ISRCTN15166640 https://doi.org/10.1186/ISRCTN15166640

Bonding Before Birth: An mHealth Intervention for first-time expectant couples

Submission date
24/10/2025

Recruitment status
Recruiting

Registration date
29/10/2025

Overall study status
Ongoing

Last Edited
29/10/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This study is looking at whether short weekly exercises delivered through a mobile app can help first-time parents feel better emotionally during pregnancy. These exercises are designed to help people manage their emotions and stress. Researchers want to know if doing these exercises, along with getting weekly feedback and encouragement, can reduce signs of depression and improve emotional control.

Who can participate?
Expecting mothers and fathers who are having their first child may be able to join the study if they meet certain conditions. Participants should be planning to stay in Singapore for the next two years and be comfortable using a smartphone and answering questions in English.

What does the study involve?
Participants will wear a Fitbit watch to track activity. They will complete a short weekly survey about their well-being during pregnancy and a monthly survey about their work productivity until six months after the baby is born. They will also answer online surveys about their health, relationships, and background at the start, three times during pregnancy, and three times after birth. In addition, they will visit the research lab twice to take part in tasks that measure thinking and behaviour.

What are the possible benefits and risks of participating?
Participants may benefit from learning new ways to manage stress and emotions, which could help improve their mental health during pregnancy. There are no known major risks, but some people might find the surveys or tasks time-consuming or emotionally difficult.

Where is the study run from?
Institute for Human Development and Potential, A*STAR (Singapore)

When is the study starting and how long is it expected to run for?
March 2022 to December 2028

Who is funding the study?
Institute for Human Development and Potential, A*STAR (Singapore)

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2023-068

Study information

Scientific Title
Bonding Before Birth: a cluster-randomized, controlled, mHealth trial for developing mindfulness and emotional regulation in expectant couples

Acronym
B³

Study objectives
Emotional regulation is a key component of reducing parenting stress, a sense of self-efficacy, and thus successful parenting, child outcomes, and productivity amongst working parents. However, few interventions begin building these necessary components in pregnancy prior to the extremely stressful period immediately post-partum, where little trait and behavioural modification occurs. More importantly, most interventions overlook the importance of having both partners, despite fathers/partners playing a significant role in influencing maternal stress and mood symptoms.

The goal of this intervention study is to learn if weekly recommendations to short, mobile app-based self-regulation exercises, combined with weekly feedback and reinforcement, can improve self-reported well-being of both mothers and fathers who are expecting their first child. This intervention takes place during pregnancy.

The study involves 286 expectant couples (572 individuals) in a two-arm, cluster-randomized controlled trial with longitudinal observational follow-up until the child turns 6 months old. The study employs an adaptive intervention tailored to the expectant couples, using reinforcement learning and micro-randomization to deliver clinically designed audio coaching and educational modules from a mobile health (mHealth) app tailored to each couple.

The study aims to answer the following main questions:
• Does the intervention improve parents' depressive symptoms scores, using the Edinburgh Postnatal Depression Scale as a proxy?
• Does the intervention improve parents' emotional regulation skills?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 11/04/2024, A*STAR Human Biomedical Research Office Institutional Review Board (2 Fusionopolis Way. Innovis #08-05, Singapore, 138634, Singapore; +65-64070100; hbro@a-star.edu.sg), ref: 2023-068

Study design
Single-center interventional two-arm cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Improvement of first-time parents' depressive symptoms, using Edinburgh Postnatal Depression Scale as a proxy

Interventions
The proposed study will be a two-arm, cluster-randomized, controlled trial with longitudinal observational follow-up. The active intervention comprises of customized, weekly recommendations of short (2-5 minute) audio clips featuring activities such as breathing exercises, meditation, mindful walking. These will be provided to adult participants (expectant couples). Couples enrolling in the study will randomly be allocated to either the control or intervention group by prespecified block sizes of 10. That is, a random number generator will be used to preset the assignments in groups of 10, such that every 10 consecutive enrolments will have exactly 5 controls and 5 interventions (1:1 allocation). While it is not possible to blind operational staff to assignments (different protocols to follow, highly unbalanced assignment), scheduling of enrolment visits will be done by different staff than those conducting the enrolment visits, and the assignment will only be made known to enrolment staff while conducting the visit itself and they will also not have access to the blocking and randomization algorithm.

Participants in the control, no-intervention group will have access to a mobile app with similar functions as the participants in the intervention group, except that no personalized modules are given. Data will also be collected from online and in-app surveys, as well as via the Fitbit watch.

Participants in the intervention group will have access to the mHealth app that will be installed on their mobile devices and have access to weekly personalized recommendations. Participants will also be re-randomized weekly to different modules within the app. Data will also be collected from online and in-app surveys, as well as via the Fitbit watch.

The intervention will take place throughout pregnancy, beginning at enrollment (when the mother is less than 15 gestational weeks), and continuing until the child is born. As gestational duration varies among participants, the total intervention period will range approximately from 25 to 28 weeks, depending on the timing of recruitment and delivery. All study arms will be assessed up to 6 months after birth.

Intervention Type
Behavioural

Primary outcome(s)
Parents' level of depressive symptoms measured using the Edinburgh Postnatal Depression Scale, administered upon enrollment, once at 16-20 gestation weeks, once at 24-28 weeks, once at 37-40 gestation weeks, and postnatal 1-, 3-, and 6-months. A composite outcome of the three postnatal EPDS measurements will be used as a primary outcome assessment.

Key secondary outcome(s))
Examining self-reported parental emotional regulation skills measured using the Cognitive Emotion Regulation Questionnaire, administered upon enrollment, once at 16-20 gestation weeks, once at 24-28 weeks, once at 37-40 gestation weeks, and postnatal 1-, 3-, and 6-months.

Completion date
31/12/2028

Eligibility

Key inclusion criteria
Mothers:
1. 21–50 years of age
2. Less than 15 weeks of pregnancy, confirmed by ultrasonography upon enrolment
3. Singleton pregnancy
4. Nulliparous
5. Plan to deliver in Singapore
6. Proficient and able to respond to questionnaires in English
7. Intends for herself and her child to stay in Singapore for the next 2 years
8. Access to a smartphone
9. Willing to download the study app
10. Score of 7 or more in the Edinburgh Postnatal Depression Scale

Fathers:
1. 21–75 years of age
2. Proficient and able to respond to questionnaires in English
3. Intends for himself and his child to stay in Singapore for the next 2 years
4. Access to a smartphone
5. Willing to download the study app

Participant type(s)
Healthy volunteer, Population, Resident

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
21 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
Mothers:
1. Any pre-existing or history of psychotic depression, schizophrenia, and bipolar disorders
2. Currently on oral/IV steroids and/or thyroid medication
3. History of thyroid disease
4. Pregnant using assisted reproductive technologies
5. Multiple pregnancies
6. Currently enrolled in interventional randomised controlled trials
7. Responded "Yes, quite often" to EPDS item 10 ("The thought of harming myself has occurred to me")

Fathers:
1. Currently enrolled in interventional randomised controlled trials

Date of first enrolment
31/10/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Singapore

Study participating centre
Human Development Research Centre (HDRC), A*STAR
10 Medical Drive
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Sponsor information

Organisation
Institute for Human Development and Potential, A*STAR

Funder(s)

Funder type
Research organisation

Funder Name
A*STAR Human Health and Potential Prenatal/Early Childhood Grant (H22P0M0001 and H22P0M0009)

Results and Publications

Individual participant data (IPD) sharing plan

The decision regarding the availability of individual participant data for sharing requires further discussions between the institutes 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	Participant information sheet	11/11/2025	11/11/2025	No	Yes