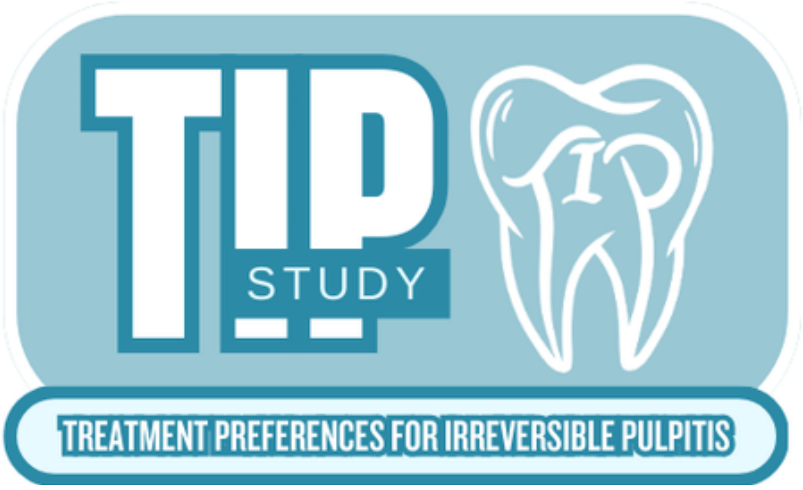

TIP
STUDY
TREATMENT PREFERENCES FOR IRREVERSIBLE PULPITIS

FULL/LONG TITLE OF THE TRIAL

Treatment Preferences for the management of **I**rreversible **P**ulpitis (TIP): Comparing two prototypes of a Patient Decision Aid for shared decision making: a pilot randomised control study.

SHORT TRIAL TITLE / ACRONYM

TIP STUDY

PROTOCOL VERSION NUMBER AND DATE

TIP study protocol V2 07.01.2026

RESEARCH REFERENCE NUMBERS

IRAS Number: 343640

Research Register Number: TBC

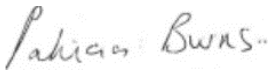
SPONSORS Number: 2-062-25

This protocol has regard for the HRA guidance and order of content V1.2 March 2016

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and approved by the Sponsor and that the Chief Investigator agrees to conduct the study in compliance with this approved protocol and will adhere to the principles of GCP, the Sponsor SOPs, and any other applicable regulatory requirements as may be amended from time to time.

For and on behalf of the Trial Sponsor:

Signature:  Date: 03.11.25

Name: Patricia Burns
Position: Senior Research Governance Manager

Chief Investigator:

Signature:  Date: 22.10.2025

Name: Dr Thibault Colloc,

KEY TRIAL CONTACTS

Chief Investigator	Dr Thibault Colloc, Dental Health Services Research Unit, Dundee Dental School, The University of Dundee, Dundee, 9th Floor, Park Place, Dundee DD1 4HN, UK Email: tcolloc001@dundee.ac.uk
PhD Supervisor	Professor Janet Clarkson Professor David Ricketts Professor Craig Ramsay Dr Carol Tait
Sponsor	University of Dundee Patricia Burns, Senior Research Governance Manager, Research & Development Office, TASC, Residency Block Level 3, George Pirie Way, Ninewells Hospital, Dundee DD1 9SY, 01382 383297, TASCgovernance@dundee.ac.uk
Funder(s)	Royal College of Physicians and Surgeons of Glasgow, TC White Researcher Grant Award 2024
Statistician	Dr Thibault Colloc

I. LIST OF ABBREVIATIONS

AE	Adverse Event
AAE	American Association of Endodontics
CHI	Community Health Index
CI	Chief Investigator
CNORIS	Clinical Negligence and Other Risks Indemnity Scheme
CRF	Case Report Form
DMC	Data Monitoring Committee
ESE	European Society of Endodontology
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
ICF	Informed Consent Form
IF	Incidental Findings
ISF	Investigator Site File
IPDAS	International Patient Decision Aids Standards
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
PDA	Patient Decision Aid
PIS	Patient Information Sheet

PPI	Patient and Public Involvement
PrepDM	Preparation for Decision Making scale
REC	Research Ethics Committee
SAE	Serious Adverse Event
SIMD	Scottish Index of Multiple Deprivation
SDM	Shared Decision Making
SOP	Standard Operating Procedures
SMF	Study Master File
SMG	Study Management Group
TCU	Trial Clinical Unit

II. TRIAL SUMMARY

Study Title	Treatment Preferences for the management of Irreversible Pulpitis (TIP): Comparing two prototypes of a patient decision aid for shared decision making: a pilot randomised control study.	
Study Design	Pilot Randomised Controlled Study	
Study Population	Adult patients (18 years and older) attending routine appointments at Dundee Dental Hospital and Research School.	
Sample Size	120 participants	
Planned Study Period	24 months	
Follow up phase duration	None	
Primary	Objectives: Effectiveness of the Patient Decision Aids (PDA) in preparing patients to make a decision regarding the management of irreversible pulpitis	Outcome Measures: - Preparation for Decision Making Scale
Secondary	Objectives: Acceptability of the PDAs and patients' understanding of irreversible pulpitis disease and its management	Outcome Measures: - Acceptability questionnaire - Knowledge questionnaire
Inclusion Criteria	- Adult patients (18 years and older) - Able to consent - Attending for routine or new patient appointments at the Dundee Dental Hospital and Research School	
Exclusion Criteria	- Patients attending with emergency treatment needs (e.g. pulpitis, pain, infection) - Unable to read and/or understand written English	

III. FUNDING AND SUPPORT IN KIND

FUNDER	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
Royal College of Physicians and Surgeons of Glasgow	Funding (£10,000)

IV. ROLE OF TRIAL SPONSOR AND FUNDER

The roles and responsibilities of the Sponsor and Funder will be detailed in the Clinical Research Agreement.

V. ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The study will be coordinated by a Study Management Group (SMG), consisting of the grant holders, including the Chief Investigator (CI), and PhD Supervisors. SMG membership details will be held in the Study Master File (SMF). The SMG will meet regularly to ensure all practical details of the study are progressing and working well and everyone within the study understands them. Minutes of the SMG meetings will be maintained in the SMF.

The CI will be responsible for the conduct of the study. Site delegate(s) will oversee the study and will be accountable to the CI. A study-specific Delegation Log will be prepared for each study site, detailing the duties of each member of staff working on the study.

VI. PROTOCOL CONTRIBUTORS

CI: Dr Thibault Colloc, initial and final approval

PhD Supervisors: Janet Clarkson, David Ricketts, Craig Ramsay, Carol Tait, review

TCTU Senior Trial Manager: Margaret Band, review

TCTU Clinical Trials Statistician: Petra Rauchhaus, review

PPI members: Stuart Anderson and Siobhan MacAndrew, patient facing documentation review

VII. KEY WORDS

Irreversible/Severe Pulpitis, Patient Decision Aid

VIII. STUDY FLOW CHART

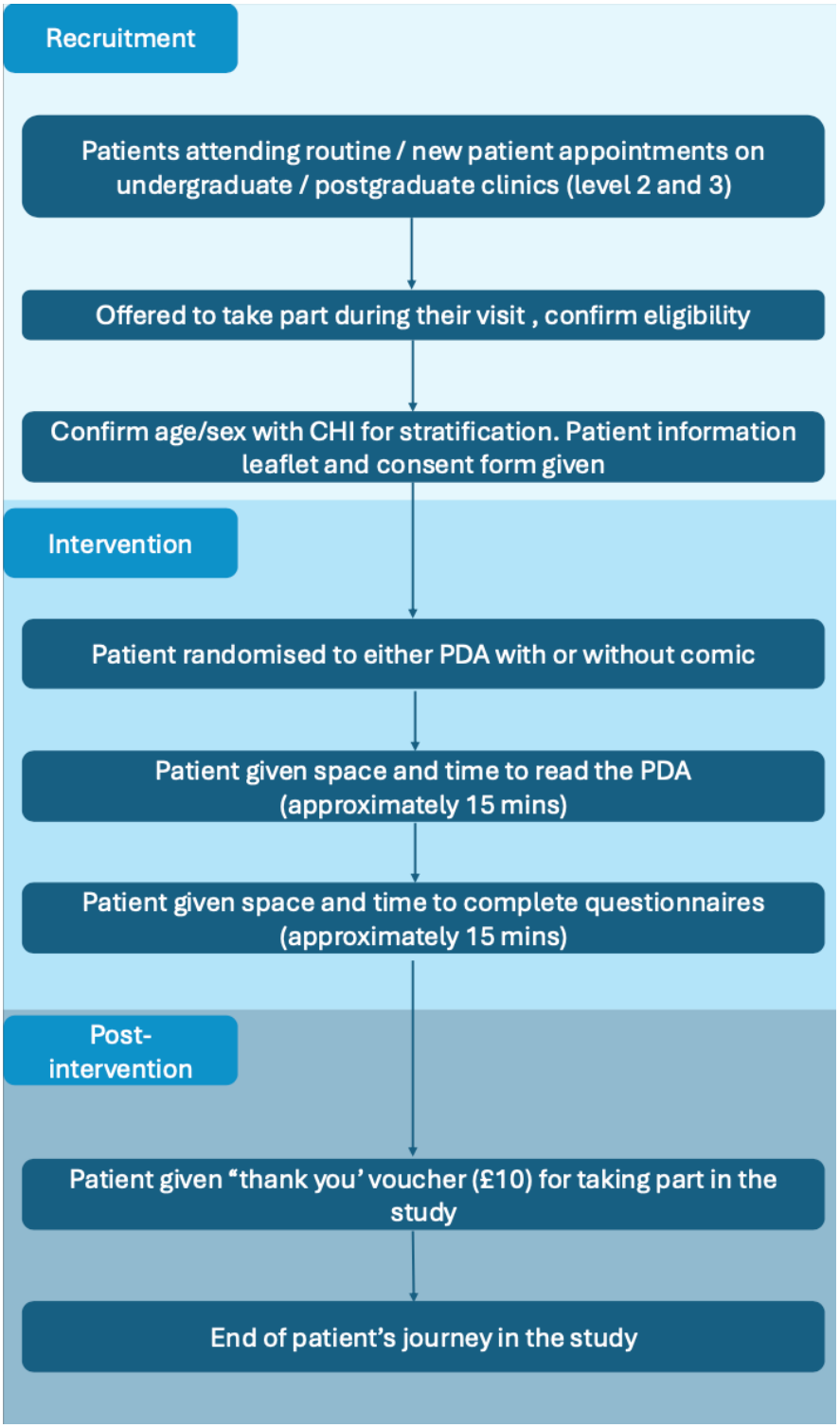


Figure 1: TIP Study matrix

1 INTRODUCTION / BACKGROUND

Background:

Value-based health and care, along with Realistic Dentistry, are increasingly recognized in healthcare, as highlighted by the Chief Medical Officer of Scotland's Realistic Medicine and Vision for 2030. Central to these concepts are informed consent and shared decision-making (SDM), which enhance patients' control over their healthcare by facilitating conversations between clinicians and patients about proposed treatments, alternatives, and associated risks and benefits (Whitney et al., 2004). Effective health communication tools, such as patient decision aids (PDAs), are crucial in supporting informed consent and SDM by providing patients with balanced information about treatment options and procedures and their advantages and disadvantages (Stacey et al., 2024).

A novel approach to informing patients involves using educational comics, defined as a subset of comics aimed at transferring information or communicating concepts rather than entertaining (Caldwell, 2012). Educational comics can foster empathy and understanding by helping patients and their relatives relate to the experiences depicted (McNicol, 2017). Evidence from systematic reviews and meta-analyses suggests that incorporating pictorial health information, such as educational comics, can significantly enhance patient knowledge and recall, particularly in populations with lower health literacy, thereby supporting SDM and informed consent processes (Schubbe et al., 2020).

Disease and treatment investigated:

Untreated carious lesions in permanent teeth are a prevalent non-communicable disease, affecting 35% of the global population in 2010 (Kassebaum et al., 2015). When these lesions extend near the dental pulp (nerve of the tooth), they can lead to irreversible pulpitis, historically treated with extraction or endodontic treatment (Glickman, 2009). However, preserving pulp vitality (healthy blood supply) through minimally invasive procedures is now emphasized, as highlighted by the European Society of Endodontology (ESE) (Duncan et al., 2019). Full pulpotomy, a less invasive vital pulp therapy, is recommended for managing irreversible pulpitis in restorable permanent posterior teeth by both the ESE and the American Association of Endodontists (AAE) (AAE, 2021). The ongoing NIHR-funded PIP study in the UK is exploring the success of pulpotomy compared to root canal treatment in primary care settings, highlighting the potential for a more conservative and less complex procedure for managing irreversible pulpitis (Clarkson et al., 2022).

Design of the Patient Decision Aids with public involvement:

Two novel PDAs were designed following the International Patient Decision Aids Standards (IPDAS) and National Institute for Health and Care Excellence (NICE) guidelines. The process adopted a co-design approach, involving patients and members of the public. The focus was on developing adequate information resources to ensure all treatment options are considered.

Guidance from the National Institute for Health Research (NIHR) highlighted the increased need for, and almost requirement of, public involvement in new research. This aims to create an active partnership between patients, carers, and the public with researchers, influencing and shaping research (NIHR, Briefing Notes for Researchers, April 2021). A diverse team, including a comic artist, dentists, dental

researchers, a dental student, a dental nurse, and public representatives, collaborated to co-design the two PDAs.

2 RATIONALE

In line with the latest national (NICE guidelines for PDA design, 2023) and international guidelines (IPDAS), two PDAs were co-designed (one with comics and one without) with Patients and Public Involvement (PPI) to ensure they meet the highest standards of patient-centered care. This co-design process is particularly topical as it aligns with the current emphasis on involving patients in the development of healthcare tools to enhance their relevance and effectiveness.

3 STUDY OBJECTIVES & OUTCOMES

Aim: To evaluate, in an adult population without the disease (Participants), the effectiveness of a PDA with health educational comics (Intervention) compared to a PDA without such comics (Control Comparator) in informing patients about irreversible pulpitis disease and its management and helping them prepare to make informed decisions for treatment (Outcomes). To achieve this, the patients consenting to take part will be randomised to one PDA or the other and will complete a validated questionnaire exploring the acceptability of the PDA, their understanding of the disease and whether the information provided would help them make a decision for treatment (Statistical Design).

Null hypothesis: There is no significant difference in the effectiveness of a PDA with health educational comics compared to a standard PDA without comics in informing patients about the irreversible pulpitis and its management.

Primary objective: To evaluate the effectiveness of the two versions of PDAs in preparing patients to make a decision regarding the management of irreversible pulpitis.

Primary outcome: Evaluation of the level of preparation for decision making using validated Preparation for Decision Making scale.

Secondary objectives:

- To evaluate the acceptability of the PDAs regarding patients' understanding of irreversible pulpitis disease and its management.
- To evaluate patients' understanding of irreversible pulpitis disease and its management

Secondary outcome:

- Evaluation of acceptability of the PDAs using validated acceptability questionnaire
- Evaluation of knowledge of the disease with validated knowledge questionnaire

Table 1: Primary Objectives and Outcome Measures

Primary Objective:	**Outcome Measure:**	**Timepoint of outcome measured**
Effectiveness of the Patient Decision Aids (PDA) in preparing patients to make a decision regarding the management of irreversible pulpitis	- Preparation for Decision Making scale (PrepDM)	- Following recruitment and review of the allocated PDA

Table 2: Secondary Objectives and Outcome Measures

Secondary Objective:	**Outcome Measure:**	**Timepoint of outcome measured**
Acceptability of the PDAs	- Acceptability measure	- Following recruitment and review of the allocated PDA
Patients' understanding of irreversible pulpitis disease and its management	- Knowledge measure	- Following recruitment and review of the allocated PDA

4 STUDY DESIGN

Single-centre, pilot, randomised control study with a 1:1 allocation ratio

5 STUDY SETTING

The study will be taking place in a single centre, the Restorative Department, Dundee Dental Hospital and Research School.

6 PARTICIPANT ELIGIBILITY CRITERIA

6.1 INCLUSION CRITERIA

- Adult patients (18 years and older)
- Able to consent
- Attending for routine or new patient appointments

6.2 EXCLUSION CRITERIA

- Patients attending with emergency treatment needs (pain, infection)
- Unable to read and/or understand written English

7 STUDY PROCEDURES

SCHEDULE OF PROCEDURES

	Visit
Eligibility check	X
Informed consent	X
Randomisation	X
Provision of PDA	X
Questionnaires	X

7.1 RECRUITMENT

Patients attending the Restorative department will be identified by the research team and/or the clinical team when attending for non-emergency clinic visits. Staff will assess if a participant is eligible to take part.

7.1.1 PAYMENT

Once the questionnaire is completed, the patient will be given a £10 “thank you” voucher for their participation and time.

7.2 CONSENT

The CI retains overall responsibility for the conduct of the research, including obtaining informed consent from participants. The CI may delegate the task of taking consent to other trained members of the research team, with all delegation documented in a Delegation Log. Staff involved in the consent process will receive training appropriate to the study procedures.

Participants will be provided with a Patient Information Sheet (PIS) outlining the study protocol. If they express interest in participating, a member of the study team will guide them to a designated bay or surgery to obtain consent. Participants will be given time to ask questions and will be asked to provide written consent. Since the intervention involves reading a document and answering questions about it, it will be administered immediately after written consent is obtained.

Once the consent process is completed, participants will be offered the option to receive a copy of the signed consent form—either as a paper copy or a digital copy, if they have provided an email address.

7.3 RANDOMISATION & BLINDING

To ensure even distribution of participants into the two intervention groups (total sample size: 120), stratified randomisation will be used via the Sealed Envelope website. Stratification will be based on age and sex, with both values derived from the Community Health Index (CHI) number—a unique identifier used in NHS Scotland.

- Age is determined from the date of birth encoded in the CHI.

- Sex is identified using the 9th digit of the CHI number: odd digits indicate male, and even digits indicate female.

This method allows for accurate and consistent stratification without requiring additional data collection. Participants will be divided into four strata of approximately 30 individuals each:

- Males under 50
- Females under 50
- Males 50 and over
- Females 50 and over

These strata reflect the typical demographic distribution of patients attending NHS dental clinics, where age and sex are known to influence health literacy and treatment preferences. Stratification ensures these variables are balanced across intervention groups, reducing potential confounding.

Within each stratum, participants will be randomly assigned to one of the two groups using permuted block randomisation, which maintains balance throughout recruitment. Once a stratum reaches its target sample size (n=30), recruitment for that group will close. This approach ensures proportional representation and prevents over-recruitment from any one demographic group.

Although the research team will not be blinded due to the nature of the intervention, participants will remain blinded to group allocation. They are not informed of the existence of different types of decision aids (e.g. with or without comics) and are therefore unaware of which version they have received. This preserves the integrity of the blinding process and reduces the risk of performance bias.

7.4 TRIAL ASSESSMENTS

The patients will be assessed with validated questionnaires and will be asked to complete basic demographics as part of the study. They will be given the pack with the allocated PDA and will be given time to read the document (approximately 15 mins).

Following reading the document, they will then be asked to complete questionnaires.

- **Demographics:** Age, gender, ethnicity, level of education, partial postcode (for calculation of Social Deprivation Index), whether English is their first language and confidence at understanding written English

As part of their working group the IPDAS have created a series of validated questionnaires aimed at evaluating PDAs. The following ones have been selected to assess the two PDAs tested in this study:

- **Acceptability questionnaire**: Refers to ratings regarding the comprehensibility of components of a decision aid, its length, amount of information, balance in presentation of information about options, and overall suitability for decision making (appendix 1). Responses for this part will be reported descriptively in terms of proportions responding positively or negatively on each criteria (O'Connor and Cranney, 1996).
- **Knowledge questionnaire**: The knowledge questionnaire measures respondent's cognizance of a clinical problem, its alternatives, rationale, main benefits, risks and side effects. Items focus on information considered essential for decision making. Items will be scored based on the number of correct answers out of the 32 items. Any item not answered or marked as unsure will be considered

incorrect. A mean knowledge score can then be calculated. For comparison to a 0-100 scale, the score can be converted into a percentage of correct responses (O'Connor, 2000).

- **Preparation for decision making scale (PrepDM):** The prepDM scale assesses a patient's perception of how useful a decision aid or other decision support intervention is in preparing the respondent to communicate with their practitioner at a consultation and making a health decision (treatment/diagnostic/screening, etc.). Items will be summed and scored (sum score for 10 items and divide by 10). Scores can also be converted to a 0-100 scale, a higher score indicating a higher perceived level of preparation for decision making (Bennett et al., 2010).

7.5 END OF STUDY

The end of study will be defined as the last participant completing the study assessments. The Sponsor, CI and/or the SMG have the right at any time to terminate the study for clinical or administrative reasons. The end of the study will be reported to the Sponsor and Research Ethics Committee (REC) within 90 days, or 15 days if the study is terminated prematurely.

8 INTERVENTION

Patient Decision Aid 1:

This document was co-designed to inform patients about irreversible pulpitis, its origin, its symptoms, a description of its treatment options, including no treatment and the benefits and risks associated with each of the options:

- No intervention
- Root Canal Treatment
- Pulpotomy
- Extraction

Patient Decision Aid 2:

This document includes all the features of the PDA 1 but also incorporates a comic that illustrates the journey of a patient suffering from irreversible pulpitis. The comic spans four pages, each depicting a step in the patient's journey from experiencing symptoms to receiving treatment options at a dental practice.

Intervention:

Patients who consent to take part in the study will be randomly allocated to receive either PDA 1 or PDA 2. They will then be given 15 minutes to read through the assigned decision aid in a quiet area of the clinic. During this time, participants will be asked to review the material on their own, without input from any accompanying individuals, to minimise external influence on their perceptions and responses. After reading the decision aid, participants will complete a questionnaire, which is expected to take approximately 10-15 minutes. The questionnaire will include:

- An acceptability questionnaire to assess their views on the decision aid,
- A knowledge questionnaire to evaluate their understanding of the treatment options,

- A pre-decision-making scale to measure their readiness to make a decision,
- And a short section collecting demographic information.

9 DATA COLLECTION & MANAGEMENT

9.1 DATA COLLECTION TOOLS

Data management will be conducted in compliance with Sponsor SOPs on Data Management. The approved Data Management System (DMS) for this study is JISC Online Surveys, which meets UK GDPR requirements and institutional data protection standards.

The DMS will be structured according to the study protocol and will collect only the data necessary to meet the study's objectives. To facilitate efficient and accurate data collection, participants will complete questionnaires using either:

- A tablet provided by the research team, or
- Their own mobile device by scanning a QR code linking to the secure JISC form.
- An alternative format upon request if required (e.g. Paper questionnaire)

When using a tablet, a member of the research team will be present nearby to assist if needed and to ensure privacy and proper data submission. Once the participant completes the questionnaire, the tablet will be returned to the researcher, who will confirm that the data has been securely submitted.

When a paper questionnaire is required, a member of the research team will be present nearby to provide assistance if needed and to ensure privacy throughout completion. After the participant leaves, the researcher will immediately transfer the responses onto the JISC platform to ensure accurate data entry. Once the information has been securely uploaded, the paper questionnaire will be confidentially and securely discarded.

The JISC platform offers robust features for secure data handling, including encrypted transmission, secure storage, and real-time analytics. No identifiable data will be stored on the JISC platform. After consent is obtained, each participant will be assigned a study number, which will be manually entered into the questionnaire. This number will be recorded in an enrolment log and used for randomisation, allowing linkage to participant details if necessary. This process ensures participant confidentiality, supports blinding at the analysis level, and enables secure and structured data collection to evaluate the effectiveness of the two patient decision aids.

9.2 DATA HANDLING & RECORD KEEPING

The database is managed in line with all applicable principles of medical confidentiality and UK law on data protection, namely, the Data Protection Act 2018. The Data Controller will be the University of Dundee (UoD), and the Data Custodian will be the CI.

Data will be securely stored on the JISC Online Surveys platform, which is password-protected and accessible only to the CI and delegated members of the research team. JISC Online Surveys is GDPR-compliant and certified to the ISO/IEC 27001 information security standard. Access permissions are strictly limited to authorised personnel, and user access will be reviewed periodically to ensure continued

compliance with data protection requirements. Only the CI will have permissions to modify or delete data; all other authorised team members will have view-only access.

Following data collection, responses will be exported into Microsoft Excel and .csv file formats. These files will be securely stored on the University of Dundee's password-protected cloud storage system (OneDrive), which complies with institutional data security policies. Access to these files will be restricted to the CI and authorised members of the research team. As with JISC, access rights on OneDrive will be periodically reviewed, and only the CI will have the ability to make changes or delete data, while other team members will retain view-only access.

This approach ensures that all data are handled, transferred, and stored in a secure and controlled manner throughout the study lifecycle.

9.3 ACCESS TO DATA

Only authorised members of the research team will have access to the JISC Online Surveys platform, which will be used to collect questionnaire responses. Access will be restricted through secure login credentials, and permissions will be reviewed periodically to ensure continued compliance. Within the platform, only the CI will have the ability to modify or delete data; all other team members will have view-only access.

The enrolment log will be maintained in a password-protected Excel file stored securely on the University of Dundee's OneDrive system, in accordance with institutional data security policies. Access to this file will be limited to authorised research team members for the sole purpose of updating participant records. As with JISC, only the PI will have editing or deletion rights, while other team members will retain view-only access.

All data handling procedures will comply with the UK General Data Protection Regulation (GDPR) and the Data Protection Act 2018, ensuring that personal data are processed lawfully, fairly, and transparently. Identifiable information will be stored separately from research data, and all data will be anonymised prior to analysis.

9.4 ARCHIVING

All study data will be archived digitally for 10 years in accordance with the University of Dundee's data retention policy. These records will be securely stored on the University of Dundee's OneDrive cloud storage system, which is protected by institutional security protocols including password authentication and multi-factor identification. OneDrive is managed under the University's Microsoft 365 environment, which complies with UK GDPR and institutional data governance standards.

Access to the archived data will be strictly limited to authorised members of the research team. Permissions will be configured to ensure that only the CI has editing and deletion rights, while other team members will have view-only access. Folder-level permissions will be applied to restrict access to specific files, and access logs may be monitored periodically to ensure compliance.

All documentation, including the SMF, will be stored digitally within this secure environment. No physical records will be retained. This setup ensures that all data are preserved in a secure, controlled,

and compliant manner, meeting both regulatory and ethical standards throughout the study lifecycle and archiving period.

10 STATISTICS AND DATA ANALYSIS

10.1 SAMPLE SIZE CALCULATION

As this is a pilot study, a formal sample size calculation was not performed due to lack of reference data. The primary aim is to explore whether there is a clinically significant difference in patient preparedness for theoretical decision-making when using PDA 1 compared to a PDA 2, but so far no studies have been performed on this outcome.

Based on available time and funding resources, we estimate that we can recruit approximately 120 participants over a one-year recruitment period. To ensure balanced representation and allow for exploratory subgroup analysis, participants will be stratified by age and sex (based on CHI number and confirmed with patient at eligibility stage) at the point of randomisation into four subgroups: males over 50, females over 50, males under 50, and females under 50, with an aim of recruiting 30 participants per subgroup. This sample size is considered sufficient to obtain basic data to establish a clinically significant difference in decision making, either in the whole group or subgroups. This will inform future study design and provide preliminary insights into potential differences between the two intervention arms.

10.2 PLANED RECRUITMENT RATE

Participant recruitment will take place at the Dundee Dental Hospital and Research School. Recruitment sessions are planned to occur two to three times per week, with each session lasting approximately half a day. Based on clinic flow and eligibility criteria, we anticipate enrolling 3 to 4 eligible patients per session.

To reach the target sample size of 120 participants, recruitment is expected to take a minimum of 12 weeks, assuming consistent eligibility rates and willingness to take part. However, due to the use of stratified randomisation by age and sex, recruitment may be more complex, as each stratum must be filled evenly. This may result in slower enrolment for certain demographic groups. The overall recruitment phase may span up to 12 months to allow for flexibility in scheduling and recruitment.

Additional members of the research team will be present during recruitment sessions to support screening, consent, and data collection. This will ensure that participants can be enrolled efficiently and that study interventions are conducted without disrupting routine clinical care.

10.3 STATISTICAL ANALYSIS PLAN

10.3.1 Summary of baseline data and flow of patients

Baseline demographic data will be collected using a structured case report form (CRF) at the time of recruitment. The information recorded will include age group, gender, the first part of the patient's postcode (will allow to use Scottish Index of Multiple Deprivation (SIMD) data), ethnicity, and level of education. All participants will be recruited and will complete the study interventions on the same day, with no requirement for follow-up. This streamlined approach is designed to facilitate efficient data

collection and minimize participant burden, while ensuring consistency in the flow of patients through the study.

10.3.2 Primary outcome analysis

The primary outcome will be the participant's score on the PrepDM scale, which assesses the perceived usefulness of the decision aid in preparing patients to communicate with their practitioner and make a health-related decision. The scale consists of 10 items, each rated on a 5-point Likert scale. Item scores will be summed and averaged to produce a total score ranging from 1 to 5, which will also be converted to a 0–100 scale for ease of interpretation, with higher scores indicating greater perceived preparation for decision making.

Descriptive statistics (mean, standard deviation, median, and interquartile range) will be reported for each group. The distribution of PrepDM scores will be assessed using visual (e.g., histograms, Q-Q plots) and statistical methods (e.g., Shapiro-Wilk test). If the data are skewed, appropriate transformations (e.g., log or square root) will be applied to approximate normality.

Between-group comparisons (PDA with comics vs. PDA without comics) will be conducted using an analysis of variance (ANOVA), which allows for the inclusion of stratification variables (age and gender) and other baseline covariates such as SIMD and education level. This approach provides a more flexible and informative analysis than a basic t-test. Non-parametric methods such as the Mann–Whitney U test will be reserved for sensitivity analyses, as they do not accommodate covariates and may reduce statistical power. A significance level of 0.05 will be used for all statistical tests. As this is a pilot study, the analysis will be exploratory and primarily aimed at estimating effect sizes and informing the design of a future definitive study.

10.3.3 Secondary outcome analysis

Secondary outcomes will include (1) the acceptability of the PDAs (1) and patients' understanding of irreversible pulpitis and its management (2). Acceptability and knowledge will be assessed using a structured acceptability questionnaire and a knowledge questionnaire, both administered immediately following recruitment and review of the allocated PDA. Descriptive statistics will be used to summarize responses and between-group comparisons (PDA with comics vs. PDA without comics) will be conducted using appropriate statistical tests (e.g., chi-square tests for categorical variables, t-tests or Mann–Whitney U tests for continuous variables).

10.3.4 Participant population

The study population will consist of adult patients (aged 18 years and older) attending routine or new patient appointments at the Restorative Department, Dundee Dental Hospital and Research School. Eligible participants must be able to provide informed consent and engage meaningfully with the study materials.

As this study involves the evaluation of a prototype decision aid, which is currently available only in English, participants must have sufficient proficiency in written English to understand the content and

complete the associated questionnaires. This is necessary to ensure that feedback reflects the usability and clarity of the prototype itself, rather than being confounded by language comprehension issues.
To assess language background and support future development, two questions will be included in the questionnaire: *"Is English your first language?"* and *"How confident are you in reading written English?"*.
This will allow for subgroup analyses and help inform whether future iterations of the decision aid should be adapted or translated for non-native English speakers.
Patients presenting with emergency treatment needs (e.g., pain or infection) or those who are clearly unable to engage with the study materials, even with support, will be excluded.
While this approach may limit the generalisability of findings to the broader Dundee population, it is appropriate for this early-stage evaluation. Insights gained will inform future refinements and potential adaptations for a more diverse patient population.

10.4 PROCEDURE(S) TO ACCOUNT FOR MISSING OR SPURIOUS DATA

Given the single-session design of this study, missing data are expected to be minimal. However, any incomplete or missing responses on questionnaires will be documented and reported. Descriptive analyses will include the number and proportion of missing values for each variable. For the primary outcome (PrepDM score), participants with incomplete responses to more than two items will be excluded from the analysis; if one or two items are missing, mean imputation based on the participant's available responses will be applied, in line with standard scoring guidance. For secondary outcomes, missing data will be handled using complete case analysis. Spurious or implausible data entries (e.g., out-of-range values) will be reviewed and verified against source documents where possible. Sensitivity analyses may be conducted to assess the potential impact of missing or spurious data on the study findings.

11 AUDIT AND INSPECTION

The CI, and all institutions involved in the study will permit study related audits, and REC review. The CI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation.

12 ETHICAL AND REGULATORY CONSIDERATIONS

12.1 RESEARCH ETHICS COMMITTE REVIEW & REPORTS

The study will be conducted in accordance with the principles of good clinical practice (GCP).
In addition to Sponsorship approval, a favorable ethical opinion will be obtained from the appropriate REC and appropriate NHS Research & Development approval(s) will be obtained prior to commencement of the study.

12.2 PEER REVIEW

This study has undergone a comprehensive peer review process at multiple levels to ensure scientific validity, methodological soundness, and operational feasibility. Initially, the research design and objectives were reviewed and refined in collaboration with the supervisory team, who provided academic and clinical expertise. The study protocol was then peer reviewed by the Trial Clinical Unit (TCU) Tayside, which assessed the practical aspects of study delivery, regulatory compliance, and resource planning. In addition, the study has been reviewed by the project funder as part of the funding approval process, ensuring alignment with strategic research priorities and value for investment. The study sponsor will also conduct a review to confirm adherence to governance standards and institutional requirements. This multi-level peer review process supports the integrity and quality of the research.

12.3 PUBLIC AND PATIENT INVOLVEMENT

PDAs were co-designed with PPI to ensure they meet the highest standards of patient-centered care. The patient representatives have given input into the participant facing documents.

12.4 REGULATORY COMPLIANCE

The study will not commence until R&D approval.

12.5 PROTOCOL COMPLIANCE

The CI will not implement any deviation from the protocol unless necessary to eliminate an unexpected and immediate hazard to study participants. However, no such hazard is currently anticipated based on the nature of the intervention and study design.

If a protocol breach does occur, the nature and reason for the breach will be documented in the study Breach Log, and Sponsor Standard Operating Procedures (SOPs) will be followed for recording and reporting. It is Sponsor policy that waivers to the protocol will not be approved under any circumstances.

12.6 DATA PROTECTION AND PATIENT CONFIDENTIALITY

The CI and research team will comply with all applicable medical confidentiality and data protection principles and laws with regard to the collection, storage, processing and disclosure of personal data.

The CI and research team will also adhere to the NHS Scotland Code of Practice on Protecting Participant Confidentiality or equivalent.

All study records and personal data will be managed in a manner designed to maintain participant confidentiality. All records will be kept in a secure online storage area with access limited to appropriate study staff only. Computers used to collate personal data will have limited access measures via usernames and passwords.

Personal data concerning health will not be released except as necessary for research purposes including monitoring and auditing by the Sponsor, its designee or regulatory authorities providing that suitable and specific measures to safeguard the rights and interests of participants are in place.

The CI and research team will not disclose or use for any purpose other than performance of the study, any personal data, record, or other unpublished, confidential information disclosed by those individuals for the purpose of the study. Prior written agreement from the Sponsor will be required for the disclosure of any said confidential information to other parties.

Access to collated personal data relating to participants will be restricted to the CI and appropriate delegated research team.

No transfer of data will occur outside the University of Dundee organisation.

Published results will not contain any personal data that could allow identification of individual participants.

12.7 INDEMNITY

The University of Dundee is sponsoring the study.

Insurance – The University of Dundee holds Clinical Trials indemnity cover which covers the University's legal liability for harm caused to patients/participants.

Where the study involves University of Dundee staff undertaking clinical research on NHS patients, such staff will hold honorary contracts with Tayside Health Board which means they will have cover under Tayside's membership of the CNORIS scheme.

Indemnity The Sponsor does not provide study participants with indemnity in relation to participation in the Study but has insurance for legal liability as described above.

12.8 AMENDMENTS

Amendments to the protocol will be conducted in compliance with Sponsor Standard Operating Procedures. The decision to amend the protocol will lie with the CI. The CI will seek Sponsor approval for any amendments to the Protocol or other approved study documents. The Sponsor will decide whether an amendment is substantial or non-substantial. The CI will be responsible for submitting the amendment to the appropriate regulatory authorities and communicating amendments to study staff. Amendments to the protocol or other study documents will not be implemented without approval from the Sponsor and subsequent approval from the appropriate REC, as appropriate, and appropriate site approvals. The amendment history will be detailed in an Amendment Log.

12.9 ACCESS TO THE FINAL TRIAL DATASET

Anonymised study data will be retained under the control of the CI for future research use within the University of Dundee (UoD). Access to the final dataset will be strictly limited to the CI and authorised members of the research team. No data will be transferred outside the UoD. All data will be stored and managed in accordance with UoD data governance policies and relevant ethical approvals.

13 DISSEMINIATION POLICY

13.1 DISSEMINATION POLICY

Ownership of the data arising from this study resides with the study team and their respective employers. On completion of the study, the study data will be analysed and tabulated, and a clinical study report will be prepared. The clinical study report will be used for publication and presentation at scientific meetings. Investigators have the right to publish orally or in writing the results of the study.

Summaries of results will also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion).

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