Periodontal Treatment, Individual, Psychological Factors and Oral Health Related Quality of Life

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Dedication

This thesis is dedicated to my wife Coral and our children David, Jonathan and Alice.

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I am also indebted to all those who helped me clinically to undertake this project, including three excellent staff hygienists Mrs Alison Barber, Mrs Nivan Al-Hammouri and Mrs Claire Vallance-Owen. I would also like to acknowledge the nurses who assisted me in clinic, together with the receptionists and medical records staff who helped keep track of patients during the study. Not forgetting of course, my thanks to all the patients who participated in the study.

Finally, I should like to thank my wife Coral and our family for their love and support, and for giving me the time and space to complete this research.

Abstract

Introduction: Periodontitis negatively impacts on Oral Health Related Quality of Life (OHRQoL) and is ameliorated by periodontal treatment. Individual and environmental factors may affect treatment outcomes.

Aim: To determine OHRQoL and clinical changes after the diagnosis and treatment of chronic periodontitis.

Objectives: To determine: (1) OHRQoL and clinical changes after periodontal treatment. (2) OHRQoL trajectory from diagnosis to treatment and follow-up. (3) Individual (psychological) and environmental factors predicting OHRQoL and clinical changes after periodontal treatment. (4) Relationships between psychological factors, OHRQoL and clinical changes.

Methods: 140 patients with chronic periodontitis completed a prospective single arm intervention study (non-surgical treatment). Participants self-completed questionnaires: Sense of Coherence, Locus of Control, Self-esteem and Task-specific Self-efficacy before treatment, and Oral Health Impact Profile (OHIP-14) at assessment, treatment, oral hygiene review and end of study time points. Relationships between OHRQoL, clinical data, individual and environmental characteristics were explored within the Wilson and Cleary model with structural equation modelling (SEM) and Growth Curve Modelling (GCM).

Results: OHRQoL worsened before treatment, then improved along with the periodontal status afterwards. Greater sense of coherence and age, better periodontal status, lower DMFT and being male predicted better OHRQoL after treatment. Better task-specific self-efficacy predicted better baseline and end periodontal status. Greater age and higher plaque score predicted worse baseline periodontal status. Better self-esteem, but worse plaque score predicted better end periodontal status. GCM determined better sense of coherence, being male and a non-smoker predicted better OHRQoL at assessment. The rate of change was predicted by sense of coherence and locus of control. Gains in the clinical attachment level and reductions in probing depths were negatively predicted by task-specific self-efficacy.

Conclusions: OHRQoL and the periodontal status improved after periodontal treatment, and this was predicted by individual demographic and psychological factors.

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Abbreviations

AMSTAR	Methodological Quality of Systematic Reviews
BoP	Bleeding on probing
CAL	Clinical Attachment Loss
EMD	Enamel Matrix Derivative
FMD	Full Mouth Debridement
GCM	Growth Curve Modelling
GOHAI	General Oral Health Assessment Index
HRQoL	Health Related Quality of Life
IMD	Index of Multiple Deprivation
LA	Local Anaesthesia
LoC	Locus of Control
MHLC	Multidimensional Health Locus of Control
MID	Minimum Important Difference
NSPT	Non-surgical Periodontal Treatment
OHI	Oral Hygiene Instruction
OHIP-14	Oral Health Index Profile – 14
OHIP-49	Oral Health Index Profile – 49
OHRQoL	Oral Health Related Quality of Life
OHQoL-UK	Oral Health Related Quality of Life UK
OIDP	Oral Impacts on Daily Performance
PROMS	Patient Reported Outcome Measures
QoL	Quality of Life
RCT	Randomized Control Trial
RSE	Rosenberg Self-esteem
SEM	Structural Equation Modelling
SES	Socioeconomic Status
SESS	Self-efficacy Scale for Self-care
SF-36	Psychological General Wellbeing Index-36
SoC	Sense of Coherence
TSSE	Task-specific Self-efficacy

Declaration

I, the author, confirm that the Thesis is my own work. I am aware of the University's Guidance on the Use of Unfair Means. This work has not been previously presented for an award at this, or any other, university.

Andrew Rawlinson

Chapter 1
Introduction

1.1 Background

Chronic inflammatory periodontal diseases affect a large proportion of the UK population, according to the most recent Adult Dental Health Survey (White et al., 2012). It has become increasingly acknowledged that periodontal diseases have an adverse impact on the Oral Health Related Quality of Life (OHRQoL) of those affected (Ferreira et al., 2017), and there is evidence from clinical studies, that routine periodontal treatment can improve this (Shanbhag et al., 2012, Botelho et al., 2020). However, little is known about the psychological factors, that may also affect OHRQoL and the outcomes of periodontal treatment. A review of the literature suggests sense of coherence, self-efficacy, self-esteem and locus of control are worthy of further investigation.

Sense of coherence is a psychological resource important for health. It is defined as "*a global orientation that expresses the extent to which one has a pervasive, enduring though dynamic feeling of confidence that (1) the stimuli deriving from one's internal and external environments in the course of living are structured, predictable and explicable; (2) the resources are available to one to meet the demands posed by these stimuli; and (3) these demands are challenges, worthy of investment and engagement"* (Antonovsky, 1987).

Sense of coherence is related to some oral health behaviours of importance in the management of periodontal diseases. A stronger sense of coherence is associated with a better quality of life, and there is also consistent and experimental evidence that sense of coherence influences OHRQoL (Eriksson and Lindstrom, 2007, Johansson et al., 2010, Nammontri et al., 2013, Elyasi et al., 2015). However, there are no longitudinal studies that have investigated sense of coherence in relation to the clinical outcomes of periodontal treatment. High oral health care-specific self-efficacy predicts better oral hygiene behaviours and persisting with periodontal treatment, but the impact of this on OHRQoL remains unclear (Kakudate et al., 2008, Kakudate et al., 2010b, Woelber et al., 2015). The few reports on self-esteem in relation to periodontal treatment outcomes in adults also leave its relative importance unclear (Dumitrescu and Kawamura, 2010, Musurlieva and Stoykova, 2015, Syrjala et al., 2004). Improving the periodontal condition may in turn improve self-esteem, but there are no data for this. Locus of control may influence oral health behaviours (Padmaja et al., 2018), and thereby, periodontal treatment outcomes. However, there are few studies on this and the data available are not sufficiently robust to enable firm conclusions to be drawn (Galgut et al., 1987, Borkowska et al., 1998).

Elucidating the role of relevant individual factors in predicting clinical outcomes and OHRQoL may help in the development of more holistic and patient centred approaches for the management of periodontal diseases. This approach would differ from the traditional methods of treatment that are heavily based on the biomedical model of health.

The Wilson and Cleary model allows exploration of relationships between characteristics of the individual, characteristics of the environment, and the various levels of symptom status, functional status, general health perceptions and ultimately OHRQoL (Wilson and Cleary, 1995). Structural Equation Modelling (SEM) allows simultaneous testing of direct and indirect relationships between the factors outlined above together with other environmental factors, to enable a better representation of biological, psychological and social factors in the biopsychosocial model. Growth curve modelling is a special application of structural equation modelling, that is relatively new in dentistry. The technique may be used to analyse predictors of change in longitudinal studies, and is applied here to investigate changes in OHRQoL and periodontal health.

1.2 Aims and objectives

Aim

To determine the oral health related quality of life and clinical changes after the diagnosis and treatment of chronic periodontitis.

Objectives

To determine:

1. The OHRQoL and clinical changes after periodontal treatment.
2. The OHRQoL trajectory from diagnosis to treatment and follow-up.
3. Individual (psychological) and environmental factors predicting OHRQoL and clinical changes after periodontal treatment.
4. Relationships among psychological factors, OHRQoL and clinical changes.

This thesis describes a cohort study of 140 patients receiving nonsurgical periodontal treatment.

Chronic periodontitis negatively impacted on OHRQoL, mainly in the psychosocial dimension. This is likely to be a consequence of participants having largely mild to moderate chronic periodontitis, together with the absence of other significant dental problems. The periodontal status worsened from the initial clinical assessment to the time at which treatment commenced. Treatment improved the periodontal status and OHRQoL, and provided further support for the benefits of periodontal treatment.

Plaque, task-specific self-efficacy and self-esteem emerged as direct predictors of periodontal status, and periodontal status, gender, age, DMFT and sense of coherence as direct predictors of OHRQoL at the end of the study. Sense of coherence had a direct psychological effect. Plaque and the other psychological factors also predicted end OHRQoL, mediated via the periodontal status. The rate of change in OHRQoL was predicted by sense of coherence and locus of control.

These findings have not been reported before in relation to periodontal diseases, but make conceptual sense given the importance of these constructs to health. The importance of psychological factors in relation to OHRQoL and the potential for using this knowledge are discussed. The findings of this research also support the Wilson and Cleary model, and its use in future research on periodontal treatment and OHRQoL is suggested.

The negative impact of chronic periodontitis on OHRQoL and worsening in the interval between initial assessment and periodontal treatment commencing, emphasises the importance of prompt treatment. Improvements in OHRQoL, and the periodontal status after treatment provided further support for the benefits of periodontal treatment. OHRQoL and clinical outcomes measure different aspects of treatment success, and there is merit in including both in clinical practice and research.

The psychological factors investigated in this study were found to predict periodontal status and/or OHRQoL, either directly or OHRQoL indirectly via the periodontal status. Investigation of these and other psychological characteristics could have value in clinical practice to further determine their relationship to OHRQoL and clinical outcomes, and to identify people who might benefit from interventions to strengthen these characteristics.

This thesis is structured as follows. Chapter 2 is a review of the literature that commences with concepts of health and models of disease. Patient reported outcome measures are then reviewed, followed by a discussion of theoretical models, in particular those by Locker and Wilson & Cleary. Next the literature on periodontal diseases and oral health related quality of life (OHRQoL) is reviewed, with a focus on the assessment of the quality of previous studies and the identification of areas for research. Periodontal diseases are briefly considered in this chapter as a background for the clinical aspects of the study. Individual and environmental aetiological factors are discussed, and the management of chronic periodontitis is outlined. The chapter then considers psychological factors, and closes with the rationale for the research, aims and objectives, together with outcome measures.

Chapter 3 describes the methods used in this research. Ethical approval and research governance arrangements are presented, along with the methods used to recruit participants. The sample, study design and data collected are described, together with the methods of analysis.

Chapter 4 reports the results after describing the data. This commences with an analysis relating to the primary objective, the OHRQoL and clinical changes after periodontal treatment. Analysis then relates to the secondary objectives, exploration of the OHRQoL trajectory from diagnosis to periodontal treatment and follow-up. Then the relationships between psychological, individual and environmental factors with OHRQoL are explored, together with the periodontal status before and after treatment. Finally, predictors of changes in OHRQoL and clinical characteristics are analysed.

Chapter 5 is a discussion of the results in relation to the aim, primary and secondary objectives of the research, together with the strengths and limitations of the research.

Chapter 6 states the conclusions of the research, and makes recommendations for practice and research.

Chapter 7 contains the bibliography.

Chapter 8 contains the appendices.

Chapter 2
A Review of the Literature

This chapter reviews the scientific literature on oral health related quality of life (OHRQoL) in relation to periodontal disease and periodontal treatment outcomes, and the psychological factors that may influence these associations. It will review concepts of health, models of health and disease, health related quality of life (HRQoL) and oral health related quality of life (OHRQoL), instruments to measure OHRQoL, theoretical models of health, the impact of periodontal diseases on OHRQoL, the risk factors for periodontal disease and its treatment, the role of psychological factors in relation to periodontal diseases, their treatment and OHRQoL, the relevant psychological factors identified and their measurement.

2.1 Concepts of health

Two widely accepted approaches to conceptualise health are the biomedical and the biopsychosocial models. In the biomedical model, an understanding of disease is explained by only biological factors, with psychological, behavioural and social factors being excluded (Engel, 1977). In contrast, the biopsychosocial model is more holistic, and in addition includes psychological and social factors, regarding health as *"a complete state of physical, mental and social well-being and not merely the absence of disease or infirmity",* (World Health Organization, 1948).

2.1.1 Definitions of Oral Health

Three definitions of oral health that have been used are:

"A comfortable and functional dentition that allows individuals to continue their social role" (Dolan, 1993).

"A standard of health of the oral and related tissues which enables an individual to eat, speak and socialize without active disease, discomfort or embarrassment and which contributes to general well-being" (Department of Health, 1994).

“*A standard of the oral tissues which contributes to overall physical, psychological and social well-being by enabling individuals to eat, communicate and socialise without discomfort, embarrassment or distress and which enables them to fully participate in their chosen social roles.”* (Locker, 2001).

All include important elements of daily activities and the impact of oral conditions on life, and are therefore compatible with the biopsychosocial model of health and WHO definition of health.

2.1.2 Biomedical model of disease

The biomedical model links clinical signs to mechanisms of disease and diagnosis, and guides treatment and management of health conditions. Health is defined as an absence of disease, and disease is explained by the basic clinical sciences of anatomy, physiology, pathology, biochemistry, molecular biology and genetics (Wade and Halligan, 2004). Specific agents such as microorganisms are the cause of disease, and the model is organ specific with disease being a consequence of pathological processes affecting cellular function. The clinical or laboratory changes that ensue are used to establish a diagnosis, often in comparison to a normal value, and to determine the treatment to be prescribed (Boorse, 1977). However, the paradox of having disease assessed through normative methods but feeling well and vice versa is not accounted for in this model. Furthermore, the outcomes of treatment are focused on clinical, biological and biochemical measurements. This reduces health and disease to the smallest common denominator, omitting psychological, behavioural and social factors, and outcome measures that may be important to the patient (Locker, 1988, Ahn et al., 2006, Robinson et al., 2015). Furthermore, the impacts of health on functional, emotional and social daily life are not accounted for.

Clinicians also tend to overestimate the validity of the clinical data that they believe to be objective and thresholds may be socially constructed. The biomedical model also sees patients as passive rather than active participants in health care (Wade and Halligan, 2004). There is a risk of blaming patients for the development of disease, whereas disease may develop in some individuals in spite of them having few or no apparent risk factors. It is therefore important to avoid the tendency of “blaming the victim” (Marantz, 1990). Focusing preventive measures on changing behaviour does not address the underlying determinants of health within the biomedical model (Okoli and Kodet, 2015, Hefler and Chapman, 2015). It omits the broader determinants of health and cannot explain the uneven distribution of disease in society. Such social inequalities, are well recognized as having an impact on oral diseases, with a lower status increasing disease susceptibility and reducing access to dental care (Wamala et al., 2006, Sabbah et al., 2007, Thomson et al., 2012).

2.1.3 Biopsychosocial model of health

The biological component is extended in the biopsychosocial model by including the psychological component and other elements that may have a bearing on disease. These include the social component that explains how socioeconomic status, culture and poverty can influence health can be impacted by disease (Smith et al., 2013). The model is also embedded in patient care, and health care provision will generally involve a multi-disciplinary approach (Segal et al., 2013).

Taking psychological and social factors such as stress, coping strategies, beliefs about health, personality, emotion, socio-environmental and socioeconomic factors into account helps explain the link between the mind and body when in illness. Furthermore, the model is orientated towards care to improve health and well-being compared with simply the provision of treatment. The biopsychosocial model also encourages health care interactions in homes and communities (Robinson et al., 2015). The effects of disease on everyday life are considered, with health-related quality of life (HRQoL) being a main outcome (Wilson and Cleary, 1995). The Wilson and Cleary model is one way of using the biopsychosocial model and quality of life as a key outcome.

The biopsychosocial model also allows people to actively participate in the maintenance of health and in health care. This approach, requires clinicians to develop and use psychological insights, together with good communication skills to enhance the treatment provided. There is also a greater emphasis on prevention at both an individual and population level (Robinson et al., 2015). However, the biopsychosocial model has limitations (Smith et al., 2013). It is vaguely defined and not easily operationalized for predictions to be tested; it is too general, requiring virtually all biopsychosocial patient information making it not applicable for patients on a daily basis; there is no method to operationalize or define it for individual patients and no process for obtaining biopsychosocial information. The most fundamental flaw is the question of how clinicians efficiently identify essential biopsychosocial information when caring for individuals at a given time point. Smith et al. (2013) suggested these criticisms could be addressed by using a patient centred interview to define the biopsychosocial model for each patient.

In conclusion, whilst the biopsychosocial model has complex interactions, it provides a framework within which to consider individual and environmental factors, and it takes cognisance of patient reported measures.

2.2. Measuring Health

The limitation of measuring health with clinical parameters alone, making no reference to how disease and treatment affects the psychological and social wellbeing of individuals, may be addressed by using patient reported outcome measures (PROMS). These can measure satisfaction, utilising judgement, and global perception (Field et al., 2019). They may be used to assess perceived health, including multidimensional constructs such as health related quality of life (HRQoL), which represents a small subsection of PROMS. The instruments developed to measure oral health related quality of life (OHRQoL) are discussed in Section 2.2.4. This approach is consistent with the biopsychosocial model of health and has facilitated scientific progress in this area.

The ideal attributes of health status and quality of life instruments that should be considered when selecting a suitable measure are the conceptual and measurement model, reliability, validity, responsiveness, interpretability, respondent and administrative burden, alternative forms, cultural and language adaptions (Aaronson et al., 2002). This requires the domains and level of questions being appropriate for the setting and participants (Robinson et al., 2003). In addition, instruments should also be useful in decision-making if they are used to determine treatment needs (Sheiham and Spencer, 1997).

2.2.1 Patient Reported Outcome Measures

PROMS may be defined as "*Any reports coming directly from patients about how they function or feel in relation to a health condition or its therapy, without interpretation of the patients' responses by a clinician or anyone else*" (Higgins and Green, 2011). The evaluation of treatment or outcome may be obtained via self-completed questionnaires, diaries, interviews or electronic data collection directly from patients. However, it is important that data are collected using standardized, validated questionnaires that are completed by patients themselves, at the same time point relative to the intervention of interest, and that the PROM used is suitable for the study population. It is also important to minimize missing data, as this may affect the outcomes reported significantly (Dawson et al., 2010). Fitzpatrick et al. (1998), recommended and defined eight criteria to evaluate patient-based outcome measures, namely; appropriateness, reliability, validity, responsiveness, precision, interpretability, acceptability and feasibility. The importance of investigators matching an instrument to the specific purpose and question being asked in conducting the trial was also emphasised (Fitzpatrick et al., 1998, Dawson et al., 2010). Their value lies in providing a patient's perspective on the benefits of treatment beyond the markers of disease measured by clinicians, and to provide information about the outcomes of greatest importance to patients. This may include signs and symptoms (impairments), behaviours, abilities (functional status) and general perceptions of wellbeing. They are also a means of determining satisfaction with treatment, general or health related quality of life, adherence to treatment, side-effects and adverse effects of treatment. Finally, they can complement clinical outcome measures, in accordance with the biopsychosocial model of health.

Health status and Quality of Life (QoL) outcomes are important PROMS, and although they may be reported as QoL, HRQoL, health status, functional status and wellbeing, each has a specific definition and records different things. For example, HRQoL measures personal health status, whereas QoL is an evaluation of all aspects of life. It is also important for HRQoL to be recorded by the person affected, as only they are able to report subjectively on their symptoms and quality of life, in contrast to the objective signs observed by clinicians (Black and Jenkinson, 2009).

However, whilst they are useful instruments for assessing the subjective experience of health, disease and treatment, PROMS may not capture the whole picture of patients' perceptions of health because they use closed questions, and qualitative interviews with open questions may measure this better. Only reliable, validated and standardized questionnaires or interview schedules should be used and should be tested in the target population.
The importance of PROMS in dentistry in the UK has been recognized by the inclusion of the Oral Health Impact Profile questionnaire (OHIP-14) in the Adult Oral Health Survey (Bernabe and Marcenes, 2010).

2.2.2 Quality of Life and Health Related Quality of Life

Quality of life has been defined as *"An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns"* (Kuyken et al., 1995). A further definition is "*Personal well-being or satisfaction with life, as well as physical and material well-being, relations with other people, social, communal, civic activities, personal development and fulfilment, positive mental health, a degree of goodness, and is related to health"* (Eriksson and Lindstrom, 2007).

Whilst there are many definitions of health-related quality of life (HRQoL), they all include elements of health and aspects of daily life that might be influenced by health conditions. The definition of HRQoL by The National Institute of

Clinical Excellence (NICE) is a revised wording of the WHO definition, and is simply "*A combination of a person's physical, mental and social well-being; not merely the absence of disease*" (NICE). However, a definition that encompasses these elements more broadly is: *"HRQoL is multidimensional, combining physical health, perceptions of health, and/or disability"* (Robinson et al., 2015).

The outcomes can span negative impacts such as the condition having an adverse effect on HRQoL to a positive impact, for example happiness. It is interesting to note, however, that diseases may not always be directly related to quality of life, and that people with disease do not necessarily have a poor quality of life. The impact appears to depend on the experiences and expectations, of the individuals affected (Carr et al., 2001), in addition to sociodemographic aspects and psychological factors. The relationships between clinical status and health outcomes, such as functional status and quality of life, can be explored using a model developed by Wilson and Cleary (Wilson and Cleary, 1995). HRQoL, and specifically the Wilson and Cleary model (Section 2.4.3) operationalises Engels' biopsychosocial model.

2.2.3 Oral Health Related Quality of Life (OHRQoL)

OHRQoL has been most recently defined as "*The impact of oral disease and disorders on aspects of everyday life that a patient or person values, that are of sufficient magnitude, in terms of frequency, severity, or duration to affect their experience and perception of their life overall*" (Locker and Allen, 2007). There are other definitions, though this is the one adopted here.

2.2.4 Instruments for Measuring OHRQoL

The most commonly used instrument to measure OHRQoL is the Oral Health Impact Profile (Slade and Spencer, 1994), which has been modified and validated for different populations, and for a range of oral conditions including the impact of periodontal disease and its treatment on the OHRQoL (Ng and Leung, 2006, Brauchle et al., 2013, Ohrn and Jonsson, 2012). It has been recognized that subjective assessments are likely to be subject to error, and therefore attempts are made to minimize these by screening individual items, determining the consistency of responses to items and assessing the whole scale by correlating scores against other related variables (Robinson et al., 2015).

OHRQoL measures were largely based on a conceptual framework originating from the International Classification of Impairments, Disabilities and Handicaps developed by WHO (Badley, 1987), and subsequently modified to be applicable for dentistry (Locker, 1988). Clinical studies using instruments based on this provide new information about treatments, and may provide insights about the psychological factors affecting clinical and OHRQoL outcomes.

The selection of an appropriate OHRQoL instrument should be determined by the purpose of collecting the health-related quality of life information for the study, the qualities required of the measure and its intended use (Robinson, 2016). This may be to describe, discriminative or evaluative HRQoL information. Longitudinal studies of interventions also require properties such as responsiveness and interpretability, in contrast to the requirements for cross-sectional studies (Skaret et al., 2004). The most commonly used instruments for measuring OHRQoL in studies of periodontal disease or periodontal treatment in adults are shown in Table 1.

Table 1 OHRQoL instruments commonly used in periodontal research (modified and updated from Skaret et al. 2004).

Instrument	Abbreviation	Original reference	Items and main domains	Recommended use	Studies used
Oral Health Impact Profile -14	OHIP-14	(Slade, 1997)	14 items 7 domains: functional limitation, physical pain, psycho-logical discomfort, physical disability, psycho-logical disability, social disability and handicap	Intervention Evaluation research Cross-sectional population study	(Masood et al., 2019) (Kato et al., 2018) (Masood et al., 2017) (Wellapuli and Ekanayake, 2016) (Lu et al., 2015) (Jansson et al., 2014) (Douglas de Oliveira et al., 2013) (Ohrn and Jonsson, 2012) (Bernabe and Marcenes, 2010) (Jowett et al., 2009)
UK Oral Health-Related Quality of Life Measure	OHQoL-UK	(McGrath and Bedi, 2001)	16 items key areas: Comfort, breath odour, general health, eating, appearance, speech, relax and sleep, smiling/laughing, confidence, mood, carefree manner, personality, work, social life, finances, romantic relations	Intervention Cross-sectional population research	(Jonsson and Ohrn, 2014) (Eltas and Uslu, 2013) (Durham et al., 2013, Nagarajan and Chandra, 2012) (Aslund et al., 2008b) (Needleman et al., 2004)

Table 1 OHRQoL instruments commonly used in periodontal research (modified and updated from Skaret et al. 2004) (continued).

Instrument	Abbreviation	Original reference	Items and main domains	Recommended use	Studies used
Oral Impacts on Daily Performances	OIDP	Adulyanon & Sheiham 1997	8 frequency, 8 severity items 1 domain: Disability in terms of physical, psychological and social aspects of daily performances	Cross-sectional population study	(Leao et al., 2015) (Yamashita et al., 2015) (Prado et al., 2015) (Acharya and Pentapati, 2012) (Pereira et al., 2012) (Costa et al., 2011) (Pereira et al., 2011) (Tsakos et al., 2010) (Wandera et al., 2009)
Geriatric (General) Oral Health Assessment Index	GOHAI	(Atchison and Dolan, 1990)	12 items covering Physical function Psychological function Pain and discomfort	Cross-sectional population study	(Jonsson and Ohrn, 2014) (Cornejo et al., 2013) (Ohrn and Jonsson, 2012) (Zaitsu et al., 2011) (Zhao et al., 2011a) (Daradkeh and Khader, 2008) (Ozcelik et al., 2007)

2.2.5 OHIP-14

The OHIP-14 is by far the most commonly used instrument (see also Sections 2.5.3–2.5.6). The original instrument (OHIP-49) developed by Slade and Spencer (1994) included 49 items to quantify the burden of illness, and to measure the effectiveness of health services in reducing this. However, the form was subsequently shortened to include 14 questions (Slade, 1997) and has been used to measure the effect of oral conditions on OHRQoL including periodontal health (Slade, 1997).

The OHIP-14 is based on Locker's model of health, which is in turn based on the WHO model of disease-impairment-disability-handicap and focuses on the burden of disease (Locker, 1988). It includes questions about oral function, oral discomfort/pain, psychological disability, physical, psychological and social effects of the oral condition on the individual completing the form. It may be used to determine impacts attributable to specific oral conditions, recorded as adverse outcomes. The frequency that each of the 14 items affect individuals over a reference period are answered on a 5 point Likert scale coded from "very often" (5) to "never" (0), and a further option of "don't know" may be included. A threshold for scoring the number of impacts is also set, for example "fairly often". The total score is calculated for the whole questionnaire. The method of administration is important as self-completion yielded significantly higher scores compared with telephone interviews (Desai et al., 2014).

The items of the OHIP-14 may divided into 7 domains (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, handicap) (Slade, 1997), or 3 dimensions (psychosocial, pain-discomfort and functional limitation impacts) (Montero et al., 2010). This is considered further in Section 2.2.9.

The OHIP-14 has been validated for measuring OHRQoL in dental hospitals (Robinson et al., 2003, Locker et al., 2001). Table 2 summarizes a critique of OHIP-14 and OIDP instruments (Robinson et al., 2003). It is apparent that there are a number of features that make the OHIP-14 suitable for measuring

OHRQoL. These include types of impacts including psychological and correlation with self-perceived oral health, the superior face content, criterion and construct validities, internal consistency, ease of completion and score calculation.

More recently, the cross-cultural equivalence in translations of OHIP has been reviewed (MacEntee and Brondani, 2016). The breadth of use and translation of the OHIP-14 would suggest this instrument to be appropriate for use in studies of OHRQoL in relation to periodontal treatment in adults. The OHIP-14 has been suggested the most appropriate instrument for detecting psychosocial impacts (Locker, 1988).

Disadvantages of this instrument include a pronounced floor effect that limits ability to discriminate between low level/infrequent/short-duration impacts, which may limit responsiveness to change following treatment. It is also limited in capturing the global concept of health and well-being, as it only measures negative effects of oral health. In common with other instruments, cultural differences may affect the interpretation of items by participants in studies. Furthermore, only the frequency of functional and psychological impacts are measured not the meaning or significance of these (Locker and Allen, 2007), and it is acknowledged that items measuring oral symptoms may not indicate the underlying concepts (Kieffer et al., 2009). Table 2 summarizes the key aspects of the OHIP-14.

2.2.6 OIDP

The Oral Impact on Daily Performance (OIDP) focuses on ultimate impacts of oral health on the performance of daily activities (Adulyanon and Sheiham, 1997). A score is assigned for the frequency and severity of each oral impact and a total is calculated which gives an overall measure of the oral impact on daily performances. Whilst the OIDP performs adequately in many respects, it has a number of limitations and drawbacks, including being complex to complete and having a low completion rate as a consequence. It also has weak face validity and is an insensitive measure of OHRQoL with consequent profound floor effects. However, the OIDP has been validated and adapted for use in a range of settings, but has not been routinely used directly in investigations of the impact of periodontal disease.

2.2.7 GOHAI

The General Oral Health Assessment Index (GOHAI) (previously known as the Geriatric Oral Health Assessment Index) is not as widely a used instrument in the periodontal literature, but it does link self-reported oral function problems, clinical measures of oral health and socio-economic status (Atchison and Dolan, 1990). A 5 point Likert scale (never-always) is used with 3 items reversed, which may cause confusion. Greater weighting is given to oral function and pain/discomfort, and items address trouble chewing or biting food, swallowing and speaking.

The GOHAI has good construct validity and a simple scoring system and has been used in a number of cross-sectional population studies (Table 1). However, OHIP-14 attaches greater weighting to psychological and behavioural outcomes, and is better at detecting psychosocial impacts. It was also found to have better internal consistency than the GOHAI (Locker et al., 2001). The GOHAI has also been validated across wide age ranges and in different ethnic groups (Atchison et al., 1998, Wong et al., 2002).

2.2.8 OHQoL-UK

The OHQoL-UK has been widely used worldwide. It was originally developed from a large random sample of the UK population, and statements are phrased to allow both positive and negative responses (bidirectional) about the effect of oral health on specific aspects of daily lives. It was developed as an alternative to other instruments, which were criticized as being developed from and reflecting the views of certain groups, such as older people or dentally ill patients (GOHAI), and that failed to specifically ask how oral health affected their quality of life (McGrath and Bedi, 2001). A lack of theoretical underpinning in other models was also criticized. In addition, other instruments including OHIP and OIDP were criticized for only measuring negative impacts and for measuring only the prevalence of effects, not their importance. In common with other instruments, weightings were not recommended, as they do not capture individual ratings of the impact of effects, but ascribe set weights that have been generated from small non-random samples. Consequently, they do not improve the psychometric properties.

The OHQoL-UK is based on the more recent WHO model of health that considers structure-function-activity-participation, focusing on disease and health states (positive and negative) (WHO, 2001). It has 16 items (McGrath and Bedi, 2002) about the impact of oral health on the quality of life over the past year in 3 areas; physical, social and psychological functioning. In addition, socio-demographic information, self-reported oral health status and self-rating of oral health are recorded (McGrath and Bedi, 2001, McGrath and Bedi, 2003). Each item is given a score from 1 = very bad to 5 = very good and an equal weighting is used.

It has good discriminative validity and can distinguish between patients with periodontitis and periodontal health. The OHQoL-UK has a broader approach than GOHAI, focusing on well-being and impact of oral health on a person's daily life, identifying the positive effects of oral conditions, and not just the frequency of the problem.

However, the assessment of positive effects of oral health has been criticized; acceptable measures of this construct being unclear (Locker and Gibson, 2006). In addition, a question on finance is included in the OHQoL-UK, which might also trigger negative responses in patients paying for their treatment. Table 2 summarizes key points comparing instruments developed to measure OHRQoL, including some of the disadvantages associated with all three instruments.

2.2.9 The Selection of an Instrument to Measure OHRQoL

The commonly used instruments used to measure OHRQoL were reviewed in Section 2.2.4-2.2.8. All these measures are generic and have some limitations when used to measure the impacts of a specific condition. Whilst each has advantages and disadvantages, it is concluded that the OHIP-14 is the most measure to use in the present investigation on periodontal treatment.

The main limitations of OHIP-14 include being a generic measure of OHRQoL and having the potential for a floor effect in a longitudinal study. However, there are a number of reasons why it was chosen as the most appropriate questionnaire for OHRQoL in the present study. Firstly, OHIP-14 has been suggested as the most appropriate instrument for detecting psychosocial impacts (Locker, 1988), which is important in this study. The OHIP-14 also has suitable psychometric properties, having a good correlation with self-perceived oral health, good face content, criterion and construct validities, and internal consistency. The scores can be summed easily to determine a mean total score and a score for each dimension or domain. Importantly, the frequency of impacts can also be calculated to determine how often an item impacts on OHRQoL. Furthermore, despite the risk of a floor effect, OHIP-14 is reported to be responsive to change in OHRQoL following treatment. Small-to-moderate effect sizes (0.27–0.34) anticipated in longitudinal studies of periodontal treatment have been reported (Locker et al., 2004). OHIP-14 is also easy for participants to self-complete and has been validated for measuring OHRQoL in dental hospitals (the setting of the present study) (Robinson et al., 2003, Locker et al., 2001). Finally, OHIP-14 is the most widely used instrument for measuring the impact of periodontal disease on OHRQoL, and using it in the present study facilitates a comparison of the findings.

OHRQoL is generally considered to be a multi-factorial construct and the OHIP-14 is commonly used to measure impacts in 7 domains (Slade, 1997), although some authors have considered OHRQoL to be a single construct (Atchison and Dolan, 1990, McGrath and Bedi, 2001). In order to determine the dimensional structure of OHRQoL Montero et al. (2010) investigated the underlying dimensions using Exploratory Factor Analysis, and following Confirmatory Factor Analysis suggested that it could be considered as a three-dimensional construct comprising psychosocial, pain-discomfort and functional limitation dimensions. This approach has recently been used with orthodontic patients to confirm the existence of the same three dimensions of OHRQoL, and investigate the impact of gender age on each (Alqefari et al., 2019). Taking into account the focus of the present research on periodontal treatment and the impact of psychological factors on OHRQoL, using the same three-dimensions seems appropriate. Furthermore, periodontitis is also expected to have impacts in the pain-dysfunction and functional dimensions. However, whilst an analysis of the multidimensional structure of OHRQoL provides insight into the how periodontal disease impacts on particular aspects of everyday life and is of interest, OHIP-14 total scores are used for both SEM and LGCM (see chapters 3 and 4). Thus, the number of dimensions or domains used for the analysis for the primary objective of this research, which is to determine the OHRQoL and clinical changes after periodontal treatment, does not affect analysis in the secondary objectives which are to determine the predictors of both OHRQoL and change in OHRQoL after treatment using SEM and LGCM. Furthermore, comparisons can be made between the three dimensions and seven domains of OHIP-14 reported in different studies. The same items remain for functional limitation when either seven domains or three dimensions of OHIP-14 are used. The dimension of pain-discomfort includes the physical pain and physical disability domains. The remaining domains of psychological discomfort, psychological disability, social disability and handicap are included in the psychosocial domain.

Table 2 Summary of OHIP-14, OIDP, GOHAI, OHQoL-UK

(Adulyanon and Sheiham, 1997, Carr et al., 2001, McGrath and Bedi, 2001, Locker et al., 2001, Hegarty et al., 2002, Robinson et al., 2003, McGrath and Bedi, 2003, Locker et al., 2004, Ohrn and Jonsson, 2012, Jonsson and Ohrn, 2014, Popovic et al., 2015, Barkokebas et al., 2015).

Instrument	OHIP-14	OIDP	GOHAI	OHQoL-UK
Model	Locker's (Locker, 1988)	Locker's (Locker, 1988)	Locker's (Locker, 1988)	Most recent WHO (WHO, 2001)
Measures	7 dimensions of impact Variety of types of impacts including psychosocial Corresponds better to self-perceived oral health than OIDP	8 daily performance at a functional level Focuses on severe / ultimate impacts Captures full scope of oral health as perceived by individuals	12 –items Oral functional problems, pain and discomfort Psychosocial impacts associated with oral disease Better at detecting dysfunction and pain impacts	16 items Comfort, breath odour, general health, eating, appearance, speech, relax and sleep, smiling/ laughing, confidence, mood, carefree manner, personality, work, social life, finances, romantic relations
Intended use	Long-term impacts	Long-term impacts	Long-term impacts (3 months – 1 year)	Interventional Cross-sectional Population research Impacts over past year
Completion	Self	Complex and may need assistance Lower completion rate	Self	Self
Format	1 page	8 pages	1 page	1 page
Threshold	Set for reference period and response	Set for reference period and response	Set for reference period and response	-
Face validity	Good	Weak (filtered and contingency questions)	Acceptable	Good
Content validity	Reasonable Focuses on impact of same oral problem at several stages of model	Reasonable Only measures impact at functional level	-	-
Internal consistency (Cronbach's alpha)	0.76 - 0.91	0.65 - 0.88	0.75 – 0.88	0.93 – 0.96

Table 2 Summary of OHIP-14, OIDP, GOHAI, OHQoL-UK

(Adulyanon and Sheiham, 1997, Carr et al., 2001, McGrath and Bedi, 2001, Locker et al., 2001, Hegarty et al., 2002, Robinson et al., 2003, McGrath and Bedi, 2003, Locker et al., 2004, Ohrn and Jonsson, 2012, Jonsson and Ohrn, 2014, Popovic et al., 2015, Barkokebas et al., 2015) (continued).

Instrument	OHIP-14	OIDP	GOHAI	OHQoL-UK
Criterion validity	Significant, but better than OIDP Correlates closely Global Oral Health Rating	Significant Correlates less well with Global Health Rating	-	Differentiates between people who rated oral health differently
Construct validity	Number of impacts and total score related to presence of disease Inversely related to age	Number of impacts related to presence of disease, but total score is not. May be related to method of calculation Inversely related to age	Good	Good Differentiates between people of different oral health status in terms of self-reported number of teeth possessed and denture status Scores associated with age group, employment status and ethnic background
Score calculation	Can calculate: Total score Prevalence Extent Validity not compromised More suitable for questionnaire based research than OIDP	Scoring system calculates sum of products or severity and quantity of each dimension	Additive method Range 0-60 Higher score = poorer OHRQoL, or count number of items with specified response	Sum of item responses gives overall OHQoL-UK(W) score (16-144)
Disadvantages	Floor effect limits ability to discriminate between low level/infrequent/short-duration impacts which may limit responsiveness to changes in oral health following treatment	Profound floor effects limit ability to discriminate low level/infrequent/short-duration impacts which may limit responsiveness to changes in oral health following treatment	Less suited to detecting psychosocial impacts Measures frequency of functional and psychological impacts, but not meaning or significance	Positive effects of oral health has been criticized; acceptable measures of this construct being as yet unclear (Locker and Gibson, 2006). Question of finance included which might also trigger negative responses in patients paying for their treatment

2.3 Application of OHRQoL measures

OHRQoL measures have a range of applications, which are summarized in Table 3 (Robinson et al., 2015). Political uses include planning public health policies and resource allocations. Personal and social impacts are valuable indicators for planning health care, and OHRQoL data may have greater meaning for politicians than clinical data. For example, the effect of periodontal disease as captured by the effects on daily life may have more meaning than measurements of pocket depth and attachment levels. OHRQoL data is useful clinically in screening, monitoring and evaluating outcomes, both at a patient and organization level. Public health uses of OHRQoL data are a scaling up of clinical applications to determine the needs assessment, prioritization of care, to plan and evaluate health services. Other uses include research, for example to evaluate the outcomes of healthcare interventions and theoretical uses, for example to explore different models of health. The latter represents one of the objectives of this research.

Table 3 Potential uses of oral health-related quality of life measures (Robinson et al., 2015). Reproduced with permission.

Field of work	**Potential uses in health field/oral health-related quality of life**
Political	Planning public health policy Planning in resource allocation
Clinical uses	Communication tools Commissioning programs of care Evaluating interventions Assessing the outcomes of new treatments Aiding understanding of the patient’s point of view Screening Identifying and prioritizing patient problems and preferences Monitoring and evaluating individual patient care Identifying which patients have more benefit from treatment Involving patients’ perspectives in decision making and self-care Predicting outcomes in order to provide appropriate care Clinical audit
Public health	Describing and monitoring illness in populations Planning, monitoring, and evaluating services Needs assessment and prioritization Encouraging greater lay participation in health care
Research	Evaluating outcomes of health care interventions Elucidating the relationships between different aspects of health
Theoretical	Exploring models of health Describing factors influential to health

Similar uses of OHRQoL measures were also reported by Sicho and Broder (2011). In addition, they emphasized the importance of OHRQoL measures in relation to research and healthcare provision that has increasingly and justifiably become more patient-centred. However, it was also noted that disease and population specific measures, together with the use of instruments with treatment responsiveness are necessary, in order to be used effectively for evaluation purposes. This latter point emphasizes that selection of appropriate instruments is essential to investigate OHRQoL in periodontal diseases according to the population being studied.

2.4 The Value of Theoretical Models

The adoption of theoretical models in research is valuable for a number of reasons:

- Providing a framework of understanding how factors of importance in determining the outcome measure are related in the model, and enabling the exploration of explicit pathways.
- Ensuring research is based on an explicit and existing understanding.
- Guiding the design of research, selection of variables and analytical approach.
- Guiding analysis (ie arrows represent possible hypotheses) to avoid p hacking and statistical type 1 error.
- Guiding interpretation of results.

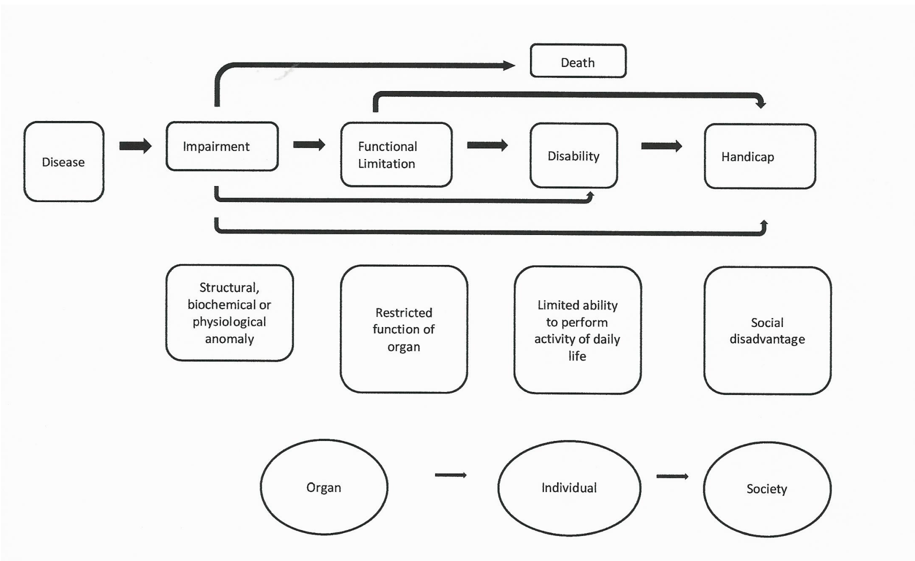
2.4.1 Oral Health Related Quality of Life Research and the use of Theoretical models

In OHRQoL research, two models have been commonly used, namely: Locker's model of oral health (Locker, 1988) and Wilson and Cleary's model (Wilson and Cleary, 1995) that links clinical variables to quality of life measures. The value of theoretical models and each of these models will now be discussed.

2.4.2 Locker’s Model

Locker’s conceptual model of oral health accounts for the adverse effects of oral conditions such as pain, discomfort, speaking, eating and smiling on aspects of life. This model represents a change from a biomedical to a biopsychosocial perspective, and has led to the development of the OHIP and OIDP questionnaires to measure OHRQoL. However, individual characteristics and environmental factors likely to be important determinants of health were not included in the original model, and OHRQoL is not accounted for. Figure 1 illustrates Locker’s model and gives definitions for each of the stages.

Figure 1 Locker’s model of oral health. Redrawn with permission (Robinson et al., 2003).



2.4.3 Wilson and Cleary Model

Wilson and Cleary (1995) found that none of the existing conceptual models included the full range of variables in QoL assessments, and had not specified links between biological, individual, environmental and other factors. They addressed these shortcomings by integrating the biomedical and psychosocial models, and in effect operationalised the psychosocial model in terms of the consequences of disease (Figure 2). Consequently, in this research the Wilson and Cleary model was adopted for selecting relevant variables and investigating the relationships between these, the components of the models, and in particular OHRQoL. This multi-dimensional model measures health in a continuum of increasing biological, social and psychological complexity, with biological measures at one end and the more complex measures of physical functioning and general health perceptions leading to overall QoL at the other. The dominant causal associations are made explicit, but the arrows could also indicate reciprocal relationships between variables and others could exist that are not shown. The model has 5 levels: biological and physiological factors, symptoms, functioning, general health perceptions and overall quality of life. Biological and physiological factors include cellular function, organs and organ systems. For example, patients with chronic periodontitis have inflamed periodontal tissues, loss of clinical attachment and periodontal pocket formation.

Symptoms are the perception of abnormal physical, emotional or cognitive state, and so here the focus moves from cells and organs to the individual. Symptoms may be physical (bleeding gums), psychophysical (fear, worry or anxiety about oral health) or psychological. Wilson and Cleary note that symptoms are not always related to the extent of biological or physical factors and may lack an organic cause. Accordingly, treatment aimed at treating only biomedical factors may not always relieve symptoms.

Functioning refers to the ability to perform a task, for example oral hygiene. Function is determined by symptom status, patient specific factors or the social environment. This level comprises 4 domains of physical, social, role and psychological function. Wilson and Cleary suggest that symptoms, biological and physiological variables correlate with functioning, but additional factors may need to be considered when these do not explain functional impairment.

General health perceptions represent an integration of all the health concepts and other factors such as mental health. The functional status is associated with general health perceptions and is also related to biological and physiological factors.

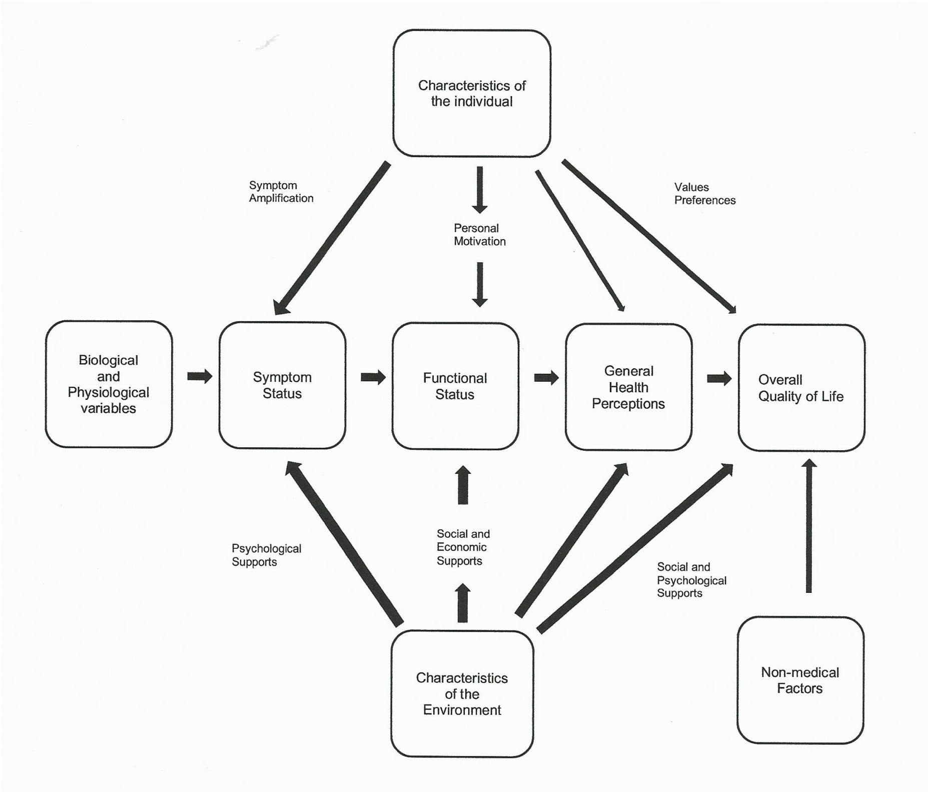
Overall quality of life is influenced by health-related factors including psychological, the functional status and general health perceptions, but also by non-medical factors. Thus, overall QoL represents a wide range of experiences, circumstances and feelings. It represents a summary measure of QoL and includes a wide range of experiences, circumstances and feelings. Wilson and Cleary point out that general measures of life satisfaction and happiness are not strongly related to objective life circumstances. Low levels of functional status are not necessarily related to lower levels of satisfaction. Furthermore, changing expectations and aspirations may result in changes in life satisfaction as circumstances change. Preferences and values are also important at several points in the model, especially general health perceptions and overall QoL, and these may change. Finally, the correlation between the value for particular states of health and measures of health status may only be modest.

Individual factors are the traits or states specific to the individual and include demographic factors (age, gender, marital status, ethnicity), their developmental status, psychological factors (knowledge, beliefs, attitudes, anxiety, fear) and biological factors (BMI, family history linked to genetic disease or risk) (Ferrans et al., 2005). Psychological factors may include self-esteem, self-efficacy, locus of control, sense of coherence, which may relate to each stage of the model.

Environmental factors include socioeconomic factors that may influence symptoms, functioning, general health perceptions and thereby HRQoL via access to health care, exposure to risk factors and psychological factors such as coping strategies and social support. As well as individual socioeconomic factors (income, education and occupation), environmental factors may include inter-personal or social influences (family, friends, health care providers), and physical factors (home, neighbourhood, workplace) (Ferrans et al., 2005).

Figure 2 The Wilson and Cleary model (1995).

< Biomedical model> <---------------------------Psychosocial model-------------------------------→



Traditionally, the analysis to investigate the relationship between these factors might be undertaken using regression models (McNamee, 2005, Schneider et al., 2010). However, more recently structural equation modelling (SEM) has allowed simultaneous testing of direct and indirect relationships between variables (Kline, 2016, Rebelo et al., 2016, Holde et al., 2017, Morrison et al., 2017). This enables a better representation of biological, psychological and social factors in the biopsychosocial model, which may highlight potentially important pathways that could be investigated further to understand the determinants of oral disease and OHRQoL.

The impact of periodontal disease on OHRQoL may be measured at various time points during the journey from diagnosis, treatment and follow-up. This review will now focus on each of the factors within the Wilson and Cleary model relevant to the proposed research.

2.5 Periodontal Diseases and OHRQoL

This section will review the current evidence of the impact of chronic periodontitis on oral health related quality of life (OHRQoL), and of its treatment in adults. The objectives are to determine the current evidence on the link between periodontal disease and OHRQoL, and the effect of periodontal therapy on OHRQoL in adults.

Epidemiological experimental and observational studies were included, and the quality of evidence was appraised using tools according to the study design, and also the Oxford Centre for Evidence Based Medicine Levels of Evidence.

2.5.1 Search strategy

Electronic searches were undertaken using MEDLINE and Web of Science. For MEDLINE, an advanced search was undertaken using the keywords “periodontal” and also “oral health related quality of life”. The following search strategy was used: MeSH heading: Periodontal diseases. Scope: Pathological processes involving the periodontium including the gum (gingiva), the alveolar bone (alveolar process), the dental cementum, and the periodontal ligament.
Year of entry**:** Periodontal disease 1963-64. References: disease, periodontal; diseases, periodontal; parodontoses; parodontosis; periodontal disease; periodontal diseases; pyorrhea alveolaris. Subheadings of classification, diagnosis, epidemiology, aetiology, surgery and therapy were selected. The search selection selected was “OR”. For oral health related quality of life, subject headings were quality of life “AND” oral health. Combining searches resulted in 177 articles.

Searches were also performed using Web of Science as this is broader than MEDLINE, but includes MEDLINE amongst its databases. Other databases included in Web of Science were BIOSIS Citation Index, BIOSIS Previews, Current Contents Connect, Data Citation Index, KCL – Korean Journal Databases. Searches were undertaken up to January 2020. Individual searches of topic terms were undertaken in the basic search option and OR used to separate the term, for example periodontal OR periodontitis. The phrase "oral health related quality of life" OR "OHRQoL" were also searched. Timespan=All years. Search language=Auto. Searches of each term or phrase were combined resulting in 276 articles.

The search results were examined by the author for relevance, by reading the titles and abstracts. The reference list of identified papers was also screened to identify any further relevant papers.

Eligibility criteria

All sources were included that involved patients with periodontal disease or treatment in adolescents (>12 years of age) and adults and elderly people (no upper age limit). The focus of interest, however, was chronic periodontitis. The criteria for the diagnosis of chronic periodontitis followed Armitage (1999):

- Periodontal destruction (pocketing, loss of clinical attachment, gingival recession) is consistent with presence of local factors such as the dental biofilm and dental calculus.
- Most prevalent in adults, but can occur in adolescents and children.
- Sub-gingival calculus is a frequent finding.
- Slow to moderate progression, but may have bursts of rapid disease progression.
- Can be associated with local predisposing factors (tooth related or iatrogenic)
- Can be modified and/or associated with systemic disease, eg diabetes.
- Can be modified by other factors such as cigarette smoking and/or emotional stress.
- Associated with a variable microbial pattern.

The sources included were observational (cross-sectional, cohort, case-series and prospective cohort studies) and interventional (controlled and uncontrolled clinical trials) that assessed periodontal disease clinically, and OHRQoL in the same participants. All forms of non-surgical and surgical periodontal treatment were included, and the outcome of interest was the impact of periodontal disease and/or periodontal therapy on OHRQoL.

Virtually all studies used a validated measure of QoL or OHRQoL, and where this was not the case, this limitation was noted.

Exclusion criteria

Studies that included children, where the diagnosis was clearly aggressive periodontitis, that focussed on specific medical conditions, medication or pregnancy were excluded. Studies comparing OHRQoL instruments and where psychological factors were the main focus of investigation were also excluded.

2.5.2 Quality assessment

The characteristics of selected studies were presented in Table 4 to Table 7. Quality appraisal of clinical studies is important in order to be able to consider their validity. In addition, identification of the shortcomings of previous studies is useful when designing future investigations. Therefore, the quality of each study was evaluated using an appropriate appraisal tool (Zeng et al., 2015). Where the study design was not stated, the NICE guidelines algorithm for classifying quantitative study designs was used to determine study design (NICE, 2012).

Adaptions of the Newcastle-Ottawa Quality Assessment Scale were used for cross-sectional and cohort studies (http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp), an adapted checklist of the Institute of Health Economics Alberta Canada for case-series (Moga et al., 2012), and the quality of randomized trials was assessed using the Cochrane risk of bias tool (Higgins et al., 2011). The AMSTAR measurement tool was used to assess the methodological quality of systematic reviews (Shea et al., 2007). The criteria for each are in Appendix 4. The appraisals are presented in the next section, and the overall level of evidence was assessed using the Oxford Centre for Evidence-based Medicine- Levels of Evidence (Howick et al., 2011).

2.5.3 Cross-sectional studies

The thirty-two cross-sectional studies (Table 4) reported that periodontal disease adversely impacts on OHRQoL, which according to the diagnostic criteria or participants' age range is likely to be largely chronic periodontitis. No association between periodontal disease and OHRQoL was reported in 3 studies (Zaitsu et al., 2011, Masood et al., 2017, Kato et al., 2018). There is variability in the severity of periodontal disease included in these studies and in some the severity of disease is unclear (Meusel et al., 2015). Three studies also included younger individuals (14-16 years of age) (Bernabe and Marcenes, 2010, Zanatta et al., 2012, Masood et al., 2019), and the age of participants was not stated in one (Needleman et al., 2004).

Poorer OHRQoL appears to be associated with greater severity of disease assessed by clinical examination and also radiographic evaluation of alveolar bone support (Jansson et al., 2014, Meusel et al., 2015, Karaaslan and Dikilitas, 2019, Ustaoglu et al., 2019). Worse OHRQoL and perceived oral health has been related to the number of teeth affected by periodontal pocketing >5mm (Cunha-Cruz et al., 2007), and with CAL > 3mm (Ng and Leung, 2006). The main negative impacts reported are pain, psychological discomfort, psychosocial impacts and functional impairment (Durham et al., 2013, Borges et al., 2013, Fotedar et al., 2014, Llanos et al., 2018, El Sayed et al., 2019). However, other oral factors may also impact adversely on OHRQoL including the number of missing teeth, prostheses and xerostomia, and have a greater impact on OHRQoL than periodontal disease (Thomson et al., 2006, Aslund et al., 2008b).

The OHIP-14 was the most commonly used tool (22 studies). The OHQoL-UK was used in two studies (Needleman et al., 2004, Aslund et al., 2008b). Others used the Oral Impact of Daily Performance (Anderson et al., 2010, Srisilapanan and Sheiham, 2001), The General Oral Health Assessment Index (Swoboda et al., 2006, Zhao et al., 2011, Zaitsu et al., 2011). The OHIP-49 (Durham et al., 2013, El Sayed et al., 2019) and an unpublished OHRQoL questionnaire (Cunha-Cruz et al., 2007).

Almost all studies included a full periodontal examination, except a few that used a method for screening the periodontal condition such as the Basic Periodontal Examination (BPE) (Aslund et al., 2008b) or the Community Periodontal Index (CPI) (Montero-Martin et al., 2009, Fotedar et al., 2014). Some included radiographs to assess of the periodontal condition (Jansson et al. 2014). Tooth loss and dental caries were also recorded in 2 studies (Lawrence et al., 2008, Ustaoglu et al., 2019). One study used a non-validated measure of gingival enlargement (Zanatta et al., 2012). A clinical full periodontal examination is regarded as the gold standard for assessing the periodontal condition in patients with chronic periodontitis. The BPE and CPI are screening tools, for example the BPE considers periodontal disease is present when there is at least one periodontal pocket in the sextant being examined (probing depth ≥ 3.5mm using a WHO probe to indicate a BPE score of 3). It is also noteworthy that in almost half of studies have no information about clinical calibration.

Whilst confounders of gender, age, SES, education and smoking were accounted for in many studies, only single confounders (age) were recorded in several and were not included in the analysis in three (Needleman et al. 2004, Durham et al., 2013, Borges et al., 2013). Since all confounders may affect both clinical and OHRQoL outcomes, it is important for these to be accounted for in well-designed studies.

The quality of studies was variable and full details are in Appendix 4 (Table 53). The strongest areas in cross-sectional studies were ascertainment of exposure, control of confounders, assessment of outcome, statistical tests and ascertainment of outcome measure using a validated measurement tool. The weakest areas were use of a convenience sample, the sample size not being justified, unsatisfactory response rate for non-respondents, unsatisfactory comparability between respondents and non-respondents or no description of the response rate. However, the studies having higher methodological quality support the overall findings that OHRQoL is negatively impacted on by periodontal disease.

Eight (25%) studies fulfilled 90% of the Newcastle-Ottawa Scale criteria (Lawrence et al., 2008, Bernabe and Marcenes, 2010, Zhao et al., 2011b, Wellapuli and Ekanayake, 2016, Masood et al., 2017, He et al., 2018, Levin et al., 2018, Masood et al., 2019). Fourteen (48%) fulfilled 70-80% (Srisilapanan and Sheiham, 2001, Swoboda et al., 2006, Ng and Leung, 2006, Andersson et al., 2010, Zaitsu et al., 2011, Al Habashneh et al., 2012, Palma et al., 2013, Jansson et al., 2014, Fotedar et al., 2014, Sonnenschein et al., 2018, Kato et al., 2018, Karaaslan and Dikilitas, 2019, Ustaoglu et al., 2019, El Sayed et al., 2019), and (31%) fulfilled 40- 60% of them (Needleman et al., 2004, Cunha-Cruz et al., 2007, Aslund et al., 2008b, Aslund et al., 2008a, Montero-Martin et al., 2009, Cohen-Carneiro et al., 2010, Zanatta et al., 2012, Durham et al., 2013, Borges et al., 2013, Meusel et al., 2015, Llanos et al., 2018).

Table 4 Summary of cross-sectional studies. Study, participants recruited from dental clinics unless otherwise stated, age, sample size / sample size calculation, assessments, confounders, examiner calibration and main findings.

Study	Participants	Age (Years)	Sample size/ calculation	OHRQoL measure	Periodontal / other assessments	Confounders	Examiner calibration	Main findings
El Sayed et al. (2019)	Periodontal clinic patients.	66.79±9.4	Not stated. 64 completed.	OHIP-49 (German) at one interval 20 years after treatment.	Full mouth periodontal examination and plaque score. Medical history, smoking, education and marital status.	Accounted for in analysis.	Not stated	Good OHRQoL in long-term following periodontal treatment, especially domains of functional limitations and physical pain.
Masood et al. (2019)	Adult Dental Health Survey 2009 Periodontal pockets >5.5mm and <3.5mm	16 - ≥65	6378 (Nationally represent-ative sample).	OHIP-14	Probing depth, socio-demographic and SES status, self-reported and oral health status, smoking.	Adjusted for socio-demographic, SES, self-reported health, smoking, oral health status.	Yes.	Periodontal disease significantly associated with domains of OHRQoL.

Table 4 Summary of cross-sectional studies (continued).

Study	Participants	Age (Years)	Sample size/ calculation	OHRQoL measure	Periodontal / other assessments	Confounders	Examiner calibration	Main findings
Ustaoglu and Bulut (2019)	Periodontology clinic GAP* (100) GCP* (114) G* (109)	GAP 28.88±4.02 GCP 39.23±11.32 G 23.71±5.27	Calculated:100 each group.	OHIP-14 SF-36 (Turkish)	Full periodontal assessment. Plaque Index. Smoking. Age, gender, missing teeth.	No.	Yes.	GCP and GAP patients worse OHRQoL than G patients.
Karaaslan and Dikilitas (2019)	Dental clinic patients. Periodontitis categorized into stages I-IV.	18-40	99 (no sample size calculation).	OHIP-14 (Turkish)	Full mouth probing depths, LoA. Pittsburgh Sleep Quality Index.	Poor sleep quality had low OHRQoL.	Yes.	Higher stage (worse) periodontitis had poorer OHRQoL (total and domains).

Table 4 Summary of cross-sectional studies (continued).

Study	Participants	Age (Years)	Sample size/ calculation	OHRQoL measure	Periodontal / other assessments	Confounders	Examiner calibration	Main findings
Kato et al. (2018)	Randomly selected from cohort studies. Groups with pockets ≥6mm: none/ 1-<30%/ ≥30%.	≥70	804 (no sample size calculation).	OHIP-14 (Swedish)	Probing depths ≥6mm all teeth except 3rd molars. Pantomogram radiograph.	No.	Yes.	Periodontitis not associated with poor OHRQoL. Number of teeth significantly associated with poor OHRQoL.
Llanos et al (2018)	Dental School patients. Periodontitis groups: Generalized aggressive/ Localized aggressive/ Generalized chronic.	Mean (SD) GAP*: 30.79 (5.07) LAP: 25.56 (7.49) GCP: 50.1 (6.87)	52 completed: 33 GAP 9 LAP 10 GCP (no sample size calculation).	OHIP-14 (Brazilian)	Full mouth periodontal examination excluding 3rd molars.	No.	Trained, but not calibrated.	Periodontitis impacted on OHRQoL. GAP and GCP worse OHRQoL than LAP. Mainly physical pain and psycho-logical discomfort domains.

Table 4 Summary of cross-sectional studies (continued).

Study	Participants	Age (Years)	Sample size/ calculation	OHRQoL measure	Periodontal / other assessments	Confounders	Examiner calibration	Main findings
Sonnenschein et al. (2018)	Periodontology clinic patients at SPT at 5-year review. Chronic and aggressive periodontitis.	34-90	309 (adequate sample size reported).	OHIP-14 (German).	Full periodontal assessment. Plaque control. Risk assessment.	No.	Yes.	OHRQoL influenced by periodontal status. Better OHRQoL with regular SPT based on risk.
He, et al. (2018)	Chinese population-based. Multi-stage random sampling.	35-74	Calculated 370. 480 included.	OHIP-14 (Chinese).	Full mouth probing depths LoA**. Severity of periodontitis categorized.	Socio-demographic, other clinical variables and self-reported systemic problems.	Trained, but not calibrated.	Chronic periodontitis associated with poorer OHRQoL. Impairment correlated with severity of disease.

Table 4 Summary of cross-sectional studies (continued).

Study	Participants	Age (Years)	Sample size/ calculation	OHRQoL measure	Periodontal / other assessments	Confounders	Examiner calibration	Main findings
Levin, et al. (2018)	Consecutive clinic patients. Chronic periodontitis. Controls with no history of chronic periodontitis.	Perio-dontitis 38.8±7.8 Control: 37.7±4.3	Calculated at 141 in total (ratio 2:1). 99 chronic periodontitis 49 controls	OHIP-14 (Hebrew)	PPD, BoP, PI, bone loss. DMFT. Smoking, Corah's Dental Anxiety Scale.	Adjusted for demographic factors, smoking habits and caries experience.	Training and calibration.	Patients with chronic periodontitis had worse OHRQoL and higher anxiety levels than controls.
Masood et al. (2017)	Subset of elderly participants from UK Adult Dental Health Survey 2009.	≥65	1277 (adequate sample size).	OHIP-14.	Pocket ≥4mm, ≥1 gingival bleeding site. Socio-demographic General health, smoking, oral health status. PUFA***	Smoking, socio-demographic factors, socio-economic status, oral health status, general health. PUFA score.	Yes?	Impaired OHRQoL older adults active caries, ≥1 PUFA. Indices of periodontal health had no impact on OHRQoL.

Table 4 Summary of cross-sectional studies (continued).

Study	Participants	Age (Years)	Sample size/ calculation	OHRQoL measure	Periodontal / other assessments	Confounders	Examiner calibration	Main findings
Wellapuli and Ekanayake (2016)	Chronic periodontitis Sri Lanka Population. Cluster sampling.	35-60	Calculated 1,130. 1,400 recruited.	OHIP-14 (Sinhalese and Tamil)	Periodontal. Carious and missing teeth. Socio-demographic/ behavioural.	Chronic periodontitis independently associated with poor OHRQoL.	Yes.	OHRQoL deteriorates with severity of chronic periodontitis.
Meusel, et al. (2015)	Periodontitis Two groups: Mild /Moderate Severe.	30-58	100 (no sample size calculation).	OHIP-14 (Brazilian).	Full mouth periodontal examination.	Gender, age, marital status, SES, education, medications, smoking, oral health morbidity, use of dental services and oral hygiene habits.	Yes.	OHRQoL associated with disease severity. Severe periodontitis / low education / pronunciation difficulties.
Fotedar et al. (2014)	Outpatient dental college clinic.	21-64	291 sample size calculated. 351 completed study.	OHIP-14 (Interview using English/Hindi).	Community Periodontal Index. DMFT. Age, gender, SES.	Gender, SES, caries.	Yes.	Periodontal disease associate with functional, physical pain, psychosocial impacts.

Table 4 Summary of cross-sectional studies (continued).

Study	Participants	Age (Years)	Sample size/ calculation	OHRQoL measure	Periodontal / other assessments	Confounders	Examiner calibration	Main findings
Jansson, et al. (2014)	Randomly selected. Groups: Loss bone < 1/3 root length. ≥ 1/3 < 30% of teeth ≥ 1/3 ≥ 30% of teeth.	20-89	443 (no sample size calculation).	OHIP-14 (Swedish) Oral health questionnaire.	Full periodontal assessment, excluding third molars, radiographic assessment.	Gender, age, education, smoking.	Yes.	Reduced OHRQoL in group with ≥ one third bone loss of root length in ≥ 30% of teeth compared with other groups.
Palma et al. (2013)	Periodontics clinic.	47 ±13.5	147 calculated. 38 gingivitis 112 perio-dontitis completed.	OHIP-14 (Brazilian Portuguese)	Periodontal assessment. X-rays. SES demographic self-reported health predictors.	Controlled for in analysis.	Yes.	Worse periodontal status associated with worse OHRQoL.
Durham, et al. (2013)	Periodontology clinic. Consecutive patients.	47± 9	89 chronic periodontitis 89 age and gender matched without periodontitis. No power calculation.	OHIP-49 OHQoL-UK.	Full periodontal assessment.	Age and gender matched.	Not stated.	OHRQoL - functional, physical, psycho-logical and social impacts in participants with chronic periodontitis.

Table 4 Summary of cross-sectional studies (continued).

Study	Participants	Age (Years)	Sample size/ calculation	OHRQoL measure	Periodontal / other assessments	Confounders	Examiner calibration	Main findings
Borges, et al. (2013)	Recruitment from colleges and private clinics.	23-76	24 Generalized chronic periodontitis Sample size calculation, but under powered.	OHIP-14 (Brazilian).	Alveolar bone/Tooth ratio. Test Alveolar bone/Tooth ratio >50%. Control Alveolar bone/Tooth ratio <50%.	Not stated.	Not stated.	OHQoL and masticatory efficiency negatively impacted by loss of periodontal support. Pronunciation and taste main functional limitation.
Zanatta, et al. (2012)	Participants undergoing fixed orthodontic treatment.	14-30	330 (no sample size calculation).	OHIP-14 (Brazilian) administered by one examiner.	Full clinical examination (not used in analysis - low mean PD and CAL). Gingival enlargement (non-validated measure).	Demographic, SES, race, oral hygiene habits.	Yes.	OHRQoL adversely impacted by anterior gingival enlargement, associated with socio-demographic factors. Non-response rate <20%.
Al Habashneh, et al. (2012)	Chronic gingivitis, mild, moderate or severe periodontitis.	18-60	400 (Unclear if sample size calculation. Random sample).	OHIP-14 (Arabic).	Full periodontal examination (excluding 3rd molars).	Socio-demographic factors, oral hygiene habits.	Yes.	OHIP scores associated with severity of periodontal disease

Table 4 Summary of cross-sectional studies (continued).

Zhao et al. (2011)	Random community sample of elders.	60-80	Sample size calculated >260. 300 surveyed.	General Oral Health Assessment Index (Chinese version).	Periodontal probing, LOA**, mobility. DMFT, Tissue Health Index. Occluding teeth. Socio-demographic	Socio-demographic factors.	Yes.	OHRQoL increased with age, no root caries, LOA ≥6mm and more occluding teeth. Advanced LOA poorer OHRQoL.
Zaitsu et al. (2011)	Community sample.	40-55	459	General Oral Health Assessment Index (Japanese version).	Periodontal pockets, bleeding, calculus, oral hygiene, dryness, DMFT. Functional tooth units. Oral health, age, gender.	Gender.	No.	Periodontal disease not recognized as impacting on OHRQoL.
Cohen-Carneiro et al. (2010)	Consecutive sample comparing oral health of 2 rural Amazon communities	>18	Isidoro (52) Lauro Sodre (74) (sample size calculation not stated).	OHIP-14	Community Periodontal index. DMFT.	Socio-economic questionnaire. Data not included in analysis.	Yes.	Pain and other oral conditions more negative impacts than periodontal condition.

Table 4 Summary of cross-sectional studies (continued).

Study	Participants	Age (Years)	Sample size/ calculation	OHRQoL measure	Periodontal / other assessments	Confounders	Examiner calibration	Main findings
Andersson et al. (2010)	Consecutive patients recruited from 3 general dental clinics. Regular attenders.	Three strata: 20-39 40-59 ≥60	204 (Sample size not calculated).	Oral Impacts on Daily Performances (Swedish).	Number of proximal sites ≥6mm. General dental status. Maximal jaw opening. Bitewing radiographs.	Age, gender, education, ethnic origin, marital status.	Yes.	Missing teeth and limited jaw opening increased impacts on daily life and OHRQoL No associations pocket depths or bone loss and impacts.
Bernabe & Marcenes (2010)	1998 UK Adult Dental Health Survey. (Stratified random sampling. Periodontal disease defined).	16-93	3122 (large sample size – no sample size calculation)	OHIP-14.	Clinical condition. Periodontal disease defined.	Demographic factors, SES, clinical conditions (adjusted for).	Yes.	Periodontal disease associated with worse quality of life than patients without periodontal disease. Independent of other oral conditions or socio-demographic factors.

Table 4 Summary of cross-sectional studies (continued).

Study	Participants	Age (Years)	Sample size/ calculation	OHRQoL measure	Periodontal / other assessments	Confounders	Examiner calibration	Main findings
Montero-Martin (2009)	Clinic consecutive sample.	45.2 ±9.5	290 (no sample size calculation).	OHIP-14 (Spanish)	CPI DMFT	Socio-demographic.	Yes.	OHIP-14 (Spanish) validated. No periodontal variables significantly associated with impacts-healthy sample.
Lawrence, et al. (2008)	Birth cohort. (Dentate adults from a health and development study in New Zealand).	32	924	OHIP-14.	Periodontal clinical attachment loss. Tooth loss. Caries.	Gender, socio-economic status, use of dental services. Occupation, self-rated oral health, reasons for seeing a dental care provider.	Not stated.	OHIP-14 associated with oral health indicators. Prevalence of impacts > estimates from Australia and UK, standardized for age and gender.
Aslund, et al. (2008)	New patients. (Restorative dentistry clinic).	16-86	251 (no sample size calculation).	Self-reported signs and symptoms (5 questions) OHQoL-German.	BPE scores.	Age.	Not stated.	Periodontal condition in addition to number of teeth and prosthetic status impact on OHRQoL.

Table 4 Summary of cross-sectional studies (continued).

Study	Participants	Age (Years)	Sample size/ calculation	OHRQoL measure	Periodontal / other assessments	Confounders	Examiner calibration	Main findings
Cunha-Cruz, et al. (2007)	Periodontal specialist clinic.	35-89	1497 (3617 invited)	Perceived oral health (1 question) and oral health-related questionnaire (unpublished).	Periodontal probing depths and number of teeth.	Age.	Not stated.	OHRQoL problems and worse oral health associated with > 8 teeth with > 5mm probing depth, compared with < 3 teeth with > 5mm probing depth.
Ng & Leung (2006)	University of Hong Kong community study. Focus on upper and lower ends of range for severity of periodontal attachment loss.	25-64	727 (94.7%)	OHIP-14 (Chinese) Checklist of self-reported periodontal symptoms (previous 12 months).	CAL - 2 groups: Healthy/low periodontal attachment loss (≤2mm). High/severe attachment loss (>3mm).	Age, education, number of teeth.	Not stated.	OHRQoL and periodontal disease significantly associated. Full-mouth mean CAL >3mm significantly higher OHIP-14 scores.

Table 4 Summary of cross-sectional studies (continued).

Study	Participants	Age (Years)	Sample size/ calculation	OHRQoL measure	Periodontal / other assessments	Confounders	Examiner calibration	Main findings
Swoboda et al. (2006)	Recruited from community.	60-75	733 (large sample no size calculation).	General Oral Health Assessment Index.	CAL. Occluding pairs of teeth. Caries, systemic disease, demographic and income.	Confounders included in analysis.	Yes.	Occluding pairs of teeth and carious roots predict GOHAI and subscales. GOHAI not predicted by periodontal measures.
Needleman, et al. (2004)	Private practice periodontal patients.	Not stated.	205	OHQoL-UK.	Periodontal examination.	Social, medical, dental factors recorded (not included in the analysis).	Not stated Experienced periodontists	Periodontal status impacts on QoL.
Srisilapanan and Sheiham (2001)	Population sample Thailand.	60-74	623,549 dentate 74 edentulous (large sample no size calculation).	Oral Impacts of Daily Performance.	Periodontal examination. Missing teeth. Gender, income, education, dental attendance.	Income, dental attendance affects impacts.	Not stated.	People with attachment loss >6mm had significantly more impacts.

* G = gingivitis. GAP = generalized aggressive periodontitis. GCP = generalized chronic periodontitis. LAP = localized aggressive periodontitis. **LOA = loss of attachment. ***PUFA = presence of severely decayed teeth with visible pulpal involvement, ulceration caused by dislocated tooth fragments, fistula and abscess. SES = Socio-economic status. DMFT = Decayed Missing Filled Teeth.

2.5.4 Cohort studies

Five cohort studies fulfilled the criteria for inclusion in this review (Table 5). Collectively, these studies reported that OHRQoL is adversely affected by periodontal disease in comparison to participants with either no periodontal disease or less loss of supporting tissues. Impacts were especially related to psychological disability and discomfort, and physical pain (Brauchle et al., 2013). The adverse effects of disease appear to be ameliorated by periodontal treatment (Jowett et al., 2009, Saito et al., 2010, Shah and Kumar, 2011, Brauchle et al., 2013).

Participants in these studies were recruited from periodontology clinics or private practices. A diagnosis of periodontitis was stated in 4 studies, (Jowett et al., 2009, Saito et al., 2010, Shah and Kumar, 2011, Makino-Oi et al., 2016) and “periodontal diseases” in one study (Brauchle et al. 2013). Three studies provided sample size calculation although only one was correctly powered (Saito et al. 2010). OHQoL assessment was undertaken using OHQoL-UK and OHIP-14 (German and English according to the population being investigated). In two studies other instruments were also used including an instrument designed to acquire biopsychosocial impacts or oral conditions and diseases translated into Japanese (Saito et al. 2010), and an OHRQoL model for dental hygiene questionnaire (Makino-Oi et al., 2016). Full periodontal assessment was undertaken in 4 studies, whilst clinical outcomes were not reported in a further study (Jowett et al. 2009). Cohorts were matched for age and/or gender in all studies. Examiner calibration was reported in 1 study (Makino-Oi et al., 2016). In one study lower OHIP-14 scores were found in older people and higher scores in women and smokers (Brauchle et al. 2013). The strongest areas were selection of the non-exposed cohort, ascertainment of the exposure, demonstration of the outcome of interest, comparability of cohorts, assessment of outcome and long enough follow-up. The weakest areas were representativeness of the exposed cohort and lost to follow-up reporting. All studies except one (Brauchle et al., 2013) recruited hospital patients, and two studies had no statement on lost to follow-up (Shah and Kumar, 2011, Brauchle et al., 2013). Full details of the quality assessment are in Appendix 4 (Table 54). Two studies (40%) (Jowett et al., 2009, Makino-Oi et al., 2016) fulfilled 78% of the criteria and the remainder fulfilled 56-67% of the criteria.

Table 5 Summary of cohort studies.

Study	Participants	Age (years)	Sample size / calculation	OHQoL assessment	Periodontal / other assessment	Comparability	Examiner calibration /training	Main findings
Makino-Oi et al. (2016)	Moderate – severe periodontitis recruited from 3 clinics. Open flap debridement following initial periodontal therapy where required on re-evaluation after initial NSPT.	57.3±10.3 non-surgery. 55.8±14.1 surgery.	Sample size determined. 26 non-surgery. 50 surgery.	OHRQoL Model for Dental Hygiene questionnaire (Japanese) at baseline, after initial treatment, 12-14 weeks post surgery + oral antibiotics and NSAID's or supportive periodontal therapy +/- local antibiotic.	PPD, CAL, BoP, PI. Baseline and 3-4 weeks after initial therapy.	Cohorts matched for gender, age, number of teeth.	Yes.	Initial treatment significantly improved OHRQoL. No significant improvement in OHRQoL in either group after initial treatment.
Brauchle, et al. (2013)	Patients with symptoms of periodontal disease	27-74	82 periodontal diseases. 11 patients without periodontal diseases. No power calculation.	OHIP-14 German.	Demographic and socio-economic. Full periodontal assessment.	Cohorts matched for age and gender.	Not stated.	Psychological disability and discomfort, physical pain worse with PPD > 7mm. Treatment improved OHQoL most with pockets > 7mm in depth. OHIP-14 scores: Lower in older people. Higher in women and smokers.

Table 5 Summary of cohort studies (continued).

Study	Participants	Age (years)	Sample size / calculation	OHQoL assessment	Periodontal / other assessment	Comparability	Examiner calibration /training	Main findings
Shah and Kumar (2011)	Patients from a periodontal clinic.	Study group mean 29 years controls mean 26.	Small and not calculated. 50 with chronic periodontitis 25 study (OHI + SRP) 25 control (OHI).	OHIP-14 at baseline and at weekly intervals for 4 weeks.	Periodontal probing depth, gingival and plaque indices.	Cohorts matched at baseline for age, clinical characteristics and OHRQoL.	Not stated.	Periodontal disease adversely affects OHRQoL which was rapidly ameliorated by NSPT compared with controls.
Saito, et al. (2010)	Patients recruited from periodontal clinic.	Perio-dontitis mean 53.6 Healthy controls mean 36.4.	58 periodontitis 50 controls. Power calculation.	OHQoL before and after. Pain, dry mouth, eating/chewing, speech. Social psychological functions and health perceptions.	Full-mouth periodontal assessment.	Age <20 and other oral conditions exclusions both groups.	Not stated.	OHQoL negatively affected by periodontitis. Perception of oral health potentially ameliorated by treatment.
Jowett, et al. (2009)	Dental hospital patients.	Study: 26-53 Control: 27-61	20 moderate-severe periodontitis 16 dentally healthy controls.	OHIP-14 at examination + telephone daily for 7 days after 24-h RSD + OHI (test) or scaling + OHI (controls), and at further review.	Age, gender and IMD.	Cohorts matched for age.	Experienced examiners	OHQoL worse in patients with periodontal disease than healthy patients. Part amelioration of Impacts.

Key: RSD = Root surface debridement. OHI = Oral hygiene instruction. IMD = Index of Multiple Deprivation. PPD = Periodontal probing depth. BoP = Bleeding on probing. CAL = Clinical attachment loss. PI = Plaque index.

2.5.5 Case-series

Ten case-series fulfilled the criteria for inclusion (Table 6). These studies support the contention that periodontal treatment improves OHRQoL in affected patients, particularly in the pain and psychological domains (Wong et al., 2012). The impact of periodontal disease on mastication also seems to diminish following treatment, with little difference between non-surgical and surgical treatment on OHRQoL (Pereira et al., 2011).

A diagnosis of moderate to advanced/severe periodontitis was stated in five studies (Saito et al., 2011, Wong et al., 2012, Goel and Baral, 2017, Mendez et al., 2017, Peikert et al., 2019), however 4 others lack specific diagnoses for participants (Bajwa et al., 2007, Pereira et al., 2011, Ohrn and Jonsson, 2012, Nagarajan and Chandra, 2012). Adults were recruited in all studies, and there is a lack of sample size calculations in all but 2 of these studies (Miao et al., 2016, Goel and Baral, 2017). The interventions reported are heterogeneous and include non-surgical periodontal treatment, with or without locally applied antimicrobials, and subsequent surgery, systemic antibiotics or laser (Peikert et al., 2019) with a follow up period of up to one year (Wong et al., 2012). OHRQoL assessments in these studies are also varied and include GOHAI (Ohrn and Jonsson, 2012), OHQoL-UK16 (Nagarajan and Chandra, 2012), OIDP (Pereira et al., 2011), a dental hygiene OHQoL measure (Saito et al., 2011), and OHIP-14 (Wong et al., 2012, Bajwa et al., 2007, Peikert et al., 2019). The other assessments in these studies included periodontal assessment, electromyography, a risk assessment tool, Multidimensional Scale of Perceived Social Support, General Self-efficacy and Locus of Control. Examiner calibration was reported in 2 studies (Pereira et al., 2011, Mendez et al., 2017) .

Full details of the quality assessment are in Appendix 4 (Table 55). The strongest areas were clear hypothesis/aims/objectives, patients entering studies at similar point in disease, intervention clearly described, relevant outcome measures established a priori, relevant outcomes measured using appropriate methods, relevant outcomes measures made before and after intervention, appropriate statistical tests used to assess outcomes, conclusions supported by results, prospective design and losses to follow up reported. The weakest areas were, not being a multicentre study, lack of clarity if patients were recruited consecutively and outcome assessors not being blinded to the intervention. For the remaining items, reporting was either unclear, the item was partially met or not met (description of patients' characteristics, eligibility criteria for entry into study, long enough follow up for important events and outcomes to occur, estimates of random variability not provided in data analysis of relevant outcomes, adverse events reporting, competing interests and sources of support not reported. One third of studies fulfilled 89-95% of the criteria (Saito et al., 2011, Wong et al., 2012, Mendez et al., 2017) and the remainder fulfilled 63% - 84%.

Table 6 Summary of case-series studies.

Study	Participants	Age (years)	Sample size / calculation	Interventions	OHRQoL assessment	Periodontal / other assessments	Examiner calibration / examiner agreement	Main findings
Peikert et al (2019)	Multi-centre general practice. Chronic and aggressive periodontitis included.	22-87	Not stated, under-powered for some sub-groups.	Scaling/RSD. Systemic antibiotics or lasers for some patients.	OHIP-14 German before and after treatment.	Full mouth periodontal examination. Demographic SES Smoking.	No. Same training and treatment protocol used.	Treatment positively associated with OHRQoL, and dependent on severity, clinician and treatment modality.
Goel and Baral (2017)	Two groups: Moderate-severe generalized periodontitis/ chronic gingivitis. Matched for SES (Dental Hospital patients).	17-60	Calculated 50. 49 completed.	Periodontitis group: Scaling and RSD. Gingivitis group: Supra-gingival scaling.	OHIP-14 (Nepali)	Full mouth periodontal examination.	Not stated.	Periodontal diseases are directly associated with OHRQoL and treatment enhances quality of life. RSD more so than supra-gingival scaling.
Mendez et al. (2017)	Gingivitis and moderate – advanced chronic periodontitis (Dental clinic patients)	51±9.4	No sample size calculation. 55 completed.	OHI Scaling RSD	OHIP-14 (Brazilian) Before and following supra-gingival, and sub-gingival treatment.	Full periodontal assessment including plaque index. Socio-demographic SES	Trained and calibrated examiners.	OHRQoL improved after treatment, particularly after subgingival treatment.

Table 6 Summary of case-series studies (continued).

Study	Participants	Age (years)	Sample size / calculation	Interventions	OHRQoL assessment	Periodontal / other assessments	Examiner calibration / examiner agreement	Main findings
Miao et al. (2016)	Chronic periodontitis consecutive clinic patients.	17-74	Calculated 117. 120 completed.	OHI, NSPT	OHIP-14 (Chinese) Baseline and post-treatment.	Full mouth examination. Plaque. Scale of Perceived Social Support (PSS), General Self-efficacy (GSE). Demographic Smoking. Health, SES.	Not stated.	Treatment improved OHRQoL. PSS & GSE positive resources improving OHRQoL after treatment. GSE partly mediates association PSS & post-treatment OHRQoL.
Wong, et al. (2012)	Moderate–to-advanced chronic periodontitis (Chinese adults).	35-65	40 women and 25 men. No power calculation	OHI, NSPT quadrant-wise. 3 m recall up to 1 year. OHI and prophylaxis repeated at 1 year.	OHIP-14S at all time points.	Clinical parameters.	Not stated.	Improvement in OHRQoL (pain and psychological subdomains) associated with responses to NSPT.
Nagarajan & Chandra, (2012)	Patients undergoing NSPT (India).	18-55	183 No power calculation.	NSPT (low risk) +/- locally delivered antimicrobials (moderate risk). Surgery for high risk. *Comment: Combination of treatments.*	OHQoL-UK 16 questionnaire before and after treatment. Change assessed.	Full periodontal assessment. Periodontal risk assessment tool to determine level of risk: low, moderate, high.	Not stated.	Risk of periodontal disease related to OHRQoL. OHRQoL improved following Periodontal treatment.

Table 6 Summary of case-series studies (continued).

Study	Participants	Age (years)	Sample size / calculation	Interventions	OHRQoL assessment	Periodontal / other assessments	Examiner calibration / examiner agreement	Main findings
Ohrn, & Jonsson (2012)	Patients referred periodontal treatment.	56.4 (females) 52.6 (males).	23 females 19 male.	Initial periodontal treatment.	OHIP-14 GOHAI.	Periodontal.	Not stated - specialist periodontist	Clinical status and OHRQoL improved after treatment
Pereira, et al. (2011)	Dental clinic.	23-56	28	NSPT.	OIDP.	Electro-myography. Number of teeth and probing depth. Before and 45 days after periodontal treatment.	Single calibrated examiner masked to treatment phase.	Perceived impact of oral health on mastication reduced following treatment. Number of teeth important for perception of impact.
Saito, et al. (2011)	Moderate to severe periodontitis Recruited from dental hospital patients (Japan).	31-71	21 (5 male) *(45 recruited)* Pilot. No formal power calculation.	NSPT and flap surgery.	Dental hygiene OHRQoL. Baseline, 3 weeks after NSPT, 3-4 m after surgery.	Full periodontal assessments	Not stated.	No significant difference in OHRQoL between post-initial treatment and post-surgery intervals.
Bajwa et al. (2007)	Periodontitis	20-60	55	NSPT.	OHIP-14.	LoC.	Not stated.	No difference in LoC following treatment. Trend towards Improved OHRQoL.

Key: NSPT = Non-surgical periodontal treatment. OHI = Oral hygiene instruction. BoP = Bleeding on probing. PI= Plaque index. SES = Socioeconomic status. OHQoL-UK = Oral Health Quality of Life – UK. OIDP= Oral Impacts on Daily Performance. GOHAI= General Oral Health Assessment Index. OHIP-14= Oral Health Index Profile- 14. LoC = Locus of Control. OHRQoL- Oral Health Related Quality of Life.

2.5.6 Randomized controlled trials

Six randomized controlled trials in which periodontal disease was treated fulfilled the inclusion criteria (Table 7). These studies support the findings of observational studies that chronic periodontitis adversely affects OHRQoL, and support the notion that periodontal treatment improves OHRQoL. This improvement during randomized clinical trials of treatment is experimental evidence that periodontal disease adversely affects OHRQoL. Furthermore, there were no differences in OHRQoL or Oral Impacts on Daily Performance when quadrant-wise and full-mouth debridement were compared (Santuchi et al., 2016).

All participants recruited to these studies had periodontitis, although in only one study was this described as being severe (Tsakos et al., 2010). All studies report the inclusion of adult participants, with one exception in which the age is not reported (Ozcelik et al., 2007). Whilst power calculations were undertaken in three out of the six studies, all except one (Aslund et al., 2008b) were underpowered.

Interventions were variable in these studies and included comparisons of full-mouth debridement (FMD) and quadrant-wise non-surgical treatment (NSPT) (Santuchi et al., 2016), intensive versus a more conservative approach to treatment (Tsakos et al., 2010), comparison of different instruments to perform root surface debridement (Aslund et al., 2008b), and non-surgical versus a surgical approach (Ozcelik et al., 2007). OHRQoL measures used included OIDP (Santuchi et al., 2016), GOHAI and OHQoL-UK (Jonsson and Ohrn, 2014), a questionnaire on self-perceived perceived impacts (D'Avila et al., 2005), OHIP-14 (Ozcelik et al., 2007) and self-perceived impacts before and after treatment (D'Avila et al., 2005). Three of the six studies clearly reported examiner calibration.

A good level of evidence comes from one study at a low risk of bias (Tsakos et al., 2010), and one (Aslund et al. 2008) fulfilling 6 out of seven of the criteria (bias unclear in relation to blinding of participants and personnel) (Appendix 4, Table 56). For the remaining studies, there was a high risk of bias. Three of the studies were underpowered (D'Avila et al., 2005, Tsakos et al., 2010, Jonsson and Ohrn, 2014), and two studies had no power calculation (Jonsson and Ohrn 2014, Tsakos et al. 2010), as shown in Table 7.

Table 7 Summary of Randomized Controlled Trials

Study	Participants	Age (years)	Sample size / calculation	Intervention Assessments	OHQoL Measure	Periodontal / other assessment	Follow-up period	Calibration of examiners	Main findings
Santuchi, et al. (2016)	Chronic periodontitis	35-60	45 each group. 78 competed study. Sample size calculation (90). Study under-powered.	Comparison of quadrant-wise SRP and FMD.	OIDP	Full clinical assessment.	180 days	Yes.	No significant differences between groups in OHRQoL. Periodontal parameters improved in both groups.
Jonsson & Ohrn, (2014)	Chronic periodontitis	20-60	87 completed out of 113. No power calculation for OHRQoL.	NSPT.	GOHAI and OHQoL-UK.	Two educational programmes investigated.	12 months	Not stated, but all clinical measures by 1 periodontist.	OHRQoL improved after NSPT in both groups. Fewer oral problems. OHQoL-UK greater effect size and mean change scores. Both questionnaires associated with participants' self-rated change in oral health. Changes meaningful for patient (MID analysis).

Table 7 Summary of Randomized Controlled Trials (continued).

Study	Participants	Age (years)	Sample size / calculation	Intervention Assessments	OHQoL Measure	Periodontal / other assessment	Follow-up period	Calibration of examiners	Main findings
Tsakos, et al. (2010)	Severe generalized periodontitis	30-63	17 intensive periodontal treatment. 28 conservative periodontal treatment. No power calculation.	All OHI. Intensive group: Extraction of teeth with hopeless prognosis. FMD under LA and locally applied Minocycline microspheres Conservative group: Supragingival debridement.	OIDP	Periodontal examination at baseline.	1 month	Yes.	OHRQoL improved after treatment. No difference intensive versus conservative group. MID for OIDP index corresponded to a moderate effect size.
Aslund, et al. (2008)	Mild – moderate periodontitis	47 -55	30 piezo : 29 curettes. Matched for age, gender, smoking and deeper pockets. Power calculation.	NSPT: piezo – ceramic or curettes.	OHQoL-UK baseline, treatment 1, 4 and 8 weeks after treatment	Periodontal examination baseline and 8 weeks. Short-form McGill pain questionnaire	1, 4 & 8 weeks	Yes.	Periodontitis may negatively affect OHRQoL. Treatment had small impact on pain and OHQoL-UK scores.

Table 7 Summary of Randomized Controlled Trials (continued).

Study	Participants	Age (years)	Sample size / calculation	Intervention Assessments	OHQoL Measure	Periodontal / other assessment	Follow-up period	Calibration of examiners	Main findings
Ozcelik, et al. (2007)	Periodontitis	Not stated, but matched.	20 NSPT: 20 surgical treatment: 20 surgical treatment + EMD Matched age, psychologically and sociodemo-graphically. Under-powered.	NSPT / Surgical treatment +/ - EMD.	OHIP-14 and GOHAI, 1 week post-operative	-	1 week	Not stated.	OHQoL in immediate post-operative period better in the NSPT and surgery + EMD groups than surgical alone group.
D'Avila et al. (2005)	Chronic periodontitis	Control 46±8 Test 1 44±9.4 Test 2 44±7.8 Test 3 41±4.6	No sample size calculation. Control = 13 Test 1 = 15 Test 2 = 14 Test 3 = 13 (small sample) Random allocation	Control = SRP, OHI, placebo. Test groups: 1 = as above + MET. 2 = SRP, OHI, placebo, weekly cleaning 3 months. 3 = SRP, OHI, MET, weekly supra-gingival cleaning 3 months.	Questionn-aire on self-perceived perceived impacts before and after treatment	Probing depths, CAL, BoP, plaque score, suppuration, Smoking.	3 months.	Yes.	Reduced self-perceived impacts regardless of treatment group.

Key to interventions: NSPT = Non-surgical Periodontal Treatment. Quadrant-wise SRP = Provision of scaling and root planing a quarter mouth at a time. FMD = Full Mouth Debridement by supra- and subgingival cleaning in one visit. OHI = oral hygiene instructions. LA = local anaesthesia. EMD = Enamel Matrix Derivative.

2.5.7 Review articles on OHRQoL

Seven relevant review articles were found, of which 6 were systematic reviews. Systematic reviews of observational, epidemiological, interventional and uncontrolled studies (Shanbhag et al., 2012, Buset et al., 2016, Baiju et al., 2017, Ferreira et al., 2017, Botelho et al., 2020) reported periodontal diseases have negative impacts on OHRQoL. Whilst severe periodontitis adversely affects function and aesthetics, gingivitis may be associated with pain, difficulty in partial denture wearing and also difficulties in performing oral hygiene procedures. Furthermore, non-surgical periodontal treatment can improve OHRQoL (Shanbhag et al., 2012). Improvements may be achieved in a short time after treatment and remain stable after 3 months (Botelho et al., 2020). Furthermore, changes in OHRQoL following surgical treatment were not significant in patients who had already received non-surgical treatment (Shanbhag et al., 2012).

A narrative review of 7 observational studies (Al-Harthi et al., 2013) also concluded that periodontitis had a negative impact on OHRQoL. However, heterogeneity of method and reporting, together with other oral conditions (confounders) not controlled for in analyses, made interpretation of results difficult.

One of the most recent systematic reviews met all the AMSTAR criteria and four met 91% of the criteria. Most higher quality reviews failed to report the assessment of the likelihood of publication bias. These systematic reviews can otherwise be considered as being of high quality. The earlier systematic review (Naito et al., 2006) fulfilled 64% of the criteria. A summary of the quality assessment of review articles using the AMSTAR measurement tool is found in Appendix 4 (Table 57).

2.5.8 Levels of Evidence

The included studies were assessed using the Oxford Centre for Evidence-based Medicine Levels of Evidence.

Strong (Level 1) evidence comes from two systematic reviews reporting periodontal disease negatively impacts on OHRQoL (Buset et al., 2016, Ferreira et al., 2017), and three systematic reviews that surgical and/or non-surgical treatment can improve OHRQoL (Shanbhag et al., 2012, Baiju et al., 2017, Botelho et al., 2020). All five systematic reviews are of high quality. Further relevant papers identified in these reviews were incorporated here to ensure all relevant literature had been considered. Level 2 evidence comes from 6 randomized controlled trials that provide good quality experimental evidence that chronic periodontitis adversely affects OHRQoL, and that its treatment improves OHRQoL. One study fulfils all the criteria for a low risk of bias (Tsakos et al., 2010), and in a further study all except one of the criteria were fulfilled (blinding of participants and personnel were unclear) (Aslund et al. 2008). For the remaining studies, there was either an unclear risk of bias (Santuchi et al. 2016), or a risk of bias in two or more aspects of the study (D'Avila et al., 2005, Ozcelik et al., 2007, Jonsson and Ohrn, 2014).

Lower levels of evidence come from 32 cross-sectional studies, 5 cohort and 10 case-series studies (Level 4 and Level 3 for cohort therapeutic studies). All studies support the notion that periodontitis negatively impacts on OHRQoL, whilst cohort and case-series studies suggest that non-surgical treatment can improve OHRQoL.

Twenty-five percent of cross-sectional studied fulfilled 90% of the quality criteria, 44% fulfilled 70-80% of the criteria and 31% fulfilled 40- 60% of the criteria. Forty percent of cohort studies fulfilled 78% of the criteria and the remainder fulfilled 56-67% of the criteria. Sixty-three to ninety-five percent of the quality assessment criteria were met case in series studies. One third of studies met 89-95% of the criteria and the remainder between 63% and 79% of the criteria.

Whilst statistical significance between pre- and post-treatment OHRQoL is used as an outcome of success in many of the publications included in the preceding review of the literature, these differences are not always of a magnitude to be perceived by patients as being clinically meaningful. For example, the review by Botelho et al. (2020) includes studies reporting statistical significance, but with values for differences that are too low to be clinically meaningful. Conversely, a difference that is meaningful to a patient may not be statistically significant. Accordingly, other methods are recommended in addition to statistical testing when evaluating the outcomes of these measures.

Health status scales (such as OHRQoL) unlike physical measurements of health, have no direct biological meaning (Kazis et al., 1989), and a number of methods have been recommended to evaluate changes. These include effect size, which is defined as the mean change in a variable divided by the standard deviation of the variable, and can be interpreted using Cohen's general guidelines of 0.2 (small), 0.5 (medium) and ≥0.8 (large) (Kazis et al., 1989). Other methods to determine the minimally important difference (MID) have also been recommended as a benchmark to assist the interpretation of clinical change in longitudinal studies (and cross-sectional studies) reporting participant (patient) based outcome measures (Tsakos et al., 2012). They described two broad approaches to determining the MID, namely the distribution based (internally referenced) and anchor-based methods. Distribution-based methods include effect size (as already discussed), standardized response mean and standard error of measurement. The anchor-based (externally referenced) methods use a population norm or subjective global transition scale as the reference or anchor point.

2.5.9 Conclusions

This comprehensive review adopted a systematic approach. The evidence reviewed suggests that periodontal diseases adversely impact on OHRQoL. Impacts increase with severity of periodontal diseases and the number of teeth affected. This means that periodontal diseases are not silent, with those affected experiencing significant problems such as pain, discomfort, impaired taste, difficulty pronouncing words, eating and cleaning teeth. These may in turn lead to psychological impacts and social embarrassment as a consequence of having periodontal disease. Improvement of OHRQoL is an important goal in the management of periodontal diseases meaningful to patients.

Treatment can improve the periodontal status and OHRQoL; however, the evidence on which these findings are based has limitations in research methodology that are summarized below. Furthermore, no studies to date have investigated OHRQoL at multiple time points on the journey from assessment through treatment and follow-up. Further research taking cognisance of this may also lead to better understanding of health trajectories and expected outcomes after treatment. Moreover, existing knowledge is based on an understanding of disease based on a biomedical model, that does not include other potentially important factors that may determine OHRQoL outcomes. Whereas, using a biopsychosocial theoretical model of health (Wilson and Cleary) in future research would provide a framework to investigate the relationships between characteristics of the individual, environment and clinical variables with OHRQoL and clinical outcomes. Individual factors, including psychological factors such as sense of coherence, locus of control, self-esteem and task-specific self-efficacy are of potential importance in relation to OHRQoL and clinical outcomes of treatment. These psychological factors are important for health and/or favourable health behaviours, and are discussed fully later (Section 2.9). Socioeconomic factors are also important in relation to both periodontal diseases, clinical and OHRQoL outcomes of treatment, and should also be taken into account (Section 2.7).

Further research provides an opportunity to investigate the relationships of these factors with OHRQoL and clinical outcomes that have not been investigated previously by using a theoretical model. Greater understanding of the relationships of these factors may also help to determine the factors related to the outcomes of treatment, and to develop approaches to enhance OHRQoL and clinical outcomes of periodontal treatment for the benefit of those affected. These might include insight into where and how best to intervene with treatment or advice, and in developing a treatment strategy tailored to an individual patient's needs. This may also include approaches to enhance psychological factors identified of importance, where this is possible and appropriate. Knowledge of the individual psychological and environmental factors predicting outcomes would also be valuable in case selection. A public health approach however, would be need to address the socioeconomic determinants of health. Further knowledge, would be of benefit to patients, health care professionals and those responsible for directing professional resources appropriately. Finally, further research provides an opportunity to learn about and contribute to theory on OHRQoL, and identify areas for future research.

Summary of the limitations of previous research:

- No studies have used theory based models to investigate the factors relating to periodontal status and OHRQoL in relation to periodontal treatment.

- No studies have followed OHRQoL from diagnosis at multiple time points in the care journey after treatment to follow-up.
- The individual and environmental predictors of both clinical and OHRQoL outcomes of periodontal treatment are unclear.
- The relationship of psychological factors with OHRQoL after periodontal treatment are unclear.
- Previous studies have methodological limitations. These include:

  The precise periodontal diagnosis is unclear in many studies.

  Periodontal outcomes are not reported in all studies.

  Sample size calculation is often unclear or lacking.

  A variety of OHRQoL measures have been used (e.g. OIDP, GOHAI, OHQoL-UK, OHIP-14).

  There is a high risk of bias in 40% of RCTs.

  There is unclear reporting (criteria for entry, patient characteristics, relevant environmental factors, clinical outcomes, losses to follow up and estimates of random variability) in many studies.

  Examiner calibration and reliability of measurements are unclear.

  Common confounding factors are often not accounted for.

  Response rate and analysis of the characteristics of those lost from the study is not clearly reported.

  Periodontal treatment and follow-up periods are heterogeneous.

2.6 Risk Factors and Treatment of Chronic Inflammatory Periodontal Diseases

The initiation and progression of chronic inflammatory periodontal diseases together with clinical treatment outcomes is primarily related to dental plaque (Theilade et al., 1966, Axelsson and Lindhe, 1978, Axelsson and Lindhe, 1981a, Axelsson and Lindhe, 1981b, Axelsson et al., 1991). Evidence from clinical studies demonstrates the periodontal status may be stabilized following treatment in which plaque is controlled (Axelsson and Lindhe, 1981b). Other factors of importance include smoking, stress, systemic disease and the socioeconomic status (Albandar, 2002, Paulander et al., 2004).

A 2-7 fold higher risk of periodontitis is attributable to smoking and the severity of disease is related to the pack-years smoked (Albandar, 2002). Quitting smoking may improve periodontal health, and result in the risk for severity of periodontitis in former smokers falling somewhere between current smokers and non-smokers. Furthermore, past and current smoking habits are attributed to over 50% of the prevalence periodontitis (Albandar, 2002). The adverse effect of smoking is also apparent when corrections are made for confounders, such as plaque levels (Genco and Genco, 2014). Smoking adversely affects the clinical outcomes of periodontal treatment (Labriola et al., 2005), and is associated with an increased risk of tooth loss in patients on long-term periodontal maintenance (Chambrone et al., 2010). Smoking cessation has also been associated with additional benefits for the periodontal status following non-surgical treatment (Chambrone et al., 2013). However, former smokers were also found more likely to have significant probing depth reductions than smokers or those oscillating between smoking and not smoking (Fiorini et al., 2014). Whilst smoking is a risk factor for periodontal diseases and treatment outcomes, a recent study also reported smoking was associated with worse OHRQoL (Bakri et al., 2018). Since smoking is common amongst patients referred for treatment, smokers were included in the present study to investigate the relationship between smoking and periodontal status, together with clinical and OHRQoL outcomes of treatment.

Stress may also have negative effects on periodontal health (Peruzzo et al., 2007, Decker et al., 2020), and treatment outcomes (Vettore et al., 2005, Bakri et al., 2013). The effects however, appear to be moderated by adequate coping behaviours (Genco et al., 1999).

The most common systemic disease cited as a risk factor for the development of periodontal diseases is diabetes (Martins Chavarry et al., 2009, Ryan et al., 2003). However, the clinical outcomes following periodontal treatment in diabetic patients are overall comparable to those in non-diabetic patients. The main factor determining this seems to be glycaemic control (Tervonen et al., 1991, Christgau et al., 1998, Navarro-Sanchez et al., 2007, da Cruz et al., 2008). Furthermore, the burden of diabetes may minimise the impact of oral health issues on OHRQoL (Irani et al., 2015). Prescribed medications may also affect the periodontium, the best known of which are calcium channel antagonists, medications used to control epilepsy and to prevent transplant rejection. Accordingly, patients with a history of diabetes and those taking medications that may affect the periodontal tissues were excluded from the present study.

2.7 Socioeconomic Status

Socioeconomic status is defined as *"a measure of one's combined economic and social status and tends to be positively associated with better health"* (Baker, 2014). Higher socioeconomic status is associated with higher levels of education, income, occupation, social class and more affluent areas of residence, each of which has been used as an indicator of socioeconomic status (Locker, 1993, Costa et al., 2012, Borrell and Crawford, 2012, Darin-Mattsson et al., 2017).

2.7.1 Socioeconomic Status and Periodontal Status

There is a strong social gradient in the prevalence of periodontal diseases in both high and low income countries, resulting in people from the most disadvantaged backgrounds affected disproportionately (Sabbah et al., 2007, Petersen and Ogawa, 2012). People in a lower socioeconomic position may have poor access to dental services and be more likely to be irregular attenders prompted by an acute oral condition, rather than participate in a programme of regular preventive care (Thomson et al., 2012). Furthermore, social and psychological factors may also determine unhealthy behaviours such as smoking and poor oral hygiene that are closely linked with periodontal diseases (Sheiham and Netuveli, 2002). This inequality cannot be addressed by the provision of dental treatment alone, and the need to tackle underlying social determinants of oral health inequalities is well recognised (Watt et al., 2015).

Education and income emerge as important closely linked indicators of socioeconomic status in relation to periodontitis, with higher education and income being inversely associated with periodontal disease severity (Torrungruang et al., 2005, Krustrup and Petersen, 2006). A low educational attainment is associated with an increased risk of periodontitis (Boillot et al., 2011, Zini et al., 2011, Lundegren, 2012, Lundegren et al., 2012) along with those having a lower income (Bastos et al., 2011). A study by Borrell and Crawford (2012), found periodontitis was inversely associated with education, income and poverty-income ratio after controlling for age and gender, and differences were explained by racial disparities (Borrell and

Crawford, 2012). Lower socioeconomic position was associated with higher prevalence or greater odds of periodontitis, whereas people with higher levels of education may have greater access to health-related knowledge and be better able to apply health promoting activities in their lives. In relation to periodontal diseases, this might include better oral hygiene related behaviours and not smoking. They may also have the social and financial resources to adopt healthier lifestyles, as education is also linked with occupation. However, education and income capture related but distinct constructs, and as a consequence are not proxies for each other. The characteristics of the neighbourhood are less consistently associated with periodontitis than individual level indicators of socioeconomic status (Borrell and Crawford, 2012). A low level of education and low income were also associated with the progression of attachment loss and tooth loss, during the follow up period of 5 years in a longitudinal study (Buchwald et al., 2013).

2.7.2 Socioeconomic Factors and the Management of Periodontal Diseases

People having a lower socioeconomic status have greater treatment need and poorer adherence with maintenance care (Klinge and Norlund, 2005, Lee et al., 2015). In addition, increasing levels of socioeconomic disadvantage has also been associated with decreased utilization of dental care services (Wamala et al., 2006).

Socioeconomic status was associated with the frequency of tooth cleaning, the use of oral hygiene aids and the level of plaque (Abegg et al., 1999). Patients from socioeconomic class I (professionals or managers), are also least likely to drop out of supportive periodontal care (Demetriou et al., 1995). Treatment options chosen by patients may also be affected by socioeconomic factors. More years of education and a higher income were associated with a tendency for patients opting for surgical treatment rather than non-surgical treatment (Patel et al., 2006).

Low socioeconomic position may limit access to dental care, as a consequence of a lack of awareness about oral conditions and financial constraints making dental care unaffordable. Time limitations due to work or carer commitments, illness and disability may also make access to health care providers difficult, and social group norms or other factors related to low socioeconomic position may also adversely influence the uptake of treatment.

The strong relationship between socioeconomic factors, preventive measures and periodontal treatment, means indicators of socioeconomic position should be taken into account in future studies.

2.7.3 Socioeconomic Status and OHRQoL

The same social gradient is found with people of lower socioeconomic status having worse OHRQoL. An inverse association between age-standardized prevalence of oral impacts (OHRQoL) and indicators of socioeconomic position was found for dentate, although not edentate older adults (Tsakos et al., 2011). Race, low education and income are associated with worse OHRQoL (Makhija et al., 2006). Worse OHRQoL was associated with lower occupations in participants with 2 or more sites having clinical attachment loss >4mm and 1 or more missing teeth in a birth cohort study (Lawrence et al., 2008). Low education had a an independent negative impact on OHRQoL in older people, that was not explained by differences in income (Tsakos et al., 2009), and inequality in OHRQoL in older people due to educational levels was also reported in a further study (Fuentes-Garcia et al., 2013). Low education and income was associated with OHRQoL, with the strongest gradients for younger people (Guarnizo-Herreno et al., 2014). Low income was associated with poor OHRQoL (Wide and Hakeberg, 2018, Boman et al., 2012), and household income had most effect on OHRQoL in a study of young adults (Sun et al., 2018). Few studies have investigated changes in OHRQoL over time, but one population study reported improvements in occupational social class explained improvements in OHRQoL for the youngest quasi-cohort over a period of 11 years (Tsakos et al., 2017).

Smoking is a confounding factor in studies of socioeconomic factors and OHRQoL, and in a study by Bessa Rebelo (2016), the periodontal status was reported to have a mediating effect for the link between smoking, income and OHRQoL (Bessa Rebelo et al., 2016). More recently, poor dental clinical status was identified as a mediator of the relationship between low economic status and worse OHRQoL in adolescents (Vettore et al., 2019).

In summary, the social gradient influences the periodontal status, treatment and OHRQoL, and justifies including socioeconomic status in this research.

2.8 The Management of Plaque-Related Periodontal Diseases

2.8.1 Plaque Control

Regular removal of dental plaque is important in the management of periodontal diseases (Jepsen et al., 2017, Figuero et al., 2017, Van der Weijden and Slot, 2015, Chapple et al., 2015). In the long-term, optimal plaque control is also important for the stability of periodontal health and the prevention of disease recurrence (Axelsson and Lindhe, 1978, Trombelli et al., 2015).

Evidence suggests the dental plaque biofilm should be removed daily, and that brushing twice daily is usually required (van der Weijden and Slot, 2011). Most people are not effective brushers, and there appears to be little evidence to suggest one manual toothbrush design is superior to another. A Cochrane systematic review however, concluded that oscillation rotation powered brushes can significantly reduce plaque and gingivitis in short and long-term studies (Deery et al., 2004).

Inter-dental cleaning is similarly important for periodontal health. The levels of periodontal disease are lower, and periodontal health is better in those cleaning between their teeth. Furthermore, additional oral health benefits could be gained by increasing the frequency of cleaning in those with severe disease (Marchesan et al., 2018). The best available evidence suggests interdental brushes should be used for interdental cleaning where an interdental space exists, as meta-analysis has shown these are superior to floss for plaque removal. However, tape or floss is easier to use when there has been no loss of tissue or where close tooth contact prevents the use of inter-dental brushes (van der Weijden and Slot, 2011).

The adherence to plaque control regimens may be affected by many factors, including psychological factors (see below). Similarly, susceptibility to plaque varies between individuals with a number of other co-factors influencing the aetiology and progression of disease (Albandar, 2002). Consequently, the amount of plaque that individuals can tolerate and be free from disease may vary.

2.8.2 Non-surgical Periodontal Treatment

Non-surgical periodontal treatment includes root surface debridement, usually using ultrasonic instruments. Work by numerous groups has demonstrated that it is unnecessary to remove cementum to achieve a biologically acceptable root surface compatible with healing of periodontal pockets, and that this can be achieved using a more conservative approach to instrumentation (Borghetti et al., 1987, Fukazawa and Nishimura, 1994). Periodontal pockets may subsequently heal with a reduction in depth by either the close adaption of the epithelium pocket lining against the root surface or the formation of a long-junctional epithelium (Haegi et al., 2014).

Eight relevant systematic reviews were identified using Web of Science, and the methodological quality of these was assessed using the AMSTAR Assessment Tool (Shea et al., 2007) (Appendix 4, Table 58). Systematic reviews on quadrant wise and/or full-mouth debridement were included. Where adjunctive or surgical treatments were included, the findings relating to root surface debridement alone were considered as the outcomes of interest when assessing these systematic reviews.

These reviews provide evidence supporting root surface (subgingival) debridement as the treatment of choice for treating chronic periodontitis. However, clinical mean values reported mask variations in change at patient and site levels. The most recent systematic review by Mailoa et al., (2015) also confirms previous findings that root surface debridement has a negative effect in sites ≤3mm, resulting in increased pocket depth and further loss of clinical attachment. For periodontal pockets ≥4mm, root surface debridement leads to reductions in probing depths and gains in clinical attachment. Furthermore, these outcomes are greater for deeper pockets (Mailoa et al., 2015). Reviews comparing full mouth debridement with a quadrant-wise approach with or without the adjunctive use of antiseptics, report no significant difference in clinical outcomes (Eberhard et al., 2008, Lang et al., 2008). In addition, the clinical outcomes of ultrasonic and hand instrumentation are similar (Tunkel et al., 2002). Full mouth debridement with ultrasonic instruments however, is quicker to perform and is less fatiguing for the operator. The provision of full mouth treatment in one session is also more convenient for patients and consequently was the treatment of choice offered to participants in this study.

2.8.3 Review of Treatment Outcomes

Patients are reviewed after 1 month in order to determine whether there have been any problems such as dentine hypersensitivity arising after treatment, and plaque control is also reviewed at this time. The full evaluation of clinical outcomes involves repeating all clinical measurements in order to determine changes following non-surgical periodontal treatment. This should take place no sooner than 4 weeks after treatment and healing is usually complete after 3 to 6 months (Morrison et al., 1980, Rylander and Lindhe, 2003). OHRQoL could also be reassessed at these times, but this outcome is not currently used routinely in clinical practice.

Patients with satisfactory clinical outcome are then placed on a maintenance care programme and those with an unsatisfactory response can choose to undergo further treatment if they wish. A programme of monitoring and maintenance care commonly includes regular recalls to monitor plaque control, reassessment of the periodontal status and professional subgingival and/or supragingival cleaning as necessary. This should be based on an assessment of risk of further disease progression (Heasman et al., 2002, Farooqi et al., 2015). Further treatment may include non-surgical treatment with or without the adjunctive use of locally applied or systemic antimicrobial agents and possibly periodontal surgery in a few cases. These are outside the scope of this thesis and accordingly are not considered further.

2.9 Individual Factors

Individual factors including gender, age, ethnicity and education may influence the initiation and progression of periodontal diseases, their treatment and/or clinical and OHRQoL outcomes, and are briefly discussed here. Whilst a higher prevalence of periodontal disease has been reported in men, there is a lack of evidence for differences in periodontal treatment outcomes according to gender (Haytac et al., 2013, Ioannidou, 2017). Worse OHRQoL in women has been suggested in some studies (Brauchle et al., 2013, Foetedar et al., 2014), whilst other studies report no gender differences (Masood et al., 2017). The periodontal condition is related to age, with periodontal attachment loss continuing with age, having been shown to accelerate through the fourth decade in vulnerable individuals (Thomson et al., 2013). However, there is much variation between populations. For example, a secondary analysis of representative data from oral health surveys conducted in 2009 in China and New Zealand, found 4-5mm attachment loss in approximately 31% of Chinese and in 43% of New Zealanders aged 35-44. The proportion having ≥6mm attachment loss was approximately 5% and 8% respectively in each population. Greater severity of periodontal disease was found with increasing age with almost 75% of Chinese and almost 64% of New Zealanders aged 65-74 having 4-5mm attachment loss. The proportions having ≥6mm attachment loss had risen to approximately 42% and 20% respectively (He and Thomson, 2018).

OHRQoL is reportedly better in older people (Steele et al., 2004, Slade and Sanders, 2011). Disparities in periodontal disease have also been found between White British and different ethnic groups in the UK, and that this may be related to education rather than socioeconomic classification (Delgado-Angulo et al., 2016). Nonetheless, socioeconomic factors have been associated with both periodontal treatment and OHRQoL as discussed in Section 2.7.

The psychological factors identified of importance in this research are discussed in more depth in the following sections. This commences with sense of coherence, and then continues to consider self-efficacy, self-esteem and locus of control. Finally, other psychological factors are discussed briefly.

2.9.1 Sense of Coherence

Sense of coherence is: "*a global orientation that expresses the extent to which one has a pervasive, enduring through dynamic feeling of confidence that (1) the stimuli deriving form one's internal and external environments in the course of living are structured, predictable and explicable; (2) the resources are available to one to meet the demands posed by these stimuli; and (3) these demands are challenges, worthy of investment and engagement*" (Antonovsky, 1987). Sense of coherence has three key elements; comprehensibility, manageability and meaningfulness. Comprehensibility is the way that an individual interprets factors that may cause them stress as being understandable and ordered rather than the converse. Manageability is the extent to which individuals are able to cope with these, and meaningfulness the extent to which individuals feel their lives make sense. Individuals with high development in all three areas have high sense of coherence, and those with a weaker response in one or more area have a poorer sense of coherence. The three components are separate, but linked. It is believed that the sense of coherence develops in early childhood, but may be modified throughout life, being influenced by factors such as environment, work and social aspects. However, sense of coherence appears to be developed fully by the age of 30, and afterwards remains stable according to Antnovsky (1987).

Antonovsky rejected the traditional medical model dichotomy of health and illness, and instead described the relationship as a continuum between health-ease and dis-ease. He called the framework in which life experiences help to shape ones sense of coherence, salutogenesis. In this model, health promoting resources improve resilience and help to develop positive mental and physical health. Sense of coherence is a measure of how people view life and use general resistance resources to maintain health despite stressful situations and hardships by coping with stressors successfully (Lindstrom and Eriksson, 2005). Antonovsky identified general resistance resources including genetic factors, constitutional, psychological character, ego identity, coping strategy, commitment, cultural stability and a preventive health orientation (Antonovsky, 1979, Antonovsky, 1987).

2.9.2 Sense of Coherence and Health

A direct or indirect relation between perceived good health and a strong sense of coherence was found in relation to a number of disorders in varied populations and ages in a systematic review by Eriksson and Lindstrom (2006). A strong sense of coherence was reported to decrease the number of circulatory health problems in adults, and measures of mental health including locus of control, self-esteem, and self-efficacy. The relationship between sense of coherence and mental health was stronger than for physical health, and that there was a strong and negative relationship with perceived depression. Overall, sense of coherence was also found to predict good health in both long and short-term longitudinal studies of both physical and mental health. However, it was also noted that some studies failed to find evidence of a direct relationship between sense of coherence and health (Eriksson and Lindstrom, 2006).

2.9.3 Sense of Coherence and Periodontal Health

The findings of relationships between sense of coherence and health have led to studies of periodontal health. There are a number of ways in which sense of coherence could impact on periodontal health, including the way in which individuals cope with stress, the selection of health promoting behaviours and by central neuro-endocrine pathways. Indeed, a strong sense of coherence has been associated with good oral health related behaviours, periodontal health and socioeconomic status (Bernabe et al., 2010, Reddy et al., 2016). Resources including sense of coherence may be influenced by socioeconomic status, and as a consequence mediate stress and affect subjective oral health outcomes, for example OHRQoL (Gupta et al., 2015).

Two cross-sectional (and one longitudinal) studies have reported on sense of coherence and periodontitis, with conflicting findings. No association between sense of coherence and periodontal pocketing ≥4mm was found in a cross-sectional analysis of the Health 2000 Survey of data from adults in Finland (Bernabe et al., 2010), whereas a higher sense of coherence score was associated with fewer periodontal pockets in Sweden (Lindmark et al., 2011). The findings were reported after adjustment for confounders in both studies. However, neither study employed a theoretical model.

The only longitudinal study to date included adults in the Finnish Health 2000 Survey and a follow-up study of oral health (Kanhai et al., 2014). In this study sense of coherence was not associated with a change in the number of teeth with periodontal pocketing ≥4mm over a 4-year interval, and as such did not predict periodontal disease progression. Furthermore, sense of coherence was not associated with the number of periodontal pockets after 4 years amongst those with no pocketing at baseline.

The above studies do have some limitations. Two studies were cross-sectional, and all three studies used periodontal pocketing rather than attachment loss as a measure of disease severity and progression. Furthermore, the intermittent nature of periodontal disease activity, the characteristics of being site specific, the moderate inter-examiner agreement and omission of one of the items of the sense of coherence scale used in the one longitudinal study also limit the interpretation of these findings. These limitations suggest that further research might elucidate the impact of sense of coherence in destructive periodontal diseases and in the context of this research, in relation to clinical outcomes of periodontal treatment. Therefore, sense of coherence and the response to treatment was investigated in the present study.

2.9.4 Sense of Coherence and Quality of Life

The findings from cross-sectional and longitudinal studies generally demonstrate that sense of coherence has a positive relationship with quality of life. In addition, some qualitative studies also confirmed the importance of sense of coherence as an internal resource for controlling the quality of life (Eriksson and Lindstrom, 2007).

2.9.5 Sense of Coherence and Oral Health Related Quality of Life

Most studies on sense of coherence and oral health have reported on aspects of health behaviours and clinical status; few have investigated its relationship with OHRQoL. The first of these investigated the relationship between socioeconomic and demographic factors, oral health behaviour and oral health (Savolainen et al., 2005a). Moderate or strong sense of coherence was associated with fewer problems due to oral conditions indicating better OHRQoL than those with a weak sense of coherence. The associations were greatest in relation to psychological discomfort, disability and handicap domains. These findings seemed also to be independent of socioeconomic factors, clinical status or oral health behaviours, suggesting a psychological mechanism linking sense of coherence and OHRQoL (Savolainen et al., 2005a).

Overlap between concepts of sense of coherence and other psychological measures such as self-esteem and self-efficacy also support the idea of sense of coherence having strong psychological features, and this is supported by the findings on the association of sense of coherence with the psychological subscale of OHIP-14 in particular. However, the strengths and weaknesses of the study by Savolainen et al., (2005a) should also be borne in mind. Whilst it involved a large sample, most participants had no oral health problems, and consequently there was little variation in OHIP scores. In addition, it is not known if these findings are applicable to other populations.

More recently, sense of coherence and OHRQoL were included in an investigation of whether the system for funding dental care was associated with OHRQoL (Johansson et al., 2010). Multivariate analysis showed that patients in a contracted care system in which dental care is covered by a contractual agreement in which patients pay an annual fee to cover the cost of care, had better OHRQoL than those in a fee-for-service care. OHRQoL was related to sense of coherence and to some extent, other psychological (e.g. self-esteem) and also economic factors. The limitations of this study include the cross-sectional design that enabled only associations to be investigated, differences between the participants in that non-respondents had fewer problems, and that the experience of pain increased the likelihood of response. The study therefore had potential bias in the findings reported.

Low sense of coherence was associated a worse OHRQoL in a population study of women in Sweden by Boman et al. (2012). Furthermore, self-reported susceptibility to periodontal disease was also an important predictor of OHRQoL. However, it is also noteworthy that self-reporting may also be influenced by sense of coherence (internal resources). The study also considered socioeconomic status and perceived oral functional status, but did have some limitations including the inclusion of only females, a narrow age range and cross-sectional design.

The findings on sense of coherence were also affirmed in a more recent study, in which strong sense of coherence was associated with fewer oral related quality of life impacts in a Norwegian adult population (Holde et al., 2018). Interestingly, this study also reported a strong sense of coherence was related to worse periodontal status. Furthermore, a longitudinal study in Iranian adolescents found sense of coherence significantly and directly predicted OHRQoL, and also had a mediating effect via OHRQoL on general health related quality of life (Pakpour et al., 2018).

Most interestingly, experimental evidence that sense of coherence influences OHRQoL comes from a cluster-randomized trial, albeit in children, that tested a health promotion intervention focusing on child participation and empowerment. The intervention increased sense of coherence and consequently OHRQoL along with oral health beliefs and gingival health (Nammontri et al., 2013). Furthermore, sense of coherence was found to have an important influence on OHRQoL in a further study on children, in contrast to clinical factors which were not consistently related to OHRQoL (Gururatana et al., 2014). It was suggested in this study that interventions to increase sense of coherence may improve OHRQoL.

In summary therefore, there is consistent and experimental evidence that sense of coherence influences OHRQoL. It therefore needs to be accounted for in a study of the OHRQoL outcomes of periodontal treatment.

2.9.6 Sense of Coherence and the Management of Periodontal Diseases

So far as the author is aware, there are no studies that have investigated relationships between sense of coherence, and periodontal health before and after periodontal treatment. A recent cross-sectional study of employees of a large corporation in Brazil found perceived oral, gum and periodontal health was associated with sense of coherence, but found no associations between sense of coherence and gingivitis, periodontitis, plaque index, gingival index, probing depth or clinical attachment level (Cyrino et al., 2016). However, a strong sense of coherence was linked to favourable oral health behaviours (Eriksson and Lindstrom, 2007, Elyasi et al., 2015), whereas poor oral hygiene and adverse dental health behaviours have been related to a weak sense of coherence (Savolainen et al., 2005b).

The impact of sense of coherence on oral health behaviours was reported in a systematic review (Elyasi et al., 2015). The behaviours relevant to periodontal care included tooth cleaning, dental attendance and smoking. A strong sense of coherence was associated with brushing twice a day, attending for regular dental check-ups and not smoking. There are however, some limitations in the studies reported, including all but one of those selected being cross-sectional, and as a consequence the authors recommend future research should include longitudinal studies. In relation to changing oral health care behaviour, one longitudinal study was included by Elyasi et al. (2015).

2.9.7 Summary of Sense of Coherence

In summary, sense of coherence appears to be associated with some behaviours important in the management of periodontal diseases and is also an important psychological resource influencing OHRQoL. Thus, sense of coherence may have a role in the treatment of periodontitis. However, no studies have investigated sense of coherence in relation to periodontal treatment outcomes, and therefore further investigation is warranted.

2.9.8 Measurement of Sense of Coherence

In the aforementioned systematic review, all investigators used the Sense of Coherence-13 scale, which is a validated shortened version of the original questionnaire developed by Antonovsky (1987), and all used either a 7 or 5-point Likert scale (Elyasi et al., 2015). The potential for measurement error to hide relationships in studies using the Sense of Coherence questionnaire however, has been highlighted (Eriksson and Lindstrom, 2006).

2.9.9 Self-efficacy

Self-efficacy is *"the extent or strength of one's belief in one's own ability to complete tasks and reach goals"* (Ormrod, 2006). People with high self-efficacy tend to view tasks as something they can do rather than not. Self-efficacy is embedded in the health behaviour theory, related to other models such as the Health Belief Model to which it has been added. It also forms part of the Transtheoretical Model as a core construct, and self-efficacy variables explains the variables in oral hygiene behaviours in the Theory of Reasoned Action (Kakudate et al., 2010a). According to Bandura, self-efficacy predicts actions and controls the subsequent emotional response when an individual determines a course of action, based on the desired expected outcome, and their expectations in relation to ability (Bandura, 1977).

Bandura described three dimensions of self-efficacy: Magnitude, strength and generality. Magnitude refers to the difficulty of the task, thus those with low self-efficacy only feel able to perform the simplest of tasks. Strength relates to confidence in performing a task, and generality refers to the number of areas in which individuals may consider themselves to be effective. The strength of self-efficacy may also vary according to the nature of the task being undertaken, and this can also be influenced by experience. Consequently, self-efficacy is classified as either general or task-specific. The latter is of importance in the context of oral health, and is related to oral hygiene behaviours such as tooth brushing and flossing.

Self-efficacy develops as a result of an interaction of information from four sources; accomplishments (enactive mastery), modelling on others (vicarious experiences), coaching (verbal persuasion), and physiological/emotional state (physiological and affective states) (Kakudate et al., 2010a).

2.9.10 Self-efficacy and Periodontal Diseases

Only one study to which Japanese university students were recruited has reported on self-efficacy and periodontal diseases. In this longitudinal study over 3 years, low self-efficacy self-care was associated with periodontal disease progression, and interestingly with an improvement in oral health behaviours amongst participants receiving initial advice on oral hygiene (Mizutani et al., 2015).

2.9.11 Self-efficacy and Oral Health Behaviours

Most studies on self-efficacy are concerned with behavioural aspects of importance in periodontal treatment. Stewart et al., (1997) and Syrjala et al., (1999) found scores for self-efficacy were related to behaviours including brushing, flossing and dental visits. Kakudate et al. (2008) found patients with a high score on the Self-efficacy Scale for Self-care (SESS), particular those having higher self-efficacy for the dentist consultations subscale, were more likely to remain in periodontal treatment. Furthermore, SESS predicted completion of treatment. Limitations of the study, however, include a focus on mild to moderate chronic periodontitis and hence exclusion of individuals having severe disease, the relatively short period of maintenance care, and the study being undertaken in one private dental clinic. Patients with lower SESS are also more likely to be lost to treatment and follow-up (Kakudate et al., 2008, Kakudate et al., 2010b). No gender associations were found, but older people were less likely to be lost. Educational and socioeconomic factors were not examined however, and the authors suggested that future studies should be conducted in other settings and consider socioeconomic status. More recently, Wu et al (2018) also found that in long-term supportive periodontal therapy, low self-efficacy, along with age, severity of periodontitis and periodontal surgery, was a predictor of lost to follow-up in patients with chronic periodontitis (Wu et al., 2018).

Mizutani et al. (2012) found students with high self-efficacy had better oral hygiene behaviours, less plaque and calculus and fewer sites with bleeding on probing. However, socioeconomic factors, psychological factors (stress, distress and coping behaviours) and social capital were not investigated, all of which may have had an impact. In addition, the study was cross-sectional and only a part-mouth examination was performed. Since the study was also restricted to university students, the findings may not be applicable to the general population of people having periodontal diseases (Mizutani et al., 2012).

A further study found oral hygiene-related self-efficacy influenced oral hygiene, patients efforts to receive professional cleaning and future oral health behaviour (Woelber et al., 2015). The Self-efficacy for Self-care Scale was positively related with less gingival bleeding in non-smokers, attendance at the second appointment for professional tooth cleaning, and higher goals for inter-dental hygiene planning. Furthermore, bleeding and plaque scores were reduced at the second appointment in those having a high oral hygiene self-efficacy. Brushing and inter-dental hygiene oral hygiene self-efficacy were the strongest influencing factors for gingival bleeding, whilst the dental visiting component of oral hygiene self-efficacy was the strongest predictor for subsequent attendance. Oral hygiene self-efficacy was related to plaque indices, suggesting the importance of using this measure. Oral hygiene self-efficacy was higher in females, and similar in smokers and non-smokers. Finally, knowledge about oral hygiene did not appear to correlate with plaque.

The pertinent limitations of this study are inclusion of intrinsically well-motivated patients and the lack of validation of the knowledge questionnaire. In addition, there was no assessment of the educational level of participants, standardization at the first visit, and lack of control for some factors that might affect oral hygiene, such as periodontal disease status and the oral hygiene aids used. These are all important factors to take into account when planning future studies on oral hygiene self-efficacy.

The relationship between self-efficacy and dental cleaning behaviours has also been associated with social support, and was reported to be the most important predictor of dental cleaning behaviour in pregnant women with gingivitis (Rahmani et al., 2019).

The importance of self-efficacy in relation to oral health behaviours has led to the development of interventions to improve it. According to Bandura (1997) an individual's actions are dependent on the interaction between efficacy expectations and outcome expectations. Therefore, a scale to assess outcome expectancy in patients with periodontal disease has been developed (Kakudate et al., 2011) to use in conjunction with the self-efficacy scale for self-care. When both self-efficacy and outcome expectancy are high, patients tend to feel personal satisfaction; however, when both are low, patients feel resigned. A high self-efficacy and low outcome expectancy is associated with patients likely to express their dissatisfaction, whereas a low self-efficacy and high outcome expectation is associated with a tendency for patients feeling a sense of self-devaluation.

2.9.12 Summary of Self-efficacy

In summary, the assessment of self-efficacy might be useful in predicting oral health behaviour, in risk assessment, treatment planning and adherence to dental treatment regimens. Enhancing self-efficacy might be useful in improving preventive measures and completion of periodontal treatment. Changes in oral hygiene-specific self-efficacy may be achieved using approaches including Motivational Interviewing, and targeting specific factors. Indeed, tailored approaches that can enhance self-efficacy have been shown to improve adherence to oral hygiene in periodontal treatment, and particularly in relation to inter-proximal plaque control (Jonsson et al., 2009, Jonsson et al., 2010). A recent systematic review however, concluded that whilst motivational interviewing might be useful in relation to self-efficacy, the evidence was insufficiently robust and that further studies were required for this to be determined (Kopp et al., 2017).

More recently, Newton and Asimakopoulou (2018) suggested the most important factors in behavioural change are the perceived benefits of a behaviour and self-efficacy beliefs. Interventions can lead to an increased self-efficacy and enactive attainment may enhance perception of self-efficacy. Better self-efficacy may follow successful behaviour change in addition to or instead of being a predictor of behaviour change (Newton and Asimakopoulou, 2018).

Given the importance of self-efficacy and specifically task-specific self-efficacy in relation to oral health behaviours, risk assessment, treatment planning and adherence to dental treatment regimens, further research is justified in relation to the clinical and OHRQoL outcomes of periodontal treatment.

2.9.13 Measurement of Self-efficacy

Self-efficacy may be measured using a number of scales (Stewart et al., 1997, Syrjala et al., 1999, Kakudate et al., 2008, Woelber et al., 2015). However, the measurement of task-specific self-efficacy is most relevant in the context of oral health, because questions are related to oral hygiene behaviours that are of importance in the treatment of plaque-related periodontal diseases. Oral health care-specific self-efficacy assessment (SESS) scores, especially dentist consultation subscale, predict completion of periodontal treatment, and loss to long-term follow-up (Kakudate et al., 2008, Kakudate et al., 2010b). Accordingly, the scale selected for the present research was task specific, having 3 subscales with questions about brushing, interdental cleaning, and visiting the dentist (Syrjala et al., 1999, Woelber et al., 2015).

2.9.14 Self-esteem

Self-esteem, as described by Rosenberg (1965) and Coopersmith (Coopersmith, 1967), may be defined as a confidence in own worth and abilities. It is akin to self-respect, and includes positive and negative evaluations of self in relation to reflections on self-worth, judgment and attitude about oneself. In addition, beliefs such as feeling competent, and emotions of triumph or despair may be reflected in self-esteem. The construct is believed to predict achievement, happiness, satisfaction with life and risk taking. It also has a dimensional aspect in relation to performing tasks and work. Self-esteem develops in childhood, where unconditional parental love and support increases a child's self-esteem, and where negative experiences may have an adverse effect (Orth, 2018). Social experiences encountered when growing up influence self-esteem and throughout adult life self-esteem increases to about middle age, after which it may decline with age, although it may also remain stable throughout life (Robins and Trzesniewski, 2005). There are gender and cultural differences in self-esteem, with males generally having higher self-esteem, but the magnitude of the gap differing between cultures (Hornsey et al., 2018, Bleidorn et al., 2016).

Self-esteem is considered to be important for good psychological health, the development of interpersonal relationships, happiness and the ability to cope with stress. It is related to other psychological concepts including locus of control, neuroticism and self-efficacy, and is considered to be one of the most essential core self-evaluation dimensions.

It is plausible, taking into account the adverse effects on appearance and function, that periodontal diseases may adversely influence self-esteem, and conversely that self-esteem may affect the response to treatment in relation to aspects on which health care behaviour depends. However, there are relatively few reports on self-esteem and periodontal diseases and fewer still in relation to treatment.

2.9.15 Self-esteem and Periodontal Diseases

Periodontal disease is often quoted as having an adverse effect on self-esteem (Chapple et al., 2017), however whilst this would seem plausible, there are few data to support it. In one study of the relationship between psychological factors, periodontal disease and obesity, lower self-esteem was found in overweight patients having mean probing depths >3mm and a bleeding index of > 25% (Dumitrescu and Kawamura, 2010). However, the impact of self-esteem alone on peridontal disease, in contrast to the impact of obesity in this study is unclear.

The stability of self-esteem, along with a number of other psychological factors, in relation to oral health-related behaviours and oral health has also been investigated (Dumitrescu et al., 2012). People with unstable self-esteem may have their self-esteem influenced by reflection on factors such as aspects of their social life and externally received evaluations of this. Whereas people with a stable self-esteem, are less affected by everyday positive or negative experiences. Patients at two private dental practices in Romania were investigated in this study, using self-administered questionnaires. The limitations of this study include the cross-sectional design, the participants being mainly females having above average earnings, and being recruited from private practices in one geographical location. In addition, all the data were self-reported using a number of questionnaires, and it is acknowledged that self-esteem may influence self-reports rather than disease.

The remainder of studies focus on self-esteem in relation to quality of life. Higher self-esteem was directly linked with better health-related quality of life, along with other factors including higher sense of coherence, greater social support, less smoking and a higher frequency of toothbrushing (Gomes et al., 2019). In this study, higher self-esteem was directly predicted by greater social support.

2.9.16 Self-esteem and OHRQoL

The relationship between self-esteem and OHRQoL has largely been focussed on orthodontics and the literature on OHRQoL in relation to periodontal diseases is sparse. A significant modest to weak association was found between self-esteem and OHRQoL in a cross-sectional study of adults seeking orthodontic treatment (Clijmans et al., 2015). Higher self-esteem was associated with better OHRQoL, with lower impacts in all OHIP-14 domains. The impact of self-esteem along with negative affectivity on OHRQoL was also investigated in a cross-sectional study of adults with partial tooth loss (Ozhayat, 2013). Low self-esteem was associated with worse OHRQoL, and it was suggested that self-esteem may help to explain some of the impact of tooth loss on OHRQoL.

In the only study to date focussed on patients with periodontal disease, self-esteem was found to be the second most prevalent domain having an adverse effect on quality of life (Musurlieva and Stoykova, 2015). The questionnaire used however, simply asked if patients considered that their periodontal condition had influenced their self-esteem.

2.9.17 Self-esteem and Oral Health Behaviours

Self-esteem has been related to adherence to dental self-care (Kneckt et al., 2001). Self-esteem was associated with a high frequency of tooth brushing, but there was no association with dental visiting frequency. No correlations were found in relation to self-esteem and plaque or gingival bleeding indices. The association between self-esteem and tooth brushing may be related to a persevering character, which may require high self-esteem. Whilst high self-esteem may promote the worthiness and self-confidence needed for good self-care, success in self-care can also strengthen self-esteem. In addition, the stability of this trait may also be important in determining adherence to the health-related behaviours required to maintain periodontal health in the long-term.

Self-esteem, self-efficacy, locus of control and intention were investigated predictors of oral health behaviours, oral health, diabetes adherence and metabolic control (Syrjala et al., 2004). Whilst self-esteem was associated with oral health habits (routine of behaviour) more than the clinical characteristics, self-efficacy was the best determinant of health behaviour practices (actions). The authors also report that whilst psychological characteristics had limited use in explaining oral health, improvement of self-efficacy in particular may lead to a positive effect on health behaviours. Self-esteem would therefore seem to be of secondary importance to self-efficacy in relation to promoting oral health behaviours according to this study.

Recent papers also report associations between self-esteem, oral health beliefs and oral hygene habits. Higher self-esteem predicted more frequent toothbrushing, and together with oral health beliefs predicted ginigval bleeding via toothbrushing frequency and oral hygiene effectiveness in socially deprived adolescents (Koga et al., 2019). A further study of adolescents however, found higher self-esteem was associated with better oral health behaviours and in particular tooth brushing, irrespective of gender or socioeconomic characteristics (Costa Pazos et al., 2019). It was suggested that self-esteem should be evaluated to target improving oral health behaviours.

2.9.18 Summary of Self-esteem and Periodontal Health

The few reports on self-esteem in relation to periodontal diseases and their treatment in adults, and patient reported outcomes leave its relative importance unclear. It has been suggested that periodontal diseases negatively impact on self-esteem, and that improving periodontal health may in turn improve self-esteem, but there are no robust data on this.

Self-esteem and health in general are linked (Marmot, 2003), and studies outside of dentistry have also focus on low self-esteem being linked with health damaging behaviours. For example, a recent systematic review found an association between higher self-esteem and healthier behaviours in most studies (Arsandaux et al., 2020). Lowered self-esteem is also consistently found in people diagnosed with chronic illnesses, and is a predictor of stress in these individuals. Lowered self-esteem may also hinder social relationships due to those with chronic illness being less likely to seek out social activities (Juth et al., 2008). Perceived symptom severity may also be worse and the reported frequency of symptoms increased. Self-esteem therefore matters in relation to health, and it seems plausible that it may be important in relation to both clinical and OHRQoL outcomes in patients with chronic periodontitis. This might be as a consequence of health promoting behaviours and/or a direct psychological effect.

Given the potential bidirectional relationship between self-esteem and health and the sparse data on this in relation to periodontal diseases, there is a case for research on the relationship between self-esteem, periodontal status and treatment outcomes.

2.9.19 Measurement of Self-esteem

The measurement of self-esteem may be undertaken using the Rosenberg Self-esteem Scale (Rosenberg, 1965), and the Coopersmith Inventory (Coopersmith, 1967).

2.9.20 Locus of Control

Locus of control describes an individual's belief about how much control they have over events that affect them (Rotter, 1954). In essence, the concept is broadly that an individual believes either they have control over their own life or that their decisions and life are controlled by external factors over which they have no control. The external dimension in this concept has been divided into significant or powerful others and chance. Locus of control has applications in all aspects of life, for example in education, and in the context of health care this will affect the perceptions about where the responsibility for disease, prevention or treatment rests. Locus of control is an aspect of core self-evaluations that include neuroticism, self-efficacy and self-esteem (Judge et al., 1998).

2.9.21 Locus of Control and Periodontal Disease

There are few reports on locus of control and periodontal disease, which is perhaps surprising given its importance in relation to self-care. In one study, the effect of occupational stress and disease progression was investigated in a 5 year cohort of regular dental attendees having moderate to established periodontitis (Linden et al., 1996). Locus of control explained 65% of the variance in the loss of clinical attachment. Those who felt in less control of their environment tended to have more lost clinical attachment. This was predicted by increasing age, lower socioeconomic status, low job satisfaction and Type A personality. However, this was a small sample size of only 23 patients, and so clearly further studies with larger samples are needed to further explore the possible relationship between locus of control and periodontal disease progression.

In a study of the relationship of negative life events and psychological factors on periodontal disease, having extreme external control was linked with a slightly increased risk of severe periodontal disease (Hugoson et al., 2002). This cross-sectional study used clinical and radiographic examinations along with questionnaires to investigate socioeconomic factors, smoking status, life events, and psychological stress. The ability to cope with stressful events was related to the severity of periodontal disease. Those with a strong external focus coped less well with psychological stress and had more severe periodontal disease than those having strong internal beliefs with better coping strategies.

2.9.22 Locus of control and Oral Health Related Quality of Life

Locus of control appears to have been included in only one investigation of OHRQoL and periodontal care (Johansson et al., 2010). Higher OHIP scores were associated with higher scores for the chance element of the Multidimensional Health Locus of Control Scale used. The authors acknowledged that their results in relation to locus of control should be considered as tentative due to the revisions made to the scale used.

2.9.23 Locus of Control and Periodontal Treatment

People whose locus of control is strongly internal may respond well to instruction to undertake their own preventive care, and those with a strong powerful other locus of control might be influenced by their dental care professional, whilst those with a locus of control strongly related to chance may not believe that the oral hygiene measures or other actions will influence their disease (Galgut et al., 1987).

Plaque scores, gingival inflammation and Multidimensional Health Locus of Control Scale were measured in office workers at intervals up to 18-weeks after dental prophylaxis dental health education and oral hygiene instruction (Galgut et al., 1987). Progressive decreases in plaque and gingival scores were observed, but no correlation was found between any of the 3 Multidimensional Health Locus of Control Scale dimensions and plaque or gingivitis scores prior to commencing the plaque control programme, other than for high internal dimension scores and gingivitis at baseline, which the authors could not account for. At the end of the study patients with stronger powerful others and internal dimensions of the Multidimensional Health Locus of Control Scale had lower plaque scores. Those with a strong internal dimension of the Multidimensional Health Locus of Control Scale also had lower levels of gingival inflammation at the end of the study. There was minimal correlation between the Multidimensional Health Locus of Control Scale dimension of chance and the clinical data. These results suggest high scores for powerful other and internal dimensions, support responses to oral hygiene instruction.

The relationship between health beliefs and adherence to oral hygiene advice was also investigated longitudinally (Borkowska et al., 1998). Patients referred for periodontal treatment underwent clinical measurements and questionnaires repeated 4-6 weeks later, and subsequently received scaling and root surface debridement. The dental beliefs questionnaire had internal, powerful others and chance locus of control subscales. Whilst most patients had improvements in their clinical scores at the end of the study, inflammatory variables were related to health beliefs in the chance domain, and plaque scores were related to the internal domain, in contrast to Galgut et al. (1987). It may be that a single behavioural factor is unable to predict each of the clinical variables in patients with periodontal disease.

Dental locus of control beliefs, the frequency of dental visiting and plaque index, were investigated in a cross-sectional study of control beliefs in relation to diabetes control monitoring HbA1c levels (Kneckt et al., 1999). Correlations were found between dental and diabetes locus of control beliefs, but only the dental locus of control belief predicted health behaviour and health status, which supports the notion of a behaviour-specific locus of control.

Beliefs about control in relation to periodontal disease appear to remain stable after periodontal treatment (Bajwa et al., 2007). However, whilst no difference in locus of control was found, oral health related quality of life improved. The investigators suggested that further studies were required to confirm these findings. Locus of control was also investigated in relation to the clinical outcomes of a dental health education intervention in students (Stenstrom et al., 2009). Baseline measurements of plaque and gingivitis scores were compared with measurements 10 weeks following a video programme. The students also completed Multidimensional Health Locus of Control Scale, Dental Health Locus of Control Scale, and Dental Health Values questionnaires. The findings suggest that the Dental Health Locus of Control, Dental Health Values and gender are associated with dental health. However, the study was limited to young adults and gingivitis, and so it is not known if these findings may be generalised to apply to older people or those with more severe periodontal disease.

In a similar study, plaque and gingival indices were measured in college students before and 10 weeks after oral health education and the Multidimensional Health Locus of Control Scale questionnaire at both time points (Potdar et al., 2015). Plaque and gingival scores decreased significantly between time points, and were associated with stronger powerful others and internal locus of control. In contrast, a positive correlation was found between plaque and gingivitis scores and the chance domain of locus of control. However, only the pre- and post-test comparisons of powerful others locus of control scores were significant. These findings suggest that the powerful others aspect of locus of control could change after oral health education. The participants in this investigation are not the typical age and social profile of many patients with advanced periodontal disease, and the findings of this study should be may not be generalised to other age groups, people in different populations or having more severe disease. In common with a similar previous study (Stenstrom et al., 2009), a control group was not included and so it could be argued that the changes oral health behaviour may not be attributed solely to the oral health education programme.

2.9.24 Summary of Locus of Control

In summary, locus of control may influence the response to periodontal treatment, as a consequence of its relationship to oral self-care. However, there are few studies on this or OHRQoL and the data available is not sufficiently robust to enable any firm conclusions to be drawn.

2.9.25 Measurement of Locus of Control

Commonly used measures of locus of control in health psychology include the Health Locus of Control Scale and the Multidimensional Health Locus of Control Scale (Galgut et al., 1987). The Multidimensional Health Locus of Control Scale enquires about beliefs concerning health and outcomes of treatment to determine whether participants' beliefs are in the domains of internal, chance or powerful others (Wallston, 2005).

2.9.26 Summary of Psychological Factors

Sense of coherence, self-efficacy, self-esteem and locus of control may directly influence health behaviours, adherence to periodontal treatment, maintenance care, and may have effects by psychological pathways. Whilst there is extensive literature on the benefit of periodontal treatment for periodontal health and improved OHRQoL, there are fewer reports on the psychological factors that may influence these outcomes and the potential pathways. Furthermore, the lack of patient centred outcomes has been reported as a short-coming in the literature, and identified as being important to include in future research on periodontal diseases (Inglehart, 2015).

Although overlapping, each of these factors differ from one another and measure different psychological aspects. Further investigation may provide insight into those of importance in determining OHRQoL and clinical outcomes of treatment. This knowledge would be useful to identify the psychological factors that may predict the outcomes of periodontal treatment, for example whether these are by behavioural and/or psychological pathways. It may also help identify where and when to intervene. For instance, if stronger sense of coherence predicts better clinical and/or OHRQoL outcomes, then interventions to enhance this early in the care pathway may help to improve outcomes in a person with a low sense of coherence.

Furthermore, knowledge about the influence of psychological factors may also help with case selection and understanding health trajectories after treatment.

2.9.27 Summary of Measurement of Sense of Coherence, Self-efficacy, Self-esteem and Locus of Control

Table 8 identifies the instruments most frequently used to measure each psychological factor and OHRQoL.

Table 8 Instruments most frequently used to measure psychological factors and OHRQoL, together with comments about the validity of each.

Factor	Instrument	Comments
Sense of Coherence	13-point Sense of Coherence Scale	Measures how people manage stress and stay well. Health resource influencing quality of life. Predicts a good quality of life. Multidimensional, predicts positive outcome in long-term. Reliable, valid, cross-cultural applicability, stable with age, but increases with age. Cronbach's α 0.7-0.92. Mean sense of coherence 35.39 (SD 0.10)-77.60(SD 13.80) points (Eriksson and Lindstrom, 2005, Eriksson and Lindstrom, 2007).
Self-efficacy	Task specific Self-efficacy Scale (3 subscales, 5 questions each)	Task specific instrument important (oral health care-specific self-efficacy). Scores, especially dentist consultation subscale, predict completion of periodontal treatment, and long-term follow-up. General self-efficacy scores do not predict completion or drop out of periodontal therapy. Cronbach's α 0.83. Mean scores 56.5 ± 10.1 (range 40-71) (Kakudate et al., 2008, Kakudate et al., 2010b).
Self-esteem	Rosenberg Self-Esteem Scale - 10 items	Excellent internal consistency, with a Guttman scale coefficient of reproducibility of .92. Excellent stability, with a test-re-test reliability over 2-weeks correlation of .85 and .88. Validity - concurrent, predictive and construct validity using known groups. Correlates significantly with other measures of self-esteem including the Coopersmith Self-Esteem Inventory, and correlates in a predictive direction with measures of depression and anxiety (Rosenberg, 1979).
Locus of control	Multi-dimension Health Locus of Control 3 sub-scales 6 items in each	Subscales measure individuals' health locus of control beliefs. Widely used and validated (Halpert and Hill, 2011). Validity depends of the purpose and is modest. Varies according to the subscale, appropriateness of the statistical analyses and context being examined (Wallston, 2005).

2.9.28 Other Psychological Factors Potentially Affecting the Management of Periodontal Diseases

Individual factors including neuroticism, extraversion, openness to experience, agreeableness and conscientiousness have also been identified as being potentially important in patient adherence to periodontal care (Umaki et al., 2012). Non-adherence has been linked with negative aggression and immaturity, passivity, dependence and depression, emotion-focused coping and poor coping abilities, low emotional intelligence, neuroticism and perceived control.

Personality traits in particular may influence self-reported subjective health measures. For example, negative affectivity has been consistently associated with subjective health measurements, and in one study a higher Negative Emotionality score (and lower Constraint and Positive Emotionality Multidimensional Personality Questionnaire (MPQ) superfactor scores) reported 1+ OHIP-14 impacts than those who did not (Thomson et al., 2011). Individuals scoring higher on Negative Emotionality also had 3 + OHIP-14 impacts and worse-than-average oral health after controlling for gender, clinical status, and the other two MPQ superfactors. In summary, the MPQ, constraint comprises traditionalism, harm avoidance and control subscales, positive emotionality comprises wellbeing, social potency, achievement and social closeness subscales, and negative emotionality comprises aggression, alienation and stress reaction subscales.

Whilst there is some overlap between personality factors with the constructs outlined earlier, some areas can be identified whereby personality factors might be taken into account to develop approaches designed to improve patient adherence with periodontal treatment. These might include developing alternatives to overcome perceived weakness and limitations, for example, working to remove barriers for patients with low self-efficacy and strategies aimed at changing behaviour by Motivational Interviewing.

2.9.29 Overall Conclusions from a Review of the Literature

From the foregoing review, the following conclusions may be drawn:

- Periodontal diseases are not silent, but negatively impact on the oral health related quality of life of people affected.
- Chronic periodontitis may be effectively treated by a combination of non-surgical periodontal treatment and patient performed plaque control, together with adherence with treatment regimens and maintenance care programmes.
- Periodontal treatment improves oral health related quality of life.
- Sense of coherence and locus of control may impact on oral health related quality of life in patients undergoing periodontal treatment.
- Self-efficacy, self-esteem, sense of coherence and locus of control may impact on oral health behaviours and adherence to treatment regimens.
- Other psychological factors and low socioeconomic status may increase susceptibility to periodontal diseases and adversely affect treatment outcomes.
- An understanding of relevant psychological factors is important in improving the management of periodontal diseases in clinical practice. Further research might be useful in identifying the predictors of clinical and OHRQoL treatment outcomes, lead to a greater understanding of where and how best to intervene, aid case selection and the understanding of health trajectories after treatment. Further knowledge of these may be useful for dental professionals, those responsible for the management of health care resources, and most importantly benefit patients affected by periodontal diseases.
- The use of a theoretical model will help determine the characteristics of importance in predicting OHRQoL and clinical outcomes of periodontal treatment.

2.10 Rationale for Research

The rationale for further research is firstly to identify factors that may be important in relation to clinical and OHRQoL outcomes of periodontal treatment and that have not been adequately investigated in the existing literature, as identified in this review. Secondly, to address some of the methodological failings of existing studies that compromise our understanding of the factors predicting these outcomes.

OHRQoL

Whilst previous studies have demonstrated that periodontitis negatively impacts on OHRQoL and that non-surgical periodontal treatment improves this, many studies have limitations that compromise the quality of evidence. Most studies are cross-sectional or cohort designs, and the limitations in the quality of methodology and reporting of these and other studies are discussed in Sections 2.5.2 to 2.5.6.

There are no studies that have followed OHRQoL in patients from the time point of being assessed and diagnosed with disease by a specialist, then during the interval before treatment can be provided (untreated disease), and through the care journey from treatment, interim oral hygiene review and follow-up after the completion of a single course of non-surgical periodontal treatment. Furthermore, few studies have investigated the other psychological and individual factors which may impact on outcomes after periodontal treatment, and none were guided by theory. Further longitudinal studies are therefore justified taking these factors into account.

Sense of Coherence

Sense of coherence is related to some oral health behaviours that are important in the management of periodontal diseases. Since no studies have investigated sense of coherence in relation to periodontal treatment clinical outcomes, investigation of this is warranted.

The forgoing review of the literature also suggests a stronger sense of coherence is associated with a better quality of life, and there is also consistent and experimental evidence that sense of coherence influences OHRQoL. Therefore, it would be of interest to investigate this further in research on OHRQoL and periodontal treatment outcomes.

Self-efficacy

High oral health care specific self-efficacy appears to predict better oral hygiene behaviours and remaining in periodontal treatment, and consequently is of importance when investigating the periodontal treatment outcomes. The limitations of previous studies include being largely cross-sectional, in selected patient groups and focusing on mild or moderate disease. Previous studies have also been criticised for a lack of standardization at the first study appointment, and a lack of control for periodontal status and oral hygiene aids used. Furthermore, socioeconomic factors and other psychological factors have been omitted. Consequently, further investigation of self-efficacy addressing these short-comings is justified.

Self-esteem

The few reports on self-esteem in relation to periodontal diseases and their treatment in adults, leave its relative importance unclear. It is also claimed that periodontal diseases can negatively impact on self-esteem and improving the periodontal condition may improve self-esteem, but here are no data for this. Accordingly, there is a case for research on the impact of self-esteem on clinical and OHRQoL outcomes of periodontal treatment.

Locus of Control

Locus of control may be related to periodontal treatment outcomes. However, there are few studies on this and the data available is not sufficiently robust to enable any firm conclusions to be drawn. Consequently, further research on locus of control in relation to periodontal treatment outcomes is justified.

The Wilson and Cleary model allows exploration of relationships between characteristics of the individual, characteristics of the environment, and the various levels of symptom status, functional status, general health perceptions and ultimately OHRQoL. Structural equation modelling allows simultaneous testing of direct and indirect relationships between the factors outlined above together with other individual and environmental factors, to enable a better representation of biological, psychological and social factors in the biopsychosocial model.

Elucidating the role of relevant personal factors in predicting clinical outcomes and OHRQoL, may help in the development of more holistic and patient centred approaches for the management of periodontal diseases. This approach would differ from the traditional methods of treatment that are heavily based on the biomedical model of health.

2.11 Aims and objectives of the research

2.12.1 Aim

To determine the oral health related quality of life and clinical changes after the diagnosis and treatment of chronic periodontitis.

2.12.2 Objectives

To determine:

1. The OHRQoL and clinical changes after periodontal treatment.
2. The OHRQoL trajectory from diagnosis to treatment and follow-up.
3. Individual (psychological) and environmental factors predicting OHRQoL and clinical changes after periodontal treatment.
4. Relationships between psychological factors, OHRQoL and clinical changes.

2.12.3 Outcome measures

Primary outcome

Oral Health Related Quality of Life.

Secondary outcome

The clinical condition (periodontal status) (characterized by measurements of periodontal probing depth, clinical attachment loss, bleeding on probing and tooth mobility).

Chapter 3
Methods

The aim of this research was to determine the oral health related quality of life and clinical changes after the diagnosis and treatment of chronic periodontitis.
The objectives of this research were to determine:

1. The OHRQoL and clinical changes after periodontal treatment.
2. The OHRQoL trajectory from diagnosis to treatment and follow-up.
3. Individual (psychological) and environmental factors predicting OHRQoL and clinical changes after periodontal treatment.
4. Relationships between psychological factors, OHRQoL and clinical changes.

3.1 Study Design and Sampling

This was a prospective (follow-up) single arm intervention study. The target population was all UK patients with periodontal disease. The accessible population were patients attending the specialist periodontology clinics at the Charles Clifford Dental Hospital. The included sample were patients who wished to participate in the study.

The sample size was calculated based on the aim to determine the OHRQoL outcomes of the diagnosis and treatment of chronic periodontitis. The few longitudinal studies reporting effect size for OHRQoL measures have used a variety of instruments. The effect size reported ranges from 0.2 to 0.8 (Jonsson and Ohrn, 2014, Saito et al., 2011). In a study assessing the responsiveness of OHRQoL measures to evaluate a dental care programme using the OHIP-14, small-to-moderate effect sizes (0.27 – 0.34) were reported depending on the domain (Locker et al., 2004). Taking into account the difference in that study from this, but anticipating a small–moderate effect size, a conservative effect size of 0.25 was estimated by dividing the OHIP-14 change scores by the baseline standard deviation (Cohen, 1992, Locker et al., 2004, Saito et al., 2011).

G*Power 3.1 (2-tail testing, effect size 0.25 alpha 0.05 and power 0.8) calculated a minimum sample size of 128 participants. The target for recruitment also took into account the anticipated drop-out rate of 15% calculated from a recent study of patients within the same clinic. Therefore a further 20 patients were recruited (Gul et al., 2017). Accordingly, the target recruitment was 148 participants.

During modelling, it became apparent that the model included 2 latent and 10 observed variables. Using an online tool, it was calculated that a minimum sample size of 136 would be required to detect a minimum effect size of 0.25, statistical power 0.8 and probability level 0.05. Accordingly, a calculation of 136 completed participants was accepted as the sample size (https://www.danielsoper.com/statcalc/calculator.aspx?id=89).

3.2 Ethical and Research Governance Approval

Protocol V2 19.4.16 for this study was approved by East Midlands-Nottingham Research Ethics Committee (reference 16/EM/0236) 23.5.16, by the Health Research Authority (IRAS ID 207130) 5.7.16, and sponsored by Sheffield Teaching Hospitals NHS Foundation Trust (STH Project Reference number 19323). In addition, insurance for the study was obtained from the University of Sheffield (Appendix 2).

3.3 Recruitment

Consecutive patients were recruited from those attending a specialist new patient periodontology clinic between 14.7.16 and 4.10.17. After clinical examination by the consultant periodontist (AR), patients who fulfilled the inclusion criteria were informed about the objectives of the study and given a Patient Information Sheet. Informed consent was taken at a subsequent treatment visit from those who wished to take part.

Inclusion criteria

1. Patients aged 18 years and over
2. A diagnosis of chronic periodontitis (Armitage, 1999) with at least 3 sites having periodontal probing depths of 4mm or more and bleeding up to 30 seconds after probing.

Exclusion criteria

1. Periodontal treatment in the previous 3 months.
2. Antibiotics in the previous month.
3. Diabetes, any medical condition or medication that may affect the susceptibility to periodontal disease or the outcomes of treatment.
4. Patients who did not have the capacity to consent for themselves or to answer self-completed questionnaires.
5. Pregnancy and lactating females.
6. Non-English speaking participants.

3.4 Variables

The observed variables were demographic data, oral hygiene habits, clinical data, and OHRQoL, sense of coherence, task-specific self-efficacy, self-esteem and locus of control. Data were collected from clinical records, questionnaires and by using a data capture form during study visits.

3.4.1 Demographic variables

Information about gender, smoking habits (current, ever, never); ethnicity (Sheffield Teaching Hospital NHS Foundation Trust coding of ethnicity), Index of Multiple Deprivation (IMD) (from the postcode using http://tools.npeu.ox.ac.uk/imd/), education (ISCED 2011 levels of education) and occupation (Office of National Statistics) were recorded. The IMD is used in England to measure deprivation at area-level considering the following indicators: income, employment, education, skills and training (measured by proportion of working age adults with no or low qualifications, English language proficiency, children key stage 2 and 4 attainment, secondary school absence, post-16 education and entry to higher education), health and disability, crime, barriers to housing and services, and living environment. These indicators are based on data collected each tax year. An overall relative measure of deprivation combines data from all domains, each of which is weighted. The IMD ranks the deprivation of an area in relation to other areas in England (Department of Communities and Local Government, 2015). However, it is important to appreciate that the IMD is an area-based rather than individual-based measure. The demographic variables were used in structural equation modelling (Section 3.9.3).

3.4.2 Oral hygiene

Information about oral hygiene included questions about the type of tooth brush used (manual/electric), frequency of brushing, type of toothpaste used (fluoride/other additives), interdental brushing, use of tape or floss and the frequency of interdental cleaning, and the use of mouthwash (type and frequency of use). These data were collected at each study time point.

3.4.3 Clinical data

All patients underwent a full periodontal examination as part of routine assessment in accordance with the departmental protocol to record:

- Number of natural teeth, number of decayed, missing and filled teeth, excluding third molar teeth.
- Periodontal probing depth measurements (mm) at 6 points around each tooth.
- Gingival recession from the cement-enamel junction to gingival crest (mm).
- Clinical attachment loss (CAL) was calculated as follows: It was assumed that a normal sulcus depth ≤3mm and for these sites CAL = recession measurement. For probing depth >3mm, CAL = probing depth - 3mm + recession. For probing depth >3mm and recession = 0, CAL = probing depth – 3mm.
- Bleeding upon probing up to 30 seconds for each site (Wilson and Magnusson, 1996) was scored as present or absent = 1 or 0, and the score for the patient calculated as a percentage of the total number of sites examined.
- Tooth mobility was recorded using the following classification (Lindhe, 1989):
  0 = No detectable mobility
  1 = Movement of the crown of the tooth up to 1mm in a horizontal direction.
  2 = Movement of the crown of the tooth exceeding 1 mm in a horizontal direction.
  3 = Movement of the crown of the tooth in a vertical direction as well as a horizontal direction.

Measurements were by the same examiner (AR) using 2 X magnification loupes with participants reclined in a dental chair and using direct illumination. These measurements were completed at the initial assessment and at the end of study review appointment, not less than 3 months and no longer than 9 months after treatment.

In addition, a plaque score (present or absent at 6 points around each tooth) was calculated as a percentage of total tooth surfaces with visible plaque when patients attended for treatment, but before treatment being undertaken, at an interim visit to review plaque control and at the end of study review appointment (Oleary et al., 1972).

3.4.4 Questionnaires

The Oral Health Related Quality of Life: Oral Health Impact Profile (short version) (OHIP-14) (Appendix 3, Section 8.3.1) was self-completed by participants at 4 time points: assessment, treatment, interim oral hygiene review and end of study review. A booklet of 4 questionnaires (Appendix 3, Section 8.3.1) was also self-completed at the appointment for treatment, before treatment. The questionnaires were chosen to capture the psychological characteristics relevant for the study:

1. Sense of Coherence (Antonovsky, 1987)
2. Task Specific Self-efficacy (Woelber et al., 2015)
3. Rosenberg Self-esteem Scale (Rosenberg, 1965).
4. Locus of Control Form C (Wallston, 2005)
   (Form C: https://nursing.vanderbilt.edu/projects/wallstonk/form_c.php)

3.5 Intervention

All patients received standard non-surgical periodontal treatment. This included advice on tooth brushing and interdental cleaning. Interdental brushes were recommended, based on the evidence for this as the method of choice for interdental cleaning in patients with open interdental spaces (van der Weijden and Slot, 2011). The use of disclosing tablets was recommended to aid the identification of plaque deposits. All patients underwent scaling and root surface debridement with Dentsply® slimline ultrasonic instruments under local analgesia. The departmental protocol is to provide full mouth debridement in one visit, which nearly all patients received. However, where patients preferred treatment in a part-mouth, multi-visit approach, this was accommodated. All treatment was provided by one of three Staff Hygienists (AB, CV-O or N A-H).

3.6 Reassessment at Follow-up Time Points

Participants' oral hygiene was reassessed at an interim oral hygiene review and end of study review.

3.6.1 Interim Oral Hygiene Review

Symptoms and oral hygiene were recorded 1 month after root surface debridement. This interval was longer on occasions due to the availability of patients or clinic appointments. Advice on plaque control was given where necessary. The interim review was undertaken by one of three Staff Hygienists (AB, CV-O or N A-H), or the investigator (AR), depending on availability.

3.6.2 End of Study Review

The end of study review was undertaken 3 months to 9 months after the completion of treatment by the examiner who performed the initial assessment (AR). Patients were then either discharged having completed treatment satisfactorily or further treatment arranged. The study time points, procedures and data collected at each time point are shown in Table 9

Table 9 Study time points and data collected

Study time points	Procedures and data collected
Assessment	Diagnosis and screening for study. OHIP-14. Clinical measurements. Potential participants informed about study. Patient information sheet given.
Treatment (Intervention: Non-surgical periodontal treatment)	Consent and recruitment to study. Baseline demographic and environmental factors. OHIP-14 and SoC, TSSE, RSE, LoC (before treatment). Plaque score. Oral hygiene and smoking habits.
Interim oral hygiene review	OHIP-14. Plaque score. Oral hygiene and smoking habits.
End of study full periodontal reassessment	OHIP-14. Clinical measurements. Plaque score. Oral hygiene and smoking habits.

3.7 Examiner Training and Calibration

All clinical examinations were conducted by one examiner (AR), a specialist periodontist with extensive experience in clinical examination and research. Plaque scores were recorded by experienced staff dental hygienists at the treatment and oral hygiene time points, and by AR at the end of study visit for logistic reasons.

3.7.1 Intra-examiner reliability of measurements

The intra-examiner reliability of all clinical measurements was assessed for the examiner (AR) on a sample of patients selected using a 10-sided dice and a 6-sided dice to allocate a sextant (1-6) for repeat measurements. This took place after the clinical assessment at the final review appointment so the examiner was unprepared to undertake repeat measurement. All clinical measurements in the sextant were recorded shortly after the periodontal examination had been completed at the same visit. Thus, complete repeat clinical data for probing depths, recession, tooth mobility, bleeding on probing and plaque scores were available for 16 participants. Intra-examiner reliability of plaque score measurements was also calculated for each Staff Hygienist on 10 patients each.

3.7.2 Inter-examiner reliability of measurements

Inter-examiner reliability was assessed for plaque scores between each Staff Hygienist and AR on 10 patients, as these were the only measures recorded by two examiners.

Inter- and intra-examiner agreement was measured using the Intra-Class Correlation Coefficient. A 2-way mixed model with absolute agreement and a 95% confidence interval was used for each measure, other than mobility which was determined using Cohen's Kappa. Missing data were entered as 99 and then specified as missing in the statistical package used (SPSS version 24).

3.8 Scoring Questionnaires

OHIP-14: Oral Health Related Quality of Life (Slade, 1997)

This was used to measure three dimensions of OHRQoL, namely psychosocial (8 items), pain-discomfort (4 items) and functional limitation (2 items) (Montero et al, 2010). Each of the 14 questions was scored from 0 (never) to 4 (very often). A total score was calculated as the sum of the item response codes, and a higher score indicated worse OHRQoL.

Questionnaire 1: Sense of Coherence (SoC-13) (Antonovsky, 1987)

This was used to measure three dimensions of sense of coherence: meaningfulness (4 items), manageability (4 items) and comprehensibility (5 items). Each of the 13 items were scored 1-7 (see questionnaire for descriptor at each end of the scale). Negatively worded questions (items 1,2,3,7 and 10) were reverse scored. The total score was calculated, and a high score indicates a strong sense of coherence. Data were treated as missing if > 3 items missing.

Questionnaire 2: Task Specific Self-efficacy (TSSE) (Woelber et al., 2015)

This was used to measure 3 sub-scales of task-specific self-efficacy, namely, confidence in tooth brushing (5 items), interdental cleaning (5 items) and visiting the dentist (7 items). Each item was scored 4 (completely confident) – 1 (completely not confident to undertake task or visit the dentist) and the sum of all items in each subscale was calculated as the Task Specific Self-efficacy score. A higher score indicates better task-specific self-efficacy.

Questionnaire 3 : Rosenberg Self-esteem Scale (Self-esteem) (Rosenberg, 1965).

This was used to measure self-esteem in one dimension.

Each item is scored 4 (strongly agree) – 1 (strongly disagree). The negative items (2,5,6,8,9) were reverse scored. The total score was used to determine self-esteem, and the higher the score indicates higher self-esteem.

Questionnaire 4 Multidimensional Health Locus of Control questionnaire C (condition specific) (Locus of Control) (Wallston, 2005)

Questionnaire C was used because it is condition-specific. A separate score was given for each dimension (Galgut 1987):

Internal statements: 1,6,8,12,13,17

Chance statements: 2,4,9,11,15,16

Powerful others: 3,5,7,10,14,18

Each item was scored 1-6 (disagree slightly-agree slightly).

The total score for each dimension was calculated for the Locus of Control. For each of the three statements, a higher score indicates stronger Locus of Control in that dimension.

3.9 Analysis

Data were analysed in four phases:

1. Descriptive analysis.
2. Analysis relating to the primary objective: The OHRQoL and clinical changes following periodontal treatment.
3. Analysis relating to the secondary objectives: Exploration of the OHRQoL changes from diagnosis to treatment, and of relationships of individual, psychological and environmental factors with OHRQoL and clinical outcomes of periodontal treatment: Confirmatory Factor Analysis and Structural Equation Modelling.
4. Changes in OHRQoL over time: Growth Curve Modelling.

3.9.1 Descriptive Analysis Plan

Variables were summarised according to overall number and distribution by proportion, central tendency and spread as appropriate. Where necessary, normality of data was assessed by goodness of data fit using Q-Q plots, together with skewness and kurtosis. Data having skewness between +/-2, and kurtosis between +/-7 was considered not to have severe skew or kurtosis and not severely non-normal (George and Mallery, 2010, Hair et al., 2010).

3.9.2 Analysis relating to the first objective

The first objective of this research was to determine the OHRQoL and clinical changes after periodontal treatment. The trajectory for OHIP scores was followed from assessment, through treatment and interim oral hygiene review to the end of the study. The treatment time point (before treatment) was used as the baseline from which changes in OHRQoL were analysed after treatment. Repeated Measures ANOVA was used for analysis of the OHIP-14 total and dimension scores at 3 time points: from treatment to an interim oral hygiene review and up to 9 months later at the end of the study, in order to determine any OHRQoL effects of periodontal treatment. The prevalence of impacts with a threshold of fairly often was also calculated. Further analysis of change in OHRQoL over time from assessment to the end of the study was undertaken using growth curve modelling (Section 3.9.4).

The clinical changes after treatment were analysed using paired t-tests for parametric data or related samples Wilcoxon Signed Rank Test for non-parametric data. Means of probing depths, clinical attachment level, mobility scores, plaque indices and bleeding upon probing were compared between baseline and end of the study. In addition, the plaque scores at the interim oral hygiene review were compared with baseline and end of study scores. Probing depths were also calculated as changes in the proportion of sites ≥ 1mm and clinically meaningful changes of ≥ 2mm, together with changes in clinical attachment levels, bleeding and plaque scores following treatment.

Comparisons of categorical data were tested using cross-tabulations and Chi-squared tests. A *p*-value of <0.05 was taken as statistically significant. SPSS version 24 was used for statistical analysis.

3.9.3 Analysis relating to the secondary objectives

Secondary objectives of this research included analysis of the OHRQoL trajectory from diagnosis to treatment and follow-up, together with an exploration of how individual, psychological and environmental factors influenced OHRQoL and clinical outcomes of treatment.

Accordingly, analysis aimed to investigate the changes in OHRQoL from the time point of diagnosis to treatment, then from treatment to the oral hygiene and final reviews. The clinical changes were investigated following standard periodontal treatment determined at two time points (before treatment and end of study review) and the influence of psychological factors, together with other individual and environmental factors on these changes.

Repeated Measures ANOVA was used to investigate the mean changes in OHRQoL, and the prevalence of impacts before and after treatment with a threshold of fairly often was calculated. Bivariate analysis using Spearman's rank correlation and Pearson's correlation identified associations between variables, however all potential predictors of OHRQoL and periodontal status were considered in structural equation modelling in order to test all variables within the Wilson and Cleary Model in accordance with the overall aim of the research.

Confirmatory Factor Analysis determined whether observed variables adequately indicated latent variables, and was used to test the measurement models that included the baseline or end of study periodontal status. Structural equation modelling (SEM) explored the relationship between the baseline predictors (observed variables) and OHRQoL (latent variable) at the oral hygiene review and at the end of the study. Predictors of periodontal status at the end of the study were also explored. A parsimonious model was developed from the full SEMs by removing non-significant paths ($P>0.05$). The full and parsimonious models were compared, and the parsimonious model was accepted if it was not significantly different to the full model ($P>0.05$). This was calculated using the difference in Chi-square and degrees of freedom between full and parsimonious models (Werner and Schermelleh-Engel, 2010), in an online programme https://www.graphpad.com/quickcalcs/pValue1/. The parsimonious models were used to determine the predictors of OHRQoL following treatment, together with baseline and end-of-study periodontal status.

SEM used Amos version 25 using maximum likelihood estimation in which 900 bootstrap samples were resampled to produce less biased standard errors and 95% CI bootstrap percentiles. Direct, indirect and total effects (β) for paths linking variables were estimated by the software. The statistical significance of indirect effects was used to assess mediation using bias-corrected bootstrap confidence intervals. Model fit was assessed using Chi-squared, root-mean square error of approximation (RMSEA) with 90% CI, standardized root mean square residual (SRMR), goodness of fit index (GFI) and comparative fit index (CFI). Thresholds for a good model fit were Chi-squared/degree of freedom ratio <3.0, SRMR $\leq$0.08, RMSEA $\leq$0.06, GFI and CFI $\geq$0.90 (Hu and Bentler, 1999).

The SEM tested the direct and indirect relationships among observed and latent variables as predictors of baseline and end of study periodontal status in separate models, and OHRQoL following periodontal treatment, according to the Wilson and Cleary model (Wilson and Cleary, 1995). It was hypothesized *a priori* for both periodontal status before and after treatment, that individual factors (age, gender, smoking, ethnicity, occupation and education) and psychological factors (including total scores for Sense of Coherence, Task-specific Self-efficacy, Self-esteem, Locus of Control), and the environmental factor (Index of Multiple Deprivation) would be significant in these models. The model predicting periodontal status (baseline and end of study) and end-of-study OHRQoL is shown in Figure 3. The indicators of baseline or end of study periodontal status were included in each model to determine the predictors of periodontal status at each respective time point.

Both full models omitted the Index of Multiple Deprivation, qualifications and education, because these observed variables did not fit within an acceptable model and were unrelated to the other variables in the model. Furthermore, these variables were not associated with either OHRQoL or periodontal measures in bivariate analysis. Occupation and smoking were included in the full SEM, but subsequently removed in the parsimonious model because their paths were not significant. Covariances were added to the models between error terms and/or observed variables that made both statistical and conceptual sense in accordance with suggested modification indices in the Amos programme. These signified non-causal relationships (UCS-Education., Al-Zubi, 2015, Steinmetz, 2019, Henseler, 2010). The covariances added to a model predicting baseline periodontal status and end of study OHRQoL are presented in Table 10 and for a model predicting end-of-study periodontal status and end of study OHRQoL in Table 11 for clarity, together with the rationale for each covariance.

Table 10 Covariances added to SEM for baseline periodontal status and end of study OHRQoL

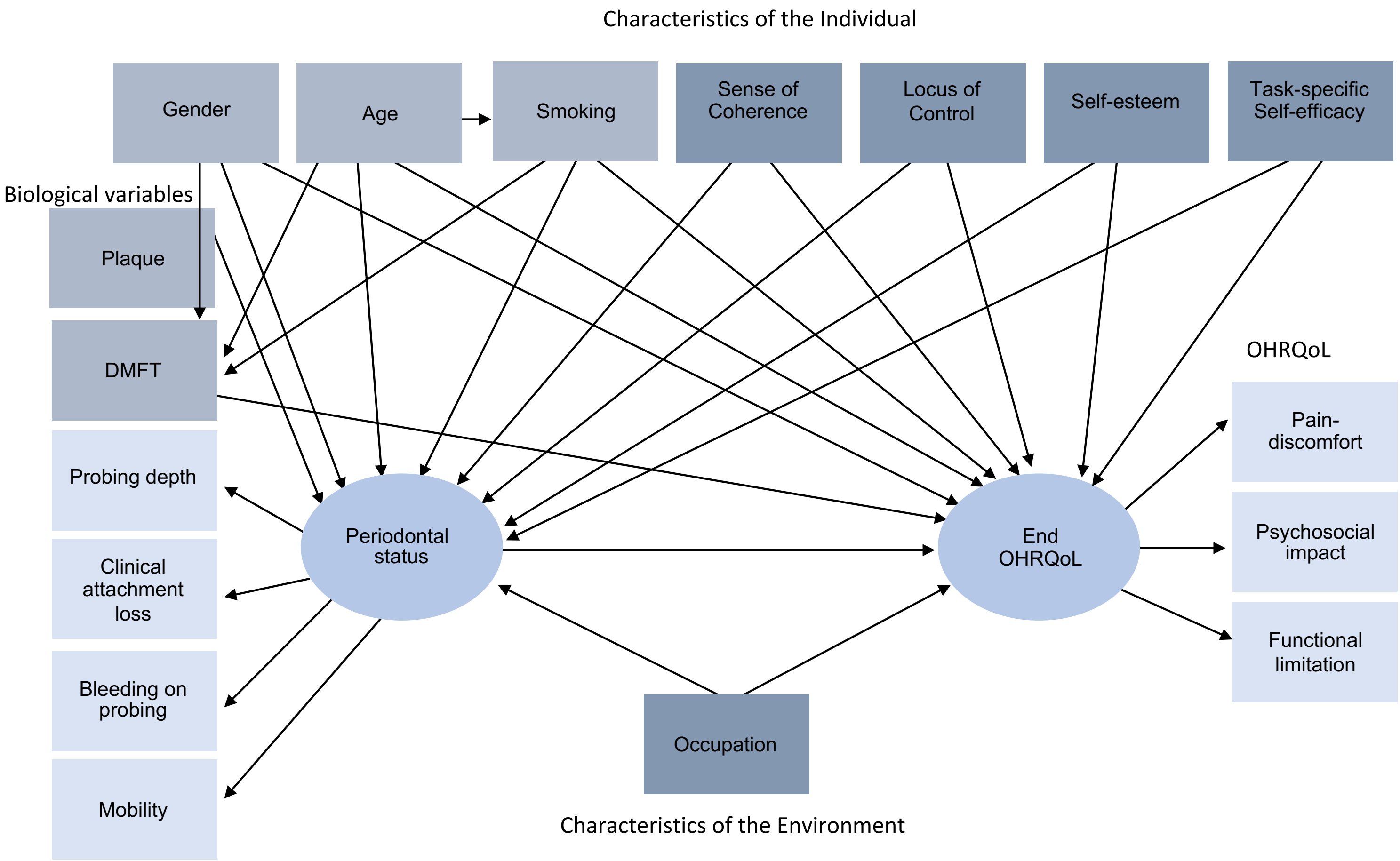
Covariance between	Rationale
Self-esteem and sense of coherence.	Linked psychological factors (Pallant and Lae, 2002).
Self-esteem and occupation.	Self-esteem may be linked with occupation (Gecas and Seff, 1989).
Plaque score (error term) and age.	Plaque score may be linked with age. Periodontal disease progression with age may lead to development of interdental spaces. Drifted, missing and restored teeth may render optimal plaque control more difficult to achieve (Corbet and Smales, 2012).
Clinical attachment loss (error term) and age. Mobility (error term) and age.	Clinical attachment loss may increase with age due to progression of periodontitis, and mobility related to clinical attachment (White et al., 2012, Giannakoura et al., 2019).
Bleeding on probing (error term) and pain-discomfort dimension of OHIP-14 (error term).	Bleeding on probing is a common sign of periodontal disease. Periodontal disease adversely affects OHRQoL (Ferreira et al., 2017). All domains (including pain-discomfort) affected (Masood et al., 2019).
Decayed missing and filled teeth (DMFT) (error term) and pain-discomfort (error term).	DMFT may adversely affect OHRQoL (Yamane-Takeuchi et al., 2016). Decayed, filled and missing teeth may have impacts in pain-discomfort dimensions of OHIP-14.

Table 11 Covariances added to SEM for end of study periodontal status and end of study OHRQoL

Covariance	Rationale
Self-esteem and sense of coherence.	Linked psychological factors (Pallant and Lae, 2002).
Self-esteem and locus of control.	Related psychological factors (Saadat et al., 2012).
Self-esteem and occupation.	Self-esteem may be linked with occupation (Gecas and Seff, 1989).
Functional limitation and mobility (error terms).	Increasing severity of periodontal disease leads to increased tooth mobility. Severity of disease adversely affects all domains of OHRQoL (Masood et al., 2019). Tooth mobility related to OHRQoL (Kishi et al., 2015). Mobility affects function (Giargia and Lindhe, 1997)
Bleeding on probing and plaque score (error terms) and with mobility (error term).	Plaque linked with gingival inflammation (Loe et al., 1965). Bleeding on probing associated with increased risk of disease progression (Lang et al., 1986). Disease progression associated with tooth mobility (Nyman and Lindhe, 2003).
Probing depth (error term) and age.	Probing depth increase with age in population surveys (White et al., 2012).
Probing depth and DMFT (error terms).	Probing depth linked with loss of clinical attachment, which leads to increased risk of tooth loss (missing element of DMFT) (Gilbert et al., 2002).
DMFT and pain-discomfort (error terms).	DMFT may adversely affect OHRQoL (Yamane-Takeuchi et al., 2016). Decayed, missing, filled teeth may trigger items in pain-discomfort dimensions of OHIP-14.
Pain-discomfort and bleeding on probing (error terms).	Bleeding on probing is a common sign of periodontal disease. Periodontal disease adversely affects OHRQoL (Ferreira et al., 2017). All domains (including pain-discomfort) affected (Masood et al., 2019).

Figure 3 Hypothesised SEM of predictors and indicators of periodontal status and end of study OHRQoL.

The hypothesised model includes locus of control, task-specific self-efficacy, sense of coherence, self-esteem, gender, age, smoking, DMFT, plaque score and occupation. Direct relationships are shown by arrows. Error terms and covariances omitted for clarity.



3.9.4 Changes in OHRQoL Over Time

Latent growth curve modelling (GCM) was used to determine the predictors of changes in OHRQoL after periodontal treatment, conducted within SPSS Amos version 25. The minimum number of time points for a GCM is 2, but generally 3 or more are used.

The possible points for growth curve modelling were assessment (when the participant was first examined and diagnosed), treatment, oral hygiene review following treatment and end of study. It was necessary to construct two growth curve models, each having 3 time points, rather than incorporating all 4 time points into one model, due to OHRQoL deteriorating from the initial assessment whilst participants waited for treatment and then improving after treatment. This produced both negative and positive slopes for changes in OHRQoL over time, which did not allow the calculation of estimates in one model. In the first model, treatment was used as the baseline because this research primarily aimed to determine the longitudinal effects of periodontal treatment on OHRQoL. The second model used the initial assessment time point as the baseline, and subsequent time points were the oral hygiene review and end of study. This enabled the predictors of longitudinal changes to be determined from initial assessment.

Two latent variables are used to measure growth over time in growth curve modelling, namely the starting value for the observed variable termed ICEPT, and the rate of change termed SLOPE (Duncan and Duncan, 2009). Growth curve modelling commenced with a univariate model, having paths from the starting OHRQoL (ICEPT) and rate of change of OHRQoL (SLOPE) to each time point at which OHRQoL was measured (OHIP-14). This enabled analysis of the variation in starting OHRQoL and rate of change in OHRQoL longitudinally during the study. In the first model the time points were treatment, oral hygiene and end OHRQoL. A regression weight of 0 was given for the path from slope to treatment OHRQoL. This represented baseline from which change was measured. The path from the rate of change in OHRQoL (SLOPE) to the oral hygiene time point OHIP score was given a regression weight 2, representing the interval rounded up in months between baseline and oral hygiene review. The path from rate of change in OHRQoL (SLOPE) to the end time point OHRQoL was given a regression weight of 3, representing the interval rounded down in months between baseline to the end of study.

For the second univariate growth curve model (assessment, oral hygiene review and end time points), the number of months for each interval from assessment (treated as 0) were used as the regression weights for the paths from the rate of change of OHRQoL (SLOPE), to respective intervals (4 and 6 months). The paths from the starting OHRQoL (ICEPT) to each time point at which OHRQoL was measured were all given a regression weight of 1 in both models.

The outputs of interest from analysis in Amos were the data for ICEPT and SLOPE values for OHRQoL, together with their covariance and correlation of covariance. The value for ICEPT was the mean starting OHRQoL (OHIP-14 score). The value for SLOPE was a measure of change in OHRQoL over time, and was either positive (indicating an increase in OHIP-14 scores / worsening OHRQoL) or negative (indicating a decrease in OHIP-14 scores / improving OHRQoL). The variance of ICEPT indicated how much OHIP-14 scores of individuals differed at the starting time point used in the model (assessment or treatment). The variance of the SLOPE indicated the difference in the rate of change in OHIP-14 scores during the study. Covariance tested whether individuals starting with a higher ICEPT (higher OHIP-14 mean) also changed at a faster rate (steeper SLOPE / higher OHIP-14 changes). A negative correlation of covariance indicated individuals with higher ICEPT (worse OHRQoL / higher OHIP-14 scores) had lower SLOPE’s (smaller changes in OHRQoL at each interval), and a positive correlation that individuals with higher ICEPT’s (worse OHRQoL / higher OHIP-14 scores) had higher SLOPEs (greater changes in OHRQoL at each interval).

The observed variables identified within the Wilson and Cleary model which were compatible with an acceptable model fit were added to each univariate GCM in order to develop multivariate GCM’s. This enabled the predictors of OHRQoL at each time point together with the rate of change of OHRQoL, and the clinical changes during the study to be determined. The same fit criteria used for SEM were applied to GCMs. Paths having non-significant regression weights were then removed to give parsimonious models used to determine predictors of OHRQoL longitudinally, together with rate of change in OHRQoL and clinical changes. A significance level of

0.05 was adopted for all analyses. Significant β values were used to identify direct effects and the magnitude indicated the strength of the association. Positive values of β indicated a direct relationship (both increasing) and negative values indicated an inverse relationship between parameters. R-squared values were also generated in the analysis.

Chapter 4
Results

4.1 Introduction

These results refer to the changes in OHRQoL from assessment to periodontal treatment time points, at an interim review and an end-of-study review up to a maximum of 9 months after the completion of periodontal treatment. The clinical changes following nonsurgical periodontal treatment are presented, and the influence of psychological factors, together with other individual and environmental factors on these changes are investigated. The structure of this chapter is:

1. Descriptive results.
2. Results relating to primary objective: The OHRQoL and clinical changes after periodontal treatment.
3. Results relating to secondary objectives: Exploration of the OHRQoL trajectory from diagnosis to periodontal treatment and follow-up, and of relationships between individual (demographic and smoking), psychological and environmental factors, with OHRQoL and clinical outcomes of periodontal treatment: Confirmatory Factor Analysis and Structural Equation Modelling.
4. Predictors of OHRQoL changes over time: Growth Curve Modelling.
5. Summary

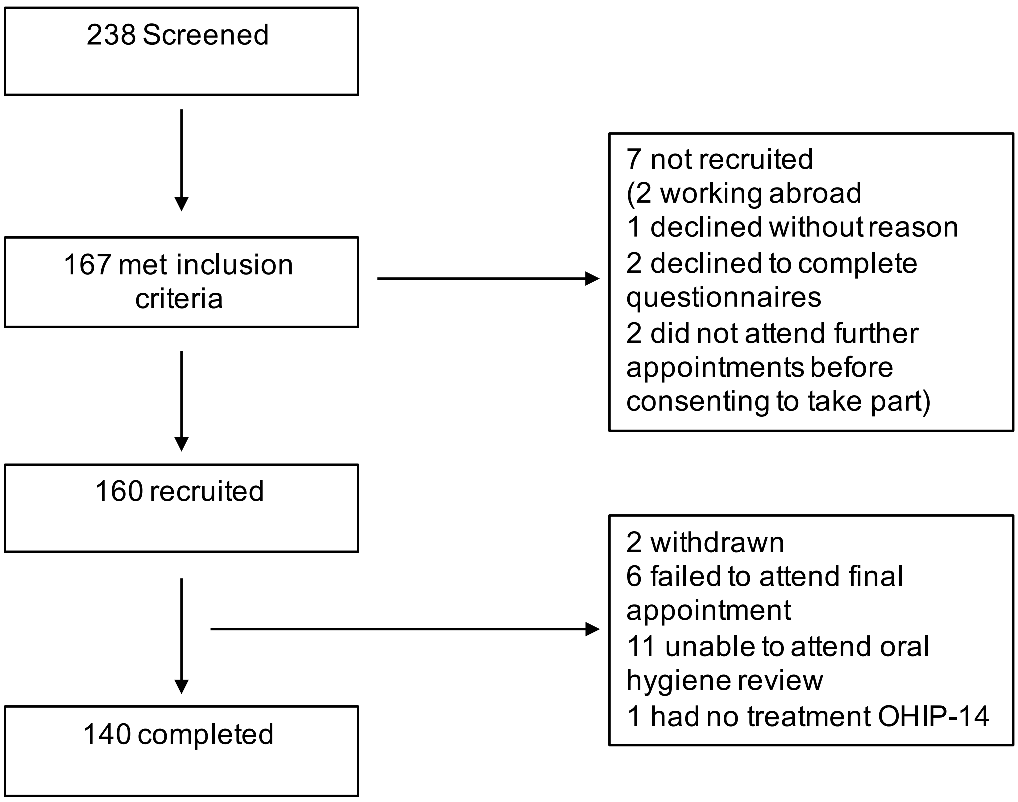
4.2 Descriptive analysis

4.2.1 Recruitment of participants

The recruitment flow chart (Figure 4) indicates that 238 consecutive new patients referred to a specialist periodontology clinic were screened, of which 167 (70%) met the inclusion criteria. The 71 who did not meet the inclusion criteria had other forms of periodontal disease (gingivitis or aggressive periodontitis), did not meet the threshold for patients with chronic periodontitis (≥3 sites with probing depths ≥4mm having bleeding on probing up to 30 seconds afterwards), had a medical history or were taking medication that could adversely affect periodontal health, did not speak English or could not consent for themselves. From those meeting the inclusion criteria, 2 were not recruited because they repeatedly cancelled appointments after screening and before being recruited, 2 did not wish to complete questionnaires, 1 declined without reason and 2 were working abroad and unable to attend further appointments. Two were subsequently withdrawn after recruitment (1 was recruited to the wrong study and the other failed to attend further appointments after being recruited), 6 failed to attend the final review, 11 failed to attend the interim oral hygiene review and 1 had no baseline OHIP-14 data due to an administrative error. One hundred and forty people provided complete data as the intended sample.

Nearly all (95%) participants completed periodontal treatment in one dental visit, with only 7 (5%) needing two sessions. The number of visits required to complete treatment was therefore omitted from further analysis. The mean interval from initial assessment to the provision of treatment was 2 months, completion of nonsurgical periodontal treatment to oral hygiene (interim) review 1.7 months and oral hygiene review to end of study 1.9 months. The mean interval from initial assessment to end of study was 5.6 months. The mean interval from completion of nonsurgical periodontal treatment to end of study was 3.6 months and 85% of participants completed the study in this time.

Figure 4 Participant flow chart



4.2.2 Participants Completing and Lost to Follow-up

One hundred and forty participants completed the study and 18 did not. Ten lost participants were male and 8 were female. The gender balance, smoking status and ethnicity for participants completing and those not completing the study were similar (Table 12). The mean age of participants completing the study was 50.4 years (range 30-78 years, standard deviation 10 years). Fifty-one (36.4 %) participants were male, 89 (63.6 %) were female. The mean age of the 18 who were lost to follow-up was 47.7 years (range 35-58 years, standard deviation 6.4 years). *P*>0.05 for all demographic variables.

Table 12 Smoking status and ethnicity of participants who completed and those lost to follow-up (percentage).

Variables	Participants who completed study (N = 140) %	Participants lost to follow-up (N = 18) %
Smoking status		
Current	14.3	11.1
Former	47.8	55.6
Never	37.9	33.3
Ethnicity		
White British	85.7	77.8
Any other white background	2.1	16.6
Mixed White and Black Caribbean or African	1.4	0.0
Mixed White and Asian or other mixed background	1.4	0.0
Asian or Asian British Indian, Pakistani or other Asian background	2.1	5.6
Black or Black British Caribbean or African	5.0	0.0
Any other Ethnic Group	2.1	0.0

Most participants were from high occupational bands, with over 30% educated to degree level (Table 13). The distribution amongst occupational groups was similar between those who completed the study and those lost to follow-up. The educational level of two participants was not recorded. The occupations and educational levels of those completing the study did not differ from those lost to follow-up (*P*>0.05).

Table 13 Occupation and education of participants and those lost to follow-up (percentage).

Variables	Participants who completed study (N = 140) %	Participants lost to follow-up (N = 18) %
Occupation		
Manager/Director/Senior Officer	20.7	22.2
Professional	22.9	22.2
Associate Professional and technical	9.3	5.6
Administrative and secretarial	15.0	16.6
Skilled trade	9.3	5.6
Caring, leisure and other service	5.0	0.0
Sales	5.0	5.6
Process, plant and machine operatives, and elementary	12.8	11.1
Unknown	0.0	11.1
Education		
Secondary	43.5	33.3
Post-secondary and short-cycle tertiary	22.9	27.8
Bachelor degree or equivalent	25.0	22.2
Higher degree	8.6	5.6
Unknown	0.0	11.1

The oral hygiene habits of participants during the study are shown in Table 14. The oral hygiene habits of those lost to follow-up were not significantly different to those completing the study at baseline (P>0.05). Most used an electric toothbrush only, whilst some used both manual and electric toothbrushes. A daily mouth rinse was used by less than half of participants, and most used a chlorhexidine preparation.

Oral hygiene habits did not change significantly over the study period, with the exception of using interdental brushes and the frequency of interdental cleaning which both increased during the study. This together with improvements in oral hygiene technique may have resulted in the reduced plaque scores observed (Table 16), despite oral hygiene habits not changing greatly overall. Most participants brushed twice or more daily, and all used a fluoride toothpaste at baseline and end of the study period. Toothpastes with other additives to help control hypersensitivity were also used by 26.4% (baseline) and 27.9% (end of study) of participants during the study. Whilst the use of interdental brushes (largely TePe brushes) increased during the study, the use of dental floss or tape declined in accordance with the advice given.

Table 14 Proportion of par ticipants who completed the study and those lost to follow-up performing oral hygiene habits and frequency of habit.

Oral Hygiene Habit	Participants who completed study (N = 140) %	Participants who completed study (N = 140) %	Participants who completed study (N = 140) %	Participants lost to follow-up (N = 18) %
	Baseline	OHR	End	Baseline
Tooth brushing manual	33.6	33.6	30.0	38.9
Tooth brushing electric	76.4	76.4	80.0	72.2
Frequency of brushing				
≤1	5.7	4.3	2.9	5.6
≥2	94.3	95.7	97.1	94.4
Fluoride toothpaste	100.0	97.9	100.0	100
Toothpaste other additive	26.4	32.1	27.9	33.3
Interdental brushing	52.1	91.4	87.9*	66.7
Dental tape or floss used	15.7	12.9	10.0	11.1
Frequency of interdental cleaning				
0	42.1	7.9	11.4	27.8
≥1	57.9	92.1	88.6*	72.2
Mouth rinse	40.7	47.9	47.1	40.7
Frequency of mouth rinsing				
0	59.3	52.9	52.9	61.1
≥1	40.7	47.1	47.1	38.9

OHR = oral hygiene review time point. * $P \leq 0.01$ $P>0.05$ for all other comparisons of oral hygiene habits baseline versus end of treatment.

The psychological characteristics of participants completing and lost to follow-up are presented in Table 15. The psychological characteristics of both groups did not differ significantly ($P>0.05$), other than for sense of coherence, which was greater among participants lost to follow-up ($P=0.005$) (Table 16).

For Sense of Coherence, Task-specific Self-efficacy, Rosenberg Self-esteem and Locus of Control questionnaires, the Cronbach's alpha for total scores, dimensions and sub-scales for multi-dimensional questionnaires (OHIP-14, Task-specific Self-efficacy and Locus of Control) were generally in the range from acceptable to excellent. However, Cronbach's alpha for the Locus of Control chance items is questionable. Cronbach's alpha for Locus of Control powerful other items is poor.

Table 15 Psychological characteristics of participants who completed and participants lost to follow-up.

	Participants who completed study (N = 140)			Participants lost to follow-up (N = 18)		
Variable	Mean scores (± SD)	Range	Cronbach's α	Mean scores (± SD)	Range	Cronbach's α
Sense of Coherence total	66.2 ± 12.9	38-91	0.86	73.0*± 8.2	56-89	0.72
Task-specific Self-efficacy total	57.5 ± 7.8	34-68	0.90	57.7 ± 5.6	46-66	0.78
Tooth brushing sub-scale	17.8 ± 2.3	12-20	0.83	17.8 ± 2.3	14-20	0.89
Interdental cleaning sub-scale	15.4 ± 3.8	5 - 20	0.94	15.9 ± 2.7	10-20	0.92
Dental visiting sub-scale	24.4 ± 4.3	9 - 28	0.93	23.9 ± 4.9	14-28	0.93
Self-esteem total	32.0 ± 4.4	19-40	0.88	33.4 ± 5.7	18-40	0.93
Locus of Control total	71.5 ± 8.6	44 -91	0.67	75.1 ± 7.5	63-87	0.65
Internal items	25.3 ± 5.7	8 - 36	0.78	26.8 ± 5.3	17-36	0.80
Chance items	18.1 ± 4.1	8 - 28	0.64	19.5 ± 3.5	12-25	0.57
Powerful others	28.2 ± 3.8	13-36	0.57	28.8 ± 2.7	24-33	0.29

*P=0.005 for comparison of participants completing and lost to follow-up. P>0.05 for all other comparisons between those completing and lost from the study.

4.2.3 Clinical Characteristics

4.2.3.1 Reliability of Clinical Measurements

The Intra-Class Coefficient was >0.9 (excellent) for inter- and intra-examiner measurements for plaque scores (%). Intra-examiner reliability of measurements for probing depths, bleeding on probing (%) and plaque score (%) was >0.9 (excellent), and 0.834 (good) for recession measurements. Cohen's Kappa for intra-examiner repeatability of tooth mobility indices was >0.9 (excellent).

4.2.3.2 Distribution of Clinical Data

Descriptive clinical data of study participants, before and after periodontal treatment and for those lost to follow-up are presented in Table 16. These are participant level data, calculated from data per site for periodontal probing depth, recession, clinical attachment loss, bleeding on probing and plaque scores, and per tooth for tooth mobility. The descriptive data of clinical variables for those participants lost to follow-up did not differ significantly from those completing the study, other than for DMFT (*P*=0.008).

Participants had chronic periodontitis, ranging from mild to severe disease. Before treatment, approximately 30% of sites had ≥4mm periodontal pocketing, of which 18.5% were ≥6mm in depth. Almost half of sites had clinical attachment loss, with over 30% having ≥3mm, of which 15.8% had ≥5mm clinical attachment loss (severe). Approximately 24% of sites bled on probing and visible plaque was present on 43.9% of tooth surfaces. The changes in clinical data following periodontal treatment are reported in Section 4.3.2.

TABLE 16 Clinical data for participants completing and lost to follow-up. Periodontal probing depths (PPD), clinical attachment loss (CAL), tooth mobility index, bleeding on probing, plaque scores and DMFT at baseline and end of study time points. Plaque scores at interim review are presented as a footnote.

	Participants completing study				Participants lost to follow- up	
Variable	Baseline (±SD)	Range	End of Study (±SD)	Range	Baseline (±SD)	Range
Mean number of Sites	151±18	48-168	150±18	48-168	155±15	108-168
Percentage of sites						
PPD ≤3mm	68.7 ±17.3	14.9-97.0	70.3 ± 22.3	0 -100	67.3 ±19.1	13.1-90.5
PPD 4-5mm	12.9 ± 7.9	1.2-35.7	11.6 ± 9.2	0 -39.9	15.4 ± 8.6	6.0-38.1
PPD ≥6mm	18.5 ± 14.3	0-74.4	18.1 ± 17.1	0 -89.3	17.2 ± 12.8	2.4-48.8
Mean PPD mm	3.0 ± 0.7	1.9-5.6	2.6 ± 0.6*	1.7-4.8	3.1±0.71	2.3-5.1
Percentage PPD change ≥ 1mm	-	-	91.6 ± 6.5	67.9 - 100	-	-
Percentage PPD change ≥2mm	-	-	8.4 ± 6.5	0 - 32.1	-	-
Mean recession mm	0.6 ± 0.61	0-3.02	0.7 ± 0.7*	0-3.62	0.5 ± 0.6	0.0-2.6
Percentage of sites						
CAL 0	54.5 ± 22.9	0 - 94.4	56.8 ± 24.1*	0 - 97.6	50.7 ± 22.7	1.8-83.3
CAL 1-2mm	11.1 ± 7.2	0 - 32.7	8.6 ± 6.0*	0 - 32.1	12.3 ± 7.4	2.4-33.9
CAL 3-4mm	18.6 ± 10.8	0 - 52.1	19.7 ± 11.9*	0 - 53.0	15.5 ± 7.1	3.0-31.5
CAL ≥ 5mm	15.8 ± 17.6	0 – 97.1	14.8 ± 17.7*	0 – 97.8	21.2 ± 19.6	1.8-78.6
CAL loss	-	-	13.2 ± 8.4	0.6 - 39.3	-	-
CAL gain	-	-	20.1 ± 10.1	2.1 - 47.6	-	-
CAL no change	-	-	66.8 ± 15.8	30.2 - 94.9	-	-
Mean CAL mm	1.9 ± 1.5	0.1-7.8	1.8 ± 1.5*	0.0-7.8	1.82 ± 1.36	0.4-5.62

TABLE 16 Continued. Clinical data for participants completing and lost to follow-up. Periodontal probing depths (PPD), clinical attachment levels (CAL), mobility index, bleeding on probing, plaque scores and DMFT at baseline and end of study. Plaque scores at interim review.

	Participants completing study				Participants lost to follow-up	
Variable	Baseline Mean (± SD) Percentage	Range	End of Study Mean (± SD)	Range	Baseline Mean (± SD) Percentage	Range
Mobility Score 0	78.3 ± 24.0	0-100	79.0 ± 23.3*	0 -100.0	81.8 ± 20.5	27.8-100
Mobility Score 1	13.6 ± 14.4	0-63.0	13.4 ± 14.6*	0 - 55.6	8.5 ± 9.0	0.0-30.8
Mobility Score 2	6.0 ± 9.7	0-45.0	5.6 ± 9.2	0 - 47.8	7.8 ± 10.6	0.0-38.9
Mobility Score 3	2.1 ± 5.9	0-47.6	2.0 ± 5.7	0 - 47.6	2.0 ± 6.6	0.0-27.8
Mobility score 2-3	8.2 ± 13.7	0-90.5	7.6 ± 13.5	0-90.5	9.7 ± 16.3	0.0-66.7
Mobility decreased	-	-	30.7	-0.5 - 0.0	-	-
Mobility increased	-	-	15.0	0 - 0.4	-	-
Mobility unchanged	-	-	54.3	0	-	-
Bleeding on probing	23.9 ± 13.3	1-70	17.7 ± 11.2*	1 - 56.0	27.2 ± 10.9	9.0-50.0
Plaque score	43.9 ± 21.2	0-100	30.5 ± 17.2*	0 – 86.0	49.9 ± 18.6	13.0-76.0
DMFT	13.0 ± 6.2	0-32	13.1 ± 6.3*	0 – 33.0	8.8 ± 4.7	1.0-15.0
Total teeth	25 ± 3	8-28	25 ± 3	8-28	26 ± 2	18-28
Decayed	0.2 ± 0.5	0-3	0.1 ± 0.5	0 - 3.0	0.0	
Missing	5.3 ± 3.7	0-24	5.4 ± 3.7*	0 - 24.0	3.6 ± 3.1	0.0-13.0
Filled	7.5 ± 5.4	0-28	7.5 ± 5.4	0 – 28.0	5.2 ± 4.2	0.0-14.0

* $P \leq 0.01$ Paired samples t-test, baseline versus end of study. $P > 0.05$ for all other tests.

The oral hygiene review plaque score was 31.5±19.6 range 0-86% (*P*≤0.01 Paired samples t-test versus baseline plaque score).

4.2.4 Environmental Characteristics of Participants Completing and Lost to Follow-up

The Index of Multiple Deprivation score within each quintile group for participants who completed and those lost to follow-up are presented in Table 17 (https://tools.npeu.ox.ac.uk/imd/). This reports the proportion of participants in each IMD quintile group score range. The Index of Multiple Deprivation for two participants is missing due to their postcode not being in this database. Most participants were from the 2 least deprived quintiles. The environmental characteristics data for participants who completed and those lost to follow-up were not statistically different (*P*>0.05).

Table 17 Frequency of Index of Multiple Deprivation for participants completing and lost to follow-up according to Quintile.

Quintile Group IMD score range	% Participants completing study (N = 140)	% Participants lost to follow-up (N = 18)
≤ 8.49 (Least deprived)	24.3	27.8
8.5 - 13.79	27.1	33.3
13.8 - 21.35	20.7	16.7
21.36 - 34.17	10.7	11.1
≥ 34.18 (Most deprived)	17.1	11.1

4.2.5 Oral Health Related Quality of Life of Participants Completing and Lost to follow-up

4.2.5.1 OHIP-14 Total and Dimension Scores

Table 18 summarizes OHIP-14 total and dimension mean scores at each study time point, and the effect size from treatment to end of study time points. The prevalence of impacts with a threshold of fairly often are also shown for the OHIP-14 total and dimension scores. Figure 5 illustrates the changes in mean OHIP-14 scores at each study time point. Five participants had missing data. The missing OHRQoL data were substituted with the mean score of the individual non-missing OHIP items (Tsakos et al., 2009). The OHIP-14 (total and dimensions) scores for participants who completed and those lost to follow-up at the initial assessment time point were not significantly different (*P*>0.05) (Table 18). Participants lost to follow-up had a lower proportion of OHIP-14 impacts with a threshold of fairly often, other than for pain-discomfort impacts which were higher in participants lost to follow-up.

OHIP-14 data were normally distributed according to Q-Q plots, and skewness and kurtosis analyses. The total OHIP score and scores for the dimensions of psychosocial and pain-discomfort increased from the assessment to treatment interval and then decreased during the remainder of the study after treatment. The analysis of changes from treatment to oral hygiene review and end of study time points is reported in the footnote and described in Section 4.3.1.

Table 18 OHIP-14 Scores and prevalence of impacts at study time points for participants completing and lost to follow-up at the assessment time point. Effect size for participants who completed the study.

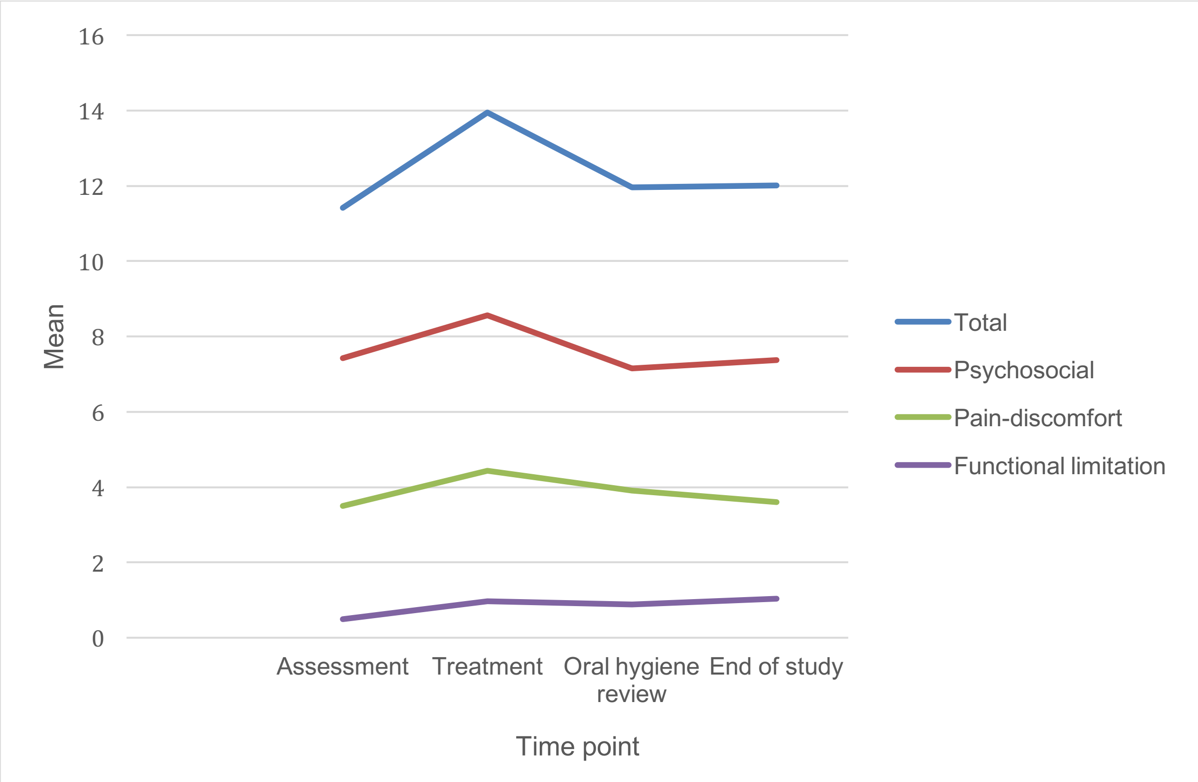
	Participants who completed study Assessment (SD)	Treatment (SD)	Review (SD)	End (SD)	Effect size treatment to end	Participants lost to follow-up Assessment (SD)
Mean scores						
Total	11.4 (10.1)	13.9 (10.8)	12.0* (10.8)	12.0* (11.9)	0.2	12.1 (14.7)
Psychosocial	7.4 (6.9)	8.6 (7.0)	7.2* (6.8)	7.4* (7.5)	0.2	7.1 (8.9)
Pain-discomfort	3.5 (3.3)	4.4 (3.8)	3.9** (3.6)	3.6* (3.7)	0.2	4.2 (5.2)
Functional limitation	0.5 (1.0)	1.0 (1.5)	0.9 (1.4)	1.1 (1.6)	0.05	0.8 (1.6)
Prevalence of impacts (%) ***						
Total	42.9	46.4	37.9	37.9	-	33.3
Psychosocial	35.0	40.0	34.3	34.3	-	33.3
Pain-discomfort	17.9	29.3	22.9	20.7	-	22.2
Functional limitation	7.1	5.0	5.7	10.0	-	5.6

Footnote: Standard deviation (SD) *P<0.01 for comparisons between treatment and oral hygiene review, between treatment and the end of study review for OHIP total and psychosocial dimension scores, and between treatment and end of study time points for pain-discomfort dimension.

** P<0.05 for dimension of pain-discomfort between treatment and oral hygiene review time points (Repeated Measures ANOVA).

*** Threshold of fairly often for at least one OHIP item for each participant.

Figure 5 Longitudinal changes in OHIP-14 total and dimensions at study time points.



4.2.5.2 Internal Reliability of OHIP-14 Questionnaire

Table 19 reports the internal reliability measures (Cronbach's alpha) of OHIP-14 questionnaire and the psychosocial, pain-discomfort and functional limitation dimensions among participants who completed the study according to the different time points. Cronbach's alpha for the total OHIP-14 questionnaires and psychosocial dimension at all time points was excellent. Cronbach's alpha was good for all the pain-discomfort questions. The internal consistency for functional limitation at baseline fell within the unacceptable range. However, the internal consistency increased at subsequent study time points and was acceptable at the end of the study.

Table 19 Internal reliability (Cronbach's alpha) for OHIP-14 total questionnaire and each dimension questions for each time point.

Time point	OHIP-14 total	Psychosocial	Pain-discomfort	Functional limitation
Baseline	0.91	0.90	0.82	0.32
Treatment	0.92	0.90	0.85	0.69
Oral hygiene review	0.94	0.91	0.85	0.66
End of study	0.95	0.93	0.87	0.73

4.3 Analysis Relating to Primary Objectives

This section reports the analysis for the primary objective of this research: to determine OHRQoL and clinical changes after periodontal treatment.

4.3.1 Changes in OHRQoL After Periodontal Treatment

Repeated Measures ANOVA was used to compare OHIP-14 scores at each time point from treatment to end of the study (Table 18). Mean total OHIP-14 scores decreased from 13.9 at the treatment time point (before treatment) to 12.0 at the interim oral hygiene review and final review time points respectively, indicating an improvement in OHRQoL *(P<0.01)*. Mean psychosocial impacts scores decreased between treatment, and both interim and end of study review time points, and pain-discomfort for treatment and end of study review time points (P<0.01). The pain-discomfort dimension also decreased significantly between treatment and oral hygiene review time points (P<0.05) and between treatment and end of study (P<0.01). The changes in OHIP-14 scores were not significant for functional limitation.

The prevalence of total OHIP-14 impacts with a threshold of fairly often for at least one item in each participant was reduced from 46.4 to 37.9 after treatment. The reductions of impacts were in the pain-discomfort and psychosocial dimensions, whereas the number of impacts increased in the functional limitation dimension after treatment.

The effect sizes (change in OHIP scores divided by baseline standard deviation) for changes in total OHIP-14 scores and OHIP dimensions from treatment to end of study were all small (Cohen, 1992, Agou et al., 2008, Locker et al., 2004): 0.18, 0.17, 0.22 and 0.05 for changes in total OHIP-14, psychosocial impacts, pain-discomfort and functional limitation respectively for the difference between treatment and end of the study.

Treatment therefore, ameliorated the effects of chronic periodontitis and improved the OHRQoL of participants.

4.3.2 Clinical Changes After Periodontal Treatment

Clinical data did not have severe skew or kurtosis according Q-Q plots. Therefore, parametric tests were used for analysis. However, tooth mobility scores of 2 and 3, and decayed teeth were slightly outside thresholds, and therefore non-parametric tests were used for these variables.

Probing depths were reduced between baseline and end of study ($P \leq 0.01$), and over 90% of periodontal sites had reductions of ≥ 1mm (rounded up to the nearest whole mm) (Table 16). Clinically meaningful reductions of ≥2mm accounted for 8.4% of these. However, changes in the proportion of probing depths categorised as ≤3mm (healthy sites), 4-5mm (moderately deep periodontal pockets) and ≥6mm (deep periodontal pockets) between baseline and end of study were not significant.

The proportion of sites having no clinical attachment loss (0 mm) increased, whilst the proportion of sites having 1-2mm decreased. The proportion of participants with 3-4mm clinical attachment loss increased and the proportion of sites having ≥5mm clinical attachment loss decreased following periodontal treatment ($P \leq 0.01$). Overall, almost 67% of periodontal sites remained stable with no changes in clinical attachment loss, 20% apparently gained attachment and 13% underwent further clinical attachment loss.

Tooth mobility decreased during the study period so that proportionally more teeth had no mobility (score 0) and fewer had scores 1-3. Changes were significant for increased mobility scores of 0 and reductions of 1 only. Mean DMF increased significantly at the end of the study due to missing teeth. Fifteen participants (11% of the sample) lost a total of 20 teeth (1%) during the study. All except 5 participants lost 1 tooth each and 5 participants lost 2 teeth each. Bleeding on probing and plaque scores reduced significantly between baseline and the end of the study.

4.4 Analysis Relating to Secondary Objectives

The secondary objectives of this research included analysis of the OHRQoL trajectory from diagnosis to treatment and up to the end of the study, together with the examination of individual, psychological and environmental factors predicting OHRQoL, baseline periodontal status and clinical changes after treatment.

4.4.1 OHRQoL Trajectory from Diagnosis to Treatment

OHRQoL worsened between the time point at which a diagnosis was made and when treatment started (mean total OHIP-14 score increased from 11.4 at initial assessment to 13.9 at the treatment visit) (Table 18 and Figure 5), but improved somewhat after treatment by the oral hygiene review.

4.4.2 Individual, Psychological and Environmental Factors: OHRQoL, Baseline Periodontal Status and Changes After Treatment

Structural equation modelling (SEM) explored the relationships between the baseline observed variables, periodontal status (latent variable), and OHRQoL (latent variable) at the oral hygiene review and at the end of the study. All variables were included in the full model according to the theoretical model adopted (Wilson and Cleary framework), rather than being limited to those identified by bivariate analysis (Chapter 8, Appendix 1). For clarity, only the analysis of OHRQoL data at the end of study is reported here. SEM for baseline predictors of OHRQoL at the oral hygiene time point is in Chapter 8 (Appendix 1 Supplementary Analysis). Confirmatory factor analysis is the first stage of SEM in which a measurement model for latent factors (periodontal status and OHRQoL) is assessed.

4.4.3 Confirmatory Factor Analysis: Indicators of Baseline Periodontal Status and End of Study OHRQoL

The proportion of sites with bleeding on probing, clinical attachment loss >4mm, periodontal probing depths PPD >5mm and tooth mobility >1 at baseline (before treatment) were selected as indicators of the latent variable of periodontal status at baseline. The end of study OHIP-14 dimensions of functional limitation, psychosocial impact and pain-discomfort data were used as indicators of OHRQoL (Figure 6). All indices fulfilled the criteria for model fit (Table 21).

Figure 6 Measurement model obtained through Confirmatory Factor Analysis including two latent variables and seven items representing baseline periodontal status and end of study OHRQoL.

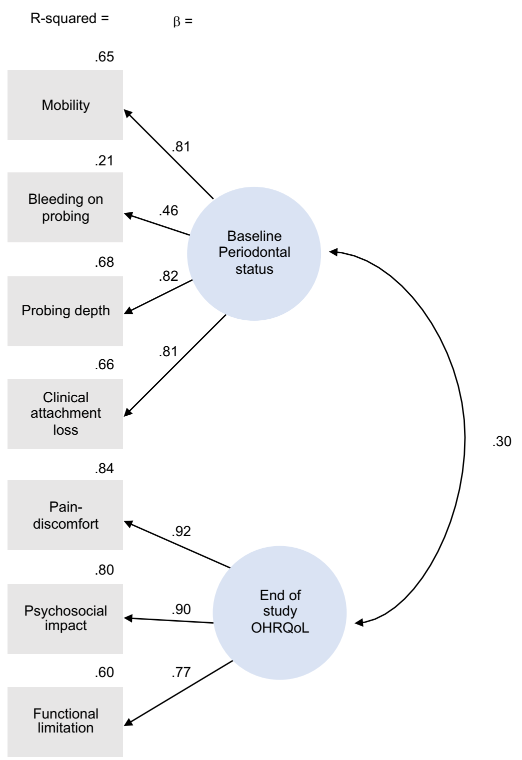


Table 20 presents the results of Confirmatory Factor Analysis of the baseline periodontal status and end of study OHRQoL. This contains the standardized regression weights, bias-corrected 95% confidence intervals, bootstrap standard errors and R-Square values, from which the proportion of total effects are calculated.

Standardized regression weights provide ß related to total effects between variables since there is no mediation in the CFA end model. All values for ß and R-Squared are significant ($P \leq 0.01$).

Table 20 Confirmatory Factor Analysis (total effects) of baseline periodontal status and end of study OHRQoL.

Parameter	ß	Bootstrap SE	Bias-corrected 95% CI	R-squared	% Total effect
Psychosocial impact → OHRQoL	0.897	0.034	0.826-0.957	0.804	80.4
Functional limitation → OHRQoL	0.772	0.050	0.649-0.850	0.596	59.6
Pain-discomfort → OHRQoL	0.919	0.029	0.850-0.970	0.844	84.4
Probing depth → Periodontal status	0.822	0.051	0.707-0.901	0.676	67.6
Clinical attachment loss → Periodontal status	0.813	0.066	0.646-0.913	0.661	66.1
Bleeding on probing → Periodontal status	0.463	0.091	0.274-0.629	0.214	21.4
Mobility → Periodontal status	0.809	0.063	0.665-0.915	0.654	65.4

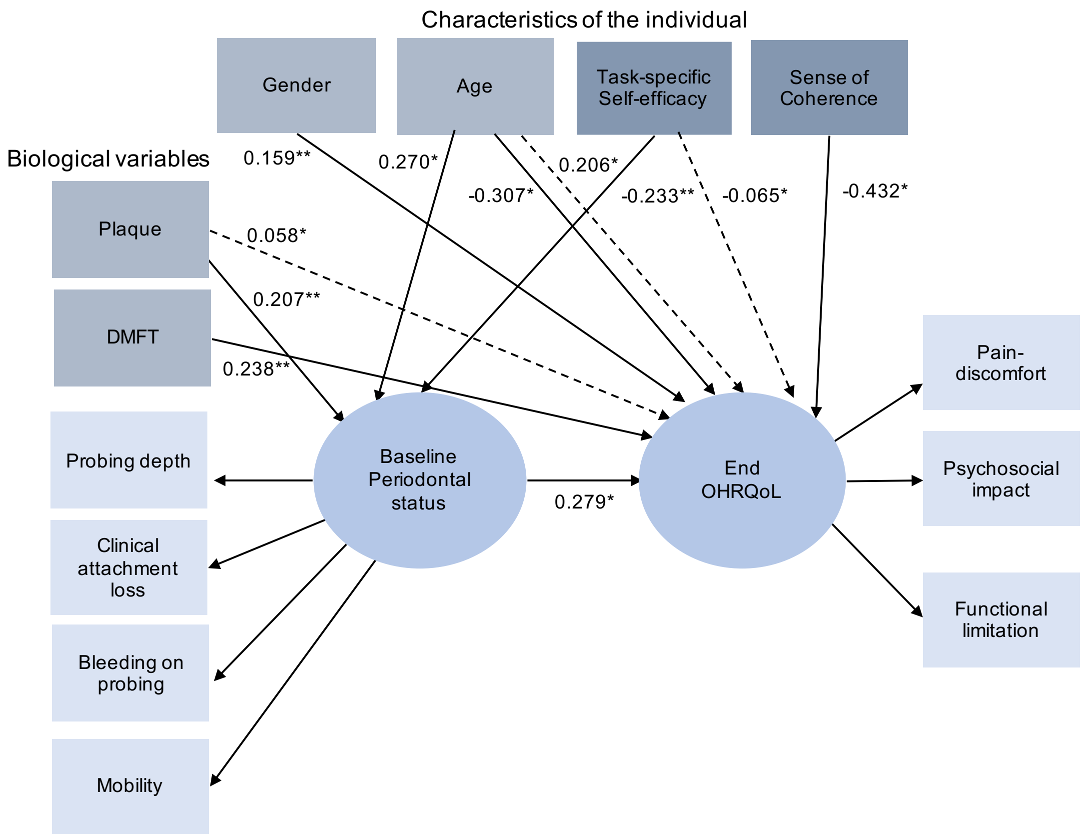
4.4.4 Predictors of Baseline Periodontal Status and End of Study OHRQoL

Observed variables were added to the measurement model to develop a full SEM model that tested predictors of OHRQoL at the end of the study. The parsimonious model was derived by removing non-significant paths as described in Chapter 3. The fit indices for the full SEM and parsimonious models fulfilled all the criteria for an acceptable model fit, and the models were not significantly different ($P = 0.2025$) (Table 21). This means that the removed links and possible variables in the parsimonious model were not relevant to the full model, therefore the parsimonious model was accepted (Figure 7). This figure shows the direct and indirect effects for characteristics of the individual (gender, age, task-specific self-efficacy sense of coherence) and biological variables (plaque and DMFT), on baseline periodontal status and end of study OHRQoL. The full model can be found in Chapter 8, Appendix 1 Supplementary Analysis, Section 8.1.2.

Table 21 Fit indices for measurement model, full and parsimonious SEM end of study models for baseline periodontal status and end of study OHRQoL.

Model	P	ChiSquare/DFRatio	GFI	CFI	SRMR	RMSEA
Measurement	0.150	1.401	0.965	0.989	0.0388	0.054
Full end	0.078	1.208	0.913	0.969	0.0675	0.039
Parsimonious end	0.112	1.232	0.931	0.978	0.0594	0.041

Figure 7 Parsimonious model predictors of the baseline periodontal status and end of study OHRQoL. Error terms and covariances omitted for clarity. Direct effects are shown by solid lines and indirect effects by broken lines.



*P<0.01 **P<0.05

Table 22 contains the direct predictors of baseline periodontal status, and the direct and indirect predictors of OHRQoL after treatment. The baseline periodontal status was predicted by task specific self-efficacy, baseline dental plaque and age. This means that people who felt more confident brushing, interdental cleaning and visiting the dentist, who had lower plaque scores at baseline and who were younger, had better periodontal status.

OHRQoL at the end of the study was predicted by sense of coherence, periodontal status, fewer decayed, missing and filled teeth before treatment baseline DMFT, age and gender. This means that people with better periodontal status and fewer decayed, missing or filled teeth before treatment, a greater sense of coherence, who were older and male, had fewer impacts of oral health on everyday life after periodontal treatment.

There were also significant indirect effects between age, task specific self-efficacy, baseline plaque score and OHRQoL mediated by periodontal status.
R-squared values indicated that 14.9% and 33.8% of the variance in periodontal status and OHRQoL were explained by the parsimonious model, respectively (Table 23).

Table 22 Direct and indirect effects of associations between individual characteristics, baseline periodontal status and end of study OHRQoL

Parameter	ß	Bootstrap SE	Bias- corrected 95% CI
Direct effects			
Better task-specific self-efficacy → better periodontal status	-0.233**	0.109	-0.439 / -0.017**
Worse baseline plaque score → worse periodontal status	0.207**	0.086	0.039 / 0.381**
Greater age → worse periodontal status	0.270*	0.100	0.052 / 0.449*
Greater sense of coherence → better OHRQoL	-0.432*	0.075	- 0.565 / -0.272*
Worse periodontal status → worse OHRQoL	0.279*	0.085	0.119 / 0.456*
Higher baseline DMFT → worse OHRQoL	0.238**	0.099	0.045 / 0.428**
Greater age → better OHRQoL	-0.307*	0.082	-0.471 / -0.147*
Being female → worse OHRQoL	0.159**	0.072	0.016 / 0.305**
Indirect effects			
Greater age → better OHRQoL	0.206*	0.072	0.085 / 0.376*
Better task-specific self-efficacy → better OHRQoL	-0.065*	0.026	-0.120 / -0.023*
Worse baseline plaque score → worse OHRQoL	0.058*	0.031	0.012 / 0.143*

*P≤0.01, **P≤0.05.

Table 23 R-squared values for baseline periodontal status and end of study OHRQoL

Parameter	R-squared	% Total effect
Periodontal status	0.149*	14.9
OHRQoL	0.338**	33.8

*P=0.017 **P=0.012

4.4.5 Summary of Predictors of Baseline Periodontal Status and End of Study OHRQoL

At the end of study:

1. Better task-specific self-efficacy predicted better baseline periodontal status.
2. Worse baseline plaque score predicted worse baseline periodontal status.
3. Greater age predicted worse baseline periodontal status.
4. Greater sense of coherence predicted better OHRQoL.
5. Worse periodontal status before treatment predicted worse OHRQoL following treatment.
6. Higher baseline DMFT predicted worse OHRQoL.
7. Greater age predicted better OHRQoL.
8. Being female predicted worse OHRQoL.
9. Area level environmental indicators (Index of Multiple Deprivation) and individual indicators of socioeconomic status (education and occupation) did not predict periodontal status or OHRQoL at the end of the study.

The indicators and predictors of periodontal status and OHRQoL at the oral hygiene review were similar to the end of study, with the following exceptions. At the end of the study, higher age predicted worse baseline periodontal status and better OHRQoL, whereas age did not predict either at the oral hygiene review. Higher baseline plaque score predicted worse baseline periodontal status at the end of study, but did not at oral hygiene review. In addition, higher baseline DMFT predicted worse OHRQoL at the end of the study but did not at the oral hygiene review (Appendix 1, Sections 8.1.4-8.1.7).

4.4.6 Indicators of End of Study Periodontal Status and End of Study OHRQoL

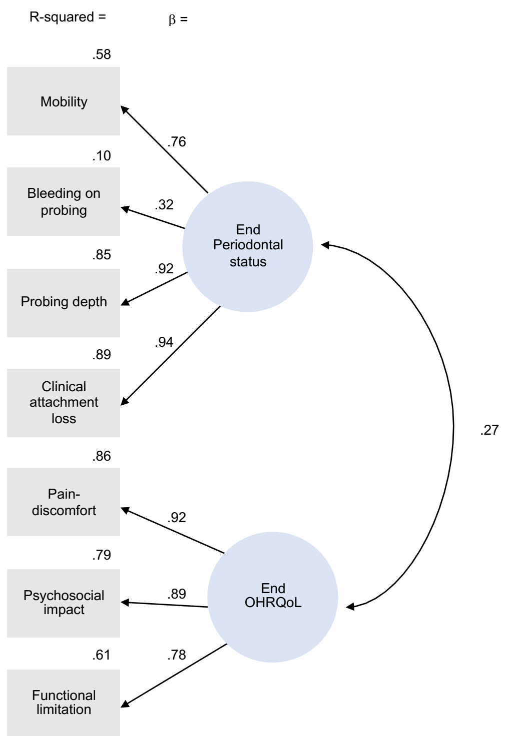
The proportion of sites with bleeding on probing, clinical attachment loss >4mm, periodontal probing depths PPD >5mm and tooth mobility >1 at the end of the study were selected as indicators of the latent variable of periodontal status. The end of study OHIP-14 dimensions of functional limitation, psychosocial impact and pain-discomfort data were used as indicators of OHRQoL (Figure 8). All indices fulfilled the criteria for model fit. Covariances were added between error terms for tooth mobility and bleeding on probing, and tooth mobility and functional limitation that made conceptual and statistical sense (Tables 24 and 26).

Table 24 Covariances added to CFA and rationale. End of study periodontal status and end of study OHRQoL

Covariance	Rationale
Mobility and bleeding on probing (error terms).	Bleeding on probing associated with higher risk of disease progression (Lang et al., 1986). Disease progression associated with tooth mobility (Nyman and Lindhe, 2003).
Mobility and functional limitation.	Increasing severity of periodontal disease leads to increased tooth mobility. Severity of disease adversely affects all domains of OHRQoL (Masood et al., 2019). Tooth mobility related to OHRQoL (Kishi et al., 2015). Mobility affects function (Giargia and Lindhe, 1997).

Furthermore, there was a moderate positive correlation between bleeding on probing and mobility in bivariate analysis (Appendix 1, Table 52).

Figure 8 End indicators of end of study periodontal status and end of study OHRQoL. Confirmatory Factor Analysis of the two latent factors and seven observed variables in the end of study measurement model.



Standardized regression weights provided values for ß related to total effects between variables since there is no mediation in the CFA model (Table 25). All values for ß and R-Squared are significant for CFA ($P \leq 0.01$) (Table 25).

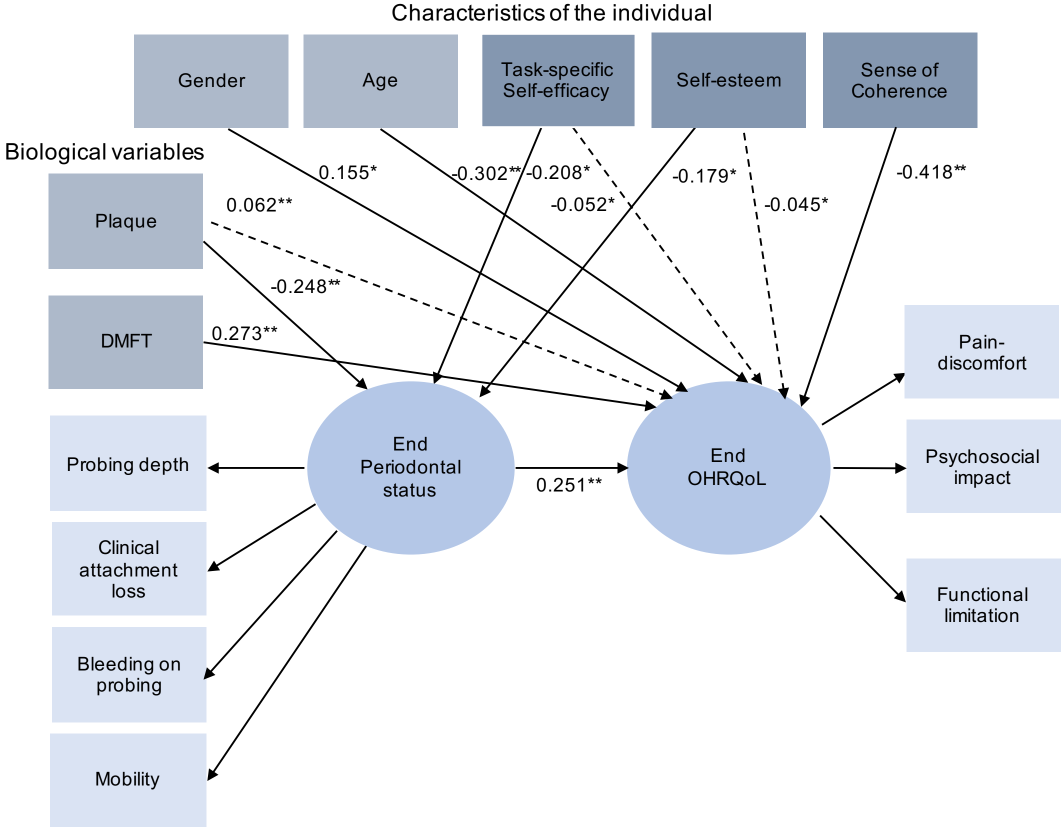
Table 25 Confirmatory Factor Analysis (total effects) of end of study periodontal status and OHRQoL.

Parameter	ß	Bootstrap SE	Bias-corrected 95% CI	R-squared	% Total effect
Psychosocial impact → OHRQoL	0.891	0.034	0.818-0.949	0.794	79.4
Functional limitation → OHRQoL	0.781	0.048	0.663-0.885	0.610	61.0
Pain-discomfort → OHRQoL	0.925	0.028	0.861-0.974	0.855	85.5
Probing depth → periodontal status	0.924	0.026	0.860-0.965	0.854	85.4
Clinical attachment loss → periodontal status	0.944	0.031	0.872-0.990	0.892	89.2
Bleeding on probing → periodontal status	0.323	0.097	0.132-0.504	0.104	10.4
Mobility → periodontal status	0.761	0.059	0.616-0.850	0.579	57.9

4.4.7 Predictors of End of Study Periodontal Status and End of Study OHRQoL

Observed variables were added to the measurement model to develop a full SEM model that tested predictors of both the periodontal status and OHRQoL at the end of the study. Covariances were added as shown in Table 11 (Chapter 3) for clarity. A parsimonious model was derived by removing non-significant paths as described in Chapter 3. The fit indices for the full SEM and parsimonious models fulfilled all the criteria for an acceptable model fit, and the models were not significantly different ($P = 0.4911$). This means that the removed links and possible variables in the parsimonious model were not relevant to the full model, therefore the parsimonious model was accepted (Table 26). The parsimonious model is shown in Figure 9.

Figure 9 Parsimonious model predictors of end periodontal status and end of study OHRQoL. Error terms and covariances omitted for clarity.



* *P* ≤0.01 ** * *P* ≤0.05

Table 26 Fit indices for measurement model, full and parsimonious SEM end of study models for end of study periodontal status and OHRQoL

Model	P	ChiSquare/DFRatio	GFI	CFI	SRMR	RMSEA
Measurement	0.082	1.637	0.966	0.988	0.0451	0.068
Full end	0.191	1.125	0.921	0.985	0.0640	0.030
Parsimonious end	0.118	1.210	0.927	0.982	0.0646	0.039

Comparison of full versus parsimonious models *P*=0.5725.

The end of study periodontal status was predicted by task specific self-efficacy, end plaque score and self-esteem. This means that people who were more confident about brushing, interdental cleaning and visiting their dentist, who had better self-esteem, but who had more plaque, had better periodontal status at the end of the study. OHRQoL at the end of the study was predicted by sense of coherence, periodontal status, end DMFT, age and gender. This means that people with a greater sense of coherence, better periodontal status, fewer decayed missing and filled teeth, who were older and male, had lower impacts of oral health on everyday life after treatment. There were also significant indirect effects between self-esteem, task specific self-efficacy, end plaque score and OHRQoL medicated by periodontal status (Table 27). R-squared values indicated that 13.7% and 35.4% of the variance in periodontal status and OHRQoL were explained by the model, respectively (Table 28).

Table 27 Direct and indirect effects. End of study periodontal status and OHRQoL.

Parameter	ß	Bootstrap SE	Bias- corrected 95% CI
Direct effects			
Better task-specific self-efficacy → better periodontal status	-0.208*	0.094	-0.377 / -0.007*
Worse end plaque score → better Periodontal status	-0.248**	0.070	-0.372 / -0.096**
Better self-esteem → better periodontal status	-0.179*	0.080	-0.331 / -0.009*
Greater sense of coherence → better OHRQoL	-0.418**	0.074	- 0.556 / -0.263**
Worse periodontal status → worse OHRQoL	0.251**	0.078	0.107 / 0.417**
Higher end DMFT → worse OHRQoL	0.273**	0.098	0.078 / 0.468**
Greater age → better OHRQoL	-0.302**	0.074	-0.455 / -0.161**
Being female → worse OHRQoL	0.155*	0.070	0.013 / 0.291*
Indirect effects			
Better self-esteem → better OHRQoL	-0.045*	0.027	-0.120 / -0.004*
Better task-specific self-efficacy → better OHRQoL	-0.052*	0.022	-0.103 / -0.014*
Worse end plaque score → worse OHRQoL	0.062**	0.028	-0.135 / -0.023**

*P≤0.01, **P≤0.05.

Table 28 R-squared values. End of study periodontal status and OHRQoL.

Parameter	R-squared	% Total effect
Periodontal status	0.137*	13.7
OHRQoL	0.354**	35.4

*P=0.011 **P=0.016

4.4.8 Summary of Predictors of Periodontal Status and OHRQoL at End of Study

At the end of study:

1. Better task specific self-efficacy predicted better end periodontal status.
2. Better end plaque score predicted worse end periodontal status.
3. Better self-esteem predicted better periodontal status.
4. Greater sense of coherence predicted better OHRQoL.
5. Worse end of study periodontal status predicted worse OHRQoL.
6. Higher end of study DMFT predicted worse OHRQoL.
7. Greater age predicted better OHRQoL.
8. Being female predicted worse OHRQoL.
9. Area level environmental indicators (Index of Multiple Deprivation) and individual indicators of socioeconomic status (education and occupation) did not predict either periodontal status or OHRQoL at the end of the study.

4.4.9 Comparison of Predictors for Periodontal Status and OHRQoL

Table 29 summarizes a comparison of the predictors of periodontal status at baseline and end of study with OHRQoL at the end of the study. These are listed below:

1. End of study OHRQoL was predicted by the same factors in models that included either baseline periodontal status or end of study periodontal status: Greater sense of coherence and greater age predicted better OHRQoL. Worse periodontal status, higher DMFT and being female predicted worse OHRQoL.
2. Better task-specific self-efficacy predicted better baseline and end of study periodontal status.
3. Worse plaque score predicted worse baseline periodontal status. Plaque score was not a predictor of baseline periodontal status at the oral hygiene review time point, but better plaque score at the end of the study predicted worse end of study periodontal status.
4. Greater age predicted worse baseline periodontal status, but did not predict end of study periodontal status.

5. Better self-esteem predicted better end of study periodontal status, but did not predict baseline periodontal status.
6. Area level (Index of Multiple Deprivation) and individual indicators of socioeconomic status (education and occupation), and locus of control did not predict end of study OHRQoL, baseline periodontal status or end of study periodontal status.
7. Indirect effects between self-esteem, age, task-specific self-efficacy, plaque score and OHRQoL were mediated by periodontal status.

Table 29 Summary of predictors of periodontal status at baseline and end of study together with end of study OHRQoL.

	Baseline	End of Study
Direct effect		
Periodontal status	Better task-specific self-efficacy, better periodontal status. Worse plaque score, worse periodontal status. Greater age, worse periodontal status.	Better task-specific self-efficacy, better periodontal status. Better plaque control, worse periodontal status. Better Self-esteem, better periodontal status.
End of Study OHRQoL	Greater sense of coherence, better OHRQoL. Greater age, better OHRQoL. Worse periodontal status, worse OHRQoL. Higher DMFT, worse OHRQoL. Female, worse OHRQoL.	Greater sense of coherence, better OHRQoL. Greater age, better OHRQoL. Worse periodontal status worse OHRQoL. Higher DMFT, worse OHRQoL. Female, worse OHRQoL.
Indirect effect		
OHRQoL	Greater age, better OHRQoL. Better task-specific self-efficacy, better OHRQoL. Worse baseline plaque score, worse OHRQoL.	Better self-esteem, better OHRQoL. Better task-specific self-efficacy, better OHRQoL. Worse end plaque score, worse OHRQoL.

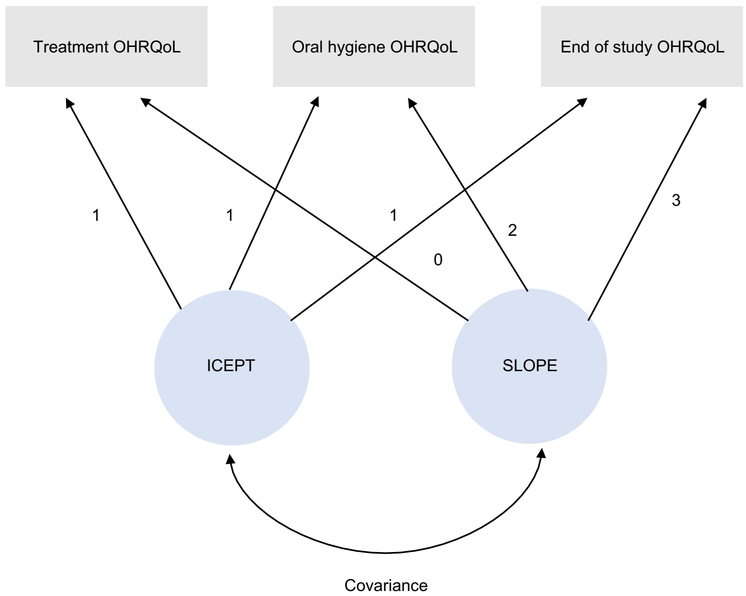
4.4.10 Predicting Longitudinal Changes in OHRQoL Following Periodontal Treatment: Latent Growth Curve Modelling

Latent growth curve modelling (GCM) determined the predictors of changes in OHRQoL following periodontal treatment as described in Chapter 3. For clarity of reporting, only the univariate, full growth curve and parsimonious models for treatment, oral hygiene review and end of study time points are presented in this chapter. The models for assessment, oral hygiene and end of study time points are found in Chapter 8 (Appendix 1 Supplementary Analysis).

4.4.11 Indicators of Change in OHRQoL Following Periodontal Treatment: Univariate Growth Curve Model

The univariate growth curve model for treatment, oral hygiene and end time points, met all the criteria for a good fit other than the RMSEA, which should ideally be ≤0.06. However, this criterion was met in all subsequent models (Figure 10, Table 34).

Figure 10 Univariate growth curve model of change in OHRQoL after periodontal treatment**.** Error terms have been removed for clarity.



The mean ICEPT value in this study for the univariate growth curve model was a OHIP score of 13.8, which is the mean baseline OHRQoL at the treatment time point (Table 30). The mean SLOPE value was -0.7 (decreasing OHIP score over time) and represents a measure of the improvement in OHRQoL expected at each study time point, from the mean starting OHIP score of 13.8. The means for the ICEPT and SLOPE were both highly significant (P<0.001). This suggests the OHRQoL is expected to improve at each studied period with an average rate of change of -0.7, beginning with an average score of 13.8.

Table 30 ICEPT and SLOPE. Treatment, oral hygiene review and end of study time points. Means, SE, CR, lower, upper and P value.

Parameter	Estimate	Lower	Upper	S.E.	C.R.	P
ICEPT Mean	13.799	11.972	15.440	.901	15.319	P<0.01
SLOPE Mean	-.695	-1.031	-.336	.183	-3.792	P<0.01

The variance of ICEPT indicated how much OHIP scores of the individuals differed at the first time point of the study, and the variance of SLOPE reflected the extent to which patients have different rates of change of OHIP scores, and both are significant (Table 31). The covariance tested whether individuals who start with higher intercepts (higher OHIP mean) also change at a faster rate (steeper slope) (higher OHIP change); however, the covariance in this case was not significant (Table 32).

Table 31 Treatment, oral hygiene review and end of study time points. Variances and covariance. Estimate, lower, upper, SE, CR and P value.

Parameter	Estimate	Lower	Upper	S.E.	C.R.	P
ICEPT Variance	101.636	74.113	131.068	13.596	7.475	<0.01
SLOPE Variance	2.099	0.852	3.291	0.640	3.278	<0.01
ICEPT <--> SLOPE Covariance	0.909	-2.920	5.004	2.035	0.447	0.655

A positive correlation of covariance means that individuals who have higher OHIP scores (worse OHRQoL) at the treatment time point (higher ICEPT) have a greater improvement in OHRQoL over time (decrease in OHIP score). However, the correlation of covariances was not significant in this case (Table 32).

Table 32 Treatment, oral hygiene review and end of study time points.
Correlation of covariances. Estimate, lower, upper and P value.

Parameter			Estimate	Lower	Upper	P
ICEPT	<-->	SLOPE	0.062	-0.182	0.435	0.665

4.4.12 Predicting Change in OHRQoL after Periodontal Treatment: Full Growth Curve Model

The univariate full growth curve model was used to test the predictors of change in OHRQoL following periodontal treatment by adding the demographic and clinical variables, and the psychological factors to the model. The model fit was improved by adding a number of covariances that made both statistical and conceptual sense (Table 33). The Amos graphic of the full growth curve model is found in Chapter 8, Section 8.1.13, Figure 22, but is not reproduced as a diagram here due to the complexity of the model. The parsimonious model is presented in Figure 11 and results of the analysis are presented in Table 36 in this chapter.

Table 33 Covariances in GCM for treatment, oral hygiene review and end time points.

Covariance	Rationale
Index of Multiple Deprivation and occupation.	Employment is an indicator for Index of Multiple Deprivation.
Sense of coherence and Task-specific self-efficacy.	Related constructs (Rothmann and Venter, 2000).
Percentage clinical attachment gain and probing depth reduction ≥2mm (error terms).	Linked clinical changes following periodontal treatment (Rylander and Lindhe, 2003).
Ethnicity with Index of Multiple Deprivation and occupation.	People from ethnic minority groups more likely to live in the most deprived neighbourhoods than White British people (https://www.ethnicity-facts-figures.service.gov.uk/uk-population-by-ethnicity/demographics/people-living-in-deprived-neighbourhoods/latest) (Gov.UK, 2018).
End DMFT (error term) and ethnicity.	DMFT is associated with ethnicity (Delgado-Angulo et al., 2018).

Table 33 Covariances in GCM for treatment, oral hygiene review and end time points continued.

Covariance	Rationale
Education with Index of Multiple Deprivation and occupation.	Education is a component of Index of Multiple Deprivation.
Smoking (error term) and sense of coherence.	Smoking behaviour associated with SOC (Igna et al., 2008).
Gender and ethnicity.	Gender (Brauchle et al., 2013) and ethnicity individual factors (van Meijeren-van Lunteren et al., 2019) linked with OHRQoL.
Baseline bleeding on probing with both task specific self-efficacy and baseline plaque score.	Link between plaque scores, gingival bleeding and oral health behaviours including tooth brushing (Mizutani et al., 2012).
Locus of control with both task-specific self-efficacy and sense of coherence.	Related constructs (Rothmann and Venter, 2000).
Percentage clinical attachment gain and end DMFT (error terms).	Clinical attachment is associated with the tooth loss element of DMFT. Loss of clinical attachment may lead to tooth loss and gain of attachment to tooth retention in dentitions affected by periodontitis (Cortellini et al., 2011).
Probing depth reduction ≥2mm and ICEPT (error terms).	Periodontal pocketing is a clinical sign of periodontitis which is linked with OHRQoL (Ferreira et al., 2017), and reductions in pocketing associated with improvements in OHRQoL (Shanbhag et al., 2012).
Percentage clinical attachment gain (error term) and baseline bleeding on probing.	Clinical attachment changes and bleeding on probing linked (Lang et al., 1986).

4.4.13 Predicting Change in OHRQoL After Periodontal Treatment: The Parsimonious Growth Curve Model

The paths having non-significant standardized regression weights (*P* > 0.05) were removed and the model was re-estimated to generate a parsimonious model for treatment, oral hygiene review and end of study time points (Figure 11). All indices met the criteria set for an acceptable model fit (Table 34). There was no significant difference between the full and parsimonious models, which suggests that the removal of non-significant links did not change the original model (*P* = 0.1589).

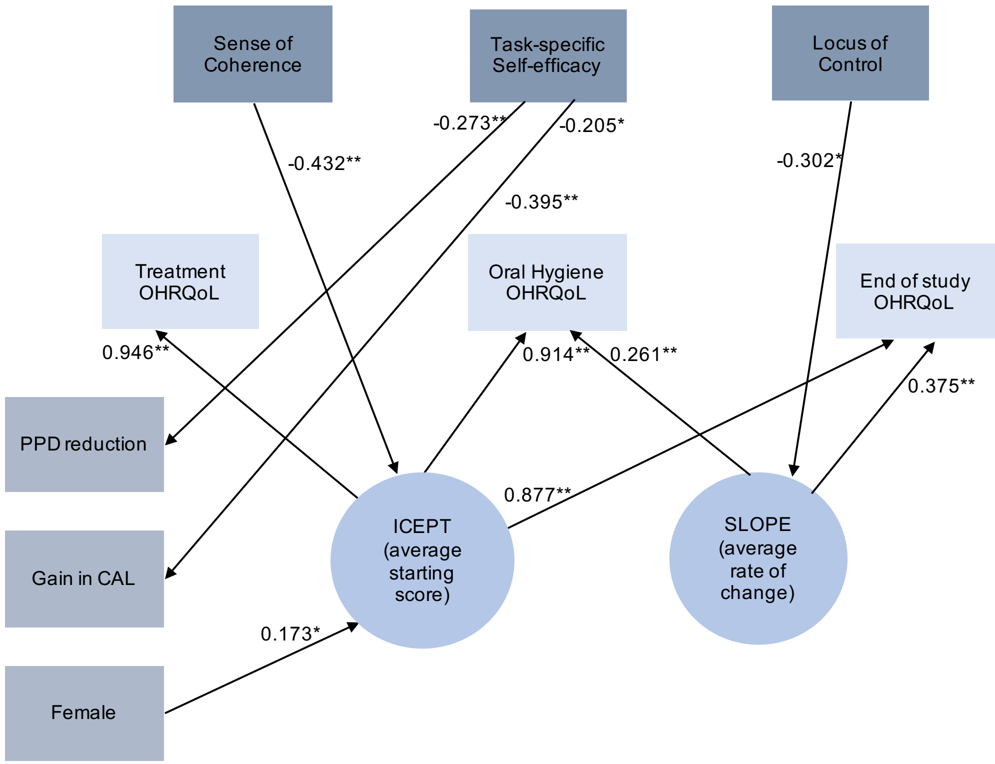
Table 34 Fit indices of univariate, full and parsimonious growth curve models treatment, oral hygiene review, end of study.

Growth Curve Model	P	Chi-squared	DF	CMIN/DF Ratio	SRMR	RMSEA	CFI
Univariate	0.095	6.357	3	2.119	0.0061	0.090	0.992
Full	0.065	103.294	83	1.245	0.0637	0.042	0.973
Parsimonious	0.098	35.689	26	1.373	0.0738	0.052	0.984

Table 35 contains the R-squared values for the parsimonious model, and show that the proportion of the variance explained by the model was 9.1% for SLOPE, 21.7% for ICEPT, 4.2% for clinical attachment level gain and 7.4% for probing depth reductions.

Figure 11 shows the direct effects of sense of coherence on average starting scores of OHRQoL (ICEPT), task-specific self-efficacy on the reductions of probing depth and gains in clinical attachment loss, and locus of control on the average change in OHRQoL (SLOPE). A direct link was also found between gender and average starting score of OHRQoL (ICEPT). These are explained below.

Figure 11 Parsimonious growth curve model of the predictors and indicators of change in OHRQoL after periodontal treatment for treatment, oral hygiene review and end of study time points. β values shown for direct paths.



*P ≤0.05 **P ≤0.01

Table 35 Parsimonious growth curve model. Treatment, oral hygiene review, end of study. Squared Multiple Correlations (R-squared). Estimate, lower, upper and P value.

Parameter	Estimate	Lower	Upper	P
SLOPE	.091	.004	.282	.002
ICEPT	.217	.095	.341	.006
Percentage clinical attachment level gain	.042	.000	.147	.003
Probing depth reduction ≥2mm	.074	.007	.207	.002
End OHIP	.910	.874	.939	.001
Oral hygiene OHIP	.903	.867	.933	.001
Treatment OHIP	.896	.857	.930	.001

The predictors of OHRQoL and clinical changes following periodontal treatment are shown in Table 36. Sense of coherence predicted the baseline OHRQoL (ICEPT OHIP), which means that people having greater sense of coherence had better OHRQoL before treatment. Task-specific self-efficacy negatively predicted reduction in probing depths ≥2mm and gain in clinical attachment loss, which means people having greater confidence in brushing, interdental cleaning and dental visiting, had a smaller proportion of periodontal pockets with clinically meaningful reductions in depth, and fewer with gains in clinical attachment loss after treatment.

Locus of control negatively predicted the rate of change in OHRQoL, which means people having greater locus of control had a slower rate of improvement in OHRQoL after treatment (decrease in OHIP scores). Gender predicted the baseline OHRQoL (ICEPT OHIP), with females having worse OHRQoL at baseline.

Table 36 Parsimonious growth curve model. Treatment, oral hygiene review, end of study. Predictors of clinical condition and changes in OHRQoL following periodontal treatment. Standardized direct effects. SLOPE (change in OHRQoL), ICEPT (starting OHRQoL), frequency of probing depth reductions ≥2mm, percentage clinical attachment loss gain, OHRQoL (OHIP total scores for each time point), gender, sense of coherence and task-specific self-efficacy.

Parameter	ß	Bootstrap SE	Bias-corrected 95% CI (lower/upper bounds)
Locus of control →SLOPE (change in OHRQoL)	-0.302*	0.128	-0.531/-0.042*
Gender →ICEPT (starting OHRQoL)	0.173*	0.074	0.025/0.311*
Sense of coherence →ICEPT (starting OHRQoL)	-0.432**	0.075	-0.566/ -0.266**
Task-specific self-efficacy →Percentage clinical attachment loss gain	-0.205*	0.094	-0.384/-0.001*
Task-specific self-efficacy →Probing depth reduction ≥2mm	-0.273**	0.094	-0.455/ -0.085**
SLOPE →End of study OHRQoL	0.375**	0.060	0.255/0.492**
ICEPT → End of study OHRQoL	0.877**	0.025	0.818/0.919**
SLOPE → Oral hygiene review OHRQoL	0.261**	0.045	0.174/0.353**
ICEPT → Oral hygiene review OHRQoL	0.914**	0.016	0.873/0.939**
ICEPT → Treatment OHRQoL	0.946**	0.010	0.926/0.963**

*P ≤0.05 **P ≤0.01

The growth curve models for assessment, oral hygiene review and end of study time points are presented in Appendix 1 Supplementary Analysis.

4.4.14 Summary of Predictors of Change in OHRQoL and Periodontal Condition After Treatment

A summary of the predictors of OHRQoL according to growth curve modelling for both assessment to end and treatment to end time points is presented in Table 37. Overall, the predictors of OHRQoL in this study were female gender predicted worse OHRQoL and a greater sense of coherence predicted better OHRQoL at assessment and treatment time points. Smoking directly predicted OHRQoL at the assessment time point. Greater locus of control predicted a slower rate of change in the treatment to end model, whereas greater sense of coherence predicted a slower rate of change in the assessment to end model. Task-specific self-efficacy negatively predicted gain in clinical attachment loss and probing depth reductions in both models.

Table 37 Summary of predictors of OHRQoL and periodontal variables according to growth curve model (assessment to end and treatment to end models).

Direct effects	Assessment to end	Treatment to end
Sense of coherence → rate of OHRQoL change	✓	Not predicted
Locus of control → rate of OHRQoL change	Not predicted	✓
Gender →Starting OHRQoL	✓	✓
Sense of coherence → Starting OHRQoL	✓	✓
Smoking → Starting OHRQoL	✓	Not significant
Task-specific self-efficacy → Clinical attachment loss gain	✓	✓
Task-specific self-efficacy → Probing depth reduction ≥2mm	✓	✓

4.4.15 Summary of Chapter

OHRQoL worsened from initial assessment to the point at which treatment commenced; however, there was a significant improvement in OHRQoL after treatment that accompanied improvement in the periodontal condition by the end of the study.

People with better baseline periodontal status and fewer decayed, missing or filled teeth before treatment, a greater sense of coherence or who were older or male had fewer impacts of oral health on everyday life after treatment (better OHRQoL).
Sense of coherence had a direct psychological effect on OHRQoL in both SEM models. Better task-specific self-efficacy, greater age and lower plaque scores had positive indirect effects on OHRQoL after treatment, mediated via baseline periodontal status. Self-esteem had a direct positive effect on the end periodontal

status and an indirect effect on OHRQoL mediated by end periodontal status at the end of the study. Task-specific self-efficacy and plaque had indirect effects on end of study OHRQoL mediated at end periodontal status.

People who felt more confident brushing their teeth, interdental cleaning and visiting the dentist, who had lower plaque scores before treatment or who were younger had better periodontal status before treatment. People who were more confident about brushing, interdental cleaning and visiting their dentist, who had better self-esteem, but who had more plaque at the end of the study, had better periodontal status at the end of the study.

People with better periodontal status before treatment, greater sense of coherence and who were male also had better OHRQoL at the oral hygiene review time point. At the oral hygiene time point, people more confident in brushing, interdental cleaning and visiting the dentist had better periodontal status before treatment. All indirect effects were mediated via the latent variable periodontal status.

Growth curve modelling confirmed the findings from SEM that people having greater sense of coherence had lower impacts of oral health on everyday life (better OHRQoL) before treatment and females had worse OHRQoL. Smokers had worse OHRQoL at the assessment time point only. In addition, it demonstrated that people with greater locus of control had a slower rate of change (improvement) in OHRQoL after treatment (decrease in OHIP scores) in the treatment to end of study model, and people with greater sense of coherence had a slower rate of change (worsening) in the assessment to end of study model (increase in OHIP scores). Paradoxically, people having greater confidence in brushing, interdental cleaning and dental visiting had fewer periodontal pockets showing gains in clinical attachment loss after treatment, and a smaller proportion of periodontal pockets with clinically meaningful reductions after treatment.

Area level and individual indicators of socioeconomic status did not predict OHRQoL or changes in OHRQoL in either SEM or growth curve modelling.

Chapter 5
Discussion

5.1 Introduction

The aim of this research was to determine the oral health related quality of life and clinical changes after the diagnosis and treatment of chronic periodontitis. The primary objective was to determine the OHRQoL and clinical changes after periodontal treatment. The secondary objectives were to determine: (1) The OHRQoL trajectory from diagnosis to treatment and follow-up; (2) The individual (psychological) and environment predictors of OHRQoL and clinical changes after periodontal treatment; and (3) The relationships between psychological factors, OHRQoL and clinical changes. The primary outcome measure was OHRQoL, and the secondary outcome was the periodontal condition.

Significant improvements in OHRQoL occurred after treatment that were consequent to improvement in the periodontal condition. OHRQoL worsened from initial assessment (diagnosis) to treatment. Structural Equation Modelling determined that better sense of coherence, baseline periodontal condition and being male predicted better OHRQoL at the oral hygiene review time point, whereas greater sense of coherence, greater age, better baseline periodontal condition, being male and lower DMFT predicted better OHRQoL 3 months after treatment. Better task-specific self-efficacy predicted better periodontal status at both time points, and greater age and higher baseline plaque score predicted worse periodontal condition at baseline. Better self-esteem and worse plaque score predicted better periodontal status by the end of the study.

Growth curve modelling determined that sense of coherence, smoking and gender directly predicted starting OHRQoL. The rate of change was directly predicted by locus of control in the treatment to the end of study model and by sense of coherence in the assessment to end of study model. Gains in clinical attachment loss and clinically meaningful changes in probing depths (≥2mm) were negatively predicted by task-specific self-efficacy in both growth curve models.

Other individual and environmental characteristics did not predict OHRQoL in either SEM or growth curve models.

The discussion of these findings is divided into nine parts:
Section 5.2 discusses the primary aim of the research.
Section 5.3 considers the OHRQoL trajectory from diagnosis to treatment and follow-up, and the predictors of OHRQoL and clinical outcomes within the Wilson and Cleary Model.
Section 5.4 considers the predictors of OHRQoL at study key time points.
Section 5.5 considers factors relating to the rate of change in OHRQoL over time.
Section 5.6 considers predictors of clinical change over time.
Section 5.7 considers how growth curve modelling has enhanced the SEM analysis of OHRQoL.
5.8 Considers the relationship of other characteristics to OHRQoL and clinical outcomes.
Section 5.9 considers strengths and possible limitations of the research.
Section 5.10 considers the relevance of the findings to patients and clinicians.

5.2 Discussion of Primary Objectives of Research

5.2.1 OHRQoL Outcomes After Periodontal Treatment

A key finding of this study is that OHRQoL improved after non-surgical periodontal treatment. OHIP-14 responses were categorized into three dimensions of OHRQoL namely, psychosocial, pain-discomfort and functional limitation (Montero et al., 2010). Psychosocial and pain-discomfort dimensions significantly improved after treatment, whereas functional limitations did not and appeared worse after treatment than when participants were initially assessed. Since the study was uncontrolled, it is not possible to definitively attribute changes to treatment.

Psychosocial questions related to feelings of being self-conscious, tense, difficulty relaxing, embarrassment, irritability with other people, difficulty in undertaking usual work, less satisfaction with life, or being totally unable to function because of problems with teeth, the mouth or dentures. Pain-discomfort questions related to pain or aching in the mouth, discomfort when eating, having an unsatisfactory diet or having to interrupt meals because of problems with teeth, the mouth or dentures. Questions on function related to trouble pronouncing words and worsening sense of taste.

Periodontal treatment appears to have partially ameliorated the way in which chronic periodontitis affected OHRQoL in participants, especially in the psychosocial dimension outcomes. Improvements in this dimension suggest participants felt less conscious or concerned about their mouth and the ways in which interactions with other people had been affected before treatment, and felt more satisfied with life. Furthermore, patients also felt less impact on the pain-discomfort dimension. However, treatment was not associated with changes in the functional dimension. Participants continued to experience difficulty in pronouncing words or that their sense of taste remained affected. Whilst these improvements may be attributable to the clinical benefits of treatment, there may also have been a direct psychological benefit akin to a placebo effect, for psychosocial and pain-discomfort dimensions. The care, attention and encouragement from specialist care providers may reinforce belief and confidence in the therapeutic measures being used, and lessen impacts in these dimensions.

Improvements in psychosocial and pain-discomfort dimensions may be a consequence of reduced gingival inflammation and treatment of infection. Instruction in brushing and interdental cleaning may have led to improved oral hygiene and oral comfort. However, treatment is also likely to have resulted in an initial increase in tooth mobility as a consequence of inflammation within the supporting tissues following tooth surface instrumentation, and non-responding teeth may undergo further loss of support. Healing of periodontal tissues appears to have reduced tooth mobility by the end of the study (Table 16). Treatment is unlikely to have led to improved tooth alignment, and gingival recession after treatment may lead to increased exposure of tooth surfaces. This may affect dental aesthetics and caused increased sensitivity, whilst teeth having a poor prognosis were removed. All of this could contribute to an increase in impacts within the functional dimension.
The total (global) OHIP-14 score before treatment in the present study indicating adverse impacts of chronic periodontitis on OHRQoL, is in agreement with previous studies reporting an adverse impact of periodontitis on OHRQoL. Similarly, impacts

appear to be mostly in relation to pain-discomfort and psychosocial domains as previously reported (Meusel et al. 2015, Borges et al. 2013, Al Habashneh et al 2012, Brauchle et al. 2013). However, functional limitation seemed less affected in the present study, and the mean starting OHIP-14 score for the functional limitation dimension was low. The total (global) OHRQoL improved after treatment in the present study, and is in agreement with findings of previous studies (Shanbhag et al., 2012, Baiju et al., 2017, Goel and Baral, 2017, Mendez et al., 2017). Improvement in pain and psychological dimensions following treatment is also in agreement with previous reports (Wong et al., 2012, Makino-Oi et al., 2016, Goel and Baral, 2017). However, treatment did not improve impacts in the functional limitation dimension (domain) (pronouncing words or sense of taste). These became worse during the study, although the deterioration in this dimension was not significant. One explanation for this finding may be that periodontal treatment is unlikely to improve tooth position (which may affect pronunciation) or the sense of taste, since it focusses on improving health of the supporting tissues of teeth. This shows the importance of always considering the face and content validity of the measure. Further treatment to improve tooth alignment or replace missing teeth may be necessary to improve function, and this is normally delayed until the periodontal condition has been stabilized. Nonetheless, this data supports the findings of previous studies reporting a negative impact of periodontal disease on OHRQoL, that periodontal treatment improves this and the clinical condition, and is of benefit to patients affected.

Many previous studies of OHRQoL and periodontitis, are limited by short-comings, including an unclear periodontal diagnosis for participants, heterogeneity of treatments, OHRQoL instruments used and follow-up periods, together with methodological issues as previously described (Sections 2.5.2 - 2.5.8). However, the findings for OHRQoL in relation to periodontal treatment in the present study are similar to previous longitudinal studies in which OHIP-14 was used, although there are some differences worthy of mention. These similarities and differences may be considered in relation to:

1. Baseline OHIP-14 score
2. Magnitude of change in OHIP-14 score after treatment
3. Comparison of OHIP-14 score with the UK norm

4. Effect size of treatment
5. Dimensions / domains impacted upon
6. Severity of periodontal disease

The changes in OHIP-14 scores in this study were analysed from a baseline at the treatment time point, at which scores were recorded prior to treatment commencing. The mean baseline total OHIP-14 score in the present study (Table 18) was 14 and after treatment this was reduced to 12, accordingly the change in OHIP-14 score was 2. In previous studies, mean baseline OHIP-14 total scores ranged from 8.0 (Ohrn and Jonsson, 2012) to 41.08 (Shah and Kumar, 2011), and after treatment 5.6 (Shah & Kumar 2011) to 16.16 (Saito et al., 2010). The difference between before and after OHIP-14 total scores range from 1.0 (Ohrn & Jonsson 2012) to 35.48 (Shah & Kumar 2011). The baseline mean score 41.08 (Shah & Kumar 2011) was however by far the largest, and most baseline OHIP-14 scores were between 8 and 17, indicating the mean total OHIP-14 score for participants in the present study was in the middle of this range. The mean OHIP-14 score after treatment (12.01) is between the values previously reported (5.6 and 16.16). Excluding one outlier (35.48) (Shah & Kumar 2011), the magnitude of change previously reported after treatment was 0.17 to 7.8, and so the magnitude of change in the present study is at the lower end of this range. This may be due to a lower potential for improvement in the total OHIP score after treatment as a consequence of modest baseline values, and that impacts in the functional limitation dimension became worse after treatment. Mean OHIP-14 scores reported in most studies for patients with periodontitis including the present study, are higher than the UK population norm. This varies according to age and gender, but is between 3.6 for men ≥65 years of age to 6.1 for 45-54 years old females (Slade et al., 2005).

A limitation of using a summation of OHIP-14 response codes is that any treatment effect may be masked for a substantial number of individuals in the sample. Therefore, the prevalence of impacts was also investigated using a threshold of fairly often for at least one OHIP-14 item in each participant. The prevalence of impacts for the total OHIP scores was reduced after treatment, and thus treatment ameliorated the negative impact of chronic periodontitis on OHRQoL in the participants. Treatment was particularly beneficial in reducing the prevalence of impacts in the psychosocial and pain-discomfort dimensions, however the prevalence of impacts in the functional dimension increased after treatment.

Calculation of the effect size is another way of interpreting OHRQoL outcomes. Whilst significant clinical outcomes were found and improvements OHRQoL according to total OHIP-14 scores, psychosocial and pain-discomfort dimensions, the effect size on OHRQoL was small in the present study (0.18 for total OHIP14 score; 0.17 for the psychosocial dimension; and 0.22 for pain-discomfort). Changes in functional limitation following treatment were not significant and had the smallest effect size (0.05).

Other studies reporting changes in OHRQoL following periodontal treatment in which a variety of instruments have been used, generally report small to moderate effect size of between 0.2 using GOHAI (Jonsson and Ohrn, 2014) and 0.72 using OHIP-14 (Mendez et al., 2017). Only one study reported a large effect size after dental hygiene in patients undergoing surgical treatment (Saito et al., 2011), and most effect sizes associated with changes in OHRQoL after non-surgical periodontal treatment are between 0.3 and 0.5. Small effect sizes in the present study may be due to due to mean scores before treatment being relatively low (13.95) compared with other studies on periodontal diseases, and compared with the maximum score 56 for the OHIP-14 questionnaire. There appears to have been a floor effect due to the number of low scoring impacts, even though mean total OHIP scores were higher than the UK population norm. The impact of chronic periodontitis on OHRQoL does not appear to have been very severe for many participants in this study. However, referring dentists considered periodontal disease was sufficiently severe to warrant referral to a specialist, and participants were sufficiently concerned and motivated to undergo specialist treatment. For most participant’s this necessitated time off work and some travelled considerable distance in order to attend appointments.

Adverse impacts were worse in the pain-discomfort dimension and these may be due to dentine hypersensitivity accompanying gingival recession, both of which commonly occur after treatment. Few participants lost teeth during the study and tooth mobility was reduced by the end of the study, which may account for the very small effect size for changes in the functional limitation dimension.

Adverse impacts of periodontal disease on OHRQoL and improvement following periodontal treatment found in the present study, are in agreement with the findings of systematic reviews (Shanbhag et al., 2012, Buset et al., 2016, Baiju et al., 2017, Ferreira et al., 2017). Cross-sectional studies included within these reviews and more recent studies, highlight the main impacts of periodontal disease on overall OHRQoL and within domains or dimensions.

In many studies OHRQoL is reported as total (global) OHRQoL, and as 7 domains (functional limitation, physical pain, psychological pain, psychological discomfort, psychological disability, physical disability and social handicap). In the present study, impacts were reduced into the 3 dimensions previously mentioned, where OHIP-14 items 1 and 2 (functional limitation domains) are included in the functional limitation dimension, items 3,4,7,8 (physical pain and physical disability domains) are included in the pain-discomfort dimension, and the remainder (psychological discomfort, psychological disability, social disability and handicap domains) are included in the psychosocial dimension (Montero et al., 2010).

In this study, the baseline impact of periodontal disease on OHRQoL was modest and varied by dimension in keeping with most other studies, but nonetheless periodontal disease caused problems for participants. The highest mean OHIP-14 scores were in the psychosocial dimension, followed by pain-discomfort and were smallest in the functional limitation dimension. This means the main impacts of periodontal disease for participants were psychosocial, such as feelings of being self-conscious, tense, difficulty relaxing, embarrassment, irritability with others, difficulty in undertaking usual work, less satisfaction with life, or being unable to function. Participants had less problems arising from pain or aching in the mouth, discomfort when eating, having an unsatisfactory diet or interrupting meals. The impacts relating to trouble pronouncing words or a worsening sense of taste do not seem to have been a main concern for the participants and if anything, treatment worsened these. A reason for this might be related to the low clinical threshold for chronic periodontitis for inclusion into the study (≥3 sites with probing depths of

≥4mm and bleeding on probing for up to 30 seconds afterwards). This means people were recruited with a range of periodontal disease severity, from mild to severe disease. One third of sites had periodontal pockets ≥4mm in depth, with approximately 18% having probing depths ≥6mm at baseline, and over a third of all sites had a clinical attachment loss ≥3mm. Accordingly, although participants with mild to severe disease were included, for a large proportion their periodontal disease was mild to moderate, and their concerns were largely related to the psychosocial impacts of periodontal disease.

Poorer OHRQoL in all domains is associated with greater severity of periodontal disease, whereas patients with moderate disease may not report effects in psychological discomfort, physical disability, psychological disability and handicap domains (He et al., 2018, Karaaslan and Dikilitas, 2019, Masood et al., 2019). Other studies report impacts mainly related to difficulties speaking, eating and pain, within functional limitation and pain–discomfort domains (Al Habashneh et al., 2012, Borges et al., 2013, Meusel et al., 2015, Wellapuli and Ekanayake, 2016, Llanos et al., 2018). Clinical studies suggest periodontal disease may impact on OHRQoL in relation to functional limitation, physical disability, psychological discomfort and disability, pain, social disability and handicap domains (Durham et al. 2013, Brauchle et al. 2013, Borges et al. 2013, Levin et al. 2018). In a systematic review, Buset et al. (2016) found that impairment in psychosocial aspects was the second most frequently mentioned subdomain having a negative impact on OHRQoL. Perceived impairment in physical aspects was most pronounced with pain and discomfort impairments being the least frequently mentioned (Buset et al., 2016). Ferreira et al. (2017) also reported that psychological discomfort, psychological disability, along with physical disability and physical pain were the most affected domains in their systematic review. Interestingly, the possibility of confounding factors such as pain from dental caries influencing the findings could not be ruled out (Ferreira et al., 2017).

The large proportion of participants with mild to moderate disease in the present study may explain why there are less troublesome impacts than reported in studies that include a greater proportion of people with severe disease. However, the findings differ somewhat from previous reports, in that psychosocial items have a greater impact than those relating to pain-discomfort and function. Most participants in this study were in the upper end of the socioeconomic gradient, were regular dental attenders and had few other dental problems. The proportion of carious teeth was very low at baseline (0.2%), and therefore pain arising from dental caries would not be expected to be a cause of impacts. Furthermore, dentitions were well restored and no other oral conditions that may have caused poorer OHRQoL were identified in participants. It seems plausible therefore, that these factors (mild to moderate periodontal disease, good socioeconomic status and few other dental/oral problems) may account for the greater importance of impacts in the psychosocial dimension amongst participants before treatment.

The OHIP scores were reduced after treatment indicating an improvement in OHRQoL, albeit with modest effect and limited to the psychosocial and pain-discomfort OHIP dimensions. The modest effect of treatment on OHIP scores may be attributable to the low baseline scores meaning there was less potential for change to occur as mentioned above. There was a significant reduction in the mean total OHIP score, with the psychosocial and pain-discomfort dimensions significantly reducing (improved OHRQoL) after treatment. However, the functional limitation dimension OHIP scores increased slightly (worse OHRQoL). Treatment reduced the impacts within psychosocial (feelings of being self-conscious, tense, difficulty relaxing, embarrassment, irritability with others, difficulty in undertaking usual work, less satisfaction with life, or being unable to function) and pain-discomfort (pain or aching in the mouth, discomfort when eating, having an unsatisfactory diet or interrupting meals) dimensions, but appears to have increased the impact relating trouble pronouncing words or worsening of taste in participants slightly.

Improvements in psychosocial, pain and function domains following periodontal treatment have been found in systematic reviews, with effect size varying from small to large (Shanbhag et. al., 2012, Baiju et. al., 2017). These findings agree with previous studies and add to the evidence for periodontal diseases negatively impacting on OHRQoL, and that treatment can improve this.

The data from the present study is consistent with the few qualitative studies on OHRQoL, which also report that periodontal disease adversely affects psychosocial and functional well-being, and which have additionally identified feelings of shame, regret, low self-esteem and social isolation to be associated with periodontal disease (Abrahamsson et al., 2008, Johannsen et al., 2012, Karlsson et al., 2009, O'Dowd et al., 2010, Stenman et al., 2009). Clinical improvements after non-surgical periodontal treatment, accompanied by marked psychosocial benefits including improved self-esteem, mood, attitudes and social well-being were also highlighted in a recent qualitative study by Horne et al. (2020). An underlying theme identified in their study was “progressing to a more positive outlook”, confirming the benefit of periodontal therapy and that might be reassuring for people commencing periodontal treatment.

5.2.2 Clinical Outcomes

The clinical outcomes of periodontal treatment were:

1. Probing depths reduced after treatment, with clinically meaningful reductions in probing depth.
2. Most sites remained stable with no perceptible change in clinical attachment loss, some sites gained attachment and a small proportion underwent further loss.
3. Bleeding on probing and plaque scores reduced by the end of the study.
4. Tooth mobility decreased during the study so that proportionally more teeth had no mobility and fewer had increased mobility.
5. Few teeth were lost (20 teeth, 1% of the total number of teeth).

The participants in this study benefited from a single course of non-surgical periodontal treatment that improved their periodontal condition. Periodontal probing depths, bleeding on probing and mobility decreased and there were gains in clinical attachment. Few teeth were lost and oral hygiene improved.

Probing depth reductions of ≥2mm occurred in 8.4% of sites after treatment. The number of sites with 0 and 3-4mm clinical attachment loss increased, and the number of sites with 1-2mm and ≥5mm decreased. Clinical attachment loss mostly remained stable, however 13% lost and 20% gained clinical attachment. Tooth mobility reduced by 30% after periodontal treatment.

The participants in this study appear to have benefitted from monitoring and advice on plaque control at treatment and oral hygiene review time points. These measures led to an improvement in plaque control during the study: full mouth plaque scores were reduced significantly from 43.9% before treatment, 31.5% at the oral hygiene review and 30.5% at the end of the study. The greatest reduction occurred between treatment and oral hygiene review time points, and thereafter changed little. This outcome would seem to justify the time and effort in providing oral hygiene instruction, although in the absence of a control group receiving no instruction, it is uncertain whether the reductions in plaque were related purely to the instruction given in the clinic.

Most participants underwent full mouth scaling and subgingival debridement under local anaesthesia, usually within a 1 or 1.5 hour appointment, depending on the amount of treatment to be completed and patient preference. The use of ultrasonic instruments enabled the dental hygienist to perform supra- and subgingival debridement rapidly and with less operator fatigue than with hand instrumentation. The clinical improvements observed suggest this approach removes sufficient plaque and plaque retentive factors to be compatible with an improvement in the periodontal status. Furthermore, a single visit approach allowed treatment to be completed in less time than multiple visits to treat one quadrant on each occasion. Single visit full mouth debridement is therefore convenient for patients and resource utilization is more efficient. Almost all patients chose this approach and seemed to accept it well.

Whilst one visit full mouth debridement means there are fewer occasions during a course of treatment for oral hygiene instruction, the reduction in plaque scores in this study suggests the two occasions when instruction was provided (treatment and interim oral hygiene review appointments) were sufficient. Participants were given specific advice on the sizes of interdental brushes to use and technique, in addition to advice on using manual and electric toothbrushes. They were also questioned at each appointment about the type of toothbrush and interdental cleaning aid being used, together with the frequency of use to determine adherence with the advice given and also whether additional measures were advisable. The number of participants using an electric toothbrush increased during the study, together with the use of interdental brushes. The use of tape or floss decreased in accordance with the advice given to use interdental brushes where possible. The frequency of tooth brushing changed little during the study, but the frequency of interdental cleaning increased.

Improvement in plaque scores was accompanied by a significant reduction in bleeding on probing from 23.9% before treatment to 17.7% at the end of the study. This provides further support for the long-term benefits of treatment.

The beneficial clinical outcomes therefore support this approach to the treatment of chronic periodontitis. The main caveat to this conclusion however, is the lack of a control group not receiving treatment. However, it would have presented ethical and recruitment difficulties to include a control group without treatment.

The clinical outcomes of non-surgical periodontal treatment in this study are consistent with the many others reporting improvements in periodontal health after non-surgical treatment (Tunkel et al., 2002, Hung and Douglass, 2002, Heitz-Mayfield et al., 2002, Lang et al., 2008, Eberhard et al., 2008, Smiley et al., 2015, Mailoa et al., 2015).

This research has shown that improving periodontal status also has a possible mediating role in improving OHRQoL. Improvement in the periodontal status after treatment, with reductions in probing depths and bleeding on probing together with gains in clinical loss of attachment, was accompanied by reductions in OHIP scores in the psychosocial and pain-discomfort domains, indicating an improvement in OHRQoL. Using the Wilson and Cleary model allowed the periodontal status, individual demographic and psychological characteristics of participants together with the individual and environmental indicators of socioeconomic status to be considered, and structural equation modelling enabled simultaneous analysis of these factors. These findings therefore support the Wilson and Cleary model. Furthermore, they suggest that OHRQoL could be used as a motivational factor for treatment, as this outcome has more meaning for people than changes in clinical measurements. Using OHRQoL as an outcome measure after periodontal treatment at oral hygiene reviews, end of treatment review, at appointments for monitoring and maintenance care, also has potential to motivate people to stay in treatment and maintenance care.

A further consideration relates to the provision of periodontal treatment in secondary care. Whilst periodontal treatment can and should be undertaken in general dental practice, there are occasions when patients may benefit from being under the care of a specialist in periodontics. All the patients in this study were referred by general dental practitioners who were concerned that their patients had not responded to the treatment they had provided. The improvements in periodontal health and OHRQoL after specialist periodontal treatment also supports periodontics as a clinical specialty, led by appropriately trained clinicians and with a team including dental hygienists/therapists and oral health educators.

There are a number of methodological considerations that may influence clinical findings that are now discussed. Examiner training and calibration is important in all clinical studies. In this study, all measurements were undertaken using the same design of probe, by the same experienced operator using magnification lenses, and the reliability of all measurements was mostly excellent. However, measurements are subject to error related to probe design, angulation of probing, tooth anatomy, position in the mouth, probing pressure and degree of inflammation of periodontal tissues. For experienced clinicians, perfect agreement of repeat measurements of probing depths has been estimated at 33-70%, 81-99% with a threshold of ±1mm, and approaching 100% for a threshold of ±2mm (Armitage, 1996). Furthermore, it is generally considered that a change of 2mm following treatment is considered to be clinically important (Listgarten, 1980) and accordingly this threshold was selected for analytical purposes.

Previous studies on OHRQoL that have included analysis of clinical changes have compared periodontal probing depths and clinical attachment levels before and at various time points following treatment (Aslund et al. 2008, Saito et al. 2010, Pereira et al. 2011, Saito et al. 2011, Brauchle et al. 2013, Miao et al. 2016, Santuchi et al. 2016, Makino-Oi et al. 2016). The means and/or categories of probing depth and clinical attachment levels, for example probing depths ≤3mm, 4-5mm, >6mm, and categories of clinical attachment loss have been reported in some studies (D'Avila et al., 2005, Wong et al., 2012, Ohrn and Jonsson, 2012). Whilst the site is widely accepted as the appropriate unit of clinical observation in analyses of change following treatment due to the site-specific nature of periodontitis, calculating a mean for full mouth probing depths and attachment levels from individual sites risks changes being “swamped” by the numbers of sites that cannot change, for example because the probing depths are normal sulcus depths. The use of site frequency distributions, such as the number or proportion of sites within categories signifying normal probing depths, moderately deep and deep periodontal pockets and in particular changes in clinical attachment levels is preferred to reflect therapeutic effects in clinical studies of periodontitis (Imrey, 1986).

Gains in clinical attachment loss should not necessarily be interpreted as gains in true periodontal attachment, but are generally accounted for by a reduction in penetration of the probe into the periodontal pocket after treatment generally regarded as gain of probing attachment (Rylander and Lindhe, 2003). The mean recession measurements increased during the study, consequently clinical attachment loss might be expected to increase. However, because clinical attachment loss is calculated from both recession and probing depth measurements, reductions in probing depth following treatment may correspond to more recession and may lead to gains in clinical attachment loss being measured. Probing depth reduction after treatment may be due to less probe penetration within periodontal pockets as a consequence of close adaption of the pocket lining to the tooth/root surface (gain in probing attachment) following the resolution of gingival inflammation. It is not possible to detect true regeneration with the formation of new cementum, periodontal ligament and bone clinically, and this does not usually occur to any significant extent after treatment, but can be enhanced with regenerative procedures (Wikesjo et al., 1992, Palmer et al., 2008). Accordingly, a likely explanation for gains in clinical attachment loss is due to reductions in periodontal pocket depths (gain in probing attachment) rather than true periodontal regeneration.

Tooth mobility may be related to loss of bone support, or inflammation within periodontal tissues, and can be exacerbated by traumatic tooth contacts or parafunctional activity (Lindhe and Nyman, 2003). Healing following non-surgical periodontal treatment is accompanied by a reduction in inflammation within the periodontal tissues, gingival recession, and in deeper sites there may be some gain in probing attachment level (Rylander and Lindhe, 2003). It is most likely that gains in probing attachment levels are due to repair with a long junctional epithelial attachment (Wikesjo et al., 1992) or close adaption of the tissues to the debrided root surface, rather than regeneration of periodontal ligament, cementum and bone (Caton and Zander, 1979) as discussed above. Accordingly, the reduction in tooth mobility amongst participants is most likely to be accounted for by reduced inflammation within the periodontium, rather than increased bone support having connective tissue attachment.

The relationship between dental plaque and periodontal diseases is well documented, along with the importance of daily plaque removal and professional maintenance care (Loe et al., 1965, Theilade et al., 1966, Axelsson and Lindhe, 1978, Axelsson and Lindhe, 1981a, Axelsson and Lindhe, 1981b, Axelsson et al., 1991, Dahlen et al., 1992). All participants were advised to use an electric tooth brush, appropriately sized interdental brushes and if necessary dental tape (Echeverria and Sanz, 2003, van der Weijden and Slot, 2011, Van der Weijden and Slot, 2015). This finding is in agreement with previous research reporting the benefit of a single instruction in oral hygiene (van der Weijden and Hioe, 2005).

Bleeding on probing is not a reliable indicator of disease progression, but a lower proportion of bleeding sites with patients or the absence of bleeding on probing at individual sites is associated with lower risk of periodontal disease progression (Lang et al., 1990, Joss et al., 1994). The mean proportion of sites bleeding on probing after treatment in the present study (17.7%), is below the mean proportion of ≤20% in patients found to be at less risk of disease progression by Joss et al. (1994). In their study, only one-fifth of sites lost further attachment in patients having this degree of plaque control.

5.3 Discussion of Secondary Objectives

5.3.1 OHRQoL Trajectory from Diagnosis to Treatment

OHRQoL worsened from the time participants initially underwent full periodontal assessment on a new patient consultant clinic, to the time when treatment commenced. The traditional view that chronic periodontitis is a slowly progressing "silent" condition has been challenged in recent years, following research demonstrating the negative impact on OHRQoL (Ferreira et al., 2017). Whilst it might be expected that OHRQoL would worsen in untreated patients, this has not been reported to occur over a relatively short period of time. In this study, the mean interval from assessment to the commencement of treatment was approximately 2 months, during which time mean total OHIP-14 scores increased from 11.5 to 14.0. It may be speculated that the worsening of OHRQoL during this time could be due to a worsening of the periodontal condition whilst awaiting treatment or possibly other reasons, such as an increased awareness of the periodontal condition and anxiety about this.

It would be unethical to deliberately withhold treatment in order to investigate the effect on OHRQoL; however, delay in this study arose due to typical difficulties in scheduling suitable appointments that patients were able to attend or due to the waiting list for treatment, and represents a period during which no treatment was provided. The reason for worsening OHRQoL is unknown; however, it is unlikely that the clinical status would have worsened appreciably during this time. It has been estimated that in over 90% of people, periodontitis is slow or moderately progressive over many years, and that disease activity may be sporadic (Socransky et al., 1984, Ramseier et al., 2017). A more plausible explanation would be related to patients perhaps becoming more anxious about their periodontal condition as a consequence of the delay in commencing treatment, or as a consequence of being diagnosed with severe disease by a specialist with the ensuing explanation. Patients with chronic periodontitis are reported to have higher anxiety, and worse global and domain OHIP-14 scores, than controls with no history of periodontal disease (Levin et al., 2018). They also have worse scores in functional limitation, physical disability, psychological disability, social disability and handicap domains (Levin et al., 2018). Further studies of a similar design, together with the analysis of perhaps other psychological factors such as anxiety, depression and phobias may reveal whether this is an isolated observation, and whether these or other individual characteristics elucidate the reason for any emerging trends. Moreover, if anxiety does influence OHRQoL, future longitudinal research is warranted and also greater patient reassurance at the appointment for assessment.

5.3.2 Predictors of End of Study OHRQoL

This research was theory driven using the Wilson and Cleary model (Figure 2). It was considered that chronic inflammatory periodontal diseases with loss of tooth support (biological variables) would lead to symptoms of periodontal disease (bleeding gums, halitosis, the appearance of unsightly gaps, changes in tooth position) that could cause discomfort or pain (symptom status), making eating more difficult and worsening the enjoyment of food (functional status). Within the Wilson and Cleary model, characteristics of the individual and environment of importance in periodontal diseases and the response to treatment that may predict OHRQoL outcome are also considered.

A review of the literature suggested age (Steele et al., 2004), gender (Brauchle et al., 2013), tooth loss (Steele et al., 2004), periodontal condition (Ferreira et al., 2017), socio-economic status (Lawrence et al., 2008), psychological factors (Johansson et al., 2010, Boman et al., 2012, Woelber et al., 2015, Musurlieva and Stoykova, 2015), ethnicity (Abdelrahim et al., 2017) and smoking (Bakri et al., 2018) are directly associated with OHRQoL, or indirectly via an influence on the periodontal status. Accordingly, these factors were investigated in this research.

It was hypothesized that OHRQoL after treatment would be predicted by the baseline periodontal status (biological characteristics), age, gender, ethnicity, smoking status, education, psychological factors (sense of coherence, locus of control, self-esteem, task-specific self-efficacy), occupation (individual characteristics), and index of multiple deprivation (environmental characteristic). The inclusion of these factors made conceptual sense, and preliminary bivariate analysis confirmed many of them to correlate with OHRQoL after treatment. Simultaneous testing of variables has been recommended rather than a series of bivariate analyses is preferable to account for confounders (Swoboda et al., 2006). Simultaneous investigation of all clinical, individual and environmental characteristics here used structural equation modelling within a conceptual model. Longitudinal studies investigating OHRQoL following non-surgical treatment are much less common than cross-sectional studies, and to the author’s knowledge this is the first prospective longitudinal study to simultaneously investigate the direct and indirect effects of clinical, individual and environmental factors on OHRQoL in participants with chronic periodontitis.

Sense of coherence, baseline periodontal condition, gender, age and DMFT predicted OHRQoL post-treatment, depending on the starting time point used for analysis (initial assessment or treatment), as discussed in detail later. Overall, older, male participants and those having a stronger sense of coherence, better periodontal status, or a lower DMFT score had a better OHRQoL. By contrast, socioeconomic status, as indicated by Index of Multiple Deprivation, education, occupation, ethnicity, smoking status, locus of control, task-specific self-efficacy, and self-esteem did not predict OHRQoL. It is also noteworthy that the participants in the present study had no other oral conditions of relevance to OHRQoL such as xerostomia. The implications of these findings are discussed in more detail in subsequent sections.

The β values for predictors were small (0.159 to -0.432). These show how much the dependent variables (OHRQoL and periodontal status) increase in standard deviations when the predictor increases by one standard deviation, and is a measure of the total effect. The size of β; is a measure of the magnitude of the relationship between predictor and outcome (OHRQoL or periodontal status). Whilst the magnitude of this was small for most predictors, direct and indirect paths had values greater than those on which some notable recommendations for medication have been made. For example, the association between asprin and reductions in heart attacks that led to the recommendation for at-risk patients to take asprin was based on a correlation of 0.03 (Swann et al., 2007). The order of β values from largest to smallest for direct effects combining the findings from both models predicting OHRQoL is sense of coherence > age > baseline periodontal status > baseline DMFT > gender, and for predicting periodontal status is age>task-specific self-efficacy>baseline plaque score. Accordingly, sense of coherence appears to be an important (and only psychological) direct predictor of OHRQoL after treatment, whereas age is the most important predictor for periodontal status before treatment. For indirect paths via periodontal status predicting OHRQoL, the order of magnitude for values of β remains age>task-specific self-efficacy>baseline plaque score.

Whilst the factors predicting OHRQoL may be inter-linked as discussed below, the selection criteria excluded other common confounding factors such as systemic disease or medication known to adversely impact on the periodontal condition, such as diabetes and medication to control raised blood pressure, epilepsy or for immunosuppression. Furthermore, smoking status was included in analyses, although it did not predict OHRQoL after treatment. Each predictor of OHRQoL is now discussed.

5.3.2.1 Sense of Coherence Predicts OHRQoL

Greater sense of coherence predicted better OHRQoL after periodontal treatment and was the strongest predictor of the end of study OHRQoL, with either baseline periodontal status or end of study periodontal status as predictors of OHRQoL. Sense of coherence directly predicted OHRQoL, and this effect was not mediated via the periodontal status.

This is of interest because sense of coherence has also been associated with good oral health behaviours, which could influence the periodontal status, such as good plaque control. However, the effect appears to be the direct psychological effects of sense of coherence on OHRQoL.

Sense of coherence may influence oral health behaviours, have an effect via physiological pathways or the development of strategies to cope with stress. A strong sense of coherence has been associated with favourable oral health behaviours in several studies (Eriksson and Lindstrom, 2007, Elyasi et al., 2015), regular dental attendance, regular tooth brushing and better OHRQoL (Ayo-Yusuf et al., 2008), and a weak sense of coherence linked to unfavourable oral health behaviours (Savolainen et al., 2005b). Favourable oral health behaviours in combination with professional tooth surface debridement considered to be important for improvements in periodontal health as discussed earlier. It may be supposed the participants having a strong sense of coherence understood the cause and consequences of their periodontal condition, how this may be managed and that treating their periodontal condition was meaningful to them.

Stress and ineffective coping mechanisms can also result in physiological changes that may influence the onset and progression of periodontitis (Warren et al., 2014). Stress has also been linked with poorer treatment response (Vettore et al., 2005). Individuals with a strong sense of coherence may have less physiological response to stress, thus this clinical effect may mediate an effect on OHRQoL, although this was not found in SEM analysis. The effect of sense of coherence was not mediated by the periodontal status, but directly predicted OHRQoL, and consequently these two pathways (health behaviour and stress) of influencing OHRQoL can be ruled out. Sense of coherence and OHRQoL have items that measure the impacts of related psychological concepts, for example satisfaction with everyday life, aspects of relationships with others and emotions, and seems a possible explanation for sense of coherence having a direct psychological effect on OHRQoL.

Having a strong sense of coherence may also equip individuals to cope better with stressors, and the successful management of these may promote positive health. These individuals tend to stay well and remain satisfied with their quality of life irrespective of adversity or stressors (Antonovsky, 1987). In the context of this research, a person who thought their periodontal condition was manageable might have fewer impacts on their everyday life. Accordingly, this would also seem to be the plausible explanation for greater sense of coherence predicting better OHRQoL. Furthermore, whilst sense of coherence may be affected by other factors such as demographic and socioeconomic status, none of these factors were linked to sense of coherence in the SEM models, although these were explored as the models were built.

Sense of coherence is consistently associated with OHRQoL. Low sense of coherence is associated with worse OHRQoL (Boman et al., 2012), and moderate to strong sense of coherence is associated with fewer OHIP impacts (better OHRQoL) (Savolainen et al., 2005a), particularly in relation to psychological discomfort, disability and handicap domains. They also suggested that OHRQoL may be determined by sense of coherence independently of socioeconomic factors, clinical status or oral health behaviours.

Individuals with strong sense of coherence have resilience and develop a positive subjective state of health (Eriksson and Lindstrom, 2006). A strong sense of coherence is reported to predict good health in long and short-term studies of both physical and mental health, irrespective of age, gender or ethnicity. Sense of coherence is also positively related with quality of life in both cross-sectional and longitudinal studies (Eriksson and Lindstrom, 2007), and furthermore, sense of coherence is able to predict perceived and mental health (Eriksson and Lindstrom, 2006).

Finally, it is of interest also to consider how sense of coherence in the participants of this study compares with the general population and participants in other studies in order to determine whether there are any differences that might account for the findings. The mean sense of coherence for participants in the present study was similar to values reported for neighbouring Northern industrial cities in the UK (Walsh et al., 2014), and in other studies (Nilsson et al., 2010, Johansson et al., 2010, Boman et al., 2012).

Sense of coherence as a direct predictor of OHRQoL after treatment has not been reported in adults with periodontal disease previously, so far as the author is aware. However, this finding is consistent with a study of 12-13-year-olds reporting that Sense of coherence was the most important psychological predictor of OHRQoL (Baker et al., 2010).

The findings of this research suggest that knowledge of a person's sense of coherence may be important when tailoring interventions for optimal OHRQoL and clinical outcomes. Interventions to strengthen sense of coherence have been suggested for patients with chronic illnesses (Galletta et al., 2019). Experimental evidence also demonstrated that sense of coherence influenced OHRQoL in children, in whom a health promotion intervention to enhance OHRQoL in was tested in a RCT (Nammontri et al., 2013). Interventions have not been tested in adults with periodontal diseases so far as the author is aware, but there is scope to investigate this to help adult patients respond better to periodontal treatment. Sense of coherence can be strengthened in health promotion activities (Kahonen et al., 2012). Whilst some people have the resources to move to a healthier state, they may be unable to identify and use them, perceiving their condition is incomprehensible, unmanageable and unmeaningful. Health professionals can help people to reflect on their situation and help them to use the resources they possess (Super et al., 2016). These interventions could help enhance sense of coherence (Galletta et al., 2019).

5.3.2.2 Age Predicts OHRQoL

Greater age predicted better OHRQoL. Since advancing age is associated with greater prevalence and severity of periodontal disease, and tooth loss (Ramseier et al., 2017), it might be expected to adversely impact on OHRQoL. However, this does not appear to be the case amongst participants in the present study. Ageing may also be associated with a greater burden of disease and disability (Nummela et al., 2011, Divo et al., 2014), which could affect OHRQoL (Masood et al., 2017). These are unlikely to be important factors in the present study, taking into account the good general health and mean age of participants (50 ±10 years). Most participants were in employment and most were from higher occupational bands. A third were educated to degree level, which might suggest greater health awareness and it is reasonable to suppose that expectations for periodontal treatment may have been relatively high amongst these participants, rather than low. Nevertheless, being older predicted better OHRQoL after treatment.

OHRQoL is a subjective measure, and it seems that better OHRQoL with increasing age may accounted for by changing expectations in response to external events with age. This is a means of coping with diminished function, appearance and other aspects of life without getting despondent, and in relation to the consequences of periodontal disease counter the worsening effect of this on OHRQoL (MacEntee, 2007). It was also suggested that better OHRQoL reported by older people may be due to lower expectations than in younger people (Steele et al., 2004, Slade and Sanders, 2011).

In contrast, the absence of an association or weak associations between age and OHRQoL were reported in almost all cross-sectional, cohort and case-series on periodontal disease and treatment reviewed in Sections 2.5.3 to 2.5.5, and in some studies including RCT’s, age was a factor controlled in the study design. A weak correlation between age and OHRQoL (Sonnenschein et al., 2018) and negative association (He et al., 2018) are among the exceptions reported in cross-sectional studies. However, higher OHIP scores (worse OHRQoL) were found associated with lower age in one cohort study (Brauchle et al., 2013).

In national population samples, lower mean OHIP-14 scores (better OHRQoL) with greater age were found, with those under 30 years of age having the highest scores in a UK sample, and so the findings of the present study are in agreement with this (Steele et al., 2004). Whilst age is immutable, it should be accounted for in research and patient care. All participants in this study had chronic periodontitis, but more aggressive forms of disease may occur in younger people and could have influenced clinical and OHRQoL outcomes if they had been included.

5.3.2.3 Periodontal Status Predicts OHRQoL After Treatment

Worse baseline and end periodontal status predicted worse OHRQoL after treatment. Worse periodontal status is associated with worse OHRQoL (Sections 2.5.2 to 2.5.8); however, few studies have investigated the periodontal status before treatment as a predictor of OHRQoL outcomes or change in OHRQoL over time. The findings of the present study may be due to participants starting with a poorer periodontal status needing greater improvements before meaningful improvements in OHRQoL were perceived. For some participants, the severity of periodontitis was such that the prognosis for treatment was poor and accordingly treatment could not realistically improve this sufficiently to lead to improvements in OHRQoL. Increased tooth mobility and migration of teeth making eating difficult, poor aesthetics, gingival bleeding, dentine hypersensitivity and halitosis are common symptoms in patients with advanced periodontitis that may continue to be troublesome for people having advanced disease even after periodontal treatment. Furthermore, generally the aim of treatment is to halt disease and stabilize the periodontal condition, rather than completely repair or heal the periodontal tissues and so not to restore perfect OHRQoL.

Whilst most improvements in the periodontal condition may occur within the first 3 months and the basis for reviewing initial treatment outcomes after this interval, it can take up to 9 months before probing depths fully stabilize, and consequently further improvements may have occurred with more time (Badersten et al., 1984, Rylander and Lindhe, 2003). However, any further changes are likely to be small in the absence of further treatment.

Good improvements in periodontal health occurred after treatment (discussed further in Section 5.2.2); however, some participants required further non-surgical periodontal treatment after the study, due to residual bleeding or other signs, indicating that treatment was not complete. Residual probing depths ≥6mm and bleeding on probing ≥30% represent a risk for further tooth loss and further treatment is usually indicated for these sites (Matuliene et al., 2008).

In previous studies, periodontal pocketing and bleeding on probing were significantly and positively correlated with the percentage of perceived OHRQoL impacts at baseline, and the percentage of sites with clinical attachment loss >6mm with perceived impacts both before and after treatment (D'Avila et al., 2005). Better post treatment OHRQoL has been associated with better pre-treatment OHRQoL, but not baseline clinical parameters (Saito et al., 2010). A significant positive association was found between probing depths ≥4mm, clinical attachment loss and the OHRQoL score after treatment (Miao et al., 2016). However, associations between clinical variables before treatment and OHRQoL following treatment were not reported in most studies previously reviewed.

5.3.2.4 DMFT Predicts OHRQoL

Higher baseline DMFT predicted worse OHRQoL after treatment. The largest component of the DMFT score was missing teeth and many participants also had heavily restored dentitions. Whilst 20 teeth (1% of the total) were removed from 15 participants as part of the periodontal treatment strategy, most dentitions had above the generally accepted threshold of >20-21 remaining teeth for a functional dentition (Steele et al., 2012). Further SEM was undertaken to determine whether missing teeth before treatment or at the end of the study predicted end of study OHRQoL, however missing teeth alone did not predict OHRQoL.

The prediction of OHRQoL after treatment by baseline DMFT is an interesting finding and worthy of further consideration. Participants appeared to have an adequate number of teeth and had generally well maintained dentitions, nonetheless it is possible that factors relating to the restorations, having lost teeth and perhaps factors in relation to the status of remaining teeth may account for this finding. Many patients had dental crowns, bridges and large fillings that can render the performance of oral hygiene more challenging, and this can be associated with poorer periodontal health in these areas of the mouth, both of which could adversely affect OHRQoL. The number of fillings and amount of decay did not change significantly during the study, however teeth having a poor prognosis that required removal early in the study could also have contributed to the finding. Frequent reasons for a poor prognosis include teeth being beyond restoration or having severely compromise periodontal support. Twenty teeth were extracted (approximately 1% of the total) during the study. It is possible that teeth having a hopeless prognosis could have adversely affected OHRQoL by being troublesome for one reason or another, for example by being painful or having increased mobility. However, having fewer teeth as a consequence of these teeth being removed may have also adversely affected OHRQoL, with no net change in impacts. This cannot be determined from the analysis undertaken and remains speculative.

Impacts on OHRQoL relating to a combination of teeth having a poor prognosis, being troublesome and having increased mobility, rather than simply the number of teeth present, may also partially explain DMFT as a predictor of OHRQoL following treatment. However, periodontal treatment will not improve the DMFT, and so this effect will persist and is the most likely explanation for this finding.

Whilst there are no studies in which DMFT predicts OHRQoL in patients with periodontitis to directly compare these findings with, generally epidemiological and cross-sectional studies suggest having decayed and/or fewer teeth is associated with poorer OHRQoL (Steele et al., 2004, Ng and Leung, 2006, Fotedar et al., 2014, Masood et al., 2017, He et al., 2018, Kato et al., 2018). Furthermore, no significant difference was found in OHRQoL between having a shortened dental arch of 20 occluding teeth (second premolar to second premolar) or having missing molars replaced (Reissmann et al., 2019).

Overall, the findings that periodontal status and DMFT both predict OHRQoL support the Wilson and Cleary and Locker models, but the weakness of relationships emphasise links with other individual and/or environmental factors.

5.3.2.5 Gender Predicts OHRQoL

Being female predicted worse OHRQoL after treatment. The underlying reason for this is unclear, as there may be other factors related to gender that were not investigated to account for this finding. Most of the participants in the present study were female (64%). Females are more likely to attend for dental care, and in so doing be diagnosed with periodontal disease and prescribed periodontal treatment. It may be speculated that the finding in the present study could also be accounted for by females having greater concern about their periodontal condition and reporting worse OHRQoL (greater impacts) after treatment than men.

There are no previous longitudinal studies in which gender has predicted OHRQoL after periodontal treatment to directly compare this finding with, and in studies specifically on periodontitis, associations between gender and OHRQoL are unclear. Some cross-sectional and cohort study data suggest that females have worse OHRQoL (Brauchle et al., 2013, Fotedar et al., 2014), or that males report lower impacts amongst participants with periodontitis (Wellapuli and Ekanayake, 2016). Other cross-sectional studies have reported no gender difference in OHRQoL in participants with periodontitis (Masood et al., 2017, Sonnenschein et al., 2018, El Sayed et al., 2019). However, studies reporting pre-treatment and post-treatment OHRQoL found no associations between gender and either post-treatment OHRQoL or changes in OHIP-14 scores (Saito et al., 2010, Miao et al., 2016, Mendez et al., 2017).

Gender differences in OHRQoL are found in studies that are not specifically focussed on periodontitis or its treatment (Mc Grath and Bedi, 2000, Mason et al., 2006). However, factors unexamined in these studies may also account for variation in OHRQoL between genders.

5.3.2.6 Indirect Effects for End of Study OHRQoL

Indirect effects for the end of study OHRQoL were all mediated via the periodontal status. For both baseline and end of study periodontal status, better end of study OHRQoL was indirectly predicted by higher task-specific self-efficacy and lower plaque score. For the baseline periodontal status, better OHRQoL was also indirectly predicted by age and for end of study periodontal status, better end of study OHRQoL was also indirectly predicted by higher self-esteem. Once again, this supports the Wilson and Cleary model and seems intuitive.

The implication of these findings is that improving the plaque score, enhancing task-specific self-efficacy and self-esteem may also have a beneficial effect on OHRQoL by enhancing the periodontal status. This is discussed further in Sections 5.3.3.2, 5.3.3.3 and 5.3.3.4.

5.3.3 Predictors of Periodontal Status

Better task-specific self-efficacy predicted better baseline and end periodontal status. Greater age and worse baseline plaque score predicted worse baseline periodontal status. However, better plaque score predicted worse periodontal status at the end of the study. Better self-esteem predicted better end periodontal status. Other individual and environmental factors did not predict periodontal status at either time point.

5.3.3.1 Age Predicts Periodontal Status

Greater age predicting worse baseline periodontal status is compatible with the initiation and progression of common chronic disease in a population. The older people are, the more chance they have to get and experience progression of the disease. Periodontal attachment loss continues with age, and has been shown to accelerate through the fourth decade in vulnerable individuals (Thomson et al., 2013). Furthermore, without treatment periodontal disease may progress with increasing age, resulting in continued loss of supporting tissues in those affected, which can ultimately result in tooth loss. The rate of progression varies, with most people having slow or moderate progression and only about 8% of people experiencing rapid progression of periodontitis. (Ramseier et al., 2017).

5.3.3.2 Task-specific Self-efficacy Predicts Periodontal Status

Better task-specific self-efficacy directly predicted better periodontal status at baseline and end of study. Self-efficacy is the strength in an individual’s belief that they are able to complete a task and reach goals. The Task-specific Self-efficacy questionnaire used captured responses about the confidence of participants in brushing and cleaning between their teeth, and also confidence in visiting the dentist, that was combined in a total score.

The finding that Task-specific Self-efficacy predicted better periodontal status both before and after treatment is of key importance in relation to clinical outcomes. This finding highlights the possibility of enhancing task-specific self-efficacy to optimize improvements in the periodontal status in those with low task-specific self-efficacy. Task-specific self-efficacy has been enhanced in the management of other chronic conditions. For example, interventions involving a mentor with and without the additional use of a mobile phone application were investigated in a randomized single-blind controlled trial in young people with cystic fibrosis. Both interventions enhanced task-specific self-efficacy compared with a control (Cummings et al., 2011). Enhancing task-specific self-efficacy has the potential to improve clinical outcomes of treatment, and to the author's knowledge this has not been investigated in the management of periodontal diseases. Accordingly, this would be an interesting topic worthy for future research.

This finding is compatible with existing data, and self-efficacy has been related to brushing, flossing and dental visiting, however the periodontal status in some previous studies was unclear (Stewart et al., 1997, Syrjala et al., 1999). Self-efficacy has been associated with better gingival health in at least one study (Mizutani et al., 2012). Furthermore, low oral-health-care-specific self-efficacy predicted greater loss to follow-up after periodontal treatment (Kakudate et al., 2010b). However, there are few reports specifically on task-specific self-efficacy in relation to periodontitis, and task-specific self-efficacy as predictor of periodontal status in patients with chronic periodontitis has not been previously reported so far as the author is aware.

Finally, it is also of interest to consider how the task-specific self-efficacy of participants in the present study compared with those in other studies. A comparison revealed these were similar to a previous study using the same scale, to which patients from dental practices and a periodontology clinic in Germany were recruited (Woelber et al., 2015).

5.3.3.3 Plaque Score Predicts Periodontal Status

Better baseline plaque score directly predicted better baseline periodontal status. This makes conceptual sense and is in agreement with strong evidence across several bodies of research that worse periodontal health is associated with high plaque levels. The role of dental plaque as the primary aetiological agent for periodontal diseases is well documented, dating from early studies demonstrating the development of gingival inflammation as a consequence of plaque formation (Theilade et al., 1966), and studies on periodontal treatment demonstrating the importance of regular plaque removal (Axelsson and Lindhe, 1978, Trombelli et al., 2015). However, better plaque control directly predicting worse periodontal health at the end of the study is difficult to explain, as plaque control clearly improved during the study and therefore an association with better periodontal status would be expected. A possible explanation might be that although plaque control improved, residual deep periodontal pockets remaining after treatment (18% ≥6mm), and probing depth is an indicator of the periodontal status. An alternative explanation might be that this is a Type 1 error.

Therefore, taking the body of evidence as supporting the notion that good plaque control is required to maintain periodontal health, it seems important to support these measures. Furthermore, good plaque control has a beneficial indirect effect on OHRQoL via periodontal status as discussed in Section 5.3.2.6.

5.3.3.4 Self-esteem Predicts Periodontal Status

Better self-esteem directly predicting better periodontal status after treatment is a new finding in relation to adults. Self-esteem is confidence in one's own worth and abilities (Rosenberg, 1965, Coopersmith, 1967). It is plausible to argue that a person with high self-esteem might attach much importance to the health of their mouth and consider it worth seeking professional help for the treatment of disease. They might also have confidence to maintain plaque control, to undergo treatment and their ability to see it through. It seems that this resource enabled participants having high self-esteem to invest time and effort undergoing periodontal treatment, undertaking self-care and hence achieved better periodontal health at the end of the study, and indirectly better OHRQoL. This may lead clinicians to anticipate that patients having high self-esteem may have a better clinical outcome than those having lower self-esteem. If this is the case, interventions to enhance self-esteem may improve clinical outcomes in those with low self-esteem. That would require clinicians making a paradigm shift from the traditional biomedical model of health to a biopsychosocial model, to include psychological factors.

Self-esteem is a construct and an overlap (to a certain extent) with the construct of self-efficacy seems likely. Self-esteem is also associated with occupation (Gecas and Seff, 1989), and a large proportion of the participants in this study were from higher occupation and well educated groups. However, neither of these factors predicted periodontal status after treatment, indicating that self-esteem was of importance regardless of socioeconomic status. Whilst there are no studies with which to directly compare these findings, studies with adolescents suggest that self-esteem is associated with oral hygiene habits, and that oral health beliefs together with self-esteem may indirectly predict gingival bleeding via tooth brushing and oral hygiene effectiveness (Koga et al., 2019).

5.4 Predictors of OHRQoL at Different Time Points

Growth curve modelling enabled simultaneous analysis of OHRQoL at three study time points, whereas in SEM OHRQoL was investigated at one time point in each model. Two Growth Curve Models were used to investigate predictors of OHRQoL from either assessment or treatment time points as the starting OHRQoL, and changes in OHRQoL over time to the end of the study. The model of primary interest included OHRQoL at treatment, oral hygiene and end of study time points, and this was used to investigate OHRQoL at the treatment time point, and changes in OHRQoL after treatment up to the end of study (see below). The model of secondary interest commenced with OHRQoL at the initial assessment, and omitted the treatment OHRQoL, but included the oral hygiene review OHRQoL and end of study OHRQoL. The use of two models was necessary because OHRQoL worsened from assessment to treatment, and then improved, and it is not possible to include both negative and positive changes in one model.

5.4.1 Sense of Coherence, Smoking and Gender Predict OHRQoL

Combining the findings of both models shows sense of coherence and gender directly predicted OHRQoL at the assessment and treatment time points. Smoking directly predicted OHRQoL at initial assessment. Other individual or environmental factors did not predict OHRQoL in agreement with SEM.

The order of magnitude of β for direct effects and starting OHRQoL for either model as appropriate was sense of coherence>smoking>gender, indicating that sense of coherence was also the strongest factor predicting starting OHRQoL, as well as OHRQoL after treatment, as discussed above, in SEM analysis. This analysis therefore supports sense of coherence as a consistent determinant of OHRQoL.
Sense of coherence and gender have already been discussed as predictors of OHRQoL after treatment using SEM, and the same points would seem applicable here.

5.4.2 Smoking Predicts OHRQoL

The role of smoking on OHRQoL directly predicted worse OHRQoL at the assessment time point only. In the present study, 38% of participants had never smoked, almost 48% were former smokers and only 14% were current smokers. The larger proportion of never smoked and former smokers may account for smoking being less important as a predictor of OHRQoL after treatment SEM analysis, and being significant in only one of the growth curve models. However, when smoking was investigated as a predictor of change in OHRQoL, former and never smoking directly predicted better starting OHRQoL than smoking at the assessment time point. This affirms the value of smoking cessation.

Smoking is an important risk factor for periodontitis (Albandar, 2002, Genco and Genco, 2014, Tonetti et al., 2015) and smoking may adversely affect treatment outcomes (Reynolds et al., 2015). Since the periodontal status directly predicted OHRQoL after treatment, smoking might also be expected to be a predictor of OHRQoL. However, a recent large cross-sectional study based on the Adult Dental Health Survey 2009 also found that smokers had worse OHRQoL independently of socio-demographic factors and oral conditions, and the OHRQoL of former smokers was not significantly different to those who had never smoked (Bakri et al., 2018). An alternative explanation might be that people who score highly on the personality trait of negative emotionality are more likely to be smokers, to have periodontitis and report poorer OHRQoL (Thomson et al., 2011).

The current research adds to this knowledge, and suggests smoking has a direct effect on OHRQoL. It would be worthwhile adding this message to the evidence-based advice on tobacco cessation, especially that given by dentists (Fiorini et al., 2014, Public Health England, 2014, British Society of Periodontology, 2016, Zhang et al., 2019).

5.5 Change in OHRQoL

The rate of change in OHRQoL during the study was directly predicted by sense of coherence in the assessment to end model and by locus of control in the treatment to end model. However, environmental and individual factors did not predict the rate of change in OHRQoL during the study.

5.5.1 Locus of Control and Sense of Coherence Predict Rate of Change in OHRQoL

A greater total locus of control predicted lower rate of improvement in OHRQoL in the treatment to end model. Greater sense of coherence predicted a lower rate of worsening OHRQoL in the assessment to end model. The strengths of β for locus of control and sense of coherence were -0.279 and -0.320 respectively, indicating a slightly stronger direct effect for sense of coherence. The reason for the differences in predictors (sense of coherence or locus of control) between models is unclear. However, as previously stated those with a strong sense of coherence may understand the nature (cause and consequences) of their periodontal condition, how it may be managed and that treating their periodontal condition was meaningful to them. Since plaque scores and bleeding on probing decreased significantly during the study, it may be supposed that participants also adopted better oral health care behaviours. This suggests behavioural and clinical change are mediated via the relationship between sense of coherence and OHRQoL. The mean scores for each dimension were similar for sense of coherence, and so the perception of comprehensibility, manageability and meaningfulness seems evenly distributed in the study participants. This analysis supports Antonovsky's salutogenesis concept in which a strong sense of coherence enables an individual to use the resources available to them to maintain health. Furthermore, This it supports investigations to enhance sense of coherence as part of periodontal treatment, as it did in a study of children in Thailand (Nammontri et al., 2013).

Locus of control has not previously been discussed and therefore receives more attention in this section. Locus of control had a direct effect on the rate of change in OHRQoL between time points (SLOPE) in the treatment to end GCM, and was unrelated to the starting OHRQoL (ICEPT). Greater locus of control predicted smaller increases in OHRQoL between time points. The effect of locus of control was unrelated to changes in the clinical status, which suggests the role of locus of control is as a psychological resource influencing OHRQoL, rather than via factors relating to clinical changes.

Locus of control is a measure of how much control an individual believes they have over events affecting them (Rotter, 1954). It is possible therefore, that individuals having a strong locus of control believed they had some degree of control over their condition, and that this in turn created a frame of mind that lessened the impacts on OHRQoL, albeit at a lower rate of change in this study. This analysis may also support investigation of interventions of locus of control to enhance periodontal treatment outcomes, or at very least greater patient empowerment.

Locus of control has an external dimension divided into significant or powerful other (dental professional) and chance, and an internal dimension in which the individual believes they have control over their own life. One study reported worse OHRQoL was associated with higher scores for the chance element of locus of control (Johansson et al., 2010). The total score was used in this research, and it is not possible to determine further any effect attributable to these dimensions within locus of control. Further investigation would be necessary to determine this.

All except the study by Johansson et al., (2010) on locus of control and periodontal diseases have investigated the clinical condition rather than OHRQoL. Using the same condition specific version of the questionnaire (Questionnaire C), with questions grouped into internal, change and powerful other statements, Galgut (1987) investigated locus of control in relation to a periodontal preventive programme. People with stronger powerful other and internal dimensions had lower plaque scores, and those with a strong internal dimension had less gingival inflammation. There was minimal correlation between chance dimension and clinical condition during the study, suggesting that powerful other and internal dimensions are important in relation to responses to oral hygiene instruction (Galgut et al., 1987). Consequently, it is thought that people with a strong internal locus of control might respond well to instruction to perform their own preventive care, whereas people with a strong powerful other locus of control might be more influenced by their dental care provider. Those with a strong chance locus of control may have little belief their personal efforts at oral hygiene will influence their disease.

The values for locus of control were compared with other studies to see whether any differences might be relevant when interpreting findings. Mean values for internal and chance items in the present study were similar to population means previously reported (Bajwa et al., 2007). However, powerful other locus of control mean scores were higher in the present study. This suggests participants may have felt more reliant on the dental care provider for the management of their periodontal condition. However, this interpretation should be considered with some caution. Whilst Cronbach's alpha for internal items was acceptable, it was questionable for chance items and poor for powerful others.

The lack of any associations being found between locus of control and the static periodontal status or changes in the clinical status in this study is in contrast to some other studies. Those who felt in less control of their environment had more clinical attachment loss (Linden et al., 1996), and people with an extreme external control had a slightly greater risk of severe periodontal disease, than those having strong internal belief and better coping strategies (Hugoson et al., 2002). In contrast to Linden et al. (1996), inflammatory variables have been positively correlated with the chance domain and plaque scores negatively correlated with the internal domain (Borkowska et al., 1998).

Dental locus of control beliefs also determined health behaviours and health status in a further study (Kneckt et al., 1999). In a more recent study, powerful others scores were lower in patients receiving non-surgical periodontal treatment than in healthy adults or people with chronic disease, whereas internal and chance scores were similar to population means (Bajwa et al., 2007). Locus of control also predicted dental care needs, with a greater need for periodontal treatment in those having an external locus of control (Mangelsdorff and Brusch, 1978).

To summarize, locus of control and sense of coherence in the present study were related to OHRQoL rather than the periodontal status, which may not be surprising given that they are both psychological ‘constructs’. Previous research has focussed on relationship of locus of control with the clinical condition. Only one previous study has investigated the relationship between locus of control and OHRQoL. Accordingly, further research is required to elucidate relationships, together with interventions to enhance locus of control and sense of coherence as part of periodontal treatment.

5.6 Task-specific Self-efficacy Predicts Clinical Changes

Task-specific self-efficacy negatively predicted clinical attachment gain and clinically meaningful changes in periodontal probing depths ≥2mm) in Growth Curve Modelling. This means that, the better the task-specific self-efficacy (confidence in undertaking tooth brushing/interdental cleaning and dental visiting), the smaller the clinical improvements were, as measured by the proportion of periodontal sites gaining clinical attachment and having clinically meaningful reductions in probing depths. This finding is at first glance counter-intuitive. However, better task-specific self-efficacy predicted better baseline periodontal status, and therefore less potential for improvement, consequently, perhaps leading to less gains in clinical attachment loss and clinically meaningful reductions in probing depth (≥2mm) after treatment. A further explanation may lie in the response of participants to instruction in plaque control. The baseline plaque score was identified as an important predictor of baseline periodontal status. Task-specific self-efficacy measures confidence in brushing, interdental cleaning and dental visiting. Therefore, this apparent negative prediction of task-specific self-efficacy for gain in clinical attachment loss and probing depth reductions ≥2mm in growth curve modelling, may be that those with a high task-specific self-efficacy before treatment responded less to advice on oral hygiene during the study, because they already felt confident about oral hygiene practices and dental visiting, whereas, those with a low task-specific self-efficacy may have responded more to advice on brushing and interdental cleaning, and gained confidence in dental visiting during the study. However, since task-specific self-efficacy was measured at one point only, before participants were given advice on tooth brushing and interdental cleaning, it is not possible to determine the validity of this line of thought from the current research. Further investigations measuring task-specific self-efficacy over time might help elucidate this.

5.7 Combining SEM and Growth Curve Modelling Findings

Finally, it is worthwhile considering how growth curve modelling has enhanced the SEM analysis of OHRQoL in this study. Growth curve modelling has:

1. Enabled the simultaneous analysis of OHRQoL at three time points (assessment, oral hygiene review and end of study, or treatment, oral hygiene review and end of study), whereas SEM considered only one time point (end of study OHRQoL);

2. Enabled the rate of change in OHRQoL to be investigated, which was not possible in SEM;

3. Confirmed the finding for SEM that sense of coherence directly predicted OHRQoL;

4. Added new knowledge that sense of coherence and locus of control predicted the rate of change in OHRQoL after periodontal treatment (this further strengthened the importance of sense of coherence in determining OHRQoL outcomes of periodontal treatment, and insight regarding a possible role for locus of control);

5. Enabled new variables of clinical change (probing depth reductions and gains in clinical attachment) to be considered, leading to the finding that task-specific self-efficacy is important in predicting changes in these; and

6. Together with the findings from SEM, has helped identify new avenues for future research, such as the consideration of psychological characteristics in the assessment of patients with periodontal diseases that may help to develop personalized treatment strategies, and interventions to strengthen important psychological characteristics.

5.8 The Relationship of Other Characteristics to OHRQoL and Clinical Outcomes

The individual and environmental characteristics included in the Wilson and Cleary Model that did not predict either OHRQoL after treatment or the rate of change in OHRQoL during the study require further consideration. Individual characteristics of ethnicity, education, occupation, and the environmental characteristic IMD are indicators of socioeconomic position and would have been expected to predict periodontal status and/or OHRQoL. However, none predicted periodontal status, OHRQoL or rate of change in OHRQoL in any SEM or Growth Curve model.

The reasons for this may be explained by the homogeneous nature of the sample in relation to the indicators or socioeconomic position. Almost 86% of participants were White British, with the remainder being from other ethnic groups. Similarly, a large proportion of participants were from higher occupational groups and educated to a high level. Over half were from associated professional and technical occupations and above, over 30% were educated to degree level and most lived in the least deprived areas, according to IMD quintile groups.

The homogeneity of ethnicity, higher occupational and well educated groups, and from more affluent areas restricts power to analyse these characteristics as predictors of OHRQoL. These factors have been consistently associated with OHRQoL in previous studies (Lawrence et al., 2008, Tsakos et al., 2009, Abdelrahim et al., 2017, Masood et al., 2017).

5.9 Strengths and Limitations of this Research

5.9.1 Study Design

Strengths of this research include being theory driven and having a longitudinal design, whereas much previous research in this area has been cross-sectional, lacked theoretical underpinning and explanatory power (Chapter 2 Sections 2.5.2-2.5.8). The Wilson and Cleary (1995) model (Figure 2), provided the theoretical framework to guide how the relevant individual and environmental factors in relation to the treatment of chronic periodontitis could be selected and analysed as predictors of OHRQoL. The direction of arrows in the model is important in guiding the analysis of individual and environmental factors as predictors of OHRQoL, along with the clinical indicators of periodontal status, and assist with the interpretation of the findings.

This is the first study to use SEM and GCM to analyse OHRQoL status and changes after periodontal treatment so far as the author is aware. The use of SEM enabled simultaneous analysis of predictors of OHRQoL and periodontal status, and gave a high-level perspective to the analysis (5.3–5.7). Growth Curve Modelling enabled simultaneous analysis of which factors predicted starting OHRQoL and the changes in OHRQoL after treatment. These analyses can be performed only with longitudinal data, which are more challenging to collect with an adequate sample than cross-sectional studies.

Most studies of periodontal treatment outcomes are based entirely on the biomedical model, in which clinical measurements are used to evaluate changes in periodontal status. Whilst changes in probing depths and bleeding on probing are important indicators of clinical success, focussing solely on these ignores an outcome of importance to patients, namely the effect of their mouths on their daily lives. Some studies have reported OHRQoL without reporting clinical outcomes (Bajwa et al., 2007, Ozcelik et al., 2007, Jowett et al., 2009, Jonsson and Ohrn, 2014). However, most report clinical outcomes, and reporting both in the present study enabled changes in OHRQoL to be related to clinical outcomes. In so doing, it illuminated the pathways by which clinical, individual and external factors interact to determine OHRQoL. As this discussion has shown, this aspect of study design has highlighted possible avenues for intervention to improve the periodontal status and/or OHRQoL. The analysis also provides strong support for the Wilson and Cleary model to help clinicians and researchers consider how OHRQoL may be influenced.

The main limitation of the study design was the lack of a control group, which restricts conclusions on the effect of treatment. However, the inclusion of a group receiving no treatment would have posed unacceptable ethical and recruitment issues that would have been extremely difficult to overcome. Quantitative analysis of mean OHIP-14 scores in the absence of a control group may lead to the impression that there was little or no change in OHRQoL as a consequence of treatment, because improvements in one item may be cancelled out by a deterioration in another item. Furthermore, the variation in responses and random measurement error between repeat administrations of OHIP-14 questionnaires may also create a potential problem of regression to the mean in longitudinal studies (Slade, 1998). This can especially be a problem in interventional studies without a control group when participants are selected on the basis of high baseline scores of the outcome measure of interest (Davis, 1976). Whilst all the participants in the present study were recruited due to having chronic periodontitis, many had mild to moderate levels of disease, and the mean OHIP-14 scores were at the lower end of the range reported in previous similar studies. Furthermore, follow-up measurements were examined in the total sample using the baseline (treatment time point) value, which also reduced the risk of regression to the mean compared with only examining a sub-sample (Barnett et al., 2005) Accordingly, although it is likely that regression to the mean has occurred in the present study, this may not be as great as if recruitment had specifically targeted patients having only severe disease or if only a sub-sample had been examined. However, further analysis would have been required to determine the impact of regression to the mean, such as repeated measures ANCOVA using the baseline scores as the covariate in a regression model of the absolute follow up score.

A further limitation of the study was the sample homogeneity. Recruitment included consecutive patients fulfilling the inclusion criteria referred to one hospital, and a significant proportion of these had less severe periodontal disease. Referrals from a relatively narrow range of backgrounds may explain why these characteristics of socioeconomic position were not found to predict OHRQoL. A wider sampling frame might be required to overcome this issue, involving a larger sample and recruitment of patients in primary care. On the other hand, the SES homogeneity of the sample is also a strength of this research.

There is both strength and weakness in the study duration. A strength is that participants underwent a single course of non-surgical treatment without adjunctive therapeutic measures that might have influenced the outcomes. Ninety-five percent of treatments were completed in one visit. Furthermore, most improvements in periodontal health are likely to occur during the first 3–6 months after treatment and so the duration seems appropriate (Rylander and Lindhe, 2003). After the initial course of non-surgical treatment, adjunctive measures including antimicrobial agents to accompany further root surface debridement or surgical treatment for the management of deep residual periodontal pockets not responding to these more conservative measures may be required, adding further confounders and complexity to the study. Since most patients benefitted clinically from the initial treatment, the numbers requiring further treatment would have been too small for analysis had the study been longer, and it would have been necessary to increase the sample size. The study duration may also represent a weakness, in that further changes in clinical status could be accompanied by further changes in OHRQoL, and a consequently greater or new effects. However, most improvements in the periodontal condition and OHRQoL occur after the initial treatment, and thereafter no important improvements in OHRQoL may occur (Makino-Oi et al., 2016).

5.9.2 Statistical methods

The use of structural equation modelling is a strength of the present study. The technique is less reliant on significance testing and less prone to data manipulation than more traditional statistical methods, and consequently the findings are likely to be more reliable. Importantly, it also requires testing of explicit theoretical models (Kline, 2016). Complex model paths can be developed using SEM with direct and indirect effects that allow more accurate modelling of causal relationships. SEM also assumes that observed variables are indicators of latent variables that represent constructs in the model (eg periodontal status), and that the measurement model can be directly incorporated into the model. Both these features of SEM led to more accurate modelling of the construct (OHRQoL) we are trying to explain. SEM also allowed testing of the Wilson and Cleary theoretical model in which the independent effect of predictors on OHRQoL and the periodontal status were simultaneously analysed. The whole model was considered in the analysis, rather than giving precedence to individual effects. The effect size for observed variables is estimated in SEM and the proportion of the explained model is also calculated. This may be more relevant than the estimates of individual effect sizes. Consequently, SEM has advantages over other statistical techniques (including correlation or regression) that are often used in OHRQoL research.

The number of participants completing the study (140) exceeded the size in the power calculation to determine the clinical and OHRQoL outcomes of diagnosis and treatment of chronic periodontitis (128). During modelling, it became apparent the model for structural equation modelling would have 2 latent and 10 observed variables, thus a subsequent calculation suggested 136 participants would be required. Accordingly, the study was sufficiently powered for the aim of the research. However, greater power might have allowed the effects of other variables (notably socioeconomic status) to emerge.

Normality of data was carefully examined before analysis and tested by inspection of histograms, Q-Q plots, skewness and kurtosis (Altman, 1991, Loy et al., 2016). Skewness and kurtosis are accepted and widely quoted in publications and online fora as alternative methods to assess normality (West et al., 1995, George and Mallery, 2010, Kim, 2013, Kline, 2016, Muzaffar, 2016). A reference of substantial departure from normality has been proposed as an absolute skew value >2 and an absolute kurtosis value of >7 (West, 1996) and >3 and >10 respectively (Kline 2016). Accordingly, values below these thresholds may be analysed using parametric tests and SEM using the maximum likelihood method of estimation.

All demographic, clinical, and questionnaire data were below these thresholds, other than ethnicity and mobility score >1. Ethnicity data were not used in the substantive analyses; however, mobility score >1 was included as an indicator of the periodontal status along with probing depths, bleeding on probing and clinical attachment loss in confirmatory factor analysis and structural equation models. The skewness and kurtosis were slightly above the threshold values for mobility>1; however, Q-Q plots had a reasonable fit, and the adverse effect of including mobility within confirmatory factor analysis and structural equation models seems likely to be small.

5.9.3 Measurement of OHRQoL and Psychological Characteristics

Selection of the OHIP-14 as the instrument used to measure OHRQoL is also a strength of this study. The OHIP-14 is the most commonly used instrument to measure OHRQoL, and has been validated in dental hospital settings (Robinson et al., 2003). It has also been suggested as the most appropriate instrument for detecting psychosocial impacts (Locker, 1988). The internal reliability was excellent for the total OHIP-14 (>0.90) and mainly excellent for psychosocial scores at all time points in the study (0.90 – 0.93). The use of this instrument also allowed the findings of the present study to be compared with the many others to have used the OHIP-14. In addition, the OHIP-14 is reported to be responsive to change in OHRQoL following treatment (Locker et al., 2004). The effect size was small in the present study which concurs with Locker et al. (2004).

Omitting a single item global self-rated oral health measure in the present study means that an externally referenced method (the anchor based method) could not be used to determine the minimally important difference (MID). Therefore, the interpretation of clinical changes was limited to using the effect size (internally referenced) as a benchmark for these changes. Effect size is a distribution based method for assessing the MID expressed in standard deviation units and is interpreted using conventional benchmarks of small, medium and large according to the criteria proposed by Cohen (1988). A limitation of this method is that the dispersion of scores can considerably affect the effect size. If there is not much dispersion, the effect size can be large even with modest difference in the change score (Tsakos et al. 2011). The standard deviations of OHIP scores in the present study were large, and so the effect size is unlikely to have been overestimated. However, a further limitation of this method is that the effect size does not take into account whether the change is meaningful to the patient or not. In contrast, anchor based methods take into account an external reference, such as a single item global self-rated oral health measure, to determine a cut-off for a change in the OHRQoL measure that patients consider to be important. However, the psychometric properties of single item global self-rated measures have been questioned (Wyrwich et al., 2005). Interestingly, a study using both distribution-based and anchor-based approaches to assess the MID for an OHRQoL measure found the same MID in a study of OHRQoL in patients treated for periodontitis, irrespective of the method used (Tsakos et al., 2010).

The questionnaire instruments were all selected as being the most appropriate to measure the characteristic being investigated, and psychometric properties for most were considered to be acceptable to excellent. The exceptions were the Sense of Coherence dimension of manageability and Locus of Control chance items, which were questionable, and poor for Sense of Coherence meaningfulness and Locus of Control powerful others. Cronbach’s alpha for total Sense of Coherence was good and should not have adversely affected analysis. Also, sense of coherence emerged as a consistent and powerful predictor, despite this low reliability, so the effects may be stronger than measured. However, Cronbach's alpha for total Locus of Control was questionable, and conclusions relating to findings in relation to this factor should be interpreted with caution. Psychological traits are not real, but are our way of conceptualising things, and so concepts such as sense of coherence and OHRQoL may overlap.

All questionnaires were tested for comprehensibility, errors and ease of completion on a small group of people before being used with study participants. The self-completion of all questionnaires without answers being influenced by the care provider, together with the high rate of completion could also be considered strengths of the present study. Inevitably, with questionnaires being self-completed, there was a risk of some items being missed or not answered. However, these were very few, and in most cases, it was possible to substitute missing data with the mean value of the individual non-missing items using the mean of the dimension in question, as previously described.

In addition to the psychological factors investigated in the present study, it is also important to be aware that these are not exhaustive, and also that personality characteristics may account for individuals interpreting their oral health differently from others (Thomson et al., 2011). This may lead to an underestimation of an intervention because of lower effect sizes resulting from more negatively emotional participants scoring more highly on subjective OHRQoL measures. Since this was not the subject of the present investigation, the "contamination" of OHRQoL by personality factors cannot be determined, but it is nonetheless important to be aware of this caveat when interpreting the findings.

5.9.4 Clinical Aspects

A strength of this study is the restriction to patients diagnosed with chronic periodontitis (Armitage, 1999). Patients with aggressive periodontitis, other forms of periodontitis and gingival conditions and those with conditions or taking medications that could affect the periodontal condition were excluded. This permitted direct comparison with previous similar studies. It permitted stronger external validity to the target population, but understandably restricted generalisation to other populations. This means the findings may be applied to other studies of non-surgical periodontal treatment in patients with chronic periodontitis in similar settings (hospital), but not necessarily to general practice or in other populations of people worldwide.

After the clinical phase had been completed, the classification system for periodontal diseases changed so that participants in this study would now be classified as having generalized or localized periodontitis (Caton et al., 2018). According to that classification, 55.7% of participants had localized and 44.3% had generalized periodontitis. The new system also includes staging and grading, with these participants in stages I to IV (mild to severe). This allowed the severity of periodontal status to be considered in the analysis, rather than including only those participants with a given severity (worse periodontal status predicted worse OHRQoL). Risk factor assessment also forms part of diagnosis in the new system. None of the participants were diabetic, but 14% were current smokers. Therefore, within these limits findings, may be compared with future studies.

A further strength of the present study was that all clinical measurements were recorded by one experienced, trained and calibrated examiner, and treatment was provided independently by three trained and experienced hygienists in accordance with a departmental protocol. All intra-examiner and where relevant, inter-examiner reliability was excellent for all measurements, other than gingival recession for which intra-examiner reliability was graded as good. Therefore, the clinical measurements recorded in the present study are considered to be reliable.

Finally, the inclusion of DMFT is a further strength in this study, as the number and state of the teeth may impact on OHRQoL (Section 5.3.2.4). In SEM, the paths for the individual components of DMFT though tested, were not significant and therefore subsequently removed in the parsimonious model. However, the path from both baseline and end of study DMFT to end OHRQoL remained significant in the respective models and consistently predicted end of study OHRQoL.

5.10 Relevance of the Findings

The findings of this research are relevant to patients and members of the dental team. OHRQoL contributes to general well-being, and so having good OHRQoL is important for everyone. This research supports the evidence that periodontitis negatively impacts on OHRQoL, which became worse whilst participants waited for treatment. The reason for this is unclear, but emphasises the importance of treating periodontal disease promptly. Periodontal treatment improved OHRQoL. Gaining a better understanding of the important factors in relation to OHRQoL in people with periodontal diseases, advances knowledge and helps develop means of caring for people affected. It also helps individuals to better understand the complexities of treating periodontal disease and that outcomes depend on more than tooth surface instrumentation provided by a dental professional.

This research has identified characteristics that predict OHRQoL and periodontal status before and after treatment. It identified the characteristics that determined treatment success, the factors that may aid patient selection and indicated where interventions should be targeted to enhance treatment (sense of coherence, locus of control, task-specific self-efficacy, self-esteem and clinical factors). Understanding these relationships may help in developing a holistic approach in the management of patients with periodontal disease, rather than relying solely on traditional clinical measurements. This may include taking a broader perspective when tailoring oral health education, preventive and intervention measures designed to improve OHRQoL and clinical outcomes to individual needs. Furthermore, it is apparent that OHRQoL is a relevant and important outcome alongside the traditional clinical measures of success in the management of periodontal diseases. Using a biopsychosocial model of health encompasses this, thereby promoting a more holistic approach. Monitoring OHRQoL during maintenance care may also be more meaningful than focussing on clinical measurements alone.

Chapter 6

Conclusions and Recommendations

This intervention cohort study investigated OHRQoL and clinical outcomes of periodontal treatment. Predictors of OHRQoL were identified using the Wilson and Cleary theoretical model (Wilson and Cleary, 1995). OHRQoL was measured at initial assessment, treatment, oral hygiene review and at the end of study (3-6 months after treatment) time points. The intervention was a single course of non-surgical periodontal treatment together with instruction in plaque control. Plaque control was monitored at an oral hygiene review appointment approximately 1 month after treatment, and further instruction given as necessary. The data collected included OHIP-14 scores at time points, and psychological factors (sense of coherence, locus of control, self-esteem and task-specific self-efficacy) before treatment. Demographic information was recorded before treatment and clinical measurements were recorded before treatment and at the end of the study.

This study has contributed to current knowledge by identifying direct and indirect predictors of OHRQoL in patients undergoing periodontal treatment. It is the first study identifying psychological factors predicting OHRQoL longitudinally, and also contributes to knowledge about the factors predicting periodontal status.

6.1 Conclusions

6.1.1 Primary Objective: OHRQoL and Clinical Outcomes of Periodontal Treatment

OHRQoL and clinical status improved after treatment. Improvements were in the psychological and pain-discomfort dimensions of OHRQoL, however functional limitation became worse.

6.1.2 Secondary Objective: OHRQoL Trajectory from Diagnosis to Treatment and Follow-up

OHRQoL worsened between initial assessment (diagnosis) and treatment. The reason for this is unclear, but is unlikely to be due to a worsening of the periodontal condition during the relatively short interval between assessment and treatment commencing. Anxiety raised by diagnosis and explanation, and other psychological factors not investigated in the present study may account for this finding.

6.1.3 Secondary Objectives: OHRQoL and Clinical Outcomes. Individual Psychological and Environmental Predictors

OHRQoL was directly predicted by the following.

- Sense of coherence. This was the only direct psychological predictor of OHRQoL, and was not mediated by the periodontal status and oral health behaviours. Interventions to enhance sense of coherence, may warrant further investigation as an avenue to improve OHRQoL.
- Periodontal status. Periodontal treatment improved the periodontal status, and OHRQoL, consequently measures (including psychological) to enhance treatment outcomes are also warranted.
- DMFT (mainly missing teeth). Preventive measures, along with periodontal and restorative treatment are important to retain more teeth for better OHRQoL.
- Gender and age. Although immutable, gender and age should be taken into account in clinical practice and research.
- Smoking the assessment time point. Smoking cessation is also important in the management of periodontal diseases.

OHRQoL was indirectly predicted by task-specific self-efficacy. Enhancing task-specific self-efficacy and plaque control, may also have an indirect effect on improving OHRQoL via the periodontal condition. Interventions to enhance task-specific self-efficacy would therefore be worthy of investigation in relation to periodontal treatment.

The rate of change in OHRQoL was directly predicted by sense of coherence and locus of control, and this seems to be as a consequence of these constructs acting as psychological resources, rather than via an effect on the periodontal status in relation to oral hygiene habits. Consequently, interventions to enhance these, warrant further investigation as future avenues to improve OHRQoL outcomes of periodontal treatment.

Higher task-specific self-efficacy was related to lower proportions of clinical attachment gain and reductions in probing depth after treatment. Since task-specific self-efficacy was measured at only one time point before treatment, it cannot be determined if this changed during the study to account for these findings.

The end of study periodontal status was directly predicted by task-specific self-efficacy, plaque score and self-esteem, and there were no indirect effects. This suggests that enhancing task-specific self-efficacy, self-esteem and plaque control may improve clinical outcomes of periodontal treatment.

Individual characteristics of ethnicity, education, occupation, self-esteem, and the environmental characteristic Index of Multiple Deprivation did not predict OHRQoL, periodontal status or changes in OHRQoL after treatment. This is likely to be due to the homogeneous nature of the sample.

The Wilson and Cleary model was supported for future work in periodontal treatment and OHRQoL.

6.2 Recommendations

Recommendations are presented for practice and research.

6.2.1 Recommendations for Practice

1. Prompt treatment of periodontitis and steps to allay anxiety during the initial assessment of patients may prevent further deterioration in OHRQoL.
2. The routine use of OHRQoL should be considered as an outcome measure of periodontal treatment with an appropriate instrument (e.g. OHIP-14), alongside traditional clinical measures. This will help to determine the patient’s perspective about the extent and way in which their periodontal condition impacts upon them.

3. Differences in predictors of periodontal status and OHRQoL suggest the use of PROMS in practice and research, to capture different aspects of treatment success.
4. Knowledge about psychological factors, in particular sense of coherence and task-specific self-efficacy, may be useful in the management of people with periodontal disease. This information may help in understanding who responds to treatment and where interventions might be targeted. This would help develop a more holistic approach to the management of periodontal disease. However, a greater understanding of psychological factors and training in the use of instruments to measure these together with appropriate interventions, would be required before these measures could be used in clinical practice.
5. A single visit full mouth scaling and root surface debridement, accompanied by detailed oral hygiene instruction together with monitoring of plaque control, may improve OHRQoL and periodontal status.
6. An emphasis on using an electric tooth brush and interdental brushes may lead to satisfactory improvements in plaque control.

6.2.2 Recommendations for Research

1. Further studies are needed to determine whether predictors of OHRQoL identified in the present study are reproduced and applicable in other populations.
2. Participants from a wider range of backgrounds should be included in future studies to investigate ethnicity, occupation, education and IMD as predictors of OHRQoL.
3. Longer adequately powered studies are needed to determine if OHRQoL outcomes significantly change over a greater period of time, for example after active treatment has been completed and participants are in maintenance care.
4. Further research is required to investigate the pathways by which sense of coherence may affect OHRQoL and clinical outcomes in people undergoing periodontal treatment.
5. The stability of important psychological factors identified in this study (task-specific self-efficacy, self-esteem and sense of coherence) over time, would

be worthy of investigation by repeat measurement in future longitudinal studies.

6. Since sense of coherence appears to be the strongest predictor of OHRQoL after treatment, further investigation is warranted to determine if sense of coherence can be enhanced in adults requiring periodontal treatment to beneficial effect.
7. Further studies are needed to investigate in more detail the domains of locus of control, and their relationship with periodontal treatment and OHRQoL outcomes.
8. Further research is needed on task-specific self-efficacy and self-esteem in relation to treatment outcomes, and to determine if these can be enhanced with positive benefit in patients with periodontal disease.
9. Further investigation is warranted to determine the relationship of other psychological factors such as anxiety, depression, phobias and personality to OHRQoL and clinical outcomes in patients undergoing periodontal treatment.
10. Further research is needed to investigate underlying reasons for gender differences in OHRQoL in people with periodontitis.

Chapter 7

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Chapter 8

Appendices

8.1 Appendix 1: Supplementary Analysis Structural Equation and Growth Curve Modelling. Bivariate Analysis

The original models and data from the software programme used for structural equation modelling (SEM) including confirmatory factor analysis (CFA), and growth curve modelling (GCM) (Amos 25) referred to in chapters 3 and 4 are presented in sections 8.1.1 to 8.1.17 of this appendix.

Sections 8.1.1 to 8.1.7 contain CFA/SEM analysis of indicators and predictors of baseline periodontal status, and end of study and oral hygiene review OHRQoL.

Sections 8.1.8 to 8.1.10 contain CFA/SEM analysis of indicators and predictors of end of study periodontal status and end of study OHRQoL.

Sections 8.1.11 to 8.1.18 contain GCM analyses.

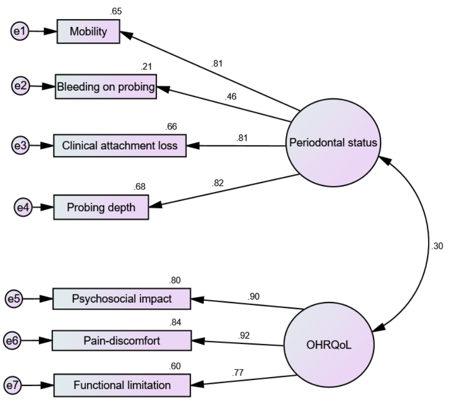
Sections 8.1.19 to 8.1.24 contain bivariate analyses.

8.1.1 Confirmatory Factor Analysis: Indicators of Baseline Periodontal Status and End of Study OHRQoL

The original Amos graphic presented in Figure 6 Chapter 4 is presented in Figure 12. The model, data and analysis were described fully in Chapter 4.

Figure 12 Measurement model obtained through Confirmatory Factor Analysis including two latent variables and seven items representing baseline periodontal status and end of study OHRQoL.

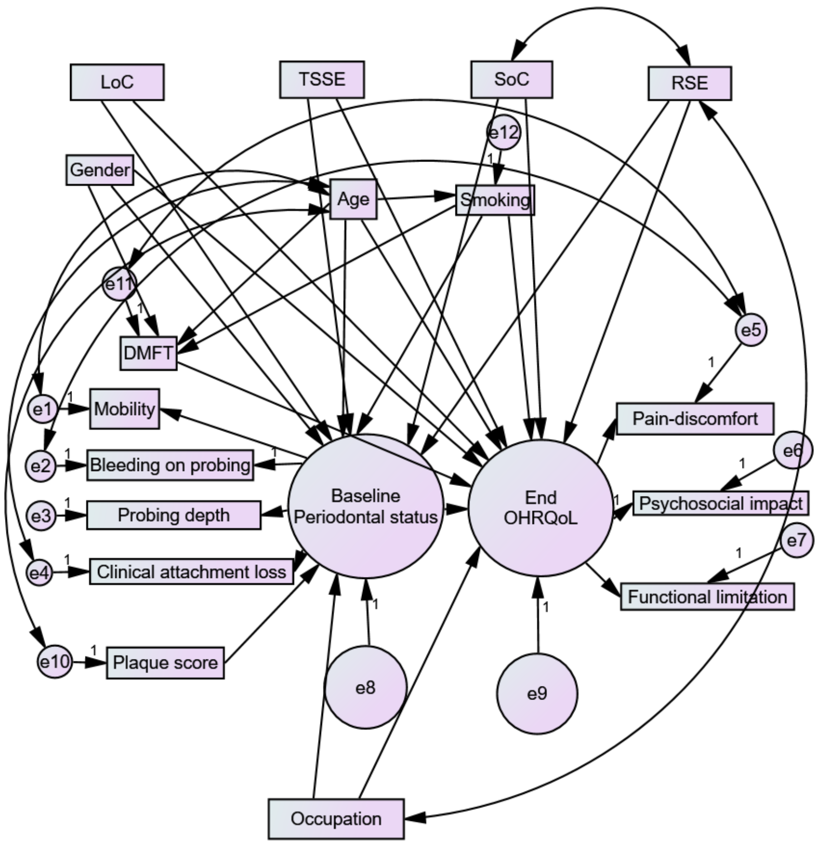
R-squared = β =



8.1.2 Predictors of Baseline Periodontal Status and End of Study OHRQoL

The original Amos graphic for the full end of study SEM model with baseline periodontal status and end of study OHRQoL is presented in Figure 13. The model, data and analysis were described in Chapter 4 (model not shown).

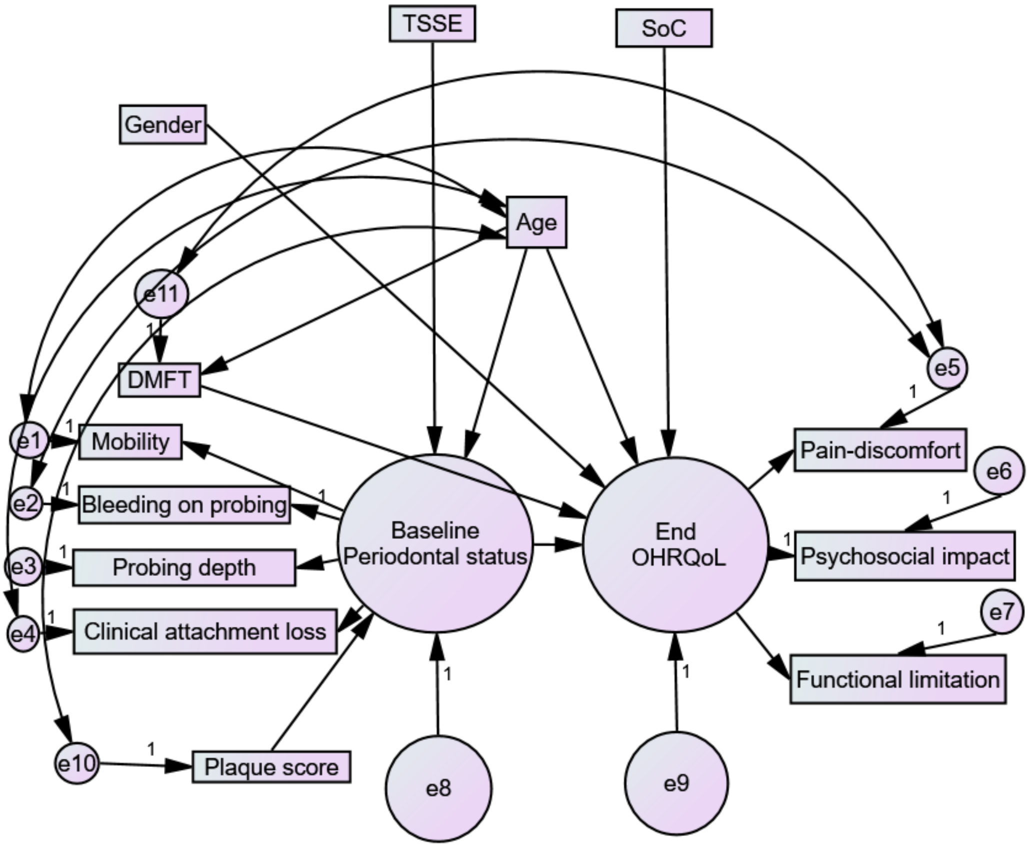
Figure 13 SEM including predictors of periodontal status at baseline and end of study OHRQoL. Full model. The model includes locus of control (LoC), task-specific self-efficacy (TSSE), sense of coherence (SoC), self-esteem (Rosenberg Self-esteem) (RSE), gender, age, smoking, baseline DMFT and plaque scores, occupation. Direct relationships are shown by arrows and covariances by double ended arrows. Error terms are designated e.



8.1.3 Parsimonious Model Predictors of Baseline Periodontal Status and End OHRQoL

The original Amos graphic for the parsimonious end of study SEM model presented in Figure 7 Chapter 4 is presented in Figure 14. The model, data and analysis were described fully in Chapter 4.

Figure 14 Parsimonious model predictors of the baseline periodontal status and end of study OHRQoL.



8.1.4 Confirmatory Factor Analysis: Indicators of Baseline Periodontal Status and Oral Hygiene Review OHRQoL

The CFA model for indicators of baseline periodontal status and OHRQoL for the oral hygiene review time point are shown in Figure 15. The model met all the criteria for a good fit (Table 38).

Figure 15 Measurement model obtained through Confirmatory Factor Analysis including two latent and seven items representing baseline periodontal status and oral hygiene review OHRQoL.

R-squared = ß =

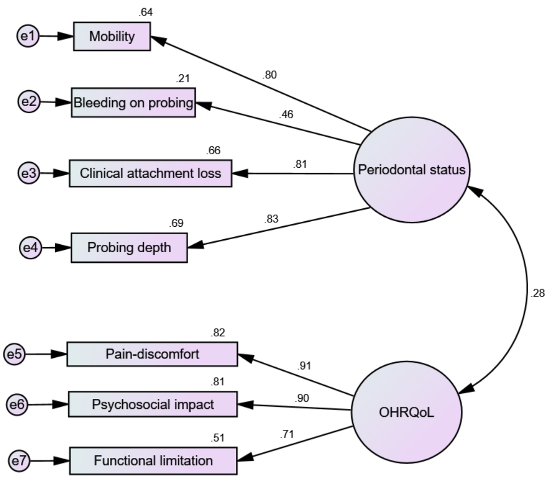


Table 38 Fit Indices for CFA Model of Oral Hygiene Review Time Point

Model	P	ChiSquare/DFRatio	GFI	CFI	SRMR	RMSEA
Measurement	0.337	1.118	0.971	0.997	0.0371	0.029

Standardized regression weights provide ß related to total effects between variables since there is no mediation in the CFA model (Table 39).

Table 39 Confirmatory Factor Analysis (total effects) of baseline periodontal status and oral hygiene review OHRQoL.

Parameter	ß	Bootstrap SE	Bias-corrected 95% CI	R-squared	% Total effect
Psychosocial impact → OHRQoL	0.901*	0.035	0.828-0.961*	0.811*	81.1
Functional limitation → OHRQoL	0.713*	0.056	0.594-0.809*	0.508*	50.8
Pain-discomfort → OHRQoL	0.907*	0.034	0.834-0.970*	0.822*	82.2
Probing depth → Periodontal status	0.828*	0.052	0.715-0.910*	0.685*	68.5
Clinical attachment loss → Periodontal status	0.814*	0.068	0.647-0.916*	0.622*	62.2
Bleeding on probing → Periodontal status	0.463*	0.092	0.269-0.631*	0.215*	21.5
Mobility→ Periodontal status	0.802*	0.064	0.664-0.912*	0.644*	64.4

*P= <0.01.

8.1.5 Predictors of Baseline Periodontal Status and OHRQoL at Oral Hygiene Review

The SEM at the oral hygiene review time point was essentially the same as for the end of study model, but with substitution of oral hygiene review OHRQoL (OHIP-14) (Figure 16).

It was predicted a priori that individual factors (age, gender, smoking, ethnicity and psychological factors including total scores for Sense of Coherence, Task-specific Self-efficacy, self-esteem (Rosenberg Self-esteem scale), Locus of Control questionnaires), education, IMD and occupation would predict the baseline periodontal condition and OHRQoL following periodontal treatment, in this case at the oral hygiene review time point (mean 1.7 months after treatment).

The full model similarly omitted IMD and education from the theoretical model as for the end of study analysis, because these observed variables did not fit within an acceptable model, and were unrelated to the other variables in the model.

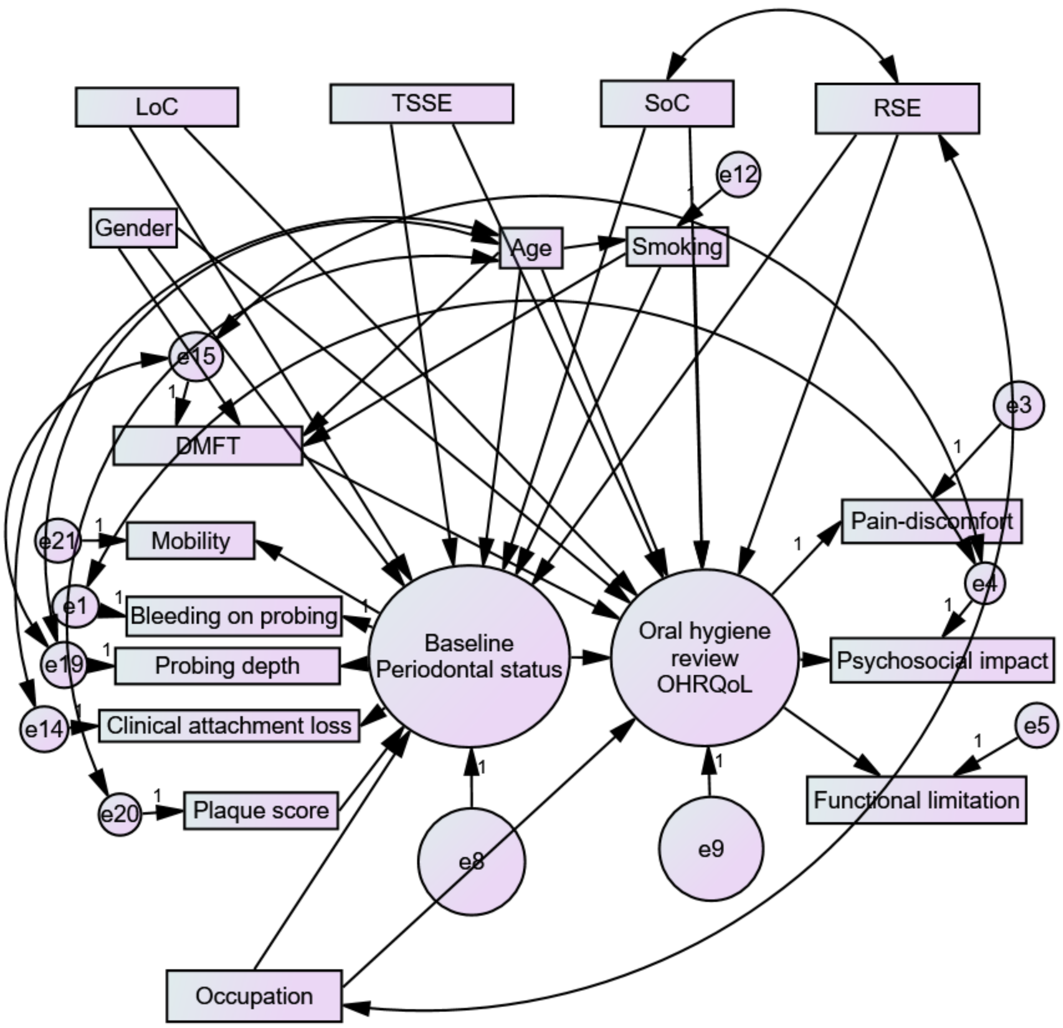
Covariances were also added to the model that made both statistical and conceptual sense These are presented in Table 40 for clarity.

Table 40 Covariances added to SEM oral hygiene review model

Covariance between	Rationale
Self-esteem and sense of coherence.	Linked psychological factors (Pallant and Lae, 2002).
Self-esteem and occupation.	Self-esteem may be linked with occupation (Gecas and Seff, 1989).
Plaque score (error term) and age.	Plaque score may be linked with age. Periodontal disease with age commonly leads to development of interdental spaces. Drifted, missing and restored teeth also render optimal plaque control difficult to achieve (Corbet and Smales, 2012).
Clinical attachment loss (error term) and age.	Clinical attachment loss may increase with age due to progression of periodontitis. Mobility related to attachment loss (White et al., 2012, Giannakoura et al., 2019).
Bleeding on probing and psychosocial impact (error terms).	Bleeding on probing is a common sign of periodontal disease. Periodontal disease adversely affects OHRQoL (Ferreira et al., 2017). Impacts in relation to all OHRQoL domains (Masood et al., 2019).
Decayed missing and filled teeth (DMFT) and psychosocial impact (error terms).	DMFT may adversely affect OHRQoL (Yamane-Takeuchi et al., 2016). May trigger impacts in relation to psychosocial items of OHIP-14.
Probing depth (error term) and age.	Probing depth increase with age in population surveys (White et al., 2012).
Probing depth and decayed missing and filled (error terms).	Deep probing pocket depth increases risk of tooth loss (Helal et al., 2019).

The fit indices fulfilled all the criteria for an acceptable model fit (Table 41).

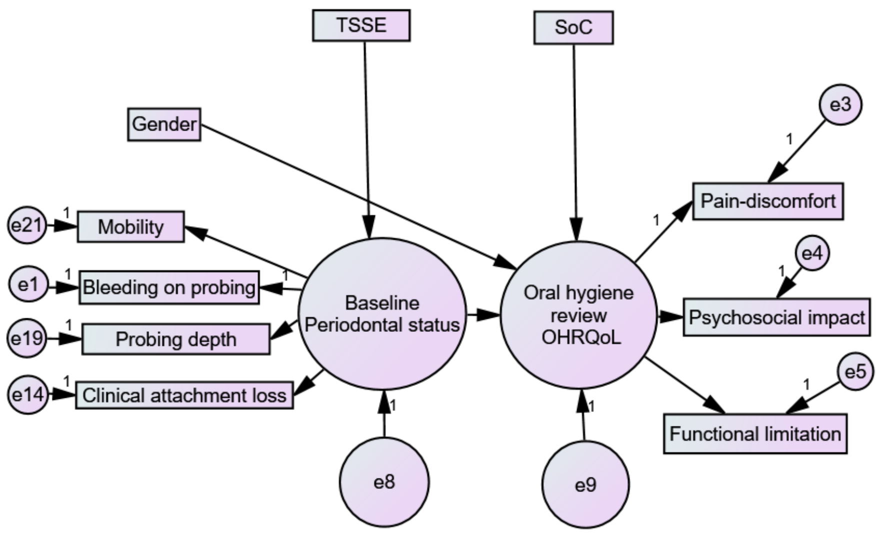
Figure 16 SEM including predictors and indicators of periodontal status at baseline and oral hygiene review OHRQoL. Full model. The model includes locus of control (LoC), task-specific self-efficacy (TSSE), sense of coherence (SoC), self-esteem (RSE), gender, age, smoking, DMFT, plaque score and occupation. Direct relationships are shown by arrows and covariances by double ended arrows. Error terms are designated e.



8.1.6 Parsimonious Model Predictors of Baseline Periodontal status and OHRQoL at Oral Hygiene Review

Paths having non-significant (P≥0.05) regression weights were removed from the full model to give the parsimonious model (Figure 17). The baseline periodontal status was predicted by task-specific self-efficacy at the oral hygiene review. OHRQoL at this time point was predicted by baseline periodontal status, gender, and sense of coherence.

Figure 17 Parsimonious model predictors of baseline periodontal status and oral hygiene review OHRQoL. task-specific self-efficacy (TSSE), sense of coherence (SoC). Error terms (e).



The fit indices for the parsimonious model indices (Table 41) met the criteria for an acceptable model fit and the models were not significantly different (P = 0.17), therefore the parsimonious model was accepted.

Table 41 Fit indices of oral hygiene review time point models

Model	P	ChiSquare/DFRatio	GFI	CFI	SRMR	RMSEA
Full	0.142	1.154	0.916	0.977	0.0660	0.033
Parsimonious	0.278	1.129	0.950	0.991	0.0476	0.030

The direct and indirect effects in the parsimonious model are shown in Table 42 and R-squared values in Table 43.

Table 42 Direct and indirect effects for oral hygiene review time point OHRQoL for the parsimonious model.

Parameter	ß	Bootstrap SE	Bias- corrected 95% CI
Direct effects			
Task-specific Self-efficacy → Baseline Periodontal status	-0.263**	0.108**	-0.460 / -0.028**
Sense of Coherence →OHRQoL	-0.446*	0.077*	- 0.580 / -0.271*
Gender →OHRQoL	0.200*	0.071*	0.057 / 0.336*
Baseline Periodontal status→ OHRQoL	0.250*	0.080*	0.102 / 0.418*
Indirect effects			
Task-specific Self-efficacy → OHRQoL	-0.066*	0.028*	-0.140 / -0.022*

*P≤0.01
**P=0.026

Significant direct effects were found between task-specific-self-efficacy and baseline periodontal status, sense of coherence and OHRQoL, gender and OHRQoL, baseline periodontal status and OHRQoL. A significant indirect relationship was found between task specific self-efficacy and oral hygiene review OHRQoL via the baseline periodontal status.

Table 43 R-squared for oral hygiene review time point parsimonious model

Parameter	R-squared	% Total effect
Periodontal status	0.069 (0.001-0.211)*	6.9
OHRQoL	0.302 (0.156-0.423)*	30.2

*P<0.01

The values for R-squared are low, but significant and indicate that baseline periodontal status and oral hygiene review OHRQoL account for 6.9% and 30.2% of the effect in the model respectively.

The direct paths in the parsimonious model show: better (higher) task-specific Self-efficacy score predicted better baseline periodontal status (lower score). Greater (higher) sense of coherence score predicted better OHRQoL (lower OHIP score) at the oral hygiene review time point. Being females (higher code) predicted worse OHRQoL (higher OHIP score). Worse baseline periodontal status (higher score) predicted worse OHRQoL (higher OHIP score).

Task-specific self-efficacy also influenced OHRQoL indirectly. The total indirect effects comprised specific indirect paths calculated as follows: Task-specific self-efficacy → baseline periodontal status → OHRQoL -0.263 x 0.250 = -0.066.

8.1.7 Summary of Predictors of Baseline Periodontal Status and OHRQoL at Oral Hygiene Review

At the oral hygiene review time point:

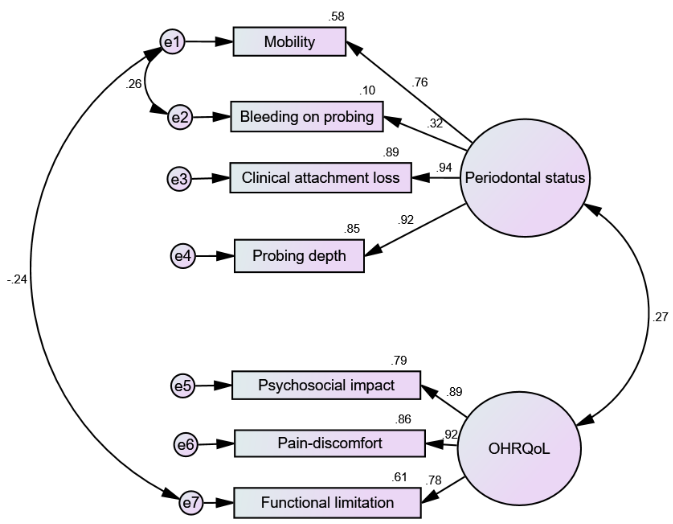
1. Worse periodontal status before treatment predicted worse OHRQoL following treatment.
2. Gender predicted OHRQoL. Females had worse OHRQoL.
3. Greater (higher) sense of coherence predicted better OHRQoL.
4. Better (higher) task specific self-efficacy directly predicted better baseline periodontal status and indirectly OHRQoL.
5. Area level environmental indicators (Index of Multiple Deprivation) and individual indicators of socioeconomic status (education and occupation) did not predict periodontal status or OHRQoL at the oral hygiene review.

8.1.8 Confirmatory Factor Analysis: Indicators of End of Study Periodontal Status and End of Study OHRQoL

The original Amos graphic presented in Figure 8 Chapter 4 is presented in Figure 18. The model, data and analysis were described fully in Chapter 4.

Figure 18 End indicators of end of study periodontal status and end of study OHRQoL. Confirmatory Factor Analysis of the two latent factors and seven observed variables in the end of study measurement model.

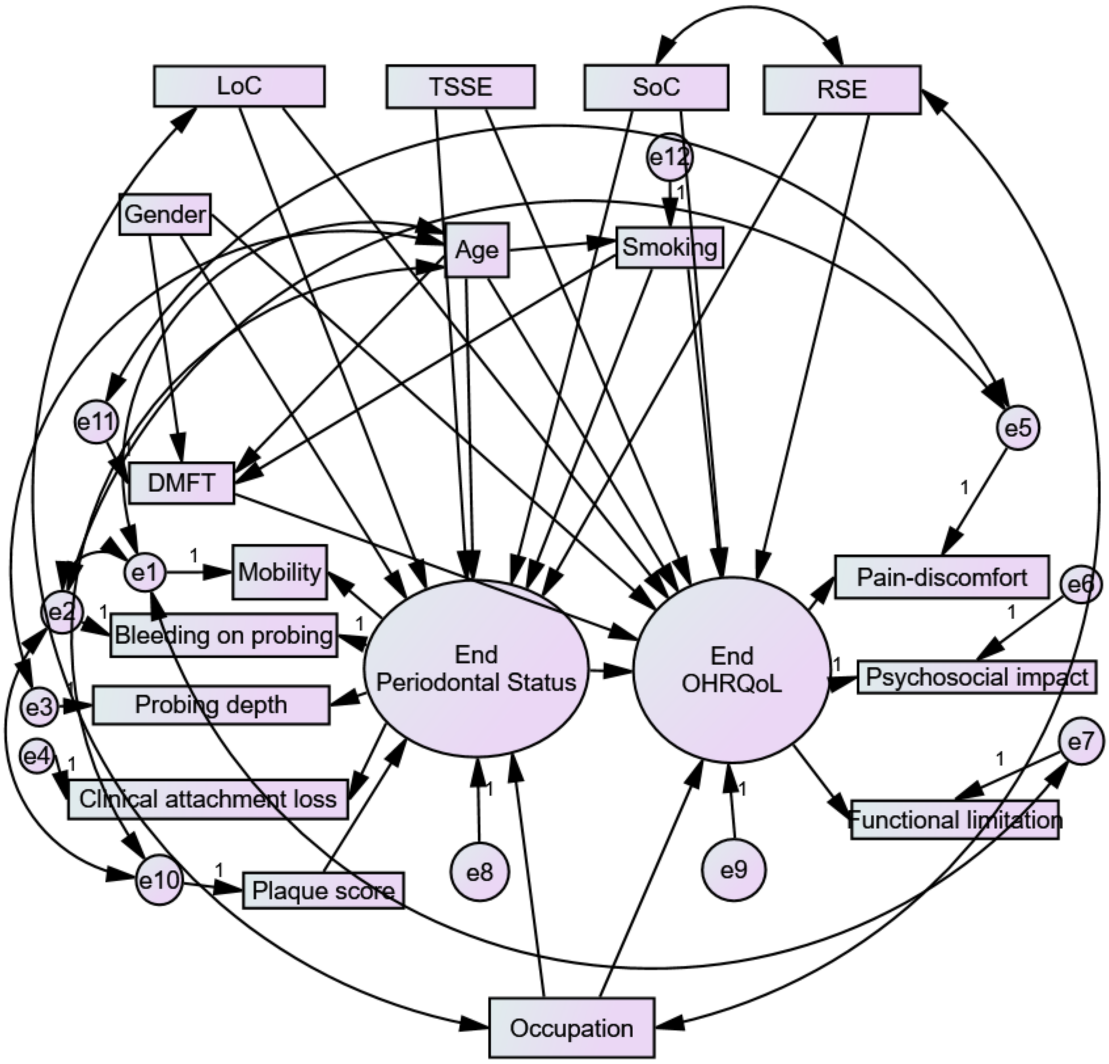
R-squared = β =



8.1.9 Predictors of End of Study Periodontal Status and End of Study OHRQoL

The original Amos graphic for the full end of study SEM model with end of study periodontal status and end of study OHRQoL is presented in Figure 19. The model, data and analysis were described in Chapter 4 (model not shown).

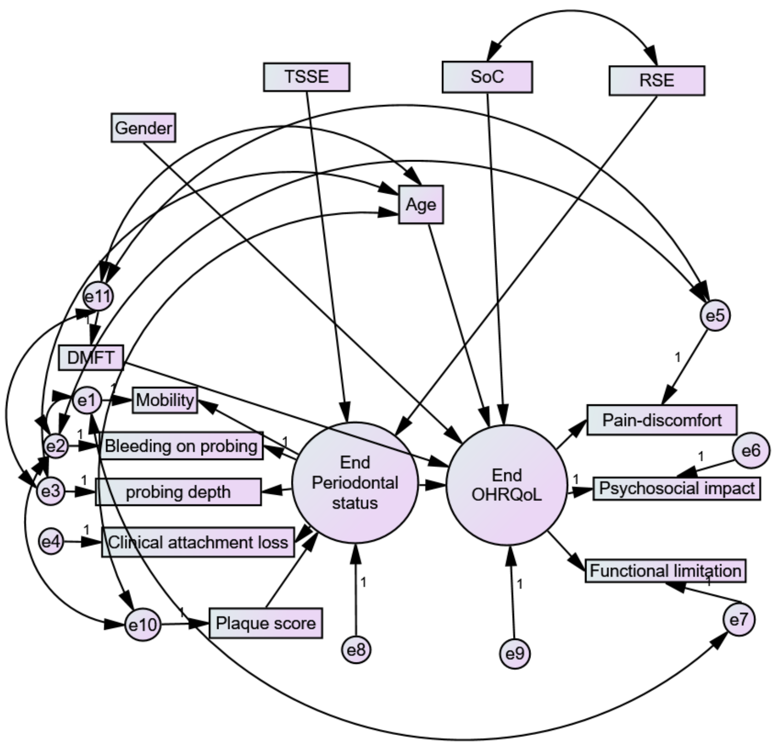
Figure 19 SEM including predictors of end of study periodontal status and OHRQoL. Full model. The model includes locus of control (LoC), task-specific self-efficacy (TSSE), sense of coherence (SoC), self-esteem (Rosenberg Self-esteem) (RSE), gender, age, smoking, end of study DMFT and plaque scores, occupation. Direct relationships are shown by arrows and covariances by double ended arrows. Error terms are designated e.



8.1.10 Parsimonious Model Predictors of End of study Periodontal Status and End OHRQoL

The original Amos graphic for the parsimonious SEM model with end of study periodontal status and end of study OHRQoL presented in Figure 9 Chapter 4 is presented in Figure 20. The model, data and analysis were described fully in Chapter 4.

Figure 20 Parsimonious model predictors of end periodontal status and end of study OHRQoL. Error terms (e).



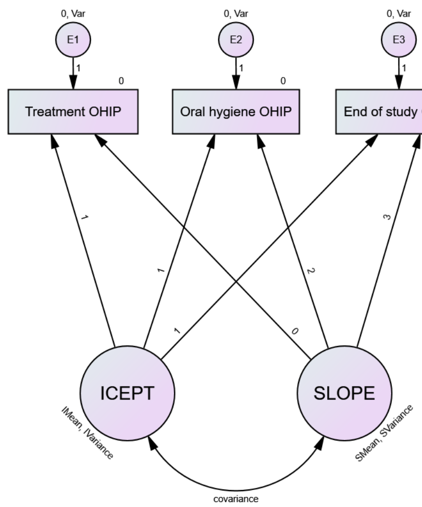
8.1.11 Predicting Longitudinal Changes in OHRQoL After Periodontal Treatment: Latent Growth Curve Modelling

Latent growth curve modelling investigated changes in OHRQoL from a baseline of assessment or treatment, at the oral hygiene and end of study time points in two models as described in Chapter 3.

8.1.12 Predicting Change in OHRQoL After Periodontal Treatment: Treatment to End of Study Univariate Growth Curve Model

The original Amos graphic presented in Figure 10 Chapter 4 is presented in Figure 21. The model, data and analysis were described in Chapter 4.

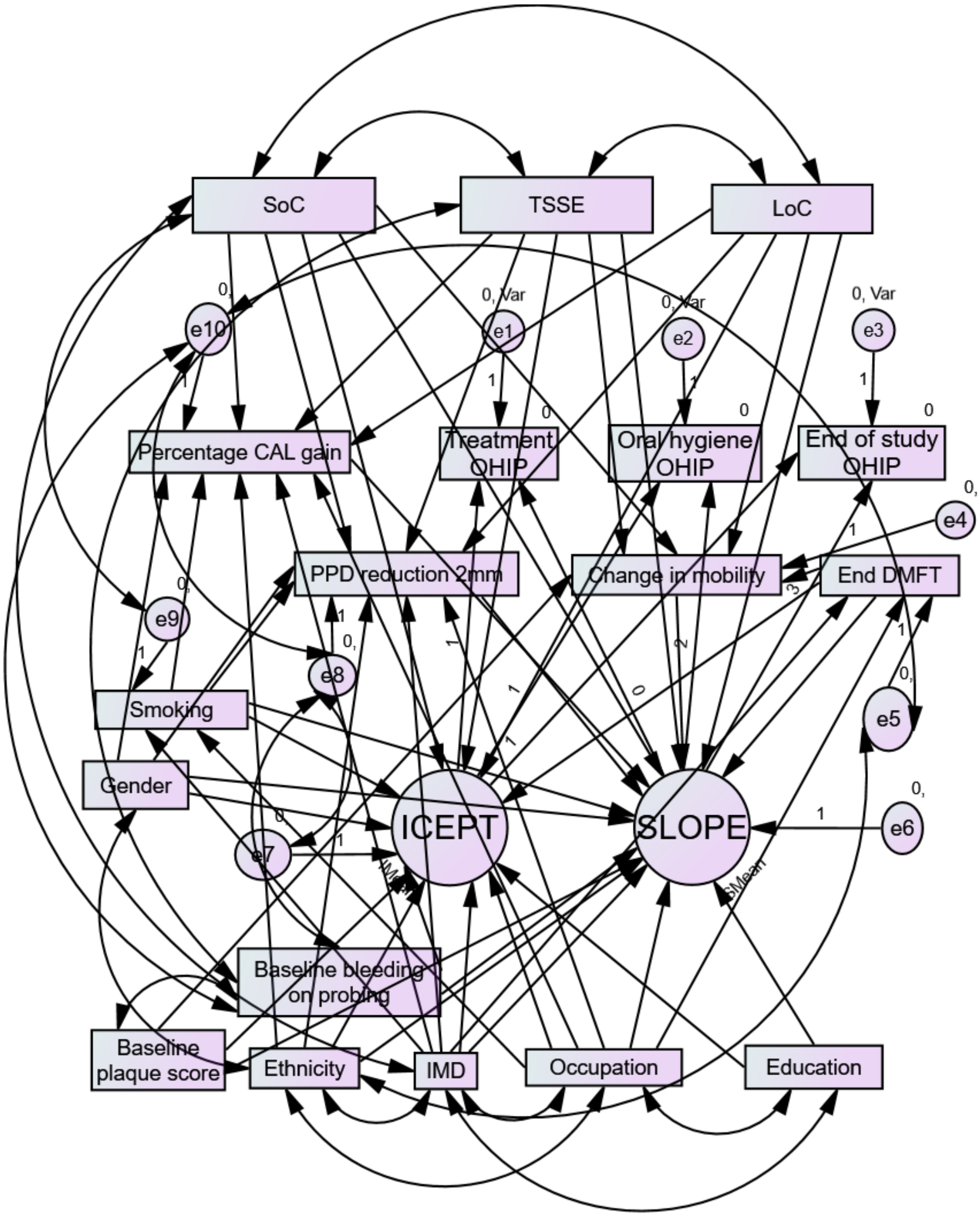
Figure 21 Univariate growth curve model of change in OHRQoL after periodontal treatment**.** Error terms (e).



8.1.13 Predicting Change in OHRQoL After Periodontal Treatment: From Treatment to End of Study: Full Growth Curve Model

The original Amos graphic is presented in Figure 22. The model, data and analysis were described fully in Chapter 4.

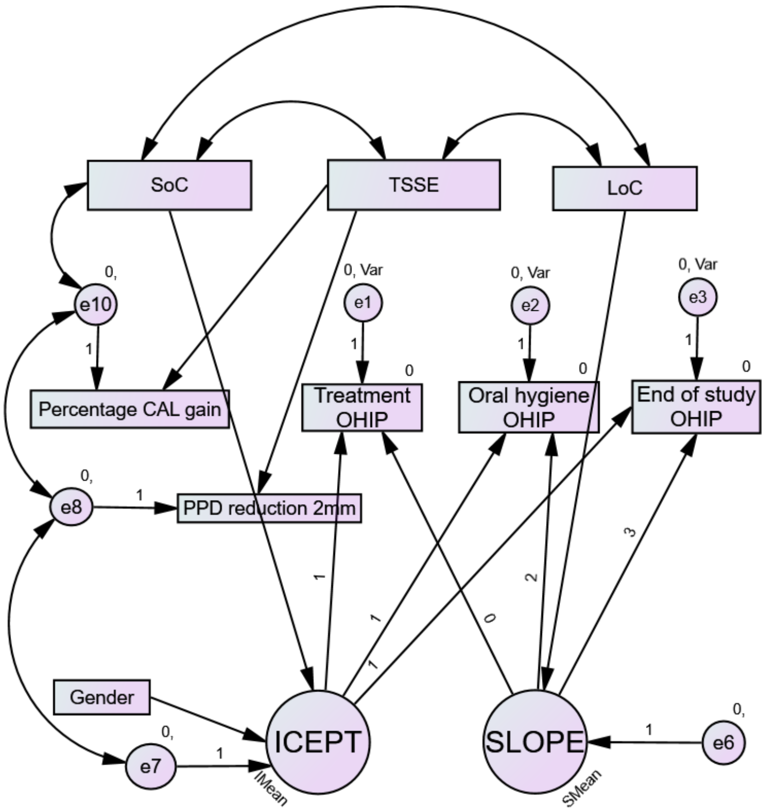
Figure 22 Full growth curve model of the predictors and indicators of change in OHRQoL after periodontal treatment for treatment, oral hygiene review and end of study time points, including observed variables of sense of coherence (SoC), task-specific self-efficacy (TSSE), locus of control (LoC) and latent variables of ICEPT and SLOPE. Error terms (e). Covariance represented by double ended arrows.



8.1.14 Predicting Change in OHRQoL After Periodontal Treatment: Treatment to End of Study Parsimonious Growth Curve Model

The original Amos graphic presented in Figure 11 Chapter 4 is presented in Figure 23. The model, data and analysis were described in Chapter 4.

Figure 23 Parsimonious growth curve model of the predictors and indicators of change in OHRQoL for treatment, oral hygiene review and end of study time points. Observed variables sense of coherence (SoC), task-specific self-efficacy (TTSE), locus of control (LoC) and latent variables (ICEPT and SLOPE). Error terms (e). Covariance represented by double ended arrows.



8.1.15 Indicators of Change in OHRQoL After Periodontal Treatment: Assessment to End of Study Univariate Growth Curve Model

The latent variables of ICEPT and SLOPE were indicated in the univariate model for changes in OHRQoL by the total OHIP scores for assessment, oral hygiene review and end of study time points. The mean number of months for each time point from assessment (treated as 0) was used as the regression weight for the path from the latent variable SLOPE to respective time points (0, 4 and 6 months), and a regression weight 1 was given for paths from the latent variable ICEPT to the total OHIP score at each time point. (Figure 24). The model fit met all the criteria for a good fit (Table 44).

Figure 24 Indicators of change in OHRQoL after periodontal treatment (Univariate growth curve model with paths between ICEPT and SLOPE for assessment, oral hygiene review and end of study time points. Error terms (e).

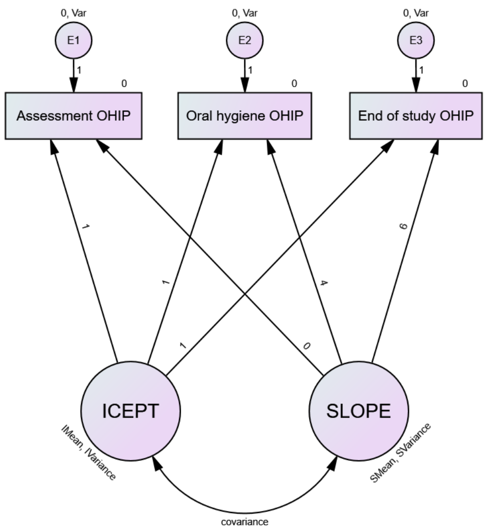


Table 44 Fit Indices for univariate growth curve model assessment, oral hygiene review and end time points.

P	Chi-squared	DF	CMIN/DF	CFI	RMSEA	SRMR
0.192	4.737	3	1.579	0.996	0.065	0.0130

The mean intercept value (OHRQoL at initial assessment) was 11.452. The mean SLOPE value was 0.104 representing the mean increase in OHIP score expected at each study time point (Table 45). Comparing OHRQoL at the assessment time point with oral hygiene review and final review time points (treatment time point omitted), OHRQoL appears to have worsened. The mean for the ICEPT is highly significant (P<0.001), however the mean for the SLOPE is not significant. This suggests the rate of deterioration in OHRQoL at each time point in this model following the assessment time point was not statistically significant (P=0.325). This suggests the OHRQoL is expected to worsen at each study period from initial assessment with an average rate of change of 0.104, beginning with an average score of 11.452.

Table 45 ICEPT and SLOPE. Assessment, oral hygiene review and end time points. Means, SE, CR, lower, upper and P value.

Parameter	Mean	S.E.	C.R.	Lower	Upper	P
ICEPT Mean	11.452	.839	13.648	9.840	13.118	***
SLOPE Mean	.104	.106	.984	-.104	.333	.325

***P<0.01.

The variance of ICEPT at assessment and the variance of the SLOPE are both significant (Table 46). This means there is a significant variation in OHRQoL at baseline and change over time between participants. However, the covariance and correlation of covariance were not significant, indicating those who start with higher ICEPT scores having worse OHRQoL (higher OHIP scores), did not change at a faster rate than those with better OHRQoL (lower OHIP scores) (Tables 46 and 47).

Table 46 Assessment, oral hygiene review and end time points. Variances and covariance. Estimate, lower, upper, SE, CR and P value. ***P<0.01

Parameter	Estimate	Lower	Upper	S.E.	C.R.	P
ICEPT Variance	86.506	68.286	114.893	11.818	7.320	***
SLOPE Variance	.894	.364	1.501	.202	4.430	***
ICEPT<--> SLOPE Covariance	.939	-.984	3.069	1.082	.868	.385

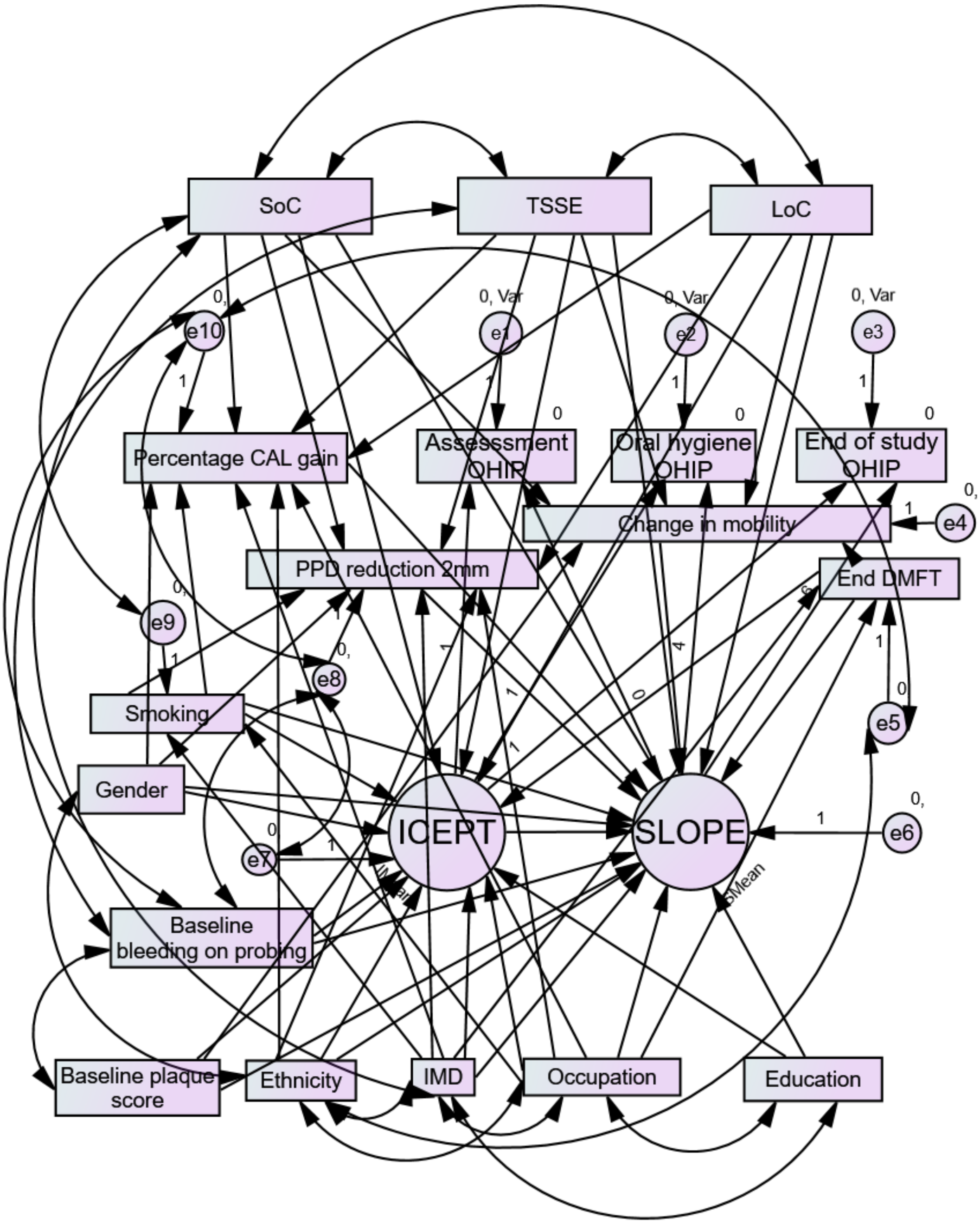
Table 47 Assessment, oral hygiene review and end time points. Correlation of covariance. Estimate, lower, upper and P value.

Parameter	Estimate	Lower	Upper	P
ICEPT<--> SLOPE	.107	-.114	.412	.347

8.1.16 Predicting Change in OHRQoL After Periodontal Treatment: Assessment to End of Study Full Growth Curve Model

The univariate model previously described was used to develop a full growth curve model to identify the predictors of change in OHRQoL over time from assessment to end of study (Figure 25). The model fit was improved by adding a number of covariances that made both statistical and conceptual sense. These are indicated with double ended arrows in Figure 25, and are the same as those previously reported in Table 33, Chapter 4.

Figure 25 Full growth curve model. Predictors and indicators of change in OHRQoL for assessment, oral hygiene review and end of study time points of all observed variables including sense of coherence (SoC), task-specific self-efficacy (TSSE), locus of control (LoC), and latent variables ICEPT and SLOPE. Error terms (e). Covariance represented by double ended arrows.



8.1.17 Predicting Change in OHRQoL After Periodontal Treatment: The Parsimonious Growth Curve Model

The paths having non-significant standardized regression weights were removed to give a parsimonious model from assessment to oral hygiene review and end of study time points (Figure 26). All indices met the criteria set for an acceptable model fit (Table 48). There was no significant difference between the two models and hence the parsimonious model was accepted (P = 0.0616).

Figure 26 shows the direct effects of sense of coherence on average starting scores of OHRQoL (ICEPT) and the average rate of change (SLOPE), task-specific self-efficacy on the reductions of probing depth and gains in clinical attachment loss. Direct links were also found between gender and smoking, and the average starting OHRQoL (ICEPT). These are explained below.

Figure 26 Parsimonious growth curve model of the predictors and indicators of change in OHRQoL for assessment, oral hygiene review and end of study time points.

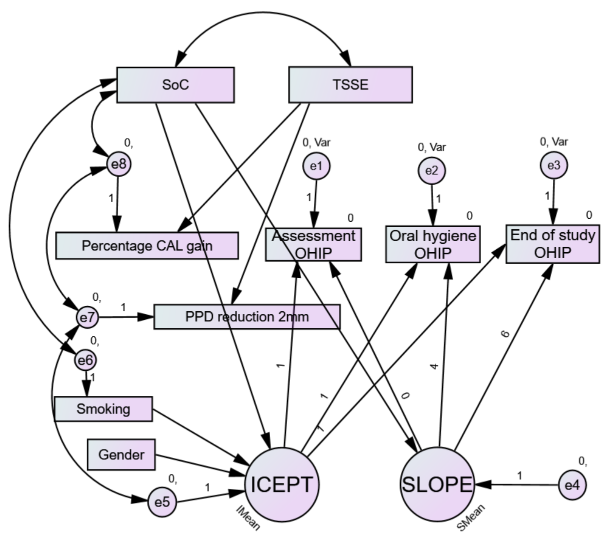


Table 48 Fit indices of full and parsimonious growth curve models.

Model	P	Chi2	DF	Ratio	SRMR	RMSEA	CFI
Full Growth Curve Model	0.043	105.215	82	1.283	0.0647	0.045	0.967
Parsimonious Model	0.191	32.06	26	1.233	0.0802	0.041	0.989

Table 49 contains the R-squared values for the parsimonious model, and shows that the proportion of the variance explained by the model was 13.7% for SLOPE, 19.4% for ICEPT, 4.2% for clinical attachment level gain and 7.3% for probing depth reductions.

Table 49 Parsimonious growth curve model. Assessment, oral hygiene review and end of study. Squared Multiple Correlations (R-squared). Estimate, lower, upper and P value.

Parameter	Estimate	Lower	Upper	P
SLOPE	.137	.008	.321	.005
ICEPT	.194	.070	.336	.005
Probing depth reduction ≥ 2mm	.073	.007	.202	.002
Percentage clinical attachment loss gain	.042	.000	.147	.003
End OHIP	.913	.875	.944	.001
Oral hygiene OHIP	.897	.857	.932	.001
Assessment OHIP	.874	.822	.917	.002

Standardized direct effects (ß values) are presented in Table 50.

The direct paths in the parsimonious growth curve model show:

A greater sense of coherence predicted a lower rate of worsening of OHRQoL (lower rate of increase in OHIP scores). Being female predicted worse starting OHRQoL (higher ICEPT value). Greater sense of coherence predicted better OHRQoL at the assessment time point (lower ICEPT). A higher smoking score (non-smoker) predicted better OHRQoL at baseline (lower ICEPT score). Higher (better) task-specific self-efficacy score predicted lower gains in clinical attachment loss and less probing depth reductions of ≥2mm.

Table 50 Parsimonious growth curve model. Assessment, oral hygiene review and end of study. Predictors of clinical condition and changes in OHRQoL. Standardized direct effects. SLOPE (change in OHRQoL), ICEPT (starting OHRQoL), frequency of probing depth reductions ≥2mm, percent clinical attachment gain, OHRQoL (OHIP total scores), Sense of Coherence, Task-specific Self-efficacy, gender and smoking.

Parameter	ß	Bootstrap SE	Bias-corrected 95% CI (lower-upper bounds)
Direct effects			
Sense of coherence → SLOPE	-0.370*	0.119	-0.562/-0.092*
Sense of coherence → ICEPT	-0.297**	0.079	-0.440/-0.128**
Smoking → ICEPT	-0.220*	0.081	-0.367/-0.059*
Gender → ICEPT	0.187*	0.075	0.031/0.321*
Task-specific Self-efficacy → Percentage clinical attachment loss gain	-0.205*	0.094	-0.383/-0.001*
Task-specific Self-efficacy → probing depth reduction ≥ 2mm	-0.269**	0.095	-0.450/-0.081**
SLOPE → End OHRQoL	0.468**	0.061	0.343/0.578**
ICEPT → End OHRQoL	0.777**	0.039	0.699/0.849**
SLOPE → Oral hygiene OHRQoL	0.339**	0.050	0.238/0.430**
ICEPT → Oral hygiene OHRQoL	0.843**	0.027	0.790/0.895**
ICEPT → Assessment OHRQoL	0.935*	0.013	0.907/0.958**

*P<0.05 **P<0.01.

Footnote: Higher Task-specific Self-efficacy scores = better task specific self-efficacy. Higher sense of coherence score = greater sense of coherence. Higher OHIP scores = worse OHRQoL. Higher clinical attachment gain and frequency of probing depth reductions ≥2mm = better clinical outcomes. Higher smoking score = non-smoker. Higher gender score = female.

8.1.18 Summary of Changes in OHRQoL: Assessment, Oral hygiene and End of Study

In summary, these results suggest that starting OHRQoL and the rate of change in OHRQoL over time are predicted by sense of coherence in this model of changes in OHRQoL from assessment to oral hygiene review and end of study time points. Individuals with a strong sense of coherence appear to have a better OHRQoL at baseline and their rate of deterioration was less than those with a weaker sense of coherence. Smoking and gender predicted starting OHRQoL (ICEPT). Females had worse OHRQoL and non-smokers better OHRQoL at baseline.

8.1.19 Bivariate Analysis

8.1.20 Aim

Bivariate analysis aimed to investigate associations between variables and identify those of importance for further analysis.

8.1.21 Analysis

Age, clinical measurements of periodontal probing depth, clinical attachment loss, changes in probing depth and clinical attachment loss, bleeding on probing, plaque scores, DMFT, OHIP-14, and psychological questionnaire data were analysed as continuous data. Gender, smoking, occupation, IMD, education, ethnicity and mobility were analysed as categorical data.

Pearson's correlation was used for bivariate analysis of continuous data and Spearman's correlations was used for comparison of continuous and categorical data. The strength of associations between variables was assessed as small (+/- 0.1-0.29), medium (+/- 0.3-0.49) or large (+/- 0.5-1.0) (Cohen, 1988).

8.1.22 Correlations between continuous variables

Correlations were explored between clinical data, age, psychological questionnaire total scores (Sense of Coherence, Task-specific Self-efficacy, self-esteem and Locus of Control) and OHRQoL. Overall these were of small to medium size (Table 51). Correlations are summarized below between OHRQoL and:

1. Probing depth reductions - small (mostly significant).
2. Probing depths, clinical attachment loss and changes in clinical attachment loss - small-medium (mostly significant).
3. Plaque scores - small (not significant).
4. DMFT - small (not significant).
5. Bleeding on probing - small (some significant).
6. Age - small (some significant).
7. Task-specific Self-efficacy - small (non-significant).
8. Locus of Control - small (non-significant).

9. Self-esteem - small (significant).
10. Sense of coherence - medium (significant).

Correlations were also explored between age and psychological questionnaire scores, and clinical data. Overall correlations were small with one exception. A large correlation was found between DMFT and age. Correlations are summarized as follow in relation to clinical data:

1. Probing depths and age – small to medium (mostly significant).
2. Probing depths and psychological data – all small (mostly significant for sense of coherence and some significant for Task-specific Self-efficacy).
3. Clinical attachment loss and age – small to medium (significant).
4. Clinical attachment loss and psychological data – all small (some significant for Task-specific Self-efficacy and self-esteem).
5. Change in clinical attachment loss and psychological factors – all small (significant for sense of coherence and gain/no change, and task-specific self-efficacy and gain in clinical attachment loss only).
6. Probing depth reductions and psychological factors – small (significant) for task-specific self-efficacy only, no correlation for other variables.
7. Bleeding on probing and task-specific self-efficacy – small (significant), no correlation for other variables.
8. Plaque scores and all variables - small (significant).
9. DMFT and age - large (significant). No correlation with other variables.

8.1.23 Correlations between continuous and categorical variables

Correlations were explored between mobility, gender, ethnicity, smoking, IMD, education and occupation, and OHRQoL. Overall these were of small to medium size (Table 52). Correlations are summarized below between OHRQoL and:

1. Mobility - small (all significant).
2. Gender - small (mostly significant).
3. Ethnicity – small (significant for assessment time point only).
4. Smoking – small (all significant).
5. IMD – small (non-significant).
6. Education – small (non-significant).
7. Occupation – small (non-significant).

Correlations were also explored between clinical data and categorical variables. The correlations are summarized as follows for clinical data:

1. Probing depths and mobility – small to large (all significant).
2. Clinical attachment loss and mobility – no correlation – large (mostly significant).
3. Change in clinical attachment loss and mobility – medium to large (all significant).
4. Probing depth reductions and mobility – medium (all significant).
5. Bleeding on probing and mobility – small-medium (all significant).
6. Plaque scores and mobility – no correlation to small (significant at baseline).
7. Clinical attachment loss and gender – no correlation to small (non-significant).
8. Change in clinical attachment loss, probing depth reductions, bleeding on probing, plaque scores, DMFT – no correlation with gender.
9. Probing depths and ethnicity – no correlation to small (significant for 4-5mm after treatment).
10. Clinical attachment loss and ethnicity – no correlation to small (significant for 3-4mm both time points).
11. Change in clinical attachment loss, probing depth reductions, bleeding on probing and ethnicity – no correlation.
12. Plaque scores and ethnicity – small at oral hygiene review (not significant).
13. DMFT and ethnicity – small at baseline (significant).
14. Probing depths and smoking – no correlation to small (significant for 4-5mm pockets at baseline).
15. Clinical attachment loss and smoking – no correlation to small (significant for 1-2mm at baseline).
16. Changes in clinical attachment loss and smoking – small (non-significant).
17. Probing depth reductions, bleeding on probing, plaque scores, DMFT and smoking – no correlations.
18. Clinical attachment loss and IMD – no correlation to small (non-significant).
19. Plaque scores and IMD – small (not significant).
20. Probing depths, change in clinical attachment loss, probing depths reductions, bleeding on probing, DMFT and IMD – no correlations.
21. Plaque scores and education – small (non-significant).
22. No other correlations between clinical data and education.

23. Clinical attachment loss and occupation – small (not-significant).
24. Probing depth reductions and occupation – small (not significant).
25. Plaque scores and occupation – small (significant).
26. No other correlations between clinical data and occupation.

8.1.24 Summary of Bivariate Analysis

Bivariate analysis suggested that all periodontal variables, plaque scores, DMFT, individual factors including gender, smoking, ethnicity, occupation, the psychological factors of sense of coherence, task-specific self-efficacy and self-esteem warranted further analysis because relevant significant associations were found between variables and OHRQoL and/or indicators of the periodontal condition.

Table 51 Correlation between continuous variables at each study time point (assessment, treatment, oral hygiene review and end of study): Pearson Correlation. Periodontal probing depth (PPD), clinical attachment loss (CAL), Oral Health Related Quality of Life (OHRQoL), sense of coherence (SoC), task-specific self-efficacy (TSSE), self-esteem (RSE), locus of control (LoC).

		OHRQoL (OHIP-14)				SoC	TSSE	RSE	LoC
Variable	Age	Assessment	Treatment	OH review	End				
Baseline PPD									
0-3mm	-0.067	-.358**	-.396**	-.370**	-.374**	0.12	.232**	0.12	-0.044
4-5mm	-.250**	.372**	.334**	.331**	.374**	-.177*	-.223**	-0.138	0.101
6mm	.218**	.230**	.297**	.267**	.248**	-0.048	-0.159	-0.07	-0.002
End of Study PPD									
0-3mm	-.358**	-.259**	-.327**	-.261**	-.271**	0.126	0.163	0.122	-0.112
4-5mm	.329**	.209*	.206*	.173*	.186*	-0.159	-0.074	-0.071	0.116
6mm	.290**	.226**	.315**	.247**	.254**	-0.079	-.173*	-0.121	0.083
Baseline CAL									
0mm	-.265**	-.338**	-.346**	-.312**	-.331**	0.151	.189*	0.093	-0.091
1-2mm	-.219**	.296**	.240**	.260**	.290**	-0.095	0.02	0.024	0.007
3-4mm	.391**	.198*	.168*	0.16	0.159	-0.059	0.031	0.077	0.041
5mm	.194*	.195*	.247**	.199*	.212*	-0.121	-.273**	-.177*	0.09
End of Study CAL									
0mm	-.267**	-.341**	-.352**	-.303**	-.322**	0.128	0.166	0.11	-0.119
1-2mm	-.215*	.328**	.254**	.261**	.284**	-0.107	0.07	-0.065	0.052
3-4mm	.392**	.187*	.173*	0.166	.173*	-0.056	0.011	0.081	0.067
5mm	.173*	.227**	.277**	.212*	.226**	-0.101	-.257**	-.183*	0.099
Change in CAL									
Loss	0.111	.402**	.421**	.371**	.391**	-0.109	-0.057	-0.117	0.139
Gain	0.112	.278**	.261**	.254**	.300**	-.169*	-.205*	-0.051	-0.031
No change	-0.131	-.393**	-.392**	-.361**	-.401**	.166*	0.162	0.095	-0.055

	OHRQoL (OHIP-14)					SoC	TSSE	RSE	LoC
Variable	Age	Assessment	Treatment	OH review	End				
PPD reduction									
None	0.046	-.268**	-.280**	-.229**	-.244**	0.028	.276**	0.062	0.019
≥2mm	-0.046	.268**	.280**	.229**	.244**	-0.028	-.277**	-0.062	-0.019
Bleeding on probing									
Baseline	-0.088	0.105	0.098	0.016	0.049	0.021	-.227**	-0.088	-0.016
End	-0.08	.178*	0.143	0.106	0.134	-0.088	-.242**	-0.125	0.002
Plaque score									
Treatment	-.227**	0.122	0.055	0.071	0.09	-0.077	-.166*	-.181*	0.032
OH review	-.174*	0.139	0.109	0.042	0.027	-.265**	-0.116	-.204*	.187*
End	-0.128	-0.014	-0.059	-0.084	-0.062	-.215*	-0.006	-.167*	0.035
DMFT									
Baseline	.549**	0.022	0.109	0.062	0.129	-0.014	0.047	0.013	0.002
End	.549**	0.041	0.133	0.083	0.15	-0.021	0.049	0.01	0.002
Age	1	-.188*	-0.079	-0.133	-0.12	0.006	0.065	0.061	0.11
OHRQoL (OHIP-14)									
Assessment	-.188*	1	.856**	.800**	.786**	-.310**	-0.155	-.257**	0.032
Treatment	-0.079	.856**	1	.855**	.840**	-.380**	-0.138	-.234**	0.033
OH review	-0.133	.800**	.855**	1	.910**	-.439**	-0.05	-.249**	-0.029
End	-0.12	.786**	.840**	.910**	1	-.429**	-0.035	-.296**	-0.094
SoC	0.006	-.310**	-.380**	-.439**	-.429**	1	0.127	.474**	-0.001
TSSE	0.065	-0.155	-0.138	-0.05	-0.035	0.127	1	.170*	-0.093
RSE	0.061	-.257**	-.234**	-.249**	-.296**	.474**	.170*	1	0.042
LoC	0.11	0.032	0.033	-0.029	-0.094	-0.001	-0.093	0.042	1

*P<0.05 **P<0.01

Table 52 Correlation between continuous and categorical variables: Spearman Correlation. Periodontal probing depth (PPD), clinical attachment loss(CAL), Decayed Missing and Filled Teeth (DMFT), Mobility before (B) and after (A) treatment, Oral Health Related Quality of Life (OHRQoL), sense of coherence (SoC), task-specific self-efficacy (TSSE), self-esteem (RSE), locus of control (LoC), Index of Multiple Deprivation (IMD). Study time points.

Variable	Mobility B	Mobility A	Gender	Ethnicity	Smoking	IMD	Education	Occupation
Baseline PPD								
0-3mm	-.628**	-.615**	-0.025	-0.032	0.144	-0.019	0.02	0.097
4-5mm	.338**	.317**	0.047	0.158	-.252**	0.126	-0.026	-0.024
6mm	.602**	.585**	0.014	-0.035	-0.032	-0.066	-0.023	-0.094
End PPD								
0-3mm	-.562**	-.568**	-0.043	0.128	0.113	0.032	0.003	0.06
4-5mm	.278**	.313**	0.071	-.171*	-0.141	-0.036	0.007	-0.058
6mm	.629**	.615**	0.037	-0.076	-0.077	-0.026	-0.025	-0.046
Baseline CAL								
0mm	-.524**	-.538**	-0.03	0.084	0.159	0.022	-0.036	0.071
1-2mm	0.012	-0.031	0.09	0.112	-.189*	0.132	-0.073	0.033
3-4mm	.187*	.205*	0.122	-.184*	-0.063	-0.095	0.07	-0.102
5mm	.526**	.557**	-0.03	-0.091	-0.121	-0.052	0.02	-0.063
End CAL								
0mm	-.511**	-.558**	-0.039	0.094	0.137	0.021	-0.032	0.061
1-2mm	-0.021	0.014	0.147	0.091	-0.159	0.143	-0.075	0.016
3-4mmr	.167*	.195*	0.103	-.188*	-0.048	-0.067	0.033	-0.128
5mm	.595**	.622**	-0.025	-0.112	-0.12	-0.044	0.025	-0.044
CAL change								
loss	.548**	.559**	0.027	0.009	-0.148	0.005	0.025	-0.044
gain	.415**	.396**	0.043	-0.078	-0.111	0.005	0.012	-0.084
no change	-.557**	-.553**	-0.036	0.051	0.164	0.001	-0.016	0.067
PPD reduction								
None	-.382**	-.333**	-0.079	-0.029	0.014	-0.05	-0.017	0.103
≥2mm	.382**	.333**	0.079	0.029	-0.014	0.05	0.017	-0.103
Bleeding on probing %								
Baseline	.282**	.309**	0.014	0.083	0.031	0.031	-0.053	-0.024
End	.346**	.381**	-0.03	0.162	-0.004	0.079	-0.025	-0.027

Variable	Mobility B	Mobility A	Gender	Ethnicity	Smoking	IMD	Education	Occupation
Plaque %								
Treatment	.259**	.240**	0.02	0.099	0.003	0.115	-0.142	.223**
OH review	0.044	0.092	0.006	0.165	0.035	0.118	-0.121	.225**
End	-0.121	-0.089	-0.004	0.038	0.015	0.134	-0.102	0.126
DMFT								
Baseline	0.029	0.011	0.023	-.188*	0.054	0.015	-0.073	-0.066
End	0.042	0.019	0.031	-.188*	0.062	0.007	-0.076	-0.074
Mobility >1								
Baseline	1	.909**	0.029	0.019	-0.116	0.069	-0.025	0.008
End	.909**	1	0.039	-0.002	-0.138	0.074	0.004	-0.005
Gender	0.029	0.039	1	0.016	0.075	0.121	-.185*	0.062
Age	-0.075	-0.061	0.012	-0.136	.182*	-0.091	-0.044	0.011
Ethnicity	0.019	-0.002	0.016	1	0.06	0.125	0.062	0.033
Smoking	-0.116	-0.138	0.075	0.06	1	-0.01	0.127	0.043
IMD	0.069	0.074	0.121	0.125	-0.01	1	-.410**	.197*
Education	-0.025	0.004	-.185*	0.062	0.127	-.410**	1	-.445**
Occupation	0.008	-0.005	0.062	0.033	0.043	.197*	-.445**	1
OHRQoL (OHIP-14)								
Assess	.341**	.357**	0.159	.191*	-.193*	0.13	-0.024	-0.101
Treatment	.327**	.334**	.211*	0.117	-.183*	0.068	-0.051	-0.047
OH review	.305**	.299**	.181*	0.11	-.195*	0.089	-0.018	-0.112
End	.313**	.306**	.167*	0.072	-.217**	0.132	-0.083	-0.053
SOC	-0.077	-0.117	-0.033	-0.039	.205*	-.181*	0.095	-0.026
TSSE	-.189*	-0.141	0.131	-0.133	-0.01	-0.133	-0.018	0.06
RSE	-0.074	-0.118	-0.164	0.034	.210*	-.271**	.369**	-.285**
LoC	0.036	0.044	-0.118	-0.013	0.078	0.093	-0.153	.191*

*P<0.05 **P<0.01

8.2 Appendix 2

8.2.1 Ethical and Health Research Authority Approvals, Research Governance and Certificate of Insurance

NHS
Health Research Authority

East Midlands - Nottingham 2 Research Ethics Committee
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

23 May 2016

Professor Andrew Rawlinson
Academic Unit of Restorative Dentistry
School of Clinical Dentistry
Claremont Crescent, Sheffield
S10 2TA

Dear Professor Rawlinson

Study title:	**Periodontal Treatment and Oral Health Related Quality of Life**
REC reference:	**16/EM/0236**
IRAS project ID:	**207130**

The Proportionate Review Sub-committee of the East Midlands - Nottingham 2 Research Ethics Committee reviewed the above application on 23 May 2016.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Assistant Miss Joanne Unsworth, NRESCommittee.EastMidlands-Nottingham2@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

1. Add the reviewing REC “Nottingham 2 Research Ethics Committee to the Participant Information Sheet.
2. Proof-read the Participant Information Sheet for typographical errors.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation’s role in the study is limited to identifying and referring potential participants to research sites (“participant identification centre”), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Summary of discussion at the meeting

The PR Sub-Committee confirmed the study raised no material ethical issues under the following headings: Social or scientific value; scientific design and conduct of the study, recruitment arrangements and access to health information, and fair participant selection, favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future), care and protection of research participants; respect for potential and enrolled participants' welfare and dignity, suitability of the applicant and supporting staff, independent review, suitability of supporting information, other general comments and suitability of research summary.

Ethical issues raised, noted and resolved in discussion:

- **Informed consent process and the adequacy and completeness of participant information**

  The Sub-Committee stated the reviewing REC "Nottingham 2 Research Ethics Committee" should be added to the Participant Information Sheet.

  The Sub-Committee added the Participant Information Sheet should be proof-read for typographical errors.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Covering letter on headed paper [Covering letter]		
IRAS Application Form [IRAS_Form_16052016]		16 May 2016
IRAS Checklist XML [Checklist_17052016]		17 May 2016
Other [Insurance certificate]		06 May 2016
Other		
Participant consent form [Consent version 1, January 2016]		
Participant information sheet (PIS) [PIS]	2	19 April 2016
Referee's report or other scientific critique report [STH19323 Lead Review]	1	14 April 2016
Referee's report or other scientific critique report [STH19323 Second Review]	1	14 April 2016
Research protocol or project proposal [OHQoL Protocol]		
Summary CV for Chief Investigator (CI) [CV]	CV short 2016	25 April 2016
Summary CV for student [CV AR short]	1	25 April 2016

Summary CV for supervisor (student research) [CV - Mario Vettore]	1	25 April 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flow chart]	1	25 April 2016
Validated questionnaire [Questionnaire]	v1	19 April 2016
Validated questionnaire [Periodontal Treatment and Oral Health Related Quality of Life Questionnaire Booklet]		

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

pp.

Professor Frances Game
Chair

Email: NRESCommittee.EastMidlands-Nottingham2@nhs.net

Enclosures:	*List of names and professions of members who took part in the review*
Copy to:	*Ms Samantha Walmsley* *Professor Simon Heller, Sheffield Teaching Hospitals NHS Foundation Trust*

NHS
Health Research Authority

East Midlands - Nottingham 2 Research Ethics Committee
Royal Standard Place
Nottingham
NG1 6FS

25 May 2016

Professor Andrew Rawlinson
Academic Unit of Restorative Dentistry
School of Clinical Dentistry
Claremont Crescent, Sheffield
S10 2TA

Dear Professor Rawlinson

Study title:	**Periodontal Treatment and Oral Health Related Quality of Life**
REC reference:	**16/EM/0236**
IRAS project ID:	**207130**

Thank you for your letter of 25 May 2016. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 23 May 2016

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant information sheet (PIS) [PIS]		

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Covering letter]		
IRAS Application Form [IRAS_Form_16052016]		16 May 2016
Other [Insurance certificate]		06 May 2016
Other		
Participant consent form [Consent version 1, January 2016]		
Participant information sheet (PIS) [PIS]		
Referee's report or other scientific critique report [STH19323 Lead Review]	1	14 April 2016
Referee's report or other scientific critique report [STH19323 Second Review]	1	14 April 2016
Research protocol or project proposal [OHQoL Protocol]		
Summary CV for Chief Investigator (CI) [CV]	CV short	25 April 2016

	2016	
Summary CV for student [CV AR short]	1	25 April 2016
Summary CV for supervisor (student research) [CV - Mario Vettore]	1	25 April 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flow chart]	1	25 April 2016
Validated questionnaire [Questionnaire]	v1	19 April 2016
Validated questionnaire [Periodontal Treatment and Oral Health Related Quality of Life Questionnaire Booklet]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/EM/0236	**Please quote this number on all correspondence**

Yours sincerely

Joanne Unsworth
REC Assistant

E-mail: NRESCommittee.EastMidlands-Nottingham2@nhs.net

Copy to: *Ms Samantha Walmsley*
Professor Simon Heller, Sheffield Teaching Hospitals NHS Foundation Trust

Health Research Authority

Professor Andrew Rawlinson
Academic Unit of Restorative Dentistry
School of Clinical Dentistry
Claremont Crescent, Sheffield
S10 2TA

Email: hra.approval@nhs.net

05 July 2016

Dear Professor Rawlinson

Letter of HRA Approval

Study title:	**Periodontal Treatment and Oral Health Related Quality of Life**
IRAS project ID:	**207130**
REC reference:	**16/EM/0236**
Sponsor	**Sheffield Teaching Hospitals NHS Foundation Trust**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

IRAS project ID	207130

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **207130**. Please quote this on all correspondence.

Yours sincerely

Michael Pate
Assessor

Email: hra.approval@nhs.net

Copy to: *Ms Samantha Walmsley – Sheffield Teaching Hospitals NHS Foundation Trust – Sponsor's representative*
Professor Simon Heller - Sheffield Teaching Hospitals NHS Foundation Trust – Lead NHS R&D contact.

IRAS project ID	207130

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
IRAS Application Form [IRAS_Form_16052016]		16 May 2016
Other [Insurance certificate]		06 May 2016
Summary CV for supervisor (student research) [CV – Peter Robinson]	1	17 May 2016
Participant consent form [Consent form]	2	27 June 2016
Participant information sheet (PIS) [PIS]	4	27 June 2016
Referee's report or other scientific critique report [STH19323 Lead Review]	1	14 April 2016
Referee's report or other scientific critique report [STH19323 Second Review]	1	14 April 2016
Research protocol or project proposal [OHQoL Protocol]	2	19 April 2016
Summary CV for Chief Investigator (CI) [CV]	CV short 2016	25 April 2016
Summary CV for supervisor (student research) [CV - Mario Vettore]	1	25 April 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flow chart]	1	25 April 2016
Validated questionnaire [Questionnaire]	1	19 April 2016
Validated questionnaire [Periodontal Treatment and Oral Health Related Quality of Life Questionnaire Booklet]	1	19 April 2016

Trust Research Governance Approval

Sent on behalf of Prof Simon Heller, Director of R&D, Sheffield Teaching Hospitals NHS FT

Dear Prof. Rawlinson

STH ref:	19323
IRAS Number:	207130
Study Title:	Periodontal Treatment and Oral Health Related Quality of Life
Principal Investigator:	Professor Andrew Rawlinson (University of Sheffield)
NIHR Target FPFV recruitment Date:	01Sep2016
The Research Department has received the required documentation as listed below:	

1.	**Clinical Trial Agreement** **Material Transfer Agreement** **Statement of Activities** **Sponsor Monitoring Arrangements**	N/A
2.	**Local ARSAC certificate/IRMER assessment**	N/A
3.	**Evidence of local Capacity and Capability** - **STH Principal Investigator** - **Clinical Director** - **General Manager** - **Research Finance** - **Data Protection Officer**	 Andrew Rawlinson, 07June2016 Alison Loescher, 07June2016 Duncan Marriott, 07June2016 Liz Fraser, 17June2016 Peter Wilson 13June2016
4.	**Honorary Contract/Letter of Access**	N/A
5.	**Protocol**	V2.0 19Apr2016
6.	**Additional Approvals noted:** ***NHS REC FO Letter (East Midlands – Nottingham 2 REC)** **HRA Approval Letter**	 23May2016 (with conditions) 25May2016 (conditions met) 05July2016

*The REC FO Letter of 25th May 2016 did not list all document version/dates, but they are listed on the HRA Approval Letter. 'Other' is listed twice on the REC Letter and is a duplicate (refers to UoS Insurance).

This email confirms that Sheffield Teaching Hospitals NHS Foundation Trust has the capacity and capability to deliver the above referenced study. Please find attached our Conditions of Confirmation of Capacity and Capability.

We agree to start this study from the date of this email. This e-mail also serves to confirm Sponsor Green light to commence your study from this date.

You will need to upload your recruitment in real time using the EDGE database. The attached STH Conditions explains how to initiate access to this.

If you wish to discuss further, please do not hesitate to contact me. I wish you the best of luck with your research.

Sam Walmsley, Research Coordinator
Research Department Sheffield Teaching Hospitals NHS Foundation Trust

Certificate of Insurance

The University Of Sheffield.

Finance and Commercial

To	Professor Andrew Rawlinson
Your ref	
Date Issued	6.5.16

Certificate of Insurances (non clinical trial)

Trial Number	NCT 15/49
Department	Clinical Dentistry
Principal Investigator	Prof. Andrew Rawlinson

Title of Trial

Periodontal Treatment and Oral Health Related Quality of Life

Name of Investigators	As stated
Commencement Date	16/05/2016

The University has in place insurance against liabilities for which it may be legally liable and this cover includes any such liabilities arising out of the above research project/study

J Rollitt

Joanne Rollitt
Insurance Section

8.3 Appendix 3

8.3.1 Patient Information Sheet, Consent Form and Questionnaires

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Patient Information Sheet

Version 4: 27th June 2016

Oral health related quality of life and periodontal treatment

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information sheet carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?

This study aims to investigate the oral health related quality of life in people with periodontal (gum) disease, and the effect of diagnosis and treatment on this. We think the knowledge gained will help us to understand how periodontal disease affects the daily lives of people affected, and the factors that might influence this.

Why have I been chosen?

You have been chosen because you are being treated for a gum condition. If you agree to take part, you will be one of several similar patients participating in this study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason and your questionnaires will be destroyed.

What will happen if I agree to take part in the study?

You will receive your treatment as normal, and the measurements taken to assess your periodontal (gum) condition will be used in the research to determine the effect of treatment on this. You will be asked to complete 5 questionnaires before your treatment commences, which collectively assess your oral health related quality of life and the factors specific to you that may affect this. Thereafter, you will be asked to complete a questionnaire that measures oral health related quality of life on two further occasions at your normal review visits following treatment. We will also use a questionnaire that you completed to assess the impact of your periodontal (gum) condition on your oral health related quality of life immediately prior to your initial consultation. The study ends after your gum health is reviewed approximately 3 months after the completion of your course of treatment. Data collected during the study will be archived.

What are the possible disadvantages and risks of taking part?

Additional time will be needed during your visits to complete the questionnaires.

What are the possible benefits of taking part?
There are no direct benefits to you of taking part. It is hoped that the information we get from this study may help to better understand the effect that periodontal disease has on the daily life of people affected, and the factors that are related to this.

What if something goes wrong?
We do not foresee anything going wrong, but if you feel unhappy about anything to do with the project, please speak to the person treating you, or Professor A Rawlinson: Telephone 0114 271 7911.
You can also talk to the Patient Services Teams (PST previously PALS) who can be contacted on pst@sth.nhs.uk or telephone 01142712400.

Will my taking part in the study be kept confidential?
The information collected about you will be kept confidential. A study number will be used to indentify your information for the purposes of analysis, and the code to information that identifies you will be kept separately to this. Information will be kept in a locked office and on a password protected laptop. Your dental case notes may be viewed by the person treating you and members of the research team, in order to determine the diagnosis of your gum condition and any relevant medical history that may affect the research. This information may also be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to your taking part in this research. Members of the University research team will also have access to your data, but this will be identified only according to your study number.

What will happen to the results of the research study?
The results will be written up as part of a PhD thesis and submitted for publication in scientific journals. No names or personal details will be mentioned in any reports of the study and care will be taken so that individuals cannot be identified from reports of the study.

Who is organising & hosting the research?
The study is organised by Professor A Rawlinson, Academic Unit of Restorative Dentistry, and is hosted by the University of Sheffield.

What if I wish to complain about the way in which this study has been conducted?
If you have *any* cause to complain about *any* aspect of the way in which you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you and you are not compromised in any way because you have taken part in a research study.

If you have any complaints or concerns please contact the project co-ordinator: Professor A Rawlinson: Telephone 0114 271 7911.
Otherwise you can use the normal hospital complaints procedure and contact the following person:
Dr David Throssell, Medical Director, Sheffield Teaching Hospitals Trust, 8 Beech Hill Road, Sheffield, S10 2SB. Telephone 0114 271 2178.
In addition, you may also contact The Patient Services Team in the following ways:
  * Telephone on 0114 271 2400,
  * Via email on PST@sth.nhs.uk
  * In person in the Patient Partnership Department on B Floor, Royal Hallamshire Hospital or the Huntsman main entrance on C Floor, Northern General Hospital.

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Patient Consent Form (Version 2: 27th June 2016)

Centre Number: 1

Study Number: 1

Patient Identification Number for this study:

CONSENT FORM

Title of Project: **Oral health related quality of life and periodontal treatment**

Principle investigator: Professor A Rawlinson

Chief investigator: Professor A Rawlinson

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 27th June **2016** (version **4**) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. I also give permission for the data collected during this research and identified according to my study patient identification number to be accessed by members of the University research team. ☐

4. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent.	Date	Signature

Original consent to site file, 1 copy to study participant and 1 copy to participant case notes.

Consent Version 2, 27th June 2016. STH19323. IRAS reference 207130.

In hospital and in the community
proud to make a difference

Chairman: Tony Pedder OBE Chief Executive: Sir Andrew Cash OBE

Sheffield Hospitals Charity

OHIP-14

In this questionnaire we would like you to tell us how often you have had some problems with your mouth, teeth or gums in the **last month**. For each question please tick the box that best describes your answer.

		Never	Hardly ever	Occasionally	Fairly often	Very often
1	Have you had trouble *pronouncing any words* because of problems with your teeth, mouth or dentures?	( )	( )	( )	( )	( )
2	Have you felt that your *sense of taste* has worsened because of problems with your teeth, mouth or dentures?	( )	( )	( )	( )	( )
3	Have you had *painful aching* in your mouth?	( )	( )	( )	( )	( )
4	Have you found it *uncomfortable to eat any foods* because of problems with your teeth, mouth or dentures?	( )	( )	( )	( )	( )
5	Have you been *self-conscious* because of problems with your teeth, mouth or dentures?	( )	( )	( )	( )	( )
6	Have you felt *tense* because of problems with your teeth, mouth or dentures?	( )	( )	( )	( )	( )
7	Has your *diet been unsatisfactory* because of problems with your teeth, mouth or dentures?	( )	( )	( )	( )	( )
8	Have you had to *interrupt meals* because of problems with your teeth, mouth or dentures?	( )	( )	( )	( )	( )
9	Have you found it *difficult to relax* because of problems with your teeth, mouth or dentures?	( )	( )	( )	( )	( )
10	Have you been a bit *embarrassed* because of problems with your teeth, mouth or dentures?	( )	( )	( )	( )	( )
11	Have you been a bit *irritable with other people* because of problems with your teeth, mouth or dentures?	( )	( )	( )	( )	( )
12	Have you had *difficulty doing your usual jobs* because of problems with your teeth, mouth or dentures?	( )	( )	( )	( )	( )
13	Have you felt that life in general was *less satisfying* because of problems with your teeth, mouth or dentures?	( )	( )	( )	( )	( )
14	Have you been *totally unable to function* because of problems with your teeth, mouth or dentures?	( )	( )	( )	( )	( )
		Never	**Hardly ever**	**Occasionally**	**Fairly often**	**Very often**

OHIP-14 version 1. 19.4.16. STH19323.

Periodontal Treatment and Oral Health Related Quality of Life

Questionnaire Booklet

This booklet contains four questionnaires we would like you to complete. Please read the instructions on how to complete each questionnaire and take your time to complete each one. It should take about 10 minutes to complete all four.

Booklet Version 1. 19.4.16. STH19323.

Questionnaire 1

This page asks questions about aspects of your life.

Each question has seven possible answers. Please mark your answer by circling one number for each question. Numbers 1 and 7 are the extreme answers for each question.

1. Do you have the feeling that you don't really care about what goes on around you?

Very seldom or never	1	2	3	4	5	6	7	Very often

2. Has it happened in the past that you were surprised by the behaviour of people whom you thought you knew well?

Never happened	1	2	3	4	5	6	7	Always happened

3. Has it happened that people whom you counted on disappointed you?

Never happened	1	2	3	4	5	6	7	Always happened

4. Until now your life has had:

No clear goals or purpose at all	1	2	3	4	5	6	7	Very clear goals and purpose

5. Do you have the feeling that you're being treated unfairly?

Very often	1	2	3	4	5	6	7	Very seldom or never

6. Do you have the feeling that you are in an unfamiliar situation and don't know what to do?

Very often	1	2	3	4	5	6	7	Very seldom or never

7. Doing the things you do every day is:

A source of deep pleasure and satisfaction	1	2	3	4	5	6	7	A source of pain and boredom

8. Do you have very mixed-up feelings and ideas?

Very often	1	2	3	4	5	6	7	Very seldom or never

9. Does it happen that you have feelings inside you would rather not feel?

Very often	1	2	3	4	5	6	7	Very seldom or never

10. Many people - even those with a strong character - sometimes feel like sad sacks (losers) in certain situations. How often have you felt this way in the past?

Never	1	2	3	4	5	6	7	Very often

11. When something happened, have you generally found that:

You overestimated or underestimated its importance	1	2	3	4	5	6	7	you saw things in the right proportion

12. How often do you have the feeling that there's little meaning in the things you do in daily life?

Very often	1	2	3	4	5	6	7	Very seldom or never

13. How often do you have feelings that you're not sure you can keep under control?

Very often	1	2	3	4	5	6	7	Very seldom or never

Questionnaire 2

On this page we would like you to tell us about your teeth and going to the dentist.

For each question please tick the box that best describes your answer.

Tooth brushing

How confident are you, that you brush your teeth in the following situations?

Question	Completely confident	Fairly confident	Fairly confident not to	Completely confident not to
When you are tired in the evening				
When you are not going to a dentist in the near future				
When you are on holiday				
When you have a lot of work				
When you have a headache or feel ill				

Cleaning between your teeth

How confident are you, that you clean teeth in the following situations?

Question	Completely confident	Fairly confident	Fairly confident not to	Completely confident not to
When you are tired in the evening				
When you are not going to the dentist in the near future				
When you are on holiday				
When you have a lot of work				
When you have a headache or feel ill				

Visiting the dentist

How confident are you, that you visit the dentist as often as advised?

Question	Completely confident	Fairly confident	Fairly confident not to	Completely confident not to
When a dentist does not invite you to visit regularly				
When you have no dental symptoms				
When you have money problems				
When you are busy				
When you are unable to make an appointment with a known dentist				
When you have earlier unpleasant experiences				
When you are frightened of painful interventions				

Questionnaire 3

On this page is a list of statements dealing with your general feelings about yourself. We would like you to indicate how strongly you agree or disagree with each statement by circling the appropriate answer.

- **On the whole I am satisfied with myself.**

Strongly agree | Agree | Disagree | Strongly disagree

2. At times I think I am no good at all.

Strongly agree | Agree | Disagree | Strongly disagree

3. I feel that I have a number of good qualities.

Strongly agree | Agree | Disagree | Strongly disagree

4. I am able to do things as well as most other people.

Strongly agree | Agree | Disagree | Strongly disagree

5. I feel I do not have much to be proud of.

Strongly agree | Agree | Disagree | Strongly disagree

6. I certainly feel useless at times.

Strongly agree | Agree | Disagree | Strongly disagree

7. I feel that I'm a person of worth, at least on an equal plane with others.

Strongly agree | Agree | Disagree | Strongly disagree

8. I wish I could have more respect for myself.

Strongly agree | Agree | Disagree | Strongly disagree

9. All in all, I am inclined to feel that I am a failure.

Strongly agree | Agree | Disagree | Strongly disagree

10. I take a positive attitude toward myself.

Strongly agree | Agree | Disagree | Strongly disagree

Questionnaire 4

This page has a belief statement about your gum condition with which you may agree or disagree. Beside each statement is a scale, which ranges from strongly disagree (1) to strongly agree (6). For each item we would like you to circle the number that represents the extent to which you agree or disagree with that statement. The more you agree with a statement, the higher will be the number you circle. The more you disagree with a statement, the lower will be the number you circle. Please make sure that you answer **EVERY ITEM** and that you circle **ONLY ONE** number per item. There are no right or wrong answers.

		Disagree Slightly	Disagree Moderately	Disagree Strongly	Agree Slightly	Agree Moderately	Agree Strongly
1	If my condition worsens, it is my own behavior which determines how soon I will feel better again.	1	2	3	4	5	6
2	As to my condition, what will be will be.	1	2	3	4	5	6
3	If I see my dentist regularly, I am less likely to have problems with my condition.	1	2	3	4	5	6
4	Most things that affect my condition happen to me by chance.	1	2	3	4	5	6
5	Whenever my condition worsens, I should consult a trained dental professional.	1	2	3	4	5	6
6	I am directly responsible for my condition getting better or worse.	1	2	3	4	5	6
7	Other people play a big role in whether my condition improves, stays the same, or gets worse.	1	2	3	4	5	6
8	Whatever goes wrong with my condition is my own fault.	1	2	3	4	5	6
9	Luck plays a big part in determining how my condition improves.	1	2	3	4	5	6
10	In order for my condition to improve, it is up to other people to see that the right things happen.	1	2	3	4	5	6
11	Whatever improvement occurs with my condition is largely a matter of good fortune.	1	2	3	4	5	6
12	The main thing which affects my condition is what I myself do.	1	2	3	4	5	6
13	I deserve the credit when my condition improves and the blame when it gets worse.	1	2	3	4	5	6
14	Following dentist's orders to the letter is the best way to keep my condition from getting any worse.	1	2	3	4	5	6
15	If my condition worsens, it's a matter of fate.	1	2	3	4	5	6
16	If I am lucky, my condition will get better.	1	2	3	4	5	6
17	If my condition takes a turn for the worse, it is because I have not been taking proper care of myself.	1	2	3	4	5	6
18	The type of help I receive from other people determines how soon my condition improves.	1	2	3	4	5	6

8.4 Appendix 4

8.4.1 Quality Assessments

Newcastle-Ottawa Quality Assessment Scale

Adaptations of the Newcastle-Ottawa Quality Assessment Scale were used for cross-sectional and cohort studies. Stars were awarded for items according to the criteria fulfilled, or a letter justifying the reason for not awarding a star for that section. A maximum of 10 * may be awarded for cross-sectional studies and 9* for cohort studies (Newcastle-Ottawa Scale) for assessing the quality of non-randomised studies (http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp).

Checklist of the Institute of Health Economics Alberta Canada

For case-series, an adapted checklist of the Institute of Health Economics Alberta Canada was used to assess the quality of publications (Moga et al., 2012). Item 9 was deleted as it was not relevant (no co-interventions). The criteria for quality assessment were: hypothesis/aim/objectives stated, a prospective study, cases from more than one centre, consecutive recruitment, patient characteristics described, eligibility criteria stated, patients entered at similar point in the disease, intervention clearly described, outcome measures established a priori, outcome assessors blinded to intervention, outcomes measured appropriate, outcome measures made before and after intervention, relevant statistical tests, follow up long enough, losses to follow up recorded, estimates of random variability reported in analyses, adverse events reported, conclusions supported by results, competing interests and support reported. Scoring for each item was based on the extent to which criteria were fulfilled: fully, not fulfilled, partially fulfilled or unclear. The quality was determined from the percentage of items fully meeting the criteria.

Cochrane Collaboration's Tool for Assessing Risk Bias

The quality of randomized trials was assessed using the Cochrane risk of bias tool (Higgins et al., 2011). The domains of bias assessed were: Selection, performance, detection, attrition, reporting and other bias. The source of bias for each domain was random sequence generation and allocation concealment (selection bias); blinding of participants and personnel (performance bias); blinding of outcome assessment (detection bias); incomplete outcome data (attrition bias); selective reporting (reporting bias) and other pre-specified (other bias). A numerical score is not awarded in this quality assessment, but the level of risk for each source of bias is considered as low, unclear or high.

AMSTAR Measurement Tool

The AMSTAR measurement tool was used to assess the methodological quality of systematic reviews (Shea et al., 2007). Eleven criteria were used to assess quality: "a priori" design, two independent data extractors, comprehensive literature search, status of publications, list of studies included/excluded, characteristics of included studies provided, scientific quality of included studies assessed and documented, scientific quality of included studies used appropriately in formulating conclusions, methods used to combine findings of studies appropriate, likelihood of publication bias assessed and conflict of interest stated. The overall percentage of fully met criteria was used to determine the quality of the review.

Table 53 Quality assessment (Newcastle-Ottawa Scale) for cross-sectional studies.

Study	Selection				Control of confounders	Outcome				
	1	2	3	4	1	1	2	3	Total (max 10)	%
Sayed et al. (2019)	c	b	c	a*	ab**	a**	a*	a*	7	70
Masood et al. (2019)	a*	a*	c	a*	ab**	a**	a*	a*	9	90
Ustaoglu and Bulut (2019)	b*	a*	c	a*	#	a**	a*	a*	7	70
Karaaslan and Dikilitas (2019)	b*	b	c	a*	a*	a**	a*	a*	7	70
Kato et al. (2018)	b*	a*	c	a*	#	a**	a*	a*	7	70
Llanos et al (2018)	c	b	c	a*	#	a**	a*	a*	5	50
Sonnenschein et al. 2018	b*	a*	c	a*	#	a**	a*	a*	7	70
He, et al. (2018)	a*	a*	c	a*	ab**	a**	a*	a*	9	90
Masood et al. (2017)	b*	a*	c	a*	ab**	a**	a*	a*	9	90
Levin, et al. (2018)	c	a*	a*	a*	ab**	a**	a*	a*	9	90
Wellapuli and Ekanayake (2016)	b*	a*	c	a*	ab**	a**	a*	a*	9	90
Meusel, et al (2015)	c	b	c	a*	a*	a**	a*	a*	6	60
Fotedar et al. (2014)	c	a*	c	a*	ab**	a**	a*	a*	8	80
Jansson, et al. (2014)	b*	b	b	a*	ab**	a**	a*	a*	8	80
Palma et al. (2013)	c	a*	c	a*	ab**	a**	a*	a*	8	80
Durham, et al. (2013)	c	b	a*	a*	#	a**	a*	a*	6	60
Borges, et al. (2013)	c	b	c	a*	#	a**	a*	a*	5	50
Zanatta, et al. (2012)	c	b	b	b	ab**	a**	a*	a*	6	60
Al Habashneh, et al. (2012)	c	b	c	a*	ab**	a**	a*	a*	7	70
Zhao et al. (2011)	b*	a*	a*	a*	a*	a**	a*	a*	9	90
Zaitsu et al. (2011)	b*	b	b	a*	a*	a**	a*	a*	7	70
Cohen-Carneiro et al. (2010)	b*	b	c	a*	#	a**	a*	a*	6	60

Table 53 Quality assessment (Newcastle-Ottawa Scale) for cross-sectional studies (continued).

Study	Selection				Control of confounders	Outcome				
	1	2	3	4	1	1	2	3	Total (max 10)	%
Andersson et al. (2010)	c	b	c	a*	ab**	a**	a*	a*	7	70
Bernabe & Marcenes (2010)	a*	a*	c	a*	ab**	a**	a*	a*	9	90
Montero-Martin (2009)	c	b	a*	a*	#	a**	a*	a*	6	60
Lawrence et al. (2008)	b*	a*	c	a*	ab**	a**	a*	a*	9	90
Aslund, et al. (2008)	c	b	c	a*	ab*	a**	a*	a*	6	60
Cunha-Cruz, et al. (2007)	c	b	b	a*	#	a**	a*	b	4	40
Ng & Leung (2006)	c	b	b	a*	ab**	a**	a*	a*	7	70
Swoboda et al. (2006)	b*	b	c	a*	ab**	a**	a*	a*	8	80
Needleman, et al. (2004)	c	a*	c	a*	#	a**	a*	a*	6	60
Srisilapanan and Sheiham (2001)	b*	b	c	c	ab**	a**	a*	a*	7	70

Footnote: Selection: **1a** = Truly representative of target population. **1b** = Somewhat representative. **1c** = convenience sample. **2a** = sample size justified and satisfactory. **2b** = sample size not justified. **3a** =Comparability between respondents and non-respondents' characteristics established and response rate satisfactory (≥30%). **3b** = response rate or comparability between respondents and non-respondents is unsatisfactory. **3c** = no description of response rate or characteristics of responders/non-responders. **4a** = validated measurement tool. **4b** = non-validated tool. **Control of confounders**: **1a** = controlled for most important factor. **1b** = controlled for additional factor. **#** = none accounted for in analysis. **Outcome**: **1a** = independent blind assessment. **2a** = statistical test used clearly described and appropriate. Measurement of association presented, including confidence intervals and p value. **3a** = validated measurement tool. **3b** = non-validated measurement tool (available or described). Total score = number of *

Table 54 Quality assessment (Newcastle-Ottawa Scale) for cohort studies.

Study	Selection				Comparability	Outcome				
	1	2	3	4	1	1	2	3	Total (max 9)	%
Makino-Oi et al. (2016)	c	a*	a*	a*	a*	a*	a*	b*	7	78
Brauchle, et al. (2013)	b*	a*	a	a*	a*	a*	a*	d	6	67
Shah and Kumar (2011)	c	a*	a	a*	a*	a*	a*	d	5	56
Saito, et al. (2010)	c	a*	a	a*	a*	a*	a*	b*	6	67
Jowett, et al. (2009)	c	a*	b *	a*	a*	a*	a*	b*	7	78

Footnote: Selection: 1c = selected group (hospital patients). 1b = somewhat representative of the average in the community. 2a = drawn from the same community as exposed cohort. 3a = secure records, * if calibrated or trained examiners stated. 3b = structured interview. 4a = Outcome of interest not present at start (OHRQoL). **Comparability:** 1a = comparability of cohorts for a factor. **Outcome:** 1a = Independent blind assessment. 2a = long enough follow-up. 3b = lost to follow-up unlikely to introduce bias. 3d = no statement on lost to follow-up. Total score = number of * awarded for each section.

Table 55 Quality assessment for case-series studies

Item -------------------------- comment or score	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	Total	%
Peikert et al (2019)	Y	Y	Y	U	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	N	Y	Y	16	84
Goel and Baral (2017)	Y	U	N	U	Y	Y	Y	Y	Y	U	Y	Y	Y	Y	Y	Y	N	Y	Y	14	74
Mendez et al. (2017)	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	18	95
Miao et al. (2016)	Y	Y	N	Y	Y	Y	Y	Y	Y	U	Y	Y	Y	N	Y	Y	N	Y	Y	15	79
Wong, et al. (2012)	Y	Y	N	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	17	89
Nagarajan & Chandra, (2012)	Y	Y	N	U	Y	N	Y	Y	Y	U	Y	Y	Y	Y	Y	P	Y	Y	N	13	68
Ohrn & Jonsson (2012)	Y	Y	N	Y	Y	N	Y	Y	Y	U	Y	Y	Y	Y	N	Y	N	Y	N	13	68
Pereira, et al. (2011)	Y	Y	N	Y	P	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	N	N	Y	Y	14	74
Saito, et al. (2011)	Y	Y	Y	U	Y	Y	Y	Y	Y	U	Y	Y	Y	Y	Y	Y	Y	Y	Y	17	89
Bajwa et al. (2007)	Y	Y	N	U	N	P	Y	Y	Y	U	Y	Y	Y	Y	Y	Y	N	Y	N	12	63

Footnote: Checklist items: 1 = hypothesis/aim/objectives. 2 = prospective study. 3 = cases from > 1 centre. 4 = consecutive recruitment. 5 = patient characteristics described. 6 = eligibility criteria. 7 = patients entered at similar point in disease. 8 = intervention clearly described. 9 = outcome measures established a priori. 10 = outcome assessors blinded to intervention. 11 = outcomes measured appropriate. 12 = outcome measures made before and after intervention. 13 = relevant statistical tests. 14 = follow up long enough. 15 = losses to follow up recorded. 16 = estimates of random variability in analysis. 17 = adverse events reported. 18 = conclusions supported by results. 19 = competing interests and support reported. **Scoring:** Yes = Y Other comments: N = no; P = partial; U = unclear. Total and percentage calculated from the number of items scoring Y.

Table 56 Quality assessment of RCT's

	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Santuchi, et al. (2016	+	?	+	+	?	+	+
Jonsson & Ohrn (2014)	−	−	+	?	−	+	−
Tsako et al. (2010)	+	+	+	+	+	+	+
Aslund, et al. (2008)	+	+	?	+	+	+	+
Ozcelik, et al. (2007)	+	−	−	+	+	+	?
D'Avila , et al. (2005)	+	−	−	−	+	+	+

+ Low risk of bias − High risk of bias ? Unclear risk of bias

Table 57 Summary of Quality Assessment of Systematic Reviews on OHRQoL

Item -------------------------- comment or score	1	2	3	4	5	6	7	8	9	10	11	Total	%
Botelho et al. 2020	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11	100
Baiju et al., (2017)	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	10	91
Ferreira et al., (2017)	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	10	91
Buset et al., (2016)	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	11	91
Shanbhag et al., (2012)	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	10	91
Naito et al., (2006)	Y	Y	Y	N	Y	Y	N	N	Y	Y	N	7	64

Footnote on Items: 1 = “A priori” design? 2 = Two independent data extractors? 3 = Comprehensive literature search? 4 = Status of publication used as inclusion criterion? 5 = List of studies included/excluded provided? 6 = Characteristics of included studies provided? 7 = Scientific quality of included studies assessed and documented? 8 = Scientific quality of included studies used appropriately in formulating conclusions? 9 = Methods used to combine findings of studies appropriate? 10 = Likelihood of publication bias assessed? 11= Conflict of interest stated? Total score = number scoring Y.

Table 58 Summary of Quality Assessment of Systematic Review Articles on Nonsurgical Periodontal Treatment

Item ----------- Comment or score	1	2	3	4	5	6	7	8	9	10	11	Total	%
(Mailoa et al., 2015)	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	11	100
(Smiley et al., 2015)	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	N	9	82
(Eberhard et al., 2008)	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	10	91
(Lang et al., 2008)	Y	N	Y	N	Y	Y	Y	Y	Y	N	Y	8	73
(Heitz-Mayfield et al., 2002)	Y	N	Y	N	Y	Y	Y	Y	Y	Y	N	8	73
(Hung and Douglass, 2002)	Y	N	Y	N	Y	Y	Y	Y	Y	N	N	7	64
(Tunkel et al., 2002)	Y	N	Y	N	Y	Y	Y	Y	Y	N	N	7	64
(Van der Weijden and Timmerman, 2002)	Y	N	Y	N	Y	Y	Y	Y	Y	Y	N	8	73

Footnote on Items: 1= "A priori" design? 2 = Two independent data extractors? 3 = Comprehensive literature search? 4 = Status of publication used as inclusion criterion? 5 = List of studies included/excluded provided? 6 = Characteristics of included studies provided? 7 = Scientific quality of included studies assessed and documented? 8 = Scientific quality of included studies used appropriately in formulating conclusions? 9 = Methods used to combine findings of studies appropriate? 10 = Likelihood of publication bias assessed? 11= Conflict of interest stated? Total score = number scoring Y.