InteRventions to rEduce inequaliTies in the Uptake of Routine deNtal care (RETURN main trial)

Trial registration No: ISRCTN 84666712

Statistical Analysis Plan

Version 2.0 28/06/2024

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1 Approval and Agreement

SAP Version Number being approved: 2.0

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Date 28 Jun 2024

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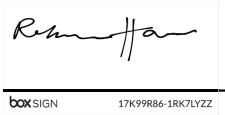
Signed* 

Date 28 Jun 2024

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3 Glossary

A&E	Accident and Emergency
NHS BSA/ BSA	NHS Business Services authority

CI	Confidence interval
CRF	Case report form
CTU	Clinical trials unit
IDSMC	Independent Data and Safety Monitoring Committee
IMD	Indices of multiple deprivation
Q1	Lower quartile
Q3	Upper quartile
LCTC	Liverpool Clinical Trails Centre
MDAS	Modified Dental Anxiety Scale
OHIP	Oral Heath Impact Profile
PMG	Project Management Group
PMT	Protection Motivation Theory
PSC	Project Steering Committee
RAE	Related adverse event
SAE	Serious adverse event
SAP	Statistical analysis plan
SOP	Standard operating procedure
SD	Standard deviation
SE	Standard error
TMF	Trial master file
TMG	Trail Management Group

4 Roles and Responsibilities

Name	Affiliation	Role
Ashley Best (AB)	Liverpool Clinical Trials Centre (LCTC), University of Liverpool	Trial Statistician
Jessica Green (JG)	Liverpool Clinical Trials Centre (LCTC), University of Liverpool	Trial Statistician
Dr Girvan Burnside (GB)	Liverpool Clinical Trials Centre (LCTC), University of Liverpool	Senior Statistician
Professor Rebecca Harris (RH)	Professor of Dental Public Health, University of Liverpool	Chief Investigator

GB, AB and JG proposed the statistical analysis plan. AB and JG drafted the statistical analysis plan. GB and RH read, amended and approved the statistical analysis plan.

5 Statement of Compliance

This Statistical Analysis Plan (SAP) provides a detailed and comprehensive description of the pre-planned analyses for the trial "RETURN (main) trial". The planned statistical analyses described within this document are compliant with those specified in brief within the RETURN protocol v5.0 12/09/2022.

The purpose of the plan is to:

a. Ensure that all analyses are appropriate for the aims of the trial, reflect good statistical practice, and minimise bias by preventing inappropriate post hoc analyses.
b. Ensure that the analyses performed are consistent with the conditions of the protocol.
c. Explain in detail how the data will be handled, covariates derived and analysed to enable the analysis to be replicated, if necessary.

This trial is carried out in accordance with the World Medical Association Declaration of Helsinki (1964) and the Tokyo (1975), Venice (1983), Hong Kong (1989) and South Africa (1996) amendments and will be conducted in compliance with the protocol, Liverpool Clinical Trials Centre (LCTC) Standard Operating Procedures (SOPs) and EU Directive 2001/20/EC, transposed into UK law as the UK Statutory Instrument 2004 No 1031: Medicines for Human Use (Clinical Trials) Regulations 2004.

6 Introduction

The independent oversight committee reports will be presented to the Project Steering Committee (PSC). The PSC will remain blinded, and any safety or efficacy data for interim reports will be presented overall only. An IDSMC will not be convened unless this is specifically requested by the PSC.

The results of the final analysis described within this statistical analysis plan will be contained within a statistical analysis report. This report will be used as the basis for the primary research publications according to the trial publication plan. Where analyses are presented, which are not included in this statistical analysis plan, justification as to their inclusion must be provided.

All analyses will be performed with standard statistical software. The finalised analysis data sets, programs and outputs will be archived following Good Clinical Practice guidelines and SOP GE018 Archiving Procedures in LCTC.

7 Background and Rationale

Dental diseases are among the most common chronic diseases worldwide, and the costs of these diseases amount to an estimated $356.80 billion in treatment expenditures and $187.61 billion in productivity losses (Righolt, et al., 2018) [1]. A large body of evidence shows that dental attendance is linked to better oral health [2][3][4][5].

Long-term consistent dental attendance is associated with better oral health compared to patients who do not visit a dentist at present but used to do so, and patients who never regularly attended dental care services [4][5][6]. Patients who attend the dentist regularly, mostly do so for planned visits, for example check-ups. These have been shown to be more beneficial for oral health than problem-based visits. The benefit of dental attendance for check-ups is not related to a specific recall time interval for all patients [7].

People with more irregular attendance patterns often wait until there is a problem. Examples of such problems are toothache and swelling. Such acute dental problems lead to pain, often over a period of several weeks [8]. Patients who experience acute dental problems often seek care in emergency dental services, or in general and emergency medical services. Such emergency service visits often result in treatment with an antibiotic prescription [9][10].

A brief psychological intervention (the RETURN intervention) has been developed to be delivered to adults attending dental services for emergency care. In order to promote planned dental visiting, and through this to improve oral health and reduce impacts of oral disease such as toothache and use of antibiotics for dental problems, the psychological intervention uses multiple behaviour change techniques.

The RETURN trial will recruit urgent dental care users to a randomised controlled trial across three types of urgent care settings: a dental hospital, in-hours urgent care and out-of-hours urgent care, over a period of 12 months, following up these patients up for a period of 18 months.

8 Objectives

The overall objective of this trial is to assess the effectiveness and cost-effectiveness of the RETURN intervention for urgent dental care service users and to explore whether the RETURN intervention has different effects across the socio-economic gradient. Full details of the specific primary and secondary objectives for the trial can be found in the "Objectives" section of the RETURN protocol.

9 Trial Design

9.1 Overall Trial Design

The RETURN main trial is a randomised controlled open trial to develop and test a way to improve the routine use of dental services by deprived populations, by delivering a psychological intervention personalised to participants to address the significant barriers to attending regular dental appointments and to encourage behavioural changes.

9.2 Blinding

RETURN is an open trial and as such the participants, investigators, LCTC trial team and site staff involved in the delivery of the intervention are not blind to allocations. This statistical analysis plan has been written prior to the trial statistics team having access to unblinded data.

10 Consent Process

Following pre-screening, consent will be sought from potentially eligible patients. Discussion of objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted are to be provided by RETURN trained staff, who are delegated and qualified to do so. Further details on the consent process for the trial are listed in the "Informed Consent" section of the RETURN protocol.

11 Study Population

11.1 Inclusion Criteria

The inclusion criteria for the trial are listed in the "Inclusion Criteria" section of the RETURN protocol.

11.2 Exclusion Criteria

The exclusion criteria for the trial are listed in the "Exclusion Criteria" section of the RETURN protocol.

11.3 Removal of Participants from Intervention or Follow-up

Participants may discontinue the intervention for reasons including, but not limited to:

- Participant-led, i.e. request by participant.
- Insufficient time to complete intervention.
- Any chance in the participants condition that justifies discontinuation of the intervention in the opinion of the person providing the intervention, the PI, or the participant.

Discontinuation from trial intervention does not mean discontinuation of the trial altogether, and the remaining trial procedures, follow up assessment/ visits and data collection should be completed as indicated in the RETURN protocol (unless consent is specifically withdrawn).

12 Method of Assignment to Intervention

Participants are randomised in a 1:1 ratio via a secure (24-hour) web-based randomisation programme managed centrally by the LCTC. The randomisation is stratified by site and uses block sizes of variable length. Randomisation lists were generated with random variable block sizes and were produced by an independent statistician (who is not otherwise involved with the RETURN trial) at LCTC.

If issues with the web-based randomisation system occur and the issues cannot be resolved promptly (e.g. out of regular office hours), each participating site shall be provided with envelopes with randomised allocations concealed within them. The allocations within the envelopes are from separate randomisation lists to the ones used in the web-based system. However, these lists are generated in the same way. More details can be found in the "Randomisation/ Registration" section of the RETURN protocol.

13 Schedule of Assessments

For the schedule of assessments, see the "Schedule for Assessments and Follow-Up" section of the RETURN protocol.

14 Interventions

Participants will be randomised in a ratio of 1:1 to either the RETURN intervention or control (standard care). Full details of the RETURN intervention and the control group can be found in the "Trial Intervention" section of the RETURN protocol.

15 Listing of Outcomes

15.1 Primary Outcome(s)

- Primary outcome 1: Attendance at a dental practice for a planned care appointment within 12 months, collected from NHS Business service Authority (BSA) data.
- Primary outcome 2: Self-reported oral health quality of life, measured by the value at 12 months of the summary score of OHIP-14.

15.2 Secondary Outcomes

- Secondary outcome 1: Attendance at a dental practice or Dental Hospital for a planned care appointment, self-reported at 6, 12 and 18 months.
- Secondary outcome 2: Attendance at a dental practice for a planned care appointment within 18 months, collected from BSA data.
- Secondary outcome 3: Attempts to make an appointment to see a dentist for planned dental care as measured by patient self-report at 6, 12 and 18 months.
- Secondary outcome 4: Self-reported oral health quality of life, measured by the final value of the summary score of OHIP-14 adjusting for baseline value, at 6 and 18 months.
- Secondary outcome 5: Urgent attendance for dental care at dental practices, A&E, GP practices, or Dental Hospital. Self-reported at 6, 12 and 18 months
- Secondary outcome 6: Halitosis and Bad Taste, measured by patient self-report at 6, 12 and 18 months.
- Secondary outcome 7: Treatment received, as measured by BSA clinical data set, patient self-report and Dental Hospital audit at 6, 12 and 18 months.
- Secondary outcome 8: Antibiotic prescription by dentists, measured by BSA data, Dental Hospital audit and self-report at 6, 12 and 18 months

- Secondary outcome 9: Antibiotic prescription for dental problems by GP/A&E/walk-in-centre measured by patient self-report at 6, 12 and 18 months
- Secondary outcome 10: Analgesic prescription for dental problems, measured by patient self-report at 6, 12 and 18 months.
- Secondary outcome 11 (safety): Dental anxiety, as measured by the Modified Dental Anxiety Scale recorded by patient self-report at 6, 12 and 18 months.
- Secondary outcome 12: Incremental cost-effectiveness ratio at 12 and 18 months derived from BSA data, patient self-report resource use and EQ-5D-5L at baseline, 6, 12 and 18 months.
- Secondary outcome 13: Attendance at a dental practice or Dental Hospital for a planned care appointment within 18 months, collected in BSA data and Dental Hospital audit.
- Secondary outcome 14: Self-reported belief to using planned dental services measured using Protection Motivation Theory questionnaire (as a mediator).

16 Sample Size Calculation

The sample size calculation can be found in the "Sample Size" section of the RETURN protocol.

17 Study Framework

The first primary objective is to assess if there is a difference between the RETURN intervention group and control group (2-sided test) in the uptake of planned dental care at a dental practice within 12 months (52 weeks), as measured by routinely collected dental data (NHS BSA data). The second primary objective is to assess if there is a difference between the RETURN intervention group and control group (2-sided test) in the OHIP-14 questionnaire scores measured at 12 months (52 weeks).

18 Timing and Objectives of Analyses

18.1 Interim Reporting

18.1.1 Reports to Independent Oversight Committees

The PSC will first meet after 2 months of recruitment to assess the stop/ go criteria identified a priori in an internal pilot plan. The PSC will also meet at least once annually, and more frequently if judged necessary (see "RETURN PSC Terms of Reference_V1.0 07 Jan 19.doc", in the trial master file (TMF)).

18.1.2 Assessments of Progression Criteria

All progression criteria will be assessed by the PSC 2 months after the first site is open to recruitment. The progression criteria are given below. More information can be found in the "Internal Pilot" section of the RETURN protocol.

Objective	Outcome Measure	Stop/Go criteria	Improvement Strategy
To identify if practice recruitment and site opening rates are achievable (including the opening of the dental hospital as a site)	Number of sites opened, per month (including the dental hospital)	Number of sites opened is 6 or above after 2 months (including the dental hospital)	Proceed to main phase of trial
		Number of sites opened is between 4 and 5 after 2 months (including the dental hospital)	Explore methods for enhancing practice recruitment and additional support opening sites
		Number of sites opened is below 4 after 2 months	Consider delaying trial until dental services have more capacity
To identify if recruitment rates are achievable across sites and site types	Number of patients recruited across sites, per month	Total recruitment is at least 33 after 2 months (≥100% of expected recruitment)	Proceed to main phase of trial
		Total recruitment is between 26 – 32 after 2 months (80%-99% of expected recruitment)	Explore methods for enhancing recruitment within the sites
		Total recruitment is below 26 after 2 months (<80% of expected recruitment)	Increase number of sites projected to deliver the trial
To determine whether the multi-faceted approach to training is successful	Proportion of staff members at each site that achieve competency sign off from all elements of training (online GCP, intervention training (assessed via role play), one day 'on the job' support)	100% of minimum staff required who undertake training at each site achieve sign off	Proceed to main phase of trial
		80% - 99% of minimum staff	Further training is delivered, concentrating

		required who undertake training at each site achieve sign off	on ensuring that all providers are up to the same standard
		< 80% of minimum staff required at each site achieve sign off	Review of training package, making changes to improve training standards
To determine fidelity of intervention delivery.	Observations and / or independently rated audio recordings of intervention delivery sessions to determine % allocated patients who at least some of the intervention materials	100% allocated participants engaged with the intervention	Proceed to main phase of trial
		80% - 99% allocated participants engaged with intervention	Booster training sessions for dental nurses delivering the intervention
		<80% allocated participants engaged with intervention	Re-training of dental nurses, further in-practice support provided by the research team

18.1.3 Formal Interim Analyses

No formal interim analyses are planned.

18.2 Final Analysis

The final analysis will take place at the end of the trial, which is defined (in the "End of Trial" section of the RETURN protocol), to be the date on which the data for all participants is locked and data entry privileges are withdrawn from the trial database. An extract of the NHS BSA data will be provided after all participants have completed 12 months (52 weeks) of follow up. This will aid in the preparation of analysis code before receiving the 18-month (78 weeks) data. The final analysis will be conducted on the 18-month data.

19 Disposition of Participants

A CONSORT flow diagram (http://www.consort-statement.org/consort-statement/flow-diagram) will be used to summarise the number of patients who were:

- Screened,
- Screened but not randomised*,
- Received the randomised allocation,
- Did not receive the randomised allocation,

- Lost to follow-up,
- Withdrew from follow-up,
- Randomised and included in the primary analysis for each primary outcome,
- Randomised and excluded from the primary analysis for each primary outcome.

* This will be further broken down into those that were ineligible at pre-screening, those that did not provide consent, those that were confirmed ineligible after consent was obtained and those that were confirmed eligible but were not randomised.

19.1 Screening, Eligibility and Recruitment

Pre-screening and screening logs will be summarised by site in a table detailing:

i. The number of patients who were pre-screened for potential eligibility,
ii. Those who were not eligible at pre-screening, expressed as a frequency and a percentage with the denominator being all patients assessed for potential eligibility (i),
iii. Those who were potentially eligible at pre-screening, expressed as a frequency and a percentage with the denominator being all patients assessed for potential eligibility (i),
iv. Those who were eligible at pre-screening and approached for consent but consent was not obtained, expressed as a frequency and a percentage with the denominator being all potentially eligible patients from pre-screening (ii),
v. Those who were eligible at pre-screening and approached for consent and the consent was obtained, expressed as a frequency and a percentage with the denominator being all potentially eligible patients from pre-screening (ii),
vi. Those who provided consent but did not meet the eligibility criteria at screening, expressed as a frequency and a percentage with the denominator being all patients who provided consent (iv),
vii. Those who provided consent and met the eligibility criteria at screening[1], expressed as a frequency and a percentage with the denominator being all patients who provided consent (iv),
viii. Those who were consented and confirmed eligible but not randomised, expressed as a frequency and a percentage with the denominator being all patients that were confirmed as eligible (vi),

[1] As some of the eligibility details are not questions routinely asked in dental care, they cannot be confirmed until after consent is obtained.

ix. Those who were consented, confirmed eligible and randomised, expressed as a frequency and a percentage with the denominator being all patients that provided consent (iv).

Reasons for ineligibility (both at pre-screening and after full screening) will be summarised overall in a table with the following categories:

- Under 18[2],
- Has visited an NHS or Private dentist for a non-emergency (i.e. when not in pain/ symptom free) in last 2 years[2],
- Not able to provide a telephone number, email or postal address for follow-up,
- Does not adequately understand written/ spoken English[2],
- Not responsible for making own dental appointments (i.e. done by carer),
- Has previously been enrolled in the RETURN programme (feasibility or main trial),
- Lives with or is related to somebody participating in the RETURN programme (feasibility or main trial).

Frequencies will be presented along with percentages using all ineligible patients at both pre-screening and full screening (ii + vii) as the denominator.

Reasons for declining consent will be summarised overall in a table with the following categories:

- Does not wish to take part in research,
- Unwilling to provide a reason,
- Other reason[3] (provided as free text),
- No reason provided.

Frequencies will be presented along with percentages using all patients where consent was not obtained (iv) as the denominator.

Reasons for patients who provided consent and were not randomised will be summarised overall in a table (provided as free text). These will be grouped into similar terms and the grouped reasons will be reported. Frequencies will be presented along with percentages using all patients where consent was obtained but randomisation did not occur (viii) as the denominator.

A recruitment summary table will be presented showing the following for each site: site code, site name, dates site opened/closed to recruitment, dates of first/last randomisation and the total number

[2] Can be confirmed at pre-screening.
[3] These will be grouped into similar terms and the grouped reasons will be reported.

of participants randomised. A recruitment graph showing the expected and actual number of sites opened and the expected and actual number of participants randomised per month will be displayed.

19.2 Post Randomisation Discontinuations

The nature of the intervention means that the intervention is delivered at one time point only. As such, discontinuation from trial intervention is not applicable for RETURN. The total number of participants lost to follow-up will be reported and any available reasons provided in the CONSORT diagram. Withdrawals of consent from follow-up will be recorded and presented as line listings detailing treatment, time from randomisation to withdrawal, the reason for withdrawal, who made the decision to withdraw the participant and any further information pertinent to the withdrawal.

20 Protocol Deviations

Protocol deviations are defined in the RETURN main trial monitoring plan (V2.0 11/09/2023) and specified as minor or major. For final analyses the number of participants experiencing each protocol deviation will be presented split by allocation group, along with the number of participants with at least: one minor deviation, one major deviation and one deviation of either classification. No formal statistical testing will be conducted.

21 Unblinding

Reporting of unblinding is not applicable for RETURN as it is an open label trial.

22 Analysis Datasets

22.1 Efficacy Analyses

The principle of intention-to-treat, as far as practically possible, will be the main strategy of analysis adopted for the primary and secondary outcomes. These analyses will be conducted on all randomised participants, in the group to which they were allocated, and for whom the outcome(s) of interest have been observed/measured. No imputations will be made for the first primary outcome and most of the secondary outcomes. For the second primary outcome and first and third secondary outcomes, sensitivity analyses will be performed using multiple imputation.

The membership of the analysis set for each outcome will be determined and documented and reasons for participant exclusion will be given prior to the blind being broken and the randomisation lists being requested. Reasons may include missing data and loss to follow-up.

22.2 Safety Analyses

The safety analysis data set will contain all participants who were randomised into the trial. They will be reported in the group of the intervention they actually received, regardless of whether they were randomised to receive that intervention. Adverse events will be reported from randomisation until the end of follow-up (maximum follow-up time 18 months +4 weeks).

23 Baseline Characteristics

Descriptive statistics will be reported split by treatment group. Categorical data will be summarised by counts and percentages. Continuous data will be summarised by mean, standard deviation (SD), median, interquartile range (IQR) and range. Percentages will be reported to one decimal place and continuous summaries will be presented to one decimal place or one significant figure. Variables to be included in the table are as follows:

Variable	**CRF**
Number randomised	CRF Tracker
Demographic details	
Sex (Male, Female, Prefer not to say)	Baseline
Age (**Years:** Continuous)	
Age (**Years:** 18 to 24, 25 to 34, 35 to 44, 45 to 54, 55 to 64, 65 to 74, 75 to 84, 85 years or above)	
Ethnicity (**White**: • English/Welsh/Scottish/Northern Irish/British • Irish • Gypsy or Irish Traveller • Any other white background **Mixed/ Multiple ethnic groups**: • White and Black Caribbean • White and Black African • White and Asian • Any other Mixed/Multiple ethnic background **Asian or Asian British:** • Indian • Pakistani	Participant first questionnaire booklet (section 1)

• Bangladeshi • Chinese • Any other Asian background **Black/ African/ Caribbean/ Black British**: • African • Caribbean • Any other Black/African/Caribbean background **Other ethnic group:** • Arab • Other ethnic group: Any other ethnic group)	
Socio-economic information	
Education level – highest level (No formal qualifications, GCSEs / O Levels (any grade)/ NVQ Level 1 or similar, 5+ GCSEs (A*-C)/O Levels (passes)/ NVQ Level 2 or similar, 2+ A Levels/ NVQ Level 3 or similar, Undergraduate degree (BA, BSc etc.), Postgraduate degree or similar (PGCE, MA, PhD etc.))	Participant first questionnaire booklet (section 1)
Employment status (Employed full time (30 hours a week or more), Employed part-time (less than 30 hours a week), Not currently employed, Prefer not to say)	
Reason for not working (Currently looking for paid work, Not currently looking for paid work, Student, Retired, Unable to work due to disability, Other)	
Benefit status (Yes, No, Prefer not to say)	
Indices of multiple deprivation (IMD) (1 – most deprived, 2, 3, 4, 5, 6, 7, 8, 9, 10 – least deprived)	BSA data and/or postcode data
Clinical findings	
Antibiotics prescribed for dental problems within the last six months (Yes from GP, Yes from another centre (e.g. A&E, walk-in-centre), Yes from dentist, No)	Participant first questionnaire booklet (section 2)
Pain killers for dental problems within the last six months (Yes, No)	
Were the pain killers prescribed (Yes, No)	

24 Compliance with Interventions

If any participants did not receive their allocated intervention, a line listing of reasons will be provided. Additionally, the number and percentage of participants who were assessed to have engaged with the intervention will be reported and will be further broken down by the reasons for not engaging. The denominator will be all participants randomised to the intervention group. No formal statistical testing will be undertaken.

25 Analysis of Outcomes

25.1 Interim Reporting

25.1.1 For Reports to Independent Oversight Committees

For meetings when there will be no assessment of progression criteria, the following information will be presented overall[4]:

- Screening and recruitment data (see Disposition of Participants),
- Baseline characteristics (excluding IMD),
- Details of **major** protocol deviations,
- Details of any withdrawals from the trial,
- Reasons for not receiving allocated intervention,
- Primary outcome completion (OHIP-14 only):
    1. Rates of return and completion – detailing the number expected, the number actually returned and the number completed to a standard that they are analysable,
    2. Number of missing items,
- Secondary outcome questionnaires return and completion rates for each follow-up time point. Detailing the number expected[5], the number actually returned and the number completed to a standard that they are analysable for the following secondary outcomes:
    1. OHIP-14 (other time points),
    2. Halitosis and Bad Taste,
    3. MDAS,

[4] The PSC are to remain blinded so will only see information presented overall. If the PSC decide that it is necessary for an IDSMC to be convened then the same summaries will be presented there but will also be presented by treatment group in a closed report.
[5] Expected will be defined as the scheduled follow-up time point + 4 weeks.

4. Protection Motivation Theory (completed twice at baseline - before allocation is provided and after being shown the thank you video),

- Any reported safety data.

25.1.2 Assessment of Progression Criteria

The first PSC committee report will include details of the progression criteria (full details in the RETURN protocol). These progression criteria are:

- Practice recruitment rates,
- Participant recruitment rates,
- Delivery of training,
- Fidelity of intervention delivery.

Practice recruitment rates

The number of sites open to recruitment will be reported after 2 months. This will be based on how many sites have completed the study greenlight checklist (information provided by the Trial Co-ordinator).

Participant recruitment rates

The total number of recruited participants will be reported after 2 months.

Delivery of training

The proportion of staff members at each site that achieve competency sign off from all elements of training will be reported (information provided by the RETURN team member responsible for staff training).

Fidelity of intervention delivery

The proportion of participants who were assessed to have engaged with the intervention will be reported after 2 months.

25.1.3 Formal Interim Analysis

There is no planned formal interim analysis.

25.2 Final Analysis

25.2.1 Levels of Significance and Multiplicity

To allow for joint primary outcomes, the type I error rate will be controlled by setting α=0.025. Therefore, confidence intervals (CI) will be presented at 97.5% for both of the primary outcomes. No other adjustments will be made for multiplicity. Secondary outcomes will be reported at the 95% confidence level.

All p-values will be reported to three decimal places or one significant figure if p<0.001. Percentages will be reported to one decimal place throughout; mean, median, SD, Q1 and Q3 will be presented to one decimal place or one significant figure; all other values will be presented to two decimal places or one significant figure.

For the purpose of measuring time points, 6 months=26 weeks, 12 months=52 weeks and 18 months=78 weeks.

25.2.2 Primary Outcomes

25.2.2.1 Primary Outcome 1 - Attendance for Planned Care within 12-months (BSA)

This outcome aims to identify whether there is a difference in attendance at a dental practice for a planned care appointment within 12 months (as measured by BSA data), between intervention and control groups.

25.2.2.1.1 Derivation

For all randomised participants, a binary variable will be derived from the BSA data. This variable will identify whether or not participants have a matched, non-urgent dental appointment within 12 months of randomisation (1=attended for a planned care appointment, 0=did not attend for a planned care appointment).

Non-urgent appointments are identified in the BSA data where the treatment charge band field is either band 1, 2 (including bands 2a, 2b and 2c) or 3. All participants with a record that is not urgent and is within 12 months of randomisation, will be deemed to have attended a dental practice for a planned care appointment. Participants that have only urgent care appointment(s) (including a post randomisation urgent visit) available in the BSA data, will not be considered as having attended a dental practice for a planned care appointment. The binary variable for dental attendance will only be

derived for participants who have a matching baseline BSA record or were randomised at the dental hospital.

25.2.2.1.2 Analysis

The number and percentage of participants found to have a planned dental appointment within 12 months (as defined above) will be reported for each treatment group separately. The denominator will be the number of participants randomised to each treatment group.

A comparison between groups will be done using logistic regression, adjusted for the stratification factor site as a random effect (random intercept only). The derived binary variable for attendance for a planned care appointment within 12 months will be the dependent variable. The odds ratio and corresponding 97.5% confidence interval will be reported along with the p-value.

A sensitivity analysis will be conducted that includes all participants. Participants who do not have a matched BSA record at follow-up, will be assumed to have not attended for planned care within 12 months.

The BSA data will contain two matching indicators:

(1) Matching postcode flag - indicates if the postcode on the claim matches any of those associated with the patient.
(2) Cheshire and Merseyside postcode flag - indicates if the postcode on the claim is one of the 35k postcodes associated with Cheshire & Merseyside.

Four additional sensitivity analyses will be performed using these flags:

(1) Only follow-up appointments with the matching postcode flag will be included in this analysis. Participants who do not have a BSA record at follow-up with the matching postcode flag will be assumed to have not attended for planned care within 12 months.
(2) Only follow-up appointments with the matching postcode flag will be included in this analysis. Participants who did not have a BSA record at baseline with the matching postcode flag will be excluded from the analysis. Participants who were randomised at the Dental Hospital will still be included.
(3) Only follow-up appointments with the matching postcode flag and/or Cheshire and Merseyside postcode flag will be included in this analysis. Participants who do not have a BSA record at follow-up with the matching postcode flag and/or Cheshire and Merseyside postcode flag will be assumed to have not attended for planned care within 12 months.

(4) Only follow-up appointments with the matching postcode flag and/or Cheshire and Merseyside postcode flag will be included in this analysis. Participants who did not have a BSA record at baseline with the matching postcode flag and/or Cheshire and Merseyside postcode flag will be excluded from the analysis. Participants who were randomised at the Dental Hospital will still be included.

A further analysis of the first primary outcome (using logistic regression) will also adjust for the following baseline covariates:

- Education level dichotomised as follows:
    - GCSE or below - No formal qualifications; GCSEs / O Levels (any grade)/ NVQ Level 1 or similar; 5+ GCSEs (A*-C)/O Levels (passes)/ NVQ Level 2 or similar.
    - Above GCSE - 2+A Levels/ NVQ Level 3 or similar; Undergraduate degree; Postgraduate degree or similar.

  "GCSE or below" will be the reference category[6],
- Indices of multiple deprivation (IMD) ("1 – most deprived" will be the reference category[6]),
- Benefit status dichotomised as Yes/ No. Participants who answered "Prefer not to say" will be classed as missing. "Yes" will be the reference category[6].
- Modified dental anxiety scale (MDAS).

To determine if there is an association between the baseline covariates of education level, benefit status and IMD, chi-square tests of independence will be performed. If one or more of the cell counts is less than 5, Fisher's exact tests will be used instead. If it is found that there is a statistically significant association between them, one or more of education level, IMD or benefit status will be removed. The variable(s) removed from the model will be the variable(s) who's exclusion results in a better fitting model.

The coefficients (and 97.5% confidence intervals) from the model will be presented. Additionally, a single p-value will be presented for the treatment effect, along with the odds ratio and corresponding 97.5% confidence interval.

25.2.2.2 Primary Outcome 2 - OHIP-14 Scores at 12 months (self-report)

This outcome aims to identify whether there is a difference in oral health quality of life (as measured by the value at 12 months of the summary score of the short form OHIP-14 questionnaire), between

[6] If there are too few participants in the reference category, the reference category may be changed.

intervention and control groups. This is a patient reported outcome and is completed at baseline and then at 6-, 12- and 18-months post randomisation (though only the 12-month time point will be used for this primary outcome).

25.2.2.2.1 Derivation

The OHIP-14 consists of 14 questions and each question is assessed on a 5-point Likert scale: 0=Never, 1=Hardly ever, 2=Occasionally, 3=Fairly often and 4=Very often.

The OHIP-14 summary score is calculated by summing the ordinal values for the 14 items [11]. If one or two items are missing, the missing values will be estimated using the sample mean computed from the non-missing responses to the same OHIP-14 item for all questionnaires, at that time point. If more than two items are missing, the questionnaire will not be included in the analysis [12].

25.2.2.2.2 Analysis

Histograms and boxplots of the change from baseline in OHIP-14 summary scores will be presented for each treatment group, alongside boxplots of OHIP-14 scores at baseline and 12 months. Summaries of the OHIP-14 scores will be presented for baseline, 12 months and change from baseline, separated by treatment group. The summaries will include mean, SD, median, IQR and range. Summaries will be based on valid questionnaires only - for questionnaires that are not valid, a summary of reasons will be provided.

The OHIP-14 summary scores at 12 months will be analysed using linear regression, adjusting for baseline OHIP-14 summary score and the stratification factor site as a random effect (random intercept only). The coefficients (and 97.5% confidence intervals) from the model will be presented. Additionally, a single p-value will be presented for the treatment effect.

The primary analysis will be a complete case analysis - only participants with valid baseline and 12-month questionnaires will be included in the analysis.

To assess the impact of the timing of the questionnaire, a sensitivity analysis will be conducted including only questionnaires completed in the 4-week time window for 12 months (12 months +/- 4 weeks). For postal questionnaires with missing or incorrect completion dates, e.g. date of births, the date the questionnaire was received by the trial team will be taken to be the completion date.

To assess the impact of missing data, a sensitivity analysis will be conducted. The 12-month OHIP-14 summary scores for patients with missing/invalid questionnaires will be imputed using multiple

imputation. The multiple imputation will be conditional on treatment group, baseline and 6-month OHIP-14 summary scores, education level, IMD, benefit status and baseline MDAS.

A further analysis of the primary outcome (using linear regression) will also adjust for the following baseline covariates:

- Education level dichotomised as follows:
    - GCSE or below - No formal qualifications; GCSEs / O Levels (any grade)/ NVQ Level 1 or similar; 5+ GCSEs (A*-C)/O Levels (passes)/ NVQ Level 2 or similar.
    - Above GCSE - 2+A Levels/ NVQ Level 3 or similar; Undergraduate degree; Postgraduate degree or similar.

  "GCSE or below" will be the reference category[7],
- IMD ("1 – most deprived" will be the reference category[7]),
- Benefit status dichotomised as Yes/ No. Participants who answered "Prefer not to say" will be classed as missing. "Yes" will be the reference category[7].
- MDAS.

To determine if there is an association between the baseline covariates of education level, benefit status and IMD, a chi-square tests of independence will be performed. If one or more of the cell counts is less than 5, Fisher's exact tests will be used instead. If it is found that there is a statistically significant association between them, one or more of education level, IMD or benefit status will be removed from the model. The variable(s) removed from the model will be the variable(s) who's exclusion results in a better fitting model.

The coefficients (and 97.5% confidence intervals) from the model will be presented. Additionally, a single p-value will be presented for the treatment effect.

25.2.3 Secondary Outcomes

25.2.3.1 Secondary Outcome 1 - Attendance for Planned Care at a Dental Practice or Dental Hospital (self-report)

This outcome aims to identify whether there is a difference in attendance at a dental practice or Dental Hospital for planned dental care (self-reported at 6, 12 and 18 months), between the intervention and control groups.

[7] If there are too few participants in the reference category, the reference category may be changed.

25.2.3.1.1 Derivation

At each follow-up time point (6, 12 and 18 months) participants will be asked to recall if they have attended a dentist for a planned (non-urgent) dental appointment in the previous 6 months.

At 6 months this will be derived into a binary variable for attendance for a planned appointment (1=attended a planned appointment within 6 months, 0=did not attend a planned appointment).
At 12 months, the response at 6 months will be combined with the response at 12 months. This will be derived into a binary variable for attendance for a planned appointment within 12 months of randomisation (1=attended a planned appointment (within 6 and/or 12 months), 0=did not attend a planned appointment).

At 18 months, the responses at 6 and 12 months will be combined with the response at 18 months. This will be derived into a binary variable for attendance for a planned appointment within 18 months of randomisation (1=attended a planned appointment (within 6, 12 and/or 18 months), 0=did not attend a planned appointment).

Note: For each time point after 6 months to still be considered as not attending for planned care, before that time point, all previous time points have to be answered. For example, if a participant answered no when asked at 6 and 18 months to recall if they attended a dental appointment in the previous 6 months but they did not answer at 12 months, this would be considered missing. However, if they answered yes at any time point then this is considered as having attended an appointment before that time point and any future follow-ups.

At each time point (6, 12 and 18 months), participants who reported they visited a dentist for a planned (non-urgent) dental appointment will be asked how many times they visited in the previous 6 months. The number of dental visits reported at each time point will be added together to determine the cumulative total number of dental visits per participant at 18 months. Participants will be considered as missing if they did not answer the question “Have you visited a dentist for a planned appointment (not an emergency) in the last six months?” and if they answered yes but did not answer the question “How many times have you visited?”, at any of the time points.

25.2.3.1.2 Analysis

The cumulative total number of dental visits per participant at 18 months will be summarised for each treatment group (anyone attending five or more dental appointments will be grouped together). The denominator for percentages will be the number of participants who answered the question “Have

you visited a dentist for a planned appointment (not an emergency) in the last six months?" and if they answered yes also answered the question "How many times have you visited?", at all of the time points.

For each time point, the number and percentage of participants reporting that they attended for planned dental care prior to that follow-up will be reported for each treatment group. The denominator will be the number of participants who either answered the question, "Have you visited a dentist for a planned appointment (not an emergency) in the last six months?", at that time point and all previous follow-ups or who answered yes at any of the previous follow-ups.

Each time point will be analysed separately in the same way as the first primary outcome (section 25.2.2.1.2). However, the odds ratio and corresponding 95% CI will be reported (instead of a 97.5% CI) along with the p-value. The sensitivity analyses in section 25.2.2.1.2 are only applicable to BSA data so will not be repeated for this outcome, but there will be an additional analysis adjusting for other baseline covariates.

To assess the impact of missing data, sensitivity analyses will be conducted for each timepoint. The binary variable for self-reported dental attendance for participants who it was unable to be derived for will be imputed using multiple imputation. The multiple imputation will be conditional on treatment group, education level, IMD, benefit status and baseline MDAS. For the 12- and 18-month timepoints, it will also be conditional on the answers to the dental attendance question at the previous timepoints.

25.2.3.2 Secondary Outcome 2 - Attendance for Planned Care within 18-months (BSA)

This outcome aims to identify whether there is a difference in attendance at a dental practice for a planned care appointment within 18 months (as measured by BSA data), between the intervention and control groups.

25.2.3.2.1 Derivation

As described in 25.2.2.1.1 but for up to 18 months post randomisation.

25.2.3.2.2 Analysis

Analysis as described in section 25.2.2.1.2. However, the odds ratio and corresponding 95% CI will be reported (instead of a 97.5% CI) along with the p-value. There will also be no sensitivity analyses or analyses adjusting for other baseline covariates.

25.2.3.3 Secondary Outcome 3 - Attempts to Make an Appointment (self-report)

This outcome aims to identify whether there is a difference in attempts to make an appointment to see a dentist for planned dental care (self-reported at 6, 12 and 18 months), between the intervention and control groups.

25.2.3.3.1 Derivation

At each follow-up time point (6, 12 and 18 months), participants will be asked if they visited a dentist for a planned (non-urgent) dental appointment in the last 6 months and if they did not, did they attempt to make an appointment in the previous 6 months. Participants who attempted to make an appointment will be identified as those who reported that they either attended for a planned dental appointment or if not, that they attempted to make an appointment.

At each time point, a binary variable will be created to denote whether attempts were made to make an appointment (1=attempts made, 0=no attempts made). The binary variables at each time point will be determined in the same way as in section 25.2.3.1.1.

25.2.3.3.2 Analysis

At each time point, the number and percentage of participants who reported that they attempted to make an appointment for planned dental care prior to that follow-up will be reported for each treatment group. For each time point, the denominator will be the number of participants who either answered the questions at that time point and all previous follow-ups or who answered yes to either question at any of the previous follow-ups.

Each time point will be analysed separately in the same way as the first primary outcome (section 25.2.2.1.2). However, the odds ratio and corresponding 95% CI will be reported (instead of a 97.5% CI) along with the p-value. The sensitivity analyses in section 25.2.2.1.2 are only applicable to BSA data so will not be repeated for this outcome, but there will be an additional analysis adjusting for other baseline covariates.

To assess the impact of missing data, sensitivity analyses will be conducted for each timepoint. The binary variable for attempts to make an appointment for participants who it was unable to be derived for will be imputed using multiple imputation. The multiple imputation will be conditional on treatment group, education level, IMD, benefit status and baseline MDAS. For the 12- and 18-month timepoints, it will also be conditional on the answers to the dental attendance and attempts to make an appointment questions at the previous timepoints.

25.2.3.4 Secondary Outcome 4 - OHIP-14 Scores at 6 and 18 months (self-report)

This outcome aims to identify whether there is a difference in oral health quality of life at 6 and 18 months (as measured by the values of the OHIP-14 summary scores), between intervention and control groups. This is a patient reported outcome and is completed at baseline and then at 6-, 12- and 18-months post randomisation.

25.2.3.4.1 Derivation

As described in section 25.2.2.2.1.

25.2.3.4.2 Analysis

Summaries of the OHIP-14 scores will be presented at 6 and 18 months, separated by treatment group. The summaries will include mean, SD, median, IQR and range. Summaries will be based on valid questionnaires only - for questionnaires that are not valid, a summary of reasons will be provided.

A repeated measures mixed effects model will be fitted. The dependent variable will be post baseline (6, 12 and 18-month) OHIP-14 scores[8]. Covariates will be baseline OHIP-14, treatment group, time (fitted as a continuous variable), and a time-treatment group interaction. Site will be fitted as a random effect (random intercept only) and the repeated measure will be the participant ID.

For both time points of interest (6 and 18 months), the mean (SE) OHIP-14 score for each treatment group and the mean difference between treatment groups in OHIP-14 scores will be estimated from the model together with a 95% CI. Additionally, a single p-value will be reported testing whether the effect of treatment group is significant over the whole follow-up period.

25.2.3.5 Secondary Outcome 5 - Attendance for Urgent Dental Care (self-report)

This outcome aims to identify whether there is a difference in urgent attendance for dental care at a dental practice, A&E, GP practice or a dental hospital at 6-, 12- and 18-months post randomisation, between the intervention and control groups. This outcome is self-reported by participants at each follow-up.

25.2.3.5.1 Derivation

Participant follow-up questionnaire booklet: Question 6a

[8] Whilst the study design defines OHIP-14 to be measured at specific time points, measurements that are not taken at per-protocol time points may be included in this analysis.

At each follow-up (6, 12 and 18 months), participants will be asked "Have you visited a dentist for an urgent appointment in the last six months (since your urgent dental appointment when you agreed to take part in this study)?". If participants answer "Yes" they will be considered as yes for attending for urgent dental care in the 6 months prior to that follow-up. To determine if a participant attended for urgent dental care before each follow-up time point, the method described in section 25.2.3.1.1 will be used.

If participants answered that they had attended a dentist for urgent dental care, they will also be asked their urgent care provider: NHS dentist, private dentist, Dental Hospital or a dentist but they were unsure if it was NHS or private. Participants may have attended more than one urgent care provider. If participants answered "NHS dentist", "Private dentist" or "I don't know if my dentist was private or NHS" they will be classed as having attended for urgent dental care at a dental practice. If they answered "Dental Hospital" they will be classed as having attended a dental hospital.

Participant follow-up questionnaire booklet: Question 8e

At each follow-up, participants will be asked about any other healthcare they have used in the last six months due to problems with their teeth, mouth or dentures. If participants give a non-zero answer for the following questions:

(1) How many times have you seen a GP at a GP surgery or at your home, or spoken to a GP by telephone due to problems with your teeth, mouth or dentures in the last six months?

(2) How many times have you seen a nurse at a GP surgery, at your home, or in any other location in the community due to problems with your teeth, mouth or dentures in the last six months? This may include GP practice nurses, health visitors district nurses and midwives etc.

(3) How many times have you been in hospital A&E due to problems with your teeth, mouth or dentures in the last six months?

they will be considered as yes for attending for urgent dental care in the 6 months prior to that follow-up. To determine if a participant attended for urgent dental care before each follow-up time point, the method described in section 25.2.3.1.1 will be used.

If participants gave a non-zero answer to (1) and/or (2), they will be classed as having attended for urgent dental care at a GP practice. If they gave a non-zero answer to (3) they will be classed as having attended A&E for urgent dental care.

For each time point, the responses to questions 6a and 8e will be used together to derive a binary variable for whether the participant attended for urgent dental care at a dental practice, A&E, GP practice or a dental hospital (1=attended for urgent care, 0=did not attend for urgent care).

25.2.3.5.2 Analysis

At each time point (6, 12 and 18 months), the number and percentage of participants reporting that they attended for urgent dental care prior to that follow-up will be reported by treatment group. For each time point, the denominator will be the number of participants who either answered questions 6a and 8e at that time point and all previous follow-ups or who were considered as yes for attending for urgent dental care at any of the previous follow-ups.

For each time point and treatment group, the number and percentage of participants reporting that they attended for urgent care prior to that time point will also be reported by type of urgent care provider (dental practice, A&E, GP practice and dental hospital). The denominators will be the same as those above.

For this outcome, each time point will be analysed separately in the same way as the first primary outcome (section 25.2.2.1.2). However, the odds ratio and corresponding 95% CI will be reported (instead of a 97.5% CI) along with the p-value. There will also be no sensitivity analyses or analyses adjusting for other baseline covariates.

25.2.3.6 Secondary Outcome 6 - Halitosis and Bad Taste Questionnaire (self-report)

This outcome aims to identify whether there is a difference in halitosis and bad taste as indicators of dental infection (self-reported) at 6, 12 and 18 months, between the intervention and control group.

25.2.3.6.1 Derivation

A binary variable will be created for each time point to represent if there have been indicators of dental infection in the previous 6 months based on the answers to the halitosis and bad taste questions (1=any indicator of dental infection, 0=no indicators of dental infection).

To determine if indicators of dental infection are present, based on the bad taste questions, a participant must answer the questions in the following way:

- In the last six months have you noticed a bad taste in your mouth? Answer: Yes.

Then the participant must answer one of the remaining bad taste questions in the following way:

- If you told us you have noticed a bad taste, how much does it bother you? Answer: Either very bothered or extremely bothered,

OR

- If you told us that you have ever noticed a bad taste in your mouth, does it affect your social life or your work life? Answer: Yes.

To determine if indicators of dental infection are present, based on the halitosis questions, a participant must answer the halitosis questions in the following way:

- Within the last six months, have you noticed you have bad breath? Answer: Yes.

Then the participant must answer one of the next questions in the following way:

- If you told us that you have ever noticed bad breath, how much does it bother you? Answer: either very bothered or extremely bothered,

  OR

- If you told us that you have ever noticed bad breath, does it affect your social life or your work life? Answer: Yes.

However, the participants must answer the final question in the following way to determine that indicators of dental infection are present and are not from other causes:

- Have you had tests or treatment from medical staff for this (bad breath) such as an examination of your throat, sinuses, stomach or blood tests? Answer: No.

To determine an indicator for dental infection overall, both the halitosis and bad taste indicators should be present. To be included in the analysis for a particular time point, the participant must answer all of the questions for that time point.

25.2.3.6.2 Analysis

At each time point (including baseline), the number and percentage of participants who have any indicators of dental infection will be reported by treatment group. The denominator will be the number of participants who have answered all of the questions on the halitosis and bad taste questionnaire for that time point (i.e. those with valid questionnaires). The number and percentage of participants with dental infection will also be broken down into those who have indicators based on only the halitosis questions, indicators based on only the bad taste questions and those who have both indicators.

The binary variable for whether there are signs of dental infection will be analysed separately for each time point (6, 12 and 18 months), in the same way as the first primary outcome (section 25.2.2.1.2). However, the odds ratio and corresponding 95% CI will be reported (instead of a 97.5% CI) along with

the p-value. There will also be no sensitivity analyses or analyses adjusting for other baseline covariates.

25.2.3.7 Secondary Outcome 7 - Treatments Received (BSA, Dental Hospital audit and self-report)

This outcome aims to identify whether there is a difference in the clinical treatment received by participants in NHS dental services (as measured by BSA data, Dental Hospital audit data and patient self-report, at 6, 12 and 18 months), between intervention and control groups.

25.2.3.7.1 Derivation

All of the available treatments from the three data sources will be categorised as follows:

BSA data	Dental Hospital audit	Patient self-report	Categorisation
Examination	Examination	Check-up	General diagnostic and prevention advice
Radiograph	Radiograph/s	X-rays	
		Toothbrushing and diet advice	
Scale And Polish	Scale & polish	Scale and polish	Periodontal treatment
		Advanced gum disease treatment, involving deeper cleaning	
Fluoride Varnish	Fluoride Varnish	Applying a gel to your teeth to stop decay or sensitivity	Preventive intervention
Fissure Sealants	Fissure sealant/s		
Permanent Fillings	Permanent filling/s	Permanent filling	Routine filling(s)
Endodontic Treatment	Endodontic treatment	Root canal treatment (a deeper filling into the nerve of the tooth)	Endodontic treatment
Extractions	Extraction/s	Removal of tooth/teeth	Routine extraction(s)
Upper Denture Acrylic Lower Denture Acrylic Upper Denture Metal Lower Denture Metal	Upper denture Acrylic Lower denture Acrylic Upper denture Metal Lower denture Metal	Dentures or mouth guard	Prosthetic or Advanced restorations
Crowns Provided Veneers Applied Inlays Bridges Fitted	Crown/s provided Veneers applied Inlays Bridges fitted	Making or mending a crown, bridge or veneer	
General Free Repair/Replacement		Screw in false tooth (implant)	
Other Treatment	Other, please specify	Other (please specify)	Other
		Treatment to teeth affected by an accident	

Sedation	Sedation		Treatment for anxiety
Referral For Advanced Mandatory Services	referral for advanced mandatory services	Referral to a specialist to check something in your mouth like an ulcer	Referral to specialist
		Whitening	Cosmetic
Incomplete treatment			Incomplete treatment
Band 1			Band 1
Band 2 (including bands 2a, 2b and 2c)			Band 2
Band 3			Band 3
Band 4 (urgent care/occasional)	Type of visit - Urgent	Treatment of the gum around where the tooth is coming through and is causing pain, usually a wisdom tooth	Urgent care
		Have you visited a dentist for an urgent appointment in the last six months? - Yes	
		Temporary filling	
		Opening up swelling (usually on your gum) to remove pus	
		Advice about your problem	

Patient reported treatments

At each follow-up (6, 12 and 18 months), participants will be asked "Could you please tell us what treatment you had at your visit(s) for either planned or urgent dental care in the last six months (all visits)". Participants will be deemed to have received a particular treatment category at that time point, if they have received any of the treatments from that category (please see above table[9]) and they answered yes to at least one of the questions: "Have you visited a dentist for a planned appointment (not an emergency) in the last six months?" and "Have you visited a dentist for an urgent appointment in the last six months?". The presence of a particular treatment type for the 6-, 12- and 18-month time points will be determined in the same way as in section 25.2.3.1.1.

NHS BSA treatments

The NHS BSA data will be provided with treatments at dental visits. For each follow-up time point and treatment category, if a dental visit occurs with any of the treatments in that category (please see above table[9]) performed before that time point, the participant will be considered as having received

[9] The free-text other treatments will be sent to the CI to determine if they can be categorised into any of the treatment categories. If they cannot be categorised they will be included in the 'Other' category.

that treatment category. The cut-off date for dental visits to be included at any time point will be 6-, 12- and 18-months post randomisation, regardless of the date the patient completed the study follow-up for that time point.

Dental Hospital audit

Dental Hospitals do not routinely provide information to BSA for database inclusion. Data will be requested from the Dental Hospital using participant name, date of birth and if available a unique hospital identifier (RQ6 number), following provision of explicit consent for this. This data will include the dates of further visits and the treatment items provided at each visit. For each follow-up time point and treatment category, if a dental visit occurs with any of the treatments in that category (please see above table) performed before that time point, the participant will be considered as having received that treatment category. The cut-off date for dental visits to be included at any time point will be 6-, 12- and 18-months post randomisation, regardless of the date the patient completed the study follow-up for that time point.

The patient recall data, NHS BSA data and Dental Hospital audit data will be used together to determine overall which treatment categories were provided at dental visits. If the data is present in one source but not in the others, it will be assumed that the treatment category was received. For each time point, a binary variable will be created for each category of dental treatment (1=dental treatment received, 0=dental treatment not received).

25.2.3.7.2 Analysis

For each time point (6, 12 and 18 months), the number and percentage of patients receiving each category of dental treatment will be reported split by treatment group. The denominator will be the number of patients randomised to each treatment group.

Each treatment category (excluding 'Other', 'Treatment for anxiety', 'Referral to specialist' and 'Cosmetic' which will only be analysed descriptively) and time point will be analysed separately in the same way as the first primary outcome (section 25.2.2.1.2). However, the odds ratio and corresponding 95% CI will be reported (instead of a 97.5% CI) along with the p-value. There will also be no sensitivity analyses or analyses adjusting for other baseline covariates.

25.2.3.8 Secondary Outcome 8 - Antibiotic Prescription by Dentist (BSA, Dental Hospital and self-report)

This outcome aims to identify whether there is a difference in patients receiving dentist prescribed antibiotics (as measured by NHS BSA data, Dental Hospital audit data and self-report) at 6, 12 and 18 months, between intervention and control groups.

25.2.3.8.1 Derivation

NHS BSA

Within the NHS BSA data, there will be a field denoting the number of antibiotics prescribed at a dental visit. For each follow-up time point, if a dental visit occurs with count > 0 for antibiotics before that time point, participants will be considered as yes for receiving dentist prescribed antibiotics. The cut-off date for prescriptions to be included at any time point will be 6-, 12- and 18-months post randomisation, regardless of the date the patient completed the study follow-up for that time point.

Dental Hospital audit

The Dental Hospital audit will also collect information on antibiotic prescriptions. For each follow-up time point, if antibiotics were prescribed before that time point the participant will be considered as yes for receiving dentist prescribed antibiotics. The cut-off date for prescriptions to be included at any time point will be 6-, 12- and 18-months post randomisation, regardless of the date the patient completed the study follow-up for that time point.

Self-report

At each follow-up time point, participants will be asked “Have you been prescribed antibiotics for dental problems within the last six months?”. If participants answer “Yes, from my dentist” to the question, they will be considered as yes for receiving dentist prescribed antibiotics in the 6 months prior to that follow-up. To determine if a participant received dentist prescribed antibiotics before each follow-up time point (6, 12 and 18 months), the method described in section 25.2.3.1.1 will be used.

For each time point, the NHS BSA data, Dental Hospital audit data and self-report data will be used together to derive a binary variable for whether the patient received dentist prescribed antibiotics (1=received dentist prescribed antibiotics, 0=did not receive dentist prescribed antibiotics). If the data is present in one source but not in the others, it will be assumed that the patient received dentist prescribed antibiotics.

The three data sources will also be used to determine the total number of times each participant was prescribed antibiotics by a dentist. For patients with both BSA and Dental Hospital data available, the count from both sources will be added together to work out the total number of times they were prescribed antibiotics. The self-reported count will be calculated using the method described in section 25.2.3.1.1 to calculate the total number of dental visits. If the self-reported count contradicts that from the BSA/Dental Hospital audit data, the count from the BSA/Dental Hospital data will be used. If a participant did not have a matched BSA record at baseline and has no matched records at follow-up, their self-reported count will be used.

25.2.3.8.2 Analysis

The cumulative total number of times antibiotics were prescribed per participant within 18 months of randomisation will be reported for each treatment group (anyone prescribed antibiotics five or more times will be grouped together). The denominator will be the number of participants randomised to each treatment group.

For each time point (6, 12 and 18 months) and treatment group, the number and percentage of participants who were prescribed antibiotics at a dental visit prior to that time point will be reported. The denominator will be the number of participants randomised to each treatment group.

Each time point will be analysed separately, in the same way as the first primary outcome (section 25.2.2.1.2). However, the odds ratio and corresponding 95% CI will be reported (instead of a 97.5% CI) along with the p-value. There will also be no sensitivity analyses or analyses adjusting for other baseline covariates.

25.2.3.9 Secondary Outcome 9 - Antibiotic Prescription by GP/A&E/Walk-in-Centre (self-report)

This outcome aims to identify whether there is a difference in patients receiving antibiotics for dental problems prescribed by GP, A&E and walk-in-centres (as measured by patient self-report) at 6, 12 and 18 months, between intervention and control groups.

25.2.3.9.1 Derivation

At each follow-up time point, participants will be asked “Have you been prescribed antibiotics for dental problems within the last six months?”. If the participant answers “Yes, from my GP” and/or “Yes, from another centre (e.g. A&E, walk-in-centre)” they will be considered as yes for receiving antibiotics prescribed by GP/A&E/walk-in-centre in the six months prior to that time point. If the participant answered “No” or only answered “Yes, from my GP”, they will be considered as no.

A binary variable for antibiotics prescribed by GP/A&E/walk-in-centre (1=prescribed antibiotics by GP/A&E/walk-in-centre, 0=not prescribed antibiotics by GP/A&E/walk-in-centre) will be created for each time point in the same way as described in section 25.2.3.1.1.

25.2.3.9.2 Analysis

For each time point (6, 12 and 18 months), the number and percentage of participants who reported that they had been prescribed antibiotics for dental problems by a GP, A&E or walk-in-centre will be reported by treatment group. The denominator will be the number of participants who either answered the question at that time point and all previous follow-ups or who answered "Yes, from my GP" and/or "Yes, from another centre (e.g. A&E, walk-in-centre)" at any of the previous follow-ups.

Each time point will be analysed separately in the same way as the first primary outcome (section 25.2.2.1.2). However, the odds ratio and corresponding 95% CI will be reported (instead of a 97.5% CI) along with the p-value. There will also be no sensitivity analyses or analyses adjusting for other baseline covariates.

25.2.3.10 Secondary Outcome 10 - Analgesic Prescription for Dental Problems (self-report)

This outcome aims to identify whether there is a difference in patients who were prescribed analgesics for dental problems (as measured by patient self-report) at 6, 12 and 18 months, between intervention and control groups.

25.2.3.10.1 Derivation

At each follow-up time point, participants will be asked "Have you taken any painkillers for dental problems within the last six months?" and if they answered yes, they will be asked "If you have taken painkillers for dental problems within the last six months, were these prescribed to you or did you buy these 'over the counter'". If the patient answers the second question with "The painkillers were prescribed to me" or "Both" they will be considered as yes for being prescribed analgesics in the six months prior to that time point. If they answered "No" to the first question or "I bought the painkillers without a prescription" to the second question they will be considered as no.

A binary variable for analgesic prescriptions (1=prescribed analgesics for dental problems, 0=not prescribed analgesics for dental problems), will be created for each time point in the same way as described 25.2.3.1.1.

25.2.3.10.2 Analysis

For each time point (6, 12 and 18 months), the number and percentage of participants who reported that they had been prescribed analgesics for dental problems will be reported by treatment group. The denominator will be the number of participants who answered the first question and if they answered "Yes", also answered the second question at that time point and all previous-follow ups or who answered "Yes" to the first question and answered "The painkillers were prescribed to me" or "Both" to the second question at any of the previous follow-ups.

Each time point will be analysed in the same way as the first primary outcome (section 25.2.2.1.2). However, the odds ratio and corresponding 95% CI will be reported (instead of a 97.5% CI) along with the p-value. There will also be no sensitivity analyses or analyses adjusting for other baseline covariates.

25.2.3.11 Secondary Outcome 11 - Modified Dental Anxiety Scale (self-report)

The aim of this outcome is to monitor any change in dental anxiety after receiving the intervention over the study period. This is a patient reported outcome and is completed at baseline and then at 6-, 12- and 18-months post randomisation.

25.2.3.11.1 Derivation

The Modified Dental Anxiety Scale (MDAS) consists of five questions and each question is assessed on a 5-point Likert scale: 1=Not anxious, 2=Slightly anxious, 3=Fairly Anxious, 4=Very anxious, 5=Extremely anxious.

The items in the MDAS are summed together to produce a total score ranging from 5 to 25, with higher scores relating to higher levels of dental anxiety [13]. MDAS scores can then be categorised into the following levels [13]:

MDAS Score	Anxiety level
5-10	Low dental anxiety
11-18	Moderate/ high dental anxiety
≥19	Very high dental anxiety

The MDAS is considered valid if at least four items are completed. If one item is missing, then a mean score based upon the remaining scores will be imputed for the missing item [14].

25.2.3.11.2 Analysis

Summaries of the MDAS scores will be presented at baseline and at each follow-up timepoint (6, 12 and 18 months), separated by treatment group. The summaries will include mean, SD, median, IQR and range. Summaries will be based on valid questionnaires only – for MDAS scores that are not valid, a summary of reasons will be provided.

The number and percentage of participants in each of the MDAS levels will be reported for each time point and treatment group. The denominator will be the number of participants who completed valid MDAS questionnaires at that time point.

A repeated measures mixed effects model will be fitted. The dependent variable will be post baseline MDAS scores[10]. Covariates will be baseline MDAS score, treatment group, time (fitted as a continuous variable) and a time-treatment group interaction. Site will be fitted as a random effect (random intercept only) and the repeated measure will be the participant ID.

For each time point (6, 12 and 18 months), the mean (SE) MDAS score for each treatment group and the mean difference between treatment groups in MDAS score will be estimated from the model together with a 95% CI. Additionally, a single p-value will be reported testing whether the effect of treatment group is significant over the whole follow-up period.

25.2.3.12 Secondary Outcome 12 - Incremental Cost-Effectiveness Ratio (BSA and self-report)

This is a health economics outcome and will not be presented in the statistical analysis report.

25.2.3.13 Secondary Outcome 13 - Attendance for Planned Care at a Dental Practice or Dental Hospital within 18-months (BSA and Dental Hospital audit)

This outcome aims to identify whether there is a difference in attendance at a dental practice or Dental Hospital for a planned care appointment within 18 months (as measured by BSA data and Dental Hospital audit data), between the intervention and control groups.

25.2.3.13.1 Derivation

NHS BSA

As described in 25.2.2.1.1 but for up to 18 months post randomisation.

[10] Whilst the study design defines MDAS to be measured at specific time points, measurements that are not taken at per-protocol time points may be included in this analysis.

Dental Hospital audit

The Dental Hospital audit data will include the dates of further visits and the type of visits, i.e. urgent or routine. If the participant had a routine visit within 18 months of randomisation, they will be considered as having attended for a planned care appointment before that time point. Participants who only had urgent visits will not be considered as having attended the Dental Hospital for a planned care appointment.

For each time point, the NHS BSA data and Dental Hospital audit data will be used together to derive a binary variable for whether participants attended a dental practice or Dental Hospital for a planned care appointment within 18 months of randomisation (1=attended for a planned care appointment at, 0=did not attend for a planned care appointment). If participants have no BSA data or Dental Hospital audit data available they will be assumed to have not attended for a planned care appointment.

25.2.3.13.2 Analysis

Analysis as described in section 25.2.2.1.2. However, the odds ratio and corresponding 95% CI will be reported (instead of a 97.5% CI) along with the p-value. There will also be no sensitivity analyses or analyses adjusting for other baseline covariates.

25.2.3.14 Secondary Outcome 14 – Protection Motivation Theory Questionnaire (self-report)

This outcome is used as mediator in Section 27.2.1.

26 Safety Evaluations

All related non-serious adverse events (RAEs) and related serious adverse events (RSAEs), reported by a suitably qualified and delegated dentist, will be presented. The number of events and the number (and percentage) of patients experiencing each RAE will be presented for each treatment group. Separate tables will further categorise these events by severity (mild, moderate, severe) and by relationship to trial procedure (possibly, probably or almost certainly). For each patient, only the maximum severity experienced of any RAE will be displayed when calculating totals for severity. Similarly, for each patient, only the most related RAE of any experienced will be displayed when calculating totals for relationship to trial procedure. No formal statistical testing will be undertaken.

If the number of RAEs is low (<20 total RAEs), the RAEs will be presented as line listings detailing: RAE description, severity and causality (possibly, probably or almost certainly related).

All RSAEs will be summarised as line listings detailing: SAE number, description, onset date, seriousness, severity, PI assessment of relationship, CI assessment of relationship, CI assessment of expectedness, patient status and outcome. No formal statistical testing will be undertaken.

27 Additional Analyses

27.1 Socio-economic effects of intervention

The secondary objective of exploring whether there is a differential intervention effect over the socio-economic gradient will be explored by adding interaction terms between intervention and socio-economic status into the primary outcome regression models (described in sections 25.2.2.1.2 and 25.2.2.2.2) and the following secondary outcome regression models:

- Secondary outcome 1 (section 25.2.3.1.2) - 18-month time point only.
- Secondary outcome 3 (section 25.2.3.3.2) - 18-month time point only.
- Secondary outcome 7 (section 25.2.3.7.2) - 18-month time point only and only for the following treatment categories of interest:
    - General diagnostic and prevention advice and preventive intervention together,
    - Routine filling(s),
    - Routine extraction(s),
    - Endodontic treatment,
    - Prosthetic or Advanced restorations.
- Secondary outcome 8 (section 25.2.3.8.2) - 18-month time point only.
- Secondary outcome 9 (section 25.2.3.9.2) - 18-month time point only.
- Secondary outcome 11 (section 25.2.3.11.2).

This analysis will be exploratory as the trial is not powered to detect these interaction effects.

The following four variables will be considered as indicators of socio-economic status:

- IMD: 1 (most deprived) – 10 (least deprived).
- Education level dichotomised as follows:
    - GCSE or below - No formal qualifications; GCSEs / O Levels (any grade)/ NVQ Level 1 or similar; 5+ GCSEs (A*-C)/O Levels (passes)/ NVQ Level 2 or similar.
    - Above GCSE- 2+A Levels/ NVQ Level 3 or similar; Undergraduate degree; Postgraduate degree or similar.

- Employment status dichotomised as follows:
    - Employed - Employed full time (30 hours a week or more); Employed part-time (less than 30 hours a week).
    - Not currently employed.

  Participants who answered "Prefer not to say" will be classed as missing.
- Benefit status: Yes/ No. Participants who answered "Prefer not to say" will be classed as missing.

Since IMD, education level, employment status and benefit status are all indicators of socio-economic status they are likely to be associated. To avoid multi-collinearity, each indicator will be modelled separately and will be modelled twice for each outcome (resulting in eight interaction models for each outcome listed above):

(1) **Unadjusted models:** For each of the outcome regression models listed above, the socio-economic status indicator and the socio-economic status indicator-treatment group interaction will be added.
(2) **Adjusted models:** As above, but the models will also adjust for ethnicity, age and gender.

For the binary outcomes (primary outcome 1 and secondary outcomes 1, 3, 7, 8, and 9), the odds ratios (and 95% CIs) for each interaction model (unadjusted and adjusted) will be presented. For the continuous outcomes (primary outcome 2 and secondary outcome 11), the coefficients (and 95% CIs) for each interaction model (unadjusted and adjusted) will be presented.

For the binary outcomes, the difference in probability between the intervention and control groups, estimated from the unadjusted interaction models, will be presented (both in a table and graphically) for each level of the socio-economic status indicators. For the continuous outcomes, the difference in 12-month OHIP-14 (primary outcome 2) and 18-month MDAS scores (secondary outcome 11), estimated from the unadjusted interaction models, will be presented (both in a table and graphically) for each level of the socio-economic status indicators. For the estimation, the mean baseline scores will be used for baseline OHIP-14 and MDAS.

27.2 Psychological factors mediating any intervention effect

The secondary objective of exploring whether there are any factors which mediate any intervention effect will be explored using the Protection Motivation Theory (PMT) questionnaire. The PMT is a patient reported outcome and is completed twice at baseline - before randomisation (pre-

intervention) and after participant's have been shown the thank you video (post-intervention). The PMT is also completed at 6- and 12-months post randomisation, but only the 6-month PMT will be considered during this analysis.

27.2.1 PMT Derivation

The PMT questionnaire consists of ten questions and each question is assessed on a 5-point Likert scale: 1=Strongly disagree, 2=Disagree, 3=Neither agree or disagree, 4=Agree and 5=Strongly agree, except for question 10 which is reversed. The PMT is broken down into five distinct constructs: perceived susceptibility, severity, response efficacy, self-efficacy and intentions, with two measures for each construct. The items of the PMT and the construct they measure are given below:

Question	Construct
1. If I only visit a dentist when I have problems my chance of developing toothache in the future are high.	Susceptibility
2. Visiting the dentist when I do not have a problem would reduce my chances of developing toothache.	Response Efficacy
3. Only visiting the dentist when I have problems means I would be likely to have tooth loss, bad breath or dental abscesses.	Severity
4. I am confident I can visit a dentist for a planned appointment (not with a problem).	Self-Efficacy
5. I intend to visit a dentist for a planned appointment (not with a problem).	Intentions
6. Visiting a dentist for a planned appointment (not with a problem) is a good way to reduce my risk of getting problems again.	Response Efficacy
7. Toothache is a serious problem which can lead to tooth loss, bad breath or getting a dentist abscess.	Severity
8. It will be easy for me to visit the dentist for a planned appointment (not with a problem).	Self-Efficacy
9. If I visit the dentist for planned appointments (not with a problem) I am unlikely to develop toothache.	Susceptibility
10. I am unlikely to visit a dentist for a planned appointment (not with a problem).	Intentions

The items for each construct will be summed together to produce a score ranging from 1 to 10 for each of the five constructs. All items must be completed for the PMT to be considered valid.

27.2.2 Analysis

For both the post-intervention and 6-month PMT, independent group t-tests will be conducted to test for differences between the RETURN intervention and control groups in each of the five constructs

from the PMT. To control for the increased type I error rate caused by multiple comparisons, the significance level ($p<0.05$) will be divided by the number of comparisons (five) - a significance level of $p<0.01$ will be adopted to indicate significant differences between treatment groups.

For the first primary outcome, only the post-intervention PMT will be considered[11]. If the treatment effect on the first primary outcome is significant and significant differences in psychological variables are found between groups, mediation analyses will be performed. One of two types of mediation analysis will be performed depending on the t-test results:

- If differences are only found in intentions, then a simple mediation analysis (adjusted for pre-intervention intentions) of Intervention -> Intentions -> Planned dental attendance will be performed.
- If differences are found in intentions and any of the other PMT variables then for each PMT variable with a significant difference, the following serial mediation (adjusted for the pre-intervention PMT construct and intentions) will be performed: Intervention -> PMT construct -> Intentions -> Planned dental attendance.

For the second primary outcome, both the post-intervention and 6-month PMTs will be considered. If the treatment effect on the second primary outcome is significant and for each PMT, if significant differences in psychological variables are found between groups, mediation analyses will be undertaken. One of two types of mediation analysis will be performed depending on the t-test results:

- If differences are only found in intentions, then a simple mediation analysis (adjusted for pre-intervention intentions and baseline OHIP-14) of Intervention -> Intentions -> 12-month OHIP-14 score will be performed.
- If differences are found in intentions and any of the other PMT variables then for each PMT variable with a significant difference, the following serial mediation (adjusted for baseline OHIP-14 and the pre-intervention PMT construct and intentions) will be performed: Intervention -> PMT construct -> Intentions -> 12-month OHIP-14 score.

All mediation analyses will be conducted using version 4 or later of the PROCESS macro [1]. For each mediation analysis, the total, direct and indirect effects will be presented alongside the bootstrap standard errors and 95% confidence intervals.

[11] Since the participant may attend for a planned appointment before their 6-month follow-up, the constructs of the 6-month PMT cannot be considered as mediators for the first primary outcome.

If the treatment effect on some of the secondary outcomes is significant (e.g. attempts to make an appointment to see a dentist for planned dental care), the appropriate[12] mediation analyses described above may also be performed for these outcomes.

28 Document History

Statistical Analysis Plan Version	Protocol Version	Section number(s) changed	Description of changes	Justification for changes	Date Implemented
2.0	6.0	25.2.2.2, 25.2.2.4, 25.2.2.11 and 27.2	Removal of text specifying that only questionnaires completed in the time window will be included. Addition of sensitivity analysis that includes only questionnaires completed in the window (25.2.2.2 only).	PSC suggested performing the main analysis on all questionnaires and a sensitivity analysis including those completed in the window for the primary outcome.	03/06/2024
2.0	6.0	25.2.2.1	Additional sensitivity analyses added that use the matching indicators from the BSA data.	To assess the impact of possible incorrect matchings.	03/06/2024
2.0	6.0	25.2.2.7	Addition of categorisations for treatments received and detailing which categories will only be analysed descriptively.	Categorisations not included in V1.0 of the SAP.	03/06/2024 and 26/06/2024

[12] For example, for attempts to make an appointment, participants may have attempted to make an appointment before their 6-month follow-up so the mediation analysis for the first primary outcome would be the appropriate method for this outcome.

2.0	6.0	25.2.2.2, 25.2.3.11 and 30	Appendices and references to appendices removed.	REDCap variables have changed since V1.0 of the SAP was approved.	03/06/2024
2.0	6.0	20	Monitoring plan updated to current monitoring plan.	Monitoring plan has been updated.	26/06/2024
2.0	6.0	22.1	Addition of multiple imputation for two secondary outcomes.	CI request due to importance of these secondary outcomes.	26/06/2024 and 27/06/2024 (to include benefit status)
2.0	6.0	25.2.2.1	Main analysis switched with sensitivity analysis that removes those without a baseline match who were not randomised at the dental hospital.	Previous main analysis did not account for if there was a high degree of unmatched records.	26/06/2024
2.0	6.0	25.2.3.1.2, 25.2.3.3.2	Addition of covariate analysis and multiple imputation sensitivity analysis.	CI request due to importance of these secondary outcomes.	26/06/2024
2.0	6.0	27.1	Addition of treatment categories for secondary outcome 7.	Categorisations not included in V1.0 of the SAP.	26/06/2024 and 27/06/2024
2.0	6.0	25.2.2.1.2, 25.2.2.2.2	Benefit status added to covariate analysis.	CI suggested to include this as a covariate.	27/06/2024

29 References

29.1 Non-standard Statistical Methods

[1] Hayes AF. Introduction to mediation, moderation, and conditional process analysis. 2nd ed. London: Guildford Press; 2018.

29.2 Data Management Plan

RETURN Data Management Plan V1.0 (08/06/2021)

29.3 Trial Master File and Trial Statistical File

RETURN Trial Master File

RETURN Trial Statistical File

29.4 Other Standard Operating Procedures to be Adhered to

LCTC_ST001: Sample Size Calculation

LCTC_ST002: Generation of a Random Allocation

LCTC_ST003: Production of Statistical Analysis Plans and Reports

LCTC_ST004: Quality control of Statistical Programming

LCTC_ST005: Statistical Programmed Data Checks

LCTC_ST006: Creating and Maintaining a Trial Statistical File

29.5 Other References

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