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

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

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 ind 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 investigating 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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
16/03/2014

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

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
England

United Kingdom

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

Sponsor details
Trust Headquarters
Cobbett House
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England
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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Planned publication of study results in a peer reviewed journal.

Intention to publish date
28/02/2018

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