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Trial of Healthy Relationship Initiatives for the Very Early-years

Submission date
08/11/2013

Recruitment status
No longer recruiting

Registration date
28/02/2014

Overall study status
Completed

Last Edited
12/05/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Background and study aims
Evidence shows that social deprivation and/or high levels of stress, anxiety and depression during pregnancy can negatively affect the developing foetus and result in permanent changes to a babys ability to cope with stress. This can affect a mothers ability to form a sensitive and nurturing bond with her baby which, in turn, can increase the risk of child maltreatment. Additionally, social deprivation and maternal mental ill-health have long-term negative effects on childrens health, social and educational outcomes. Parenting interventions show promising improvements in child outcomes. However, most are delivered after the birth (postnatal) and there is little evidence from the UK on the effectiveness of interventions delivered before the birth (antenatal) amongst women with additional health and social care needs.
This study aims to evaluate whether attending one of two antenatal parenting support programmes, Enhanced Triple P for Baby or Mellow Bumps, in addition to routine NHS antenatal and postnatal care (care as usual) helps to reduce maternal anxiety, depression and irritability and improve mother-child interactions compared to those who only receive care as usual.

Who can take part?
Women with additional health and social care needs in pregnancy residing in the NHS Greater Glasgow and Clyde and Ayrshire and Arran Health Board areas.

What does the study involve?
Women are recruited to the study after their 12th week of pregnancy. All women complete a questionnaire before the start of the study which collects demographic information and measurements of psychological distress, health status, anxiety and depression. The women are then randomly allocated to one of three groups: Enhanced Triple P for Baby, Mellow Bumps or Care As Usual. All participants receive routine NHS antenatal and postnatal care throughout their involvement in the trial. Women allocated to Enhanced Triple P for Baby and Mellow Bumps start the programmes when they are between 20 and 30 weeks pregnant. Further data is collected from the women when their babies are 6 months old using a questionnaire that includes assessments of maternal anxiety, depression and irritability. Parenting self-efficacy and maternal sensitivity, measured by analysis of video recordings, are assessed at the follow-up visits. Consent is requested for the collection of long-term health, social and educational outcomes using routine data sources (e.g., GP/social work records). Data is compared from the

three groups over the course of the trial to determine if Enhanced Triple P for Baby or Mellow Bumps have an impact on maternal mental health and the mother-infant relationship.

What are the possible benefits and risks of participating?
Participants are given a £15 voucher at each data collection timepoint. Participants allocated to the intervention arms may receive benefits from the parenting support programmes such as improved mental wellbeing and improved mother-child relationship.
We do not expect that taking part will hold any risk for the participants. Participants are allowed to leave the study at any time and without giving any reason. If any distress is caused the researchers contact the health professional caring for the participant and they also offer them a contact for the appropriate support service they may need.

Where is the study run from?
The study is conducted in NHS Greater Glasgow and Clyde and NHS Ayrshire and Arran Health Board areas, UK.
The study is being carried out by a team of experienced researchers based at the Medical Research Council/Chief Scientist Office, Social and Public Health Sciences Unit, University of Glasgow in conjunction with other researchers at the University of Glasgow, Glasgow Caledonian University, University of Manchester, University of Newcastle, University of Aberdeen and Greater Glasgow and Clyde Health Board.

When is the study take place and how long is it expected to run for?
December 2013 - July 2019

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

Who is the main contact?
Dr Marion Henderson
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Study website
http://thrive.sphsu.mrc.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Protocol number: GN12KH589 / NIHR number: 11/3002/01

Study information

Scientific Title
Trial of Healthy Relationship Initiatives for the Very Early-years (THRIVE): a three-arm randomised controlled trial for mothers identified as vulnerable in pregnancy and their babies who are at high risk of maltreatment

Acronym
THRIVE

Study objectives
We propose that the parenting support programmes, Enhanced Triple P for Baby and Mellow Bumps, will be effective in lowering depression, anxiety and outwardly directed irritability and encourage the development of sensitive and attuned mother-infant relationships in pregnant women with additional health and social care needs. Enhanced Triple P for Baby and Mellow Bumps will lead to improvements in infant language development, long-term infant health, socio-emotional and educational outcomes and changes in the number of children flagged as at risk on the social services risk register. In addition, we propose that Enhanced Triple P for Baby and Mellow Bumps will be cost-effective for the NHS and society more broadly, in the long-term.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS West of Scotland Research Ethics Service, 21/08/2013, ref: 13/WS/0163

Study design
Longitudinal three-arm randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
See additional file

Health condition(s) or problem(s) studied
Maternal mental health; parenting; attachment; child maltreatment; child language development; early years; antenatal intervention; social deprivation; pregnancy; child development

Interventions
Current interventions (as of 09/04/2018):
This trial will compare two antenatal parenting interventions with routine care using outcome, process and health economics evaluation.

Enhanced Triple P for Baby
Enhanced Triple P for Baby is a transition to parenthood intervention which aims to provide babies with a healthy start to life, by combining parenting skills training with strategies to enhance individual wellbeing and couple adjustment. It is informed by social learning theory and has evolved from the universally designed Triple P for Baby. The enhanced level has been designed to address the specific health and social care needs of vulnerable women and their families. Group sessions focus on encouraging couples to work together to develop the skills needed to maintain a harmonious family. The womens partners are invited to all of the group sessions. The programme consists of four two-hour antenatal group sessions, up to three one-hour postnatal sessions which are delivered on a one-to-one basis in person and an optional post-natal group session. The first antenatal session is delivered when women are between 20-30 weeks pregnant, and the postnatal sessions are delivered from when infants are 6-weeks old.

Mellow Bumps
Mellow Bumps is underpinned by attachment theory and aims to encourage nurturing, engagement and synchronicity between mother and baby. Focusing on maternal well-being, women are encouraged to confront and modulate their emotional state through self reflection and group support. The women explore barriers to good parenting and are encouraged to identify beneficial sources of support available to them. Neonates capacity for early social interaction is highlighted along with its importance to enhance brain development and attachment. The programme consists of seven two-hour antenatal group sessions and one two-hour postnatal group session. In order to encourage a safe, sharing environment for the participants, partners are invited to one session only. The first antenatal session is delivered when women are between 20-30 weeks pregnant, and the postnatal session occurs when infants are 3 months old.

Care As Usual
All women participating in this study will continue to receive their routine antenatal and postnatal care in line with local NHS and social work guidelines.

Previous interventions:
This trial will compare two antenatal parenting interventions with routine care using outcome,

process and health economics evaluation.
Enhanced Triple P for Baby
Enhanced Triple P for Baby is a transition to parenthood intervention which aims to provide babies with a healthy start to life, by combining parenting skills training with strategies to enhance individual wellbeing and couple adjustment. It is informed by social learning theory and has evolved from the universally designed Triple P for Baby. The enhanced level has been designed to address the specific health and social care needs of vulnerable women and their families. Group sessions focus on encouraging couples to work together to develop the skills needed to maintain a harmonious family. The womens partners are invited to all of the group sessions. The programme consists of four two-hour antenatal group sessions and up to eight one-hour postnatal sessions which are delivered on a one-to-one basis either in person or by telephone depending on the participants self-assessed needs. The first antenatal session is delivered when women are between 20-30 weeks pregnant, and the postnatal sessions are delivered from when infants are 6-weeks old.
Mellow Bumps
Mellow Bumps is underpinned by attachment theory and aims to encourage nurturing, engagement and synchronicity between mother and baby. Focusing on maternal well-being, women are encouraged to confront and modulate their emotional state through self reflection and group support. The women explore barriers to good parenting and are encouraged to identify beneficial sources of support available to them. Neonates capacity for early social interaction is highlighted along with its importance to enhance brain development and attachment. The programme consists of seven two-hour antenatal group sessions and one two-hour postnatal group session. In order to encourage a safe, sharing environment for the participants, partners are invited to one session only. The first antenatal session is delivered when women are between 20-30 weeks pregnant, and the postnatal session occurs when infants are 3 months old.
Care As Usual
All women participating in this study will continue to receive their routine antenatal and postnatal care in line with local NHS and social work guidelines.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures (as of 09/04/2018):
The primary outcome measures, which will be recorded at the 6 month follow-up, are:
1. Maternal anxiety, depression and outwardly directed irritability will be measured using the Hospital Anxiety and Depression Scale enhanced by the outwardly directed irritability measures of the Adult Wellbeing Scale (HADS+I)
2. Quality of mother-child interaction will be measured using observer-ratings of video-taped interactions using the CARE Index

Previous primary outcome measures:
The primary outcome measures, which will be recorded at the 6 month follow-up, are:
1. Maternal anxiety, depression and outwardly directed irritability will be measured using the Hospital Anxiety and Depression Scale enhanced by the outwardly directed irritability measures

of the Adult Wellbeing Scale (HADS+1)
2. Quality of mother-child interaction will be measured using observer-ratings of video-taped interactions using the CARE Index and Mellow Parenting Observation Scale.

Secondary outcome measures
Current secondary outcome measures (as of 09/04/2018):
1. Number of children flagged as 'at risk' on the social services risk register, under a child protection plan, taken into local authority care or attending accident and emergency as measured using routinely collected NHS and Social Care Records
2. Child socio-emotional development as measured using the Strengths and Difficulties Questionnaire
3. Comparison of costs and outcomes associated with intervention delivery and routine antenatal care measured using routinely collected (NHS, social care, criminal justice and education) data, the EQ-5D-3L and self-reported patient service use
4. Assessment of programme fidelity; practitioners' characteristics and motivation; mothers' engagement; the intervention mechanisms; and contextual factors affecting mother and infant outcomes using self-reported practitioner data, ethnographic observation and semi-structured qualitative interviews
5. Assessment of whether fathers' involvement or support affects mothers' engagement with intervention delivery using semi-structured qualitative interviews

Previous secondary outcome measures:
1. Maternal anxiety, depression and outwardly directed irritability at 18 month follow-up measured using the Hospital Anxiety and Depression Scale enhanced by the outwardly directed irritability measures of the Adult Wellbeing Scale (HADS+1).
2. Quality of the mother-child interaction at 18 month follow-up measured using observer-ratings of video-taped interactions using the CARE Index and Mellow Parenting Observation Scale.
3. Parent self-efficacy at 6 and 18 months measured by the Karitane Parenting Confidence Scale
4. Language development at 18 months measured by the Sure Start Language Questionnaire
5. Language development at 30 months measured by the Sure Start Language Questionnaire
6. Socio-emotional development at age 30 months routinely measured using the Strengths and Difficulties Questionnaire (SDQ).
7. Long-term education outcomes measured by routinely collected education records.
8. Number of children flagged as at risk on the social services risk register, under a child protection plan, taken into local authority care or attending accident and emergency measured using routinely collected health and social care records.

Overall study start date
01/12/2013

Completion date
31/07/2019

Eligibility

Key inclusion criteria
Current participant inclusion criteria (as of 09/04/2018):
1. Women identified by midwifery, health and social care professionals and third sector organisations as vulnerable during pregnancy using NHS Greater Glasgow and Clyde Health Boards Special Needs in Pregnancy protocol. Woman will be recruited after their 12th week of

pregnancy.
2. Living within NHS Greater Glasgow and Clyde or NHS Ayrshire and Arran, or living within NHS Lanarkshire and receiving obstetric/maternity care from NHS Greater Glasgow and Clyde or NHS Ayrshire and Arran.
3. Women have a basic understanding of written and spoken English
4. Are able to provide informed consent and are able to engage in and complete the assessments and intervention process.
5. Women must be over 16 years of age to take part (or 14 years with social work support). There is no upper age limit as the study includes all women who are of child bearing age.

Previous participant inclusion criteria:
1. Women identified by midwifery, health and social care professionals and third sector organisations as vulnerable during pregnancy using NHS Greater Glasgow and Clyde Health Boards Special Needs in Pregnancy protocol. Woman will be recruited after their 12th week of pregnancy. If they are allocated to Mellow Bumps they must attend at least 50% of the eight group sessions in order to remain a participant in the trial. If they are allocated to Enhanced Triple P for Baby they must attend at least 50% of the antenatal group sessions and at least 50% of the postnatal one-to-one sessions.
2. Women will have a basic understanding of written and spoken English
3. Are able to provide informed consent and are able to engage in and complete the assessments and intervention process.
4. Women must be over 16 years of age to take part. There is no age limit as the study includes all women who are of child bearing age.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
500 women will be recruited to the trial. Follow-up data are required from 288 participants to achieve 80% power for both primary outcomes (121 participants in both the Enhanced Triple P for Baby and Mellow Bumps groups and 48 in the Care As Usual group).

Total final enrolment
485

Key exclusion criteria
Current participant exclusion criteria (as of 09/04/2018):
1. Women with poor or no comprehension of spoken English will be excluded as Enhanced Triple P for Baby and Mellow Bumps are group-based and require spoken communication between group members.
2. Women who have passed 30 weeks of pregnancy prior to referral are excluded, as this does not allow sufficient time to complete antenatal sessions.

3. Women with acute mental illness, including active psychosis, are also excluded as their mental ill-health may not allow them to fully participate or engage in the group programmes.
4. Women who are unable to provide a contact address (e.g. home, friend/relative address or homeless shelter) are also excluded as it may be difficult to retain them in this longitudinal study.
5. Women who are involved in a child protection order are assessed on a case-by-case basis in consultation with the professional who referred them and their midwife (if not the referrer) to determine whether they would be appropriate to take part in the study.
6. Women who are participating in another trial of antenatal interventions are excluded to avoid any bias in results.

Previous participant exclusion criteria:
1. Women with poor or no comprehension of spoken English will be excluded as Enhanced Triple P for Baby and Mellow Bumps are group-based and require spoken communication between group members.
2. Women with active psychosis will also be excluded as their mental ill-health may not allow them to fully participate or engage in the group programmes.
3. Women who are unable to provide a contact address (e.g. home, friend/relative address or homeless shelter) will also be excluded as it may be difficult to retain them in this longitudinal study.
4. Women who are involved in a child protection order will be assessed on a case-by-case basis in consultation with the professional who referred them and their midwife (if not the referrer) to determine whether they would be appropriate to take part in the study.

Date of first enrolment
01/12/2013

Date of final enrolment
31/05/2018

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
MRC/CSO Social and Public Health Sciences Unit
Glasgow
United Kingdom
G2 3QB

Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

Sponsor details
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38 Church Street
Glasgow
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United Kingdom
G11 6NT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
National Institute of Health Research (NIHR) (UK) - Public Health Research Programme (Ref: NIHR /PR/11/3002/01).

Funder Name
Chief Scientist Office at the Scottish Government (UK)

Funder Name
NHS Greater Glasgow and Clyde Health Board (UK)

Funder Name
Ayrshire and Arran Health Board (UK)

Results and Publications

Publication and dissemination plan

Planned publications of primary and secondary study results in high-impact peer-reviewed journals including open access journal and the HTA series.
Key findings will be communicated in layman's terms on the Thrive website.

Intention to publish date
31/07/2020

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?
Participant information sheet	version v3	02/05/2018	02/05/2018	No	Yes
Protocol article	realist process evaluation protocol	13/06/2019	17/06/2019	Yes	No
Protocol article	protocol	14/08/2019	16/08/2019	Yes	No
Results article		16/06/2021	18/06/2021	Yes	No
HRA research summary			28/06/2023	No	No
Other publications		01/05/2025	12/05/2025	Yes	No