

Assessing the efficacy of an intervention to improve mind-mindedness in teenage mothers

Submission date 26/09/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/09/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/04/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Findings from a number of studies show that parents' ability to 'tune in' to what their baby might be thinking or feeling (so-called 'mind-mindedness') is important for secure attachment, language, play and understanding of other people's thoughts and feelings. For families in poverty, parents' ability to tune in to their babies' thoughts and feelings helps the child avoid developing problem behaviours at school-starting age. This research shows the widespread benefits of parents' willingness to see things from the child's perspective. The main aim of this project is to develop and evaluate an intervention package that will use a smartphone app to inform parents in an accessible way about mind-mindedness. The effectiveness of this intervention package will be evaluated by looking at its impact on mother-baby interaction and child outcome in teenage mothers.

Who can participate?

Pregnant women or mothers aged under 20 with babies who are 6 months old or younger.

What does the study involve?

Participants will be randomly allocated to receive either the intervention package or a control package. The intervention package consists of an animated film and booklet to inform mothers about mind-mindedness, and a mind-mindedness smartphone app that has been designed for the study. The control group will receive a film and booklet focussed on general development and a widely-available baby app. Mothers and their 6-month-old babies will meet with the researchers. Mothers will be filmed playing with their babies for 20 minutes and will fill in some questionnaires about their background and wellbeing. The researcher will then show them a film, provide a booklet, and show them how the smartphone app works. The app will be downloaded onto the mothers phone for her to keep. Altogether, this will last about an hour and mothers will be paid for their time and travel. Mothers will use the smartphone app until their babies are 12 months old, when mothers and babies will meet with the researchers again. They will again be filmed playing together and mothers will fill in some questionnaires. The session will last about an hour and mothers will again be paid for their time and travel.

What are the possible benefits and risks of participating?

The app is designed to be fun to use, and will help mothers learn about their baby's development

in a new, interactive way. Some mothers may find answering the questionnaires uncomfortable, but the researchers will be able to provide support if needed.

Where is the study being run from?

The researchers are based at the University of York and are working with GPs, health visitors and maternity sites across North Yorkshire to identify suitable participants. Testing will normally take place in the University of Yorks baby suite, but can be conducted at a local childrens centre or clinic if that is more convenient for mothers.

When is the study starting and how long is it expected to run for?

The study runs from July 2014 until June 2016.

Who is funding the study?

Economic and Social Research Council (ESRC) (UK).

Who is the main contact?

Dr Fionnuala Larkin

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Contact information

Type(s)

Scientific

Contact name

Dr Fionnuala Larkin

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

16561

Study information

Scientific Title

Assessing the efficacy of an intervention to improve mind-mindedness in teenage mothers: a randomised controlled trial

Acronym

Mind-mindedness Intervention

Study objectives

The study seeks to evaluate whether mind-mindedness can be enhanced amongst teenage mothers through the provision of a 6-month, technology-based intervention package involving a smartphone app and animated film.

Ethics approval required

Old ethics approval format

Ethics approval(s)

14/NE/0114; First MREC approval date 22/05/2014

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

Topic: Reproductive Health; Subtopic: Reproductive Health and Childbirth (all Subtopics);
Disease: Reproductive Health & Childbirth

Interventions

There will be two trial arms: the mind-mindedness intervention and the control intervention.

1. An animated film and associated booklet will inform the intervention group about mind-mindedness, and they will receive a mind-mindedness smartphone app that has been designed for the study.
2. The control group will receive a package focussed on general developmental milestones and a pre-existing baby app that is widely available.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Mind-mindedness will be assessed from transcripts of parent-child interaction using previously operationalised coding procedures (Meins & Fernyhough, 2012). Timepoint(s): After 6 months of intervention

Secondary outcome measures

1. Maternal mental health; Timepoint(s): After 6 months of intervention
 2. Parent-child attachment; Timepoint(s): When child is aged 12 months
- These will be assessed through administration of the following measures:

1. Slade Pregnancy Interview, Revised (Slade, 2011)
2. Hospital Anxiety and Depression Scales (Zigmond & Snaith, 1983)
3. Rosenberg Self-Esteem Scale (Rosenberg, 1965)
4. Parental Bonding Instrument: Brief Current (PBI-BC; Klimidis, Minis & Ata, 1992)
5. Relationship Questionnaire (Bartholomew & Horowitz, 1991)
6. Family Emotional Involvement and Criticism Scale (perceived criticism items) (FEICS; Shields, Franks, Harp, McDaniel, and Campbell, 1992)
7. Los Angeles Symptom Checklist (LASC; King, King, Leskin, & Foy, 1995)
8. Parenting Stress Index, Short Form (3rd edition). (Abidin, 1995)
9. Recent Life Events Questionnaire (Department of Health, 1985)
10. Interpersonal Reactivity Index (IRI; Davis 1980)
11. Multidimensional Scale of Perceived Social Support (MSPSS; Zimet, Dahlem, Zimet & Farley, 1988)
12. Parenting Sense of Competence Scale (Gibaud-Wallston & Wandersman, 1978)
13. Parent Development Interview Revised Short Version (Slade, Aber, Berger, Bresgi & Kaplan, 2012)
14. Laboratory Temperament Assessment Battery (Goldstein & Rothbart, 1999)
15. Strange Situation (Ainsworth & Wittig, 1969)

Overall study start date

17/02/2014

Completion date

30/06/2018

Eligibility

Key inclusion criteria

1. Aged below 20
2. Pregnant or the mother of a baby younger than 6 months of age

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Planned Sample Size: 210; UK Sample Size: 210

Total final enrolment

141

Key exclusion criteria

Mothers who are not native English speakers

Date of first enrolment

29/07/2014

Date of final enrolment

30/06/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Psychology

York

United Kingdom

YO10 5DD

Sponsor information

Organisation

University of York (UK)

Sponsor details

Room 152 Seebohm Rowntree Building

York

England

United Kingdom

YO10 5DD

Sponsor type

University/education

ROR

<https://ror.org/04m01e293>

Funder(s)

Funder type

Research council

Funder Name

Economic and Social Research Council (ESRC); grant codes: ES/K010719/1

Alternative Name(s)

ESRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Publication and dissemination plan as of 30/11/2018:
Planned publication in high impact developmental journals.

Intention to publish date

31/05/2019

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

Previous publication and dissemination plan:

Planned publication in high impact developmental journals.

IPD sharing statement:

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository: the ESRC data service provider or the University of York's data repository

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?
Results article		22/08/2019	22/04/2021	Yes	No
HRA research summary			28/06/2023	No	No