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Supporting Parents Of Children with Cleft Lip

Submission date
28/12/2012

Recruitment status
No longer recruiting

Registration date
21/01/2013

Overall study status
Completed

Last Edited
30/08/2023

Condition category
Neonatal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cleft lip affects around 1 in 700 infants and is the most common congenital (present at birth) disorder. Affected children are at increased risk for a range of psychological problems in infancy and the school years. Previous research has found that, compared to interactions between mothers and unaffected infants, interactions between mothers and infants with cleft lips are more likely to be disrupted, particularly in the first few months of life, before surgical lip repair is conducted. These interactions have been found to be significant for the cognitive (recognising and understanding things) development of the child, both in children with a cleft lip and within normal populations. We propose to test whether a treatment aimed at enhancing the quality of the mother-infant interactions, in those first few months of life before surgery is conducted, improves mothers' sensitivity to their babies and leads to a better cognitive development of the baby at 18 months.

Who can participate?
Mothers must be 18 or over. The mothers themselves are healthy, but their babies must be diagnosed with a cleft lip.

What does the study involve?
We propose to randomly assign half of the participants to 'Watch & Discover' treatment, and the other half to 'Support, Information and Advice'. 'Watch & Discover' is the test treatment, whereby we would make short films of mother and baby together and then watch them back with the mother highlighting positive interactions and their baby's cues. In this way we would hope to enhance the quality of the mother-child interaction. The control treatment group would receive support, information and advice, giving mothers the opportunity to discuss issues around having a baby with cleft lip. We would visit the mother and baby at home over six sessions, starting when the baby is between 1-2 weeks old, and ending before the baby has lip surgery at 12 weeks. We would perform assessments on the baby and mother-child interactions at 11 weeks (after the treatment has finished), 9 months and 18 months, with the final assessment of cognitive outcome at 18 months.

What are the possible benefits and risks of participating?
The information we get from this study may benefit future treatments.
We believe that there are minimal risks for mothers participating in the study, and indeed hope it will be a positive experience for them. However the study may involve discussion of

potentially emotionally sensitive areas; the study therapist has extensive experience of working with mothers in this field and this support will be addition to their routine clinical care.

Where is the study run from?
University of Oxford (lead centre), University of Reading, Spires Cleft Centre, West Midlands Regional Cleft Centre, South Thames Cleft Service.

When is the study starting and how long is it expected to run for?
The study started in Jan 2012 and will run until May 2016. The study will be recruiting participants for 35 months.

Who is funding the study?
This study is funded by the Barclay Foundation.

Who is the main contact?
Professor Alan Stein
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Contact information

Type(s)
Scientific

Contact name
Prof Alan Stein

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Improving Cognitive Outcomes of Children with Cleft Lip and/or Palate: a randomised controlled trial aimed at enhancing the quality of mother-infant interactions

Acronym
SPOCCL

Study objectives
For infants with a cleft lip, an intervention designed to enhance maternal sensitivity during mother-infant interactions will be associated with better cognitive performance at 18 months compared to a control intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central -Oxford C, 11/12/2012, ref: 12/SC/0626

Study design
Multi-centre randomised controlled assessor-blinded interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Cleft lip and palate

Interventions
There are two therapies which constitute the study interventions:
1. The index group will receive a treatment aimed specifically to improve mother-infant interaction (Watch & Discover)
2. The control group will receive a treatment called Support, Information & Advice (SIA)

Each participant will receive six therapy sessions delivered in the participants homes which will begin when the baby is less than 10 days old. The final therapy session will occur when the baby is approximately 11 weeks old prior to primary cleft lip repair (which occurs at 12 weeks old).

Intervention Type
Behavioural

Primary outcome measure
1. Maternal sensitivity in face to face interaction with the infant immediately following treatment (when infant aged 11 weeks and prior to lip cleft repair), measured using the Global Rating Scale dimension of sensitivity.
2. Infant cognitive development at 18 months (assessed by Bayley Scales of Infant and Toddler Development, 3rd edition)

Secondary outcome measures
1. Maternal gaze, measured by eye tracking at 11 weeks
2. Maternal imitation at 11 weeks
3. Infant attention (assessed by the Focused Attention Task) at 9 & 18 months
4. Infant emotion regulation (assessed by the LAB-TAB) at 9 & 18 months
5. Maternal appraisal, mood and trauma symptoms immediately after treatment and at 9 & 18 months, assessed by means of self-report questionnaires [Hospital Anxiety & Depression Scale (HADS), Parental Appraisal of Cleft Questionnaire (PAC-Q) and Post-traumatic Stress Diagnostic Scale (PDS)]

Overall study start date
21/01/2013

Completion date
31/05/2016

Eligibility

Key inclusion criteria
1. Mother is willing and able to give informed consent for participation in the study
2. Mother, aged 18 years or above
3. Infant diagnosed with cleft lip with/without cleft palate
4. Able (in the Investigators' opinion) and willing to comply with all study requirements
5. Infant born at > 35 weeks gestation
6. Infant birth weight of > 2000 grams
7. Mother willing to allow her and her infants General Practitioner and cleft Consultant to be notified of participation in the study

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
80 (40 in each arm)

Key exclusion criteria
1. Life-threatening or other serious physical illness in the mother
2. Serious illness or medical complication in the infant

3. Infant in Child Protection Plan (child protection register)
4. Mother unable to converse in English
5. Mother not primary caregiver to infant
6. Mother has severe psychiatric diagnosis
7. Mother and infant live outwith 90 minutes travel of research centre

Date of first enrolment
21/01/2013

Date of final enrolment
31/05/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Oxford
United Kingdom
OX37JX

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Joint Research Office, Block 60
Churchill Hospital
Oxford
England
United Kingdom
OX3 7LJ

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR

https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
The Barclay Foundation (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Basic results			30/08/2023	No	No