A PILOT PROJECT TO RESEARCH EXTENDING DENTAL SERVICES THROUGH THE USE OF A TEXT MESSAGING INTERVENTION TO IMPROVE THE ORAL HEALTH OF OLDER PATIENTS

*Extended dental services to provide **O**ral **H**ealth **P**romotion **T**ext messages for **O**lder **P**atients - OHP-TOP study*

Version 2

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Content:

Key Dates:

IRAS application Reference Number: 261790
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Approvals:

This study is seeking approval from the HRA Research Ethics Committee, project reference 261790.

Funding Details:

£24,000 secured from NHS England.

Insurance Arrangements:

This research is covered by the University of Portsmouth insurance policy.

Legal Compliance:

This study complies, and at all times will comply, with new GDPR legislature and the Concordat to Support Research Integrity, RCUK Policy and Guidelines on Governance of Good Research Conduct.

Sites/Locations:

University of Portsmouth Dental Academy, William Beatty Building, University of Portsmouth, PO1 2QG

PROPOSED RESEARCH PROGRAMME

Study Summary:

Over the last 60 years in England, people are retaining their natural teeth longer (Hill, Chadwick, Freeman, O'Sullivan, & Murray, 2013; Kressin, Boehmer, Nunn, & Spiro, 2003; Lang, Ronis, & Farghaly, 1995; Steele, Treasure, O'Sullivan, Morris, & Murray, 2012). The improved longevity of patient's teeth, in an increasingly ageing population, has resulted in an increase in the demand for dental care amongst the older populace in order to maintain good oral health (Hill et al., 2013; Watt et al., 2013).

According to the UK Office for National Statistics (ONS), life expectancy at birth in 2011 almost doubled that of 1841, and has been predicted to increase, over the next 30 years. Latest estimates show that there were 11.8 million UK residents aged 65 and above in 2018 (Office for National Statistics, 2018). In 2014, healthy life expectancy (or the proportion of life lived in good health) was docked around 65 years of age; opposed to life longevity, which was recorded at nearly 80 years of age (Public Health England, 2017). This suggests that both men and women are living a longer proportion of life in poor health (Manton, 1982; Public Health England, 2017; Robine, Saito, & Jagger, 2009). Research shows that access to appropriate dental healthcare services improves the overall quality of life of individuals (Borreani, Wright, Scambler, & Gallagher, 2008; Crocombe, Brennan, & Slade, 2012; Locker, Matear, Stephens, & Jokovic, 2002; MeGrath & Bedi, 2001). Effective health promotion is required in order improve and maintain the dental health of older patients. This would create a balance between longevity and a life lived in good health.

The use of media has improved health promotion and behaviour change interventions on a global scale. With 7.7 billion mobile phone users recorded worldwide in 2017, text messages or short messaging service (SMS), for text messaging interventions (TMIs), offer a simple, low cost, and readily accessible method to deliver information to patients, regardless of age or social group (Gurol-Urganci, de Jongh, Vodopivec-Jamsek, Atun, & Car, 2013; ICT Data and Statistics Division, 2016; Kannisto, Koivunen, & Välimäki, 2014; Youssef et al., 2014). Research on text message reminders in health care services has been primordially focused on two main areas; behaviour change interventions and reminders (Schwebel & Larimer, 2018). Evidence suggests that preventive studies utilising TMIs for health care reminders or intervention purposes have had a positive impact on health outcomes on several study types; i.e. smoking, diet and exercise, alcohol, CPR training, sexual health, self-efficacy with

medication or chronic conditions, and prompting self-care behaviours (Free et al., 2013; Kannisto et al., 2014).

It is well documented that older patients experience a variety of barriers related to dental services and maintaining good oral health (Department of Health, 2005; Parker, 2003). Dental professionals are faced with a cohort of patients experiencing multiple comorbidities. For the older populace this can include; mobility difficulties, dental anxiety, visual problems and cognitive challenges. Failure to attend appointments are a major cause of inefficiency in the healthcare system when concerning delivery of care and subsequent monetary costs produced by delays in diagnosis and treatment, leading to higher morbidity (Gurol-Urganci et al., 2013; Youssef et al., 2014). According to NHS England 2019, the cost of missed general practice appointments was £216 million for 2018 (Oliver, 2019). Text message reminders can be used to improve dental attendance by reducing missed appointments (Youssef et al., 2014). Research also indicates that dental health TMIs have influence on health attitudes and behaviours by increasing the knowledge of the participants and contributing to their well-being (Hashemian, Kritz-Silverstein, & Baker, 2015; Schluter et al., 2015; Sharma, Hebbal, Ankola, & Murugabupathy, 2011).

TMIs could provide an important platform for preventative health via patient reminders and additional relevant information. Additionally, TMIs have been proven to produce an alteration in oral health behaviour habits in as little as one week, however whether these outcomes are sustained is not clear (Hashemian et al., 2015). Studies with a longer intervention time frame, such as 9-12 weeks, were able to collect more baseline data for evaluation post study, permitting greater depth in analysis (Lilje, Olander, Berglund, Skillgate, & Anderberg, 2017; Müller, Khoo, & Morris, 2016; Schluter et al., 2015; Sharma et al., 2011). Previous studies sent as few as two texts per week for longer periods (12 weeks) and multiple daily reminders for week-long studies, making the case for more frequent longer intervention periods.

Some of the longer TMI interventions reported a decline in participation toward the end of the study, indicating that some participants lost interest in the study, but without affecting the increase of dental attitudes (Schluter et al., 2015). The participants who completed studies with notable declines in participation, continued to uphold the promoted health regimen. In order to overcome this loss in participation, some study strategies included in interactive element to their test message study, such as questions in which the patients could respond ‘Yes’ or ‘No’ and receive additional health care knowledge through facts or advice (Hashemian et al., 2015). This was not the case in Lilje et al., a study which looked at the

experience of older adults with text messaging for reminders for self-care home exercises. The patients, aged 67-86, thoroughly enjoyed the messages and perceived them to stimulate memory for the act of memorizing, which they counted as an exercise within itself. The patients also reported that the text messages promoted a self-consciousness in their rehabilitation and felt empowered when they received the text message after completing the exercises, in which case the text messages felt like a reward (Lilje et al., 2017).

The University of Portsmouth Dental Academy (UPDA) is an NHS primary dental care service and training centre for dental care professionals and dental students from King's College London. The Dental Academy sees approximately 400 patients over the age of 65 years. These patients, like many who attend general dental practice, have varied levels of oral health. Working with NHS England commissioners, the NHS service and University of Portsmouth Academics have set up an extended service intervention, which will be studied over time.

Aim:

The aim of this study is to investigate the impact of an extended service intervention at a primary dental care service (UPDA) to improve the oral health of patients aged over 65 years, using either text messages to communicate preventive dental advice or a leaflet providing preventive information.

Objectives:

1. To gain views of the study participants (patients) on the acceptability of the text message extended service interventions in effectively communicating preventive advice to the participants of the study.

2. To gain insight into the patients' dental attendance, oral health behaviour, and changes against the baseline clinical outcomes (Plaque Index, Bleeding Index, Basic Periodontal Exam (BPE), Decayed Missing Filled Teeth (DMFT), Number of Sound Teeth, RAG Rating (Red-Amber-Green rating according level of risk), and Recall Interval) 12 months after the initial intervention.

3. To compare dental attendance, oral health behaviour and changes in clinical outcomes between the intervention arm and control arm groups after 12 months.

4. To compare the relationship between social demographic factors, behaviour and clinical outcomes before and after the intervention for all participants.

METHODOLOGY

This is a longitudinal study with two extended service interventions assigned randomly to participants. The text message intervention is performed using several relevant protocols discussed in previous intervention studies (Hashemian, Kritz-Silverstein, & Baker, 2015; Komulainen et al., 2015; Peltola, Vehkalahti, & Simoila, 2007)**.** The study will include Quality of Life assessments, such as the Oral Health Impact Profile -14 (OHIP-14) and General Health Questionnaire 12 (GHQ-12), pre- and post-intervention for each patient (D. P. Goldberg & Blackwell, 1970; D. Goldberg & Williams, 1988; Slade & Spencer, 1994). Alongside the appropriate clinical outcomes to measure throughout the course of the study, to allow the evaluation of change in behaviour and clinical outcomes. The clinical outcomes include; Plaque Index, Bleeding Index, Basic Periodontal Exam (BPE), Decayed Missing Filled Teeth (DMFT), Number of Sound Teeth, RAG Rating (Red-Amber-Green rating according level of risk), and Recall Interval. Sociodemographic data including age, sex and indices of multiple deprivation as derived from the residence will also be collected. All data will be anonymised by the time it is shared with the research team.

Text messages will be created from evidence based guidance from the NHS Delivering Better Oral Health (DBOH) Evidence Toolkit and Mouth Care Matters. They will be based around themes such as; tooth brushing behaviours, fluoride use, denture cleaning, and xerostomia, which may be pertinent to the 65 and above age populace. For the control arm of the study, information will be disseminated on one occasion in the form of a single leaflet, whereas tri-weekly text messages will be sent for 10-weeks, limited to 150 characters, to the TMI arm. Evaluation will include an interactive two-way text, sent to all participants at the end of the 6th month to establish their views of the intervention. Those not receiving the intervention will receive a standard information leaflet on oral health advice. A methodology flow diagram is included in *Appendix 9.*

ANTICIPATED ETHICAL ISSUES:

1. Required informed consent:

Consent forms for participation will be distributed and signed by participants prior to starting the study. Principles of ethical consent are outlined below in the Recruitment Strategy.

2. Handling of confidential data:

Measures to prevent recording (and subsequent inclusion in report) of private and/or medical (dental) information of any participants discussed will be in place. This will be done by informing participants that no private/medical information should be disclosed.

All data will be anonymised, coded and stored securely using limited access folders and password secured N-drive. Files used for analysis will be anonymised and will adhere to the same access and control measures.

Any pre-screening of patients will be done by the care team – the research team will not review any non-anonymised clinical data.

Anticipated other risks:

Risks to participants: Participants may feel intruded upon following the text messages. Participants will be made aware they can withdraw from the study at any point and any participants feeling distressed or requiring help will be signposted to well-being services at the University of Portsmouth.

Risks to Researchers/University Staff/Students: N/A.

Reputational risks: N/A

Security risks: N/A

SAMPLING:

Convenience sampling has been undertaken from the patient pool at UPDA as this is an intervention being considered for adoption as an extended service. There are no existing studies on oral health text interventions in general practice targeted at older people we arrived at a target sample size informed by past studies on oral health interventions for older people dwelling in the community which suggested that 80 subjects were needed in both

groups to detect a difference of 20–25% in dichotomised outcome variables in order to achieve statistical power of 0.80 with an alpha of 0.05 (Komulainen et al., 2015). Based on studies, such as Müller et al., 2015 and Walters et al., 2017, potential participant recruitment rate from an identified pool of people is between 56-80%, with a dropout rate of 13.1% found in Komulainen et al., 2015, and a study power of 90%, we are targeting recruitment of n=202. Each study arm is anticipated to have 101 participants.

RECRUITMENT:

Population:

All patients currently attending UPDA aged 65 years old or above will be identified using our patient management system and approached to participate by a research nurse into this study. Approximately 400 patients attend in the six months between March and July as established from internal audits. n=202 for overall recruitment, with 101 participants in each study arm.

Inclusion/Exclusion Criteria:

Inclusion criteria: Dental patients, aged 65 and over from the existing pool of patients at UPDA who are dentate, are able to consent to this project, and own a mobile device that is capable of receiving text messages. Participants will need to possess an acceptable level of the English language to participate.

Exclusion Criteria: Dental patients below 65 years of age who attend UPDA. Dental patients who do not currently attend UPDA. Patients who are edentulous and patients who do not or have been deemed to not have the capacity to consent to the text messaging intervention. Patients who do not own a mobile phone and are therefore unable to receive text messages. Patients who do not possess an acceptable level of English language.

Recruitment Strategy:

Invitation to participate flyers (*Appendix 1*) will be placed around The University of Portsmouth Dental Academy. A research nurse will approach all patients aged 65 and over in a sensitive manner, either via telephone or during a clinical visit, and asked if they would like to participate in an oral health study, where they may or may not receive text messages. If they give consent, they are included in the study, if not, they are excluded from the study. No payments, reimbursements or rewards offered to participants, they will be made aware that the provision of dental treatment will in no way be affected by their participation in the

study. Information sheets will be provided for all potential participants who meet the inclusion criteria. Positive consent from potential participants via signature will be obtained before the reception of any preliminary clinical outcomes or the completion of the Quality of Life evaluation (*Appendices 10 and 11*) will take place. Each participant will receive a unique ID number.

The process of gaining consent from participants:

Participants will receive a Participation Information Sheet (PIS) (*Appendix 2*) at least 24 hours prior to starting the study. They will be provided with a consent form (*Appendix 3*) to allow anonymised data to be utilised for evaluation. The consent form will outline how the data will be used for research and will provide information on how the data will be managed. If participants require feedback this can be provided.

The process of gaining consent from other organisations:

Approval from Director of UPDA has already been sought and gained (*Appendix 4*).

Data Collection:

As outlined below in the Study Conduct; baseline clinical data will be recorded for each participant as is routine in all appointments. The research nurse will transfer the required data on to the pro-form (Appendix 1). The participants will also complete baseline Quality of Life evaluations (comprising of Oral Health Impact Profile-14 and General Health Questionnaire-12). At the 6-month period for each participant, three additional motivational texts will be sent and data will be collated from a 2-way text evaluation message. At the end of the 12-month period for each participant, after their routine dental appointment, their clinical information will be extracted from the electronic patient management system for scores before and after the dental health messaging service. Also the participants will complete post intervention Quality of Life evaluations as well.

How participants can withdraw consent and how data collected will be handled:

Participants will be provided with a consent form (*Appendix 3*) to allow anonymised data to be utilised for evaluation. The consent form will outline how the data will be used for research and will provide information on how the data will be managed. If participants require feedback this can be provided. If withdrawal is requested after the report has been produced and/or published, all data will already be anonymised so participants will not be identifiable.

STUDY CONDUCT

This is a 21-month long pilot study involving the assessment of a text messaging extended dental service for patients aged 65 and over. UPDA sees approximately 400 patients of the age bracket, aged 65 and older. All these patients will be contacted, either whilst at the UDPA (for a full dental exam, treatment or a review visit), or via telephone, and asked if they would like to participate in a study that will provide extra oral health advice, which may include texting or not. Dentate patients who own and utilise a mobile phone are eligible for the study. Those individuals who say no, will be opting out of the study entirely, whilst those individuals whom give written consent will have a patient marker added to their electronic records, for later retrieval using our patient management system.

There are 2 arms within the study, each with equal numbers of participants; a TMI arm and a control arm. The TMI segment will span a 6-month period and will have staggered start and finish dates due to different patient recruitment dates. The TMI arm will experience a 10-week intervention period, where 3 oral health messages, with a maximum of 150 characters, will be sent per week. Additionally, there will be 3 final text messages sent at the end of the 6th month period, accompanied by a 2-way interactive text with UPDA to assess the likeability/acceptability of the study by the participants (*Appendices 5 and 7*). The control arm, will be sent a sole oral health leaflet within the first week of their recruitment (*Appendix 5*).

There are several clinical outcomes that we will monitor to comment on the relevance of the oral health TMIs in making any alterations to original patient dental knowledge, attitude, behaviour, and clinical outcomes. The pre-intervention evaluation will include clinical parameters such as; plaque score, bleeding index, BPE, DMFT, number of sound teeth, RAG (red, amber and green disease risk) rating and recall interval (period of time set for their next visit), including sociodemographic information (age, sex, and deprivation index based on residence – derived from dental warehouse software) (*Appendix 6*). These results will be accompanied by Quality of Life assessments (OHIP-14 and GHQ-12; *Appendices 10 and 11, respectively*). Post-intervention, the same data will be collected, with an additional two-way evaluation text, to assess the acceptability of the study in this age bracket. After a 12-month period for each patient, change in patient attendance and dental clinical information will be evaluated using clinical records and transferred to the case report forms (CRF). Overall, the participants will experience four stages of the study:

Stage A) **MONTHS 1-6**

Consenting patient participants will be included in either the text message intervention (TMI) group or the control group that will receive a UPDA-modulated leaflet pertaining oral health, once, at the beginning of the study (*example in Appendix 5*).

A research nurse will explain the study, undertake consenting protocols, and consenting participants will be assigned a participant ID number to optimise anonymity when using a simple restricted block randomisation for data analysis. A practitioner will perform a baseline dental examination with the clinical parameters outlined in the Study Conduct and record these on a data capture form (*Appendix 6*). The research nurse will also assist the participants in completing pre-intervention Quality of Life evaluation questionnaires (OHIP-14 and GHQ-12; *Appendices 10 and 11, respectively*).

Stage B) **MONTHS 1-12:**

Initiation of intervention period. TMI arm will begin to receive messages and control arm will receive informative oral leaflet. Messages will be sent to remind the participants of information surrounding different oral health themes. Due to different recruitment dates, the intervention will be staggered for the 10 weeks, also staggering the month 6 end dates for each participant.

Stage C) **MONTHS 7-13:**

At the end of the 6-month period for each patient, three final oral health promotion messages to remind participants of dental health information will be provided, and a two-way evaluation message will be sent to ask the patients, asking how useful they found the service via a Likert score of 1-5 and about their dental health behaviours.

Stage D) ***MONTHS 13-19:***

12-months after each patient's initial recruitment date, the participant's electronic clinical records will be reviewed to establish changes in dental health outcomes and dental attendance. This will be analysed and compared with other internal reports on clinical data by age. The participants will again complete Quality of Life evaluation questionnaires (OHIP-14 and GHQ-12), post-intervention.

Text message development:

Researchers at the University of Portsmouth will construct a text messaging service sending out oral health information reminders. The information for the text messages will conform with evidence based practice from the NHS Department of Health, Developing Better Oral Health Evidence Based Toolkit and NHS Mouth Care Matters.

DATA MANAGEMENT

Description of data analysis:

Data will be collected from the clinical records, which will include clinical outcomes and sociodemographic data, outlined in *Appendix 6*. Whilst supplementary qualitative data will be obtained through the interactive 2-way text messaging portion of the study and both Quality of Life questionnaires; Oral Health Impact Profile-14 (OHIP-14) and General Health Questionnaire-12 (GHQ-12). All quantitative data, including and the 2-way text messaging scores, will be analysed on SPSS 24 statistical software. This will provide descriptive and analytical statistics, to establish differences in scores pre- and post-text message intervention, as well as control versus non-control group. Additionally, an ANOVA analysis for repeated measures or within-subjects will be undertaken to compare pre- and post-intervention scores for descriptive and analytical statistics regarding the clinical outcomes and Quality of Life assessments, as mentioned above. Data gathered from the 2-way text message evaluation (*Appendix 7*) will be analysed using SPSS and with thematic analysis using NVivo software to assess themes in any qualitative data. Primary outcomes measured encompass those outlined in *Appendix 6*, whilst secondary outcomes are those obtained through the two Quality of Life assessment questionnaires in *Appendices 10 and 11*.

Data storage during the project:

All data will be anonymised. The digitised data will be stored onto a research only, secured N Drive account (with access limited to the Principal Investigator and the research team for this study). Written data will be stored in a locked area with specific access to the Principal Investigator and research team only, before being appropriately destroyed. No identifiable data will be seen by research team – only the care team will review identifiable records.

Destruction, Retention and Re-Use of Data:

The research data on the password-protected sheet will be retained for 10 years in accordance with the University of Portsmouth Retention Schedule for Research Data. The raw data will be disposed of following study completion. Participants will be asked to confirm in the informed consent form (*Appendix 3*) that their anonymous data be used in future research by the research team.

How confidentiality will be ensured:

The study will be anonymous as participants will not be asked for their names and the demographic information they provide will not uniquely identify them. This information is mentioned in the information sheet and consent forms.

The raw data will be deleted following study completion to protect participant confidentiality. Only the care team will have direct access to the raw data and if necessary, will securely share it with the study team but not with any other party. Should the study results be presented at conferences or published in an academic journal, only the overall results, that do not refer to raw data, will be presented.

Publication/Dissemination Plans:

The information provided from this study will be disseminated through publications, on The University of Portsmouth's website and in reports.

Proposed timeline of work:

Date	Activity
January - February 2019	Ethics submission to Health Research Authority Research Ethics Committee
February - March 2019	Development of the extended dental text messaging service
March 2019	Recruitment of patients and initiation of the 10-week text messaging according to the start date of each participant
September 2019 – March 2020	Final study-closing text messages and 2-way text message evaluation
March - October 2020	Evaluation of dental attendance and oral health scores via electronic patient management system.
December 2020	Dissemination of findings, publications and reports.

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Appendix 1: Invitation to Participate Flyer

Invitation to Participate Flyer

Version 1: 08/02/19 IRAS ID: 261790

UNIVERSITY OF PORTSMOUTH

Texts for Dental Health

OHP-TOP study

An invitation to participate in research

Who are we?

We are a team of researchers from the University of Portsmouth Dental Academy working on a text messaging intervention service, designed to help improve the dental health of our patients.

Who are we looking for?

We are looking for Dental Academy patients aged 65 and over.

What would we like you to do?

We would like you to take part in our study.

Want to learn more? If you would like to take part or for further information please email: janani.sivabalan@port.ac.uk or courtney.couch@myport.ac.uk

Appendix 2: Participant Information Sheet

PARTICIPANT INFORMATION SHEET

Version 2: 12/03/19 IRAS ID: 261790

UNIVERSITY OF PORTSMOUTH

Title of Project:

A PILOT PROJECT TO RESEARCH EXTENDING DENTAL SERVICES THROUGH THE USE OF A TEXT MESSAGING INTERVENTION TO IMPROVE THE ORAL HEALTH OF OLDER PATIENTS

Name(s) and Contact Details of Research Team:

- **Dr Kristina Wanyonyi**. Research Lead/Senior Lecturer in Dental Public Health. University of Portsmouth Dental Academy, William Beatty Building, Hampshire Terrace, Portsmouth, PO1 2QG. Email: kristina.wanyonyi@port.ac.uk Tel: 023 9284 5746.
- **Miss Janani Sivabalan**. Research Practitioner and Clinical Teaching Fellow. University of Portsmouth Dental Academy, William Beatty Building, Hampshire Terrace, Portsmouth, PO1 2QG. Email: janani.sivabalan@port.ac.uk Tel: 023 9284 5748.
- **Miss Courtney Couch**. Research Associate, University of Portsmouth Dental Academy, William Beatty Building, Hampshire Terrace, Portsmouth, PO1 2QG. Email: courtney.couch@myport.ac.uk Tel 023 9284 8331

Invitation

We would like to invite you to take part in a research study undertaken by the University of Portsmouth Dental Academy (UPDA). Before you decide please read this information sheet to understand why this research is taking place and what it involves. The researcher will go through this information sheet with you, and you are free to ask questions before signing a consent form if you wish to take part.

What is the purpose of the study?

The purpose of this study is test the use of a new oral health promotion initiative using two different methods; text and information leaflets. This is with a view of improving how we can help you to take care of your teeth. Feedback collected will assess the usability of a text messaging intervention, designed to send out dental health information reminders to patients, 3 times a week for 10 weeks.

Why have I been invited?

You have been invited because you are a current patient at UPDA aged 65 or over.

Do I have to take part?

No, taking part in this research is entirely voluntary. It is up to you to decide if you want to volunteer for the study. We will describe the study in this information sheet. You can contact the investigators with questions at any time. If you agree to take part, we will then ask you to sign a consent form.

What will happen to me if I take part?

A research nurse, whose details you can find at the top of this page, will discuss the details of the study to you. If you decide to take part, you will be invited to sign a consent form. If you are happy to continue, you will be take part in one of two ways of receiving oral health advice. You will be randomly allocated into one of two groups. One group would be invited to receive 3 texts per week over a 10-week period and the second group and receive a leaflet at the beginning of the study – within one week of agreeing to take part.

Apart from this, you will receive your routine dental health check-up and you will be asked to complete a questionnaire about how you feel about your general and oral health. This will take approximately 5 minutes during your visit.

If you are a part of the group that receives text messages, after 6 months you will receive 3 additional oral health texts, and also provide feedback to the research team via a 2-way interactive text with UPDA to detail your experience. You will continue with your routine

appointments and at your 12-month appointment, you will be asked to complete a second 5-minute questionnaire about how you feel about your general and oral health.

Will my taking part in the study be kept confidential?

Yes, all your data will be kept confidential and anonymous by the researchers. Your data will be collected and analysed by the research team, and those members of the research team not involved in the data collection process will only have access to anonymised data Your contribution will be used to assess the usability and benefit of a dental health text messaging service. The researchers will not discuss individual views with anyone outside the research team. Any transcription is undertaken by professional services which will be bound by confidentiality; no names will be included in the raw data.

Your data will be made anonymous by coding. As this study involves a small sample of patients participating, there is a small chance of participants being identified by parties outside of the research team. However, we ensure that no identifiable data will be available to confirm identification. Any raw data, which identifies you will be kept securely by the research team in an encrypted password protected University of Portsmouth computer on N-Drive. Any raw data will be destroyed once data analysis has been completed. With your consent, the findings of this study may be published in academic articles, journals, presented at conferences or in future research. Only responses garnered from the 2-way interactive text evaluation, using a Likert scale of 1 to 5, will be used in these publications, and all optional, voluntary responses after this will remain anonymous throughout to safeguard your identity. Any specific patient identifiers that you may mention in your responses will be removed or replaced with pseudonyms or anonymous identifiers.

The raw data, which would identify you, will not be passed to anyone outside the research team without your expressed written permission. The exception to this will be any regulatory authority which may have the legal right to access the data for the purposes of conducting an audit or enquiry, in exceptional cases. These agencies treat your personal data in confidence. In addition, should any information shared indicate a risk to patients or the public, this information will be reported to the relevant body. The anonymised transcript will be retained for up to 10 years. When it is no longer required, the data will be disposed of securely.

GDPR (General Data Protection Regulation) information:

The University of Portsmouth, UK, is the sponsor for this study. We will be using information from your completed questionnaires and dental examination in order to undertake this study

and will act as the data controller for this study. This means that we, the University of Portsmouth, are responsible for looking after your information and using it properly.

The University of Portsmouth Dental Academy wishes to process your personal data (this includes; collecting, using, storing and destroying data that identifies you) as part of a research project. If you have any queries about this research project, please contact a member of the Research Team, whose contact details are mentioned above. If you have any general queries about how your data will be processed or the confidentiality of your data, please contact the University's Data Protection Officer using any of the following contact details:

Samantha Hill. Data Protection Officer, Information Disclosure and Complaints Manager, University House, Winston Churchill Avenue, Portsmouth, Hampshire, PO1 2UP. Email: samantha.hill@port.ac.uk or data-protection@port.ac.uk Tel: 023 9284 3642

We ask for your consent to process the data we ask for during this study, so that we can conduct the research as described in the Participant Information Sheet. Any pre-screening of patients will be done by the care team, and the research team will not review any non-anonymised clinical data. The University of Portsmouth will keep identifiable information about you until the data analysis is completed and then any raw data will be destroyed following the completion of the study to protect patient confidentiality. Only the care team will have access to the raw data, and can share it with the research team where necessary. The anonymised transcript will be retained for up to 10 years, and will only be accessible to the research team and not any other party.

All of your personal data will be anonymised, coded and securely stored using a limited access, password-secured drive on University of Portsmouth computers. Files used for analysis will be anonymised and we will not store your data outside the EU. After the 10-year period in which we will securely store your anonymised data, your data will be securely destroyed according to the University of Portsmouth Retention Schedule for Research Data.

To safeguard your rights, we will use the minimum personally-identifiable information possible. The University of Portsmouth will hold completed consent forms in a secure location. Other than sex and age, no other identifiers will be kept, including the contact details of participants. Certain individuals from the University of Portsmouth and regulatory organisations may look at your research records to check the accuracy of the research. Other than the consent form, we will only receive information without identifying information. The people who analyse the information will not be able to identify you and will not be able

find out your name or other contact details. Identifiable information will not be held at participating NHS organisations. You can find out more about how we use your information at:

http://www2.port.ac.uk/departments/services/corporategovernance/dataprotection/gdpr-faqs/

Although you have the right to request a copy of the personal data we hold about you, to restrict the use of your personal data, to be forgotten, to data portability, and to withdraw your consent for the use of your data, it is possible that we may not be able to fully comply with those rights where your data has been used for the research and / or has been anonymised. If you wish to withdraw from this research study, your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate, especially if your withdrawal would be of significant detriment to the research study aims. With that being said, we will always have in place appropriate safeguards to protect your personal data. For more information on your rights in general, please see the information on the following links:

http://www.port.ac.uk/departments/services/corporategovernance/gdpr/

You also have the right to lodge a complaint about the use of your personal data to initially the University (Email: information-matters@port.ac.uk) and then, if you are unhappy with our response, to the Information Commissioner's Office (ICO) – for more information please see https://ico.org.uk/for-the-public/raising-concerns/

Expenses and payments

You will not receive any payments for taking part in this study.

What are the possible disadvantages, burdens and risks of taking part?

Risks of the study are minimal. They include the inconvenience of participation. The text messages will relate to dental hygiene advice and are not personal messages. You will also be given relevant contacts for referral for issues raised to be attended to in the University of Portsmouth.

What are the possible advantages or benefits of taking part?

Your contribution could enable the design and implementation of a text messaging service that could help improve your own dental health as well as dental health of other patients.

What will happen if I don't want to carry on with the study?

As a volunteer you can stop your participation at any time, or withdraw from the study at any time as long as the data has not been analysed. Your contributions can be omitted prior to analysis through the removal of comments noted in the evaluation text message. However, the development of the text messaging service will continue on the basis of the feedback made to the design team. It will not be possible to remove input that has been fed into this development process.

What will happen if I can't carry on with the study?

If any detrimental health event should arise where you lose capacity to consent, and therefore cannot carry on with the study, the University of Portsmouth Dental Academy will need to be notified. It is recommended that you appoint a trusted contact (a family member, friend, neighbour, colleague, etc.) if you chose to participate in this study. The trusted contact will be expected to notify the Dental Academy care team on your behalf, regarding any external incidents that result in loss of capacity during the duration of the study. The research team will then undertake the appropriate measures to remove your data from the study. Any data collected before the incident that may hold significant value to the research will be made anonymous and securely retained for research purposes.

In what circumstances does the researcher have a responsibility to break a confidentiality agreement?

The researchers as representatives of the University of Portsmouth will comply with the University of Portsmouth Policy for Safeguarding Children and Vulnerable Adults (dated November 2016). This means the researchers will pass on any suspicions of indicators of harm, abuse or neglect that includes but is not limited to physical, emotional, sexual or online abuse and neglect. The researchers have a duty to report suspicions, allegations or actual incidents regardless of whether the information has been disclosed in confidence. Any suspicions/concerns will be reported by the researchers to the supervisory team, who will then pass the information to the Director of Corporate Governance at the University of Portsmouth who will contact the appropriate agency.

What if there is a problem?

If you have a query, concern or complaint about any aspect of this study, in the first instance you should contact the Principal Investigator (details above). If the complaint remains unresolved, please contact the University Complaints Officer, 023 9284 3642, complaintsadvice@port.ac.uk. You can also contact your nearest NHS Patient Advice and Liaison Service (PALS), which offers a point of contact for confidential advice, support and information on health-related matters for patients, their families and their carers.

Who is funding the research?

This study is supported by NHS England.

Who has reviewed the study?

Research involving human participants is reviewed by an Ethics Committee to ensure that the dignity and well-being of participants is respected. This study has been reviewed and given favourable ethical opinion by the Health Research Authority and the Nottingham 1 Research Ethics Committee.

Thank you!

Thank you for taking time to read this information sheet and for considering volunteering for this research. If you do agree to participate your consent will be sought; please see the accompanying consent form. You will then be given a copy of this information sheet and your signed consent form to keep.

Appendix 3: Consent Form

CONSENT FORM

Version 2: 12/03/19 IRAS ID: 261790

TITLE:

A PILOT PROJECT TO RESEARCH EXTENDING DENTAL SERVICES THROUGH THE USE OF A TEXT MESSAGING INTERVENTION TO IMPROVE THE ORAL HEALTH OF OLDER PATIENTS

Name and Contact Details of Researcher(s):

Dr Kristina Wanyonyi. Research Lead/Senior Lecturer in Dental Public Health. NIHR CRN Wessex Oral and Dental Specialty Lead. University of Portsmouth Dental Academy, William Beatty Building, Hampshire Terrace, Portsmouth, PO1 2QG. Email: kristina.wanyonyi@port.ac.uk Tel: 023 9284 5746

Miss Janani Sivabalan. Clinical Teaching Fellow and Research Practitioner. University of Portsmouth Dental Academy, William Beatty Building, Hampshire Terrace, Portsmouth, PO1 2QG. Email: Janani.sivabalan@port.ac.uk Tel: 023 9284 5748

Miss Courtney Couch. Research Associate, University of Portsmouth Dental Academy, William Beatty Building, Hampshire Terrace, Portsmouth, PO1 2QG. Email: courtney.couch@myport.ac.uk Tel: 023 9284 8331

Information Disclosure and Complaints Manager: Samantha Hill, Data Protection Officer, University House, Winston Churchill Avenue, Portsmouth, Hampshire, PO1 2UP. Email: samantha.hill@port.ac.uk or data-protection@port.ac.uk Tel: 023 9284 3642

Please write your initials in each box you consent to.

1. I confirm that I have read and understood the Participant Information Sheet dated 08/02/19 [Version 1] 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 data collected during this study will be processed in accordance with the data protection law as explained in the Participant Information Sheet [Version 1].	
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.	
4. I acknowledge that my anonymous patient records will be used in this study.	
5. I understand that data collected during this study will be retained in accordance with the University's data retention policy and *could* also be requested by UK regulatory authorities. All identifiable data will be disposed of following study completion and anonymised, written data will be stored in a locked area with specific access to the Principal Investigator and research team only for 10 years in line with the University of Portsmouth's retention schedule.	
6. I agree to the data I contribute being retained for any future research that has been given a favourable opinion by a Research Ethics Committee	
7. I understand that the results of this study may be published and/or presented at	

meetings or academic conferences, and may be provided to any research commissioners or funders. I give my permission for my anonymous data, which does not identify me, to be disseminated in this way.	
8. I understand that anonymised, direct, voluntary quotations may be used for publications (outputs), which may also be modified to protect any sensitive/ identifiable patient information.	
9. I consent to anonymised, verbatim quotes being used in publications.	
10. I understand that the information collected about me will be used to support other research in the future and may be shared anonymously with other researchers.	
11. I understand that if I disclose any information that could potentially harm either myself of others, that the researcher has a duty of care to report this to an appropriate person/agency.	
12. I understand that I will need to appoint a trusted contact (family member, friend, neighbour, colleague, etc.) who will notify the University of Portsmouth Dental Academy if lose the capacity to give my continued consent to participate in this study during the duration of the study.	
13. I understand that should I disclose any concerns with regard to my own, or others' professional practice in the course of the survey, the researcher might be duty bound to refer the matter to relevant agencies.	
14. I agree to take part in the above study.	

Name of Participant:

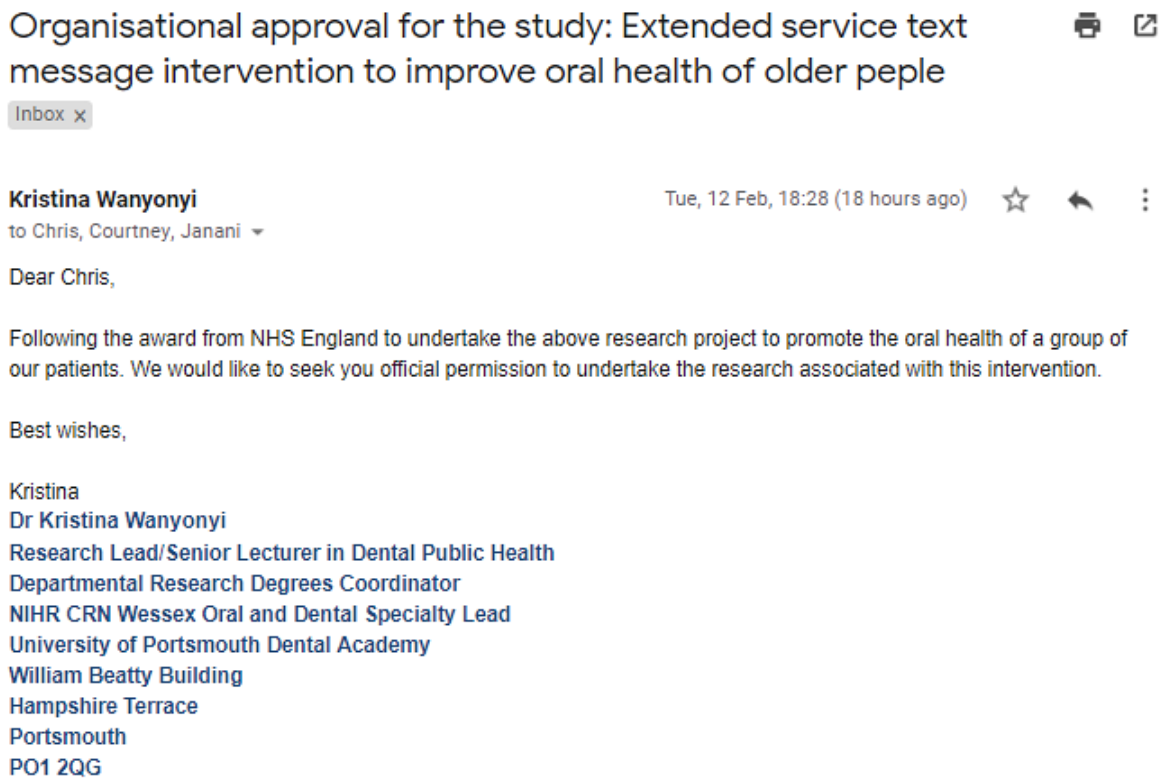
Date: **Signature:**

Name of Person taking Consent:

Date: **Signature:**

(1 copy for participants, 1 copy for researchers)

Appendix 4: Organisational Approval from Director of UPDA



Organisational approval for the study: Extended service text message intervention to improve oral health of older peple

Inbox ×

Kristina Wanyonyi Tue, 12 Feb, 18:28 (18 hours ago)

to Chris, Courtney, Janani

Dear Chris,

Following the award from NHS England to undertake the above research project to promote the oral health of a group of our patients. We would like to seek you official permission to undertake the research associated with this intervention.

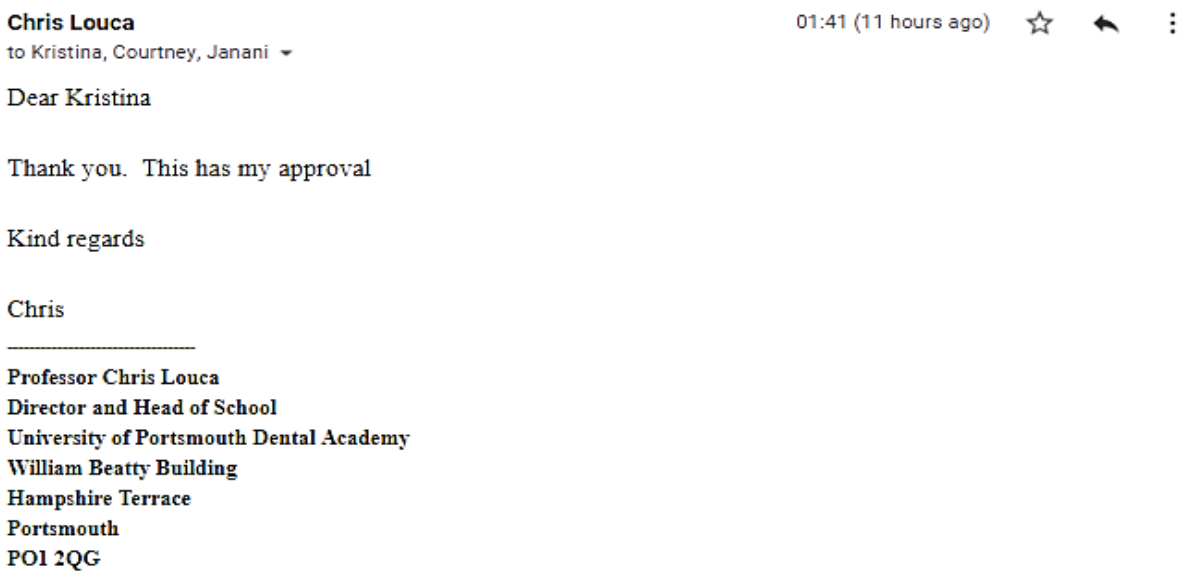
Best wishes,

Kristina
Dr Kristina Wanyonyi
Research Lead/Senior Lecturer in Dental Public Health
Departmental Research Degrees Coordinator
NIHR CRN Wessex Oral and Dental Specialty Lead
University of Portsmouth Dental Academy
William Beatty Building
Hampshire Terrace
Portsmouth
PO1 2QG

Appendix 5: Overview of Dental Health Information Themes Encompassed in Study for Both Text Messages and in Leaflet

List of Principal Themes

- Tooth-brushing and plaque control
- Flossing and interdental cleaning
- Fluoride use
- Reducing sugar intake
- Identifying sugar-free medicines
- Periodontal disease prevention
- Smoking cessation and alcohol misuse
- Xerostomia (dry mouth)
- Denture care
- Dental Attendance



Chris Louca 01:41 (11 hours ago)
to Kristina, Courtney, Janani

Dear Kristina

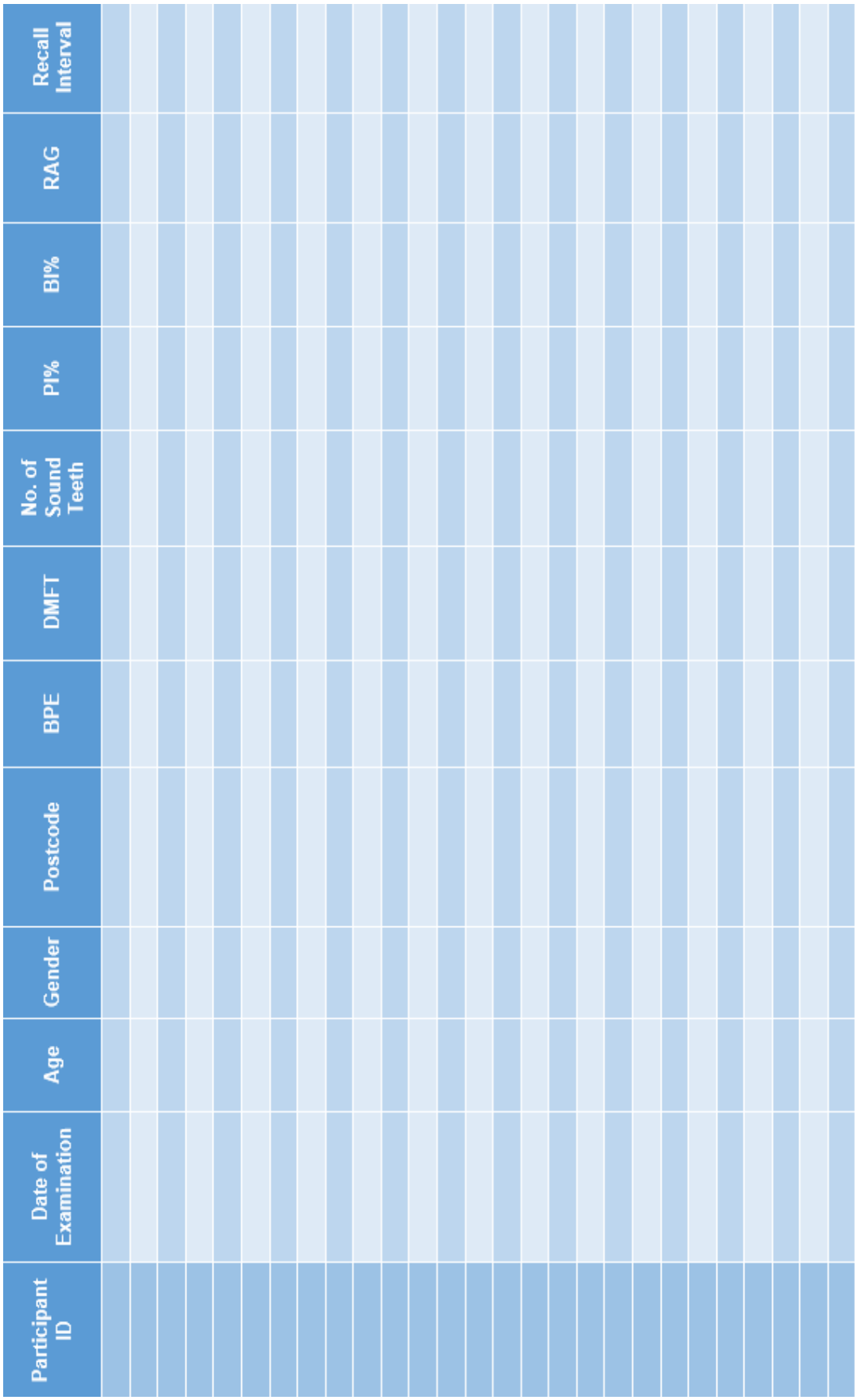
Thank you. This has my approval

Kind regards

Chris

Professor Chris Louca
Director and Head of School
University of Portsmouth Dental Academy
William Beatty Building
Hampshire Terrace
Portsmouth
PO1 2QG

Appendix 7: Overview of 2-way text to be received by participants from the TMI-arm of the study, 6-months after each initial study start date



UDPA: *How helpful did you find these texts? Please rate 1 to 5. 1 = strongly disagree, 2 = disagree, 3 = somewhat agree, 4 = agree, and 5 = strongly agree.*

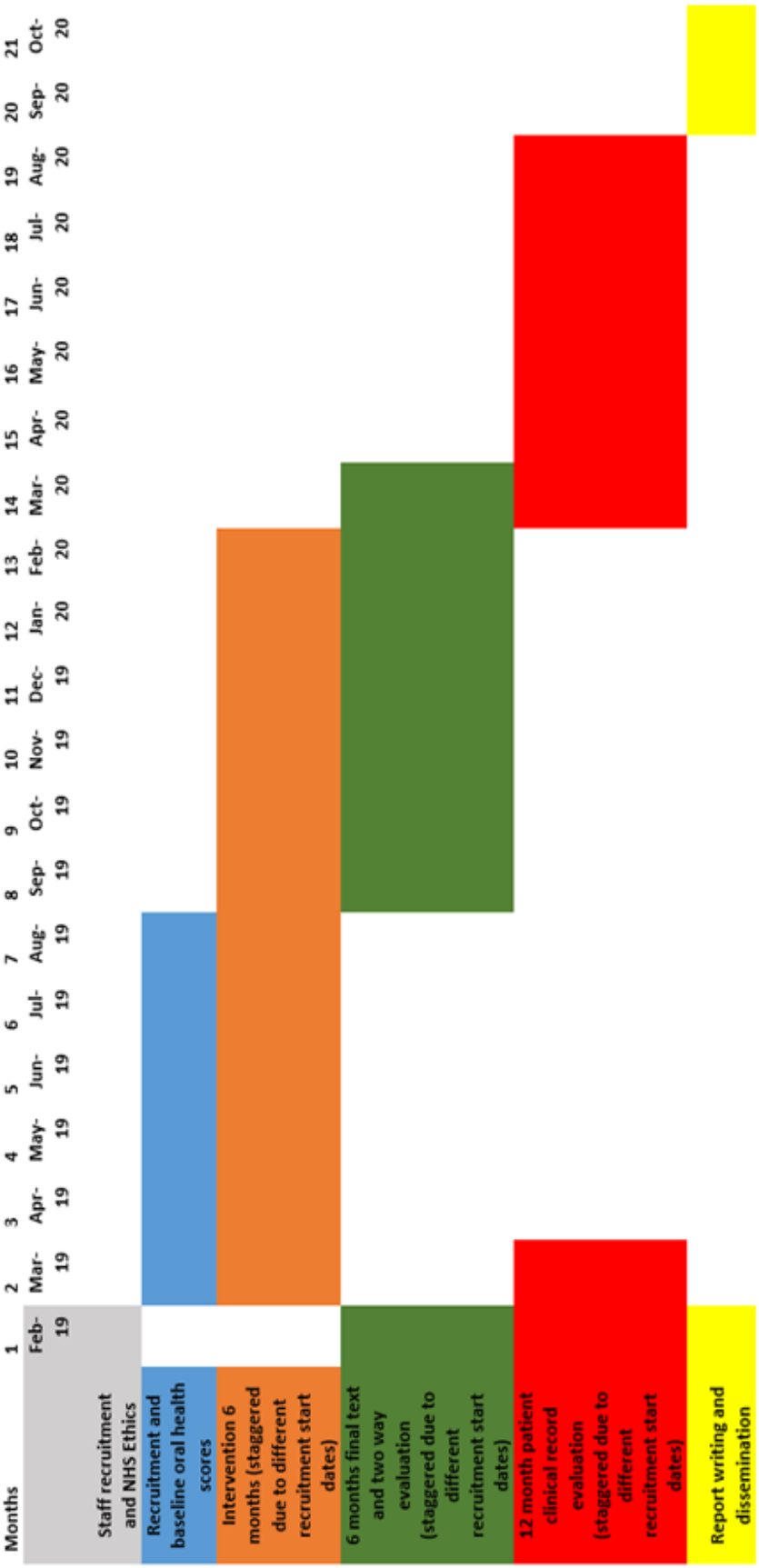
Patient: **Number rating**

UDPA: *If you have anything else to tell us, please respond to this message with*

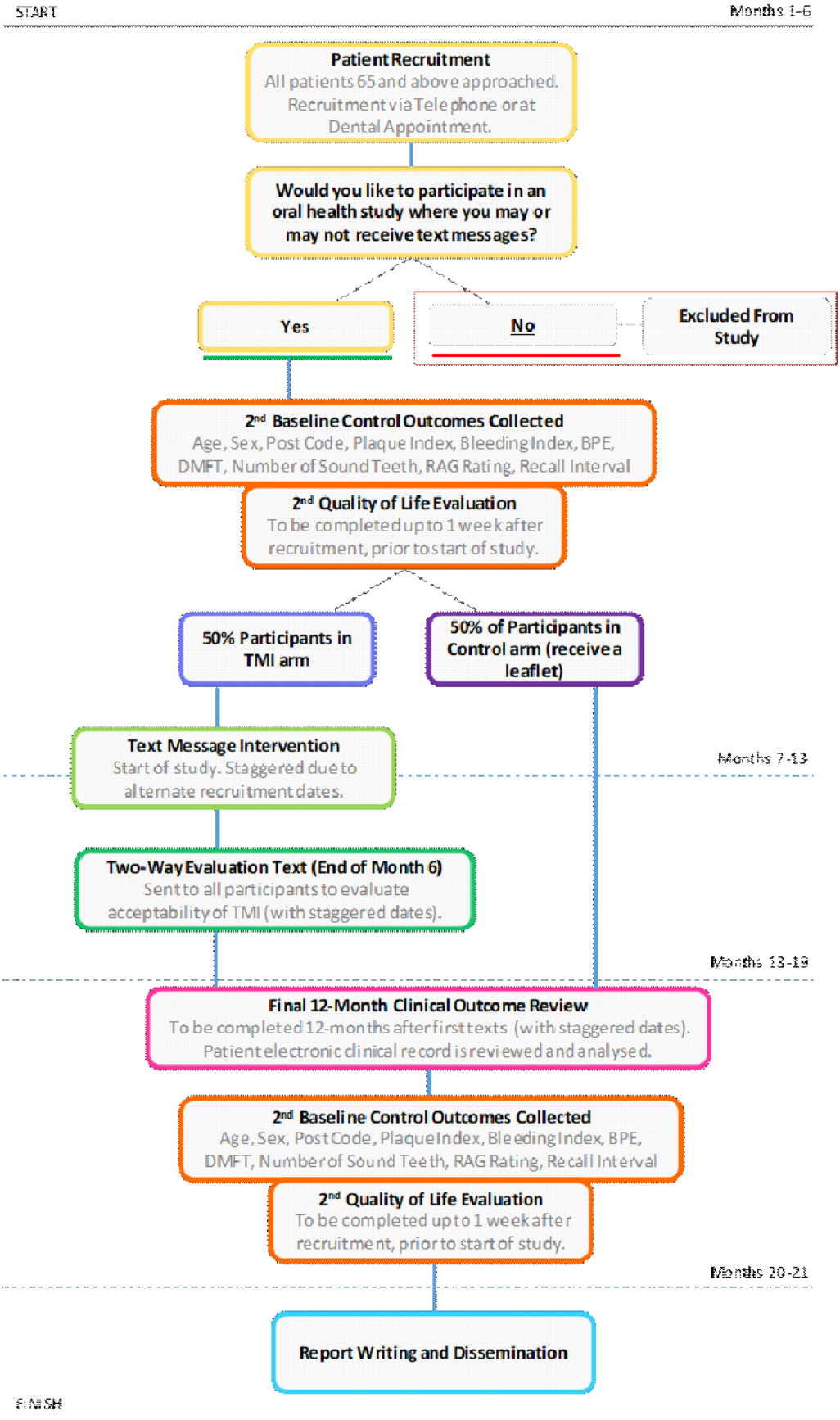
your thoughts, advice or queries. Thank you.

Patient: **Optional response**

Appendix 8: Gantt Chart Project Timeline



Appendix 9: Project Methodology Flow Chart



Appendix 10: Quality of Life Evaluation: Oral Health Impact Profile 14 Questionnaire

(Rated 1-5, using the Likert scoring. 1 = strongly disagree, 2 = disagree, 3 = somewhat agree, 4 = agree, and 5 = strongly agree. Lowest scores will associate with a lower quality of oral health.) **Secondary Outcome.**

Functional limitation:

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?

Pain and discomfort:

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?

Psychological impacts:

5. Have you been self-conscious because of your teeth, mouth or dentures?
6. Have you felt tense because of problems with your teeth, mouth or dentures?
7. Have you found it difficult to relax because of problems with your teeth, mouth or dentures?
8. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?
9. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?

Behavioural impacts:

10. Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?
11. Have you had to interrupt meals because of problems with your teeth, mouth or dentures?
12. Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?

13. Have you had difficulty doing your usual jobs 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?

Appendix 11: Quality of Life Evaluation: General Health Questionnaire 12

(Rated 1-5. 1= strongly disagree, 2 = disagree, 3 = somewhat agree, 4 = agree, and 5 = strongly agree. Lowest scores will associate with a lower quality of oral health.) **Secondary Outcome.**

1. Have you been able to concentrate on whatever you are doing?
2. Have you lost much sleep over worry?
3. Have you felt that you were playing a useful role in things?
4. Have you felt capable of making decisions about things?
5. Have you felt constantly under strain?
6. Have you felt that you could not overcome your difficulties?
7. Have you been able to enjoy your normal day-to-day activities?
8. Have you been able to face up to your problems?
9. Have you been feeling unhappy and depressed?
10. Have you been losing confidence in yourself?
11. Have you been thinking of yourself as worthless?
12. Have you been feeling reasonably happy, all things considered?