

ACORN: Improving oral health in cleft lip and/or palate

Submission date 20/06/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 21/06/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/02/2021	Condition category Oral Health	☐ Individual participant data

Plain English summary of protocol

Background and study aims

A cleft is a gap or split in the upper lip, the roof of the mouth (palate) or both. Cleft lip and/or palate (CL/P) is a common facial abnormality which begins during development in the womb. Children born with CL/P can find it difficult to look after their teeth. This can affect the success of their treatment, including bone grafts and braces. It can be hard to keep to a daily routine of mouth care, such as regular tooth brushing and avoiding sugary drinks. This study will test a new way to help children carry out good mouth care. It is based on 'if-then' plans (the technical term is 'implementation intentions', which recognise that people want to act in a healthy way but don't always manage to do so). Even simple 'if-then' plans have helped adults and children to keep to habits that many people find it hard to maintain, such as exercising and eating a healthy diet. The aim of this study is to find out whether this will help children with a cleft lip and/or palate with their mouth care, so this should help us find out.

Who can participate?

Children aged 5-9 years with CL/P and their parents.

What does the study involve?

At the initial study visit, the dental care practitioner (DCP) asks about the child's usual routine for looking after their teeth and record some general background information. They then carry out two assessments of the child's teeth. One involves looking at the child's teeth and gums and the other involves measuring any plaque on the child's teeth. The child then rinses their mouth using a disclosing tablet/solution and the dental care practitioner takes a photo of the inside of their mouth. They are then randomly assigned to one of three groups and parents are given advice about helping their child look after their teeth. Those in the first group receive leaflet about how to best look after teeth in children with CL/P. Those in the second group also receive the leaflet but also invited to make an 'if-then' plan. This involves being shown a two minute audio-visual animation to introduce implementation intention plans and a format for an individual if-then plan. They are also given a laminated sheet to write their 'if-then' plan on. The DCP will take a photo and a written record of the 'if-then' plan. Those in the third group also receive a leaflet and create an if-plan, as well as receiving a letter, text and email reminder of their i-plan. This includes a link to the animation, the photo/wording of their 'if-then' plan and a new laminated sheet and pen. Participants in both groups complete a number of questionnaires

at the start of the study and six months later, when they receive a home visit from the DCP in order to find out whether the children are caring for their teeth better.

What are the possible benefits and risks of participating?

This study may not directly benefit participants however it will help to improve understanding about how best to help children born with CL/P to care for their teeth. There are no notable risks involved with participating in this study,

Where is the study run from?

The study is run from the Central Manchester University Hospitals NHS Foundation Trust and takes place in participant's homes (UK)

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

March 2014 to December 2017

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Mrs Cath Wright

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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Protocol serial number

30803

Study information

Scientific Title

ACORN: Improving oral Health in Cleft Lip and/or Palate: A Promotion Intervention for Children and Parents: Stage 2 (A Feasibility Study)

Acronym

ACORN

Study objectives

The aim of this study is to investigate the feasibility of conducting a large-scale trial looking at whether implementation intentions can help children with cleft lip and/or palate (CL/P) improve their oral health.

Ethics approval required

Old ethics approval format

Ethics approval(s)

West Midlands – Solihull research Ethics Committee, 20/09/2015, ref: 15/WM/0352

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Prevention, Psychological & Behavioural

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Specialty: Children, Primary sub-specialty: Cleft and craniofacial anomalies; UKCRC code/
Disease: Oral & Gastro/ Diseases of oral cavity, salivary glands and jaws

Interventions

All participants have a baseline visit where consent is taken and parents and children complete questionnaires about oral health, and information about whether currently using any plans to help with oral health. Dental Care Practitioners (DCPs) then carry out assessments of level of gingivitis (gum inflammation) and presence of plaque. Participants are then randomised to one of three groups:

Group 1 (control) receive a leaflet about standard oral health information for children with a cleft lip and palate at visit 1

Group 2 (intervention) as group 1 but are also invited to make an 'if-then' plan. This involves being shown a two minute audio-visual animation to introduce implementation intention plans and a format for an individualised if-then plan. They are also given a laminated sheet to write their 'if-then' plan on. The DCP will take a photo and a written record of the 'if-then' plan.

Group 3 (intervention and booster) As group 2 but after 3 months this group will be contacted by the DCP to remind them of the 'if-then' plan. This booster/reminder will be by letter, text and

email (providing they have agreed to that at the initial visit. The booster/reminder will contain a link to the animation, the photo/wording of their 'if-then' plan and a new laminated sheet and pen.

Six months after the initial visit all participants will be visited again at home by the DCP. All the questionnaires and assessments of gingivitis and plaque will be repeated. All participants will also complete a semi-structured interview, which will be audio recorded about their experience of being in the study.

DCPs will also report their experience of carrying out the questionnaires and assessments at home.

Intervention Type

Behavioural

Primary outcome(s)

Acceptability of measures to parents and children is measured by parent and child self-report questionnaires at baseline and 6 month follow up visit and the exit interview with parents at the 6 month follow up visit.

Key secondary outcome(s)

1. Child's dental plaque is measured using the plaque scores on The Modified Gingival Index (MGI) and Plaque Control Record (PCR) at baseline and 6 months
2. Oral hygiene management is measured by a parents' questionnaire on oral health, a self-report based on Children's Dental Health Survey and children's self-report using Day in the Life Questionnaire at baseline and 6 months

Completion date

01/03/2018

Eligibility

Key inclusion criteria

1. Aged 5-9 years
2. Children with a cleft lip and/or palate (CL/P)
3. One or more parent/carer able to speak and read English

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Participation in a Stage 1 interview
2. Children allergic to food dyes
3. Participants unable to converse in English
4. Families undergoing significant psychosocial difficulties (e.g. child protection, recent bereavement of a close family member), as identified by their cleft team

Date of first enrolment

07/06/2015

Date of final enrolment

30/06/2017

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Central Manchester University Hospitals NHS Foundation Trust

Trust Headquarters, Cobbett House

Manchester Royal Infirmary

Oxford Road

Manchester

United Kingdom

M13 9WL

Sponsor information

Organisation

Central Manchester University Hospitals NHS Foundation Trust

ROR

<https://ror.org/00he80998>

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**IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/07/2017		Yes	No
Results article	results	01/02/2020	08/02/2021	Yes	No
HRA research summary			28/06/2023	No	No