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Feasibility and scalability of a digital mhealth training for personalized mental health promotion (Feel.Well)

Submission date
15/01/2025

Recruitment status
No longer recruiting

Registration date
11/02/2025

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Mental and Behavioural Disorders

[ ] 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
Mental health apps are becoming more common, but many do not clearly show how they work, what evidence they are based on, or how they keep personal data safe. The Feel.Well project explores a new mobile training program to help people regulate emotions, improve well-being, and build resilience in their daily lives. The Feel.Well training runs on a smartphone app and was developed at the Central Institute of Mental Health (ZI) in Mannheim, Germany. The study aims to find out: 1. How practical the program is (e.g., do people use it regularly, and is it easy to navigate?); 2. How it can be made widely available, including how much support participants might need from mental health coaches and how often they should be asked about their mood in daily life; and, 3. Whether it might help people feel better emotionally and improve their wellbeing.

Who can participate?
Adults aged 18 to 65 who are already enrolled in the DigiHero Study, an online cohort in Germany. Participants need to have a smartphone running iOS (version 15 or higher) or Android (version 8 or higher), which will be used for daily check-ins and short exercises offered in daily life.

What does the study involve?
• Randomization: Once participants give their consent, they are randomly placed in either an experimental group (which uses the Feel.Well training) or a control group (which does not).
• Feel.Well training: Those in the experimental group download the Feel.Well training app, answer questions about their mood and day-to-day experiences, and receive personalized feedback and short exercises for at least 40 days (up to 60 days if they choose). These exercises include breathing techniques, positive imagery and other types of tasks to help manage stress in daily life.
• Questionnaires: All participants, regardless of their group, fill out brief online questionnaires about eight to twelve weeks later to compare changes in well-being over time.
• Optional final interview: Some participants in the experimental group may have a short video call at the end of the training to discuss any questions or feedback.

What are the possible benefits and risks of participating?
• Benefits: Participants can try a new app designed to support well-being and emotional resilience. This experience may help to better understand and manage mood and thoughts. By taking part, participants also help researchers learn how to improve digital mental health tools for the wider public.
• Risks: There are no known harmful effects from this kind of digital training. It does require some time and effort, such as completing questionnaires and app-based exercises.

Where is the study run from?
The study is coordinated by the Central Institute of Mental Health (ZI) in Mannheim, Germany, in collaboration with University Medicine Halle (Saale) and Jena University Hospital. It is part of the DigiHero Study, which is conducted by the Medical Faculty at Martin-Luther-University Halle-Wittenberg.

When is the study starting and how long is it expected to run for?
April 2024 to November 2025. Recruitment started in November 2024, and the study will run until approximately November 2025.

Who is funding the study?
The project is funded by internal resources from the Central Institute of Mental Health in Mannheim.

Who is the main contact?
Dr. Christain Rauschenberg, christian.rauschenberg@zi-mannheim.de

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Feasibility and scalability of a digital ecological momentary mhealth intervention for mental health promotion: a population-based, two-arm, parallel-group, randomized controlled trial within cohorts (TwiC)

Acronym
Feel.Well

Study objectives
The current feasibility trial aims to:
1. Examine the feasibility of the trial methodology (based on successful recruitment, randomization, and retention of participants from the DigiHero cohort).
2. Examine the feasibility of delivering the Feel.Well training (based on participant satisfaction, usability, and adherence to intervention protocol).
3. Evaluate the feasibility of scalability (based on response rate and active engagement).
4. Explore signals of efficacy of the Feel.Well training on candidate outcomes, i.e., well-being, depression, anxiety, quality of life. Outcomes will be measured at post-training and 4-week follow-up as well as the the subsequent assessment wave of the digital cohort (4-8 months after randomisation).

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/07/2024, Ethics Committee of the Medical Faculty at Martin-Luther-University Halle-Wittenberg (Magdeburger Str. 12, Halle (Saale), 06112, Germany; +49 345 557-4476; ethik-kommission@uk-halle.de), ref: 2020-076

Study design
Population-based two-arm parallel-group randomized controlled trial within cohorts with a nested 2x3 factorial design within the experimental condition

Primary study design
Interventional

Study type(s)
Other, Quality of life

Health condition(s) or problem(s) studied
Promoting mental health among individuals from the general population enrolled in a digital cohort.

Interventions

In a 2-arm, parallel-group, randomised controlled Trial within Cohorts (TWiC), registered individuals from an online cohort (DigiHero Study; https://webszh.uk-halle.de/digihero/en/digi-hero-study/) will be randomly assigned to either the experimental condition, which includes the Feel.Well training in addition to Care-As-Usual (CAU), or to the control condition, which comprises CAU only.

Participants in the experimental condition will undergo further randomization using a 2×3 factorial design to evaluate the effects of contact intensity and the frequency of Ecological Momentary Assessments (EMA) during the training period on feasibility outcomes.

The first factor, contact intensity, includes three levels: (1) no additional contact, (2) a single 60-minute face-to-face online session, and (3) an enhanced contact condition that involves one 60-minute face-to-face online session, a 30-minute booster session, and a check-in call with trained mental health coaches. The second factor, EMA frequency, consists of three levels: (1) three EMAs per day (low frequency), (2) six EMAs per day (medium frequency), and (3) a flexible number of EMAs and days per week based on participant preference.

The Feel.Well training is delivered through a smartphone-based Ecological Momentary Intervention (EMI) over 40 days, with an optional extension of 20 days. The EMI aims to facilitate the real-time and real-world transfer of therapeutic content, principles, and techniques into participants' daily lives.
The Feel.Well training is grounded in the principles of Compassion Focused Therapy (CFT), Acceptance and Commitment Therapy (ACT), and Cognitive Behavioral Therapy (CBT). Key components include breathing exercises, positive imagery, diaries of joyful moments and successes, and self-monitoring through EMA data. Additionally, the intervention provides personalized feedback based on participants’ EMA responses.

The EMI consists of three different task delivery schemes and monitoring:
- Enhancing tasks: In the course of the training phase, participants are successively introduced to new tasks based on CFT, ACT, and CBT during the first 10 days.
- Consolidating tasks: Tasks that are already known to the participant (i.e., have been practised as enhancing tasks) will be offered as consolidating tasks, encouraging practice. The available consolidating tasks are continuously extended during the first 10 days.
- Interactive/adaptive tasks: Participants’ responses to short, daily EMA questionnaires on momentary affect and context variables provide the basis for delivering interactive tasks tailored to the person, moment, and context, e.g., when participants score high on momentary negative affect (i.e. moving average + 0.5 standard deviation).
- Self-monitoring: The app offers participants the ability to monitor their mental health and well-being weekly in terms of events, completed training components, activities, and well-being and their associations via a dashboard function.

Randomization was implemented using R (version 4.4.1). Participants were stratified by age (18–35 vs. 36–65), gender (male/female), and education (low/middle vs. high). The block randomization step was performed using the block.random function from the R library "psych" (version 2.4.3), with a block size of 10 to ensure equal distribution between the experimental and control groups. Within the experimental group, participants were further randomized into nine conditions based on a 3x3 factorial design, defined by contact intensity (no contact with explanatory videos; training session; or training session, booster session, and 1–2 check-in calls) and EMA frequency (three times daily, six times daily, or a flexible participant-chosen schedule).

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment measured using the weekly recruitment rate in the week of the highest recruitment rate
2. Randomization measured using the number of participants successfully randomized after informed consent
3. Retention measured using the percentage of retained participants at post-intervention and 4-week follow-up
4. Satisfaction and usability measured using subscales of the mHealth App Usability Questionnaire (MAUQ) at post-intervention
5. Participant adherence measured using the number of attended sessions and the number of completed EMA as well as EMI tasks during the intervention
6. Mental well-being measured using the Warwick–Edinburgh Mental Well-being Scale (WEMWBS) at baseline, post-intervention, 4-week follow-up, and a subsequent wave of the online cohort
7. Depression and anxiety measured using the Patient Health Questionnaire-4 (PHQ-4) at baseline, post-intervention, 4-week follow-up, and a subsequent wave of the online cohort
8. Health-related quality of life measured using one item of the EQ-5D-5L (EuroQol Group) at baseline, postintervention, and 4-week follow-up
9. Psychological distress measured using one item of the psyBel/FGBU measure at baseline, post-intervention, 4-week follow-up, and subsequent wave of the online cohort

Key secondary outcome(s))
There are no secondary outcome measures.

Completion date
30/11/2025

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years
2. Scores of <=54 on the Warwick–Edinburgh Mental Well-being Scale (WEMWBS).
3. Have access to a smartphone running iOS (version 15 or higher) or Android (version 8 or higher) that will be continuously available for the duration of the study.

Participant type(s)
Population

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Not able to give informed consent
2. Insufficient language abilities in the available languages: German

Date of first enrolment
05/11/2024

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
Germany

Study participating centre
Central Institute of Mental Health
J5
Mannheim
Germany
68159

Sponsor information

Organisation
Central Institute of Mental Health

ROR
https://ror.org/01hynnt93

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Central Institute of Mental Health

Results and Publications

Individual participant data (IPD) sharing plan

The data set will be available upon reasonable request (christian.rauschenberg@zi-mannheim.de), given permission by ethics approval and study publication strategy.

IPD sharing plan summary

Available on request

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes