

Interviews with autistic children, family members and professionals to help develop an oral health support package

Submission date 24/02/2022	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 03/03/2022	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/04/2025	Condition category Oral Health	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Tooth decay is a major health problem. A quarter of 5-year-olds have tooth decay. For autistic children, especially those with little or no verbal communication, tooth decay can lead to self-harm, impaired sleep and disrupted routines. Autistic children find it more difficult to go to a dentist or accept dental treatment. Frequently their dental treatment is provided under general anaesthetic.

Tooth decay is preventable. Twice daily toothbrushing with fluoride toothpaste and limiting sugary foods and drinks helps prevent tooth decay. These good habits should start in early childhood. For families of autistic children, establishing good habits can be complex, owing to extra challenges, such as communication, altered sensitivity and rigid behaviour patterns. In this study the researchers will work with autistic children, families of young autistic children and the professionals who care for them. Together they will explore the barriers and facilitators to good oral health habits and design a support package. This package will help families to be confident in looking after their child's teeth. This study will identify what support they need, who could provide it and the best times to provide support.

Who can participate?

Autistic children (under the age of 14 years), families of young autistic children (aged 5 years old or younger) and the professionals who care for them

What does the study involve?

This research study has two stages:

Stage 1: To find out what advice families currently receive about looking after their child's teeth; what works well and not so well. The researchers will search for published research studies and talk to families and professionals.

Stage 2: The researchers will work with families and professionals to develop a support package that they would be pleased to use and would empower families to look after their child's teeth.

What are the possible benefits and risks of participating?

There are no disadvantages to taking part, but it will take up a little bit of time (about 60

minutes). Those involved will receive a £10 “Love2shop” gift voucher. After the interview/focus group, the researchers can answer any dental questions.

Where is the study run from?

This study is carried out by the University of Leeds who are collaborating with the University of Sheffield, THE University of Manchester, and the University of Plymouth (UK)

When is the study starting and how long is it expected to run for?

September 2021 to March 2023

Who is funding the study?

National Institute of Health Research (NIHR) (UK)

Who is the main contact?

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Additional identifiers

Protocol serial number
NIHR toothPASTE - 202284

Study information

Scientific Title
toothPASTE - emPowering fAmilies of young children with autiSm to esTablish good oral hEalth habits: the development of an oral health intervention to support families of autistic children

Acronym
toothPASTE

Study objectives
This study is part of a larger NIHR RFPB funded project called "toothPASTE". The findings from this study will help us design an oral health support package for autistic children and the professionals who care for them. As such, the current study will interview autistic children, families of autistic children (aged 5 years old and younger) and professionals who care for them to explore the barriers and facilitators of optimal oral health habits at home, what oral health support is available and what support is needed. These findings will help shape the toothPASTE intervention.

Aim:
To explore how to empower families of young autistic children (aged 5 years old and younger) to establish optimal oral health habits.

Objectives:
Working with children and families of young autistic children to explore:
1. Their child's current oral health practices, including barriers and facilitators to good oral health behaviours

2. Their experiences of navigating the support services for their child and family, including oral health support
3. Their views on the design of an effective oral health intervention

Working with professionals caring for young autistic children and their families to explore:

1. Their current practice
2. Their opportunities, capabilities, and motivation for providing oral health support to families
3. Their views on the design of an effective oral health intervention

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/12/2021, Dental Research Ethics Committee (DREC) at the University of Leeds (Level 7 Wellcome Trust Brenner Building, St James' University Hospital, Leeds, LS9 7TF, UK; Tel: not available; J.K.McDermott@leeds.ac.uk), ref: 081221/PD/339

Primary study design

Observational

Study design

Single-centre intervention development study

Study type(s)

Other

Health condition(s) or problem(s) studied

Dental caries (tooth decay) of young autistic children

Interventions

This study is part of a larger NIHR RfPB funded project called "toothPASTE". The study aims to develop an intervention that helps families to be confident in looking after their autistic child's teeth. This intervention needs to be specifically tailored to the needs of families of autistic children and fit within wider early-year services; therefore, the first step is to speak to those with lived experience to understand the wider context within West Yorkshire. As such, the current study will interview autistic children, families of autistic children (aged five years old or younger) and professionals who care for them to explore the barriers and facilitators of optimal oral health habits at home, what oral health support is available, and what support is needed. These findings will help shape the co-design of the oral health intervention called toothPASTE which will be undertaken in a later part of the project and is outside this application.

Interviews/focus groups with autistic children and families of autistic children:

The researchers will interview children at home face to face, using "Talking Mats". If "Talking Mats" are not appropriate, they will work with the parent to gauge the child's level of understanding and use their way of communication to be as inclusive as possible. The researcher will follow a topic guide and use the "Talking Mats" symbols to describe the focus of the questions such as how they brush their teeth or the types of toothbrushes they like.

For family members, data collection will be undertaken online (Zoom or teams), by telephone (phone or WhatsApp Video) or face-to-face (home or a quiet setting) depending on preference. The researcher will follow a topic guide around their experiences of toothbrushing, their wider support, and what they would like to see in an oral health support package.

Interviews/focus groups with professionals:

Qualitative data gathering will be achieved online (Zoom or teams), telephone (phone or WhatsApp Video) or face-to-face (workplace), depending on preference. Like focus groups with family members, the topic guide will be based on the Theoretical Domains framework. The guide will focus on their views on potential oral health activities they, or other services, could deliver. They will also reflect on their own oral health knowledge and identify their own oral health training needs (e.g. the COM-B dimensions of capability, motivation, opportunity). Within these interviews, the researchers will also explore current oral health interventions where they will ask their opinions on the design of an effective oral health intervention, the timing/s of the intervention and the suitability of different professionals to deliver it.

Data analysis:

The aims will be assessed using the qualitative measurement of in-depth interviews and focus groups. These will be audio-recorded and notes will be written by the interviewer. All interview recordings will be transcribed verbatim and pseudo-anonymised. Interviews/focus groups will happen at one timepoint, after consent has been obtained. Focus groups with autistic children and family members will be analysed separately from professional interviews. A pragmatic approach will be adopted, which draws on both deductive and inductive processes, enabling the exploration of a priori themes identified from our research scoping review and new themes to be identified. Framework analysis (Ritchie, Spencer, Bryman, & Burgess, 1994) will be undertaken using the following steps: familiarisation, coding, developing an analytical framework, applying the analytical framework, Charting data into the framework matrix and interpreting the data (Gale, Heath, Cameron, Rashid, & Redwood, 2013).

The findings from the current study (interviews/focus groups) will be synthesised with the scoping review results. With the Patient and Public Involvement panel, professionals and stakeholders as equal partners, the researchers will codesign the toothPASTE intervention. This will be done using a series of workshops and participatory activities (Experience-Based Co-Design approach). By the end of the study, the toothPASTE intervention prototype will be finalised. This will include content and format, who will deliver it, when, how often and a training package to enable delivery

Intervention Type

Behavioural

Primary outcome(s)

1. Children's and families of young autistic children's oral health experiences, including their current oral health practices, navigating the support services and their views on the design of an effective oral health intervention, will be measured using qualitative interviews at a single timepoint. Data will be analysed using framework analysis.
2. Professionals' oral health experiences, including their current practice, their opportunities, capabilities, and motivation for providing oral health support to families and their views on the design of an effective oral health intervention, will be measured using qualitative interviews at a single timepoint. Data will be analysed using Framework analysis.

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

31/03/2023

Eligibility

Key inclusion criteria

Interviews with autistic children:

1. Diagnosed with autism or be on the autism pathway
2. Between the ages of 5-14 years
3. Predominantly located within West Yorkshire

Qualitative interviews/focus groups with families of autistic children:

1. Family member of an autistic child (aged 5 years old or younger) or have a child on the autism pathway
2. Over the age of 18 years
3. Predominantly located within West Yorkshire

Qualitative interviews/focus groups with professionals:

1. Located within West Yorkshire, where their information will provide valuable information about the differences in approach to enable a wider understanding of the West Yorkshire region. Other professionals working outside West Yorkshire may be approached if delivering "gold standard" services but only if the information they provide is relevant to the West Yorkshire region.
2. Experience of working with/supporting autistic children (aged 5 years old or younger)

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

5 Years

Upper age limit

14 Years

Sex

All

Total final enrolment

53

Key exclusion criteria

For interviews with autistic children, the researchers will exclude children under the age of 5 years old and over the age of 14 years

Date of first enrolment

01/02/2022

Date of final enrolment

28/02/2023

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Leeds

Woodhouse

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Sponsor information

Organisation

University of Leeds

ROR

<https://ror.org/024mrx33>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the ethics approval. As outlined in the ethics approval (DREC reference: 081221/PD/339), this study is carried out by the University of Leeds in collaboration with the University of Sheffield, the University of Manchester, the University of Plymouth, and the Bradford Institute for Health Research, with a fully signed collaboration agreement in place. Where needed, study data will be shared with the collaborators listed on page five of the protocol to carry out the research aims. Wider data sharing is not available.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/11/2024	11/04/2025	Yes	No
Participant information sheet	Family version 2	25/01/2022	28/02/2022	No	Yes
Participant information sheet	Parents version 2	25/01/2022	28/02/2022	No	Yes