

TIP Study: Patient information sheet

Treatment preferences for the management of Irreversible Pulpitis

How can we help patients make decisions about their treatment when they have Severe Pulpitis?

Throughout this document, we refer to:

- ‘We’ as in the study team
- ‘You’ as a potential participant in the study
- The ‘TIP’ study or ‘our’ study.

Part 1: We are inviting you to take part in a research study

Before you decide whether to take part, we want you to understand why we are doing this study.

This also explains why you have been invited to take part.

Why have I been asked?

You have been invited because you are receiving dental care and may have experienced symptoms of irreversible pulpitis. Your feedback will help us improve the information we give to patients with this condition.

Do I have to take part?

No. It is up to you to choose to take part in this study. If you choose to take part, you can stop the study at any time. You do not have to give a reason for not taking part or for stopping. If you don't want to take part or want to stop the study the dental care you get and your relationship with the dental or nursing staff looking after you will not be affected. You'll have the chance to ask further questions after reading this information sheet, before making up your mind.

When would I take part?

You would be invited to take part after your dental appointment, on the same day, and only if you have time. This ensures that taking part in the study does not affect your care at the Dental Hospital.

Why are we doing this study?

We want to see if we can improve the information we give to patients with severe pulpitis (a very painful toothache). Our goal is to help patients better understand their condition and treatment options.

What are we testing?

A group of dental researchers, members of the public, and an artist have created two different information sheets (called “decision aids”). These decision aids explain what severe pulpitis is and the different ways it can be treated.

What is severe (irreversible) pulpitis?

It’s a type of severe toothache caused by inflammation of the nerve inside your tooth.

What is the aim of this study?

To find out if the decision aids are helpful and acceptable for patients

To make sure patients have enough information to:

- Understand what severe pulpitis is
- Choose the treatment that they deem best for them according to their values

Who is running this study?

This project is part of a PhD degree in dentistry at the University of Dundee. The study is led by Thibault Colloc, supervised by Professor Jan Clarkson. It is being carried out at the Dental Hospital and Research School, University of Dundee.

Part 2: What will happen to me if I take part?

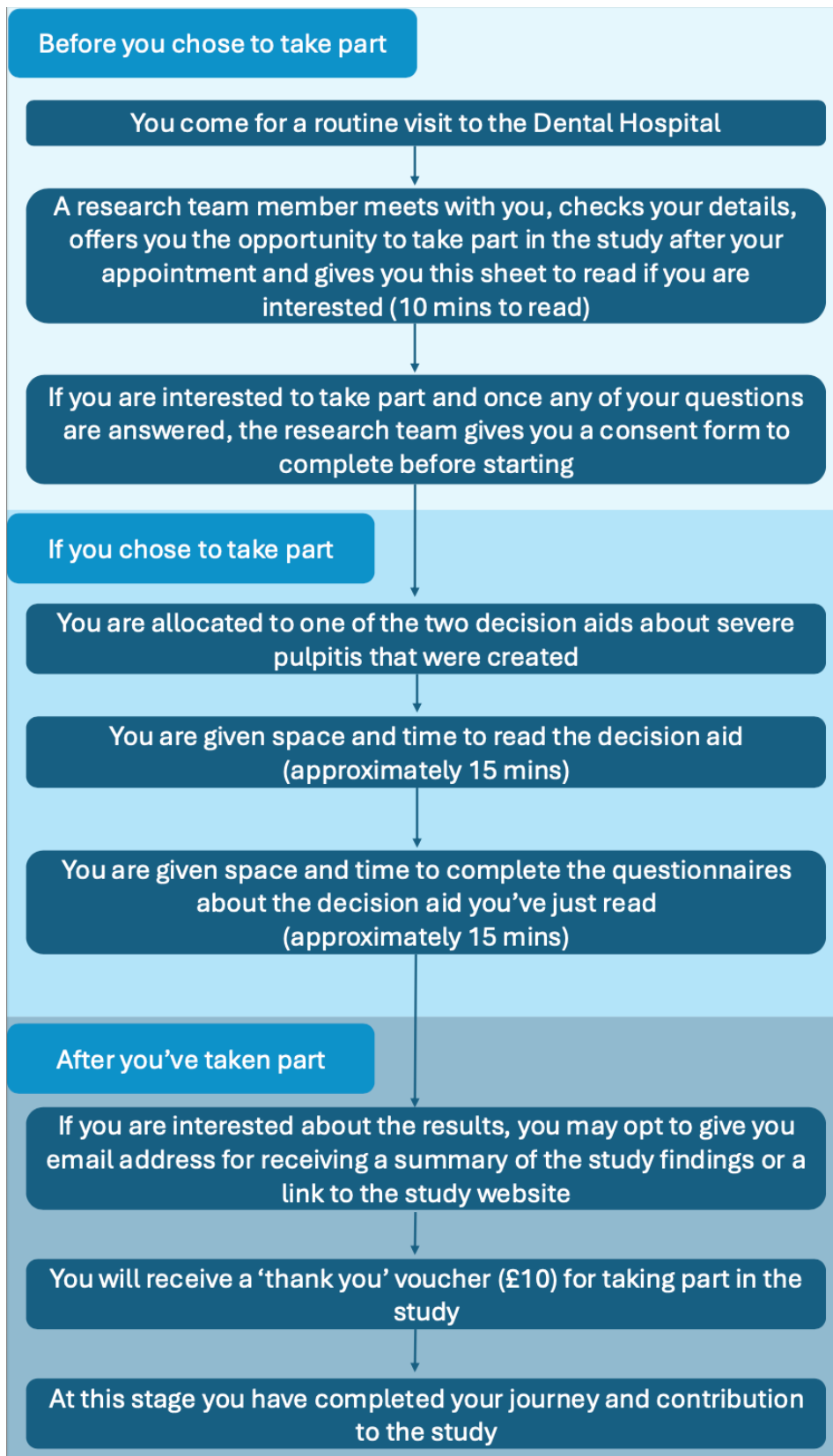
- **Consent:** We'll ask you to complete a consent form. You will be able to discuss the study and review the consent form before you sign it with a member of the research team.
- **Randomisation and blinding:** You'll be then given an anonymous study number, and we will use this number to randomly allocate you to one of the two decision aids we are testing, using an online randomisation tool. It means you are put in a group 'by chance' so no one decides which group (randomisation) You will not be aware which decision aid you are being given to prevent any bias (blinding).
- **Intervention:** You'll be then given the decision aid, and you'll be given time (about 15 mins) and private space to read it at your own pace. Once you have read it, you'll be asked to complete a questionnaire about the document on an electronic tablet. A member of the research team will be present to help you if you need.

The questionnaire will ask you about the decision aid you read. Questions will include whether the decision aid would help you to make your mind up about a preferred treatment option if you suffered from severe pulpitis, questions about what you liked about the aid, what you didn't like, if it was laid out well and if the information was easy to read and understand. The questionnaire will also ask you questions about yourself: your age, sex, ethnicity, the first part of your postcode, whether English is your first language and your confidence in reading written English. We want to collect this information to make sure that patients we include in the study are like the patients we see in our clinics with severe pulpitis.

- **As a thank you for your time:** you will receive a £10 gift voucher once you have completed all parts of the study, including the questionnaires. This is our way of showing appreciation for your contribution. After you finish the questionnaires, your participation in the study will be complete. You will also have the option to provide your email address if you would like to receive a summary of the study results. This is entirely optional.

Altogether it'll take about 45 minutes of your time.

The diagram below summarises the journey of a participant taking part in the study:



What will happen with the information you collect about me?

Your details and questionnaire answers will be kept securely and stored by the University of Dundee. All data will only be accessed by members of the research team for the purpose of the study. Once we have collected everybody's answers we will store them securely while we study the results. We will write our reports in a way that no one can work out that you took part in the study. We'll keep your personal details for up to one year after the end of the study. We'll keep your questionnaire answers for 10 years after the study end date. It will only be used for research purposes.

Will my taking part in this project be kept confidential?

All information collected during this study will be kept strictly confidential. Your questionnaire data will be identified by a study number rather than your name. Data will be stored securely, and only the research team will have access to it.

Where can you find out more about how your information is used?

You can find out more about how we use your information by asking one of the study team or at:

- www.hra.nhs.uk/patientdataandresearch
- <https://www.dundee.ac.uk/corporate-information/individual-rights-under-gdpr>
- https://www.nhstayside.scot.nhs.uk/YourRights/PROD_298457/index.htm

Part 3: Things to consider before taking part

What are the possible benefits of taking part?

Clear and accessible information is essential for patients making important health decisions. However, research shows that many patients find current information difficult to understand or overwhelming. This can lead to confusion, anxiety, or even decisions that don't fully reflect their preferences.

By taking part in this study, you will help us test different ways of presenting information to see which approach works best. While there may be no direct benefit to you, your feedback will help us design materials that are easier to understand and more helpful for future patients facing similar decisions.

What are the possible disadvantages and risks of taking part?

There are no known risks of harm from taking part in this study. You will simply be asked to review some information and answer a few questionnaires. You can stop at any time without giving a reason by just informing a member of the research team. This will have no effect on your current or future dental care or any future appointments you may have in the Dental Hospital.

Part 4: Study organisers and contact details

Who is organising and funding this research?

This study is being sponsored by the University of Dundee. This research is funded by the Royal College of Physicians and Surgeons of Glasgow.

Who has reviewed this study?

This study has been reviewed and approved by London - Bromley Research Ethics Committee, an independent group responsible for reviewing research involving people to ensure it is ethical and safe. The REC has raised no objections to the study going ahead.

What if something goes wrong? Where can I complain?

If you are concerned about your participation in the study, you have the right to discuss it with a researcher who is involved in carrying out the study or a dentist involved in your care.

If you have a complaint about your participation in the study first of all you should talk to a researcher involved in the study. You can also make a formal complaint by contacting to a senior member of the research team or to the Complaints Officer for NHS Tayside.

NHS Tayside Patient Experience Team
Ninewells Hospital
Dundee
DD1 9SY
Telephone: 0800 027 5507
Email: TAY.feedback@nhs.scot

If you think you have come to harm due to taking part in the study, there are not any automatic arrangements to get financial compensation. You might have the right to make a claim for compensation. If you wish to make a claim, you should think about getting independent legal advice, but you might have to pay for your legal costs.

Insurance

The University of Dundee is Sponsoring the study. The University of Dundee has a policy of public liability insurance which provides legal liability to cover damages, costs and expenses of claims.

As the study involves University of Dundee staff carrying out clinical research on NHS Tayside patients, these staff hold honorary contracts with Tayside Health Board. This means they will be covered under Tayside's membership of the CNORIS scheme.

Contact Information

If you have any questions or concerns about the study, please contact:

Dr Thibault Colloc, level 9, School of Dentistry, University of Dundee

2 Park Pl, Dundee DD1 4HR

Email: tcolloc001@dundee.ac.uk

Thank you for taking the time to read this information and for considering taking part in this study!



See appendix for:

- Appendix 1: Frequently asked questions
- Appendix 2: GDPR information

Appendix 1: Frequently asked questions

Q: Who can I talk to if I have any questions?

A: You will have the chance to ask any questions you may have before you decide whether to take part. A member of the research team will be available to speak with you privately at that time. We want to make sure you feel fully informed before giving consent.

Q: Can I bring someone to the visit?

A: Absolutely. You're welcome to bring a family member, friend, or carer with you to your appointment if that makes you feel more comfortable. They can stay with you while we explain the study and answer your questions. However, we kindly ask that **only you complete the questionnaire yourself**, as your personal views are important for the research.

Q: How long will it take me to participate in the study?

A: The whole session will take about 45 minutes. This includes:

- 15 minutes to read the Participant Information Sheet (PIS) and ask any questions you may have.
- 15 minutes to review the Patient Decision Aid (PDA).
- 15 minutes to complete the questionnaire.

Everything happens during a single visit, and there are no follow-up sessions.

Q: What if I want to stop taking part during the study?

A: That's completely your choice. The study only takes about **45 minutes in total**, but if you decide at any point that you no longer want to take part, you can stop without giving a reason. This will **not affect your medical care, treatment, or future appointments in any way**. Just let a member of the research team know during the session, and we'll guide and support you through the process.

Contact Information

If you have any questions or concerns about the study, please contact:

Dr Thibault Colloc, level 9, School of Dentistry, University of Dundee

2 Park Pl, Dundee DD1 4HR

Email: tcolloc001@dundee.ac.uk

Appendix 2: HRA GDPR transparency wording for TIP study

1. How will we use information about you?

We will need to use information from you for this research project.

This information will include your initials/ CHI number/ name/ contact details/ first part of your postcode. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The University of Dundee is the sponsor of this research.

The University of Dundee is responsible for looking after your information.

We will keep all information about you safe and secure by:

- All personal information will be kept confidential and stored securely.
- Data will be anonymised — your name and any identifying details will be removed.
- Only the research team will have access to the data.
- Digital files will be password-protected and stored on secure University of Dundee servers.
- Paper documents will be locked away in secure cabinets.
- We will follow all data protection laws, including the UK General Data Protection Regulation (UK GDPR).
- Your information will not be shared with anyone outside the research team without your permission.

International transfers

Your data will not be shared outside the UK.

2. How will we use information about you after the study ends?

- Once we have finished the study, we will keep some of the data so we can check the results.
- We will write our reports in a way that no-one can work out that you took part in the study.
- We will keep your study data for a maximum of 10 of years. The study data will then be fully anonymised and securely archived or destroyed.

3. What are your choices about how your information is used?

- you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

4. Where can you find out more about how your information is used?

You can find out more about how we use your information:

- our leaflet [TIP Study: Patient information sheet]
- by asking one of the research team members
- by sending an email to tcolloc001@dundee.ac.uk or infogov@dundee.ac.uk