

Mindfulness in pregnancy study

Submission date 26/06/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/07/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 30/06/2026	Condition category Pregnancy and Childbirth	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

The purpose of this research study is to compare the feasibility and acceptability of two mindfulness courses [mindfulness-based stress reduction (MBSR) and mindful self-compassion (MSC)] among pregnant women. The study will also wish to understand if the mindfulness courses change maternal mental well-being and levels of blood sugars and inflammation during pregnancy.

Who can participate?

English-speaking adults pregnant with one baby are eligible to participate.

What does the study involve?

Participation involves an 8 week standardized mindfulness course delivered virtually with each class lasting 2.5 hours. Participants will complete surveys about their background, mood/mental health states and dietary intake, and have a small blood draw taken before and after the 8-week mindfulness course.

What are the possible benefits and risks of participating?

Benefits of participation include receiving a guided mindfulness training from a qualified instructor free of charge. Participants will be provided with mindfulness audio and written materials that you may keep for ongoing home practice.

There may be direct benefits of the MBSR and MSC techniques practiced during the study, such as:

increased awareness and concentration, discovering new ways to cope more effectively with existing conditions, psychological difficulties, pain or suffering, learning to take better care of oneself. However, there is no guarantee that any particular results from participation in either MBSR or MSC courses.

Risks of participation include discomfort, stress or anxiety when completing some questionnaires and during the mindfulness course. There is a small risk of temporary pain, bruising, bleeding or swelling from blood draw in your forearm. Also, should there be a breach in confidentiality of your data, there is a slight risk that your private information could be shared with individuals who are not members of the study team.

Where is the study run from?
UCI Susan Samueli Integrative Health Institute, USA.

When is the study starting and how long is it expected to run for?
August 2021 to December 2021.

Who is funding the study?
UCI Susan Samueli Integrative Health Institute, USA.

Who is the main contact?
Dr Karen Lindsay, kllindsa@uci.edu

Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
Identifying an optimal mindfulness intervention for pregnant women: a feasibility and acceptability study

Study objectives
To compare the feasibility and acceptability of two mindfulness courses [mindfulness-based stress reduction (MBSR) and mindful self-compassion (MSC)] among pregnant women.
To explore if participation in either of the mindfulness courses is associated with a change in maternal mental well-being and levels of blood sugars and inflammation during pregnancy.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/05/2021, University of California Irvine Institutional Review Board (Aldrich Hall, Irvine, 92617, United States of America; +1 (949) 824-6068; IRB@research.uci.edu), ref: 2021-6552

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Health services research, Supportive care

Study type(s)**Health condition(s) or problem(s) studied**

Singleton pregnancy

Interventions

Overview:

Participants are randomized to one of two types of mindfulness courses, both lasting 8 weeks and delivered virtually over Zoom with a trained mindfulness instructor. For each course, weekly sessions last 2.5 hours.

Course types:

- mindfulness-based stress reduction (MBSR)
- mindful self-compassion (MSC)

Both courses also include a half-day retreat delivered online.

In depth:

- Method of randomization: A computer program was used to generate the random allocation sequence for the two mindfulness groups. The sequence was stored in an Excel file by a researcher who was not involved in delivering the intervention. This individual revealed each participant's group allocation as they were enrolled in the study

- Intervention:

- o MBSR: Those assigned to the Mindfulness Based Stress Reduction group underwent this 8-week standardized mindfulness course as developed by John Kabat-Zinn. Participants met as a group virtually by Zoom once per week for 8 weeks. Each session lasted between 2-2.5 hours and was scheduled for the same evening each week. A mindfulness instructor trained in the MBSR method led each class and participants were assigned mindfulness practices and reflections to complete at home between classes. Additionally, the instructor led a 6-hour mindfulness retreat on a weekend between weeks 6 and 7, per the standardized curriculum for MBSR.

- o MSC: Those assigned to the Mindful Self Compassion group underwent this 8-week standardized mindfulness course as developed by Kristin Neff. Participants met as a group virtually by Zoom once per week for 8 weeks. Each session lasted between 2-2.5 hours and was

scheduled for the same evening each week. A mindfulness instructor trained in the MSC method led each class and participants were assigned self-compassion practices and reflections to complete at home between classes. Additionally, the instructor led a 4-hour mindfulness retreat on a weekend between weeks 6 and 7, per the standardized curriculum for MSC.

o The same instructor led each course. The instructor was not involved in the study design, data collection, or data analysis.

Intervention Type

Behavioural

Primary outcome(s)

1. Program feasibility measured using monitoring class attendance rates within each course at weekly timepoints throughout the 8 week course

Key secondary outcome(s)

1. Maternal perceived stress measured using the Perceived Stress Scale (PSS) at baseline and follow-up, after course completion

2. Maternal depressive symptoms measured using the Edinburgh Postnatal Depression Scale (EPDS) at baseline and follow-up, after course completion

3. Maternal anxiety measured using the State-Trait Anxiety Inventory (STAI) at baseline and follow-up, after course completion

4. Blood glucose measured using ELISA at baseline and follow-up, after course completion

5. Plasma C-reactive protein measured using ELISA at baseline and follow-up, after course completion

6. Plasma Interleukin-6 measured using electrochemiluminescence at baseline and follow-up, after course completion

Completion date

20/12/2021

Eligibility

Key inclusion criteria

1. >18 years age
2. Currently pregnant with one baby (no twins, triplets, etc.)
3. Between 14-27 weeks pregnant
4. Access to a computer, tablet or laptop with internet access

Healthy volunteers allowed

Yes

Age group

Adult

Lower age limit

18 Years

Upper age limit

50 Years

Sex

Female

Total final enrolment

19

Key exclusion criteria

1. Diagnosed with a major obstetric complication (congenital malformations/ fetal chromosomal abnormalities, placenta abruption, preeclampsia, or severe systemic/local infection)
2. Taking steroid medication
3. Receiving treatment (medication or other therapy) for a psychiatric condition
4. Non-fluent in English
5. Previously completed formal mindfulness training of any type
6. Unwilling/unable to attend the full course sessions over 8 weeks

Date of first enrolment

08/08/2021

Date of final enrolment

15/09/2021

Locations

Countries of recruitment

United States of America

Sponsor information

Organisation

UCI Health Susan Samueli Integrative Health Institute

Funder(s)

Funder type

Funder Name

UCI Susan Samueli Integrative Health Institute

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available