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A study of the feasibility of testing pulpotomy treatment for toothache in primary dental care

Submission date 15/01/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 28/01/2021	**Overall study status** Completed	
Last Edited 09/10/2024	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims

Severe toothache and pain can be caused by tooth decay. Tooth decay is very common. Where the tooth decay has spread deep into the nerve, this is usually treated by taking out the tooth or by root canal treatment. Root canal treatment removes all of the nerve from the tooth.

An alternative treatment for this kind of toothache is called a pulpotomy. A pulpotomy removes only the damaged part of the nerve, which can be a quicker and less invasive treatment. Pulpotomy is already used on children's teeth and on adult teeth when they are being treated in dental hospitals. However, it is not yet routinely used on adult teeth in NHS dental practices.

The researchers are planning a large-scale study to compare pulpotomy treatment with root canal treatment in NHS dental practices. However, before they embark on a larger more expensive study, they will conduct a 12-month feasibility study. A feasibility study is a piece of research done before the main study to assess if the study can be done and to collect information, such as patients' and dentists' experiences of the pulpotomy treatment, that can be taken into account in planning the larger study.

The aim is to find out more about: how many patients might be eligible for pulpotomy treatment, how many patients might be interested in this treatment, how best to train dentists to deliver the pulpotomy treatment and the practicalities of running this kind of study in NHS dental practices.

Who can participate?

Patients from participating dental practices with toothache that needs treatment which would normally be done by root canal treatment or by taking the tooth out. Anyone over 16 who the dentist believes would be suitable for this treatment.

What does the study involve?

Dentists from 10 dental practices will be trained to deliver the pulpotomy treatment. Each participating dental practice will be asked to recruit four eligible patients to receive pulpotomy treatment on their tooth. The participant will be contacted by their preferred means around 7 days after their treatment to collect information about their satisfaction with the pulpotomy treatment. Participants who have opted to take part in a telephone interview will be asked to talk about their experience of dental treatment in the study and their thoughts about the planned larger study. Participating dentists will also be asked to take part in telephone

interviews to explore the appropriateness of the training, the feasibility of delivering the interventions and recruitment of participants to the trial.

What are the possible benefits and risks of participating?
Pulpotomy is a routine treatment carried out in dental hospitals for children and adults with toothache. There are very few risks to patients taking part. The pulpotomy treatment may be quicker and less invasive than other treatments such as root canal treatment and is an alternative to having an extraction. As with all treatments, there is a small risk that the treatment may not work, and the patient may require further treatment. This is also the case if they were to opt for a root canal treatment.

Where is the study run from?
Dundee Dental School (UK)

When is the study starting and how long is it expected to run for?
June 2020 to September 2022

Who is funding the study?
National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme (UK)

Who is the main contact?
Dr Thibault Colloc, Clinical lecturer/Honorary specialty trainee in endodontology (Restorative Dentistry),
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Study website
https://w3.abdn.ac.uk/hsru/pip

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
289464

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HTA - NIHR129230, IRAS 289464

Study information

Scientific Title
Pulpotomy for the management of Irreversible Pulpitis in mature teeth - (PIP Trial) feasibility study

Acronym
PIP Trial - Feasibility Study

Study objectives
The PIP feasibility study will assess the clinical and patient feasibility of conducting a pragmatic patient randomised controlled trial (PIP main trial). The main trial aims to evaluate the clinical and cost-effectiveness of a full pulpotomy (FP) procedure versus a root canal treatment (RCTx) for mature pre/molar teeth in adults with symptoms indicative of irreversible pulpitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/03/2021, West of Scotland Research Ethics Committee 5 (West of Scotland Research Ethics Service, Ward 11, Dykebar Hospital, Grahamston Road, Paisley, PA2 7DE, UK; +44 (0)141 3140213; WoSREC5@ggc.scot.nhs.uk), ref: 21/WS/0023

Study design
Feasibility study for a multicentre randomized controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Tooth decay (irreversible pulpitis) in adult pre/molar teeth

Interventions
Dentists (GDPs) from 10 dental practices will be trained to deliver the pulpotomy treatment. Each participating dental practice will be asked to recruit 4 eligible patients to receive pulpotomy treatment on their tooth. The participant will be contacted by their preferred means around 7 days after their treatment to collect information about their satisfaction with the pulpotomy treatment. Participants who have opted to take part in a telephone interview will be asked to talk about their experience of dental treatment in the study and their thoughts about the planned larger study. Participating dentists will also be asked to take part in telephone interviews to explore the appropriateness of the training, the feasibility of delivering the interventions and recruitment of participants to the trial.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Number of GDPs recruited to take part in the study by month 13
2. Proportion of GDPs recruited achieving success in pre-specified clinical criteria (access cavity preparation, adaption of the biodentine material, adequate final restoration) during their training
3. Proportion of radiographs that show compliance with intervention delivery using pre-specified clinical criteria by month 13
4. Proportion of patients satisfied with care measured using the Patient-Reported Experience Measures (PREMs) outlined in the NHS England Guide for Commissioning Dental Specialties (30) at up to 1-month post-intervention
5. Mean number of eligible patients per month by month 13

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/06/2020

Completion date
30/09/2022

Eligibility

Key inclusion criteria
Adults (16 years and older) with symptoms indicative of irreversible pulpitis [as defined by ESE (10)] in a pre/molar tooth with deep caries and or a deep restoration

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
40

Total final enrolment
25

Key exclusion criteria
1. Tooth with immature roots, clinical or radiographic signs of a necrotic pulp, or a poor prognosis (e.g. internal or external resorption)
2. Presence of a sinus, tenderness to percussion, buccal tenderness, pathological mobility or evidence of pathology on a periapical radiograph
3. Insufficient tooth tissue for a restoration
4. All treatment delivered under a private contract

Date of first enrolment
01/04/2021

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
United Kingdom

Study participating centre
Dental practices in the NHS. Specific site details unknown at time of registration
United Kingdom
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Sponsor information

Organisation

University of Dundee

Sponsor details
Tayside Medical Science Centre
Ninewells Hospital and Medical School
Dundee
Scotland
United Kingdom
DD1 4HN
+44 (0)1382383297
TASCgovernance@dundee.ac.uk

Sponsor type
University/education

Website
http://www.dundee.ac.uk/

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication of study protocol in a high-impact peer-reviewed journal

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		02/04/2022	04/04/2022	Yes	No
HRA research summary			28/06/2023	No	No