ISRCTN08678682 https://doi.org/10.1186/ISRCTN08678682

Supporting young mothers (aged 14-25) in the first two years of life: a randomized controlled trial of the NSPCC UK Minding the Baby Home Visiting Programme

Submission date
03/04/2014

Registration date
03/04/2014

Last Edited
25/06/2020

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
15752

Study information

Scientific Title

Supporting young mothers (aged 14-25) in the first two years of life: a randomized controlled trial of the NSPCC UK Minding the Baby Home Visiting Programme

Study objectives
Minding the Baby is an intensive and preventive home-visiting programme that helps vulnerable or high risk first time mothers aged 14-25 living in poverty. The focus of the intervention is to reduce negative infant and maternal outcomes and strengthen the attachment relationship. MTB is delivered by an interdisciplinary team of highly skilled practitioners, who have health and social work experience, integrating advanced practice nursing and mental health care for mothers and infants. The proposed Randomised Control Trial (RCT) will allow for testing the efficacy of this innovative intervention across three UK sites. Participants will be randomly assigned to one of two arms, a treatment arm Minding the Baby (MTB) or a control arm-Treatment as Usual (TAU). Potential participants will be approached by a member of the clinical care team within midwifery who will inform mothers of the project during their booking-in (8-10 weeks) or 20-week scanning appointment. Posters and leaflets will also be placed in antenatal clinics. Consenting eligible participants will be seen by a researcher before they give birth and when their child is one and two years old.

We will be evaluating the effectiveness of the MTB programme by looking at a range of maternal and infant outcomes, including infant attachment security, maternal sensitivity and verified accounts of infant maltreatment and neglect. In addition we will be assessing the cost effectiveness of the MTB programme in order to support future roll-out of services. This study, involving a collaboration between the NSPCC, University College London and three NHS hospitals, affords a unique opportunity to advance knowledge regarding effective ways to support some of the youngest and most vulnerable children in the UK.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/LO/1651; First MREC approval date 16/01/2014

Study design
Randomised; Interventional; Design type: Not specified, Prevention

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Topic: Reproductive health and childbirth; Subtopic: Reproductive Health and Childb (all Subtopics); Disease: Reproductive Health & Childbirth

Interventions
1. Minding the Baby: This is an intensive home visiting intervention in which mothers are visited weekly by a trained practitioner in the first year, and two-weekly in the second.
2. Treatment as Usual: This is usual care received by mothers during their baby's first two years.

Follow Up Length: 12 month(s); Study Entry: Registration and One or More Randomisations

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Parental sensitivity; Timepoint(s): 12 months, 24 months

Key secondary outcome(s))
1. Attachment security; Timepoint(s): 12, 24months
2. Child behavioural problems; Timepoint(s): 24 months
3. Child cognitive/language development; Timepoint(s): 24 months
4. Incidences of child abuse and neglect; Timepoint(s): 12, 24 months
5. Maternal mental health; Timepoint(s): Baseline, 12 and 24 months
6. Postponed childbearing; Timepoint(s): 24 months
7. Service cost evaluation; Timepoint(s): 24 months

Completion date
28/02/2015

Eligibility

Key inclusion criteria
1. Primparous
2. Age 19 or under at the baby's conception OR age between 20 and 25 and in receipt of means-tested benefits
Target Gender: Female; Upper Age Limit 25 years ; Lower Age Limit 14 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
84

Key exclusion criteria
1. Mothers with a psychotic illness
2. Substance abuse disorders/chronic drug dependence
3. Those with profound or severe learning disabilities
4. Those parents with a life-threatening illness
5. Parents whose child is expected to be born with a life threatening illness or profound disability

6. The mother has been screened for participation in a Family nurse Partner Service (See A-29)
7. Non-English speaking

These exclusions have been made because families need to be able to understand and give informed consent, participate in treatment, and understand and complete all research questionnaires and assessments. Not all clinicians providing the interventions for the study are able to work with interpreters when working with non-English speaking families. Also, most of the research instruments have not been validated in other languages. The programme is believed to be inappropriate for mothers with very severe mental illness or substance abuse disorders.

Date of first enrolment
14/04/2014

Date of final enrolment
30/03/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University College London
London
United Kingdom
WC1E 6BT

Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
NSPCC (UK)

Results and Publications

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?
Protocol article	protocol	07/10/2016		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes