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Development and preliminary evaluation of an intervention package to support parents of excessively crying infants

Submission date
08/05/2014

Recruitment status
No longer recruiting

Registration date
15/05/2014

Overall study status
Completed

Last Edited
11/10/2019

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

In early infancy, around 1 in 5 babies cry a lot without an apparent reason. This excessive infant crying used to be known as colic and attributed to indigestion pain. Research in the last 20 years has found that only 5-10% of infants taken to the doctor because of the crying are poorly. Most infants who cry a lot are healthy and develop normally. Research has also shown that many normal babies have a crying peak at 1-2 months of age. This and the unsoothable crying bouts which alarm parents are linked to normal infant development and stop by 5 months of age. Although most babies who cry a lot are well, the crying can distress parents and many seek help from their Health Visitor (HV) or GP. This leads to a focus not just on the crying but on parents knowledge and vulnerabilities which affect their ability to provide care. Some parents stop breastfeeding prematurely because they misinterpret the crying and think their baby is not getting enough to eat. This may hamper infant health, since breastfeeding promotes healthy infant growth and development. The crying can also give rise to maternal depression, poor parent-child relationships, problems with long-term child development, and infant abuse in a small number of cases. However, there are no tried and tested NHS practices for supporting parents in managing excessive infant crying. Instead, parents turn to popular books, magazines or websites, which give conflicting advice. By improving services, we hope to improve infant outcomes, parents satisfaction with services, and how NHS money is spent. We will develop a suitable intervention package, assess whether the new services can be delivered in NHS practice, and provide guidance on whether and how a large-scale study of their effectiveness and cost might be carried out.

Who can participate?

Parents from all ethnic backgrounds who live in the Leicestershire Partnership NHS Trust area and have a healthy baby less than 6 months old whose excessive crying causes distress to either parent.

What does the study involve?

We will recruit two groups. First, parents who approach participant clinics for help with infant excessive crying during a 6-month period will be offered the package components and, if written

informed consent is given, interviewed to obtain background information and followed up. The two areas of Leicester hosting the study have over 1000 births annually, allowing 30 excessive crying cases to be enrolled during a 6-month period. However, this number is not certain, while this approach will miss cases where parents judge their baby cries excessively but do not approach the health visitor (HV), for instance due to lack of knowledge or confidence in themselves or the NHS. Such cases may be especially needy. To overcome these drawbacks, health visitors will invite 225 families to enter the study at routine home visits in the first 10 days after birth. We expect 150 to give informed consent and to be followed up and screened for distress due to excessive infant crying by researchers. Parents entering this part of the study will be asked to complete short questionnaires to measure parenting stress, anxiety and depression. These will be repeated after the intervention, to see if there is any improvement. We will also ask parents about their use of and satisfaction with each package component; the suitability of the questionnaires; the number and duration of NHS contacts because of infant crying; the duration of sole and partial breastfeeding. We will assess how many parents and HVs complete the study. HVs will be asked to rate the package components and barriers/ facilitators to their use. A large-scale study will be justified if parents and HVs are satisfied with the package, parents remain involved in the study, and the package appears likely to reduce parental distress and be cost-effective in NHS use.

What are the possible benefits and risks of participating?
Stage 1 participants will help in developing NHS services and materials which support other parents in this position. Revisiting the experiences involved may be uncomfortable for some parents, but is unlikely to result in serious physical or psychological harm. They will receive the recognised fee for participation in research and reimbursement of expenses, as well as a summary of the findings.
Stage 2 participants will be offered a support package or materials and services designed to help parents and infants in this position. There is a risk that participation might worsen parental distress. We will monitor this and offer to contact Health Visitors or GPs. Participants will continue to receive routine health services. They will be offered the recognised reimbursement for participating in research and a summary of the findings.

Where is the study run from?
De Montfort University, Leicester, UK.

When is the study starting and how long is it expected to run for?
The study will start in September 2014 and will last for two years.

Who is funding the study?
The National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Rosemary Garratt
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Contact information

Type(s)
Scientific

Contact name
Prof Ian St James-Roberts

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NETSCC ID 12/150/04

Study information

Scientific Title
Development and preliminary evaluation of an intervention package to support parents of excessively crying infants: a feasibility study

Study objectives
This is a preliminary feasibility study, designed to develop a novel intervention and assess the feasibility of delivering and evaluating it in the NHS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This is currently being applied for

Study design
Preliminary feasibility study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Infant prolonged crying and colic; parental concern and distress because of their infant's crying.

Interventions
The study will develop and evaluate a novel evidence-based intervention package. The package components will depend on the first stage of the research, but likely elements are written information leaflets, audio-visual material presented by website and other media, a practitioner-delivered group or individual intervention for parents, and special training for NHS Health Visitors.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Successful development of an evidence-based package of support materials for parents distressed by their babys excessive crying, together with methods for assessing its effectiveness and costs in NHS use.
2. Evidence that parents take up and maintain involvement in the package, as well as rating it helpful and suitable for NHS use.
3. Evidence that Health Visitors engage and maintain involvement with the package and rate it worthwhile and suitable for routine NHS use.

Measured by scores on validated questionnaires completed by parents

Secondary outcome measures
1. Provisional evidence of improvements from baseline (pre-package) to outcome (1 month later) in parental mental health, wellbeing and quality of life from validated questionnaire measures.
2. A proposal about the feasibility and need for a large scale controlled study of the package, together with recommendations about the design and methods such a study might employ.

Overall study start date
01/09/2014

Completion date
31/08/2016

Eligibility

Key inclusion criteria

1. Parents of any ethnic origin in the Leicestershire Partnership NHS Trust area
2. Speak English, or are supported by English speakers
3. Have a healthy baby less than 6 months old whose excessive crying causes distress to either parent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Stage 1: 20 cases; Stage 2: Group 1 30 cases; Group 2: 225 recruited; 150 screened, 30 fully involved.

Key exclusion criteria
1. Infants over 6 months of age
2. Parents of infants whose crying does not distress their parents

Date of first enrolment
01/09/2014

Date of final enrolment
31/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Thomas Coram Research Unit
London
United Kingdom
WC1H 0AA

Sponsor information

Organisation
De Montfort University (UK)

Sponsor details
Nursing & Midwifery Research Centre
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Sponsor type
University/education

ROR
https://ror.org/0312pnr83

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	01/10/2019	11/10/2019	Yes	No