Oral Disease, Treatment Need and Function (ODNF) index for oral health data collection by non-dental assessors in adult population with Intellectual Disabilities (ID): validity, reliability and feasibility study

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Dr. Nurul Sa'idah Ishak
BDS (Otago), MFDS (RCS Edinburgh)

School of Dental Science
Trinity College Dublin
University of Dublin

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Dr. Nurul Sa'idah Ishak

Date:

To my late father-in-law 'Bapa' (1950-2017)

& my late grandma 'Nekdoi' (1944-2018)

"Indeed we belong to Allah, and indeed to Him we will return."

(Qur'an 2:156)

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ABSTRACT

TITLE:
Oral Disease, Treatment Need and Function (ODNF) index for oral health data collection by non-dental assessors in population with Intellectual Disabilities (ID): validity, reliability and feasibility study.

STUDENT: Dr. Nurul Sa'idah Ishak
CO-SUPERVISOR(S): Professor June Nunn, Dr. Caoimhin Mac Giolla Phadraig

BACKGROUND:
The oral health status of adults with intellectual disabilities is poor. In Ireland, there is a paucity of oral health research with this population, largely due to cost of dental surveys and thus there is little re-orientation of services to improve oral health of these individuals. An alternative oral health data collection approach, such as use of non-dental individuals as assessors, has been validated in other groups of population. However, the suitability of the existing tools for use with populations with ID has not been reported. The need for a comprehensive, valid, reliable, inexpensive and acceptable index that can be use by trained non-dental individuals on adults with ID is now recognised.

RESEARCH AIM AND OBJECTIVES:
Aim: To investigate the feasibility of utilising non-dental individuals to carry out oral health data collection in an adult population with intellectual disabilities (ID).
Objectives:

1) To construct an oral health data collection tool that can be used by non-dental individuals.
2) To develop a training programme for the newly constructed tool
3) To establish content validity and to assess concurrent validity for the tool
4) To assess inter-rater and test-retest reliability of the tool
5) To determine the feasibility of the tool; the time taken to carry out assessment, the cost of utilizing non-dental individuals for data collection and the acceptability of this tool by participants with ID and non-dental assessors

MATERIALS AND METHODS:

1. This study was completed in two phases; non-clinical and clinical. The construction of the Oral Disease, Treatment Need and Function (ODNF) index and its content validation was carried out during the non-clinical phase; meanwhile, the clinical phase investigated the concurrent validity, reliability and feasibility of the newly constructed tool.
2. The construction of the ODNF tool for people with an ID involved a systematic review of published literatures on existing oral/dental data collecting tools that utilised non-dental individuals who assessed mostly older people. Alongside the construction, the content validity was established with the use of Content Validity Ratio (CVR) approach and through consultation with a panel of experts, as well as input from non-dental assessors. The new tool and its training programme were then tested in a pilot phase with a population without ID, before finalising it for the clinical phase of this research.
3. Irish adults with ID, who are living in Dublin, were invited to participate in the clinical research phase of this study. Ethical approval was granted by the Faculty of Health Science Research Ethics Committee (FHSREC) Trinity College Dublin, the School of Dental Science Level 1 Research Ethics Committee as well as each of the Research Ethics Committees of the two ID service providers that had agreed to participate. Three (3) non-dental individuals and one (1) dentist were trained to use the ODNF index.
4. There were 49 participants examined, by the non-dental assessors as well as a gold standard dental assessor and a non-gold dental assessor. In order to test for the concurrent validity, dental assessors were asked to carry out the ODNF assessment,

followed by conventional dental assessment (Dentition status and CPITN). Secondly, test-retest reliability of the ODNF was assessed by each examiner repeating the examination on all participants after an interval of 30 minutes. Thirdly, Inter-rater reliability was tested by comparing the results of the ODNF examination results of the non-dental assessors with those of the gold standard dental assessor. Finally, the feasibility of the ODNF tool was investigated by (1) recording the time taken for each examination by each assessor, (2) by considering the expense of both the training and utilisation of the non-dental assessors to use the ODNF tool as well as (3) by considering the acceptability of the ODNF tool to both the participants with ID and the non-dental assessors.

5. Data management and analysis were then carried out using the statistics programmes R v.3.2.2 and Statistical Package for Social Science (SPSS) 20.0 (SPSS Co., Chicago, USA). Agreement tests (Percent agreement, Cohen's Kappa and Gwet's AC1 coefficients) and Spearman's correlation tests were used to determine the concurrent validity, inter-rater reliability and test-retest reliability of each ODNF category. Preliminary cost analysis was carried out to compare the cost of the ODNF assessment against conventional dental examination. Descriptive statistics were used to present the results from the questionnaire, clinical assessments, feedback from both participants and non-dental assessors as well as time sheets.

RESULTS:

1. The construction of the ODNF tool was completed by reviewing relevant items from existing oral/dental assessment tools that have been used and validated previously for use by non-dental assessors. Content validity of the tool was established during the construction with input from a panel experts, use of a content validity ratio (CVR) approach and feedback from non-dental assessors.
2. A training programme was developed specific for this ODNF tool.
3. A high level of agreement with sufficient sensitivity and specificity of ODNF categories 'Tooth count', 'Gums' and 'Visible caries' contributed to concurrent validity of ODNF tool. Further, concurrent validation is needed for the remaining categories.
4. The ODNF tool has a good level of inter-rater reliability except for 'Soft tissues', 'Oral Cleanliness' and 'Gum condition'. Results demonstrated high levels of test-retest reliability for all assessors except for the categories of 'Soft tissues', 'Oral Cleanliness'. Further research on these categories are warranted.
5. The average time taken to administer the ODNF tool was 7 minutes. The tool was found to be acceptable to participants with ID as well as to the non-dental users. Based on a preliminary cost analysis, the ODNF assessment costs 6 times less than does the conventional dental assessment.

CONCLUSION:

This thesis presents evidence that it is feasible to train non-dental individuals to use the ODNF index to collect oral health data from this population with Intellectual Disabilities (ID). The findings of this study suggest that non-dental individuals can be trained for the assessment of Tooth count, Denture wear, Soft tissues (Lips, Mucosa, Tongue, Roof of mouth and Floor of mouth), Occluding pairs, Gum condition, Oral cleanliness, Visible caries and Dental pain. The newly constructed ODNF tool was found to have high level of validity, sensitivity and specificity especially for ODNF categories 'Tooth count', 'Gum condition' and 'Visible caries'. The inter-rater and test-retest reliability of the tool was found to be good except for the items of 'Soft tissues', 'Oral Cleanliness' and 'Gum condition'. The feasibility assessment in this study has shown that the ODNF index is quick and acceptable to use; and may be less expensive compared to the use of conventional dental indices and all that these entail. However, further work can be done to strengthen the validity and reliability of this ODNF tool. Research data on this population are vital to inform clinicians and policy makers in the promotion of the oral health of individuals with ID.

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1. INTRODUCTION

Research on oral health needs of population with intellectual disabilities (ID) is essential in order to inform policy making and actions planning to promote oral health of people with ID in Ireland. Previous research consisted of cross-sectional surveys and cohort studies yielded limited data (Rawlinson, 2001, Crowley et al., 2005, Mac Giolla Phadraig et al., 2014). Ethical issues arise when researching the population with ID, who may present behavioural and communication challenges. Use of conventional dental data collection by dentist has also been difficult mainly due to financial reasons and availability of dentists for this purpose. Therefore, oral examination in a simple manner may be the solution to this problem especially if it can be carried out by non-dental professionals. The Intellectual Disability Supplement of The Irish Longitudinal Study on Ageing (IDS-TILDA) has, in previous waves, undertaken fieldwork utilising non-clinical staff to collect health data in older adult population with ID. Utilizing different health professionals (including non-dental personnel) has the potential to collect data capable of assessing the oral health need of population with ID. Hence, the aim of this study is to explore the feasibility of a novel oral health assessment tool that can be administered by non-dental individuals. This study allowed us to develop a novel tool, named **O**ral **D**isease, Treatment **N**eed and **F**unction (ODNF) index; and to assess the reliability, validity and acceptability of ODNF index.

2. LITERATURE REVIEW

2.1. Overview

The literature review starts by introducing the concept and demographics of ID, before reporting the oral health status of populations with intellectual disabilities internationally and in Ireland, highlighting the oral health inequalities experienced by people with ID. The second section will highlight the importance of oral health research data in informing policy making and action planning surrounding the population with ID and further discussed the challenges with carrying out data collection in this population. The third section discusses the possible alternative to data collection in epidemiological studies of this population, analysing the existing tools, which have been validated for this purpose. The final section highlights the need to do this present research, followed by the aim and objectives of the present research.

2.2. Oral health status of people with intellectual disabilities (ID) in Ireland

2.2.1. Introduction to people with ID

Intellectual disability (ID), as defined by the American Association on Intellectual and Developmental Disabilities (AAIDD), is characterised by significant limitations in both intellectual (general mental capacity) and adaptive behaviour (a collection of learned conceptual, social and practical skills), which originates before the age of 18 (Schalock et al., 2010, Pipan, 2012). Based on the level of cognitive functioning, people with ID can be categorised into mild, moderate, severe and profound level of ID.

Worldwide, people with ID generally makes up about 1% of the population (Pipan, 2012). In Ireland, in 2016, there were 28, 275 people with ID registered on the National Intellectual Disability Database (NIDD), representing about 0.6% of the total population (Central Statistics Office, 2016) and a prevalence rate of 6.16 per 1,000 population (Doyle et al., 2017). Table 2.1 shows the distribution of people with ID registered on NIDD in 2016 by level of ID and gender (Doyle et al., 2017). Table 2.2 shows the distribution of people registered in NIDD by age group. According to the register, 14.4% of those with ID are of age 55 years and above. It should be noted that this database may not be comprehensive in that the data collected is of people who are registered for inclusion on the database.

About 40% of adults in the 18+ age group lives in community group homes, residential centres and full-time residential services which include nursing home, mental health community residence, psychiatric hospital and intensive placements (for those with challenging behaviour and profound or multiple disability). Meanwhile the rest of this population lives at home or lives independently.

Table 2.1 The distribution of people with ID registered on NIDD in 2016 by level of ID and gender (Table adopted from HRB: NIDD)

Level of intellectual disability	Male n (%)	Female n (%)
Mild	5,316 (32.0)	3,864 (33.2)
Moderate	6,743(40.5)	4,881 (41.9)
Severe	2,309 (13.9)	1,689 (14.5)
Profound	467 (2.8)	394 (3.4)
Not verified	1,794 (10.8)	818 (7.0)
Total	**16,629 (58.5)**	**11,646 (41.2)**

Table 2.2 The distribution of people with ID registered on NIDD in 2016 by age group (Table adopted from HRB: NIDD)

Age groups	n (%)
0-19 years	9,142 (35.8)
20-34 years	6,352 (22.5)
35-54 years	7,701 (27.2)
55 years & over	4,080 (14.4)
Total	**16,629**

2.2.2. Oral health status of people with ID internationally and in Ireland

Internationally, adults with ID are shown to have poorer oral health, poorer oral hygiene, more gingival inflammation and more periodontal disease, than their counterparts in the general population (Cumella et al., 2000, Sakellari et al., 2005, Oredugba, 2007). Level of plaque control in this population depends on certain factors, which include lack of manual dexterity, impaired natural cleansing of oral musculature and impaired cognitive skills to carry out independent tooth brushing (Thornton et al., 1989, Shaw et al., 1989, Owens et al., 2006). For those who rely on a caregiver, oral hygiene of these individuals with ID is thus also dependent on the caregiver's attitude, skills, awareness and knowledge on oral health (Thornton et al., 1989, Cumella et al., 2000, Anders and Davis, 2010). They have similar or lower caries experience when compared to the general population (Vázquez et al., 2002, Oredugba, 2007, Cheng et al., 2007, Anders and Davis, 2010), however, the rate of untreated dental caries is higher in people with ID (Gizani et al., 1997, Cumella et al., 2000, Gallagher and Fiske, 2007, Anders and Davis, 2010, McKelvey et al., 2014). They are also more likely to have extractions (more missing teeth), rather than restorations (fewer filled teeth), as treatment of dental caries (Cumella et al., 2000, Cheng et al., 2007, Oliveira et al., 2013, McKelvey et al., 2014).

The oral health status of adults with ID in Ireland seems to follow a similar trend, however data on the oral health of Irish with intellectual disabilities are scarce. Irish adults with ID were found to have more untreated decay, more missing teeth and lower numbers of restored teeth than their counterparts in the general population (Crowley et al., 2005). There seems to be a trend of higher normative need and low expressed need in treatment of decayed teeth (Crowley et al., 2005). What this study did not determine or at least, did not report, was the differences in oral health between residents with varying levels of ID. Very few studies report oral health data by severity of intellectual impairment; limited data on edentulousness was reported by Morgan and colleagues (2012) and indicated a trend towards increasing edentulousness with increasing severity of intellectual impairment (Morgan et al., 2012). Similarly, Diab and colleagues (2017) reported on both clinical and non-clinical parameters by disability type, in a group of 652 children and adults with intellectual disabilities (Diab et al., 2017). Most authors reporting studies that differentiate between different intellectual impairment types do so on the basis of likely cooperation (Francis et al., 1991, Meurs et al., 2010) or by level of function for activities of daily living (Pregliasco et al., 2001).

The majority of adults with ID in Ireland had some evidence of gingivitis with reported higher severity in older age group. When periodontal health was assessed, a similar pattern of periodontal disease severity was also found, in that as age increases, the higher the proportion of individuals who were found to have moderate to severe periodontal disease (Crowley et al., 2005). Simple cleaning or simple scaling, and deep scaling were reported to be required in this group of population. Despite the similar prevalence of gingival inflammation and periodontitis to the rest of the world, more recent, local data are required to assess the need of this population in order to improve their periodontal health.

The level of edentulousness (total tooth loss), especially in the older age group, was found to be more prevalent compared to the general population. In the Wave 1 of Intellectual Disability Supplement (IDS) to The Irish Longitudinal Study on Ageing (TILDA), 165

participants (34.1%) had reported having no teeth (edentulousness), and this is higher than the proportion of participants (14.9%) without intellectual disability in TILDA study. Of those in IDS-TILDA wave 1 who are edentulous, only 38.7% reported wearing dentures, compared to 94.8% of the edentulous participants in TILDA (Mac Giolla Phadraig et al., 2015). This prevalence is similar to the findings collected via wave 2 of IDS-TILDA, 4 years later in the same group of population, where only 30.6% of the 186 edentulous participants wore complete removable dentures (CRDs) (Mac Giolla Phadraig et al., 2015).

2.3. Oral health research in population with ID

2.3.1. Oral health research among the population with ID in Ireland

Oral health research data are crucial in policy making and action planning in order to promote oral health of this population, which includes reorientation of health services to meet the demands. This can be made in a timely and productive manner if the needs of the population are known (Tomar, 2008, Daly et al., 2013)

However, there is paucity of data on the oral health status of Irish adults with ID. The previous national oral health survey was conducted almost fifteen years ago and surveyed only 250 adults with ID living in residential settings (Crowley et al., 2005). It did not capture the diversity of this poulation, 50% of whom lived at home or lived independently (Doyle et al., 2016). Without reliable up-to-date data, it is impossible to identify health inequalities, carry out monitoring of changes in the oral health of this population, or evaluate the effectiveness of oral health initiatives.

Oral health research recognises the need for such initiatives. Data from the 2003 Oral Health Survey has informed the need for re-organisation of both primary and secondary dental services for adults with ID in residential care (Crowley et al., 2005). Additionally, Mac

Giolla Phadraig and colleagues (2015) recommended that in order to prevent edentulism in this cohort of the population, a range of targeted, evidence-based prevention, conservative and rehabilitation programmes appropriate for people with ID (Mac Giolla Phadraig et al., 2015), and more recently, also suggested In terms of training, previous studies have recommended the requirement for education and training of care staff in oral health for adults with ID, in order to upgrade the skills of current dental service providers and to increase the content on special care training in undergraduate dental courses (Mac Giolla Phadraig et al., 2017).

More recently, research in Ireland were mainly cross-sectional, comparing data collected from interviews conducted during wave 1 and wave 2 of the IDS-TILDA and survey data collected for groups without intellectual disability in The Irish Longitudinal Study on Ageing (TILDA) (Mac Giolla Phadraig et al., 2015, Mac Giolla Phadraig et al., 2017). Firstly, this comparison has its own limitation that the TILDA population is free-living and different from the IDS-TILDA population who are largely in residential settings. Secondly, the self-reported nature of these latter data sets is considered the major limitation of studies of this kind. Third limitation is that these studies were only looking at edentulism and denture, which only gives a partial picture of oral health status, and not level of need and function in this population. Therefore, the current data on oral health status of Irish population with ID needs to be complemented with recent clinical data on oral health and assessment of need.

In summary, there is limited research comparing between the oral health status of Irish adults with ID and the general population. It is hard to establish that oral health inequalities exist in this population and hence there is no data to inform public health strategies to address the inequalities if any were found.

2.3.2. Challenges in data collection in population with ID

In this next section, we highlight the challenges in undertaking epidemiological surveys and regular dental assessments in population with ID.

2.3.2.1. Access to regular dental data collection and assessments

Dental indices, such as DMF-T(Klein and Palmer, 1938), Gingival Index (Löe and Silness, 1963) and Community Periodontal Index (CPI) (WHO, 2013), are routinely used by dentists to collect data reflecting the oral health at population level. However data collection with these indices in epidemiological studies of population with ID may be difficult due to the cost and availability of dentists. There is insufficient evidence on the cost-related analyses on data collection in epidemiological studies or regular dental assessments by dental professionals.

There is little consensus on the preferred time period between dental visits for the population with ID (Davenport et al., 2003). In order to assess the oral health needs of individual with intellectual disabilities (ID), it is recommended to visit the dentist once or twice yearly, depending on individual risk (British Society for Disability and Oral Health, 2012). There is no current standard for frequency of dental assessment for individuals with ID for those outside residential care but for those living in residential care, standards in Ireland suggest that a minimum interval of once yearly, or more frequently where indicated (Health Information & Quality Authority, 2017). Political, social and health care policies and practices differ across countries and states and these will dictate the frequency of dental examinations and assessments for those in residential settings.

When examinations or assessments are applied to the population with ID, who have behavioural and communication differences, a specific skillset, which may come with experience, is essential. Dental examination may or may not be tolerated by this group of individuals. Dental professionals who are experienced in assessing these individuals would

have some form of specialised dental training (for example, specialists in Special Care Dentistry [SCD], and general dentists with special interest in SCD). Supporting person or staff that work with these individuals would also have specific skill sets and they would have known them well, their behaviour, likes, dislikes and habits.

2.3.2.2. Ethical issues with research in ID population

Individuals with ID may present with varying degrees of disability, characterised by a range of expressive and receptive speech, hearing or vision impairments, as well as cognitive and functional impairments. These factors have an impact on their decision-making capacity and they may require support in deciding whether to participate in research or not. Lack of decision making capacity should neither be a reason for individuals with ID to be unfairly excluded from the research participation, which may have potential benefits; nor for them to be inappropriately included in research that may pose more risks (such as fatigue and anxiety) than benefits.

Efforts must be made by researchers to provide people with support in making their decision and also with appropriate tools to maximise their decision-making ability as per National consent guideline in Ireland (Health Service Executive, 2017b). Participants with ID may have their own support person that helps them to understand and sometimes assist in making decision. The research's objectives, potential risks and benefits have to be explained in as detailed a way as possible to the prospective participants and their supporting person, using easily comprehensible language and at the level of their understanding. The participants must also be informed that participation is voluntary and they have the right to withdraw from the study at any time without negative impact on themselves and their access to dental services. It is important to make sure that they are fully informed before deciding to participate.

Informed consent must be signed by the participant, or if the research participant has decision-making capacity but is unable to provide written consent due to physical impairments, informed consent can be signed by the supporting person. For a research participant who lacks capacity, informed consent must be obtained from the person's legal representative (Office of the Attorney General, 2004, Health Service Executive, 2017b).

In summary, access of population with ID to epidemiological surveys and regular dental assessments can be limited due to ethical concerns with this vulnerable cohort of population as well as the cost and availability of dentists. In order to address the latter concern, the use of non-dental professionals to undertake oral health data collection and assessments may offer a solution. The use of oral health indices/indicators by non-dental professionals may facilitate clinical data collection from the population which is important in understanding the population immediate needs and risk. To date, a number of oral health assessment and screening tools have been developed to be administered by non-dental professionals. These will be reviewed in the third section.

2.4. Oral health assessments of adult population with ID administered by trained non-dental individuals

Recognising the issues of cost, and lack of availability of dentists (and their opportunity cost) and the benefits of having people with specific skills and experience to undertake data collection, many researchers have looked to develop tools for use by non-dental assessors. Accordingly, this section presents the case of using non-dental individuals to carry out data collection to assess oral health status of population with ID. This is followed by discussing the current evidence on the existing oral assessment tools that have been validated for use

by non-dental individuals, highlighting on the purpose of the tool, the population they were used for and the non-dental assessors using the tools.

2.4.1. Advantages of non-dental individuals to carry out data collection

To start this section we review the potential advantages as well as limitations of non-dental individuals carrying out data collection to assess oral health.

Firstly, the cost of non-dental labour may be less than the dentists carrying out oral health data collection and assessments. It is not surprising that employing dentist to carry out dental examinations on-site day centre or residential settings, or epidemiological surveys in population with ID can be very expensive, as per local payscales for dentists (Health Service Executive, 2017a). However, cost-benefit analysis studies on these alternative data collection are rarely done.

Secondly, researchers who are in close proximity with this population may be able to carry out oral health data collection. Ireland, through the IDS-TILDA study, has successfully collected substantial health information on an older population with ID in Ireland with the help of non-clinical individuals who have experienced working with people with ID. To date, no clinical assessment of their oral health could be carried out, mainly due to the cost and availability of appropriately trained dental professionals and recording clerks. This is also because there is not a simplified oral health data collection tool that can be used by the assessors. In the IDS-TILDA study, these non-clinical individuals who have experienced working with people with ID were chosen and trained as health assessors for the collection of anthropometric data. Thorough training on communicating and managing data collection around people with ID were provided in IDS-TILDA. It is probable that with these extra skillsets, such assessors would be suitable non-dental professionals to be trained and

calibrated to collect oral health data in epidemiological surveys, such as in the IDS-TILDA study in Ireland. This needs to be investigated.

Those (non-dental) who work closely with individuals with ID are in favourable position to carry out assessment of oral health. An example of this would be staff in residential settings. In a study at geriatric nursing home, the use of nursing staff to undertake assessment was beneficial because nursing staff were shown to be more successful in examining residents who have severe cognitive impairments because they were well acquainted with each other, and the nursing staff know their likes, dislikes, habits and behaviours (Kayser-Jones et al., 1995). In instances where residents refused to be examined on a particular day, assessment could be attempted on the next 'good day', which can be easily undertaken by the nursing staff. This could be applicable to the population with ID in residential settings, however, no current research has looked at this and

Thirdly, in addition to being a data collection tool, there is also a potential for non-dental personnel to use the tool to detect dental problems, allowing timely and swift referral to dentist and physicians. They may be trained to screen for common oral problems such as dental caries and periodontal diseases, as well as for oral problems which have systemic manifestations. It is not surprising that with good training and calibration, and use of a tool that has been validated to assess oral health, non-dental assessors may be able to screen for oral problems and make appropriate referral so that early and accurate diagnosis can be made (Ribeiro et al., 2014). With the assessment tool, the carers or staff in residential settings may also assist the dental health care team in planning an individualised care plan for the individuals with ID that they care for, as well as assist with triaging and prioritization of residents' dental needs. However, consideration must made carefully considering the nature of limitation of clinical screening tools.

What are the benefits to the non-dentists? Training non-dental assessors would involve education in oral health, thus increasing knowledge about oral problems and how to prevent them. The whole experience of assessing the mouth would increase awareness of the carers and those who work closely with individuals with ID about the importance of routine oral hygiene and may possibly improve health outcomes (Chalmers et al., 2005). In one of the studies, it was reported that this education and training had increased the staff interest in dental health (Chalmers et al., 2005). In term of oral health outcomes, such awareness and knowledge does not always result in improved health outcomes for people with ID (Hithersay et al., 2014). Finally, this demystification of dental knowledge to professionals other than the dental team would allow dental health to be integrated into the general health assessment (Saintrain and Vieira, 2012).

Finally, this alternative oral health data collection may be beneficial to the dentists as this would allow them to carry out to do jobs that require their skills that cannot be transferrable to non-dental individuals such as clinical diagnosis or curative procedures (due to Dental Council regulation), or actions that are better developed in presence of dentist like dental health promotion (Saintrain and Vieira, 2012).

2.4.2. Limitations of non-dental individuals

In discussing the potential advantages and application of this tool by non-dental assessors, it is also important to acknowledge that oral health assessment by staff in residential settings would add considerably to the workload (Kayser-Jones et al., 1995, Chalmers et al., 2005). It would therefore be important to consider this in developing a tool that is easy and quick to implement. There would be merit in exploring the integration of an oral health assessment alongside the other tasks that nursing staff are required to undertake.

Secondly, simplification of dental assessment and its delegation to non-dental individuals may legitimately raise concerns that serious problems such as oral cancers may be missed by the non-dental (Kayser-Jones et al., 1995).

Finally, with delegation of this oral assessment to non-dental individuals, it becomes a concern that dentists may become less involved in providing dental care for this population (Kayser-Jones, 1995). However, as pointed out by Ribeiro and colleagues (2014), the oral assessment by non-dental assessors should not replace the periodic recall for a comprehensive examination by a dentist. Dentists are still required to provide the definite diagnosis and dental care, which cannot be delegated to non-dental individuals (Ribeiro et al., 2014).

In summary, previous literature has mentioned potential advantages and limitations of delegating the task of oral health data collection and assessment to our non-dental colleagues. However, these need to be appropriately evaluated in a research study to understand these mechanisms.

2.4.3. Data collection tools to assess oral health administered by non-dental individuals

A systematic literature review was carried out to look for published literature on data collection tools, which have been used by non-dental individuals in population with ID. In particular, we were interested in any data collection tools that are able to determine the level of oral disease, treatment need and oral function in population with ID. This section presents the development of oral health assessment tools and their initial validation studies.

There are currently 6 existing data collection tools to assess oral health status that have been validated for use by non-dental individuals. One of the earliest oral assessment tools developed for use by non-dental individuals was the oral assessment guide (OAG) (Eilers et al., 1988). The OAG was developed to measure oral changes secondary to stomatotoxic chemotherapy or radiation therapy. Eilers and colleagues had first tested the OAG on 20 patients undergoing bone marrow transplant (BMT), receiving high-dose radiation and/or chemotherapy (Eilers et al., 1988). This tool was further revised in Sweden for use in 16 patients with Acute Leukaemia, Non-hodgkin's Lymphoma, Hodgkin's disease and Myeloma (Andersson et al., 1999). Andersson and colleagues (2002) then further modified OAG and renamed it as Revised Oral Assessment Guide (ROAG) for use in older population; ROAG was utilised with 133 patients in a geriatric rehabilitation ward (Andersson et al., 2002). In Portugal, recently, the ROAG was further validated in 116 elderly individuals living in the community (Ribeiro et al., 2014).

Following the positive outcomes from the development and utilisation of OAG (Eilers et al., 1988) to assess oral mucosal changes, Kayser-Jones and colleagues (1995) went on to develop a comprehensive assessment tool for oral health, named Brief Oral Health Status Examination (BOHSE) (Kayser-Jones et al., 1995). BOHSE was said to be one of the first comprehensive oral health assessment tools that was validated for use by nursing staff (carers) to assess oral health status of nursing home residents in Australia, especially

residents with moderate-severe dementia (Kayser-Jones et al., 1995). BOHSE was developed and first validated in the assessment of 100 nursing home residents with various levels of functional and cognitive status.

In 2003, BOHSE was modified into the Oral Health Assessment Tool (OHAT), in order that it was more practical and simple for use by residential care staff. OHAT was then considered an oral health screening tool in a group of geriatric residents with dementia (Chalmers et al., 2005). In the initial validation studies, OHAT was tested nationwide on a population of 455 residents in 21 Australian residential care facilities (Chalmers et al., 2005). In addition to the use of OHAT in geriatric populations in residential care settings, OHAT had also been developed for those being hospitalised in an acute geriatric department (Simpelaere et al., 2016). In the study by Simpelaere and colleagues (2016) on 132 patients in 3 nursing homes, 2 assisted living facilities and 1 acute geriatric department general hospital, OHAT was tested as a possible part of a comprehensive clinical swallowing assessment, to be administered by speech pathologists (Simpelaere et al., 2016).

In Brazil, efforts had also been made to develop a simplified oral examination tool that would enable collection of population data in a simple manner, to be used by other professionals (Saintrain, 2007). The significance of the tool, the Community Oral Health Indicator (COHI), was that it had been developed for use in the community and was tested in the community, not just in a geriatric population. The COHI was developed and testing in 60 residents of the city of Guaiúba Brazil: to check the masticatory capacity, the need for curative treatment as well as the use and need of dental prostheses (both partial and complete dentures).

Mouth Self Examination (MSE), on the other hand, was developed as a potential tool to screen for detection of oral cancer and potentially malignant oral lesions that could be administered by those at risk of oral cancer themselves (Mathew et al., 1995a, Mathew et

al., 1995b). In a study in South East London, United Kingdom, 53 participants who demonstrated risks for oral cancer were asked to carry out self-examination of their mouth by following instructions on the MSE leaflet (Scott et al., 2010). A large scale study in Kerala, India, had involved 30,342 individuals using MSE to detect suspicious lesions inside their own mouth (Elango et al., 2011).

The characteristics of these tools including the items/categories, conduct of clinical examination, equipment used can be found in the APPENDIX I.

In summary, none of the existing tools administered by non-dental assessors that has been developed and validated for population with intellectual disabilities (ID). None of the assessment tools listed above had reported inclusion of people with ID. Upon further analysis on the items/categories and domains of the existing tools, none of them met our comprehensive criteria of data collection tool for population with ID.

2.4.4. Types of non-dental professionals

As the foregoing describes, a number of different assessment tools have been developed and validated for use by different types of non-dental professionals; these include nurses, residential home carers, other non-dental healthcare professionals as well as individuals from the community. The following paragraphs will describe these non-dental professionals, which shows their potential roles as data collectors in population surveys and clinical screening.

Since the intention was to develop an assessment tool to improve nursing care, most of the assessment tools have been developed and tested amongst nursing staff. OAG and ROAG were developed for use by registered nurses; similarly in Australia, BOHSE was tested in 3 categories of nurses: registered nurses (RNs), licensed vocational nurses

(LVNs) and certified nursing assistants (CNAs). In Australia, few RNs are placed in nursing homes and often, LVNs are employed as charge nurses. It is significant to note that LVN examiners were found to be as capable as the RNs in using BOHSE to assess oral health status. Thus, both RNs and LVNs can be trained to conduct the oral assessment (Kayser-Jones et al., 1995). The implication of OHAT modification by Chalmers and colleagues in 2005, was that it can be used as a practical screening tool and it can be used by a diverse range of nursing home 'carers' , namely Personal Care Attendants, Registered Nurses, Enrolled Nurses, and Nurse Assistants. OHAT was also validated for use by Speech pathologists as part of their comprehensive swallowing assessments (Simpelaere et al., 2016).

In an attempt to implement the use of such indices beyond the nursing home setting, there have been reports on the employment of individuals from the community, who do not have health professional training, utilising such assessments. COHI is a health assessment epidemiological tool that was developed in Brazil, to be used by non-dental personnel from the community. These individuals, which are known as community health agents (CHAs), were trained to carry out oral assessments using COHI. CHAs are non-dental persons from the community who have a high school degree and have been trained to be the liaisons between the community and the Health Care Unit. This study had concluded that COHI can be used by other professionals including those without formal health or dental training, such as the CHA.

Similarly, community health workers (CHWs) in Portugal act as liaisons between community and health services and it is understood that they undertake more than a million home visits in a year. The tasks of community health workers (CHWs) in Portugal are to identify health problems in frail and elderly individuals, refer them to the health unit and keeping the health unit staff informed about such patients. Due to the low cost and easy accessibility of these CHWs, in a study by Ribeiro and colleagues (2014), CHWs were trained and asked to perform oral assessments using ROAG, on 116 elderly individuals in

the community (Ribeiro et al., 2014). It was shown that CHWs, when trained, can collect dental data of elderly population and hence, improved access to dental services.

In summary, use of non-dental professionals such as nurses, residential home carers, other non-dental healthcare professionals as well as individuals from the community, were shown to be potential data collectors in population surveys. It seems that these non-dental assessors did not have formal dental training before and it did not include allied dental professionals like dental hygienists or dental nurses.

2.4.5. Validation studies of the existing tools (include pilot, training, calibration)

In evaluating an index or measurement tool, it is essential to review the assessment of the psychometric properties. This section discusses the tests or considerations used in the construction and initial validation studies of these tools. This includes the validity and reliability tests, feasibility tests looking at time taken to administer the tool, as well as aspects of training, calibration and a pilot study. Firstly, these concepts and their relationship to the ideal features of a dental index are concisely introduced.

2.4.5.1. Reliability assessments

The first assessment is to determine how reliable a measure the instrument is, in other words, to determine that the instrument is measuring something in a reproducible fashion. This is 'Reliability'. The index is considered 'reliable' when the results of a measure are reproducible under different conditions. This means that similar results will be produced when measures were administered on different occasions, or by different assessors or by similar or parallel tests (Streiner, 2015). Three of the most common reliability attributes are internal consistency (a measure of the correlation of items which may tell the same function), inter-observer reliability (agreement between different observers), intra-observer reliability

(agreement between the same measurement made by the same assessor on two different occasions) and test-retest reliability (measurements on the same patient on two occasions separated by some time interval) (Adamson and Prion, 2012a). Reliability is expressed as a number between 0 (no reliability) and 1 (perfect reliability). Interpretation on the reliability level would depend on the use of the tool. For example, in the calibration of examiners following WHO guidelines, the level of inter-observer agreement needs to be between 0.85 and 0.95 (WHO Oral Health Surveys, Basic Methods 5th Edition 2013).

The most important inter-rater reliability assessment in the previous indices was to compare the results between the non-dental assessors and a dental examiner. Most of the reliability assessments reported in the previous indices had used various dental professionals including dentists (Kayser-Jones et al., 1995, Chalmers et al., 2005, Scott et al., 2010, Saintrain and Vieira, 2012, Ribeiro et al., 2014) and dental hygienists (Andersson et al., 2002), as gold standard assessors. The result of the inter-rater reliability assessments can be found in APPENDIX II.

In order to check for reliability at two different occasions by the same examiner, either intra-rater or test-retest reliability assessments were carried out. This was done by carrying out examinations on the same subjects, twice, with a determined time interval. The difference between the two types is that intra-rater reliability is carried out by asking the same assessor, after a time interval, to measure the original condition, which is usually recorded in the form of photographs or videotapes. Meanwhile test-retest reliability can be done by asking the same assessors to measure the same patient after a time interval. Despite the difference, these terms are used interchangeably in many validation studies in published literatures. Test-retest reliability assessment for BOHSE was carried out by asking each examiner to repeat examinations on one-third of the subjects within 1 or 2 days (Kayser-Jones, 1995). In another study, intra-rater reliability of OHAT was tested by asking the carer to re-examine a group of the same residents, after 48 hours (Chalmers et al., 2005). Intra-rater reproducibility of ROAG was tested out on a sample of 58 participants, with each

community health worker carrying out assessments on 5 to 6 elderly individuals twice, after 7 days (Ribeiro et al., 2014). The result of the tests can be found in the APPENDIX III.

2.4.5.2. Validity assessments

Reliability assessment is, however, not sufficient on its own as we need to determine whether the instrument would allow us to make accurate conclusions, that is, it is valid. 'Validity' assessment is more than merely expert judgments. It involves an empirical assessment to prove that the instrument is measuring 'what' is intended (Adamson and Prion, 2012b). The scale is 'valid' if it is measuring what it was intended to measure. There are different processes in establishing 'validity' of an instrument. Content and face validity are simply technical descriptions of a judgment that the scale appears reasonable (Streiner, 2015). Hence, content validity is routinely the first form of validity to be mentioned within the context of issues surrounding construction of a new tool. The aim of the content validation process, therefore, is to ensure that the new scale has sufficient items to adequately cover the relevant or important content or domains specified for the new tool. Content validity is different from other forms of validity testing that it is actually based on the judgment of one or more experts, either through systematic reviews of published literature, through discussion or consultation with a panel of experts or through one of the empirical approaches such as use of the content validity ratio (CVR) (Lawshe, 1975, Streiner et al., 2015, Gilbert and Prion, 2016).

A review of the previous indices utilizing non-dental assessors was reported to be used to determine content and face validities in the initial studies for ROAG (Andersson et al., 2002), BOHSE (Kayser-Jones et al., 1995) as well as OHAT (Chalmers et al., 2005). Content and face validity of both BOHSE and OHAT were also established in a number of studies for older populations in residential care facilities (Kayser-Jones et al., 1995, Lin et al., 1999, Chalmers et al., 2005). None of the studies, however, have described the use of content validity ratio (CVR) approach to carry out content validation.

The next step in validity assessment is to test if the new instrument/tool would correlate with some gold standard measure which have been validated and widely used and accepted in the field. This is criterion validity and the gold standard measure is called 'criterion measure'. There are two types of criterion validity; concurrent validation and predictive validation. The only different between the two types is when the criterion measure is available. Concurrent validation is when the both the new measure and criterion measure can be concurrently administered at the same time. On the other hand, in predictive validation, the new scale is administered first and correlation can only be made once the criterion measure becomes available sometime in the future.

The Initial study of OHAT reported that concurrent validation was carried out by carrying out comprehensive oral epidemiological examination on a proportion of participants, using established assessments, including the Plaque index (Silness and Löe, 1964), saliva and soft tissues categories (WHO, 2013), denture assessment (Rise, 1979) as well as natural teeth category (Miller, 1987). Adequate concurrent validity was not established for several categories, namely gums, saliva, oral cleanliness and dental pain (Chalmers et al., 2005). In the validation study of Community Oral Health Indicators (COHI), Decayed Missing Filled Teeth (DMFT) was used to compare the 'dental cavities' item in COHI. Excellent correlation and agreement were reported between COHI 'dental cavities' and DMFT (Saintrain and Vieira, 2012). Details on the concurrent validity assessments and results are shown in Table 2.3.

So far, none of the previous indices used by non-dental assessors has reported on the adequacy of concurrent validity in all of the categories. The remaining validation studies did not report concurrent validity in their research (Kayser-Jones et al., 1995, Andersson et al., 2002).

Table 2.3 Results of concurrent validity assessments in previous instrument validation studies.

Indices	Concurrent validity assessments per item, & results
OHAT (Chalmers et al., 2005)	**Comparison between OHAT & standard dental assessments by Dentist** **Percent agreements (%Ag):** 0.81-1.00 Almost perfect or excellent - Lips, Tongue, Gums and tissues, Natural teeth, Denture, Dental pain 0.61-0.80 Substantial (0.61-0.80) - x 0.41-0.60 Moderate (0.41-0.60) - Saliva, oral cleanliness 0.21-0.40 Fair - x 0.00-0.20 Slight - x <0.00 Poor - x **Pearson correlations (C):** Perfect – Lips, Tongue, Natural teeth, Substantial – x Moderate – Gums & tissues Fair – x Poor – Saliva, Oral cleanliness, Dental Pain
COHI (Saintrain and Vieira, 2012)	**Comparison between COHI & DMF-T by Dentist** **Spearman's correlation (r_s):** >80% - Number of teeth & residual roots <80% - x **Cohen's Kappa agreements & Chi square tests:** 0.81-1.00 Almost perfect or excellent - Number of teeth & residual roots, Dental cavities, Gingival inflammation, Soft tissue injury, Dental prosthesis 0.61-0.80 Substantial - x 0.41-0.60 Moderate - x 0.21-0.40 Fair - x 0.00-0.20 Slight - x <0.00 Poor -x Perfect or excellent – Substantial – x Moderate – x Fair – x Poor – x

2.4.5.3. Feasibility assessments

In implementing a new instrument, there will usually be consideration of 'feasibility'. The most common aspects of feasibility such as cost, time, scoring, method of data recording and acceptability to the end-users (Streiner et al., 2015). Firstly, 'time' is an important issue in developing a tool and in using it. The process of instrument development, assessing various forms of reliability, carrying out preliminary validation would be an extremely time-consuming, laborious process. It would also be reasonable to consider how long it would take for the end-user to administer the tool (i.e., for the subjects to endure the tool being administered) and for the researchers to enter results to database. In addition to time consideration, it is also important to analyse the 'cost' of developing and implementing the tool. Other aspects include method of administration (For example, hard copy or computed), scoring options (descriptive or numerative), intrusiveness or acceptability of the tool (For example, causing pain and discomfort, causing fatigue because it is too long). Additional to the validity and reliability assessments, other assessments were carried out in the initial development studies of these indices, as shown in Table 2.4.

Feedback from assessors and subjects examined is significant to explore as they are the ultimate end-users of the newly constructed tool. Questionnaires were given to the non-dental assessors to evaluate the use of OHAT, the average time taken to carry out OHAT, as well as problems encountered during OHAT administration (Chalmers et al., 2005). The non-dental assessors were able to complete all OHAT categories except for some responded that they were not able to complete the dental pain category. Mean reported time to complete OHAT examination was 7.8 minutes (range = 1 to 30 minutes). Main themes from the comments and focus groups were: ease of integration of the OHAT into daily workload, more training required, inadequate understanding of 3 OHAT categories (namely dental pain, saliva and gums), a section to enter other findings and resident issues. Assessors did not encounter any major problems administering the OHAT (Chalmers et al., 2005). None of the studies evaluated feedback from the subjects examined using the newly constructed tool.

Table 2.4 Other assessments reported in the previous initial validation studies of the tools.

Assessments mentioned	Studies	Descriptions
Questionnaire: 2 questions with a four-point Likert response scale from strongly disagree to strongly agree.	OHAT (Chalmers et al., 2005)	Use of OHAT, Average time taken, Comments concerning any problems with OHAT
Qualitative focus groups held with carers at each residential care facility at baseline, three months and six-months using key questions to facilitate discussion.	OHAT (Chalmers et al., 2005)	Ease of use, OHAT training, OHAT categories, Comments
Feasibility	OHAT (Simpelaere et al., 2016)	Time required to complete OHAT, Ability to score OHAT, Problems encountered
Self-report questionnaire	MSE (Scott et al., 2010)	Awareness of the lesion prior to using MSE, Socio-demographic details, Health related behaviour, Rate of difficulty using MSE,

Analysis of the cost of use of the tools by non-dental individuals is important to determine if this alternative approach is more cost-effective than utilizing dental assessors. None of the previously published initial validation studies reported cost-related analyses on the development of the novel indices.

In summary, there are existing tools that were validated for use by various non-dental individuals. Initial validation studies of these tools showed good level (moderate to perfect correlation and agreement) of inter-rater reliability for all categories tested, all were statistically significant ($p<0.05$) except for Saliva, Tissues and Lymph nodes; and diagnostic accuracy of the inter-rater agreement showed high sensitvitiy except for Dental cavities, Lips, Saliva and Mucosa. With intra-rater and test-retest reliability, the correlation

and agreement values were high (range of 0.40 to 1.00) except for 'Teeth/denture cleanliness'. All existing tools reported high level of content validity, through systematic review of published literatures as well as consultation with experts in the field. Concurrent validity was tested extensively in validation studies for OHAT (Chalmers et al., 2005) where high agreement was noted for all categories but correlation was low for 'Saliva', 'Oral cleanliness' and 'Dental pain' categories. Feasibility-wise, OHAT reported time taken to administer the tool was 7.8 minutes and non-dental assessors were able to administer OHAT without major problems.

2.4.5.4. Statistical tests used

Statistical tests used for validity and reliability assessments above are summarised in Table 2.5 below.

Table 2.5 Statistical and statistical correlation tests from previous studies

Assessments	Statistical and statistical correlation tests from previous studies
Concurrent validity	Percent agreement, Cohen's Kappa (simple and weighted), Fleiss Kappa, Pearson correlation, Spearman's correlation, Chi Square test
Inter-rater reliability	Percent agreement, Cohen's Kappa (simple and weighted), Sensitivity, Specificity and Accuracy, Correlation coefficients, Analysis of variance (ANOVA), Post hoc Scheffe comparisons, Intraclass correlation (ICc), ICc with a two-way random-effects model with measures of absolute agreement (ICCabsolute agreement).
Intra-rater reliability / test-retest reliability)	Cohen's Kappa (simple and weighted), Percent agreement, Paired t-tests, ICc with a one-way random effects model with measures of absolute agreement (ICCabsolute agreement).
Internal consistency	Cronbach's Alpha
Other correlation	Kendall rank-order correlation coefficient T, Kruskal-Wallis test, Chi square test
Assessment for normality	Shapiro-Wilk test, QQ-plots

Correlation tests (such as Spearman's correlation) allow the evaluation of correlation or association between variables, while Percent agreement and Cohen ' s Kappa agreements are used for level of agreement between the variables. In the previous validation studies, they were used for concurrent validity, inter-rater reliability and intra-rater reliability tests. For some categories with more than 2 level of responses (ordinal variables), the value of Weighted Kappa was calculated. For more than 3 raters (or examinations), reliability test was carried out using Fleiss Kappa (Simpelaere et al., 2016). In one of the studies, Cronbach's alpha was used to analyse the consistency of assessments for each rater (Andersson et al, 1999).

Another important common finding was that inter-rater Cohen's Kappa scores for individual categories were often lower than desired despite a high percent agreement. This phenomenon has been described in the literature as Kappa paradoxes (Cicchetti and Feinstein, 1990, Gwet, 2002b, Gwet, 2014). An explanation is that, for many items, abnormality is rarely present; hence, even a low number of disagreements would cause Kappa scores to drop. Kappa paradoxes had been noted and discussed in the previous studies of the non-dental tools (Kayser-Jones et al., 1995, Andersson et al., 2002).

It has been recommended that an agreement coefficient named AC1 (Gwet's AC1) can be used alongside Cohen's Kappa, to overcome the kappa paradox (Wongpakaran et al., 2013, Gwet, 2014). Gwet's AC1 has proven to be the most robust to the paradox (Gwet, 2002b, Gwet, 2002a). Despite being recognised by biostatisticians (Chan, 2003), Gwet's AC1 was rarely used in the medical literature (Gisev et al., 2013). In the previous validation studies of tools by non-dental personnel, none of them had used Gwet's AC1 in assessing inter-rater agreement.

2.4.5.5. Training, calibration and pilot study

With a newly constructed tool, training is an essential component of the whole process. The duration of training was between 2 to 5 hours. Detailed summary on the training, calibration and pilot study for the existing indices can be found in APPENDIX IV.

2.5. Conclusions from the literature review

The oral health status of individuals with intellectual disabilities (ID), worldwide, is still poor. The trend seems to be the same in Ireland, although there has not been enough research data either produced or published on the oral health status of this diverse population. This is to the detriment of people with ID, since dental research data has been shown to inform policy change around improving oral health in this cohort of population, to indicate the need to reorient dental services for adults with intellectual disabilities as well as the need for education and training for dental undergraduates, dental professions and carers of population with ID.

Collecting dental data for this cohort of population in Ireland, nationally, has not been feasible in the recent years due to the high cost and availability of dental professionals. To confound data collection, individuals with ID may present with behavioural and communication challenges. Non-dental health professionals and individuals who work closely with these individuals have the potential to carry out an oral assessment with a simple valid and reliable assessment tool. In Ireland, data collectors for IDS-TILDA study have been successfully collecting non-anthropometric health data in older adults with ID and hence, it opens up opportunity to explore the use of these alternative data collectors. This alternative approach may have limitations but may be inexpensive and may offer other advantages, which need to be further investigated.

Previous validation studies on existing tools for non-dental assessors have shown that nursing staff and non-dental community health liaison persons could be trained to use a

simplified tool to assess oral health status. Existing non-dental assessment tools have only been validated for use in older populations and those in the community, however, none of them have validated their use in a population with intellectual disabilities (ID).

In summary, a valid data collection tool is required that will inform policy planning towards improving oral health and oral health related quality of life in the population with intellectual disabilities (ID) in Ireland. To shape policy, this tool will ideally offer information on burden of oral diseases, the likely level of treatment need and crucially, oral function in populations with intellectual disabilities. To make data collection a reality, in the current research climate, it is essential that this tool can be applied by non-dental professionals. To date, there is no single tool for use by non-dental assessors that has been developed and validated to indicate burden of oral diseases, level of treatment need and crucially, oral function in populations with intellectual disabilities population with intellectual disabilities (ID).

2.5.1. Aim & objectives of the study

Therefore, the aims of this study are:

1) To develop an index that would allow an objective assessment of the burden of oral diseases, the likely treatment need as well as the oral function in population with intellectual disabilities (ID) for epidemiological purposes;
2) To investigate the feasibility of utilising non-dental individuals to carry out the oral health data collection using the index.

The objectives were:

1) To construct an oral health data collection tool that allows objective assessment of oral health, disease and function, and that can be used by non-dental individuals.
2) To develop a training programme for the newly constructed tool

3) To establish content validity and concurrent validity for the tool

4) To assess inter-rater and test-retest reliability of the tool

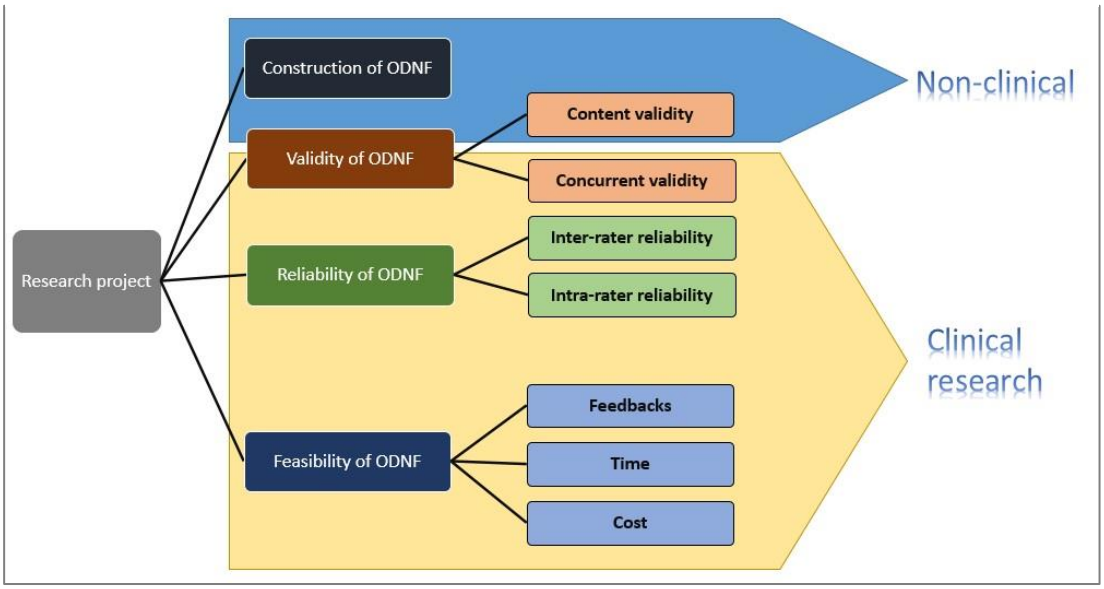
5) To determine the feasibility of the tool; the time taken to carry out assessment, the cost of using the assessment and the acceptability of this tool by participants with ID and non-dental assessors.

3. MATERIALS AND METHODS

3.1. Overview of design and research process

This research project focused on the construction of a new oral health assessment tool, as well as its initial validation, when used by non-dental examiners to collect dental data. The research project occupied two major phases, as shown in Fig 3.1; a non-clinical phase, followed by a clinical phase. This first phase involved the construction of a new oral health data collection tool and its content validation and the second phase then applied clinical measurement to test the concurrent validity, reliability and feasibility of the new data collection tool (**O**ral **D**isease Treatment **N**eed and Oral **F**unction -ODNF).

Figure 3.1The outline of the research project in two phases; non-clinical and clinical phase.



3.1. Ethical approval

Ethical approval for the study in its entirety was granted by the Faculty of Health Science Research Ethics Committee (FHSREC), Trinity College Dublin (TCD) (APPENDIX V). For the pilot phase of this project, ethical application was submitted to the School of Dental Science Level 1 Research Ethics Committee (APPENDIX VI), and was approved. Separate submissions were made for the clinical phase of this research to the research ethics committees of the service providers from which participants were to be recruited: Stewart Care Ltd (SCL), St John of God Community Service (SJGCS) and St Michael's House (SMH) (APPENDIX VII and APPENDIX VIII).

3.2. Data protection and confidentiality

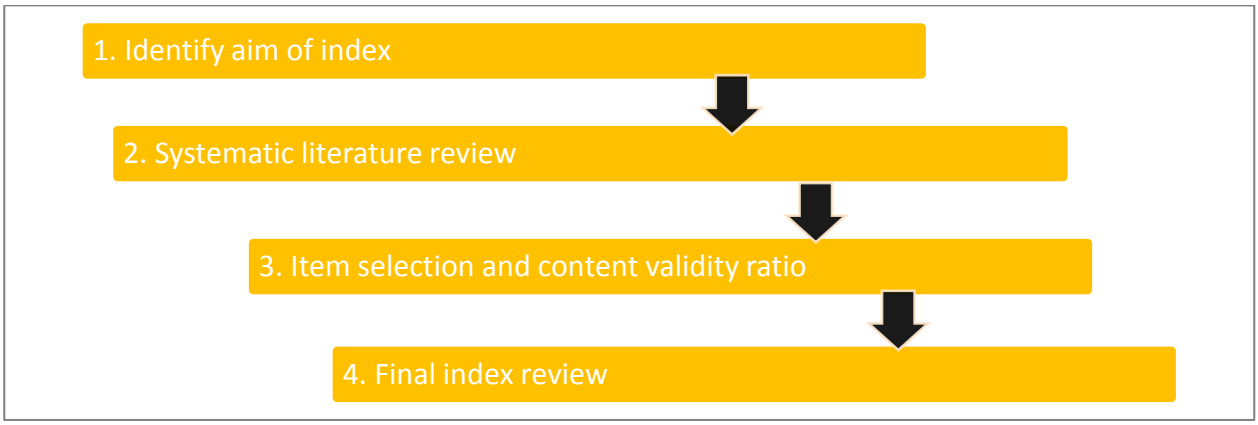
All data were collected and stored in compliance with the Data Protection Act 1988 and the Data Protection (Amendment) Act 2003. Data stored in computer (offline and online) are encrypted, password-protected, and stored on a secured server, as well as only accessible to the principal researcher (NSI). Hard copies of data were stored in a locked cabinet in a pass-card secured section of the Dublin Dental University Hospital (DDUH). Records will be stored for the duration of study, until work is fully reported and disseminated. At the end of the five years, all soft and hard copies of the data will be securely destroyed, according to protocols for management of such research data under the National Data Protection guidance as well as Trinity College Dublin data protection policy.

Documents bearing identifiable information on the consent/assent forms were only accessible to principal author (NSI). The details collected were pseudo-anonymised using unique codes for participants. Participants could withdraw inclusion of their data after collection. This was also to allow the study organiser to identify any participant who may need follow-up with their dental provider. These participants codes were only accessible to the principal researcher (NSI).

3.3. Construction and content validation of the 'Oral Disease, Treatment Need and Oral Function' (ODNF) index

The aim of the systematic literature review was to look for existing oral health tools, which have been validated for use by non-dental individuals, in population with Intellectual Disabilities (ID), to assess oral health needs and function. From a preliminary review of the literature, none of the existing tools utilised by non-dentists have been validated for use in the population with ID. Hence, it was necessary to construct a novel oral health data collection tool. The '**O**ral **D**isease, treatment **N**eed and oral **F**unction' (ODNF) index was constructed in a standardised approach as outlined in Fig. 3.2.

Figure 3.2 Approach to construction and content validation of ODNF index



3.3.1. The purpose of ODNF index

The first task in constructing an assessment tool was to identify its purpose. The main purpose of the ODNF Index was to collect oral health information (data collection) in population surveys that could be used to inform policy making. The index was designed to facilitate trained, non-dental individuals to assess the oral health status of population with ID. As this was intended for the non-dental individuals, the tool was not designed to be a treatment planning tool for individual patient.

Having determined the purpose of the new tool, the key domains were identified and discussed with co-researchers. These specific domains were selected to illustrate the gap in oral health parameters between the adult population with ID and those in the the general population. The ODNF index was designed to:

1) Identify common oral conditions and diseases (presence of pain, soft tissue disorders, periodontal disease and untreated visible dental caries).
2) Suggest the likely outline treatment need for the population (such as urgent referral for dental assessment, referral for routine treatments).
3) Identify the level of oral functioning, including the masticatory capacity and denture wear.

Although this was designed for non-dental individuals, the ODNF was expected to have the ideal properties of a dental index (Burt and Eklund, 2005). Hence, the ODNF index had to be:

1) Valid and reliable
2) Able to assess components of oral health in population surveys
3) Clear and simple to be administered by non-dental assessors
4) Acceptable to the people with ID
5) Inexpensive to be used in oral health assessments, compared to dentist carrying out a conventional dental assessment.

In summary, the ODNF index was developed to enable collection of substantial information that would potentially inform policy makers. Domains were specifically chosen to highlight the oral health disparities between the population with ID and the general population. Based on the intended purpose, selected domains, the methodology around the index development and its content validation will be clearly laid out in the next section 3.3.2 (Content validity).

3.3.2. Content validity: Systematic literature review

Content validity is usually the first test of validity as it is usually carried out during the construction of a new tool. To recall, the aim of the content validation process is to ensure that the new tool has sufficient items that would adequately cover the relevant or important content or domains specified for the new tool but for which it would be reasonable to expect that non-clinicians would be able to utilise it. Content validity is based on the judgment of one or more experts, either through systematic reviews of published literature, through discussion or consultation with a panel of experts or through one of the empirical approaches such as use of the content validity ratio (CVR) (Streiner et al., 2015; Lawshe, 1975).

The systematic review of the literature describing previous, similar instruments, assisted in the content validation of items selected for inclusion in the novel index. The main aim of the systematic literature review was to analyse previously published, dental assessment tools used by non-dental individuals, if any, in populations with ID. In order to focus this research project as well as acknowledging the possible limitations of self-reporting tools (as discussed in literature review), it was decided to focus the review on tools with clinical items only.

For this systematic review of the literature, a search protocol (APPENDIX IX) was devised to allow a focused literature search to be carried out. This protocol was reviewed by an expert (CW) in systematic reviews. Inclusion and exclusion criteria were determined before beginning the actual search. In order to access only peer-reviewed literature, it was decided to exclude opinions, ideas, editorials, continuous education courses papers and books or commentaries. Discussions with co-researchers were conducted to identify appropriate search terms, to include: dentist, oral, assessment, examination, screening, survey, data collection, tools, indices, indicator, adults, middle-aged, and older. The search string was then agreed upon and subsequently used for the systematic review of literature. The search string allows for replication of the review methodology in the future. Due to the

nature of literature review in this thesis, the literature search was limited to one database only. The PubMed database was deemed to be the most appropriate of the databases in yielding more articles related to dentistry and populations with intellectual disability (ID).

An electronic search was then conducted, followed by 'Title and abstracts' review by author NSI and co-supervisor CMGP individually, with inclusion and exclusion criteria being considered. The articles were grouped for inclusion into 'yes', 'no' and 'maybe'. Further discussions between reviewers were carried out to assist in the elimination or inclusion of some of the papers for full-text review.

Following full-text review, the relevant information in the indices was extracted: name of assessment tools or indices, author's details, purpose of index, items in the index, descriptive or numerical scores, characteristics of participants assessed, non-dental individuals, gold standard assessor, training protocol (and materials), data collection protocol (clinical assessment tools and equipment), data collected (type of variables, including data collection tools), data collection methods for concurrent validity and reliability assessments, statistical programs used, statistical tests for the validity and reliability assessments, other assessments, and results of validity and reliability tests.

3.3.3. Content validity: Items selection and content validity ratio (CVR)

Content validity was further developed by seeking the views of an international panel of dental experts from various specialties, who are experienced in providing dental care for patients with ID. The aim, criteria and domains of the ODNF index were explained to the expert panel and their role in the process was outlined.

As a result of the systematic literature review process, a list of potential items for inclusion in the novel index was generated. Items that met the objectives of the ODNF index were identified and selected to undergo the content validation process. Each member of the expert group was given a clear description of the domains and a list of items within the domain. The raters were required to score each item as well as its descriptive ratings, according to its relevance to the key domains considered for ODNF index, using a 4-point scale: 1=Not relevant, 2=Somewhat relevant, 3=Quite relevant or Highly relevant but needs rewording, 4=Highly relevant. This scoring was used to calculate the Content Validity Ratio (CVR) for all the potential items (Streiner *et al*, 2014). Depending on the number of raters, the CVR agreement value was set at a level that the items would be acceptable for inclusion as relevant to the novel index (Streiner *et al*, 2014). The suggestions of the CVR raters on the items, as well as the descriptors, were listed for inclusion in the final instrument.

Items that were selected based on the CVR were then grouped under 8 main categories; soft tissues (which include lips and gums, cheeks, tongue, roof of mouth and under the tongue), Gum condition, oral cleanliness, number of teeth, teeth in occlusion, presence of denture in the mouth, visible caries, and dental pain. For the categories that did not have relevant items (CVR of below the set agreement value), items from the other, identified assessment tools were reviewed, discussed and adopted where appropriate.

3.3.3.1. Final index review

In the final stage, the novel ODNF index was re-reviewed by the research team. Descriptive and numerical ratings were further discussed and modified to suit this cohort of population, as well as to make it simple for non-dental assessor to apply. This novel ODNF index was trialled in the pilot phase by the gold standard dental assessor and the dental assessor (Section 3.4.5). The draft index was further refined during training to include feedback from the gold standard assessor, the dental assessor and the non-dental assessors. Some

changes to the descriptions of the items were indicated to facilitate data collection by non-dental assessors and these were discussed and incorporated into the final ODNF tool.

3.4. Development of training programme for the newly constructed tool

As this was a newly compiled index, a new training programme for ODNF index was developed with input from co-researchers. Objectives and structure of training were first laid out. As part of the training tool, diagnostic codes and criteria were discussed with co-researchers. An explanation of how to carry out the examination for each of the ODNF items was also given. Using WHO training tools as guidelines, intra-oral photographs were also included in the training tool to aid learning. The training tool was then combined with training tool for dentition status and CPITN in the data collection protocol. The training tools for dentition status and CPITN were adopted from the WHO with permission (APPENDIX XVII).

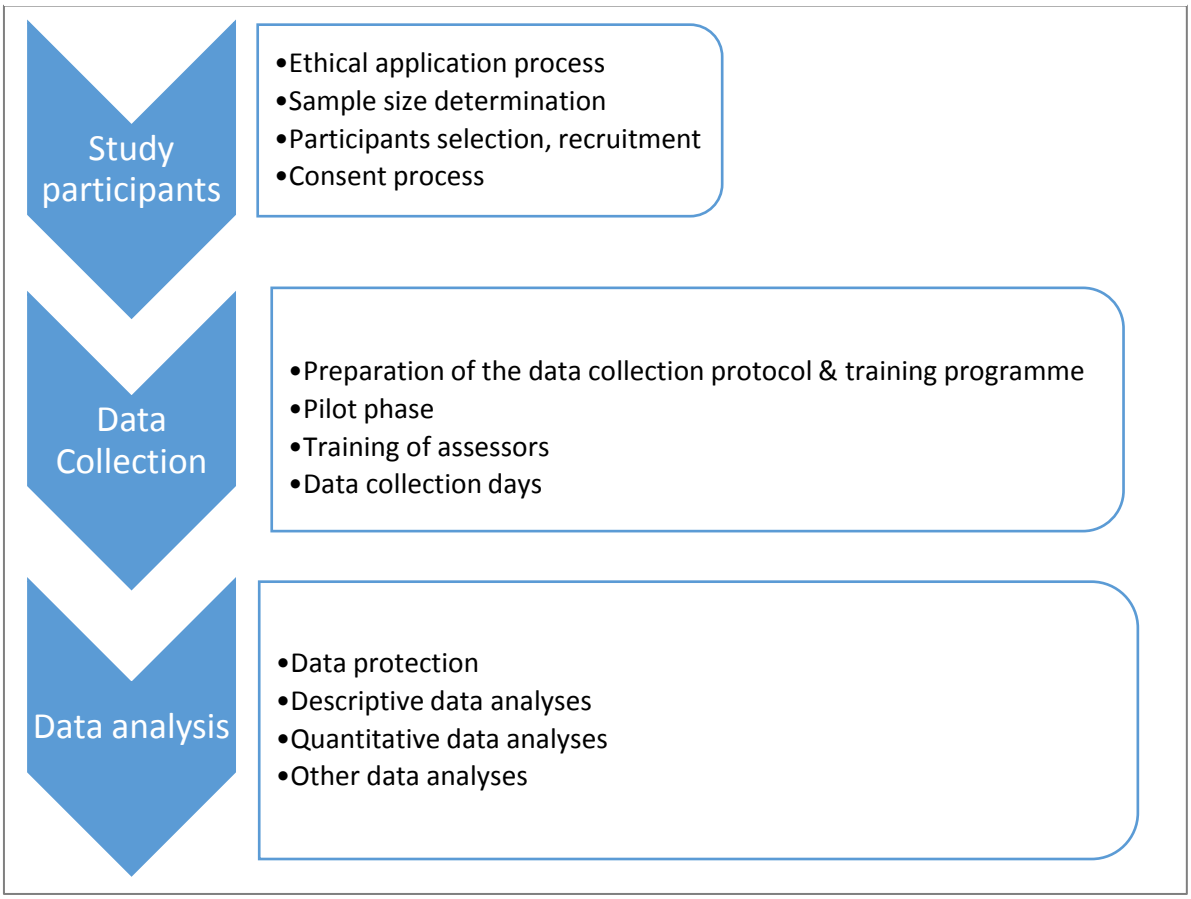
The training tool and the data collection protocol were then tested in the pilot phase with dental assessors, and then finalised for use in the clinical phase of the study.

3.5. Concurrent validity and reliability of ODNF

3.5.1. Clinical research Design

Once the final index was constructed, the next phase of this project is to establish the concurrent validity and to test the reliability and feasibility of use of this tool. This phase involved data collection by non-dental assessors alongside dental assessors, trialling the novel index on an adult population with ID. The process used to carry out concurrent validity and reliability assessments is summarised in Fig 3.3.

Figure 3.3Summary of the process for the clinical phase of the project



3.5.2. Adult population with ID (study participants)

From the available list of Intellectual Disability (ID) service providers in Dublin, a convenience sample of three (3) service providers was selected and approached to

participate, namely Saint Michael's House (SMH), Saint John of God Community Service (SJOGCS) and Stewarts Care Ltd (SCL). The criteria for selection were:

1) Service providers are based in Dublin (where the feasibility study is to be conducted).
2) Provides service for adults (Age 18 & above) with ID.
3) Ethical approval from respective research ethics committee is granted.

3.5.2.1. Ethical application process

Ethical approval was first obtained from the Faculty of Health Sciences Research Ethics Committee and applications were made to the research ethics committees of the service providers from which participants were to be recruited: Stewart Care Ltd (SCL), Saint John of God Community Service (SJGCS) and Saint Michael's House (SMH).

For SMH, an Internal Research Sponsor (IRS) was first identified before submitting the research proposal to the research ethics committee (REC). The IRS, who had to be a permanent staff member of SMH, was then required to review and sign the application before submission. Once the ethical approval was obtained, the IRS then identified a centre that would be able to facilitate this research within the care facility. A liaison person from the care facility was chosen to assist with the project. The liaison person was involved in participant selection, participant recruitment and organising the venue for data collection.

For SJOGCS, any research project had to be registered before sending the application to the REC. As part of the registration, a 'Service Sponsor' needed to be identified to facilitate the research in their area of service. The role of service sponsor was to ensure that the 'Quality Assurance Checklist' form and a 'letter of support' for the research would be submitted with the research registration. An application to the REC was submitted following registration, and the principal investigator was required to present the research proposal during a REC meeting. Upon approval from the REC, arrangements for participant

recruitment and data collection were then undertaken with the Service Sponsor, who became the liaison person for the centre.

For SCL, it was a requirement that the research proposal must first be approved by the Stewarts Research Committee before application to the Stewarts Research Ethics Committee could be considered.

Ethical approval was obtained from two (2) service providers but ethical application was not approved by third service provider's REC (APPENDIX VII and APPENDIX VIII). The reasons given were "invasive nature of study", "no significant tangible benefit to service users" and "unavailability of staff member to become gatekeeper in facilitating this research within the unit".

3.5.2.2. Sampling/Sample size

In order to test the reliability of the assessors collecting dental data using the ODNF, the World Health Organisation (WHO) recommendations were followed (World Health Organisation, 2013). All assessors were to examine the same group of at least 20 subjects for inter-rater reliability testing; for intra-rater reliability testing, each examiner should examine a group of 25 subjects twice, with an ideal interval of at least 30 minutes between examinations. With this in mind, and discussion with a biostatistician, at least 25 participants with ID would be required to carry out the relevant statistical tests.

Power calculations (see Footnote) were conducted based on clinical data and evidence from both the World Health Organisation (WHO, 2013) and the UK's British Association for the Study of Community Dentistry's (BASCD) national epidemiological programme (Public Health England, 2016). Assuming five assessors (2 dental and 3 non-dental), each participant would have to undergo at least 10, five-minute assessments to determine the intra- and inter-assessor reliability. It was acknowledged that this would place an excessive

burden on this vulnerable group, who may, in addition, have limited cooperation. In taking the possibility of limited cooperation and participant drop-out into account, especially during duplicate assessment (test-retest) for intra-assessor reliability, a sample of sixty (60) participants was chosen in order to ensure statistical power.

To achieve this sample size, at least 150 'information packs' were distributed to the two participating centres, as a previous, similar study (Mac Giolla Phadraig et al, 2015) had indicated a 49% response rate and an 18% refusal rate. If, hypothetically, 150 participants agreed to join the study, then 60 patients would be randomly selected for inclusion in the study.

**Footnote: the expected lower bound for kappa is 0.664 (assuming 60 participants, 2 raters, level of significance is 0.05 and the prevalence of decayed, missing, filled and sound teeth are 0.564, 0.235, 0.141, 0.06, respectively)*

3.5.2.3. Participants selection

Inclusion criteria:

- 18 years old and above
- Mild or moderate levels of intellectual disability (ID)

Exclusion criteria:

- Below the age of 18
- Refuse / withdraws participation
- Cardiac conditions that would require antibiotics prophylaxis before gingival examination to prevent infective endocarditis (Wilson et al., 2007).
- Severe/profound intellectual disability with no likely cooperation for assessment

3.5.2.4. Participants recruitment

Upon obtaining ethical approval (section 2.1), letters seeking access (APPENDIX X), with detailed information on the study, were sent out to directors of each service to obtain permission to invite their service users to the study.

Initial contact was made through a nominated gatekeeper (liaison person) within each service where the 'information pack', which included an invitation letter (APPENDIX XI), participant information booklets (APPENDIX XII), and participant consent form (APPENDIX XIII) were distributed to at least 150 service users who met the inclusion criteria. Information packs for service users were designed to be in an Easy to Read format to access all users with different levels of literacy. Information packs for family members, carers and legal representatives were also provided (APPENDIX XIV). For users for whom it was judged they had capacity but were unable to provide written consent due to, for example, physical disabilities, the information pack was to be used to support the consent process. For users lacking decision-making capacity, the 'information pack' was given to the participant's legal representative.

Following distribution of the information packs, information-sharing sessions were conducted in the centres before the study, to ensure that potential participants and carers were fully informed of the research project. The sessions provided opportunities for service

users to ask questions to the research team, ensuring informed decision making about participation.

3.5.2.5. Consent

A minimum of a two-week period was set aside between giving information and seeking consent. This was more than the normal 7 days required, but in doing so, there was more time for the consent-seeking process, which might have involved the participant's next of kin or legal representatives.

Service users and/or carers, who expressed an interest in joining the study, were asked to complete the written consent form. Research participants who had decision-making capacity were asked to sign the form, whereas participants who were unable to provide written consent due to, for example, physical inability or poor levels of literacy, had the consent forms signed by a person supporting them. The person supporting the participant was required to read all the information, to explain the information to the participant and to ensure that consent was freely given. For adults lacking decision-making capacity to consent, a consent form was signed by the participant's legal representative, as required by the HSE guidance on consent and vulnerable adults (National Consent Policy, 2014, p63-79).

Completed consent forms were returned to the research team before the data collection. On the day of data collection, consent was re-confirmed by the research team before data collection proceeded, by checking with the participants and support person accompanying the participants, or by contacting the participant's legal representative, if necessary. This was to ensure that consent was still valid at the time of data collection.

3.5.3. Data to be collected

3.5.3.1. Demographics of participants, Questionnaire

A questionnaire (APPENDIX XV) was developed to capture the participant's ID, demographics (age and gender) as well as to confirm that they did not have a cardiac condition that would require antibiotics prophylaxis before the periodontal assessment (Wilson et al., 2007).

3.5.3.2. Clinical assessments

Conventional dental assessments

In order to carry out a comparison between the ODNF assessment and conventional dental assessments, standard, World Health Organisation (WHO) criteria for assessing dental caries and periodontal diseases burden were chosen for the latter indices. The Decayed, Missing, Filled Teeth (DMFT) and Community Periodontal Index of Treatment Needs (CPITN) are widely used internationally in epidemiological surveys as well as research tools. However, these dental indices, which have good specificity and sensitivity, can only be used by trained dentists (Saintrain & Vieira, 2012). For the items on dentition status and CPITN, the data collection forms (APPENDIX XVI) were adapted from the World Health Organisation (WHO) assessment form (adult), with permission granted from the WHO (APPENDIX XVII).

ODNF assessment

For the ODNF index assessment, once the items of the ODNF assessment were finalised (Section 4.2.1), the data collection form (APPENDIX XVIII) was then developed as a spreadsheet in Microsoft Excel 2013. Data collection forms for both the conventional dental and ODNF assessments were formatted for capture on tablet devices (Microsoft Surface Pro 4 tablets and Apple iPad®).

Conduct of clinical assessment and equipment

Participants were seated on a normal chair. For the ODNF assessment, an examination was carried out using a pen torch and disposable No.4 plain dental mirror only. For dentition status and CPITN assessments, examination was undertaken using a disposable No.4 plain mouth mirror, a pen torch as well as a disposable CPITN probe. A list of equipment and instruments needed for the assessments can be found in APPENDIX XIX. It is important to note that the ODNF assessment was to be completed first, followed by dentition status and finally, the CPITN assessment.

Gold standard dental assessor, dental assessor

Two qualified dentists were selected to be the dental assessors for this study, namely the principal author NSI, and co-researcher BD. NSI is undergoing specialist clinical training in Special Care Dentistry. BD, who is a trained, calibrated and experienced epidemiologist, was chosen to be the gold standard (GS) dental assessor for this study. Specifically for this study, the gold standard assessor underwent calibration with the team who were conducting a large-scale dental epidemiological study in the UK, prior to commencement of the study. Both gold standard assessor and dental (non-gold) assessors were asked to carry out the conventional dental assessments as well as the ODNF assessment.

Non-dental assessors

Three research colleagues from various areas in Trinity College Dublin were invited as non-dental assessors to carry out the ODNF assessment. The Dental Council of Ireland had indicated that it would be acceptable to deploy non-dental workers to collect the type of data proposed for assessment in this study (APPENDIX XXXVIII). Criteria for selection were:

1) Agreed to participate in this study;
2) No dental qualification;
3) Had never attended a structured dental assessment and/or training and calibration event.

3.5.3.3. Feedback forms

The aim of the feedback forms was to determine the acceptability of ODNF index to the participants and the assessors (end-users). For the participants with ID, feedback forms (APPENDIX XX) were given to them immediately after the ODNF assessment conducted by the first assessor. The closed question format was selected to determine whether the ODNF assessment was acceptable to the participants with ID (no pain/discomfort, safe and quick).

All assessors were asked to complete a semi-structured feedback form (APPENDIX XXI) at three points, namely, after completion of part 1 training (self-learning material), at completion of part 2 training, and at completion of data collection. This questionnaire was adopted from a questionnaire used in the OHAT study by Chalmers et al 2005; a four-point Likert scale was used to rate the statements, ranging from strongly agree to strongly disagree. Each assessor was also asked to record the time taken to complete part 1 training (self-learning materials). Additional, open-ended questions were also included to evaluate the length of training, training materials, problems encountered during data collection as well as suggestions on the training and data collection.

3.5.3.4. Time taken to carry out ODNF assessment, field logs and cost

The time taken for each ODNF assessment was also recorded (APPENDIX XXII). Information on survey expenses, cost of planning, training sessions, field examination, statistical analysis and salaries were recorded as part of the requirement to answer the

research question. Field logs collected by co-researchers (CGMP and JHN) as well as the assessors during the pilot, training and data collection phases, were also kept.

3.5.4. Data collection protocol

A data collection protocol (APPENDIX XXIII) was developed to inform the research team and the assessors about the protocol for the conduct of this study, as well as to train both the dental and non-dental assessors.

The contents are as follows:

1. Brief introduction to the study
2. Infection prevention and control guidelines as per Dental Council and WHO guidelines
3. Training tool for clinical assessments (Criteria and codes for various diseases and conditions to be observed and recorded)
    a. Dental assessments (WHO: Dentition status & CPITN)
    b. ODNF assessment
4. Data collection conduct:
    a. Interaction with participants
    b. Set up of examination area & instruments
    c. Obtaining consent from participants with ID (content contributed by co-researcher Dr. Eilish Burke [EB] of the IDS-TILDA team)
    d. Conduct of assessments : questionnaire, ODNF, dentition status and CPITN
    e. Data handling: Recording of data onto tablet devices (Microsoft Surface Pro 4 tablets and Apple iPad®), submitting data to research team and data protection.

3.5.5. Pilot phase

As a newly developed health tool, the ODNF index was piloted in an ideal environment (O'Mullane, 1976), i.e., a population without ID. Ethical approval (APPENDIX VI) was sought from the School of Dental Science Level 1 Research Ethics Committee (REC). This pilot phase tested the training manual and data collection protocol. The ten (10) first year dental nursing students were invited to participate in the pilot phase. The procedure (Table 3.1) was followed in this pilot phase.

Table 3.1 Procedures carried out in the pilot phase.

1. The first part of the pilot phase was testing the training programme. This was carried out one (1) week before the pilot data collection with the dental assessors. An interval of at least a few days between training and data collection is recommended to allow time for the assessors to integrate their knowledge of the indices and to practise the assessment procedures.
2. Pilot phase of data collection: Each participant was examined by one dental assessor first, followed by the other dental assessor. Clinical assessments were carried out as per section 3.4.3.2. The data collection protocol was followed. *After assessments on six (6) of the participants, results were reviewed, variations between assessors were discussed and any major discrepancies were resolved by group discussion. This step was necessary to ensure that both assessors were highly consistent when using the ODNF, dentition status and CPITN assessments, in this ideal group of population. Data collection was then completed for the remaining four (4) participants. Repeat examinations were carried out after at least 30 minutes had elapsed; in order to assess test-retest reliability of each individual assessor.*
3. Feedback was collected from both assessors and participants; and was incorporated into a revised data collection protocol for the main study.

3.5.6. Training

Once the training manual was finalised, training was then carried out for all assessors. The dental assessors were trained and calibrated to use the dentition status, CPITN and ODNF assessments, while the non-dental assessors were trained on the ODNF assessment only.

The training was divided into three (3) parts. All assessors were given the complete training manual one (1) week prior to the training day. The first part of the training was to be completed by using the training manual, before attending the training day. This first part included a brief introduction to the study as well as an introduction to the criteria and codes for various diseases and conditions in the standard dental assessment (dental assessors only) and ODNF assessment (all assessors). A self-grading quiz was inserted after each item of the ODNF assessment to aid preliminary understanding of the ODNF assessment tool. Each assessor was also asked to record the time taken to complete this directed self-learning part of the training. Assessors returned feedback (APPENDIX XXI) upon finishing the first part.

The second part of the training opened with a presentation by Dr. Eilish Burke, who has experience in data collection for older adult people with ID; focusing on the ethics of research with populations with ID, followed by refinement of the ODNF assessment based on discussion on the self-learning material in Part 1. Comments from non-dental assessors were taken into account in refining the descriptions for the ODNF assessment.

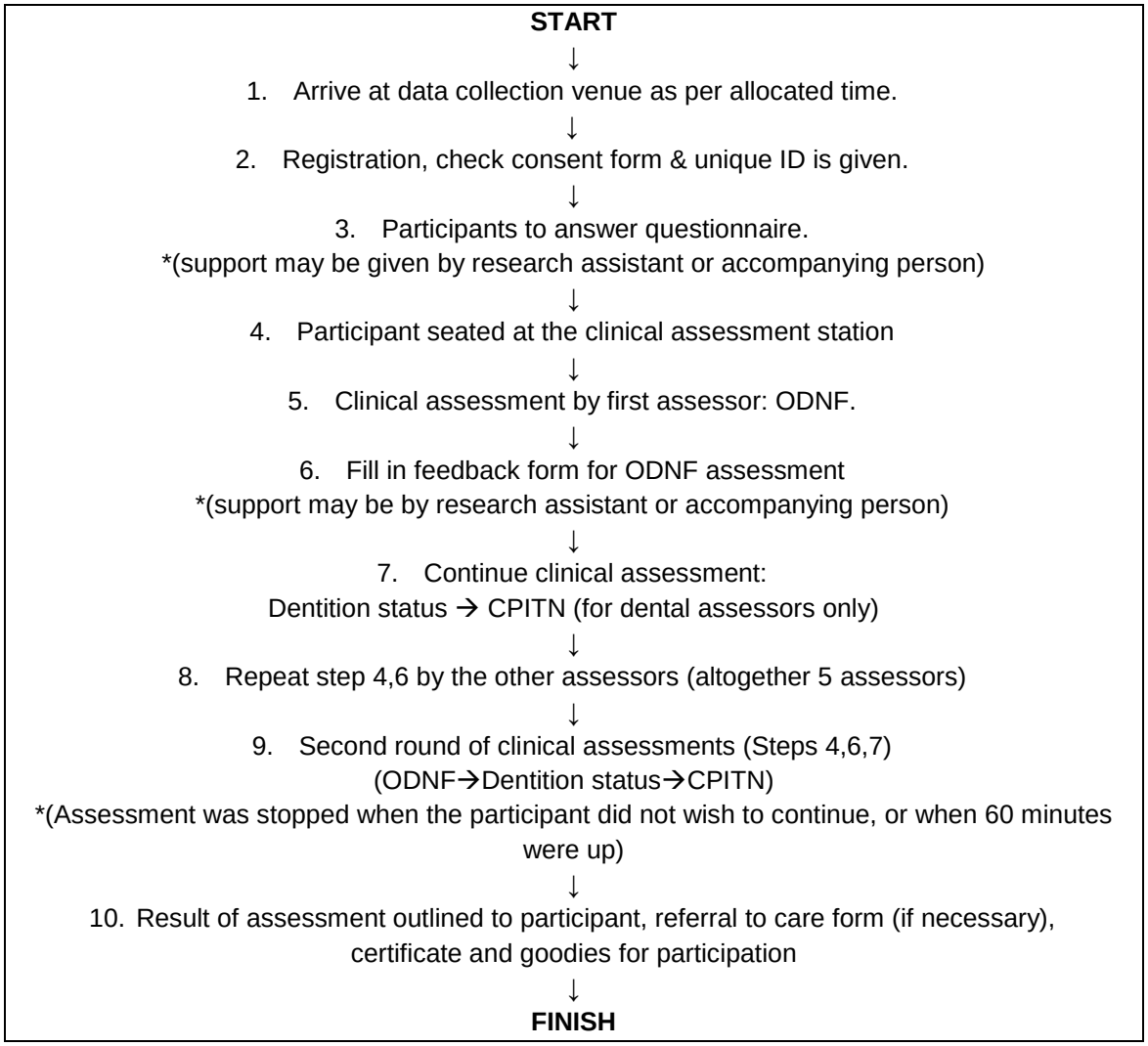
The final part of training involved a practical session on setting up the examination area, conduct of examination and use of the clinical assessment forms. All assessors had an opportunity to examine at least five people who had volunteered to be part of this training (co-researchers in the study and colleagues in the dental hospital). At the end of training, a feedback form was again completed by all assessors.

By the end of piloting and training, assessors were expected to have completed all training necessary for data collection in the study using the piloted data collection, but not necessarily calibrated in the use of ODNF as this was to be established in the main study which involved the study sample (n=60 people with ID).

3.5.7. Data collection day

The flow of data collection during the day is shown in Figure 3.4.

Figure 3.4 Sequence of events for each participant with ID



Appointment

The location of the data collection was in selected centres of each service provider. Each participant with ID was given a specific time to attend the data collection (APPENDIX XXIV). A maximum 5 participants with ID were allocated to each appointment slot.

Registration and consent

When the participants arrived, they were registered and given a unique participant ID. The consent form was checked and re-confirmed with participants and the accompanying person. This was to ensure that consent was still valid before the start of data collection.

Questionnaire

The first part of data collection involved answering the questionnaire (APPENDIX XV). The Next of Kin or key worker ('proxy') were encouraged to accompany the research participants with ID. The participants could then get assistance from their accompanying person in answering the questions. Once the questionnaire was completed, each participant was given a sticker label with their unique participant ID and all 5 participants were sent to their allocated clinical assessment stations, with or without the key worker for support.

Clinical assessment sequence

The next part of the data collection was the clinical assessment. Conduct of clinical assessments were carried as per section 3.4.3.2. There were 5 assessors; namely 2 dental assessors (BD and NSI) and 3 non-dental assessors (N1, N2 and N3). There were 5 clinical assessment stations set up; each assessor was to move around the 5 stations to examine the 5 patients.

At each station, all dental and non-dental assessors carried out the ODNF assessment first; thereafter only the dental assessors carried out the dentition status and CPITN assessments. Only the gold standard assessor BD carried out the CPITN assessment. This decision was made, not only for good clinical reasons but also, following discussion with the Research Ethics Committee, who had felt that the CPITN assessment might cause discomfort to the participants and hence should only be carried out once during the clinical assessment. A table on the clinical assessment sequence can be found

in APPENDIX XV. Standard operating procedures, including infection prevention and control protocols for clinical assessments, were followed (APPENDIX XXVI).

After the first ODNF assessment by the first assessor, each participant was asked to complete a feedback form (APPENDIX XX). This was only completed once for each participant and was used to determine the acceptability of ODNF assessment. Then, the rest of clinical assessments were carried out.

After completing the first round of assessments on each participant, all assessors re-evaluated the same participants during the second round of assessment, at least 30 minutes later, as in the WHO guidelines (WHO, 2013). The second (re-test) examination was only carried out on participants who had agreed to continue. The time taken to complete the test-retest assessments was recorded; and, on advice from service managers, sixty (60) minutes was decided as an appropriate cut-off assessment time before participants were likely to become tired or anxious. If participants decided at any stage not to continue, for example, due to fatigue or anxiety, the examination was discontinued. Not all assessors were able to do a repeat examination for some participants. The number of examinations and time that could be sustained by the participants were assessed as part of this feasibility study.

Data were recorded by the assessors directly onto the clinical assessment forms on the tablet devices. Since dental assessors had to carry out the ODNF and the standard dental assessments, research assistants were recruited to record data in order to reduce the time burden on the participants. All data collected were then saved and password-protected so that it was only accessible to the principal author, NSI.

Results (+/- referral), certificate of participation, toothbrush, and OH advice

If an acute oral/dental condition was identified, the participants (with their family/advocate's consent) were informed and their agreement was sought to refer them to their usual dental provider for care. Each participant was given a token of appreciation (toothbrush, toothpaste and certificate of participation) as well as the written result of their clinical assessment. Brief oral hygiene advice was also given to all participants by a dental hygienist (CW).

No routine dental care was provided during the study. All participants were verbally reassured again that there was no need to take part in the study and that refusal to engage with the study would in no way impact on their current or any future dental care.

3.5.8. Data analysis

Data recorded on the clinical assessment forms on the tablets were sent to the principal author NSI via a secured connection within the institution. All data collected were password-protected and only accessible to the principal author NSI. In order to compile the data entered for each assessment, Macro was created in Microsoft Excel 2013. Macro enables automated compilation of data entered into one worksheet, hence no manual data entry and compilation needs to be carried out by the research team.

Data management and analysis were then carried out using the statistics programmes R v.3.2.2 and Statistical Package for Social Science (SPSS) 20.0 (SPSS Co., Chicago, USA).

3.5.8.1. Descriptive analysis

Descriptive statistics were used to present the results from the questionnaire, clinical assessments, feedbacks from participants and non-dental assessors and time sheets.

3.5.8.2. Quantitative analysis:

Quantitative analyses were carried out according to the following sequence:

1. Test-retest and inter-rater reliability tests of gold standard dental assessor and non-gold dental assessor using conventional dental indices.
2. Concurrent validity of the ODNF by comparing the ODNF index values against conventional dental assessments.
3. Inter-rater reliability of the ODNF index by comparing assessments carried out by the non-dental assessors, against the gold standard dental assessor.
4. Intra-rater (test-retest) reliability of the ODNF assessments by comparing the first and second ODNF assessments carried out by all assessors.

1. <u>Test-retest and inter-rater reliability tests of gold standard dental assessor and non-gold dental assessor using conventional dental indices.</u>

In order to establish the dental assessor BD as a gold standard in this study, reliability assessments were carried out on the conventional dental indices. Test-retest reliability was tested using Spearman's correlation ($\mathbf{r_s}$), Cohen's Kappa and Gwet's coefficient tests. The Null hypothesis was that there was no statistically significant level of agreement between first and second assessments using the conventional dental indices by the gold standard dental assessor BD.

Then, additional inter-rater reliability tests were carried out comparing the conventional dental assessments between the non-gold dental assessor and the gold standard assessor. The Null hypothesis was that there is no statistically significant level of agreement between the gold standard dental assessor BD and the non-gold dental assessor, NSI.

Finally, the test-retest reliability for the dental (non-gold) assessor, NSI, administering the conventional dental indices was also carried out and tested using the statistical tests as

above. The Null hypothesis was that there is no statistically significant level of agreement between first and second assessments of dental indices by non-gold dental assessor BD.

For both Cohen's Kappa and Gwet's coefficient, statistical values of > 0.80 were interpreted as indicating almost perfect or excellent agreement, 0.61–0.80 as indicating substantial agreement, 0.41–0.60 as indicating moderate agreement, 0.00–0.20 as indicating slight agreement and <0.00 indicating poor agreement (Portney and Watkins, 2000, Landis and Koch, 1977).

2. Concurrent validity of the ODNF by comparing the ODNF index values against conventional dental assessments.

Criterion validity was tested by means of the concurrent validity of the ODNF index against standard dental assessments (Dentition status and CPITN). Concurrent validation was carried out by comparing the results of assessments by the gold standard assessor and using the statistical tests indicated in APPENDIX XXVI. An additional, concurrent validity assessment was carried out on results obtained from the other dental (non-gold) assessor, using the same statistical tests. The null hypothesis stated that there was no statistically significant level of agreement between the ODNF assessment and the conventional dental assessments.

3. Inter-rater reliability of ODNF

The inter-rater reliability assessment was carried out by comparing the ODNF assessments made by the three (3) non-dental assessors against the gold standard dental assessor. The statistical tests used for the inter-rater reliability assessments are shown in APPENDIX XXVIII. For this, the null hypothesis stated that there was no statistically significant level of agreement between the ODNF assessments administered by the gold standard assessor and the non-dental assessors.

As an additional exercise, the inter-rater reliability of the ODNF was also determined comparing ODNF assessments made by the non-dental assessors against the non-gold dental assessor. Statistical tests used were similar to the inter-rater reliability mentioned previously. For this, the null hypothesis stated that there was no statistically significant level of agreement between the ODNF assessments administered by the non-gold dental assessor and the non-dental assessors.

Finally, the inter-rater reliability of the ODNF was also determined comparing ODNF assessments made by the dental (non-gold) assessor against the gold standard assessor. This was to compare the inter-rater agreement results of the dental assessor using the ODNF. The assessments were tested using the same statistical methods. For this, the null hypothesis stated that there was no statistically significant level of agreement between the ODNF assessments administered by the gold standard assessor and the dental (non-gold) assessor.

4. <u>Test-retest reliability of ODNF</u>

In completing the reliability assessments, test-retest reliability was tested by comparing the first and second ODNF assessments for all assessors. For this, the statistical tests used were Spearman's correlation, Cohen's Kappa and Gwet's coefficient tests. The null hypotheses stated that there was no statistically significant level of agreement between the ODNF assessments administered by the first and second assessments for each assessor.

3.5.8.3. Preliminary cost analysis of ODNF

The aim of cost analysis is to estimate the cost per participant in a hypothetical survey, between data collection by non-dentist using the ODNF against data collection adopting conventional dental indices. This information is vital to inform policy making, as scarcity of

resources is a driving factor in initiation of this research study. In this study, preliminary cost analysis was carried out by comparing the time taken to examine using ODNF versus literature-based estimates relating to conventional indices, cost of non-dental assessors versus dental data collector and by comparing clinical examination equipment for both conditions.

4. RESULTS

4.1. Introduction

This chapter starts by presenting data arising from the Content Validation process (section 4.2). Following this, in section 4.3, data on the concurrent validation exercise are presented, comparing the ODNF assessment against conventional dental assessments. The next stage of reliability testing, for Inter-rater and test-retest reliability tests, comparing the data from the ODNF assessments by the gold standard assessor, dental non-gold assessor and non-dental assessors. Finally, to determine the feasibility of the newly constructed assessment tool, which includes the time taken to carry out the assessments, the outline cost of using the assessment tool and training as well as the feedback from the participants with ID and the non-dental assessors, are reported in section 4.4.

4.2. Construction and content validity of the ODNF

Before piloting and refining the assessment tool, prior to its application in the feasibility study, there were four steps in the content validation process: identifying objectives of the ODNF index, content validation with a systematic literature review, items selection, content validation using a content validity ratio (CVR) approach and lastly, final review.

4.2.1. Construction and content validation of ODNF

Content validity was developed using a systematic literature review concerning oral assessment tools used by non-dental individuals as well as a consultation and CVR approach with a panel of experts.

Systematic review of literature

An electronic search of the literature, pertaining to indices for used by non-dental assessors, was conducted on the 15th February 2016; 411 articles that met the inclusion criteria were selected. Following title and abstract review, 45 articles were identified for further discussions between reviewers before finalising the articles for full-text review. A full-text review and data extraction were then carried out by NSI. The reference sections were also screened for other relevant papers.

The literature review identified the following relevant indices; Oral assessment guide (Eilers *et al*, 1988), Brief Oral Health Status Examination (Kayser-Jones *et al*, 1995), Oral Health Assessment Tool (Chalmers et al, 2005), Community Oral Health Indicator (Saintrain & Vieira, 2012), Mouth Self Examination (Scott et al, 2010), WHO oral toxicity scale (Vagliano *et al*, 2011), Oral Health Risk Assessment (Fiske et al., 2006) and Minimum Data Set 2.1 (Arvidson-Bufano et al., 1996). Following the content validation process, 6 studies were included for full analysis. Full report of the systematic literature review can be found in Appendix XXIX

Items selection and content validity ratio (CVR)

Items from all the existing tools above were reviewed and some were selected as potential items. These potential items then went through content validation using the CVR approach. Eight (8) dental professionals from various dental specialties, with extensive experience in managing patients with intellectual disabilities, were asked to score the potential items identified for each domain. The content validity ratio (CVR) was calculated and it was determined at the outset that with the scores from the eight (8) raters, items with an agreement of 0.85 and above were acceptable for inclusion as relevant to the newly constructed data collection tool (Streiner et al, 2014). Items with an agreement lower than 0.85 were not considered as relevant. The full result of CVR can be found in APPENDIX XXX.

Items that were selected (based on the CVR value), were then reviewed (APPENDIX XXXI). Items were grouped under main categories namely: soft tissues (which include lips and gums, cheeks, tongue, roof of mouth and under the tongue), Gum condition, oral cleanliness, number of teeth, teeth in occlusion, presence of denture in the mouth, visible caries, and dental pain. For the categories which did not have relevant items (CVR < 0.85), new items from other, identified assessment tools were reviewed, discussed and adopted (Table 4.1)

Final index reviews

In the final review of the assessment tool, discussion was carried out to refine each item and its ratings. Descriptive and numerical ratings for the ODNF items were developed following the routine scale, the lowest rating indicated the healthy end and the highest numerical rating was indicative of unhealthy conditions. Following the pilot phase and training of assessors, the ODNF assessment was further refined (Table 4.2) and was considered ready to be used for data collection for the clinical phase of this research.

Table 4.1ODNF Index construction: Index review with modifications highlighted

Name of items	Original indices	How to measure	Descriptive ratings		
Soft tissues: Lips, cheeks, tongue, roof of mouth, under the tongue (combined); redness and white patches, ulcers, lumps & swelling	**MSE**	Pull down lower lips and look inside lip and look at gums; repeat this on upper lip; pull out right cheek look at the inside of your right cheek; stick out tongue and look at the top surface, stick out tongue and move it from side to side to look at one side then the other; open mouth and tilt head back to look at the roof of your mouth; place the tip of the tongue on the roof of mouth and look at the underside of your tongue and the floor of mouth	Absent	Present	
Gums: bleeding, swelling, ulcers;	**OHAT**	Look for bleeding, swelling, ulcers; On gums in between teeth	Pink, moist, soft, no bleeding; swollen, bleeding, ulcers, white/red patches,	dry, shiny, rough, red, swollen, or one ulcer/sore spot on gums;	generalized redness on gums
Oral cleanliness	**OHAT**	observe, use light	clean and no food particles or tartar in mouth or dentures;	food particles/ tartar/ plaque in 1-2 areas of the mouth or on small area of dentures or halitosis (bad breath);	food particles/ tartar/ plaque in most areas of the mouth or on most of dentures or sever halitosis (bad breath)
Visible caries	**COHI**	observe, use light	0 visible caries;	1-2 visible caries;	3 or more visible caries

Name of items	Original indices	How to measure	Descriptive ratings		
Dental pain	**OHAT**	observe, use light	no behavioural, verbal or physical signs of dental pain;	are verbal &/or behavioural signs of pain such as pulling at face, chewing lips, not eating, aggression;	physical pain signs (swelling of cheek or gum, broken teeth, ulcers), as well as verbal &/or behavioural signs (pulling at face, not eating, aggression)
Tooth count – upper teeth		observe, use light, count Count upper teeth	0,1,2,3…		
Tooth count - lower teeth		observe, use light, count Count lower teeth	0,1,2,3…		
Denture wear – upper	**COHI**	observe, use light, check for present of denture	Absent	Present	
Denture wear - lower	**COHI**	observe, use light, check for present of denture	Absent	Present	
Occluding pairs	**Eichner's index**	observe, use light, identify posterior teeth, count teeth in contact	1 or more posterior contacts	Anterior contacts only	No contacts at all

Table 4.2 ODNF Index construction: Final index after training and pilot phase

ODNF category	Method	Descriptive ratings		
Tooth count (Upper)	Count the number of upper teeth	0, 1, 2, 3…		
Tooth count (Lower)	Count the number of lower teeth	0, 1, 2, 3….		
Denture wear (Upper)	Check for presence of upper denture	0 Absent	1 Present	
Denture wear (Lower)	Check for presence of lower denture	0 Absent	1 Present	
Occluding pairs	Count the number of anterior and posterior contacts	0 No occlusal contacts	1 1 or more posterior contacts	2 Anterior contacts only
Soft tissues	Examine **lips, labial and buccal mucosa, tongue, roof of mouth, floor of mouth**. Check for the presence of **redness, white patches, ulcers, lumps & swelling.**	0 Absent	1 Present	
Oral cleanliness	Check for **food particles, tartar & plaque** in the **mouth** or on **dentures**; and presence of **halitosis (bad breath)**	0 **Clean**, and **no** food particles or tartar in the mouth or dentures	1 **Little** food particles/tartar/plaque in the mouth or on dentures	2 **A lot of** food particles/tartar/plaque in the mouth or on dentures; or halitosis (bad breath)
Gum	Check for **redness, swelling, bleeding & ulcers on gums**	0 **No**; Pink, moist, soft, no bleeding	1 **Yes;** **Localised** redness, swelling, bleeding & ulcers on gums	2 **Yes;** **Generalised** redness, swelling, bleeding & ulcers on gums
Visible caries	Count the number of visible caries	0 **0** visible caries	1 **1-2** visible caries	2 **3 or more** visible caries
Dental pain	Check for signs of dental pain. **Verbal**: Ask patient if there is pain in the mouth. **Behavioural**: Check for signs such as **pulling at face, chewing lips, not eating & aggression**. **Physical**: Check for signs such as **swelling of cheek or gums, broken teeth, ulcers**.	0 **No** verbal, behavioural or physical signs of dental pain	1 **Verbal**; And/or **behavioural** signs of pain such as pulling at face, chewing lips, not eating, aggression; No physical signs.	2 **Physical** pain signs (swelling of cheek or gum, broken teeth, ulcers), & verbal; **&/or behavioural signs** (pulling at face, not eating, aggression)

4.3. Development of training tool for ODNF index.

This section reports the development of training tool for ODNF index. Diagnostic codes and criteria for ODNF index assessment was laid out in APPENDIX XXXII

The **objectives** of the training were identified; there are:

- To understand the importance of developing a tool that can be carried out by non-dental personnel.
- To have a brief idea how the tool was constructed.
- To gain a preliminary understanding of the tool for oral assessment.
- To learn methods in obtaining consent
- To discuss the ODNF index items in detail.
- To be able to carry out ODNF assessment on subjects.
- To be able to carry out field examination set up.

The **structure** of the training was set; as follows:

1) Trainers: Lead author (NSI), assistant professor in Dental Public Health (BD), experienced researcher from IDS-TILDA Study (EB); Training assistants: Co-researchers (JHN and CMGP).
2) Training manual is to be given to the assessors 1 week prior to training.
3) There will be 2 sessions of training (a total of 8 hours).
4) Contents of training manual: Data collection protocol, training tool for ODNF, training tool for WHO Dentition status and CPITN and data handling protocol after data collection.
5) Part 1 is to be completed before training day. Time taken to complete part 1 is to be recorded as part of feedback of the feasibility assessment. Queries on this part can be made during part 2 of training.
6) Part 2 and 3 are to be completed during training day.

7) Part 2 of training involves discussion on part 1, lecture on obtaining consent and explanation on the data collection protocol.
8) Part 3 is hands-on practical component of this training.

As part of the training manual, a set of intra-oral photographs was collated to demonstrate the diagnostic codes and criteria of each item of this index. In this training tool, an explanation of how to carry out the examination for each of the items listed above, was given. Training tool of ODNF can be found in the data collection protocol (APPENDIX XXIII). The training tool for the ODNF index was tested in the pilot phase with ideal population without ID, before being incorporated into the final training manual.

4.4. Concurrent validity & reliability

4.4.1. Sample oral health characteristics of the study population

This section reports sample oral health characteristics of the study population using the ODNF index. A total of 49 adults participated in this study, with a mean age of 43.2 years (SD=16.2, Range 19-70 years): of this sample, 22 (44.9%) were female and 27 (55.1%) were male. Table 4.3 shows the oral health (OH) characteristics of the whole population when measured using the ODNF assessment tool.

As scored by the Gold Standard dental assessor, 35 out of 49 participants (71.4%) were found to have less than 20 teeth. Two participants (4.2%) were fully edentulous. Six participants (12.5%) were found to be wearing at least one denture in the mouth during the assessment. Thirty-eight participants (77.6%) had one or more posterior contacts, meanwhile 10 participants (20.4%) had anterior contacts only or no contacts at all. Soft tissue lesions (red, white patches, ulcers, lumps or swelling) were only found in 4 participants (8.2%). Thirty-two participants (65.3%) were found to have food particles or

tartar (localised or generalised) in the mouth or on dentures. Thirty-three participants (67.3%) had at least one form of gum condition (redness, swollen, bleeding & ulcers) either localised or generalised in the mouth. Thirty-six subjects (73.5%) had no visible caries, whereas only 2 participants had 3 or more visible carious teeth. Ten participants (20.4%) presented with either verbal, behavioural or physical signs of dental pain.

Table 4.3 Sample OH characteristics using ODNF assessments tool by gold standard assessor

ODNF ITEMS		Frequency (N=49)	Percent (%)
Total number of teeth (grouped)	20 & more teeth	13	26.5
	Less than 20 teeth	35	71.4
	Missing data	1	2.0
Denture wear	Absent	42	85.7
	Present	6	12.2
	Total	48	98.0
	Missing data	1	2.0
Occluding pairs	1 or more posterior contacts	38	77.6
	Anterior contacts only	7	14.3
	No contacts at all	3	6.1
	Missing data	1	2.0
Soft tissues (Lips, cheeks, tongue, roof & floor of mouth): Redness, white patches, ulcers, lumps and swelling	Absent	44	89.8
	Present	4	8.2
	Missing data	1	2.0
Oral cleanliness: Food particles or tartar in the mouth or dentures	None	16	32.7
	Localised	18	36.7
	Generalised, +/- severe halitosis (bad breath)	14	28.6
	Missing data	1	2.0
Gums: Redness, swollen, bleeding & ulcers on gums	None	15	30.6
	Localised	22	44.9
	Generalised	11	22.4
	Missing data	1	2.0
Number of visible caries lesions	0	36	73.5
	1 or 2	10	20.4
	3 or more	2	4.1
	Missing data	1	2.0
Dental pain	No pain	38	77.6
	Verbal &/or behavioural signs of pain	7	14.3
	Physical signs of pain, as well as verbal &/or behavioural signs	3	6.1
	Missing data	1	2.0

4.4.2. Test-retest and inter-rater reliability tests of gold standard and non-gold dental assessors using conventional dental indices

This section reports the result of the test-retest reliability of the gold standard dental assessor when using conventional dental indices, followed by results of the inter-rater reliability test between gold standard and non-gold dental assessors. and lastly, the results of the test-retest reliability for the non-gold dental assessor. Tables of results from this section can be found.

Test-retest reliability for the gold standard dental assessor using conventional dental indices

First, intra-rater reliability was tested to determine the level of agreement between first and repeat assessments of the dental indices by the gold standard dental assessor. For evaluating test retest (intra-rater) reliability of the assessor using conventional dental assessments, Weighted Kappa, Weighted Gwet's and Spearman's correlation (r_s) were used to compare discrete variables (DMFT – decayed, DMFT – missing, DMFT – filled, DMFT – Total DMFT, Total Upper teeth, Total lower teeth, Total teeth, Total Missing teeth), meanwhile only Weighted Kappa and Weighted Gwet's tests (APPENDIX XXXIII) were used to assess agreement of categorical ODNF data (DMFT – decayed (grouped), and Total teeth (grouped)).

The results of test-retest examinations on the conventional dental assessment items for the gold standard assessor showed high percentage agreement (>0.90). For the gold standard assessor (APPENDIX XXXIII) the agreements between first and second examinations on all items were above 0.64 (substantial agreement) for kappa test and above 0.84 (almost perfect agreement) for Gwet's test. For the discrete variables, the agreement was above 0.75 for spearman (r_s) test.

Inter-rater reliability of conventional dental assessments: dental (non-gold) assessor, against gold standard assessor

The following section reports the results of the inter-rater reliability tests between the gold standard dental assessor and the non-gold dental assessor. Inter-rater reliability tests between gold standard assessor and dental (non-gold) assessor were carried out using the statistical tests as above (APPENDIX XXXIV)

The results of examinations performed by both gold standard and non-gold dental assessors using the conventional dental assessment presented a high percentage of inter-rater agreement (>0.80) for all items. The level of agreement on the majority of the items was above 0.80 (perfect/excellent agreement) on the majority of the items except 'DMFT – grouped', where there was lower kappa agreement and lower Spearman's correlation values but higher Gwet's agreement values.

Test-retest reliability of non-gold dental assessor using the conventional dental assessments.

Following on, test-retest reliability assessments were carried out for the non-gold dental assessor, using statistical tests described previously (APPENDIX XXXV).

The results of the test-retest reliability for the dental non-gold standard assessor, showed a high percentage agreement (>0.90), statistically significant high level of kappa value (above 0.87) as well as Gwet's value (above 0.90). For the discrete variables, the agreement was above 0.90 for spearman (rs) test.

In summary, the above section demonstrates that there was a statistically significant level of agreement between first and second assessments of dental indices by the gold standard dental assessor BD, between the gold standard dental assessor BD and the dental (non-

gold) assessor, NSI; and between first and second assessments of dental indices by the non-gold dental assessor.

4.4.3. Concurrent validity of ODNF

This section assesses the validity of the novel index by calculating agreement between measures of the phenomena as scored adopting conventional assessments, thereby demonstrating concurrent validity, in addition to the content validity incorporated during the construction of ODNF.

Concurrent validity was assessed for the ODNF items (tooth count, Gum condition and visible caries), against conventional dental indices (WHO Dentition status and CPITN). Weighted Kappa, Weighted Gwet's and Spearman's correlation (r_s) were used to compare discrete variables (upper teeth, lower teeth and total teeth) between the ODNF and the conventional dental assessments, as evaluated by the gold standard assessor and the (non-gold) dental assessor. For the categorical data (Total teeth – grouped, Gum condition and Visible caries), Weighted Kappa and Weighted Gwet's (Table 4.4),as well as sensitivity and specificity (Table 4.5) tests were applied.

The results of the examinations undertaken by both the gold standard and the dental (non-gold) assessors, using the ODNF and conventional dental assessments (Table 4.4), showed strong percentage agreement (>0.85) for all the variables tested (Upper teeth, Lower teeth, Total teeth, Total teeth-grouped, Gums, Visible caries).

On the Weighted Kappa and Weighted Gwet's tests, there was highly statistically significant agreement ($p<0.001$) between all the ODNF and the conventional dental assessments (Table 4.4).

For tooth variables and visible caries, the level of agreement was above 0.90 for kappa, Gwet's and spearman (r_s) tests. The results for the variable 'Gums' showed moderate (Weighted Kappa = 0.59) and substantial (Weighted Gwet's = 0.62) agreement.

When looking at the diagnostic accuracy, high (H) sensitivity and high specificity were noted for 'Total teeth (Grouped)'. For variable 'Gum condition', high sensitivity and high specificity were noted for Scores 0 and 1; but low sensitivity and high specificity were noted for Score 3. This was found to be similar to 'Visible caries' (Table 4.5).

Table 4.4 Concurrent validity of ODNF (against conventional dental assessments); Percentage agreement (%Ag), weighted Cohen's Kappa coefficient, Weighted Gwet's AC2 coefficient & Spearman's correlation (r_s)

ITEMS	GOLD STANDARD ASSESSOR				DENTAL ASSESSOR (NON-GOLD)			
	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s
Upper teeth	0.99	0.97*** (0.94,0.99)	0.98*** (0.96,0.99)	0.95	0.99	0.97*** (0.94,0.99)	0.98*** (0.96,0.99)	0.95
Lower teeth	0.99	0.97*** (0.95,0.99)	0.99*** (0.96,0.99)	0.94	0.99	0.98*** (0.97,0.99)	0.99*** (0.97,0.99)	0.96
Total teeth	0.99	0.97*** (0.95,0.99)	0.98*** (0.97,0.99)	0.95	0.99	0.98*** (0.97,0.99)	0.98*** (0.97,0.99)	0.97
Total teeth (Grouped)	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x	1.0	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x
Gums	0.85	0.59*** (0.40,0.78)	0.62*** (0.44,0.79)	x	x	x	x	x
Visible caries	0.95	0.73*** (0.55,0.92)	0.92*** (0.85,0.98)	x	0.86	0.51*** (0.29,0.72)	0.73*** (0.56,0.90)	x

Key: *p<0.05 **p<0.01 ***p<0.001; x: Not calculated; highlighted – blue (below 0.61), green (increased value with Gwet's)

Foot note: CPITN was only recorded by 1 assessor (gold standard), as CPITN is a non repeatable measure as the first assessment changes the condition of the tissue making repeatable measurement impossible; Spearman's correlation was calculated for discrete variables.

Table 4.5 Concurrent validity of ODNF (between ODNF and conventional dental assessments); Sensitivity and specificity

ITEMS	GOLD STANDARD ASSESSOR		DENTAL ASSESSOR (NON-GOLD)	
	Sensitivity	Specificity	Sensitivity	Specificity
Total teeth (Grouped) 0: 20 & more 1: Less than 20	1.00	1.00	1.00	1.00
Gums (Grouped) 0: None 1: Localised 2: Generalised	1.00 0.67 0.43	0.88 0.62 0.95	x	x
Visible caries 0: 0 caries 1: 1,2 caries 2: 3 or more caries	0.97 0.62 0.50	0.73 0.94 0.98	0.89 0.57 0.14	0.71 0.79 0.95

Key: blue (below 0.61), red (below 0.41) x: Not calculated
Foot note:
CPITN was only recorded by 1 assessor (gold standard), as CPITN is a non repeatable measure as the first assessment changes the condition of the tissue making repeatable measurement impossible; Spearman's correlation was calculated for discrete variables.

4.4.4. Inter-rater reliability of ODNF

4.4.4.1. Comparison of ODNF assessments by non-dental assessors, against gold standard assessor

An inter-rater reliability test was carried out at two levels: non-dental assessors 'individually' against the gold standard dental assessor (Table 4.6 and 4.8) then non-dental assessors 'combined' (Table 4.7 and 4.9) against the gold standard dental assessor.

Weighted Kappa, Weighted Gwet's coefficients and Spearman's correlation (r_s) were used to compare the values of the discrete ODNF variables (upper teeth, lower teeth and total teeth) recorded by the non-dental assessors. For categorical variables in the ODNF (Total teeth – grouped, Upper denture, Lower denture, Occluding pairs, Soft tissues, Oral cleanliness, Gum condition, Visible caries and Dental Pain), the Weighted Kappa and

Weighted Gwet's values (Table 4.6 & 4.7) as well as sensitivity and specificity (Table 4.8 & 4.9) tests were used to assess agreement between the gold standard assessor and non-dental assessors.

The results of examination performed by both the gold standard assessor and the non-dental assessors 'individually' and 'combined' showed very high percentage inter-rater agreement (above 0.90)) on all ODNF items except for soft tissues (Table 4.6 & 4.7). The agreement achieved for ODNF Tooth count, Denture wear and Occluding pairs items showed moderate to perfect/excellent agreement (0.41-1.00) for Kappa and Gwet's values (Table 4.6 & 4.7) except for soft tissues, Oral cleanliness and Gums.

When non-dental assessors were assessed individually, agreement and correlation values showed lower values for the variable Lower denture (Table 4.6). Between the gold standard and both non-dental assessors 2 and 3, the differences show no statistical significance and moderate kappa values (0.48; $p>0.05$), however, highly statistically significant, almost-perfect Gwet's values (0.95; $p<0.001$) were noted.

Sensitivity and specificity values are shown in table 4.8 (non-dental assessors individually) and table 4.9 (non-dental assessors combined). For all non-dental assessors, high sensitivity (>0.60) and high specificity (>0.60) were noted for ODNF variables 'Total teeth (Grouped)', 'Upper denture' and 'Occluding pair score 2' (Table 4.8). When non-dental assessors' results were assessed together (combined), a similar pattern was observed and better results for 'Occluding pair score 0', 'Gums score 2' and 'Dental pain score 0' (Table 4.9). There are mixed results on the sensitivity and specificity for all non-dental assessors individually, however, there was no consistent trend for one non-dental examiner to be better than the others (Table 4.7). When combined, lower sensitivity values (<0.41) were reported for 'Occluding pairs score 1', 'Oral cleanliness scores 0 and 1', 'Gums score 1', 'Visible caries scores 1 and 2' and 'Dental Pain score 1 and 2' (Table 4.9) but the

corresponding specificity values were high (Table 4.9). Specificity values were better, with the lowest values for 'Oral cleanliness score 2' (0.54) and 'Visible caries score 0' (0.58) (Table 4.9).

4.4.4.2. Comparison of ODNF assessments by non-dental assessors, against dental (non-gold) standard assessor

Similar statistical tests were carried out between the dental (non-gold) assessor and non-dental assessors. Result of these assessments on levels of agreement for the ODNF assessments administered by the non-dental assessors against non-gold dental assessor showed similar patterns to results of inter-rater reliability test against non-gold dental assessor. More details can be found in the table (APPENDIX XXXVI).

In summary,

1. There is a statistically significant level of inter-rater agreement between the ODNF assessments administered by the gold standard assessor and the non-dental assessors on all items except for 'Soft tissue', 'Oral cleanliness', and 'Gum condition'.
2. High inter-rater sensitivity and specificity values (>0.61) were noted for ODNF variables 'Total teeth (Grouped)', 'Upper denture' and 'Occluding pair score 0 and 2', 'Gums score 2' and 'Dental pain score 0' (Table 4.9).
3. Similar pattern of inter-agreement results found when non-dental assessors were compared to non-gold dental assessor (APPENDIX XXXIV).

Table 4.6 Inter-rater reliability of ODNF (between non-dental assessors 'individually' and gold standard assessor); Percentage agreement (%Ag), weighted Cohen' s Kappa coefficient, Weighted Gwet's AC2 coefficient, Spearman's correlation (r_s)

ODNF ITEMS	Gold standard against non-dental assessor 1				Gold standard against non-dental assessor 2				Gold standard against non-dental assessor 3			
	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s
Upper teeth	0.99	0.99*** (0.98,0.99)	0.99*** (0.98,0.99)	0.98	0.99	0.91*** (0.78,1.00)	0.94*** (0.85,1.00)	0.95	0.98	0.86*** (0.74,0.98)	0.90*** (0.81,0.99)	0.89
Lower teeth	0.99	0.94*** (0.89,0.99)	0.95*** (0.91,0.99)	0.91	0.97	0.85*** (0.68,1.00)	0.88*** (0.74,1.00)	0.80	0.99	0.94*** (0.89,0.99)	0.96*** (0.92,0.99)	0.90
Total teeth	0.99	0.98*** (0.96,0.99)	0.98*** (0.97,0.99)	0.97	0.99	0.91*** (0.81,1.00)	0.93*** (0.86,1.00)	0.92	0.99	0.92*** (0.83,1.00)	0.96*** (0.92,0.99)	0.93
Total teeth (Grouped)	0.98	0.95*** (0.84,1.00)	0.96*** (0.88,1.00)	x	0.94	0.84*** (0.65,1.00)	0.90*** (0.77,1.00)	x	0.96	0.89*** (0.75,1.00)	0.93*** (0.83,1.00)	x
Upper denture	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x
Lower denture	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x	0.96	0.48 (-0.13,1.00)	0.95*** (0.89,1.00)	x	0.96	0.48 (-0.14,1.00)	0.95*** (0.89,1.00)	x
Total number of dentures	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	1.00	0.99	0.87*** (0.70,1.00)	0.98*** (0.96,1.00)	0.91	0.99	0.87*** (0.70,1.00)	0.98*** (0.96,1.00)	0.91
Occluding pairs	0.82	0.39* (0.09,0.69)	0.69*** (0.47,0.90)	x	0.82	0.42* (0.16,0.68)	0.68*** (0.47,0.89)	x	0.90	0.53** (0.20,0.86)	0.85*** (0.73,0.97)	x
Soft tissues	0.47	0.09 (-0.02,0.20)	0.04 (-0.31,0.39)	x	0.53	0.01 (-0.16,0.18)	0.22 (-0.11,0.55)	x	0.5	0.12 (-0.01,0.25)	0.1 (-0.22,0.43)	x
Oral cleanliness	0.78	0.29* (0.06,0.52)	0.44*** (0.24,0.64)	x	0.65	0.14 (-0.08,0.35)	0.12 (-0.16,0.40)	x	0.72	0.25** (0.06,0.43)	0.29 (0.03,0.58)	x
Gums	0.76	0.33** (0.09,0.57)	0.37*** (0.13,0.60)	x	0.72	0.25* (0.03,0.46)	0.31 (0.08,0.54)	x	0.78	0.40*** (0.18,0.61)	0.42*** (0.23,0.61)	x
Visible caries	0.88	0.26** (0.09,0.43)	0.78*** (0.65,0.90)	x	0.84	0.24 (-0.02,0.49)	0.73*** (0.56,0.90)	x	0.81	0.09 (-0.17,0.35)	0.67*** (0.49,0.84)	x
Dental Pain	0.87	0.35** (0.09,0.61)	0.80*** (0.65,0.94)	x	0.83	0.34* (0.07,0.61)	0.70*** (0.51,0.90)	x	0.94	0.69*** (0.45,0.93)	0.92*** (0.84,1.00)	x

Key: *p<0.05 **p<0.01 ***p<0.001; highlighted – blue (below 0.61), green (increased value with Gwet's); x- not calculated

Table 4.7 Inter-rater reliability of ODNF (between all non-dental assessors 'combined' and gold standard assessor); Percentage agreement (%Ag), weighted Cohen's Kappa coefficient, Weighted Gwet's AC2 coefficient.

ODNF ITEMS	Gold standard against all non-dental assessors		
	% Ag.	Kappa (95% CI)	Gwet's (95% CI)
Upper teeth	0.99	0.91*** (0.82,1.00)	0.94*** (0.87,1.00)
Lower teeth	0.98	0.92*** (0.84,0.99)	0.94*** (0.88,0.99)
Total teeth	0.99	0.94*** (0.88,1.00)	0.96*** (0.92,0.99)
Total teeth (Grouped)	0.94	0.86*** (0.73,0.98)	0.90*** (0.81,0.99)
Upper denture	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)
Lower denture	0.97	0.65** (0.23,1.00)	0.97*** (0.92,1.00)
Total number of dentures	0.99	0.91*** (0.80,1.00)	0.99*** (0.97,1.00)
Occluding pairs (Re-grouped)	0.85	0.55*** (0.37,0.74)	0.75*** (0.61,0.88)
Soft tissues	0.53	0.10 (-0.00,0.20)	0.08 (-0.06,0.22)
Oral cleanliness	0.76	0.27*** (0.12,0.42)	0.40*** (0.25,0.55)
Gums (Grouped)	0.75	0.35*** (0.20,0.50)	0.33*** (0.18,0.48)
Visible caries	0.81	0.23** (0.07,0.39)	0.64*** (0.48,0.79)
Dental Pain	0.88	0.45*** (0.25,0.64)	0.80*** (0.69,0.91)

Key: *p<0.05 **p<0.01 ***p<0.001;

highlighted – blue (below 0.61), green (increased value with Gwet's)

Table 4.8 Inter-rater reliability of ODNF (between non-dental assessors and gold standard assessor); Specificity and sensitivity

ODNF ITEMS	Gold standard against non-dental assessor 1		Gold standard against non-dental assessor 2		Gold standard against non-dental assessor 3	
	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
Total teeth (Grouped) 0: 20 & more 1: Less than 20	0.97	1.00	0.97	0.85	0.97	0.92
Upper denture 0: Absent 1: Present	1.00	1.00	1.00	1.00	1.00	1.00
Lower denture 0: Absent 1: Present	1.00	1.00	1.00	0.33	1.00	0.33
Occluding pairs 0: 1 or more 1: Anterior contacts 2: No contacts	0.76 0.43 1.00	0.70 0.95 0.83	0.75 0.29 1.00	0.80 0.93 0.80	0.92 0.14 1.00	0.50 1.00 0.91
Soft tissues 0: Absent 1: Present	0.43	1.00	0.53	0.50	0.45	1.00
Oral cleanliness 0: None 1: Localised 2: Generalised	0.33 0.50 0.42	0.90 0.44 0.76	0.31 0.17 0.62	0.94 0.76 0.35	0.13 0.44 0.93	0.97 0.77 0.50
Gums (Grouped) 0: None 1: Localised 2: Generalised	0.43 0.35 0.73	0.77 0.72 0.71	0.73 0.05 0.36	0.44 0.73 0.83	0.60 0.19 0.70	0.68 0.72 0.75
Visible caries 0: 0 caries 1: 1,2 caries 2: 3 or more caries	0.61 0.44 0.00	0.82 0.67 0.85	0.80 0.20 0.00	0.50 0.84 0.89	0.64 0.40 0.00	0.50 0.68 0.93
Dental Pain 0: No Pain 1: Verbal +/- Behavioural 2: Physical, verbal, behavioural signs	0.85 0.29 0.00	0.60 0.84 0.93	0.76 0.57 0.33	0.80 0.85 0.86	0.97 0.57 0.33	0.80 0.95 0.96

Key: blue (below 0.61), red (below 0.41)

Table 4.9 Inter-rater reliability of ODNF (between all non-dental assessors 'combined' and gold standard assessor); Sensitivity and specificity.

ODNF ITEMS	Gold standard against all non-dental assessors	
	Sensitivity	Specificity
Total teeth (Grouped)		
0: 20 & more	0.97	0.92
1: Less than 20		
Upper denture		
0: Absent	1.00	1.00
1: Present		
Lower denture		
0: Absent	0.98	0.67
1: Present		
Occluding pairs (Re-grouped)		
0: 1 or more occluding pairs	0.80	0.67
1: Anterior contacts only	0.29	0.95
2: No contacts	1.00	0.84
Soft tissues		
0: Absent	0.47	0.78
1: Present		
Oral cleanliness		
0: None	0.27	0.93
1: Localised	0.37	0.68
2: Generalised	0.69	0.54
Gums		
0: None	0.57	0.63
1: Localised	0.19	0.72
2: Generalised	0.63	0.77
Visible caries		
0: 0 caries	0.68	0.58
1: 1,2 caries	0.33	0.74
2: 3 or more caries	0.00	0.89
Dental Pain13		
0: No Pain	0.87	0.73
1: Verbal +/- Behavioural	0.47	0.88
2: Physical, verbal, behavioural signs	0.22	0.92

Key: blue (below 0.61), red (below 0.41).

4.4.4.3. Comparison of ODNF assessments by non-gold dental assessor, against gold standard assessor

Inter-rater reliability tests between assessments made by the gold standard assessor and those of the non-gold dental assessor were carried out using Weighted Kappa, Weighted Gwet's and Spearman's correlation (r_s) on the discrete variables of the ODNF. This was carried out to investigate inter-rater agreement values of non-gold dental assessor using ODNF, compared to previous section (4.3.4.1).

High percentage agreement values (above 0.70) were noted for all ODNF items (Table 4.10). Similar pattern of Kappa, Gwet's agreement and Spearman's correlation (r_s) values for all ODNF items except for Oral cleanliness (Table 4.10). Agreements values were generally better compared to those of non-dental assessors (against gold standard) (Section, 4.3.4.1; Table 4.6).

Lower sensitivity values were noted for 'Occluding pairs Score 1', 'Oral cleanliness Score 2', 'Visible caries Score 2' and 'Dental Pain Score 2'. Similar pattern were noted when compared to inter-rater non-dental assessors (against gold standard) (Table 4.8 and 4.9), except for oral cleanliness where there is no consistent pattern of sensitivity and specificity values. Low specificity was noted for 'Soft tissues' and 'Oral cleanliness score 1'.

In summary,

1. There is statistically significant level of agreement between the ODNF assessments administered by the non-gold dental assessor compared against the gold standard dental assessor on all ODNF items ('Tooth count', 'Denture wear', 'Occluding pairs', 'Gum condition', 'Soft tissue', 'Visible caries' and 'Dental Pain') except for Oral cleanliness' (Table 4.10).
2. High inter-rater sensitivity and specificity values (>0.61) were noted for ODNF variables 'Total teeth (Grouped)', 'Upper denture', 'Lower denture', 'Occluding pair

score 0 and 2', 'Visible caries' scores 0 and 1, and 'Dental pain' score 0 (Table 4.11) for these two examiners.

Table 4.10 Inter-rater reliability of ODNF (between non-gold dental assessor and gold standard assessor); Percentage agreement (%Ag), weighted Cohen's Kappa coefficient, Weighted Gwet's AC2 coefficient & Spearman's correlation (r_s)

ODNF ITEMS	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s
Upper teeth	0.99	0.98*** (0.97,0.99)	0.99*** (0.98,0.99)	0.98
Lower teeth	0.99	0.97*** (0.95,0.99)	0.98*** (0.96,0.99)	0.94
Total teeth	0.99	0.98*** (0.97,0.99)	0.99*** (0.98,0.99)	0.97
Total teeth (Grouped)	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x
Upper denture	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x
Lower denture	0.97	0.79*** (0.37,1.00)	0.98*** (0.93,1.00)	x
Total number of dentures	0.99	0.94*** (0.82,1.00)	0.99*** (0.97,1.00)	0.91
Occluding pairs (Re-grouped)	0.90	0.57*** (0.25,0.88)	0.85*** (0.73,0.98)	x
Soft tissues	0.72	0.12 (-0.16,0.39)	0.60*** (0.35,0.84)	x
Oral cleanliness	0.75	0.19 (-0.04,0.42)	0.39*** (0.16,0.59)	x
Gums (Grouped)	0.87	0.54*** (0.35,0.73)	0.67*** (0.55,0.80)	x
Visible caries	0.87	0.38** (0.12,0.64)	0.77*** (0.61,0.93)	x
Dental Pain	0.94	0.67*** (0.35,0.98)	0.92*** (0.82,1.00)	x

Key: *p<0.05 **p<0.01 ***p<0.001;
x –Spearman's correlation was calculated for discrete variables only
highlighted – blue (below 0.61), green (increased value with Gwet's)

Table 4.11 Inter-rater reliability of ODNF (between non-gold dental assessor and gold standard assessor); Specificity and sensitivity

ODNF ITEMS	Sensitivity	Specificity
Total teeth (Grouped)		
0: 20 & more	1.00	1.00
1: Less than 20		
Upper denture		
0: Absent	1.00	1.00
1: Present		
Lower denture		
0: Absent	1.00	0.67
1: Present		
Occluding pairs (Re-grouped)		
0: 1 or more occluding pairs	0.92	0.60
1: Anterior contacts only	0.29	1.00
2: No contacts	1.00	0.91
Soft tissues		
0: Absent	0.74	0.50
1: Present		
Oral cleanliness		
0: None	0.44	0.81
1: Localised	0.53	0.40
2: Generalised	0.14	0.85
Gums (Grouped)		
0: None	0.53	0.91
1: Localised	0.67	0.54
2: Generalised	0.55	0.89
Visible caries		
0: 0 caries	0.77	0.83
1: 1,2 caries	0.80	0.82
2: 3 or more caries	0.00	0.93
Dental Pain		
0: No Pain	0.94	0.89
1: Verbal +/- Behavioural	1.00	0.95
2: Physical, verbal, behavioural signs	0.33	0.98

Key: blue (below 0.61), red (below 0.41)

4.4.5. Test-retest reliability of ODNF

Comparison between first and second ODNF assessments (test-retest reliability) for gold standard assessor, dental non-gold assessor and 3 non-dental assessors

For evaluating test-retest reliability of all the assessors using the ODNF, Weighted Kappa, Weighted Gwet's and Spearman's correlation (r_s) tests were used to compare the discrete ODNF variables (upper teeth, lower teeth and total teeth). In addition, only Weighted Kappa and Weighted Gwet's tests were used to assess agreement of the categorical ODNF data (Total teeth – grouped, Upper denture, Lower denture, Occluding pairs, Soft tissues, Oral cleanliness, Gum condition, Visible caries and Dental Pain).

The results of the test-retest statistical analyses for the gold standard, non-gold dental and non-dental assessors showed high percentage agreement (above 0.90) and a high value for the spearman's correlation test (>0.90) and for the discrete variables (Table 4.12 & 4.13).

For non-dental assessors, there are statistically significant agreements between the first and second examinations; the test-retest reliability agreement values were above 0.60 (substantial agreement) for all ODNF items except for 'Soft tissues' and 'Gum condition' (Table 4.12).

For the gold standard assessor (Table 4.13), there are statistically significant agreements between the first and second examinations, where the majority of the data were above 0.65 (substantial agreement) for the Kappa and Gwet's tests, except for Oral cleanliness and for Visible caries (Kappa=0.24,p>0.05 and 0.60,p<0.001; respectively).

For the test-retest reliability assessment of the non-gold dental assessor using ODNF (Table 4.13), almost all values showed high percentage agreement (>0.90) with a Kappa value > 0.6, except for the item, Visible caries (Kappa=0.45). All Gwet's values were above 0.60 for all items, which were statistically significant (p<0.001).

In summary,

1. There is statistically significant level of test-retest agreement between the first and second ODNF assessments administered by all assessors on all ODNF items (‘Tooth count’, ‘Denture wear’, ‘Occluding pairs’, ‘Oral cleanliness’, ‘Gum condition’, ‘Visible caries’ and ‘Dental Pain’) except for ‘Soft tissue’ (Table 4.12 and 4.13).

Table 4.12 Test retest (intra-rater) reliability of ODNF for all non-dental assessors; Percentage agreement (%Ag), weighted Cohen's Kappa coefficient, Weighted Gwet's AC2 coefficient & Spearman's correlation (r_s)

ODNF ITEMS	Non-dental assessor 1				Non-dental assessor 2				Non-dental assessor 3			
	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s
Upper teeth	0.98	0.86*** (0.63,1.00)	0.92*** (0.77,1.00)	0.93	0.99	0.96*** (0.90,1.00)	0.98*** (0.95,1.00)	0.95	0.91	0.60** (0.26,0.93)	0.65*** (0.31,0.99)	0.72
Lower teeth	0.99	0.95*** (0.87,1.00)	0.97*** (0.92,1.00)	0.94	0.99	0.95*** (0.90,1.00)	0.97*** (0.94,0.99)	0.92	0.92	0.65*** (0.35,0.96)	0.68*** (0.39,0.97)	0.66
Total teeth	0.99	0.95*** (0.88,1.00)	0.97*** (0.92,1.00)	0.98	0.99	0.96*** (0.93,0.99)	0.97*** (0.95,0.99)	0.94	0.91	0.63** (0.30,0.94)	0.60** (0.22,0.98)	0.70
Total teeth (Grouped)	0.94	0.82*** (0.45,1.00)	0.92*** (0.74,1.00)	x	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x	0.85	0.65*** (0.34,0.97)	0.75*** (0.48,1.00)	x
Upper denture	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x
Lower denture	0.94	0.64 (,0.07,1.00)	0.9344*** (0.78,1.00)	x	0.95	0.00*** (0.00,0.00)	0.95*** (0.84,1.00)	x	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x
Total dentures	0.98	0.82*** (0.63,1.00)	0.98*** (0.92,1.00)	0.99	0.98	0.74*** (0.72,0.76)	0.98*** (0.94,1.00)	1.00	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	1.00
Occluding pairs	0.85	0.59*** (0.15,1.00)	0.72*** (0.38,1.00)	x	0.87	0.62** (0.19,1.00)	0.78*** (0.51,1.00)	x	0.85	0.58** (0.21,0.95)	0.76*** (0.51,1.00)	x
Soft tissues	0.67	0.33 (-0.16,0.81)	0.34 (-0.14,0.83)	x	0.92	0.57** (0.24,0.90)	0.85*** (0.71,0.98)	x	0.70	0.43** (0.11,0.75)	0.41 (0.04,0.78)	x
Oral cleanliness	0.91	0.63** (0.29,0.96)	0.80*** (0.61,0.98)	x	0.94	0.59** (0.22,0.96)	0.89*** (0.77,1.00)	x	0.85	0.51** (0.18,0.84)	0.65*** (0.37,0.94)	x
Gums	0.81	0.49* (0.08,0.90)	0.52** (0.19,0.86)	x	0.90	0.74*** (0.44,1.00)	0.76*** (0.47,1.00)	x	0.90	0.69*** (0.48,0.90)	0.75*** (0.57,0.92)	x
Visible caries	0.94	0.62** (0.33,0.91)	0.87*** (0.79,0.99)	x	0.89	0.61** (0.22,1.00)	0.81*** (0.58,1.00)	x	0.94	0.69*** (0.38,0.99)	0.88*** (0.78,0.99)	x
Dental Pain	0.92	0.58** (0.26,0.90)	0.86*** (0.71,1.00)	x	0.89	0.73*** (0.46,1.00)	0.76*** (0.50,1.00)	x	0.93	0.65*** (0.39,0.92)	0.88*** (0.76,0.99)	x

Key: *p<0.05 **p<0.01 ***p<0.001; x –Spearman's correlation was calculated for discrete variables only; highlighted – blue (below 0.61), green (increased value with Gwet's)

Table 4.13 Test retest (intra-rater) reliability of ODNF for the dental assessors; Percentage agreement (%Ag), weighted Cohen's Kappa coefficient, Weighted Gwet's AC2 coefficient & Spearman's correlation (r_s)

ODNF ITEMS	Gold standard dental assessor				Non-gold dental assessor			
	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s
Upper teeth	0.99	0.98*** (0.96,1.00)	0.98*** (0.97,0.99)	0.99	0.99	0.97*** (0.93,1.00)	0.98*** (0.95,1.00)	0.96
Lower teeth	0.99	0.99*** (0.97,1.00)	0.99*** (0.98,1.00)	0.98	0.99	0.97*** (0.94,1.00)	0.98*** (0.95,0.99)	0.96
Total teeth	0.99	0.99*** (0.99,1.00)	0.99*** (0.98,1.00)	0.99	0.99	0.97*** (0.94,1.00)	0.98*** (0.96,0.99)	0.96
Total teeth (Grouped)	0.95	0.85*** (0.55,1.00)	0.92*** (0.74,1.00)	x	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x
Upper denture	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x	0.96	0.66 (,0.04,1.00)	0.95*** (0.84,1.00)	x
Lower denture	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x	0.96	0.78** (0.33,1.00)	0.95*** (0.83,1.00)	x
Total dentures	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	1.00	0.97	0.80*** (0.51,1.00)	0.96*** (0.91,1.00)	0.81
Occluding pairs	0.91	0.65** (0.23,1.00)	0.85*** (0.63,1.00)	x	0.96	0.86*** (0.58,1.00)	0.94*** (0.80,1.00)	x
Soft tissues	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x	0.91	0.77*** (0.45,1.00)	0.86*** (0.64,1.00)	x
Oral cleanliness	0.82	0.24 (-0.18,0.65)	0.64*** (0.21,0.96)	x	0.93	0.68** (0.29,1.00)	0.85*** (0.63,1.00)	x
Gums	0.93	0.71*** (0.45,0.98)	0.83*** (0.66,1.00)	x	0.90	0.64*** (0.38,0.89)	0.76*** (0.59,0.93)	x
Visible caries	0.93	0.60** (0.26,0.93)	0.86*** (0.72,1.00)	x	0.88	0.45* (0.05,0.84)	0.77*** (0.54,0.99)	x
Dental Pain	0.94	0.71** (0.33,1.00)	0.92*** (0.81,1.00)	x	0.99	0.93*** (0.79,1.00)	0.98*** (0.92,1.00)	x

Key: *p<0.05 **p<0.01 ***p<0.001; x –Spearman's correlation was calculated for discrete variables only; highlighted – blue (below 0.61), green (increased value with Gwet's)

4.4.6. Feedback after completion of the initial ODNF assessment by participants

The feedback forms were completed by 42 participants. 95.2% of participants considered the ODNF assessment was quick, 23.8% of them reported pain during the assessment but 95.2% of all participants considered that the ODNF assessment was acceptable.

Table 4.14 Feedback after completion of the initial ODNF assessment by participants

Questions on the feedback form for participants with ID		Frequency (N=42)	Percent (%)
Was it quick for you?	Yes	40	95.2
	No	0	0.0
	I don't know	2	4.8
Did it hurt?	Yes	10	23.8
	No	32	76.2
	I don't know	0	0.0
Was it okay for you?	Yes	40	95.2
	No	0	0.0
	I don't know	2	4.8

4.4.7. Feedbacks from non-dental assessors.

Feedback forms were given to non-dental assessors at 3 points: after completing the self-learning part 1 of training, after completion of part 2 training and after data collection. All of the non-dental assessors completed the self-learning material in 30 to 60 minutes (Table 4.15). All non-dental assessors thought that the training material for the ODNF assessment was sufficient however, one assessor thought that an additional session, of four-hours, would be required for the ODNF assessment training (Table 4.15). The training was completed in 2 sessions (total of 8 hours).

Table 4.15 Feedback form for non-dental assessor before the training day

Questions on feedback form for non-dental assessors		Frequency (N=3)	Percent (%)
Time taken to complete the self-learning material before the training day	<30 mins	0	0.0
	30 – 60 mins	3	100.0
	>1 hour	0	0.0
	Not completed	0	0.0
Do you think the training material for this assessment was sufficient?	Yes	3	100.0
	No	0	0.0
Sessions (of 4 hours) of training would be needed	1	0	0.0
	2	2	66.7
	3	1	33.3
	4	0	0.0

Comments from the non-dental assessors were collected from the feedback forms as well as in the field diary collected by the study coordinator. Some of the comments are as follows:

Items	Comments
Training manual	“Manual was very clear and quiz was a very good element” “More concise training slides, although quiz/interactive element was good.” “Perhaps add in a sample structured consultation transcript.”
Training	“Slight issues with time management in relation to getting enough practice of the test.” “I would have liked another chance to practice the assessment, perhaps in more volunteers?” “I was more confident with practice, so maybe more practice opportunities”
Data collection	"I was a bit scared at the start but I got used to it after the second one." "It is getting infinitely easier. I am getting better at knowing if teeth are dirty. " "I felt a bit rushed because I felt I was a bit afraid. I wanted to make sure I wasn’t missing something. But look that was just me. Being a non-expert I was afraid" "I felt there was no time for comments." "I could not see everything in Mr A’s mouth. He just wouldn’t open for me. These patients can be difficult.” “Some participants were reluctant to open their mouth, or move their tongue.” "Sometimes the first answer was not the correct answer. One person said no pain - when I put my finger in he said that there was a pain when being examined." “It wasn’t always clear if this was pain or something.” “Issue with using iPad touch screen with barriers.”

All non-dental assessors agreed that the ODNF assessment tool improved the ability to detect dental pain and problems in the mouth. Comparing the answers on their confidence in completing the assessment of all the ODNF items between the three occasions (after self-learning, after training and after data collection), all of them had shown an improvement of confidence. They had 'strongly agreed' that they were able to complete almost all categories of the ODNF assessment tool, except for oral cleanliness, gum condition, visible caries and dental pain.

4.4.8. Time taken to carry out the ODNF assessment

The average time for non-dental assessors to complete the ODNF assessment was 7 minutes (minimum 3 minutes, maximum 17 minutes). The dental assessors (gold standard and non-gold) were only slightly faster (average 6.5 minutes) in completing the assessments (Table 4.16).

Table 4.16 Time taken to carry out ODNF assessment

Assessor (Assessments completed)	Average time taken (mins)	Range (mins)
Gold standard assessor (ODNF, Dentition & CPITN)	6	2-14
Dental assessor 1 (ODNF, Dentition)	7	3-12
Non-dental assessor 1 (ODNF)	8	4-17
Non-dental assessor 2 (ODNF)	7	4-12
Non-dental assessor 3 (ODNF)	6	3-13

4.4.9. Preliminary Cost analysis

A preliminary cost analysis was undertaken concurrent to data collection to identify the cost of data collection associated with the ODNF to identify comparative cost with the use of existing indices. The main difference in the cost between the conventional dental assessments and ODNF assessment were noted (Table 4.17) as following:

1) The time taken to examine using ODNF is shorter than conventional dental assessment
2) The employment cost of non-dental individuals is cheaper than dentist labour during the training, calibration and data collection
3) The cost of clinical examination equipment used

The time taken for one assessment of ODNF was 7 minutes in this study and a complete dental examination of an adult may take 15 to 20 minutes (WHO, 2013). The cost of non-dental individuals was paid at €11.00/hour in this study. The cost of dentist per hour was calculated using the following formula:

$$= \frac{Annual\ salary}{\left(\frac{48 hours}{week}\right) \times \left(\frac{52 weeks}{year}\right)}$$

Cost of equipment for oral health data collection are laid out in Table 4.17. Conventional dental examination in oral health surveys would require at least a dental mirror and CPI probe. In this study, we reported use of a dental mirror to retract the cheek for better visualisation. Use of ODNF did not require any special equipment except for good source of lighting and a suitable examination area for subjects; and this is similar to oral health surveys by dentist (WHO, 2013). In order to identify the difference between cost of data collection using ODNF index and conventional dental assessment, simple comparison was made on the main differences between the two assessments (Table 4.17). Cost of using ODNF per subject during data collection is 6 times cheaper than conventional dental examination.

Table 4.17 Cost of data collection by non-dental assessors per patient, compared to cost of dentist carrying out data collection

	Cost of ODNF assessment	Cost of Dental assessment
Assessment time	7 minutes	15 minutes*
Employment cost	Non-dental €11.00 / hour** No recording clerk needed	Dentist €23.75 / hour*** Recording clerk €11.00 / hour****
Equipment cost	Sterile Mirror only €0.43	Sterile examination kit (Mirror, Probe) €1.56

Footnote:

1. Time taken for one dental assessment in adult = 15-20 minutes (Oral health surveys 5th Edition, WHO, Page 23).
2. Cost of non-dental labour was set at €11.00 / hour as per Trinity College Dublin date and actual rate paid during the study.
3. Cost of dentist as HSE Pay scale for General Dental Surgeon (LRA 1/04/17) – basic rate €59,270 per annum http://www.hse.ie/eng/staff/benefitsservices/pay/Consolidated-Payscales-1st-April-2017.pdf.
4. Employment cost did not include Pay Related Social Insurance (PRSI) contributions and employer pension contributions (EPC); 52 weeks in one year; 48 working hours (maximum) per week.
5. Rate of recording clerk was set to non-dental individuals, but cost will be higher if allied dental professionals were employed.
6. Cost of remaining equipments and expense for participants with ID are considered the same during data collection (APPENDIX XXXVII).
7. Training and calibration cost were not included in the preliminary analysis

5. DISCUSSION

5.1. Introduction

This research study explored the development and validation of an assessment tool (ODNF index) that can be administered by non-dental assessors. It is the first study of its kind in an adult population with intellectual disabilities (ID). This new tool has the potential for data collection tool to assess oral health in this cohort of population, who have tended to be excluded from epidemiological surveys in the past.

There are existing assessment tools, which were validated for use by non-dental assessors such as OHAT (Chalmers et al., 2005), ROAG (Andersson et al., 2002) and COHI (Saintrain, 2007). They were mainly validated for patients undergoing cancer therapies (Eilers et al., 1988, Andersson et al., 1999) as well as older adult populations in rehabilitation wards (Andersson et al., 2002), in residential care (Kayser-Jones, 1995; Chalmers et al., 2005) as well as in community settings (Saintrain and Vieira, 2012; Ribeiro et al., 2014). However, following analysis during systematic literature review, none met the specific needs of a comprehensive data collection tool, necessary for data collection in this population. Such a tool would cover oral disease, oral treatment need and oral function. In addition, there is no evidence that these existing tools and their constituent items would be acceptable and valid in this population. Therefore, development of a new assessment tool was deemed necessary. This study reports the development and initial validation of this index in a feasibility study.

In developing a new index, it is imperative to understand the psychometric criteria in an ideal health index such as the ideal properties of a dental index (Burt and Eklund, 2005).

Table 5.1 The ideal properties of a dental index (Burt and Eklund, 2005)

Validity: "The index must measure what it is intended to measure, so it should correspond with clinical stages of the disease under study at each point."
Reliability: "The index should be able to measure consistently at different times and under a variety of conditions. The term reliability is virtually synonymous with reproducibility, repeatability and consistency, meaning the ability of the same of different examiners to interpret and use the index in the same way."
Clarity, simplicity and objectivity: "The criteria should be clear, unambiguous, with mutually exclusive categories. Ideally it should be readily memorized by examiner after some practice."
Quantifiability: "The index must be amenable to statistical analysis, so that the status of a group can be expressed by a distribution, mean, median or other statistical measures."
Sensitivity: "The index should be able to detect reasonably small shifts, in either direction, in the condition."
Acceptability: "The use of the index should not be painful or demeaning to the subject."

During the construction of the new tool, a content validation process is usually concurrently conducted to gather expert opinion whether the new index is measuring what it is supposed to be measuring. Input from a panel of experts, co-researchers and non-dental assessors was taken into consideration to ensure that the items and their descriptions are clear, simple and objective. 'Concurrent validity' is another validation process where the new index is assessed against a conventional index ('criterion' measure), which is usually a well-known standard index that has been tried and tested before.

Then, it is also important to assess if it can be reproducible on different occasions. Intra-rater, test-retest, inter-rater reliability and internal consistency tests are the common tests used to measure reproducibility of an index.

Consideration of the variables and possible statistical tests would indicate that the index can be used to quantify the oral health status. This was shown in the sample of oral health characteristics of the study population in Section 4.3.1. As an example, this 'Tooth count' item informs us of the mean number of teeth, the minimum and maximum number of teeth and allows categorisation into groups such as 'less than 20 teeth' and '20 teeth or more',

edentulous and fully dentate. Thus, the items in this unique index allow surveillance, agreed at international level as global goals for oral health 2020, for the population with ID (Hobdell et al., 2003).

Finally, feedback from the participants with ID and non-dental assessors would be necessary to assess the acceptability of the index to the intended population and the intended end-user.

5.2. Statement of principal findings

This study investigated content validity, concurrent validity, inter-rater reliability, test-retest reliability and feasibility of the ODNF assessment tool. The following summarises the ODNF instrument's development according to these critical attributes.

5.2.1. Construction and content validity of ODNF tool

Based on the systematic review of the published literature, there are existing oral assessment tools that have been validated for use by various non-dental individuals, with differing backgrounds. However, through content validation process (consultation and discussion with a panel of experts and content validity ratio (CVR) approach), no single, existing tool had all the items that are relevant to the specific content requirement of a tool for use with an adult population with ID. The construction of a new data collection tool started with adopting the relevant shortlisted items from a CVR approach (Mathew et al., 1995b, Chalmers et al., 2005, Saintrain and Vieira, 2012). Further consultation was then carried out, and more items added to the new tool, to ensure it had enough items to cover the domains specified for the ODNF assessment tool.

The panel of experts in the study consisted of academics and experienced clinicians in special care dentistry (SCD) (co-researchers, JHN and CMGP), dentist undergoing full-time clinical doctorate training programme in SCD (main author, NSI), Associate Professor in Dental Public Health and experienced epidemiologist (Co-researcher and gold standard dental assessor, BD), experienced researchers in populations with ID (co-researchers, MM and EB) and fellow experienced clinicians (Specialist Oral Surgery, Dental Public Health, Specialist Paediatric dentist, Specialist Orthodontist, Senior Dental Hygienist) in Ireland and Brunei Darussalam. Although there is no defined guidance in the number of expert views to be sought (Streiner, 2015), an effort was made to include experts and researchers who are familiar with this group of the population. Content validation was then further developed, taking into account the feedback from non-dental and dental assessors during the piloting and training phases.

In summary, content validity of the ONDF index was established through input from a panel of experts, use of empirical content validation approach (the CVR) as well as input from the non-dental assessors, which were then reviewed and incorporated into the final ODNF tool.

5.2.2. Development of training for ODNF assessment tool

The training programme was developed specifically for this new tool. There are two parts to this training: a self-learning component and a training day (including practical). The self-learning component of the training material was developed to be completed by the non-dental assessors, on their own, prior to the main training. The aim of this self-learning training material was to introduce the ODNF assessment and for the assessors to be familiar with the conduct of the examination prior to the actual training day. This material was emailed to the non-dental assessors one week prior to the training day. Sufficient time was given for them to complete this in their own time, to have a good background knowledge on what this tool aimed to do, to be familiar with the items and assessment

criteria as well as to come up with queries on areas that were unclear. Although this approach was not described in previous, initial validation studies of the existing non-dental oral assessment tools (Chalmers et al., 2005; Saintrain and Vieira, 2012), the non-dental assessors in this study found this self-learning material was clear and easy to understand. The non-dental assessors completed this within 60 minutes in their own time. They also found that the interactive self-grading quiz was a helpful element of the manual as they could test their basic understanding of each item. Being involved in this initial validation study, it was crucial for the non-dental assessors to develop their thoughts on this tool and provide feedback during the training. The feedback was considered in refining the new assessment tool and its training programme. Suggestions to improve the training material included a consultation transcript, particularly useful for data collectors who have no prior experience working with this population. The non-dental assessors also recommended more practical experience (hands-on) during the training.

5.2.3. Concurrent validity

Concurrent validation is one of two types of criterion validation that measures the correlation of a scale (in this case, the new assessment tool deployed by non-dental individuals), with some other measure, usually a 'gold standard' (in this case, conventional dental indices) of the trait or disorder under study (Streiner et al., 2015). At the feasibility study with both the dental and the three non-dental assessors, concurrent validity assessments showed very high percentage agreement (% Ag). There was substantial to excellent level of agreement on both Kappa and Gwet's values as well as using Spearman's correlation (r_s), for all the variables tested. All the results were statistically significant ($p<0.001$). High levels of correlation and agreement are desirable, indicating that both the ODNF assessment tool and conventional dental assessment are measuring virtually the same phenomenon (Streiner, 2015).

The concurrent validity of the ODNF assessment tool was further established by carrying out sensitivity and specificity tests, which evaluate the ability to differentiate between those with and without disease (Altman, 1999). Although there were statistically significantly high levels of agreement between the ODNF and conventional dental indices, assessments on diagnostic accuracy (sensitivity and specificity) on the variables 'Total teeth', 'Gum' and 'Visible caries' showed mixed results. The high sensitivity result means that the ODNF assessment is highly accurate, identifying that the participants actually have 20 or more teeth. High specificity means that the ODNF 'Tooth count' assessment is also very accurate at identifying those who do not have 20 or more teeth. This outcome demonstrated that the ODNF 'Tooth count' category, as applied by non-dental assessors, is as valid as a conventional dental index at counting the number of teeth in the mouth.

For the ODNF assessment of 'Gums' and 'visible caries' categories, the results showed lower sensitivity values for the more severe categories of the conditions, which means that ODNF assessment is not good at identifying accurately those with generalised gum redness, swelling, ulcers and bleeding; or those with 3 or more visibly decayed teeth. On the other hand, the results showed very high (0.95) specificity which means that the ODNF assessment will correctly identify 95% of participants who do not have such severe conditions.

The results from the concurrent validity assessment for the ODNF 'Gums' category should be treated with caution as not all components of the category are directly comparable with those of the CPITN. That is, CPITN assesses the presence of bleeding and calculus as well as the severity of periodontal pockets. By contrast, the ODNF 'Gum' category assesses the presence of gingival redness, swelling, bleeding and ulcers. In an effort to compare like with like during the data analysis, CPITN variables were re-grouped into the number of sites with a CPITN code of 1 or greater. This was chosen because CPITN code 1 equates to bleeding. This is assuming that the presence of bleeding also occurs with the higher codes of 2, 3 and 4. This is the limitation of this study, in that there is currently no way to carry out

concurrent validity of the ODNF 'Gums' with the criterion in CPI/CPITN (whichever is used in WHO), used to screen for periodontal disease. In this study, one aim was to see if the ODNF would screen for periodontal disease as does CPITN. Diagnosis of periodontal disease is not straightforward in that it involves comprehensive clinical and radiographic examination. CPITN/BPE is a standard conventional screening tool for periodontal disease but this would involve visual and minimal probing examinations. The addition of a probing component into the ODNF tool might not be acceptable for individuals with ID and would also increase the duration of the assessment.

5.2.4. Inter-rater reliability

Inter-rater reliability tests reproducibility between different assessors. The study showed that ODNF measurements of 'Tooth count', 'Denture wear', 'Occluding pairs', 'Visible caries' and 'Dental Pain' are reproducible when administered by different assessors but this was not the case for 'Soft tissues', 'Oral Cleanliness' and 'Gum condition'. Similar trends were noted when the inter-rater reliability of non-dental assessors were assessed individually and combined.

When both dental assessors (gold standard and non-gold) were compared, the dental assessors also showed lower inter-rater agreement values for 'soft tissues' and 'oral cleanliness', similar to the results of non-dental assessors. So that, even between dentists, who are familiar with dental assessments, there is difficulty in calibration on 'soft tissues' and 'oral cleanliness' using the ODNF index. The difficulty of calibrating multiple examiners, as well as the ethical and methodological issues surrounding the application of periodontal indices is well recognised (Morris et al., 2001).

It is not uncommon to observe lower levels of inter-rater agreement for oral cleanliness as the first examination may have affected the subsequent examination, even between dentists. Descriptions of localised and generalised deposits in the assessment tool are also

considered subjective, which may need further objective clarification during training, that is, what is considered as localised and generalised in the ODNF assessment. This is also applicable to the inter-rater reliability test for ODNF 'Gums' category. In order, to improve the level of inter-rater agreement between the dental and non-dental assessors, clarification of the criteria during training, alongside more practical time may achieve better levels of agreement.

High sensitivity and high specificity were noted for all non-dental assessors when assessing the ODNF criteria: 'Total teeth (grouped)', 'Upper denture' and 'Lower denture'. This means that ODNF has a good diagnostic accuracy for ODNF items 'Total teeth' and 'Denture wear'. Despite a high sensitivity (1.00), slightly lower specificity values were noted for the inter-rater reliability assessment of the ODNF criterion 'Lower denture', for non-dental assessors 2 and 3, respectively. Low specificity usually mean that they are not very accurate at identifying those without a lower denture. There were mixed results also for sensitivity and specificity for all levels of score in the ODNF measurement of 'Occluding pairs', 'Oral cleanliness', 'Gums', 'Visible caries' and 'Dental Pain'. This means that the diagnostic accuracy of the non-dental assessors was poorer in terms of differentiating between the 3 responses, than those with 2 responses.

In some of the cases, low values may be explained by low counts of participants for some of the ODNF assessments; for example, participants with 'Lower denture' (n=3), 'Soft tissue Score 1' (n=4), 'Visible caries score 2' (n=2) and Dental pain score 2 (n=3).

Given that it is difficult to achieve high sensitivity/specificity scores for trained dental assessors on some of these variables, it is questionable whether these sensitivity/specificity data for non-dental assessors would be much improved by additional training on application of the criteria. A further consideration in the development of the ODNF index might be to collapse some of the categories in the domains that produced the variability, perhaps without sacrificing much diagnostic accuracy.

5.2.5. Test-retest reliability

This study also reported consideration of the reproducibility of ODNF measurements made by the same assessor on the same patient on two different occasions; test-retest reliability. In this study, the term intra-rater reliability was not used because it relates to the agreements of the same assessor after a time interval but on the same original measurements that are usually recorded using videotapes or photographs. Hence, test-retest reliability was more appropriate considering this study design. The test-retest reliability assessment for all assessors revealed high percentage agreement (above 0.80) for all the ODNF assessments. Only two non-dental assessors had lower test-retest agreement (not statistically significant, $p>0.05$), and for soft tissues and oral cleanliness only. For the rest of the ODNF items, all 3 non-dental assessors achieved high levels of agreement (statistically significant, $p<0.05$). This showed that the ODNF assessment tool has good test-retest reliability. Overall, the ODNF criteria and categories are clear, simple and can be readily memorized by the assessor after some practice. Non-dental assessors would need to have more practice on soft tissues and oral cleanliness.

5.2.6. Feasibility of use

In assessing the 'feasibility of use' of this new tool, this study reported the following:

a) The time taken for the assessors to administer the ODNF assessment tool
b) The acceptability of the tool to the subjects as well as the assessors
c) The preliminary cost analysis of employing non-dental individuals using ODNF index during data collection.

The main reason for collecting the time taken for the non-dental assessors to carry out the ODNF assessment was to determine, alongside the feedback from the participants, if the length of examination is reasonable but importantly, acceptable for the individuals with ID

as well as the non-dental assessors. The average time taken for non-dental assessors to carry out one ODNF assessment was 7 minutes. This was similar to the time taken by to the dental assessors carrying out the ODNF assessment (6.5 minutes). A complete dental assessment of an adult in oral health surveys may take between 15 to 20 minutes (WHO, 2013).

It would appear from the feedback that the ODNF assessments were not too intrusive for the participants with ID. In the feedback forms, ten (10) participants reported pain when the ODNF assessment tool was administered. This could be explained in part by the way in which the ODNF was carried out, for example, stretching of cheeks may be uncomfortable for the individuals with ID. However, when compared with the actual results of the ODNF assessment by the gold standard assessor, 10 participants either reported pain in the mouth, or were assessed as having behavioural signs or physical signs of dental pain in the mouth.

The non-dental assessors commented that examination could be difficult especially if the participants with ID were reluctant to open their mouth. Despite the comments, all the non-dental assessors were able to complete the assessment using the new tool, just like the gold standard and non-gold dental assessors. With more practical (hands-on) training and time with individuals with ID, they are likely to become more confident with communicating with the participants and this was indicated on their feedback forms completed after the data collection days.

Preliminary cost analysis indicated that utilizing non-dental individuals to administer the new data collection tool is 6 times cheaper than dentists carrying out conventional dental examination. This is because the cost of non-dental labour itself is cheaper than dentist labour. The ODNF is quicker (7 minutes) than the conventional dental examination of an adult which may take up to 20 minutes (WHO, 2013). The ODNF assessment is to be

completed without recording clerks, and a direct-entry system. In the conventional dental examination, recording clerks need to be trained and calibrated (WHO, 2013).

5.3. Strengths and weaknesses of the study

In this second section of the discussion, I will elaborate on the strengths and weaknesses of this study.

5.3.1. Strengths of the study

1. Development of unique assessment tool

This is the first study to validate a non-dental oral assessment tool in a population with ID. Research among this population is scarce and what this study reported hopefully has added knowledge on the oral health needs in this group of the population.

The study has answered all of its objectives. The first objective was to construct an oral health data collection tool that could be used by non-dental assessors on adult populations with ID. A comprehensive set of key domains were selected so that this ODNF assessment tool can be used to collect oral health data which can be used as part of the process in prioritising and organising care for this population. In satisfying the second objective, this study has also developed a new training programme to be used specifically with the newly constructed tool. Both the construction of the ODNF assessment tool and its associated training package have undergone an extensive process of content validation. This study has also successfully investigated the concurrent validity, inter-rater reliability and test-retest reliability of the ODNF assessment tool; thus answering the third and fourth objectives of this study. The final objective was to determine the feasibility of this tool by looking at the time taken for non-dental assessors to administer the oral assessment tool, the acceptability of this tool for participants with ID as well as, in outline, the cost of developing and using this tool.

2. Nature of the Pilot phase

The aim of this pilot phase was to ensure that both the training material and the data collection protocol (data collection sheet, clinical conduct, data recording and data transfer) were sufficiently comprehensive, as tested by dentists, before the actual training of the non-dental assessors commenced. In this study, the pilot phase of the study was carried out with adults without ID. It was considered important not to overburden the population with ID to whom access may be restricted, due to ethical issues and limited numbers. It was decided therefore, to reserve such groups for the validation study (i.e., the main feasibility study). It was acknowledged, however, that there would be an opportunity for further content validation and refining of both the training tool and data collection protocol during the training of the non-dental assessors. Undertaking a preliminary study, where the conditions are almost ideal, before moving on to more pragmatic field studies is accepted as a means of testing systems and processes before embarking on a full trial (O'Mullane, 1976).

3. Statistical approach adopted

A strength of this study is the use of tests to strengthen validation and reliability testing of this ODNF assessment tool, not commonplace in the dental literature to date. Correlation tests (such as Spearman's correlation) allow the evaluation of correlation or association between variables. It is possible that two variables have a high level of correlation (association) but this does not necessarily mean that they have a high level of agreement. This is the reason why Cohen's Kappa coefficient was used in the data analyses for this study. The use of both correlation and agreement tests strengthened the validity and reliability assessments of the ODNF assessment tool, as described in previous validation studies (Saintrain and Vieira, 2012).

In this study, Cohen's Kappa test was used to compare discrete variables (namely Upper teeth, Lower teeth, Total teeth, Total number of dentures). Despite the indication for its usage on categorical variables, this method was adopted to allow comparison with previous dental literature, which have widely used Cohen's Kappa for discrete variables, such as number of present teeth, number of roots (Saintrain & Vieira, 2012).

Percentage agreement (%Ag) and kappa values are commonly used to give a more appropriate representation of agreement level. However, in many instances in this study, it was observed that even with a high level of percentage agreement, low kappa values were noted (Cicchetti and Feinstein, 1990, Gwet, 2002b, Gwet, 2014). As described in the literature review, this 'Kappa paradox' phenomenon was commonly observed in previous validation studies. The low kappa values were due to skewness in the proportions, as the value of kappa depends on the proportion of subjects (prevalence) in each agreement/disagreement category. Hence, when an abnormality is rarely present, even a low number of disagreements would cause the kappa scores to drop.

Table 5.2 An example of the 'kappa paradox'

Lower denture		**Gold standard dental assessor**	
		Absent	Present
Non-dental assessor	Absent	44	2
	Present	0	1

An example is on the assessment of 'Presence of lower denture' where the result of the inter-rater reliability assessment between the non-dental assessor and the gold standard assessor, gave a %Ag of 0.96 (perfect/excellent agreement) but a Kappa value of 0.48, $p>0.05$ (moderate agreement). Due to the low count for 'presence of lower denture' (n=3) (Table 5.2), a slight disagreement (2/3) would cause the kappa score to drop. One way to overcome the kappa paradox is by using the agreement coefficient named AC1 (Gwet's AC). In this study, a Gwet's coefficient test was carried out and it was noted that the level

of agreement in the above example of ‘Presence of lower denture’, increased to a statistically significant perfect/excellent level of agreement (0.95, p<0.001).

4. Gold standard examiner and role of second dental assessor.

Good inter-rater reliability results between the non-gold dental assessor and the gold standard assessor showed that the ODNF has good inter-rater reproducibility. This would mean that the non-gold dental assessor can be utilised as a reference dentist in validation and reliability assessments. However, in order to become gold standard the assessor has to undergo accredited training and a calibration process.

5.3.2. Weakness/limitations

This section reports the weakness of this study which includes concerns on the systematic literature review, sample size, ethical issues, sampling bias as well as issues on training and calibration.

1. Limited systematic literature review

During the construction of the new tool, a systematic review of literature was carried out to source existing tools that had been used by non-clinical assessors, which might satisfy the requirements for this tool in this particular population (Streiner et al., 2015). Due to time restrictions, the systematic review of the literature was restricted to one database only. It is possible therefore, that other, existing tools and items, which may be relevant to the domains identified for the ODNF assessment tool, might have been missed. The content validation process aims to overcome this limitation as it is a process to ensure that this tool has appropriate content coverage.

2. Sample size did not reach 60

One of the weaknesses of this study is that the number of participants recruited to the study fell below the number estimated as part of the power calculation (sample size of 60). Three service centres for ID in Dublin were approached for this study, in order to provide us with at least 20 research participants with ID from each centre. However, after almost 5 months of an ethical application process, ethical approval was not given by the third service provider's Research Ethics Committee (REC). Despite the drop-out, there were 49 research participants in this study from 2 centres. Upon consideration of the time left for this study and in consultation with the biostatistician on the sample we already had, it was deemed that no further ethics application and further participants recruitments were feasible or necessary.

A sample population of 49 individuals might be argued as being a small number of subjects. However, this study was not an epidemiological one, hence it is not essential to replicate a sample size that would represent the dental findings of this cohort in the community. Nonetheless, in a tool validation study, it is recommended to achieve a sample size sufficient to guarantee enough individuals to simulate all range of presentations evaluated in the ODNF assessment tool (Saintrain and Vieira, 2012). Although this was not an epidemiological survey, the World Health Organisation (WHO) guidelines for data collection were followed. The number of participants in this study met the minimum recommended set by the WHO for inter-rater and intra-rater reliability testing (WHO, 2013).

3. Ethical concerns

In the discussion of sample size, it is reasonable to look at the ethical concerns of the one centre which decided not to join this study. The reasons given by the research ethics committee (REC) from this ID service provider were: 'possible invasive nature of the study', 'no significant tangible benefits' as well as 'unavailability of staff to facilitate the research in the centre'. In the following section, these ethical issues will be discussed in details.

The first concern voiced by the Research Ethics Committee in this third institution was that participants may be overwhelmed with the number of assessments to be carried out as part of this study. It is the nature of validation studies that each participant will have 2 or more assessments, either by different examiners (or by the same examiner at different time points) or using different types of assessments, to allow reliability and validity assessments to be undertaken. In our study, this was clearly stated in the research protocol when applying for ethical approval. During the field work, each of the five (5) assessors took turns in examining each participant with ID. In addition, subjects underwent repeat examinations as part of the reliability exercises. Participants were allowed to have a break or even to discontinue if they were overwhelmed. During the data collection, all examinations were ceased within the time limit of 60 minutes, which is a cut-off time decided as acceptable for these participants with ID.

The use of the CPITN probe in the concurrent application of the conventional dental indices by the gold standard dental examiner in this validation study could be considered as 'invasive' to the participants with ID. Given the unreliability of repeated CPITN measurements by subsequent examiners (for example, bleeding already elicited by the first examiner) and hence the limited benefit of doing this, it was decided that the probing would be carried out by only the gold standard dental assessor (Morris et al., 2001). As well, this part of the assessment was not repeated as part of the test-retest reliability evaluation.

Is the ODNF assessment tool 'invasive'? This assessment tool is designed primarily as a visual assessment which does not require manipulation of oral tissues by non-dental assessors, neither does it require special equipment such as a dental mirror and CPITN probe. However, during the training of non-dental assessors, feedback from them was that it was helpful to use a disposable plastic dental mirror to help in retracting the cheeks, for better visualisation of the teeth and intra-oral tissues. This was to prevent the non-dental assessors from using their gloved fingers and in any event, the non-dental assessors were reluctant to use their fingers inside the patients' mouths. In the initial validation study for BOHSE (Kayser-Jones, 1995), a tongue blade was used for this purpose but it was found that their use was perceived as challenging. As a consequence, tongue blades were discontinued in use when BOHSE was simplified into OHAT (Chalmers et al., 1995). In terms of time, the ODNF assessment tool was also quick and participants indicated in the feedback that it was acceptable to them.

In any research programme, there is a possibility of participants being coerced into joining, especially in this vulnerable population (Health Service Executive, 2017b). This study made every effort to ensure participation was totally voluntary and this was stated in the participants' information leaflet/booklets and also during the information-sharing session. This information was also offered, in the case of lack of decision making capacity, to the participant's representative. It is acknowledged that no one else can give consent on behalf of an adult, however, according to the Ireland's national consent guideline, there is a requirement that a consent form for participation in a research study needs to be signed (Health Service Executive, 2017b). For those whom it was deemed lacked decision making capacity or for those with physical limitations who were unable to sign, a representative would be involved in the decision-making process and would sign the consent form for the participant, after indicating that they had informed the participant, as much as was possible, about the detail of what was involved in possible participation. In this study, the supporting person (or proxy) was allowed to accompany the participant during the data collection day to support the participant.

The next ethical concern was that this study would have no tangible benefits to the participants. This study provided an oral assessment by qualified dentists, who are trained to identify problems and treatment need for the participants. The results of the oral assessments were given to the participants, and any need for referral for treatment or further dental assessment was also identified, and discussed with participants and their supporting person. The participants in the study were given oral hygiene advice by a qualified dental hygienist during the data collection day, as part of an oral health promotion component of any oral health screening. Participation in this study also helped the participants to become familiar with dental assessments, although it was good to know that most of the participants indicated that they do go to their dentist for a check-up. This study was carried out at the participant's daycentre itself; hence the participants were in an familiar setting without any extra travel for them. From a research perspective, involvement of all stakeholders is key and in this instance, feedback from the participants with ID was taken into consideration and their involvement as Research respondents, making this research 'inclusive' of individuals with ID (National Disability Authority, 2002).

Finally, 'Unavailability of staff to facilitate the research in the centre' was indicated as another reason for not joining this study. As described abundantly in the literature, carrying out an additional assessment, be it for the nursing staff to carry out the assessment or the staff to facilitate research, it is still an additional workload (Kayser-Jones, 1995). The extra workload for staff in facilitating this study were: role as gatekeeper in arranging for information-sharing sessions, recruitment of participants (PIL and consent forms), organisation of venues for the field work, arranging time for participants to come in and, during the day of examination itself, to facilitate the data collection. It was, therefore, important to state clearly the role of facilitator (gatekeeper) in the ethics application. This study was totally voluntary and it is acknowledged that there are no financial incentives for the staff to facilitate the study. Rather, it was for the service providers to engage, as others did, by seeing the more global benefits from involvement in this study.

4. Sampling bias - participants with mild to moderate intellectual disabilities

The next major limitation of this study is that the sample was comprised of volunteers (a convenience sample) hence bias cannot be ruled out. The study recruited participants with ID whom the liaison person in the centre felt had enough cooperation for data collection in this tool validation study. A limitation to this study is the inability to include participants who would not be able to cooperate (those with moderate or severe ID). Hence, this study cannot conclude that this tool will be accepted by all adults with ID. However, this study reported diversity of participants in term of age (range of 19-70 years old), as well oral health condition (no conditions with zero count) and hence, this ensured our assessors were exposed to different realities. Despite that, there is no reassurance that all range of conditions were present, which is important in a study looking at validation.

5. Training and calibration

Although the training was completed in 2 days (a total of 8 hours), the majority of the non-dental assessors recommended more time to practice on more volunteers before going into the field (ie data collection). This study showed that during the field work, the majority of the non-dental assessors felt more confident with the more examinations they did. This concurs with a suggestion in the feedback forms that an additional session would be sufficient and in future deployment of the ODNF, there would need to be consideration given to including more practice time in the training protocol. It is acknowledge that calibration of assessors would strengthen the validation of a tool (Streiner, 2015) however, in this study, calibration was not carried out because it was part of this validation study to assess the reliability of the assessors. It was also in line with our aim not to overburden this population.

6. Soft tissues item

When the construction and content validation of this new index was carried out, assessment of the soft tissues were considered relevant to be included. The 5-item assessment was grouped into single item as an attempt to make it clear, simple and objective for the non-dental assessors to use. Additional information collected (the type of soft tissue lesion found and its location) in the comment box would give substantial information required in epidemiological surveys. However, the usefulness of this assessment for individual patient was not explored in this research and it is recommended to test this upon further development of this tool.

7. Treatment need

The use of term 'treatment need' implies that an index that would assess the conditions which are potentially responsive to treatment. Index of treatment need usually will specify the treatment need required for each code and criteria recorded. As for the ODNF index, it will give some indication of the likely treatment need. However, it will not specify the type of treatments such as restoration or extraction. This is justifiable for the intended purpose of data collection in community level as we are not expecting non-dental individuals to diagnose the treatment needed for person examined. This domain of the ODNF index will be further explored in the next phase of this study.

8. Concurrent validity

Adequate concurrent validity was not established for Denture wear, Occluding pairs, Soft tissues, Oral cleanliness and Dental Pain; in order to limit the length of examination for the participants with Intellectual disabilities (ID).

9. Cost analysis

This study was limited by not fully examining the cost of data collection associated with ODNF. The function of a cost analysis was to understand the expense of dental data collection in large scale cross-sectional surveys. This study reported preliminary cost analysis by reporting how much cheaper it is to utilise ODNF data collection tool by non-dental, compared to conventional dental examination. However, this analysis has not included the cost of training and calibration. To fully understand the expense of ODNF data collection tool, cost analysis warrants further assessment, which will be carried out in the next phase of this research.

5.4. Strengths and weaknesses in relation to other studies,

In this third section of the discussion, strengths and limitations of this validation study will be considered in the broader context of the initial validation studies of existing, assessment tools applied by non-dental assessors .

5.4.1. Validity and reliability

The ODNF index is the first oral assessment tool developed with the aim of being utilised to assess the oral status of people with intellectual disabilities. This study was the first to assess the validity and reliability of this data collection tool. The methods of index development and validation in this study reflected similar processes in previous studies (Andersson et al., 2002; Chalmers et al., 2005, Saintrain and Vieira, 2012). Lawshe's Content Validity Ratio (CVR) approach was used in this study to quantify the validity of the

ODNF assessment tool. Although this is internationally recognised as the method of establishing content validity, none of the existing, similar indices had used CVR in their initial validation.

This study also reported development of the constructed tool. Once the items deemed to be relevant were compiled under the main categories identified (For example, tooth count, soft tissues), discussions were carried out between the co-researchers. At this stage, modifications and simplifications were made in view of this tool being acceptable to individuals with ID (safe, does not cause pain or discomfort and quick) as well as acceptable to non-dental assessors (easy to learn, no special equipment needed, no prior or extensive dental knowledge needed and easy to carry out). From the 13 relevant items identified by experts, the tool was simplified to develop the 8-item ODNF assessment tool. This step was part of ensuring that the tool will not take too long to administer. Similarily, Chalmers and colleague had simplified the BOHSE tool (Kayser-Jones et al., 1995) from 10 categories into an 8-category OHAT tool (Chalmers et al., 2005).

The results from this study have established concurrent validity in the ODNF categories of Tooth count', 'Gum condition' and 'Visible caries'. Adequate concurrent validity for the other categories were not established for the remaining categories. However, the concurrent validity scores established in this study are similar to, or better than, those from previous concurrent validation tests on these categories (Chalmers et al., 2005; Saintrain & Vieira, 2012). Using OHAT, Chalmers and colleagues reported a high level of agreement (Percent agreement, % Ag, and Kappa) and both good correlations (Pearson, C and Spearman's, r_s) for 'Natural tooth' and 'Number of teeth' categories (Chalmers et al., 2005; Saintrain & Vieira, 2012), as well as high %Ag and moderate correlation for 'Gums & tissues' categories (Chalmers et al, 2005), and a high level of agreement (Kappa) for 'Dental cavities' category (Saintrain & Vieira, 2012). The initial validation of OHAT had reported the use of a parallel, comprehensive oral epidemiological examination using criterion (gold standard) dental assessments (Chalmers et al., 2005). The COHI study only

reported the use of DMFT as a gold standard for comparison (Saintrain & Vieira, 2012). Despite this, none of the previous indices have established concurrent validity for all of the items. Our study with ODNF also reported good diagnostic accuracy during the concurrent validity tests, although a recent OHAT validation study did not evaluate diagnostic accuracy in their concurrent validation assessments (Simpelaere et al., 2016).

The inter-rater reliability of the ODNF assessment tool is considered comparable to previous initial validation studies. Tables 5.3 and 5.4 below outline the comparison of inter-rater agreement and correlation values, as well as sensitivity and specificity values for this tool against values from the original validation studies (Saintrain & Vieira, 2012; Scott et al., 2010, Chalmers et al., 2005). This study reported lower inter-rater agreement values for 'Oral cleanliness' and 'Gums' than those reported in previous study (Chalmers et al., 2005). One possible explanation is that the previous study was conducted over 3 time periods (at baseline, 3-month and 6-month), whereas this study was conducted at one point in time. Thus, the non-dental assessors did not have more time to be familiar with the ODNF index before reliability test was conducted.

Finally, this study reported good test-retest reliability of all ODNF categories, which were similar to or even higher than previous studies (Table 5.5). This showed that the ODNF index has good test-retest reproducibility.

Table 5.3 Comparison of inter-rater agreement and correlation values (%Ag, Kappa, Gwet's and r_s) in this study against previous initial validation studies

ODNF Categories	This study	Previous study
Denture wear	%Ag: 96.0-100, Perfect/excellent Kappa: 0.65-1.00 Substantial to Perfect/excellent Gwets: 0.97-1.00 Perfect/excellent r_s: 0.91-1.00	Kappa: 0.82-0.95 Perfect/excellent Saintrain & Vieira, 2012
Soft tissues	%Ag: 53.0 Moderate Kappa: 0.10 Poor to Fair Gwet's: 0.08 Poor to Fair	No %Ag & kappa reported Scott et al., 2010
Oral cleanliness	%Ag: 76.0 Substantial Kappa: 0.27 Fair Gwets: 0.40 Fair	%Ag: 72.6, Substantial Kappa: 0.54, Moderate Chalmers et al., 2005
Gums	%Ag: 75 Substantial Kappa: 0.35 Fair Gwets: 0.33 Fair	Kappa: 0.57 Moderate Chalmers et al., 2005
Visible caries	%Ag: 76-87% Kappa: 0.23 Fair Gwets: 0.64 Moderate	Kappa: 0.51-0.52 Moderate Saintrain & Vieira, 2012
Dental pain	%Ag: 88.0 Perfect/excellent Kappa: 0.45 Moderate Gwets: 0.80 Substantial	%Ag: 92.6 Perfect/excellent Kappa: 0.62 Substantial Chalmers et al., 2005

* Tooth count and occluding pairs were not adopted from tools which are used by non-dental individuals.

Table 5.4 Inter-rater sensitivity and specificity results of non-dental assessors compared against gold and non-gold dental assessors in ODNF study and COHI

	This study		COHI (Saintrain & Vieira, 2012)	
	Sensitivity	**Specificity**	**Sensitivity**	**Specificity**
Dental prosthesis	98.0-100.0%	67.0-100.0%	80.0-92.0%	98.2-100.0%
1 or 2 cavities	33.0%	74.0%	68.4%	83.3%
3 or more cavities	0.0%	89%	63.6%	87.2%

Table 5.5 Comparison of test-retest/intra-rater agreement and correlation values (%Ag, Kappa, Gwet's and r_s) in this study against previous initial validation studies

ODNF Categories	This study	Previous study
Oral cleanliness	%Ag: 85.0-91.0, Perfect/excellent Kappa: 0.51-0.63, Moderate to substantial Gwets: 0.65-0.89, Substantial to perfect/excellent	%Ag: 74.4, Substantial Kappa: 0.56, Moderate Chalmers et al., 2005
Gums	%Ag: 81.0-90.0, Perfect/excellent Kappa: 0.49-0.74, Moderate to Substantial Gwets: 0.52-0.76, Moderate to Substantial	%Ag: 90.5, Perfect/excellent Kappa: 0.71, Substantial Chalmers et al., 2005
Dental pain	%Ag: 89.0-93.0, Perfect/excellent Kappa: 0.58-0.73, Moderate to Substantial Gwets: 0.76-0.88, Substantial to Perfect/excellent	%Ag: 93.9, Perfect/excellent Kappa: 0.66, Substantial Chalmers et al., 2005

5.4.2. Feasibility

This validation study reported that the ODNF assessment was acceptable to the participants with ID as well as for the non-dental assessors. Any assessment tool should not cause pain or discomfort to the participants. As well as comfort and ease of use, an assessment tool should not take too long, which may cause fatigue to the participants. In the initial validation studies of the other, existing tools, feedback from the subjects were not reported.

The time taken to carry out the ODNF assessment was acceptable and comparable to the reported mean time (7.8 minutes) to complete the OHAT examination (Chalmers et al, 2005).

The preliminary cost analysis reported in this study is insufficient to give complete information of the expense of data collection using ODNF in any large scale, cross-sectional survey. Previous validation studies did not report cost analyses either, hence, there is no evidence to compare the cost of utilising ODNF index with the existing oral assessment tools. The next phase of this research will be to determine the expense of non-dental assessors utilizing ODNF.

In conclusion, this initial validation study for the ODNF assessment tool showed promising results. The assessment of its validity, reliability and feasibility were considered to be comprehensive for an initial validation study and comparable or better than those of other indices developed for use by non-dental assessors, albeit not on populations of adults with ID.

5.5. Implications from this study: considerations and implications for clinicians and policymakers

This section highlights the advantages and disadvantages of employing non-dental individuals to carry out ODNF assessment in population with ID. This is then followed by a summary on how to use ODNF index.

5.5.1. Advantages on the use of oral assessment tools by non-dental individuals.

Oral assessment by non-dental assessors has advantages and limitations, each of which should be individually considered according to the intended use of the tool. A major consideration in the genesis of this study was the question of whether it would be possible even to train non-dentists to collect clinical dental data on what might be a challenging population.

None of the non-dental assessors had any formal dental training. With the training and data collection protocol developed for this ODNF assessment tool, the non-dental assessors were able to understand the use of this tool, able to be trained in its use and were able to complete the data collection using the tool. This study offers initial evidence to support the use of a new tool that has much potential across different situations.

Secondly, the ODNF assessment tool may be used by any non-dental individuals who are interested in oral health data collection in adults with ID. This would include those who work closely with individuals with ID (carers, staff in residential settings, and health workers in the ID community) who are familiar with this population will know these individuals with ID personally, know their habits, behaviours, likes and dislikes and, therefore, they are more likely to know a successful way to approach an oral examination (assessment) in these individuals with ID (Kayser-Jones et al., 1995). Previous studies have shown that in cognitively impaired older adults, staff who are familiar with them were more successful in

examining the residents than a dental professional (Chalmers et al., 2005). This study did not test this hypothesis as it was not indicated in the selection of non-dental assessors that they have experience with adults with ID. This study, however, did show that even non-dental assessors who had no prior experience of working with adults with ID and who found some patients difficult to examine, were able to complete the examinations using the tool. Hence, it will not be surprising that those who work closely with population with ID would be in the favourable position to use this tool to record oral health data; this would require further validation studies among this non-dental assessors population.

As importantly, the ODNF assessment tool can be used by current researchers in epidemiological surveys of the population with ID. This study reported that this tool can be administered by non-dentists, or even dentists, to collect data on tooth count, denture wear, pattern of occluding pairs, soft tissue conditions, level of oral cleanliness, Gum condition, number of teeth with visible caries and presence of dental pain. Further work is required to evaluate if this can be incorporated as part of data collection in epidemiological surveys of adults with ID. It was a premise of this study that developing and successfully deploying an assessment tool, for use by non-dental assessors, would facilitate the collection of dental data that would not otherwise be gathered in large-scale studies of these vulnerable groups. For the first time, it would be possible to have oral/dental incorporated as part of a health assessment and all that this implies for inclusivity and health promotion.

Thirdly, it will not be a surprise that employing a dentist to carry out dental examinations at day centres or residential settings, or for epidemiological surveys in populations with ID can be very expensive. Dentists with extra sets of skills to deal with this cohort of individuals can be costly to employ (Health Service Executive, 2017a). In Ireland, no clinical dental data have been collected in the current longitudinal health surveys (example, IDS-TILDA) in population with ID because employing dental personnel would be prohibitive, although the cost analysis of this has not been carried out. Hence, training and using non-dental individuals might be an inexpensive alternative. There is a paucity of research on cost-

effectiveness analysis of this approach and such analyses have not been undertaken in the validation studies of the existing oral assessment tools carried out by non-dental personnel (Chalmers et al, 2005; Saintrain & Vieira, 2012). This study reported the cost of training in, and administration of, the ODNF data collection tool by non-dental assessors in the field. Simple comparison was made between the dentists and non-dentists using this ODNF tool. These data showed that it was more expensive to use a dentist to carry out the ODNF data collection. Further cost analysis has been planned as a follow-up to this study.

In this feasibility study, the ODNF tool has demonstrated its potential to become a screening tool that can be used by non-dental individuals, such as physicians, allied health professionals, health community workers or even carers who work closely with this group in the population. Existing tools like OHAT and ROAG are currently being used by community health workers, carers and nursing staff as a screening tool to evaluate common clinical lesions and detect serious problems in older people, to indicate the need for better access to oral hygiene as well as to indicate the need for referral to dentists for further examination and accurate diagnosis (Chalmers et al, 2005; Andersson et al, 2002). In the United Kingdom, NICE guidelines recommended oral health assessment on admission using OHAT (NICE, 2016). A pilot investigation had also been carried out on physicians using ROAG in 126 older adults in a geriatric hospital in Germany. However, evidence on the physician ability to screen for oral health was found to be insufficient (Hassel et al., 2008). ODNF can collect oral health data which can be used for dental professionals to assess oral health status of this population. However, further validation studies on the ODNF assessment tool would be needed before this tool can be used as a screening tool.

Previous validation studies involving nursing staff have shown that education and training on using oral assessment tools would increase the users' knowledge about oral problems and how to prevent them (Kayser-Jones, 1995; Chalmers et al., 2005). The whole experience of assessing the mouth has been shown to increase awareness of the carers and those who work closely with individuals with ID about the importance of routine oral

hygiene (Kayser-Jones, 1995). This demystification of dental knowledge to professionals other than the dental team would allow dental health to be integrated into the general health assessment (Saintrain and Vieira, 2012, Saintrain et al., 2014). However, such awareness and knowledge does not always result in improved health outcomes for people with ID (Hithersay et al., 2014). If this ODNF assessment tool is to be administered by nursing staff, it would be useful to carry out an evaluation of the impact of using the ODNF assessment tool on their attitude, skills and knowledge of oral health, as well as evaluation of the oral health outcomes.

5.5.2. Disadvantages/limitations of the use of oral assessment tools by non-dental individuals.

Despite the obvious potential as an oral assessment tool for use by non-dental assessors in populations with ID, possible limitations need to be considered and will need further investigation .

Firstly, if the carers for those in residential settings are asked to carry out the oral assessment, this will add to their workload for already overburdened staff (Kayser-Jones, 1995). Application of this ODNF tool may incur an extra workload in training, calibration and fieldwork with non-dental assessors. This study recorded the number of hours spent in the training and data collection, however, evaluation of the additional workload for the non-dental was not investigated in this study. The benefit of these data being collected, however, is not to be understated. With the paucity of dental information in this population, dental data collection is urgently needed to allow health care teams (clinicians and policymakers) to organise and prioritise care so that people with ID will get effective, equitable, affordable, accessible, safe and sustainable oral health care (Elliot et al., 2005).

Secondly, simplification of dental assessment and its delegation to non-dental individuals may legitimately raise concerns that serious problems, such as oral cancers, might be missed by this tool. This is definitely a known limitation of an assessment or screening tool utilising professionals without dental qualification (Hassel et al., 2008). It is also a concern that, with delegation of this oral assessment to non-dental individuals, dentists may become less involved in providing dental care for this population. It is difficult to support or reject this claim as this would need further evaluation. However, as pointed out by Ribeiro and colleagues (2012), the oral assessment by non-dental assessors should not replace the periodic recall for a comprehensive examination by a dentist. Dentists are still required to provide definitive diagnosis and dental care, which cannot be delegated to non-dental individuals. It is also important to note that, with extra funding, data collection in an epidemiological study by dentists is still considered a gold standard and should not be totally discounted.

5.5.3. Application of ODNF assessment tool

Before using this ODNF index to collect data, it is recommended that the aim of the ODNF index and scope of its application be understood.

The aim of the ODNF oral assessment tool is to enable non-dental assessors to collect data regarding the oral health status (also treatment need and function) of individuals and populations with ID and hence facilitate health care teams to organise and prioritise care for this group.

Prior to using this tool, non-dental assessors will have to undergo a dedicated training programme (which involves education and hands-on practical session), which have been developed specifically for this oral assessment tool. Further refinement and validation of the training will be carried out in the next phase of this research. Calibration of assessors

is recommended and will be developed further in refining the data collection protocol for the ODNF assessment tool.

This tool can be administered in less than 10 minutes, in any setting, without the need for a dental chair and special dental equipment. From the initial validation study, this ODNF assessment tool has demonstrated that it may be used by individuals with no dental training to record the oral health status of individuals with ID.

This would enable health care teams and policymakers to organise and prioritise care based on population need, which may include access to routine oral hygiene, referral for dentist evaluation and treatment, urgent referrals, better access to dental service and reorientation of services around population with intellectual disabilities (ID).

5.6. Unanswered questions and areas for future research

This is the first validation study of a novel tool for populations with ID. Further development of this ODNF assessment tool is required and future validation studies of this tool would concentrate on the following areas:

In terms of the tool itself, the following areas need further development:

1) Clarification of the descriptions of ODNF categories: Occluding pairs, Soft tissues, Oral cleanliness and Gum condition.
2) Refining the training manual and process; making it accessible online.
3) More practical, hands-on time during the training period.
4) Reducing the time required to carry out the ODNF assessment.
5) Possible modifications which may necessitate a new validation study: addition of more items to ensure content coverage, dichotomizing some of the categories such as Oral cleanliness and Gum condition and determination of the clinical value of doing this.

In terms of the design of further studies:

6) Ongoing content validation by expert judgment and consideration of the new literature need be carried out.
7) Calibration of non-dental assessors on at least 20 individuals with ID, who presents a wide range of conditions to be tested in the tool (as per WHO recommendation).
8) A sufficient sample size, large enough to allow enough counts to assess specificity and sensitivity, and also reduce the kappa paradox.
9) Participants to have only a maximum of two assessments to assess validity and reliability, hence reducing ethical concerns. However, this requires a very large sample size.

10) Concurrent validity needs to be fully established for the ODNF categories of: ‘Denture wear’, ‘Occluding pairs’, ‘Soft tissues condition’, ‘Oral cleanliness’ and ‘Dental pain’. Concurrent ODNF validation can be carried out by comparing results from a comprehensive dental examination using standard criteria; Denture wear category with denture assessment (Rise, 2009), Soft tissues category with the presence of oral lesions (WHO), Oral cleanliness with Plaque Index (Silness and Loe) and Dental pain category with self-reported pain (Chalmers et al., 2005).

11) Use of the same correlation and agreement tests, as in this study, so that the values can be compared to this initial validation study of the ODNF assessment tool.

12) Validation with various intended users such as carers in residential settings or researchers in epidemiological surveys on adults with ID.

13) Validation for further application such as screening or as pre-diagnostic tool for dental conditions.

6. CONCLUSIONS

The findings of this study show that it is feasible for trained non-dental individuals to use ODNF index adult population with Intellectual Disabilities (ID), for the assessment of Tooth count, Denture wear, Soft tissues (Lips, Mucosa, Tongue, Roof of mouth and Floor of mouth), Occluding pairs, Gum condition, Oral cleanliness, Visible caries and Dental pain. The ODNF data collection tool and its training programme were developed and validated in this study, with high level of content validity. Concurrent validity was established with sufficient sensitivity and specificity, for ODNF categories 'Tooth count', 'Gum condition' and 'Visible caries'. There was good reliability for almost all categories except for 'Soft tissues', 'Oral Cleanliness' and 'Gum condition'. We conclude that ODNF index is a valid, reliable, quick, inexpensive and acceptable tool to assess oral health status of adults with ID, for use by non-dental individuals. The use of this tool has the potential to collect data capable of assessing the oral health care of population with ID and informing policy making and re-organisations of the services to promote oral health. Further work on the more challenging categories of ODNF index ('Soft tissues', 'Oral Cleanliness' and 'Gum condition') is needed and follow-up validation study is recommended to strengthen validity and reliability.

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8. GLOSSARY

BOHSE: Brief Oral Health Status Examination (Kayser-Jones).

Calibration: to ensure uniform interpretation, understanding and application by all examiners of the criteria and codes (WHO).

COHI: Community Oral Health Indicator (Saintrain).

Cognitive functioning: an intellectual process by which one becomes aware of, perceives, or comprehends ideas. It involves all aspects of perception, thinking, reasoning, and remembering (AAIDD).

Comprehensive dental examination: conducted by a qualified dentist (using visual and tactile evaluation of all oral structures and hard and soft tissues using specific extra-oral and intraoral light sources and dental equipment) (Pearson & Chalmers, 2004).

Content validation: "a closely related concept, consisting of judgement whether the instruments samples all the relevant or important content or domains" (Streiner).

Criterion measure: some other measure (usually 'gold standard') of the trait or disorder under study (Streiner).

Cost analysis: Analysis of the comparative costs of alternative interventions or programs. Does not include consequences. (Drummond).

Cost-effectiveness Analysis (**CEA**): An economic evaluation in which the costs and consequences of alternative interventions are expressed cost per unit of health outcome. CEA is used to determine technical efficiency; i.e., comparison of costs and consequences of competing interventions for a given patient group within a given budget.

Dental assessment screening: conducted by a carer, nurse, allied health professional or medical practitioner (using an extraoral light source but not the use of any intraoral light sources or specific dental equipment such as a mouth mirror) (Pearson & Chalmers, 2004).

DMF-T: DMFT (number of decayed, missing, and filled teeth due to caries) index, which tells the number of teeth affected by caries (WHO).

Expressed need: "defined as those people who demand a service" (Bradshaw).

Epidemiology: Epidemiology is the study of the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems (WHO).

Face validity: Simply indicated whether on the face of it, the instrument appears to be assessing the desired qualities (Streiner).

IDS-TILDA: Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (TILDA); a longitudinal study researching ageing in Ireland among people with an intellectual disability aged 40 and over (TCD).

Index: A numerical scale with upper and lower limits, with scores on the scale that correspond to specific criteria (Streiner).

Intellectual Disabilities (**ID**): as defined by the American Association on Intellectual and Developmental Disabilities (AAIDD), is characterised by significant limitations in both intellectual (general mental capacity) and adaptive behaviour (a collection of learned conceptual, social and practical skills), which originates before the age of 18 (AAIDD).

Inter-observer reliability: agreement between different observers (Streiner).

Internal consistency: a measure of correlation of items which may tell the same function (Streiner).

Intra-observer reliability: agreement between measurements made by sane assessor on two different occasions (Streiner).

Manual dexterity: the ability to make coordinated upper and lower arms movements to grasp and manipulate objects; includes muscular, skeletal, and neurological functions to produce small, precise movements (Springer Link)

MSE: Mouth Self Examination (Mathew)

Non-dental: individuals without formal dental training.

Normative need: “that which the expert or professional, administrator or social scientist defines as need in any given situation” (Bradshaw).

OAG: Oral Assessment Guide (Eilers).

OHAT: Oral Health Assessment Tool (Chalmers)

Power calculation: Power calculation indicate the smallest sample size required for an evaluation design to detect a meaningful difference.

Reliability: How reproducible the results of a scale are under different conditions (Streiner).

ROAG: Revised Oral Assessment Guide (Andersson).

Test-retest reliability: measurements on the same patient on two occasions separated by some time interval (Streiner).

TILDA: The Irish Longitudinal Study on Ageing (TILDA). TILDA collects information on all aspects of health, economic and social circumstances from people aged 50 and over in a series of data collection waves once every two years (TCD).

Validity: measure what it is intended to measure (Streiner).

9. APPENDICES

APPENDIX I. Characteristics of the existing tools used by non-dental individuals to collect oral health data

Items that reflect status of oral health and function

The items developed in the indices described above were chosen to reflect the status of oral health and function. When the items from the previous indices were reviewed, it was decided that the items can be grouped under the related categories, which are tooth count, dentures, occluding pairs, soft tissues, oral cleanliness, gums and dental pain.

Tooth count

In any dental assessment, we look at the number of natural teeth present as well as the total loss of natural teeth (edentulousness). This enables us to gauge the effect of losing teeth on oral function. It has been shown that a minimum of 20 teeth is only required to meet the optimal masticatory function. Shortened dental arches are found to be sufficient to maintain adequate clinical oral function (Käyser, 1981). Hence, if an index intends to assess masticatory function, it is only reasonable to be able to assess the number and location of teeth using the proposed screening tool. Only two items, namely 'Number of natural teeth' and 'Number of teeth', in BOHSE and COHI respectively, were developed to assess the total number of natural teeth present in the mouth; meanwhile the other items related to the tooth count category looked at the number of decayed and broken teeth (including roots). The numerical and descriptive ratings developed for the items of difference indices, related to the number and condition of natural teeth are shown in Table 9.1.

Table 9.1 Detailed summary of items reflecting 'Natural teeth' or 'Tooth count'

Assessment tools	Items	Ratings (Numerical /Descriptive)
BOHSE (Kayser-Jones et al., 1995)	Number of natural teeth	Count____
	Condition of natural teeth	0: No decayed or broken teeth/roots 1: 1-3 decayed or broken teeth/roots 2: 4 or more decayed or broken teeth/roots; or fewer than 4 teeth in either jaw
ROAG (Andersson et al.,2002)	Teeth/Dentures	1: Clean, no debris 2: 1) Plaque or debris in local areas; 2)Decayed teeth or damaged dentures
OHAT (Chalmers et al., 2005)	Natural teeth	Yes/No 0: No decayed or broken teeth/roots 1: 1-3 decayed or broken teeth/roots or very worn down teeth 2: 4 or more decayed or broken teeth/roots or very worn down teeth; or less than 4 teeth
COHI (Saintrain, M. V., & Vieira, A.P 2012)	Number of teeth	Count____
	Visible caries	1: Without visible cavities 4: 1 or 2 visible cavities 5: 3 or more visible cavities

9.1.1. Dentures

Just like natural teeth, another essential item in a screening tool is the ability to reflect the number and location of artificial teeth, whether artificial teeth or dentures are indicated, as well as, if indicated, whether the dentures are being worn regularly or not. From previous indices, items were included to reflect the presence of denture in the mouth, the condition of these dentures, whether they are labelled or not, as well as usage and need of dentures (see Table 9.2)

Table 9.2 Detailed summary of items reflecting presence of dentures or artificial teeth in the mouth.

Assessment tools	Items	Ratings (Numerical /Descriptive)
BOHSE (Kayser-Jones et al., 1995)	Condition of artificial teeth	0: Unbroken teeth, worn most of the time 1: 1 broken/missing tooth, or worn for eating or cosmetics only 2: More than 1 broken or missing tooth, or either denture missing or never worn
	Upper/Lower dentures labelled	Yes/No/None
OHAT (Chalmers et al., 2005)	Dentures	Yes/No 0: No broken areas or teeth, dentures regularly worn, and named 1: 1 broken area/tooth or dentures only worn for 1-2 hours daily, or dentures not named, or loose 2: more than 1 broken area/tooth, denture missing or not worn, loose and needs denture adhesive, not named.
COHI (**Saintrain, M. V., & Vieira, A.P, 2012)**	Owns prosthesis Total, Partial	Mark with an X

9.1.2. Occluding pairs (natural and artificial)

Assessment of the teeth in contacts determines the clinical oral function (Käyser, 1981). Based on the systematic literature review, only BOHSE developed an item to reflect the number of occluding pairs in the mouth. According to the ratings developed for BOHSE, 12 or more pairs of teeth in a chewing position, is considered the healthy end of the scale. Ikebe and colleagues (2010) found that bilateral occluding contacts on either premolars or molars is a key predictor of occlusal force and unilateral occluding posterior teeth is critical for masticatory performance (Ikebe et al., 2010) This study supports the hypothesis that clinical masticatory function and effectiveness can be achieved with shortened dental arches with a minimum of one posterior occluding pair.

Table 9.3 Detailed summary of items reflecting occluding pairs in the mouth.

Assessment tools	Items	Ratings (Numerical /Descriptive)
BOHSE (Kayser-Jones et al., 1995)	Pairs of teeth in chewing position (natural or artificial)	0: 12 or more pairs of teeth in chewing position 1: 8-11 pairs of teeth in chewing position 2: 0-7 pairs of teeth in chewing position Count ____

9.1.3. Soft tissues

It is evident that the status of soft tissues has been included in most of the previous indices. Three main soft tissues commonly assessed were lips, intra-oral mucous membranes and tongue. This is significant as a screening tool should be able to identify lesions that need simple intervention by nursing staff, or those that requires further and possibly urgent consultation with physicians or dentists. Different descriptions were developed in these indices for each item, as shown in Table 9.4

Table 9.4 Detailed summary of items reflecting soft tissues condition in the mouth.

Assessment tools	Items	Ratings (Numerical /Descriptive)
OAG (Eilers et al., 1988)	Lips	1: Smooth and pink 2: Dry or cracked 3: Ulcerated or bleeding
	Mucous membranes right cheek, inside lip upper jaw, left cheek, inside lip lower jaw, palate, floor of mouth	1: Pink and Moist 2: Reddened or coated (increased whiteness) without ulcerations 3: Ulcerations with or without bleeding
	Tongue	1: Pink and moist and papillae present 2: Coated or loss of papillae with a shiny appearance with or without redness 3: Blistered or cracked
OAG (Andersson et al.,1999)	Lips	1: Smooth and pink 2: Dry or cracked 3: Ulcerated or bleeding
	Mucous membranes: right cheek, inside lip upper jaw, left cheek, inside lip lower jaw, palate, floor of mouth, Tongue	1: Pink and moist 2: Change in colour, redness, blue-red or white blisters, no ulceration 3: Very red or thick, white coating, Ulceration with or without bleeding

Assessment tools	Items	Ratings (Numerical /Descriptive)
ROAG (Andersson et al.,2002)	Lips	1: Smooth and pink 2: Dry or cracked, and/or angular chelitis 3: Difficulty talking or painful
	Mucous membranes	1: Pink and moist 2: Dry and/or change in colour, red, blue-red or white 3: Very red, or thick, white coating; Blisters or ulceration with or without bleeding
	Tongue	1: Pink, moist and papillae present 2: Dry, no papillae present or change in colour, red or white 3: Very thick white coating; Blisters or ulceration
BOHSE (Kayser-Jones et al., 1995)	Lips	0: Smooth, pink, moist 1: Dry, chapped or red at corners 2: White or red patch, bleeding or ulcer of 2 weeks duration
	Tongue	0: Normal roughness, pink and moist 1: Coated, smooth, patchy, severely fissured or some redness 2: Red, smooth, white or red patch, ulcer of 2 weeks duration
	Tissue inside cheek, floor & roof of mouth	0: Pink and moist 1: Dry, shiny, rough, red or swollen 2: White or red patch, bleeding, hardness; ulcer of 2 weeks duration
OHAT (Chalmers et al., 2005)	Lips	0: Smooth, pink, moist 1: Dry, chapped or red at corners 2: Swelling or lump, white/red/ulcerated patch, bleeding/ulcerated at corners
	Tongue	0: Normal, moist roughness, pink 1: patchy, fissured, red, coated 2: Patch that is red and/or white, ulcerated, swollen
	Gums & Tissues	0: Pink, moist, smooth, no bleeding 1: Dry, shiny, rough, red, swollen, one ulcer/sore spot under dentures 2: Swollen, bleeding, ulcers, white/red patches, generalised redness under dentures
COHI (Saintrain, M. V., & Vieira, A.P 2012)	Soft tissue injury	Yes/No
	Soft tissue injury (Type) Lesions and/or wound, Red lesion, White lesion, Blisters, Other aggravation	Mark with an X

Assessment tools	Items	Ratings (Numerical /Descriptive)
	Soft tissue injury (Location): Lips, cheeks, roof of the mouth, tongue, other places	Mark with an X
MSE (Scott et al., 2010)	Lips and gums, Inside cheeks Tongue, Roof of the mouth, Under the tongue *Separate categories	Presence of red patches, white patches, ulcers, lumps and swellings

9.1.4. Oral cleanliness: food particles, dental tartar (on natural or artificial teeth)

Similar to soft tissues, almost all of the previous indices discussed, developed items to reflect oral cleanliness. This was captured by the presence of localised or generalised plaque, debris and tartar in the mouth or on artificial teeth/dentures. In addition, presence of bad breath was also rated in OHAT (Chalmers et al., 1995). Ratings for the items reflecting oral cleanliness can be found in Table 9.5. Screening outcomes for oral cleanliness may indicate the need for oral care supports and/or referral for tooth debridement and polishing.

Table 9.5 Detailed summary of items reflecting oral cleanliness.

Assessment tools	Items	Ratings (Numerical /Descriptive)
OAG (Eilers et al., 1988)	Teeth or dentures	1: Clean and no debris 2: Plaque or debris in localised areas (between teeth if present) 3: Plaque or debris generalised along gum line or denture bearing area
OAG (Andersson et al.,1999)	Teeth & Dentures	1: Clean, no debris 2: Plaque or debris in localised areas 3: Plaque or debris generalised
ROAG (Andersson et al.,2002)	Teeth & Dentures	1: Clean, no debris 2: 1) Plaque or debris in local areas 3: Plaque or debris generalised
BOHSE (Kayser-Jones et al., 1995)	Oral cleanliness	0: Clean, no food particles/tartar in the mouth or on artificial teeth 1: Food particles/tartar in 1 or 2 places in the mouth or on artificial teeth 2: Food particles/tartar in most places in the mouth or on artificial teeth
OHAT (Chalmers et al., 2005)	Oral cleanliness	0: Clean, no food particles/tartar in the mouth or on dentures 1: Food particles/tartar/plaque in 1 or 2 areas of the mouth, or on small area of dentures, or halitosis (bad breath) 2: Food particles/tartar/plaque in most areas of the mouth or on most of dentures or severe halitosis (bad breath)
COHI (Saintrain, M. V., & Vieira, A.P 2012)	Presence of dental tartar	Mark with an X

9.1.5. Gums: between teeth, underneath artificial teeth

Previous existing tools have looked into ways to collect oral health data to inform about the level of Gum condition and disorders. Swelling, redness, bleeding, ulceration and white/red patches were included among the descriptions for the items and their ratings (Table 9.6).

Table 9.6 Detailed summary of items reflecting Gum condition in the mouth.

Assessment tools	Items	Ratings (Numerical /Descriptive)
OAG (Eilers et al., 1988)	Gingiva	1: Pink and stippled and firm 2: Oedematous with or without redness 3: Spontaneous bleeding or bleeding with pressure
OAG (Andersson et al.,1999)	Gums	1: Pink and firm 2: Oedematous and/or redness, White coating 3: Bleeding easily of finger pressure and/or Thick, white coating
ROAG (Andersson et al.,2002)	Gums	1: Pink and firm 2: Oedematous and/or red 3: Bleeding easily under finger pressure
BOHSE (Kayser-Jones et al., 1995)	Gums between teeth and/or under artificial teeth	0: Pink, small indentations; firm, smooth, and pink under artificial teeth 1: Redness at border around 1-6 teeth; one red area or sore spot under artificial teeth 2: Swollen or bleeding gums, redness at border around 7 or more teeth, loose teeth; generalised redness or sores under artificial teeth
OHAT (Chalmers et al., 2005)	Gums & Tissues	0: Pink, moist, smooth, no bleeding 1: Dry, shiny, rough, red, swollen, one ulcer/sore spot under dentures 2: Swollen, bleeding, ulcers, white/red patches, generalised redness under dentures
COHI (Saintrain & Vieira, 2012)	Gingival inflammation	Mark with an X
MSE (Scott et al., 2010)	Lips & Gums	Presence of red patches, white patches, ulcers, lumps and swellings

9.1.6. Dental pain: pain in the mouth; from teeth or gums, voice, swallowing

The presence of dental pain in the mouth indicates oral/dental pathology so that items must be chosen, for inclusion in the proposed index, to accurately indicate whether the pain is of dental or intra-oral soft tissue origin. Pain in projecting the voice and swallowing would indicate further consultation by a physician. The presence of behavioural or physical signs of dental pain would specify the need for referral to dentist in the first instance.

Table 9.7 Detailed summary of items reflecting presence of dental pain in the mouth.

Assessment tools	Items	Ratings (Numerical /Descriptive)
OAG (Eilers et al., 1988)	Voice	1: Normal 2: Deeper or raspy 3: Difficulty talking or painful
	Swallow	1: Normal swallow 2: Some pain on swallow 3: Unable to swallow
OAG (Andersson et al.,1999	Voice	1: Normal 2: Deeper or raspy 3: Difficulty talking or painful
	Swallow	1: Normal swallow 2: Some pain on swallow 3: Unable to swallow
ROAG (Andersson et al.,2002)	Voice	1: Normal 2: Deeper or raspy 3: Difficulty talking or painful
	Swallow	1: Normal swallow 2: Some pain on swallow 3: Unable to swallow
BOHSE (Kayser-Jones et al., 1995)	Is your mouth comfortable?	Yes/No If No, please explain: ___

Assessment tools	Items	Ratings (Numerical /Descriptive)
OHAT (Chalmers et al., 2005)	Dental pain	0: No behavioural, verbal or physical signs of dental pain 1: Verbal and/or behavioural signs of pain such as pulling at face, chewing lips, not eating, aggression 2: Physical pain signs (swelling of cheek or gum, broken teeth, ulcers) as well as verbal and/or behavioural signs (pulling at face, not eating, aggression)

9.1.7. Other categories

COHI included extra items (see Table X) to reflect the number of residual roots, need for dentures, use of toothbrush and fluoridated toothpaste and the patient's pattern of dental attendance.

Table 9.8 Detailed summary of other categories

Assessment tools	Items	Ratings (Numerical /Descriptive)
COHI (Saintrain, M. V., & Vieira, A.P 2012)	Residual root (quantity)	Count ____
	Need of prosthesis Total, Partial	Mark with an X
	Do you have toothbrush?	Yes/No
	Do you use fluoridated toothpaste?	Yes/No
	Have you been to a dentist in the last year?	Yes/No If yes, due to: Dental emergency / Regular check-ups

9.1.8. Scores

Most indices (OAG, ROAG, BOHSE and OHAT) developed items with three descriptors and rated on a 3-point scale; the lowest rating indicated the healthy end and the highest numerical rating indicative of unhealthy conditions. OAG and ROAG had used a 3-point scale of 1, 2, 3 (1 being 'healthy' and 3 being 'diseased'), whilst BOHSE and OHAT had used a 3-point scale of 0, 1, 2 (0 being 'healthy' and 2 being 'diseased'). Only BOHSE and OHAT screening tools allowed for a total score to be calculated by adding scores from each

numerical and descriptive rating. Although it is understood that the higher score indicates the severe deviation from the healthy, normal status, the clinical significance of calculating the total scores from all the numerical ratings of items had not been researched in previous studies (Simpelaere et al., 2016).

9.1.9. Conduct of Clinical examinations & equipment used

Pearson and Chalmers delineated between dental examination and dental assessment screening; where dental examination is a comprehensive oral hard and soft tissues evaluation conducted by a qualified dentist using specific dental equipment as well as extra-oral and intraoral light sources; and dental assessment screening defined as an evaluation that is carried out by a carer, nurse, allied health professional or medical practitioner without using specific dental equipment and intra-oral light sources (Pearson & Chalmers, 2004).

As the assessment screening tools were not developed for use by dental clinicians, a simplified set of dental instruments was expected to constitute the examination kit. The majority of the examinations were carried out using only clean gloves and an adequate light source (natural or hand-held light). Some extra equipment mentioned included a mirror (Ribeiro et al., 2014) and wooden tongue depressor (Saintrain & Vieira et al., 2012). Examinations were mainly carried out at home with patients seated on normal chairs, or on the bed (Kayser-Jones et al., 1995; Chalmers et al., 2005). For mouth self-examination, participants were asked to check their own mouth in front of a mirror (Scott et al., 2010). Routine personal protective equipment was used by the examiners in the previous studies.

Table 9.9 Detailed summary of conduct of clinical assessments and equipment used for each assessment tool.

Assessment tools	Conduct of examination	Equipment used
OAG (Eilers et al., 1988)	No information on where the examination was carried out.	A light mouth mirror (Microlite, Bulter Company, Chicago, USA).

Assessment tools	Conduct of examination	Equipment used
OAG (Andersson et al., 1999)	No information on where the examination was carried out. Examination took a maximum of 5 mins.	A light mouth mirror (Microlite, Bulter Company, Chicago, USA).
ROAG (Andersson et al., 2002)	Examinations were performed at home. Mean exam time by RNs, LVNs and CNAs was 7.4, 7.9 and 8.7 minutes respectively.	Disposable medical gloves and mirrors.
BOHSE (Kayser-Jones et al., 1995)	The residents were usually examined in their rooms, sitting either on the bed or in a chair and occasionally, in the lounge or corridor for those who refused to return to their room were examined.	Small compartmentalized plastic baskets, containing the necessary equipment (e.g., tongue blades, a hand-held light, gauze squares, and disposable gloves).
OHAT (Chalmers et al., 2005)	As per BOHSE	As per BOHSE
COHI (Saintrain, M. V., & Vieira, A.P 2012)	Seated in dental chairs under natural light.	A wooden spatula (tongue depressor).

APPENDIX II. Inter-rater reliability assessments in previous validation studies

Table 9.10 Results of inter-rater reliability assessments

Indices	Results of inter-rater reliability assessments per item
OAG (Andersson et al., 1999)	**Between Registered nurses (RN) and Dental hygienist (DH)** **Cohen's Kappa agreements:** *Early assessment:* 0.81-1.00 Perfect or excellent – 0.61-0.80 Substantial - Saliva, Swallow 0.41-0.60 Moderate - Voice, Gums 0.21-0.40 Fair - Teeth/dentures, Lips, Mucous membranes <0.20 Poor – x *Late assessment:* Substantial - Saliva, Voice Moderate - Swallow, Teeth/dentures, Mucous membranes Fair - Lips, Gums Poor – x
ROAG (Andersson et al., 2002)	**Between Registered nurses (RN) and Dental hygienist (DH)** **Percentage agreements:** 81-100% = Voice, Swallow, Lips, Mucous membrane, Gums, Saliva 61-80% = Tongue 41-60% = Teeth/dentures 21-40% = x <20% = x **Cohen's Kappa agreements:** 0.81-1.00 Perfect or excellent - Swallow 0.61-0.80 Substantial - Gums, Lips 0.41-0.60 Moderate - Voice, Mucous membranes, Tongue, Teeth/dentures, Saliva 0.21-0.40 Slight – x <0.20 Poor – x
ROAG (Ribeiro et al., 2014)	**Between Community Health Workers (CHW) and Dentist; Between the CHW themselves.** **Sensitivity, Specificity & Accuracy:** Voice – High (H) sensitivity, specificity, accuracy Lips – Low (L) sensitivity, H specificity, H accuracy Saliva (Mirror) - L sensitivity, H specificity, H accuracy Saliva (Gloved finger) - L sensitivity, H specificity, H accuracy Swallow - H sensitivity, H specificity, H accuracy Mucosa - L sensitivity, M specificity, M accuracy Tongue - M sensitivity, M specificity, M accuracy Gums - M sensitivity, H specificity, M accuracy Teeth/dentures - M sensitivity, M specificity, M accuracy

Indices	Results of inter-rater reliability assessments per item
	Low sensitivity – lips saliva mucosa
BOHSE (Kayser-Jones et al., 1995)	**Between RN, LVN, CNA and Dentist (DDS)** **Correlation coefficients:** *Total BOHSE score* All positive, & statistically significant (***p<0.001). DDS-RN: 0.63*** DDS-LVN: 0.68*** (Highest) DDS-CAN: 0.47*** (Lowest) RN-LVN: 0.56*** RN-CNA: 0.40*** LVN-CNA: 0.65*** **ANOVA:** significant (F3,297 = 9.97, p < .001) **Post hoc Scheffe:** the mean total scores for RNs were significantly greater than those of the dentist and the CNAs (p < .001). **Percent agreement (%Ag):** >80%: Lymph nodes, Tongue, Saliva, Condition of natural teeth, Condition of artificial teeth, Pairs of teeth in chewing position [natural or artificial] <80%: Tissue inside cheek, floor, and roof of mouth; Lips, Gums between teeth and/or under artificial teeth, Oral cleanliness Lymph nodes: 92.0,98.0 Pairs of teeth in chewing position: 88.7,88.8 Artificial teeth: 75.4,86.0 Tissues: 75.3,79.6 Natural teeth: 73.2,81.6 Tongue: 72.6,97.0 Lips: 70.0,74.2 Gums: 68.4,69.1 Saliva: 66.7,82.0 Oral cleanliness: 50.5,54.6 **Cohen's Kappa agreement:** Perfect or excellent - Pairs of teeth in chewing position [natural or artificial] Substantial - Condition of natural teeth, Condition of artificial teeth Moderate - Lymph nodes, Tongue, Gums, Saliva Slight – Lips, Oral cleanliness; Tissue inside cheek, floor, and roof of mouth Poor - x Pairs of teeth in chewing position: 0.81***,0.82*** Artificial teeth: 0.54***,0.74*** Natural teeth: 0.38***,0.63*** Gums: 0.34***,0.45*** Lips: 0.26*,0.32** Tongue: 0.25*,0.44***

Indices	Results of inter-rater reliability assessments per item
	Oral cleanliness: 0.24***,0.27*** Saliva: 0.12,0.49*** Tissues: 0.09,0.26 Lymph nodes: -0.02,0.49*** *p<0.05, **p<0.01, ***p<0.005
OHAT (Chalmers et al., 2005)	**Between the non-dental assessors.** **Percent agreement (%Ag):** Referral to dentist 96.8 Dental pain 92.6 Saliva 86.9 Gums and tissues 86.1 Dentures 80.9 Tongue 80.4 Lips 78.1 Natural teeth 77.9 Oral cleanliness 72.6 **Cohen's Kappa agreement:** 0.81-1.00 Perfect or excellent - x 0.61-0.80 Substantial – Natural teeth, Dentures, Dental Pain 0.41-0.60 Moderate – Lips, Tongue, Gums and tissues, Saliva, Oral cleanliness, Referral to dentist 0.21-0.40 Slight – x 0.00-0.20 Poor - x Natural teeth 0.66* Dentures 0.65* Dental pain 0.62* Gums and tissues 0.57* Oral cleanliness 0.54* Tongue 0.53* Saliva 0.48* Lips 0.48* Referral to dentist 0.47*
COHI (Saintrain & Vieira, 2012)	**Between Community health agents (CHA) and dentist.** **Cohen's Kappa agreements:** 0.81-1.00 Perfect or excellent - Number of teeth & residual roots, Dental prosthesis 0.61-0.80 Substantial – Soft tissue injury, Gingival inflammation, Presence of tartar 0.41-0.60 Moderate – Dental cavities 0.21-0.40 Slight – x 0.00-0.20 Poor – x Dental prosthesis Use prosthesis: total upper kappa = 0.95 (p,0.001) Use prosthesis: total lower kappa = 0.88 (p,0.001) Use prosthesis: partial upper kappa = 0.82 (p,0.001)

Indices	Results of inter-rater reliability assessments per item
	Need prosthesis: total upper kappa = 0.88 (p,0.001) Need prosthesis: total lower kappa = 0.94 (p,0.001) Need prosthesis: partial upper kappa = 0.86 (p,0.001) Need prosthesis: partial lower kappa = 0.95 (p,0.001) Dental cavities 1 or 2 cavities Kappa = 0.51 (p,0.001) 3 or more cavities Kappa = 0.52 (p,0.001) **Spearman's correlation:** >80%: Number of teeth & residual roots <80%: x **Sensitivity:** >80.0% - Dental prosthesis <80.0% - Soft tissue injury, <0.60: Dental cavities, Gingival inflammation, Presence of tartar **Specificity:** >80.0% – All items Dental prosthesis Use prosthesis: total upper 92.3 100 Use prosthesis: total lower 80 100 Use prosthesis: partial upper 83.3 98.2 Need prosthesis: total upper 90 98 Need prosthesis: total lower 100 98 Need prosthesis: partial upper 92.9 95.7 Need prosthesis: partial lower 92.9 93.9 Dental cavities 1 or 2 cavities 68.4 83.3 3 or more cavities 63.6 87.2 Presence of tartar 88.4 88.6 Dental prosthesis: High sensitivity, high specificity Soft tissue injury: sensitivity, high specificity Dental cavities: Low (68.4, 63.5) sensitivity, high specificity Gingival inflammation: High sensitivity, high specificity Presence of tartar: High sensitivity, high specificity
MSE (Scott et al., 2010)	**Between patients themselves & dentist** **Accuracy:** Sensitivity - 33% Specificity - 54% Positive predictive value - 17% Negative predictive value - 73%

APPENDIX III. Intra-rater and test-retest reliability assessments of previous validation studies

Table 9.11 Results of intra-rater / test-retest reliability assessments

Indices	Results of intra-rater / test-retest reliability assessments
ROAG (Andersson et al., 2002)	**Cohen's Kappa agreements:** 0.81-1.00 Perfect /excellent – Voice, Lips, Swallow, Buccal Mucosa, Tongue, 0.61-0.80 Substantial – Gums 0.41-0.60 Moderate – Saliva (Mirror), Saliva (gloved finger) 0.21-0.40 Fair – Teeth/dentures <0.20 Poor – x
BOHSE (Kayser-Jones et al., 1995)	**For Total BOSE scores:** Correlations (r-value): high, close to or above the 0.80 level 0.81 & above – DDS 0.83, RN 0.88, <0.80 – LVN 0.79, CNA 0.79 All were statistically significant (p<0.001) **Paired t-tests:** No difference in the magnitude of the total BOHSE scores between Time 1 and time 2 for each category of examiner. **No item level intra-rater agreement was reported**
OHAT (Chalmers et al., 2005)	**INDIVIDUAL** **Percent agreements (%Ag):** Highest: dental pain, referral to dentist Lowest: oral cleanliness Referral to dentist 96.6 Dental pain 93.9 Gums and tissues 90.5 Saliva 88.8 Tongue 84.6 Dentures 83.7 Natural teeth 80.6 Lips 79.8 Oral cleanliness 74.4 **Cohen's Kappa agreements:** 0.61-0.80 Substantial: other 0.41-0.60 Moderate: Lips, Saliva, Oral cleanliness, Referral to dentist Gums and tissues 0.71* Natural teeth 0.70* Dentures 0.70* Dental pain 0.66* Tongue 0.61* Oral cleanliness 0.56*

Indices	Results of intra-rater / test-retest reliability assessments
	Lips 0.52* Saliva 0.51* Referral to dentist 0.51* *P<0.001 **TOTAL OHAT SCORES** Correlation coefficient 0.78 All were statistically significant

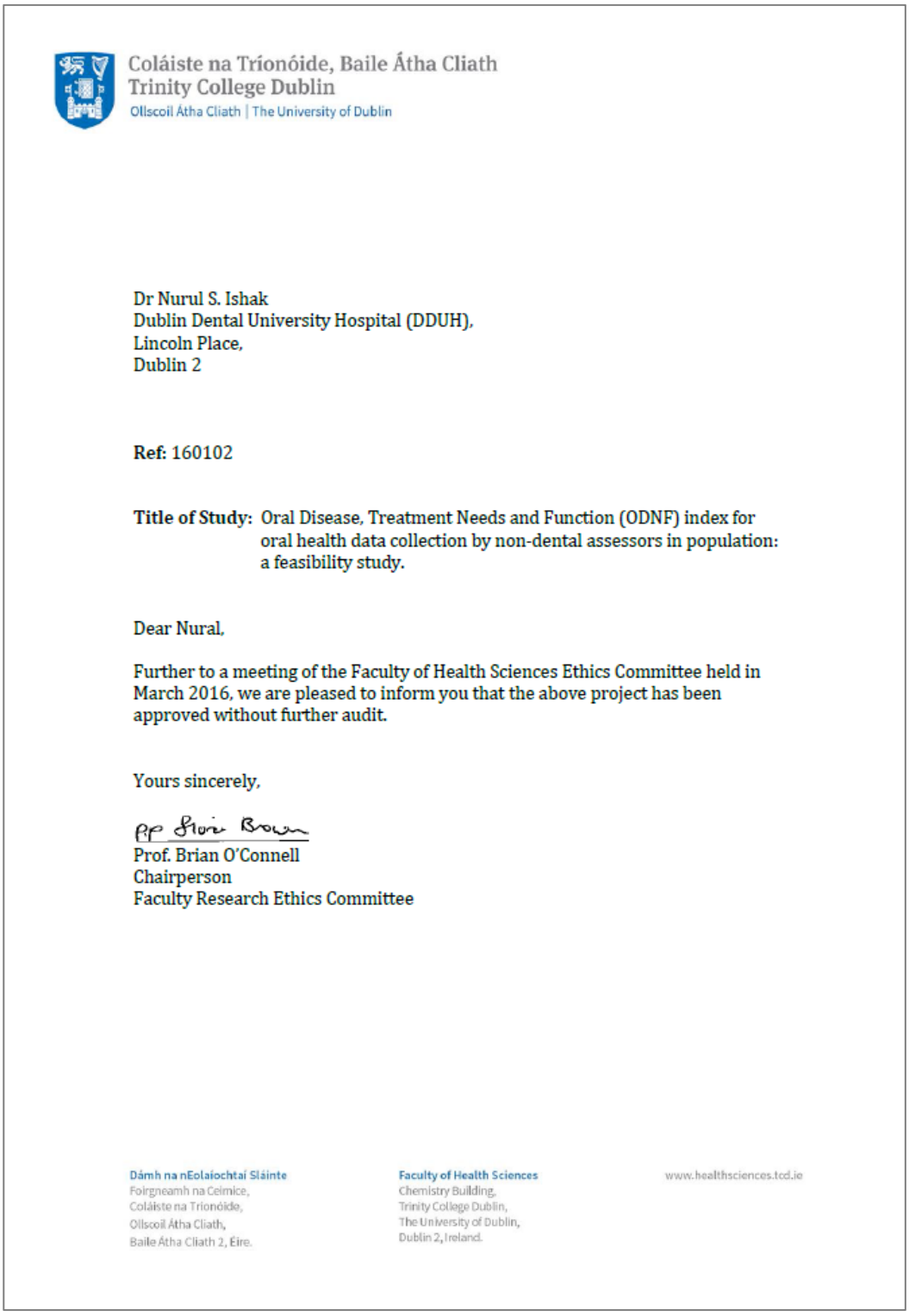
APPENDIX IV. Details on the training and calibration of examiners as well as pilot study conducted in previous validation studies

Table 9.12 Details on the training, calibration and pilot study conducted

Assessment tools	Details on training, calibration & pilot study
OAG (Andersson et al., 1999)	**Training:** 2 hours training on the assessment of the oral cavity. **Calibration:** None; Inter- & intra-rater reliability as part of study. Pilot study/phase: None.
ROAG (Andersson et al., 2002)	**Training**: Carried out by dental hygienist (DH); 3 hours training, 3 days before the start of study; a lecture of oral health problems; Oral assessments performed on five patients by both RN and DH. **Calibration**: None; Inter- & intra-rater reliability as part of study. Pilot study/phase: None.
ROAG (Ribeiro et al., 2014)	**Training**: An illustrated teaching manual was produced, detailing different oral health conditions likely to be encountered in the elderly; with input from experts in cariology, periodontology, stomatology, prosthesis and speech. Photographs of the oral structures in normal condition, slightly altered or severely altered were included. For voice, audio files of normal, slightly or severely altered voice were selected. Training manual was recorded on compact disc (CD). 10 CHWs were included in the full training. 4-hour training (with discussion). 1 week later, another 1-hour practical training until consensual diagnosis was achieved. **Calibration**: as part of training. **Pilot study**: CHWs performed assessments on 5 seniors independently by the researcher assessed the 5 seniors. Sensitivity values were calculated & were used to calculate sample size.
BOHSE (Kayser-Jones et al., 1995)	**Training**: 2 hours training. A lecture on the purpose of study, overview of oral anatomy, discussion of oral and dental diseases commonly found among the elderly, review of BOHSE instruments, illustrations of health and pathological conditions, on how to score for each variable Examination on resident using BOHSE, demonstration by dentist-examiner, followed by repeat examination under supervision of dentist-examiner. **Calibration**: Research team dentist calibration dentist-examiner on the use of the BOHSE instrument by examining 5 nursing home residents. **Pilot study**: None.
OHAT (Chalmers et al., 2005)	**Training**: A focus group and a 3-hour training; programme was completed with carers at each facility. Training was carried out as per BOHSE. Focus groups were conducted at baseline, 3-months and 6-months. **Calibration**: As per BOHSE. **Pilot study**: None.
COHI	**Training**: Slides show, Introduction to COHI; photos with different diseases of the oral cavity were used to recognize healthy teeth, teeth

Assessment tools	Details on training, calibration & pilot study
(Saintrain, M. V., & Vieira, A.P 2012)	with dental cavities, use and need of prosthesis and soft tissue injuries, including those arising from the use of a maladaptive prostheses, candidiasis and periodontal diseases. Then, the examiners (dentists separated from the CHA) got the chance to practice on patients, and discussion on conflicting findings until consensus was reached. **Calibration**: Following WHO guidelines; each CHA or dentist examine at least 20 individuals from the community, using COHI. Intra- and inter-rater kappa values were assessed. If kappa value was below 0.8, calibration process repeated with another 10 subjects from community. Dentist-examiner was also calibrated against researcher dentist-examiner, on the dental assessment. **Pilot study**: None.
MSE **(Scott et al., 2010)**	**Training**: Participants were provided with a leaflet on ‘‘How to spot mouth cancer early”. The leaflet gave details on oral cancer, risk factors, symptoms, stepwise instructions, and illustrations of MSE (Figure 1 for the section relating to MSE), and information on when and how to seek help for potentially malignant oral lesions. **Calibration**: None; Inter- & intra-rater reliability as part of study. **Pilot study**: No further information given.

APPENDIX V. Ethical approval from the Faculty of Health Sciences Research Ethics Committee (FHSREC), Trinity College Dublin (TCD).



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

Dr Nurul S. Ishak
Dublin Dental University Hospital (DDUH),
Lincoln Place,
Dublin 2

Ref: 160102

Title of Study: Oral Disease, Treatment Needs and Function (ODNF) index for oral health data collection by non-dental assessors in population: a feasibility study.

Dear Nural,

Further to a meeting of the Faculty of Health Sciences Ethics Committee held in March 2016, we are pleased to inform you that the above project has been approved without further audit.

Yours sincerely,

pp Brian Brown
Prof. Brian O'Connell
Chairperson
Faculty Research Ethics Committee

Dámh na nEolaíochtaí Sláinte
Foirgneamh na Ceimice,
Coláiste na Tríonóide,
Ollscoil Átha Cliath,
Baile Átha Cliath 2, Éire.

Faculty of Health Sciences
Chemistry Building,
Trinity College Dublin,
The University of Dublin,
Dublin 2, Ireland.

www.healthsciences.tcd.ie

APPENDIX VI. Ethical approval from the School of Dental Science Level 1 Research Ethics Committee.

Reply Reply All Forward

Wed 20/04/2016 10:09

Gary Moran

Re: DR ISHAK Ethics Application 21.03.16

To Nurul Sa'idah Ishak

Cc June Nunn

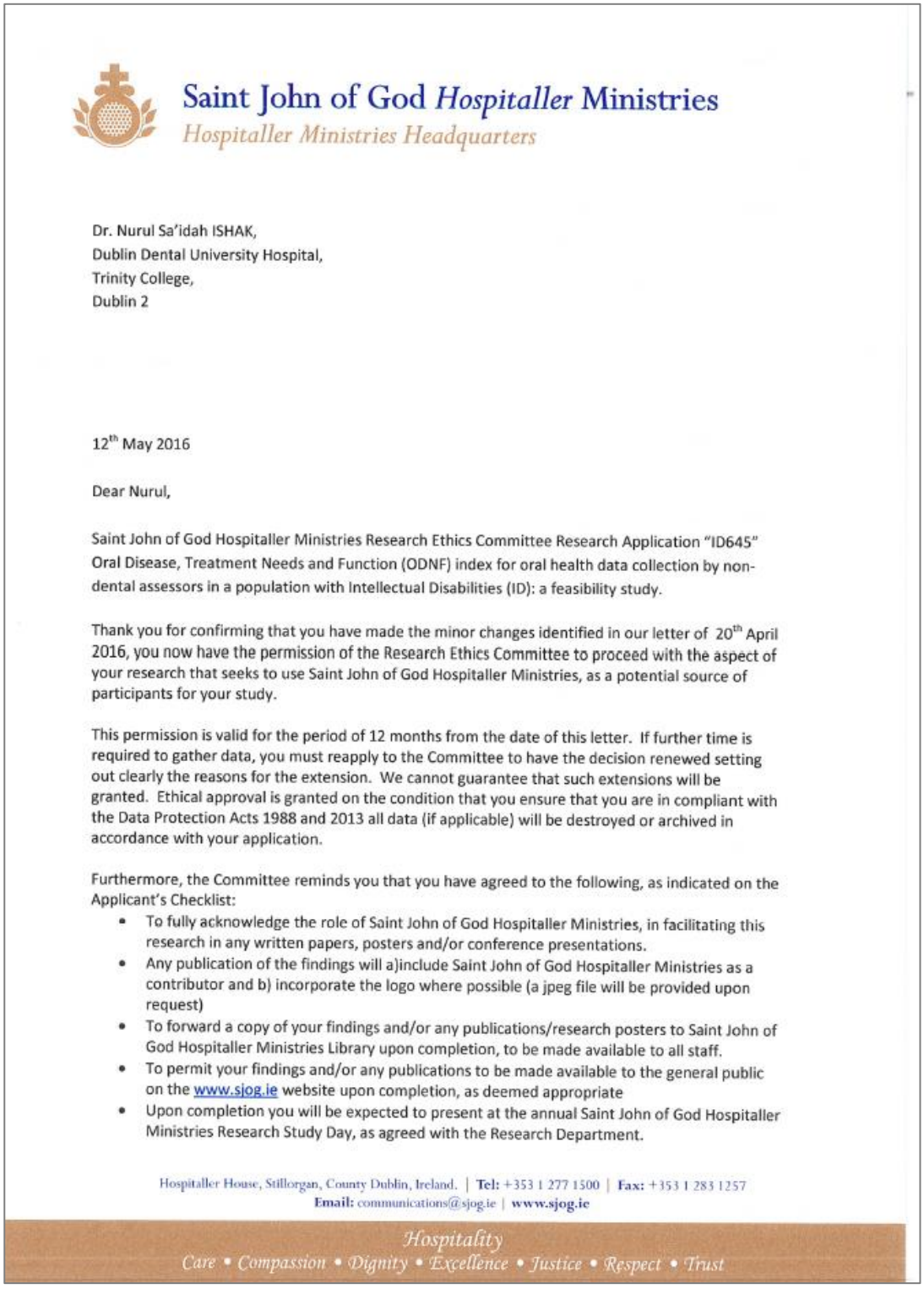
Dear Nurul,
Thank you for considering the reviewers' comments on your proposal. The comments have been dealt with to my satisfaction and on behalf of the Dental School Research Ethics Committee, I grant approval for this pilot exercise to proceed,

Sincerely,
Gary Moran
Chair of Ethics Committee
****

Gary Moran,
Associate Professor in Microbiology,
Dublin Dental University Hospital,
Trinity College Dublin,
Dublin 2,
Republic of Ireland.

Tel: +353-1-612-7245
Email: gpmoran@dental.tcd.ie
https://sites.google.com/site/dduhmicrobiology/home

APPENDIX VII. Ethical approval from Saint John of God Community Service (SJGCS).



Saint John of God *Hospitaller* Ministries
Hospitaller Ministries Headquarters

Dr. Nurul Sa'idah ISHAK,
Dublin Dental University Hospital,
Trinity College,
Dublin 2

12th May 2016

Dear Nurul,

Saint John of God Hospitaller Ministries Research Ethics Committee Research Application "ID645" Oral Disease, Treatment Needs and Function (ODNF) index for oral health data collection by non-dental assessors in a population with Intellectual Disabilities (ID): a feasibility study.

Thank you for confirming that you have made the minor changes identified in our letter of 20th April 2016, you now have the permission of the Research Ethics Committee to proceed with the aspect of your research that seeks to use Saint John of God Hospitaller Ministries, as a potential source of participants for your study.

This permission is valid for the period of 12 months from the date of this letter. If further time is required to gather data, you must reapply to the Committee to have the decision renewed setting out clearly the reasons for the extension. We cannot guarantee that such extensions will be granted. Ethical approval is granted on the condition that you ensure that you are in compliant with the Data Protection Acts 1988 and 2013 all data (if applicable) will be destroyed or archived in accordance with your application.

Furthermore, the Committee reminds you that you have agreed to the following, as indicated on the Applicant's Checklist:

- To fully acknowledge the role of Saint John of God Hospitaller Ministries, in facilitating this research in any written papers, posters and/or conference presentations.
- Any publication of the findings will a)include Saint John of God Hospitaller Ministries as a contributor and b) incorporate the logo where possible (a jpeg file will be provided upon request)
- To forward a copy of your findings and/or any publications/research posters to Saint John of God Hospitaller Ministries Library upon completion, to be made available to all staff.
- To permit your findings and/or any publications to be made available to the general public on the www.sjog.ie website upon completion, as deemed appropriate
- Upon completion you will be expected to present at the annual Saint John of God Hospitaller Ministries Research Study Day, as agreed with the Research Department.

Hospitaller House, Stillorgan, County Dublin, Ireland. | **Tel:** +353 1 277 1500 | **Fax:** +353 1 283 1257
Email: communications@sjog.ie | **www.sjog.ie**

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Meanwhile, may I take this opportunity to wish you well in your research. We look forward to hearing of your progress over the coming months.

Yours sincerely,

Jane McEvoy
Chair, Saint John of God Hospitaller Ministries Ethics Committee

c.c.: Pauline Bergin Regional Director of Service

APPENDIX VIII. Ethical approval from Saint Michael's House (SMH).

St. Michael's House

Services for people with intellectual disabilities

Ballymun Road, Dublin 9. Tel: [illegible] Fax: [illegible] Email: [illegible] Website: [illegible]

Research Department

8th March 2016

Dr. Nurul Sa'idah Ishak,
Dublin Dental University Hospital,
Lincon Place,
Dublin DO2F859.

Research Title:

Oral Disease, Treatment Needs and Function (ODNF) index for oral health data collection by non-dental assessors in population with Intellectual Disabilities (ID): a feasibility study.

Dear Dr. Ishak,

Thank you for submitting your Research Proposal to the Research Ethics Committee in St. Michael's House.

The committee has considered and approved your research proposal, and you now have the permission of the Research Ethics Committee to proceed with your research.

May I take this opportunity to wish you well with your research.

Yours sincerely,

Eilín de Paor,
On Behalf of the
Research Ethics Committee

APPENDIX IX. Search protocol

Systematic literature review protocol

Question:

What is the nature of research on oral health assessment tools utilizing non-dental individuals in adult population with Intellectual Disabilities (ID)?

Sub-questions:

- What are the existing oral health assessment tools administered by non-dental individuals?
- What were the population the tools have been validated in?
- Did they report inclusion of individuals with ID?
- Who were the non-dental data collectors?
- What were the characteristics of the items in the oral health assessment tools?
- How did they train the non-dental individuals? How were they calibrated?
- What assessments were carried out in the instrument development and initial validation study? What were the results?

Literature search criteria

1. **Identify search words**

Population - adult population with intellectual disabilities (18 years and above)

Search words: Adult, young adult, middle-aged adult, older adult

Intervention - Oral health assessment tools administered by non-dental individuals; Comparison - Oral health assessment by dentists

Search words: Oral health, dental health, mouth health; assessment, examination, screening, data collection, surveys; Index, indicator; Non-dentist, non-dental, physician, nurse, allied health professionals; Dentist, dental, dental hygienist, dental therapist, dental nurse, allied dentals

Outcome - Validity, reliability, feasibility

Search words: Validaty/validation, content validity, concurrent validity, criterion validity, construct validity; Reliability, inter-rater reliability, test-retest reliability, intra-rater reliability; Cost analysis; acceptability

2. **Search string**

((((("oral health"[Title/Abstract] OR "Health oral"[Title/Abstract] OR "dental health"[Title/Abstract] OR "health dental"[Title/Abstract] OR "mouth health"[Title/Abstract] OR "oral disease"[Title/Abstract] OR "oral diseases"[Title/Abstract] OR "dental disease"[Title/Abstract] OR "dental diseases"[Title/Abstract] OR "mouth disease"[Title/Abstract] OR "mouth diseases"[Title/Abstract]) OR ("Stomatognathic Diseases"[Mesh])) AND (Exam*[Title/Abstract] OR Assess*[Title/Abstract] OR screen*[Title/Abstract] OR survey*[Title/Abstract] OR "data collection"[Title/Abstract] OR "collecting data"[Title/Abstract]) AND (index[Title/Abstract] OR indices[Title/Abstract] OR tool[Title/Abstract] OR tools[Title/Abstract] OR indicator[Title/Abstract] OR indicators[Title/Abstract])) AND ((Non-dentist[Title/Abstract] OR "non dentist"[Title/Abstract] OR non-dental[Title/Abstract] OR "non dental"[Title/Abstract] OR community[Title/Abstract] OR caregiver[Title/Abstract] OR caregivers[Title/Abstract] OR caretaker[Title/Abstract] OR caretakers[Title/Abstract] OR "key worker"[Title/Abstract] OR "key workers"[Title/Abstract] OR nurse[Title/Abstract] OR nurses[Title/Abstract] OR nursing[Title/Abstract] OR physician[Title/Abstract] OR physicians[Title/Abstract] OR "speech pathologist"[Title/Abstract] OR "speech pathologists"[Title/Abstract] OR physiotherapist[Title/Abstract] OR physiotherapists[Title/Abstract]) OR ("Health Personnel"[Mesh]))) AND ((Adult[Title/Abstract] OR adults[Title/Abstract] OR middle-age*[Title/Abstract] OR aged[Title/Abstract] OR aging[Title/Abstract] OR Older[Title/Abstract] OR "older people"[Title/Abstract] OR "older adults"[Title/Abstract] OR "older adult"[Title/Abstract] OR "older patients"[Title/Abstract] OR "older patient"[Title/Abstract] OR "older population"[Title/Abstract] OR "older populations"[Title/Abstract] OR "older persons"[Title/Abstract] OR "older person"[Title/Abstract] OR "older men"[Title/Abstract] OR "older women"[Title/Abstract] OR "elderly"[Title/Abstract] OR "elderly people"[Title/Abstract] OR "elderly patient"[Title/Abstract] OR "elderly patients"[Title/Abstract] OR "geriatric population"[Title/Abstract] OR "geriatric patient"[Title/Abstract] OR "geriatric patients"[Title/Abstract]) OR ("Adult"[Mesh]))

3. Inclusion and exclusion criteria

Inclusion criteria:	Exclusion criteria:
1 database only, PubMed	Databases other than PubMed
English language	Non-English
Peer-reviewed journals	Non peer-reviewed journals
Any type of studies	Opinions, editorials, continuous education courses papers and books or commentaries
Assessors not dentist or other allied dental professionals	Dentist, dental hygienist, dental therapist, dental nurse, dental surgery assistant, dental specialist; Anyone with formal dental training
Age: Adult, 18 years and above	Children, below 18
Full-text available	No full-text available
Assessment of Oral health	Questionnaire, non-clinical

4. Data extracted

- Name of assessment tools or indices
- Author's details, original developer
- Purpose of index
- Items in the index
- Descriptive or numerical scores
- Characteristics of participants assessed, non-dental individuals
- Gold standard assessor
- Training protocol (and materials)
- Data collection protocol (clinical assessment tools and equipment)
- Data collected (type of variables, including data collection tools)
- Data collection methods for concurrent validity and reliability assessments
- Statistical programs used
- Statistical tests for the validity and reliability assessments, & results
- Other assessments & results

APPENDIX X. Letter seeking access (Participants with ID)

Letter Seeking Access (Participants with ID)

DR NURUL S ISHAK *(Principal investigator)*
Postgraduate clinical trainee in Special Care Dentistry
Dublin Dental University Hospital,
Lincoln place,
Dublin 2

Director,
(Name of Service Provider)
Dublin

Dear Sir/Madam,

RE: REQUEST FOR PERMISSION TO RECRUIT PARTICIPANTS FOR RESEARCH

I am a postgraduate clinical trainee in Special Care Dentistry, at the School of Dental Science, Trinity College Dublin, The University of Dublin. I am asking for your consent to invite service users in your institution to participate in my research. The topic of my research is 'Oral Disease, Treatment Needs and Function (ODNF) index for oral health data collection by non-dental assessors in population with Intellectual Disabilities (ID): a feasibility study.' The main aim of this study is to carry out a feasibility study on the use of a novel index of Oral Disease, Treatment Needs and Function (ODNF) that could be used by non-dental assessors to collect oral health data in individuals with intellectual disabilities (ID). My supervisor is Professor June Nunn.

For this study, we hope to extend invitations to 150 service users 18 years of age and above. We may randomly select 60 participants who meet our inclusion criteria for this study. We would also appreciate if you could nominate a gatekeeper within your centre, who would pass the information about this study to subjects and their carers or advocates. With this letter, we also ask your permission to conduct information-sharing sessions at the care sites where you will determine. This is an opportunity for the service users and their carers to ask questions on the study before making an informed decision on the consent form. Attached in the information pack are the invitation letter for users and their carers, participation information leaflet and participant consent form. All users should be made aware that they do not have to be part of the study. Refusal to engage with the

study will in no way affect their current or any future dental care. The study will be anonymous to protect each person's confidentiality.

Location of data collection will be centralised to main centres for each provider. Upon your permission to access the centres, discussion with unit manager will be conducted on which main centres can facilitate the study. Travel expenses for participants will be covered, if required.

This study will involve two parts: answering a brief questionnaire and then a clinical assessment. More details on the study are included in the information booklet. If an acute oral/dental condition is found, the participants (with their consent or advocate's permission) will be referred to their usual dental service provider for care. Otherwise, no routine dental care will be provided during the study. Ethical approval has been granted by The Faculty of Health Sciences Ethics Committee. Ethical application has also been sought from the Ethics Committee in your institution.

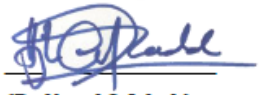
Should you require any further information, please do not hesitate to contact me or my supervisor. Our contact details are as follows:

Dr Nurul S. Ishak (Principal Investigator)
Phone: 01-6127303 or 083-8042024
Email: nurul.ishak@dental.tcd.ie

Professor June Nunn (Project supervisor)
Phone: 01-6127303
Email: june.nunn@dental.tcd.ie

We do hope that you will want the people you work with to be included in developing a better way to find out what dental problems they might have and for them to be included in future health surveys. That way, their dental needs and service requirements will be recognized and included in health service plans. .

Yours sincerely,



(Dr Nurul S. Ishak)
Principal investigator

ODNF/FHS/LetterSeekingAccess

APPENDIX XI. An invitation letter

Invitation to participate in research project

(Participants with ID)

Dear friend,

My name is Dr Nurul Ishak. I am a dentist working at the Dublin Dental Hospital.

I would like you to help me with my work.

We want to find an easy way to check mouths to see that they are healthy.

We will do this by finding 60 people like you to join my work.

If you agree, five of us will look at your mouth and count your teeth.

Picture of centre

You will come to (*name of centre*)

You can bring a friend with you

You can read the information booklet.

It tells you more about my work.

If you want to join, you can fill in the consent form and return it to (name of nominated gate keeper).

ODNF/invites/subjects

If you have any questions, please ask:

Mr/Mrs [Name] (Nominated gatekeeper for your centre)

Phone:

Email:

You can also ask me:

Dr Nurul S. Ishak (Principal Investigator)

Phone: 6127303 or 083-8042024

Email: nurul.ishak@dental.tcd.ie

Or my supervisor:

Professor June Nunn (Project supervisor),

Phone: 6127303

Email: june.nunn@dental.tcd.ie

Or write to us at:

Dublin Dental University Hospital,

Trinity College Dublin , The University of Dublin

Lincoln place, Dublin 2. D02 F859

Thank you for your time.

Yours sincerely,
Dr Nurul S. Ishak

ODNF/invites/subjects

**Some of the illustrations are courtesy of IDS-TILDA.*

APPENDIX XII. Participant information booklets

Participant Information Leaflet

(Participants with ID)

INFORMATION BOOKLET

(Participants)

Title:

Oral Disease, Treatment Needs and Function (ODNF) index for oral health data collection by non-dental assessors in population with Intellectual Disabilities (ID): a feasibility study.

The study is carried out by:

TRINITY COLLEGE DUBLIN | THE UNIVERSITY OF DUBLIN

COLÁISTE NA TRÍONÓIDE

ODNF/Information-Booklet/participants

This book tells you about the study.

What is it about?

The study is about the mouth and teeth of people with intellectual disabilities (ID).

We want to find an easy way to check mouths to see that they are healthy.

We want to know:

1. If you have problems with your mouth

2. If you can use your teeth (or false teeth) to eat

This study will help us to see if this is an easy and good way to check your mouth.

You can be in this study

- ✓ if you are 18 years old and above
- ✓ if you have intellectual disabilities
- ✓ if your dentist is in Dublin

You do not have to be in this group if you do not want to.

Picture of centre

What will happen?

You will come to (name of centre).

You can bring a friend if you want to.

First, we will ask you some questions on your age, gender and heart problems.

Your friend can help you write your answer.

This will take a few minutes.

Then, we will look inside your mouth, count your teeth and check your gums.

This will not hurt.

There will be 5 people who will take turns checking your mouth. All of them have been trained in checking the mouth.

This part will take a bit longer.

If you are happy, we will check your mouth twice.

If you get tired, you can have a rest.

You will stay at least 1 hour with us.

You can choose to go home if you are tired.

We will write everything on to an iPad.

Nobody will know it is about you.

No-one will know your name.

How this will help you:

You can find out if you have problems in your mouth.

If you have something wrong with your mouth, we will help you find a dentist who can fix it for you.

If you can help us with this study, we will have a way to help other people who might need a dentist to fix their mouth.

Your carers, keyworkers, nurses (and anyone!) can be trained to use this method to check your mouth.

Other people like you will be able to go to a dentist for help looking after their mouth and teeth.

Risks:

There is nothing bad that can happen to you if you say yes to helping us.

If you change your mind you do not have to do this.

Confidentiality

We will keep all the facts about you private.

Your name will not be printed on our report and published papers.

Compensation:

If you have to spend money to do this, we will give you that money back.

Voluntary participation:

You have more than 2 weeks to think.

If you want to join, please fill in the consent form and return it to (Name of nominated gatekeeper).

We may choose 60 people to join this study.

We will let you know if we chose you. Only the selected ones will be called to come for clinical assessment.

You do not have to take part in this study if you don't want. It is your choice.

Your decision will not affect the support and care you receive now or in the future.

You can stop taking part at any time.

THE UNIVERSITY OF DUBLIN

This study has the ethical approval from Faculty of Health Sciences, Trinity College Dublin and your institution.

ODNF/Information-Booklet/participants

If you have any questions, please ask:

Mr/Mrs [Name] (Nominated gatekeeper for your centre)

Phone:

Email:

You can also ask me:

Dr Nurul S. Ishak (Principal Investigator)

Phone: 6127303 or 083-8042024

Email: nurul.ishak@dental.tcd.ie

Or my supervisor:

Professor June Nunn (Project supervisor),

Phone: 6127303

Email: june.nunn@dental.tcd.ie

Or write to us at:

Dublin Dental University Hospital,

Trinity College Dublin , The University of Dublin

Lincoln place, Dublin 2. D02 F859

**Some illustrations are courtesy of IDS-TILDA.*

ODNF/Information-Booklet/participants

APPENDIX XIII. Participant consent form

Participant Consent form

Title: "Oral Disease, Treatment Needs and Function (ODNF) index for oral health data collection by non-dental assessors in population with Intellectual Disabilities (ID): a feasibility study"

Principle Investigators: Dr Nurul S. Ishak (Principal Investigator)

Professor June Nunn (Project supervisor)

INSTRUCTIONS FOR CONSENT FORM

Participants **who have the capacity** to consent:

1. Section A and section B must be filled signed by participants.
2. For participants who need help to read or sign the consent form, Section C must be signed by a person supporting the participant provided that the person supporting the participant:
   - ✓ has read all information
   - ✓ has explained the information to participant
   - ✓ has ensured that consent was freely given.

Participants **lacking decision-making capacity** to consent

Section C must be filled and signed by their proxy

SECTION A - Consent form

Please **read** the information below and **sign** this consent form if you wish to take part in this study. Please tick [√] if you **agree** with the following statement:

I have read the information about this study ☐

I understand that I will be asked questions about how old I am, if I am a man or a woman, and if I have heart problems. ☐

I understand that I do not have to answer questions I don't feel happy about. ☐

I understand that I will have 5 people look at my mouth and my teeth ☐

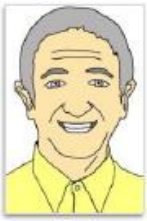
ODNF/consent-form

I understand that I can stop for a break if I am tired. ☐

I know it is my choice to take part in this study ☐

I can stop taking part in this study when I want to. ☐

I do not have to give a reason for stopping. ☐



I understand that there are no known bad things that could happen to me in this study. ☐

I understand that anything I say will be kept safe and private. ☐

I will not be named in any reports. ☐

ODNF/consent-form

Any questions I had were answered. ☐

I know who to get in touch with if I have any questions. ☐

SECTION B - Your consent

Your name: _____

Your phone number: _____

Your address: _____

☐

_____

Copy of this form received: (please tick √)

Please sign here: _____

Date: _____

ODNF/consent-form

SECTION C - The person supporting you

I have supported *participant's name* to fill out this form. Please tick √ that are relevant:

◯ I believe they understand the information and have freely agreed to take part in this study.

◯ I believe that the person named above is unable to understand the scope, nature and significance of the study.

◯ I am the proxy for this person; I have read the information provided in the participant information booklet about this study and I give my consent on behalf of the participant to take part in this study.

Name: _____

Relation to participant: _____

Phone: _____

Signature: _____ **Date:** _____

Please return this consent form **before (Date to be confirmed)** to:

Dr. Caoimhin Mac Giolla Phadraig (Research coordinator)

Dublin Dental University Hospital, Lincoln Place, Dublin 2.

Phone: 01-6127303 Email: Caoimhin.macgiollaphadraig@dental.tcd.ie

SECTION D - To be filled by research team

I have explained the nature and purpose of this research study, the procedures to be undertaken and any risk that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

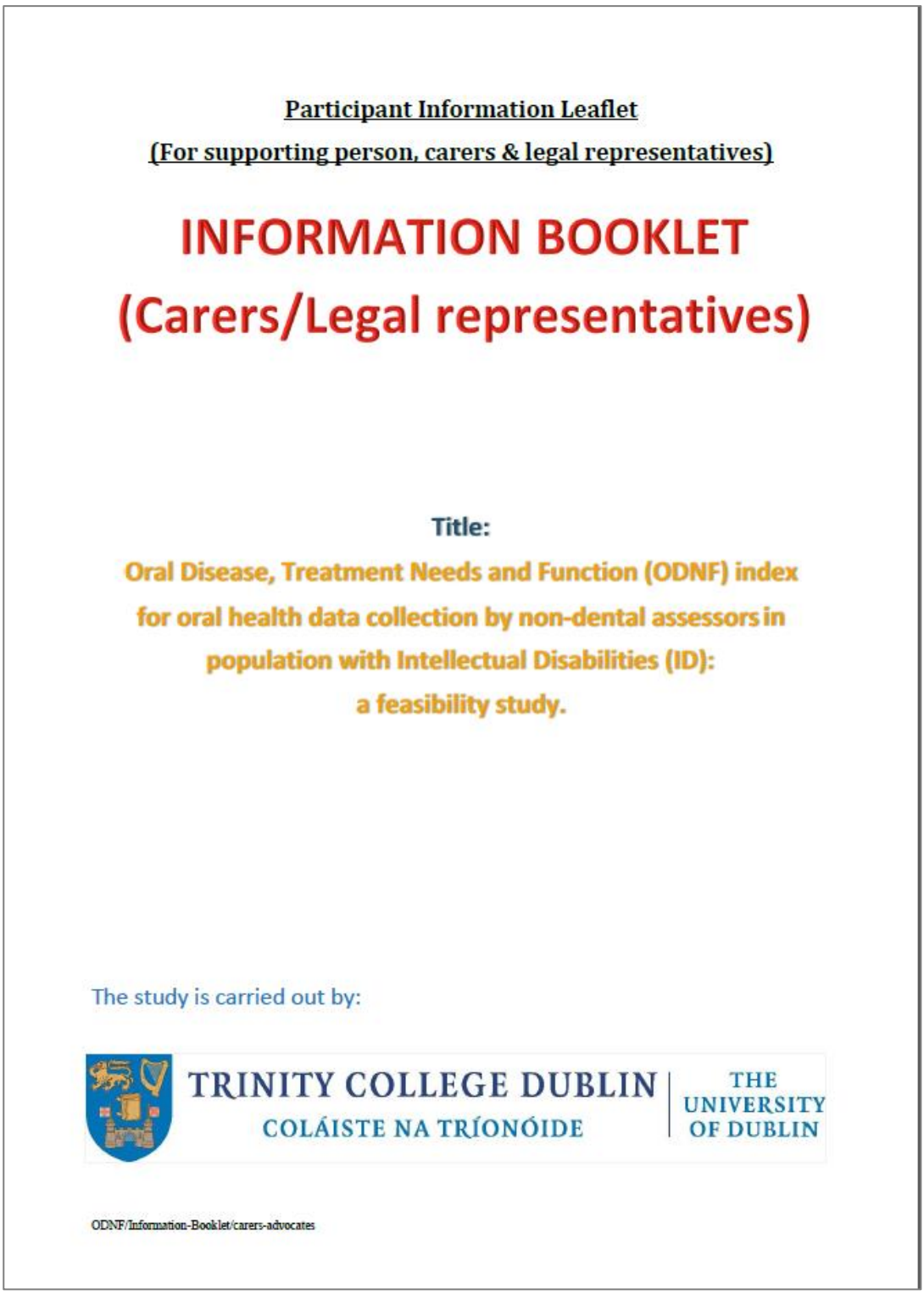
***Copy of this form given to participant** (Yes/No)

Investigator's signature: _____ **Print Name:** _____

Date: _____

ODNF/consent-form

APPENDIX XIV. Information packs for family members, carers and legal representatives



Participant Information Leaflet

(For supporting person, carers & legal representatives)

INFORMATION BOOKLET

(Carers/Legal representatives)

Title:

Oral Disease, Treatment Needs and Function (ODNF) index for oral health data collection by non-dental assessors in population with Intellectual Disabilities (ID): a feasibility study.

The study is carried out by:

TRINITY COLLEGE DUBLIN | THE UNIVERSITY OF DUBLIN

COLÁISTE NA TRÍONÓIDE

ODNF/Information-Booklet/carers-advocates

This information book tells you about the study.

What is it about?

This study is about the person/people you look after. The study is looking for new method to do dental check-ups for individuals with intellectual disabilities (ID).

We want to know,

1. If there is any problem inside their mouth
2. If there is any problem with their dentures

This study will help us to see if this is an easy and better way to do dental check-ups.

The person/people you look after can join this study if:

- ✓ they have mild to moderate intellectual disabilities (ID)
- ✓ they are 18 years old and above
- ✓ their primary dentist is in Dublin

The person/people you look after do not have to be in this study if they do not want to.

What will happen?

The study will take place at the St John of God Community service day centre (location to be confirmed by gatekeeper for your centre). Participants can be accompanied throughout the process.

First, the participants, or their carer will be asked to answer a few questions on age, gender, heart and mouth conditions. You, or their carer, can help them write their answers. This will take 5-10 minutes.

Then, the participants will have a check-up for their mouth and teeth. This will not be uncomfortable. Five assessors will take turns carrying out the dental check-up on each participant. This part will take at least 45 minutes. It may take up to 60 minutes because participants can take a break if they get tired.

Some of the participants who have good cooperation will be selected for a repeat examination after 30 minutes break. This repeat examination is carried out is to ensure that the examiner is consistent with their assessment. Repeat examination may take another 45 minutes. So, participant will have to stay up to 2 hours for the clinical assessment.

All answers will be recorded onto an iPad. All the information collected will be anonymous to protect their (and your/carers) confidentiality.

Benefits

If there is pain or urgent problems in the mouth, participants (with their or their advocate's consent) will be referred to their local dentist for care. No routine dental treatment will be provided during this study.

By taking part in this study, we will be able to develop a reliable way to do mouth checks that make sure that people with intellectual disabilities can get their dental needs included in general health checks as well as in services for them. We hope that this research will show how carers, keyworkers and nurses can be trained to use this method to check mouths.

Risks

There is no risk in being part of the study. Participants can withdraw from joining at any point of this study.

Confidentiality

All the information collected will be anonymous to protect their (and carers) confidentiality.

Compensation:

We will reimburse money spent on transport to and from (data collection site).

Voluntary participation:

Participants will have given enough time (more than 2 weeks) to decide if they want to join. Information sharing sessions will be conducted, and you can ask us questions on their behalf.

If you think that the person you look after wants to join this study, please fill in and sign the consent form and return it to us. We will carry out random selection of 60 participants who will join our study. We will inform you if the person you look after has been chosen. Only selected participants will be called to attend the clinical assessment.

Participation is absolutely voluntary. Participants can withdraw from joining at any point of this study. Refusal to take part in the study will in no way impact on their current or any future dental care. We will inform you if we have to stop the study.

This study has ethical approval from Faculty of Health Sciences, Trinity College Dublin and your institution.

If you need more information or if you have any questions, please ask:
Mr/Mrs [Name] (Nominated gatekeeper for your centre)
Phone:
Email:

OR please **contact** us:

Dr Nurul S. Ishak (Principal Investigator)
Phone: 6127303 or 083-8042024
Email: nurul.ishak@dental.tcd.ie

Professor June Nunn (Project supervisor),
Phone: 6127303
Email: june.nunn@dental.tcd.ie

Or **write** to us at:
Dublin Dental University Hospital,
Trinity College Dublin , The University of Dublin
Lincoln place, Dublin 2. D02 F859

APPENDIX XV. Questionnaire

Date: **Study Participant ID: _____ Age_____**

Tick (√) one box for each question. Ask for help if you need it.

1 **Are you a male or a female?**

- ☐ Male
- ☐ Female

2 **Do you have a heart condition?**

- ☐ Yes
- ☐ No
- ☐ Don't know

Details here_____

3 **Are you happy to stay an extra 30 minutes for a repeat examination?**

- ☐ No
- ☐ Yes
- ☐ Don't know

4 **Who completed this questionnaire?**

- ☐ I did (Participant alone)
- ☐ We did (Participant supported by proxy)
- ☐ Someone else did (Proxy alone)

End of document

ODNF/participants/questionnaire

APPENDIX XVI. Dentition status & CPITN data collection forms

DENTITION STATUS

8	7	6	5	4	3	2	1	1	2	3	4	5	6	7	8
8	7	6	5	4	3	2	1	1	2	3	4	5	6	7	8

0-Sound
1-Caries,
2-Filled, with caries
3-Filled, no caries
4-Missing due to caries (<30 years of age)
5-Missing due to another reason (>30 years of age), ortho, perio
6-Fissure sealant
7-Fixed dental prostheses (Crown, veneer, bridge, implant)
8-Unerupted
9-Not recorded

Comments: _____
_____
_____

PERIODONTAL STATUS (CPITN TRADITIONAL)

16/17	11	26/27
46/47	31	36/37

0 healthy
1 bleeding observed, directly or by using mouth mirror, after sensing
2 calculus felt during probing but all the black area of the visible
3 pocket 4 or 5 mm (gingival margin situated on black area of probe)
4 pocket > 6 mm (black area of probe NOT visible)
9 Not recorded
X Excluded sextant (Less than 2 teeth present)

Comments: _____
_____
_____

APPENDIX XVII. Permission granted from the WHO

Wed 06/04/2016 16:40

permissions <permissions@who.int>

RE: 200996 Permission request for WHO copyrighted material

To Nurul Sa'idah Ishak

Dear Dr Ishak,

Thank you for your interest in WHO publications.

If you wish to use the extract for research, private study or in a non-commercial document with limited circulation (such as an academic thesis or dissertation), you may do so without seeking permission. Our only requirement is that the WHO source should be appropriately acknowledged. (Example Source: © World Health Organization, TITLE, YEAR)

If you wish to reproduce the extract by a method that gives it wider circulation, commercial or non-commercial, please contact us using the permission request form http://www.who.int/about/licensing/copyright_form/en/index.html or by return of this message.

In the latter case please specify exactly which WHO Oral health assessment form for adult you wish to reproduce. Please note that all materials are available on the WHO website at http://www.who.int/oral_health/publications/9789241548649/en/

Should you have further questions, please do not hesitate to contact us.

Kind regards,
Tatiana Titova

World Health Organization Press
(Permissions Management, Licensing and Reprint Rights)
20 Avenue Appia, CH-1211 Genève 27,
Switzerland

PERMISSION TEAM: permissions@who.int

APPENDIX XVIII.ODNF data collection form

Date of assessment	Participant ID	First/Duplicate	Examiner ID
		1 First 2 Duplicate	1 B 2 N 3 E 4 R 5 J

ODNF ASSESSMENT

1 TOOTH COUNT — count the number of teeth (0,1,2....)

No. of upper teeth ☐ 0,1,2..

No. of lower teeth ☐ 0,1,2..

X Not recorded Comments _____

2 WEARING DENTURES

Upper dentures ☐

Lower dentures ☐

0 Absent

1 Present

X Not recorded Comments _____

3 OCCLUDING PAIRS

No. of occluding pairs ☐

0 No occlusal contacts at all

1 1 or more posterior contacts

2 Anterior contacts only

X Not recorded Comments _____

4 SOFT TISSUES

Redness, white patches, ulcers, lumps and swelling ☐

0 Absent

1 Present

X Not recorded Comments _____

5 ORAL CLEANLINESS

Status ☐

0 Clean & no food particles or tartar in mouth or dentures

1 Little food particles/tartar/plaque in areas of the mouth or dentures

2 A lot of food particles/tartar/plaque in any areas of the mouth or on most of dentures; halitosis (bad breath)

X Not recorded Comments _____

1

6 GUM CONDITION

Condition ☐

0 Pink, moist, soft, no bleeding
1 **Localised** redness, swollen, bleeding / ulcers on gums
2 **Generalised** redness, swollen, bleeding / ulcers on gums
X Not recorded Comments _____

7 VISIBLE CARIES

No. of visible caries ☐

0 0 visible caries
1 **1-2** visible caries
2 **3 or more** visible caries
X Not recorded Comments _____

8 DENTAL PAIN

Behavioural, verbal or physical signs ☐

0 **No** behavioural, verbal or physical signs of dental pain
1 **Verbal +/- behavioural** signs of pain such as pulling at face, chewing lips, not eating, aggression; **No physical signs**
2 **Physical** pain signs (swelling of cheek or gum, broken teeth, ulcers), as well as **verbal** &/or **behavioural** signs (pulling at face, not eating, aggression)
X Not recorded Comments _____

Comments: _____

_____

APPENDIX XIX. List of equipment and instruments

Items	Quantity
Pen torch, Pen Torch Reusable (Black)	5 pcs
Spare Battery AAAs, 10pcs required	10 pcs
Nitrile gloves **Size: XS – 2bx, S – 2bx, M – 4bx, L – 2bx +1bx**	11 boxes
Face mask	3 boxes
Protective eye wear	5 pcs
PDI Sani wipes (Tub of 200s)	2 bottles
Purell advanced handrub	5 bottles
Protective barriers – Disposable shield No.1	5 rolls
Disposable Paper towel	15 packs
Disposable examination kit; Mirror, explorer, CPITN probe	73 packs
Sterile gauze	73 packs
Clinical yellow waste bag	5 rolls
Sharps container	1
iPad(s), power adapter	3pcs
Tablet(s) **Microsoft Surface Pro 4, power adapter**	2pcs
Sticker labels	1 pack
Marker pens	2pcs
Pens	1 pack
Spare data collection forms, incase computer breaks down	60pcs
Spare consent forms	20pcs
Appointment time, participants list	3
Questionnaires	60pcs
ODNF assessment feedback forms (Participants)	60pcs
ODNF assessment feedback forms (Assessors)	5pcs
Time record sheets	60pcs
Result sheet, referral to care forms	60pcs
Participants certificate	60pcs

APPENDIX XX. Participants with ID, feedback forms

Participant ID: _____

Feedback Forms (for Participants)

Thank you for taking part in the assessment. So that we can improve the assessment process, will you please answer the questions below?

1. Was it quick enough for you?

☐ Yes ☐ No ☐ I don't know

2. Did it hurt when I checked your mouth?

☐ Yes ☐ No ☐ I don't know

3. Was it okay for you?

☐ Yes ☐ No ☐ I don't know

4. If No.3 is NO, what did you not like about it?

_____

_____

5. Your suggestions to improve the assessment procedure

_____

_____

Your time and participation are much appreciated.

Page 1 of 1

APPENDIX XXI. Feedback forms for non-dental assessors

Feedback Forms (before training)

Title: "Oral Disease, Treatment Needs and Function (ODNF) index for oral health data collection by non-dental assessors in population with Intellectual Disabilities (ID): a feasibility study"

Thank you for taking part in the assessment. So that we can improve the assessment process, please will you answer the questions below?

1. **Type of assessor:**

☐ Non-dental ☐ Dental

2. **I feel knowledgeable and prepared to use the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

3. **Using the ODNF assessment tool improves my ability to detect dental pain and problems in subjects' mouths**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

4. **I had enough time to learn about the ODNF assessment tool before it was implemented.**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

5. **I am able to complete 'lips and gums' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

6. **I am able to complete 'cheeks' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

7. **I am able to complete 'tongue' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

8. **I am able to complete 'roof of mouth' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

9. **I am able to complete 'under the tongue' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

10. **I am able to complete 'own teeth' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

11. **I am able to complete 'denture' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

12. **I am able to complete 'swallowing' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

13. **I am able to complete 'salivary function' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

14. **Estimated time taken for you to complete the first part of training material:**

_____

15. **Please list down any problems encountered with the self-learning material suggestions on how it could be improved:**

Problems: _____

_____

_____

_____

Improvements: _____

_____

_____

_____

_____

Thank you for your time and contribution to this project.

Feedback Forms for Assessor (after 2 sessions of training)

Title: "Oral Disease, Treatment Needs and Function (ODNF) index for oral health data collection by non-dental assessors in population with Intellectual Disabilities (ID): a feasibility study"

Thank you for taking part in the training. So that we can improve the training process, please will you answer the questions below?

1. **Type of assessor:**

☐ Non-dental ☐ Dental

2. **I feel knowledgeable and prepared to use the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

3. **Using the ODNF assessment tool improves my ability to detect dental pain and problems in subjects' mouths**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

4. **I will have enough time to learn about the ODNF assessment tool before I use it on subjects.**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

5. **I will be able to complete 'Tooth Count' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

6. **I will be able to complete 'Denture' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

7. **I will be able to complete 'Occluding pairs' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

8. **I will be able to complete 'Soft tissues' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

9. **I will be able to complete 'Oral cleanliness' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

10. **I will be able to complete 'Gum condition' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

11. **I will be able to complete 'Visible caries' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

12. **I will be able to complete 'Dental Pain' category of the ODNF assessment tool**

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

13. **How long did you take to complete the self-learning material before the training day?**

☐ < 30 mins ☐ 30 - 60 mins ☐ > 1hour ☐ Not completed

14. **Do you think the training material for this assessment was sufficient?**

☐ Yes ☐ No; Comments: _____

15. **How many sessions (of approximately 2-3hours) of training would be sufficient for this assessment tool?**

☐ 1 ☐ 2
☐ 3 ☐ 4

16. **Please list down any problems encountered during the training and suggestions on how it could be improved:**

Problems: _____

_____

_____

Improvements: _____

_____

_____

Thank you for your time and contribution to this project.

Feedback Forms (for assessors) – after data collection

Thank you for taking part in the assessment. So that we can improve the assessment process, please will you answer the questions below?

1. Type of assessor:

☐ Non-dental ☐ Dental

2. I feel knowledgeable and prepared to use the ODNF assessment tool

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

3. Using the ODNF assessment tool improves my ability to detect dental pain and problems in subjects' mouths

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

4. I had enough time to learn about the ODNF assessment tool before it was implemented.

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

5. I am able to complete 'Tooth Count' category of the ODNF assessment tool

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

6. I am able to complete 'Denture' category of the ODNF assessment tool

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

7. I am able to complete 'Occluding pairs' category of the ODNF assessment tool

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

8. I am able to complete 'Soft tissues' category of the ODNF assessment tool

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

9. I am able to complete 'Oral cleanliness' category of the ODNF assessment tool

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

10. I am able to complete 'Gum condition' category of the ODNF assessment tool

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

11. I am able to complete 'Visible caries' category of the ODNF assessment tool

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

12. I am able to complete 'Dental Pain' category of the ODNF assessment tool

☐ Strongly agree ☐ Agree ☐ Disagree ☐ Strongly disagree

13. Was the time taken to carry out assessment acceptable?

☐ Yes, it was acceptable ☐ No, it was not acceptable

14. Please list down any problems encountered during the clinical assessment and suggestions on how it could be improved:

Problems:_____

_____

_____

Improvements:_____

_____

_____

_____

Thank you for your time and contribution to this project.

APPENDIX XXII. Time taken for each ODNF

FIELD LOGS (TIME) ***Please keep this at the assessment station*

Date: _____ Site: _____

Station:	1	2	3	4	5

Group: (please circle)	A	B	C	D	E	F	G	H

Participant ID: ☐

Assessor ID	Time start	Time end	Comments:

Notes:

Group: (please circle) A B C D E F G H

Participant ID: ☐

Assessor ID	Time start	Time end	Comments:

Notes:

Group: (please circle) A B C D E F G H

Participant ID: ☐

Assessor ID	Time start	Time end	Comments:

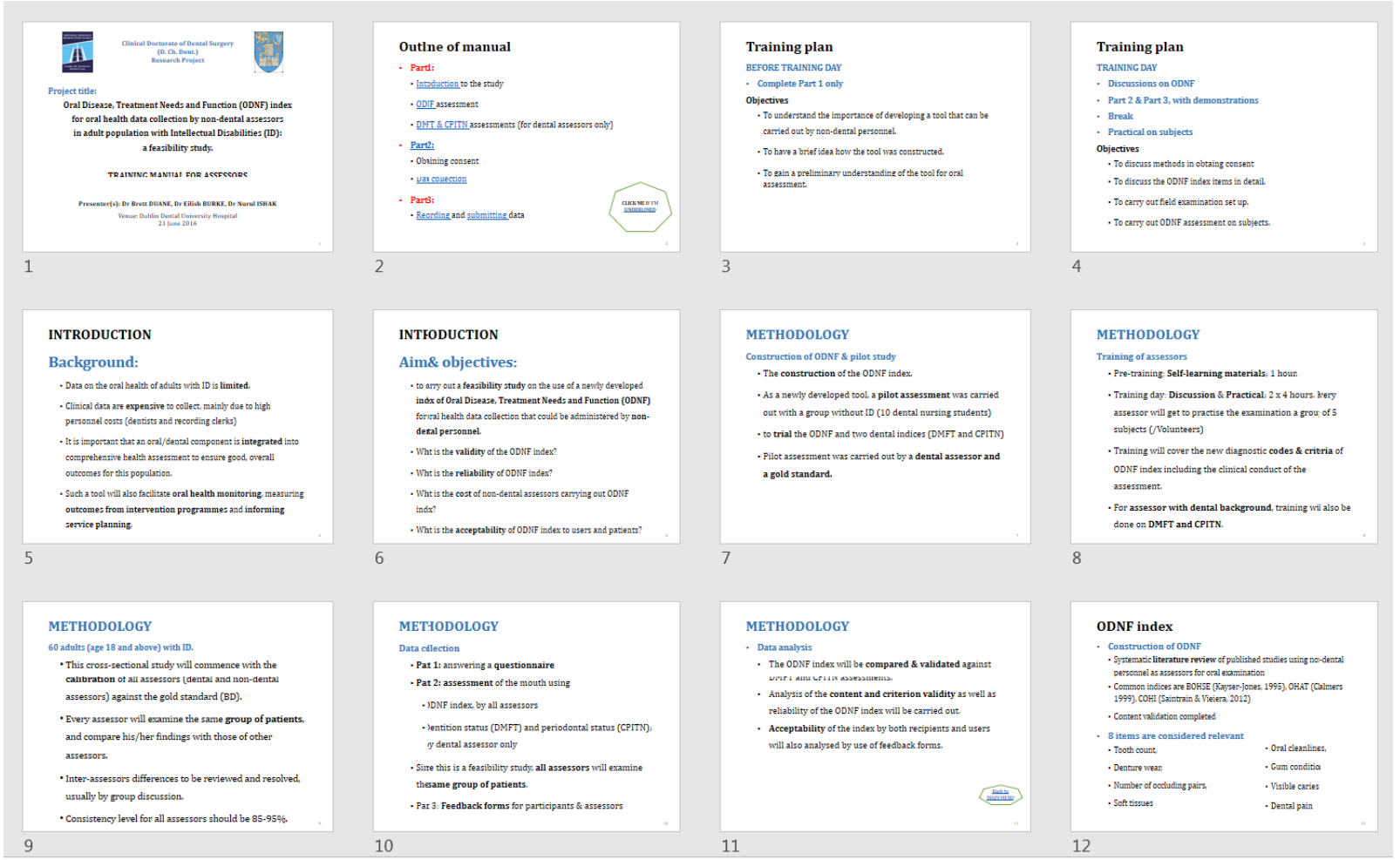
Notes:

Group: (please circle) A B C D E F G H

Participant ID: ☐

Assessor ID	Time start	Time end	Comments:

Notes:



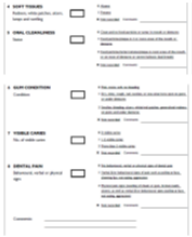
APPENDIX XXIII. A data collection protocol and training tool

ODNF assessment

- This is the assessment form for ODNF (first half)

13

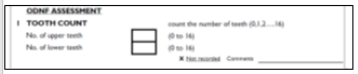
- 2nd half



14

ITEM 1: Tooth Count

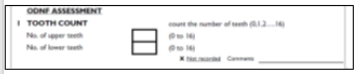
- 1st item of ODNF
  - Simple **count of teeth** present in the mouth
  - Upper teeth: **teeth on the upper jaw**
  - Lower teeth: **teeth on the lower jaw**
  - Include '**false teeth**' that **cannot be removed** (eg. Bridges, crowns, implants)



15

ITEM 1: Tooth Count

- *How to carry out examination?*
  - Use lighting.
  - Ask participant to **open their mouth**, & remove **denture**
  - Look at the **upper jaw**, **count** the number of teeth. Record on the form.
  - Then, look at the **lower jaw**, **count** the number of teeth. Record on the form.



16

UPPER TEETH

- These are pictures of upper jaw & teeth


= 17


= 11


= 0


= 8

17

LOWER TEETH

- Lower jaw & teeth


= 14


= 0


= 12


= 12

18

QUIZ 1 : TOOTH COUNT

- Please click one answer below

UPPER TEETH
a) 0
b) 10
c) 17

LOWER TEETH
a) 0
b) 12
c) 16

19

CORRECT

- Back to Quiz , next arch
- Next ODNF item

20

WRONG

- Try again here

21

ITEM 2: Wearing dentures

- 2nd item:
  - To see if the participants have false teeth (dentures) in their mouth.
  - Upper dentures on the upper jaw
  - Lower dentures on the lower jaw

22

ITEM 2: Wearing dentures

- *How to carry out examination?*
  - Use lighting.
  - Ask participant to **open their mouth**
  - Look at the upper and lower jaw.
  - Check if the patient is **wearing dentures.**
  - Record on the form.

23

UPPER DENTURES

- These are different types of UPPER DENTURES

Acrylic (plastic) denture

Cobalt Chrome (metal) denture

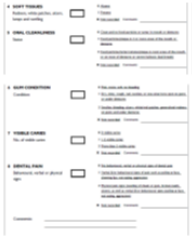
24

ODNF assessment

- This is the assessment form for ODNF (first half)

13

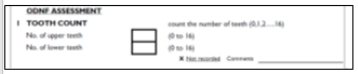
- 2nd half



14

ITEM 1: Tooth Count

- 1st item of ODNF
  - Simple **count of teeth** present in the mouth
  - Upper teeth: **teeth on the upper jaw**
  - Lower teeth: **teeth on the lower jaw**
  - Include '**false teeth**' that **cannot be removed** (eg. Bridges, crowns, implants)



15

ITEM 1: Tooth Count

- *How to carry out examination?*
  - Use lighting.
  - Ask participant to **open their mouth**, & remove **denture**
  - Look at the **upper jaw**, **count** the number of teeth. Record on the form.
  - Then, look at the **lower jaw**, **count** the number of teeth. Record on the form.

16

UPPER TEETH

- These are pictures of upper jaw & teeth


= 17


= 11


= 0


= 8

17

LOWER TEETH

- Lower jaw & teeth


= 14


= 0


= 12


= 12

18

QUIZ 1 : TOOTH COUNT

- Please click one answer below

UPPER TEETH
a) 0
b) 10
c) 17

LOWER TEETH
a) 0
b) 12
c) 16

19

CORRECT

- Back to Quiz , next arch
- Next ODNF item

20

WRONG

- Try again here

21

ITEM 2: Wearing dentures

- 2nd item:
  - To see if the participants have false teeth (dentures) in their mouth.
  - Upper dentures on the upper jaw
  - Lower dentures on the lower jaw

22

ITEM 2: Wearing dentures

- *How to carry out examination?*
  - Use lighting.
  - Ask participant to **open their mouth**
  - Look at the upper and lower jaw.
  - Check if the patient is **wearing dentures.**
  - Record on the form.

23

UPPER DENTURES

- These are different types of UPPER DENTURES

Acrylic (plastic) denture

Cobalt Chrome (metal) denture

24

LOWER DENTURES

- These are different types of LOWER DENTURES

Acrylic (**plastic**) denture

Cobalt Chrome (**metal**) denture

25

QUIZ 2

Please click your answer below

UPPER DENTURE

0 Absent

1 Present

LOWER DENTURE

0 Absent

1 Present

26

CORRECT

- Back to Quiz - next Arch
- Next ODNF item

27

WRONG

- Try again here

28

ITEM 3: Occluding pairs

- 3rd ODNF item
  - Counting the number of back teeth are meeting each other

29

ITEM 3: Occluding pairs

- *How to carry out examination?*
  - Use **lighting**
  - Ask participant to take out **dentures**
  - Ask participant to **bite down with their back teeth** together.
  - Retract right check using **hand mirror**, **identify canine** (eye tooth).
  - Look at the teeth after canine (eye tooth); **count the number** of upper teeth occluding /meeting the lower teeth.
  - **Check** on left side; if there are **1 or more pairs** altogether on both sides, record as 1.
  - If no contacts on the premolar and molars, observe the **contacts on the front teeth** (from eye tooth to another).
  - If there is **no occlusal contacts** at all, record as 0.

30

OCCLUDING PAIRS

Retract RIGHT CHEEK

Identify canine (eyetooth)

Identify Posterior teeth (back teeth)

31

Count posterior teeth in contact

No. of posterior contacts (RIGHT) = 4

32

Retract LEFT CHEEK

Identify canine (eyetooth)

Posterior teeth (back teeth)

33

Count posterior teeth in contact

No. of posterior contacts (LEFT) = 3

Total = 7

OCCLUDING PAIRS	
0	1 or more posterior contacts
1	Anterior contacts only
2	No occlusal contacts at all

Code 1 (1 or more posterior contacts)

34

Retract RIGHT CHEEK.
Identify **canine**.
Identify **Posterior** teeth.
Count posterior teeth in contact.

Retract LEFT CHEEK.
Identify **canine**.
Identify **Posterior** teeth.
Count posterior teeth in contact.

Right= 0

Left= 0

No posterior contact

IF NO POSTERIOR CONTACT
Count anterior teeth in contact.

35

IF NO POSTERIOR CONTACT

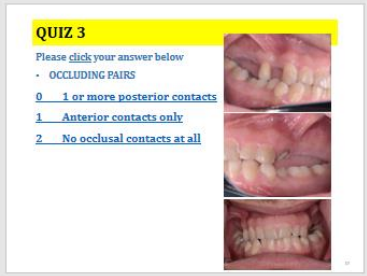
Count **anterior teeth in contact.**

Anterior contacts = 2

OCCLUDING PAIRS	
0	No occlusal contacts at all
1	1 or more posterior contacts
2	Anterior contacts only

Code 2 (anterior contacts only)

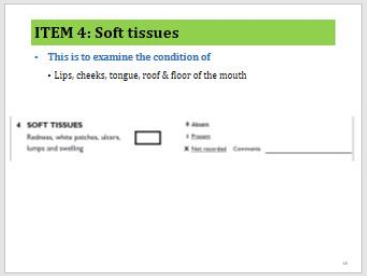
36



37

38

39



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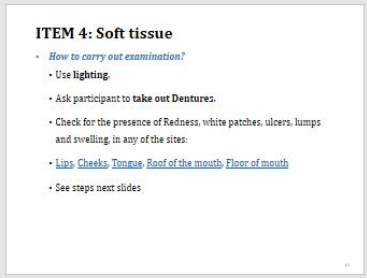

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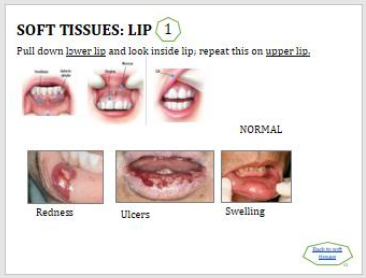

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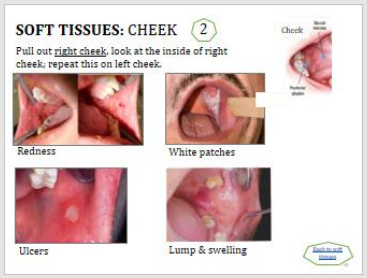

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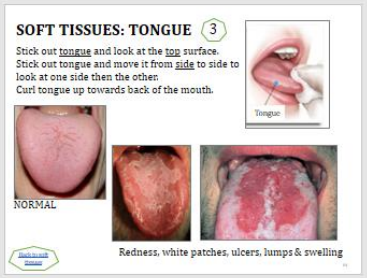
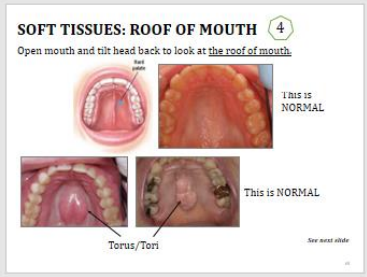


44



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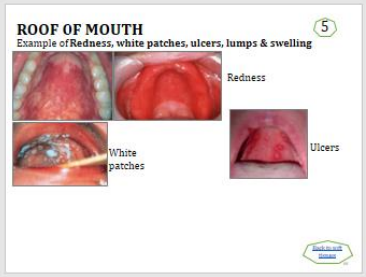
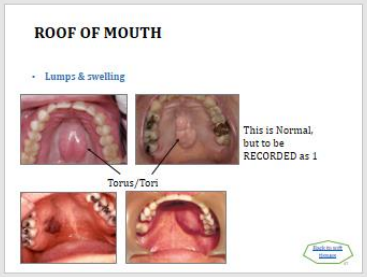


46



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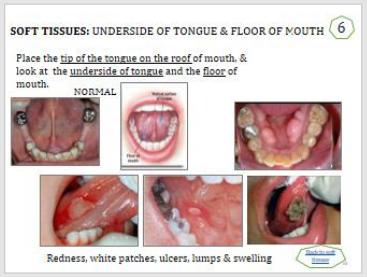


48

QUIZ 4 A

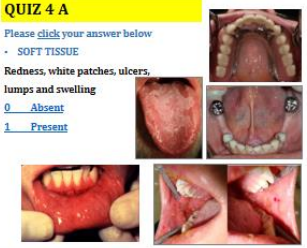
Please click your answer below

- SOFT TISSUE

Redness, white patches, ulcers, lumps and swelling

0 Absent

1 Present



49

CORRECT

- Next QUIZ
- Back to Quiz

50

WRONG

- Try again here

51

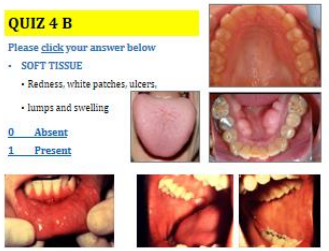
QUIZ 4 B

Please click your answer below

- SOFT TISSUE
  - Redness, white patches, ulcers,
  - lumps and swelling

0 Absent

1 Present



52

CORRECT

- Next ODNF item
- Back to Quiz

53

WRONG

- Try again here

54

ITEM 5: Oral cleanliness

- 5th item:
  - To measure the **cleanliness** of the **mouth** and **dentures**
  - Look for **food particles, plaque, calculus/tartar**
  - Food particles and plaque – **can be removed**
  - **Calculus / tartar – cannot be wiped off**
  - Also to assess for **Halitosis**, which means '**Bad breath**'

55

ITEM 5: Oral cleanliness

- *How to carry out examination?*
  - Use lighting.
  - Ask participant to **open their mouth**, Observe areas with **food particles, plaque or calculus/tartar**
  - Observe the **dentures** on exam tray, observe areas with **food particles, plaque or calculus/tartar**
  - Anything **with calculus/tartar**, record as 2
  - Does patient have **bad breath**?, record as 2

56

ORAL CLEANLINESS

- Code 0 means…
  - clean and no food particles or tartar in mouth or dentures

57

ORAL CLEANLINESS

- Code 1
  - **A little of food particles, plaque** in areas of the mouth or dentures
  - Can be wiped off.

58

ORAL CLEANLINESS

- Code 2
  - **A lot of** food particles, plaque & **calculus/tartar** in most areas of the mouth or on most of dentures or severe halitosis (bad breath)

59

QUIZ 5

Please click your answer below

- ORAL CLEANLINESS

0 **clean** and no food particles or tartar in mouth or dentures

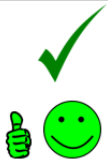
1 **Food particles, plaque** in areas of the mouth or dentures

2 food particles, plaque & **calculus/tartar** in areas of the mouth or on most of dentures or severe **halitosis** (bad breath)

60

CORRECT

- Next ODNF item
- Back to Quiz 5



61

WRONG

- Try again here

62

ITEM 6: Gum condition

- This is to assess the condition of the gums
  - Gum is the structure that holds the tooth at its neck.
  - When there is not teeth, gum is also considered under **false teeth (dentures)**

63

ITEMS 6: Gum condition

- *How to carry out examination?*
  - Use **lighting**.
  - Ask participant **to open mouth**, **retract** lips and cheeks, look at the gums generally.
  - **Clean debris** with dry gauze.
  - Observe gums **in between teeth**; Gums on **ridge (where there** is **missing teeth)**, and under **dentures.**

64

GUMS

- Code 0 **Pink, moist, soft, no bleeding**

Racial variations of normal & health gums

65

GUMS

Code 1

- **Localized redness, swollen, bleeding or ulcers on gums;**

66

GUMS

Code 2

- **Generalized redness, swollen, bleeding, or ulcers on gums**

67

QUIZ 6 A

Please click your answer below

- Gum condition

0 Pink, moist, soft, no bleeding

1 Localised redness, swollen or one ulcer/sore spot on gums or under dentures

2 Generalised redness, swollen, bleeding, ulcers, white/red patches on gums and under dentures

68

CORRECT

- Next QUIZ 6B
- Back to Quiz 6 A

69

WRONG

- Try again here

70

QUIZ 6B

Please click your answer below

- Gum condition

0 Pink, moist, soft, no bleeding

1 Localised redness, swollen or one ulcer/sore spot on gums or under dentures

2 Generalised redness, swollen, bleeding, ulcers, white/red patches on gums and under dentures

71

CORRECT

- Next ODNF item
- Back to Quiz 6A, Quiz 6B

72

WRONG

- Try again here

73

ITEM 7: Visible caries

- 7th item
  - This is to count the number of **decayed teeth** in the mouth
  - **Caries** means '**decayed**', '**broken down**', has '**holes**'
  - Count the teeth with caries that **can be seen**
  - **Hole** & usually **brown or dark brown in colour**
  - If in doubt, **score low (no caries)**

74

ITEM 7: Visible caries

- *How to carry out examination?*
  - Clean & dry teeth with a **gauze.**
  - Use **lighting.**
  - Ask participant to **open their mouth**, observe the upper and count the number of teeth that have '**holes**', then do the same for the lower teeth.
  - Count the **total number** of teeth which have **dental decay / holes**

75

VISIBLE CARIES

Code 0 **No visible caries**

This picture shows
Metal fillings (Amalgam)
With no caries

This picture shows
White fillings (Composite)
With no caries

76

VISIBLE CARIES

77

VISIBLE CARIES

White fillings (Composite)
With caries

Metal fillings (Amalgam)
With caries

78

QUIZ 7

Please click your answer below

- VISIBLE CARIES

0 0 visible caries

1 1-2 visible caries

2 3 or more visible caries

79

CORRECT

- Next ODNF item
- Back to Quiz 7

80

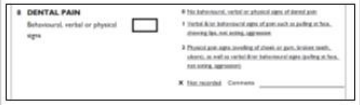
WRONG

- Try again here

81

ITEM 8: Dental Pain

- 8th item, to assess if patient has signs of dental pain
  - **Verbal** indication of pain ("yes it hurts", "ouch")
  - **behavioural** signs of pain such as pulling at face, chewing lips, not eating, aggression
  - **physical** pain signs (swelling of cheek or gum, broken teeth, ulcers)



82

ITEM 8: Dental Pain

- *How to carry out examination?*
  - Observe face; look for **pulling at face**
  - Use lighting.
  - Retract cheeks and lips; look for **swelling and ulcers**
  - Ask participant to open their mouth; look for **broken teeth**
  - Ask participant/carer; if they are **not eating**; if they show change in behavior eg. **Chewing lips, Aggression**

83

DENTAL PAIN

Behavioural signs of pain: Pulling at face, chewing lips, not eating, aggression, self-injurious behaviours.

84

DENTAL PAIN

Physical pain signs (swelling of cheek or gum, broken teeth, ulcers)

85

QUIZ 8

Please click your answer below

- DENTAL PAIN

0 no behavioural, verbal or physical signs of dental pain

1 **Verbal &/or behavioural signs** of pain such as pulling at face, chewing lips, not eating, aggression

2 **physical pain** signs (swelling of cheek or gum, broken teeth, ulcers), as well as **verbal &/or behavioural signs** (pulling at face, not eating, aggression)

86

CORRECT

- Next
- Back to Quiz 8

87

WRONG

- Try again here

88

WELL DONE

- You have completed Part 1 of ODNF training
- See you at Training day!

89

Dentition & Periodontal Status

- For dental assessors only

CLICK HERE to skip to DATA COLLECTION

90

DENTITION STATUS

Code 0 - Sound: none of the conditions are found

Code 1 - Caries: cavitated carious lesions or/and lesions with dentinal involvement on previously affected tooth surfaces

91

Code 3 - Filled, with caries: visible caries with existing restoration

Code 4 - Filled, no caries: restoration placed without caries detected

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Code 4 - Missing due to caries (<30 years of age): tooth was extracted because of caries. History of pain or treatment and status of a contralateral tooth should be checked.

Code 5 - Missing due to another reason (>30 years of age): tooth is extracted for reasons other than caries. This included a tooth extracted for orthodontic reasons or missing due to trauma.

Code 6 - Fissure sealant: pit and fissures surfaces only

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Code 7 - Fixed dental prostheses (Crown, veneer, bridge, implant)

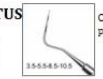
Code 8 - Unerupted: When a tooth space is not occupied by a tooth and there is no history of tooth extraction.

Code 9 - Not recorded

94

PERIODONTAL STATUS

Sextant 1	2	3
17/16	11	26/27
46/47	31	36/37
6	5	4



CPITN probe

- Periodontal examination is done by on index teeth of each sextant
- A sextant should be examined only if there are two or more teeth present and not indicated for extraction.
- When only one tooth remains in a sextant, it should be included in the adjacent sextant.
- Example, if there is only tooth 36 in the 4th sextant, then the tooth 36 should be included in the adjacent sextant (ie 5th sextant).

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PERIODONTAL STATUS

CPITN probe

Sextant 1	2	3
17/16	11	26/27
46/47	31	36/37
6	5	4

1: bleeding observed, directly or by using mouth mirror, after sensing; all black area of probe visible
2: calculus felt during probing but all the black area of the probe visible
3: pocket 4 or 5 mm; gingival margin situated on black area of probe)
4: pocket > 6 mm; black area of probe not

96

WELL DONE

- You have completed Part 1 of ODNF training
- See you at Training day!

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Clinical Doctorate of Dental Surgery
(D. Ch. Dent.)
Research Project

WELCOME to

Part 2 – ODNF Training of assessors

Programme of the day:
20th June 2016

8.30-9.30: Obtaining consent (Dr Eilish Burke)
9.30-10.30: Discussion on Part 1 learning materials
10.30: Break (Refreshments provided)
10.45-11.30: Clinical set up
Recording & submitting data
Practical

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Data collection day

Receiving consent and assigning study participants for clinical examination

- Venue: Day centres
- Responsible person: CMGP & Mark Smith
- **Consent will be re-confirmed** by Research coordinator
- Each participant will be assigned a **unique ID**
- Format of ID: P1, P2, P3 & so on...
- Each participant will be given their **participant ID labels**

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Part 1 : Questionnaires

- **Protocol for Questionnaires**
  - All participants will be required to **answer a questionnaire.**
  - **Support** can be given by **coordinator**, or **accompanying person.**
  - Research coordinator to receive and ensure all questions have been answered.
  - Runner will then take the **participant to examination room** or to **Oral Health Promotion activity**, as per schedule.

100

Part 2: Clinical assessment

- **Set up for clinical examination site**
  - Chairs for study participants, at least 5? For carers: ??TBC
- **Examination area set up:**

Patient's protective eyewear	Ipads/tablets
Latex-free glove Face mask	Pen torch Extra batteries
Disposable disinfectant wipes Sterilsium® instant hand sanitizer	Disposable instruments tray
Clinical yellow waste bag CSSD container for sharps	Disposable examination kit; Mirror, CPITN probe
Protective barriers – Disposable shield No.1	Sterile gauze
Disposable Paper towel	

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- **Set up**

102

Equipments


Safety eyewear

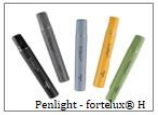

Clinical yellow wastebag


Hand sanitizer


Hand sanitizer

103


Examination kit


Penlight - fortelux® H


Gauze

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Conduct components of examination

- **Before examination:**
  - Set up yellow **clinical waste bags** and **sharp containers**
  - Wear **gloves.**
  - Wipe **iPad & Pen torch** surface with disinfectant **wipes**; Dispose wipes into **yellow clinical waste bags.**
  - Discard **gloves** into **yellow clinical waste bags.**
  - Carry out **hand hygiene.**
  - Place **protective barriers** on **iPads/tablets** and **light handle.**
  - **Open instruments pack.**

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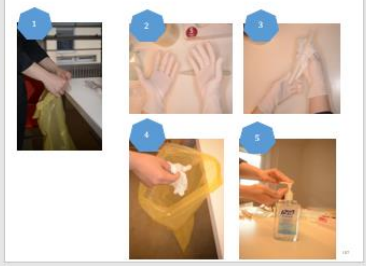
Using Pen torch

- Switch **light on**, by sliding the **red tab upwards.** Please do not loose the red tab.
- Place **protective barriers** on the handle.
- Always use **a new protective barrier** for each examination
- **Dispose** of the barrier after single use, into yellow clinical waste bags.
- **Wipe the mirror light handle** using disinfectant wipes after each examination.
- Make sure the light is switched off after use in order to preserve battery power

106



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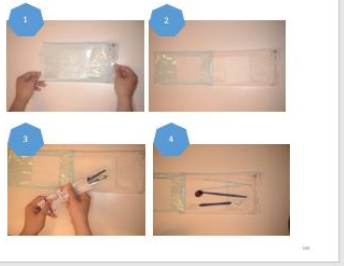

108

- Placement of barriers on Penlight and tablets/ipads

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- **Examination:**
  - **Welcome & seat** the participant.
  - ask patient **to wear protective glasses.**
  - Carry out **hand hygiene.**
  - **Wear gloves.**
  - Use **lighting.**
  - Carry out **examination.**
  - **Record data** into tablet.
  - Check for completion, then **submit** data.

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- **At the end of examination:**
  - Discard **gauze** and **barriers** into **yellow clinical waste bags.**
  - Discard **mirror** and **probes** into **CSSD container.**
  - Discard **gloves** into **yellow clinical waste bags.**
  - Carry out hand hygiene.

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Disposing used instruments and supplies

- **Yellow clinical waste bags**
  - Paper towel
  - Protective barriers – Disposable shield No.1
  - Gauze
  - Gloves
  - Face mask
- **Sharp box/container**
  - Examination kit: mirror, probes

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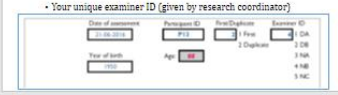
Recording data

- **Open file with the correct participant ID**
- **First, Click on the ODNF tab**
  - Enter general information
  - Date of assessment: enter date (DD-MM-YYYY) OR select 'Today'
  - Participant ID: ask and confirm with badge
  - First or Duplicate assessment: Repeat assessment as 'Duplicate'
  - Your unique examiner ID (given by research coordinator)



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Recording data

- **Enter scores for ODNF items 1 to 8.**
- **For Dental assessors carrying out dentition and periodontal assessments.**
  - For Dentition status DMFT assessment. Click the tab "DMFT".
  - For CPITN assessment. Click the tab "CPITN"
- **Save**
- **Main author (NSI) to put password**

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Submit data

- **Via email:**
  - Ensure there in internet connection
  - SHARE > **SEND A COPY** >
  - CHOOSE A FORMAT > **EXCEL**
  - CHOOSE HOW TO SEND> **MAIL**>
  - TO> ODNFstudy.dduh@gmail.com
  - Press **SEND**

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Receiving data:

- Venue: Location
- Equipment: Laptop (NI) with C:\ODNF set up.
- Coordinator: CMGP
- Open inbox ODNFstudy.dduh@gmail.com
- **Download** file and move file **into C:\ODNF.**
- Ensure the form has been **named correctly.**
- Secure all data with **password** (only known to NSI).
- Open file; ensure all forms are completed. Any box without data must be marked as 'Unrecorded', code 9.
- Go to 'Data collection' tab. Check that all data has been entered in the correct format; if #VALUE! Appears, re-check back the original data entered in the assessment forms.

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Combining data:

- Ensure all forms are saved in C:\ODNF
- Go to **C:\Users\my computer\Downloads\0 ODNF DATA COLLECTION\30 JUNE.**
- Open the file **NURUL ODNF Assessment Macro x30.6**
- Follow the instructions in the 'Macro Sheet'
- Run Macro.
- Ensure the heading row is added onto the top of combined data.
- Save file as "NURUL ODNF macro result (date)".
- **Password protect** (only known to researchers).

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APPENDIX XXIV. Time to attend the data collection

NAME OF CENTRE

Schedule for clinical assessment

DAY 1

Date: _____

Time	Participant's Name	Contact no.
9.30AM		
11.30AM		
BREAK		
2.00PM		

APPENDIX XXV. Clinical assessment sequence

	Station 1 = Participant 01	**Station 2 = Participant 02**	**Station 3 = Participant 03**	**Station 4 = Participant 04**	**Station 5 = Participant 05**
1st examination					
START STATION	Dental assessor 1	Dental assessor 2	Non-dental assessor 1	Non-dental assessor 2	Non-dental assessor 3
MOVE	Dental assessor 2	Non-dental assessor 1	Non-dental assessor 2	Non-dental assessor 3	Dental assessor 1
MOVE	Non-dental assessor 1	Non-dental assessor 2	Non-dental assessor 3	Dental assessor 1	Dental assessor 2
MOVE	Non-dental assessor 2	Non-dental assessor 3	Dental assessor 1	Dental assessor 2	Non-dental assessor 1
LAST STATION	Non-dental assessor 3	Dental assessor 1	Dental assessor 2	Non-dental assessor 1	Non-dental assessor 2
Ask patient if he/she wants to stay					
2nd examination					
START STATION	Dental assessor 1	Dental assessor 2	Non-dental assessor 1	Non-dental assessor 2	Non-dental assessor 3
MOVE	Dental assessor 2	Non-dental assessor 1	Non-dental assessor 2	Non-dental assessor 3	Dental assessor 1
MOVE	Non-dental assessor 1	Non-dental assessor 2	Non-dental assessor 3	Dental assessor 1	Dental assessor 2
MOVE	Non-dental assessor 2	Non-dental assessor 3	Dental assessor 1	Dental assessor 2	Non-dental assessor 1
LAST STATION	Non-dental assessor 3	Dental assessor 1	Dental assessor 2	Non-dental assessor 1	Non-dental assessor 2

APPENDIX XXVI. Standard operating procedures, including infection prevention and control protocols for clinical assessments

Main study: Examination of 1 participant by 5 assessors

Sequence of events at each station
Wipe surface with disposable disinfectant wipes. Protective barrier on iPad and lights (Dentlite® or pen torches). Open instruments pack.
Call & seat participants.
Assessor 1
Carry out Hand hygiene. Wear gloves.
Examination. Record data on iPad.
Remove gloves, into yellow waste bags Carry out Hand hygiene.
Assessor 2
Carry out Hand hygiene. Wear gloves.
Examination. Record data on iPad.
Remove gloves, into yellow waste bags Carry out Hand hygiene.
Assessor 3
Carry out Hand hygiene. Wear gloves.
Examination. Record data on iPad.
Remove gloves, into yellow waste bags Carry out Hand hygiene.
Assessor 4
Carry out Hand hygiene. Wear gloves.
Examination. Record data on iPad.
Remove gloves, into yellow waste bags Carry out Hand hygiene.
Assessor 5:
Carry out Hand hygiene. Wear gloves.
Examination. Record data on iPad.
Remove gloves, into yellow waste bags Carry out Hand hygiene.
Participants leave
Throw Instruments pack into yellow waste bags. Remove protective barriers, into yellow waste bags.

APPENDIX XXVII. Statistical tests involved in the concurrent validity assessment

Table 9.13 Statistical tests involved in the concurrent validity assessment

ODNF items	Dentition status & CPITN items	Variables	Statistical tests
Upper teeth 0,1,2,3…	**Total Upper teeth** 0,1,2,3…	Discrete	Weighted Kappa Weighted Gwets Spearman's correlation
Lower teeth 0,1,2,3…	**Total lower teeth** 0,1,2,3…	Discrete	Weighted Kappa Weighted Gwets Spearman's correlation
Total teeth 0,1,2,3…	**Total number of teeth** 0,1,2,3…	Discrete	Weighted Kappa Weighted Gwets Spearman's correlation
Total teeth (Grouped) 0: 20 & more teeth 1: Less than 20	**Total number of teeth (grouped)** 0: 20 & more teeth 1: Less than 20	Categorical, Ordinal	Weighted Kappa Weighted Gwets Sensitivity & Specificity
Gums 0: None 1: Localised 2: Generalised	**Number of sextants with CPITN of 1 & more (grouped)** 0: 0 sextant 1: 1 or 2 2: 3 or more	Categorical, Ordinal	Weighted Kappa Weighted Gwets Sensitivity & Specificity
Visible caries 0: 0 visible caries 1: 1 or 2 2: 3 or more	**DMFT - Number of decayed teeth (grouped)** 0: D = 0 1: D = 1 or 2 2: D= 3 or more	Categorical, Ordinal	Weighted Kappa Weighted Gwets Sensitivity & Specificity

APPENDIX XXVIII. Statistical tests for inter-rater reliability assessment of ODNF items.

Table 9.14 Statistical tests for inter-rater reliability assessment of ODNF items.

ODNF ITEMS	Statistical tests
Upper teeth 0,1,2,3…	Weighted Kappa, Weighted Gwets Spearman's correlation
Lower teeth 0,1,2,3…	Weighted Kappa, Weighted Gwets Spearman's correlation
Total teeth 0,1,2,3…	Weighted Kappa, Weighted Gwets Spearman's correlation
Total teeth (Grouped) 0: 20 & more 1: Less than 20	Weighted Kappa, Weighted Gwets Sensitivity & Specificity
Upper denture 0: Absent 1: Present	Weighted Kappa, Weighted Gwets Sensitivity & Specificity
Lower denture 0: Absent 1: Present	Weighted Kappa, Weighted Gwets Sensitivity & Specificity
Total number of dentures 0,1,2	Weighted Kappa, Weighted Gwets Spearman's correlation
Occluding pairs (Re-grouped) 0: 1 or more occluding pairs 1: Anterior contacts only 2: No contacts	Weighted Kappa, Weighted Gwets Sensitivity & Specificity
Soft tissues 0: Absent 1: Present	Weighted Kappa, Weighted Gwets Sensitivity & Specificity
Oral cleanliness 0: None 1: Localised 2: Generalised	Weighted Kappa, Weighted Gwets Sensitivity & Specificity
Gums (Grouped) 0: None 1: Localised 2: Generalised	Weighted Kappa, Weighted Gwets Sensitivity & Specificity
Visible caries 0: 0 caries 1: 1,2 caries 2: 3 or more caries	Weighted Kappa, Weighted Gwets Sensitivity & Specificity
Dental Pain 0: No Pain 1: Verbal +/- Behavioural 2: Physical, verbal, behavioural signs	Weighted Kappa, Weighted Gwets Sensitivity & Specificity

APPENDIX XXIX. Report of literature review using PRISMA reporting (Moher et al., 2009)

TITLE

Existing tools to assess oral health utilising non-dental individuals as assessors – a systematic review.

INTRODUCTION

This systematic literature review was carried out as part of index development and content validation of a tool that can be used by non-dental personnel to assess and collect substantial oral health information in epidemiological surveys involving population with intellectual disabilities (ID).

The purpose of the ODNF Index was to facilitate trained non-dental individuals to collect epidemiological data that could be used to assess the oral health status of population with ID. To meet the purpose of the ODNF tool, it must be:

1) Simple to be administered by non-dental assessors
2) Able to assess components of oral health in population surveys
3) Acceptable to the people with ID
4) Valid and reliable
5) Inexpensive to be used in data collection to asses oral health, compared to dentist carrying out a conventional dental assessment.

Preliminary review revealed that there is no existing tools that have been developed purposely for and validated in this population. Hence a new tool had to be developed to meet this purpose.

Interventions

Assessments of oral health that are carried out by non-dental assessors.

Non-dental assessors were defined as those without formal dental training, hence this excludes:

- Dentists, dental hygienists and therapists, dental nurses (or dental surgery assistants) and dental students.

Assessment of oral health will include:

- Soft tissues (lips, labial and buccal mucosae, hard and soft palate, tongue, floor of the mouth),
- Hard tissues (teeth, occlusal units, dental caries, missing teeth, filled teeth)
- Periodontal health (gingival redness, swelling, bleeding, ulcers, deep pocket (>5mm), root furcation, presence of abscess, plaque accumulation, calculus accumulation,)
- Presence of dental pain
- Assessment of dry mouth, swallowing and voice
- Assessment of denture

Why is it important to do this review?

Index development from scratch is a laborious process, not to mention the loss of comparability with previous data. Analysis of tools of similar nature will help identify items

which are relevant to the purpose of this new tool. This systematic review was an important part in establishing high level of content validity of this ODNF index.

OBJECTIVES:
To identify and analyse the existing tools that have been developed for use by non-dentists to assess and collect oral health information (objective measure).

Population – any patient population group
Intervention – Non-dentists as assessors
Comparisons – Dentist (dental examination) as gold standard
Outcome – construction of index, development of training, content validity, concurrent validity, inter-rater reliability, intra-rater reliability, test-retest reliability, feasibility

METHODS

Protocol and registration:
Review protocol can be accessed as part of this thesis in the University's open institutional repository, subject to Irish copyright Legislation and Trinity College Library conditions of use and acknowledgement.

Eligibility criteria:

Inclusion criteria:	**Exclusion criteria:**
1 database only, PubMed	Databases other than PubMed
English language	Non-English
Peer-reviewed journals	Non peer-reviewed journals
Index development, validation	Opinions, editorials, continuous education courses papers and books or commentaries
Assessors not dentist or other allied dental professionals	Dentist, dental hygienist, dental therapist, dental nurse, dental surgery assistant, dental specialist; Anyone with formal dental training
Age: Adult, 18 years and above	Children, below 18
Full-text available	No full-text available
Assessment of Oral health	Questionnaire, non-clinical

Rationale:

- 1 data base only as there is limited time for this DCHDENT research.
- The PubMed database was deemed to be the most appropriate of the databases in yielding more articles related to dentistry and populations with intellectual disability (ID).
- English is the only language both reviewers are familiar with.

Information sources:
PubMed
Initial search – 15th February 2016
Last search – 30th November 2017

Electronic search strategy
Search words:
Population - adult population with intellectual disabilities (18 years and above)

Search words: Adult, young adult, middle-aged adult, older adult

Intervention - Oral health assessment tools administered by non-dental individuals; Comparison - Oral health assessment by dentists
Search words: Oral health, dental health, mouth health; assessment, examination, screening, data collection, surveys; Index, indicator; Non-dentist, non-dental, physician, nurse, allied health professionals; Dentist, dental, dental hygienist, dental therapist, dental nurse, allied dentals

Outcome - Validity, reliability, feasibility
Search words: Validity/validation, content validity, concurrent validity, criterion validity, construct validity; Reliability, inter-rater reliability, test-retest reliability, intra-rater reliability; Cost analysis; acceptability

Search string in PubMed:
((((("oral health"[Title/Abstract] OR "Health oral"[Title/Abstract] OR "dental health"[Title/Abstract] OR "health dental"[Title/Abstract] OR "mouth health"[Title/Abstract] OR "oral disease"[Title/Abstract] OR "oral diseases"[Title/Abstract] OR "dental disease"[Title/Abstract] OR "dental diseases"[Title/Abstract] OR "mouth disease"[Title/Abstract] OR "mouth diseases"[Title/Abstract]) OR ("Stomatognathic Diseases"[Mesh])) AND (Exam*[Title/Abstract] OR Assess*[Title/Abstract] OR screen*[Title/Abstract] OR survey*[Title/Abstract] OR "data collection"[Title/Abstract] OR "collecting data"[Title/Abstract]) AND (index[Title/Abstract] OR indices[Title/Abstract] OR tool[Title/Abstract] OR tools[Title/Abstract] OR indicator[Title/Abstract] OR indicators[Title/Abstract])) AND ((Non-dentist[Title/Abstract] OR "non dentist"[Title/Abstract] OR non-dental[Title/Abstract] OR "non dental"[Title/Abstract] OR community[Title/Abstract] OR caregiver[Title/Abstract] OR caregivers[Title/Abstract] OR caretaker[Title/Abstract] OR caretakers[Title/Abstract] OR "key worker"[Title/Abstract] OR "key workers"[Title/Abstract] OR nurse[Title/Abstract] OR nurses[Title/Abstract] OR nursing[Title/Abstract] OR physician[Title/Abstract] OR physicians[Title/Abstract] OR "speech pathologist"[Title/Abstract] OR "speech pathologists"[Title/Abstract] OR physiotherapist[Title/Abstract] OR physiotherapists[Title/Abstract]) OR ("Health Personnel"[Mesh]))) AND ((Adult[Title/Abstract] OR adults[Title/Abstract] OR middle-age*[Title/Abstract] OR aged[Title/Abstract] OR aging[Title/Abstract] OR Older[Title/Abstract] OR "older people"[Title/Abstract] OR "older adults"[Title/Abstract] OR "older adult"[Title/Abstract] OR "older patients"[Title/Abstract] OR "older patient"[Title/Abstract] OR "older population"[Title/Abstract] OR "older populations"[Title/Abstract] OR "older persons"[Title/Abstract] OR "older person"[Title/Abstract] OR "older men"[Title/Abstract] OR "older women"[Title/Abstract] OR "elderly"[Title/Abstract] OR "elderly people"[Title/Abstract] OR "elderly patient"[Title/Abstract] OR "elderly patients"[Title/Abstract] OR "geriatric population"[Title/Abstract] OR "geriatric patient"[Title/Abstract] OR "geriatric patients"[Title/Abstract]) OR ("Adult"[Mesh]))

Study selection:
An electronic search was then conducted through database searching. Although only 1 database search was carried out, duplicates were identified and removed.

Screening:

Two reviewers (Nurul Sa'idah Ishak (NSI) and Caoiminh Mac Giolla Phadraig (CMGP)) independently screened the titles and abstracts from the electronic searches to identify potential eligible studies. The articles were grouped for inclusion into 'yes', 'no' and 'maybe'. Further discussions between reviewers were carried out to assist in the elimination of the papers which are irrelevant.

Full text copies were then obtained of all eligible and potential eligible studies. The two review authors further evaluated in detail these studies for inclusion.

As for articles in languages other than English, their translated abstracts were assessed for eligibility however since this was a rapid systematic review it was decided to exclude these studies.

Data collection process and data items:
One review author extracted the data using data extraction form.

Main data extracted were:

- Name of assessment tools or indices
- Author's details
- Publication details (Year of publication)
- Original developer? If not, please state
- Purpose of index
- Characteristics of participants assessed, non-dental individuals
- Items in the index and its diagnostic codes and criteria
- Non-dental assessors
- Gold standard assessor
- Methods for establishing content validity
- Methods and statistical tests for the concurrent validity, reliability and feasibility assessments
- Results of the study

Additional data extracted include:

- Statistical programs used
- Training protocol (and materials)
- Data collection protocol
- Other assessments & results

Summary measures

Assessments	**Statistical and statistical correlation tests from previous studies**
Concurrent validity	Percent agreement, Cohen's Kappa (simple and weighted), Fleiss Kappa, Pearson correlation, Spearman's correlation, Chi Square test
Inter-rater reliability	Percent agreement, Cohen's Kappa (simple and weighted), Sensitivity, Specificity and Accuracy, Correlation coefficients, Analysis of variance (ANOVA), Post hoc Scheffe comparisons, Intraclass correlation (ICc), ICc with a two-way random-effects model with measures of absolute agreement (ICCabsolute agreement).
Intra-rater reliability / test-retest reliability)	Cohen's Kappa (simple and weighted), Percent agreement, Paired t-tests, ICc with a one-way random effects model with measures of absolute agreement (ICCabsolute agreement).

Internal consistency	Cronbach's Alpha
Other correlation	Kendall rank-order correlation coefficient T, Kruskal-Wallis test, Chi square test
Assessment for normality	Shapiro-Wilk test, QQ-plots

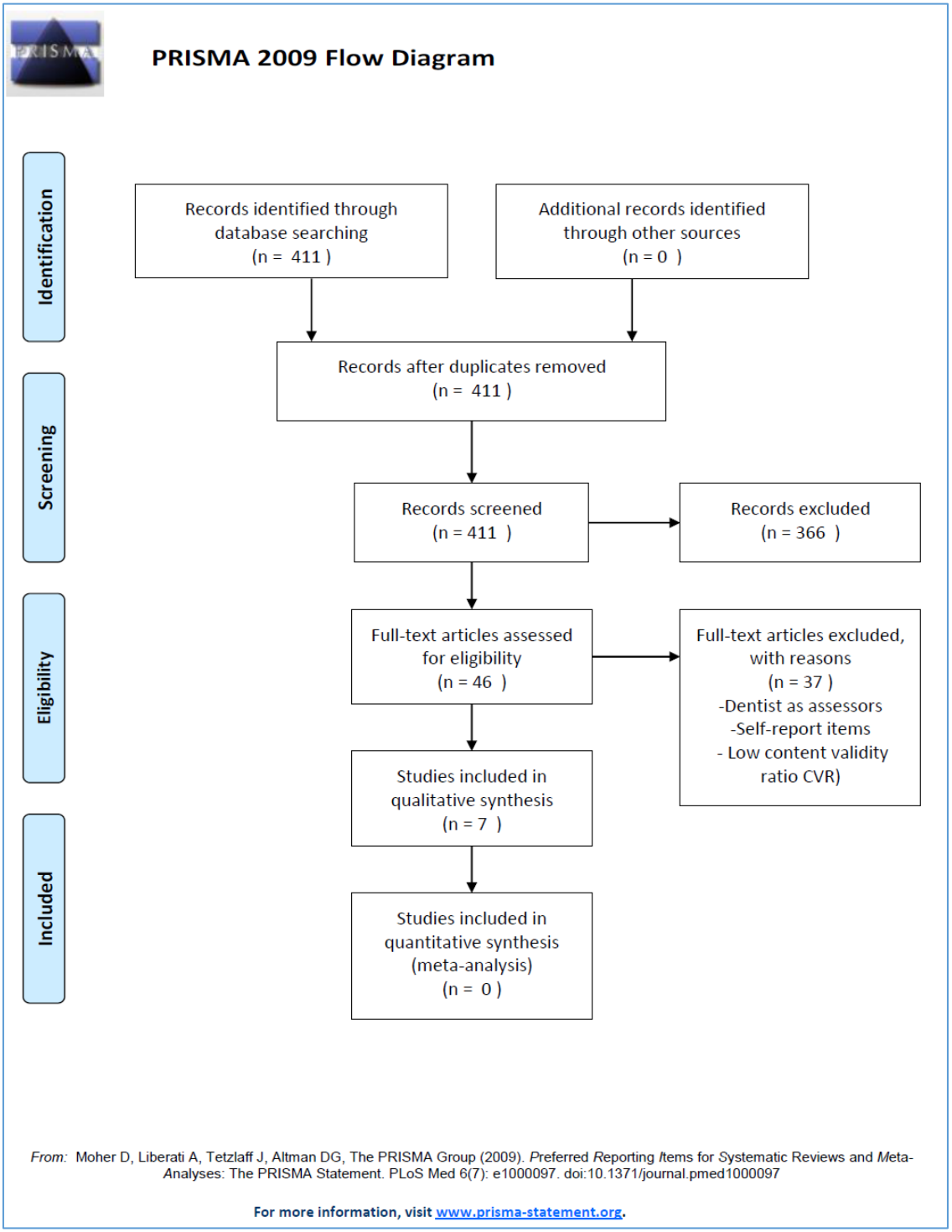
Synthesis of results:
No meta-analysis was carried out.

Additional analyses
None.

RESULTS

Study selection
An electronic search of the literature, pertaining to indices for used by non-dental assessors, was conducted on the 15th February 2016; 411 articles that met the inclusion criteria were selected and duplicates were removed. Following title and abstract review, 46 articles were identified for further discussions between reviewers before finalising the articles for full-text review. A full-text review and data extraction were then carried out by NSI. The reference sections were also screened for other relevant papers.

Figure 9.1PRISMA Flow diagram for this study



Study characteristics, Results of individual studies

Study:
Andersson, P., Persson, L., Hallberg, I. R., & Renvert, S. (1999). Testing an oral assessment guide during chemotherapy treatment in a Swedish care setting: a pilot study. J Clin Nurs, 8(2), 150-158

Methods	**Study design**: Validation study **Location**: Sweden **Setting**: Hospital **Sample**: Convenience **Statistical test**: Correlation test - Kendall rank-ordr correllation coefficient T Interrater agreement between the nurses and dental hygienist - Cohen's Kappa * takes into account the frequencies of exact agreements and agreements by chance Internal consistency - Cronbach's alpha (Cronbach, 1951)
Participants	**Subjects assessed**: 16 patients Mean age was 60.7 years; Age range 25th-75th percentiles 53-71; Male 13; Female 3 Diagnoses: Acute Leukaemia, Non-Hodgkin's Lymphoma, Hodgkin's disease, Myeloma **People with ID included:** Not specified
Interventions	**Intervention (Non-dental assessors):** Registered Nurses **Control (Gold standard):** Dental hygienist
Outcomes	Outcomes: **Name of tool:** Oral Assessment Guide (OAG) - Revised 1999 **Purpose of the index:** To measure oral changes secondary to stomatotoxic chemotherapy or radiation therapy **Items:** 1) Voice 2) Swallow 3) Lips 4) Tongue + mucous membrane 5) Saliva

	6) Gingiva 7) Teeth 8) Denture bearing surfaces score 1 to 3 1 - normal 2 & 3 – changes, *3 = severe alteration *Revised in Andersson 1999 **Original developer:** Eilers, J., Berger, A. M., & Petersen, M. C. (1988). Development, testing, and application of the oral assessment guide. Oncol Nurs Forum, 15(3), 325-330. **Content validity:** Not evaluated in this study – established in Eilers et al 1988. **Concurrent validity:** Not reported **Inter-rater reliability:** Cohen's Kappa agreements: *Early assessment:* 0.81-1.00 Perfect or excellent – 0.61-0.80 Substantial - Saliva, Swallow 0.41-0.60 Moderate - Voice, Gums 0.21-0.40 Fair - Teeth/dentures, Lips, Mucous membranes <0.20 Poor – x *Late assessment:* Substantial - Saliva, Voice Moderate - Swallow, Teeth/dentures, Mucous membranes Fair - Lips, Gums Poor – x **Test-retest reliability:** Not reported **Time taken to carry out assessment:** Not reported **Cost analyses:** Not reported **Feedbacks from non-dental assessors:** Not reported **Feedbacks from individuals examined:** Not reported **Other assessment:** Not reported **Training:** 2 hours training on the assessment of the oral cavity. **Calibration:** None; Inter- & intra-rater reliability as part of study. Pilot study/phase: None.

Study:

Andersson, P., Hallberg, I. R., & Renvert, S. (2002). Inter-rater reliability of an oral assessment guide for elderly patients residing in a rehabilitation ward. Spec Care Dentist, 22(5), 181-186.

Methods	**Study design:** Validation studies **Location:** Sweden **Setting:** rehabilitation ward **Sample:** Convenience **Statistical test:** Inter-rater agreement between RN and DH 1) Percentage agreement 2) Cohen's Kappa coefficient - weighted kappa (except for voice and gums) *Agreements by chance were used for Voice and Gums - because no patient was assessed as having score of 3. 3) Investigations of differences between oral assessments performed by the DH and RN using the number and mean value
Participants	**Subject assessed:** 133 patients Mean age 81 years Age range 61 - 96 years Male 48; Female 85 **People with ID included:** Not specified
Interventions	**Intervention (Non-dental assessors):** Registered Nurses; **Control (Gold standard):** Dental hygienist
Outcomes	Outcomes: **Name of tool:** Revised Oral Assessment Guide (ROAG) 2002 **Purpose of the index:** To measure oral changes in geriatric population **Items:** 1) Voice 2) Lips 3) Mucous membranes 4) Tongue 5) Gums 6) Teeth/dentures 7) Saliva 8) Swallowing Lips: + Assessment of angular chelitis Mucous membranes: + Assessment of dryness (Henricsson, 1994) Teeth/dentures: + Assessment of decayed teeth Gums: (minus) White coating **Original developer:**

	Eilers, J., Berger, A. M., & Petersen, M. C. (1988). Development, testing, and application of the oral assessment guide. Oncol Nurs Forum, 15(3), 325-330. **Clinical-assessment:** As per OAG. **Content validity:** Content validity was re-carried out; a review of the literature & suggestions by expert panel **Concurrent validity:** Not reported **Inter-rater reliability:** Percentage agreements: 81-100% = Voice, Swallow, Lips, Mucous membrane, Gums, Saliva 61-80% = Tongue 41-60% = Teeth/dentures 21-40% = x <20% = x Cohen's Kappa agreements: 0.81-1.00 Perfect or excellent - Swallow 0.61-0.80 Substantial - Gums, Lips 0.41-0.60 Moderate - Voice, Mucous membranes, Tongue, Teeth/dentures, Saliva 0.21-0.40 Slight – x <0.20 Poor – x Investigations of differences between oral assessments: performed by the DH and RN using the number and mean value Number of oral assessments: RN: Better oral score > worse oral score - 60 assessments: Mucous membranes, Gums, Teeth/dentures, Saliva RN: Worse oral score > better oral score - 36 assessments: Voice, Lips, Tongue, Swallow **Intra-rater reliability:** Cohen's Kappa agreements: 0.81-1.00 Perfect /excellent – Voice, Lips, Swallow, Buccal Mucosa, Tongue, 0.61-0.80 Substantial – Gums 0.41-0.60 Moderate – Saliva (Mirror), Saliva (gloved finger) 0.21-0.40 Fair – Teeth/dentures <0.20 Poor – x **Time taken to carry out assessment:** Not reported **Cost analyses:** Not reported **Feedbacks from non-dental assessors:** Not reported **Feedbacks from individuals examined:** Not reported **Other assessment:**

	Training: Carried out by dental hygienist (DH); 3 hours training, 3 days before the start of study; a lecture of oral health problems; Oral assessments performed on five patients by both RN and DH. **Calibration**: None; Inter- & intra-rater reliability as part of study. Pilot study/phase: None.

Study: Ribeiro, M. T., Ferreira, R. C., Vargas, A. M.,& e Ferreira, E. F. (2014). Validity and reproducibility of the revised oral assessment guide applied by community health workers. Gerodontology, 31(2), 101-110. doi:10.1111/ger.12014

Methods	**Study design:** Validation study **Location:** Portugal **Setting:** Community settings **Sample:** Randomly selected from area covered by the CHWs **Statistical test:** Intra-rater agreement -simple kappa coefficient, -or weighted kappa for categories with 2 or 3 level responses *For categories with only codes 1 or 2, the value of the simple K is presented; for the categories in which code 3 has non-zero values, the table shows the value of Kw. The Kw values in the table are classified according to codes. Validity test: -sensitivity, specificity -accuracy The categories with three levels of responses were dichotomised (score 1 = healthy; scores 2 and 3 = changed) for the construction of 2 x 2 contingency tables. calculated 95% confidence intervals for sensitivity, specificity and accuracy.
Participants	**Subject assessed:** 116 patients Mean age was 70.6years Age range: 60-94 years Male 44, Female 66 **People with ID included:** Not specified
Interventions	**Intervention (Non-dental assessors):** Community health workers (CHWs) **Control (Gold standard):** Dentist
Outcomes	Outcomes:

	Name of tool: Revised oral assessment guide (ROAG) **Purpose of the index:** A tool for pre-diagnosis of oral health conditions in the elderly population. **Items:** 1) Voice 2) Lips 3) Mucous membranes 4) Tongue 5) Gums 6) Teeth/dentures 7) Saliva 8) Swallowing Saliva: - Sliding mouth mirror - a gloved finger against the buccal mucosa A scale of 1-3; according to degree of impairment 1- Normal, 2-Minor changes, 3-Severe alterations **Conduct of examination:** Examinations were performed at home, with the use of disposable medical gloves and mirrors **Original developer:** Eilers, J., Berger, A. M., & Petersen, M. C. (1988). Development, testing, and application of the oral assessment guide. Oncol Nurs Forum, 15(3), 325-330. **Content validity:** Not reported **Concurrent validity:** Not reported **Inter-rater reliability:** On Sample B of 58 CHW and dentist independently performed oral examinations using OAG **Sensitivity, Specificity & Accuracy:** Voice – High (H) sensitivity, specificity, accuracy Lips – Low (L) sensitivity, H specificity, H accuracy Saliva (Mirror) - L sensitivity, H specificity, H accuracy Saliva (Gloved finger) - L sensitivity, H specificity, H accuracy Swallow - H sensitivity, H specificity, H accuracy Mucosa - L sensitivity, M specificity, M accuracy Tongue - M sensitivity, M specificity, M accuracy Gums - M sensitivity, H specificity, M accuracy Teeth/dentures - M sensitivity, M specificity, M accuracy Low sensitivity – lips saliva mucosa **Intra-rater & Test-retest reliability:** Intra-rater reproducibility On Sample A of 58, CHW examines 5-6 elderly individuals, twice with an interval of 7 days between the tests. Intra-rater reproducibility assessment: Very good >0.80 - Voice, Lips, Swallow, Buccal Mucosa, Tongue,

	Good 0.61-0.80- Gums Moderate 0.41-0.60 - Saliva (Mirror), Saliva (gloved finger) Fair 0.21-0.40 - Teeth/dentures Poor <0.21 - **Time taken to carry out assessment:** 11 minutes **Cost analyses:** Not reported **Feedbacks from non-dental assessors:** Not reported **Feedbacks from individuals examined:** Not reported Other assessment: **Training**: An illustrated teaching manual was produced, detailing different oral health conditions likely to be encountered in the elderly; with input from experts in cariology, periodontology, stomatology, prosthesis and speech. Photographs of the oral structures in normal condition, slightly altered or severely altered were included. For voice, audio files of normal, slightly or severely altered voice were selected. Training manual was recorded on compact disc (CD). 10 CHWs were included in the full training. 4-hour training (with discussion). 1 week later, another 1-hour practical training until consensual diagnosis was achieved. **Calibration**: as part of training. **Pilot study**: CHWs performed assessments on 5 seniors independently by the researcher assessed the 5 seniors. Sensitivity values were calculated & were used to calculate sample size.

Study: Kayser-Jones, J., Bird, W. F., Paul, S. M., Long, L., & Schell, E. S. (1995). An instrument to assess the oral health status of nursing home residents. Gerontologist, 35(6), 814-824.

Methods	**Study design:** Index development, initial validation. **Location:** Australia **Setting:** Nursing home **Sample:** 1 facility, convenience sample, 140 invited, 40 refused **Statistical test:** INTERRATER RELIABILITY -between the dentist and the nursing home staff examiners -between the nursing home staff examiners themselves 1) Total BOHSE Score Test: -Correlation coefficients -Analysis of variance (ANOVA) - performed to determine

	if there was a difference in the magnitude of the total BOHSE score among the four categories of examiners. -Post hoc Scheffe comparisons 2)Item level between the dentist and the nursing home staff examiners -Percent agreement -Cohen's kappa values TEST RETEST RELIABILITY -between examination Time 1 and time 2 1)Total BOHSE Score -Coefficient correlations -Paired t-tests 2)Item level -Percent agreement -Cohen's kappa values
Participants	**Subject assessed:** 100 Proprietary nursing home residents Mean age was 82 years; Age range between 50-106 years old 9 participants : Age 50 to <65 55% : 80 and older Length of stay: 1 month - 11 years Mean length of stay: 18 months Functional status; Activities of Daily Living Scale (Katz, Ford, Moskowitz, Jackson, & Jaffee, 1963) 11% of the residents had no or mild functional impairment, 33% were moderately impaired, 56% were severely impaired. Cognitive status; Kahn and Goldfarb mental status questionnaire (Kahn, Goldfarb, Pollack, & Peck, 1960) 18% of the residents had no or mild cognitive impairment, 34% were moderately impaired, 48% were severely impaired. **People with ID included:** Not specified
Interventions	**Intervention (Non-dental assessors):** 2 registered nurses [RNs], 2 licensed vocational nurses [LVNs], 2 certified nursing assistants [CNAs] **Control (Gold standard):** Dentist Details:
Outcomes	Outcomes: **Name of tool:** Brief Oral Health Status Examination (BOHSE) **Purpose of the index:** 1) Oral health assessment tool that reflects the status of oral health and function 2) Can be administered by Nursing staff

	3) For Nursing home residents **Items:** 1) Lymph nodes 2) Lips; 3) Tongue; 4) Tissue inside cheek, floor, and roof of mouth; 5) Gums between teeth and/or under artificial teeth; 6) Saliva; 7) Condition of natural teeth; 8) Condition of artificial teeth; 9) Pairs of teeth in chewing position [natural or artificial], 10) Oral cleanliness Each item score: 3 descriptors: 3-point scale (0, 1, 2); 0 indicating the healthy end and 2 the unhealthy end of the scale. Final score: The sum of the scores from the 10 categories and ranged from 0 (very healthy) to 20 (very unhealthy). **Conduct of examination:** The residents were usually examined in their rooms, sitting either on the bed or in a chair. Occasionally, those who refused to return to their room were examined in the lounge or corridor. Small compartmentalized plastic baskets, containing the necessary equipment (e.g., tongue blades, a hand-held light, gauze squares, disposable gloves), were provided for the examiners. **Content validity:** 1) Review of dental and nursing literatures describing previous instruments 2) Critique by 6 faculties in the School of Dentistry; suggestions on items to be included and descriptors **Concurrent validity:** Could not be established due to the lack of a comparable oral health assessment tool. Dentate status: natural teeth pairs of teeth in chewing edentulous dentures in the mouth **Inter-rater reliability:** 1) Interrater reliability: -between the dentist and the nursing home staff examiners; -between the nursing home staff examiners themselves Correlation coefficients: *Total BOHSE score* All positive, & statistically significant (***p<0.001). DDS-RN: 0.63*** DDS-LVN: 0.68*** (Highest) DDS-CAN: 0.47*** (Lowest) RN-LVN: 0.56*** RN-CNA: 0.40*** LVN-CNA: 0.65*** ANOVA: significant ($F_{3,297} = 9.97$, $p < .001$) Post hoc Scheffe:

	the mean total scores for RNs were significantly greater than those of the dentist and the CNAs ($p < .001$). Percent agreement (%Ag): >80%: Lymph nodes, Tongue, Saliva, Condition of natural teeth, Condition of artificial teeth, Pairs of teeth in chewing position [natural or artificial] <80%: Tissue inside cheek, floor, and roof of mouth; Lips, Gums between teeth and/or under artificial teeth, Oral cleanliness Lymph nodes: 92.0,98.0 Pairs of teeth in chewing position: 88.7,88.8 Artificial teeth: 75.4,86.0 Tissues: 75.3,79.6 Natural teeth: 73.2,81.6 Tongue: 72.6,97.0 Lips: 70.0,74.2 Gums: 68.4,69.1 Saliva: 66.7,82.0 Oral cleanliness: 50.5,54.6 Cohen's Kappa agreement: Perfect or excellent - Pairs of teeth in chewing position [natural or artificial] Substantial - Condition of natural teeth, Condition of artificial teeth Moderate - Lymph nodes, Tongue, Gums, Saliva Slight – Lips, Oral cleanliness; Tissue inside cheek, floor, and roof of mouth Poor - x Pairs of teeth in chewing position: 0.81***,0.82*** Artificial teeth: 0.54***,0.74*** Natural teeth: 0.38***,0.63*** Gums: 0.34***,0.45*** Lips: 0.26*,0.32** Tongue: 0.25*,0.44*** Oral cleanliness: 0.24***,0.27*** Saliva: 0.12,0.49*** Tissues: 0.09,0.26 Lymph nodes: -0.02,0.49*** *p<0.05, **p<0.01, ***p<0.005 **Intra-rater, Test-retest reliability:** 2) Test Retest Reliability: dentist and each staff member repeated the examination on one-third of the subjects within 1-2 days For Total BOSE scores: Correlations (r-value): high, close to or above the 0.80 level 0.81 & above – DDS 0.83, RN 0.88, <0.80 – LVN 0.79, CNA 0.79 All were statistically significant (p<0.001) Paired t-tests: No difference in the magnitude of the total BOHSE scores between

	Time 1 and time 2 for each category of examiner. No item level intra-rater agreement was reported **Time taken to carry out assessment:** Length of time to complete examination 5 to 20 minutes, mean length is for the dentist was 5.6 minutes; for the RNs, LVNS, and CNAs, the exam time was 7.4, 7.9, and 8.7 minutes respectively. **Cost analyses:** Not reported **Feedbacks from non-dental assessors:** Not reported **Feedbacks from individuals examined**: Not reported **Other assessment:** Not reported **Qualitative:** Examination process, examiners, residents, instruments, uncooperative patients, strategies used by nursing staff to gain cooperation, referral pathway, problems encountered. **Training**: 2 hours training. A lecture on the purpose of study, overview of oral anatomy, discussion of oral and dental diseases commonly found among the elderly, review of BOHSE instruments, illustrations of health and pathological conditions, on how to score for each variable Examination on resident using BOHSE, demonstration by dentist-examiner, followed by repeat examination under supervision of dentist-examiner. **Calibration**: Research team dentist calibration dentist-examiner on the use of the BOHSE instrument by examining 5 nursing home residents. **Pilot study**: None.

Study: Chalmers, J. M., King, P. L., Spencer, A. J., Wright, F. A., & Carter, K. D. (2005). The oral health assessment tool--validity and reliability. Aust Dent J, 50(3), 191-199.

Methods	**Study design:** Index development; Validation **Location:** Australia **Setting:** Residential care facilities **Sample:** A convenience sample of the 50 highest-ranked facilities from South Australia, New South Wales and Victoria, was selected, 23 individual facilities were approached to participate, 23 facilities participated, 2 refused to continue participation, 21 residential care facilities completed the project. **Statistical test:** Reliability

	Individual categories: Percent agreement Cohen's Kappa Statistic Total Score: Intraclass correlation Concurrent validity Percent agreement Pearson correlation significance level of p<0.05
Participants	**Subject assessed:** 455 residents, 21 Australian residential care facilities Mean age of the 455 residents who completed all three phases was 82.1 years, 56.5% had a diagnosed dementia, 88.9% were Resident Classification Scale categories 1-4 (most dependent). **People with ID included:** Not specified
Interventions	**Intervention (Non-dental assessors):** Personal Care Attendants, with some Registered Nurses, Enrolled Nurses, and Nurse Assistants; **Control (Gold standard):** one calibrated qualified dentist (JC) Details:
Outcomes	Outcomes: **Name of tool:** Oral Health Assessment Tool (OHAT) **Purpose of the index:** 1) As a comprehensive dental assessment screening; 2) To be used by non-dental; 3) For those in residential care settings with cognitively impaired residents **Items:** 1) Lips 2) Tongue 3) Gums and tissues 4) Saliva 5) Natural teeth 6) Oral cleanliness 7) Dental Pain 8) Referral to dentist A score of 0=healthy, 1=oral changes, or 2=unhealthy was given in each of the assessment categories, and a score over the eight categories was summed to give a total score. **Conduct of examination:** As per BOHSE; The residents were usually examined in their rooms, sitting either on the bed or in a chair. Occasionally, those who refused to return to their room were examined in the lounge or corridor. Small compartmentalized plastic baskets, containing the necessary equipment (e.g., tongue blades, a hand-held light, gauze squares, disposable gloves), were provided for the examiners. **Content validity:**

	1) Systematic review of literature 2) By consultation during the piloting stage with numerous peers in geriatric dentistry, dementia care, and residential aged care including dentists, registered nurses, directors of nursing, dental hygienists, and personal care attendants in both Australia and the USA. **Concurrent validity:** Comprehensive oral epidemiological dental examinations on 21 participants by calibrated qualified dentist JC; Examining dental pain and behavioural problems, oral mucosal lesions, denture status, tooth status and plaque accumulation using standardized assessments and indices. Oral cleanliness category: Plaque Index (Silness and Loe – this was also extended to dentures); Saliva category: a clinical evaluation of dry mouth; Lips, tongue, gums and tissues categories: the presence of oral lesions (WHO); Dentures category: denture assessment (Rise)36; Natural teeth category: tooth status (NIDR); Dental pain/behaviour category: self-reported pain and a list of problems with oral hygiene care from The Adelaide Dental Study of Nursing Homes Complete agreement: Lips Significant, high correlation, high percent agreements: Natural teeth, dentures & tongue. Significant, lower correlation: Gums. Non-significant, low correlations, low percent agreement: Saliva, Oral cleanliness, dental pain Plaque accumulation >> than those in OHAT **Inter-rater reliability:** Using duplicate assessments on randomly selected residents. It was carried out at the 2nd data collection time (3-month interval). Inter-carer reliability; each resident examined by a second carer. Percent agreement (%Ag): Referral to dentist 96.8 Dental pain 92.6 Saliva 86.9 Gums and tissues 86.1 Dentures 80.9 Tongue 80.4 Lips 78.1 Natural teeth 77.9 Oral cleanliness 72.6 Cohen's Kappa agreement: 0.81-1.00 Perfect or excellent - x 0.61-0.80 Substantial – Natural teeth, Dentures, Dental Pain 0.41-0.60 Moderate – Lips, Tongue, Gums and tissues, Saliva, Oral cleanliness, Referral to dentist 0.21-0.40 Slight – x 0.00-0.20 Poor - x Natural teeth 0.66*

	Dentures 0.65* Dental pain 0.62* Gums and tissues 0.57* Oral cleanliness 0.54* Tongue 0.53* Saliva 0.48* Lips 0.48* Referral to dentist 0.47* **Intra-rater, Test-retest reliability:** Intra-carer reliability: re-examining a group of same residents, within 48 hours. INDIVIDUAL Percent agreements (%Ag): Highest: dental pain, referral to dentist Lowest: oral cleanliness Referral to dentist 96.6 Dental pain 93.9 Gums and tissues 90.5 Saliva 88.8 Tongue 84.6 Dentures 83.7 Natural teeth 80.6 Lips 79.8 Oral cleanliness 74.4 Cohen's Kappa agreements: 0.61-0.80 Substantial: other 0.41-0.60 Moderate: Lips, Saliva, Oral cleanliness, Referral to dentist Gums and tissues 0.71* Natural teeth 0.70* Dentures 0.70* Dental pain 0.66* Tongue 0.61* Oral cleanliness 0.56* Lips 0.52* Saliva 0.51* Referral to dentist 0.51* *P<0.001 TOTAL OHAT SCORES Correlation coefficient 0.78 All were statistically significant **Time taken to carry out assessment:** Mean reported time taken to complete the Oral Health Assessment Tool was 7.8 minutes (minimum time taken = 1 minute; maximum time taken = 30 minutes) (SD=5.6). **Cost analyses:** Not reported

	Feedbacks from non-dental assessors: Not reported **Feedbacks from individuals examined:** Not reported **Other assessment:** **Focus groups** Qualitative focus groups held with carers at each residential care facility at baseline, three months and six-months using key questions to facilitate discussion. **Questionnaires** Questionnaires: on the use of OHAT, average time taken, comments concerning any problems with OHAT. 12 questions with a four-point Likert response scale from strongly disagree to strongly agree. **Training**: A focus group and a 3-hour training; programme was completed with carers at each facility. Training was carried out as per BOHSE. Focus groups were conducted at baseline, 3-months and 6-months. **Calibration**: As per BOHSE. **Pilot study**: None.

Study: Saintrain, M. V., & Vieira, A. P. (2012). Application of the community oral health indicator by non-dental personnel and its contribution to oral healthcare. PLoS One, 7(7), e39733. doi:10.1371/journal.pone.0039733

Methods	**Study design:** Validation **Location:** Brazil **Setting:** Community setting **Sample:** convenience sample **Statistical test:** PART 1 - COHI against DMF-T, by DS1 and DS2 Continuous - Number of teeth, Number of residual root Test used: Weighted kappa, spearman correlation Categorical - Dental cavities (Ordinal) Test used: kappa, chi square test PART 2 - CHA against Dentist; on COHI Continuous - Number of teeth, Number of residual root Test used: Weighted Cohen's kappa Categorical data - Dental cavities, Tartar, Inflammed gums, Soft tissue injury Test used: Kappa, Sensitivity, Specificity
Participants	**Subject assessed:** 60 residents of the city of Guaiu´ba, Brazil Mean age of 60 residents was 39.3 (SD 22.10); Range of age was 6 to 87 years;

	37 (62.2%) were female. **People with ID included:** Not specified
Interventions	**Intervention (Non-dental assessors):** Community Health Agents (CHA); a person from the community, with high school degree, who is properly trained to be the link between the community and the Health Care Unit **Control (Gold standard):** 2 qualified dentists
Outcomes	Outcomes: **Name of the tool:** Community Oral Health Indicator (COHI) **Purpose of the tool:** 1) Check masticatory capacity 2) Need for curative treatment 3) Use and need of dental prosthesis **Items of the tool:** 1) number of teeth 2) No dental cavity 3)Tartar 4) Gingival inflammation 5) One or two dental cavities 6) Three or more dental cavities 7) Residual root 8) Soft tissue injury 9) Soft tissue injury and localisation: lesions and/or wound, red lesion, white lesion, blisters, other aggravation base of the mouth, lips, cheek, root of the mouth, tongue, other places 10)needs prosthesis upper total, upper partial, lower total, lower partial 11)Owns prosthesis upper total, upper partial, lower total, lower partial 12) Owns a toothbrush 13) Use fluoridated toothpaste 14) Have been to a dentist in the last year 15) if yes, Dental emergency or regular check-ups 1) Discrete; Others) Yes or No **Conduct of examination:** The volunteers were sitting in dental chairs under natural light. The survey was conducted with the help of a wooden spatula (tongue depressor). **Content validity:** Carried out by DS1 and DS2. Visible cavities: DMF-T assessment. Concurrent validity - comparing results using the COHI and DMFT/dmft index by dentists, Comparison between COHI and DMF-T; by Dentist Continuous variables: Number of teeth & residual roots Weighted Kappa & Spearman correlation tests: Strong agreement (>0.9)

	Categorical: dental cavities, Gingival inflammation, Soft tissue injury, Dental prosthesis kappa & chi square tests: very Significant values **Inter-rater reliability**: Comparing the findings of dentists and CHA using the COHI. Cohen's Kappa agreements: 0.81-1.00 Perfect or excellent - Number of teeth & residual roots, Dental prosthesis 0.61-0.80 Substantial – Soft tissue injury, Gingival inflammation, Presence of tartar 0.41-0.60 Moderate – Dental cavities 0.21-0.40 Slight – x 0.00-0.20 Poor – x Dental prosthesis Use prosthesis: total upper kappa = 0.95 (p,0.001) Use prosthesis: total lower kappa = 0.88 (p,0.001) Use prosthesis: partial upper kappa = 0.82 (p,0.001) Need prosthesis: total upper kappa = 0.88 (p,0.001) Need prosthesis: total lower kappa = 0.94 (p,0.001) Need prosthesis: partial upper kappa = 0.86 (p,0.001) Need prosthesis: partial lower kappa = 0.95 (p,0.001) Dental cavities 1 or 2 cavities Kappa = 0.51 (p,0.001) 3 or more cavities Kappa = 0.52 (p,0.001) Spearman's correlation: >80%: Number of teeth & residual roots <80%: x Sensitivity: >80.0% - Dental prosthesis <80.0% - Soft tissue injury, <0.60: Dental cavities, Gingival inflammation, Presence of tartar Specificity: >80.0% – All items Dental prosthesis Use prosthesis: total upper 92.3 100 Use prosthesis: total lower 80 100 Use prosthesis: partial upper 83.3 98.2 Need prosthesis: total upper 90 98 Need prosthesis: total lower 100 98 Need prosthesis: partial upper 92.9 95.7 Need prosthesis: partial lower 92.9 93.9 Dental cavities 1 or 2 cavities 68.4 83.3 3 or more cavities 63.6 87.2

	Presence of tartar 88.4 88.6 Dental prosthesis: High sensitivity, high specificity Soft tissue injury: sensitivity, high specificity Dental cavities: Low (68.4, 63.5) sensitivity, high specificity Gingival inflammation: High sensitivity, high specificity Presence of tartar: High sensitivity, high specificity **Intra-rater reliability:** Not reported **Test-retest reliability:** Not reported **Time taken to carry out assessment:** Not reported **Cost analyses:** Not reported **Feedbacks from non-dental assessors:** Not reported **Feedbacks from individuals examined:** Not reported **Other assessment:** **Training**: Slides show, Introduction to COHI; photos with different diseases of the oral cavity were used to recognize healthy teeth, teeth with dental cavities, use and need of prosthesis and soft tissue injuries, including those arising from the use of a maladaptive prostheses, candidiasis and periodontal diseases. Then, the examiners (dentists separated from the CHA) got the chance to practice on patients, and discussion on conflicting findings until consensus was reached. **Calibration**: Following WHO guidelines; each CHA or dentist examine at least 20 individuals from the community, using COHI. Intra- and inter-rater kappa values were assessed. If kappa value was below 0.8, calibration process repeated with another 10 subjects from community. Dentist-examiner was also calibrated against researcher dentist-examiner, on the dental assessment. **Pilot study**: None.

Study: Scott, S. E., Rizvi, K., Grunfeld, E. A., & McGurk, M. (2010).
Pilot study to estimate the accuracy of mouth self-examination in an at-risk group.
Head Neck, 32(10), 1393-1401. doi:10.1002/hed.21341

Methods	**Study design:** Validation - accuracy **Location:** United Kingdom **Setting:** General dental practitioner

	Sample: Convenience sample; from a general practitioner's list in South East London, UK. Patients who were at risk of oral cancer (aged 45 years or older and who smoked). **Statistical test:** Accuracy: sensitivity, specificity, Positive predictive value, Negative predictive value
Participants	**Subject assessed:** 53 patients Mean age 54 years (SD 5.9 years) Age range 45 – 64 years Male 36; Female 17 **People with ID included:** Not specified
Interventions	**Intervention (Non-dental assessors):** Patients themselves **Control (Gold standard):** Dentist
Outcomes	Outcomes: **Name of the tool:** Mouth Self-Examination (MSE) **Original developer:** Glass RT, Abla M, Wheatley J. Teaching self-examination of the head and neck: another aspect of preventive dentistry. J Am Dent Assoc 1975;90:1265–1268. **Purpose of the tool:** To screen potentially malignant symptoms & oral cancers **Items:** 1)Lips and gums 2)Inside cheeks 3)Tongue 4)Roof of your mouth 5)Under the tongue Red patches, White patches, Ulcers, Lumps/swellings Presence / Absence **Conduct of examination:** Participants were asked to read the leaflet carefully and follow the instructions to check their own mouth for any ulcers, white or red patches, or lumps/swellings. Intra-oral mirrors were not used. The dentist remained in the room but did not assist the participant in conducting the MSE.

	Content validity: Not reported **Concurrent validity:** No dental assessment used (e.g. Conventional oral examination by dentist, oral cancer specialist) **Inter-rater reliability:** Compare MSE scores by dentists and participants: Accuracy: sensitivity, specificity, Positive predictive value, Negative predictive value **Accuracy:** Sensitivity - 33% Specificity - 54% Positive predictive value - 17% Negative predictive value - 73% **Intra-rater reliability:** Not reported **Test-retest reliability:** Not reported **Time taken to carry out assessment:** Not reported **Cost analyses:** Not reported **Feedbacks from non-dental assessors:** Not reported **Feedbacks from individuals examined:** Not reported **Other assessment:** **Questionnaire** Self-report questionnaire on: - Presence and location of potentially malignant lesions - Their awareness of the lesion prior to MSE - Sociodemographic details - Health related behaviour Rate how difficult they found the MSE Measurement of alcohol intake **Training**: Participants were provided with a leaflet on ‘‘How to spot mouth cancer early”. The leaflet gave details on oral cancer, risk factors, symptoms, stepwise instructions, and illustrations of MSE (Figure 1 for the section relating to MSE), and information on when and how to seek help for potentially malignant oral lesions. **Calibration**: None; Inter- & intra-rater reliability as part of study. **Pilot study**: No further information given.

DISCUSSION

Summary of evidence

Population group:
None has been validated in population with ID.

Non-dentists:
Nurses, carers and community health workers.

Construction and content validation:
Systematic review and consultation with panel of experts were conducted for content validation. No other contemporary approach was used. Modifications of the original index were made to fit the purpose of each tool.

Concurrent validity:
None of the previous indices used by non-dental assessors has reported on the adequacy of concurrent validity in all of the categories. Non-significant, low correlations, low percent agreement were noted for Saliva, Oral cleanliness, dental pain. The remaining validation studies did not report concurrent validity in their research (Kayser-Jones et al., 1995, Andersson et al., 2002).

Inter-rater reliability:
Gum, soft tissues, oral cleanliness and saliva were found to have lower values of inter-rater agreement. None of the values were below 0.41.

Intra-rater reliability or test-retest reliability:
Oral cleanliness, Lips, saliva and referral to dentist were found to have lower intra-rater or test-retest reliability agreement, however, none of the values were below 0.51.

Time taken:

Cost analyses:
None of the studies carried out cost analysis as part of the initial validation.

Feedbacks from non-dental assessors:
Only 1 study reported feedback from non-dental assessors using 12 questions with a four-point Likert response scale from strongly disagree to strongly agree.

Limitations

Study level:
One database only; other assessment tools may not be included.

Outcome level:
Different statistical tests were used, hence comparison cannot be done on all items.

Conclusions

A limited number of existing tools had been developed and validated for use by non-dental personnel. None of them had been tested in population with ID. Potential items can be adopted in developing a new tool with possible modifications to use the specific purpose of the new tool.

FUNDING

As part of the D. Ch. Dent. Research budget.

APPENDIX XXX. ODNF Index construction: Result of CVR from eight (8) raters

Table 9.15 ODNF Index construction: Result of CVR from eight (8) raters

Name of indices	List of potential items (with description for non-normal)	Content areas for the domain identified for ODNF																					
		Soft tissue injuries & disorders	Periodontal diseases	Oral cancer	Dental caries	Toothwear	Dry mouth	Sialorrhea	Dysphagia	Pain	Urgent referral	Fillings	Extraction	Periodontal debridement	New/reline/ remake denture	Denture adjunct (adhesive)	Orthodontic treatment		Cannot wear denture	Swallowing	Salivary function	Speech	Esthetics, social element
OHAT	Gums & tissues; dry, shiny, rough, red, swollen, one ulcer/sore spot under dentures; swollen, bleeding, ulcers, white/red patches, generalised redness under dentures	0.667	0.667							0.333			-0.667	0.333									
OHAT	Saliva; dry, sticky tissues, little saliva present, resident thinks they have a dry mouth, tissues parched and red, very little or no saliva, saliva is thick, resident thinks they have a dry mouth																				0.667		

Name of indices	List of potential items (with description for non-normal)	Content areas for the domain identified for ODNF																				
		Soft tissue injuries & disorders	Periodontal diseases	Oral cancer	Dental caries	Toothwear	Dry mouth	Sialorrhea	Dysphagia	Pain	Urgent referral	Fillings	Extraction	Periodontal debridement	New/reline/ remake denture	Denture adjunct (adhesive)	Orthodontic treatment		Cannot wear denture	Swallowing	Salivary function	Speech	Esthetics, social element
OHAT	Natural teeth; 1-3 dcayed or broken, roots or very worn down teeth; 4+ decayed or broken teeth/roots or very worn down teeth, or less than 4 teeth					0.333						0.667	0.667										0.667
OHAT	Dentures; broken area/tooth or dentures, only work for 1-2 hrs daily, or dentures not named, loosed; more than 1 broken area/tooth, denture missing or not worn, loose and needs denture adhesive, or not named.														1.000	1.000			1.000				1.000

Name of indices	List of potential items (with description for non-normal)	Content areas for the domain identified for ODNF																				
		Soft tissue injuries & disorders	Periodontal diseases	Oral cancer	Dental caries	Toothwear	Dry mouth	Sialorrhea	Dysphagia	Pain	Urgent referral	Fillings	Extraction	Periodontal debridement	New/reline/ remake denture	Denture adjunct (adhesive)	Orthodontic treatment		Cannot wear denture	Swallowing	Salivary function	Speech	Esthetics, social element
OHAT	Oral cleanliness; food particles/tartar/plaque in one of two places in mouth or on small area of dentures or halitosis (bad breath); food particiles/tartar/plaque in most places in mouth, or on most dentures or sever halitosis (bad breath)		1.000											1.000								0.333

Name of indices	List of potential items (with description for non-normal)	Content areas for the domain identified for ODNF																						
		Soft tissue injuries & disorders	Periodontal diseases	Oral cancer	Dental caries	Toothwear	Dry mouth	Sialorrhea	Dysphagia	Pain	Urgent referral	Fillings	Extraction	Periodontal debridement	New/reline/ remake denture	Denture adjunct (adhesive)	Orthodontic treatment		Cannot wear denture	Swallowing	Salivary function	Speech	Esthetics, social element	
OHAT	Dental pain; verbal &/or behavioral signs of pain such as pulling at face, chewing lips, not eating, aggression; physical pain signs (swelling of cheek or gum, broken teeth, ulcers), as well as verbal &/or behavioural signs (pulling at face, not eating, aggression)									1.000	1.000								0.333				0.667	
COHI	number of teeth																	0.667					1.000	
COHI	O visible cavities																	0.333						

Name of indices	List of potential items (with description for non-normal)	Content areas for the domain identified for ODNF																					
		Soft tissue injuries & disorders	Periodontal diseases	Oral cancer	Dental caries	Toothwear	Dry mouth	Sialorrhea	Dysphagia	Pain	Urgent referral	Fillings	Extraction	Periodontal debridement	New/reline/ remake denture	Denture adjunct (adhesive)	Orthodontic treatment		Cannot wear denture	Swallowing	Salivary function	Speech	Esthetics, social element
COHI	gingival inflammtion		0.667											0.333									
COHI	1-2 visible cavities											1.000											
COHI	3 or more visible cavities											1.000											
COHI	residual root												0.000										
COHI	own/ need a set of dentures														1.000			1.000	0.333				0.667
ROAG	Gums; edematous, bleeding easily under finger pressure		0.667											0.333									

Name of indices	List of potential items (with description for non-normal)	Content areas for the domain identified for ODNF																				
		Soft tissue injuries & disorders	Periodontal diseases	Oral cancer	Dental caries	Toothwear	Dry mouth	Sialorrhea	Dysphagia	Pain	Urgent referral	Fillings	Extraction	Periodontal debridement	New/reline/ remake denture	Denture adjunct (adhesive)	Orthodontic treatment		Cannot wear denture	Swallowing	Salivary function	Speech	Esthetics, social element
ROAG	teeth/dentures; plaque or debris in local areas, decayed teeth / damaged denture, generalised pllaque or debris											0.667	0.333	0.667	0.333								0.333
ROAG	Saliva; slightly increased friction, no tendency to the mirror to adhere the mucosa, significantly increase friction, the mirror adhering of tending to adhere to the mucosa						0.333												0.333	0.333	0.333		
MDS-NH	Debris in mouth before going to bed at night													0.000									
MDS-NH	some/all natural teeth lost														0.333			0.667					1.000

Name of indices	List of potential items (with description for non-normal)	Content areas for the domain identified for ODNF																				
		Soft tissue injuries & disorders	Periodontal diseases	Oral cancer	Dental caries	Toothwear	Dry mouth	Sialorrhea	Dysphagia	Pain	Urgent referral	Fillings	Extraction	Periodontal debridement	New/reline/ remake denture	Denture adjunct (adhesive)	Orthodontic treatment		Cannot wear denture	Swallowing	Salivary function	Speech	Esthetics, social element
MDS-NH	broken, loose or carious teeth					-0.333						0.333	0.333	-0.667				0.333					0.333
MDS-NH	inflamed gums		0.667							0.000				0.333				0.000	0.000				
MDS-NH	oral pain									1.000	0.667							0.667	0.667	0.333			0.333
OHRA	Does the patient have natural teeth														0.000			0.667					0.333
OHRA	Does the patient wear dentures														0.333			0.333	0.667				0.333

Name of indices	List of potential items (with description for non-normal)	Content areas for the domain identified for ODNF																				
		Soft tissue injuries & disorders	Periodontal diseases	Oral cancer	Dental caries	Toothwear	Dry mouth	Sialorrhea	Dysphagia	Pain	Urgent referral	Fillings	Extraction	Periodontal debridement	New/reline/ remake denture	Denture adjunct (adhesive)	Orthodontic treatment		Cannot wear denture	Swallowing	Salivary function	Speech	Esthetics, social element
OHRA	does the patient have any problems (eg. Pain, discomfort, difficulty eating, decaying teeth, denture problems, ulcers, dry mouth or halitosis)?	0.667			0.667		0.333			0.667	0.667	0.333	0.333	-0.333	0.000	0.333		0.333					0.333
OHRA	is urgent dental treatment needed?										0.667												
WHO Oral toxicity scale	soreness,erythema (redness); erythema, ulcers,patient can swallow solid diet; ulcers, extensive erythema, patient cannot swallow solid diet, mucositis to extent that alimentation not possible	0.667								0.000	0.333							0.333	0.333	0.667			0.000

Name of indices	List of potential items (with description for non-normal)	Content areas for the domain identified for ODNF																					
		Soft tissue injuries & disorders	Periodontal diseases	Oral cancer	Dental caries	Toothwear	Dry mouth	Sialorrhea	Dysphagia	Pain	Urgent referral	Fillings	Extraction	Periodontal debridement	New/reline/ remake denture	Denture adjunct (adhesive)	Orthodontic treatment		Cannot wear denture	Swallowing	Salivary function	Speech	Esthetics, social element
MSE	lips and gums; red patches, white patches, ulcers, lumps / swellings	1.000	0.667	0.667						0.667	1.000								0.667				0.333
MSE	Cheeks; red patches, white patches, ulcers, lumps / swellings	1.000		1.000						0.667	1.000							0.000					
MSE	Tongue red patches, white patches, ulcers, lumps / swellings	1.000		1.000						0.667	1.000							0.333				0.667	0.333
MSE	roof of mouth red patches, white patches, ulcers, lumps / swellings	1.000		0.667						0.667	1.000							0.333	0.667	0.333		0.667	0.000
MSE	under the tongue; red patches, white patches, ulcers, lumps / swellings	1.000		1.000	1.000					0.667	1.000							0.333				0.667	0.333

APPENDIX XXXI. ODNF Index construction: selected items from CVR

Table 9.16 ODNF Index construction: selected items from CVR

Main categories	Soft tissue injuries & disorders	Periodontal diseases	Dental caries	Pain	Urgent referral	Fillings	Extraction	Periodontal debridement	Masticatory capacity (eating)	Cannot wear denture	Swallowing	Salivary function	Speech	Esthetics, social element	Original indices	Scores	How to measure
Lips and gums	X				X										**MSE**	redness and white patches; YES/NO ulcers, YES / NO lumps & swelling YES / NO	pull down lower lips and look inside lip and look at gums; repeat this on upper lip
Cheeks	X				X										**MSE**	redness and white patches; YES/NO ulcers, YES / NO lumps & swelling YES / NO	pull out right cheek look at the inside of your right cheek
Tongue	X				X								X		**MSE**	redness and white patches; YES/NO ulcers, YES / NO lumps & swelling YES / NO	sitck out tongue and look at the top surface, stick out tongue an dmove it from side to side to look at one side then the other

Main categories	Soft tissue injuries & disorders	Periodontal diseases	Dental caries	Pain	Urgent referral	Fillings	Extraction	Periodontal debridement	Masticatory capacity (eating)	Cannot wear denture	Swallowing	Salivary function	Speech	Esthetics, social element	Original indices	Scores	How to measure
Roof of mouth	X				X								X		**MSE**	redness and white patches; YES/NO ulcers, YES / NO lumps & swelling YES / NO	open mouth and tilt head back to look at the roof of your mouth
Under the tongue	X				X								X		**MSE**	redness and white patches; YES/NO ulcers, YES / NO lumps & swelling YES / NO	place the tip of the tongue on the roof of mouth and look at the underside of your tongue and the floor of mouth
Oral cleanliness		X						X							**OHAT**	clean and no food particles or tartar in mouth or dentures; food particles/tartar/plaque in 1-2 areas of the mouth or on small area of dentures or halitosis (bad breath); food particles/tartar/plaque in most areas of the mouth or on most of	observe, use light

Main categories	Soft tissue injuries & disorders	Periodontal diseases	Dental caries	Pain	Urgent referral	Fillings	Extraction	Periodontal debridement	Masticatory capacity (eating)	Cannot wear denture	Swallowing	Salivary function	Speech	Esthetics, social element	Original indices	Scores	How to measure
																dentures or sever halitosis (bad breath)	
Visible caries			X			X									**COHI**	0 visible caries; 1-2 visible caries; 3 or more visible caries	observe, use light
Dental pain				X	X										**OHAT**	no behavioural, verbal or physical signs of dental pain; are verbal &/or behavioural signs of pain such as pulling at face, chewing lips, not eating, aggression; are physical pain signs (swelling of cheek or gum, broken teeth, ulcers), as well as verbal &/or behavioural signs (pulling at face, not eating, aggression)	observe, use light
Own teeth									X					X	**COHI**		observe, use light, count

Main categories	Soft tissue injuries & disorders	Periodontal diseases	Dental caries	Pain	Urgent referral	Fillings	Extraction	Periodontal debridement	Masticatory capacity (eating)	Cannot wear denture	Swallowing	Salivary function	Speech	Esthetics, social element	Original indices	Scores	How to measure
Dentures: Condition										X				X	**OHAT**	No broken areas or teeth, dentures regularly worn, and named; 1 broken area//tooth or dentures only worn for 1-2 hrs daily, or dentures not named, or loose; more than 1 broken area/tooth, denture missing, or not worn, loose and needs denture or severe halitosis (bad breath)	observe, use light

APPENDIX XXXII. Conduct of assessment and diagnostic code and criterias for ODNF index.

Item:
Tooth count (upper)

Definition:
The number of teeth on the upper jaw

How to carry out examination:
Use pen light and dental mirror. Ask participant to open their mouth, & remove denture. Look at the upper jaw, count the number of teeth from one end to another (systematic approach). Record on the form.

Diagnostic codes & criteria:
Discrete variables – 0, 1, 2, 3, …

Other remarks:
The tooth should be considered present when any part of it is visible.
Does not need to identify primary or permanent teeth

Item:
Tooth count (lower)

Definition:
The number of teeth on the lower jaw

How to carry out examination:
Use pen light and dental mirror. Ask participant to open their mouth, & remove denture. Look at the upper jaw, count the number of teeth from one end to another (systematic approach). Record on the form.

Diagnostic codes & criteria:
Discrete variables – 0, 1, 2, 3, …

Other remarks:
The tooth should be considered present when any part of it is visible. Assessor will not need to identify primary or permanent teeth. Tooth count includes false teeth that are fixed (and patient cannot remove from the mouth) such as crown, bridges, and implant fixed prosthesis.

Item:
Wearing denture (upper)

Definition:
Upper denture is present inside the mouth during data collection.

How to carry out examination:
Use pen light and dental mirror. Ask participant to open their mouth. Look at the upper jaw. Check if the participant is wearing dentures. Record on the form.

Diagnostic codes & criteria:

Code	Category	Diagnostic criteria
0	Absent	No denture in the mouth
1	Present	Presence of denture in the mouth: Partial denture – Acrylic or cobalt chrome Complete denture

Other remarks:
Exclude those who have denture but did not wear it during the examination, or not accessible. Exclude false teeth that are fixed and cannot be removed from the mouth such as fixed partial denture (bridge).

Item:
Wearing denture (lower)

Definition:
Lower denture is present inside the mouth during data collection.

How to carry out examination:
Use pen light and dental mirror. Ask participant to open their mouth. Look at the lower jaw. Check if the participant is wearing dentures. Record on the form.

Diagnostic codes & criteria:

Code	Category	Diagnostic criteria
0	Absent	No denture in the mouth
1	Present	Presence of denture in the mouth: Partial denture – Acrylic or cobalt chrome Complete denture

Other remarks:
Exclude those who have denture but did not wear it during the examination, or not accessible. Exclude false teeth that are fixed and cannot be removed from the mouth such as fixed partial denture (bridge).

Item:
Occluding pairs

Definition:
Pattern of occlusal contacts (teeth in contact)

How to carry out examination:
Use pen light and dental mirror. Ask participant to bite down with their back teeth together. Retract right check using hand mirror, identify canine (eye tooth). Look at the teeth after canine (eye tooth); count the number of upper teeth occluding/meeting the lower teeth. Then, check on left side. Add the number of teeth contacts from right and left sides. If there is no posterior teeth in contacts, count the number of front teeth in contact. Record on the form

Diagnostic codes & criteria:

Code	Category	Diagnostic criteria
0	No occlusal contacts at all	No teeth are biting on each other.
1	1 or more posterior contacts	Total number of posterior teeth contacts is more than 1. This is in presence of anterior teeth contacts.
2	Anterior contacts only	No posterior teeth in contacts. Only front teeth are in contact.

Other remarks: n/a

Item:
Oral cleanliness

Definition:
Presence of food particles, tartar and plaque in the mouth or on dentures. Presence of bad breath (halitosis)

How to carry out examination:
Use pen light and dental mirror. Ask the patient to take out dentures/false teeth. Ask the patient to open their mouth, use dental mirror to retract the buccal cheek. Check for presence of food particles, tartar and plaque on the teeth surface. Check on the dentures too. Check for presence of bad breath and foul smell.

Diagnostic codes & criteria:

Code	Category	Diagnostic criteria
0	Clean, and no food particles or tartar in the mouth or dentures	No food particles, tartar and plaque on teeth and dentures.
1	Little food particles/tartar/plaque in the mouth or on dentures	Food particles, tartar and plaque are present on some parts (less than 1/3) of teeth and/or dentures.
2	A lot of food particles/tartar/plaque in the mouth or on dentures; or halitosis (bad breath)	Food particles, tartar and plaque are present on most or all parts (more than 1/3 or fully covered) of teeth and/or dentures. Presence of bad breath, awful/foul smell.

Other remarks:
Calculus/tartar cannot be wiped off.
If in doubt, score lower.

Item:
Soft tissue

Definition:
Presence of redness, white patches, ulcers, lumps and swelling; on either Lips, Cheeks, Tongue, Roof of the mouth, Floor of mouth.

How to carry out examination:
Use pen light and dental mirror. Ask the patient to take out dentures/false teeth. Ask the patient to open their mouth.

Lip: Pull down lower lip and look inside lip; repeat this on upper lip.
Cheek: Use dental mirror to retract right cheek, look at the inside of right cheek; repeat this on left cheek.
Tongue: Ask participant to stick out tongue and look at the top surface, then stick out tongue and move it from side to side to look at one side then the other; and curl tongue up towards back of the mouth.
Roof of the mouth: Ask participant to open mouth and tilt head back to look at the roof of mouth.
Underside of tongue and Floor of mouth: Ask participant to place the tip of the tongue on the roof of mouth, and look at the underside of tongue and the floor of mouth.
Check for redness, white patches, ulcers, lumps and swelling. Record on the form. Mark what and where on comment box.

Diagnostic codes & criteria:

Code	Category	Diagnostic criteria
0	Absent	No redness, white patches, ulcers, lumps and swelling; on Lips, Cheeks, Tongue, Roof of the mouth, Floor of mouth.
1	Present	Presence of redness, white patches, ulcers, lumps and swelling; on Lips, Cheeks, Tongue, Roof of the mouth, Floor of mouth. Torus/tori on roof of mouth and lower jaw are considered normal but to be recorded as present
	Comment	Record the type of soft tissue lesion found (redness, white patches, ulcers, lumps and swelling); or normal lumps (torus/tori). Record location where the soft tissue lesion was found (Lips, Cheeks, Tongue, Roof of the mouth, Floor of mouth).

Other remarks:
Nil

Item:
Gum condition

Definition:
The presence of gingival redness, swelling, bleeding and ulcers.

How to carry out examination:
Use pen light and dental mirror. Ask the patient to take out dentures/false teeth. Ask the patient to open their mouth, use dental mirror to retract the buccal cheek. Clean debris with gauze where necessary. Observe the appearance of gum above the teeth, in between the teeth, on the ridge where there is no teeth and on the area under dentures.

Diagnostic codes & criteria:

Code	Category	Diagnostic criteria
0	Pink, moist, soft, no bleeding	No gingival redness, swelling, bleeding and ulcers. Racial variations of normal & health gums are considered as 0.
1	Localised redness, swelling, bleeding and ulcers.on gums or under dentures	Gingival redness, swelling, bleeding and ulcers are present on some parts (less than 1/3) of the mouth.
2	Generalised redness, swelling, bleeding and ulcers on gums or under dentures	Gingival redness, swelling, bleeding and ulcers are present on most or all parts (more than 1/3 or fully covered) of the mouth

Other remarks:
Nil

Item:
Visible caries

Definition:
The presence of caries which can be detected by visual examination.

How to carry out examination:
Use pen light and dental mirror. Ask the patient to take out dentures/false teeth. Ask the patient to open their mouth, use dental mirror to retract the buccal cheek. Use gauze to clean and dry teeth surfaces if possible. Check the upper teeth from one end to another (systematic manner). Check the occlusal, buccal and lingual surfaces of teeth. Check for cavitates caries. Count the number of teeth with cavitated caries (holes, different in colour, broken down). Do the same for the lower teeth and count the total number of teeth. Record on the form.

Count the teeth with caries that can be seen. If in doubt, consider no caries.

Diagnostic codes & criteria:
Cavitated caries means:

- At least one hole on tooth.
- Different colour from tooth – usually shades of brown.
- Hole next to restoration (caries)

Code	Category	Diagnostic criteria
0	0 visible caries	No teeth with cavitated caries.
1	1 or 2 visible caries	1 or 2 teeth with cavitated caries.
2	3 or more visible caries	3 or more teeth with cavitated caries.

Other remarks:
This will exclude non-cavitated early caries lesion. This will exclude cavities/caries interproximal as there is no radiograph examination. This will not determine active or arrested caries as no probing is required.

Item:
Dental pain

Definition:
The presence of verbal, or behavioral or physical signs of pain inside the mouth.

How to carry out examination:
Verbal: First, ask participant if there is pain inside the mouth and ask for toothache. Ask participant to show where inside the mouth. If they answer yes, this is verbal sign of dental pain.
Behaviour: Ask participant or supporting person if eating is affected, if there is pain behaviours such as chewing lips, pulling at face, aggression and self-injurious behaviours.
Physical: Use pen light and dental mirror. Ask the patient to take out dentures/false teeth. Ask the patient to open their mouth, use dental mirror to retract the buccal cheek. Ask participant to show where the pain is inside their mouth. Check for swelling on the face or inside the mouth, broken teeth and ulcers).

Diagnostic codes & criteria:

Code	Category	Diagnostic criteria
0	no behavioural, verbal or physical signs of dental pain	No signs of verbal, behavioural and physical dental pain.
1	Verbal &/or behavioural signs of pain such as pulling at face, chewing lips, not eating, aggression	Participant answered yes when asked about the pain. Participant (and/or supporting person) indicated that there is pain behaviours such as refused eating or certain food, chewing lips, pulling at face, aggression and self-injurious behaviours.
2	physical pain signs (swelling of cheek or gum, broken teeth, ulcers), as well as verbal &/or behavioural signs (pulling at face, not eating, aggression)	Presence of physical signs of dental pain such as swelling on the face or inside the mouth, broken teeth and ulcers. Participant answered yes when asked about the pain. Participant (and/or supporting person) indicated that there is pain behaviours such as refused eating or certain food, chewing lips, pulling at face, aggression and self-injurious behaviours.

Other remarks:
Nil

APPENDIX XXXIII. Test-retest reliability of Dentition and CPITN assessments (gold standard assessor)

Table 9.17 Test-retest reliability of Dentition and CPITN assessments (gold standard assessor)

DENTAL ITEMS	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s
DMFT (Decayed) 0,1,2,3…	0.93	0.64*** (0.32,0.97)	0.84*** (0.64,1.00)	0.78
DMFT (Decayed)- grouped 0: 0 caries 1: 1 or 2 caries 2: 3 or more	0.96	0.82*** (0.59,1.00)	0.93*** (0.83,1.00)	x
DMFT (missing) 0,1,2,3…	0.99	0.99*** (0.98,1.00)	0.99*** (0.97,1.00)	0.99
DMFT (Filled) 0,1,2,3…	0.97	0.94*** (0.89,0.99)	0.96*** (0.92,1.00)	0.96
DMFT (Total DMFT) 0,1,2,3…	0.99	0.99*** (0.98,0.99)	0.99*** (0.98,0.99)	0.99
Total Upper teeth 0,1,2,3…	0.99	0.99*** (0.98,1.00)	0.99*** (0.99,1)	0.99
Total Lower teeth 0,1,2,3…	0.99	0.99*** (0.98,1.00)	0.99*** (0.98,1.00)	0.99
Total Teeth 0,1,2,3…	0.99	0.99*** (0.98,1.00)	0.99*** (0.99,1.00)	0.99
Total Teeth – grouped 0: 20 & more 1: Less than 20	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x
Total Missing teeth 0,1,2,3…	0.99	0.99*** (0.98,1.00)	0.99*** (0.99,1.00)	0.99

*p<0.05 **p<0.01 ***p<0.001; %Ag. – percentage agreement, r_s – Spearman's correlation
x- not calculated

APPENDIX XXXIV. Inter-rater reliability of Dentition and CPITN assessments (non-gold dental assessor against gold standard assessor)

Table 9.18 Inter-rater reliability of Dentition and CPITN assessments (non-gold dental assessor against gold standard assessor); Percentage agreement (%Ag), weighted Cohen's Kappa coefficient, Weighted Gwet's AC2 coefficient & Spearman's correlation (r_s)

ITEMS	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s
DMFT (Decayed)	0.93	0.28 (-0.04,0.61)	0.86*** (0.74,0.98)	0.46
DMFT (Decayed)- grouped	0.84	0.38** (0.11,0.64)	0.67*** (0.47,0.88)	x
DMFT (Missing)	0.99	0.96*** (0.94,0.98)	0.96*** (0.94,0.99)	0.92
DMFT (Filled)	0.98	0.89*** (0.82,0.96)	0.95*** (0.92,0.98)	0.83
DMFT (Total DMFT)	0.98	0.95*** (0.92,0.98)	0.95*** (0.92,0.97)	0.95
Total Upper teeth	0.99	0.98*** (0.96,0.99)	0.98*** (0.97,0.99)	0.97
Total Lower teeth	0.99	0.98*** (0.97,0.99)	0.98*** (0.97,0.99)	0.96
Total Teeth	0.99	0.99*** (0.98, 0.99)	0.99*** (0.98, 0.99)	0.98
Total Teeth – grouped	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x
Total Missing teeth	0.99	0.99*** (0.98, 0.99)	0.99*** (0.98,0.99)	0.98

*p<0.05 **p<0.01 ***p<0.001; highlighted – blue (below 0.61), green (increased value with Gwet's)

APPENDIX XXXV. Test-retest reliability of Dentition and CPITN assessments (non-gold dental assessor)

Table 9.19 Test-retest reliability of Dentition and CPITN assessments (non-gold dental assessor); Percentage agreement (%Ag), weighted Cohen's Kappa coefficient, Weighted Gwet's AC2 coefficient & Spearman's correlation (r_s)

DENTAL ITEMS	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s
DMFT (Decayed)	0.98	0.87*** (0.78,0.97)	0.96*** (0.92,1.00)	0.93
DMFT (Decayed)- grouped	0.97	0.87*** (0.70,1.00)	0.94*** (0.85,1.00)	x
DMFT (missing)	0.99	0.98*** (0.95, 0.99)	0.98*** (0.96, 0.99)	0.96
DMFT (Filled)	0.99	0.97*** (0.94,0.99)	0.98*** (0.96,0.99)	0.98
DMFT (Total DMFT)	0.99	0.97*** (0.95,0.99)	0.97*** (0.95,0.99)	0.98
Total Upper teeth	0.99	0.99*** (0.97,1.00)	0.99*** (0.98,1.00)	0.99
Total Lower teeth	0.99	0.98*** (0.96,1.00)	0.99*** (0.97,1.00)	0.98
Total Teeth	0.99	0.99*** (0.98,0.99)	0.99*** (0.98,0.99)	0.98
Total Teeth – grouped	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x
Total Missing teeth	0.99	0.99*** (0.98,0.99)	0.99*** (0.98,0.99)	0.98

*p<0.05 **p<0.01 ***p<0.001

APPENDIX XXXVI. Comparison of ODNF assessments by non-dental assessors, against dental (non-gold) standard assessor

There is highly statistically significant agreement ($p<0.001$) between dental non-gold assessor and non-dental assessors on the discrete data (Upper teeth, Lower teeth, Total teeth and Total number denture) (Table 9.20). The results of examination performed by both gold standard assessor and non-dental assessors presented high percentage agreement (>0.90). The agreement between the tooth count variables (upper teeth, lower teeth and total teeth) and total number of dentures were above 0.80 for kappa, Gwet's and spearman (r_s) tests.

Weighted Kappa and Weighted Gwet's (Table x) as well as sensitivity and specificity (Table 9.21) tests were used to assess agreement of categorical data of ODNF (Total teeth – grouped, Upper denture, Lower denture, Occluding pairs, Soft tissues, Oral cleanliness, Gum condition, Visible caries and Dental Pain) between gold standard assessor and non-dental assessors.

The results of examination performed by both gold standard assessor and non-dental assessors presented high percentage agreement (>0.60) for all categorical data except for Soft tissues. For the agreement between gold standard assessor and non-dental assessors on Total teeth – grouped, Upper denture, Lower denture and Occluding pair), the results show very significant values (>0.80; $P<0.05$) for kappa and Gwet's tests. For Soft tissues, Oral cleanliness and Gum condition; result show lower Kappa values (between 0.09-0.61) and lower Gwet's values (between 0.01-0.76).

When compared to dental non-gold assessor, non-dental assessors 1 and 2 showed fair Kappa agreement values for visible caries (0.15 and 0.25 respectively) and Dental pain

(0.34 and 0.36 respectively). The Gwet's values, on the other hand, show substantial agreement for visible caries (0.73 and 0.67 respectively) and Dental pain (0.80 and 0.73 respectively). Agreement between dental and non-dental assessor 3 on visible caries show very low Kappa value (-0.07) and moderate Gwet's value (0.53); meanwhile result show moderate to substantial agreement on ODNF item Dental pain (Weighted Kappa 0.66, Weighted Gwet's 0.92).

Very high level of sensitivity (>0.97) and specificity (>0.85) were found on ODNF items, Total teeth – grouped and upper denture for comparison between dental non-gold assessor and all non-dental assessors. For Lower denture, very high level of sensitivity (1.00) but low specificity (0.50) were found between gold standard and non-dental assessors 2. Very low sensitivity (<0.20) and high specificity (>0.85) were found when comparing data between dental non-gold assessor and non-dental assessors on Occluding pairs, Visible caries and Dental Pain. This pattern is similar to comparison between gold standard assessor and non-dental assessors. For soft tissues, Oral cleanliness and Gum condition, some of the results shows a lower sensitivity and higher specificity.

Table 9.20 Inter-rater reliability of ODNF (between non-dental assessors and non-gold dental assessor); Percentage agreement (%Ag), weighted Cohen's Kappa coefficient, Weighted Gwet's AC2 coefficient & Spearman's correlation (r_s)

ODNF ITEMS	Gold standard against non-dental assessor 1				Gold standard against non-dental assessor 2				Gold standard against non-dental assessor 3			
	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s	% Ag.	Kappa (95% CI)	Gwet's (95% CI)	r_s
Upper teeth	0.99	0.98*** (0.96,1.00)	0.99*** (0.97,0.99)	0.99	0.98	0.91*** (0.77,1.00)	0.93*** (0.85,1.00)	0.94	0.98	0.86*** (0.73,0.99)	0.90*** (0.81,0.99)	0.90
Lower teeth	0.99	0.96*** (0.91,1.00)	0.97*** (0.93,1.00)	0.96	0.97	0.86*** (0.69,1.00)	0.88*** (0.74,1.00)	0.86	0.99	0.96*** (0.91,0.99)	0.97*** (0.93,0.99)	0.94
Total teeth	0.99	0.98*** (0.97,0.99)	0.99*** (0.98,0.99)	0.98	0.99	0.91*** (0.80,1.00)	0.93*** (0.84,1.00)	0.94	0.99	0.92*** (0.83,1.00)	0.94*** (0.88,1.00)	0.94
Total teeth (Grouped)	0.98	0.95*** (0.84,1.00)	0.96*** (0.88,1.00)	x	0.93	0.84*** (0.65,1.00)	0.89*** (0.76,1.00)	x	0.96	0.89*** (0.74,1.00)	0.93*** (0.83,1.00)	x
Upper denture	1.00	1.00** (1.00,1.00)	1.00*** (1.00,1.00)	x	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x	1.00	1.00*** (1.00,1.00)	1.00*** (1.00,1.00)	x
Lower denture	0.98	0.79** (0.37,1.00)	0.97*** (0.92,1.00)	x	0.98	0.66* (0.01,1.00)	0.98*** (0.93,1.00)	x	0.98	0.66* (0.01,1.00)	0.98*** (0.93,1.00)	x
Total number of dentures	0.99	0.94*** (0.81,1.00)	0.99*** (0.97,1.00)	0.91	0.99	0.93*** (0.81,1.00)	0.99*** (0.97,1.00)	0.99	0.99	0.93*** (0.81,1.00)	0.99*** (0.97,1.00)	0.99
Occluding pairs	0.89	0.68*** (0.44,0.93)	0.82*** (0.66,0.97)	x	0.87	0.63*** (0.38,0.88)	0.78*** (0.60,0.95)	x	0.98	0.92*** (0.82,1.00)	0.97*** (0.93,1.00)	x
Soft tissues	0.60	0.27* (0.03,0.51)	0.22*** (-0.09,0.52)	x	0.58	0.15 (-0.13,0.42)	0.20 (-0.11,0.51)	x	0.50	0.09 (-0.15,0.32)	0.01 (-0.30,0.32)	x
Oral cleanliness	0.89	0.61*** (0.43,0.80)	0.76*** (0.63,0.88)	x	0.72	0.27** (0.08,0.50)	0.27* (0.01,0.54)	x	0.72	0.25** (0.06,0.43)	0.29 (0.00,0.58)	x
Gums (Grouped)	0.80	0.36** (0.15,0.57)	0.48*** (0.3,0.65)	x	0.80	0.42*** (0.23,0.62)	0.49*** (0.30,0.68)	x	0.77	0.32** (0.10,0.54)	0.39*** (0.20,0.58)	x
Visible caries	0.87	0.15 (-0.15,0.46)	0.73*** (0.60,0.86)	x	0.82	0.25* (0.01,0.48)	0.67*** (0.48,0.87)	x	0.76	-0.07 (-0.33,0.18)	0.53*** (0.34,0.72)	x
Dental Pain	0.88	0.34* (0.07,0.62)	0.80*** (0.66,0.95)	x	0.84	0.36* (0.07,0.64)	0.73*** (0.53,0.92)	x	0.94	0.66*** (0.39,0.93)	0.92*** (0.84,1.00)	x

*p<0.05 **p<0.01 ***p<0.001; highlighted – blue (below 0.61), green (increased value with Gwet's); x- not calculated

Table 9.21 Inter-rater reliability of ODNF (between non-dental assessors and dental non-gold assessor); Specificity and sensitivity

ODNF ITEMS	Gold standard against non-dental assessor 1		Gold standard against non-dental assessor 2		Gold standard against non-dental assessor 3	
	Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
Total teeth (Grouped) 0: 20 & more 1: Less than 20	0.97	1.00	0.97	0.85	0.97	0.92
Upper denture 0: Absent 1: Present	1.00	1.00	1.00	1.00	1.00	1.00
Lower denture 0: Absent 1: Present	0.98	1.00	1.00	0.50	1.00	0.50
Occluding pairs (Re-grouped) 0: 1 or more 1: Anterior contacts only 2: No contacts	0.79 0.50 1.00	0.89 0.90 0.92	0.78 1.00 1.00	1.00 0.93 0.87	0.97 0.00 1.00	0.78 0.98 1.00
Soft tissues 0: Absent 1: Present	0.50	0.85	0.56	0.62	0.42	0.69
Oral cleanliness 0: None 1: Localised 2: Generalised	0.67 0.68 0.71	1.00 0.68 0.78	0.38 0.27 1.00	0.94 0.90 0.41	0.13 0.44 0.93	0.97 0.77 0.50
Gums (Grouped) 0: None 1: Localised 2: Generalised	0.50 0.31 0.75	0.76 0.67 0.69	1.00 0.23 0.56	0.51 0.90 0.86	0.70 0.23 0.56	0.69 0.74 0.69
Visible caries 0: 0 caries 1: 1,2 caries 2: 3 or more caries	0.52 0.43 0.50	0.56 0.67 0.87	0.86 0.20 0.00	0.44 0.87 0.88	0.55 0.20 0.00	0.33 0.59 0.93
Dental Pain 0: No Pain 1: Verbal +/- Behavioural 2: Physical, verbal, behavioural signs	0.85 0.38 0.00	0.60 0.86 0.93	0.78 0.63 0.50	0.80 0.89 0.86	0.97 0.50 0.50	0.70 0.97 0.96

Key: blue (below 0.61), red (below 0.41)

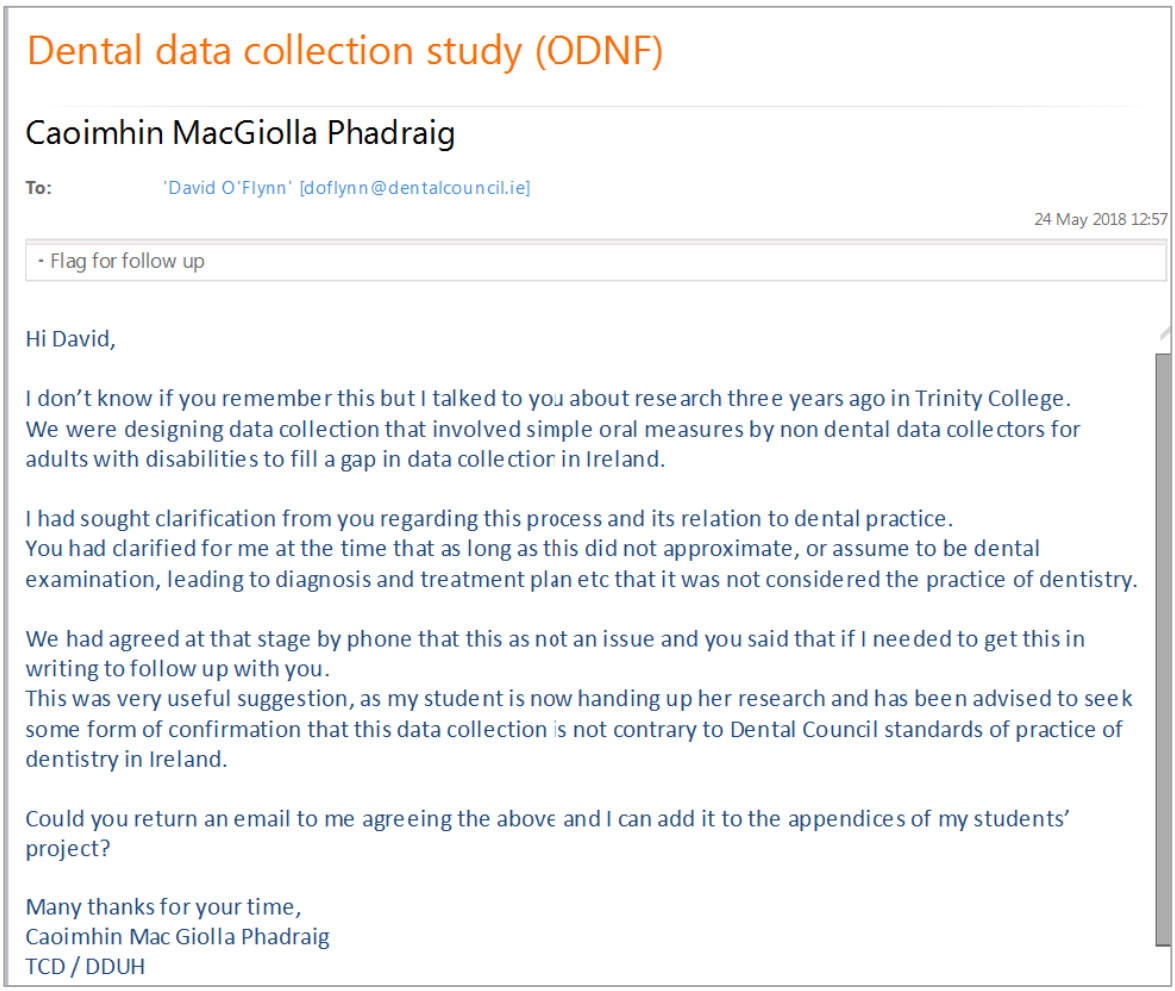
APPENDIX XXXVII. Estimated expense of ODNF data collection compared to conventional dental assessment by dentist

Table 9.22 Estimated expense of ODNF data collection (CAPEX – Capital expense; OPEX – Operating expense), compared to conventional dental assessment by dentist

Items	Description	CAPEX /OPEX	Same as dental assessments?
Personnel: Training 8 hours Calibration 2 hours Field examination	Non-dental assessors €11.00/hr	CAPEX	No; Dentist assessor; €23.75/hr
Volunteer as subjects, For practical during training	For practical only, 5 pax, 2 hours max Travel voucher €10.00 Toothbrush-toothpaste pack €1.35	OPEX	Yes
Participants with ID 25pax For calibration – 2hours	Travel voucher €10.00 Toothbrush-toothpaste pack €1.35	OPEX	Yes
Participants with ID For data collection	Travel voucher €10.00 Toothbrush-toothpaste pack €1.35	OPEX	Yes
Researchers	Opportunity cost	CAPEX	Yes
Research assistants	€11.00/hr	OPEX	Yes
Room with projector	For Training & Calibration FOC	CAPEX	Yes
Examination station	Table, chair FOC	CAPEX	Yes
Tablets device Microsoft Surface Pro 4	1/station €814.00 ex. VAT	CAPEX	Yes
Light source w/ battery included	1/station €13.52	CAPEX	Yes, can be used
Examination kit (Mirror only)	1/station €0.43	OPEX	Dental €1.56
Safety eyewear for participant	1/station FOC	CAPEX	Yes
Hand sanitizer	1/station €5.33	OPEX	Yes
Gloves	1/station €3.33	OPEX	Yes

Items	Description	CAPEX /OPEX	Same as dental assessments?
Disinfectant wipes	1/station €6.15	OPEX	Yes
Paper towel	1/station €2.04	OPEX	Yes
Disposable barriers	1/station €21.52	OPEX	Yes
Gauze	1/station CSSD	OPEX	Yes
Yellow biohazard plastic bags	1/station €6.63	OPEX	Yes
Biohazard sharp bins	1/station CSSD	OPEX	Yes

APPENDIX XXXVIII. Email to request written confirmation from Dental Council



Dental data collection study (ODNF)

Caoimhin MacGiolla Phadraig

To: 'David O'Flynn' [doflynn@dentalcouncil.ie]

24 May 2018 12:57

- Flag for follow up

Hi David,

I don't know if you remember this but I talked to you about research three years ago in Trinity College. We were designing data collection that involved simple oral measures by non dental data collectors for adults with disabilities to fill a gap in data collection in Ireland.

I had sought clarification from you regarding this process and its relation to dental practice.
You had clarified for me at the time that as long as this did not approximate, or assume to be dental examination, leading to diagnosis and treatment plan etc that it was not considered the practice of dentistry.

We had agreed at that stage by phone that this as not an issue and you said that if I needed to get this in writing to follow up with you.
This was very useful suggestion, as my student is now handing up her research and has been advised to seek some form of confirmation that this data collection is not contrary to Dental Council standards of practice of dentistry in Ireland.

Could you return an email to me agreeing the above and I can add it to the appendices of my students' project?

Many thanks for your time,
Caoimhin Mac Giolla Phadraig
TCD / DDUH

Confirmation was seek over phone with the Dental Council representative before the start of the research. It was advised that written confirmation could be requested if necessary. Internal examiner requested this as part of the minor corrections, however internal examiner agreed it may take a while to get the written response and it could not be included in time of thesis printing. Lead researcher may be contacted to get a copy of this written clarification.

END OF DOCUMENT