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

Submission date
03/08/2022

Recruitment status
No longer recruiting

Registration date
08/03/2023

Overall study status
Completed

Last Edited
24/06/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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)
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Study website
https://www.fh-potsdam.de/studium-weiterbildung/projekte/babyhelfer

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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
Ethics approval required

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

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
02/03/2021

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

Age group
Adult

Sex
Female

Target number of participants
170 total expected. Two groups. 85 per group.

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
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Funder(s)

Funder type
Government

Funder Name
European Regional Development Fund

Alternative Name(s)
Europski Fond za Regionalni Razvoj, Den Europæiske Fond for Regionaludvikling, Europees Fonds voor Regionale Ontwikkeling, Euroopa Regionaalarengu Fond, Fonds Européen de Développement Régional, Europäischer Fonds für regionale Entwicklung, Európai Regionális Fejlesztési Alap, Fondo Europeo di Sviluppo Regionale, Eiropas Reģionālās attīstības fonds, Europos Regionines Pletros Fondas, Europejski Fundusz Rozwoju Regionalnego, Fundo Europeu de Desenvolvimento Regional, Fondul European de Dezvoltare Regională, Európsky Fond Regionálneho Rozvoja, Fondo Europeo de Desarrollo Regional, Европейски фонд за регионално развитие, Evropský fond pro regionální rozvoj, Ευρωπαϊκό Ταμείο Περιφερειακής Ανάπτυξης, Il-Fond Ewropew għall-Iżvilupp Reġjonali, Evropski sklad za regionalni razvoj, Euroopan aluekehitysrahasto, Europeiska regionala utvecklingsfonden, ERDF, FEDER, EFRE, ΕΦΠΑ, EFRR, EFRU, ERFi, ETPA, FEDER, FESR, ERAF, ERPF, ERFA, L-FEŻR, EFRO, EFRR, FEDR, ESRR, EAKR, Eruf

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2024

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