SCRiPT: Selective Caries Removal in Permanent Teeth

Statistical Analysis Plan

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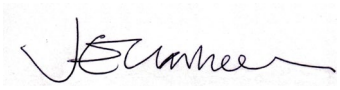
Signatures

By signing this document, I am confirming that I have read, understood and approve the statistical analysis plan (SAP) for the SCRiPT trial.

Clinical Chief Investigator [Janet Clarkson]	
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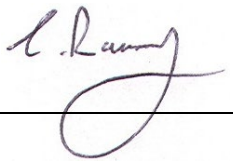
Co- Chief Investigator [Craig Ramsay]	
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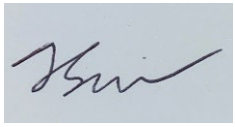
Trial Statistician [author] [James Swingler]	
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Version History

SAP version	Protocol version*	Section number changed	Description of and reason for change	Date of change
Version 1.0	Version 7		New document, based on SAP template Version 2	09/09/2024
Version 1.1	Version 7	10	Minor edits to wording	27/05/2025
Version 1.2	Version 7	11	Compartmentalized tables	25/06/2025
Version 1.3	Version 7	11	Minor edits to table formats	11/07/2025
Version 1.4	Version 7	1, 10, 11	Edit sections 1, 10.6, 10.7, 11.11	25/08/2025

* Please refer to 'Statistical Analysis Plan (SAP) review after Protocol updates' document that will be updated throughout the trial, documenting any amendments to the protocol and its relevance to the SAP.

Glossary of Abbreviations

Table containing all abbreviations used in the statistical analysis plan

AE	Adverse Event
ACE	Aberdeen Centre for Evaluation
CCR	Complete Caries Removal
CHaRT	Centre for Healthcare Randomised Trials
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CTU	Clinical Trials Unit
DCE	Discrete Choice Experiment
DMC	Data Monitoring Committee
DMS	Data Management Service
EQ-5D-5L	EuroQol Group's 5-dimension health status questionnaire
GCP	Good Clinical Practice
GDP	General Dental Practitioner
HEAP	Health Economics Analysis Plan
HRQoL	Health Related Quality of Life
HTA	Health Technology Assessment
ICF	Informed Consent Form
ISD	Information Statistics Division

ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial Number
ITT	Intention-to-Treat
IVR	Interactive Voice Response (randomisation)
OMG	Operations Management Group
OHIP-14	Oral Health Impact Profile-14
MRC	Medical Research Council
NCT	National Clinical Trial
NHS	National Health Service
NIHR	National Institute Health Research
NPRS	Numerical Pain Rating Scale
PI	Principal Investigator
PIL	Patient Information Leaflet
PMG	Progress Meeting Group
PPI	Patient and Public Involvement
PQ	Patient Questionnaire
PROM	Patient Recorded Outcome Measure
QALY	Quality Adjusted Life Year
RCT	Randomised Clinical Trial
R&D	Research and Development
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SCR	Selective Caries Removal
SD	Standard Deviation
SOP	Standard Operating Procedures
TMF	Trial Master File
TSC	Trial Steering Committee
UK	United Kingdom
UKCRC	United Kingdom Clinical Research Collaboration
UoA	University of Aberdeen

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SCRiPT

1. Introduction

This statistical analysis plan (SAP) documents the analysis for the SCRiPT trial. The health economics analysis plan (HEAP) will be outlined and described as a separate document. The SAP will describe the clinical effectiveness analysis and is based on protocol version 7. Any deviations from the plan will be described in the statistical report and where substantive in the corresponding publication.

2. Study Aims and Objectives

The **primary objective** of the study is to assess the clinical effectiveness of selective caries removal (SCR) compared to complete caries removal (CCR) in permanent teeth in NHS dental attenders aged 12 years and over who have deep caries in an adult pre-molar or molar tooth.

The **secondary objective** pertains to evaluation of pulp exposure during caries removal, progression of caries, dental pain and need for dental pain relief, restoration failure and patient oral health-related quality of life.

3. General Study Design

This is a multi-centre single-masked pragmatic superiority randomised controlled trial of Selective Caries Removal (SCR) with Complete Caries Removal (CCR) in permanent posterior teeth. Participants, NHS dental attenders aged 12 years and older who have deep caries in an adult pre-molar or molar tooth, will be randomised into one of the two groups for which follow-up will take place for at least 3 years and will be conducted in multiple sites across the UK. The design includes an internal pilot to assess the recruitment of practices and participants and monitor compliance with the clinical protocol and acceptability for patients and clinicians. Please refer to the corresponding trial protocol for more information.

4. Interventions to be evaluated

Intervention: Selective caries removal (SCR)

- Gain access to the dentine caries by removing superficial enamel or existing restoration.
- Remove caries from the periphery of the cavity to allow for good adaptation and seal to the restoration either at the enamel dentine junction or the peripheral 2mm of dentine if the cavity margin is on root dentine.
- Remove remaining carious dentine to soft dentine "that deforms when an instrument is pressed into it and can be easily scooped up (e.g. with a spoon hand excavator) with little force being required".[1]

Control: Complete caries removal (CCR)

- Gain access to the dentine caries by removing enamel or existing restoration.
- Remove caries to firm dentine "physically resistant to hand excavation and some pressure needs to be exerted through an instrument to lift it".[1]

5. Randomisation, Allocation and Blinding

All participants who agree to enter the study will be logged with the central trial office and given a unique Study Number. Randomisation will utilise the existing proven remote automated computer randomisation application in the central trial office in the Centre for Healthcare Randomised Trials (CHaRT, a fully registered UK CRN clinical trials unit) in the Aberdeen Centre for Evaluation (ACE), University of Aberdeen.

Randomisation will be at patient level. Eligible and consenting patient participants will be randomised to one of two intervention groups using the proven 24-hour web-based application, hosted by the Centre for Healthcare Randomised Trials (CHaRT). The randomisation algorithm will use recruitment site, number of eligible teeth (1; >1) and type of caries (primary and secondary) as minimisation covariates to allocate to treatment intervention and control groups in a ratio of 1:1. A random element will be incorporated into the randomisation algorithm. If the person has more than one eligible tooth, a trial tooth will be selected at random (the index tooth) by the randomisation application. The person with delegated authority will access the web-based system. Patient screening identification initials, recruiting site and eligible teeth will be entered into the web-based

system which will return the allocation status. To maintain participant blinding, participants will not be informed of their allocated treatment group following randomisation. Participants can only be randomised once to the study. The trial statistician will not be blinded to participant's group allocation.

The person with delegated authority will be informed of the allocation immediately. Should they not be the clinician performing the intervention they will inform the clinician of the allocation. In addition, a separate confirmatory email will inform the trial office, the site principal investigator and other delegated individuals at the site of the allocation. The participant will not be informed. All eligible teeth will be treated in the same way. All other carious lesions after baseline will be treated as the clinician prefers. This will be recorded on Case Report Forms (CRFs) so appropriate sensitivity analyses can be completed at the end of the trial.

6. Outcome Measures

6.1. Primary Outcome

The primary outcome for the study is sustained tooth vitality recorded up to the trial end date, with a 34-month median follow-up.

6.2. Secondary Outcomes

The secondary outcome measures will include:

- pulp exposure during caries removal
- progression of caries
- tooth-restoration failure and re-restoration
- dental pain (NPRS) [2]
- need for dental pain reliefs
- health status (EQ-5D-5L) [3]
- oral health-related quality of life (OHIP-14) [4]
- patient satisfaction
- oral health behaviours

7. Timing of Outcome Measurements

		Post-randomisation				
Outcome Measure	**At intervention**	**In each routine dental visit**	**Baseline**	**1 year**	**2 years**	**3 years**
Sustained tooth vitality		✓				
Pulp exposure during caries removal	✓					
Progression of caries		✓				
Tooth-restoration failure and re-restoration		✓				
Dental pain*		✓	✓	✓	✓	✓
Need for dental pain relief*		✓	✓	✓	✓	✓
EQ-5D-5L*		✓	✓	✓	✓	✓
OHIP-14*		✓	✓	✓	✓	✓
Patient satisfaction*		✓		✓	✓	✓
Oral health behaviours*		✓	✓	✓	✓	✓

*If a patient does not have a return of the annual patient questionnaire (APQ), collected from home, then a patient questionnaire offered to all patients at every clinical visit will be used to supplement the outcomes if recorded within 6 months of the relevant missing APQ.

8. Adverse Events

Each initial Adverse event (AE), described as any untoward medical occurrence in a clinical research participant which does not necessarily have a causal relationship with trial participation, will be considered for severity, causality or expectedness.

A serious adverse event (SAE) is any AE that:

- Results in death
- Is life threatening
- Required hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Is a congenital anomaly or birth defect
- Or is otherwise considered serious.

We do not anticipate any related AEs/SAEs in this trial. In addition, events that are not related to caries treatment in the trial tooth will not be recorded. SCRIPT involves procedures and treatment which are well established in current NHS clinical practice and use. In this trial, failure of tooth vitality with associated signs or symptoms (e.g. pain, infection, swelling, periodontitis) and further treatment required are captured as primary or secondary outcomes from the time a participant has their initial trial tooth caries treatment until their last trial follow-up, rather than being captured through adverse event or serious adverse event reporting processes. This reflects the routine care the trial is designed to measure. Outcomes within the trial will be regularly summarised and reported to the Data Monitoring Committee in their regular reports.

Death (from any cause) will be recorded on the CRFs. Elective admissions and hospitalisations for treatment planned prior to randomisation, where appropriate, will not be considered as an SAE.

9. Sample Size and Power Calculation

The sample size calculation is event-based. We aim to detect an absolute improvement in sustained tooth vitality at three years of 12% from 80% (CCR) to 92% (SCR). The control rate of 80% is based upon the existing evidence base, clinical experience and confirmed by Scottish tooth-level routine data. However, as this is a patient RCT there are concerns around contamination (participants receive the intervention that they were not randomly allocated to). Originally, we conservatively allowed for up to 25% contamination and therefore the sample size for SCRIPT aimed to detect an absolute improvement of 9%; from 83% to 92% at three years. Recruitment of 623 participants (71

events) was needed to detect a hazard ratio of 0.42 between experimental and control strategies and provide, using the log-rank test, assuming an exponential failure rate, 90% power at a 2-sided 5% significance level. The calculation also assumes 17 months of recruitment, a minimum of 33 months of follow-up and a 30% follow-up attrition at the end of year three. Recruitment is assumed to be staggered and builds in seasonal variation. We used the Stata package ARTSURV for calculations.

9.1. Revised sample size

During recruitment we found the rate of contamination to be far less than the 25% as it was originally assumed. Instead, a conservative rate of 5% (more than double our observed rate as of March 2024), means we are confident that a study recruiting 369 participants will conservatively have at least 80% power to detect the important difference the study was originally set up to detect. The funder has agreed to this revision.

10. Statistical Methods

10.1. General Methods

All the main analyses will be based on the Intention-to-Treat (ITT) principle. Final analysis will take place after full recruitment and follow-up. The results of the trial will be presented following the standard CONSORT recommendations.[5] Baseline and follow-up data will be summarised using the appropriate descriptive statistics and graphical summaries. Treatment effects will be presented with 95% confidence intervals (CIs) (apart from subgroup analysis).

There will be no adjustment to secondary outcomes for multiple testing. All eligible participants who provided consent will be included in the analysis. Any post-randomisation exclusions will be removed and reported as such and agreed with the PMG. Model assumptions will be checked and dealt with appropriately. See Appendix (Section 14) for how patient reported outcome measures (PROMS) are derived along with Stata code for the analysis of the primary outcome.

10.2. Interim Analysis

There are no planned interim analyses for efficacy or futility, but an independent Data Monitoring Committee (DMC) will monitor trial progress and specifically any safety issues.

10.3. Primary Outcome

The primary endpoint, sustained tooth vitality, will be analysed within a time-to-event framework using a Cox proportional hazards model, adjusted for number of eligible teeth and type of caries (minimisation covariates) and a random effect for clinician included. The treatment effect will be summarised by the hazard ratio with a 95% confidence interval. The estimated survival function will be graphed.

10.4. Secondary Outcomes

Secondary clinical time-to-event outcomes (progression of caries; tooth restoration failure, and re-restoration) will be analysed in a similar manner to the primary outcome. Pulp exposure will be analysed using logistic regression adjusted for number of eligible teeth and type of caries (minimisation covariates) and a random effect for clinician included. Secondary outcomes reported by participants will be analysed using mixed effects generalised linear models (using the appropriate link function for the outcome distribution) for repeated measures. Models will make use of data available at all time points where relevant, adjusted for minimisation covariates, fixed effects for treatment and (nominal) time points, and random effects for participant and clinician. The primary time point of interest will be 3 years post-randomisation. Treatment effects will be estimated using a treatment-by-time interaction and presented with 95% confidence intervals.

10.5. Subgroup Analyses

Planned subgroup analyses are intended to explore potential effect modifications of treatment effect by age (under 18; 18 and over), number of surfaces affected (1; >1), number of eligible teeth (1; >1) and type of caries (primary; secondary) on the primary outcome. Subgroup by treatment interaction will be assessed by including interaction terms in the models outlined above and will be classified as exploratory analyses. A stricter level of statistical significance (2-sided 1% significance level) will be applied to these analyses given their exploratory nature. Corresponding 99% confidence intervals will therefore be calculated.

10.6. Sensitivity analysis

Primary and secondary time-to-event outcome analyses assume proportional hazards. Further, a key assumption of the trial is that any participant who does not visit the dentist at least once during follow-up will be assumed to have sustained tooth vitality until their date of censoring - the final date of trial follow-up (31 Aug 2025).

Sensitivity analyses will be conducted, when necessary, to assess the validity of the findings from the primary analysis as outlined below:

- Change censoring date for those with no event, but at least one visit, from date of last visit to end of trial follow-up (31 Aug 2025)
- Participants who do not return for any dental visit after randomisation are censored at the start of the study (i.e. on date of their last observation),
- Participants with missing outcome data will have their primary outcome (outcome and time to event) imputed using a missing at random assumption (if deemed relevant/necessary).[6]
- Participants with missing outcome data will have their primary outcome imputed informed by routinely collected data if applicable and reliable.
- To explore the proportional hazards assumption if deemed necessary, a non-parametric superiority test – such as restricted mean survival – will be considered.[7]
- Include site as a random effect in addition to clinician.

10.7. Additional analysis

- In participants with more than one eligible tooth, we will descriptively analyse tooth vitality status between the number of eligible teeth subgroups (see table 11.11).

10.8. Compliance and Fidelity

Compliance with randomised allocation will be assessed and presented descriptively via clinician's self-report at the time of treatment delivery. Non-compliance will be reported descriptively and, if deemed necessary, a per protocol analysis (such as Complier Average Causal Effect) will be considered. Treatment fidelity will be assessed via two sources: 1) Expert assessment of patient's radiographs at follow-up (evidence of residual caries (SCR) or no evidence of residual caries (CCR)), summarised as the proportion of dentists implementing the allocated intervention of the patient to expert satisfaction; 2)

Dentist reporting of tooth characteristics at intervention - pertaining to colour and consistency/texture of the dentine - at the peripheral margin and over the pulp, summarised as the proportion reporting tooth characteristics that are in agreement with the allocated intervention of the patient. Each fidelity measure will be summarised independently and presented descriptively to support interpretation of trial findings.

10.9. Missing Data

10.9.1. Missing Outcome Data

Participants who have visited the dentist at least once during follow-up with no event will be censored at their last dental visit with sustained tooth vitality. As mentioned previously, participants who do not visit the dentist at least once during follow-up will be assumed to have sustained tooth vitality until their date of censoring - the final date of follow-up (31 Aug 2025). Participants with a change of status during the trial – such as changing dentist, passing away or decline further follow-up - will be censored at the date of last observation at the dentist. The handling of missing outcome data, if present, will be conducted as outlined as per section 10.6.

10.9.2. Missing Baseline Data

Data missing at baseline will be reported as such. If required for analyses purposes, primary and/or secondary outcome data will be imputed with centre specific mean for continuous data and missing binary/categorical data will include a missing indicator.

10.10. Statistical software

All analysis will be carried out in Stata 18 or the latest current version available.[8]

10.11. Estimands framework

The handling of intercurrent events, as described in the estimands framework, will be dependent on the observed intercurrent event of interest such as death.[9] The analysis will follow the treatment policy approach, i.e. the occurrence of the intercurrent event is taken to be part of the treatment condition, and as such the 5-point core attributes of estimands is as follows:

Attribute	Definition
Population	NHS patients, 12 years or over, who have deep caries in an adult pre-molar or molar tooth
Treatment conditions	Intervention group: assignment to SCR Control group: assignment to CCR
Endpoint	Number of months with sustained tooth vitality until failure or censoring
Summary measure	Hazard rate
Handling of intercurrent events	Treatment policy

Other treatment strategies may be considered and explored where necessary if an unanticipated intercurrent event presents itself in the data, following the completion of this document, that warrants the use of a strategy other than the treatment policy approach.

11. Dummy Tables

11.1. Recruitment by Centre

Centres	SCR	CCR

11.2. Baseline Questionnaire & Clinical Characteristics

Variable	SCR	CCR
Age – mean (SD); n		
Section 1: You and Your Oral Health – n (%)		
Gender		
Male		
Female		
Pay for dental treatment		
Yes		
No		
Dental Insurance		
Yes		
No		
Smoked in the last 12 months		
Yes		
No		
Consider yourself as:		
Regular Attendee		
Attend dentist when in pain or trouble		
Section 2: You and Your Oral Health – n (%)		
OHIP-14 – mean (SD); n		
Section 3: Oral health Behaviours – n (%)		
How often do you brush your teeth?		
Less than once a day		
Once a day		
Twice a day		

More than twice a day		
How long do you brush your teeth?		
Less than 1 minute		
1 minute to 2 minutes		
2 minutes		
More than 2 minutes		
How often do you use interdental brushes and/or floss?		
At least once a day		
At least once a week		
At least once a month		
Never		
Type of toothbrush		
Manual		
Electric		
Both		
Don't use toothbrush		
Post-brush behaviour		
Rinse with water		
Rinse with mouthwash		
Spit but not rinse		
Section 4: Dental Pain		
Dental Pain – mean (SD); n		
Take medication for this dental pain – n (%)		
Section 5: Describing Your Own General Health Today		
EQ-5D-5L - mean (SD); n		
EQ-5D Visual Analog Score		
Clinical Characteristics		
DMFT – mean (SD); n		
Number of eligible teeth		
One		
More than one		

Type of Caries		
Primary		
Secondary		
Type of Study Tooth		
Pre-molar		
Molar		
Type of surface affected (participants can have more than one affected surface)		
Occlusal		
Mesial		
Distal		
Buccal		
Lingual		
Palatal		
Number of surfaces affected by caries		
1		
2		
3-5		

11.3. Initial Treatment Visit – Clinical Characteristics

Variable – n (%)	**SCR**	**CCR**
Pulp exposure		
Yes		
No		
If exposed, was pulp tissue vital?		
Yes		
No		
If **vital** pulp tissue present, what treatment was provided?		

CaOH		
MTA		
Biodentine		
Pulpotomy		
Extirpation		
Extraction		
Other		
If **non-vital** pulp tissue present, what treatment was provided?		
Extirpation		
Extraction		
Other		
If pulp was not exposed, was a pulp lining used?		
Yes		
No		
If pulp lining was used, what material was used?		
CaOH		
GIC		
RMGIC		
Other		
What methods of moisture control were used?		
Rubber dam		
Cotton wool		
Absorbent Pad		
Suction		
None		
Restorative material used on study tooth?		
Amalgam		
Composite		
GIC		
RMGIC		
Surfaces involved in restoration		

Occlusal		
Mesial		
Distal		
Buccal		
Lingual		
Palatal		
Use of additional retentive techniques		
None		
Box/grooves		
Bonded amalgam		
Pins		
Other		

11.4. Compliance and Treatment Fidelity

	SCR	CCR
Recorded at initial treatment visit		
Compliance		
Have you provided treatment as allocated? – n (%)		
Reason treatment could not be provided as allocated - n(%)		
Painful/unable to anaesthetise		
Pulp exposed		
Tooth unrestorable		
Other		
What alternative treatment was provided?		
Free text to be grouped		
Fidelity		
Patients with tooth characteristics in agreement with allocated intervention* (Periphery) – n (%)		
Patients with tooth characteristics not in agreement with allocated intervention (Periphery) – n (%)		
Patients with tooth characteristics in agreement with allocated intervention* (Over the pulp) – n (%)		

Patients with tooth characteristics not in agreement with allocated intervention (Over the pulp) – n (%)		
Recorded at radiograph follow-up		
Dentists implementing the allocated intervention for the patient aligned with expert opinion (radiographic follow-up assessment) – n (%)		
Dentists not implementing the allocated intervention for the patient to expert satisfaction – n (%)		

*SCR at periphery: Colour should be light & texture should be hard. CCR at periphery: Colour should be light & texture should be hard.

*SCR at pulp: Colour should be medium/dark & texture should be soft. CCR at pulp: Colour should be light/medium & texture should be leathery/hard.

11.5. Primary outcome (analysis)

	SCR	CCR	Hazard ratio
Time to event (in months)			
Number of events (loss of vitality) – n (%)			
Sensitivity analyses			
Censoring date for those with no event changed to end of trial follow-up	NA	NA	
No dental visit censored at start of study	NA	NA	
Missing data imputation (MAR assumption) *	NA	NA	
Missing data imputation (Routinely collected)	NA	NA	
Non-parametric superiority test *	NA	NA	
Site included as a random effect in addition to clinician	NA	NA	

* If deemed necessary

11.6. Primary outcome (descriptive)

Reason for event – n(%)			
• Root filled			
• Extracted			
• Showing signs and/or symptoms of loss of vitality			
• Diagnosed Periradicular pathology			
• Root canal treatment			
Time to event – median (P25-P75), n			
Duration of follow-up – median (P25-P75), n			

11.7. Clinical secondary outcomes

Outcomes	SCR	CCR	Effect size
Pulp exposure during caries removal			
Caries progression – n(%)			
Tooth restoration failure – n(%)			
• Deficient			
• Fractured			
• Lost			
• Carious			
Re-restoration– n(%)			

11.8. Patient reported outcomes at baseline and end of study

Outcomes	SCR	CCR	Effect size
Pain – mean (SD), n			
Need for dental pain relief – n(%)			
Yes			
No			
EQ5D – mean (SD), n			
OHIP – mean (SD), n			
Oral health behaviours			
How often do you brush? – n(%) year 3 only			
Best practice (at least twice a day)			
Not best practice (less than twice a day)			
Missing			
How long do you take to brush? – n(%) year 3 only			
Best practice (at least 2 minutes)			
Not best practice (less than 2 minutes)			
Missing			
Do you use interdental brushes? – n(%) year 3 only			
Yes			
No			
Missing			

What do you do after brushing? – n(%) year 3 only			
Best practice (spit but not rinse)			
Not best practice (all other options)			
Missing			
How satisfied are you with the filling you received as part of the SCRIPT study? – n(%)			
• Not at all			
• Somewhat satisfied			
• Very satisfied			
• Completely satisfied			
Did you have any problems in the hours after the procedure was carried out? (year 1 only)			
• No problems			
• Slight problems			
• Considerable problems			
• Significant problems			
Are you still suffering ill effects from the procedure that you had? (year 1 only)			

• No ill effects			
• Ill effects persist slightly			
• Ill effects persist considerably			
• Ill effect effects persist completely			
Did you seek advice or assistance relating to the procedure and its effects in the days after? (year 1 only)			
• No			
• Yes, passive advice			
• Yes, active advice			

11.9. Adverse events

Participants with adverse events – n (%)	
Adverse events – n	
Related to the trial – n	
Expected - n	

11.10. Subgroup analysis for the primary outcome

	SCR	CCR	Estimate (99% CI), p-value
Age			
Under 18			
18 and over			
No. of affected surfaces			
1			
More than 1			

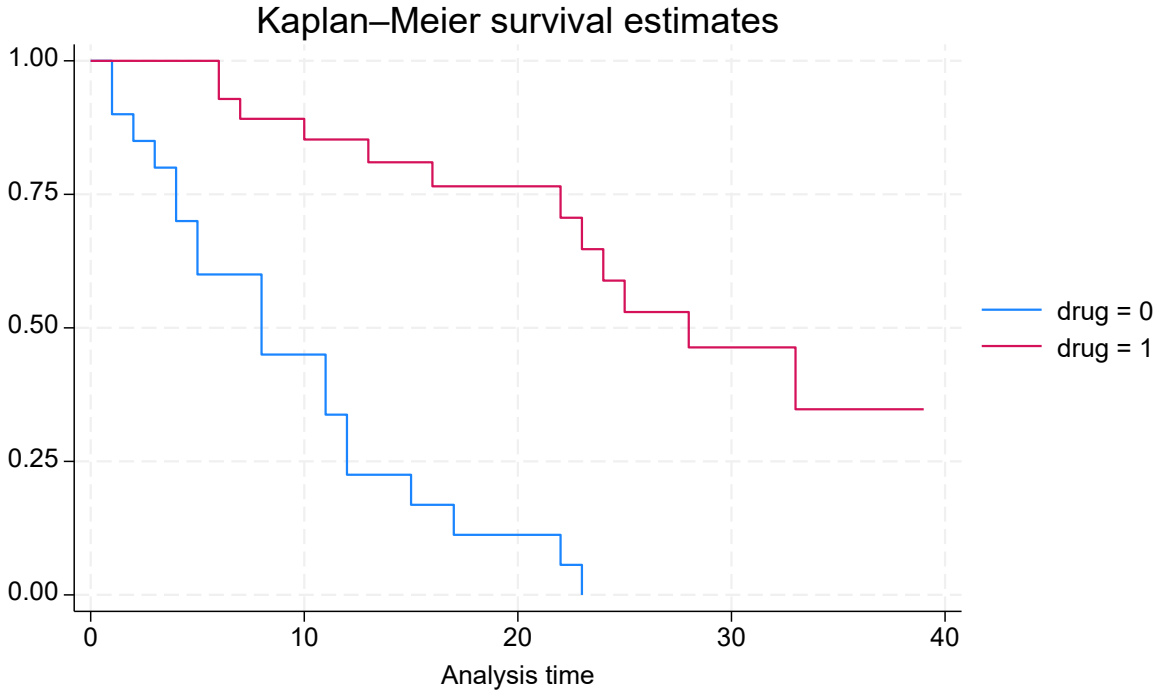
No. of eligible teeth			
1			
More than 1			
Type of Caries			
Primary			
Secondary			

11.11. Tooth status extended to all teeth eligible at randomisation

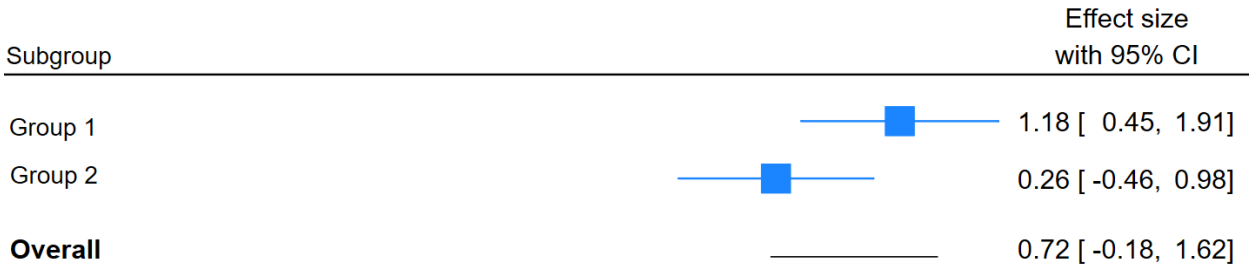
Tooth Status – n (%)	**SCR**	**CCR**
Vital		
Not vital		
Extracted		
Information not available		

12. Dummy Figures

12.1. Dummy Kaplan-Meier Curve



12.2. Dummy Subgroup Plot



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14. Appendices

14.1. Derived Patient reported Outcome Measures (PROMs)

The PROMs are Dental pain, need for dental pain relief, EQ-5D-5L, OHIP-14, Patient Satisfaction & a suite of oral health behaviours. Codes developed in-house will be checked and validated by an independent statistician using dummy data where relevant. Table 14.1 describes how each score will be calculated.

Table 14.1 Calculation of PROMs score

PROMs	Calculation	Reported
Dental Pain (NPRS)	Scored 0-10 (No pain – Worst possible pain). See https://www.physio-pedia.com/Numeric_Pain_Rating_Scale for more details.	As intended
Need for dental pain relief	Binary Yes/No outcome	As intended
EQ-5D-5L	Scored -0.59 to 1 (worst to best possible health state). See https://euroqol.org/information-and-support/euroqol-instruments/eq-5d-5l/ for more details.	As intended
OHIP-14	Scored 0-56 (worst to best state of oral health). See https://eprovide.mapi-trust.org/instruments/oral-health-impact-profile-14-items for more details.	As intended
Patient Satisfaction	Scored 1-4 (Not at all – Completely satisfied)	As intended
How often do you brush?	Scored 1-4 (Less than once a day – More than twice a day)	Best practice vs not best practice
How long do you take to brush?	Scored 1-4 (Less than 1 minute – More than 2 minutes)	Best practice vs not best practice
Do you use interdental brushes?	Scored 1-4 (At least once a day - Never)	Inverse score 1-4 (Never – at least once a day)
What do you do after brushing?	Scored 1-3 (Rinse with water, rinse with mouthwash, spit but no rinse)	Best practice vs not best practice

14.2. Stata code

Table 14.2 provides sample stata code for the analysis of the primary outcome.

Outcome	Stata code
Primary Outcome:	
Sustained Tooth Vitality	stset Time, failure(outcome) stcox i.TreatmentNo i.TypeofCaries i.NumberofEligibleTeeth, shared(ClinicianID)