Tooth loss, dentures and psychological morbidities: A quantitative questionnaire study

Zaki Kudsi

Thesis submitted in fulfilment of the requirement for the Degree of Doctor of Philosophy in The Institute of Dentistry, Barts and The London School of Medicine and Dentistry
Queen Mary University of London

October 2019

Statement of originality

I, Zaki Kudsi, confirm that the research included within this thesis is my own work or that where it has been carried out in collaboration with, or supported by others, that this is duly acknowledged below and my contribution indicated. Previously published material is also acknowledged below.

I attest that I have exercised reasonable care to ensure that the work is original, and does not to the best of my knowledge break any UK law, infringe any third party's copyright or other Intellectual Property Right, or contain any confidential material.

I accept that the College has the right to use plagiarism detection software to check the electronic version of the thesis.

I confirm that this thesis has not been previously submitted for the award of a degree by this or any other university.

The copyright of this thesis rests with the author and no quotation from it or information derived from it may be published without the prior written consent of the author.

Signature: Zaki Kudsi
Date: 31-10-2019

Aim of the Thesis:

To investigate the psychological impact associated with tooth loss, and the effect of provision of dentures on this psychological impact.

Abstract:

Background: Previous qualitative studies indicated that although many patients cope well with tooth loss and removable dentures, some might have less psychological resilience and capacity to adapt to new changes. Those individuals may endure negative emotions and psychological morbidities. There have been few quantitative studies to assess the psychological impact of tooth loss and dentures. There has also been a lack of suitable or validated tools to screen and measure such impact.

Aims: To investigate the psychological impact associated with tooth loss, and the effect of provision of dentures on this psychological impact

Method: Phase one included the development and validation of a disease-specific measure to assess the psychological impact associated with tooth loss, and the effect of provision of dentures on this psychological impact. Inclusion criteria included adults (age ≥18) with tooth loss and technically successful removable dentures. The quality of these dentures was assessed by a calibrated clinician (ZK). Exclusion criteria included patients with a history of psychotic mental illness or patients who had treatment with dental implants. 128 participants (100 patients - 28 clinicians) were recruited to participate in the development and validation of the questionnaire. The development processes included the following steps: Defining the aims/target population of the questionnaire, generating a pool of items, defining the constructs to be measured, adapting psychological morbidity screening tools, Items reduction,

iv

content validation, face validation, establishing construct validity, pilot testing and establishing reliability.

Phase two, the validated questionnaire was distributed to a sample of patients with tooth loss and technically successful removable dentures (n=70) and a control group of patients who had tooth loss with no dentures (n=68). For this study, the phase one criteria were also used for inclusions and exclusions. The short-form revised Eysenck personality questionnaire was distributed to assess the impact of personality traits on denture acceptance.

Results: In phase one, face and content validation indicated that the questionnaire was an appropriate tool to measure the impact of tooth loss and related psychological morbidities. Reliability analysis (Test re-test reliability/internal consistency) demonstrated that the questionnaire has satisfactory reliability (correlation >0.7). Testing the theoretical hypothesis structure of the impact of tooth loss has also enhanced the construct validity of the questionnaire (domains correlated mildly (r>5 & <3) to strongly (r>5). Pilot testing confirmed the scale adequacy and wording clarity (>90% of respondents). Results indicated that the developed questionnaire has adequate psychometric properties.

Phase two: There was a significant difference in body image dissatisfaction between the denture and control groups ($\chi 2$ =7.72, p value=0.005). The denture group had 5.75 times a higher probability to suffer from body image disturbance related to dentures than the control. There was no significant difference in

psychological disturbance between the denture and control groups. However, participants in both groups presented with somatic symptoms related to depression or anxiety, which is nearly double of that, recorded in the general population (15.7% and 7.8% respectively). Furthermore, participants who complained about body image impairment were more likely to have higher scores on the neuroticism scale (OR=3.64).

Conclusion: Tooth loss and dentures could be associated with psychological morbidity. Therefore, planning for patient centred-care is paramount before extracting any teeth and providing replacement options, especially removable dentures.

Acknowledgement

TABLE OF CONTENTS

CHAPTER TWO: METHODS

CHAPTER THREE: RESULTS

CHAPTER FOUR: DISCUSSION

CHAPTER FIVE: IMPLICATION FOR PRACTICE AND DIRECTION FOR FUTURE RESEARCH

8. LIST OF TABLES

9. LIST OF FIGURES

ABBREVIATIONS

AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
DASS 21	Depression, Anxiety, Stress Scale - 21 Items
FDA	Functional Dental Assessment Tool
GAD-7	Generalised Anxiety Disorder Assessment
GHQ	General Health Questionnaire
HADS	Hospital Anxiety and Depression Scale
DT	Distress Thermometer
DMC	Data Monitoring Committee
ICF	Informed Consent Form
Participant	An individual who takes part in a clinical trial
PHQ-9	Patient Health Questionnaire
PI	Principal Investigator
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
REC	Research Ethics Committee
RP	Removable prosthesis
SAS	Self-Rating Anxiety Scale
WHO-5	World Health Organisation-5 (Well-Being Index)

CHAPTER ONE:
LITERATURE REVIEW

1.1. Introduction:

This literature review aims to investigate the current published evidence on the link between tooth loss/replacement options and psychological morbidity. The review will explore the various consequences of tooth loss and specifically the dimensions of any psychological reactions associated with tooth loss and/or denture treatment.

1.2 Tooth loss: prevalence and risk factors:

Adult Oral Health in the UK has improved over time, and the prevalence of tooth loss has been in decline over the last 30 years; nevertheless about 6% of people are edentulous, and 14% have experienced significant tooth loss, i.e. >11 tooth loss (Steele *et al.*, 2012). This figure still represents millions of people who may need treatment to restore function and appearance.

Although tooth loss is not fatal, it is a major health problem due to its high prevalence globally. Tooth loss also represents a major burden on the individual well-being as it affects appearance, ability to eat, speak and socialise (Marcenes *et al.*, 2013; Kassebaum *et al.*, 2014). Some researchers even concluded that tooth loss was associated with the onset of disability and morbidity in old age (Holm-Pedersen *et al.*, 2008).

Some of the risk factors, which were found to be associated with tooth loss included: poor oral health, dental caries, periodontal disease, smoking, age, gender, diabetes, hypertension and lower socioeconomic status (Eklund and Burt, 1994; Locker *et al.*, 1996; Albandar *et al.*, 2000; Al-Shammari *et al.*, 2005).

Edentulous patients or those with significant tooth loss have limited rehabilitation options including a removable denture, an implant-supported denture or fixed implant prosthesis. Due to the high cost of implant rehabilitation, many patients end up having a replacement with a removable denture. Within the National Health System in England, edentulous patients or those with significant tooth loss are usually treated with removable dentures. Only patients with specific medical conditions are offered implant rehabilitation within the NHS (Alani *et al.*, 2014).

1.3 Tooth loss: impact on oral health:

The loss of natural teeth has a direct negative impact on the ability to chew, articulate words and may alter facial structures/appearance (Oosterhaven *et al.*, 1988; Slade *et al.*, 1996; Fiske *et al.*, 1998; Ueno *et al.*, 2008). Allen and McMillan (2003) reported that those who lost their teeth are regarded as "impaired individuals".

As for the ability to chew/eat, research showed that the masticatory efficiency is directly linked to the number and location of retained teeth with several researchers agreeing that retention of minimum ten occluding pairs (20 teeth) are needed for adequate masticatory function (Hatch *et al.*, 2001; Gotfredsen and Walls, 2007; Steele, 2012; Emami *et al.*, 2013). Therefore, significant tooth loss would have a direct impact on the ability to chew and the choice of food. There have also been reports stating that tooth loss may have consequences

on food choices and nutritional intakes (Walls *et al.*, 2000; Sheiham and Steele, 2001).

Concerning appearance, tooth loss can have a direct impact on facial structures, as it is associated with an ongoing decline of residual ridge height and volume. Those changes in the residual ridges might lead to alteration in the facial soft tissue profile and facial height (Allen and McMillan, 2003; Divaris *et al.*, 2012). Those facial transformations may enhance ageing features and trigger functional problems such as temporomandibular joint disorders (Allen and Macmillan, 2003; Divaris *et al.,* 2012).

Finally, tooth loss could also have an impact on articulation, phonetics and speech, although patients usually attribute more significance to appearance and mastication (Gotfredsen and Walls, 2007).

1.4 Tooth loss: Impact on general health:

Oral health is essential to the public health and well-being of individuals. That is due to the high prevalence of oral disease and its correlation with several systematic conditions (Joshipura *et al.,* 2000; Baiju *et al.*, 2017). Rousseau et al. (2014) have even regard tooth loss as a "chronic illness" which could be biologically disturbing.

One hypothesis that explains the link between tooth loss and general health is that tooth loss is associated with a significant negative impact on chewing and

eating (Sheiham and Steele, 2001). The location and number of retained teeth may also affect the masticatory efficiency, the ability to eat a particular food and the nutritional intakes (Walls *et al.*, 2000; Sheiham & Steele, 2001; Sheiham *et al.*, 2001). In a four-day diary study, Sheiham *et al.* (2001) found that individuals with tooth loss had significantly fewer intakes of non-starch polysaccharides, protein, calcium, non-heme iron, vitamin C and niacin. Hutton *et al.* (2002) indicated that this compromised nutrition status might be a risk factor for various health disorder. There is evidence of an association between tooth loss and increased risk of heart disease, with a higher risk of cardiovascular mortality (Okoro *et al.,* 2005; Abnet *et al.*, 2005; Holmlund *et al.,* 2010). Tooth loss was also associated with a higher risk of aortic valve stenosis (Volzke *et al.,* 2005), arrhythmia (Takata *et al.*, 2001) and cerebral vascular accidents (Abnet *et al.,* 2005).

Other medical disorders which were associated with tooth loss included developing non-insulin-dependent diabetes mellitus (Cleary and Hutton, 1995), rheumatoid arthritis (de Pablo *et al.*, 2008), obstructive sleep apnoea (Bucca *et al.,* 2006) and a higher risk of death from gastrointestinal cancer (Stolzenberg-Solomon *et al.,* 2003; Abnet *et al.*, 2005).

In addition, some studies indicated that tooth loss was associated with various psychological and emotional impairments (Davis *et al.*, 2000; Fiske *et al.*, 2001; Scott *et al.,* 2001; Emami *et al.,* 2013).

1.5 Psychological disturbance: Definitions

The World Health Organisation (WHO) defines mental health as "*A state of well-being in which every individual realizes his or her own potential, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to her or his community*" (WHO, 1948). However, psychological morbidity arises when this state of well-being is disrupted. Nevertheless, it is essential to note that having an abnormal reaction or feeling is not adequate to fulfil the diagnosis of a disorder or a disease, i.e. healthy individuals may endure grief/distress over the death of a loved one. Those reactions are normal human reactions to extreme stressors.

To differentiate between psychological health and psychological morbidity, the WHO published the International Classification of Diseases (ICD-10), which help classify various mental and behaviour disorders. Depression, anxiety and stress are recognised as the most common psychological disturbance (NICE, 2011). The WHO ICD-10 diagnostic criteria for those disorders will is described below:

1.5.1 Depression:

Depression is a disorder of low mood and/or loss of interest/pleasure in most activities (Mian *et al.,* 2015). To diagnose depression using the ICD-10 (WHO, 2010), a combination of depressive symptoms should be present at least two weeks, and each symptom presents most of the day each day. Those depressive symptoms are classified into three primary symptoms and seven secondary symptoms (Appendix 1).

A mild depressive episode is diagnosed when two primaries and two secondary criteria are experienced by the individual. A moderate depressive episode is defined when two primaries and four secondary criteria are met. A severe depressive episode is when three primaries and five secondary criteria are met. A mild, moderate or severe depressive episode could present with or without somatic symptoms. The diagnosis is usually through a consultation with a psychiatrist (WHO, 2010).

The severity of depression is determined by the severity/number of symptoms and the degree of functional disruption (Mian *et al.*, 2015). However, there is also evidence that the depressive symptoms below the ICD-10 defined threshold could also be disabling (WHO, 2010). Therefore "*sub-threshold depressive symptoms*" were re-defined to allow diagnosis of depression with one key symptom (low mood, loss of interest or energy).

1.5.2. Anxiety:

Generalised anxiety disorder described as "*prominent tension, worries about everyday events/problems*" (WHO, 2010). To meet the ICD diagnosis criteria of general anxiety disorder, the individual should have at least four somatic or general symptoms (Appendix 2).

1.5.3. Stress and distress:

Distress is a broad diagnostic definition that has no clear definitional boundaries. Selye (1976), a leading researcher who studied stress and distress, defines stress as "*nonspecific response of the body of any demand on it*". Selye further proposed different types of stress: good stress, which he named eustress, and bad stress, defined as distress. Eustress is when the stressor is perceived as positive, whilst distress is when it perceived as negative. Distress is usually persistent, fails to resolve by coping and may have an adverse impact on the general health and quality of life (Table 1).

Table 1: Types of stress

Stress		
Distress		Eustress
The stressor is perceived as negative and is persist (not resolved through coping)		The stressor is perceived as positive
Not pathological - Not persist -Resolved through coping	Pathological - Persist - Not Resolved through coping	

Adapted from Selye (1976). Stress without distress. Philadelphia: J.B. Lippincott Company

The ICD-10 (WHO, 2010) classifies three categories of a stress reaction: mild, moderate and severe stress reaction. The mild stress reaction is when an individual is exposed to a stressor and then experience the various somatic/general symptoms (Appendix 2).

The moderate stress reaction is similar to the mild plus two secondary symptoms (Appendix 3). The severe stress reaction is similar to moderate stress with either two secondary symptoms or dissociative stupor.

The Distress Continuum (Figure 1) presents the distress on a scale, on which the difference between the normal and disease, is basically, the difference in severity.

Figure 1: The Distress Continuum

The Distress Continuum

| Normal Adjustment | Adjustment Disorders | Subthreshold to Mental Disorders | Diagnosable Mental Disorders (e.g., major depressive disorder) |

Adapted from NCCN practice guidelines for the management of psychosocial distress. National Comprehensive Cancer Network (2016)

Psychological distress, when persistent and severe, needs management, as it has a negative impact on the quality of life, can cause physical morbidity, social isolation and can also increase the risk of mental disorders such as depression (Kendler *et al*., 1999).

Although stress and anxiety share similar symptoms, however, it should be noted they are different. Stress mainly emphasise a reaction to an identified external pressure, i.e. exams/deadline. On the other hand, anxiety illustrates sustained apprehension and worries in which the triggers are not always identified. The difference between the two is illustrated in Appendix 4.

1.6 The psychological impact of tooth loss

Various researches indicated that the loss of a body part (limb, breast, testicle) is associated with psychological morbidity (Franchelli *et al.*, 1995; Atherton and Robertson, 2006). Likewise, the loss of teeth could be associated with a decline in the psychological well-being in some individuals (Davis *et al.*, 2000; Davis *et al.*, 2001; Fiske *et al.*, 2001; Scott *et al.*, 2001; Ommerborn *et al.*, 2008; Okoje *et al.*, 2012; Emami *et al.*, 2013; Dable *et al.*, 2014).

Two cross-sectional studies indicated a potential correlation between tooth loss, depression and anxiety. Wiener *et al.* (2015) analysed data collected through telephone interviews, and Roohafza *et al.* (2015) used the Hospital Anxiety and Depression Scale (HADS) and the General Health Questionnaire (GHQ-12) to estimate the psychological variables in subjects with tooth loss. Though, in both studies, a clinician failed to assess the participant's oral health. Self-reported data were collected by asking participants to report their oral health by counting their missing teeth. Also, Wiener *et al.* (2015) assigned participants to have depression/anxiety by asking them if they were diagnosed with those disorders. While self-reporting measures could be useful in conducting large-scale surveys; however, they also carry a risk of respondents' error/bias in reporting oral health and psychological status (Althubaiti, 2016).

Furthermore, Anttila *et al.* (2001) used the Zung Self-Rating Depression Scale (ZSDS) to explore the relation between tooth loss/depression. These authors reported an association between depressive symptoms and tooth loss in non-

smoker men. However, depressive symptoms were not associated with dental caries, periodontal disease or the number of retained teeth. Another study (Casanova-Rosado *et al.*, 2005) also found this correlation between tooth loss and psychological impairment such as anxiety and depression. However, both studies failed to use well-defined control groups to compare the significance of these results.

Other researchers investigated the emotions and feelings associated with tooth loss (Fiske *et al.,* 1998; Rousseau *et al.,* 2014). Fiske *et al.* (1998) interviewed a total of 50 edentulous patients and concluded that tooth loss could have a devastating impact on patients' lives, including individuals who have worn dentures for many years. Tooth loss resulted in "*grief, bereavement, loss of confidence, social withdrawal and negative impact on body self-image*". Similarly, Rousseau *et al.* (2014) interviewed 39 patients and concluded that tooth loss could cause a major "*biographical disruption*" to some patients. It was subsequently proposed that the tooth loss should be perceived as a "*chronic illness*" which negatively affects patients' lives (Rousseau *et al.,* 2014).

Furthermore, Davis *et al.* (2000, 2001) in two separate qualitative studies measured the prevalence of emotional impact of tooth loss. The first study included edentulous participants, whilst the second study included partially dentate participants (Davis *et al.,* 2000; Davis *et al.,* 2001). Surprisingly, there was a similar level of emotional disturbance in both groups (45% and 53% respectively). Candidates in both studies also expressed sadness, felt old, were less confidence, disliked the change in their appearance, and had less satisfactory social interactions. Other authors also reported a similar correlation

between tooth loss and psychological morbidity (Graham *et al.*, 2006; Ommerborn *et al.*, 2008; Okoje *et al.,* 2012; Dable *et al.*, 2014; Shah *et al.*, 2015; Scott *et al.*, 2001; McMillan and Wong, 2004).

In this respect, some researchers indicated that tooth loss did not have a considerable emotional impact; however, tooth loss mainly affected their daily social interactions (Naik and Pai, 2011; Shah *et al.*, 2015). Naik and Pai (2011) studied the emotional impact of tooth loss in the aged North Indian population. A total of 400 patients above the age of 60 were interviewed using twenty-four open-ended question questionnaires. No significant link between tooth loss and emotional disturbance was found; however, there was a marked impact on social interaction. It seems that the social and cultural context in which an individual would live their life, shapes their reaction to disease and health. Hence many researchers indicated that the cultural difference influences the emotional and psychological reaction to tooth loss. For instance, in some cultures, tooth loss is seen as a natural ageing process which could not be prevented (Scott *et al.,* 2001; Anjum *et al.*, 2017). While in some other religious communities, tooth loss was seen as fate, the will of God, which should be accepted and should not be questioned (Omar *et al.*, 2003).

There are several possible explanations for why tooth loss could be correlated with psychological morbidity:

- The stigma of old age. Tooth loss may illustrate body degeneration and loss of attractiveness and is seen as "*premature ageing*" (Allen and

McMillan, 2003; Friedman *et al.*, 1987; Fiske *et al.,* 1998; Davis *et al.*, 2001; Rousseau *et al.,* 2014).

- Tooth loss is viewed as a status of self-neglect (Rousseau *et al.,* 2014; Dable *et al.,* 2014). In recent years, the attitudes towards tooth loss have changed, and individuals have greater expectations of retaining their natural teeth (Allen and McMillan, 2003). Individuals with tooth loss may be regarded as "*a deviating person*" by patients with tooth loss and by society (Trulsson *et al.*, 2002). Those individuals may feel guilt, shame and believe that others view them as "*neglected subjects*" because of their oral health status (Trulsson *et al.,* 2002). While losing a limb or other body part may attract sympathy form others, edentulousness is a condition, which is not viewed with sympathy (Blomberg and Lindquist, 1983).

- Tooth loss could restrict function like eating, speaking and cause discomfort. Fiske *et al.* (1998) indicated that tooth loss results in marked disabilities with significant disturbance to social activities. For the edentulous patient, replacement with a full denture only restores between one-fourth to one-fifth of the masticatory ability (Michael *et al.*, 1990). Therefore, the functional limitation could affect various social activities. For example, in some communities, there is great emphasis on food-related social gathering and festivals. When tooth loss restricts food choices, this leads to impaired eating experience and less enjoyment (Scott *et al.*, 2001, Shah *et al.*, 2015). In those communities,

it was function rather than appearance, which impacted their social interaction (Shah *et al.*, 2015).

- Tooth loss may affect appearance/body image perception. It could be the abrupt changes in facial appearance that may affect the individual psychological well-being (Anjum *et al.,* 2017). The ideal body image is viewed as a youth, beauty and health, and therefore the loss of teeth represent the depletion of those characteristics (Cronan, 1993; Trulsson *et al.,* 2002). Trulsson *et al.* (2002) in a qualitative study, concluded that "Alteration in self-mage" was the main theme related to tooth loss and dentures. These authors concluded that the desire to restore self-image and attractiveness was the main reason why patients aimed to have implant treatment. Patients with tooth loss sensed that "*appearance no longer corresponded to their self-image*" (Davis *et al.,* 2001, Davis *et al.*, 2000). That is why some individuals with tooth loss did not want to look into the mirror, nor allowed their partners/friends to see them without dentures (Davis *et al.,* 2000).

The relationship between tooth loss and psychological morbidity could be summarised by Locker conceptual module (Locker, 1988) explaining how oral disease (like tooth loss) could cause impairment, discomfort/pain, functional limitation and this could lead to physical, psychological and social disability (Figure 2).

Figure 2: Conceptual Model for oral health (Locker, 1988)

Subsequently, there is some evidence of a correlation between psychological disturbance and tooth loss; however, the direction of this relationship is not clear. Okoro *et al.* (2012) determined that those who have psychological disorders are less likely to use oral health services and more likely to have tooth loss. Some studies also indicated that psychological impairment, i.e. depression might indirectly affect oral health through behaviours changes (such as loss of motivation in oral hygiene, dietary choices, and smoking), effect of medication and biological changes (Friedlander and Norman, 2002; D'Mello, 2003; Anttila *et al.*, 2006; Dumitrescu *et al.*, 2010). Therefore, it could be that psychological impairment may lead more teeth being removed, and that having more teeth removed may exacerbate psychological morbidity. It could be a bi-directional relationship, in which psychological disturbance could be a risk factor and a consequence of tooth loss.

While the studies mentioned above have enhanced our understanding of the relationship between tooth loss and psychological morbidity, nevertheless,

results should be interpreted with caution due to several limitations and drawbacks:

- Firstly, several studies used a 24-item questionnaire to measure emotional disturbance in patients with tooth loss (Davis *et al.,* 2000; Davies *et al.*, 2001; Fiske *et al.*, 2001; Scott *et al.*, 2001; Macmilan and Wong 2004; Okoje *et al.,* 2012; Naik and Pai, 2011; Shah *et al.*, 2015; Anjum *et al.,* 2017). This questionnaire was developed and validated in two previous qualitative research (Fiske, 1997; Fiske *et al.,* 1998). However, the process of how this was developed and validated remains unclear. Also, some of the questions used to quantify the emotional impact of tooth loss may lead participants to answer in a specific way (potentially leading questions). i.e. "*Did you find it difficult to accept losing your teeth?*". The approach of the authors using a negative connotation, such as "difficult" could introduce bias. The use of more neutral words is recommended to avoid the possible risk of leading questions and incorrect responses. Although the additional space for comments might assist in clarifying any issues, this would still not be quantified, and thus, the risk of measurement bias was considered as high. This 24-item questionnaire used explores the functional disability and feelings associated with tooth loss and this tool measures how the emotional impact of tooth loss affects participants. However, this questionnaire is not designed to screen and quantify psychological distress caused by tooth loss. Therefore, further tools are required for this purpose.

- Secondly, there were no definite control groups in any of those studies. Without a well-designed control group, it is difficult to assess the impact of a disease or the effectiveness of an intervention.

1.7 The psychological impact of dentures

The Adult Dental Health Survey (Steele *et al.*, 2012) reported that "one in every five" adults in the UK have a denture. Dentures are considered an effective intervention to restore function and appearance in edentulous patients. However, it is unclear whether dentures also improve the psychological well-being of those individuals. Research from the medical field indicated that replacing a missing body part with a prosthesis (e.g. limb or breast prosthesis) is sometimes associated with psychological morbidity (Atherton and Robertson, 2006; Franchelli *et al.,* 1995). This fact raises the question of whether treatment with a removable denture could also be associated with psychological morbidity.

Limited research has been conducted to investigate the psychological impact of dentures. The replacement of tooth loss using dentures is regarded as a major life event that will require time and capacity to adapt functionally and psychologically. (Bergendal, 1989) used "The Social Adjustment Rating Questionnaire" to compare different significant life events with the use of denture and tooth loss. This author interestingly concluded that tooth loss and the use of denture required more adaption when compared to other major life events, i.e. marriage and retirement.

Some researchers suggested that dis/satisfaction with dentures depends on the technical quality of the denture and specific patient factors (Allen and McMillan, 2003). With this regard, a technically successful denture does not always guarantee success if the patient did not adapt to its use. Fiske *et al.,* (1989) explained that using a removable denture requires functional and psychological adjustment. Furthermore, Friedman *et al.* (1987) described that while many individuals cope well with tooth loss and accept the limitation of dentures, some become "maladaptive". Those were classed into three categories:

- Individuals who adapt physically but not emotionally

- Individuals who are not able to adapt physically or emotionally

- Individuals cannot tolerate or use their denture and are depressed and isolated.

Anjum *et al.* (2017) investigated the emotional impact of tooth loss in a cross-sectional study between two groups: full dentures users (n=50) and edentulous candidates who are in the processes of having their first denture constructed (n=53). The authors concluded that participants with dentures had less difficulties accepting tooth loss, were more satisfied with their appearances, had less functional difficulties (speaking/eating) and experienced more social interactions. These findings indicate that in an edentulous cohort, when comparing the "intervention with denture" against "no treatment", the various functional and psychosocial benefits of denture treatment became evident.

However, a different outcome was reported when authors compared denture against dental implants. Kent and Johns (1993, 1994) noted in two subsequent studies that there was a significant decline in psychological impairment in patients who had dental implants while there was an increase in distress in patients who had removable dentures. Those authors used the General Health Questionnaire (Goldberg and Williams, 1981) to record the psychological impairment in 47 subjects over two years. Several other researchers also reported improvement in self-confidence and psychological well-being when patients had fixed dental implants instead of removable dentures (Blomberg and Lindquist 1983; Harle and Anderson, 1993). By contrast, some researchers determined that there is a lack of sound evidence to support the hypothesis that treatment with osseointegrated dental implants improves the psychological well-being in denture wearers (Lindsay, 2000; Walton and MacEntee, 2005).

Interestingly, wearing and coping with dentures might fail to indicate sound psychological health. Fiske *et al.* (1998) reported that social and psychological distress is continuous even in patients who have been using dentures successfully for many years. Other authors also found similar results (Hogenius *et al.*, 1992; Trulsson *et al.,* 2002; Dirik *et al.*, 2006). On the other hand, some authors questioned the correlation between dentures and psychological impairment and indicated that more research is required (Smith and Hughes, 1988; Lindsay *et al.,* 2000).

While the evidence relating to dentures and psychological morbidity is not clear, some researchers tried to examine the possible factors that could impact the

psychological health of denture wearers. In-depth-interviews indicated that dentures were seen as a "*marker of old age*", which should be resisted, especially among the younger generation (Rousseau *et al.,* 2014). Furthermore, dentures illustrated the feeling of self-neglect. Therefore, patients with removable dentures felt shame, degraded, embarrassed and could not discuss their dentures with their friends/family (Trulsson *et al.,* 2002). Furthermore, dentures failed to restore body image after tooth loss. On the contrary, the use of denture caused biological disruption and represented "*an immediate sense of the mouth being invaded*" (Rousseau *et al.,* 2014). Denture wearing was described as "*the unreliable mouth*" by referring to failed dentures as "*failed appearance*" (Rousseau *et al.,* 2014). This body image impairment could cause psychological impairment and hinder the individual ability to cope with tooth loss and dentures (Friedman *et al.,* 1987).

While the various studies mentioned above demonstrated the various emotions and feelings associated with dentures; however, few limitations should be noted:

Firstly, it was unclear whether the technical quality of denture was assessed in some of the studies (Dirik *et al.,* 2006; Kent and Johns, 1993; Anjum *et al.,* 2017). While there have been conflicting reports on the relation between denture quality and denture usage/satisfaction (van Waas, 1990; Wolff *et al.,* 2003; Fenlon and Sherriff, 2004; Anastassiadou and Heath, 2006), nevertheless denture quality is a critical variable if the psychological morbidity is to be assessed correctly. That is due to poor retention and/or stability may cause discomfort, affect chewing ability, interfere with articulation and disrupt

appearance if the retention of the denture is suboptimal. Therefore, psychological morbidity could be a result of the technical features of a denture. Hence, controlling the quality of dentures is vital prior to assessing any possible correlation between dentures and psychological well-being.

Secondly, in some of the studies, there was an absence of well-defined control group (Dirik *et al.,* 2006; Kent and Johns, 1993; Anjum *et al.,* 2017). Kent and Jones (1993) had a control group in their study; however, this control group was created from the patients who were denied having dental implant treatment since being found unfit for such procedure. The authors indicated that this rejection could be a cause of biased psychological distress in the control group. A well-designed control group is important to be able to assess the responsiveness to an intervention like dentures.

Thirdly, some of the above studies failed to clearly illustrate the length of time patients had their dentures (Anjum *et al.,* 2017). Evidence suggests that patients need time to adapt functionally and psychologically to their dentures (Friedman *et al.,* 1987; Michaud *et al.*, 2012). Therefore, it is necessary to allow denture adaptation time prior to assessing the effectiveness/psychological morbidity of dentures.

Finally, there are some deficiencies in the questionnaires used to assess psychological morbidity. Some researchers failed to clarify how the questionnaires were validated (Smith and Hughes, 1988; Kent and Johns, 1993). To be able to capture the psychological disturbance associated with

tooth loss, a validated questionnaire should be used. Furthermore, some studies used inappropriate tools, i.e. the General Health Questionnaire. Kent and Johns (1993) employed the General Health Questionnaire to record the psychological morbidity in their denture subjects. However, the GHQ tool is only sensitive to short-term psychiatric disorder, whereas the distress related to tooth loss/removable dentures is regarded a long-term disorder; therefore, the GHQ is not suitable to measure such impact (Goldberg and Williams, 1988). Moreover, some authors used tools that explore the functional disability and feelings associated with tooth loss; however, those tools are not suitable to screen and quantify psychological morbidity caused by dentures treatment (Anjum et al., 2017).

1.8 Personality traits and denture's satisfaction

There have been some reports that the psychological and emotional reaction to tooth loss/denture may also be determined and shaped by the individual personality (al Quran et al., 2001; Ozdemir et al., 2006; Fouda et al., 2014). Therefore, the possible relationship between the acceptance of dentures and the different personalities has also been investigated. It was previously reported that there is a correlation between denture dissatisfaction and personality traits (al Quran et al., 2001; Ozdemir et al., 2006; Fouda et al., 2014). Al Quran et al. (2001) used personality profiles and denture satisfaction questionnaires to assess the influence of psychological factors on denture acceptance. Their research reported a significant link between the acceptance of dentures and different personalities (especially neuroticism). Patients with high neuroticism scores had limited psychological resilience and less capacity

to adapt to new changes. Interestingly, those patients complained more and were often not satisfied with their dentures. Similar outcomes were concluded by other researchers (Fouda *et al.,* 2014; Ozdemir *et al.,* 2006). Furthermore, Fenlon *et al.* (2007) also reported that denture wearers with neurotic personalities were significantly less satisfied with their dentures. However, this did not affect whether or not the dentures were worn. On the other hand, some previous studies found no correlation between personality traits and complete dentures acceptance (Smith, 1976).

Nevertheless, one drawback in some of the above studies was sample recruitment (al Quaran *et al.,* 2001; Fenlon *et al.,* 2007). Participants were recruited at the Dental Hospitals, and it could be speculated that those patients who sought treatment in the Dental Hospital setting or had been referred to the Secondary Dental Care presented with more complicated dental issues and had a different personality type when compared to the patients seen in the General Dental Practice setting.

The relationship between personalities, denture acceptance and denture usage are still unclear and inconsistent. That could be due to the different methods used to assess personalities/dissatisfaction (Berg *et al.*, 1986). Those researchers suggest that only "focused interviews" could predict personality impact on denture accepted.

1.9 Psychological morbidity measures

1.9.1 Introduction

Screening tools have widely been used to assess depression, anxiety and distress in patients with various medical conditions, such as amputations, prosthesis replacements, chronic illness, cancer and palliative (Plourde *et al.*, 2016). The possibility of implementing some of the available tools could be considered to screen and measure psychological morbidities in patients with tooth loss.

To-date, there are many screening tools that measure symptoms of depression, emotional distress, and psychological disorder in patients with different chronic systemic diseases. Within the scope of this study, we will discuss the available screening measure and their suitability for the assessment of psychological disturbance in patients with tooth loss.

1.9.2 Health and disease outcome measures:

To measure the burden of a disease (tooth loss) or the effectiveness of an intervention (denture), two outcome measures could be utilised:

Firstly: an assessment by a professional clinician should be considered. This assessment is usually objective, defined by the knowledge and experience of the clinician. The clinician assessment aims to establish if the patient is disease-free, and assess the benefits of an intervention. In the case of tooth loss, the clinician determines the health of the oral structures, and the

technical quality of the denture in terms of retention, stability, appearance and articulation.

Secondly: patient-centred outcome measures also play an important role. This assessment is usually subjective, defined by the patient personal, social and cultural factors (Allen, 2003). This assessment aims to establish the patient perception of the impact of the disease and the benefits of an intervention, i.e. the effect of tooth loss on patient's mastication, social interaction and psychological well-being. Patient-centred outcome measures include OHRQoL measures, disease-specific impact measures and satisfaction surveys.

There have been reports that the clinician objectives assessment of a disease provides little insight into the patient's daily living (Slevin *et al.*, 1988; Allen, 2003). There has also been growing emphasis on the patient-centred outcome measures, like OHRQoL measures to establish the impact of a disorder on the patient daily living. The Work Health Organization Constitution defines health as: "*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*" (WHO, 1948). Therefore, the absence of disease merely is not enough to meet the WHO definition of health. Normal function and social interaction are also required to meet the WHO well-being threshold.

Therefore, both the clinician and the patient's perceptions are needed to fully capture all the dimensions of the disease. For example, a patient with

advanced periodontal disease could be symptom-free, and with good OHRQoL score. Therefore, an objective clinician assessment is also required to fully assess and monitor the periodontal disease. A patient outcome measurement would enhance the clinician assessment to capture all aspects of the disease.

Measures that record a disorder/intervention could be generic or disease-specific measures. This research mainly aims to investigate the disease-specific measure, i.e. the disease of tooth loss and psychological morbidities. While the OHRQoL measures are useful in assessing the impact of tooth loss/dentures, nevertheless there are some concerns about using those measures to assess the psychological morbidities associated with tooth loss:

Firstly: OHRQoL are generic oral health measures, and they may not be sensitive to specific oral health outcomes like tooth loss or denture (Allen *et al.,* 2001; Allen, 2003; Sischo and Broder, 2011), i.e. OHP-14 includes triple barrel items asking about three aspects in each question: tooth loss/dentures/oral health. Therefore, when the patient answers the question, it will be difficult to know whether the impact relates to tooth loss, denture or oral health. Many researchers advise avoiding double and triple barrels questions to improve the sensitivity of a measure (Artino *et al.*, 2014).

Secondly: a disease-specific measure has a higher "floor effect", i.e. no impact (Sischo and Broder, 2011). That is because some of the symptoms, which are included in some of the OHRQoL measures, are less relevant to specific

conditions, i.e. bleeding gingivae is more relevant to periodontal disease and less relevant to tooth loss.

Thirdly, OHRQoL might not have enough responsiveness to measure the changes in a specific disease like tooth loss or an intervention like dentures (Allen *et al.,* 2001; Allen, 2003), i.e. in the OHIP-14 scale, the general problems in oral health may mask benefits after successful denture treatment. Hence, a disease-specific measure is more capable of capturing small changes (Allen, 2003).

Fourthly, it was reported that changes recorded in the OHRQoL are not always meaningful for patients. Sischo and Broder (2011) reported that even when the OHRQoL changes are statistically significant, those changes could be clinically negligible to patients.

Finally, OHRQoL only illustrates the functional and psychosocial well-being of patients (subjective measures). However, those questionnaires have not been developed or validated to screen for psychological morbidity (objectives measures), i.e. an individual may not interact socially with their environment as they use to do (recorded as a negative impact on the OHRQoL); however, this individual may not meet the threshold for defining a psychological disorder (i.e. depression, anxiety or stress). The psychosocial impact and psychological morbidity are related, but different domains. Therefore, a disease-specific measure should be used to measure psychological morbidities associated with tooth loss.

1.9.3 Measures for psychological morbidities:

As discussed in chapter one, there is a bi-directional relationship between oral health and general health. Nevertheless, trying to measure the psychological morbidity that is associated with tooth loss is problematic and complicated for the following reasons:

- There are various definitions and different thresholds that diagnose psychological disorders (WHO, 2010; DSM-5 2013).

- The causes of psychological disorders are usually multifactorial (WHO, 2010, DSM-5 2013).

- There are multiple confounding factors that could influence psychological morbidities (i.e. age, gender, general health, socioeconomic factors, genetic) (DSM-5 2013).

- Psychological disorders could be inconsistent, unpredictable, and changes from time to time (ICD-10 2010, DSM-5 2013).

- There are various tools available to measure psychological morbidities; however, there is also disagreement among researchers about their validity and reliability to measure such disorders.

Various questionnaires and tools have been used to detect psychological disorders in various chronic and acute medical conditions. The validation and psychometric properties of those tools have been examined and studied extensively. The possibility of implementing some of those tools to screen and measure psychological morbidities in patients with tooth loss are briefly outlined below:

1.9.3.1 Zung Self-Rating Depression Scale (ZSDS)

ZSDS is a self-reporting questionnaire to screen for symptoms of depression (Zung, 1965). ZSDS has 20 items, which generates scores calculated on a point scale of 20 to 80. A cut-off point of 39/40 is validated for depression screening in working-aged populations (Zung, 1973). The psychometric properties of the ZSDS have been validated with a sensitivity range of 79%-100% and specificity range of 55-57% (Kitchell *et al.*, 1982; Okimoto *et al.*, 1982). Zung has also created the Zung Self-Rating Anxiety Scale (SAS), which also has 20 items and screens anxiety disorders (Zung, 1971).

1.9.3.2 Distress Thermometer (DT)

The Distress Thermometer (DT) is a single item visual analogue scale developed to screen for distress in oncology patients (NCCN, 2016). While a systematic review by Stewart-Knight et al. (2012) concluded that further research is needed to validate the DT, another recent systematic review by O'Donnell (2013) concluded that The DT is a fast and effective way to screen for psychological distress in cancer patients. There have also been conflicting studies about the sensitivity and specificity of a single-item screening tool. Chochinov *et al.* (1997) reported that a single item question, e.g. "*Are you depressed*" had 100% sensitivity and specificity whereas Lloyd-Williams et al. (2004) found this single item has a sensitivity of 54% and specificity of 74%. The use of a single item tool to screen and measure emotional distress in patients with tooth loss is unlikely to capture all the dimensions of a possible psychological disorder.

1.9.3.3 Generalised Anxiety Disorder Assessment (GAD-7):

GAD-7 is a 7-item questionnaire developed by Spitzer *et al.* (2006). It takes 1-3 minutes to complete and measures anxiety symptoms over the last two weeks. Each item generates a score of 0 to 3 with a cut-off point of ≥10, indicating severe anxiety and a recommendation for further assessment. At the threshold of ≥10, the GAD has a sensitivity of 89% and specificity of 82% (Kroenke *et al.*, 2007). However, the GAD-7 does not measure all the dimensions of emotional distress, and thus, it is not suitable for patients with a chronic medical condition such as tooth loss (Spitzer *et al.,* 2006).

1.9.3.4 General Health Questionnaire (GHQ):

The GHQ created by Goldberg and Williams (1988) is used to screen for minor psychiatric disorders. It has four versions: GHQ-60, GHQ-30, GHQ-28 and a brief version GHQ-12 (with a various number of items: 60, 30, 28 and 12 respectively). While the GHQ 12/30/60 calculates a global score, the GHQ-28 has four sub-scores and a total score. The GHQ-12 had a variation in sensitivity and specificity between different cities for a given threshold value (sensitivity range was from 68.0 to 93.5% and the specificity ranged from 59 to 93% (Goldberg *et al.*, 1997). Although the GHQ is widely used to screen psychiatric disorders, it is not suitable to screen for psychological distress in patients with tooth loss as it is not sensitive to long-standing psychiatric disorders as in the case of tooth loss (Goldberg and Williams, 1988).

1.9.3.5 Hospital Anxiety and Depression Scale (HADS)

HADS was developed to screen anxiety and distress in a hospital setting (Zigmond and Snaith, 1983). It is one of the most used tools to screen depression and anxiety (Herrmann, 1997). It has 14 items (7 items to measure depression and 7 to measure anxiety). A total score of >11 indicates anxiety or depression. The sensitivity and specificity for HADS was approximately 80% (Bjelland *et al.*, 2002). However, Cosco *et al.* (2012) concluded in a recent systematic review of 50 studies that the HADS has an inconsistent structure with serious psychometric problems, and that is highly dependent on statistical methods. Other researchers also recommended abandoning the HADS and concluded that its structure certainly does not match anxiety and depression subscales (Coyne and van Sonderen, 2012). Consequently, the use of HADS is not suitable to measure psychological morbidities in patients with tooth loss.

1.9.3.6 Depression, Anxiety and Stress Scales (DASS)

DASS (Lovibond and Lovibond, 1995) measures the negative emotional symptoms (depression, anxiety and stress). DASS is based on a dimensional measure of psychological disorder, which assumes that the differences between the normal and the clinically disturbed are differences of severity (Lovibond & Lovibond, 1995). DASS has two versions, DASS 42 (42 items) and a short version DASS 21 (21 items). Both have their psychometric properties validated (Antony *et al.*, 1998). DASS 21 has a set of three self-reported scales for screening depression, anxiety and stress (seven items for each scale). Each item generates a score from 0 to 3. The item scores are multiplied by two and

a final score calculated. A recommended cut-off score for normal/emotionally disturbed with a degree of severity is shown on the DASS threshold table.

DASS-21 is preferred over the other screening tools to screen for psychological morbidities in patients with tooth loss, as it has been extensively researched for its psychometric properties (Brown *et al.*, 1997; Henry and Crawford, 2005), it has also been tested in clinical samples (Brown *et al.,* 1997; Antony *et al.,* 1998) and it can identify and differentiate the degree of depression from anxiety and stress (Henry and Crawford, 2005). However, further validation is needed before implementation of DASS-21 in patients with tooth loss.

1.9.3.7 WHO (Five) Well-being Index:
WHO-5 is a brief screening tool designed to measure the "well-being" in primary care (Bech *et al.,* 1996). The WHO-5 has five positive phrased questions, which ask about the well-being in the last two weeks. It generates a percentage score of 0 to 25, with a cut-off score of <13, indicating poor well-being. Topp *et al.* (2015) concluded in a recent systematic review that the WHO-5 has adequate validity to screen for depression and it could be used as a measuring tool in clinical trials with average sensitivity and specificity of 86% and 81% respectively. The WHO-5 has been validated to screen for depression in elderly populations (Lucas-Carrasco *et al.,* 2012; Allgaier *et al.*, 2013), in chronic illness such as Parkinson's disease (Schneider *et al.*, 2010) and in patients with diabetes (Furuya *et al.*, 2013; Hajos *et al.*, 2013). However, the WHO-5 is not ideal for measuring psychological morbidities associated with tooth loss as it

only screens depressive symptoms but not anxiety and distress (Bech *et al.,* 1996).

1.9.3.8 Patient Health Questionnaire PHQ-9

The PHQ-9 is a self-assessment questionnaire to monitor and measure depressive disorders (Kroenke *et al.,* 2001). The PHQ-9 also rates the frequency of the symptoms. The PHQ-9 has nine items, which uses the diagnostic criteria of the DSM-IV. A threshold of ≥10 indicates major depression with sensitivity and a specificity of 88%. The PHQ-9 has been validated to screen and measure for depression in primary care (Cameron *et al.*, 2008), in patients with coronary heart disease (Haddad *et al.*, 2013), in patients with cerebral vascular accidents (de Man-van Ginkel *et al.*, 2012) and in diabetic patients (van Steenbergen-Weijenburg *et al.*, 2010). However, the PHQ-9 does not screen/measure anxiety or distress, and additional tools are needed to screen for those dimensions of psychological disorders (Kroenke *et al.,* 2001).

There are several other less common scales; however, they are beyond the scope of this review. Examples of the less used scales: The Beck Depression Inventory (BDI), the Center for Epidemiological Studies Depression Scale (CES-D), Present State Examination (PSE), Hamilton Rating Scale for Depression, the Diagnostic Interview Schedule (DIS), the Composite International Diagnostic Interview (CIDI), the Schedules for Clinical Assessment in Neuropsychiatry (SCAN) and the CIDI-depression short-form (CIDI-SFMD).

1.10 Conclusion

This literature review illustrated that although many patients cope well with tooth loss and removable dentures, some might have less psychological resilience and capacity to adapt to new changes. Those individuals may endure negative emotions and psychological disturbance.

Although screening tools have been widely used to measure depression, anxiety and distress in patients with various medical conditions; nevertheless, there have been few quantitative studies which have used such tools to assess the psychological impact of tooth loss and dentures.

To further explore the suitability of those tools to assess the psychological disturbance in patients with tooth loss and denture, a systematic review has been conducted and is being presented in the following chapters.

CHAPTER TWO: METHODS

2.0 Introduction:

The main aim of this thesis is to test the null hypothesis "*Tooth loss and the provision of dentures is not associated with psychological disturbance*". The method to test the null hypothesis involved three consecutive studies:

- The first study: was a systematic review, which assessed the availability of questionnaires to test the null hypothesis.

- The second study: was a qualitative and quantitative study that developed and validated a questionnaire to test the null hypothesis.

- The third study: was a quantitative cross-sectional study which used the validated questionnaire to test the null hypothesis.

The methods 2nd and the 3rd studies are illustrated in Figure 3.

Define aims of questionnaire
&
Identify questionnaire constructs

Generating a pool of items

Focus interviews
-Patients (n=30)
-Clinicians (n=10)

Review of published literature and scales

16 scales

35 statement/problems

12 statement/problems

Items reduction (n=10)
Participants were asked to report the frequency of each problem/symptom on a five-point Linkert scale (Don't know, Never, Rarely, Sometimes, Often, Very Often). For each item, an importance score was produced by calculating the mean score. The least important items were removed.

Discussion with psychologist

9 statement/problems

3 extra items were added to assess implant/denture acceptance

12 items (Part B)

Identify Psychological morbidities tools (page 53) DASS-21 & DT (Part A)

37

Questionnaire version 1 (page 100)

Content validation
Experts panel review (n=10)

Initial **face validation**
Interviews with patients (n=10)

**Questionnaire version 2
(page110)**

Final **face validation**
Interviews with patients (n=10)

**Questionnaire version 3
(page 115)**

Construct validation
(n=20)

Pilot cross sectional survey
+
Test re-test reliability
+
Internal consistency

(n=20)

**Questionnaire version 4
(Final version, page 123)**

Questionnaire
changes table: 23

Questionnaire
changes table: 23

Questionnaire
changes table: 25.26

No changes

Questionnaire
changes table 31

Validity testing

Reliability testing

Cross sectional study
(n=138)

Identify primary care sites for recruitment

Inclusion criteria
- Male or female
-≥ 18 years of age
-Stable medical health
-Extensive tooth loss (section 2.2.2.2)
-Satisfactory dentures (section 2.2.2.2)
-Dentures ≥ 1 year
-Stable dentition (free of active dental disease)

Exclusion criteria
-Unable to speak/read English
-Complicated medical history
-History of psychotic mental illness
-History of previous dental implant treatment
-Presence of primary dental disease

Eligible participants
(both locations)
(denture n=70, control n=70)

Recruited participants
(both locations)
Denture group (n=70)
Control group (n=70)

Completed data collection
(n=138)
Denture (n=70)
Control (n=68)

Drop out
(incomplete data)
Denture (n=0)
Control (n=2)

Data analysis
(n=138)
Denture (n=70)
Control (n=68)

Recruitment

Data collection

Data analysis

2.1 Psychological morbidity measures for patients with tooth loss/dentures: a systematic review

2.1.1 Aim

This systematic review aimed to assess the available validated questionnaires which measure the psychological impact of tooth loss and the effect of provision of dentures on this psychological impact.

2.1.2 Data sources and searches

The study protocol was registered with the National Institute of Health Research Database (Registration I.D. CRD42017082125). An extensive search was conducted to identify relevant studies by searching the electronic databases (Medline via Ovid, Scopus, and Embase). Furthermore, reference searches were also undertaken to identify any other relevant studies. The search was carried out without applying any time limits (up to 12/2017) or language restrictions. The list of keywords used in the search process, and the results of the electronic database search are illustrated in Appendixes 9 and 10, respectively.

2.1.3 Study selection

The PICOS tool (Table 2) was used to formulate a search strategy. Participants were adults (≥ 18 years of age), of any ethnic group who were edentulous or with significant tooth loss (< 9 remaining teeth). The interventions included undergoing replacement with technically successful removable dentures. A control group of adults' participants (≥18), who were either edentulous or with significant tooth loss (< 9 remaining teeth) and without any replacement

prosthesis, i.e. denture. Outcomes included assessing psychological distress

due to treatment with RD or due to no treatment using a validated tool.

Table 2: PICOS Research Question Development

	Inclusion criteria	Exclusion criteria
P – patients/problem	Adults ≥18 with significant tooth loss	-History of mental illness -Replacement with dental implants
I - intervention	Patients who had a replacement with technically successful RD	Poor quality RD
C - control	Patients who had no replacement with RD	
O – outcomes measures	Patients' psychological distress caused by tooth loss	Non validated tool/measure
S -study design	Quantitative Randomised controlled trials Non-randomised controlled trials Retrospective, prospective, or concurrent cohort studies cross-sectional studies	Qualitative Opinion, editorials

Concept one (Population)

    #1 Tooth loss

    #2 Teeth loss

    #3 Edentulous

    #4 Edentulism

    #5 Toothless

    #6 Denture

    #7 prosthesis

#8 Concept one (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7)

Concept Two (Outcome Measure)

    #9 Depression

    #10 Anxiety

    #11 Distress

    #12 Psychological

    #13 Psychology

    #14 Emotional

#15 Concept two (#9 or #10 or #11 or #12 or #13 or #14)

Concept Three (Assessment):

    #16 Screening

    #17 Measure

    #18 Instrument

    #19 Questionnaire

    #20 Validation

    #21 Scale

    #22 Diagnosis

    #23 Test

    #24 Assessment

#25Concept Three (#16or #17or #18or #19or #20or #21or #22 or#23or #24)

#26 (#8 AND #15 AND #25)

The study design included quantitative, randomised controlled clinical trials, non-RCTs, cross-sectional, prospective and retrospective. Furthermore,

studies that involved the replacement of tooth loss either with dental implants or unsatisfactory dentures were excluded.

Based on these selection criteria, the titles and abstracts were examined independently by two examiners (ZK, AB) and any disagreements were resolved according to a predefined strategy, using consensus and arbitration as appropriate. If however, the disagreement could not be resolved, then a third investigator (MF) agreed to be approached to help reach consensus.

2.1.4 Data extraction and quality assessment

The relevant titles and abstracts of articles were collected and then double-checked by a second examiner (AB). Studies not meeting the inclusion criteria were recorded under 'Characteristics of excluded studies' along with their reasons for exclusion in Table 3. Subsequently, full texts were independently reviewed by two examiners (ZK & AB). The references cited in the included studies were further checked.

2.1.5 Risk of bias

Two authors assessed independently the risk of bias in the included studies (ZK, AB) and any disagreement was resolved by discussion with a third author (MF). Five domains were scored to quantify the risk of bias: selection bias, measurement bias, interviewer bias, response bias and other potential sources of bias. Subsequently; an overall judgment was made to mark each study as low risk of bias, high risk of bias or unclear.

2.1.6 Data analysis

Data homogeneity was assessed in regards to the screening tools to measure psychological distress following the management of tooth loss with RD. The significance level was set at 0.05, using IBM SPSS Statistics 24.0 (SPSS Inc., New York 10504-1722, USA). The psychometric properties and the validation processes of the screening tools were assessed. Tooth loss pattern/number, RD quality and functional/psychological impact of tooth loss were also recorded.

2.2 Development and validation of a questionnaire to measure the impact of tooth loss/dentures

2.2.1 Aim

To develop and validate a questionnaire which measures the psychological impact of tooth loss and the effect of provision of dentures on this psychological impact.

The development of such questionnaire was required to test the null hypothesis, as the systematic review in Study 1 reported that there were no validated disease-specific measures to investigate the psychological impact of tooth loss/removable dentures (section 4.1.1).

2.2.2 Methods for recruitment of participants for the questionnaire development/validation

2.2.2.1 Inclusion Criteria

- Male or female ≥ 18 years of age.

- Participants who are capable of giving informed consent

- Any cultural/socioeconomic backgrounds

- NHS or private patients with tooth loss, who attend a routine dental appointment at the selected primary care locations (Oasis Steeple Grange Dental Surgery, 36 Steeple Grange, Wirksworth DE44FS, Ware Dental Care, 3 West Street, Ware, Hertfordshire, SG12 9EE).

  (There is a risk a bias between the technical qualities of dentures made for NHS and private patients. To reduce this risk, the technical quality of

all dentures will be checked against a validated tool to confirm all dentures included in the study are technically successful).

- Stable medical health: ASA I, ASA II, stable ASA III.

- Either acquired or congenital tooth loss

- Edentulous or partially dentate:

  — Kennedy's classification Class I with at least two missing teeth

  — Kennedy's classification Class II with at least two missing teeth

  — Kennedy's classification Class III with at least four missing teeth

  — Kennedy's classification Class IV with at least four missing teeth

- Technically and clinically satisfactory dentures

- Dentures used by participants for ≥ 1 year

- Stable dentition (if present), free of primary dental disease (active dental caries/periodontal disease).

The primary care premises were selected for the following reasons:

- Sample from primary care (not hospital-based sample)

- Access: The Principal Investigator has access to those locations.

- Management: Motivated and efficient management team who will grant access/permission for research following ethical approval.

2.2.2.2 Exclusion criteria

- Unable to speak/read English

- Complicated medical history: unstable ASA III and ASA IV

- History of psychotic mental illness

- History of previous dental implant treatment

- Presence of primary dental disease (active decay, periodontal disease)

- Presence of active/chronic periodontal disease (purulent exudate, tooth mobility, and/or extensive bone loss)

- Participation in another dental study during the previous three months and also during the study period

2.2.2.3 Study Design

This part of the study is qualitative in nature, will involve a series of patients interviews, clinician and experts feedback to develop and validate a questionnaire which will be used to measure the psychological disturbance associated with tooth loss/dentures.

Ethical approval for this project ware obtained from the Health Research Authority (REC reference 17/NI/0098).

2.2.2.4 Screening and informed consent procedures

Patients with tooth loss, who presented for a routine dental appointment at the selected primary dental care locations, and were eligible to join according to the inclusion/exclusion criteria, were approached by the PI to participate in the study.

Those who wished to participate were handed the Patient Information Sheet (PIS), which explained the nature of the study (Appendix 5). The leaflet ensured that participants understood the sensitive nature of the personality screening questions. Participants were given 30 minutes to read the PIS, and then they decided if they wish to participate in the study on the same day or if they wish

to take more time to think about joining the study (candidates were given up to two weeks to consider joining).

The PIS also clarified that participating in the study was not compulsory, and all data was strictly anonymised and confidential (questionnaires were identified by codes only). Written consent forms (Appendix 6), were signed by all participants prior to the study. This phase took around 15 minutes.

2.2.2.5 Examiner calibration:

The purpose of the examiner calibration was to assess intra/inter-examiner reliability of the denture's quality assessment. Two examiners ZK & AB assessed denture's functional quality using items from the Functional Dental Assessment tool (Corrigan *et al.,* 2002). The first calibration attempt at SGDP was not successful as many subjects who agreed to join the study, cancelled their proposed appointment on short notice. Therefore, there were not enough subjects available to conduct the calibration test. A second calibration attempt was conducted at WDC. A £25 M&S voucher was provided to the subjects who expressed willingness to attend the calibration test (vouchers sponsored by QMUL, Dental Department). A total of 10 patients with conventional dentures expressed willingness to join the calibration study; however, only nine (n=9) attended the calibration test.

The intra-examiner calibration was conducted by ZK. Nine candidates with conventional dentures (n=9) were recruited. Each candidate had his/her

denture examined twice (with a 60 min gap). Excel (Microsoft 2010) was used to calculate the intra/inter-examiner calibration.

2.2.3 Methods for questionnaire development

Systematic development of a questionnaire is essential to improve data collection and minimise measurement errors. Some questionnaires used in research failed to establish validity, and this could lead to measurement error (Radhakrishna, 2007). Different methods were suggested to develop and test a questionnaire. The Scientific Advisory Committee of the Medical Outcomes Trust (Aaronson *et al.*, 2002) produced a list of eights attributes with quality criteria to help develop questionnaires and enhance their validity. Firstly, designing a conceptual and measurement model that should include: a measurable concept, a defined target population, an established the level of measurement. Secondly, assessing reliability, validity, responsiveness and interpretability. Finally, the burden to use the questionnaire should be assessed, i.e. time and efforts for respondents/administrators to use the questionnaire. The SAAC (Aaronson *et al.,* 2002) has also recommended additional attributes to be used if alternative methods are implemented when the questionnaire is used (using a computer, an interviewer or using a self-administrated questionnaire). If there are language and/or cultural influences on the questionnaire validity, then those should be managed as well (Aaronson *et al.,* 2002).

Other researchers also described similar methods to design and validate a questionnaire, focusing on defining the objectives of the questionnaire and the

research (Radhakrishna, 2007; Terwee *et al.*, 2007; Artino *et al.,* 2014). The development process should include feedback from experts and focus interviews with participants. Validity and reliability of the questionnaire should be adequate for the research aims and the targeted population.

Although there are different strategies to design and validate a questionnaire as outlined above, all the methods share common consensuses, which will be used to develop the questionnaire for this study. The various steps outlined below:

- Describe the aim of the questionnaire and define the target population

- Define the constructs to be measured

- Literature review

- Generate items and develop a preliminary measure

- Focus interviews/face validation

- Experts validation

- Establish reliability (Test re-test reliability – Internal consistency)

- Establish construct validity

- Pilot testing and final refinement

2.2.3.1 Defining the aims and constructs of the questionnaire

2.2.3.1.1 Aims of the questionnaire

One of the first steps in designing a measure is to identify the questionnaire aims (Terwee *et al.,* 2007; Artino *et al.,* 2014). This step is critical as the same questionnaire could be valid for one aim and not valid for another (Terwee *et al.,* 2007; Artino *et al.,* 2014), i.e. items that explore the impact of tooth loss could differ from items that assess the impact of periodontal disease. Although

both are related, and periodontal disease may lead to tooth loss, nevertheless, they have different characteristics, and therefore, different items are needed to capture the impact of each disorder.

This study aims to assess the impact of tooth loss in patients who have good quality dentures. Therefore, this is a self-reported measure of a specific disease (tooth loss) and a self-reported outcome measure of an intervention (technically successful denture). Specifically, the questionnaire aims to assess the psychological health and wellbeing of adults with technically successful dentures.

2.2.3.1.2 Constructs of the questionnaire

Construct is defined as "*hypothetical theory that a researcher is attempting to assess*" (Artino *et al.,* 2014). Many constructs are not observable such as intelligence, satisfaction, motivation and emotions. These constructs are more difficult to measure, as they have no metric unit to record them. The best way to measure such non-observable constructs is to identify the various conceptual elements of each construct (Artino *et al.,* 2014), i.e. to assess the body image impact of tooth loss, one could ask a general question, "*have tooth loss affected your self-image/appearance*?" However, this question may not capture the various impacts of tooth loss on body image, and a better approach will be to ask a series of questions about "*tooth loss self-awareness*", "*impact on socializing*" and "*impact on relationships*" etc. As those elements are related and represent this specific construct (De Velllis, 2003).Therefore, when designing a questionnaire, the dimensions of the construct which will be measured should be identified and described (Aaronson *et al.,* 2002; De Vellis,

2003, Terwee *et al.,* 2007). This is done through generating a bank of items and then assigning the related items into subscales to represent the construct. This process should be progressive and multi-perspective to ensure that all aspects of the "impact of tooth loss" are identified. The multi-perspective steps include literature review, examining existing scales, professional opinions and patient's feedback (Aaronson *et al.,* 2002; De Vellis, 2003; Artino *et al.,* 2014).

2.2.3.2 Development of preliminary items

When generating items for the questionnaire, there is a risk that the items might represent biased opinions of a researcher and not the actual problems/ difficulties experienced by respondents. Therefore, items should be developed based on participants' feelings and experiences (Aaronson *et al.,* 2002; Artino *et al.,* 2014). Clinicians' feedback could also enhance the questionnaire quality as some "*difficult to measure items*" could be identified (Artino *et al.,* 2014).

In this study, a pool of items that relate to all problems which were observed and/or experienced with tooth loss/dentures was produced through focus interviews with participants (n=30), clinicians' feedback (n=10) and the literature review (chapter one). The number of participants/clinicians was adequate to generate a large pool of items as advised by Devon *et al.,* (2007). Willis and Artino (2013) also suggested that between 10 and 30 participants are adequate for qualitative studies.

Participants were recruited according to the study protocol (section 2.2.2.2). Each participant was asked to list all problems, difficulties and emotions that

2.2.3.3 Psychological morbidity screening tools

The items that have been generated from the patients/clinicians interviews and the literature review were used to create a preliminary questionnaire to measure the impact of tooth loss. Nevertheless, further items are still required to screen for somatic symptoms of depression, anxiety, and distress, as the aim of the study was to assess the psychological morbidities associated with tooth loss/dentures. Researchers recommend that in the processes of developing a questionnaire, if suitable scales/items were identified in the literature review, then it is more practical to use them, and built on them, rather than start with a completely new questionnaire (Artino *et al.,* 2014). Based on that, two measures identified in chapter one were used in this study: the DASS-21 and the DT.

2.2.3.3.1 The Depression, Anxiety and Stress Scale (DASS-21)

The DASS-21 (Lovibond and Lovibond, 1995) that screen for Stress, Depression and Anxiety has been identified as the most suitable questionnaire to investigate the psychological disturbance associated with tooth loss (chapter one). The DASS-21 has been extensively researched for its psychometric properties (Brown *et al.,* 1997; Henry and Crawford, 2005; Brown *et al.*, 1997), has been tested in clinical samples (Antony *et al.*, 1998) and it can identify and

differentiate the degree of depression from anxiety and stress (Henry and Crawford, 2005).

The suitability to use the DASS-21 in the study was confirmed after further extensive discussion with an expert psychologist Dr Kirsty Hill (Dental School, Birmingham University).

The DASS-21 (Table 5) has 21 items, divided into three subscales with seven items to screen for depression, seven items for anxiety and seven items for distress. The scale generates scores for depression, anxiety and stress. The DASS-21 proposes that the differences between depression, anxiety and stress experienced by the normal and the pathological, are differences of degree (Table 6). The DASS-21 has been previously validated to be used on a general population. Its validity will be assessed again to confirm suitability for the tooth loss/denture population.

Table 5: DASS21 Questionnaire (Lovibond and Lovibond, 1995)

Please read each statement and circle a number 0, 1, 2 or 3, which indicates how much the statement applied
 to you. The rating scale is as follows:
0   Did not apply to me at all
1   Applied to me to some degree, or some of the time
2   Applied to me to a considerable degree or a good part of time
3   Applied to me very much or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (e.g. in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

Table 6: DASS21 Scores (Lovibond and Lovibond, 1995)

	Depression	Anxiety	Stress
Normal	0-9	0-7	0-14
Mild	10-13	8-9	15-18
Moderate	14-20	10-14	19-25
Severe	21-27	15-19	26-33
Extremely Severe	28+	20+	34+

2.2.3.3.2 Distress Thermometer (DT)

The Distress Thermometer (DT) is a visual analogue scale (Table 7), adapted from The Distress Thermometer that is used by the NCCN to screen for distress in cancer patients (NCCN, 2016). While the DASS-21 measures the general somatic symptoms related to psychological disturbance, the DT measure distress directly. The validity of those two measures will be assessed during the validation processes.

Table 7: DT visual analogue scale

How would you rate the impact of tooth loss and dentures on your quality of life?										
0	1	2	3	4	5	6	7	8	9	10
No distress					Mildly distress					Severe distress

The result of the first phase of questionnaire development generated items that capture body image, functional difficulties and the DASS-21 and DT measures that assess psychological morbidities. The 2_{nd} phase will assess the validities of all those measures.

2.2.3.4 Questionnaire Item reduction

Willis and Artino (2013) recommended that a small sample (10-30) of participants is adequate for qualitative analysis; therefore, ten participants were recruited to review the items. The number of items which were generated in phase one was then reduced according to a five-point Likert Scale.

Recruitments were carried out according to the study protocol (section 2.2.2.2). The list of items/problems, which was generated in phase one, was presented

56

to ten participants. Each participant was asked to report the frequency of each problem/symptom in the last year on a five-point Linkert scale (Don't know, Never, Rarely, Sometimes, Often, Very Often). Answers "Never" to "Very Often" were allocated numbers "0" to "5" ("Don't Know" answers were dropped). For each item, an importance score was produced by calculating the mean score. The item presented with a high importance score, if more participants experienced the same problems and/or the frequency of the problems reported more often. The decision to report the frequency of the problems/symptoms (rather than intensity/severity) was due to the reported frequency that was less subjective and easier to define, i.e., individuals interviewed found the frequency scale less challenging to understand.

2.2.4 Methods for questionnaire validation

To assure the integrity of a measurement tool, the psychometrical properties (validity and reliability) of the tool should be confirmed. Validity is defined as the "*ability of the instrument to measure the attributes of the construct under study*" whereas reliability refers to "*the ability of an instrument to measure an attribute consistently*" (DeVon *et al*., 2007). Validity and reliability are related, and the questionnaire can be reliable but not valid; however, a questionnaire that is valid does have some degree of reliability (DeVon *et al.,* 2007). The interaction between the two concepts are illustrated in Figure 4:

Figure 4: Graphical presentation of validity and reliability (Bolarinwa, 2015)

Neither valid nor reliable
The research methods do not hit the heart of the research aim (not 'valid') and repeated attempts are unfocussed

Reliable but not valid
The research methods do not hit the heart of the research aim, but repeated attempts get almost the same (but wrong) results

Fairly valid but not very reliable
The research methods hit the aim of the study fairly closely, but repeated attempts have very scattered results (not reliable)

Valid and reliable
The research methods hit the heart of the research aim, and repeated attempts all hit in the heart (similar results)

Validating a questionnaire can be done by exploring the theoretical or empirical constructs of the measure. The former method establishes to what level the theoretical construct is portrayed in the questionnaire. This is done through face validation and content validation. The latter method compares different scales and attributes to establish validity. To improve the questionnaire validity, aspects of both methods need to be tested (Bolarinwa, 2015). Methods and types of validation are illustrated in Figure 5.

Figure 5: Subtypes of validity tests (Bolarinwa, 2015)

Validity tests	Theoretical construct	Face validity
		Content validity
	Empirical construct	Predictive validity
		Concurrence validity
		Convergence validity
		Discriminant validity
		Know-group validity
		Factorial validity
		Hypothesis testing validity

The following steps will be employed in the validation process (Aaronson *et al.,* 2002; Artino *et al.,* 2014; Bolarinwa, 2015)

- Content validation / item editing

- Focus interviews/item editing

- Cognitive and face validity testing / Questionnaire / item editing

- Reliability

- Construct Validity

2.2.4.1 Content validation

Content validity is defined as the extent to which a measure includes all the items needed to represent the construct (Roach, 2006). The content validity

was established by recruiting a panel of experts to review the questionnaire items for readability, clarity, comprehensiveness and redundancy of items (Aaronson *et al.,* 2002; Bolarinwa, 2015). Content validity helps to enhance the questionnaire validity (DeVon *et al.,* 2007; Artino *et al.,* 2014). Recruiting experts for content validity should be based on their expertise in questionnaire development and their willingness to participate (Artino *et al.,* 2014). Experts could be selected from the list of researchers identified during the literature review (Artino *et al.,* 2014). There is no agreement on the required number of experts required to assess content validation; seven or more experts are usually recommended by many authors (DeVon *et al.,* 2007, Artino *et al.,* 2014).

Recruitment of experts:

Forty-two potential experts were identified from the literature review (chapter one). Experts were contacted through emails. The purpose of the research explained, and they were invited to participate. Twenty-seven experts agreed to participate. Eighteen experts have returned their feedback within the required time. Eight experts provided partial feedback (Table 8).

Table 8: Expert panel recruitment

n= 42 (invited to join)
n=27 (willing to join the expert panel)
n=18 (experts returned the forms within the time frame)
n=8 (partial form completion and/or qualitative feedback only)
n=10 (fully completed the form)

Experts who expressed willingness to participate were emailed the preliminary items, the DASS-21 and the DT. Each expert was then asked to identify which items were essential for the measuring tool and to provide feedback about the structural design of the measure (Table 9).

Table 9: Content validation form

1. Overall, do you feel the questionnaire is appropriate tool to measure distress caused by tooth loss
   - Strongly disagrees
   - Somewhat disagree
   - Neither Agree nor Disagree
   - Somewhat Agree
   - Strongly Agree
2. Dose this questioner measure what it intends to measure? (Psychological disturbance caused by tooth loss)
   - Strongly disagrees
   - Somewhat disagree
   - Neither Agree nor Disagree
   - Somewhat Agree
   - Strongly Agree
3. Did you find it difficult to complete the questionnaire
   - Strongly disagrees
   - Somewhat disagree
   - Neither Agree nor Disagree
   - Somewhat Agree
   - Strongly Agree
4. The language & vocabulary used were appropriate
   - Strongly disagrees
   - Somewhat disagree
   - Neither Agree nor Disagree
   - Somewhat Agree
   - Strongly Agree

5. The second component of part "A" aims to correlate psychological distress with tooth loss/RP to identify tooth loss/RP as a direct cause of psychological distress and not just an association. Is this item
   - Essential
   - Useful, but not essential
   - Not necessary
6. If you would like to share any additional comments or experiences about, please enter them below.

The Lawshe method (1975) was used to assess which items are essential. Lawshe (1975) indicated that if 50% or more of the experts agreed that an item is essential, then that item has some content validity. The more experts agree on a specific item, the more content validity this item has.

2.2.4.2 Face validation

Face validity is defined as "*the degree to which test respondents view the content of a test and its items as relevant to the context in which the test is being administered*" (Holden, 2010). Face validation is important, as if respondents misinterpret or misunderstood the question (due to poor wording inadequate response options etc.), then the tool may fail to capture the intended construct, and this may lead to measurement errors (Artino *et al.,* 2014).

There are two different methods to test face validity, including "*think aloud method*" and "*verbal probing method*" (Artino *et al.,* 2014). In the first method, participants articulate their thoughts loudly while completing the questionnaire, and the researcher take notes to analyse the results later. In the verbal probing

method, researchers ask specific questions about the items to probe comprehension and interpretation (Willis and Artino, 2013).

In this study, both those method were used to face test the preliminary questionnaire. Artino and Willis (2013) recommended a sample size of 20-30 for qualitative analysis. For this study, ten participants were recruited for the initial face validation, and for the final validation, another ten individuals were approached.

2.2.4.2.1 Initial face validation

This phase included the evaluation of wording, clarity, and readability of the preliminary items. Table 10 illustrates DeVon *et al.,* (2007) method to evaluate the preliminary items. Eleven participants were recruited for the initial face validation. Recruitment followed the same processes as per the protocol (section 2.2.2.2). One participant was excluded, as the questionnaire was not fully completed. Participants were informed about the aims of the validation. The ten participants completed the proposed questionnaire in a quiet room with the PI present. This was followed by focused interviews to assess items, constructs and layout of the questionnaire. The focus interviews also asked about the suitability of the DASS-21 and DT as psychological measures related to tooth loss.

1. Overall, do you feel the questionnaire is appropriate tool to measure distress caused by tooth loss
    - Strongly disagrees
    - Somewhat disagree
    - Neither Agree nor Disagree
    - Somewhat Agree
    - Strongly Agree

2. Dose this questionnaire measure what it intends to measure? (Psychological disturbance caused by tooth loss)
    - Strongly disagrees
    - Somewhat disagree
    - Neither Agree nor Disagree
    - Somewhat Agree
    - Strongly Agree

3. Did you find it difficult to complete the questionnaire?
    - Strongly disagrees
    - Somewhat disagree
    - Neither Agree nor Disagree
    - Somewhat Agree
    - Strongly Agree

4. Do you feel that the language & vocabulary used were appropriate?
    - Strongly disagrees
    - Somewhat disagree
    - Neither Agree nor Disagree
    - Somewhat Agree
    - Strongly Agree

5. If you would like to share any additional comments or experiences about, please enter them below.

2.2.4.2.2 Final face validation

The final face validation aimed to test the revised items cognitively. This is done by probing the respondent's thoughts processes and determining that participant's understanding and interpretation of each item is accurate.

The assessment also included comprehension, recall, judgment and response of items in the questionnaire. Ten participants were recruited as per the study protocol (section 2.2.2.2). Their answers, feedback, opinion and criticism were recorded.

2.2.4.3 Questionnaire construct validity

Construct validity is defined as the extent to which items in a measure relate to the theoretical construct (DeVon *et al.,* 2007). Therefore, the items in the proposed questionnaire should be able to measure the concepts that are theoretically and structurally related to functional difficulties and body image.

Many methods exist to assess construct validity of a new measure, including hypothesis testing, testing against gold standard test and factor analysis (DeVon *et al.,* 2007). One of the common ways to assess construct validity is to develop and test a hypothesis about the expected relationship between constructs. This could be conducted by hypothesising a theoretical and structural relationship between different but related constructs. If this logical relationship existed, then this proves that the theoretical hypothesis of the new scale, and therefore indicates that the new scale has some degree of construct validity. (Aaronson *et al.,* 2002; Terwee *et al.,* 2007; DeVon *et al.,* 2007). The hypothesis testing method was used to assess construct validity in this study, as there were no gold standards to test against and factor analysis was no feasible due to the small sample size in this study.

To establish construct validity, it was hypothesised that the theoretical framework of the subscales of the body image and the functional difficulties should both correlate strongly (R>0.5) with the global DT scale (as all those three tools assess theoretical characteristic of tooth loss). It was also hypothesised that the functional difficulties domain of Part A would correlate strongly (r>0.5) with OHIP-14 functional limitation, physical pain and psychical disability domains. Furthermore, the body image domain of Part A would correlate strongly (r>0.5) with psychological discomfort and psychological disability and social disability domains. All those subscale measures are different, but related concepts. Therefore, construct validity will be supported if the scores reflected the framework as hypothesised. There is no clear agreement among researchers about the sample size needed to test construct validity (Roach, 2006; Devon *et al*., 2007; Artino *et al.,* 2014). Psychometric experts recommend that the minimum sample for factor analysis should be five participants *per* item/construct for correct analysis (Munro, 2005). Therefore, a sample of 20 participants were recruited as *per* the protocol (section 2-2-2).

2.2.4.4 Pilot test and final validation

A pilot study is defined as "*a version of the main study that is run in miniature to test whether the components of the main study can work together. It is focused on ensuring that the processes of the main study (e.g. recruitment, randomisation, treatment, and follow-up assessments) all run smoothly*" (NIHR, 2015). Pilot studies do not guarantee the success of the main study, but it increases the likelihood of success (van Teijlingen and Hundley, 2002). Pilot

testing also improves the internal validity of the questionnaire and helps to maximize response and completion rate (Puleo *et al.*, 2002). The pilot test in this study aimed to:

- Assess the reliability of the proposed scale (Test re-test and internal consistency)

- Test the questionnaire and identify any issues with wording, layout, instruction

- Assess the feasibility of the study and identify logistical/practical problems

2.2.4.4.1 Subject size and pilot test recruitment strategy

Different authors have different views on the size needed to pilot a survey study. Neuman simply suggested a "*small set of respondents*" (Neuman, 1997). Some authors suggested between 10-30 subjects (Julious, 2005). Other researcher proposed that a pilot test sample should be 10% of the sample projected for the main study (Connelly, 2008). Nevertheless, the size of the pilot test should not be considered a major issue as the main aim of the pilot test is to determine the feasibility of the study (Thabane *et al.*, 2010).

The pilot sample for this study was calculated the sample size for this pilot test based on 10% of the sample projected for the main study. Therefore, a sample size of 20 participants was recruited. Recruitment followed the same sampling strategy as reported in the protocol (section 2.2.2.2). The same inclusion and exclusion criteria have been implemented in the pilot sample recruitment

processes. Participants completed the questionnaire in a quiet room, and a retrospective interview was conducted after that to collect feedback.

2.2.4.4.2 Questionnaire reliability

Reliability is defined as "*The extent to which a measure is free from random error*" (Aaronson *et al.,* 2002). Hence, for a questionnaire to be reliable, it should generate reproducible and consistent measures. This consistency should be over time (measured by test re-test reliability), and across items (measured by internal consistency) (Aaronson *et al.,* 2002). Therefore, the proposed questionnaire in this study should be assessed for test re-test reliability and internal consistency to establish whether the proposed measure has acceptable reliability.

2.2.4.4.3 Questionnaire test re-test reliability

Test re-test reliability is confirmed if a measure is stable over time (Aaronson *et al.,* 2002). Test re-test reliability is assessed by administering the questionnaire to the same participants and under the same conditions twice with a specific time interval. Test re-test reliability is established when the same participant produces same or similar scores on repeated testing, i.e. the attributes measured maintain stability over time (Bolarinwa, 2015).

There have been different recommendations for the time interval between the test and the re-test, ranging from few days to few months. This time span between the two interviews should be long enough to avoid simple recall of previous answers, but short enough to avoid change in symptoms over time. Most researchers suggest a timing interval of 2 - 4 weeks. (Aaronson *et al.,*

2002, Bolarinwa, 2015) As the domains measured in this study are cognitive and emotional, it was decided to use two weeks intervals, as those attributes are not likely to change in this short period. The sample size recommended for test re-test reliability is between 20-30 participants (Radhakrishna, 2007).

The pilot sample was used to test re-test the questionnaire. Participants, who agreed to join the pilot testing, filled the questionnaire in a quiet room after signing the consent form. The same questionnaire was completed again by each participant under the same condition two weeks later. The re-testing questionnaire was completed just before the participants were scheduled for the pilot interview appointment. The reason for distributing the re-test questionnaire before the interview appointment was to prevent the interview interactions from influencing the re-test responses.

The test re-test reliability is assessed by measuring correlations between scores (Aaronson *et al.,* 2002). There are different ways to assess this correlation, including the ICC and Pearson Coefficient. However, some researchers argue that Pearson coefficient solely is not adequate, as the systematic differences in the test and re-test are not considered, and therefore the ICC should be used (Aaronson *et al.,* 2002; Terwee *et al.,* 2007).

As for test interpretation, the reliability coefficient (alpha) can range from "0" (indicating the tool is full of error) to "1" (indication total absence of error and perfect reliability). Therefore, a reliability coefficient of 0.50, indicates that 50% of the variations in measurement is due to real scoring, while 50% is

measurement errors. A reliability coefficient >0.7 indicated the acceptable reliability (Aaronson *et al.,* 2002; Roach, 2006; Radhakriskhna, 2007).

2.2.4.4.4 Questionnaire internal consistency

Internal consistency assesses whether the items that are measuring a specific domain generate consistent scores (Aaronson *et al.,* 2002). Cronbach's alpha is a reliable test to assess internal consistency (Cronbach, 1951; Artino *et al.,* 2014). The correlations between the different items are calculated, and this produces an internal consistency score, which ranges from negative infinity to one. Cronbach's alpha increases as the correlations among different items increase. A score of ≥0.7 indicates acceptable internal consistency (Table 11).

Table 11: Cronbach's alpha scores

Cronbach's alpha	Internal consistency
α ≥ 0.9	Excellent
0.9 > α ≥ 0.8	Good
0.8 > α ≥ 0.7	Acceptable
0.7 > α ≥ 0.6	Questionable
0.6 > α ≥ 0.5	Poor
0.5 > α	Unacceptable

A sample size of 20-30 is adequate to establish internal consistency (Bolarinwa, 2015). The data from the pilot sample (n=20) was used to assess internal consistency. SPSS Statistics Version 25 was used to analyse the data.

2.2.4.4.5 Questionnaire clarity, wording and layout:

The pilot test was also used to assess the questionnaire about the following:

- The time needed to complete the questionnaire

- Layout and design

- Clarity, wording and phrasing of items

Items clarity, scale adequacy and responses choices were verbally probed. The following questions were introduced:

- Was the question clear? Did you need to read more than once to understand the question?

- Was the answer scale adequate? Did you find the answer options adequate for this question?

- Reply? In your opinion, was the item written in such a way that there was ONLY one OBVIOUS answer for you?

- Further comments and suggestions for improvements

2.3 Psychological morbidities associated with tooth loss and dentures: a quantitative study

2.3.1 Aim and objectives

Aim:

- To investigate the psychological impact associated with tooth loss, and the effect of provision of dentures on this psychological impact.

Objectives:

- To assess any possible differences/correlations related to age, gender or tooth loss distribution (anterior/posterior/upper/lower teeth).
- To assess any possible differences/correlations related to personalities traits.

2.3.2 Hypothesis:

Patients with tooth loss might still have psychological disturbance despite treatment with technically successful dentures.

2.3.3 Inclusion/exclusion Criteria

The inclusion/exclusions criteria are the same criteria used to recruit candidates for the questionnaire development phase (Section 2.2.2.2).

2.3.4 Study Design

This is a quantitative questionnaire study, with the use of a screening tool, to measure the psychological disturbance associated with tooth loss/dentures.

Ethical approval was obtained from the Research Health Authority (REC17/NI/0098). The psychological screening tool was evaluated, validated and piloted (Section 2.2).

2.3.5 Informed Consent Procedures

The informed consent procedure is the same used in the questionnaire development phase (Appendix 6).

2.3.6 Screening

Patients with tooth loss, who presented for a routine dental appointment at the selected primary dental care locations, and were eligible to join according to the inclusion/exclusion criteria, were approached to participate in the study.

Participants completed the validated questionnaire in a separate quiet room in the dental surgery. Participants who wished to complete the questionnaires at home were handed a self-addressed stamped envelope and posted the forms back to the PI. The envelopes were marked strictly confidential. No identifiable personal data was recorded on the questionnaire. All data was held in a locked and secure office. The keys for this office kept by the PI only.

2.3.7 Procedure for Collecting Data

The following clinical data were collected and stored:

- Information related to patients' demographics

- Dental history including reasons for tooth loss

- Medical history

- Classification of tooth loss (Kennedy Classification)

- Denture type/location.

- The completed psychological screening questionnaire

All data was anonymised and kept confidential.

Figure 6: Study Scheme Diagram

Ethical approval

| Development and validation of the psychological screening measure (5 months) |

| Pilot study (1 month) |

⬇

| Primary endpoint |

⬇

| Recruitment of eligible participants in primary dental setting (10 months) |

⬇

| Participant Information Sheets distributed to potential participants |

⬇

| Medical, dental and social history collected (DEMOG) |

⬇

| Participants filled the validated questionnaire |

⬇

| Secondary endpoint: questionnaires completed |

⬇

| End of data collection / Statistical analyses (2 months) |

2.3.8 Number of Participants

Sample size calculation was completed by Dr Jonathan Bestwick at Queen Mary University, London. As this is a preliminary study, the sample size calculation was based on the qualitative study by Davis *et al.* (2000).

A table giving a range of percentage with psychological disturbance in the control group for 45% with disturbance in the group with dentures, at typical levels of power (80, 85 and 90%) is presented in Table 12.

Table 12: Sample size calculation

	Sample size required when 45% of test group have disturbance according to percentage of control group with disturbance								
	50%	55%	60%	65%	70%	75%	80%	85%	90%
Power									
80%	3210	822	372	212	136	94	68	52	40
85%	3660	934	422	240	154	104	78	58	44
90%	4270	1086	488	276	176	120	88	66	50

A sample size of 136 participants (n=68 test group and n=68 control) would be required to show a 25% point decrease in "psychological disturbance" in the test group compared with the control group with 80% power at a significance level of 5% using Fisher's exact test.

The sample size has been increased by 10% to allow drop-outs to give a final sample size of 150 participants (n=75 test group and n=75 control)

The recruitment phase ended once all participants fully completed the screening questionnaires.

The statistical analysis was set at a significant level of 0.05.

2.3.9 Recruitment:

A total of 140 participations were recruited (control group n=70; denture group n=70). Five individuals declined to participate in the study (Three did not have their reading glasses, and two participants did not have time to complete the questionnaire at the surgery or at home). As the questionnaire was used to assess the effectiveness of dentures, participants instructed to report on the impact of tooth loss after they had treatment with a denture (i.e. bearing in mind the effectiveness of the dentures they are wearing).

Each participant completed a questionnaire in a quiet room and handed it back to the PI. Subsequently, the PI (ZK) checked that all items/sections had been completed.

The PI further explored the reason behind the incomplete items; i.e. whether they were missed by mistake or if the individual preferred not to answer those items. 15 participants mistakenly missed some items and were happy to complete them. Two participants from the control group only filled Part A of the questionnaire and left the surgery before the PI was able to check the questionnaire. Those two participants were considered to have dropped out of the study; therefore, the data of 138 participants were included in the final analysis (control group n=68; denture group n=70).

Most participants completed the questionnaire in the surgery (n=131), and only seven participants opted to return the questionnaires by coded self-addressed

envelopes. The time needed to complete the questionnaire was not recorded as some participants completed the questionnaire at home.

Participants who were identified to have a high level of distress were informed about the results and advised to see their GP for further assessment.

2.3.10 Data transfer and analysis

The data from the coded questionnaires and clinical exam forms were all transferred into Excel Sheet. Variables recorded included: age, gender, number and location of tooth loss.

Analysis including descriptive statistical of all data including the percentage of patients with significant psychological disturbance in the sample. An independent T-test, Chi-Square and Logistic regression analysis have been used to further investigate these psychological morbidities and identify any differences/correlations related to age, gender or location of teeth loss (anterior/posterior/upper/lower teeth).

2.3.10.1 Part "A" analysis

The data from Part A items were analysed under two domain, functional difficulties (4 items) and body image impairment (5 items). Each item was assigned a numeric value that represented the frequency of the difficulty/impairment. Values were recorded as below:

- *"Don't know" = this was coded as missing score*
- *"Never = 0*

- *"Rarely = 1*

- *"Sometime = 2*

- *"Often = 3*

- *"Very often = 4*

The data was interpreted on ordinal (not additive) method with scaled hierarchical grades of the frequency on each item. The outcome measure of functional difficulties or body image satisfaction/dissatisfaction were based on the maximum weight of every item in each of the two domains at a specific threshold. With higher frequency representing a higher degree of functional problems or body image dissatisfaction. For example, if a participant has a frequency score of ≥3 on any of the functional difficulties' items, then this was considered to represent some degree of functional difficulties. However, this then raises the question about where to locate the threshold for impact? Should it be set ≥4 or ≥2? One way to solve this problem was to assess the threshold for impact at level ≥3 and then compare it with higher and lower thresholds (≥4 and ≥2) to confirm that the results consistency.

2.3.10.2 DASS-21 Analysis

The DASS-21 data were recorded on a four-point Likert scale with values ranging from 0 to 4 and recording the intensity and frequency of the somatic symptoms. Items of the different domains were distributed across the scale. Table 10 illustrates how items were later coded to calculate scores for each of the three domains: (s) for stress, (a) for anxiety and (d) for depression.

Table13: DASS21 coding

1 (s)	I found it hard to wind down	0	1	2	3
2 (a)	I was aware of dryness of my mouth	0	1	2	3
3 (d)	I couldn't seem to experience any positive feeling at all	0	1	2	3
4 (a)	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5 (d)	I found it difficult to work up the initiative to do things	0	1	2	3
6 (s)	I tended to over-react to situations	0	1	2	3
7 (a)	I experienced trembling (e.g. in the hands)	0	1	2	3
8 (s)	I felt that I was using a lot of nervous energy	0	1	2	3
9 (a)	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10 (d)	I felt that I had nothing to look forward to	0	1	2	3
11 (s)	I found myself getting agitated	0	1	2	3
12 (s)	I found it difficult to relax	0	1	2	3
13 (d)	I felt down-hearted and blue	0	1	2	3
14 (s)	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15 (a)	I felt I was close to panic	0	1	2	3
16 (d)	I was unable to become enthusiastic about anything	0	1	2	3
17 (d)	I felt I wasn't worth much as a person	0	1	2	3
18 (s)	I felt that I was rather touchy	0	1	2	3
19 (a)	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20 (a)	I felt scared without any good reason	0	1	2	3
21 (d)	I felt that life was meaningless	0	1	2	3

(The DASS-21 scores is multiplied by 2 to calculate the final score)

The calculated sum of each of the three domains produced numeric values, which indicated the degree of the psychological tendency for depression, anxiety and stress (Table 14).

Table 14: DASS 21 scoring

	Depression	Anxiety	Stress
Normal	0-9	0-7	0-14
Mild	10-13	8-9	15-18
Moderate	14-20	10-14	19-25
Severe	21-27	15-19	26-33
Extremely Severe	28+	20+	34+

To facilitate the statistical analysis of the psychological disturbance of each domain, the degree of severity of the disturbance were allocated numerical values which ranged from 0 (indicating normality) to 4 (indicating extremely severe disturbance). The statistical analysis of the DASS-21 data was based on categorical values (and not the sum of the results) because the original scores were not equal across the different domains. For example, a score "21" indicated different levels of severity across the different domains, i.e. it indicated "severe" for the depression domain, "extremely severe" for the anxiety domain and "moderate" for the stress domain. Therefore, the use of a categorical score of 0-4 was more reliable across all the domains. Categorical scores used in the analysis are illustrated in Table 15.

Table 15: Categorical scores for the DASS21

	Score 0	Score 1	Score 2	Score 3	Score 4
Depression Score	Normal	Mild	Moderate	Severe	Extreme Severe
Anxiety Score	Normal	Mild	Moderate	Severe	Extreme Severe
Stress Score	Normal	Mild	Moderate	Severe	Extreme Severe

The DASS-21 data were measured by using the DASS-21 calculator (Breakthrough, 2007). Data were analysed with the Statistical Package for Social Sciences (SPSS) program version (2018). The analysis included a descriptive analysis of all data, comparing the categorical variables with the questionnaire outcomes using χ2 test and T-tests.

4.2.6 Definition of tooth location (anterior/posterior)

The developed questionnaire assessed the impact of tooth loss and related psychological health. To relate those findings to the location of tooth loss and/or removable denture, it was decided to define tooth loss into two main categories: anterior tooth loss and posterior tooth loss.

From a clinician perspective, incisors and canines are usually labelled anterior teeth, whereas the premolars and molars are considered as posterior teeth (Chapter three). However, patients could have a different view/perspective related to the location of teeth, i.e. premolars were categorised by some patients as anterior teeth. To explore this further, a sample of 20 patients was recruited for this purpose. Each participant was given a face mirror and was asked to point out which teeth they considered as front teeth. Participants feedback was then used to define the location of tooth loss, i.e. anterior/posterior regions.

CHAPTER THREE:
RESULTS

3.1 Psychological morbidity measures for patients with tooth loss/dentures: A systematic review

3.1.1 Study characteristics

The search methodology has been conducted according to the PRISMA STATEMENT (Liberati *et al.*, 2009) and presented in Figure 7. The electronic database search identified 3,510 articles, from which 1,059 were excluded as duplicates (Appendix 9,10). The titles and, where necessary abstracts, were examined against the inclusion/exclusion criteria and 1,043 articles were further excluded, leaving a total of 16 studies. Following the evaluation of the complete text of these studies, a further eight were excluded, since these studies were either related to the invalidated assessment tools to measure psychological distress related to tooth loss (n=5) or failed to meet the selection criteria (n=3) (Table3). Therefore, only eight texts were included in the current review. All of the included studies had a cross-sectional design. The characteristics of the included studies were reported in Table 14.

The eight studies included in this review (Table 17) all used the same 24-item questionnaire to measure the emotional impact of tooth loss. Two studies were based in the UK (Davis *et al.*, 2000; Davis *et al.*, 2001), three in India (Shah *et al.*, 2015; Naik and Pai, 2011; Anjum et al., 2017), one in Hong Kong (McMillan and Wong, 2004) and two were multi-centre studies including the United Kingdom and Hong Kong (Scott *et al.*, 2001; Fiske *et al.*, 2001). Six studies recruited participants from dental hospitals and universities, while the other two

studies recruited participants from Social Centers and Dental Check Campus (McMillan and Wong, 2004; Naik and Pai, 2011). Three studies examined the emotional impact of tooth loss in edentulous patients, two studies screened partially dentate participants, and two studies examined a group of edentulous and partially dentate patients (Table 17). Only one study compared the emotional impact of tooth loss between completed denture wearers and non-denture wearers (Anjum *et al.*, 2017). Sample size varied from 94 to 400 participants.

One study (Shah *et al.*, 2015) calculated the power based on previous studies, and it was unclear if a sample size calculation was carried out in any of the other seven included studies. The reported response rate was only available in three studies, as 100%(Fiske *et al.*, 2001), 95% (Scott *et al.*, 2001) and 73% (Davis *et al.*, 2000) respectively.

Figure 7: PRISMA Flow Diagram

Records identified through database searching (n = 3510)	Additional records identified through other sources (n = 0)

Records after duplicates removed (n = 1059)

Records screened (n =1059)	Irrelevant articles removed (n =1043)

Full-text articles assessed for eligibility (n = 16)	Full-text articles excluded, with reasons (n =8)

Studies included in quantitative analysis (n = 8)

3.1.2 Risk of bias of the included studies

A high inter-examiner agreement (IRR of 0.88) was observed with six out of eight studies (Table 16). However, these studies had a potentially biased selection process since participants were recruited from the Dental Hospitals and Universities. Consequently, these studies had a high risk of selection bias as the patients who sought treatment in the Dental Hospital setting or have been referred to the Secondary Dental Care presented with more complicated dental issues.

Two studies (Table 16) recruited participants from the dental check camps and daytime social centres for the elderly. This recruitment process is more likely to enrol a homogenous sample, which better represents the general population. Therefore, the risk of selection bias in these studies was considered to be low.

In addition, four studies (Scott *et al.*, 2001; Fiske *et al.*, 2001; McMillan and Wong, 2004; Naik and Pai, 2011) used trained dental officers to conduct interviews to help complete the questionnaire, as some participants were illiterate. Interviewer and response bias risks are likely to be low in these studies, as the interviewers were independent and trained prior to the study. In the remaining two studies (Shah *et al.*, 2015; Anjum *et al.*, 2017), it was unclear if the interviewers had any training prior to the interviews for illiterate participants and therefore the risk of interviewer and response bias could not be excluded. The authors in the remaining two studies (Davis *et al.*, 2000; Davis *et al.*, 2001) requested the participants to complete the questionnaire at home and return their anonymous responses by post. Therefore, the risk of response bias was considered low.

Regarding the study designs, there were no clearly defined control groups in any of the included studies. Whilst one study compared tooth loss in participants who had dentures with those who did not. However, the technical quality of the dentures was unfortunately not

described. Without a well-designed control group, it was impossible to conclude whether the emotional distress was present beforehand or as a result of tooth loss. Therefore, the risk of bias was regarded as high in all eight included studies.

The same measurement tool was used in all included studies. This questionnaire was developed and validated in two previous qualitative studies (Fiske *et al.*, 1998; Fiske, 1997). However, the process of how this was developed and validated remains unclear. In addition, some of the questions used to quantify the emotional impact of tooth loss may lead participants to answer in a specific way (potentially leading questions). i.e. "*Did you find it difficult to accept losing your teeth*"? The approach of the authors using a negative connotation, such as "difficult" could introduce bias. The use of more neutral words is recommended to avoid the possible risk of leading questions and inaccurate responses. Although the additional comments space might assist in clarifying any issues, this would still not be quantified, and thus, the risk of measurement bias was considered high. The 24-item questionnaire, which was used, explores the functional disability and feelings associated with tooth loss. However, this questionnaire is not designed to screen and quantify psychological morbidities associated with tooth loss.

One study (Shah *et al.*, 2015) used the Patient Health Questionnaire (PHQ-9) questionnaire, which was a self-assessment questionnaire to monitor and measure depressive disorders (Kroenke *et al.*, 2001). The PHQ-9 has been validated to screen and measure depression in primary care (Cameron *et al.*, 2008). However, the PHQ-9 fails to either screen or measure anxiety or distress. Therefore, additional tools are required to screen for those dimensions of emotional distress (Kroenke *et al.*, 2001).

Table 16 Risk of Bias in the included studies

	Davis *et al.*, 2000	Davis *et al.*, 2001	Scott *et al.*, 2001	Fiske *et al.*, 2001	McMillan and Wong, 2004	Naik and Pai, 2011	Shah et al., 2015	Anjum et al., 2017
Selection bias	H	H	H	H	L	L	H	H
Measurement bias	H	H	H	H	H	H	H	H
Interviewer bias	N/A	N/A	L	L	L	L	?	?
Response bias	L	L	L	L	L	L	?	?
Other bias*	H	H	H	H	H	H	H	H

? Unknown risk of bias
* Control bias, denture quality bias

3.1.3 The impact of tooth loss

Two studies (Davis *et al.*, 2000; Davis *et al.*, 2001) concluded that significant numbers of patients have difficulties in accepting tooth loss (45% in the edentulous sample, and 52% in the partially dentate sample). The same studies also reported that those patients were reluctant to accept the loss of teeth, and they were less self-confident as a result. Four other studies mentioned similar outcomes (Scott *et al.*, 2001; Fiske *et al.*, 2001; Shah *et al.*, 2015; Anjum *et al.*, 2017). On the contrary, two studies (McMillan and Wong, 2004; Naik and Pai, 2011) reported no significant link between tooth loss and emotional disturbance. The latter studied the emotional impact of tooth loss in an aged North Indian population (400 patients, above the age of 60 years). There was an insignificant link between tooth loss and emotional disturbance. However, there was a marked impact on functional activities and social interaction. The contradictory results of these studies could be related to the cultural and socioeconomic differences, as tooth loss could be perceived as an inevitable or normal consequence of the ageing process in some cultures. Another study compared the impact of tooth loss between patients who have dentures and those who did not have dentures (Anjum *et al.,* 2017). The authors reported a significant difference in the acceptance of tooth loss

between non-denture wearers (69.8%) and those with dentures (46%). Equally, there were significant differences reported in the impact on self-confidence between two groups (39.6% non-denture wearers and 20% denture wearers).

Table 17: Key characteristics of the included studies

Study	Method	Participants	Intervention	Outcome measures
Davis *et al.*, 2000	Location: Department of Prosthetic Dentistry at Guy's, King's and St Thomas' Dental Institute Recruitment period: not reported Funding source: not reported	94 edentulous (48M; 46F) Age 31-50 (n=7) 51-70 (n=40) > 71 (n=47)	Full removable dental prosthesis replacement (n=92). No removable prosthesis (n=2)	Emotional effect /acceptance of tooth loss Activity/ functional impairment
Davis *et al.*, 2001	Location: Department of Prosthetic Dentistry at Guy's, King's and St Thomas' Dental Institute Recruitment period: not reported Funding source: not reported	91 partially dentate (38M; 53F) Age <30 (n=1) 31-50 (n=22) 51-70 (n=43) 71 (n=25) Anterior teeth missing (78%) Only posterior missing (22%)	Partial denture replacement (n=91)	Emotional effect /acceptance of tooth loss Activity/ functional impairment
Scott *et al.*, 2001	Location: Guy's, King's and St Thomas's Dental Institute, London; the Dental School, Dundee, Scotland; and the Faculty of Dentistry, University of Hong Kong Recruitment period: not reported Funding source: not reported	Number participants: 142 Edentulous 31-15 (n=8) 51-17(n=57) >71(n=77)	Full removable dental prosthesis replacement in all Dundee subjects, in 96% of London subjects and 78% of Hong Kong subjects.	Emotional effect /acceptance of tooth loss Activity/ functional impairment

Study	Method	Participants	Intervention	Outcome measures
Fiske *et al.*, 1998	Location: Guy's, King's and St Thomas's Dental Institute, London; the Dental School, Dundee, Scotland; and the Faculty of Dentistry, University of Hong Kong Recruitment period: not reported Funding source: not reported	(n=149) partially dentate (64M; 86F) Age: <31 years (n=1) 31-50 years (n=28) 51-70 years (n=89) > 71 years (n=32) Tooth loss: 64% some upper anterior teeth 97% some upper posterior 39% some lower anterior 94% some lower posteriors	Partial removable dental prosthesis 88% of Dundee subjects, 81% of London and 50% in Hong Kong subjects.	Emotional effect /acceptance of tooth loss Activity/ functional impairment
Naik and Pai, 2011	Location: dental check camps in the locality of Uttar Pradesh (North India) Recruitment period: not reported Funding source: not reported	400 participants (41M; 59F) Age > 60 years Edentulous (n=128) Partially dentate (n=272) Tooth loss Anterior upper (n=10) Posterior upper (n=88) Anterior lower (n=13) Posterior lower (n=96)	Full removable dental prosthesis (n=128) Partially removable dental prosthesis (n=140) Partial dentate/ no replacement (n=132)	Emotional effect /acceptance of tooth loss Activity/ functional impairment
McMillan and Wong, 2004	Recruited at day-time social centers for the elderly located through- out Hong Kong Recruitment period: not reported Funding source: University Grant	233 participants (80M; 153F) Age 60-80 Edentulous (n=65) Partially dentate (n=168)	Complete removable prosthesis (n=65) Partial removable prosthesis (n=95) No removable prosthesis (n=73)	

Study	Method	Participants	Intervention	Outcome measures
Shah *et al.,* 2015	Location: Department of Prosthodontics, Govt. Dental College and Hospital. Ahmedabad Recruitment period: Dec 14 – Feb 15 Funding source: not reported	100 participants edentulous (62M; 38F) 31-50 years (n=70) 51-70 years (n=7) > 71 years (n=23)	Complete removable prosthesis (n=100)	Emotional effect /acceptance of tooth loss Activity/ functional impairment Depression
Anjum *et al.,* 2017	Location: Dental hospital at Vikarabad, Telangana Recruitment period: Sep16 – Oct 16 Funding source: not reported	103 participants edentulous (73M;30F) 45-55 years (n=39) 55-65 years (n=64)	Complete removable prosthesis (n=50) No intervention (n=53)	Emotional effect /acceptance of tooth loss Activity/ functional impairment

Table 18: Comparison of the included studies

Factors related to tooth loss	Time	Davis et al., 2000 (n=94)	Davis et al., 2001 (n=91)	Scott et al., 2001 (n=142)			Fiske et al., 1998 (n=149)			McMillan and Wong, 2004 (n=233)	Naik and Pai, 2011 (n=400)	Shah et al., 2015 (n=100)	Anjum et al, 2017 (n=103)
				Du n=45	Lon n=47	HK n=50	Du n=50	Lo n=49	HK n=50				
Difficulty in accepting tooth loss		42 (45%)	48 (53%)	63 (44%)			26%	62%	60%	51 (22%)	92 (23%)	58%	46%
Time before accepting tooth loss	Immediately	5%	4%	47%	47%	60%	51%	23%	62%	34%	35%	14%	-
	With 6 months	12%	15%	25%	11%	20%	28%	17%	20%	54%	53%	29%	-
	Within a year	10%	6%	5%	4%	2%	4%	-	6%	6%	5%	12%	-
	> a year	38%	25%	13%	23%	12%	6%	23%	4%	4%	3%	3%	-
	Still have not accepted it	35%	50%	10%	15%	6%	11%	37%	8%	2%	4%	-	16%
Impact on self confidence	More confidence	2%	-	5%	6%	0%	2%	-	-	1%	-	-	-
	Confidence unaffected	22%	22%	62%	40%	60%	62%	37%	72%	95%	96%	-	-
	Less confidence	69%	76%	24%	45%	40%	26%	59%	28%	2%	-	38%	20%
	Don't know	7%	2%	9%	9%	0%	10%	4%	-	2%	16	-	-

Table 4: Characteristics of excluded studies

Study	Reasons for exclusion
Dirik *et al.*, 2006	Tools not validated to measure psychological morbidities related to tooth loss
Okoje *et al.,* 2012	Sample/recruitment not suitable (sample not random)
Ommerborn *et al.,* 2008	Tools not validated to measure psychological morbidities related to tooth loss
Roohafza *et al.*, 2015	Tools not validated to measure psychological morbidities related to tooth loss
Dable *et al.,* 2014	Tools not validated to measure psychological morbidities related to tooth loss
Allen and McMillan, 1999	Sample/recruitment not suitable (sample exposed to dental implants)
Anttila *et al.,* 2001	Tools not validated to measure psychological morbidities related to tooth loss
Hogenius *et al.,* 1992	Sample/recruitment not suitable (sample exposed to dental implants)

3.2 Development and validation of a questionnaire to measure the impact of tooth loss/dentures

3.2.1 Examiner calibration results

The inter-examiner agreement on denture quality was 82.4%. Further discussion and assessments identified two problems. Firstly: the dental nurse who recorded the assessments made several errors in recording data on the assessment sheets (marked the wrong line). This was probably due to the small print, and the answers lined too close together. Secondly, some differences were due to lack of clarity in some items in the assessment tool (e.g. "item 10" Lower Stability "anterior-posterior movement") has been clarified as "accepted" with 1-2 mm movement and "dysfunctional" with movement >2 mm). The correction and clarification of the assessment method helped to improve in the inter-examiner agreement to 92.9%. The Intra-examiner agreement on denture quality was 98.1%. The Intra-examiner agreement on denture quality was 97.2%.

3.2.2 Development a pool of preliminary items

The interviews from participants and general dental practitioners generated 167 statements/problems/difficulties. 35 statements remained after removing the duplicate and repetitive statements (Table 19).

Table 19: Preliminary items

Difficult to speak / trouble pronouncing / speech altered
Voice/accent different
Trouble articulating words
Do not enjoy my food (Difficult to chew, can not taste my food, can not eat steak)
Slow eating (difficult to chew)
Change eating habits (have to cut my food pieces)
Can not chew as denture moves
Digestions problems
Avoided certain food/ Eating the food I can eat (not food that I want to eat)
Can not taste food
Denture uncomfortable (self-aware)
Uncomfortable when I eat
Uncomfortable (not used to them)
Pain in jaw
Face changed (Do not like how I look)
Looking older
Feeling old
Self-conscious about their smile (missing teeth may show)
Does not like how denture teeth look
Preoccupied tooth loss/dentures when out
Worries dentures drop eating/speaking
Going out less
Worried denture may drop when socialising/talking/eating

Less confidence to meet new people

Avoid eating outside

Avoid contact with a partner without denture

Worried impact of tooth loss/denture on their relationship

Feel embarrassed/less confidence/nervous in their relationship

Worried (denture may drop?)

Embarrassed

Stressed (may lose denture while on holiday?)

Find it difficult to relax

Life less enjoyable

Need implants

Dentures not acceptable

The literature review and the examination of all existing tools (chapter one) generated 41 further items. After removing duplicates, a 12-items remained (Table 20).

Table 20: Items generated from published literature:

Problems speaking because of tooth loss/dentures

Problems eating/digesting/tasting because of tooth loss/dentures

Pain/discomfort because of tooth loss/denture

Denture stability

Self-conscious about tooth loss/dentures

Denture is seen as a foreign body (not part of the body)

Impact on social life because of tooth loss/dentures

Less confidence because of tooth loss/dentures
Lift less satisfying because of tooth loss/dentures
Wearing denture is not acceptable!
Replacing dentures with fixed implants helps!
Distress caused by tooth loss/dentures. Anything which may help to ease distress?

3.2.3 Questionnaire item reduction

Questionnaire items reduction task resulted in 9 statements/problems (Table 21), and two distinctive concepts were identified:

First concept: Functional difficulties, including problems speaking and eating (food choices, enjoying eating, discomfort).

Second concept: Dissatisfaction with self-image related to tooth loss/replacement with dentures.

Table 21: Items reduction results (impact of tooth loss/denture)

Speaking	Thinking about tooth loss/dentures
Eating	Social interactions
Food choice	Relationships
Discomfort/pain	Difficult to relax
Appearance	

Additional items that assess patients' perceptions for dental implants (or other treatment) has been add to the preliminary questionnaire (concepts identified in the literature review). Therefore, the preliminary questionnaire consisted of 12-

items, the DASS-21 and the DT. Version (1) of the questionnaire is presented in

Table 22.

<mark>Table 22: Questionnaire Version (1)</mark>

Please read each statement and circle a number 0, 1, 2 or 3, which indicates how much the statement applied
to you. The rating scale is as follows:
0   Did not apply to me at all
1   Applied to me to some degree, or some of the time
2   Applied to me to a considerable degree or a good part of time
3   Applied to me very much or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (e.g. in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

How would you rate the impact of tooth loss and dentures on your quality of life?										
0	1	2	3	4	5	6	7	8	9	10
No distress					Mildly distress					Severe distress

Please read each statement and circle Yes or No, which indicates how much the statement applied to you.

1	Have you had trouble speaking because of your tooth loss or denture?	Yes	No
2	Have you had trouble eating because of your tooth loss or denture?	Yes	No
3	Have you had discomfort / pain because of your dentures?	Yes	No
4	Have you had trouble with the stability of your dentures?	Yes	No
5	Are you self-conscious about your tooth loss or denture?	Yes	No
6	Have you been preoccupied or do you think a lot about your tooth loss or denture?	Yes	No
7	Do you avoid situations, activities or socializing because of your tooth loss or dentures?	Yes	No
8	Have you had trouble in you relationship or trouble developing a relationship because of tooth loss or denture?	Yes	No
9	Have you felt your quality of life is less satisfying because of your tooth loss or dentures?	Yes	No
10	Do you regard that wearing dentures is unacceptable?	Yes	No
11	Do you feel that replacing your dentures with fixed implants teeth may ease your distress?	Yes	No
12	Do you feel that anything could help to ease your distress if present?	Yes	No

3.2.4 Content validation results

Interestingly, feedback from experts was contradictory, and there were different opinions on how to improve the questionnaire. This wide range of different opinion made the content validation task more complicated and challenging. However, one main change that many experts recommended was to avoid double-barrelled items. Comments/feedback from experts and the changes to the questionnaire listed in Table 19 and explained below:

Firstly: One expert suggested that the DASS-21 items are strong and that tooth loss could not cause such symptoms

> FV "*The items are clear and measure distress, I am not sure if they are appropriated to measure the stress that causes the loss of a tooth. I believe those are strong symptoms. I do not know if a person can experience them when losing a tooth*"

The same expert has concluded, that by adding Part B items, causality could be determined between tooth loss and psychological disturbance.

> FV *"The part B calls more my attention. It seems novel and leads me to understand that the association is causal and not only correlational. I find it very meaningful, as the person is aware of that association. In other words, the person himself identifies that the distress is caused by the loss of a tooth, and it cannot be the result of other factors"*

The items in the DASS-21 have been developed and validated to identify psychological morbidities, regardless of the cause, and thus the intensity of each question's wording is irrelevant to the cause of the distress (whether it was tooth loss or other stressors). Furthermore, the DASS21 can differentiate normal, mild, moderate and severe distress, depression and anxiety symptoms, and therefore, if tooth loss could not cause a severe psychological disturbance, the DASS 21 scale should be able to identify that. Also, previous qualitative studies have shown that tooth loss could cause a significant emotional disturbance in some individuals; therefore, the use of the scale that can identify the different degree of distress would help this study.

Secondly: Two experts were concerned about the ability of DASS-21 to determine causality between distress and tooth loss

> DR *"I have another construct in mind when talking about psychological distress. Of course the DASS captures psychological distress, i.e., depression and anxiety. However,*

*any impairment in these two concepts does not necessarily
have be related to tooth loss (or dentures). But this does not
have to be a limitation. I just wanted to mention it"*

*TD "I am not sure the DASS 21 will truly reflect oral
health=related distress but it will identify general distress. The
challenge will be to determine whether they are linked in any
way"*

The concepts of depression, anxiety, and distress are multifactorial and could be
caused by various triggers and factors. The DASS-21 identifies somatic symptoms
related to psychological disturbance. Therefore, if a patient has those somatic
symptoms, then this indicates he or she has some degree of psychological
morbidities regardless of the cause (wheatear it was tooth loss or other causes).
The DT, which is a direct self-measure for psychological disturbance, could help to
identify tooth loss as one of the causes of psychological disturbance.

Furthermore, most experts (7/10) agreed that by adding the DT and Part A items
to the DASS-21, this has helped to identify tooth loss/dentures as one of the
possible causes of psychological distress, and that the questionnaire is an
appropriate tool to screen for psychological disturbance in patients with tooth
loss/dentures.

Thirdly, one expert has suggested using SCL-90-R rather than the DASS21

*AM: "The DASS21 scale is an interesting tool that involves
depression and anxiety; I could say those are handled as a*

comorbidity. Probably this scale may be not the best scale to be

correlated to tooth loss. I have worked with SCL-90-R to

measure distress; you could review and compare the scales

symptoms"

The SCL-90-R is also a self-reporting questionnaire that was developed for research purposes. However, the SCL-90-R is not suitable for this research as it includes 90-items and takes a long time to complete. Many researchers recommend avoiding lengthy measures, to reduce the burden on participants, and avoid respondent fatigue (Bolarinwa, 2015).

<u>Fourthly</u>: some experts were concerned about the dichotomous response scale as it limited the respondent answers choices, and it is more difficult to quantify.

> *FB: " A dichotomous response scale is not very good for*
>
> *quantifying the overall impact of whatever you are trying to*
>
> *measure. I think you would be better with a four or five point*
>
> *response option scale"*
>
> *RR: "a 5 point likert scale would be more appropriate as*
>
> *responses for Part B rather than a Yes/No*

The dichotomous response scale was to be used only in the preliminary items. A 5-Likert scale will be used in the proposed questionnaire to widen the response options and avoid forcing unintentional answers.

Fifthly: some experts were concerned about the double-barrel questions (tooth loss/ denture):

> IT : *"The questions number 1,2,5,6,7,8,9 have two meaning, I mean is it about of the tooth loss or denture? I think, the question can be separate especially for tooth loss and denture, so you can know the problem is because the tooth loss without the denture or because of the denture"*
>
> NF: *"I feel that tooth loss and denture use are different aspects, and might be better to address each aspect alone".*

The questionnaire used in this study aim to measure the impact of tooth loss in patients with tooth loss and technically successful dentures. To screen for the impact of tooth loss and dentures, some items included double-barrel items, i.e. "*Did you had have any problems speaking because of your tooth loss or denture?*" Double-barrel questions reduce the questionnaire reliability, validity and responsiveness, as the question is asking about two elements "tooth loss" and "denture", while the answer allows only one response (Artino *et al.,* 2014). The choice of responses was discussed extensively (this was further explored with participants in the face validation phase). It was decided to use a single barrel item that asks about tooth loss (the disease), rather than denture (the intervention). The rationale for that is by asking about the impact of the tooth loss (after replacement with denture), the item also indirectly assesses satisfaction/dissatisfaction of the intervention (the denture). For example, if a patent with vision impairment (the disease) has cataract surgery (the intervention) to improve his or her vision. The question to assess the outcome asks about problems/improvements related to the

vision (the disease) rather than problems with the lens (the intervention), which was implanted to improve vision. So, the question to be asked in this example will be "*How much difficulties do you currently have reading small print?*" And not *"How much difficulties do you currently have reading small print using your new lens"*. Similarly to the vision impairment example, tooth loss (the disease) will be assessed while the patient is wearing the denture (the intervention). If patients indicated on the questionnaire that tooth loss caused no functional difficulties and/or body image, then that is an indirect indication of satisfaction with the dentures (clinician assessment meets patients' expectation). While if the patient indicated functional difficulties or body image impairment because of tooth loss, then that is indicated that the technically successful denture did not restore function and/or appearance from the patient's perspective.

Sixthly: two experts have suggested that one construct was missing "aesthetic".

> *PR: "how did you ensure that all relevant aspects are in the questionnaire? I miss an item addressing esthetic impairments. We know from our studies on OHRQoL that this is highly important for the patients. Besides functional limitation, orofacial pain, and psychosocial impact, orofacial appearance is one of the four dimensions of OHRQoL"*
>
> *IT : "Maybe you can add the question about esthetic in part B section 1"*

The aesthetic impairment element will be captured as part of the body image construct. Items that assess self-image and the behaviour that is influenced by self-

image will be included in the questionnaire. Previous analysis (chapter one) showed that self-image dissatisfaction was a factor in emotional disturbance despite the appearance being restored with successful dentures.

Seventhly: one expert questioned why the Oral Health Impact Profile (OHIP-14) was not used, as many of the items listed for the new questionnaire are similar to OHIP-14. The OHIP-14 was not suitable to be used for this study for two reasons:

1- OHIP-14 is not disease-specific, as it examines the "generic" oral health impact on the quality of life. Furthermore, the OHIP-14 uses triple barrel items, which asks about teeth, mouth and denture. Therefore, it is not sensitive enough to assess a specific disease like "tooth loss" and may not captures responsiveness for interventions (i.e. dentures).

2- The OHIP-14 does not cover all the dimension of psychological disturbance (depression, anxiety, distress)

Responses from experts were also quantitatively analysed. The result of the content validity ratio ranged from 0 to +1 (Appendix 11). Several items have been eliminated as they had low content validity score. This included items: "*Self-conscious about tooth loss/dentures*", "*Confidence problems because of tooth loss/ dentures*", "*Quality of life less satisfying because of dentures*" and "*Regarding wearing dentures unacceptable*". The remaining items had a satisfactory score (>0.62), indicating that those items are essential and have some degree of content validity. Changes are presented in table 23.

3.2.5 Face validation results

3.2.5.1 Initial face validation

80% of participants (n=8) indicated that the language and vocabulary used were appropriate, whereas 20% (n=2) were neutral (neither agree nor disagree). Furthermore, 60% (n=6) indicated that the questionnaire, in general, was an appropriate tool to explore the impact of tooth loss and any associated psychological disturbance. 40% of participants (n=4) indicated neutral response (neither agree nor disagree). The DASS-21 was seen as appropriate measures to screen for negative mood, which may be related to tooth loss (depression, anxiety, stress). The initial face validation resulted in changes to items/wording/layout (Table 23) and the questionnaire version 2 is presented in Table 24.

Table 23: Face and content validation results

F: Face validation, C: Content Validation,			
Item	Revision / Changes	Justification	Validation
Part A Part B	**Layout**: Swap Part A & Part B	Start with simple / recognizable items	F, C
Part A	**Clarity**: Highlight the introduction: "circle your answer"	Simplify how to complete the questionnaire	F
DT Part A	**Layout**: Responses in DT options changed to similar spacing	Avoid drawing respondents' eyes to certain options over others	C
DT Part A	**Clarity**: Clarify how to answer: "circle your answer"	Simplify how to complete the questionnaire	F
DT Part A	**Construct clarity**: Remove double-barreled items	Improve validity	C
Part B	**Construct clarity**: Remove double-barreled item	Improve validity	C, F
Part B	Replace "dentures stability" to "Change your diet"	Clarify question to assess functional construct	F, C
Part B	**Clarity**: Change "self- conscious about your tooth loss" to "Have you been uncomfortable because of the impact of tooth loss on your appearance"	Body image construct	F, C
Part B	**Clarity**: Remove "have you been preoccupied" Do you think a lot about your tooth loss?	Use simple language vocabulary	F, C
Part B	**Clarity**: Remove "activities", "situations" and "socializing" and replace with "Do you avoid social situations because of your tooth loss?	Avoid multiple questions	C
Part B	**Clarity**: Remove "trouble in relationship" and replace with "stress in your relationship" Have you had stress in your relationship/marriage because of your tooth loss?	Use simple language vocabulary	F, C
Part B	Change "dichotomous response scale" to "Likert response scale"	-Help quantify and analyse data -Expand patient's choices	F, C
Part B	Remove question Q9, 11,12	Leading question	F, C
Part B	Remove "Do you regards wearing denture unacceptable", replace with "Have you found it difficult to relax because of your tooth loss?"	Wording was amended to make it clearer and to prevent misunderstanding	F, C

Table 24: Questionnaire version 2

Part A: Please read each statement and <u>circle</u> how much your agree / disagree with each statement

1	Have you had trouble speaking because of your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
2	Have you had trouble eating because of your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
3	Have you had to change your diet because of your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
4	Have you had discomfort / pain because of your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
5	Have you been uncomfortable because of the impact of tooth loss on your appearance?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
6	Do you think a lot about your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
7	Do you avoid social situations because of your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
8	Have you had stress in your relationship / marriage because of your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
9	Have you found it difficult to relax because of your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know

Part B:

Please read each statement and circle a number 0, 1, 2 or 3, which indicates how much the statement applied to you. The rating scale is as follows:

0   Did not apply to me at all
1   Applied to me to some degree, or some of the time
2   Applied to me to a considerable degree or a good part of time
3   Applied to me very much or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (e.g. in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

How would you rate the impact of tooth loss on your quality of life? (Circle your answer)										
0	1	2	3	4	5	6	7	8	9	10
No distress					Mildly distress					Severe distress

3.2.5.2 Final face validation

The feedback from the final face validation resulted in minor revisions/changes (Tables 25,26). Each revision or change was backed by explanation, rationale and justification for that change. Discussion included types of Likert response options to be used in Part A. The two choices included "*frequency of problems*" and "*level of agreement with the statement*". Following discussion with face validation sample, it was decided that frequency scale (Very Often/often sometimes/rarely/never) was less subjective and more meaningful as participants found it easier to report the frequency of each problem.

Questionnaire version 3 is presented in Table 27.

Table 25: Questionnaire Revision (readability and understanding)

Feedback /observation	Revisions	Justification
Part A (Page 1) Clarify the meaning of the introduction question: "How much agree/disagree?". Measuring the intensity of tooth loss is "vague". Relate the introduction to personal experience, rather than general opinion.	Replace the intensity phrase "*How much agree / disagree?*" to frequency phrase: *"how often?"*	Wording was amended to make it clearer and to prevent misunderstanding. Authors concluded it was more meaningful to measure impact of tooth loss by frequency rather than intensity
Part A (Page 1) Responses suitability: As the introduction question was amended (from intensity to frequency), the responses should follow	Change Likert Scale from intensity measure "agree/disagree" to frequency measure "often/rarely"	Authors concluded that it was more meaningful to measure the impact of tooth loss by frequency rather than intensity
Part B: DT (Page 2) Some participants confused by the meaning of "quality of life"	Rephrase question from "*rate the impact of tooth loss on your quality of life*" to "*rate the impact of tooth loss on your life*"	Improve readability

Table 26: Questionnaire Revisions (Layout)

Feedback /observation	Revisions	Justification
Layout part A (Page 1) Lines spaced too close	Change layout of Likert Scale from vertical to horizontal	Improve readability
Questionnaire has 3 pages, printed on two A4 papers, first paper double sided. Some participants missed the back page (page2), The author has considered numbering pages.	Print the 3 pages questionnaire on 3 papers (Each of three parts A, B and C on a separate paper)	The questionnaire was originally printed on two papers (environment friendly). However, this changed to improve readability and avoid respondents missing page 2 (back-sided). The authors have considered numbering pages; however, respondent feedback was to print on 3 pages.

Part A:

Please <u>circle</u> how often have you had any of the following during the <u>last year?</u>

1	Have you had trouble speaking because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
2	Have you had trouble eating because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
3	Have you had to change your diet because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
4	Have you had discomfort / pain because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
5	Have you been uncomfortable because of the impact of tooth loss on your appearance?	Very often	Often	Sometimes	Rarely	Never	Don't know
6	Do you think a lot about your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
7	Do you avoid social situations because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
8	Have you had stress in your relationship / marriage because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
9	Have you found it difficult to relax because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know

Part B:

Please read each statement and circle a number 0, 1, 2 or 3, which indicates how much the statement applied to you **over the past week**. The rating scale is as follows:

0   Did not apply to me at all
1   Applied to me to some degree, or some of the time
2   Applied to me to a considerable degree or a good part of time
3   Applied to me very much or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (e.g. in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

How would you rate the impact of tooth loss on your life? (Circle your answer)										
0	1	2	3	4	5	6	7	8	9	10
No distress					Mildly distress					Severe distress

Note: The internal consistency and test re-test were also done at this stage; however, there was an error in the statistical method used, and the results were abandoned. Those two tests were repeated again in the pilot stage.

3.2.6 Construct validation results

The results indicated that all domains correlated strongly (r>5) as hypothesized except the social disability domain that correlated only mildly (r>5 & <3) with the body image domain. Nevertheless, this moderate correlation is still accepted that the framework is structured as hypothesized (Table 28).

Table 28: Pearson's correlation coefficients between OHIP-14 & Proposed Questionnaire

Part A	OHIP-14 domains	(r)	DT (r)
Functional Difficulties	Functional limitation	0.743	
	Physical pain	0.700	0.756
	Physical disability	0.819	
Body image	Psychological discomfort	0.710	
	Psychological disability	0.732	0.808
	Social disability	0.478	

(n=20), All correlations significant at 0.01

3.2.7 Pilot test and final validation

3.2.7.1 Questionnaire reliability

3.2.7.1.1 Questionnaire test re-test reliability

The results of test re-test reliability are presented in Table 29. The correlation coefficients for the functional and the body image domains were 0.86 and 0.79. The Pearson coefficients were 0.93 and 0.94 (significant at 0.01). The items correlation for Part A ranged from 0.7 to 0.9. All scores indicating adequate

reliability for Part A subscales and items. The correlation coefficients for DASS-21 three domains were also >0.7 indicated satisfactory reliability.

Table 29: Test re-test reliability

Part A	Domains		Correlation coefficients (For each Items)		Correlation coefficients (For Domains)	
			ICC	Pearson	ICC	Pearson
Part A	Functional	Q1	0.793	0.787*	0.86	0.93*
	Health	Q2	0.762	0.893*		
		Q3	0.782	0.815*		
		Q4	0.701	0.724*		
	Body	Q5	0.705	0.830*	0.79	0.94*
	image	Q6	0.705	0.770*		
		Q7	07.16	0.754*		
		Q8	0.765	0.800*		
		Q9	0.759	0.861*		
DASS 21	Depression				0.874	0.917*
	Anxiety				0.849	0.893*
	Stress				0.820	0.893*
DT			0.757	0.798*		

* Correlation is significant at 0.01

3.2.7.1.2 Questionnaire internal consistency

Results are presented in Table 30. Cronbach's α for functional and body image domains were 0.84 and 0.88, respectively. Cronbach's α of 0.84 for the functional domain indicates that the combined scores for that domain (items Q1-Q4), do represent the correct scores in 84% of cases, which further indicates some degree of internal consistency between those four items. As for the DASS21 subscales of depression, anxiety and stress, the Cronbach's α were 0.95, 0.81 and 0.88 respectively. All scores indicate satisfactory reliability (as Cronbach's α >0.7).

Table 30: Reliability coefficient for each subscale (n=20)

Questionnaire parts and domains		No of items	Cronbach's α Coefficient (n=20)
Part A	Functional domain	4	0.846
	Body image domain	5	0.883
DASS21	Depression	7	0.953
	Anxiety	7	0.818
	Stress	7	0.886

One of the problems with Cronbach alpha is that it is sensitive to the number of items (Artino *et al.,* 2014; Bolarinwa, 2015). Therefore, a questionnaire that has a small number of items <10 (like the questionnaire used in this study) may generate low Cronbach alpha score. Increasing the number of items that measure each construct in this questionnaire could increase questionnaire reliability (Bolarinwa, 2015). However, a lengthy questionnaire may cause respondents fatigue, responses errors and participants are less likely to engage in completing lengthy questionnaires. A brief well-constructed instrument is more likely to engage more participants and produces more data to answer the research question (Bolarinwa, 2015). Therefore, it decided to accept the satisfactory reliability results and not to increase the items in each subscale.

3.2.7.2 Outcome of the pilot test

The outcomes of the pilot test divided into three categories:

One: Demographics of the pilot sample.

Two: Assess feasibility of the study, logistical and practical issues.

Three: Test the questionnaire and identify any issues with wording, layout, and instruction.

3.2.7.2.1 Demographic of the pilot sample

A total of 23 participants were approached to participate in the pilot test. 20 participants with tooth loss (Ten with conventional dentures & ten with tooth loss without replacement) were randomly recruited from the target population. All completed forms were anonymised and coded. The participant code was linked to a secured manual file. Two participants declined to join the pilot test, as they did not have their reading glasses with them at the time (response rate 95%). One participant entry has been removed as they missed some items in the questionnaire. The mean age of the patients was 47.4 years (range: 22–80), and 12 of the participants were male (46.2%). The mean time required to answer all the questions was 11.7 minutes (range: 5–35).

3.2.7.2.2 Feasibility of the study / logistical issues

The assessment of the feasibility of the study included:

- Suitability of venues

- The time needed to explain/obtain consent

- Feasibility/problems with recruitment

- Data collection, coding and filling

The two locations (SGDP, WDC) where the pilot test was undertaken were suitable as it was possible to recruit participants and the examination room/waiting rooms were convenient. Therefore, those two locations are appropriate to be used in the main study. As for timing, the introduction and explanation took about 3-5min. All

suitable participants decided to participate in the pilot on the same day (only two declined because they had not their reading glasses with them at the time). Problems with the coding system were identified, and a new system for coding has been used in the final study (Appendix 12).

3.2.7.2.3 Testing the questionnaire

Respondents reported that the timing needed to complete the questionnaire was reasonable; nevertheless, some advocated to make it shorter. As for the layout and design, the following revisions and changes were adapted (Table 31). Each revision or change was backed by explanation, rationale and justification for that change.

The analysis concluded that items of the questionnaire are clear and easy to understand. The answer scale options were also adequate and representative. However, some minor typographical revisions implemented (Table 31). The full assessment of the pilot questionnaire presented in appendix 13. The final version of the developed questionnaire is presented in Table 32.

Table 31: Questionnaire final revision

Feedback /observation	Revisions	Justification
Part B DASS21 (Page 2) Some participants struggled to visually relate and match questions to answers, as lines spaced too close, this resulted in missing a line or error in circling answers.	Alternatives questions have been grey shaded	Improve readability Avoid unintentional errors of miss circling answers or missing lines.
Part C Eysenck (Page 3) Some participants struggled to visually relate and match questions to answers, as lines spaced too close, this resulted in missing a line or error in circling answers.	Alternatives questions have been grey shaded	Improve readability Avoid unintentional errors of miss circling answers or missing lines.
Typographical errors. One pilot participant identified two typographical errors in Part C Q1 and Q23.	Q1 (Part C): correct "Dose" to "Does" Q23 (Part C): correct "Are" to "Can"	Correct typographical errors

Table 32: Questionnaire Version 4

Part A:

Please <u>circle</u> how often have you had any of the following during the <u>last year?</u>

1	Have you had trouble speaking because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
2	Have you had trouble eating because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
3	Have you had to change your diet because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
4	Have you had discomfort / pain because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
5	Have you been uncomfortable because of the impact of tooth loss on your appearance?	Very often	Often	Sometimes	Rarely	Never	Don't know
6	Do you think a lot about your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
7	Do you avoid social situations because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
8	Have you had stress in your relationship / marriage because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
9	Have you found it difficult to relax because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know

Part B:

Please read each statement and circle a number 0, 1, 2 or 3, which indicates how much the statement applied to you **over the past week**. The rating scale is as follows:

0   Did not apply to me at all
1   Applied to me to some degree, or some of the time
2   Applied to me to a considerable degree or a good part of time
3   Applied to me very much or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (e.g. in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

How would you rate the impact of tooth loss on your life? (Circle your answer)										
0	1	2	3	4	5	6	7	8	9	10
No distress					Mildly distress					Severe distress

3.3 Psychological morbidities associated with tooth loss and dentures: A quantitative study

3.3.1 Descriptive statistics of data

Most participants lost their teeth due to dental carious and or periodontal disease (n=137). There was one incident of tooth loss due to trauma (n=1). As for the denture group, participants had their denture for an average time of 4 years (range 2 - 20 years).

Table 33 and 34 illustrate the gender and age distribution for both the denture and the control groups. Both groups have a majority of female's participants (F: 62.3% M: 37.7%). The control group were relatively younger population compared to the denture group.

Table 33: Age/gender difference for the denture and control groups

			Control		Denture	
	N	%	N	%	N	%
Observations	138		68	49.3%	70	50.7%
Age group						
<60	51	37.0%	39	57.4%	12	17.1%
≥60	87	63.0%	29	42.7%	58	82.9%
Gender						
Female	86	62.3%	45	66.2%	41	58.6%
Male	52	37.7%	23	33.8%	29	41.4%

Table 34: Age distribution for the denture/control groups

Control group   Denture group
<31 years (n=3)   <31 years (n=0)
31-50 years (n=13)   31-50 years (n=7)
51-71 years (n=40)   51-71 years (n=31)
> 71 years (n=12)   > 71 years (n=32)

Table (35) shows the pattern of tooth loss (number and location) for both denture and control groups. It is clear that the denture and the control groups differ in the number and location of teeth loss. Firstly, the denture group have nearly double the number of tooth loss compared to the control group. Secondly, anterior tooth loss in the denture group was almost three times more than the control group.

Table 35: Pattern and location of tooth loss in both groups

	All N=138		Control N=68		Denture N=70	
	Mean	SD	Mean	SD	Mean	SD
Tooth Loss Total	9.31	5.67	6.16	2.35	12.4	6.26
Anterior Tooth Loss	4.95	4.42	2.24	1.72	7.59	4.64
Posterior Tooth Loss	4.33	2	3.93	1.51	4.73	2.32

Table (36) illustrate that tooth loss pattern and location between the denture and the control group is significantly different.

Table 36: Differences in pattern of tooth loss (location and number) between the denture and the control group

Dependent	Group	N	Mean	SD					Prob > |t|	W	Prob<W
Tooth Loss Total	Control	68	6.16	2.35	Difference	6.21	t Ratio	7.75	<.0001	0.94	<.0001
	Denture	70	12.37	6.26	Std Err Dif	0.80	DF	88.61			
Anterior Tooth Loss	Control	68	2.24	1.72	Difference	5.35	t Ratio	9.03	<.0001	0.90	<.0001
	Denture	70	7.59	4.64	Std Err Dif	0.59	DF	88.07			
Posterior Tooth Loss	Control	68	3.93	1.51	Difference	0.80	t Ratio	2.41	0.0173	0.97	0.0055
	Denture	70	4.73	2.32	Std Err Dif	0.33	DF	118.93			

Dependent	Group	N	Score Sum	Expected Score	Score Mean	(Mean-Mean0)/Std0	S	Z	Prob>|Z|
Tooth Loss Total	Control	68	3124	4726	45.9	-6.8	3124	-6.85	<.0001
	Denture	70	6467	4865	92.4	6.8			
Anterior Tooth Loss	Control	68	2827	4726	41.6	-8.1	2827	-8.13	<.0001
	Denture	70	6764	4865	96.6	8.1			
Posterior Tooth Loss	Control	68	4179.5	4726	61.5	-2.4	4180	-2.35	0.0186
	Denture	70	5411.5	4865	77.3	2.4			

Table 37 demonstrates the frequencies of the functional difficulty related items (Q1-Q4) and the body image items (Q5-Q9). For speaking, discomfort and diet changes, the majority of subjects in both groups had infrequent functional problems. However, both groups have frequent troubles during eating.

For the body image domain, many candidates reported frequent dissatisfaction with appearance (Q5), with the denture group reported as twice negative self-image as the control group. The same finding was noted for the self-awareness item (Q6). However, no major impacts on relationships/marriage in both groups were recorded.

Table 37: Frequencies for each response category for Part A

Denture Group (D), Control Group (C)
Response category (%)

Patient impact tooth loss		Never	Rarely	Sometime (L2)	Often (L3)	Very often (L4)
Trouble speaking	D	48.5 (n=34)	12.8 (n=9)	30 (n=21)	4.2 (n=3)	4.2 (n=3)
	C	79.4 (n=54)	11.7 (n=8)	5.8 (n=4)	2.9 (n=2)	0 (n=0)
Trouble eating	D	24.2 (n=17)	15.7 (n=11)	30 (n=21)	22.8 (n=16)	7.1 (n=5)
	C	25 (n=17)	16.1 (n=11)	38.2 (n=26)	14.7 (n=10)	5.8 (n=4)
Diet changes	D	45.7 (n=32)	17.1(n=12)	24.2 (n=17)	11.4 (n=8)	1.4 (n=1)
	C	58.8 (n=40)	11.7 (n=8)	19.1 (n=13)	10.2 (n=7)	0 (n=0)
Discomfort	D	30 (n=21)	34.2(n=24)	27.1 (n=19)	7.1 (n=5)	1.4 (n=1)
	C	38.2 (n=26)	22 (n=15)	26.4 (n=18)	8.8 (n=6)	4.4 (n=3)
Negative impact on appearance	D	28.5 (n=20)	10 (n=7)	20 (n=14)	18.5 (n=13)	22.8 (n=16)
	C	48.5 (n=33)	11.7 (n=8)	22 (n=15)	8.8 (n=6)	8.8 (n=6)
Think a lot about tooth loss	D	24.2 (n=17)	11.4 (n=8)	24.2(n=17)	25.7(n=18)	14.2(n=10)
	C	23.5 (n=16)	25 (n=17)	32.3 (n=22)	10.2 (n=7)	8.8 (6)
Avoid social situation	D	54.2 (n=38)	21.4 (n=15)	12.8 (n=9)	7.1 (n=5)	4.2 (n=3)
	C	76.4 (n=52)	10.2 (n=7)	5.8 (n=4)	0 (n=0)	7.3 (n=5)
Stress in relationship/marriage	D	81.4 (n=57)	11.4 (n=8)	7.1 (n=5)	0 (n=0)	0 (n=0)
	C	92.6 (n=63)	5.8 (n=4)	1.4 (n=1)	0 (n=0)	0 (n=0)
Difficult to relax	D	52.8 (n=37)	21.4 (n=15)	20 (n=14)	4.2 (n=3)	1.4 (n=1)
	C	67.6 (n=46)	11.7 (n=8)	17.6 (n=12)	1.4 (n=1)	1.4 (n=1)

Table 38 compares the frequency of functional difficulties and the body image dissatisfaction in both groups. The functional difficulties were assessed at three different frequency thresholds (sometimes, often and very often). The highest threshold "very often" was met when the individual reported a frequency of "very often" in at least one of the four items of the functional difficulty domain (this threshold was labelled as level four). The same criteria were applied to the other thresholds "often" and "sometime". Those were labelled level three and level two, respectively.

Although the denture group had nearly double the number of lost teeth compared to the control group, the functional difficulties in both groups were similar at the three different thresholds.

Body image dissatisfaction was assessed at three different frequency thresholds in the same way as the functional difficulties were assessed. However, with regards to body image dissatisfaction, the individuals in the denture group were more likely to have body image dissatisfaction compared to the control group.

Table 38: The frequencies of functional difficulties and body image dissatisfaction in the denture and control groups.

Functional difficulties domain

| | Groups | | | |
| | Control | | Denture | |
	N	%	N	%
Sometimes difficulties	47	69.1%	51	72.9%
Often difficulties	25	36.8%	26	37.1%
Very often difficulties	8	11.8%	6	8.6%

Body image domain

| | Control | | Denture | |
Body image	N	%	N	%
Sometimes dissatisfaction	42	61.8%	52	74.3%
Often dissatisfaction	21	30.9%	38	54.3%
Very often dissatisfaction	8	11.8%	19	27.1%

Table 39 indicates that various aspect of psychological disturbance (depression, anxiety and stress) in both groups. This table shows the mean of values of the score which ranges from "0" (normal) to "4" (extremely severe).

It is noted that various aspects of psychological disturbance were comparable in the denture and control groups.

Finally, the mean scoring for denture satisfaction was about 6 (on a 0-10 self-rating scale), which correlates to the inclusion criteria (only technically successful dentures were included in this study).

Table 39: DASS-21 analysis in the denture and the control groups

| | Control N=68 | | Denture N=70 | |
	Mean	SD	Mean	SD
DASS Depression	0.54	0.95	0.49	1.06
DASS Anxiety	0.6	1.15	0.67	1.33
DASS Stress	0.34	0.8	0.37	0.92
DT	2.99	2.77	3.96	2.99
Denture Self rating 1-10			5.89	2.95

Table 40 demonstrates the frequency and intensity of the somatic symptoms for depression, anxiety and stress. The majority of the candidates in both groups fall into the "normal to moderate" which the DASS-21 views as a normal emotional response to stressors. DASS-21 measures the emotional disturbance based on a dimensional rather than a categorical aspect of psychological disturbance where the difference between the normal and the abnormal individuals is a difference in intensity/frequency of symptoms (Lovibond & Lovibond 1995).

Table 40: Frequencies/intensity for each response category DASS 21
 Denture group (D) and control group (C)
 Response category (%)

| | Normal | | Mild | | Moderate | | Severe | | Extrem severe | |
| | D | C | D | C | D | C | D | C | D | C |
	(n=70)	(n=68)	(n=70)	(n=68)	(n=70)	(n=68)	(n=70)	(n=68)	(n=70)	(n=68)
Depression	78.5	69.1	5.7	13.2	8.5	14.7	1.4	0	5.7	2.9
	(n=55)	(n=47)	(n=4)	(n=9)	(n=6)	(n=10)	(n=1)	(n=0)	(n=4)	(n=2)
Anxiety	74.2	72	8.5	10.2	2.8	8.8	4.2	2.9	10	5.8
	(n=52)	(n=49)	(n=6)	(n=7)	(n=2)	(n=6)	(n=3)	(n=2)	(n=7)	(n=4)
Stress	81.4	80.8	8.5	8.8	4.2	7.3	2.8	1.4	2.8	1.4
	(n=57)	(n=55)	(n=6)	(n=6)	(n=3)	(n=5)	(n=2)	(n=1)	(n=2)	(n=1)

Definition of tooth location (anterior/posterior)

Feedback from the participants indicated that anterior teeth *started* from central incisor and *ended by* canine (n=2), 1st premolar (n=3), 2nd premolar (n=13), 1st molar (n=1) and 2nd molar (n=1). Respondents defined an anterior tooth as "*any tooth that is visible or show during smiling, speaking or eating*". As this study was mainly patient-centred, thus the patient definition of anterior/posterior tooth was used in this study, i.e. front teeth were used to code teeth 15 to 25 and 35 to 45 (FDI notation system). The molars were categorised as posterior teeth.

3.3.2 Functional difficulties/body image in the denture and control groups

In order to assess differences between groups in functional disturbance, a χ^2 test was performed (Table 41). The distribution of patients with functional disturbances is similar between the groups (37%) and not significantly different. On the other hand, a significant difference was found between the groups in terms of body image dissatisfaction (χ^2 =7.72, *p* value=0.005) with an odds ratio of 0.38 (about two fifths).

Table 41: Functional and body image differences across denture and control groups - χ2 tests.

Functional	Whole sample		Control		Denture		OR	χ_2	Prob> χ_2
	N	%	N	%	N	%			
No difficulties	87	63.0%	43	63.2%	44	62.9%	0.98	0.00	0.9633
Difficulties	51	37.0%	25	36.8%	26	37.1%			
Body image									
Not impairment	79	57.2%	47	69.1%	32	45.7%	0.38	7.72	0.0055
Impairment	59	42.8%	21	30.9%	38	54.3%			

The functional difficulties and body image domain items in Part A were set up at the frequency threshold "often". To check the robustness of the results and enhance the validity of the initial scoring, the data were analysed again at lower and higher frequency thresholds "sometimes" and "very often". (Appendix 15).

3.3.3 Psychological disturbance in the denture and control groups:

Table 42 shows the results after inspecting the psychological differences between the two groups in the sample. Results in the last column in the tables indicate that there is no statistical difference between the denture and control groups. Therefore, this sample is considered balanced in terms of psychological morbidities between the two groups.

Table 42: Psychological morbidities by group – Wilcoxon rank sums tests.

Dependent	Group	N	Score Sum	Expected Score	Score Mean	(Mean-Mean0)/Std0	S	Z	Prob>|Z|
DASS Depression	Control	68	4908.5	4726	72.2	1.0	4909	1.01	0.3145
	Denture	70	4682.5	4865	66.9	-1.0			
DASS Anxiety	Control	68	4748	4726	69.8	0.1	4748	0.12	0.9064
	Denture	70	4843	4865	69.2	-0.1			
DASS Stress	Control	68	4732	4726	69.6	0.0	4732	0.03	0.9726
	Denture	70	4859	4865	69.4	0.0			
DT	Control	68	4278.5	4726	62.9	-1.9	4279	-1.94	0.0527
	Denture	70	5312.5	4865	75.9	1.9			

3.3.4 Relation between the various variables and functional difficulties/body image/psychological disturbance

To investigate the impact of denture and tooth loss on the denture group candidates, the influence of various independent variables: age, gender, number and location of teeth loss were analysed.

3.3.4.1 Relation between number/location of tooth loss and functional difficulties, body image and psychological disturbance

In order to assess the relationship between the number of teeth lost and their location with functional difficulties and body image dissatisfaction, six separate logistic regression models were estimated. Table (43) provides all six models indicating no statistically significant relationship between the three measures of lost teeth and the dependent variables.

Table 43: Logistic regression for functional difficulties and body image by tooth loss among the denture group.

Dependent	Term	Estimate	S.E	OR	χ^2	Prob> χ^2
Functional	Intercept[difficulties]	-1.13	0.57		3.95	0.0469
	Tooth Loss Total	0.05	0.04	1.05	1.43	0.2321
Functional	Intercept[difficulties]	-0.91	0.48		3.56	0.0591
	Anterior Tooth Loss	0.05	0.05	1.05	0.9	0.3439
Functional	Intercept[difficulties]	-1.34	0.61		4.77	0.0289
	Posterior Tooth Loss	0.17	0.11	1.18	2.22	0.1362
Body image	Intercept[Negative]	0.41	0.54		0.59	0.4406
	Tooth Loss Total	-0.02	0.04	0.98	0.26	0.6133
Body image	Intercept[Negative]	0.49	0.47		1.09	0.2965
	Anterior Tooth Loss	-0.04	0.05	0.96	0.62	0.4295
Body image	Intercept[Negative]	0.16	0.55		0.08	0.776
	Posterior Tooth Loss	0.00	0.10	1.00	0	0.9739

To assess the relationship between tooth loss and the resulting psychological disturbance, spearman's ρ was estimated between the variables, as shown in Table 44. The P values in the table are arranged in an ascending manner and therefore descending by the correlation strength. Using Cohen's effect size scale DASS Anxiety and posterior tooth loss show a medium-size correlation (ρ=0.35) while DASS Anxiety and the total number of teeth lost show a small correlation (ρ=0.24).

Therefore, only the number of posterior tooth loss has a significant correlation with anxiety; however, as the posterior tooth loss was not associated with distress on the DT, the association between posterior tooth loss and psychological disturbance is unlikely to be significant.

Table 44: Spearman's ρ for emotional distress by tooth loss among the dentures.

Variable	by Variable	Spearman ρ	Prob>|ρ|
DASS Anxiety	Posterior Tooth Loss	0.35	0.003
DASS Anxiety	Tooth Loss Total	0.24	0.0462
Distress Thermometer Scoring	Tooth Loss Total	-0.14	0.2487
DASS Anxiety	Anterior Tooth Loss	0.12	0.3145
Distress Thermometer Scoring	Posterior Tooth Loss	-0.12	0.3244
DASS Stress	Anterior Tooth Loss	-0.11	0.3468
Distress Thermometer Scoring	Anterior Tooth Loss	-0.11	0.355
DASS Stress	Tooth Loss Total	-0.11	0.3612
DASS Stress	Posterior Tooth Loss	-0.11	0.3675
DASS Depression	Tooth Loss Total	0.10	0.419
DASS Depression	Posterior Tooth Loss	0.07	0.5772
DASS Depression	Anterior Tooth Loss	0.06	0.648

3.3.4.2 Relation between gender and functional difficulties/body image

In order to test for differences in functional difficulties among the dentures group between males and females, two separate chi-square tests were performed. Table 38 indicates a statistically significant difference between the two gender groups ($\chi2$= 8.40,

PV= 0.004). Thus, the odds of no functional difficulties are one fifth (OR=0.2) of that for females versus males.

The last half of Table 45 provides results of two more χ2 tests for body image as a function to gender. Here, both tests show statistically significant differences. In addition, the test across gender yields a significant result (χ2= 10.794, PV= 0.001) indicating similar odds between the categories.

Table 45: Functional difficulties and body image differences across age and gender among the dentures group.

| | Functional | | | | | | |
| | No difficulties | | Difficulties | | | | |
Gender	N	Column %	N	Column %	OR	χ2	Prob> χ2
Female	20	45.45%	21	80.77%	0.20	8.399	0.0038
Male	24	54.55%	5	19.23%			

| | Body image | | | | | | |
| | Not impairment | | impairment | | | | |
Gender	N	Column %	N	Column %	OR	χ2	Prob> χ2
Female	12	37.50%	29	76.32%	0.19	10.786	0.001
Male	20	62.50%	9	23.68%			

3.3.4.3 Gender and psychological disturbance

Wilcoxon tests were utilised for the estimation of differences in emotional distress variables across age groups and gender. This test has the advantage of not assuming a parametric distributional form of the error terms. Wilcoxon test performs a test on sum ranks instead of the original variable units, and therefore is robust with respect to distributional characteristics of the error terms.

Table (46) provides the results of Wilcoxon test. For the gender divide, only Distress

Thermometer Scoring was found to be marginally significant (Z=-1.97, *P*=0.049).

Table 46: Emotional distress by gender among the dentures – Wilcoxon rank sums tests.

Dependent	Gender	N	Score Sum	Expected Score	Score Mean	(Mean-Mean0)/Std0	S	Z	Prob>|Z|
DASS Depression	Female	41	1570.5	1455.5	38.3	1.90	914.5	-1.90	0.0569
	Male	29	914.5	1029.5	31.5	-1.90			
DASS Anxiety	Female	41	1516.5	1455.5	37.0	0.94	968.5	-0.94	0.3471
	Male	29	968.5	1029.5	33.4	-0.94			
DASS Stress	Female	41	1542.5	1455.5	37.6	1.52	942.5	-1.52	0.1281
	Male	29	942.5	1029.5	32.5	-1.52			
Distress Thermometer Scoring	Female	41	1618	1455.5	39.5	1.97	867	-1.97	0.0491
	Male	29	867	1029.5	29.9	-1.97			

3.3.4.4 Relation between gender/age and body image

To investigate the probability of body image disturbance, a multiple logistic is shown in Table 47. The model includes the following predictors: group, age, gender and the number of lost teeth. In this case, all predictors are significantly linked except for tooth loss total.

The model predicts that the denture group has 5.75 times a higher probability than the control to suffer from body image disturbance. Meanwhile, older participants are predicted to have 75% less probability body image disturbance (OR=0.25), and men can expect 70% less disturbance (OR=0.3).

Table 47: Multiple logistic regression for Body image - whole sample.

Term	Estimate	OR	S.E.	χ^2	Prob>χ^2	VIF
Intercept	-0.09		0.40	0.05	0.8302	
Group[Denture-Control]	1.75	5.75	0.55	10.14	0.0015	1.6
Age group[≥60-<60]	-1.38	0.25	0.52	7.08	0.0078	1.3
Gender[Male-Female]	-1.21	0.30	0.42	8.24	0.0041	1.1
Tooth Loss Total	0.02	1.02	0.04	0.17	0.6809	1.5

N=138.
For log odds of Disturbance/No disturbance

For ease of interpretation of the size of the estimates and the derived probabilities for body image disturbance, Figure 8 provides a prediction profiler for the model. Panel "a" illustrates the predicted probability for disturbance for a control group member who is younger than 60 years old, female and with the average number of missing teeth. As illustrated, this individual is predicted for having a body image disturbance in 52% of cases. On the other hand, a denture group member with the same characteristics is predicted to have a 86% probability for disturbance (panel b). Panel "c" predicts the probability of 32% for having a disturbance for a denture group, elder, male with the average number of teeth lost.

Figure 8: Prediction profiler for multiple logistic regressions for Body image disturbance.

3.3.5 Personalities traits and body image/functional difficulties

To assess the relationship between personality traits, body image impairment and functional difficulties, χ2 test was conducted. As reported in Table 48 the statistically significant result (χ2(70,1) =4.45, p=0.035) indicate higher probability to have body image impairment among neurotic personality patients (76%) than in the non-neurotic personality group (47%) (OR=3.64).

Similarly, that the probability of complaining of functional difficulties among those with neurotic personality is higher (65%) than for those of non-neurotic personality individuals (28%) (OR=4.64).

Table 48: Negative body image and Neurotic personality, χ2 test.

		Negative body image			
		Yes	No		
		38 (54.3%)	32 (45.7%)	χ2	*P*
Neurotic personality	Yes	76%	24%		
	No	47%	53%	4.45	0.035

Table 49: Functional difficulties and Neurotic personality, χ2 test.

		Functional difficulties			
		Yes	No		
		38 (54.3%)	32 (45.7%)	χ2	*P*
Neurotic personality	Yes	65%	35%		
	No	28%	72%	7.306	0.007

CHAPTER FOUR:
DISCUSSION

4.1 Psychological morbidity measures for patients with tooth loss/dentures: a systematic review

4.1.1 Discussion

Various questionnaires and tools have been used to detect emotional distress in different acute and chronic medical conditions. The validation and the psychometric properties of those tools have been assessed and validated extensively. However, the performance of questionnaires and tools identified in this review were inadequate to screen for all the dimensions of psychological morbidities in patients with tooth loss and dentures. These tools are limited by their contents and lack of focus on chronic medical and dental conditions such as tooth loss.

To screen for psychological morbidities associated with tooth loss, the tool should identify and differentiate the "temporary normal" from the "pathological" adjustment disorders. This is done by measuring the severity and/or frequency of negative emotional symptoms.

All the studies in the current review used the same measurement tool, which was developed from previous qualitative research. This questionnaire mainly explores the functional disability and feelings associated with tooth loss, designed to measure how widespread the emotional impact of tooth loss is. However, it is not designed to screen and quantify psychological distress caused by tooth loss. Therefore, further tools are required for this purpose. Furthermore, many of the participants in the included studies had activities/functional difficulties; therefore, it would have been beneficial if the technical quality of dentures was investigated and clarified, to exclude technically unsatisfactory dentures, as a possible cause of functional disability and psychological disturbance.

Measuring and quantifying the psychological impact of tooth loss faces many challenges. Firstly, there are many important variables, which may have a confounding impact on the

measurement. A detailed dental, medical and demographic history should be taken in order to account for any such confounding factors. Secondly, the technical quality of removable dentures should be measured to exclude technically suboptimal dentures as the cause of distress. Thirdly, personality type should be analysed, since this dimension could be related to denture satisfaction/dissatisfaction.

However, as mentioned earlier, the DASS-21 has some advantages over currently available tools, and it could be one of the suitable tools to screen and measure psychological morbidities in patients with tooth loss. Therefore, this tool initially needs to be validated for patients with tooth loss. In addition, a supplemental tool to assess the technical quality of dentures should also be implemented, alongside with the DASS-21 to exclude the potential technical faults related to dentures as a causative factor for a psychological disturbance.

To-date, the available tools are neither suitable nor validated to screen and measure psychological morbidities in patients with tooth loss. Further research is required to create tools to identify and measure such impact and to recommend suitable interventions.

4.2 Development and validation of a questionnaire to measure the impact of tooth loss/dentures

4.2.1 Psychometric properties of the questionnaire

Face and content validation indicated that the questionnaire was an appropriate tool to measure the impact of tooth loss and the related psychological morbidities. Reliability analysis showed that each of the two subscales (functional & emotional) were internally reliable (items explored related questions) and the scores on each subscale were also related to the tooth loss impact construct. The DASS-21 also showed similar results. Finally,

testing the theoretical hypothesis structure of the impact of tooth loss has also enhanced the construct validity of the questionnaire. Therefore, the validation process indicated that the questionnaire has satisfactory reliability and validity to measure the impact of tooth loss and related psychological health.

4.2.2 Pilot test outcome:

The pilot test illustrated that the questionnaire was appropriate and that the main study was feasible. There were no issues with recruitment. The process did not disrupt the activities in the two locations, nor did it have an impact on other patients attending the surgeries. Coding, data entry and file handling was problematic in the pilot test; however, lessons learned and the author has now better understanding about the coding and filling process. New strategy to code, file and organise data will be implemented in the main study. Minor revisions needed to the questionnaire design and two typographic errors were also corrected. Therefore, the final questionnaire is ready to be used in the main study. The steps that led to developing the screening tools are illustrated in appendix 14.

4.2.3 Body image construct:

The development process of this questionnaire indicated that functional difficulties and body image were the main concepts related to tooth loss. Therefore, studying the psychological impact of tooth loss is more meaningful when assessed in relation to those two concepts, as some individuals misattribute negative emotions to a specific source when in fact it is caused by another source (Cohen *et al.,* 1983).

Body image is defined as "*internalised view of one's appearance that drives behaviour and influences information processing*" (Altabe and Thompson, 1996). The dissatisfaction with

the self-image that is related to tooth loss fulfils the definition of body image impairment described by Altabe and Thompson (1996), as this self-image impairment could influence individual's behaviours, social interaction and relationships. Therefore, the concept of body-image should be included in the proposed questionnaire. The subscale of this concept should include items which relate to "*perception*" and "*attitude*" (Gleeson and Frith, 2006). "*Perception*" relates to how the individual picture the image of their mouth/face in their own mind, and the "*attitude*", is how this perceived self-image affects their interaction with their surrounding (Gleeson and Frith, 2006).

The construct body image could be provoked by self-perceived body weight, body shape or a specific body feature. However, the term body image used in the study is intended to describe solely the dissatisfaction related to tooth loss/denture treatment.

4.2.4 Body image and psychosocial concept

The psychosocial and body image are closely related but different concepts. While the former illustrates the social and psychological aspects of tooth loss, the later represent the main trigger that provokes those disturbances. This relation was described in patient's feedback through the processes of developing this questionnaire. Also, similar impacts on perception and behaviours were suggested by researches who studied the "global body image" construct (Gleeson and Frith, 2006). Therefore, the possible dissatisfaction of body image after tooth loss/replacement with dentures may influence social interaction, feelings, emotions, and relationships. Based on that, the psychosocial concept was regarded as part of the body image domain and was assessed as part of the body image domain.

4.2.5 Suitability of the developed questionnaire to measure disorders and interventions

During the processes of developing this questionnaire, extensive discussion was carried out on how to measure the impact of tooth loss and the effectiveness of treatment with dentures. The following options were considered:

1- Develop two versions of the questionnaire (one to measure the impact of tooth loss, and one to measure the effectiveness of dentures).

2- Develop one questionnaire "with double-barrel items" to directly assess the impact of tooth loss and RD.

3- Develop one questionnaire "with single barrel items" to assess the impact of tooth loss, and indirectly assess the effectiveness of RD.

Option one is problematic, as it would be challenging to assess responsiveness. This method of assessment is complex and not reliable to compare the differences between two different questionnaires and conclude improvements following an intervention.

The second option is also controversial, as double-barrel items reduce the questionnaire reliability, validity and responsiveness. That is because the question is asking about two elements "*tooth loss*" and "*denture*", while the answer allows only one response (Artino *et al.,* 2014).

The third option is to use a single barrel item to assess the impact of tooth loss and indirectly assess the effectiveness of dentures. For example, the item: "*Have you had problems eating because of problems with your tooth loss?*" directly assess the functional impact of tooth loss. However, it less clear what this item means for respondents who wear a denture. Do they cognitively interpret the question as what is "*the remaining*" impact of tooth after it

was treated with a denture? Or do the respondents merely state the impact of tooth loss only (overlooking any benefits gained from treatment RD)? In other words, when a respondent who has tooth loss and denture read and analyse the question "*have you had problems eating because of problems with your tooth loss*?" Does he or she answer the question bearing in mind the denture they are wearing and the benefits gained from it?   To understand how respondents understand and interpret those single barrel questions, ten participants were asked during the cognitive interviews how they understand and interpret those items. Eight out of ten participates pictured their dentures while they were completing the questionnaire, and their answers were based on their experience, feeling and satisfaction of tooth loss and dentures. Therefore, the single barrel items that asked about tooth loss, also "indirectly" assessed the effectiveness of dentures.

However, it should be noted that the population sampled in this study had their dentures for at least one year (allowing time to adapt to dentures). Those who had their dentures for shorter periods may have different interpretation and understanding of the single barrel items used in the developed questionnaire.

Therefore, to use the questionnaire on those patients, either the questionnaire should be validated for this population, or an explanatory line could be added to the introduction, explaining that the questions also aim to assess satisfaction with denture after tooth loss.

Definition tooth location (anterior/posterior)

As this study was mainly patient-centred, thus the patient definition of front/back tooth will be used in this study, i.e. anterior teeth were used to code teeth 15 to 25 and 35 to 45 (FDI notation system). The molars were categorised as posterior teeth.

4.2.7 Interpretability of the proposed questionnaire

Interpretability is defined as "*clarity and simplicity in understanding a measure quantitative scores*" (Aaronson *et al.,* 2002). To interpret the results of a tool, the different levels of the measured construct should be identified. To be able to do that, systematic rules should be constructed to convert the subjective measured constructs into numerical grades (Roach, 2006). This is done by developing a scoring system for the questionnaire to help measure difficult-to-measure psychosocial constructs similar to the constructs in this study (Artino *et al.,* 2014). To develop a scoring system for the Part A questionnaire, response items were assigned numeric values as below:

- *"Don't know" = coded as missing score*
- *"Never = 0*
- *"Rarely = 1*
- *"Sometime = 2*
- *"Often = 3*
- *"Very often = 4*

However, it should be noted that the intervals between items are not equal, i.e. the interval between "often" and "Very often", is not the same as between "Never" and "rarely". Furthermore, the weight of items is also not equal, i.e. a patient who score "4" on the "*problem with speaking" item* could have much more (or lower) impact than the score "4" on the "*problems with eating*" item. This problem could be potentially solved by adding weight

to responses and items, but this process is quite difficult in this study as the studied sample is not homogenous, and therefore, it will be difficult to measure the difference between intervals and responses. Furthermore, weighting questionnaire items are less desirable, as they increase the complexity of using the measure and interpreting the data and they only slightly improve the questionnaire validity. Many authors questioned the advantage of adding weight to items (Allen and Locker, 1997; Allen, 2003).

Another method to interpret the results and compare responsiveness is to use aggregates scores or calculate the mean changes; however, there have also been doubts about the meaning or the clinical relevance to such figures (Locker, 1998; Tsakos *et al.*, 2012). Therefore, it was decided to interpret the data on ordinal (not aggregates scoring) method with scaled hierarchical grades of the frequency on each item. The outcome measure of functional difficulties or body image satisfaction/dissatisfaction would be based on the maximum weight of every item in each of the two domains at a specific threshold. With higher frequency representing a higher degree of functional problems or body image dissatisfaction, i.e. if a participant has a frequency score ≥3 on any of the functional difficulties' items, then this represents some degree of functional difficulties. However, then the question could be raised as to where should be the threshold for the impact? Should it be set ≥4 or ≥2? One way to define the threshold is by assessing the impact of tooth loss at different levels, and analyses the results at each threshold. These assessments/analyses at different levels have been implemented in this study.

4.2.8 Limitations of the developed questionnaire

The validated questionnaire has several limitations:

Firstly, one of the limitations is the small number of items (9 items) used to capture the domains in Part A. However, it was intentional to produce a short questionnaire, to reduce the burden on participants, to decrease response fatigue and increase the number of

participants who are willing to join the study (Bolarinwa, 2015). Nevertheless, reducing the Part A questionnaire to nine items might mean that some functional or psychological difficulties which are applicable to a small number of patients may not be recorded and missed. Regardless of that, the main construct is still measured by the other items in the questionnaire, i.e. if a patient has problems with denture stability, this could be measured with a direct question specifically asking about denture stability. However, if this question is missing, it does not mean that the impact of denture stability on the respondent has been missed. This functional problem could still be identified indirectly by an item that is asking about "trouble eating" or "discomfort". Therefore, the validity of the scale is still satisfactory as long as each subscale have items that represent all the problems.

Secondly, only relatively small numbers of participants have been used to develop and validate this questionnaire. Nevertheless, those numbers were in line with the recommendations set by researchers (Aaronson *et al.,* 2002; DeVon *et al.,* 2007; Artino *et al.,* 2014). Furthermore, questionnaire validation is not static; however, an ongoing process, and further analysis of the data in the recruitment phase could be used to enhance the validity of the questionnaire (Artino *et al.,* 2014).

Thirdly, the sample for the development and validation has been recruited only from two primary dental practices. This might question the transferability and generalisability of the tool and raises the issue of representativity of the general population. Further validation would be required to assess whether this tool is suitable for other populations such as secondary care patients.

To conclude, a disease-specific measure was developed and validated. This validated questionnaire aimed to:

- Assess the impact of tooth loss (functional difficulties, self-body image)

- Screen for psychological morbidities.

- Assess the effectiveness of intervention, i.e. dentures.

This questionnaire is not a diagnostic measure, but a screening tool, which might highlight the potential emotional problems related to tooth loss. The questionnaire could also be considered for future longitudinal studies to compare the effectiveness of different interventions (dentures, dental implants, cognitive behavioural therapy, *etc.*).

4.3 Psychological morbidities associated with tooth loss and dentures: A quantitative study

4.3.1 Descriptive statistics of data

The descriptive statistics of data indicate that there are differences between the participants in the denture and control groups.

Firstly, the control group were relatively younger population compared to the denture group. This variation is expected, as ageing is associated with an increased in the number of tooth loss, and more tooth loss is associated with more denture users (Graham *et at.,* 2006).

Secondly, the denture and the control groups differ in the number and location of teeth loss. The denture group have nearly double the number of tooth loss compared to the control group. Furthermore, anterior tooth loss in the denture group was almost three times more than the control group. Those differences between the two groups are not surprising, as it is anticipated that individuals who lost their anterior teeth and/or lost a larger number of teeth are more likely to seek a replacement for those missing teeth (Graham *et al.,* 2006). Both groups are nearly comparable in terms of posterior tooth loss. Appearance is prioritised over function, and individuals are less likely to seek denture replacement for posterior tooth loss (Graham *et al.,* 2006).

4.3.2 Functional difficulties and body image in the denture and control groups

The result of this study indicated that there is no significant difference in functional difficulties between the denture and the control groups. Nevertheless, both groups reported some comparable levels of functional problems. In both groups, nearly 50% indicated trouble when eating, 30% needed to change diet and 30% had discomfort related to tooth loss/denture restoration (frequencies range from "sometimes" to "often"). Nevertheless, keeping in mind that the denture group candidates had twice as much tooth loss compared with the control group, it could be speculated that technically successful dentures have helped to restore some aspect of function in the denture group.

On the other hand, there was a significant difference in body image dissatisfaction between the denture and the control groups, with a statistically significant number of denture users had some degree of body image impairment. This might indicate that the technically successful denture failed to restore normal appearance in those individuals.

Therefore, this study indicates that while patients might still have functional difficulties after the denture rehabilitation phase, the negative changes in body image (triggered by denture wearing) have priority over those functional difficulties. This could be concluded from our findings indicating that the denture group patients registered more body image impairment than the control group, while the functional impairment was comparable in both groups. Therefore, dentures helped to rehabilitate functional ability but did not restore body image for some of the denture-wearing individuals.

Although all the participants in this study had technically successful dentures, nevertheless, dentures were still associated with negative body image. The possible reasons why dentures are correlated and possibly triggering body image dissatisfaction are discussed below:

4.3.1.1 Denture: deviation from normality

Dentures could be associated with negative body image because dentures presumably do not restore "normality" in some individuals. In other words, dentures help to improve the appearance and the "external image", but do not restore the "internal self-body image" that has been distorted by tooth loss.

The difference between restoring "external" appearance and restoring "internal self-image" could be viewed as the difference between patient's and clinician's perceptions of what is regarded as normal appearance. (Albino *et al.*, 1990) explained that patient's views about the satisfactory appearance are based on personal experience and their daily interactions, i.e. influenced by their social and cultural norms. On the other hand, clinician's perception of restoring appearance is influenced by their clinical experience and understanding of the limitations of treatment options. Therefore, it could be presumed that the issue of denture body image results from the difference between patient's expectation and the limitations of treatment with dentures. Similarly, (Locker, 2004) indicated that successful treatment of tooth loss with dentures should no longer be assessed based on the clinician perspective of successful dentures, but based on the patient's ability to eat, speak, smile, socialise and get engaged in relationships. In other words, re-establishing the personal, social and cultural norms for that individual.

4.3.1.2 The social stigma of denture

Dentures combine a series of stigmas, judgments and perceptions that are influenced by personal, social and cultural factors that each individual belongs to and relates to. The two main misperceptions that are linked to dentures are the stigma of older age, and the indication of neglected oral health. These misperceptions are discussed below:

4.3.1.2.1 Denture: an indicator of older age

Dentures can be viewed in some western cultures as an indicator of older age. The stigma of ageing is probably why some individuals do not like to talk about having dentures and may choose not to disclose their dentures to their friends and partners (Fiske *et al.*, 2001). This stigmatisation of denture could be one of the reasons why dentures were associated with negative body image in this study. Maria *et al.* (2013) indicate that ageing leads to lower self-esteem and may trigger body image distortion. Although the stigma of denture-related ageing is a misconception, this stigma could still affect the individual indirectly through threats to personal and social identity (Major and O'Brien, 2005). Therefore, the rejection of the "denture body image" could be a rejection of "ageing". Other researchers echoed similar findings, as discussed in chapter one. Rousseau *et al.* (2014) explained that the biographical disruption caused by tooth loss and dentures was partially related to older age stigma. Furthermore, similar stereotyping is associated with some other prosthesis, like hearing aid. Many adults deny hearing loss and decline hearing aids to avoid the older age stigma associated with those prostheses (Erler and Garstecki, 2002). On the other hand, some prostheses like glasses are more accepted and are seen as a fashion as they are not viewed as an indicator of older age (Rousseau et al., 2014).

4.3.1.2.2 Denture: an indicator of neglected oral health

The loss of permanent teeth is undesirable and is associated with public stigmatisation of deficient oral health care and unhealthy dietary habits (Rousseau et al., 2014).

For some individuals, tooth loss and denture restorations represent "*the neglected mouth*" and the failure to maintain their own teeth (Rousseau *et al.,* 2014). Tooth loss and denture restoration are also associated with lower socioeconomic status (Hamasha *et al.,* 2000; Wu *et al.,* 2014; da Veiga Pessoa *et al.,* 2017). Furthermore, many individuals who were interviewed during the questionnaire development (chapter three) expressed remorse, guilt and shame for not taking better care of their teeth. One patient stated in the face-to-face interview: "*it is more easy to admit that I have knee replacement rather than a denture*". Hip replacement may indicate a disease process like arthritis, which is viewed as inevitable and is not associated with public or self-blame. However, tooth loss and dentures are often stereotyped as self-neglected oral hygiene. Albino et al. (1990) indicated that such stereotyping could change self-concept to produce behaviours consistent with the negative stereotype. This perception of mouth neglect may explain why dentures are associated with the negative body image in this study.

4.3.1.3 Denture: An insecure image

The denture group in this study had their function and appearance restored by technically successful dentures. Nevertheless, for some individuals, the removable denture represented an "insecure image", as there is a risk that the denture may move or drop during social or formal rituals, and consequently, the appearance may fail. This prospect of an insecure image may lead some individuals to become hyper-self-conscious about their dentures and their self-image.

The size and/or location of dentures were not significantly correlated to denture body image in this study. This could be due to the insecure image that a denture might represent for some individuals. Those who accept their dentures would have endorsed them as a replacement for function and appearance regardless of their size or location. Whereas those

who resented their dentures, disliked them, regardless of whether the denture is large or a small, and whether it was replacing anterior or posterior teeth.

The denture represented an insecure image for those individuals, and hence, this replacement option failed to restore body image for this group. The notion of the insecure image is consistent with the qualitative studies discussed in chapter one. Rousseau et al. (2014) illustrated that even when some individuals anticipated tooth loss, the use of dentures represented "failed appearance".

4.3.1.4 Denture: a foreign object

For some individuals, dentures are perceived as foreign objects. This notion was observed through patient's face-to-face interviews in the questionnaire development phase (chapter four). Dentures were described as "foreign object", "not part of me" and "the plastic thing".

The difficulties in integrating the denture as part of the body could be why dentures do not restore body image in some individuals. This concept mirrors the outcomes described earlier in the literature review. Davis *et al.* (2000) reported that 55% of individuals who had difficulties accepting dentures, considered them to be foreign bodies. Rousseau *et al.* (2014) explained that the use of a denture for some individuals represented "*an immediate sense of the mouth being invaded*", and since dentures are not fixed (needed to be removed for cleaning and at night time), they therefore were conceptualised as abnormal/alien teeth, and they do not restore the body image. On the other hand, fixed prostheses were conceptualised as normal (Rousseau *et al.,* 2014).

4.3.1.5 Limited pre/post denture rehabilitation

Some individuals foresee dentures as a simple fix to eliminate tooth disease, pain and avoid alternatives costly and extensive dental treatment. This is sometimes associated with a

misconception that dentures represent an equal replacement for natural teeth. However, the shift from dentate to edentulous, and the rehabilitation with a denture is a major life event, that could have enormous effects on patient's quality of life (Friedman *et al.,* 1987). This shift requires the individual to go through a process of physical and psychological adaptation and rehabilitation. Nevertheless, many individuals who are treated with dentures receive limited support and pre/post-rehabilitation.

When an individual is about to lose a limb, there is an extensive program of rehabilitation and support to help adaptation. The process involves extensive pre-amputation rehabilitation, meeting with a multidisciplinary team including, physiotherapy, and psychological support if needed (BSRM, 2018). This process helps to define realistic rehabilitation goals, and assist the individual to adapt to the new anatomy physically and psychologically.

Similarly, emotional and psychological adjustment is also needed when natural tooth/teeth are replaced by dentures (Friedman *et al.,* 1987). Therefore, the limited preparation/support/rehabilitation for tooth loss and denture treatment could be another reason why some individuals do not adapt psychologically to their new body image after denture treatment.

4.3.3 Psychological disturbance in the denture and control group

No significant difference in psychological disturbance between the denture and control groups was detected in this study. Nevertheless, some of the participants in this study presented with somatic symptoms related to depression or anxiety (15.7%). This level of psychological disturbance is nearly double of that recorded in the general population 7.8% (McManus, 2016). Therefore, it could be speculated that tooth loss and denture are

correlated with psychological morbidity in some individuals. Sanders *et al.* (2007) indicated that psychological disturbance emerges when stress stimulus exceeds the individual's coping capacity. Therefore, those individuals, who did not manage to adapt (and adjust) to tooth loss and dentures, tend to develop psychological disturbance. Response to stressful events (like tooth loss and dentures), is not based only on the intensity of the event, but rather based on the individual personal ability to deal with it (Cohen *et al.*, 1983).

Those findings correlated with some of the qualitative studies presented in chapter one and illustrated the impact of the denture as a major life event, which needed major adaptation and adjustment (Bergendal, 1989; Fiske *et al.,* 1998; Davies *et al.,* 2000; Rousseau *et al.,* 2014). Fiske *et al.* (1998) reported that some individuals have emotional disturbance related to tooth loss even amongst those who are apparently coping well with dentures.

It should be noted that the somatic symptoms related to depression, anxiety and stress recorded through the DASS-21 screening tool only investigate the prevalence of those symptoms. However, the diagnosis of depression, anxiety and stress could only be confirmed through clinical assessment by a qualified clinician.

4.3.4 Relation between various variables and functional difficulties, body image and psychological disturbance:

Many variables could influence the body image dissatisfaction resulting from tooth loss and denture treatment.

The analysis of the impact of independent variables on denture group indicated younger adults have significantly more body image dissatisfaction, compared to older adults. This age relation was anticipated because dentures have a stigma of older age, and this

stigmatisation diminishes as the individual gets older. Furthermore, some older individuals have other health problems and are less concerned about tooth loss and dentures (Rousseau *et al.,* 2014).

The predication analysis also showed that females are more likely to be dissatisfied with the alteration to body image caused by dentures. Similar gender differences responses were reported in chapter one (Silverman *et al.*, 1976; Rudy *et al.*, 1993; Pan *et al.*, 2008). Females are generally more preoccupied with their bodies than men (Algars *et al.*, 2009), and that could be the reason why tooth loss and dentures have more impact on their body image.

Finally, this study showed no correlation between the location and the number of tooth loss and body image dissatisfaction. This finding was surprising, as previous research indicated that the reduction in the number of natural teeth was associated with poorer OHRQoL (Steele *et al.*, 2004). As this questionnaire also indirectly assesses the impact of dentures on patients (section 4.2.5), it could be further concluded that the size or location of denture was not correlated with body image dissatisfaction, possibly because some individuals resent and dislike their denture, regardless of the denture size or location. In other words, whether replacing anterior or posterior teeth, and whether a larger or a smaller denture was used, dentures are associated with stigmatising, represented an insecure image and are perceived as a foreign/alien object by some individuals.

4.3.5 Personalities traits and body image/functional difficulties:

This study indicates that those who complained about body image impairment and functional difficulties are more likely to have higher scores on the neuroticism scale. Since the dentures in this study are technically successful, we assumed this indicates that neuroticism may affect dentures acceptance. This comes in line with previous studies discussed in chapter one (al Quran *et al.,* 2001; Klages *et al.,* 2005; Ozdemir *et al.,* 2006; Fenlon *et al.,* 2007;

Fouda *et al.*, 2014). One possible explanation for the association between body image impairment and neuroticism is that neurotic individuals are usually more outgoing, have more social interaction, are more sensitive have less coping capacity (Vollrath and Torgersen, 2000); therefore, their appearance and functionality could be more centric to their social life compared to other personalities traits. Another possible explanation is that neurotic patients have lesser coping/adaptation capacity than other individuals (al Quran *et al.,* 2001).

4.3.6 The denture body image construct

For some patients, treatment with dentures is anticipated to represent a positive intervention with improved outcome, as dentures may help to eliminate pain (by replacing the diseased teeth), improve function (by restoring occlusion), and restore appearance (by providing new artificial teeth and support the facial soft tissue structure). However, this study indicates that the emotional and psychological reactions to tooth loss and denture replacement can vary and are complex. For some individuals, tooth loss and treatment with denture represents an abrupt alteration in anatomy, appearance and function. Individuals are suddenly forced to adapt and adjust to their "new" figures. They need to "re-learn" how to drink, eat, speak, laugh, kiss, etc. This abrupt change may result in altering how the individual perceives their new body image. For some, this represented an identity alteration. This study indicates that the denture-related body image does "exist". This alteration of self-image symbolises the individual's subjective perceptions, thoughts and experiences about their dentures. Gleeson and Frith, (2006) characterise "body image" as a hypothetical construct, created to explain and describe patterns of behaviours, which are related to how an individual picture their body in their mind. Likewise, this study indicated the presence of denture self-awareness domain and the related psychosocial reaction. More than 60% of the participants reported

negative self-image and over 24% avoided social interactions as a result of this self-image alteration (Frequency scale: sometimes – very often).

Various testimonies expressed by participants during the validation of the questionnaire (chapter three) illustrated similar issues. The personal inter-relations with denture were described as "*the plastic thing*", "*nothing like my natural teeth*" and "*hate my denture*". Furthermore, behavioural reactions to dentures included: secretiveness statements "*Don't take denture out in front my husband*", dentures worries/anxiety "*worried my students will call me names*" and impact on social interaction "*not comfortable smiling*".

Similar findings were echoed by various studies discussed in chapter one including: altered body image, diminished self-esteem, dislike of appearance, concerns about dignity, biographical disruption, feeling older, denture secretiveness, adjusted socialising and relationship (Silverman *et al.,* 1976; Rudy *et al.,* 1993; Fiske *et al.*, 2001, Rousseau *et al.,* 2014). While many of those studies describe the various feelings, emotions and experiences associated with tooth loss and denture, this study indicates that the "predominant factor" that generate those feelings is the burden of the negative body image attributed to tooth loss and further enhanced by wearing dentures. It seems that the functional difficulties associated with dentures were a secondary priority for many participants. Other researchers also indicated that for many individuals with tooth loss, restoring appearance has priority over function (Graham *et al.,* 2006).

Gleeson and Frith (2006) described body image as a process, which develops and progress after a series of reflections, active engagement and negotiation between the embodied experience, identity and display. However, it should be noted, that the denture body image, is not a perceptual/imaginary distortion of the natural body image, but is a subjective dissatisfaction with extreme changes to facial appearance caused by tooth loss/dentures.

Therefore, when patients dislike their denture's appearance, this should be classified as "*body image dissatisfaction*", and not "*body image distortion*". The denture body image dissatisfaction differs from the dysmorphic body syndrome, where there is an apparent discrepancy between the individual perception of body image/shape/size and the reality, i.e. there is an imagined defect in appearance (Scott and Newton, 2011). Furthermore, in the dysmorphic body syndrome, the desire to achieve an unrealistic ideal body image is in many cases impossible to reach.

4.3.7 Limitations of the study:

This study has four main limitations:

Firstly, this study is a questionnaire-based research. Questionnaires are less likely to be objective, since the questionnaire's items might restrict the depth of participant's response, and the risk of reporting bias could not be excluded (Rattray and Jones, 2007). Furthermore, items in the questionnaire might fail to capture emotional triggers, as some individuals could misattribute negative emotions to specific source, when in fact it may be related to another cause (Cohen *et al.,* 1983). However, as discussed in Chapter Three, the structural development and extensive validation of this questionnaire has increased the reliability of the data collected via this questionnaire.

The second limitation of this study is the cross-sectional design of the study. This design allows the data to be collected simultaneously, and therefore, it would be difficult to draw a satisfactory causal relationship between the various variables in this study. To confirm the causality, a longitudinal study should be conducted. However, as tooth loss occurs over many years, conducting such randomised clinical studies could be quite complex and lengthy, as it would be challenging to define a starting point for any dental diseases related to tooth loss.

The third limitation is the potential bias caused by exclusion and inclusion criteria. The exclusion criteria involved participants with active dental diseases (dental caries, periodontal disease); however, participants have not been screened for extensive tooth surface loss (TSL). TSL could also be a possible cause for distress, and ideally those participants should have been excluded in the study design. Nevertheless, it is unlikely that this limitation had a significant impact on the study results, as none of the participants included in this study had severe TSL and also reported symptoms related to TSL.

Furthermore, the exclusion criteria eliminated participants who don't speak/read English. This exclusion resulted in deficient representative data from non-English speaking ethnic minority groups. However, it was impossible to translate the questionnaire to different languages since each version would have required to be validated again and this was beyond the scope of this study.

Finally, the sample size was small and the recruitment of participants was limited to only two sites. A larger sample size with multiple locations would enable the results to be adapted to general population.

Despite those limitations, this study provides useful understanding and insights about the emotions and feelings associated with tooth loss, and patients' perspectives related to their dentures.

4.3.8 Conclusion

This study highlights various psychological impacts of tooth loss and denture restoration on some individuals. While treatment using optimum technically quality dentures is regarded

as an effective intervention by clinicians, for some individuals, tooth loss and dentures are associated with body image dissatisfaction and psychological morbidity. It also seems that the females and the younger age group are more likely to experience denture-related body image dissatisfaction.

CHAPTER FIVE: IMPLICATION FOR PRACTICE AND DIRECTION FOR FUTURE RESEARCH

5.1 Implication for practice

This study has two potential implications for practice:

Firstly, this study highlights various psychological impacts of tooth loss and dentures on some individuals despite treatment with optimum technically satisfactory dentures. Therefore, this study recommends adopting a patient-centred approach prior to any management strategy, i.e. extraction of teeth and/or providing dentures. It is recommended that clinicians could explore patients' priorities and what aspects of treatment is most important for them, i.e., function, appearance etc. Communication with patients could also include the possible body image impairment and psychological disturbance that might be associated with tooth loss/dentures.

Secondly; the questionnaire developed in the study could be used in the general dental practice to investigate the possible psychological impact of tooth loss/dentures. Patients who have tooth loss and/or were treated with dentures could be asked to complete the questionnaire which was developed in this study. Patients who report body image dissatisfaction and/or psychological disturbance could then be investigated by the general dental practitioner to assess if any further interventions might help i.e., pre and post tooth extraction rehabilitation.

5.2 Direction for future research:

This study raises several opportunities for future research.

Firstly, the developed questionnaire was validated by recruiting participants from two primary care dental practices. Further research could attempt to re-validate the developed questionnaire with an expanded sampling strategy; i.e., recruitment of participants from a wider geographic area (diverse sampling). This wider recruitment strategy would further enhance the validity of this developed questionnaire.

Secondly, as discussed in section (2-2-2), the inclusion/exclusion criteria failed to screen for patients who had extensive tooth surface loss (TSL). TSL could be a possible cause for distress; therefore, further research could attempt to replicate this study with a more defined inclusion/exclusion criteria to control dental disease such as TSL.

Thirdly, the questionnaire that has been developed in this study offers the opportunity to conduct future research to further analyse the psychological impact of tooth loss, and compare the effectiveness of different interventions such as removable/fixed prostheses. In addition, this developed questionnaire could be used in a longitudinal comparative study to compare the psychological impact of tooth loss in patients who have different interventions, i.e., removable dentures, dental implants and cognitive behaviour therapy.

6. References

Aaronson, N., Alonso, J., Burnam, A., Lohr, K. N., Patrick, D. L., Perrin, E. and Stein, R. E. (2002), SAC Assessing health status and quality-of-life instruments: attributes and review criteria, Quality of Life Research, 11(3), pp. 193-205.

Abnet, C. C., Qiao, Y. L., Dawsey, S. M., Dong, Z. W., Taylor, P. R. and Mark, S. D. (2005), Tooth loss is associated with increased risk of total death and death from upper gastrointestinal cancer, heart disease, and stroke in a Chinese population-based cohort, International Journal of Epidemiology, 34(2), pp. 467-74.
al Quran, F., Clifford, T., Cooper, C. and Lamey, P. J. (2001), Influence of psychological factors on the acceptance of complete dentures, Gerodontology, 18(1), pp. 35-40.

Al-Shammari, K. F., Al-Khabbaz, A. K., Al-Ansari, J. M., Neiva, R. and Wang, H. L. (2005), Risk indicators for tooth loss due to periodontal disease, Journal of Periodontology, 76(11), 1910-8.

Alani, A., Bishop, K., Renton, T. and Djemal, S. (2014), Update on guidelines for selecting appropriate patients to receive treatment with dental implants: priorities for the NHS--the position after 15 years, British Dental Journal, 217(4), pp. 189-90.

Albandar, J. M., Streckfus, C. F., Adesanya, M. R. and Winn, D. M. (2000), Cigar, pipe, and cigarette smoking as risk factors for periodontal disease and tooth loss, Journal of Periodontology, 71(12), pp. 1874-81.

Albino, J. E., Alley, T. R., Tedesco, L. A., Center. Tobiasen, J. A., Kiyak, H. A., Buffalo., Lawrence, S. D. and Buffalo. (1990), Esthetic Issues in Behavioral Dentistry, Annals Behavioral Medicine, 12(4), pp. 148-155.

Algars, M., Santtila, P., Varjonen, M., Witting, K., Johansson, A., Jern, P. and Sandnabba, N. K. (2009). The adult body: how age, gender, and body mass index are related to body image, Journal of Aging and Health, 21(8), pp. 1112-32.

Allen, P. F. (2003). Assessment of oral health related quality of life, Health and Quality of Life Outcomes, 1, pp. 40.

Allen, P. F. and Locker, D. (1997). Do item weights matter? An assessment using the oral health impact profile, Community Dental Health Journal, 14(3), pp. 133-8.

Allen, P. F. and McMillan, A. S. (1999). The impact of tooth loss in a denture wearing population: an assessment using the Oral Health Impact Profile, Community Dental Health Journal. 16(3), pp. 176-80.

Allen, P. F. and McMillan, A. S. (2003). A review of the functional and psychosocial outcomes of edentulousness treated with complete replacement dentures, Journal of the Canadian Dental Association, 69(10), pp. 662.

Allen, P. F., McMillan, A. S.; Locker, D. (2001). An assessment of sensitivity to change of the Oral Health Impact Profile in a clinical trial, Community Dentistry and Oral Epidemiology, 29(3), pp. 175-82.

Allgaier, A. K., Kramer, D., Saravo, B., Mergl, R., Fejtkova, S. and Hegerl, U. (2013). Beside the Geriatric Depression Scale: the WHO-Five Well-being Index as a valid screening tool for depression in nursing homes, International Journal of Geriatric Psychiatry, 28(11), pp. 1197-204.

Altabe, M. and Thompson, J. K. (1996). Body image: A cognitive self-schema construct?, Cognitive Therapy and Research, 20(2), pp. 171-193.

Althubaiti, A. (2016). Information bias in health research: definition, pitfalls, and adjustment methods, Journal of Multidisciplinary Healthcare, pp. 211-7.

Anastassiadou, V. and Robin Heath, M. (2006). The effect of denture quality attributes on satisfaction and eating difficulties, Gerodontology, 23(1), pp. 23-32.

Anjum MS, M. M., Rao K Y, Reddy P P, Hameed IA, Jyothi M. (2017). Does tooth loss have an emotional effect? A cross-sectional and comparative study on nondenture wearers and complete denture wearers, Journal of Indian Association of Public Health Dentistry, 15(3), pp. 247-251.

Antony, M. M., Bieling, P. J., Cox, B. J., Enns, M. W. and Swinson, R. P. (1998). Psychometric properties of the 42-item and 21-item versions of the Depression Anxiety Stress Scales in clinical groups and a community sample, Psychological Assessment, 10(2), pp. 176.

Antony MM, B. P., Cox BJ, Enns MW, Swinson RP. (1998). Psychometric properties of the 42-item and 21-item versions of the Depression Anxiety Stress Scales in clinical groups and a community sample, Psychological Assessment, 10, pp. 176-181.

Anttila, S., Knuuttila, M., Ylostalo, P. and Joukamaa, M. (2006). Symptoms of depression and anxiety in relation to dental health behavior and self-perceived dental treatment need, European Journal of Oral Science, 114(2), pp. 109-14.

Anttila, S. S., Knuuttila, M. L. and Sakki, T. K. (2001). Relationship of depressive symptoms to edentulousness, dental health, and dental health behavior, Acta Odontologica Scandinavica, 59(6), pp. 406-12.

Artino, A. R., La Rochelle, J. S., Dezee, K. J. and Gehlbach, H. (2014). Developing questionnaires for educational research: AMEE Guide No. 87, Medical Teacher, 36(6), pp. 463-74.

Atherton, R. and Robertson, N. (2006). Psychological adjustment to lower limb amputation amongst prosthesis users, Disability and Rehabilitation, 28(19), pp. 1201-9.

Baiju, R. M., Peter, E., Varghese, N. O. and Sivaram, R. (2017). Oral Health and Quality of Life: Current Concepts, Journal of Clinical and Diagnostic Research, 11(6), pp. Ze21-ze26.

Bech, P., Gudex, C. and Johansen, K. S. (1996). The WHO (Ten) Well-Being Index: validation in diabetes, Psychotherapy and Psychosomatics, 65(4), pp. 183-90.

Berg, E., Johnsen, T. B. and Ingebretsen, R. (1986). Psychological variables and patient acceptance of complete dentures, Acta Odontologica Scandinavica, 44(1), pp. 17-22.

Bergendal, B. (1989). The relative importance of tooth loss and denture wearing in Swedish adults, Community dental health Journal, 6(2), pp. 103-111.

Bjelland, I., Dahl, A. A., Haug, T. T. and Neckelmann, D. (2002). The validity of the Hospital Anxiety and Depression Scale. An updated literature review, Journal of Psychosomatic Research, 52(2), pp. 69-77.

Blomberg, S. and Lindquist, L. W. (1983). Psychological reactions to edentulousness and treatment with jawbone-anchored bridges, Acta Psychiatrica Scandinavica, 68(4), pp. 251-62.

Bolarinwa, O. A. (2015). Principles and methods of validity and reliability testing of questionnaires used in social and health science researches, Nigerian Postgraduate Medical Journal, 22(4), pp. 195-201.

Brown, T. A., Chorpita, B. F., Korotitsch, W. and Barlow, D. H. (1997). Psychometric properties of the Depression Anxiety Stress Scales (DASS) in clinical samples, Behaviour and Research Therapy, 35(1), pp. 79-89.

BSRM, British Society of Rehabilitation Medicine. Amputee and Prosthetic Rehabilitation – Standards and Guidelines, 3rd Edition; Report of the Working Party. British Society of Rehabilitation Medicine, London 2018.

Bucca, C., Cicolin, A., Brussino, L., Arienti, A., Graziano, A., Erovigni, F., Pera, P., Gai, V., Mutani, R., Preti, G., Rolla, G. and Carossa, S. (2006). Tooth loss and obstructive sleep apnoea, Respiratory Research, 7, pp. 8.

Cameron, I. M., Crawford, J. R., Lawton, K. and Reid, I. C. (2008). Psychometric comparison of PHQ-9 and HADS for measuring depression severity in primary care, British Journal of General Practice, 58(546), pp. 32-6.

Casanova-Rosado, J. F., Medina-Solis, C. E., Vallejos-Sánchez, A. A., Casanova-Rosado, A. J., Maupomé, G. and Avila-Burgos, L. (2005). Lifestyle and psychosocial factors associated with tooth loss in Mexican adolescents and young adults, The Journal of Contemporary Dental Practice, 6(3), pp. 70-77.

Chochinov, H. M., Wilson, K. G., Enns, M. and Lander, S. (1997). Are you depressed? Screening for depression in the terminally ill, American Journal of Psychiatry, 154(5), pp. 674-6.

Cleary, T. J. and Hutton, J. E. (1995). An assessment of the association between functional edentulism, obesity, and NIDDM, Diabetes Care, 18(7), pp. 1007-9.

Cohen, S., Kamarck, T. and Mermelstein, R. (1983). A global measure of perceived stress, Journal of Health and Social Behaviour, 24(4), pp. 385-96.

Connelly, L. M. (2008). Pilot studies, Medsurg Nursing, 17(6), pp. 411-2.

Cosco, T. D., Doyle, F., Ward, M. and McGee, H. (2012). Latent structure of the Hospital Anxiety And Depression Scale: a 10-year systematic review, Journal of Psychosomatic Research, 72(3), pp. 180-4.

Coyne, J. C. and van Sonderen, E. (2012). No further research needed: abandoning the Hospital and Anxiety Depression Scale, Journal of Psychosomatic Research: Vol. 3, pp. 173-4.

Cronan, L. (1993). Management of the patient with altered body image, British Journal of Nursing, 2(5), pp. 257-61.

D'Mello, D. A. (2003). Are your patients depressed? Implications for dental practice, The Journal of Michigan Dental Association, 85(5), pp. 26-32.

da Veiga Pessoa, D. M., Roncalli, A. G. and de Lima, K. C. (2017). Economic and sociodemographic inequalities in complete denture need among older Brazilian adults: a cross-sectional population-based study, BMC Oral Health; 17. pp. 55.

Dable, R. A., Yashwante, B. J., Marathe, S. S., Gaikwad, B. S., Patil, P. B. and Momin, A. A. (2014). Tooth loss--how emotional it is for the elderly in India?, Journal of Oral Health and Dental Management, 13(2), pp. 305-10.

Davis, D. M., Fiske, J., Scott, B. and Radford, D. R. (2000). The emotional effects of tooth loss: a preliminary quantitative study, British Dental Journal. 188(9), pp. 503-6.

Davis, D. M., Fiske, J., Scott, B. and Radford, D. R. (2001). The emotional effects of tooth loss in a group of partially dentate people: a quantitative study, European Journal of Prosthodontics and Restorative research. 9(2), pp. 53-7.

de Man-van Ginkel, J. M., Gooskens, F., Schepers, V. P., Schuurmans, M. J., Lindeman, E. and Hafsteinsdottir, T. B. (2012). Screening for poststroke depression using the patient health questionnaire, Nursing Research, 61(5), pp. 333-41.

de Pablo, P., Dietrich, T. and McAlindon, T. E. (2008). Association of periodontal disease and tooth loss with rheumatoid arthritis in the US population, The Journal of Rheumatology, 35(1), pp. 70-6.

De Velllis, R. (2003). Scale Development: Theory and Applications, 2nd ed, Thousand Oaks, CA: Sage Publications.

DeVon, H. A., Block, M. E., Moyle-Wright, P., Ernst, D. M., Hayden, S. J., Lazzara, D. J., Savoy, S. M. and Kostas-Polston, E. (2007). A psychometric toolbox for testing validity and reliability, Journal of Nursing Scholarship, 39(2), pp. 155-64.

Dirik, G., Kiliçarslan, M. A., Gençöz, T. and Karanci, N. (2006). Correlates of anxiety and depression in Turkish complete denture patients, Social Behavior and Personality, 34(10), pp. 1311-1322.

Divaris, K., Ntounis, A., Marinis, A., Polyzois, G. and Polychronopoulou, A. (2012). Loss of natural dentition: multi-level effects among a geriatric population, Gerodontology, 29(2), pp. e192-9.

Dumitrescu, A. L., Kawamura, M., Dogaru, B. C. and Dogaru, C. D. (2010). Relation of achievement motives, satisfaction with life, happiness and oral health in Romanian university students, Oral Health and Preventive Dentistry, 8(1), pp. 15-22.

Eklund, S. A. and Burt, B. A. (1994). Risk factors for total tooth loss in the United States; longitudinal analysis of national data, Journal of Public Health Dentistry, 54(1), pp. 5-14.
Emami, E., de Souza, R. F., Kabawat, M. and Feine, J. S. (2013). The impact of edentulism on oral and general health, International Journal of Dentistry, 2013, pp. 498305.

Erler, S. F. and Garstecki, D. C. (2002). Hearing loss- and hearing aid-related stigma: perceptions of women with age-normal hearing, American Journal of Audiology, 11(2), pp. 83-91.

Fenlon, M. R. and Sherriff, M. (2004). Investigation of new complete denture quality and patients' satisfaction with and use of dentures after two years, Journal of Dentistry, 32(4), pp. 327-33.

Fiske, J., Davis, D. M., Frances, C. and Gelbier, S. (1998). The emotional effects of tooth loss in edentulous people, British Dental Journal, 184(2), pp. 90-3; discussion 79.

Fiske, J., Davis, D. M., Leung, K. C., McMillan, A. S. and Scott, B. J. (2001). The emotional effects of tooth loss in partially dentate people attending prosthodontic clinics in dental schools in England, Scotland and Hong Kong: a preliminary investigation, International Dental Journal, 51(6), pp. 457-62.

Fiske, J., Davis, D. M., Frances, C, and Gelbier, S (2000). The emotional effects of tooth   loss. The Proceedings of the European Prosthodontic Association, 21:24 (abs).

Fouda, S. M., Al-Attar, M. S., Virtanen, J. I. and Raustia, A. (2014). Effect of Patient's Personality on Satisfaction with Their Present Complete Denture and after Increasing the Occlusal Vertical Dimension: A Study of Edentulous Egyptian Patients, International Journal of Dentistry, 2014, pp. 635943.

Franchelli, S., Leone, M. S., Passarelli, B., Perniciaro, G., Capelli, M., Baracco, G., Alberisio, A. and Santi, P. L. (1995). Psychological assessment of patients who have undergone breast reconstruction using 2 different technics: autologous tissue versus prosthesis, Minerva Chirurgica, 50(5), pp. 481-8.

Friedlander, A. H. and Norman, D. C. (2002). Late-life depression: psychopathology, medical interventions, and dental implications, Oral Surgery, Oral Medicine, Oral Pathology and Oral Radiology, 94(4), pp. 404-12.

Friedman, N., Landesman, H. M. and Wexler, M. (1987). The influences of fear, anxiety, and depression on the patient's adaptive responses to complete dentures, Journal of Prosthetic Dentistry, 58(6), pp. 687-9.

Furuya, M., Hayashino, Y., Tsujii, S., Ishii, H. and Fukuhara, S. (2013). Comparative validity of the WHO-5 Well-Being Index and two-question instrument for screening depressive symptoms in patients with type 2 diabetes, Acta Diabetologica, 50(2), pp. 117-21.

Gleeson, K. and Frith, H. (2006). (De)constructing body image, Journal of Health Psychology, 11(1), pp. 79-90.

Goldberg, D. P., Gater, R., Sartorius, N., Ustun, T. B., Piccinelli, M., Gureje, O. and Rutter, C. (1997). The validity of two versions of the GHQ in the WHO study of mental illness in general health care, Psychological Medicine, 27(1), pp. 191-7.

Goldberg, D. P. and Williams, P. (1988). A user's guide to the GHQ. Windsor.

Gotfredsen, K. and Walls, A. W. (2007). What dentition assures oral function?, Clinical Oral Implants Research, 18 Suppl 3, pp. 34-45.

Graham, R., Mihaylov, S., Jepson, N., Allen, P. F. and Bond, S. (2006). Determining need for a Removable Partial Denture: a qualitative study of factors that influence dentist provision and patient use, British Dental Journal. 2/11/2006, 200(3), pp. 155.

Haddad, M., Walters, P., Phillips, R., Tsakok, J., Williams, P., Mann, A. and Tylee, A. (2013). Detecting depression in patients with coronary heart disease: a diagnostic evaluation of the PHQ-9 and HADS-D in primary care, findings from the UPBEAT-UK study, PLoS One, 8(10), pp. e78493.

Hajos, T. R., Pouwer, F., Skovlund, S. E., Den Oudsten, B. L., Geelhoed-Duijvestijn, P. H., Tack, C. J. and Snoek, F. J. (2013). Psychometric and screening properties of the WHO-5 well-being index in adult outpatients with Type 1 or Type 2 diabetes mellitus, Diabetic Medicine, 30(2), pp. e63-9.

Hamasha, A. A., Sasa, I. and Al-Qudah, M. (2000). Risk indicators associated with tooth loss in Jordanian adults, Community Dentistry and Oral Epidemiology, 28(1), pp. 67-72.

Harle, T. J. and Anderson, J. D. (1993). Patient satisfaction with implant-supported prostheses, International Journal of Prosthodontics, 6(2), pp. 153-62.

Hatch, J. P., Shinkai, R. S., Sakai, S., Rugh, J. D. and Paunovich, E. D. (2001). Determinants of masticatory performance in dentate adults, Archives of Oral Biology, 46(7), pp. 641-8.

Henry, J. D. and Crawford, J. R. (2005). The short-form version of the Depression Anxiety Stress Scales (DASS-21): construct validity and normative data in a large non-clinical sample, British Journal of Clinical Psychology, 44(Pt 2), pp. 227-39.

Herrmann, C. (1997). International experiences with the Hospital Anxiety and Depression Scale--a review of validation data and clinical results, Journal of Psychosomatic Research, 42(1), pp. 17-41.

Hogenius, S., Berggren, U., Blomberg, S., Jemt, T. and Ohman, S. C. (1992). Demographical, odontological, and psychological variables in individuals referred for osseointegrated dental implants, Community Dentistry and Oral Epidemiology, 20(4), pp. 224-8.

Holm-Pedersen, P., Schultz-Larsen, K., Christiansen, N. and Avlund, K. (2008). Tooth loss and subsequent disability and mortality in old age, Journal of American Geriatric Society, 56(3), pp. 429-35.

Holmlund, A., Holm, G. and Lind, L. (2010). Number of teeth as a predictor of cardiovascular mortality in a cohort of 7,674 subjects followed for 12 years, Journal of Periodontology, 81(6), pp. 870-6.

Hutton, B., Feine, J. and Morais, J. (2002). Is there an association between edentulism and nutritional state?, Journal of the Canadian Dental Association, 68(3), pp. 182-7.
Joshipura, K., Ritchie, C. and Douglass, C. (2000). Strength of evidence linking oral conditions and systemic disease, Compendium of Continuing Education in Dentistry, (30), pp. 12-23.

Julious, S. (2005). Sample size of 12 per group rule of thumb for a pilot study, Pharmaceutical Statistics, Wiley Online Library, 4, pp. 287-291.

Kassebaum, N. J., Bernabe, E., Dahiya, M., Bhandari, B., Murray, C. J. and Marcenes, W. (2014). Global Burden of Severe Tooth Loss: A Systematic Review and Meta-analysis, Journal of Dental Research, 93(7 Suppl), pp. 20s-28s.

Kendler, K. S., Karkowski, L. M. and Prescott, C. A. (1999). Causal relationship between stressful life events and the onset of major depression, American Journal of Psychiatry, 156(6), pp. 837-41.

Kent, G. and Johns, R. (1993). Psychological effects of permanently implanted false teeth: A 2-year follow-up and comparison with dentate patients, Psychology and Health, 8(2-3), pp. 213-222.

Kitchell, M. A., Barnes, R. F., Veith, R. C., Okimoto, J. T. and Raskind, M. A. (1982). Screening for depression in hospitalized geriatric medical patients, Journal of American Geriatric Society, 30(3), pp. 174-7.

Kroenke, K., Spitzer, R. L. and Williams, J. B. (2001). The PHQ-9: validity of a brief depression severity measure, Journal of General Internal Medicine, 16(9), pp. 606-13.

Kroenke, K., Spitzer, R. L., Williams, J. B., Monahan, P. O. and Lowe, B. (2007). Anxiety disorders in primary care: prevalence, impairment, comorbidity, and detection, Annals of Internal Medicine, 146(5), pp. 317-25.

Lawshe, C. H. (1975). A quantitative approach to content validity, Personnel Psychology, (28), pp. 563-575.

Liberati, A., Altman, D. G., Tetzlaff, J., Mulrow, C., Gøtzsche, P. C., Ioannidis, J. P. A., Clarke, M., Devereaux, P. J., Kleijnen, J. and Moher, D. (2009). The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration, British Medical Journal, b2700., pp. 339.

Lindsay, S. M., K. Jennings, K. (2000). The psychological benefits of dental implants in patients distressed by untolerated dentures, Psychology and Health, 15, pp. 451-466.

Lloyd-Williams, M., Dennis, M. and Taylor, F. (2004). A prospective study to compare three depression screening tools in patients who are terminally ill, General Hospital Psychiatry, 26(5), pp. 384-9.

Locker, D. (1988). Measuring oral health: a conceptual framework, Community Dental Health Journal, 5(1), pp. 3-18.

Locker, D. (1998). Issues in measuring change in self-perceived oral health status, Community Dentistry and Oral Epidemiology, 26(1), pp. 41-7.

Locker, D. (2004). Oral health and quality of life, Oral Health and Preventive Dentistry, 2 Suppl 1, pp. 247-53.

Locker, D., Ford, J. and Leake, J. L. (1996). Incidence of and risk factors for tooth loss in a population of older Canadians, Journal of Dental Research, 75(2), pp. 783-9.

Lovibond, P. F. and Lovibond, S. H. (1995). The structure of negative emotional states: comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories, Behaviour Research and Therapy, 33(3), pp. 335-43.

Lucas-Carrasco, R., Allerup, P. and Bech, P. (2012). The Validity of the WHO-5 as an Early Screening for Apathy in an Elderly Population, Current Gerontology and Geriatric Research, 2012, pp. 171857.

Major, B. and O'Brien, L. T. (2005). The social psychology of stigma, Annual Review of Psychology, 56, pp. 393-421.

Marcenes, W., Kassebaum, N. J., Bernabe, E., Flaxman, A., Naghavi, M., Lopez, A. and Murray, C. J. (2013). Global burden of oral conditions in 1990-2010: a systematic analysis, Journal of Dental Research, 92(7), pp. 592-7.

Maria, L., Mariano da Rocha, M. and Terra, N. (2013). Body image in older adults: a review, Scientia Medica, 23, pp. 255-261.

McManus S, B. P., Jenkins R, Brugha T (2016). Mental health and wellbeing in England: Adult psychiatric morbidity survey 2014, NHS Digital. URL: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/556596/apms-2014-full-rpt.pdf. Accessed August 2019.

McMillan, A. S. and Wong, M. C. (2004). Emotional effects of tooth loss in community-dwelling elderly people in Hong Kong, The Internal Journal of Prosthodontics, 17(2), pp. 172-6.

Michael, C. G., Javid, N. S., Colaizzi, F. A. and Gibbs, C. H. (1990). Biting strength and chewing forces in complete denture wearers, The Journal of Prosthetic Dentistry, 63(5), pp. 549-53.

Michaud, P. L., de Grandmont, P., Feine, J. S. and Emami, E. (2012). Measuring patient-based outcomes: is treatment satisfaction associated with oral health-related quality of life?, Journal of Dentistry, 40(8), pp. 624-31.

Munro, B.H. (2005). Statistical methods for health care research (4th ed.). Philadelphia: Lippincott, Williams & Wilkins.

Naik, A. V. and Pai, R. C. (2011). Study of emotional effects of tooth loss in an aging north Indian community, International Scholarly Research Notices: Dentistry, 2011:, pp. 10.5402/2011/395498.

National Institute for Health Research (2015). NIHR Evaluation, Trials and Studies. Pilot studies, Available: http://www.nets.nihr.ac.uk/glossary/pilot-studies. Accessed Aug 2019. Neuman, W. L. (1997) Social Research Methods: Qualitative and Quantitative Approaches. 3rd edn. Boston: Allyn and Bacon, p. 232.

NICE (2011). Common mental health problems: identification and pathways to care, Guidance. Clinical guideline [CG123]. URL: https://www.nice.org.uk/guidance/cg123. Accessed August 2019

O'Donnell, E. (2013). The distress thermometer: a rapid and effective tool for the oncology social worker, The International Journal of Health Care Quality Assurance, 26(4), pp. 353-9.

Okimoto, J. T., Barnes, R. F., Veith, R. C., Raskind, M. A., Inui, T. S. and Carter, W. B. (1982). Screening for depression in geriatric medical patients, American Journal of Psychiatry, 139(6), pp. 799-802.

Okoje, V. N., Dosumu, O. O., Alonge, T. O. and Onyeaso, C. (2012). Tooth loss: Are the patients prepared, Nigerian Journal of Clinical Practice, 15(2), pp. 172-175.

Okoro, C. A., Balluz, L. S., Eke, P. I., Ajani, U. A., Strine, T. W., Town, M., Mensah, G. A. and Mokdad, A. H. (2005). Tooth loss and heart disease: findings from the Behavioral Risk Factor Surveillance System, American Journal of Preventive Medicine, 29(5 Suppl 1), pp. 50-6.

Okoro, C. A., Strine, T. W., Eke, P. I., Dhingra, S. S. and Balluz, L. S. (2012). The association between depression and anxiety and use of oral health services and tooth loss, Community Dentistry and Oral Epidemiology, 40(2), pp. 134-44.

Omar, R., Tashkandi, E., Abduljabbar, T., Abdullah, M. A. and Akeel, R. F. (2003). Sentiments expressed in relation to tooth loss: A qualitative study among edentulous Saudis, The International Journal of Prosthodontics, 16(5), pp. 515-520.

Ommerborn, M. A., Hugger, A., Kruse, J., Handschel, J. G., Depprich, R. A., Stuttgen, U., Zimmer, S. and Raab, W. H. (2008). The extent of the psychological impairment of prosthodontic outpatients at a German University Hospital, Head and Face Medicine, 4, pp. 23.

Oosterhaven, S. P., Westert, G. P., Schaub, R. M. and van der Bilt, A. (1988). Social and psychologic implications of missing teeth for chewing ability, Community Dentistry and Oral Epidemiology, 16(2), pp. 79-82.

Ozdemir, A. K., Ozdemir, H. D., Polat, N. T., Turgut, M. and Sezer, H. (2006). The effect of personality type on denture satisfaction, The International Journal Prosthodontics, 19(4), pp. 364-70.

Pan, S., Awad, M., Thomason, J. M., Dufresne, E., Kobayashi, T., Kimoto, S., Wollin, S. D. and Feine, J. S. (2008). Sex differences in denture satisfaction, Journal of Dentistry, 36(5), pp. 301-8.

Plourde, A., Moullec, G., Bacon, S. L., Suarthana, E. and Lavoie, K. L. (2016). Optimizing screening for depression among adults with asthma, Journal of Asthma, 53(7), pp. 736-43.

Puleo, E., Zapka, J., White, M. J., Mouchawar, J., Somkin, C. and Taplin, S. (2002). Caffeine, cajoling, and other strategies to maximize clinician survey response rates, Evaluation and the Health Professions, 25(2), pp. 169-84.

Radhakrishna, R. (2007). Tips for Developing and Testing Questionnaires/Instruments, 45. The Journal of Extension,V45, pp, 234-43

Rattray, J. and Jones, M. C. (2007). Essential elements of questionnaire design and development, Journal of Clinical Nursing, 16(2), pp. 234-43.

Roach, K. (2006). Measurement of Health Outcomes: Reliability and Validity, Journal of Prosthetics and Orthotics, 18(6), pp. 8-12.

Roohafza, H., Afghari, P., Keshteli, A. H., Vali, A., Shirani, M., Adibi, P. and Afshar, H. (2015). The relationship between tooth loss and psychological factors, Community Dental Health Journal, 32(1), pp. 16-9.

Rousseau, N., Steele, J., May, C. and Exley, C. (2014). 'Your whole life is lived through your teeth': biographical disruption and experiences of tooth loss and replacement, Sociology and Health Illness, 36(3), pp. 462-76.

Rudy, S. F., Guckes, A. D., Li, H. H., McCarthy, G. R., Brahim, J. S. and Li, S. H. (1993). Body and orofacial cathexis in edentulous complete-denture-wearing clients, Clinical Nursing Research, 2(3), pp. 296-308.

Saba Mian, M. P., Bowen Su, Roger Newson, Bowen Su, Peter Tyrer and Michael Soljak (2015). Health Survey for England, 2014, NHS Digital, available at: https://digital.nhs.uk/data-and-information/publications/statistical/health-survey-for-england/health-survey-for-england-2014.

Sanders, A. E., Slade, G. D., Turrell, G., Spencer, A. J. and Marcenes, W. (2007). Does psychological stress mediate social deprivation in tooth loss?, Journal of Dental Research., 86(12), pp. 1166-70.

Schneider, C. B., Pilhatsch, M., Rifati, M., Jost, W. H., Wodarz, F., Ebersbach, G., Djundja, D., Fuchs, G., Gies, A., Odin, P., Reifschneider, G., Wolz, M., Bottesi, A., Bauer, M., Reichmann, H. and Storch, A. (2010). Utility of the WHO-Five Well-being Index as a screening tool for depression in Parkinson's disease, Movement Disorders, 25(6), pp. 777-83.

Scott, B. J., Leung, K. C., McMillan, A. S., Davis, D. M. and Fiske, J. (2001). A transcultural perspective on the emotional effect of tooth loss in complete denture wearers, The International Journal of Prosthodontics. 14(5), pp. 461-5.

Scott, S. E. and Newton, J. T. (2011). Body dysmorphic disorder and aesthetic dentistry, Dental Update, 38(2), pp. 112-4, 117-8.

Selye, H. (1976). Stress without Distress, Boston, MA, SpringerLink, p. 137-146.

Shah, R. J., Diwan, F. J., Diwan, M. J., Chauhan, V. J., Agrawal, H. S. and Patel, G. C. (2015). A study of the emotional effects of tooth loss in an edentulous Gujarati population and its association with depression, The Journal of Indian Prosthodontics Society, 15(3), pp. 237-43.

Sheiham, A. and Steele, J. (2001). Does the condition of the mouth and teeth affect the ability to eat certain foods, nutrient and dietary intake and nutritional status amongst older people?, Public Health Nutrition, 4(3), pp. 797-803.

Sheiham, A., Steele, J. G., Marcenes, W., Lowe, C., Finch, S., Bates, C. J., Prentice, A. and Walls, A. W. (2001). The relationship among dental status, nutrient intake, and nutritional status in older people, Journal of Dental Research, 80(2), pp. 408-13.

Silverman, S., Silverman, S. I., Silverman, B. and Garfinkel, L. (1976). Self-image and its relation to denture acceptance, The Journal of Prosthetic Dentistry, 35(2), pp. 131-41.

Sischo, L. and Broder, H. L. (2011). Oral health-related quality of life: what, why, how, and future implications, Journal of Dental Research, 90(11), pp. 1264-70.

Slade, G. D., Spencer, A. J. and Roberts-Thomson, K. (1996). Tooth loss and chewing capacity among older adults in Adelaide, Australian and New Zealand Journal of Public Health, 20(1), pp. 76-82.

Slevin, M. L., Plant, H., Lynch, D., Drinkwater, J. and Gregory, W. M. (1988). Who should measure quality of life, the doctor or the patient?, British Journal of Cancer, 57(1), pp. 109-12.

Smith, J. P. and Hughes, D. (1988). A survey of referred patients experiencing problems with complete dentures, The Journal of Prosthetic Dentistry, 60(5), pp. 583-586.

Smith, M. (1976). Measurement of personality traits and their relation to patient satisfaction with complete dentures, The Journal of Prosthetic Dentistry, 35(5), pp. 492-503.

Spitzer, R. L., Kroenke, K., Williams, J. B. and Lowe, B. (2006). A brief measure for assessing generalized anxiety disorder: the GAD-7, Archives of Internal Medicine, 166(10), pp. 1092-7.

Steele, J. G., Sanders, A. E., Slade, G. D., Allen, P. F., Lahti, S., Nuttall, N. and Spencer, A. J. (2004). How do age and tooth loss affect oral health impacts and quality of life? A study comparing two national samples, Community Dentistry and Oral Epidemiology, 32(2), pp. 107-14.

Steele, J. G., Treasure, E. T., O'Sullivan, I., Morris, J. and Murray, J. J. (2012). Adult Dental Health Survey 2009: transformations in British oral health 1968-2009, British Dental Journal, 213(10), pp. 523-7.

Stewart-Knight, K., Parry, R., Abey, A. and Seymour, J. (2012). Does the distress thermometer work? A systematic review of the evidence for its use and validity, British Medical Journal, pp. A30.

Stolzenberg-Solomon, R. Z., Dodd, K. W., Blaser, M. J., Virtamo, J., Taylor, P. R. and Albanes, D. (2003). Tooth loss, pancreatic cancer, and Helicobacter pylori, The American Journal of Clinical Nutrition, 78(1), pp. 176-81.

Takata, Y., Ansai, T., Matsumura, K., Awano, S., Hamasaki, T., Sonoki, K., Kusaba, A., Akifusa, S. and Takehara, T. (2001). Relationship between tooth loss and electrocardiographic abnormalities in octogenarians, Journal of Dental Research, 80(7), pp. 1648-52.

Terwee, C. B., Bot, S. D., de Boer, M. R., van der Windt, D. A., Knol, D. L., Dekker, J., Bouter, L. M. and de Vet, H. C. (2007). Quality criteria were proposed for measurement properties of health status questionnaires, Journal of Clinical Epidemiology, 60(1), pp. 34-42.

Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L. P., Robson, R., Thabane, M., Giangregorio, L. and Goldsmith, C. H. (2010). A tutorial on pilot studies: the what, why and how, BMC Medical Research Methodology, 10, pp. 1.

Topp, C. W., Ostergaard, S. D., Sondergaard, S. and Bech, P. (2015). The WHO-5 Well-Being Index: a systematic review of the literature, Psychotherapy and Psychosomatic, 84(3), pp. 167-76.

Trulsson, U., Engstrand, P., Berggren, U., Nannmark, U. and Branemark, P. I. (2002). Edentulousness and oral rehabilitation: experiences from the patients' perspective, The European Journal of Oral Sciences 110(6), pp. 417-24.

Tsakos, G., Allen, P. F., Steele, J. G. and Locker, D. (2012). Interpreting oral health-related quality of life data, Community Dentistry and Oral Epidemiology, 40(3), pp. 193-200.

Ueno, M., Yanagisawa, T., Shinada, K., Ohara, S. and Kawaguchi, Y. (2008). Masticatory ability and functional tooth units in Japanese adults, Journal of Oral Rehabilitation, 35(5), pp. 337-44.

van Steenbergen-Weijenburg, K. M., de Vroege, L., Ploeger, R. R., Brals, J. W., Vloedbeld, M. G., Veneman, T. F., Hakkaart-van Roijen, L., Rutten, F. F., Beekman, A. T. and van der Feltz-Cornelis, C. M. (2010). Validation of the PHQ-9 as a screening instrument for depression in diabetes patients in specialized outpatient clinics, BMC Health Survives Research, 10, pp. 235.

van Teijlingen, E. and Hundley, V. (2002). The importance of pilot studies, Nursing Standard, 16(40), pp. 33-6.

van Waas, M. A. (1990). The influence of clinical variables on patients' satisfaction with complete dentures, The Journal of Prosthetic Dentistry, 63(3), pp. 307-10.

Vollrath, M., Torgersen, S. (2000). Personality types and coping. Personality and Individual Differences, Volume 29, Issue 2, pp. 367-378.

Volzke, H., Schwahn, C., Hummel, A., Wolff, B., Kleine, V., Robinson, D. M., Dahm, J. B., Felix, S. B., John, U. and Kocher, T. (2005). Tooth loss is independently associated with the risk of acquired aortic valve sclerosis, American Heart Journal, 150(6), pp. 1198-203.

Walls, A. W., Steele, J. G., Sheiham, A., Marcenes, W. and Moynihan, P. J. (2000). Oral health and nutrition in older people, Journal of Public Health Dentistry, 60(4), pp. 304-7.

Walton, J. N. and MacEntee, M. I. (2005). Choosing or refusing oral implants: a prospective study of edentulous volunteers for a clinical trial, The International Journal of Prosthodontics, 18(6), pp. 483-8.

W.H.O., (2010). ICD-10 International Statistical Classification of Diseases and Related Health Problems: WHO, Available at:
 https://www.who.int/classifications/icd/ICD10Volume2_en_2010.pdf.   (Accessed   August 2019).

W.H.O., (1948). World Health Organization Constitution, Available at:
 https://www.who.int/about/who-we-are/constitution (Accessed: August 2019).

Wiener, R. C., Wiener, M. A. and McNeil, D. W. (2015). Comorbid depression/anxiety and teeth removed: Behavioral Risk Factor Surveillance System 2010, Community Dentistry and Oral Epidemiology, 43(5), pp. 433-43.

Willis, G. B. and Artino, A. R. (2013). What Do Our Respondents Think We're Asking? Using Cognitive Interviewing to Improve Medical Education Surveys, Journal of Graduate Medical Education, Vol. 3, pp. 353-6.

Wolff, A., Gadre, A., Begleiter, A., Moskona, D. and Cardash, H. (2003). Correlation between patient satisfaction with complete dentures and denture quality, oral condition, and flow rate of submandibular/sublingual salivary glands, The International Journal of Prosthodontics, 16(1), pp. 45-8.

Wu, B., Hybels, C. F., Liang, J., Landerman, L. R. and Plassman, B. L. (2014). Social Stratification and Tooth Loss Among Middle-Aged and Older Americans from 1988–2004, Community Dentistry and Oral Epidemiology, 42(6), pp. 495-502.

Zigmond, A. S. and Snaith, R. P. (1983). The hospital anxiety and depression scale, Acta Psychiatrica Scandinavica, 67(6), pp. 361-70.

Zung, W. W. (1965). A self-rating depression scale, Archives of General Psychiatry, 12, pp. 63-70.

Zung, W. W. (1971). A rating instrument for anxiety disorders, Psychosomatics, 12(6), pp. 371-9.

Zung, W. W. (1973). From art to science: the diagnosis and treatment of depression, Archives of General Psychiatry, 29(3), pp. 328-37.

6. Appendices

Appendix 1: Primary and secondary depressive symptoms

Primary symptoms
• Depressed mood to a degree that is definitely abnormal for the individual, present for most of the day and almost every day, largely uninfluenced by circumstances, and sustained for at least 2 weeks.
• Loss of interest or pleasure in activities that are normally pleasurable
• Decreased energy or increased fatiguability.

Secondary symptoms
• Loss of confidence and self-esteem"
• "Unreasonable feelings of self-reproach or excessive and inappropriate guilt"
• Recurrent thoughts of death or suicide, or any suicidal behaviour"
• Diminished ability to think or concentrate"
• Change in psychomotor activity, with agitation or retardation
• Sleep disturbance"
• Change in appetite (decrease or increase) with corresponding weight change".

Appendix 2: Anxiety somatic and general symptoms

- Autonomic arousal symptoms: Palpitations, sweating, shaking, dry mouth (not due to medication or dehydration).

- Chest and abdomen symptoms: Difficulty breathing, feeling of choking, chest discomfort, nausea or abdominal distress.

- Brain and mind symptoms: Feeling dizzy, feelings that objects are unreal (derealization), or that one's self is distant or "not really here" (depersonalization), fear of losing control or passing out and fear of dying.

- General symptoms: Hot flushes or cold chills, numbness or tingling sensations.

- Symptoms of tension: Muscle tension/pains, restlessness and inability to relax, a sensation of difficulty with swallowing.

- Other non-specific symptoms: Exaggerated response to minor surprises or being startled, Difficulty in concentrating, or mind going blank, because of worrying or anxiety, Persistent irritability, Difficulty getting to sleep because of worrying.

Appendix 3: Secondary stress symptoms:

- Withdrawal from social interaction

- Narrowing of attention

- Disorientation

- Anger

- Despair

- Purposeless over-activity

- Excessive grief.

Appendix 4: Differences between stress and anxiety

Stress

- Stress is a normal s a reaction to external stresses (known triggers like an exam or interview)

- Stress is a short-term experience (ends once the stressor gone)

- Stress could become negative/pathological if impact on function

Anxiety:

- Anxiety is a reaction to stress (Internal stressor, triggers could not be identified)

- Anxiety is Sustained & persistent disorder,

- Anxiety is a disorder, which can cause impairment in function, social

Appendix 5 Patient Information Sheet

Queen Mary
UNIVERSITY OF LONDON

Barts and The London **NHS**
NHS Trust

Participant Information Sheet

Invitation paragraph:

We would like to invite you to take part in this study in which we hope to investigate the emotional impact of tooth loss and dentures. We would like to explain the purpose of this research and what the participation would involve before you decide to take part.

Please read the following information provided in your own time. If you require further clarification, feel free to ask the principal investigator directly.

Tooth loss & the quality of life:

Teeth loss has often-significant impact on the general health and the oral health-related quality of life. Extensive research has been done to explore the functional aspect of tooth loss, however limited research was done to explore the emotional impact of tooth loss.

What is the purpose of this study?

The aim of this study is to measure the emotional impact of tooth loss and dentures and to create tools to

recommend interventions if indicated.

Why Me?

You were invited because you are aged >18 and had experienced of tooth loss.

Where will the study be taken?

If you decided to take part, you will invited to attend the clinic to have your mouth examined and then you will be asked to fill in a questionnaire

Do I have to take part?

No. Taking part is completely optional.

If you agree to take part, you will be asked to fill in a consent form. Participants would have the opportunity to withdraw consent at any time and also ask for their data to be excluded from research.

What happen to me if I take part?

192

What happen to me if I take part?

If you agree to take part, you will be asked to undergo the following assessments:

- Clinical examination: your oral health will be examined. This will take 5 minutes.
- You will be asked to complete a questionnaire (three parts), which measure emotional distress caused by tooth loss. The questionnaire takes about 15 minutes to complete. The first two parts of the questionnaire measure the emotional distress caused by tooth loss and the third part of the questionnaire measure personality traits
- Medical and dental history will be taken

How long do I have to participate?

All the information required would be collected during the same visit. This will take about 20 minutes.

What are the possible risks of taking part in the study?

Non.

Will my taking part in this study be kept confidential?

Yes, we will follow ethical and legal practice and all information about participants will be confidential. The only people who will know about you taking part in this study will be the lead researcher and the supervisor.

What will happen to results of this study?

In order to share the knowledge gained from the study, the finding will published in a dental journal and presented at National/international meetings using only anonymised date.

Expenses and payment

Taking part in this study is voluntary so you will not receive any payment. . However, you will benefit from free dental examination.

If you have any questions or concerns about the manner in which the study was conducted, please contact the researcher responsible for this study:

CI Dr Aylin Baysan   Phone: 0207 882 8663   Email:a.baysan@qmul.ac.uk

PI Dr Zaki Kudsi   Phone: 0207 882 8663 Email: z.kudsi@nhs.net

If you feel these procedures are inappropriate, please contact the following:
The secretary at Queen Mary Ethics of Research Committee, Room W117,
Queens' Building, Queen Mary University of London, Mile End Road, London E1 4NS

Appendix 6 Consent form

CONSENT FORM

STUDY NUMBER:

Participant Idnetifiction Number for this trial:

Title of Project: Psychological distress caused by tooth loss and replacement options

Name of Researcher: Dr Zaki Kudsi

Please initial box

I confirm that I have read the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily	
I understand that my participation is voluntary and that I am free to decline to take part or withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.	
I agree to take part in the above study.	

Name of Participant	Date	Signature
Name of Researcher	Date	Signature

Appendix 7 Content validation

7. Overall, do you feel the questionnaire is appropriate tool to measure distress caused by tooth loss
    - Strongly disagrees
    - Somewhat disagree
    - Neither Agree nor Disagree
    - Somewhat Agree
    - Strongly Agree

8. Dose this questioner measure what it intends to measure? (Psychological disturbance caused by tooth loss)
    - Strongly disagrees
    - Somewhat disagree
    - Neither Agree nor Disagree
    - Somewhat Agree
    - Strongly Agree

9. Did you find it difficult to complete the questionnaire
    - Strongly disagrees
    - Somewhat disagree
    - Neither Agree nor Disagree
    - Somewhat Agree
    - Strongly Agree

10. The language & vocabulary used were appropriate
    - Strongly disagrees
    - Somewhat disagree
    - Neither Agree nor Disagree
    - Somewhat Agree
    - Strongly Agree

11. The second component of part "A" aims to correlate psychological distress with tooth loss/RP to identify tooth loss/RP as a direct cause of psychological distress and not just an association. Is this item
    - Essential
    - Useful, but not essential
    - Not necessary

12. If you would like to share any additional comments or experiences about, please enter them below.

Appendix 8: Face Validation form

7. Overall, do you feel the questionnaire is appropriate tool to measure distress caused by tooth loss
    - Strongly disagrees
    - Somewhat disagree
    - Neither Agree nor Disagree
    - Somewhat Agree
    - Strongly Agree

8. Dose this questionnaire measure what it intend to measure? (Psychological disturbance caused by tooth loss)
    - Strongly disagrees
    - Somewhat disagree
    - Neither Agree nor Disagree
    - Somewhat Agree
    - Strongly Agree

9. Did you find it difficult to complete the questionnaire
    - Strongly disagrees
    - Somewhat disagree
    - Neither Agree nor Disagree
    - Somewhat Agree
    - Strongly Agree

10. Do you feel that the language & vocabulary used were appropriate
    - Strongly disagrees
    - Somewhat disagree
    - Neither Agree nor Disagree
    - Somewhat Agree
    - Strongly Agree

11. If you would like to share any additional comments or experiences about, please enter them below.

Appendix 9: Search Strategy

Concept one (Population)

#1 Tooth loss

#2 Teeth loss

#3 Edentulous

#4 Edentulism

#5 Toothless

#6 Denture

#7 prosthesis

#8 Concept one (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7)

Concept Two (Outcome Measure)

#9 Depression

#10 Anxiety

#11 Distress

#12 Psychological

#13 Psychology

#14 Emotional

#15 Concept two (#9 or #10 or #11 or #12 or #13 or #14)

Concept Three (Assessment):

#16 Screening

#17 Measure

#18 Instrument

#19 Questionnaire

#20 Validation

#21 Scale

#22 Diagnosis

#23 Test

#24 Assessment

#25Concept Three (#16or #17or #18or #19or #20or #21or #22 or#23or #24)

#26 (#8 AND #15 AND #25)

Appendix 10: Results of electronic database search

Database	Keywords	Result
CCRCRT	As described in Table 1	177
PubMed	As described in Table 1	496
Embase	As described in Table 1	680
Psycho info	As described in Table 1	104
WOS	As described in Table 1	774
Google Scholar	(1) Tooth loss / edentulous / denture (2) Depression, anxiety, distress, psychological, psychology, emotional	217
LiLACS	As described in Table 1	465
Scopus	As described in Table 1	597
Other resources	Cross references of papers	
Total		**3510**
	After removal duplicates	**1059**

Appendix 11: Content validity results

Q1	+1
Q2	+1
Q3	+0.8
Q4	+0.8
Q5	+0.6
Q6	+0.8
Q7	+0.8
Q8	+0.4
Q9	+0.6
Q10	0
Q11	+0.2
Q12	-0.2

CVR = (n − N/2) / (N/2)
CVR = content validity ratio
n= sum of panelist indication "essential"
N=total number of panelist

Appendix 12:   Logistical and practical outcome of the pilot study

Observation / problems	Action
Recruitment venue / strategy	No changes
Patient information leaflet/consent	No changes
Visual impartment. Two participants could not join the pilot, as they did not have there reading glasses.	This problem could unlikely to influence the main study recruitment, as participants could complete questionnaire at home and return the questionnaire in the post
Difficulties in data coding and filling strategy: Pilots' sheets delayed filing Pilot' sheets mixed with other files. This led to difficulties to identify files when re-examined and analysed at the end of pilot recruitment.	Improve organizing flies: "Immediate" filling of all forms on the same day. Establish distinctive files for each stage of recruitment

Appendix 13: Pilot test for Part A of the questionnaire

Pilot	% yes		
	Clarity	Scale Adequate	Only one response
Part A	100	100	100
Q1	100	100	100
Q2	100	100	95.3
Q3	100	100	100
Q4	100	100	100
Q5	100	100	100
Q6	100	100	100
Q7	95.3	100	100
Q8		100	100
Q9	95.3	100	100
Part B DT	100	100	95.3

Appendix 14: steps and Versions of the developed questionnaire

QV1

Please read each statement and circle a number 0, 1, 2 or 3, which indicates how much the statement applied to you. The rating scale is as follows:

0   Did not apply to me at all
1   Applied to me to some degree, or some of the time
2   Applied to me to a considerable degree or a good part of time
3   Applied to me very much or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (e.g. in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

How would you rate the impact of tooth loss and dentures on your quality of life?										
0	1	2	3	4	5	6	7	8	9	10
No distress					Mildly distress					Severe distress

Please read each statement and circle Yes or No, which indicates how much the statement applied to you.

1	Have you had trouble speaking because of your tooth loss or denture?	Yes	No
2	Have you had trouble eating because of your tooth loss or denture?	Yes	No
3	Have you had discomfort / pain because of your dentures?	Yes	No
4	Have you had trouble with the stability of your dentures?	Yes	No
5	Are you self-conscious about your tooth loss or denture?	Yes	No
6	Have you been preoccupied or do you think a lot about your tooth loss or denture?	Yes	No
7	Do you avoid situations, activities or socializing because of your tooth loss or dentures?	Yes	No
8	Have you had trouble in you relationship or trouble developing a relationship because of tooth loss or denture?	Yes	No
9	Have you felt your quality of life is less satisfying because of your tooth loss or dentures?	Yes	No
10	Do you regard that wearing dentures is unacceptable?	Yes	No
11	Do you feel that replacing your dentures with fixed implants teeth may ease your distress?	Yes	No
12	Do you feel that anything could help to ease your distress if present?	Yes	No

Part C

The following questions are personality traits questions. Please read each statement and circle Yes or No, which indicates how much the statement applied to you.

1	Dose your mood often go up and down?	Yes	No
2	Do you take much notice of what people think?	Yes	No
3	Are you a talkative person?	Yes	No
4	If you say you will do something, do you always keep your promise no matter how inconvenient it might be?	Yes	No
5	Do you ever feel 'just miserable' for no reason?	Yes	No
6	Would being in debt worry you?	Yes	No
7	Are you rather lively?	Yes	No
8	Were you ever greedy by helping yourself to more than you share of anything?	Yes	No
9	Are you an irritable person?	Yes	No
10	Would you take drugs, which may have strange or dangerous effects?	Yes	No
11	Do you enjoy meeting new people?	Yes	No
12	Have you ever blamed someone for doing something you knew was really your fault?	Yes	No
13	Are your feeling easily hurt?	Yes	No
14	Do you prefer to go your own way rather than act by the rules?	Yes	No
15	Can you usually let yourself go and enjoy yourself at lively party?	Yes	No
16	Are all your habits good and desirable ones?	Yes	No
17	Do you often feel 'fed up'?	Yes	No
18	Do good manners and cleanliness matter much to you?	Yes	No
19	Do you usually take the initiative in making new friends?	Yes	No
20	Have you ever taken anything (even a pin or button) that belonged to someone else?	Yes	No
21	Would you call yourself a nervous patient?	Yes	No
22	Do you think marriage is old-fashioned and should be done away with?	Yes	No
23	Are you easily get some life into a rather dull party?	Yes	No
24	Have you ever broken or lost something belonging to some else?	Yes	No
25	Are you a worrier?	Yes	No
26	Do you enjoy co-operating with others?	Yes	No
27	Do you tend to keep in the background on social occasions?	Yes	No
28	Dose is worry you if you know there are mistakes in your work?	Yes	No
29	Have you ever said anything bad or nasty about anyone?	Yes	No
30	Would you call yourself tense or 'highly strung'?	Yes	No
31	Do you think people spend too much time safeguarding their future with savings & insurance?	Yes	No
32	Do you like mixing with people?	Yes	No
33	As a child, were you ever cheeky to your parents?	Yes	No
34	Do you worry too long after an embarrassing experience?	Yes	No
35	Do you try not to be rude to people?	Yes	No
36	Do you like plenty of bustle and excitement around you?	Yes	No
37	Have you ever cheated at a game?	Yes	No
38	Do you suffer from 'nerves'?	Yes	No
39	Would you like other people to be afraid of you?	Yes	No
40	Have you ever taken advantage of someone?	Yes	No
41	Are you mostly quiet when you are with other people?	Yes	No
42	Do you often feel lonely?	Yes	No
43	Is it better to follow society's rules than go your own way?	Yes	No
44	Do other people think of you as being very lively?	Yes	No
45	Do you always practice what you preach?	Yes	No
46	Are you often troubled about feelings of guilt?	Yes	No
47	Do you sometimes put off until tomorrow what you ought to do today?	Yes	No
48	Can you get a party going?	Yes	No

Part A:

Please read each statement and <u>circle</u> how much your agree / disagree with each statement

1	Have you had trouble speaking because of your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
2	Have you had trouble eating because of your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
3	Have you had to change your diet because of your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
4	Have you had discomfort / pain because of your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
5	Have you been uncomfortable because of the impact of tooth loss on your appearance?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
6	Do you think a lot about your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
7	Do you avoid social situations because of your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
8	Have you had stress in your relationship / marriage because of your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know
9	Have you found it difficult to relax because of your tooth loss?	• Strongly agree • Agree • Disagree • Strongly disagree • Don't know

Part B:

Please read each statement and circle a number 0, 1, 2 or 3, which indicates how much the statement applied to you. The rating scale is as follows:

0   Did not apply to me at all
1   Applied to me to some degree, or some of the time
2   Applied to me to a considerable degree or a good part of time
3   Applied to me very much or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (e.g. in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

How would you rate the impact of tooth loss on your quality of life? (Circle your answer)										
0	1	2	3	4	5	6	7	8	9	10
No distress					Mildly distress					Severe distress

Part C: The following questions are personality traits questions. Please read each statement and circle Yes or No, which indicates how much the statement applied to you.

1	Dose your mood often go up and down?	Yes	No
2	Do you take much notice of what people think?	Yes	No
3	Are you a talkative person?	Yes	No
4	If you say you will do something, do you always keep your promise no matter how inconvenient it might be?	Yes	No
5	Do you ever feel 'just miserable' for no reason?	Yes	No
6	Would being in debt worry you?	Yes	No
7	Are you rather lively?	Yes	No
8	Were you ever greedy by helping yourself to more than you share of anything?	Yes	No
9	Are you an irritable person?	Yes	No
10	Would you take drugs, which may have strange or dangerous effects?	Yes	No
11	Do you enjoy meeting new people?	Yes	No
12	Have you ever blamed someone for doing something you knew was really your fault?	Yes	No
13	Are your feeling easily hurt?	Yes	No
14	Do you prefer to go your own way rather than act by the rules?	Yes	No
15	Can you usually let yourself go and enjoy yourself at lively party?	Yes	No
16	Are all your habits good and desirable ones?	Yes	No
17	Do you often feel 'fed up'?	Yes	No
18	Do good manners and cleanliness matter much to you?	Yes	No
19	Do you usually take the initiative in making new friends?	Yes	No
20	Have you ever taken anything (even a pin or button) that belonged to someone else?	Yes	No
21	Would you call yourself a nervous patient?	Yes	No
22	Do you think marriage is old-fashioned and should be done away with?	Yes	No
23	Are you easily get some life into a rather dull party?	Yes	No
24	Have you ever broken or lost something belonging to some else?	Yes	No
25	Are you a worrier?	Yes	No
26	Do you enjoy co-operating with others?	Yes	No
27	Do you tend to keep in the background on social occasions?	Yes	No
28	Dose is worry you if you know there are mistakes in your work?	Yes	No
29	Have you ever said anything bad or nasty about anyone?	Yes	No
30	Would you call yourself tense or 'highly strung'?	Yes	No
31	Do you think people spend too much time safeguarding their future with savings & insurance?	Yes	No
32	Do you like mixing with people?	Yes	No
33	As a child, were you ever cheeky to your parents?	Yes	No
34	Do you worry too long after an embarrassing experience?	Yes	No
35	Do you try not to be rude to people?	Yes	No
36	Do you like plenty of bustle and excitement around you?	Yes	No
37	Have you ever cheated at a game?	Yes	No
38	Do you suffer from 'nerves'?	Yes	No
39	Would you like other people to be afraid of you?	Yes	No
40	Have you ever taken advantage of someone?	Yes	No
41	Are you mostly quiet when you are with other people?	Yes	No
42	Do you often feel lonely?	Yes	No
43	Is it better to follow society's rules than go your own way?	Yes	No
44	Do other people think of you as being very lively?	Yes	No
45	Do you always practice what you preach?	Yes	No
46	Are you often troubled about feelings of guilt?	Yes	No
47	Do you sometimes put off until tomorrow what you ought to do today?	Yes	No
48	Can you get a party going?	Yes	No

QV3

Part A:

Please circle how often have you had any of the following during the last year?

1	Have you had trouble speaking because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
2	Have you had trouble eating because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
3	Have you had to change your diet because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
4	Have you had discomfort / pain because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
5	Have you been uncomfortable because of the impact of tooth loss on your appearance?	Very often	Often	Sometimes	Rarely	Never	Don't know
6	Do you think a lot about your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
7	Do you avoid social situations because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
8	Have you had stress in your relationship / marriage because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
9	Have you found it difficult to relax because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know

Part B:

Please read each statement and circle a number 0, 1, 2 or 3, which indicates how much the statement applied to you **over the past week**. The rating scale is as follows:

0   Did not apply to me at all
1   Applied to me to some degree, or some of the time
2   Applied to me to a considerable degree or a good part of time
3   Applied to me very much or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (e.g. in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

How would you rate the impact of tooth loss on your life? (Circle your answer)										
0	1	2	3	4	5	6	7	8	9	10
No distress					Mildly distress					Severe distress

Part C

The following questions are personality traits questions. Please read each statement and **circle Yes or No**, which indicates how much the statement applied to you.

1	Dose your mood often go up and down?	Yes	No
2	Do you take much notice of what people think?	Yes	No
3	Are you a talkative person?	Yes	No
4	If you say you will do something, do you always keep your promise no matter how inconvenient it might be?	Yes	No
5	Do you ever feel 'just miserable' for no reason?	Yes	No
6	Would being in debt worry you?	Yes	No
7	Are you rather lively?	Yes	No
8	Were you ever greedy by helping yourself to more than you share of anything?	Yes	No
9	Are you an irritable person?	Yes	No
10	Would you take drugs, which may have strange or dangerous effects?	Yes	No
11	Do you enjoy meeting new people?	Yes	No
12	Have you ever blamed someone for doing something you knew was really your fault?	Yes	No
13	Are your feeling easily hurt?	Yes	No
14	Do you prefer to go your own way rather than act by the rules?	Yes	No
15	Can you usually let yourself go and enjoy yourself at lively party?	Yes	No
16	Are all your habits good and desirable ones?	Yes	No
17	Do you often feel 'fed up'?	Yes	No
18	Do good manners and cleanliness matter much to you?	Yes	No
19	Do you usually take the initiative in making new friends?	Yes	No
20	Have you ever taken anything (even a pin or button) that belonged to someone else?	Yes	No
21	Would you call yourself a nervous patient?	Yes	No
22	Do you think marriage is old-fashioned and should be done away with?	Yes	No
23	Are you easily get some life into a rather dull party?	Yes	No
24	Have you ever broken or lost something belonging to some else?	Yes	No
25	Are you a worrier?	Yes	No
26	Do you enjoy co-operating with others?	Yes	No
27	Do you tend to keep in the background on social occasions?	Yes	No
28	Dose is worry you if you know there are mistakes in your work?	Yes	No
29	Have you ever said anything bad or nasty about anyone?	Yes	No
30	Would you call yourself tense or 'highly strung'?	Yes	No
31	Do you think people spend too much time safeguarding their future with savings & insurance?	Yes	No
32	Do you like mixing with people?	Yes	No
33	As a child, were you ever cheeky to your parents?	Yes	No
34	Do you worry too long after an embarrassing experience?	Yes	No
35	Do you try not to be rude to people?	Yes	No
36	Do you like plenty of bustle and excitement around you?	Yes	No
37	Have you ever cheated at a game?	Yes	No
38	Do you suffer from 'nerves'?	Yes	No
39	Would you like other people to be afraid of you?	Yes	No
40	Have you ever taken advantage of someone?	Yes	No
41	Are you mostly quiet when you are with other people?	Yes	No
42	Do you often feel lonely?	Yes	No
43	Is it better to follow society's rules than go your own way?	Yes	No
44	Do other people think of you as being very lively?	Yes	No
45	Do you always practice what you preach?	Yes	No
46	Are you often troubled about feelings of guilt?	Yes	No
47	Do you sometimes put off until tomorrow what you ought to do today?	Yes	No
48	Can you get a party going?	Yes	No

QV4

Part A:

Please circle how often have you had any of the following during the last year?

1	Have you had trouble speaking because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
2	Have you had trouble eating because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
3	Have you had to change your diet because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
4	Have you had discomfort / pain because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
5	Have you been uncomfortable because of the impact of tooth loss on your appearance?	Very often	Often	Sometimes	Rarely	Never	Don't know
6	Do you think a lot about your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
7	Do you avoid social situations because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
8	Have you had stress in your relationship / marriage because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know
9	Have you found it difficult to relax because of your tooth loss?	Very often	Often	Sometimes	Rarely	Never	Don't know

Part B:

Please read each statement and circle a number 0, 1, 2 or 3, which indicates how much the statement applied to you **over the past week**. The rating scale is as follows:

0   Did not apply to me at all
1   Applied to me to some degree, or some of the time
2   Applied to me to a considerable degree or a good part of time
3   Applied to me very much or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (e.g. in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

How would you rate the impact of tooth loss on your life? (Circle your answer)										
0	1	2	3	4	5	6	7	8	9	10
No distress					Mildly distress					Severe distress

Part C

The following questions are personality traits questions. Please read each statement and circle Yes or No, which indicates how much the statement applied to you.

1	Does your mood often go up and down?	Yes	No
2	Do you take much notice of what people think?	Yes	No
3	Are you a talkative person?	Yes	No
4	If you say you will do something, do you always keep your promise no matter how inconvenient it might be?	Yes	No
5	Do you ever feel 'just miserable' for no reason?	Yes	No
6	Would being in debt worry you?	Yes	No
7	Are you rather lively?	Yes	No
8	Were you ever greedy by helping yourself to more than you share of anything?	Yes	No
9	Are you an irritable person?	Yes	No
10	Would you take drugs, which may have strange or dangerous effects?	Yes	No
11	Do you enjoy meeting new people?	Yes	No
12	Have you ever blamed someone for doing something you knew was really your fault?	Yes	No
13	Are your feeling easily hurt?	Yes	No
14	Do you prefer to go your own way rather than act by the rules?	Yes	No
15	Can you usually let yourself go and enjoy yourself at lively party?	Yes	No
16	Are all your habits good and desirable ones?	Yes	No
17	Do you often feel 'fed up'?	Yes	No
18	Do good manners and cleanliness matter much to you?	Yes	No
19	Do you usually take the initiative in making new friends?	Yes	No
20	Have you ever taken anything (even a pin or button) that belonged to someone else?	Yes	No
21	Would you call yourself a nervous patient?	Yes	No
22	Do you think marriage is old-fashioned and should be done away with?	Yes	No
23	Can you easily get some life into a rather dull party?	Yes	No
24	Have you ever broken or lost something belonging to some else?	Yes	No
25	Are you a worrier?	Yes	No
26	Do you enjoy co-operating with others?	Yes	No
27	Do you tend to keep in the background on social occasions?	Yes	No
28	Does is worry you if you know there are mistakes in your work?	Yes	No
29	Have you ever said anything bad or nasty about anyone?	Yes	No
30	Would you call yourself tense or 'highly strung'?	Yes	No
31	Do you think people spend too much time safeguarding their future with savings & insurance?	Yes	No
32	Do you like mixing with people?	Yes	No
33	As a child, were you ever cheeky to your parents?	Yes	No
34	Do you worry too long after an embarrassing experience?	Yes	No
35	Do you try not to be rude to people?	Yes	No
36	Do you like plenty of bustle and excitement around you?	Yes	No
37	Have you ever cheated at a game?	Yes	No
38	Do you suffer from 'nerves'?	Yes	No
39	Would you like other people to be afraid of you?	Yes	No
40	Have you ever taken advantage of someone?	Yes	No
41	Are you mostly quiet when you are with other people?	Yes	No
42	Do you often feel lonely?	Yes	No
43	Is it better to follow society's rules than go your own way?	Yes	No
44	Do other people think of you as being very lively?	Yes	No
45	Do you always practice what you preach?	Yes	No
46	Are you often troubled about feelings of guilt?	Yes	No
47	Do you sometimes put off until tomorrow what you ought to do today?	Yes	No
48	Can you get a party going?	Yes	No

Appendix 15: Functional and body image (further analysis)

	Functional (3)					
	Difficulties		No difficulties			
Age group	N	%	N	%	ChiSquare	Prob>ChiSq
<60	6	23.10%	6	13.60%	1.025	0.3112
≥60	20	76.90%	38	86.40%		
Fisher's Exact Test	Prob	Alternative Hypothesis				
Left	0.9085	Prob(Functional=No disturbance) is greater for Age group=<60 than ≥60				
Right	0.2442	Prob(Functional=No disturbance) is greater for Age group=≥60 than <60				
2-Tail	0.3408	Prob(Functional=No disturbance) is different across Age group				

	Functional (2)					
	Difficulties		No difficulties			
Age group	N	%	N	%	ChiSquare	Prob>ChiSq
<60	10	19.60%	2	10.50%	0.804	0.37
≥60	41	80.40%	17	89.50%		
Fisher's Exact Test	Prob	Alternative Hypothesis				
Left	0.9	Prob(Functional 2=No disturbance) is greater for Age group=<60 than ≥60				
Right	0.3054	Prob(Functional 2=No disturbance) is greater for Age group=≥60 than <60				
2-Tail	0.4909	Prob(Functional 2=No disturbance) is different across Age group				

	Functional (4)					
	Difficulties		No difficulties			
Age group	N	%	N	%	ChiSquare	Prob>ChiSq
<60	2	33.30%	10	15.60%	1.211	0.2711
≥60	4	66.70%	54	84.40%		

Fisher's Exact Test	Prob	Alternative Hypothesis
Left	0.9416	Prob(Functional 4=No disturbance) is greater for Age group=<60 than ≥60
Right	0.2719	Prob(Functional 4=No disturbance) is greater for Age group=≥60 than <60
2-Tail	0.2719	Prob(Functional 4=No disturbance) is different across Age group

Functional (3)

	Disturbance		No disturbance			
	N	%	N	%	ChiSquare	Prob>ChiSq
Female	21	80.80%	20	45.50%	8.399	0.0038
Male	5	19.20%	24	54.50%		

Fisher's Exact Test	Prob	Alternative Hypothesis
Left	0.9994	Prob(Functional=No disturbance) is greater for Gender=Female than Male
Right	0.0035	Prob(Functional=No disturbance) is greater for Gender=Male than Female
2-Tail	0.0054	Prob(Functional=No disturbance) is different across Gender

Functional (2)

	Disturbance		No disturbance			
	N	%	N	%	ChiSquare	Prob>ChiSq
Female	31	60.80%	10	52.60%	0.379	0.538
Male	20	39.20%	9	47.40%		

Fisher's Exact Test	Prob	Alternative Hypothesis
Left	0.8132	Prob(Functional 2=No disturbance) is greater for Gender=Female than Male
Right	0.3637	Prob(Functional 2=No disturbance) is greater for Gender=Male than Female
2-Tail	0.5922	Prob(Functional 2=No disturbance) is different across Gender

Functional (4)

	Disturbance		No disturbance			
	N	%	N	%	ChiSquare	Prob>ChiSq
Female	4	66.70%	37	57.80%	0.177	0.6738
Male	2	33.30%	27	42.20%		

Fisher's Exact Test	Prob	Alternative Hypothesis
Left	0.8	Prob(Functional 4=No disturbance) is greater for Gender=Female than Male
Right	0.5136	Prob(Functional 4=No disturbance) is greater for Gender=Male than Female
2-Tail	1	Prob(Functional 4=No disturbance) is different across Gender

Body image

	Disturbance		No disturbance			
Age group	N	%	N	%	ChiSquare	Prob>ChiSq
<60	10	26.30%	2	6.30%	4.924	0.0265
≥60	28	73.70%	30	93.80%		

Fisher's Exact Test	Prob	Alternative Hypothesis
Left	0.9961	Prob(Body image=No disturbance) is greater for Age group=<60 than ≥60
Right	0.0259	Prob(Body image=No disturbance) is greater for Age group=≥60 than <60
2-Tail	0.0307	Prob(Body image=No disturbance) is different across Age group

Body image 2

	Disturbance		No disturbance			
Age group	N	%	N	%	ChiSquare	Prob>ChiSq
<60	12	23.10%	0	0.00%	5.013	0.0252
≥60	40	76.90%	18	100.00%		

Fisher's Exact Test	Prob	Alternative Hypothesis
Left	1	Prob(Body image 2=No disturbance) is greater for Age group=<60 than ≥60
Right	0.0194	Prob(Body image 2=No disturbance) is greater for Age group=≥60 than <60

2-Tail			0.0284		Prob(Body image 2=No disturbance) is different across Age group

Body image 4

Age group	Disturbance		No disturbance		ChiSquare	Prob>ChiSq
	N	%	N	%		
<60	8	42.10%	4	7.80%	11.44	0.0007
≥60	11	57.90%	47	92.20%		

Fisher's Exact Test	Prob	Alternative Hypothesis
Left	0.9998	Prob(Body image 4=No disturbance) is greater for Age group=<60 than ≥60
Right	0.002	Prob(Body image 4=No disturbance) is greater for Age group=≥60 than <60
2-Tail	0.002	Prob(Body image 4=No disturbance) is different across Age group

Body image (3)

Gender	Disturbance		No disturbance		ChiSquare	Prob>ChiSq
	N	%	N	%		
Female	29	76.30%	12	37.50%	10.786	0.001
Male	9	23.70%	20	62.50%		

Fisher's Exact Test	Prob	Alternative Hypothesis
Left	0.9998	Prob(Body image=No disturbance) is greater for Gender=Female than Male
Right	0.0011	Prob(Body image=No disturbance) is greater for Gender=Male than Female
2-Tail	0.0015	Prob(Body image=No disturbance) is different across Gender

Body image (2)

Gender	Disturbance		No disturbance		ChiSquare	Prob>ChiSq
	N	%	N	%		
Female	34	65.40%	7	38.90%	3.869	0.0492
Male	18	34.60%	11	61.10%		

Fisher's Exact Test	Prob	Alternative Hypothesis
Left	0.9874	Prob(Body image 2=No disturbance) is greater for Gender=Female than Male
Right	0.0462	Prob(Body image 2=No disturbance) is greater for Gender=Male than Female
2-Tail	0.0582	Prob(Body image 2=No disturbance) is different across Gender

	Body image (4)					
	Disturbance		No disturbance			
Gender	N	%	N	%	ChiSquare	Prob>ChiSq
Female	17	89.50%	24	47.10%	10.263	0.0014
Male	2	10.50%	27	52.90%		

Fisher's Exact Test	Prob	Alternative Hypothesis
Left	0.9999	Prob(Body image 2=No disturbance) is greater for Gender=Female than Male
Right	0.0011	Prob(Body image 4=No disturbance) is greater for Gender=Male than Female
2-Tail	0.0021	Prob(Body image 4=No disturbance) is different across Gender

Appendix 16 Emotional distress by gender among the dentures – t-tests and Shapiro–Wilk tests

Emotional distress by gender among the dentures – t tests and Shapiro–Wilk tests for normality of the errors.

Dependent	Gender	N	Mean	SD					Prob > |t|	W	Prob<W
DASS Depression	Female	41	0.68	1.23	Difference	-0.48	t Ratio	-2.07	0.0424	0.662	<.0001
	Male	29	0.21	0.68	Std Err Dif	0.23	DF	64.52			
DASS Anxiety	Female	41	0.83	1.50	Difference	-0.38	t Ratio	-1.27	0.2101	0.643	<.0001
	Male	29	0.45	1.02	Std Err Dif	0.30	DF	67.93			
DASS Stress	Female	41	0.51	1.08	Difference	-0.34	t Ratio	-1.68	0.0969	0.588	<.0001
	Male	29	0.17	0.60	Std Err Dif	0.20	DF	65.05			
Distress Thermometer Scoring	Female	41	4.56	3.23	Difference	-1.46	t Ratio	-2.15	0.035	0.935	0.0012
	Male	29	3.10	2.44	Std Err Dif	0.68	DF	67.65			

Appendix 17: Publication

ACP | AMERICAN COLLEGE OF PROSTHODONTISTS
Your smile. Our specialty.

Assessment of Psychological Disturbance in Patients with Tooth Loss: A Systematic Review of Assessment Tools

Zaki Kudsi, DDS, MBChB (iD),[1] Michael R. Fenlon, MA, PhD, BDentSc, FDS, MGDS,[2] Ama Johal, BDS (Hons), MSc, PhD, FDS, MOrth RCS, DMS, FDS (Orth) RCS,[3] & Aylin Baysan, BDS, MSc, PhD, MFDS, RCSEd[4]

[1]MFDS Specialist Oral Surgeon, Institute of Dentistry, Queen Mary University of London, London, UK
[2]Professor of Prosthodontics, Hon. Consultant in Restorative Dentistry, Restorative Dentistry & Special Care Dentistry Service Lead, King's College London, Guy's & St Thomas' Hospitals' NHSFT, London, UK
[3]FHEA Professor/Hon. Consultant Orthodontist, Centre Lead Bioengineering, Academic Lead Orthodontics, Institute of Dentistry, Queen Mary University of London, London, UK
[4]SFHEA Clinical Senior Lecturer in Oral Bioengineering, Institute of Dentistry, Queen Mary University of London, London, UK

Abstract

Purpose: To systematically review the available evidence on screening tools to detect the psychological disturbance in patients with tooth loss and technically successful removable dentures (partial and complete).
Materials and Methods: The study protocol was registered with the National Institute of Health Research Database (I.D. CRD42017082125). The PICOS tool (patients, intervention, control, outcomes measure, and study design) was used to formulate an effective search strategy. Participants were adults ($\geq$ 18), who were edentulous or had significant tooth loss ($<$ 9 remaining teeth). The intervention included undergoing replacement with technically successful dentures (partial or complete). A control group of adults were either edentulous or had significant tooth loss and without dentures. Outcomes included assessing psychological disturbance due to treatment with dentures or due to no treatment using a validated tool. A structured search strategy was used to complete a standard systematic search of the electronic database without any date limit and/or language restriction. Only quantitative studies using a validated measuring tool to screen for psychological distress in adults with significant tooth loss were included. Two authors independently assessed the risk of bias in the included studies. Data homogeneity was assessed in regards to the screening tools to measure psychological disturbance following the management of tooth loss with dentures. The significant level was set at 0.05, using IBM SPSS Statistics 24.0 (SPSS Inc., New York, NY). The psychometric properties and the validation processes of the screening tools were assessed.
Results: From the original 3510 studies identified, only eight studies were found to meet the inclusion criteria. All eight studies used the same questionnaire to screen for the emotional distress of tooth loss. In addition, one study also used the Patient Health Questionnaire-9 (PHQ-9) to screen for the association of depression with tooth loss. Six studies suggested that a significant number of patients have difficulties in accepting tooth loss, were less confident, and had emotional distress related to tooth loss. However, two studies reported no significant link. All studies found a marked impact on functional activities and social interaction. However, four studies had a potentially biased selection process, and the questionnaire used was assessed to be at high-risk of measurement bias, as the development and validation process was not clear. There was also a lack of well-defined control groups in all studies.
Conclusion: Tooth loss could cause psychological disturbance in some patients. To date, there is a lack of available tools that are suitable to screen and measure psychological disturbance in patients with tooth loss. Additional research is required to develop tools to identify and measure such impact and to recommend suitable interventions when needed.

Adult oral health has been gradually improving, and the prevalence of tooth loss has been in decline in the last 30 years with the global age-standardized prevalence of edentulous subjects decreasing from 4.4% to 2.4% between 1990 and 2010.[1] Nevertheless, there are still a significant number of denture users. A recent survey in the UK indicated that "one in every five" adults has removable dentures (either partial or complete).[2] Previous research has shown that tooth loss can have a significant impact on both general and oral health-related quality of life.[3] Edentulous or partially dentate patients may require either removable dentures or osseo-integrated dental implants to restore their dentition. Removable dentures can restore function and provide a relatively noninvasive treatment option for management of tooth loss. While some patients cope and adapt well with tooth loss and removable dentures; others experience emotional impairment as they have less psychological resilience and ability to adapt to changes. Davis et al reported that tooth loss could cause a significant emotional and psychological disturbance in some patients, despite being successful denture wearers.[4]

Screening tools have widely been used to assess psychological morbidities in patients with various medical conditions, such as amputations, artificial prosthesis replacements, chronic illness, cancer, and palliative care.[5] The possibility of implementing some of the available tools could be considered to screen and measure psychological morbidity in patients with tooth loss.

To date, there are many screening tools that measure symptoms of depression, anxiety, and distress in patients with different chronic systemic diseases. In this systematic review, available screening tools will be discussed in relation to their suitability for the assessment of psychological disturbance in patients with tooth loss.

The General Health Questionnaire (GHQ) and the Hospital Anxiety and Depression Scale (HADS) are generic measures, which were used to screen for psychological morbidities in the community and hospitals.[6,7] However, these tools are not suitable to screen for psychological disturbance in patients with tooth loss, since the GHQ is not sensitive for long-standing psychological disorders as in the case of tooth loss,[6] and the HADS has been reported to have inconsistent psychometric structure.[8,9] Furthermore, Depression, Anxiety and Stress Scale (DASS-21) measures the negative emotional symptoms (depression, anxiety, and stress).[10] Therefore, the DASS-21 is preferred over other screening tools to screen for psychological disorders in patients with tooth loss, as it has been extensively validated for its psychometric properties[11,12] and assessed in a clinical setting.[12,13] The DASS-21 is also able to identify and differentiate the degree of depression from anxiety and stress.[11] However, further validation is needed before implementation of the DASS-21 in patients with tooth loss. Finally, the Patient Health Questionnaire (PHQ-9)[14] has also been validated to screen and measure for depression in primary care,[15] for patients with coronary heart disease, cerebral vascular accident, and diabetes.[16-18] However, the PHQ-9 fails to screen or measure anxiety or distress. Therefore, additional tools are required to screen for those dimensions of emotional distress.[14]

The loss of teeth with the use of removable dentures is recognized as a major life event that would require the patient to adapt functionally and psychologically.[19] Many patients fail to cope and endure significant emotional and psychological distress, despite being successful denture wearers.[4] Identification and measurement of these negative emotional symptoms is important since they could cause social and physical disability, and in turn have a significant impact on the quality of life.[3] Some studies also report that stressful life events may trigger depression in vulnerable patients.[20] Therefore, a psychological screening tool would be beneficial for identification, measurement, and outcome purposes.

The current systematic review aimed to assess available evidence for validated screening tools, which measure psychological disturbance in patients with tooth loss.

Materials and methods

The study protocol was registered with the National Institute of Health Research Database (Registration I.D. CRD42017082125). A comprehensive search was conducted to identify potentially relevant studies by exploring a range of electronic databases (Medline via Ovid, Scopus, and Embase). Additionally, a Google scholar and reference search were undertaken to identify any other relevant published work. The search was carried out without applying any time limits (up to 12/2017) or language restrictions.

The search strategy used three concepts: concept one included any word that relates to tooth loss/dentures (e.g., edentulous, prosthesis, denture, etc.). The second concept incorporated words that relate to the various aspects of psychological disturbance (depression, anxiety, distress, etc.). Finally, the last concept contained various outcome measure wordings (scale, test, diagnosis, etc.)

Most of the identified studies were extracted from Embase (680), WOS (774), and Scopus (597). The rest of the studies identified were obtained from the other databases (PubMed, Psycho info, LILACS, and Google Scholar).

The PICOS (Table 1) tool was used to formulate an effective search strategy by defining the selection criteria based on a range of clinical questions relative to the participant, intervention, comparison, outcomes, and study design. Participants were adults (≥18 years of age), of any ethnic group who were edentulous or had significant tooth loss (<9 remaining teeth). The interventions included undergoing replacement with technically successful removable dentures (partial or complete), that is, rated by an experienced clinician in removable prosthodontics using an established criterion, such as systematic assessment of the technical quality of denture using the Functional Dental Assessment.[21] The ultimate outcome demonstrated that function and aesthetics were restored with the removable denture.

A control group of adult participants (≥18) were either edentulous or had significant tooth loss (<9 remaining teeth), and without any replacement with a removable denture. Outcomes included assessing psychological distress due to treatment with a denture, or due to no treatment using a validated tool.

The study design included quantitative, randomized controlled clinical trials, non-randomized controlled trial (RCT), cross-sectional, prospective, and retrospective studies. Furthermore, studies that involved the replacement of tooth loss either with dental implants or unsatisfactory dentures were excluded.

Table 1 PICOS research question development

	Inclusion criteria	Exclusion criteria
P – patients/problem	Adults ≥18 with significant tooth loss	History of psychotic mental illness Replacement with dental implants
I – intervention	Patients who had a replacement with technically successful dentures*	Poor quality dentures
C – control	Patients who had no replacement with dentures	
O – outcome measures	Patients' psychological distress caused by tooth loss	Nonvalidated tool/measure
S – study design	Quantitative	Qualitative
	Randomized controlled trials	Opinion, editorials
	Nonrandomized controlled trials, Retrospective, prospective, or concurrent cohort studies, cross-sectional studies	

*Rated by an experienced clinician in removable prosthodontics using an established criterion, such as systematic assessment of the technical quality of denture using the Functional Dental Assessment.[21] The ultimate outcome demonstrated that function and aesthetics were restored with the removable denture.

Based on these selection criteria, the titles and abstracts were examined independently by two examiners (ZK and AB), and any disagreements were resolved according to a predefined strategy, using consensus and arbitration as appropriate. If, however, the disagreement could not be resolved, then a third investigator (MF) agreed to be approached to help reach consensus.

The relevant titles and abstracts of articles were independently collected and then double-checked by a second examiner (AB). Studies not meeting the inclusion criteria were removed. Subsequently, full texts were independently reviewed by two examiners (ZK and AB). The references cited in the included studies were further checked.

Two authors assessed independently the risk of bias in the included studies (ZK and AB), and any disagreement was resolved by discussion with a third author (MF). Five domains were scored to quantify the risk of bias: selection bias, measurement bias, interviewer bias, response bias, and other potential sources of bias. Subsequently, an overall judgment was made to mark each study as low risk of bias, high risk of bias, or unclear.

Data homogeneity was assessed in regards to the screening tools to measure psychological distress following the management of tooth loss with dentures. The significant level was set at 0.05, using IBM SPSS Statistics 24.0 (SPSS Inc., New York, NY). The psychometric properties and the validation processes of the screening tools were assessed. Tooth loss pattern/number, denture quality, and functional/psychological impact of tooth loss were also recorded.

Results

The search methodology has been reported in line with the PRISMA Statement[22] and is presented in Figure 1. The electronic database search identified 3510 articles, from which 2451 were excluded as duplicates. The titles and, where necessary abstracts, were examined against the inclusion criteria and 1043 articles were further excluded under the criteria of exclusion mentioned earlier in the data extraction section, leaving a total of 16 studies. Following the assessment of these studies, eight studies were also excluded, since these were either related to

Figure 1 PRISMA flow diagram.

the invalidated assessment tools to measure psychological distress related to tooth loss[23-27] or failed to meet the selection criteria.[28-30] Therefore, only eight texts were included in the current review; all of the included studies had a cross-sectional design. The key characteristics of the included studies are reported in Table 2.

The eight studies included in this review (Table 2) all used the same 24-item questionnaire to measure the emotional impact of tooth loss. Two studies were based in the UK,[4,31] three in India,[32-34] one in Hong Kong,[35] and two were multicenter studies, including the UK and Hong Kong.[36,37] Six studies recruited participants from dental hospitals and universities, while the other two studies recruited participants from social centers and dental check camps.[33,35] Three studies examined the emotional impact of tooth loss in edentulous patients, two studies screened partially dentate participants, and two studies examined a group of edentulous and partially dentate patients

221

Table 2 Key characteristics of the included studies

Study	Method	Participants	Intervention	Outcome measures
Davis et al[4]	Location: Department of Prosthetic Dentistry at Guy's, King's and St Thomas' Dental Institute Recruitment period: not reported Funding source: not reported	94 edentulous (48 M; 46 F) Age: 31 to 50 (n = 7) 51 to 70 (n = 40) >71 (n = 47)	Full removable dental prosthesis replacement (n = 92) No removable prosthesis (n = 2)	Emotional effect /acceptance of tooth loss Activity/functional impairment
Davis et al[31]	Location: Department of Prosthetic Dentistry at Guy's, King's and St Thomas' Dental Institute Recruitment period: not reported Funding source: not reported	91 partially dentate (38 M; 53 F) Age: <30 (n = 1) 31 to 50 (n = 22) 51 to 70 (n = 43) 71 (n = 25) Anterior teeth missing (78%) Only posterior missing (22%)	Partial denture replacement (n = 91)	Emotional effect /acceptance of tooth loss Activity/functional impairment
Scott et al[36]	Location: Guy's, King's and St Thomas's Dental Institute, London; the Dental School, Dundee, Scotland; and the Faculty of Dentistry, University of Hong Kong Recruitment period: not reported Funding source: not reported	Number of participants: 142 Edentulous 31 to 15 (n = 8) 51 to 17 (n = 57) >71 (n = 77)	Full removable dental prosthesis replacement in all Dundee subjects, in 96% of London subjects and 78% of Hong Kong subjects	Emotional effect /acceptance of tooth loss Activity/functional impairment
Fiske et al[38]	Location: Guy's, King's and St Thomas's Dental Institute, London; the Dental School, Dundee, Scotland; and the Faculty of Dentistry, University of Hong Kong Recruitment period: not reported Funding source: not reported	(n = 149) partially dentate (64 M; 86 F) Age: <31 years (n = 1) 31 to 50 years (n = 28) 51 to 70 years (n = 89) >71 years (n = 32) Tooth loss: 64% some upper anterior teeth 97% some upper posterior 39% some lower anterior 94% some lower posterior	Partial removable dental prosthesis 88% of Dundee subjects, 81% of London, and 50% in Hong Kong subjects	Emotional effect /acceptance of tooth loss Activity/functional impairment
Naik & Pai[33]	Location: dental check camps in the locality of Uttar Pradesh (North India) Recruitment period: not reported Funding source: not reported	400 participants (41 M; 59 F) Age: >60 years Edentulous (n = 128) Partially dentate (n = 272) Tooth loss Anterior upper (n = 10) Posterior upper (n = 88) Anterior lower (n = 13) Posterior lower (n = 96)	Full removable dental prosthesis (n = 128) Partially removable dental prosthesis (n = 140) Partial dentate/no replacement (n = 132)	Emotional effect /acceptance of tooth loss Activity/functional impairment
McMillan & Wong[35]	Recruited at day-time social centers for the elderly located throughout Hong Kong Recruitment period: not reported Funding source: University Grant	233 participants (80 M; 153 F) Age: 60 to 80 Edentulous (n = 65) Partially dentate (n = 168)	Complete removable prosthesis (n = 65) Partial removable prosthesis (n = 95) No removable prosthesis (n = 73)	
Shah et al[32]	Location: Department of Prosthodontics, Govt. Dental College and Hospital. Ahmedabad Recruitment period: Dec 14 to Feb 15 Funding source: not reported	100 participants Edentulous (62 M; 38 F) 31 to 50 years (n = 70) 51 to 70 years (n = 7) >71 years (n = 23)	Complete removable prosthesis (n = 100)	Emotional effect /acceptance of tooth loss Activity/functional impairment Depression
Anjum et al[34]	Location: Dental hospital at Vikarabad, Telangana Recruitment period: Sep16 to Oct 16 Funding source: not reported	103 participants Edentulous (73 M;30 F) 45 to 55 years (n = 39) 55 to 65 years (n = 64)	Complete removable prosthesis (n = 50) No intervention (n = 53)	Emotional effect /acceptance of tooth loss Activity/functional impairment

(Table 3). Only one study compared the emotional impact of tooth loss between completed denture wearers and nondenture wearers.[34] Sample size varied from 94 to 400 participants.

One study[32] calculated the power, based on previous studies and it was unclear if a sample size calculation was carried out in any of the other seven included studies. The reported response rate was only available in three studies, as 100%,[37] 95%,[36] and 73%,[4] respectively.

A high inter-examiner agreement (IRR of 0.88) was observed with six out of eight studies (Table 4). However, these studies had a potentially biased selection process since participants were recruited from dental hospitals and universities. Consequently, these studies had a high risk of selection bias as the patients who sought treatment in the dental hospital setting or were referred to secondary dental care presented with more complicated dental issues.

Two studies (Table 4) recruited participants from the dental check camps and day-time social centers for the elderly. This recruitment process is more likely to enroll a homogenous sample, which better represents the general population. Therefore, the risk of selection bias in these studies was considered to be low.

In addition, four studies[33,35-37] used trained dental officers to conduct interviews to help complete the questionnaire, as some participants were illiterate. Interviewer and response bias risks are likely to be low in these studies, as the interviewers were independent and trained prior to the study. In the remaining two studies,[32,34] it was unclear if the interviewers had any training prior to the interviews for illiterate participants; and therefore, the risk of interviewer and response bias could not be excluded. The authors in the remaining two studies[4,31] requested the participants to complete the questionnaire at home and return their anonymous responses by post. Therefore, the risk of response bias was considered low.

Regarding the study designs, there were no clearly defined control groups in any of the included studies. One study compared tooth loss in participants who had dentures with those who did not; however, the technical quality of the dentures was unfortunately not described. Without a well-designed control group, it was difficult to conclude whether the emotional distress was present beforehand or as a result of tooth loss. Therefore, the risk of bias was regarded as high in all eight included studies.

The same measurement tool was used in all included studies. This questionnaire was developed and validated in two previous qualitative studies.[38,39] However, the process of how this was developed and validated remains unclear. In addition, some of the questions used to quantify the emotional impact of tooth loss may lead participants to answer in a specific way (potentially leading questions), that is, "*Did you find it difficult to accept losing your teeth.*" The approach of the authors using a negative connotation, such as "*difficult*" could introduce bias. The use of more neutral words is recommended to avoid the possible risk of leading questions and incorrect responses. Although the additional comments space might assist in clarifying any issues, this would still not be quantified, and thus, the risk of measurement bias was considered high. The 24-item questionnaire used explores the functional disability and feelings associated with tooth loss, and measures how the emotional impact of tooth loss

Table 3 Comparison of included studies

Factors related to tooth loss	Time	Davis et al[4] n = 94	Davies et al[31] n = 91	Scott et al[36] (n = 142) Du n = 45	Lon n = 47	HK n = 50	Fiske et al[38] (n = 149) Du n = 50	Lo n = 49	HK n = 50	McMillan & Wong[35] n = 233	Naik & Pai[33] n = 400	Shah et al[32] n = 100	Anjum et al[34] n = 103
Difficulty accepting tooth loss		42 (45%)	48 (53%)	63 (44%)			26%	62%	60%	51 (22%)	92 (23%)	58%	46%
Time before accepting tooth loss	Immediately	5%	4%	47%	47%	60%	51%	23%	62%	34%	35%	14%	—
	Within 6 months	12%	15%	25%	11%	20%	28%	17%	20%	54%	53%	29%	—
	Within a year	10%	6%	5%	4%	2%	4%	—	6%	6%	5%	12%	—
	>a year	38%	25%	13%	23%	12%	6%	23%	4%	4%	3%	3%	—
	Still have not accepted it	35%	50%	10%	15%	6%	11%	37%	8%	2%	4%	—	16%
Impact on self-confidence	More confidence	2%	—	5%	6%	0%	2%	—	—	1%	—	—	—
	Confidence unaffected	22%	22%	62%	40%	60%	62%	37%	72%	95%	96%	—	—
	Less confidence	69%	76%	24%	45%	40%	26%	59%	28%	2%	—	38%	20%
	Do not know	7%	2%	9%	9%	0%	10%	4%	—	2%	16	—	—

223

Table 4 Risk of bias in the included studies

	Davies et al[4]	Davies et al[31]	Scott et al[36]	Fiske et al[37]	Macmillan & Wong[35]	Naik & Pai[33]	Shah et al[33]	Anjum et al[34]
Selection bias	H	H	H	H	L	L	H	H
Measurement bias	H	H	H	H	H	H	H	H
Interviewer bias	N/A	N/A	L	L	L	L	?	?
Response bias	L	L	L	L	L	L	?	?
Other bias*	H	H	H	H	H	H	H	H

?Unknown risk of bias; H, high risk of bias; L, low risk of bias.
*Control bias, denture quality bias.

affects participants. However, this questionnaire is not designed to screen and quantify psychological morbidity associated with tooth loss.

One study[32] used the Patient Health Questionnaire (PHQ-9) questionnaire, which is a self-assessment questionnaire to monitor and measure depressive disorders.[14] The PHQ-9 has been validated to screen and measure depression in primary care.[15] However, the PHQ-9 fails to either screen or measure anxiety or distress. Therefore, additional tools are required to screen for those dimensions of emotional distress.[14]

Two studies[4,31] concluded that significant numbers of patients have difficulty accepting tooth loss (45% in the edentulous sample and 52% in the partially dentate sample). The same studies also reported that those patients were reluctant to accept the loss of teeth, and they were less self-confident as a result. Four other studies mentioned similar outcomes.[32,34,36,37] On the contrary, two studies[33,35] reported no significant link between tooth loss and emotional disturbance. The latter studied the emotional impact of tooth loss in an aged North Indian population (400 patients, above the age of 60 years). There was an insignificant link between tooth loss and emotional disturbance. However, there was a marked impact on functional activities and social interaction. The contradictory results of these studies could be related to the cultural and socioeconomic differences, as tooth loss could be perceived as an inevitable or normal consequence of the aging process in some cultures. Another study compared the impact of tooth loss between patients who have dentures and those who did not have dentures.[34] The authors reported a significant difference in the acceptance of tooth loss between nondenture wearers (69.8%) and those with dentures (46%). Equally, there were significant differences reported in the impact on self-confidence between two groups (39.6% non-denture wearers and 20% denture wearers).

Discussion

To assess the burden of a specific disease, that is, tooth loss and/or the effectiveness of an intervention, that is, prosthesis, appropriate measures should be considered to ensure the correct data are collected. This review is the first step to identify suitable tools that capture the psychological impact of tooth loss.

Various questionnaires and tools have been used to detect emotional impairment in different acute and chronic medical conditions. The validation and the psychometric properties of those tools have been assessed and validated extensively. However, the performance of the questionnaires and tools identified in this review was inadequate to screen for all the dimensions

of psychological disturbance. These tools are limited by their contents, lack of focus on the chronic medical and dental conditions, such as tooth loss, and inconsistent outcome with psychometric problems.

To screen for psychological disturbance caused by tooth loss, the tool should identify and differentiate the temporary normal adjustment from the pathological adjustment disorders, by measuring the severity of negative emotional symptoms.

All the studies in the current review used the same measurement tool, which was developed from previous qualitative research. This questionnaire mainly explores the functional disability and feelings associated with tooth loss, designed to measure how widespread the emotional impact of tooth loss is; however, it is not designed to screen and quantify psychological morbidities associated with tooth loss. Therefore, further tools are required for this purpose. Furthermore, many of the participants in the included studies had activities/functional difficulties; therefore, it would have been beneficial if the technical quality of dentures were investigated and clarified, to exclude technically unsatisfactory dentures, as a possible cause of functional disability and psychological distress. Therefore, it could be speculated that psychological distress might be related to dysfunctional dentures.

The possible psychological impact of tooth loss for some patients has been demonstrated, yet few tools have been proposed to measure this impact. Measuring and quantifying the psychological impact of tooth loss faces many challenges. First, there are many important variables, which may have a confounding impact on the measurement. A detailed dental, medical, and demographic history should be taken in order to account for any such confounding factors. Second, the technical quality of removable dentures should be measured, to exclude technically suboptimal dentures as the cause of distress. Third, personality type should be analyzed, since some personality traits could be related to denture satisfaction/dissatisfaction.

As mentioned earlier, the DASS-21 has some advantages over the currently available tools, and it could be one of the suitable tools to screen and measure psychological disturbance in patients with tooth loss. Therefore, this tool initially needs to be validated for patients with tooth loss. In addition, a supplemental tool to assess the technical quality of dentures should also be implemented, alongside with the DASS-21 to exclude the potential technical faults related to dentures as a causative factor for the psychological disturbance.

In addition, the OHRQoL questionnaires are beneficial in assessing the impact of tooth loss/dentures from the patient perspective; however, those questionnaires have not been

developed or validated to screen for psychological morbidity, that is, to measures somatic symptoms as classified by the ICD-10 or DSM-5. An individual might have negative/low OHRQoL; however, this individual may still not meet the threshold for defining a psychological disorder, that is, depression, anxiety, or stress as defined by the ICD-10 or DSM-5. The OHRQoL and psychological morbidity are related, but assess different domains. Therefore, a disease-specific measure should be used to measure psychological morbidities associated with tooth loss/dentures. The aim of this systematic review was to assess the psychological morbidities related to tooth loss/dentures (not assessing the quality of life for patients with tooth loss). This is the reason that OHRQoL measures were not evaluated in this systematic review.

One possible limitation in this review is that the defined inclusion/exclusion criteria applied in the electronic searches might have excluded some relevant publications. The aim of narrowing the inclusion criteria was to find a suitable screening tool that captures all the dimensions of psychological disturbance. Nevertheless, as the authors reviewed all the abstracts of the publications that were identified in the initial searches, this risk of publication bias is minimized.

Conclusion

The current tools are not suitable to screen and measure psychological disturbance in patients with tooth loss. Additional research is required to create tools to identify and measure such impact and to recommend suitable interventions.

References

1. Kassebaum NJ, Bernabe E, Dahiya M, et al: Global burden of severe tooth loss: a systematic review and meta-analysis. J Dent Res 2014;93:20-28
2. Steele JG, Treasure ET, O'Sullivan I, et al: Adult Dental Health Survey 2009: transformations in British Oral Health 1968–2009. Br Dent J 2012;10:523-527
3. Gerritsen AE, Allen PF, Witter DJ, et al: Tooth loss and oral health-related quality of life: a systematic review and meta-analysis. Health Qual Life Outcomes 2010;8:1
4. Davis DM, Fiske J, Scott B, et al: The emotional effects of tooth loss: a preliminary quantitative study. Br Dent J 2000;188:503-506
5. Plourde A, Moullec G, Bacon SL, et al: Optimizing screening for depression among adults with asthma. J Asthma 2016;53:736-743
6. Goldberg DP, Williams P: A user's guide to the GHQ. Windsor, 1988
7. Zigmond AS, Snaith RP: The hospital anxiety and depression scale. Acta Psychiatr Scand 1983;67:361-370
8. Cosco TD, Doyle F, Ward M, et al: Latent structure of the Hospital Anxiety and Depression Scale: a 10-year systematic review. J Psychosom Res 2012;72:180-184
9. Coyne JC, van Sonderen E: No further research needed: abandoning the Hospital and Anxiety Depression Scale (HADS). J Psychosom Res 2012;72:173-174
10. Lovibond PF, Lovibond SH: The structure of negative emotional states: comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. Behav Res Ther 1995;33:335-343
11. Henry JD, Crawford JR: The short-form version of the Depression Anxiety Stress Scales (DASS-21): construct validity and normative data in a large non-clinical sample. Br J Clin Psychol 2005;44:227-239
12. Brown TA, Chorpita BF, Korotitsch W, et al: Psychometric properties of the Depression Anxiety Stress Scales (DASS) in clinical samples. Behav Res Ther 1997;35:79-89.
13. Antony MM, Bieling PJ, Cox BJ, et al: Psychometric properties of the 42-item and 21-item versions of the Depression Anxiety Stress Scales in clinical groups and a community sample. Psychol Asment 1998;10:176-181
14. Kroenke K, Spitzer RL, Williams JB: The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med 2001;16:606-613
15. Cameron IM, Crawford JR, Lawton K, et al: Psychometric comparison of PHQ-9 and HADS for measuring depression severity in primary care. Br J Gen Pract 2008;58:32-36
16. Haddad M, Walters P, Phillips R, et al: Detecting depression in patients with coronary heart disease: a diagnostic evaluation of the PHQ-9 and HADS-D in primary care, findings from the UPBEAT-UK study. PLoS One 2013;8:e78493
17. de Man-van Ginkel JM, Gooskens F, Schepers VP, et al: Screening for poststroke depression using the patient health questionnaire. Nurs Res 2012;61:333-341
18. van Steenbergen-Weijenburg KM, de Vroege L, Ploeger RR, et al: Validation of the PHQ-9 as a screening instrument for depression in diabetes patients in specialized outpatient clinics. BMC Health Serv Res 2010;10:235
19. Bergendal B: The relative importance of tooth loss and denture wearing in Swedish adults. Commun Dent Health 1989;6:103-111
20. Kendler KS, Karkowski LM, Prescott CA: Causal relationship between stressful life events and the onset of major depression. Am J Psychiatry 1999;156:837-841
21. Corrigan PJ, Basker RM, Farrin AJ, et al: The development of a method for functional assessment of dentures. Gerodontology 2002;19:41-45
22. Liberati A, Altman DG, Tetzlaff J, et al: The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. BMJ 2009;2700:339
23. Dirik G, Kiliçarslan MA, Gençöz T, et al: Correlates of anxiety and depression in Turkish complete denture patients. Soc Behav Personal 2006;34:1311-1322
24. Ommerborn MA, Hugger A, Kruse J, et al: The extent of the psychological impairment of prosthodontic outpatients at a German University Hospital. Head Face Med 2008;4:23
25. Roohafza H, Afghari P, Keshteli AH, et al: The relationship between tooth loss and psychological factors. Commun Dent Health 2015;32:16-19
26. Dable RA, Yashwante BJ, Marathe SS, et al: Tooth loss–how emotional it is for the elderly in India? Oral Health Dent Manag 2014;13:305-310
27. Anttila SS, Knuuttila ML, Sakki TK: Relationship of depressive symptoms to edentulousness, dental health, and dental health behavior. Acta Odontol Scand 2001;59:406-412
28. Okoje VN, Dosumu OO, Alonge TO, et al: Tooth loss: are the patients prepared? Niger J Clin Pract 2012;15:172-175
29. Hogenius S, Berggren U, Blomberg S, et al: Demographical, odontological, and psychological variables in individuals referred for osseointegrated dental implants. Commun Dent Oral Epidemiol 1992;20:224-228
30. Allen PF, McMillan AS: The impact of tooth loss in a denture wearing population: an assessment using the Oral Health Impact Profile. Commun Dent Health 1999;16:176-180

31. Davis DM, Fiske J, Scott B, et al: The emotional effects of tooth loss in a group of partially dentate people: a quantitative study. Eur J Prosthodont Restor Dent 2001;9: 53-57

32. Shah RJ, Diwan FJ, Diwan MJ, et al: A study of the emotional effects of tooth loss in an edentulous Gujarati population and its association with depression. J Indian Prosthodont Soc 2015;15:237-243

33. Naik AV, Pai RC: Study of emotional effects of tooth loss in an aging north Indian community. ISRN Dent 2011;2011: 395498

34. Anjum MS, Monica M, Rao KY, et al: Does tooth loss have an emotional effect? A cross-sectional and comparative study on nondenture wearers and complete denture wearers. J Indian Assoc 2017;15:247-251

35. McMillan AS, Wong MC. Emotional effects of tooth loss in community-dwelling elderly people in Hong Kong. Int J Prosthodont 2004;17:172-176

36. Scott BJ, Leung KC, McMillan AS, et al: A transcultural perspective on the emotional effect of tooth loss in complete denture wearers. Int J Prosthodont 2001;14:461-465

37. Fiske J, Davis DM, Leung KC, et al: The emotional effects of tooth loss in partially dentate people attending prosthodontic clinics in dental schools in England, Scotland and Hong Kong: a preliminary investigation. Int Dent J 2001;51:457-462

38. Fiske J, Davis DM, Frances C, et al: The emotional effects of tooth loss in edentulous people. Br Dent J 1998;184:90-93

39. Fiske J, Frances C, Gelbier S: The emotional effects of tooth loss. Proceedings of the European Prosthodontic Association, 1997

226

Appendix 18: Publication

Developing a questionnaire to measure psychological disturbance associated with tooth loss

Introduction

Adult Oral Health in the UK has been gradually improving, and the prevalence of tooth loss has been in decline in the last 30 years. Nevertheless, it is estimated that 6% of the population remain edentulous, a further 14% have experienced significant tooth loss (>11 tooth loss) and "one in every five" adults have removable dentures (either partial or complete)[1]. Previous research has shown that tooth loss can have a significant impact on the general and oral health-related quality of life[2,3]. Edentulous or partially dentate patients may require either removable dentures or osseointegrated dental implants to restore their dentition. Dentures could restore function and is a non-invasive treatment option. Whilst some patients cope with and adapt well to tooth loss and dentures; others experience emotional distress as they might have less psychological resilience and ability to adapt to changes[4]. Some authors also reported that tooth loss could cause significant emotional and psychological distress in some patients despite being successful denture wearers[5]. Therefore, it is important to assess the psychological disturbance and wellbeing in those patients.

Screening tools have widely been used for depression, anxiety and distress in patients with various medical conditions, such as amputations, artificial prosthesis replacements, chronic illness, cancer and palliative care[6,7,8].

Different methods were suggested to develop and test questionnaires that assess outcome measures. The Scientific Advisory Committee of the Medical Outcomes Trust (SAAC) produced a list of eights attributes with quality criteria to help develop questionnaires and enhance their validity[9]. Firstly, designing a conceptual and measurement model that needs to include: a measurable concept, a defined target population, an established the level of measurement. Secondly, assessing reliability, validity, responsiveness and interpretability. Finally, the burden to use the questionnaire needs to be assessed, i.e. time and efforts for respondents/administrators to use the questionnaire. The SAAC has also recommended additional attributes to be used if alternative methods are implemented when the questionnaire is used (using a computer, an interviewer or using a self- administrated questionnaire)[9]. Other researchers also described similar methods to design and validate a questionnaire.[10,11,12]

Unfortunately to date, the available tools are neither suitable nor validated to screen and measure psychological distress in adult patients with tooth loss[13]. Therefore, a disease-specific measure is required to investigate the psychological health and wellbeing of people with tooth loss and evaluate outcome measure of the intervention with technically successful removable dentures. The aim of this study was to develop a measure to assess psychological disturbance and wellbeing in patient with tooth loss and dentures.

Study methods

Although there are different strategies to design and validate a questionnaire as outlined in the introduction, all the methods share common consensuses, and were used to develop the questionnaire for this study. There were two consecutive phase as follows:

Phase 1. Development of questionnaire

- Describing the aims/target population of the questionnaire

- Generating a pool of items, defining the constructs to be measured

- Adapting psychological morbidity screening tools

- Items reduction, and producing a preliminary questionnaire

Phase 2. Validation of questionnaire

- Content validation

- Face validation (participants feedback)

- Establishing Construct Validity

- Pilot test and establishing reliability

Study population

Ethical approval was obtained from the Health Research Authority NHS England, reference 17/NI/0098 (This study was part of a large scale clinical study that aimed to investigate the psychological disturbance caused by tooth loss). Recruitment of participants to validate the questionnaire was carried out at two Primary Dental Clinics in England.128 participants (100 patients and 28 clinicians) were recruited to participate in the development and validation of the questionnaire. Inclusion criteria included adults (age ≥18) with tooth loss and

technically successful dentures (used by participants for ≥ 1 year) and stable
dentition (if present), free of primary dental disease (active dental
caries/periodontal disease). Exclusion criteria included patients with a history
of psychotic mental illness or patients who had treatment with dental implants.
Participants were given patient information sheet (PIS) and signed written
consent forms.

Phase 1. Questionnaire development

Defining the aims/target population of the questionnaire:

This proposed questionnaire aimed to assess the impact of tooth loss in
patients who had tooth loss and technically good quality dentures. Specifically,
the questionnaire aims to assess the psychological health and wellbeing of
adults with technically successful dentures.

Generating a pool of items, defining the constructs to be measured:

A pool of items that relate all problems observed or experienced with tooth
loss/dentures was produced through focus interviews with participants (n=30),
clinician feedback (n=10) and extensive literature review. Each participant was
asked to list all problems, difficulties and emotions that they experienced as a
result of tooth loss. Ten general dental practitioners (with >10 years
experiences) were also asked to describe the problems and difficulties related
to patients with tooth loss/dentures. The generated items were assigned into
subscales to represent the constructs of the questionnaire.

Psychological morbidity screening tools:

The Depression, Anxiety and Stress Scale (DASS-21)[14] was added to the proposed questionnaire to screen for somatic symptoms of depression, anxiety, and distress. The DASS-21 has been identified in a previous study as a possible suitable questionnaire to investigate the psychological disturbance associated with tooth loss, as the DASS-21 has been extensively researched for its psychometric properties[15]. Furthermore, the DASS-21 can also identify and differentiate the degree of depression, anxiety and stress[15].

The Distress Thermometer (DT), which is a visual analogue scale, was adapted from the NCCN[16], and was also added to the proposed questionnaire. While the DASS-21 measures the general somatic symptoms related to psychological disturbance, the DT measure distress directly "direct patient's self-perceived measure of the impact of tooth loss". Therefore, a two-dimensional measurement is captured by combining the two tools.

Questionnaire Item reduction:

Ten participants were recruited to review and then reduce the number of items generated from the literature review/feedback. Each participant was asked to review the generated items/problems, and then report the frequency of each on a five-point Linker scale. Answers "Never" to "Very Often" were allocated numbers "0" to "5" ("Don't Know" answers were dropped). For each item, an importance score was produced by calculating the mean score. The item had a higher importance score if more participants experienced the problems and/or the frequency of the problems was reported more often.

Phase 2. Questionnaire validation:

To assure the integrity of a measurement tool, the psychometrical properties (validity and reliability) of the tool should be confirmed. Validity is defined as the "ability of the instrument to measure the attributes of the construct under study" whereas reliability refers to "*the ability of an instrument to measure an attribute consistently*"[17].

Content validation

Establishing content validity was carried out by recruiting a panel of experts to review the questionnaire items for readability, clarity, validity, comprehensiveness and redundancy.[9] Experts in questionnaire development were selected from the list of researchers identified during the literature review[12]. There is no agreement on the required number of experts needed to assess content validation; seven or more experts are recommended by many authors.[12,17]

Forty-two potential experts were identified from the literature review. Experts were contacted through emails. 27 experts agreed to participate, and 18 out of 27 experts have returned their feedback within the required time. Eight experts only partially completed the feedback form. Each expert was asked to identify which items are essential for the measuring tool and to provide feedback about the structural design of the measure.

The Lawshe method[18] was used to assess which items were essential. Lawshe indicated that if 50% or more of the experts agreed that an item is essential, then that item had some content validity.

Face validation

Face validation is important, as if respondents misinterpret or misunderstood the question (due to poor wording inadequate response options etc.), then the tool may fail to capture the intended construct, and this may lead to measurement errors[12]. A sample of 20-30 is recommended for face validity[19].

Initial face validation: Ten participants were recruited to evaluate the wording, clarity, and readability of the preliminary items. Participants completed the proposed questionnaire in a quiet room. This was followed by focused interviews to assess items, constructs and layout of the questionnaire. The focus interviews also asked about the suitability of the DASS-21, DT as psychological measures related to tooth loss.

Final face validation: Further ten participants were recruited to test the revised items cognitively. This was carried out by probing the respondent's thoughts processes and determining that participant's understanding and interpretation of each item is accurate. The assessment also included comprehension, recall, judgment and response of items in the questionnaire. Participants answers, feedback, opinion and criticism were recorded.

Construct validity:

Construct validity is defined as "*the extent to which items in a measure relate to the theoretical construct*"[17]. Therefore, the items in the proposed questionnaire should be able to measure the concepts that are theoretically and structurally related to the impact of tooth loss.

Many methods exist to assess construct validity of a new measure, including hypothesis testing, testing against a gold standard test and factor analysis[17]. One of the common ways to assess construct validity is to develop and test a hypothesis about the expected relationship between constructs. This could be

conducted by hypothesising a theoretical and structural relationship between different but related constructs. If this logical relationship existed, then this proves that the theoretical hypothesis of the new scale, and therefore indicates that the new scale has some degree of construct validity[9,17]. The hypothesis testing method was used to assess construct validity in this study, as there were no gold standards to test against.

To establish construct validity, it was hypothesised that the theoretical framework of the subscales of the body image and the functional difficulties should both correlate strongly (R>0.5) with the global DT scale (as all those three tools assess theoretical characteristic of tooth loss). It was also hypothesised that the functional difficulties domain of Part A would correlate strongly (r>0.5) with OHIP-14 functional limitation, physical pain and psychical disability domains. Furthermore, the body image domain of Part A would correlate strongly (r>0.5) with psychological discomfort and psychological disability and social disability domains. All those subscale measures are different, but related concepts. Therefore, construct validity was supported if the scores reflected the framework as hypothesised. A sample of 20 participants was recruited to complete the questionnaire and the subscales of the OHIP-14. Pearson correlation coefficient test was used to measure the correlation between those concepts.

Pilot test and reliability

Pilot testing improves the internal validity of the questionnaire and helps to maximize response and completion rate[20]. The pilot sample for this study was calculated the sample size for this pilot test based on 10% of the sample projected for the main study. Therefore, a sample size of 20 participants was

recruited. The pilot test in this study was to assess the questionnaire clarity/readability and investigate the reliability of the proposed questionnaire (Test re-test and internal consistency).

Questionnaire clarity/readability

Each participant from the pilot sample was probed about clarity of these items, scale adequacy and choices of responses.

Questionnaire internal consistency

Internal consistency assesses whether the items that are measuring a specific domain generate consistent scores[9]. Cronbach's alpha was used to assess internal consistency[21].

Questionnaire test re-test reliability

Test re-test reliability is confirmed if a measure is stable over time[9]. Test re-test reliability was assessed by administering the questionnaire to the same participants and under the same conditions twice with a specific time interval. Test re-test reliability is established when the same participant produces same or similar scores on repeated testing, i.e. the attributes measured maintain stability over time [22].

There have been different recommendations for the time interval between the test and the re-test, ranging from few days to few months. Most researchers suggest a timing interval of 2 - 4 weeks[9,22] . As the domains measured in this study were cognitive and emotional, it was decided to use the two weeks intervals, and those attributes were not likely to change in this short period.

Participants filled the questionnaire in a quiet room at the dental practice after signing the consent form. The same questionnaire was completed again by each participant under the same condition two weeks later. The re-testing questionnaire was completed just before the participants were scheduled for the pilot interview appointment. The reason for distributing the re-test questionnaire before the interview appointment was to prevent the interview interactions from influencing the re-test responses. The test re-test reliability was assessed by measuring correlations between scores.

Statistical analyses

Pearson correlation coefficient, Cronbach's α Coefficient and ICC were used to assess the psychometric properties of the questionnaire. Data was analysed using IBM SPSS Statistics (Version 25.0)

Results

Generating a pool of items and defining the constructs to be measured:

The interviews from participants and general dental practitioners generated 167 statements/problems/difficulties. 35 statements remained after removing the duplicate and repetitive statements. The literature review and the examination of all existing tools generated 41 further items. The items/statements that have been generated were analysed, and two distinctive constructs were identified:

First construct: Functional difficulties, including problems speaking and eating (food choices, enjoying eating, discomfort).

Second construct: Dissatisfaction with self-image related to tooth loss/replacement with dentures.

Questionnaire item reduction

The questionnaire item reduction task resulted in a total of 12 items (based on the highest importance score). Those 12 items and the psychological morbidities tools produced a preliminary questionnaire that has been validated in the next phase.

Content validation

Experts had different opinions on how to improve the questionnaire. However, one main change that most experts recommended was to remove the double-barrelled items. Items with low content validity were edited (Table 1)

Initial face validation

80% of participants (n=8) indicated that the language and vocabulary used were appropriate. Furthermore, 60% (n=6) indicated that the questionnaire, in general, was an appropriate tool to explore the impact of tooth loss and any associated psychological disturbance. The DASS-21 was seen as appropriate measures to screen for negative mood, which might be related to tooth loss (depression, anxiety, stress). The initial face validation resulted in changes to items/wording/layout (Table 1).

Final face validation

Discussion with participants included types of Likert response options to be used in Part A. The two choices included "frequency of problems" and "level of agreement with the statement". Following discussion with participants, it was decided that frequency scale (very often/often sometimes/rarely/never) was

less subjective and more meaningful as participants found it easier to report the frequency of each problem.

Construct validation

The results indicated that all domains correlated strongly (r>5) as hypothesised except the social disability domain that correlated only mildly (r>5 & <3) with the body image domain. Nevertheless, this moderate correlation was still accepted that the framework is structured as hypothesized (Table 2).

Table 2: Pearson's correlation coefficients between OHIP-14 & proposed questionnaire

Part A	OHIP-14 domains	(r)	DT (r)
Functional Difficulties	Functional limitation	0.743	0.756
	Physical pain	0.700	
	Physical disability	0.819	
Body image	Psychological discomfort	0.710	0.808
	Psychological disability	0.732	
	Social disability	0.478	

(n=20), All correlations significant at 0.01

Questionnaire test re-test reliability

The correlation coefficients for the functional and the body image domains were 0.86 and 0.79. The Pearson coefficients were 0.93 and 0.94 (significant at 0.01). The items correlation for Part A ranged from 0.7 to 0.9. All scores are indicating adequate reliability for Part A subscales and items. The correlation coefficients for DASS-21 three domains were also >0.7 indicated satisfactory reliability (Table 3).

Table 3: Test re-test reliability

	Correlation coefficients (For each Items)	Correlation coefficients

					(For Domains)	
Part A	Domains		ICC	Pearson	ICC	Pearson
	Functional	Q1	0.793	0.787*	0.86	0.93*
	Health	Q2	0.762	0.893*		
		Q3	0.782	0.815*		
		Q4	0.701	0.724*		
	Body	Q5	0.705	0.830*	0.79	0.94*
	image	Q6	0.705	0.770*		
		Q7	07.16	0.754*		
		Q8	0.765	0.800*		
		Q9	0.759	0.861*		
DASS 21	Depression				0.874	0.917*
	Anxiety				0.849	0.893*
	Stress				0.820	0.893*
DT			0.757	0.798*		

* Correlation is significant at 0.01

Questionnaire internal consistency

Cronbach's α for functional and body image domains were 0.84 and 0.88, respectively. Cronbach's α of 0.84 for the functional domain indicates that the combined scores for that domain (items Q1-Q4), represents the correct scores in 84% of cases, which further indicates some degree of internal consistency between those four items (Table 4). As for the DASS21 subscales of depression, anxiety and stress, the Cronbach's α were 0.95, 0.81 and 0.88 respectively. All scores indicate satisfactory reliability (as Cronbach's α >0.7).

Table 4: Reliability coefficient for each subscale (n=20)

Questionnaire parts and domains		No of items	Cronbach's α Coefficient (n=20)
Part A	Functional domain	4	0.846
	Body image domain	5	0.883
DASS21	Depression	7	0.953
	Anxiety	7	0.818

Stress	7	0.886

Testing questionnaire clarity

The pilot test analysis concluded that the items of the questionnaire are clear and easy to understand (>90% of respondents). The answer scale options were also adequate and representative. However, some minor typographical revisions were implemented.

Discussion:

Psychometric properties of the questionnaire:

Face and content validation indicated that the questionnaire was an appropriate tool to measure the impact of tooth loss and the related psychological morbidities. Reliability analysis showed that each of the two subscales (functional & emotional) was internally reliable, i.e. items explored related questions, and the scores on each subscale were also related to the tooth loss impact construct. The DASS-21 also showed similar results. Finally, testing the theoretical hypothesis structure of the impact of tooth loss has also enhanced the construct validity of the questionnaire. Therefore, the validation process indicated that the questionnaire has satisfactory reliability and validity to measure the impact of tooth loss and related psychological health.

Body image construct:

The development process of this questionnaire indicated that functional difficulties and body image were the main concepts related to tooth loss. Therefore, studying the psychological impact of tooth loss is more meaningful

240

when assessed in relation to those two concepts, as some individuals misattribute negative emotions to a specific source when in fact it is caused by another source [23].

Body image is defined as "*internalised view of one's appearance that drives behaviour and influences information processing*" [24]. The dissatisfaction with the self-image that is related to tooth loss fulfills the definition of body image impairment described by Altabe and Thompson[24], as this self-image impairment could influence individual's behaviours, social interaction and relationships. Therefore, the concept of body-image should be included in the proposed questionnaire. The subscale of this concept should include items which relate to "*perception*" and "*attitude*"[25]. "*Perception*" relates to how the individual picture the image of their mouth/face in their own mind, and the "*attitude*", is how this perceived self-image affects their interaction with their surrounding[25].

Body image and psychosocial concept:

The psychosocial and body image are closely related but different concepts. While the former illustrates the social and psychological aspects of tooth loss, the later represent the main trigger that provokes those disturbances. This relation was described in participants' feedback through the processes of developing this questionnaire. In addition, similar impacts on perception and behaviours were suggested by researches who studied the "global body image" construct[25]. Therefore, the possible dissatisfaction of body image after tooth loss/replacement with dentures may influence social interaction, feelings, emotions, and relationships. Based on that, the psychosocial concept was

regarded as part of the body image domain and was assessed as part of the body image domain.

Interpretability of the proposed questionnaire:

Interpretability is defined as "*clarity and simplicity in understanding a measure quantitative scores*"[9]. To interpret the results of a tool, systematic rules should be constructed to convert the subjective measured constructs into numerical grades[26]. This is carried out by developing a scoring system for the questionnaire to help measure difficult-to-measure psychosocial constructs similar to the constructs in this study. To develop a scoring system for the Part A questionnaire, response items could be assigned numeric values; however, it should be noted that the intervals between items are not equal, i.e. the interval between "often" and "Very often", is not the same as between "Never" and "rarely". Furthermore, the weight of items are also not equal, i.e. a patient who score "4" on the "*problem with speaking" item* could have much more (or lower) impact than the score "4" on the "*problems with eating*" item. This problem could be potentially solved by adding weight to responses and items, but this process is quite difficult in this study as the studied sample is not homogenous, and therefore, it will be difficult to measure the difference between intervals and responses. Furthermore, weighting questionnaire items are less desirable, as they increase the complexity of using the measure and interpreting the data and they only slightly improve the questionnaire validity. Many authors questioned the advantage of adding weight to items [27] [28].

Another method to interpret the results and compare responsiveness is to use aggregates scores or calculate the mean changes; however, there has also

been doubts about the meaning or the clinical relevance to such figures [29,30]. Therefore, it was decided to interpret the data on ordinal (not aggregates scoring) method with scaled hierarchical grades of the frequency on each item. The outcome measure of functional difficulties or body image satisfaction/dissatisfaction would be based on the maximum weight of every item in each of the two domains at a specific threshold. With higher frequency representing a higher degree of functional problems or body image dissatisfaction, i.e. if a participant has a frequency score ≥3 on any of the functional difficulties items, then this represents some degree of functional difficulties.

The validated questionnaire has several limitations. Firstly, the small number of items (9 items) used to capture the domains in Part A was one of the limitations. However it was intentional to produce a short questionnaire, to reduce the burden on participants, decrease response fatigue and increase the number of participants who are willing to join the study[22]. Nevertheless, reducing the Part A questionnaire to nine items might mean that some functional or psychological difficulties which are applicable to a small number of patients may not be recorded and missed. Regardless of that, the main construct is still measured by the other items in the questionnaire; i.e., if a patient has problems with denture stability, this could be measured with a direct question specifically asking about denture stability; however, if this question is missing, it does not mean that the impact of denture stability on the respondent has been missed. This functional problem could still be identified indirectly by an item that is asking about "trouble eating" or "discomfort". Therefore, the validity of the scale

is still satisfactory as long as each subscale have items that represent all the problems.

Secondly, only relatively small numbers of participants have been used to develop and validate this questionnaire. Nevertheless, those numbers were in line with the recommendations set by researchers[9,17,12]. Furthermore, questionnaire validation is not static, but an ongoing process, and further analysis of the data in the recruitment phase could be used to enhance the validity of the questionnaire[12].

Thirdly, the sample for the development and validation has been recruited only from two primary dental practices. This calls into question the transferability and generalisability of the tool and raises the issue if this sample was representative of the general population. Further validation will be needed to assess whether this tool is suitable for other populations like secondary care patients.

This questionnaire is not a diagnostic measure, but a screening tool, which might highlight potential emotional problems related to tooth loss. This proposed questionnaire could also be considered for future longitudinal studies to compare the effectiveness of different interventions (dentures, dental implants, cognitive behavioural therapy, etc.).

Conclusion:

A disease-specific measure was developed and validated. This validated questionnaire could assess the impact of tooth loss (functional difficulties, self-

body image), screen for psychological morbidities and assess the effectiveness

of intervention, i.e. dentures.

References;

1.   Steele JG, Treasure ET, O'Sullivan I, Morris J, Murray JJ. Adult Dental
       Health Survey 2009: transformations in British oral health 1968|[ndash]|2009.
       British Dental Journal. 2012;213(10):523-527.
2.   Allen PF, McMillan AS. The impact of tooth loss in a denture wearing
       population: an assessment using the Oral Health Impact Profile. *Community
       Dent Health.* 1999;16(3):176-180.

3.   Gerritsen AE, Allen PF, Witter DJ, Bronkhorst EM, Creugers NH. Tooth loss and oral health-related quality of life: a systematic review and meta-analysis. *Health and Quality of Life Outcomes.* 2010;8(1):1.

4.   Friedman N, Landesman HM, Wexler M. The influences of fear, anxiety, and depression on the patient's adaptive responses to complete dentures. Part I. *J Prosthet Dent.* 1987;58(6):687-689.

5.   Davis DM, Fiske J, Scott B, Radford DR. The emotional effects of tooth loss: a preliminary quantitative study. *Br Dent J.* 2000;188(9):503-506.

6.   Plourde A, Moullec G, Bacon SL, Suarthana E, Lavoie KL. Optimizing screening for depression among adults with asthma. *J Asthma.* 2016;53(7):736-743.

7.   Hawamdeh ZM, Othman YS, Ibrahim AI. Assessment of anxiety and depression after lower limb amputation in Jordanian patients. *Neuropsychiatr Dis Treat.* 2008;4(3):627-633.

8.   Hopko DR, Bell JL, Armento ME, et al. The phenomenology and screening of clinical depression in cancer patients. *J Psychosoc Oncol.* 2008;26(1):31-51.

9.   Aaronson N, Alonso J, Burnam A, et al. SAC Assessing health status and quality-of-life instruments: attributes and review criteria. *Qual Life Res.* 2002;11(3):193-205.

10.   Radhakrishna R. Tips for Developing and Testing Questionnaires/Instruments. 2007;45.

11.   Terwee CB, Bot SD, de Boer MR, et al. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol.* 2007;60(1):34-42.

12.   Artino AR, La Rochelle JS, Dezee KJ, Gehlbach H. Developing questionnaires for educational research: AMEE Guide No. 87. *Med Teach.* 2014;36(6):463-474.

13.   Kudsi, Z, Fenlon M, Baysan A. Assessment
of Psychological Distress in Patients With Tooth Loss: A Systematic Review of Assessment Tools. 2018;97 (B).

14.   Lovibond PF, Lovibond SH. The structure of negative emotional states: comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. *Behav Res Ther.* 1995;33(3):335-343.

15.   Henry JD, Crawford JR. The short-form version of the Depression Anxiety Stress Scales (DASS-21): construct validity and normative data in a large non-clinical sample. *Br J Clin Psychol.* 2005;44(Pt 2):227-239.

16.   (NCCN) NCCN. Managing Stress and Distress. MCCN. https://www.nccn.org/patients/resources/life_with_cancer/distress.aspx. Accessed2019.

17.   DeVon HA, Block ME, Moyle-Wright P, et al. A psychometric toolbox for testing validity and reliability. *J Nurs Scholarsh.* 2007;39(2):155-164.

18.   Lawshe CH. A QUANTITATIVE APPROACH TO CONTENT VALIDITY. *Personnel Psychology.* 1975(28,):563-575.

19.   Willis GB, Artino AR. What Do Our Respondents Think We're Asking? Using Cognitive Interviewing to Improve Medical Education Surveys. In: *J Grad Med Educ.* Vol 5.2013:353-356.

20.   Puleo E, Zapka J, White MJ, Mouchawar J, Somkin C, Taplin S. Caffeine, cajoling, and other strategies to maximize clinician survey response rates. *Eval Health Prof.* 2002;25(2):169-184.

21.   Cronbach L. Coefficient alpha and the internal structure of tests. *Psychometrika.* 1951;16(3):297-334.
22.   Bolarinwa OA. Principles and methods of validity and reliability testing of questionnaires used in social and health science researches. *Niger Postgrad Med J.* 2015;22(4):195-201.
23.   Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav.* 1983;24(4):385-396.
24.   Altabe M, Thompson JK. Body image: A cognitive self-schema construct? *Cognitive Therapy and Research.* 1996;20(2):171-193.
25.   Gleeson K, Frith H. (De)constructing body image. *J Health Psychol.* 2006;11(1):79-90.
26.   Roach K. Measurement of Health Outcomes: Reliability, Validity and Re... : JPO: Journal of Prosthetics and Orthotics. *Journal of Prosthetics and Orthotics.* 2006;18(6):8-12.
27.   Allen PF, Locker D. Do item weights matter? An assessment using the oral health impact profile. *Community Dent Health.* 1997;14(3):133-138.
28.   Allen PF. Assessment of oral health related quality of life. *Health Qual Life Outcomes.* 2003;1:40.
29.   Locker D. Issues in measuring change in self-perceived oral health status. *Community Dent Oral Epidemiol.* 1998;26(1):41-47.
30.   Tsakos G, Allen PF, Steele JG, Locker D. Interpreting oral health-related quality of life data. *Community Dent Oral Epidemiol.* 2012;40(3):193-200.