

Effects of an 8-week birth preparation intervention on women's mental well-being

Submission date 03/08/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/03/2023	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/06/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

MyDoula is an 8-week online application. The program contains scientific-based elements for reducing fear of childbirth and depression, psycho-educational elements about pregnancy and birth, mindfulness and coping exercises. At the same time, personal resources and confidence-building exercises are implemented. In Germany, the MyDoula App is a novel approach to pregnancy apps, as it focuses on the mental health of the healthy population to prevent severe fear of childbirth and depression. Furthermore, it takes a systemic therapy approach into account. This study aims to investigate the potential effects of a smartphone app-based self-directed 8-week intervention on the mental well-being of pregnant women.

Who can participate?

Pregnant women between 20.1 and 27.0 weeks pregnant with an android system smartphone

What does the study involve?

The study participants will be randomly divided into two groups (intervention and control groups). The control group will do the pregnancy preparation as usual. The intervention group will get access to an 8-week pregnancy program run via an online application called MyDoula. The program consists of a daily morning mindfulness exercise as well as a daily evening mindfulness meditation. Additionally, the participants run units with psychoeducation and exercises related to certain psychological topics (e.g. stress relief). The daily stress level will be tracked.

Both the intervention and control groups will complete 2 questionnaires. The first of four before the app intervention and the second after the app intervention.

What are the possible benefits and risks of participating?

As a participation fee, the women received 30-50€ after completing the second questionnaire. There were no participating risks expected.

Where is the study run from?

University of Applied Sciences Potsdam (Fachhochschule Potsdam) (Germany)

When is the study starting and how long is it expected to run for?
March 2021 to October 2023

Who is funding this study?
European Regional Development Fund (Europäische Fonds für regionale Entwicklung – Land Brandenburg)

Who is the main contact?
1. Prof Dr Gerlind Große (Project Lead) (Germany)
grosse@fh-potsdam.de

Contact information

Type(s)
Scientific

Contact name
Mrs Carmen Birner

ORCID ID
<https://orcid.org/0000-0002-8605-7280>

Contact details
Kiepenheuerallee 5
Potsdam
Germany
14469
+49 151 12960013
carmen.birner@fh-potsdam.de

Type(s)
Scientific

Contact name
Prof Gerlind Große

ORCID ID
<https://orcid.org/0000-0002-3596-5561>

Contact details
Kiepenheuerallee 5
Potsdam
Germany
14469
+49 331 580 4126
gerlind.grosse@fh-potsdam.de

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Comparing the MyDoula app intervention with standard care for pregnant women regarding mental wellbeing: Randomized controlled trial

Acronym

MyDoula

Study objectives

1. Participants using MyDoula App will show greater reductions in fear of childbirth compared with CG participants
2. Participants using MyDoula App will show greater improvements in depressive scores compared with CG participants
3. Participants using MyDoula will show greater improvements in secondary outcomes (bonding, psychological wellbeing, mindfulness) compared to CG participants

Ethics approval required

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Ethics approval(s)

approved 08/09/2021, University of Potsdam Ethics Review Committee (Ethikkommission Universität Potsdam) (Universität Potsdam, Am Neuen Palais 10, Potsdam, 14469 , Germany; +49 (0)3 31 9 77 17 91; Nadine.Mohaupt@uni-potsdam.de), ref: 40/2021

Study design

Pre/post longitudinal experimental design with group randomization

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Fear of childbirth; mental health in pregnant women

Interventions

The intervention group undergoes an eight-week psychological birth preparation program, which is provided via an online application with the name MyDoula. The program contains daily

morning mindfulness exercises, evening meditations and two units per week, each including psychoeducation and an exercise part (e.g. reflection exercises run via chatbot). The app use was self-guided.

Participants randomized to the control group receive Treatment as Usual (TAU)/no treatment.

Intervention Type

Behavioural

Primary outcome(s)

1. Negative birth expectations measured using the Wijma Delivery Expectations (W-DEQ) questionnaire at baseline and after 8 weeks
2. Support within the relationship measured using the "Relationship Assessment Scale" questionnaire at baseline
3. Depression Scores are measured using the "Edinburgh Depression Scale" questionnaire at baseline and 8 weeks later
4. Support within relationships measured using the "Social support instrument" questionnaire at baseline
5. Mother-Child-Bonding measured using the "Maternal antenatal attachment scale" questionnaire at baseline and 8 weeks later
6. Mental Wellbeing measured using the "Mental Wellbeing Scale" questionnaire at baseline and 8 weeks later
7. Mindfulness measured using the "Frankfurter Fragebogen Achtsamkeit (FFA)" questionnaire at baseline and 8 weeks later
8. Birth mindset measured using the "Mindset and Birth" questionnaire at baseline

Key secondary outcome(s)

1. Dyadic coping mechanisms of participants measured using two items of the dyadic coping inventory (DCI) at baseline
2. Quality of current relationship measured using the relationship assessment scale (RAS) at baseline
3. Social support measured using the social support instrument (ESSI) at baseline
4. Prenatal mother-child bonding measured using the Maternal antenatal attachment scale (MAAS) at baseline and 8 weeks after baseline
5. Mental wellbeing measured using the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline and 8 weeks after baseline
6. Mindfulness measured using the Frankfurter Fragebogen Achtsamkeit (FFA) at baseline and 8 weeks after baseline
7. Birthyear, sex, gender, German spoken and understood as native language, graduation, professional qualification, employment, professional position, management position, salary, number of persons in household, persons under 14 in household, marital status, taking psychotropic drugs (exclusion criteria), having psychotherapy (exclusion criteria), having a psychological diagnosis (exclusion criteria), having biological children, type of previous birth(s), type of previous negative birth experiences, abortion, miscarriage, pregnancy week, single /multiple pregnancy, planned pregnancy, worries about high/size of baby, complications during pregnancy, diseases regarding the unborn child, medical risk during pregnancy, worries/fears, main care person, satisfaction with pregnancy care, planned caesarian section (CS) and reasons, trauma, carrying out mindfulness exercises regularly, regular use of other pregnancy apps, using a birth preparation course, use of health apps, using online/offline offers regarding mental health, using online/offline offers regarding mindfulness measured using a Likert scale questionnaire at baseline

8. Pregnancy week, worries about high/size of the unborn baby, complications during pregnancy, diseases regarding the unborn child, medical risk during pregnancy, worries/fears, and planned CS measured using a Likert scale questionnaire at 8 weeks after baseline
9. A possible stressful event during pregnancy measured using a Likert scale questionnaire at 8 weeks after baseline
10. Stress tracking measured daily using a Likert scale questionnaire from baseline until 8 weeks after baseline

Completion date

31/10/2023

Eligibility

Key inclusion criteria

Pregnant women between the 20.1 and 27.0 week of pregnancy

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Aged 17 years old and younger
2. German is not at a native language level
3. Taking psychotropic drugs, having a psychological diagnosis or being counselled by a psychologist, psychotherapist or psychiatrist at the time of the study
4. Pregnant women that give birth before finalizing the 8 weeks-MyDoula-App-Program (e.g. due to premature birth)
5. When people didn't agree to be informed about incidental findings, e.g. high scores in the Edinburgh Postnatal Depression Scale (EPDS) screening

Date of first enrolment

08/09/2021

Date of final enrolment

15/10/2022

Locations

Countries of recruitment

Austria

Germany

Switzerland

Study participating centre
Fachhochschule Potsdam
Kiepenheuerallee 5
Potsdam
Germany
14469

Sponsor information

Organisation
Fachhochschule Potsdam

ROR
<https://ror.org/0191jdv19>

Funder(s)

Funder type
Government

Funder Name
European Regional Development Fund

Alternative Name(s)
Fondo Europeo de Desarrollo Regional, Europäischer Fonds für regionale Entwicklung, Европейски фонд за регионално развитие, Evropský fond pro regionální rozvoj, Fundo Europeu de Desenvolvimento Regional, ERDF, FEDER, EFRE, EФPP, EFRR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to these datasets comprising sensitive health data

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes