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Exploration into families' experience following a traumatic dental injury

Submission date 15/06/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 06/07/2021	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 15/10/2026	**Condition category** Oral Health	[_] Individual participant data

Plain English summary of protocol

Background and study aims
The term 'traumatic dental injuries' (TDI) encompasses any injury to a tooth including fractures of the crown and/or root of the tooth, luxation injuries (a tooth that has moved position and been pushed sideways, into the gum or down), and avulsions (a knocked-out tooth).

TDIs are a common occurrence in children. The initial emergency care and advice provided are vital for the long-term survival of the tooth. The worse the tooth injury, the more important it is to receive appropriate management. Traumatised teeth also require careful follow-up, if the injury is not identified, diagnosed and managed in a timely manner, it decreases the prognosis of the tooth and can lead to tooth loss. Tooth loss not only has an effect on the child's dentition and need for long-term replacement options but also has a huge effect on the child's mental wellbeing. It is therefore imperative that families follow a clear pathway and receives the appropriate management in the appropriate place at the appropriate time. Unfortunately, despite professional guidelines on how to manage TDIs, there is evidence to suggest that there is a lack of both public and professional awareness of the optimal care pathway in the emergency management of such injuries.

The study aims to explore how the tooth injury happened, what happened after the injury, where did they decide to sought advice and management, and what urgent management was undertaken. Additionally, the study will explore what families felt went well, what did not go well, and what families would have liked to have happened following the tooth injury The study also aims to investigate what follow up management the child has received for the tooth injury and how COVID-19 has impacted the families' experience of dental trauma management

Who can participate?
Children/young people aged 7-15 years who experienced dental trauma to a permanent (adult) tooth from January 2019 onwards, and their parent/guardian

What does the study involve?
Qualitative interviews with a family dyad including a child who has experience of dental trauma and an adult family member (parent/legal guardian), about their journey and experience following a traumatic dental injury (TDI). The interview will be held either face to face if

restrictions allow, or virtually via a video platform. The child and their family member will be interviewed together by one researcher and there will be another researcher present as a chaperone for the interview who will remain silent. The interview is likely to take between 30-60 minutes. The interview will be audio-recorded and then transcribed. Both the child and their family member should be present throughout the interview and be able to hear all questions.

What are the possible benefits and risks of participating?
There is no direct benefit for taking part in the study. However, it could be an opportunity to share their experience and expertise in a way that can benefit others.

There are no perceived disadvantages or risks involved. The information that is given will be kept confidential, but the research team may have to pass on information in accordance with the local safeguarding policy if there is a concern for anyone's safety and welfare.

Where is the study run from?
University of Liverpool (UK)

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

Who is funding the study?
University of Liverpool (UK)

Who is the main contact?
Dr Nathalie Gallichan, ngalli@liverpool.ac.uk
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
285158

Protocol serial number
UoL001608

Study information

Scientific Title
Qualitative semi-structured interviews to explore families' experience following a traumatic dental injury

Study objectives
To explore families' experience and their management pathway following a dental trauma injury

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/04/2021, HRA and Health and Care Research Wales (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB; no telephone number provided; HCRW.approvals@wales.nhs.uk), ref: 21/PR/0416

Primary study design
Observational

Study design
Qualitative interview study

Study type(s)
Other

Health condition(s) or problem(s) studied
Acute management of paediatric traumatic dental injuries

Interventions
Qualitative interviews with a family dyad including a child who has experience of dental trauma and an adult family member (parent/legal guardian), about their journey and experience following a traumatic dental injury (TDI).

A topic guide has been developed and piloted. All interviews will be recorded with a digital voice recorder and transcribed to enable thematic framework analysis to be undertaken. Thematic analysis will be conducted using NVivo software. Key themes will be identified surrounding their experience, their thoughts on how their experience could have been improved and whether the impact of COVID affected their journey and experience.

Intervention Type
Other

Primary outcome(s)
Children's experience of acute dental trauma management using qualitative semi-structured interviews with family dyads (consisting of a child and a family member) and thematic analysis at a single timepoint

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
03/03/2022

Eligibility

Key inclusion criteria
1. Children/young people aged 7-15 years who experienced dental trauma to a permanent (adult) tooth from January 2019 onwards
2. The child/young person lives with a parent/guardian who can consent, this adult does not have to have been present at the time of injury
3. The participant is able to communicate in spoken English
4. Minimum of 6 months between injury and date of recruitment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 Years

Upper age limit
15 Years

Sex
All

Total final enrolment
16

Key exclusion criteria
1. Unable to speak English
2. Children under the age of 7 years or aged 16 years and older at the time of the TDI
3. Children in care who do not live with someone who can consent for them

Date of first enrolment
01/06/2021

Date of final enrolment
24/02/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Alder Hey Children's Hospital
E Prescot Road
Liverpool
England
L14 5AB

Study participating centre
Liverpool University Dental Hospital
Pembroke Place
Liverpool
England
L3 5PS

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
University/education

Funder Name
University of Liverpool

Alternative Name(s)
The University of Liverpool, , Universidad de Liverpool, UoL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from either the PI/CI (ngalli@liverpool.ac.uk or lauramg@liverpool.ac.uk). Thematic analysis will be conducted using NVivo (© QSR International 2020) software. Key themes will be identified surrounding their experience, their thoughts on how their experience could have been improved, and whether the impact of COVID affected their journey and experience. These will be interpreted according, with the involvement of experienced topic and qualitative researchers. An independent researcher will also be involved to check the themes and data analysis and ensure that the CI has not over-represented some aspects of the data. Recordings will be kept until the end of the postgraduate studies. Transcripts and written data will be held securely on the password protected hard drive of the lead investigator for up to 10 years. Each participants/family will be assigned a pseudonym name during the transcription process. The PI will share the pseudonym with the CI/primary supervisor only. The pseudonym will be used on any transcripts sent to supervisors to discuss analysis and would be used pseudonym in all coding, themes and quotes in the final thesis/papers. All information will be stored on a password protected University computer in a locked office. Only the principal investigator and supervising team will be able to access and view the data.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/07/2026	15/10/2026	Yes	No
Basic results		28/05/2024	28/05/2024	No	No
HRA research summary			28/06/2023	No	No
Protocol file			08/07/2021	No	No