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The Mellow Babies Trial

Submission date
10/01/2019

Recruitment status
No longer recruiting

Registration date
30/01/2019

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The Mellow Babies Trial is a research study looking at whether a group programme called 'Mellow Babies' can improve mothers' and babies' wellbeing. Being a parent can be wonderful but also brings some tough challenges. It can be harder if parents are not in a good emotional state themselves. All young children have social and emotional ups and downs, but sometimes problems can continue. Research shows that if families have the right help and support then this can prevent long term problems for the child. Mellow Babies is a group for mothers who want to develop and improve their relationship with their baby. The groups look at mothers' feelings of wellbeing (happiness and sadness / feeling hopeless or not being able to cope as well as they would wish). It also looks at the way mothers talk to and behave with their baby. Mellow Babies aims to help mothers both feel better in themselves and about how they talk and play with their babies. This research study will compare outcomes for families who take part in Mellow Babies with families who do not take part in Mellow Babies (referred to as 'usual care' or 'comparison group'). Usual care can include a range of things relevant to a specific family, but is likely to include support from health visitors, GPs and maybe other professionals.

Who can participate?
Participants will be eligible to take part in the Mellow Babies Trial if:
1. They are a mother 16 years old or older
2. Their baby is between 6 and 18 months old (when the Mellow Babies group would be starting)
3. They live in the Highland Council region
4. They are experiencing low mood or anxiety
5. They would like to develop and improve their relationship with their baby.
Participants will not be eligible to take part if they are currently dependent on alcohol or illegal drugs or if they are not confident enough in spoken English to be able to take part in group discussion and research assessments.

What does the study involve?
Participants will usually be referred to the study by their health visitor or other health/social care professional. The study research nurse will phone the participant and tell her more about the study and check if she's eligible. If the participant is interested in taking part the study research nurse will make an appointment to visit each new participant at home. They will be asked to sign a consent form and to answer some questions about their wellbeing. After this they will be chosen at random (like tossing a coin) to either join a Mellow Babies group, or the

comparison group (who will not take part in a Mellow Babies group). If randomised to join a Mellow Babies group, a practitioner will contact the participant to discuss when and where the next Mellow Babies group will be held. The group lasts 14 weeks, and participants may have to wait a few weeks before the next available group starts. Groups run within school hours, and a crèche, transport and refreshments and lunch for mums and babies are provided. Participants in both the Mellow Babies and comparison groups will be contacted by a researcher to arrange for another study visit about 8 months later, and again when their baby reaches 30 months old. All the research information collected is treated confidentially and entered directly onto a secure part of the study website. Only the research staff can access this.

What are the possible benefits and risks of participating?
Participants may or may not benefit personally from taking part. They will receive usual care from their health visitor and other health and social care staff whether or not they choose to participate in the study. By taking part, participants will be helping to find out if the support provided to mothers experiencing difficulties in their relationship with their baby can be improved by the Mellow Babies program. The visits from the researchers to complete questionnaires will take up some of their time (although a £10 voucher is included for each visit as a thank you for this). It is possible that completion of some of the research questionnaires or participation in the Mellow Babies group could bring up strong feelings. If participants feel they need further support, the research team at the Study Office or the Mellow Babies group leader (if allocated to the intervention) will help them get the relevant support.

Where is the study run from?
The research is being carried out in the Highland Council region of Scotland by a group of experienced practitioners and researchers from the Centre for Rural Health, the NHS Highland Clinical Research Facility, and the Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered Clinical Trials Unit at the University of Aberdeen. All research information is collected over the phone or in participant's own homes.

When is the study starting and how long is it expected to run for?
The study will start recruiting on 21st January 2019 until September 2020 with follow-up visits until summer 2022. The final results of the study will be available in early 2023.

Who is funding the study?
The study is funded by the National Institute for Health Research (NIHR) Public Health Research (PHR) committee. The Mellow Babies groups are funded by the Chief Scientist Office of the Scottish Government Health and Social Care Directorates.

Who is the main contact?
Hope Christie, Research Fellow, Centre for Rural Health, University of Aberdeen, Centre for Health Science, Old Perth Rd, Inverness IV2 3JH, Tel: +44 (0)1463 255903, Email: mellowbabies@abdn.ac.uk

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Public

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Additional identifiers

Protocol serial number
2-086-18

Study information

Scientific Title
Does "Mellow Babies" improve the psychosocial health of mothers and their children? The Mellow Babies Trial

Acronym
MBT

Study objectives
Does Mellow Babies delivered to mothers who are anxious or depressed, along with their 6-18 month-old children, improve maternal mental health and the social, emotional and language development of their children at 8 months post randomisation and 30 months of age?

Ethics approval required
Old ethics approval format

Ethics approval(s)

East Midlands - Nottingham 1 Research Ethics Committee, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, Tel: +44 (0)207 104 8104, Email: NRESCommittee.EastMidlands-Nottingham1@nhs.net, 11/12/2018, ref: 18/EM/0304

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Mothers who are having difficulties in their relationship with their baby. Mothers' feelings of wellbeing (depression, anxiety, stress, etc), and the way mothers interact with their baby

Interventions
Participants are randomised to either the Mellow Babies group-based parenting programme (MB) plus Usual Care or Usual Care. Mothers are randomised (following consent) and screened to ensure inclusion and exclusion criteria are matched (the maternal score on the HADS exceeds either 10 on the Anxiety subscale or 6 on the Depression subscale, corresponding to the 85th centile for the UK female population).

The MB programme involves attendance on 14 consecutive weeks within school hours and there is a reunion 1-3 months later. Groups can be offered at weekends, and transport (or transport cost), meals and a crèche are provided. MB aims to enhance close parent-infant attunement directly using a combination of video feedback and hands-on practice in baby-massage, interaction coaching and infant-focussed speech. Video material of mealtime interactions is shared, and mothers are encouraged to discuss solutions to parenting difficulties.

Intervention Type
Behavioural

Primary outcome(s)
Maternal mental health measured using self-complete Hospital Anxiety and Depression Scale (HADS) at 8 months post randomisation and when children are 30 months old

Key secondary outcome(s))
At 8 months post-recruitment:
1. Child's expressive language performance in the 50-word Sure Start Language Measure (SSLM)
2. Child's overall social and emotional development measured with Brief Infant-Toddler Social and Emotional Assessment (BITSEA)
3. Caregiver accounts of the experience of interventions measured using participant interviews
4. Participants' service use and out of pocket expenses measured using bespoke Participant Cost Questionnaire
5. Mothers' quality of life as measured by EQ-5D-5L
6. Positive and negative parenting behaviours during a videoed family meal using the Mellow Parenting Observational System (MPOS)

At 30 months of age:
1. Child's social and emotional functioning as measured by the total difficulties scale of the maternally-reported SDQ at age 30 months
2. Specific aspects of child's social and emotional functioning as measured by the emotional problems, conduct problems, hyperactivity/inattention and peer relationship problems, and prosocial behaviour subscale of the SDQ
3. Child's expressive language performance in the 50-word Sure Start Language Measure (SSLM)
4. Child's overall development the Bayley III Scales of Infant and Toddler Development (65), including Behavior Observation Inventory
5. Positive and negative parenting behaviours during a videoed family meal using the Mellow Parenting Observational System (MPOS)
6. Within-trial cost analysis of participants' service use and out of pocket expenses using bespoke Participant Cost Questionnaire
7. Cost-consequence analysis of the MB intervention vs usual care
8. Mothers' quality of life as measured by EQ-5D-5L
9. Satisfaction with intervention/usual care measured using participant feedback questionnaire and interviews

Completion date
30/11/2022

Eligibility

Key inclusion criteria
1. Mothers with principal caregiving responsibilities scoring >11 on HADS-A or >7 on HADS-D
2. With a child who will be aged 6-18 months at the time of randomisation
3. Living in Highland Council region

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Current substance dependence
2. Inability to complete questionnaires or participate in groups because of limited English language comprehension
3. Child with learning difficulties sufficient to make outcome assessment impossible
4. Mother has already participated in the trial (e.g., second eligible baby within life of the study)
5. Mother under 16 years

Date of first enrolment
21/01/2019

Date of final enrolment
30/09/2020

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Highland
Assynt House
Old Perth Road
Inverness
United Kingdom
IV2 3BW

Sponsor information

Organisation
University of Aberdeen

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
Results article		01/12/2024	17/01/2025	Yes	No
HRA research summary			28/06/2023	No	No
Protocol file	version v3	17/01/2019	14/05/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes