

HABIT: Health visitors delivering Advice in Britain on Infant Toothbrushing - an exploration of an oral health intervention

Submission date 19/09/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/11/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/10/2022	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

We have worked with Bradford parents and Health Visitors to develop an oral health resource called HABIT. The resources include training for Health Visitors and an information package accompanied online video resources. HABIT was designed to be used by Health Visitors when they visit parents who have babies aged 9-12 months. We wanted to study how these materials are used by health visitors and whether they help the adoption and maintenance of optimum oral health behaviours.

Who can participate?

Eligible parents of babies aged 9-12 months old, who were about to receive a home or clinic visit from a HABIT-trained Health Visitor, were contacted to take part in the study.

What does the study involve?

If parents agreed to take part, they met with our research team four times.

The first meeting was arranged two weeks before the 9-12 month universal home visit by a Health Visitor. We asked questions about current toothbrushing practices, dietary behaviours, and undertook a dental check-up. A trained dental professional looked in the baby's mouth and counted their teeth. As part of this dental examination, they also used a food dye to look for plaque. Following this, the researchers video-recorded parent-child toothbrushing.

The universal home visit by the Health Visitor was arranged shortly after. The Health Visitor discussed health practices and as a part of this, they discussed optimal oral health behaviours using their HABIT training and oral health resources.

Two weeks and three months after the HABIT intervention, a second and third data collection visit was organised. They followed the same structure as the initial visit and included the same activities.

The fourth visit was arranged soon after the third meeting. At this visit, we explored parents' experience of brushing their baby's teeth and the oral health advice provided by the Health Visitors using the HABIT oral health materials.

What are the possible benefits and risks of participating?

The HABIT oral health materials and advice provided by Health Visitors will help parents to look after their baby's teeth and adopt good oral health behaviours. In addition, to compensate participant time after each meeting, we issued a £10 'Love2Shop' gift voucher.

Where is the study run from?

The study was undertaken by staff working at the University of Leeds, School of Dentistry, however, all research visits were undertaken in a home setting around the City of Bradford (UK).

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

May 2017 to February 2019

Who is funding the study?

The study has been funded by the Medical Research Council (MRC) (UK) - MR/P017185/1.

Who is the main contact?

Professor Peter Day, p.f.day@leeds.ac.uk

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

230315

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 230315, CPMS 35892

Study information

Scientific Title

HABIT: Health visitors delivering Advice in Britain on Infant Toothbrushing – An early phase feasibility study of a complex oral health intervention

Acronym

HABIT

Study objectives

Tooth decay (dental caries) is the most prevalent non-communicable childhood disease. The impact of dental caries is significant, with the disease affecting the child, their family, and wider society. The establishment of habitual, positive, oral health behaviours in early childhood is a strong predictor for future oral wellbeing - these protective oral health behaviours include toothbrushing as per national guidance and limiting dietary sugars.

In the UK, members of the Health Visiting Team have an important role in promoting oral health to families of young children. However, financial and staffing pressures can lead to inconsistent training, delivery, content, and use of supporting resources. This variation demonstrates a vital missed opportunity to embed an early life intervention in the prevention of dental caries.

“Health visitors delivering Advice in Britain on Infant Toothbrushing” (HABIT) is a co-designed, complex, oral health intervention developed to support Health Visitors to have effective oral health conversations with parents of children aged 9-12 months old to reduce childhood caries experience. The primary aim was to conduct an early phase feasibility study of an oral health intervention, HABIT, delivered by Health Visitors to parents of children aged 9-12 months old.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/09/2017, Yorkshire & The Humber - Leeds East Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8018; leedseast.rec@hra.nhs.uk), ref: 17/YH/0301

Study design

Mixed-methods early-phase non-controlled feasibility study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Home

Study type(s)

Prevention

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Prevention of dental caries in young children

Interventions

Our multi-disciplinary research team, together with health visiting teams and parents of children aged 9–12 months, have co-designed training and materials (HABIT) to support oral health discussions between parents and health visitors. Using professional contacts, we collected examples of materials already developed for health visitors to support their oral health conversations across England. We discussed these materials with parents and health visitors in a series of focus groups and interviews to identify which are most likely to lead parents to adopt appropriate oral health behaviours. These conversations informed the development of the HABIT intervention in conjunction with our extensive research which has followed the complex intervention development framework laid out by the Medical Research Council. The intervention consists of two packages: training for health visitors to deliver the HABIT intervention and HABIT resources for parents.

The training for health visitors incorporated important oral health messages for parents, knowledge related to toothbrushing and diet, as well as an introduction to the oral health resources. We used already available resources which comply with national guidance such as SOAP videos (<http://www.soap.media/our-courses/letstalkaboutteeth/>) and the NHS e-learning package <http://www.e-lfh.org.uk/programmes/healthy-school-child/>. The one-day training also included training around how to effectively use HABIT resources to enable behaviour change conversations with parents.

The HABIT resources for parents aim to support the adoption of optimum oral health practices for their children and to tackle barriers that prevent them from achieving this goal. The provided resources focused on aspects such as 'Why is oral health important?', 'How to adopt protective home-based oral health behaviours?' and 'When to start these oral-health behaviours?' The HABIT intervention included short video vignettes, provision of a toothbrush and toothpaste, and simple advice sheets on issues such as oral health knowledge and skills, managing children's behaviour, the wider social environment and knowledge about optimal dietary behaviours. The video vignettes include a mixture of parent stories and professional advice.

If parents agreed to take part, they met with our research team four times. At these visits, we enquired about their toothbrushing practices and oral health behaviours.

The baseline meeting was arranged two weeks before the 9-12 month universal home visit by a Health Visitor. A researcher and dental professional collected information about current toothbrushing practices, dietary behaviours, and undertook a dental check-up. A trained dental professional looked in the baby's mouth and counted their teeth. As part of this dental examination, food dye was used to identify plaque. If permission was given, the researchers video-recorded parent-child toothbrushing - this material will only be accessed by the research team and no one else will see these videos.

The universal home visit by the Health Visitor was arranged two weeks after the baseline meeting. The Health Visitor discussed the baby's development and as a part of this, they discussed oral health practices using their HABIT training and oral health resources. Two weeks and three months after the HABIT intervention, we organised a second and third data collection visit. These visits followed the same structure as the baseline and collected the same data.

The final visit was arranged as close to the third data collection visit as possible. This was a qualitative interview, which explored parents' experience of brushing their baby's teeth and the oral health advice provided by the Health Visitors using the HABIT oral health materials.

Intervention Type

Behavioural

Primary outcome measure

To assess the feasibility and acceptability of the HABIT intervention with Health Visitors and parents:

1. Recruitment, retention, and feasibility of intervention delivery measured as part of the descriptive analysis at baseline, 2 weeks and 3 months post HABIT-intervention.
2. Qualitative exploration was twofold. For health visiting teams, focus groups were undertaken after the HABIT intervention had been delivered to all parents. For parents, qualitative interviews were undertaken in the home setting shortly after the 3-month data collection visit.

Secondary outcome measures

To explore the impact of HABIT on oral health behaviors, a questionnaire collecting self-reported toothbrushing and dietary habits, plus three objective measures of parental supervised brushing (PSB) were collected at baseline, 2 weeks and 3 months after the intervention:

1. Teeth were examined for cavitated dentinal caries and restorations using the BASCD criteria
2. Children's pre-brushing plaque levels per sextant using the Oral Hygiene Index
3. Duration of toothbrushing and parent-child interaction, using video recordings of parent-child toothbrushing

Overall study start date

17/05/2017

Completion date

28/02/2019

Eligibility

Key inclusion criteria

1. Parents of a child aged 9-12 months old about to receive a universal home visit by a HABIT-trained Health Visitor.
2. Child with at least one erupted tooth

Participant type(s)

Mixed

Age group

Child

Lower age limit

9 Months

Upper age limit

12 Months

Sex

Both

Target number of participants

30

Total final enrolment

35

Key exclusion criteria

1. Non-English-speaking families, as translator services were not available to the research team.

Date of first enrolment

18/12/2017

Date of final enrolment

12/10/2018

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University of Leeds

School of Dentistry

Worsley Building

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Sponsor type

University/education

Website

<http://www.leeds.ac.uk/>

ROR

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

Funder(s)

Funder type

Not defined

Funder Name

Medical Research Council

Results and Publications

Publication and dissemination plan

Results planned for publication in peer-reviewed journals.

Outcomes relating to feasibility, acceptability, and impact will be covered in two publications to ensure a full exploration of study aims and outcomes.

Intention to publish date

01/12/2022

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study are available upon request from Dr. Peter Day, p.f.day@leeds.ac.uk. These include transcripts of qualitative interviews and spreadsheets with the quantitative data. The data is kept for 20 years. Videos of child-parent toothbrushing are not available owing to the ethical assurances made to participants at the time of consent.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	14/08/2017	25/10/2021	No	Yes
Protocol article		27/03/2018	25/10/2021	Yes	No
Other publications	Co-design of intervention	16/06/2022	18/07/2022	Yes	No
Other publications		24/09/2022	29/09/2022	Yes	No
Results article		10/10/2022	11/10/2022	Yes	No
HRA research summary			28/06/2023	No	No