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Surviving crying: trial of a service to support the mental health and coping of parents with excessively crying infants

Submission date
20/04/2022

Recruitment status
Recruiting

Registration date
01/06/2022

Overall study status
Ongoing

Last Edited
15/11/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The Surviving Crying package has been created to support parents and carers of babies who cry for prolonged periods. Excessive crying affects one in five babies, with peak crying often happening around 5 weeks of age but common in the first 4 months of life. This is sometimes known as infant 'colic', although in the majority of cases it has nothing to do with digestion or any physical illness. The project team has developed a support package to help parents understand and cope with prolonged crying, which can be extremely traumatic for parents and carers. This package includes written and online materials and a support programme provided by Health Visitors (HVs) trained as part of the research to use cognitive behaviour therapy (CBT) approaches to support parents of babies who cry excessively. This study aims to find out if the support package used in conjunction with usual care given by Health Visitors is more effective in supporting parents and carers to cope with an excessively crying baby than usual care alone.

Who can participate?
Parents/Carers aged 18 years or older with an infant up to 20 weeks old (at the time of consent), who express concern about their infant's excessive crying

What does the study involve?
The study involves the recruitment of 392 participating parents/carers who have expressed concerns to their Health Visitor/other Health Visitor services/GP/or directly to the research team about their crying baby. Their relevant contact with the agreement of the parent, refers them to the study. A local member of the research team will invite the parent/carer to attend an initial appointment which lasts around 90 minutes. This can be completed by phone, video call or in person in their own home although face-to-face contact is preferred.
During the initial appointment, the researcher will explain what is involved and answer any questions the parent/carer may have. Participants will be asked to give written consent (in hard copy or electronically) to join the study. Following this, general questions about background, health and the baby's crying and feeding are asked. Some of these questions will be completed by the participant themselves and others will be asked by the researcher.
Participants will then be randomly allocated into one of two groups, control or intervention.

Control group participants will receive usual care from their Health Visitor. Intervention group participants receive usual care from their Health Visitor and in addition receive their choice of some, or all of three intervention packages.
1. Surviving Crying Booklet
2. Surviving Crying Website
3. Cognitive Behaviour Therapy (CBT) sessions with a Surviving Crying trained Health Visitor
If the participant chose CBT sessions they will be offered between one and four sessions of one-to-one support from a Surviving Crying Trained Health Visitor. These sessions will normally be delivered at home but could be delivered remotely where circumstances demand. All sessions will be delivered on a weekly basis but must not exceed 6 weeks from the date of the first CBT session.
Following the initial appointment with the researcher, two further meetings at 8 and 16 weeks after that initial meeting will be arranged to ask further research questions. Participants will be given £30 shopping vouchers for completing all the assessments.
As the study comes to an end the researchers are also undertaking a number of recorded interviews with parents/carers, Health Visitors, managers and commissioners to discuss their experience of the Surviving Crying package. The researchers are also conducting a study within the main part of the study to help enhance uptake within ethnic minority communities who could be underrepresented in studies such as this one. They propose to do this by conducting a community-based awareness campaign in addition to developing more accessible recruitment and trial documents.

What are the possible benefits and risks of participating?
Participants randomly allocated to receive extra support beyond their usual health visits will have access to a choice of any or all three elements of the package available: website, booklet and CBT sessions. Not all participants will be allocated to receive extra support, but all participants will continue to receive standard Health Visiting services. Participants who only receive THE standard Health Visiting service will have the option to access the website/booklet at the end of their participation in the study.

Where is the study run from?
Nottingham Trent University (UK)

When is the study starting and how long is it expected to run for?
September 2021 to August 2025

Who is funding the study?
National Institute for Health Research (NIHR) Health Technology Assessment (HTA) (UK)

Who is the main contact?
Prof. Jayne Brown
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
306620

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
v1.0, IRAS 306620, NIHR HTA 306620, CPMS 52165

Study information

Scientific Title
Cluster randomised controlled trial of a service to support the mental health and coping of parents with excessively crying infants

Study objectives
Usual health visiting (HV) services supplemented by the Surviving Crying (SC) package are more clinically effective and cost-effective than usual services alone in improving the mental health and coping of parents/carers with an excessively crying infant up to 20 weeks of age.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/05/2022, Brighton & Sussex REC (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ, UK: +44 (0)207 1048241; brightonandsussex.rec@hra.nhs.uk), ref: 22/LO/0284

Study design
Cluster randomized controlled trial

Primary study design

Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Mental health to help parents/carers cope with an infant's excessive crying

Interventions
The overall aim of the trial is to test the clinical effectiveness and cost-effectiveness of statutory health visiting (HV) services supplemented by SC-based service compared to statutory health visiting (HV) services alone. A cluster randomised controlled trial has been chosen to minimise the contamination between the control and intervention groups. The sites participating in the trial have been chosen to represent diverse urban and rural settings and socio-economic and cultural groups. HV teams within sites vary in size and the communities they serve. Therefore, with their clinical leaders, the researchers will identify the team(s) that will form a cluster within the trial, comprising of HVs working closely together.

All parents will be provided with a study introduction leaflet sent with their new birth letter sent to all new parents from Health Visiting Services. If an infant then goes on to cry excessively parent will express their concern to their regular health visitor who will identify if the parent wishes and is eligible to take part.
Parents will be excluded from taking part where the infant is not under 20 weeks of age, where the infant's excessive crying is judged by a doctor to be due to an illness requiring medical management or the parent is taking part in a clinical trial at the time of consent of 3 months prior. Regular Health Visitors will request verbal consent to provide the SC researcher with their contact details.

Parents will be randomised into two groups depending on the HV team that introduced the parent into the study. The control group will receive usual HV services as normal. The intervention group will receive usual HV services as normal in addition to receiving the choice as to which of three intervention packages they can access. They can access one or all three of these elements:
1. Surviving Crying booklet
2. Surviving Crying website
3. Cognitive Behaviour Therapy (CBT) sessions
They can choose all of these elements or a combination of any of the three. If the participant chooses CBT Sessions they will be offered between one and four sessions of one-to-one support from a Surviving Crying Trained Health Visitor which will normally be delivered at home but could be delivered remotely for circumstances that demand this. All sessions will be delivered on a weekly basis but must not exceed 6 weeks from the date of the first CBT session. All groups

will be asked to attend a baseline assessment and two follow-up assessments at 8 and 16 weeks after their baseline assessment.

Intervention Type
Behavioural

Primary outcome measure
Parental depression measured using the Edinburgh Postnatal Depression Scale (EPDS) score at 8 weeks post-baseline

Secondary outcome measures
1. Parental depression measured using the Edinburgh Postnatal Depression Scale (EPDS) score 16 weeks post-baseline; proportion of parents/carers with EPDS score of 10 or more
2. Anxiety measured using the Generalised Anxiety Disorder Assessment (GAD-7) Scale at 8 and 16 weeks post-baseline
3. Self-rated health utility and quality of life measured using EuroQol-5D-5L at 8 and 16 weeks post-baseline
4. Confidence of a parent/carer in their parenting role measured using the Maternal Confidence Scale (MCQ) at 8 and 16 weeks post-baseline
5. Knowledge of infant crying, amount of perceived infant crying, and parents/carers' ratings of how frustrating and problematic the crying is for them, measured using the crying knowledge scale at 8-week post-baseline follow-ups
6. Relationship satisfaction measured using the Partner Relationship Quality (CSI-4) at 8 and 16 weeks post-baseline
7. Parental and infant health, breastfeeding persistence measured using researcher asked questions at 8 weeks and 16 weeks post-baseline
8. Health economic measures assessed using researcher asked questions at 8 weeks and 16 weeks post-baseline
9. Contacts with the NHS, parents' use and parents' and HVs' ratings of services assessed using researcher asked questions at 8 weeks post-baseline

Overall study start date
01/09/2021

Completion date
28/02/2026

Eligibility

Key inclusion criteria
1. Parents/carers aged 18 years or older with a healthy infant up to 20 weeks old (at time of consent), who express concern about their infant's excessive crying to their Health Visitor
2. Written/electronic informed consent

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
392

Key exclusion criteria
1. Any infant where excessive crying is judged by a doctor to be due to illness requiring medical management
2. Involved with any other clinical trial at the time of consent or 3 months prior

Date of first enrolment
29/09/2022

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sheffield Childrens Hospital
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
London Borough of Newham
Newham Dockside
1000 Dockside Road
London
United Kingdom
E16 2QU

Study participating centre
South Warwickshire NHS Foundation Trust
Warwick Hospital

Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
Nottinghamshire Healthcare NHS Trust Headquarters
Duncan Macmillan House
Porchester Road
Nottingham
United Kingdom
NG3 6AA

Study participating centre
Barnsley Metropolitan Borough Council Public Health
Town Hall
Church Street
Barnsley
United Kingdom
S70 2TA

Study participating centre
Doncaster CAMHS
Balby Court
Balby Carr Hill
Doncaster
United Kingdom
DN4 8DE

Study participating centre
Hmr Integrated Community Services (rochdale)
Rochdale Infirmary
Whitehall Street
Rochdale
United Kingdom
OL12 0NB

Sponsor information

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De Montfort University

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Sponsor type
University/education

Website
http://www.dmu.ac.uk/home.aspx

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
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/09/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

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