

A UK case-control study of the "Mellow Babies" effectiveness: An attachment-based early intervention parenting programme for Mums & Dads

Submission date 10/04/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 18/04/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/05/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input checked="" type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The early years are one of the most important stages in a person's life. During this time, children gain their first experiences of bonding with another person, often their parents. However sometimes, if mum's and dad's wellbeing, sense of self-efficacy, and confidence is low, it can be difficult to build and maintain a safe and warm relationship with their babies. In turn, babies that feel their parents to be distant or inconsistent may experience more complications in their social and emotional development. Mellow Babies (MB) is a 14-week early intervention (a programme that starts early in a child's life) group programme for mums and dads who face difficulties in their role as a parent due to various and complex reasons, such as their own mental health or their involvement with child protection services. The programme aims to help parents to be the best parent they can by using a mixture of group discussions and activities with a focus on both parents as individuals and as parents, and by promoting positive parent-child interactions. The aim of this study is to evaluate the effectiveness of MB by comparing the wellbeing and confidence of parents, the quality of the parent-baby interactions and the social-emotional development of babies that have participated to MB to those that have not.

Who can participate?

Mums and Dads who need extra support and have at least one child under the age of 18 months.

What does the study involve?

Participants are allocated into one of two groups depending on when they agree to take part in the study. Those in the first group take part in the Mellow Babies (MB) programme. A typical Mellow Babies group runs for 14 weeks, one day a week, with the day is split over three sessions. A Personal Group, in which parents discuss and reflect about their parenting experiences and relationships with their children; a joint lunch/activity, where parents eat together and take part in an activity with their children to help them bond; and a Parenting Workshop, which involves using strength-based video feedback to improve parent-infant interaction. Those in the second group receive the care and help that they would have received anyway (usual care). At the start

of the study and after 14 weeks, parents complete a range of questionnaires in order to assess the quality of the parent-baby interactions, parent wellbeing and attitudes and child development.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
The study runs from the Evaluation Team of the Mellow Parenting charity and takes place in family support services across the UK.

When is the study starting and how long is it expected to run for?
February 2017 to June 2018

Who is funding the study?
The AIM Foundation (UK)

Who is the main contact?
Mr Raquib Ibrahim
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Contact information

Type(s)
Scientific

Contact name
Mr Raquib Ibrahim

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

"Mellow Babies": an attachment-based group intervention for families with complex & additional social care needs

Acronym

Mellow Babies

Study objectives

Participants in the intervention group will show greater improvements than participants in the control group in:

1. Parental wellbeing, confidence and engagement
2. Child social and emotional indicators
3. Quality of parent-child relationship and interaction

Ethics approval required

Old ethics approval format

Ethics approval(s)

School of Health in Social Science (SHSS), University of Edinburgh (UoE), 26/09/2017

Study design

Multi-centre non-randomised study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Prevention

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

Parental mental health, child social-emotional development, parent-child relationship and social inclusion.

Interventions

Recruitment of parents is facilitated by participating organisations/ family services. An invitation poster for the study has been sent from the Mellow Parenting (MP) Evaluation Team to all MP

practitioners in the UK via email and has been shared in the Mellow Parenting website and social media pages. Eligible Mellow Babies practitioners (based on their experience and availability) receive detailed information about the aims and procedures of the research project and are required to sign a consent form. All participants recruited for this research project are thoroughly assessed by the practitioners for their eligibility to participate in a Mellow Babies group. Allocation to intervention and control group follows an opportunity sampling procedure, where participants are selected based on naturally occurring groups. Control group is recruited by parents that fulfil the criteria of participating in a Mellow Babies group and during the research project are either in a waiting list or are receiving a different type of support within the services due to the services' resources.

Intervention group: The intervention group comprising of parents and infants who participate in the Mellow Babies (MB) programme. The programme is underpinned by attachment theory, social learning theory and cognitive behaviour therapy. Mellow Babies is an early intervention relationship-based group programme for mums and dads who have at least one child under the age of 18 months. Mixtures of reflective and practical techniques are used to allow parents to address their personal challenges and the challenges they face with their baby. A typical Mellow Babies group will run for 14 weeks, one day a week and the day is split over three sessions; Personal Group, joint lunch/activity and Parenting Workshop, with follow-up tasks to reinforce learning. The programme uses strength-based video feedback to facilitate improved parent-infant interaction.

1. In the personal group, parents discuss and reflect how their own experiences of being parented are affecting their current well-being and relationships with their children now
2. Over lunch, the parents and children eat together and participate in a joint activity. This allows the parent and child to share in fun activities which build and strengthen their relationship. Lunchtime activities build up a repertoire of cheap or free activities to draw on at home or later.
3. In the Parenting Workshop, the parents participate in strengths-based video feedback of their own videos which helps them build on their existing skills and practice new ways of relating to their child. Parents also explore how children develop, discuss practical issues around parenting and are encouraged to "HAVE A GO!" at home putting into practice the things they have learned.

The control group which will be the comparison/control group comprising of parents and infants who receive care as usual (CAU), Control groups will be recruited by participating organisations; they will identify parents that meet the criteria for taking part in a Mellow Babies group but are receiving care as usual for one of the following two reasons:

1. The existing group is full and they are on a waiting list
2. Parents who meet the criteria have been identified but the service is unable to offer a Mellow Babies group within the timescale of the research project.

A follow-up data collection is scheduled 14 weeks after the baseline assessment. This includes administration of questionnaires, video observation and semi-structured interviews with parents, and if applicable with group facilitators, child care workers and participant's partners. "The Tunnel" task is additionally administered at week 7. Optional permission for a 6-month follow-up is included in the consent form. The 6-month follow-up assessment will consist of questionnaires, video observation and semi-structured interview with parents. Demographic information will be collected at baseline, 14 weeks and 6 months for information that may change over time, such as parent's employment, marital, and baby's living status. Please see Table 1 for more information on measurements, key outcomes and timing of assessments.

Intervention Type

Behavioural

Primary outcome measure

1. Quality of parent-child relationship. Interaction is measured using the Mellow Parenting Observation System (MPOS) and Elizabeth Meins & Charles Fernyhough (2015) Mind-Mindedness video observation at baseline and 14 weeks
2. Parents attitudes and beliefs about self and relationship with their child will be measured by using a 10 point Likert scale referred to as the "the tunnel" at baseline, 7 and 14 weeks

Secondary outcome measures

Child:

Child social and emotional indicators are measured using Ages and Stages Questionnaire: Social and Emotional (ASQ: SE-2) at baseline and 14 weeks.

Parent:

1. Parental well-being is measured using the Brief Symptom Inventory 18 (BSI-18) and Quality of Life Enjoyment and Satisfaction Questionnaire (Short Form) at baseline and 14 weeks
2. Parental confidence is measured using the Karitane Parenting Confidence Scale (KPCS) at baseline and 14 weeks
3. Ongoing parental engagement with services is measured using qualitative feedback from parents and professionals at 14 weeks. In addition to data collected through semi-structured interviews, at week 14 group facilitators will provide a "Further Service Uptake" and a "Group Attendance" sheet for each participant

Overall study start date

17/08/2016

Completion date

30/06/2018

Eligibility

Key inclusion criteria

1. Mums and dads
2. Experience complex and additional care needs (e.g. mental health issues, substance misuse, poor parenting, involvement to statutory child protection) and who have at least one child (girl or boy) under the age of 18 months
3. Who are referred by a health-related professional (e.g. health visitor, social worker, midwife, GP) or are self-referred to a family support service with trained Mellow Babies practitioners in the regions of England, Scotland and Northern Ireland
4. Have been informed about the aims and procedures of the research project and have signed a written consent form
- 5.1. Attend a Mellow Babies early intervention group starting between 1/2/2017 and 30/6/2017 (Study Group)
- 5.2. On a waiting list for attending a Mellow Babies group beyond the project's timescale or are receiving another group intervention/ activity (Care as Usual) within the service during the set time period due to reasons such as service's availability/funding (Control Group)

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

A minimum total sample size of 102 participants and of 51 participants per group (Study/Control) has been indicated by an a-priori power analysis.

Total final enrolment

91

Key exclusion criteria

1. Do not have a child (girl or boy) under the age of 18 months
2. To attend a Mellow Babies early intervention group within the project's timescale, but all or the majority (2 out of 3) of the practitioners facilitating the group have not had a previous Mellow Babies delivery experience. This criterion is applied to ensure fidelity to the Mellow Babies intervention programme.
3. Satisfy the rest of the inclusion criteria but do not wish to take part in the research project

Date of first enrolment

01/02/2017

Date of final enrolment

31/12/2017

Locations**Countries of recruitment**

England

Scotland

United Kingdom

Study participating centre**Mellow Parenting**

Unit 4

Six Harmony Row

Glasgow

United Kingdom

G51 32BA

Study participating centre**Barnet, Enfield and Haringey Mental Health NHS Trust**

Orton Grove

Enfield

London

United Kingdom
EN1 4TU

Study participating centre

Barnardo's

Westwood Business Centre
69 Aberdalgie Road
Easterhouse
Glasgow
United Kingdom
G34 9HJ

Study participating centre

First Step

37 Galt Avenue
Musselburgh
Midlothian
United Kingdom
EH21 8HU

Study participating centre

Coram Thurrock Thinking Families Services

The Church House, West Street
Grays
United Kingdom
RM17 6LN

Study participating centre

Central Bedfordshire Council

Priory House, Monks Walk
Shefford
United Kingdom
SG17 5TQ

Study participating centre

Family Support Fife

Rothsay House, Rothsay Place
Glenrothes
Fife
United Kingdom
KY7 5PQ

Sponsor information

Organisation

The AIM Foundation

Sponsor details

Yeo Farm

Chagford

Devon

United Kingdom

TQ13 8ES

Sponsor type

Charity

Funder(s)

Funder type

Charity

Funder Name

The AIM Foundation

Results and Publications

Publication and dissemination plan

Dissemination of findings will be sought through publication, conference presentations, posters and social media.

Intention to publish date

30/09/2019

Individual participant data (IPD) sharing plan

The current 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	Date	Date	Peer	Patient-
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type	Details	created	added	reviewed?	facing?
Results article	results	03/02/2021	04/02/2021	Yes	No
Results article	qualitative data collected as part of the study via semi-structured interviews with parents who completed the MB groups	18/10/2022	22/12/2022	Yes	No
Dataset			10/05/2024	No	No