and physical activity energy expenditure (measured using accelerometry) and with the BAPAD-1 score and cardiorespiratory fitness (Brazeau, Mircescu et al. 2012). Therefore the BAPAD-1 scale reveals that perceived barriers are related to physical activity behaviour, confirming its predictive validity (Brazeau, Mircescu et al. 2012).

Several barriers to exercise in type 1 diabetes have been identified using the BAPAD-1 scale. The highest barrier scores were fear of hypoglycaemia (3.58 ± 2.02), work schedule (3.05 ± 1.98), loss of control over diabetes (2.83 ± 1.80), and low levels of fitness (2.83 ± 1.95) (Brazeau, Rabasa-Lhoret et al. 2008). Physical activity can predispose to hypoglycaemia and as a result participants may be apprehensive and reluctant to participate in physical activity. This barrier, coupled with a lack of knowledge of effective strategies for hypoglycaemia avoidance often discourages individuals to partake in exercise (Brazeau, Rabasa-Lhoret et al. 2008).

A qualitative study using semi-structured interviews with long standing type 1 diabetic adult participants showed that many of the barriers to exercise are the same as that of the non-diabetic population (lack of time and work related factors; lack of motivation; access to facilities; embarrassment and body image; and weather), with the primary difference being the requirement for education around the effect of exercise on diabetes control (Lascar, Kennedy et al. 2014). Among adults with type 1 and type 2 diabetes interview based questionnaires were used, and key modifiable barriers to participants participation in exercise were identified (Thomas, Alder et al. 2004). These included availability of cheap facilities and education regarding the health benefits of exercise and mechanisms of avoiding hypoglycaemia (Thomas, Alder et al. 2004). This study also found that active participants were more positive, believing that exercise would positively impact on diabetes control and were less likely to think that exercise would increase the chance of hypoglycaemia.

The objectives of our study was to determine among an Irish adult type 1 diabetes population the barriers to regular physical activity using the BAPAD-1 scale and also to assess the factors associated with these barriers (i.e. physical activity levels, diabetes control and incidence of hypoglycaemia).

5.3. Participants and methods

5.3.1. Participants

(a) An observational cross-sectional study was used to examine the barriers to physical activity and determine the relationship between the BAPAD-1 score and accelerometer measured physical activity and diabetes control. Participants were recruited as previously described (Chapter 2; 2.1 Study design and participants). 72 participants attending the diabetes day centre in Tallaght Hospital met the inclusion criteria [having a diagnosis of Type 1 diabetes for greater than 1 year; on multiple daily injections (MDI) of rapid and long acting insulin or on Insulin pump therapy; and aged ≥ 18 years] and participated in the study.

(b) All participants attending a weekly type 1 diabetes outpatient clinic over a 4 month period were asked to complete the BAPAD-1 scale. 168 participants (excluding the 72 participants above) completed the questionnaire. The inclusion criteria was the same as that above. All participants completing the questionnaire signed a consent form to allow this information to be used as part of the research project and for us to access their health information from the diamond database or their medical notes.

5.3.2. Measurements

5.3.2.1. Barriers to physical activity:

All participants wearing the ActiGraph accelerometer were asked to complete the BAPAD-1 scale (Appendix V). An additional 168 participants attending a weekly type 1 diabetes outpatient clinic completed the BAPAD-1 scale (but did not wear the accelerometer). See Chapter 2 (2.2.3. Barriers to physical activity) for information on the BAPAD-1 scale. Associations between total BAPAD-1 score and physical activity level, HbA1c and number of hypoglycaemic events were explored.

5.3.2.2. Physical activity measurement

72 participants wore the Actigraph accelerometer (wGT3X-BT) for 7 consecutive days during waking hours. Participants recorded the time they put the accelerometer on and off (for shower / sleeping / swimming) and any activity they did when not wearing monitor (e.g. swimming) or it they forgot to put the monitor on. All information was downloaded from the Actigraph monitor as soon as it was returned. Refer to Chapter 2 (2.2.1 Physical activity assessment) for details on the ActiGraph accelerometer, classifying wear and non-wear time and cutpoints used to define different intensities of physical activity and "activity bouts" (used to determine adherence to physical activity recommendations: ≥ 150 mins moderate-to-vigorous-intensity physical activity per week).

5.3.2.3. Anthropometric, biochemical and clinical measures

(a) As previously described anthropometric measures (weight, height, BMI, waist and hip circumference) were taken. Body composition was measured using a bio-electrical impedance analyser (BIA) (Tanita body composition analyser BC-420MA) (Chapter 2; 2.2.6 Anthropometry and body composition).

Biochemical and clinic measures included HbA1c, renal and lipid profile, urine albumin and urine albumin:creatinine, blood pressure, and the presence of diabetic retinopathy and nephropathy (Refer to Chapter 2; 2.2.5 CVD risk factors). Participant's glucometer data was downloaded for the week they wore the accelerometer. Information such as average blood glucose reading; blood glucose standard deviation; number of blood glucose readings and number of hypoglycaemic events were recorded from their glucometer downloads (Refer to Chapter 2; 2.2.4 Glycaemic control).

(b) Participant's most recent anthropometry, biochemistry and clinical data were taken retrospectively, following collection of the questionnaires, from the hospital's Diamond diabetes database. Any missing data was searched for using alternate sources (participants' medical notes and hospital's KEY iSoft database). For further information refer to Chapter 2 (2.4.3. Anthropometry, biochemistry and clinical data).

5.4. Statistics

Analysis was performed using IBM SPSS Statistics 24. Continuous variables were inspected for normality of distribution prior to analysis using the Kolmogorov-Smirnov test. Descriptive statistics were calculated for study variables and displayed as mean (SD) or median (25th - 75th percentile). Spearman's rho and Pearsons correlations were used to evaluate the association between the BAPAD-1 score and measures of physical activity, measures of diabetes control and anthropometric measures. A p value of less than 0.05 was regarded as statistically significant in all analysis.

5.5. Results

(a) A total of 72 participants wore the ActiGraph accelerometer and completed the BAPAD-1 scale. The characteristics of the participants are presented previously in Chapter 4 (Table 4-1).

The ActiGraph accelerometer was worn for a median of 7 days (7, 8). The majority of time was spent sedentary (8.4 ± 1.6 h/day) or in light activity (4.4 ± 1.5 h/day), with a mean of 33.9 ± 22.2 min/day in moderate-to-vigorous-intensity activity. However time spent in moderate-to-vigorous-intensity activity in at least 10 minute bouts was much less with a daily average of 8.6 (2.3 – 23.3) min/day. Only 23 (32%) participants met the physical activity recommendations. Refer to Chapter 3 (Table 3-2) for details of the descriptive data for the accelerometer.

Mean BAPAD-1 score was 2.4 ± 1.0 (Range 1.0 - 5.4) (Table 5-1). This corresponds to a low level of perceived importance for the assessed barriers (Brazeau, Mircescu et al. 2012). The highest barrier scores were fear of hypoglycaemia (3.4 ± 2.0); low fitness level (2.9 ± 1.9); weather (2.8 ± 1.9) and loss of control over your diabetes (2.7 ± 1.9) (Table 5-1).

There were no associations seen between BAPAD-1 score and glycaemic control (HbA1c, BG variability or incidence of hypoglycaemia) or physical activity level measured by the accelerometer (moderate-to-vigorous-intensity physical activity in 10 min bouts or total moderate-to-vigorous-intensity physical activity). As % body fat (Figure 5-1) and fat mass increased there was a significant increase in BAPAD-1 score ($r = 0.338$; $p = 0.004$ and $r=0.263$; $p = 0.026$ respectively).

As fear or risk of hypoglycaemia was found to the strongest barriers we investigated associations with this item of the BAPAD-1 scale. There were no associations seen with risk of hypoglycaemia score and level of physical activity or sedentary time measured by the accelerometer. Also no associations were seen between risk of hypoglycaemia score and actual incidence of hypoglycaemia.

Items	**Mean score ± SD**
1. The loss of control over your diabetes	2.7 ± 1.9
2. The risk of hypoglycaemia	3.4 ± 2.0
3. The fear of being tired	2.2 ± 1.5
4. The fear of hurting yourself	1.9 ± 1.5
5. The fear of suffering a heart attack	1.5 ± 1.1
6. A low fitness level	2.9 ± 1.9
7. The fact that you have diabetes	2.1 ± 1.6
8. The risk of hyperglycemia	2.1 ± 1.5
9. Your actual physical health status excluding your diabetes	2.5 ± 1.9
10. Weather conditions	2.8 ± 1.9
11. The location of a gym	2.2 ± 1.6
Average Score	**2.4 ± 1.0 (Range 1.0 - 5.4)**

Table 5-1 Barriers to Physical Activity in Diabetes (BAPAD1) scale. Indicate the likelihood that each of these items below would keep you from practicing regular physical activity during the next 6 months (1, extremely unlikely to 7, extremely likely).

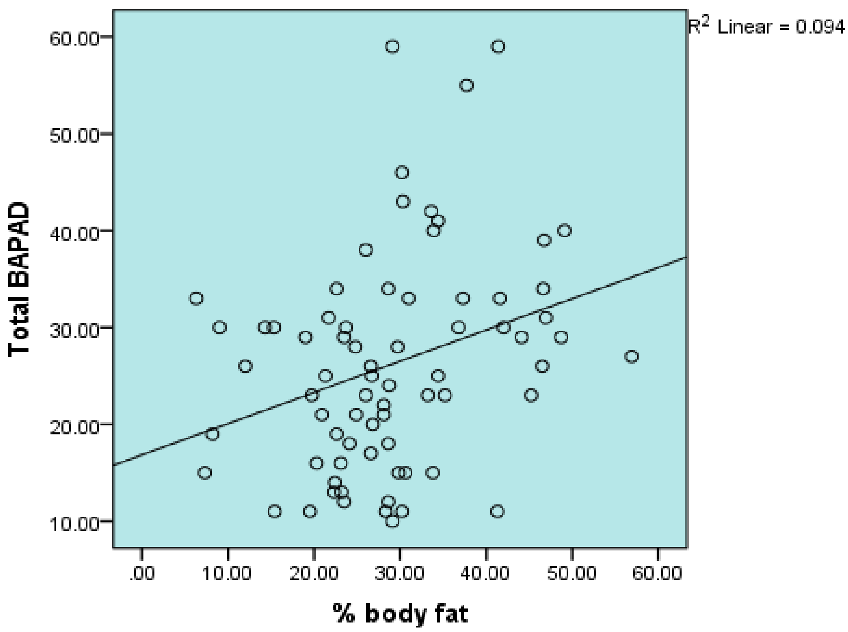

Figure 5-1 Association between total BAPAD1 score and % body fat

(b) 187 participants completed the questionnaires and signed the consent form. This was a 69% response rate. 1 participant was removed as he had type 2 diabetes which left 186 participants.

The main clinical characteristics of the group are presented in Chapter 4 (Table 4-4) and described in Chapter 4 [Results (b)].

Of the 186 participants, 18 did not complete the BAPAD1 scale [13 male and 5 female, average age 48.5 (range 22 – 76 years)]. Therefore a total of 168 BAPAD-1 scale questionnaires were complete.

The mean BAPAD1 score was 2.4 ± 1.1 (Table 5-2). The highest barrier scores were fear of hypoglycaemia (3.3 ± 1.9); low fitness level (2.8 ± 1.9); weather (2.8 ± 1.9) and loss of control over your diabetes (2.7 ± 1.9).

Glycaemic control, as measured by HbA1c, was positively correlated with BAPAD1 score ($p=0.047$, $r = 0.155$). No correlations were seen between BAPAD1 score and reported physical activity level as per the IPAQ. As fear of hypoglycaemia was the strongest barrier we investigated associations between this and HbA1c and reported physical activity levels but no significant association were seen.

BAPAD-1 scale items	Mean score ± SD
1. The loss of control over your diabetes	2.7 ± 1.9
2. The risk of hypoglycaemia	3.3 ± 1.9
3. The fear of being tired	2.3 ± 1.7
4. The fear of hurting yourself	1.9 ± 1.5
5. The fear of suffering a heart attack	1.8 ± 1.4
6. A low fitness level	2.8 ± 1.9
7. The fact that you have diabetes	2.1 ± 1.6
8. The risk of hyperglycemia	2.3 ± 1.6
9. Your actual physical health status excluding your diabetes	2.5 ± 1.8
10. Weather conditions	2.8 ± 1.9
11. The location of a gym	2.4 ± 1.7
Average Score	**2.4 ± 1.1 (Range 0.64 - 5.9)**

Table 5-2 Barriers to Physical Activity in Diabetes (BAPAD1) scale. Indicate the likelihood that each of these items would keep you from practicing regular physical activity during the next 6 months (1, extremely unlikely to 7, extremely likely)

5.6. Discussion

Fear of hypoglycaemia was found to be the strongest barrier to physical activity. There were no associations found between BAPAD-1 score and physical activity level measured by the accelerometer or diabetes control as measured by HbA1c. As percentage body fat and fat mass increased there was a significant increase in BAPAD-1 score.

Similar to these findings, other studies have also found fear of hypoglycaemia as the strongest barriers to physical activity (Brazeau, Rabasa-Lhoret et al. 2008). The other main barriers that were found in this study were low fitness level (2.9 ± 1.9); weather (2.8 ± 1.9) and loss of control over your diabetes (2.7 ± 1.9). This was not dissimilar to the findings by Brazeau et al (2008) where fear of hypoglycaemia, work schedule, loss of control over diabetes and low fitness levels were the four main barriers found to physical activity. Evidence that fear of hypoglycaemia limits ones activities was evident in a small qualitative study among those with insulin-treated diabetes as concern over hypoglycaemia reactions is constantly present (Richmond 1996). Basic knowledge of insulin pharmokinetics and implementation of strategies for hypoglycaemia avoidance (i.e. eating an evening snack after evening activity to avoid nocturnal hypoglycaemia) were associated with less fear of hypoglycaemia (Brazeau, Rabasa-Lhoret et al. 2008).

From the findings here, and from reviewing the literature, it is apparent that fear of hypoglycaemia is a great concern among those with type 1 diabetes, and does perhaps influence the level of physical activity among this population. Not only was fear of hypoglycaemia found as the greatest barrier but also a significant increase in hypoglycaemic events (p=0.003) was found as total time in moderate-to-vigorous-intensity physical activity increased. This remained significant when controlled for HbA1c (p=0.022). Therefore better education and implementation of strategies to avoid exercise induced hypoglycaemia is essential to help reduce the fear of hypoglycaemia as well as the incidence of hypoglycaemia.

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The overall level of perceived barriers to physical activity was relatively low among the study cohort (2.4 ± 1.0). This is consistent with our previous finding that participants believed they were doing a lot more physical activity than they were actually doing when measured by accelerometry (Chapter 4; Results). Other studies have also found a similar low level of perceived barriers (Brazeau, Rabasa-Lhoret et al. 2008; Brazeau, Mircescu et al. 2012) (2.51 ± 1.00 and 2.4 ± 1.0 respectively). Studies have shown that <10% of physical activity variance is due to perceived barriers among the general adult population (Salmon et al, 2003) and those with type 1 diabetes (Brazeau, Mircescu et al. 2012). Despite the low level of perceived barriers found in the study by Brazeau et al. (2012), there was a significant negative association with physical activity energy expenditure as measured by a SenseWear Armband (motion sensor) and BAPAD-1 score. This study showed that the perception of barriers explained 6% of the physical activity variance (Brazeau, Mircescu et al. 2012). This study found no significant correlations between the BAPAD-1 score and physical activity level as measured by the ActiGraph accelerometer. It has been recommended in the literature to look also at other determinants of physical activity variance, for example analysis of psychosocial correlates (self-efficacy and motivators) which can explain up to 30% of physical activity variance (Brazeau, Mircescu et al. 2012).

There was no association found in this study between glycaemic control as measured by HbA1c and BAPAD-1 scale. Associations have been found in other studies where participants with greater perceived barriers to physical activity had poorer glycaemic control as measured by HbA1c (Brazeau, Rabasa-Lhoret et al. 2008). The sample size was larger in this study (n=100), therefore perhaps a larger sample size in our study would have shown a significant association. The association found between HbA1c and perceived barriers suggests that those able to manage barriers to physical activity are also better able to cope with other issues such as their diabetes care (Brazeau, Rabasa-Lhoret et al. 2008).

A significant association with BAPAD-1 score and cardiorespiratory fitness has been found in a previous study (Brazeau, Mircescu et al. 2012), which is influenced by genetics, body composition, age, gender, diabetes control and past and past activities. Cardiorespiratory fitness was not measured in this study, however as percentage body fat and fat mass increased there was a significant increase in BAPAD-1 score. Previously we showed that as percentage body fat and fat mass increased there was a significant decrease in time spent in moderate-to-vigorous-intensity physical activity (P = 0.006 and 0.013 respectively) (Refer to Chapter 3; Results). Therefore participants with a higher fat mass perceive more barriers to physical activity and this is associated with less time spent physically active. These participants are at great risk of CVD, and with the greatest barriers to physical activity, are the group most likely resistant to change.

Finally the frequency of hypoglycaemia was not associated with the level of perceived barriers in this study which is similar to that found by Brazeau, Rabasa-Lhoret et al. (2008).

5.7. Strengths and limitations

Limitations to this study include the small sample size. Perhaps a larger sample could detect associations between physical activity and HbA1c with BAPAD-1 score. Also our participants volunteered to take part in the study, therefore selection bias could mean that the study cohort were more motivated and positive than the general population with type 1 diabetes and thus had less perceived barriers to physical activity. Strengths to the study included the use of an objective measure (accelerometry) to determine physical activity. Also the use of the BAPAD-scale which is a validated tool used to adequately barriers to regular physical activity among those with type 1 diabetes.

5.8. Conclusion

Fear of hypoglycaemia was identified as the strongest barrier to physical activity. The other main barriers to physical activity included low fitness levels, weather and loss of control over diabetes. Identifying these barriers through use of the BAPAD-1 scale could help to explain some of the factors influencing levels of physical activity. These factors should be taken into consideration when planning future physical activity interventions looking to address physical inactivity among this population. In particular efforts to reduce the fear of hypoglycaemia through increasing knowledge on the effect of exercise on diabetes control and effective strategies to prevent exercise induced hypoglycaemia.

6. Chapter 6: Use of focus groups to assess the attitudes, needs and expectations of an mHealth app for the management of exercise with type 1 diabetes

6.1. Abstract

Context: Management of exercise with type 1 diabetes can be problematic for the participant. Also education in this area can be resource intensive and challenging for the health care professional. It remains to be explored whether technology such as mHealth apps could be used to educate and inform our participant's in this complex area.

Aims: We used qualitative research to explore the attitudes, needs and expectations of an mHealth app for the management of type 1 diabetes and exercise.

Materials and methods: Three focus groups were conducted with a total of 25 participants with type 1 diabetes. Mean age was 38 (SD 11.1) years and mean HbA1c of 7.4 % (SD 1.4). Dictaphones were used and focus groups were transcribed verbatim. Qualitative analysis of the focus group data was performed using Interpretative Phenomological Analysis.

Results: From the themes that emerged there appear to be many frustrations and issues with currently available apps. Previously used apps were found to be burdensome, time consuming, complicated, and the data they received back to be overwhelming. Suggestions that will aid in the design of a type 1 diabetes and exercise app included tailoring advice to the individuals based on their individual profile and data entry, advice in the form of suggestions rather than specific figures, and making the app uncomplicated and user friendly.

Conclusion: Involving individuals with type 1 diabetes early in the design process ensures that our design satisfies the specific requirements of those looking to commence or increase exercise. If designed and developed successfully this will be the first app of its kind to take the needs and opinions of those with type 1 diabetes into consideration as well as getting the expertise of clinicians and health care professionals in this complex area.

6.2. Introduction

With limited staffing / resources within the hospital setting we must come up with a more efficient way to educate and inform our patents in the complex area of type 1 diabetes. Use of technology such as smartphone applications is one way to do this. The increased prevalence of mobile phone use makes them a powerful tool for providing individualized healthcare in a convenient and efficient way to our participants. Smartphones have the potential to be used to manage disease using mobile health (mHealth) applications (‘apps’) (Hoppe, Cade et al. 2016). Apps can be used to change participant behaviours in health-related areas such as diet and exercise and also to improve adherence to prescribed treatment regimens (Becker, Miron-Shatz et al. 2014). Among those with diabetes use of smartphone apps have been shown to improve diabetes self-management and glycaemic control (Kirwan, Vandelanotte et al. 2013). When it comes to the use of technology to promote physical activity most of the available evidence has been among those with type 2 diabetes. A systematic review on the effectiveness of technology-based interventions (mobile phones and text messages, websites, CD-ROMS, and computer based learning) showed their effectiveness at increasing physical activity among those with type 2 diabetes with all studies showing an increase in physical activity (9/15 showing a significant increase) (Connelly, Kirk et al. 2013).

Insulin dose calculators, intended to recommend an appropriate insulin dose, are a popular feature in medical apps. A small number of these apps extended the basic meal bolus calculation to incorporate additional adjustments for exercise (Huckvale, Adomaviciute et al. 2015). A systematic assessment of available rapid/short acting insulin dose calculators revealed many issues, most importantly that the majority of these apps contributed to incorrect or inappropriate insulin dose recommendations, thus putting individuals at risk (Huckvale, Adomaviciute et al. 2015). Also none of the apps met the FDA criteria for formal regulation and review (due to their high probability of causing harm). Worryingly however these apps remained available in app stores (Hoppe, Cade et al. 2016). This highlights major concerns and risks associated with mobile health apps. An issue highlighted is that many app developers have little or no formal medical training and do not involve clinicians in the development process and may therefore be unaware of participant safety issues raised by inappropriate app content or functioning (Lewis and Wyatt 2014). Also another concern is the threat to privacy and security of information transmitted through mobile apps as system developers, app companies, advertisers etc can access a wealth of personal consumer information from the phone (Eng and Lee 2013). As recommended by the Federal Trade Commission (FTC) developers in the mobile industry must give consumer disclosures as to what data is being collected and how it is being used (Commission 2013). However there is no current enforcement of these regulations and therefore few apps actually have these disclosures (Eng and Lee 2013).

We aimed to explore, through use of focus groups, the attitudes, needs and expectations of an mHealth app for the management of type 1 diabetes and exercise. Focus groups have the ability to collect in-depth data and to study the ways in which participants actively manage their conditions, develop strategies for dealing with their illness, and share information with each other (Barbour 1999). By including consumers in the design process (user-centered design) this allows development of an mHealth app in response to the user's needs (Fonda, Kedziora et al. 2010). Insight into factors that affect a participant's self-efficacy (belief in being in control over their disease) can be ascertained through focus groups and are important considerations in the design phase (Årsand and Demiris 2008). This process has been employed in a previous study among adolescents with type 1 diabetes and has successfully led to the development of the mobile app *Bant*, which when piloted showed that frequency of blood glucose measurements increased by 50%. Also satisfaction was high and 88% reported that they would continue to use the app (Cafazzo, Casselman et al. 2012).

Studies among the general population have looked both motivators and barriers to continued engagement in the use of mobile health apps (Fukuoka, Kamitani et al. 2011). Motivators included real time peer or professional social support; providing real time feedback based on individuals needs and preferences; realistic goal setting with self-monitoring tools; and a mobile virtual community. Potential barriers to use or continued use of apps included fear of failing to meet goals or expectations of others; diminished motivation and lack of commitment to the app over time; and features that were burdensome and effortful. These are important considerations for developers looking to design such apps.

Our aim was to gain an insight into individual's experiences of using mobile health apps, as well as increasing our knowledge of their needs for a mobile application for the management of exercise with type 1 diabetes.

6.3. Participants and Methods

Qualitative research was employed in this study in order to achieve an in-depth understanding of the phenomenon being studied (Patton 1990). The qualitative approach of Interpretative Phenomological Analysis (IPA) was chosen. Focus groups were identified as the most appropriate way to explore the needs and opinions of those with type 1 diabetes. A total of 3 focus groups were held in the diabetes day centre in Tallaght Hospital. The researcher (Mary Finn, Research Dietitian) facilitated all three focus groups.

6.3.1. Recruitment

Information on inclusion and exclusion criteria, methods of recruitment and purposive sampling can be found in Chapter 2 (2.8. Recruitment).

A total of three focus groups were conducted. 34 participants with type 1 diabetes were recruited. 5 participants (3 females) cancelled in the one to two days before the focus group (main reason stated was work commitments) and 4 participants (3 females) did not attend on the evening. Therefore a total of 25 participants took part in the focus groups (n=8 FG1; n=7 FG2; n=10 FG3). Mean age was 38 (SD 11.1) years, ranging from 21 to 64 years. All participants had type 1 diabetes with a mean HbA1c of 7.4 (SD 1.4) %, ranging from 5.1 to 12.9%. All participants owned a smartphone. 80% (n=20) reported previously using apps on their phone. Table 6-1 shows the descriptive data on focus group participants.

Participants characteristics	Total sample (n=25)
Gender n (%)	
Male	15 (60)
Female	10 (40)
Age mean (SD)	38 (11.1)
Diabetes duration (years) mean (SD)	14.5 (11.7)
HbA1c (%) mean (SD)	7.4 (1.4)
Insulin Regimen n (%)	
MDI	16 (64)
Insulin pump	9 (36)
Current employment n (%)	
Working full time	17 (68)
Retired	1 (4.2)
Working in the home	1 (4.2)
Unemployed	1 (4.2)
Working part time	2 (8.3)
Ill/unable to work	2 (8.3)
Education n (%)	
Junior or intermediate certificate, technical or vocational training	3 (12)
Leaving certificate, A-level, technical training	5 (20)
Non-degree qualification	5 (20)
Degree, professional qualification or both	7 (28)
Postgraduate qualification	2 (8.3)

Table 6-1 Descriptive data on focus group participants (n=25). Values are expressed as number (%) or mean (SD). MDI; Multiple Daily Injections

6.3.2. Focus group procedures

See Chapter 2 (section 2.9) for a detailed description of focus group procedures. All participants were emailed a participant information leaflet prior to attending the focus group (Appendix VI). A facilitator's guide (including focus group questions) was drafted prior to the focus groups (Appendix VII). Participants completed written informed consent prior to partaking in the focus group (Appendix IX). The average duration of the focus groups was approximately 75 minutes. Focus groups were taped and transcribed verbatim following each group and all participants' identifiable details were removed and pseudonyms inserted. The researcher (Mary Finn) listened to tapes and checked transcripts for accuracy.

6.4. Data analysis

For data analysis details see Chapter 2 (2.11. Data Analysis). Focus group were analysed manually by the researcher (Mary Finn). Information was coded according to key themes and emerging categories and a coding frame was developed (Appendix XI) with superordinate and subordinate themes. Triangulation was conducted by a researcher separate to data collection and an interrater reliability as percent agreement was calculated at 94.7% which demonstrated a high level of agreement between both raters. Key phrases from focus group individuals were used to illustrate emerging themes. Finally the COREQ criteria were applied when reporting this qualitative research.

6.5. Results

Following analysis of focus group transcripts four superordinate themes and twelve subordinate themes were developed (see Table 6-2). These themes are discussed below using participant quotations to illustrate each theme. The full coding frame and sample quotes can be found in Appendix XI and XII.

Superordinate themes	Subordinate themes
1. Challenges with exercise and type 1 diabetes	1.1 Balancing insulin and carbohydrate for different types of exercise
	1.2 Avoiding hypo and hyperglycaemia
	1.3 General feelings and attitudes around exercise and type 1 diabetes
2. Participant opinions on mobile apps and other technology	2.1 Current app use
	2.3 Negative opinions towards apps
	2.2 Positive opinions towards apps and other technology
	2.4 Privacy / security concerns
	2.5 Cost of apps
3. Participants opinions on an available bolus calculator app	3.1 Potential benefits of the bolus calculator app
	3.2 Scepticism and concerns towards a bolus calculator app
4. Ideas / suggestions for an app	4.1 Possible ideas/ suggestions
	4.2 Potential barriers

Table 6-2 Superordinate and subordinate themes from focus groups

6.5.1. Challenges with exercise and type 1 diabetes:

Participants discussed how exercising with type 1 diabetes can be very challenging. Adjusting insulin around exercise can be very much down to trial and error, with one participant stating ‘it's just so frustrating, because it's very hard to judge...’ [Grainne, FG2]. This makes individuals vulnerable and lacking confidence in this area. Participants report feelings of frustration with trying to keep blood glucose under control, with one participant stating ‘*It's not worth it sometimes...’ [Bethany, FG1]*

The different type of exercises and the stress of competition can have a huge impact on their blood glucose readings as a result of changes in counter-regulatory hormones, making it very difficult for individuals to predict glycaemic changes with exercise:

> *‘...if you're doing 10K in training, your blood sugar will drop is what I find - whereas if you're running a 10K race, because you've got nerves beforehand...it won’t drop...definitely the nerves before the start of the race, you can see your blood sugars going up’ [Barry, FG1]*

Many participants have a huge fear of hypoglycaemia during and after exercise and as a result find themselves taking in large amounts of carbohydrate which is counterproductive if their goal for exercise is weight loss:

> *‘What I was used to doing was Lucozade... and I had to overcome that, and step away from it because I was putting calories in that I was burning off, and it was just such a fear, I had Lucozade in the hand constantly’. [Grainne, FG2]*

6.5.2. Participant opinions on mobile applications and other technology

6.5.2.1. Current app use

In summary the main apps previously used by individuals included:

a. Physical Activity trackers: Garmin; Strava, My Fitness Pal, iWatch apps – BPM, Map My Ride, Fitbit app, MyFit, 3,2,1 Run

b. Social media apps: Facebook, Linkedin, News apps,

c. Nutrition related apps: MY Fitness Pal, Carbs and Cals, Nutrino

d. Diabetes logbook apps: My Sugr, myDiary.net, Glooko, Libre app

6.5.2.2. Negative opinions towards apps

For the large part participants were very critical towards apps they had previously tried. The main reason highlighted across all groups were that many health related apps they had tried were burdensome, time-consuming, complicated and difficult to use.

> *'They're over complicated some of them. I've tried a few diabetes apps, but they're just over complicated. There's just too much going on….'* [Kevin, FG3]

Many participants stressed the burden of having to input large amounts of data manually into apps. Participants didn't want to have to log in every time they had a meal / snack or exercised, for example one participant stated '…*everything seems like an effort, that's what puts me off all these apps as well. Every time I eat, and I have to go back in... move everything up and down... change it around...'* [Leona, FG2]. This resulted in them discontinuing use of the apps or just using it for a brief period.

Participants found that the amount of data you get back from apps and other technology (e.g. continuous glucose monitor, FreeStyle Libre flash glucose monitoring system) can be overwhelming. Several participants commented that this information without putting it into context is often worthless. More often than not they do not end up reviewing it or making any changes based on the data as it's just too much information to process, with one participant stating '…*with the Libre, it gives me all the information I need, but I don't go back at the end of the week and review it all and make changes, I just don't do that'.* [Leona, FG2]. If however it used the data to tell you what the problem or issue is many participants felt this would be helpful. This same participant commented *'If an app tracked trends...and then it prompted you, it gave you feedback on the trends they pick up…'* [Leona, FG2].

Other issues participants had with apps included not trusting the accuracy at all times (this was to do with determining portion sizes using the visual aids from the Carbs and Cals app without having weighed the food); not liking the fact that you had to keep your phone on you when using activity tracking apps; and they found ads and prompting annoying. Participants felt most apps were incomplete and one comment was '*they all have bits and pieces of what I want, but none of them have it all together…'* [Tony, FG1]

6.5.2.3. Positive opinions towards apps and other technology

Participants did however have some positive experiences with apps they had used. Participants liked apps that helped them monitor and track their nutrition and physical activity. These included the Carbs and Cals app and My Fitness Pal app which were good for estimating the nutritional content of foodstuffs, especially when out and about or in restaurants. Participants liked the convenience of having a barcode option on My Fitness pal where you can scan the food and it will give you the nutritional information and also the option of taking a picture of your food on the MySugr app, with feedback from one participant being '…*instead of writing down what you've eaten, you just take a picture and it'll save the picture so you can come back in and write oh yeah that many units spent so far...'* [Kevina, FG3]. All of these options helped reduce the burden of data input. Finally participants liked apps that can give them instant access to up to date live information, like the activity tracking apps, with one participant who used Strava stating '…*I just press record on Strava, and Strava collects all the* *information - how far I ran, how many calories I burned, all this kind of stuff.... So that's easy to use...and I didn't have to do anything extra other than hit Go'* [Barry, FG1].

There was a lot of discussion and overall positivity around apps that synced with other technology (such as glucometers and the FreeStyle Libreflash glucose monitoring system).

> *'My meter hooks up to my phone. It's called Contour link, it's a new one out.... Yeah, this helps me out so much'*. [Aisling, FG2]

In relation to other technology, those that were on sensor augmented pumps and the FreeStyle Libre discussed their benefits:

> *'The great thing is it* [Freestyle libre] *actually tells you if you're down trending…when you scan you see it's going 12 to 10 to 8... you're like I better take a bit of glucose and then continue the game'* [Ryan, FG3]

6.5.2.4. Privacy and security concerns

Participants voiced concerns around the privacy and security of their health related data. Their key concern was the risk that their personal information would get into the hands of third parties, including pharma companies but most worryingly health insurance companies as this could impact on their health insurance quote.

> *'If your information is out there, you know for sure the insurance companies - they can get a hold of it'.* [Cathy, FG1]

Others however were quite relaxed and felt that *'So long as the data protection requirements are met around who can view the information, and how it's stored….*' [Barry, FG1]; as long as their information remained anonymous; or if it helped them and others, they would have no concerns. Overall participants had no issue sharing their information with their clinician and health care professionals.

6.5.2.5. Cost of apps

Participants felt willing to pay if they knew beforehand that the app was of value and would be worthwhile to them.

> *'I remember with Carbs & Cals, I think it was a fiver - but there was no problem paying the fiver, because I knew before I bought it, it was worth buying. I heard it from so many people that it was so beneficial*…' [Cathy, FG1]

Some felt a free trial for a month would be helpful before deciding to purchase the app stating '….*a month of a free trial and that way, if you make it clear enough that it's gonna help somebody not have a hypo - I'd pay any money'.* [Bethany, FG1]

Others felt they would not pay for an app as *'There's always like another app that's like it that you can just get for free so there's no point paying'* [Kevina, FG3]. Finally participants felt it was important to consider the users as they felt students would not pay for an app.

> *'Coming up through college or whatever, I definitely wouldn't have paid for an app... If any of the demographic is students, I would say they are less likely to pay for an app'.* [Anthony, FG1]

6.5.3. Participant opinions towards an existing bolus calculator app

6.5.3.1. Potential benefits of the bolus calculator app

Following presentation of the bolus calculator app as trigger material there was in fact very little positive feedback from the groups.

One participant felt it might be useful if on MDI therapy but not on insulin pump therapy, stating '…*I maybe would have bought when I was on pens, but not now that I'm on a pump because I've various bits of equipment telling me the same thing'.* [Michael, FG3]

Another participant felt that it could be useful before exercise to let you know how much insulin you have on board from your previous insulin bolus. One individual liked the fact you could photograph your food using the app.

6.5.3.2. Sceptism and concerns towards a bolus calculator app

Overall however the majority of opinions were negative towards this type of app and participants were really quite sceptical. Overall participants felt that the bolus calculator would be a useful feature for them, and there were several reasons for this:

Participants felt they would not trust it as it did not collect the correct information from them (mainly around the type of exercise and their individual insulin therapy):

> *'I wouldn't trust that in the slightest...I wouldn't entertain any part of that because it didn't ask me the right questions, it doesn't have the right information so the advice it's giving me is based on nothing that's of value to me. I wouldn't trust it'.* [Cathy, FG1]

As a result participants felt they would not trust the number or percentage it gives them.

> *'Given the fact from what we're all saying here, it's very difficult to actually get an accurate number here, and nobody really trusts what the number's going to be... there's not enough intelligence here to understand everything that's going on - to be able to come up with that absolute number...'* [Barry, FG1]

Others would not use the bolus calculator before exercise as they cannot exercise with any rapid acting insulin on board:

> *'I can't have insulin in my system when I exercise. 3 hours... I can't put insulin near me for 3 hours beforehand'.* [Grainne, FG2]

Finally it was felt that the app was too basic for the cost, that it was out-dated and very manual.

> *'It looks very manual... Yeah. Like you've six things in the first screen you need to populate...'* [Sam, FG2]

6.5.4. Ideas / suggestions for an app

6.5.4.1. Possible ideas / suggestions

There were many ideas and suggestions for an exercise and type 1 diabetes app discussed among the 3 focus groups:

A. Syncing the app with other technology

Again the discussion went back to the burden of data entry when they already have numerous technological devices to input data into. Therefore the benefits of the app syncing with their already existing devices resonated throughout the groups.

> *'Some of the devices now, like the FreeStyle Libre for example, you can scan that now if you have the android app and you can get all of that information...some of the pumps now send it directly to the phone, that's the way it needs to be. That's where the examples start to become less of a burden on people to have to put in the information manually'.* [Barry, FG1]

B. Tailoring advice to individual needs & tracking trends

The importance of tailoring advice to the individuals was discussed a lot among the groups. To do this the importance of the app knowing what insulin therapy the individuals are currently on and also what type of exercise they are about to do or have already performed. Otherwise the app will ask for information that they don't have / know and give incorrect advice based on the wrong insulin therapy / exercise type. It was agreed that this would result in annoyance and frustration with the app.

> *'If it knows that I'm on injections, it shouldn't ask me for that, because I can't give it that information, I can't say whether it's going up or down. So there should be somewhere in your settings - or in your profile or something that says what type of therapy you're on - you're on MDI, or you're on pump'.* [Barry, FG1]

> *'And I think the type of training...like the difference between doing an interval session and doing a long run is just light years...on the effect it' s gonna have on you'.* [Cillian, FG3]

Therefore based on your individual profile and your data history entry the app gives advice that's specific to you. This advice / education will be based on your needs or issues you are currently having. Participants liked the idea of the app tracking their trends and then predicting and prompting you based on this information. This would be far more helpful then the app sending you large amounts of data that you have to try and decipher. Also if you want information specific to a problem that you're having, again that it can point you directly to that piece of information you are looking for rather than sending you reams of information that you are unlikely to read. All of these features are making life a little easier for the individuals and is reducing the burden of data / information overload.

'If an app tracked trends...and then it prompted you, it gave you feedback on the trends they pick up … So if it prompted me to say ok well you've had three lows last week, at 5pm, maybe you should reduce your lunch time insulin or you've had high blood sugars at this time... rather than me going back and checking'. [Leona, FG2]

'If somebody says the thing I struggle most with is hypos, in the evening, after exercise, then to be able to show them the right piece of information… You don't need to give them all of the information. That's another mistake a lot of the apps make…' [Barry, FG1]

C. Suggestions rather than specific numbers

Interestingly the discussion went back to the bolus calculator as a feature of the app and again participants said they felt they would not trust specific numbers or percentages but would prefer suggestions based on their profile and data they have given the app. These suggestions would initially be based on the guidelines and body of evidence that's currently available, allowing the app thereafter to build a profile for the individual. One individual suggested a possible name for the app could be "Advice recommender" [Barry, FG1].

'It's a good guide - I mean suggestions; that they make more sense than specific numbers, which you can never trust anyway...that there's too many variables to get to that number so I think suggestions - they're more practical' [Cathy, FG1]

'It's just about giving the right suggestions, initially based on the evidence, and then tailoring those suggestions based on what worked or didn't work and what works…' [Barry, FG1]

D. User-friendly

User-friendliness was highlighted as being extremely important in the design of an app.

'It's trying to simplify it just so you do keep it up. Because the more complex it is, the more you won't do It'. [Aine, FG2]

E. Considering the user

Participants discussed the importance of considering who the users of the app will be and also how you market the app. Considering the user is important as individuals can have very different needs based on length of their diagnosis with type 1 diabetes and their fitness levels. One participant felt that the app might be more important for someone newly diagnosed or exercising for general health or just starting out exercising. Then once they have figured out what works for them they may stop using it. However this participant felt that individuals may go back to it if they decide to take up a new type of exercise / sport.

'People who have just been diagnosed would have totally different needs from people who have had diabetes for a number of years and are exercising...and then people who are doing exercise for just recreational health benefits would have totally different needs from people who are more seriously into their sport...so it's worth thinking about who the users are that you're aiming it at because again, they will have different needs, and they won't always want the same thing'. [Barry, FG1]

Participants felt that how you market the app will depend on the main purpose and goal of the app.

'I think it's how it's marketed though, I mean that's in my view, if there is something to help a diabetic not be afraid to move - be it in the gym, in the pool...that in itself is a fantastic achievement'. [Bethany, FG1]

F. Possible additional features

Participants liked the idea of some additional features like incorporating nutrition advice (what to eat before and after your exercise), useful logbooks to keep track of their exercise and blood glucose readings, motivational techniques and social networking. One individual suggested using other people's success stories to help improve motivation to exercise and also that the app highlights how often you've been successful in order to instil motivation:

> *'Then people say right, well actually, I can do this, because I'm being successful more often than not, so you're showing progress, you're showing that you're winning. That's important for people from a motivational point of view'* [Barry, FG1]

A few individuals liked the idea of a social networking type app where they could see in their area or perhaps at a race who with type 1 diabetes was exercising and perhaps meet up or just see how successful they were from the app.

6.5.5. Potential barriers

Possible barriers to the development of the app were discussed. Again it went back to the burden of data entry and the app needing to limit the amount of data it needed and be kept simple.

> *'I couldn't be arsed sitting here, trying to fill in loads, and loads and loads...you know - I'd just say ah feck it and I wouldn't bother. So something that's kind of easy enough to kinda... that you don't have to fill out your life's history... perfect.'* [Hilary, FG3]

> *'…how the app is designed is important but it might ask for only the minimum set of information, and make it very, very simple for them to tap into your information'* [Barry, FG1]

The fact that everyone is so individual and there are many variables impacting on your blood glucose when it comes to exercise with type 1 diabetes they felt that this will make the design of the app very difficult.

'I think it's hard to trust anything really, especially technology - take a look at everybody here, we're all very different' [Bob, FG1]

'I do think it is really good to have it more general, because for me, I find even it depends on the time of day that I exercise, on top of the type of exercise that I'm doing. So if I go for a run first thing in the morning, I actually need to take insulin before I go, even if I'm not eating. Whereas if I was doing that later in the day, I wouldn't need to do that. So to get into nitty gritty could be dangerous I think'. [Lisa, FG1]

Other potential barriers that participants identified was potentially the large amount of information you need in one app, keeping the app updated and finally syncing it to other devices.

'You'll probably find that very quickly you'll come up with a plethora of stuff that you've to try and squeeze into this one app and then maybe your output again is... if it becomes unwieldy...' [Michael, FG2]

'It's all there, and it all lives in its own little silos...and they don't really talk to each other... so that's sort of the issue'. [Barry, FG1]

6.6. Discussion

From the themes that emerged there appear to be many frustrations and issues with currently available apps. Participants felt that apps they had previously used were burdensome, time consuming, complicated, and the data that they received back to be overwhelming. Any positivity expressed were around features of the app that reduced the burden of data input, such as the app syncing with their glucometer to avoid them having to input their blood glucose readings. Also valuable information and suggestions arose that will aid in the design of a type 1 diabetes and exercise app. This included tailoring advice to the individuals based on their data entry, advice in the form of suggestions rather than specific figures, and making the app straightforward and user friendly. It is extremely important to take participants opinions, suggestions and ideas based on their own individuals experiences into consideration when designing an app for this participant cohort. Involving the end users early in the design process, although more time consuming, will ensure that the design satisfies the specific requirements based on the end users' needs and expectations (Årsand and Demiris 2008).

To the researchers knowledge this is the first study using qualitative research to report the needs and expectations for a mobile app designed specifically for individuals with type 1 diabetes to help them improve glycaemic control around exercise. The approach to the design of this study was to capture the end users requirements for the mobile app. Similar qualitative research has been used successfully among those with type 1 diabetes to help design mobile health applications, mainly around improving diabetes self-management (Fonda, Kedziora et al. 2010; Cafazzo, Casselman et al. 2012). In a user-centered design process adolescents with type 1 diabetes took part in ethnographic interviews to design and develop a diabetes tele management system to improve diabetes self-management (Cafazzo, Casselman et al. 2012). Based on the users needs the resultant app included features like gamification, social networking and automated transfer of glucometer readings. Pilot of the app revealed a 50% increase in the frequency of blood glucose measurements (Cafazzo, Casselman et al. 2012). A study among adults with type 1 and type 2 diabetes used a series of 90 minute focus groups to design a prototype personal health application for diabetes self management in response to participants needs (Fonda, Kedziora et al. 2010). Following its design further focus groups were held to obtain feedback about the prototype and changes to the prototypes presentation and function were made thereafter.

Other studies done among obese individuals (Fukuoka, Kamitani et al. 2011) and young adults (Dennison, Morrison et al. 2013) without diabetes have used qualitative research and focus groups to explore the opinions, requirements, motivators and barriers to continued engagement and willingness to use health-related apps that support behaviour change. Interestingly despite very different participant cohort's similar themes to those in our study emerged, including the importance of tailoring advice, user friendliness, low user burden, safety and accuracy (Fukuoka, Kamitani et al. 2011; Dennison, Morrison et al. 2013).

In this study focus group participants highlighted many frustrations and concerns that exist around available mobile health apps. In general they found most apps burdensome, requiring too much time and effort. Participants felt the amount of data apps require actually make life more complicated. As a result participants only used them transiently. Participants also found the data from apps overwhelming and off little use when it is not put into context for the individual. Similar issues have been identified in the literature (Årsand, Tatara et al. 2010; Fukuoka, Kamitani et al. 2011; Dennison, Morrison et al. 2013) and challenges for future apps will be to maintain low user burden, provide relevant and timely advice, be as automatic and easy to use as possible and support and resolve issues with lack of long term commitment and use (Årsand, Tatara et al. 2010; Dennison, Morrison et al. 2013). Any positivity demonstrated in this study around existing apps were related to features that reduced the burden of data input (e.g. app syncing with other technologies; barcode scanner; camera). The design of this app will need to take the issues highlighted with current apps into consideration to design a more effective and user friendly tool that will avoid adding burden to people's lives.

Concerns around security and privacy has been highlighted in the literature (Fonda, Kedziora et al. 2010; Lewis and Wyatt 2014) and also in this study by some but not all participants. Individuals had no concern sharing their health related data with their clinician and health care professionals. However participants were concerned about their personal information getting into the hands of third parties, including insurance companies.

As part of our focus group discussion we explored the attitudes to a popular feature in medical apps – the insulin dose calculator. To the authors knowledge this has never been assessed previously using qualitative research. A recent review showed that insulin dose calculators carry a risk of incorrect insulin dose recommendations and that health care professionals should only recommend them after thoroughly testing their accuracy (Huckvale, Adomaviciute et al. 2015). However the majority of these insulin dose calculator apps were developed without medical expertise and guidance, which highlights the importance of clinicians and healthcare professionals being involved in the design and development of such apps (Huckvale, Adomaviciute et al. 2015). This study explored the participant's interest in an insulin dose calculator that extended beyond the meal bolus calculation to incorporate adjustments for exercise. Overall attitudes were very negative towards this feature, generally because the specific insulin dose calculator that was presented did not collect the correct and necessary information and there is too much individual variability in this complex area. As a result participants felt that they would not trust the number or percentage that the app gives them. Many therefore felt that this was not a feature they would like as part of the app.

Some knowledge already exists around the barriers to exercise with type 1 diabetes. Fear of hypoglycaemia has been identified as the strongest barrier (Brazeau, Rabasa-Lhoret et al. 2008). Increased knowledge about insulin pharmokinetics and strategies to help prevent exercise-induced hypoglycaemia including education around insulin adjustment and carbohydrate intake were factors that helped reduce the barriers to exercise (Brazeau, Rabasa-Lhoret et al. 2008). Using qualitative research a study among adults with type 1 diabetes identified low levels of knowledge about managing diabetes around exercise as one of the barriers to exercise (Lascar, Kennedy et al. 2014). Our results also demonstrate lack of confidence and feelings of frustration in terms of trying to manage insulin adjustments and carbohydrate intake for exercise. This only serves to highlight a gap in knowledge, which must be addressed in order to improve physical activity levels among this population. For overall glycaemic control to be enhanced, individuals with type 1 diabetes are required to skilfully balance insulin dosing and carbohydrate intake to maintain blood glucose levels in a more normal range before, during, and after exercise. There are multiple factors that can complicate glycaemic management during exercise in those with type 1 diabetes. Thus individuals are faced with many challenges when exercising with type 1 diabetes, and therefore strategies and tools are needed to offer assistance and increase their knowledge and confidence in this complex area.

Ideas were sought around the needs and expectations for the type 1 diabetes and exercise app and the focus group participants presented with some very useful data. Key things included the possibility of the app syncing with other technologies to reduce the burden of data input; the app tailoring advice specific to them (based on exercise type; insulin regimen and specific issues they are having); and the app offering advice in the form of suggestions rather than specific figures based on their profile history, needs and requests. A tool that's user friendly, uncomplicated and off low user burden were all important features highlighted.

Participants also highlighted challenges that we will possibly face with the design and development of this app. One of these was again around the burden of data entry and the need to limit the amount of necessary data in order to keep it simple and easy to use. This challenge to app design has been highlighted in the literature (Årsand, Tatara et al. 2010; Dennison, Morrison et al. 2013). Similar to the study by Dennison et al (2013) they felt they did not want to have to go into the app regularly to manually enter data and if they had to do this they were likely to forget (Dennison, Morrison et al. 2013). Another important challenge that was highlighted by participants was the fact that exercising with type 1 diabetes is a complex area with many individual variables impacting on their glycaemic control (e.g. insulin regimen, counter-regulatory hormones, exercise type and intensity etc). Therefore they felt that this will make the design and development of this app difficult. These ideas and challenges that have been highlighted will play a crucial role in the design of the app.

6.7. Strengths and limitations

This is the first qualitative study looking at the needs and expectations of an app to help individuals exercise safely with type 1 diabetes. The study sample included a good mix of gender, insulin therapy, diabetes duration (ranging from 8 months – 45 years) and a broad age range (21-64 years), thus was a good representation of the overall type 1 diabetes population.

Multiple methods of recruitment were used to help make our sample stronger by eliminating bias and convenience sampling. It is possible that individuals that agreed to participate in our focus groups were more active and had an interest in exercising with type 1 diabetes. Therefore those individuals less motivated and more sedentary were perhaps unwilling to take part for fear of feeling vulnerable, thus skewing the range to views expressed by our participants.

6.8. Conclusion and recommendations

This study adds to the current evidence around barriers and challenges faced by those exercising with type 1 diabetes. It serves to highlight the need to develop an effective tool that can help address some of the barriers to exercise, including the need for education about the effect of exercise on diabetes and very importantly reducing the incidence of exercise induced hypoglycaemia. It also presents important messages for our app design, as well as to other developers of smartphone apps for use among this participant cohort, including many frustrations with currently available apps and ideas for future designs.

If our type 1 diabetes and exercise app is designed and developed successfully this will be the first app of its kind to take the needs and opinions of those with type 1 diabetes into consideration as well as getting the expertise off clinicians and health care professional in this complex area when designing this app. This will serve to assure the apps safety and efficacy.

Taking the ideas from the focus group participants into the apps design, including the incorporation of evidence based guidelines in the form of easy to understand suggestions, could lead to the development of a readily available educational tool that offers individuals the support and guidance they need to help manage insulin adjustment and carbohydrate intake around exercise. Ensuring that the tool is easy to use and has a low user burden will be a challenge we will endeavour to resolve in order to ensure commitment to using the tool. However, long term commitment to using the app could be a challenge we may not overcome. Therefore, an app that provides intermittent support for when it is needed may be what people living with type 1 diabetes actually need and want. Finally, effort will be made to ensure anonymity is maintained by avoiding data transfers to third parties. Detailed information will be provided to users about any data being collected and how it may be used.

Finally this tool, once developed, will take into account the limited time resources within the healthcare system by providing necessary information at hand in this complex area for those looking to start exercising or increase exercise. Providing individuals with more knowledge and therefore confidence will overall help to reduce the high level of inactivity among this population, thereby reducing the risk of diabetes related complications.

7. Chapter 7: General Conclusions and Future Directions

To the authors knowledge this is the first available observational study looking at the level of physical activity and sedentary behaviour among an Irish adult type 1 diabetes population and the impact this is having on glycaemic control and CVD risk factors.

Physical activity levels had a strong positive influence on glycaemic control and CVD risk factors. Significant independent associations were observed between time spent in moderate-to-vigorous-intensity physical activity and HbA1c, BMI, waist circumference, fat mass and triglycerides. The impact of physical activity levels had important clinical significance, with those meeting physical activity guidelines having a HbA1c closer to target (7.7% vs 8.4%) and a BMI within the healthy range (24.5kg/m^2 vs 27kg/m^2). On the other hand time spent sedentary or in light-intensity physical activity did not influence glycaemic control or CVD risk factors. This has important clinical and public health implications as it suggests that in order to achieve metabolic benefits individuals must perform physical activity at an intensity that is at least moderate. Thus public health messages must continue to encourage individuals to meet at least 150 minutes of at least moderate-intensity physical activity per week.

Unfortunately it appears that individuals with type 1 diabetes are failing to meet physical activity recommendations with only 32% meeting the recommended physical activity level of ≥150 minutes of moderate-to-vigorous-intensity physical activity per week. In fact, the majority of waking hours (96%) were spent either sedentary or in light-intensity physical activity. Those currently undertaking mainly light-intensity physical activity must be encouraged and instructed on how to increase the intensity of this activity to at least moderate-intensity.

Interestingly, individuals believe (report) they are doing a lot more physical activity than they are actually doing (as measured by accelerometry). This could therefore contribute to their failure to meet physical activity recommendations. Individuals over-report moderate and vigorous-intensity physical activity using the IPAQ. They also likely under-report the amount of time they spend sedentary. It is likely that individuals misclassify sedentary and light activity as moderate, leading to this overestimation of physical activity duration. Thus the majority of individuals with type 1 diabetes are exercising at suboptimal intensities. More education is necessary on the health benefits of physical activity and the required intensity of physical activity in order to achieve these benefits. Also use of self-reported measures of physical activity should be used with caution among this population and perhaps not in isolation.

We cannot ignore the fact that individuals with type 1 diabetes have many perceived barriers to physical activity, including fear of hypoglycaemia, low fitness levels, loss of control over diabetes and weather. Fear of hypoglycaemia and loss of control over diabetes are barriers that must be taken into consideration when planning future interventions looking to address physical inactivity. Increasing awareness of how physical activity can impact their diabetes control, along with education on strategies to prevent exercise induced hypoglycaemia is of utmost importance.

We are aware that education in the area of type 1 diabetes and exercise can be resource intensive and challenging and busy clinics often leave health care professionals with insufficient time to provide the necessary education in this complex area. To the authors knowledge this is the first study to explore whether the use of technology such as mHealth apps could be used to educate and inform our participants in this complex area. Using focus groups we involved individuals with type 1 diabetes early in the design process, thus ensuring that our apps design satisfies the specific requirements of those looking to commence or increase exercise.

Future direction of this research with be the design and development of a type 1 diabetes and exercise app. If designed and developed successfully this will be the first app of its kind to take the needs and opinions of those with type 1 diabetes into consideration, as well as getting the expertise of clinicians and health care professionals in this complex area. Once developed this app will need to be piloted among those with type 1 diabetes to determine its safety, suitability and efficacy. Whether individuals can overcome some of the barriers to physical activity, including fear of hypoglycaemia, as well as improve their diabetes control through use of this app should ideally be examined using a randomized controlled trial.

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9. Chapter 9: Appendices

Appendix I. Patient Information Leaflet

Participant Information Sheet

1. Study title

Establishing the effect of physical activity levels on glycaemic control and CVD risk factors among Irish adults with Type 1 diabetes and identify the barriers to physical.

2. Introduction

My name is Mary Finn. I am a senior dietitian working in Type 1 diabetes in Tallaght Hospital. I’m sure you are aware of the many benefits of exercise which include improvements in weight, reductions in cholesterol and lowering of blood pressure. We are recommended to do 150 minutes / week (30 minutes five days / week) of moderate intensity aerobic physical activity. It has been shown that people with type 1 diabetes fail to meet these recommendations; however this evidence comes mainly from children and young adults. I am presently setting up a study to look at the levels of physical activity among our adult type 1 diabetes population and examine the effect this is having on blood glucose, cholesterol, blood pressure, weight and body composition. One of the main barriers to physical activity that has been identified is fear of hypoglycaemia. In my study I will also look at the barriers to physical activity among people with type 1 diabetes.

3. Why are we doing this research?

We are hoping to better understand the level of physical activity that people with type 1 diabetes are partaking in and the impact that this physical activity level is having on their diabetes control and overall health. We would also like to explore the barriers to physical activity and look at ways we can overcome these barriers.

4. Why have I been asked to take part?

By partaking in this study you can contribute to research attempting to understand the effect physical activity levels are having on blood glucose control and cardiovascular disease risk factors.

5. What will happen to me if I take part?

- At your routine clinic visit you will be asked to complete a physical activity questionnaire and a barriers to physical activity questionnaire, which together, should take no longer than 15 minutes.
- You will be asked to wear an ActiGraph accelerometer for 1 week which will record all activity you do. You will be asked to return the accelerometer in the post 1 week after receiving it. You will be given a stamped addressed envelope to do this.
- Following this you will be invited to education workshops on type 1 diabetes and exercise held in Tallaght hospital. You will be given all newly developed patient information factsheets and flowcharts to help you better manage your blood glucose around exercise.

6. Do I have to take part?

Taking part in the research is entirely voluntary so you do not have to participate in this study. Also, you are free to withdraw from the study at any time during the course of the testing without giving a reason. This will in no way affect the care that you will receive.

7. What are the possible disadvantages of taking part in the study?

There are very few disadvantages to taking part in this study. You might consider wearing the ActiGraph accelerometer for 1 week cumbersome. However this will give you lots of interesting information on your day to day physical activity and sedentary behaviour patterns.

8. What are the possible benefits of taking part in the study?

As above wearing the ActiGraph accelerometer can give you lots of interesting information. You will be given a summary of the report from the accelerometer. You will also be invited to take part in the education intervention arm of this research which will include talks, workshops and access to new education materials specifically around exercise in type 1 diabetes. This should help you better manage your blood glucose control around activities such as walking, jogging, gardening etc. It will also help you to become more confident in terms of making adjustments to insulin and carbohydrate intake around exercise, thus avoiding hypoglycaemia and hyperglycaemia around exercise. Finally your results, in combination with other participants, will help give us a better understanding of the effects of different physical activity levels on diabetes control and complications.

9. Will my taking part in the study be kept confidential?

Yes, we value your contribution to this project and all data gathered from you will be treated in the strictest of confidentiality. Only members of the research team will have access to the data. Also, although the data may be published, your data will be compiled with others and expressed as the average response to exercise so you will not be individually identified.

10. Will anyone else know I'm doing this?

Only members of the research team will have access to the data. Some of your medical records may be examined to check that you are suitable for participation and your bloods (HbA1c, lipids, blood pressure) will be recorded from your medical records and diabetes database. All information which is collected during this research study will be kept strictly confidential.

11. Who is organising and funding the research? The Meath Foundation in Tallaght Hospital are funding this research. It has been reviewed by the Tallaght Hospital Research Ethics Committee.

Appendix II. Patient Consent

Department of Nutrition and Dietetics, Tallaght Hospital

Participant Name: Hospital Number:

CONSENT FORM

Title of Project: Explore the effect of physical activity, or lack of, on glycaemic control and CVD risk factors among Irish adults with Type 1 diabetes

Name of Researcher: Mary Finn (Diabetes Dietitian)

Please initial box:

1	I confirm that I have read and understand the information sheet dated........................... for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3	I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from Tallaght Hospital, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
4	I agree to take part in the above study	☐

____________________ ______________ ________________

Name of Patient Date Signature

____________________ ______________ ________________

Researcher Date Signature

Appendix III. ActiGraph Frequently Asked Questions

ActiGraph Activity Monitor

Try not to change your activity levels while wearing the monitor as our aim is to get an idea of <u>normal</u> activity patterns

Thank you for agreeing to wear the ActiGraph Activity Monitor. The ActiGraph measures your physical activity levels and provides us with information on the about of time you spend engaging in different intensities of activity. The following information leaflet addresses some frequently asked questions. Should you have any queries please contact:

Mary Finn (Senior Diabetes Dietitian); Diabetes Day Centre, Tallaght Hospital, Tallaght, Dublin 24. Telephone (work): (01) 4143220 Email: **mary.finn@amnch.ie**

1. How many days do I wear the monitor?

You are requested to wear the activity monitor for one week (7 days) during waking hours.

2. Do I wear the monitor to bed?

No. You put the monitor on first thing in the morning and take it off last thing at night. You are requested to record the time you put the monitor on in the morning and the time you take if off at night in the activity diary provided.

3. Do I wear the monitor in the shower?

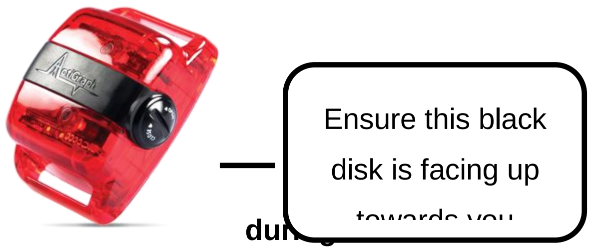
No. You should remove the monitor during any water-based activity such as showering, bathing or swimming. You are requested to record these activities, including the times your take the monitor on and off in the activity diary provided.

4. Do I need to press any button to start / finish the monitor?

No. The monitor is set-up by the researcher leading your study. You do not have to press any button to activate or stop the monitor.

5. Where on my body is the monitor worn?

The monitor is connected to a flexible strap with a clip. The strap should be worn like a belt around your waist with the monitor sitting at hip level on the right side of your body (see picture). Ensure the black disk on the side of the monitor is pointing towards your head. The strap should not be too tight or too loose. You can adjust the strap size if necessary. You may wear the monitor under or over your clothes.



6. Do ... monitor du...

No. Do ... o any power source or connect to any USB cable during the week ar ... a collected.

7. I forgot to wear the monitor – what should I do?

If you forget to wear the activity monitor on a particular day don't worry. Please write down clearly in the activity diary which day you forgot to wear the monitor and just carry on wearing it as normal the following day.

8. What should I do when I finish wearing the activity monitor?

When you finish wearing the monitor please return it to us in the stamped addressed envelope provided. Please return the monitor to us as soon as possible to ensure that the battery does not die before we receive it. Also please return your food diary (including the completed ActiGraph activity monitor diary section as per example below).

Try not to change your activity levels while wearing the monitor as our aim is to get an idea of <u>normal</u> activity patterns

ActigGraph Activity Monitor Diary

You are requested to wear your ActiGraph Activity Monitor during **<u>all waking hours</u>**. You will have to remove the activity monitor when you are going to bed or during water-based activities such as showering or swimming. Please record the time you put the activity monitor and the time you take it off in the following activity diary. If you forget to wear the monitor for a day please record this clearly in the activity diary. This record will help us to analyse your physical activity data as accurately as possible.

Should you have any queries please contact Mary Finn (Diabetes Dietitian) 0n 01- 4143220. The following example outlines the details required.

<u>Example:</u>

On Date	On Time	Off Date	Off Time	Activity completed while not wearing the monitor
04.10.2013	8.20am	04.10.2013	7.10pm	Shower
04.10.2013	7.30pm	04.10.2013	10.30pm	Sleeping in bed

Appendix IV. International Physical Activity Questionnaire

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE
(October 2002)

LONG 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 encouraged 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.

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

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** and **moderate** 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. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

PART 1: JOB-RELATED PHYSICAL ACTIVITY

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do any unpaid work outside your home?

   ☐ Yes

   ☐ No → *Skip to PART 2: TRANSPORTATION*

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

2. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

   _____ **days per week**

   ☐ No vigorous job-related physical activity → *Skip to question 4*

3. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

   _____ **hours per day**
   _____ **minutes per day**

4. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads **as part of your work**? Please do not include walking.

   _____ **days per week**

   ☐ No moderate job-related physical activity → *Skip to question 6*

LONG LAST 7 DAYS SELF-ADMINISTERED version of the IPAQ. Revised October 2002.

5. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

_____ **hours per day**
_____ **minutes per day**

6. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

_____ **days per week**

☐ No job-related walking → ***Skip to PART 2: TRANSPORTATION***

7. How much time did you usually spend on one of those days **walking** as part of your work?

_____ **hours per day**
_____ **minutes per day**

PART 2: TRANSPORTATION PHYSICAL ACTIVITY

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

8. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

_____ **days per week**

☐ No traveling in a motor vehicle → ***Skip to question 10***

9. How much time did you usually spend on one of those days **traveling** in a train, bus, car, tram, or other kind of motor vehicle?

_____ **hours per day**
_____ **minutes per day**

Now think only about the **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

10. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

☐ No bicycling from place to place → ***Skip to question 12***

11. How much time did you usually spend on one of those days to **bicycle** from place to place?

_____ **hours per day**
_____ **minutes per day**

12. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go **from place to place**?

_____ **days per week**

☐ No walking from place to place ➡ *Skip to PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY*

13. How much time did you usually spend on one of those days **walking** from place to place?

_____ **hours per day**
_____ **minutes per day**

PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY

This section is about some of the physical activities you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, chopping wood, shoveling snow, or digging **in the garden or yard**?

_____ **days per week**

☐ No vigorous activity in garden or yard ➡ *Skip to question 16*

15. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?

_____ **hours per day**
_____ **minutes per day**

16. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, sweeping, washing windows, and raking **in the garden or yard**?

_____ **days per week**

☐ No moderate activity in garden or yard ➡ *Skip to question 18*

17. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

_____ **hours per day**
_____ **minutes per day**

18. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

_____ **days per week**

☐ No moderate activity inside home → *Skip to PART 4: RECREATION, SPORT AND LEISURE-TIME PHYSICAL ACTIVITY*

19. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

_____ **hours per day**
_____ **minutes per day**

PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY

This section is about all the physical activities that you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioned, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **in your leisure time**?

_____ **days per week**

☐ No walking in leisure time → *Skip to question 22*

21. How much time did you usually spend on one of those days **walking** in your leisure time?

_____ **hours per day**
_____ **minutes per day**

22. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming **in your leisure time**?

_____ **days per week**

☐ No vigorous activity in leisure time → *Skip to question 24*

23. How much time did you usually spend on one of those days doing **vigorous** physical activities in your leisure time?

____ **hours per day**
____ **minutes per day**

24. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis **in your leisure time**?

____ **days per week**

☐ No moderate activity in leisure time ➡ *Skip to PART 5: TIME SPENT SITTING*

25. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time?
____ **hours per day**
____ **minutes per day**

PART 5: TIME SPENT SITTING

The last questions are about the time you spend sitting while 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. Do not include any time spent sitting in a motor vehicle that you have already told me about.

26. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekday**?

____ **hours per day**
____ **minutes per day**

27. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekend day**?

____ **hours per day**
____ **minutes per day**

This is the end of the questionnaire, thank you for participating.

Appendix V. Barriers to Physical Activity in Type 1 Diabetes (BAPAD-1) scale

Name: ________________________________ Date: _________________________________

Do you consider that the factors below could keep you from practicing regular physical activity during the next 6 months?

For each answer you will have to choose between 7 options (from extremely unlikely to extremely likely). Please circle the number that meets your answer the best.

Indicate the likelihood that each of these items below would keep you from practicing regular physical activity during the next 6 months	**Extremely unlikely**	**Much unlikely**	**Lightly unlikely**	**Not likely nor unlikely**	**Lightly likely**	**Much likely**	**Extremely likely**
1. The loss of control over your diabetes	1	2	3	4	5	6	7
2. The risk of hypoglycaemia	1	2	3	4	5	6	7
3. The fear of being tired	1	2	3	4	5	6	7
4. The fear of hurting yourself	1	2	3	4	5	6	7
5. The fear of suffering a heart attack	1	2	3	4	5	6	7
6. A low fitness level	1	2	3	4	5	6	7
7. The fact that you have diabetes	1	2	3	4	5	6	7
8. The risk of hyperglycemia	1	2	3	4	5	6	7
9. Your actual physical health status excluding your diabetes	1	2	3	4	5	6	7

10. Weather conditions	1	2	3	4	5	6	7
11. The location of a gym	1	2	3	4	5	6	7

Appendix VI. Focus Group Patient Information Leaflet

Participant Information Sheet

1. Study title

Use of focus groups to design and develop a mobile health application for the management of Type 1 diabetes and exercise.

2. Introduction

My name is Mary Finn. I am a senior dietitian working in Type 1 diabetes in Tallaght Hospital. Following on from a recent study I undertook looking at the level of physical activity and the barriers to physical activity we are undertaking a project to design and develop a mobile health application to help people with type 1 diabetes increase exercise more safely and with increased confidence.

I'm sure you are aware of the many benefits of exercise which include improvements in weight, reductions in cholesterol and lowering of blood pressure. We are recommended to do 150 minutes / week (30 minutes five days / week) of moderate intensity aerobic physical activity. It has been shown that people with type 1 diabetes fail to meet these recommendations. One of the main barriers to physical activity that has been identified is fear of hypoglycaemia, coupled with the lack of knowledge of effective strategies to prevent hypoglycaemia.

3. Why are we doing this research?

We are hoping to overcome some of the barriers to physical activity (mainly fear of hypoglycaemia). To help do this we will look for your input into the design of a mobile health application to better manage your blood glucose around exercise.

4. Why have I been asked to take part?

We are looking for the input of people with type 1 diabetes to help design this mobile health application as we want to make it as applicable and beneficial to your use as we can.

5. What will happen to me if I take part?

- You will be asked to take part in one 90 minute focus group. This will involve a group of 6-12 individuals with type 1 diabetes and the group will be facilitated by Mary Finn (research Dietitian) and a member of the Applied Research and Connected Health team who will be developing the app once designed. Discussions in this group will revolve around what you feel is necessary in this app. In order to analyse the information for the focus group we will need to tape the conversations. However you will remain anonymous and information will be kept strictly confidential. To do this you will be coded (no names or information that can identify you will be used) e.g. Participant A.
- You will be asked to volunteer to trial the app once it is developed for a 2 week period and we will look for feedback from you in order that we can make necessary changes to it if necessary.
- We will record your most recent HbA1c, cholesterol, renal profile and insulin dosages. Again using your code all of this information will remain anonymous.

6. Do I have to take part?

Taking part in the research is entirely voluntary so you do not have to participate in this study. Also, you are free to withdraw from the study at any time during the course of the study without giving a reason. This will in no way affect the care that you will receive.

7. What are the possible disadvantages of taking part in the study?

There are no disadvantages to taking part in this study.

8. What are the possible benefits of taking part in the study?

This is an opportunity to be involved in the design of an app specific to you living with type 1 diabetes and what you would like and deem necessary for this app.

You will also have the opportunity to pilot the use of app, the aim of which will be to help you increase exercise safely while having less hypo and hyperglycaemia. Long term benefits will be to improve your health and fitness levels through use off the app. The app should help you better manage your blood glucose control around activities such as walking, jogging, gardening etc. It will also help you to become more confident in terms of making adjustments to insulin and carbohydrate intake around exercise, thus avoiding hypoglycaemia and hyperglycaemia around exercise.

9. Will my taking part in the study be kept confidential?

Yes, we value your contribution to this project and all data gathered from you will be kept strictly confidential. Only members of the research team will have access to the data. As mentioned previously you will remain anonymous throughout.

10. Will anyone else know I'm doing this?

We will inform your Diabetes Consultant off your participation and contribution to this research.

11. Who is organising and funding the research? The Meath Foundation in Tallaght Hospital are funding this research. It has been reviewed by the Tallaght Hospital Research Ethics Committee.

Appendix VII. Focus Group Facilitators Guide

Focus Group Schedule

Title: Use of focus groups to design and develop an mHealth application for the management of Type 1 diabetes and exercise.

Research Questions:

- **What are the opinions of participants on currently available apps?**
- **What are participant's needs and expectations for an app to facilitate improved glycaemic control around exercise?**

Focus group introduction

Welcome

Thanks for agreeing to be part of this focus group and the willingness to give up your time to participate.

My name is Mary Finn and I am going to facilitate the focus group which will last approx 1 hour.

Purpose

Firstly just to give you some information as to why we are conducting this focus group. This research is following on from a recent study I undertook looking at the level of physical activity and the barriers to physical activity. This showed that many people with type 1 diabetes fail to meet physical activity recommendations. One of the main barriers to physical activity that has been identified is fear of hypoglycaemia, coupled with the lack of knowledge of effective strategies to prevent hypoglycaemia. Therefore we are undertaking a project to design and develop a smart phone app to help individuals manage their blood sugars better around exercise (so less hypoglycaemia and hyperglycaemia). To design this we are looking for your input into what your expectations and needs are for an app you could use to better manage your blood glucose around exercise. We would like you to share your honest and open thoughts with us.

Ground rules

Before we start some housekeeping things to run through. Firstly the session will be taped and written up afterwards. I'll take your names first, that's just to make sense of who is talking when we listen back to the tape. For writing up everyone will be given a fake name to ensure you remain anonymous. Therefore anything you say this evening will not be linked back directly to you.

As the session will be taped I will ask each of you to speak loudly and clearly. It is important that one person speaks at a time as if everyone talks over each other, when we listen back on the tape we will not be able to make sense of it. Therefore if you have something to say would you mind waiting until the other person is finished speaking so that everyone can be heard on the tape. There are no right and wrong answers but rather differing points of view. You don't need to agree with others but you must listen respectively as others share their views. Remember we are just as interested in negative comments and positive comments.

Before we begin I would like each of you to sign the consent form and also a demographic form – remember all of this information will remain anonymous.

Read through the consent form to make sure everybody understands.

Does this all make sense?

If you have a mobile phone would you mind turning it off please so there are no interruptions?

And just to begin and get everyone familiar with each other would you mind if we go around the table and say you name, where you attend for your diabetes.

Opening question…..

Focus group questions

Section 1 (previous experience using apps): Duration approx 10mins

- **Can I start by asking about your experience using any apps on your mobile phones?**

PROBE: What type of apps do you use? Do you use any health related apps and if so what type - are they diabetes / nutrition / physical activity related apps?

- **Can you tell me about any positive experiences or anything you found useful with the apps you have used?**

PROBE: Did they have any benefits in terms of your health / fitness / diabetes? What sort of things made you want to continue to use it e.g. certain features?

- **Tell me about the negatives / disappointments you have experienced with apps you have used?**

PROBE: For example if you stopped using it, why did you stop?

- **To those of you who have not used any previous apps before is this technology something you knew about?**

PROBE: Why have you not used any apps? Would you be interested in using apps? Can you tell me why / why not?

- **Finally what's your thoughts on having to pay for an app?**

<u>PROBE</u>: What's the most you would pay? What would influence your decision to pay for a specific app?

<u>Section 2 (Available apps): Duration approx 15mins</u>

Trigger material (see below):

- **What do you think about this app?**

<u>PROBE:</u> Would be interested in using it? Is there any features in it that you like or might be useful to you? Are there any features that you do not like? Could you explain how and when you might use it?

- **How would this app help you improve your blood sugars around exercise?**

- **What about any problems / concerns you can see with it?**

<u>PROBE</u>: Any concerns around privacy and security e.g. app keeping your data private and secure?

<u>Section 3 (What do we want in our design): Duration approx 20-25mins</u>

Trigger material (see below)

- **Use the flip chart to come up with ideas for our design. Next list in order of importance**

- **Can you see any problems / concerns with any of these features?**

<u>PROBE</u>: Any concerns around privacy and security e.g. app keeping your data private and secure?

These are all my questions but is there anything I have missed or anything else anyone would like to add.

Thank you for taking part in the focus group today.

Trigger material: Section 2

I'm going to take you some features of a diabetes apps that's currently available that takes exercise into consideration. I'll point out some negatives and positives that I noticed. This app is not specific for managing BG around exercise. I have some printouts of these which I will have out also.

RapidCalc

- Bolus Calculator with a logbook. Explain what a bolus calculator does.
- Cost €7.99

Using the images below I'll go through some of the features and how it works:

- During setup you will input your blood sugar targets, your correction factor, your insulin to carb ratio
- This app has a bolus calculator (see image 1) that takes into account your current blood sugar (if you need a correction it will calculate this) and your IOB from a previous bolus you have taken and your carb intake.
- Its one of the few bolus calculators that takes exercise into consideration when calculating how much bolus insulin you need. It describes exercise as light/moderate/intense and you input the duration: 15-30mins/30-60mins/>60mins (image 3). Note you cannot input the type of exercise (e.g. weight session/football training/jogging) which can have very different effects on your BG – the weights session may increase your BG whereas a 45min jog will likely decrease your BG
- Note also its only allowing you to use the calculator for upcoming exercise in next 2 hours, what about if you are having a meal after exercise and you want to know how much to adjust your bolus by to avoid hypos.
- When setting up there is default setting to decide how much % reduction of RAI is needed based on light/moderate/intense exercise. Unfortunately this is not based on current guidelines, likely needs updating and as above not all types of exercise needs a % insulin reduction.
- You can adjust the suggested dose (image 4). Also if you have forgotten to input a bolus you can retrospectively to this by adjusting the time (image 4)
- 90-day rolling history – you can look at more detailed information (image 5)
- Charting of blood glucose readings and trend data (image 6)
- Summary statistics for glucose and carbohydrates (average number readings / day, % within target, est HbA1c, average insulin dose, average carb intake)
- You can email this to yourself – table is not very user friendly; large table with huge amount of data

Image 1

Image 2

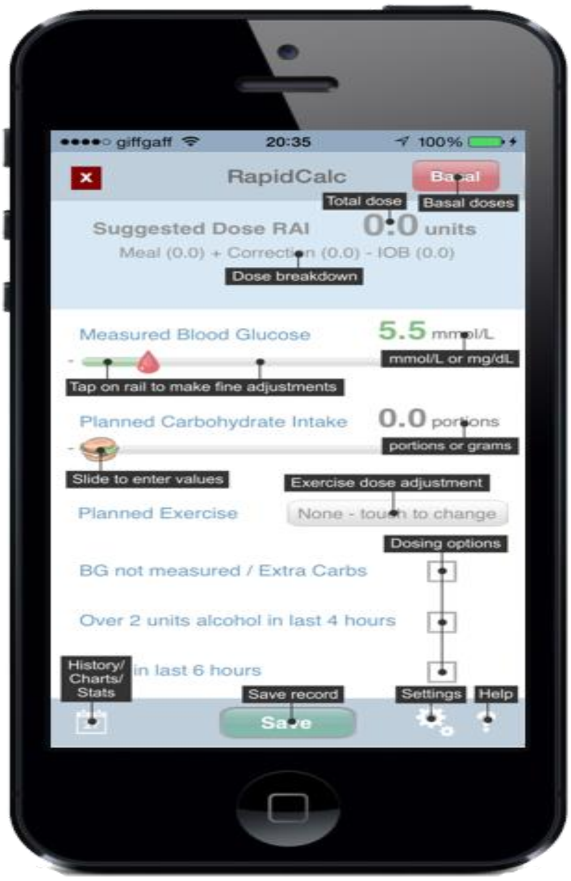


Image 3

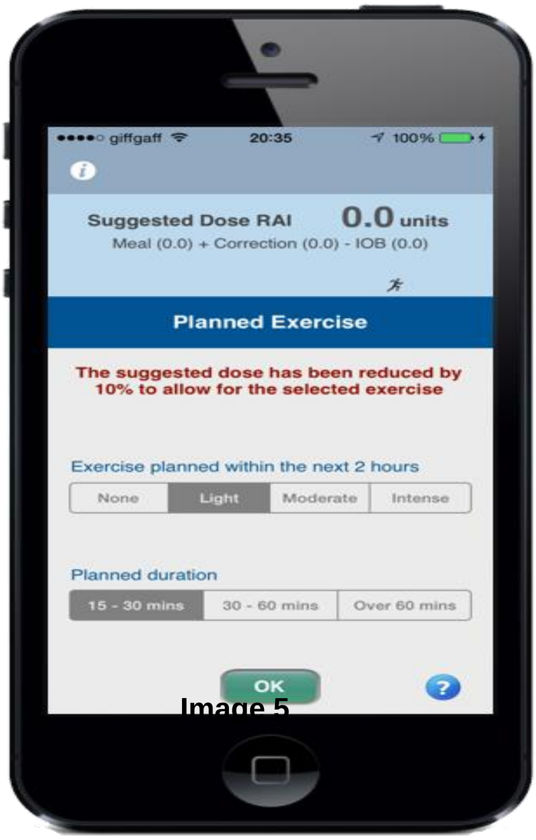


Image 5

Image 4

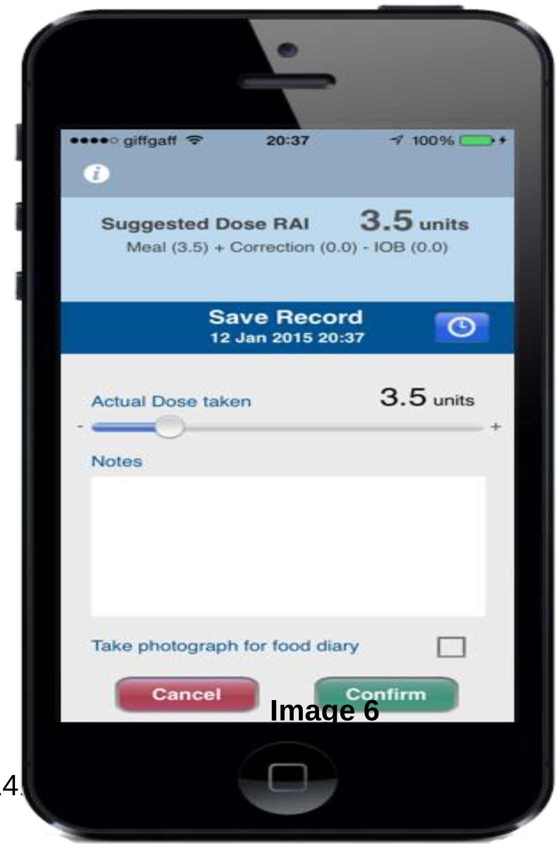
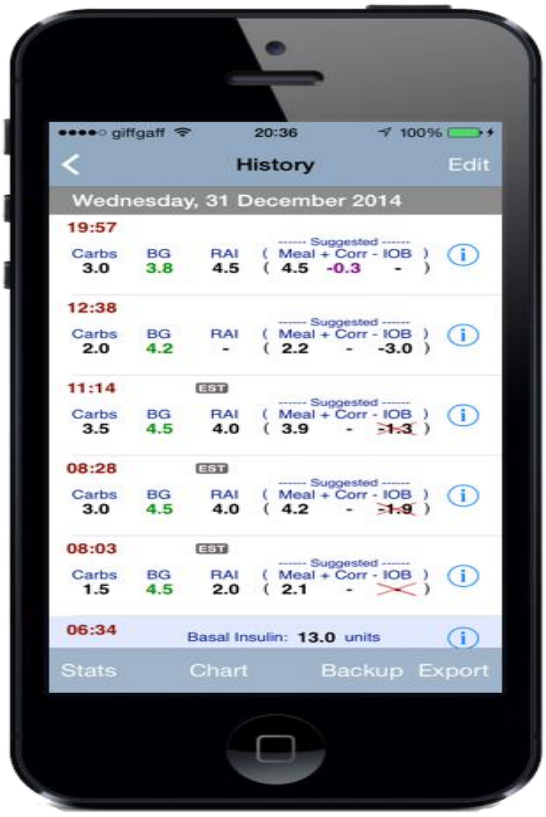


Image 6



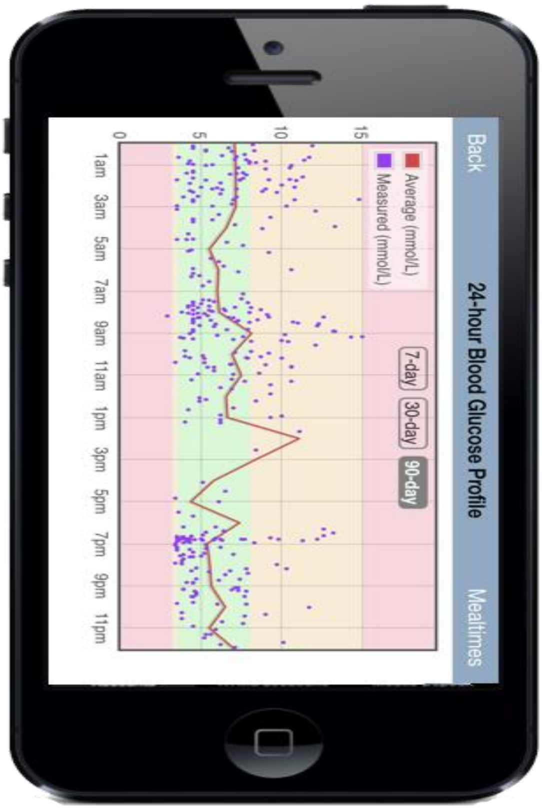
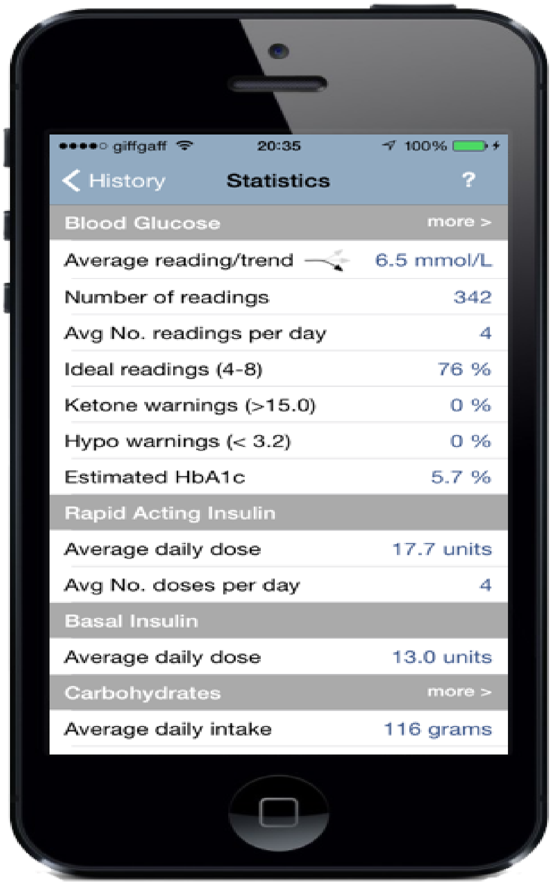


Image 7



Trigger material: Section 3

Now I'm going to ask for your help to come up with ideas for our design (some of the possible features that our app could contain). Remember the purpose of the app is to help individuals increase exercise or continue to exercise as the have been doing while helping to control their blood sugars better around exercise. I'm going to use a flip chart to jot down the ideas and at the end we can list them in order of importance.

(Remember there is no right or wrong answer here, don't be afraid to share your thought / ideas, however small)

Appendix VIII. Focus Group Demographic Form

Participant Demographic form

Name: ____________________________

Date of birth: ____________________________

Diabetes Duration: ___________________________

Diabetes Treatment (please circle): Insulin Pump MDI (basal & bolus)

Where do you attend for your diabetes care? _______________________

What was your most recent HbA1c? _____________________________

Have you ever used any diabetes or other health related apps? Yes / No

If yes, which ones have you used? _______________________________

Highest level of education attained (please tick applicable box):

Primary education or less	
Junior or intermediate certificate, technical or vocational training	
Leaving certificate, A-level, technical training	
Non-degree qualification	
Degree, professional qualification or both	
Postgraduate qualification	

Current employment status (please tick applicable box):

Working full time	
Retired	
Working in the home	
Unemployed	
Working part time	
Ill/unable to work	
In education	

Appendix IX. Focus Group Consent

Department of Nutrition and Dietetics, Tallaght Hospital

Participant Name: Hospital Number:

CONSENT FORM

Title of Project: Use of focus groups to design and develop a mobile health application for the management of Type 1 diabetes and exercise.

Name of Researcher: Mary Finn (Diabetes Dietitian)

Please initial box:

1	I confirm that I have read and understand the information sheet dated........................... for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	☐
3	I understand that relevant sections of any of my medical notes and data collected during the study may be looked at by responsible individuals from Tallaght Hospital, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	☐
4	I understand that conversation during the focus groups will be taped and later transcribed but individuals will remain anonymous.	
5	I agree to take part in the above study	☐

Name of Patient Date Signature

Researcher Date Signature

Appendix X. Focus Group Flyer for Recruitment

Type 1 Diabetes and Exercise
Design an App

Have you got Type 1 diabetes and struggle to exercise without experiencing highs and lows in your blood sugar readings?

Could a '**Type 1 diabetes & Exercise App'** help you manage you blood sugars better around exercise?

If you think so we are looking for your input to help us design this app.

For further information contact:

Mary Finn (Diabetes Research Dietitian, Tallaght Hospital):
Phone (01) 4143220 or email at mary.finn@amnch.ie

Appendix XI. Focus Group Coding Frame

Coding Frame

Title: Use of focus groups to design and develop an mHealth application for the management of Type 1 diabetes and exercise.

Research Questions:

- **What are the opinions of participants on currently available apps?**
- **What are participant's needs and expectations for an app to facilitate improved glycaemic control around exercise?**

Patient opinions and expectations of mobile health technology

1. Challenges with exercise and type 1 diabetes:

1A. Balancing insulin and carbohydrate for different types of exercise

(Challenges around insulin adjustment and carbohydrate intake when faced with many variables including exercise type, counter-regulatory hormones…..)

1B. Avoiding hypo and hyperglycaemia

(i) Increasing carbohydrate to avoid hypoglycaemia

('eating your way through exercise to avoid hypos')

(ii) Managing post exercise hyperglycaemia

1C. Overall general feelings around exercise and type 1 diabetes

2. Patient opinions on mobile applications and other technology

2A. Current app use:

(Examples of current apps used)

2B. Positive opinions towards apps and other technology:

(Positive experiences, beneficial features)

(i) Benefits of health related apps (nutrition, physical activity, diabetes apps)

(ii) Apps syncing with other technology (e.g. libre, glucometer, insulin pump etc)

(iii) Benefits of other technology (libre sensor, sensor augmented pumps)

2C. Negative opinions towards apps:

(Disappointments, barriers, challenges)

(i) Burdensome (Require too much information, time and effort, complicated, difficult to use)

(ii) Information without context

(iii) Difficulty trusting accuracy

(iv) Other discontents

2D. Privacy / security concerns

(i) No concerns

(ii) Wrong people getting access to information

2E. Cost of apps

(i) Willing to pay (if of value; option of free trial; once off payment)

(ii) Not willing to pay (consider demographics e.g. students)

3. Patients opinions on a bolus calculator app (used as trigger material)

3A. Potential benefits of the bolus calculator app

(i) Patients on MDI

(ii) Patients on insulin pump therapy

(iii) Positive attitudes towards the bolus calculator

3B. Scepticism and concerns towards a bolus calculator app

(i) Did not request/collect the necessary or correct information leading to lack of trust

(ii) Outdates/ basic/ very manual

(iii) Negative attitudes towards the bolus calculator as a feature

4. Ideas / suggestions for an app & potential barriers

4A. Possible ideas/ suggestions

(i) Syncing other technologies to app

(ii) Differentiate between insulin regimen and type of exercise

(different profiles for insulin pump users and MDI; different exercise types)

(iii) Advice based on your profile

(advice/prompts/reminders based on your profile/history/needs/requests)

(iv) Suggestions rather than numbers/percentages

(v) Simple to use

(vi) Consider the user and marketing

(vii) Additional features

(nutrition advice, logbook, motivational aspect, social networking, success stories)

4B. Potential barriers

(i) Burdensome

(ii) Too many variables

(everyone is so different, leading to lack of trust)

(iii) Lot of information in one app

(iv) Keeping app updates

(v) Syncing other devices to app)

5. Miscellaneous:

(anything else of interest which does not fit in the above categories)

Appendix XII. Focus Group Sample Quotes

Codebook

Title: Use of focus groups to design and develop an mHealth application for the management of Type 1 diabetes and exercise.

Research Questions:

- **What are the opinions of participants on currently available apps?**
- **What are participant's needs and expectations for an app to facilitate improved glycaemic control around exercise?**

<u>1. Challenges with exercise and type 1 diabetes:</u>

1A. Balancing insulin and carbohydrate for different types of exercise

(Challenges around insulin adjustment and carbohydrate intake when faced with many variables including exercise type, counter-regulatory hormones…..)

ID	Line	Quote
1.6	419	It depends, if it's cardio, I'll adjust, but if I put back insulin for half an hour or an hour beforehand, I'm just...I'm gone high and I can't move so... So I would eat breakfast and give it an hour, depending, if it was cardio and I was going in at 5 - I wouldn't go in that low to a cardio session. But if it's weights, I know, actually I don't reduce, because I know I'm gonna default.
1.8	425	I'd increase my insulin, I'd up it so it would go into the pump and just put it to 120% if I'm doing weights because I know it's gonna...
1.5	428	I'd always have breakfast, but I'd wake up starving. I'm a morning eater. But it's two and a half hours later before I'd get to the gym. So I have to have eaten, I have to have taken insulin before that food, so I just have to be super careful - I can't get interrupted during my workout, I have to balance the cardio and the weights. If I only do cardio, I'm on the floor... I have to balance them...and if I balance them both, I make no adjustment. I might start at 6, and finish close enough - I'd be fine...but I have to balance it to within minutes.
1.7	440	I play rugby, so sometimes I have my pump off...if it's training, I'll for the most part have it on, and have a reduced basil but any time there's contact I would have to have it off otherwise it'll get smashed, or I'll get injured from having it on so it's a really difficult on in terms of especially for a match - I basically have to take something close enough to the match that I'll have a bolus active while I have the pump off to try to keep me down for a while...it still doesn't work for the second half, so that's one thing.
2.7	481	Well, I just went on the pump; it's only a month and a half ago, so I'm quite new to the pump. But I got up and down Carrantuohill with no lows, which is great. I didn't have to eat my way up so... I had it to 20% and I think I

		was 6 leaving, and it did go down and it actually switched off the basal totally - the background, and then stayed steady - we were out for 4.5 - 5 hours. I think I had a banana on top of the mountain, and didn't take anything for it, and came down and was fine. That was so liberating...
1.5	470	The adrenaline will throw it off completely doesn't it... adrenaline can be like the stress of the game or just actual stress, anxiety...there's so many situations where your adrenaline level just surges...all the equations are gone off the table at that point.
1.2	475	...if you're doing 10K in training, your blood sugar will drop is what I find - whereas if you're running a 10K race, because you've got nerves beforehand...it won't drop...definitely the nerves before the start of the race, you can see your blood sugars going up. Whereas normally they don't because you're not nervous going out for your training run or whatever...
2.3	488	I think I would start at 6 as well and because I have the pump, I'd just have to lower it a little bit or depending on what kind of exercise... because I notice from doing resistance exercises, it's kind of like the hormones kick in, so then I'd have to take more insulin then. and then I'd have to lower that.
3.10	351	What I've experienced myself with mixed exercises is always unpredictable, but fixed exercise - if I may call it pure exercise, where you know you're just gonna walk, it always lands the same way. I experienced it myself, I play soccer all the time, so one game of soccer might shoot me up, the other game might keep me the same, third game, it might drop. It depends on what sort of activity level, what the conditions are, whatever else plays in it. But I started walking from work, and every day was the same thing when I would stop by the bus stop and walk, and that walk always dropped me at the same time, the same way. It was just kind of knowing exactly what... how far I'll reach before I drop my sugars, and I realised that the pure exercise is very predictable, but a mixed exercise...
2.7	618	Because technically, you could reduce your Lantus the night before, if you know you're exercising the next day, and not have any NovoRapid the next day, before your exercise, and then, maybe the night afterwards as well, reduce your Lantus. When I was on pens, I managed to exercise that way, and not have lows. But you've to mess around with the Lantus as well as the NovoRapid.

1B. Avoiding hypo and hyperglycaemia

1B(i) Increasing carbohydrate to avoid hypoglycaemia

('eating your way through exercise to avoid hypos')

ID	Line	Quote

2.1	606	I'm not trying to put words in anyone else's mouth, but I think, we exercise because we want to be well, lose a bit of weight, whatever the case may be but I just think it's so sort of ridiculous say to have to eat your way through exercises...
2.2	610	What I was used to doing was Lucozade... and I had to overcome that, and step away from it because I was putting calories in that I was burning off, and it was just such a fear, I had Lucozade in the hand constantly.
2.1	613	I went out with a Tesco bag... a shop... with bananas, and cereal bars and everything, and would eat my way through the day...and it was...now I think there's a little bit of pens having a bit more of a rigid - you have to have a slightly more rigid lifestyle than the pump can afford you some bit of flexibility...

1B(ii) Managing post exercise hyperglycaemia

ID	Line	Quote
2.2	475	……t's just so frustrating, because it's very hard to judge... and you get to a stage where you're going to bed (I do a lot of classes at night), and I'm going to bed with my sugars high, but I can't take any more insulin because I know they'll go low. In the morning I wake up and I'm perfect, but sometimes I've set my alarm and checked it - sometimes they go so high that I'm saying to myself that's affecting my overall reading, and my control.
3.8	293	And then the post-exercise as well probably the bigger thing, like certain training, like if you're doing anaerobic stuff, your blood sugar's spiking, and you could under treat it or over treat it, and that kinda ripple effects then a few hours

1C. Overall general feelings around exercise and type 1 diabetes

ID	Line	Quote
2.2	599	I'd like something that would give me the freedom to be able to go and relax and do a class, and not have to keep stopping, and worrying about my blood sugars, and going and checking them. But just something to give me a bit of confidence... I have to keep stopping and...
3.2	243	I suppose my biggest problem is I don't plan my exercise. I might just decide I'm going to go for a walk now, so I'll have taken my insulin, I'll have had my meal, and I know I should be more organised, but I can't always be.
1.6	687	It's not worth it sometimes...

2. Opinions of mobile applications and other technology

2A. Current app use:

(Examples of current apps used)

ID	Line	Quote
1.2	15	most of the apps I would use, on a day-to-day basis at least, are ones that have content of some sort - so news apps, some social media apps, Facebook, LinkedIn for example, but generally they're things that have something new on them every day in terms of content. There's a couple of other apps I would use which are...say Strava for work-outs or for cycling and running, stuff like that... and podcast apps, and things like that
1.1	26	I use MyFitnessPal because it has a very good index of foods. I use Carbs & Cals as the app for recording what you eat as well. mySugr, and I'm trying to use Glooko as well... and myDiary.net as well.
3.1	11	I use a Garmin. . I also use an app called Strava for mapping all my mountain biking and em... I use Carbs & Cals as well.
3.8	23	I use My Fitness Pal just for tracking food throughout the day, **, and then the apps on the iWatch - the BPM and all that...**
1.3	2	I mainly use social media, and MyFitnessPal - they would be the main ones
2.3	8	Map My Ride is what I actually use

In summary the main apps mentioned included:

Activity trackers: Garmin; Strava, My Fitness Pal, iWatch apps – BPM, Map My Ride, Fitbit app, MyFit, 3,2,1 Run

Social media apps: Facebook, Linkedin, News apps,

Nutrition related apps: MY Fitness Pal, Carbs and Cals, Nutrino

Diabetes logbook apps: My Sugr, myDiary.net, Glooko, Libre app

2B. Positive opinions towards apps:

(Positive experiences, beneficial features)

2B (i) Benefits of health related apps (nutrition, physical activity, diabetes apps)

ID	Line	Quote
1.5	44	I find Carbs & Cals very handy - it's ok if you're at home, you can measure something out, you know exactly what it is. When you're out, you're not even entirely sure what's in your food, but you can make a reasonable

		assessment and adjust later so I find it's eh... if you're going to eat something unusual - I find it very convenient. You can just eyeball something, and you'll be close enough.
2.7	37	I go through phases of being strict, weighing everything, but then if there's sauces mixed in, Sometimes I'll try and weigh my pasta first but then other times, I'm like oh just give me it with the sauce on so the weight is gonna be obviously more, so it's a guide... but it definitely, I think is the best diabetes app for type 1 anyway. (referring to carbs and cals)
2.5	43	I use that a good bit on my iPhone, because if you're out for a meal or something, it's very hard to judge what's on the plate is to what's on the app. Whereas, if you cook yourself, you know exactly what's in the sauces…(referring to carbs and cals).
2.3	126	I use My Fitness Pal to find carbs because the majority of the time it has been quite helpful. It has all the nutritional information for you, and then you can even adjust...you can put in 1 or 2 if you're having more than 1 serving of it. Then you can put in the actual amount of servings you're having, so it does the calculations for you there and then.
3.8	83	Like that with My Fitness Pal - you can set it from 100g down to 1g, weigh your food, and then put the exact grammes into it and it just gives you total carbs then. So it's just easier for getting the exact carbs and a bar-code option on it as well for when you're out. And then it just records everything so even if you eat the kinda same stuff over the few weeks like, it's still there under breakfast or lunch or whichever's kinda more frequent. It's much easier to... It's quicker, rather than going through like the Carbs and Cals, searching for the food just when you go in its like breakfast - and you have a whole list it's just quick and easier. You have the option of searching for it or scanning the bar code so when you're in the shop you can just scan it, and it comes up with 100g or you can set it to 1g with the exact weight in and it just gives you the exact carbs. Proteins, fats, the calories... You can also set your details, like your age, weight, if you want to gain weight or lose weight, you can set how many lbs per week you want to lose, and it calculates how many calories you need per day... so the more food you're scanning, it's eating away at your calories until you know not to go over or under.
3.7	69	The Carbs & Cals one is pretty good. D'ya know, I mean you can sorta see well...you can relate to what your portion size is, compared to what it gives you, you know what I mean, it has the calories and carbs and fat proteins and all that kind of stuff on it
2.3	10	I was trying Nutrino as well.....it's very based on food, so it's kinda helping you with your food - how to eat healthier, actually, when you have the premium account, it gives you sets out meals for you for the day and you can even get these recipes as well for these foods and there's a part where they've introduced there for diabetics where they design food menus for diabetics now. It's been helpful when I was using it, but I haven't used it in a while.
2.1	69	MySugr's spelled Sugr... It's an app that has been made by diabetics... there's little monsters... the whole base of the app is that it's done on a little widget or a little monster guy. You're supposed to feed him during the day, and I think feeding him is bits of information... or you interacting with the

		app...you'll sing and you'll fart or do whatever... but it's a good app, and it is quite user friendly.
3.5	124	There's another one eh... MySugr - where instead of writing down what you've eaten, you just take a picture and it'll save the picture so you can come back in and write oh yeah that many units spent so far...
2.6	8	Map My Ride it's called... when I'm cycling, it'll show you where you went and tell you how fast and all the saga...
3.9	16	I use 3,2,1 run which is again for distance covered, when I'm running I was thinking about why do I use apps or which ones... if I download apps, the next thing I realise I'm not using them so the ones that you use are ones that are actually giving you benefit. So 3,2,1, run gives me benefit because I can just look, I can time it, I can do my intervals, I can do my timings off of it... But even other apps that I've used like going to music festivals is that they actually are different than what you get on a website. So they're just something that you can instantly...live access of up to date.
3.2	11	It's pretty good... I use this more for mountain biking but because I do a lot on my feet all day at work - like today I done 11,854 steps, 8.98km, and you know you don't realise it - I never realised it since I got it, but it's great. (referring to Garmin)
3.1	7	Well it's connected to my phone... but eh it give me the time, it gives me the amount of steps I take in a day and I've set it to take 10,000 (I don't always get there) and some days I go over. (referring to myfit)
1.2	101	When I use Strava for example to go for a run, I just press record on Strava, and Strava collects all the information - how far I ran, how many calories I burned, all this kind of stuff...it never asked me to put in how far did you run? It figures this out from GPS, or it figures out the calories you've burned based on how fast your pace and it's all done. So that's easy to use, and at the end I get a nice picture of my run and how fast I went and whatever...and I didn't have to do anything extra other than hit Go

2B (ii) Apps syncing with other technology (e.g. libre, glucometer, insulin pump etc)

ID	Line	Quote
2.3	79	My meter hooks up to my phone. It's called Contour link, it's a new one out.... Yeah, this helps me out so much. You can log food on it as well. I've been logging my food, and you can actually log how much medication you take as well, but I don't bother doing the medication part because I have my pumps on. I don't do it that way.
2.3	93	because my blood sugars are going straight over, I'm then able to go into it and tell it that it's before a meal or it's an after meal blood sugar, and then I'm able to say which kind of meal it is - whether it's a breakfast, or if it's a lunch or if it's a dinner, or it's a snack... Then I can also from there write in how many carbs it is for/per serving in that food (for one serving) and then you can do it for one serving and a quarter, up to about maybe 10 servings you can give yourself as in logging it in. Then it would give you the overall

		amount at the very end of how much carbohydrates you've actually taken in your food. From there, you just take your insulin...(referring to contour link app)
3.9	339	But I think the interesting thing about expensive eh... there's a bit of beauty in the eye of the beholder - is that what benefit is it giving? So again like you're coming back to the Libre... like the Libre is actually almost, because of the other technology, is almost leap-frogged with benefit... and that live... you know being live, and knowing exactly what's happening, and not having to put in the information - the information is there.

2B (iii) Benefits of other technology

3.3	331	I think the idea of just knowing what your level is like maybe on a constant basis or not, d'ya know, when you're taking readings or something maybe every 4 hours maybe between, or 2 hours, I don't kinda know what's in between... so just to be able to know that would be a huge help yeah.
		There's augmented pumps, with sensor communication, and it just kind of buzzes and tells you, even stops your insulin before it goes low so it's already there.
3.4	28	It's quite useful in that it calculates everything, it shows you your line throughout the day, your target range - you can go back then to whatever day you want for the last 90 days and it calculates H1 as well, over a period of time you know, em...that's how you scan yourself with the phone as well, and it automatically takes a reading every 5 minutes and then when you scan your phone it shows you since your last scan... so even through the night, it'll show me the whole... how the night went, you know...So it's pretty effective in that sense you know... (referring to the libre)
3.4	38	For sport I do play football a bit, and that was interesting to see how it affected me, you know in certain games - I might just be say 7 or 8 all the way through but then certain games - it would go up to 15 like if I was stressed or something happened during the game, it'd just shoot up and then literally after the game it'd go right down low then so quickly like in the space of 40 minutes... but it was interesting to see, even just having a bit of a row on the pitch or whatever how it would affect your...(referring to the libre)
3.1	55	I find that with the Libre em... it's great, cos doing the Berger course you do your 2am check, and I was doing that for quite a while and then just different things...the alarm won't go off or whatever, I kind of fell out of routine with it and em...I found with the Libre, it's great - even on the monitor, it shows you a graph, and a time scale and I could go to bed, and I've taken my Lantus just before I go to bed...say 10 o'clock, and it could be 6.5 or whatever, and I wake up and I'd scan and it could be like 6 or 7... and it's like ahh that's great if I have to prick my finger but you look at that fucking bastard of a thing and you'd see it go up to like 19... in the middle of the night, for no known reason, and then it would just shoot down. And like but if I just prick my finger, it'll be 6.5 going to bed, I wake up and like 6.7, ahh that's great. You know what I mean, I'm deadly... but youve gone up... and then, I dunno, and like I haven't like I'm not getting up in the

		middle of the night and going to the fridge, like I don't know why was happening so bad (that I know of, yeah)

2C. Negative opinions towards apps:

(Disappointments, barriers, challenges)

2C(i) Burdensome

(Require too much information, time and effort, complicated, difficult to use)

ID	Line	Quote
1.1	59	The amount of data on the Carelink download is incredible... like a blood sugar reading every 10 minutes, all the insulin you've taken, it is a phenomenal amount of data... and unfortunately, it is very awkward to use, very awkward to log into, very awkward to print out...
1.2	75	the other thing I'd say about a lot of the apps is that a lot of the apps ask you to put in a lot of information, so in terms of...I need to put in my blood sugar, I need to put in how much insulin I took, I've gotta put in numbers all the time. I've got enough things to be doing, I've got enough other devices that I've got to do things on, that I've got...metres, pens, pumps (if you have them on), and now there's an app asking me to do more. That's making my life more complicated, not simpler. That's the reason I've not used a lot of the apps. For me, there's this cost benefit thing - so it costs me time and effort and head space to bother to put stuff into it and if I don't get a whole lot out of it - I'm not gonna do it, so I think that's hugely important
1.5	93	There are so many apps that I kinda looked at them and thought who has time? and they may be beneficial - I just do not have time to be inputting all of that.
1.5	116	I think you lose data - if you start off and you're inputting a little bit, you're kind of enthused at the beginning, and then you don't have time later on in the day, to do it the following day, the information you give back is worthless because it is so sporadic. There really isn't a valid pattern in there. So unless you're going to be that vigilant and just do it all day, every day...you just need to be a full-time diabetic and not doing anything else to do that.
2.1	53	which is kind of ok... when I say ok, it was ok at the start - it's an absolute pain in the arse to have to log everything that you've eaten and exercise that you've done so I very quickly ran out of patience with it (referring to MySugr)
2.2	143	There are positives but sometimes they can be too time-consuming that you lose interest. I did try that one you tried. I tried that and I found it too time consuming. You want something quick and easy. (referring to MySugr)

3.5	139	That's why I stopped… It was just the picture part that I liked...when I had to fill in everything else it was like ahh here I'm over it…(referring to MySugr)
3.1	130	Yeah, I done that one as well - MySugr. I didn't like that one at all. It's way too much effort. No, it was... not that... it was just too much like... too complicated, just too much of like... before like...being at work, you only get a set amount of time for lunch - and you've to try and work out your carbs and everything and then take your insulin... do all that, and you know make your lunch or cook your lunch or whatever you're having... and then you're trying to fill out this as well...It's just so much... it's just too... way too long, so that's why I...
3.5	128	But like that, it was saying like some of it was confusing - that's why I would use it for the week or so…
3.8	114	There's one where rather than filling out the diary, you could track a diary on the app itself, but it's real kinda... the layout for it and just kinda entering all the information just gets a bit messy and that. Yeah, it's just much easier to fill in the book like.
3.8	111	They're over complicated some of them. I've tried a few diabetes apps, but they're just over complicated. There's just too much going on like you know, it's not as laid out or...
2.5	174	You go into... it's supposed to be able to help you, but then you actually go in and it requires more work to actually get you up to speed.
2.3	153	There's this app, I remember using it years ago - I haven't used it since because I think I only used it for a week and I wasn't able for it. It was Diabetes PA. There was so much that you just had to log in yourself, that I think I was getting put off it because I had to log so much myself. And it was the fact that with the whole linking problem... that was my biggest problem with it.
2.5	144	If you have to log the whole time, what did I have and then I have a snack I have to log in again to record that. Especially when you're having the same thing might be an idea to just copy ... you can just copy the meals from yesterday

2C(ii) Information without context

ID	Line	Quote
2.7	125	When I first went on the CGM a few months ago, I kind of got burnt out with the amount of information I was getting and trying to make adjustments off that. So I actually went off it for a while, I've come back on it on and off...
1.7	128	The amount of information you get from it - more isn't always better...it's a lot about the quality, and then it depends on the person's own use...sometimes they might want to get all their information out of the app,

		sometimes they won't. That's just part of the app. Sometimes more information is just too much, and you have to give up.
1.2	157	One of the things I would say with a lot of apps is that they get data, and they show you graphs, and actually, you haven't said or they haven't asked you what's the problem you're trying to solve? What's the question you need the answer to?
1.2	195	That's another mistake a lot of the apps make is they say go into some section in the app and you can learn all about diabetes. I don't want to know all about diabetes, I want to know the information that helps me with the specific problem I'm having at the moment. The piece I want right now...and then it might be a different piece that I want from the piece I wanted two weeks ago, or in two weeks' time.

2C(iii) Difficulty trusting accuracy

ID	Line	Quote
2.7	35	I use the Carbs & Cals a lot. That's good, but just sometimes it's hard to estimate - you're looking at the potato and you're like trying to match up the potato, and I know the grammes are there, but sometimes you have a...
2.4	118	Carbs & Cals as well. The size stresses me out as well... trying to determine... because if it was chips or something, two portions might look really, really similar in the photos, but there could be 20g of carbohydrates in the difference. There's no way to tell, because it's a big plate on the picture, and it looks like a tiny amount, but then they say there's 50g of carbohydrates so it's too hard to tell by looking at the photos, unless you weigh everything out. Then if you weigh it out, then you can just Google how many grammes there is so I don't know how helpful

2C(iv) Other discontents

ID	Line	Quote
1.1	30	Yeah, they all have bits and pieces of what I want, but none of them have it all together, no matter how much I've tried to get one to do what I needed, it wouldn't do it. For about three weeks, I was very determined to record what was going on, but I gave up in the end.
1.7	52	Just in terms of some of the ones I use like Instagram or Facebook - there's quite a limited functionality in the phone app compared to the original programme online, so perhaps that won't happen if it's already... like it's directly made for an app... but being able to notice a difference between a full-scale programme and the app can be a bit frustrating, because you can know oh if I was on my laptop I could do more, but on my phone I'm limited. So that would just be something that I sometimes get frustrated with, with apps

1.5	7	I have a Samsung one built into the phone, and I find it absolutely pointless, because a lot of the exercises I do is sort of, you know, free weights or something... the phone doesn't know I'm moving... so I've completed an hour in the gym, and the phone thinks I did two minutes, so it does nothing for me.
2.2	4	I tried that Map My Fitness. But with the classes I do, I can't keep my phone on, and you have to have your phone on your body for that to work, so they didn't work for me.
2.2	188	Map My Fitness did prompting, and it wrecked my head.
3.1	110	Ads

2D. Privacy / security concerns

2D(i) No concerns

ID	Line	Quote
1.2	846	So long as the data protection requirements are met around who can view the information, and how it's stored, and all that kind of stuff. But the principle of having my information at least available to my team as such is perfectly fine with me.
2.2	304	It wouldn't bother me. If it would help me, or it would help others, maybe. It wouldn't bother me, people knowing.
1.7	828	Not really with my blood glucose readings I suppose. There was that question on the pump next to that site - it asks about data protection, but as long as my name isn't necessarily attached to the blood glucose readings, there's probably a small population that could read those readings, and make sense of them anyway. Generally, I suppose, I wouldnt have concerns

2D(ii) Wrong people getting access to information

ID	Line	Quote
1.2	843	I think it's about who has access to information too. In principle, I don't think anyone has any objections to sharing data with their clinic, dietitians.
2.4	336	That's like the whole ethical thing around 23 and me...like paying to know what's in your DNA... there's like... a lot of people in America bought into it but whatever the company is - sequence your whole DNA from a blood sample let's say, or a hair sample, anything... and you pay €100 plus and they send you back all the details of your DNA... what possible risks you have genetically, or this and that. But they still then can access that data, they have the right to that data now, and so there's all these ethical issues

		and fears about insurance companies getting their hands on these so... I don't know if I want big pharmas connected to my phone...knowing this sort of information. But it comes hand in hand still, like the positive with the negative...
2.5	345	I think it might even be a problem say like you said the pharmas, the third parties selling on from that again - who are they selling it on to on the other side of it?
1.5	836	If your information is out there, you know for sure the insurance companies - they can get a hold of it. So I think data protection is enormously important for just that as one example. I know that from my own experience, because I literally put myself on the floor to get my HbA1c low enough and it was very hard on my own body to do it, but I had to do it, to get a quote I could live with. I falsely pushed it down.. I couldn't have kept that up. But I did get it very low, and got a good quote.

2E. Cost of apps

2E(i) Willing to pay (if of value; option of free trial; once off payment)

ID	Line	Quote
3.9	192	I would have paid for the Libre app because if you were getting the connection... cos it was... actually, it was almost like technological jump... from pricking your finger, suddenly you could have this it was giving you a spot-check, it was giving you history... you could do it, in my case when you were running, so that actually was break through, that was almost a leap...really good. So I probably would have paid for that.
3.4	198	Yeah, like most people, I wouldn't pay for apps really but, if I had to pay for the Libre app, I probably would, you know, because it helps me a lot you know. So I think if suited somebody, if they're getting worth out of it, you might be inclined to pay something towards it but if it's just like any other app that you can get then what's the point?
1.5	223	I remember with Carbs & Cals, I think it was a fiver - but there was no problem paying the fiver, because I knew before I bought it, it was worth buying. I heard it from so many people that it was so beneficial, that it was no problem. But you're taking a chance before you open it - you really have no idea...we've all gotten apps, and you've no idea until you start to use them if they're any good. I'm not sure you'd be inclined to pay for something that you haven't had enough information yet to say that's worth every penny that they're charging. Whereas, the likes of Carbs & Cals, just as an example, it could have been three times that price, but I'm still gonna buy it.
1.5	232	I knew what I was buying; I knew the value of what I was buying - as opposed to something new I really have no idea what I'm being sold.
1.1	241	If an app could do all the things I want to do, it’s worth anything...it's worth hundreds, thousands...to me. If an app can, in effect, cure me of diabetes,

		comes to it is telling me what my blood sugars are, is telling the pump how much insulin to give to me or telling...
2.5	225	I definitely think it's linked to how much benefit you have from it as well. If you do see you get benefit from it, you're more inclined to pay €20.00 a year or whatever...
2.2	227	With that Carbs & Cals - you knew what it was - we'd all seen the book, and you knew what you were getting so you didn't mind paying for it.
3.4	205	Yeah, as I say, and if you're getting some worth out of it, you're more likely to pay for it, whereas if it's just going to be like any other fitness app that's out there, or blood sugar app, then maybe you wouldn't bother paying for it.
1.6	236	I would say do a free trial - do a month of a free trial and that way, if you make it clear enough that it's gonna help somebody not have a hypo - I'd pay any money.
2.2	206	I'd like a trial first. If they give you a trial, cos you'll find out you're not going to be wasting your money on it maybe...if it's something that you'd use...
2.5	212	Maybe a month's free trial just to get used to it, and what it is, and then after that, jump on board or…Well whatever it's going to be whether it's going to be an annual fee or a once-off fee...
2.1	210	I'd be more inclined to pay a one-off cost...

2E(ii) Not willing to pay (consider demographics e.g. students)

ID	Line	Quote
3.9	187	I think there's a standard there that there's so much good free apps, that to pay at all... like you actually sound like you're mean, it's €0.99 or something like that, but it's actually there's an issue of having to put in your details and your... you know give away data, and all that... so for me, like I don't pay for apps, like to pay for an app - it would have to be very good.
3.5	181	There's always like another app that's like it that you can just get for free so theres so point paying
3.1	183	I'm an android user I never pay for any app. I don't know if anyone else does... I would probably tolerate ads, if it came for free like.
1.7	278	Just as a point for paid for apps - my initial thought was no... I've pretty much got no apps that I've paid for; I just always go for free ones. Coming up through college or whatever, I definitely wouldn't have paid for an app... If any of the demographic is students, I would say they are less likely to pay for an app.
2.3	253	When I was a teenager, I wouldn't have had the funds to support paying for the app - in fact, I didn't get Carbs & Cals until I was working….. With

		the likes of teens, they wouldn't buy the app, but they would need the app. I could say definitely young people will need it. Most of the time I come across a diet app and go ahh I'm not gonna buy it because I'm probably not gonna even use it then.

3. Patients opinions on a bolus calculator app (used as trigger material)

3A. Potential benefits of the bolus calculator app

3A(i) Patients on MDI

ID	Line	Quote
2.1	433	For someone that's on pens - I think that's quite useful... it's doing what a pump does...
2.1	511	so for me to buy an app like this - I maybe would have bought when I was on pens, but not now that I'm on a pump because I've various bits of equipment telling me the same thing.

3A(ii) Positive attitudes towards the bolus calculator

ID	Line	Quote
2.1	438	I don't think the report specifically is the intended outcome...really it's the bolus for what you're going to take, and your insulin. So there's a set up involved in it, but if you were just at work and you were going for your lunch and you got out your phone, and you're thinking oh right, I'll have the spag bol, 90g of carbs, my reading's 4.5, you pop in 4.5 and 90g and it's going to spit out ok - you need to take 12 units or whatever the case may be ....
3.10	248	Would that take into account if for example you had already input your insulin in there? And it would have told you like you have 4 units of active insulin, don't go for a walk right now...or take some carbs and then a walk if you're a quick moderate exercise for 30 minutes, it would tell you that you have active insulin, that's hanging around right now. But it depends that you'd have input it beforehand. But I think that you were saying that this app allows you to go beforehand and say an hour ago, I took this amount of insulin, Not many apps allow you to do that.

3A(iii) Photograph your food

ID	Line	Quote

3.10	224	part of this is taking a picture of what you're eating, I never thought of that as part of an app that you could actually... but that's part of this as well - that you can take a picture of what you're eating. This helps so much.

3B. Scepticism and concerns towards the bolus calculator app

3B(i) Did not request/collect the necessary or correct information leading to lack of trust

ID	Line	Quote
1.8	363	I wouldn't really use that. The fact that you can't put in the type of exercise when you're using it, I think it would be useless. Because you could put in I'm doing light weights, and your sugars are only going up and you know that yourself, but you could be going on a hard cycle and its two totally different things so the fact that you can't put in what exercise you're doing, I wouldn't be using it.
1.5	369	I agree with you, because that completely dictates whether you're likely to go hypo, when you should eat, how much insulin you take with it - it doesn't know you've just been lifting weights or cycling or whatever. You can't trust what information it gives you next.
1.2	374	How does that app work? I'm on MDI - how does this work with a pump? One of the main ways in managing on a pump is to suspend or reduce your basil rate - but this is a bolus calculator...
1.2	404	It's almost as if a question needs to be asked first, before you get to that screen it's are you about to exercise? or have you exercised? Then the next question is well, if you're about to exercise, what exercise are you going to do? and then you need to figure out whether you normally go high or low for that exercise, and then it's either tell me how much carbohydrates to eat or tell me how much insulin to take depending...and the same afterwards then as well. So this is kinda like... here it is - just use it, whereas actually you need to be able to identify what needs to be shown in blue there at the end is kinda different depending on what peoples issue is.
1.5	435	I wouldn't trust that in the slightest...I wouldn't entertain any part of that because it didn't ask me the right questions, it doesn't have the right information so the advice it's giving me is based on nothing that's of value to me. I wouldn't trust it.
2.5	536	I think it's a big difference between going for a run, a swim, or something, going for a brisk walk... I think none, light, moderate and intense is very vague.

3B (ii) Outdated/ basic/ very manual

ID	Line	Quote

2.3	424	I think it's very out-dated.
2.3	431	It looks too basic for something that costs about €8.00 - I wouldn't pay €8.00 for it at all... I wouldn't pay €1.00 for it...
2.3	436	When I was on pens, I was doing carb counting on pens, and I'd still rather just write it all down, than to use an app for it because that just doesn't look good enough...
2.5	437	Especially if you're getting a crap report at the end of it.
2.5	428	IT looks very manual... Yeah. Like you've six things in the first screen you need to populate...

3B(iii) Negative attitudes towards the bolus calculator as a feature

ID	Line	Quote
1.2	482	Given the fact from what we're all saying here, it's very difficult to actually get an accurate number here, and nobody really trusts what the number's going to be... Is there a case for... that's actually not a feature that people would want because you can't get an accurate number - you can't get an accurate - you need to reduce your... you need to take x units, or you need to eat so many grammes because really there's not enough intelligence here to understand everything that's going on - to be able to come up with that absolute number...
1.1	389	I don't know about other people here but I won't say never ever...it's dangerous taking...for me it's dangerous taking insulin up to three hours before I go exercising - also, I generally don't eat because I get upset, even if I was really, really hungry, I'd try and eat as little as I possibly could, but I'd hold off until after I exercised. Normally, I try to have no active insulin in my system before exercising. The occasion on which I would be doing this would be very rare.
2.2		I can't have insulin in my system when I exercise. 3 hours... I can't put insulin near me for 3 hours beforehand. I'd have the Lantus in my system, and that's fine, but I couldn't have the NovoRapid for 3 hours - I couldn't inject myself within 3 hours of going to do a class.
2.1	460	Yeah, and when I was on pens, I was the same - not so much for the NovoRapid, it was the Lantus that killed me. It was how rigid Lantus makes your life... you can't even decide you're going to play football with the lads, or if something came up, or go for a run or whatever, I had to eat my way through everything because of the Lantus.
2.2	464	I find I'm ok with the Lantus, it's the NovoRapid I have to keep cutting back on, and watching, and I can't have it in my system for 3 hours... that's what kind of drags me low.

1.2	395	They've got it the wrong way around. So actually what a lot of people would needing to do is to bolus carbohydrates, rather than bolus insulin. So how much carbohydrate should I eat to get me through? It's probably the question more so than how much insulin should I take. Now I know it's not for exercise - the purpose of it is not for exercise as you said, but actually, then it comes back to the problem that people are having is that they are going hypo during the exercise, then what you need here is a carbohydrate bolus- calculator. So how much carbs should I take on before my exercise, or during my exercise? or during my exercise? That's the question that you need the answer to. And then, this comes into play I guess afterwards - so if you're somebody for example who is struggling with hypos in the hours after the exercise, then absolutely, a bolus calculator is useful then.
1.7	445	The other thing I was thinking was something like this app is close to what I was imagining coming in, basically about a bolus calculator to inform me before I go into a session, but there's just not enough functionality or being able to tailor enough...and that's probably the problem with all of these apps. Because I've exercised the day before, maybe I need 10% less...if I've exercised both days before, I need 20% less...and if I didn't know that, the app probably doesn't even know that so I think…(interupted by Brian)

4. Ideas / suggestions for an app and potential barriers

4A. Possible ideas/ suggestions

4A(i) Syncing other technologies to app

ID	Line	Quote
1.1	67	It would be brilliant if you had Carelink linked to a fitness app for say Garmin, linked to an accurate food app, and you could superimpose all of them on top of each other - so you could have a good analysis of interactions between your blood sugars, your activity, and your food, and your insulin... and any other events that you care to record as well. They're the four important things...if you could figure out just what's going on, and of course each day of the week, using that information agreed...
1.2	83	if there's a way that whatever the information you're trying to collect from a patient, that you can get it without having to ask them, I think that's massively important.
1.2	88	some of the devices now, like the FreeStyle Libre for example, you can scan that now if you have the android app and you can get all of that information...some of the pumps now send it directly to the phone, that's the way it needs to be. That's where the examples start to become less of a burden on people to have to put in the information manually.

1.1	205	A couple of other things is the information in the metre or is in the pump for the CGM - it would be good if that was, with the permission of the owner, which is the patient, diabetic, that information can be released onto apps just either down the line, or some sort of link is created so that the app can suck all the information from that into it. Medtronic I think are doing it for some of the pumps, but not for others - not for the one that I'm using, which is a pity. It would be good if the app could let the information be...
2.1	56	my thing about this age of technology that we're in and there's the libre that you can swipe and my pump talks to my reader by Bluetooth, yet nothing talks to my phone. I would love if I had an app that could correlate all that data in for me without me having to really do anything...
2.1	61	every time I test my bloods, it's registered on the phone. Sure maybe then, kinda like MySugr, I could go back in at night time or and go right, ok, that was alright and might write it in, that would probably drive in food stuffs...
3.4	44	Yeah and then I suppose from the fact I was only probably pricking my fingers for maybe a month or 6 weeks, and doing it 5-6 times a day. But now I can't get my head around how... you don't really know what's going on in between those periods, it could be 3 hours before you... and it could be going up and down like that, so you could check yourself at 9 O'clock in the morning, and you could be 5, you could check yourself at 12 and you could be 5, and you'd be like oh that wasn't too bad but then you don't know what happened... but the app shows you what happened like you know so as I say, being so new to it that I can't get my head around how people pricking their fingers, it's only giving you that reading there and then, what's happened beforehand, you don't really know. So... (referring to the libre)
3.9	286	I really think that the Libre, where it's actually almost, it's actually live, because you're actually measuring, and you're getting results from your blood sugar, because what is an app supposed to be? I mean if it can actually tell you what the blood sugar is right now, and how you're trending, I think that's something that would be really, really important.
3.4	392	that kind leads it back into you really need live sugar levels, you know cos as you're exercising, things change... looking at an app that's just black and white, just …
3.7	395	If you had that live kind of thing, maybe you could start building a trend after that so you know ok, Mondays I'm going in for my heavy day - and I should be... I know my bloods are gonna spike after that heavy day but then see Wednesday, Thursday, Friday, you're just doing your reps so they're not as much, so you don't need to pile on the carbs as much as the heavy day... you know that kinda way and maybe the more you use the app, it sorta learns what you're doing so it gets into the... d'ya know what I mean, and you can sorta see on the screen well today's your heavy day or today's trending that you're gonna be high, so take maybe less after... less... you know your bolus after and all that kind of stuff. I think that would be...

1.4	800	if you had a smart device that's recording this, that the app could be compatible with - for example, your FitBit in essence, you can see what you did every day. ...Also, for those not on a pump - I'm one of them, then the machine or the blood sugars should be read in Bluetooth into the machine so that you're not going in and putting 6.2 or whatever it is so that it could upload over it so you get the data, without someone having to sit down and input it.
2.5	633	I definitely think the Libre... that kind of I guess just scan, and you can see what your blood sugar is straight away or like a finger prick is a really good idea and I guess maybe that you can set your targets that when your blood starts going below 5, you get a notification to say look - your blood's starting to go a bit low. If it goes above - your blood's starting to go a bit high. For me, that's something that I would be interested in. I think once you have that then the exercise will come a bit easier.
2.4	697	But if that linked to more detail... like an exercise app, but it was on the same device, where everything linked to my phone - I think it's just having it all as one thing, rather than going constantly between different apps or machines...
2.1	709	if somebody could give us a little attachment that we could stick into our phone, and I wouldn't have to carry around a blood glucose meter any more.
3.4	435	I just think, without live information now, I don't know if there is a future for another app... I dunno, I could be wrong
3.4	440	I just can't see anything really, without live data, really working, I mean if you're doing a class - 40 minutes or whatever, you know half way through it, it'd be nice to get...the phone starts ringing in the corner... But if your phone started beeping in the corner or something like that 20 minutes in, like you know, it'd be great like, cos it's showing the trend's starting to go down - warning you this is starting to go down quicker than it should be
3.4	463	Maybe it's probably an app that works with - you know I'm not saying that the Libre is perfect, but maybe there's more information that... they don't do anything for carbs counting or anything like that on the app so I'd say it's probably an app that would work with something like a Libre, rather than by itself, you know.
3.4	487	I suppose, what I'm saying is, it's kind of pigeon holing everybody down the Libre route, but I can imagine, like I wouldn't say we're too far away that like in 5, 10 years that we'll all have... even non-diabetics, we'll all have something stuck to us, and you can scan and tell your cholesterol or you know your temperature or whatever, and you know that's gonna be how... they have this for diabetics now, there has to be something like that that you will have some thing stuck on you and everybody will be scanning themselves for this and that you know. That can't be too far away really.
3.9	490	I think that's been a positive disruptive technology, and now that you have it, you're nearly starting from there. If you were starting from a year ago, or whatever it was, getting to there, but now you actually have Libre, so if you're inventing a new app, it's gotta be Libre plus...eh... in some way...

3.10	554	The great thing is it actually tells you if you're down trending, a finger prick and say you're 8, you're like happy days but if when you scan you see it's going 12 to 10 to 8... you're like I better take a bit of glucose and then continue the game
3.1	557	It is quite good, cos it has the arrow, and it does tell you that you're trending, like I notice when I go out on the bike - I try to go out - I tend to go out high, trying to keep my sugars high, so that I would use it and then it'll start dropping and then I'd stop say an hour in, scan, and I might have gone out at say 10 or 11 blood glucose and I'm at 4, and it's the arrow pointing straight down and says you're dropping rapidly, and I take a gel, and I go off again, and then I scan again, and I might still only be at 4.9, but it's showing that I've gone up, but have come back down again, and I'm still dropping and just to keep your eye on it.

4A(ii) Differentiate between insulin regimen and type of exercise

(different profiles for insulin pump users and MDI; different exercise types)

ID	Line	Quote
2.1	514	Just sitting here, thinking this evening, what would prompt me to buy a diary, sport/nutrition app - possibly something that would have maybe different profiles, one for pen users and one for pumps… all within the one app - one for pens, and one for pumps, purely because some people seem to switch between the two and there's two types of type 1 diabetic management
2.7	597	I think definitely aerobic, anaerobic, are you on pens? Are you on the pump?
1.2	553	One of the things I find annoying with apps is when they ask you for information that you don't have or can't give it - so if it knows that I'm on injections, it shouldn't ask me for that, because I can't give it that information, I can't say whether it's going up or down. So there should be somewhere in your settings - or in your profile or something that says what type of therapy you're on - you're on MDI, or you're on pump. Say I'm on MDI - when it's asking me about my blood sugar before exercise, just ask me what my blood sugar is, because if you ask me if it's going up or down, I can't tell you. It's about just being a little bit clever about what you ask from the user, so that you don't (a) annoy them, and (b) make them feel like there's something I should be putting in here but I can't.
1.2	573	So don't give any suggestions based on reducing your temporary basil rate if I don't have a pump. So that it's a filter almost that you can apply to the suggestions.
2.7	535	And then anaerobic versus aerobic - it would need to divide between those.
3.9	290	And I think the type of training... I just think that that's...like the difference between doing an interval session and doing a long run is just light years...on the effect it' s gonna have on you.

3.10	360	I wonder if one of the options should have been mixed exercise instead of light, moderate and then mixed where that can be defined by the user - mixed exercise for one person would be completely different for another user.
3.10	404	Could all our exercises be categorised as aerobic, and aerobic and mixed? Because, like it makes sense to me when I read about aerobic and anaerobic from the likes of... you're going to deadlift - you're going anaerobic for sure. If you're doing it just for reps, small weight, you're definitely going aerobic, d'ya know, whether that makes more sense... and then add light, medium or intense onto that. But then it makes the app more complicated, because if the app is geared to exercise, yes, it makes a lot of sense. But then you know aerobic, anaerobic, mixed... light, moderate or how intense, and then it starts making more sense.

4A(iii) Advice based on your profile

(advice/prompts/reminders based on your profile/history/needs/requests)

ID	Line	Quote
1.4	133	you need to tell the app what you're looking for and give you the information in a way that suits the question you want answered. So we need to understand exceptions, because if everything is running within the ranges, then we don't need to do anything with the information, it can sit there. But once it goes outside the range of normality, then we would like the thing, the app to advise us, and then you can go dig deep into that area. But once the norms...the information you needed for the models and the graphs, it's not useful to run through a whole list of readings...
1.4	146	yeah it's big data, but it's about trying to tailor the app or being smart enough to understand the questions that a typical person would need answers to. Just to build on that then - you're then into the area of predictive analysis - so we're using the past to drive the history with algorithms so that might be something of interest so if it's today, or whatever day it is, you've typically done this exercise so you've arrived at work, and you've cycled in, then your range should be within this...and you can get an alert then for that kind of thing....that might be where the app might take a little bit more of the control statistically, that the human may have done in the past.
1.2	164	if the app was to know that the problem you're having is that you've always or tend to have hypos at night, after you exercise - then maybe for example, the type of feature that the app needs is a feature to say to remind you to check your blood sugar two hours after exercise. Whereas, if the problem is that you're having hypos before you start exercise, what it needs to do is to remind you to check your blood sugar before you exercise. So information without putting it in the context of what you need it for is kind of...it's there in front of you, and it's on a graph, and I've got a history...but how does it help me with what I'm actually struggling with?

2.3	176	One thing that I think would be good though is if it prompted you, if you got a notification saying have you checked your blood sugars today? What is it? and then maybe you'll log it there and then or something. Once you see a reminder - because that was one thing I always forgot about... I wouldn't even think about it. I wouldn't even log it that way. The way I have it now, linked with my phone, I'd go oh yeah, I forgot about that. Then I'd just turn on my Bluetooth, and then it links straight away.
1.5	503	That makes a lot more sense - because it's like predictive prompts and hints based on the history that you've got so it's your history, it's your record, so it's telling you you go to the gym on a Monday morning and at 3:00 you're gone hypo, and this happens to you every single Monday, you know, wake up, and look at this...
1.2	507	Last Monday, you did exactly the same exercise, at the same time, and you tried this, and your blood sugars went high. And it could suggest maybe this time, try something different...and give a suggestion as to what that might be based on the outcome. And where you're kind of getting out of the having to come up with the accurate calculators and calculations then, which are just not going to be right.
2.1	521	if you could key in your stats - weight, height, blood pressure, heart rate... all from using some of the addendums onto the app and then your current glucose readings etc. and the level of exercise that you're going to do and if the app, no. 1 could learn with you, (you would have to be true to the app) but let's say you were going to do some sort of circuit training and you could key this in in some way, shape or form into the phone, and then do your blood glucose and your heart rate afterwards, and the app would learn with you and help you plan then for if you do have a weekly exercise routine, that it could say well you know on a Tuesday, you should be eating this amount of carbs for lunch, because you're going to expend it when you're at your football or your training or whatever. That to me is something that's working with me and helping me grow...So it's learning how my body reacts to the exercise I give it and also to the carbs that I give it.
2.1	605	But that's kind of what I was getting at - if you could... I know you're asking a machine to be predictive, and it's never going to be 100%
		where people who are doing mixed will know that this is unpredictable and warning check afterwards or something like that. Simple as check after exercise. I've read something interesting as well regarding that is the pre-exercise levels, and what you should do. Some like there are different parts of it, not found something really... I don't know if you know of anything like that. Where if you're 16, what you should do, if you're 12, what you should do, if you're 8, what you should do, if 6, what you should do. Do you give a correction or not, do you eat something or not, I suppose everyone uses their own judgement for the time being, but is there any kind of guideline? Can that (referring to guidelines) be integrated on the app?
2.4	763	If an app tracked trends...and then it prompted you, it gave you feedback on the trends they pick up because …. even with the Libre, it gives me all the information I need, but I don't go back at the end of the week and review it all and make changes, I just don't do that. So if it prompted me to say ok well you've had three lows last week, at 5pm, maybe you should reduce

		your lunch time insulin or you've had high blood sugars at this time... rather than me going back and checking.
2.7	769	Pattern recognition - that's quite clever isn't it
2.1	796	So then if it's building a profile all the time, and you're saying well I'm on a pump, or I'm on pens and I'm on Lantus and I'm on NovoRapid, and I had 24 units of Lantus at noon, and whatever NovoRapid for a couple of meals, and let's say you were going out playing 5-a-side later on that evening - and you sit down and have your meal and you say well yeah, well I had 8 units of NovoRapid there... into the bolus calculator and I'm saying well...let's say for a pen user, I would expect it to be saying you need to take 45g carbs now, before you go out and play that match. That'd be good. Or for a pump user - it'd be saying well you'd want to drop down to a temporary basil of 10, 20, whatever...
2.1	819	Now if you can encompass that - both the nutritional side of the house, with the exercise side, and then bring in your bolus calculator as well, split down between your pens and your pumps... And you see if the app can... if there's some AI out there (and I don't know if there is) that can factor in well ok, looking by how you're trending, from the information you've put in, I wouldn't suggest weights today...you should probably go for endurance training or you know, whatever... that it might suggest a different style of exercising, and here's a couple of things you could do...
1.2	185	if somebody says the thing I struggle most with is hypos, in the evening, after exercise, then to be able to show them the right piece of information - there's loads of information out there say on the Runsweet site for example, but reading through the whole Runsweet site...there's a lot...and there's probably 10% of it which is specific to the actual problem I'm having at the moment, so say as somebody who had just started exercise and they were having hypos after exercise, they don't need to read the whole Runsweet site they just need to read one page or piece of information that says...after certain types of exercise you may have low blood sugars because of this and here's what you should maybe think about doing. If they say that's the problem I'm having, then show them that piece of information...condense down what they need to know and then give them that. You don't need to give them all of the information. That's another mistake a lot of the apps make is they say go into some section in the app and you can learn all about diabetes.

4A(iv) Suggestions rather than numbers/percentages

ID	Line	Quote

1.6	245	Or giving you a suggestion at the end like if you say you know, you do that exercise, you'll notice you're going low? On average 4 or 5 days at that time - be active, check it. It gives you an action at the end of it to...rather than giving you graphs and graphs and graphs and all this information...it could say the last four times you've done that exercise - you've gone low three hours later...that is an action for you to do something. It's time for action, for you to...why don't you try this? and that way, I think you would...people would pay for it.
1.2	488	... Maybe it's a case of thinking about it more, in a general sense... So I'm gonna do a certain type of exercise - the evidence based advice for what happens during that type of exercise is as follows...you might want to consider doing this... particularly for people starting off - you might want to consider this... and you say ok, and you can say I'll do this, or I won't do it... and then at the end of your exercise, you say what happened. Every time you say I'm gonna go and do that exercise again - the app will tell you well the last time you did it, you followed the advice, and this is what happened... This time around you might want to try something else. But without getting too specific so it might wanna say try reducing your basal rate beforehand, or try eating 30 grammes of carbohydrate before starting... There's a few different options that you could have... so it's a question of maybe suggesting something, the person trying it out, and seeing if saying yes that worked, or no, that didn't work and then the next time you go to try and do it - the app's remembered what you told it worked or didn't work, and you've never got into the case where you're actually asking, you're giving them a specific number, or a specific percentage... because that's never going to be accurate.
1.5	509	Yeah, that would make more sense - you'd be more inclined to believe that rather than it telling you a percentage...
1.2	530	A recommender, or advice recommender type of system...
1.2	545	It should give you a suggestion, and the suggestion should be based on the body of evidence that's there which would be plenty...
1.2	574	In terms of suggestions then, so what would need to happen... so try a, b or c... three options let’s say - so maybe the patient needs to say well I'll try a - this is what I'm going to try today.
1.2	581	Well the suggestions are based on the evidence that's there . It's not based on your history at the start at least, it's based on what the experts know
1.5	590	No, but it's a good guide - I mean suggestions that they make more sense than specific numbers which you can never trust anyway...that there's too many variables to get to that number so I think suggestions - they're more practical

1.2	688	I'm just trying to think through on the suggestions idea there... so if I said I'm gonna try a. So I do a - let's say a says take your blood sugar is 5, and you've said you're going for a 60 minute cycle, so probably the suggestion there would be to take on some carbohydrates or on a pump... so that might be a... b might be (if you're on a pump) could be set a temporary basil - so I could say I'm gonna try a. Grand, I go off I do my exercise, and we need to know whether a worked or not? So when we come back in for our exercise then, the app should maybe ask us or remind us, or we need to tell it what happened... So I tried a - and a worked or didn't work, maybe we could say tick, or x or good or bad... and maybe say what our blood sugar was finishing up which might be a reasonable couple of things you need to enter. Based on that then, so next time you come along, and say next week I come along and I'm gonna do a 60 minute cycle and my blood sugar is 5.5 or 6 or something... the app should tell me here are the options - last week you tried a - and it worked. Try a again. So it should remember what we did, and then tell us what worked. Whereas, let's say we're the opposite case - let's say the first week, I tried a, and when I came back in, I take on the carbs, and my blood sugar's still dropped that I had too high a pulse, or my blood sugar was 3 when I came back in from a cycle or something... it didn't work basically...without getting into the details, but no, it didn't work. When I come back the following week, and I say I'm going for a 60 minute cycle and my blood sugar is 5.5, similar to what it was last week - the app should say here's the options - last week you tried a - it didn't work. Try b or c this week and then I'd go through that and do it again and I'd say I'll try b, do b, it works...
1.2	712	what's important here is that the person who wants to do the exercise, was able to go and do the exercise, and they finished up the exercise, and they were happy that they were able to safely exercise, and that their blood sugar was in a reasonable range... now for some people, that reasonable range is gonna be different to others.
1.2	737	It's just about giving the right suggestions, initially based on the evidence, and then tailoring those suggestions based on what worked or didn't work and what works and what didn't work is definitely, in my view, it's a subjective thing to an extent.
1.5	930	I like some of these ideas - I think there's something that really can be developed... the general consensus here tonight seems to be suggestions as opposed to trying to get into specific numbers... they would make so much sense.
1.2	935	It's soft data, rather than hard data - because the hard data won't be right.
1.5	935	Because I don't think any of us would have trusted any version of this... so if you were trying to get into numbers, you'd only be producing another version of this - perhaps with a little bit more data, but you couldn't adjust for the variables, so it's still not trustworthy.

4A(v) Simple to use / user-friendly

ID	Line	Quote

2.7	151	It's trying to simplify it just so you do keep it up. Because the more complex it is, the more you won't do it.
3.9	217	I think if it's not user friendly, you're not gonna use it, like even looking at Cathal's - the Libre, like that's user friendly. You can just look at it, you can look at the graph, you can look at the... even the size of font on it, 4.9... and so I think user friendliness is really important. Actually, I think it's got to the stage where if it's not user friendly, you just tune out of it very quickly.
3.4	228	I'd say, to make it more user friendly, maybe have just everything on one screen, so you're not going from this screen...and you go into this screen for the exercise, and this screen... if you could somehow have everything on one screen, you're more likely just to go down through the one screen, rather than going right I've done this part, now I have to go to the next part, and the next part, and you know you lose interest pretty quick, but if it was all on one screen, you might just flick through it a lot quicker.
1.5	825	You don’t have to start at perfection just improvement
3.9	601	And on the reports which...we talked about user friendly is just having information that's just user friendly. Like sometimes, more is actually less... more information, or more data, in the non-friendly way. Sometimes less is more actually, the opposite, sorry.

4A(vi) Consider the user and marketing

ID	Line	Quote
1.2	282	It's an important point actually to think about who the users are, because, from a demographics point of view, but also from a point of view of people who have just been diagnosed would have totally different needs from people who have had diabetes for a number of years and are exercising...and then people who are doing exercise for just recreational health benefits would have totally different needs from people who are more seriously into their sport...so it's worth thinking about who the users are that you're aiming it at because again, they will have different needs, and they won't always want the same thing.
1.2	291	I know from experience that starting off - when I was diagnosed, I was logging everything, so the ability to record stuff very detailed was important and I think it probably is for a lot of people when you're starting off. But once you get the hang of it, and you know what's going on, you don't need to record it to that extent...then you get seriously into sport, you start looking for things...well I want to know how do my blood sugar and heart rate correlate for example so if my heart rate is high, for an extended period of time with different types of exercise - how is that affecting my blood sugar? How does lifting weights and the stressed response affect the hormones and blood sugar response later. But that's more...call it advanced usage of it, and it's totally different from the basic needs that people have when they're starting off...I think you just triggered there, when you said about different types of users, and different types of people -

		there's lots of different types of people, and they will have different needs on it.
1.2	611	So the value for this will be more for people starting out, and over time, once you've figured out what's worked, the value's going to be much less to you, because you're gonna know... you're gonna have gone through these suggestions and figured out whether a, b or c works for you when you do this type of exercise, at this time of the day or whatever it is - you'll have figured it out. So it kind of goes back to who is it for? If it's for somebody who's starting out, there's more value for them. There's less value or less benefits as you go on, and start to be more familiar with the exercise and use it for
1.2	629	At the same time, if you decide to do a new sport, or a new type of exercise, you'll probably go back to it. So you might use it for a while, you figure out what to do, what works for you, what doesn't work, you might not use it again for a while because now you know what works and then let’s say you decide well I'm gonna take up swimming or something - you'll probably go back to day zero again almost at that point and say right, I'm going to be swimming today - what the hell should I do? So you'll maybe go back to it in that sense.
1.6	636	I think it's how it's marketed though, I mean that's in my view, if there is something to help a diabetic not be afraid to move - be it in the gym, in the pool...that in itself is a fantastic achievement.
1.6	638	The other thing is... the back end of that is that I have diabetes 35 years. It has changed so many times with age and with all sorts of things, that boy I pick up something new every single day. So I might, as you say, drop it for 6 months or a year, or whatever, then I see it and I pick it up again that's how it works. I've changed, so again, I'm gonna go back to...it is the audience - but market it to...there's a huge... I mean I know when I started heavy exercise, I was afraid of my life... I was... no, no... I can't do that... I can't do that... and then I found actually, I can... so if you can get that message out - if that's the message you want to send - that's positive isn't it?
1.2	646	Yeah, I think that's important - to market it correctly and stuff. What the purpose of it is, so if it's to break down barriers around people being able to be active and exercise... focus a the goal of the app but also the messaging around how you market it, and how you advertise it and how you put it out there - based on that...

4A(vii) Additional features

(nutrition advice, logbook, motivational aspect, social networking, success stories)

ID	Line	Quote
3.7	71	it has the calories and carbs and fat proteins and all that kind of stuff on it so I mean trying to pull some of that into what we're trying to do would be helpful. D'ya know what I mean as... what you can eat before and after your exercise, you know what I mean...all the different kinds of exercises you're doing whether its aerobic, anaerobic... you know what I mean, stuff like that. (referring to carbs and cals)
3.8	118	But if there was another app kinda suited more for the diary, it'd be so much handier, because you can just track then and there, rather than bringing the diary with you and all this stuff. Especially if you're not on the likes of the ones that like scan like you're just on the normal em mobile devices, rather than going back all the time.
1.2	759	I think it's important to when people start to say yeah, I tried that, and that worked - that you can show them that over the last month, you've been successful more than you've failed. Because then people say right, well actually, I can do this, because I'm being successful more often than not, so you're showing progress, you're showing that you're winning. That's important for people from a motivational point of view
1.8	850	I'd like to do something on it that by say, I'm a runner, and you could log and say I'm going for a run, and it could flag up on the app that Brian's going for a run...and oh jeez I'd love to meet him - and that two type 1 diabetics could go for a run together... just for training... that you know that there's someone there with you that they knew exactly, if you got in trouble, what to do.
1.6	894	you could do something - build in and say somebody has done that half hour walk in your area, and they're type 1 and you don't have to say who they are, their blood sugar was that... and they were successful.
1.4	904	So you're moving into some sort of a social networking site around diabetics and exercise...
1.2	860	what I found when I was starting out with the exercise, was that seeing how other people were doing it successfully was really, really helpful. Whether that's other people that you meet... or stuff from the web, say for example, Team Novonordisk the cycling team, all that kind of stuff - I remember reading the guy who runs that his book, and stuff like that is very, very helpful and you sense well loads of other people can do this - so can I. So it's about having success stories, so if you can see that other people are doing it, if you're starting out, and you're not sure, being able to see that and maybe get some... read about how they go about their day, and how they structure their runs or their cycles or how they manage... and a lot of these guys are into their high-level...there's plenty of people who blog about it and that kind of stuff... success stories and that - to have some sort of a section where you could do that I know you can get it on the web or whatever...

1.5	875	If you're finding the vast majority of people with type 1 do far less exercise than the general population for the demographics that they're in... even just, not everyone's going to be an athlete. But to show them that regular people can go for a half an hour walk, 3 days a week, it mightn't be a huge amount, but you need to get going in the first place, and if you're afraid to exercise, maybe you need to see just the ordinary, bog standard just walking down to the shop and I came home and I'm still ok... and then you can build up if you're so inspired...

4B. Potential barriers

4B(i) Burdensome

ID	Line	Quote
2.1	76	I'm one of these people - I wouldn't keep a log book going or anything like that. If I was sitting in with one of the Reg's or whatever, I'd go through my meter and say that's what happened...not that you don't need any more information than that but…
2.1	231	The thing we get through to... all this stuff... all the technology that's out there - as long as I've been diagnosed, it's all been available to us, but you have to install stuff - I did it when I was diagnosed, and full of gusto, and didn't want bits and pieces falling off... I was logging things on the laptop, and downloading...or they send you out CDs for.. sort of home-based software that they have to manage your diabetes, but that's a nuisance, writing stuff in a diary and then going back and doing it... I wish there was an app...and now there is an app, and I'm still not doing it.
2.7	238	You go through phases, it's hard to be like that all the time... consistent... because with the pump and the CGM, I've got CareLink, and I've only logged in once.
3.6	144	Oh I'm just listening, I didn't know any of these apps existed...d'ya know what I mean... but like that now, I couldn't be arsed sitting here, trying to fill in loads, and loads and loads...you know - I'd just say ah feck it and I wouldn't bother. So something that's kind of easy enough to kinda... that you don't have to fill out your life's history... perfect. D'ya know what I mean...
3.1	164	I've checked that a long time ago, and never used it again or looked for any apps, but I feel like already I'm using a pump, so I'm kind of inputting the carb and the blood sugar level and the amount of insulin already in one device - if you put it that way, you can download that device. I don't see the point of downloading or adding more information, I have a device and then trying to mix the two...I suppose... I don't know if any app kind of can merge with your other - it does not do that, or you'll have to print two pages and bring it separately I suppose to your consultation. You just prefer keeping to one and using that and you're doing enough effort, putting all the information as much as you can in one device... more and more I suppose people are using devices from Libre to pumps, you're kind of sticking to one and just kind of... though it might be limited, not giving you a carb count or anything like that, but...

1.2	791	If you can minimise the set of data and make it easy for people to put it in - that's too complicated, there's too much stuff they're asking for there, the forms, the yellow books, there's too much stuff to do - a lot of the apps are the same. But if you can, and I think it's where the user interface design and how the app is designed is important but it might ask for only the minimum set of information, and make it very, very simple for them to tap into your information
2.4	690	See with that app - whether you have a pump or a pen, if I'm using my pen and then using the Libre, I don't want to then go to the app... something that links them... sort of having the option to link to something else. Because with the Libre, if I scan and my sugars go up, you can tick a box to say fast-acting, long acting, exercise... whatever... you can tick to say and then when you look at the graph and have like a little apple, or a little pen... but where you've taken
2.4	741	That's the thing with the app as well - I know everything seems like an effort, that's what puts me off all these apps as well. Every time I eat, and I have to go back in... move everything up and down... change it around...but if you don't do that then what is your app learning from you? If it just says I've taken insulin now, it can't do anything else unless it has actually all your information. I think you just have to put the work in
2.3	756	Because that's one thing that bothers me is the consistency of having to do it all the time. Sometimes you miss logging a meal and then you go ah I've to go back and do that. Then sometimes, you might put that off for nearly a week and you might just not follow it at all.
2.1	543	But all those apps like Strava, and Map My Run and Map My Ride - they're all based on you carrying the phone with you at all times, so it's monitoring you on GPS but...
1.2	96	They may be for some people, in some cases, and maybe if you're starting off, and you've just been diagnosed and you really need to put the effort in to start to understand...you know I'm sure everybody went through the yellow book, and we all had to write in the yellow book for God knows how many months starting off right? But you stopped doing that after a while, and there's no way you're going to continue to do that forever and we shouldn't have to now with the technologies out there...

4B(ii) Complex / Many variables

(everyone is so different, leading to lack of trust)

ID	Line	Quote
1.2	452	That’s the problem with diabetes in general, with type 1 is that there are too many variables. And the variables are different for everybody. So it's very hard to design...there's too many inputs, too many things...so it's actually very difficult to come up with a calculation which is correct for everybody let's say...it's going to be very difficult.

2.1	507	If I was looking at an app like that Mary - if I'm looking at an app to download it onto my phone - I want to know what it's going to do for me. What's its primary output? Its unique selling point? I want it to do something for me.
2.7	553	It's hard, because everyone's so different. I've only been on the pump 6 weeks, so I've worked out some things, like if I'm going for a steady run say a 5 mile run... 10 minute miles kind of thing - I need to have it on 20% otherwise I keep going low. I figured out the other day from walking that walking is not that great but it's better than you'd think so yeah, I should've went down to 50% because I had to have Dextrose when I was out getting lost by the Dodder...so that for me is like running 20%, walking 50% basal rate if I'm doing it for 40 minutes or whatever. Then if I'm going to Pilates, or lifting weights, I don't take anything, and I don't tend to go... I might creep up a little bit...but I know that it will come back down, so I don't panic. But that's me - I know other people are different, so I do think that even though you could try - and I'd definitely differentiate between pens and pump...
3.9	281	I think sometimes averages or... just don't work. So it's even with... you know I know from training teams, training people, you have to say well I can actually do this, it'll give you that...but there's other variables, your mood, you know, other issues...stress levels...and I know even with athletes or some of them that I train anyway, if they're after being out an having a skin full of drink the night before, it's gonna be different...how the session is going to react on them, so...
3.4	309	I think it's hard to trust anything really, especially technology - take a look at everybody here, we're all very different, and I'm sure we're all very different in how diabetes affected you so to trust... trust is a hard thing, I think a lot of the apps and stuff... even the Libre, you have to... it's more of a tool to help you along rather than...you can't trust it 100% all the time, you know, or any app really. So yeah, it's probably hard to trust everything 100%, I think it's just there to help you along really.
3.7	383	I think it's gonna be hard trying to get the right exercise you know what I mean like with your pump or tone or whatever you're doing if you wanna just get on a treadmill for 40 minutes or you wanna go out and dead lift 150kg, how you're gonna try and build that into an app is gonna be a challenge in itself. That's what it is. Because it's all well and good saying weight training... what kind of weight training are you doing? Are you on a heavy day? Are you on just a rep day? Are you on a break kinda thing, you know what I mean, what are you going out to do? It should be I suppose, being able to tailor it to your own needs I suppose...
1.3	746	I do think it is really good to have it more general, because for me, I find even it depends on the time of day that I exercise, on top of the type of exercise that I'm doing. So if I go for a run first thing in the morning, I actually need to take insulin before I go, even if I'm not eating. Whereas if I was doing that later in the day, I wouldn't need to do that. So to get into nitty gritty could be dangerous I think. So I think it is good to keep it as a general guide.

4B(iii) Lot of information in one app

ID	Line	Quote
2.1	544	you'll probably find that very quickly you'll come up with a plethora of stuff that you've to try and squeeze into this one app and then maybe your output again is... if it becomes unwieldy...
2.5	832	I think it's a lot to try and put into any app - especially if you're budgeted to a certain amount as well.

4B(iv) Keeping app updates

ID	Line	Quote
1.4	593	There's a few things to consider...is whose going to keep these things consistent so as medical opinion changes, will the algorithms have to be adjusted? Or a set of suggestions improved or whatever...
1.2	605	I know the clinical evidence for these kind of things tends to move quite slowly - so you're not going to get new suggestions every couple of months or whatever, then it's just years before they update this stuff...

4B(v) Syncing other devices to app

ID	Line	Quote
1.2	817	It's all there, and it all lives in its own little silos...and they don't really talk to each other... so that's sort of the issue. The data is there - data can get from a pump or from a sensor, to somewhere on your phone - and then making that available to other apps is doable, but it's not straight-forward. Whether it's in the scope of what you want to do or not...but it's another level of technology that you've got to put into it. But ideally that's what we...
2.1	721	... like there's no compatibility between... you're on Contour, I'm on Accu-Chek, you're mobile, you're mobile as well...

5. Miscellaneous:

(anything else of interest which does not fit in the above categories)

ID	Line	Quote
1.2	266	I'm kind of just broadening out the problem - rather than constraining to the solutions an app. The problem is that people are having problems controlling their blood sugar around exercising - doesn't necessarily mean its solution is an app
1.2	274	I don't know what the other options are but one of the things we've said is we've all tried apps to some extent or other, so it might be useful just to

		maybe keep the box open...in terms of maybe the solution isn't what we think it might be.