

A feasibility study of a smartphone app to support mental well-being in people with Long COVID

Submission date 13/05/2026	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 17/06/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 09/07/2026	Condition category Mental and Behavioural Disorders	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Individuals with Long COVID frequently experience poor mental health outcomes, including elevated levels of depression and anxiety as well as reduced quality of life. Given the often persistent and fluctuating nature of symptoms, accessible and scalable forms of support are needed. Smartphone apps present a promising avenue to reach and support affected individuals in their daily lives. Building on our prior work in a diverse range of populations, a new app-based ecological momentary intervention (EMI) was developed to promote mental health in people with Long COVID by helping to regulate emotions and building resilience in their daily lives. The intervention, which is delivered via smartphone, was developed at the Central Institute of Mental Health in Mannheim, Germany. The aim of this study is to establish the feasibility of conducting a Trial within Cohort and delivering this new smartphone app as well as to examine initial outcome signals in individuals with Long COVID.

Who can participate?

Participants will be recruited from the Long COVID registry embedded within the DigiHero Study, a digital cohort study in Germany. Adults aged 18 years or older were assigned to the Long COVID registry if they reported symptoms related to a SARS-CoV-2 infection that persisted for at least 12 weeks, such as fatigue, rapid exhaustion, shortness of breath, concentration difficulties, memory problems or sleep difficulties. In follow-up assessments, participants are asked whether symptoms related to their infections are still ongoing. Participants are no longer invited to further follow-ups once they report that symptoms have resolved. Participants need to have a smartphone running iOS or Android, which will be used to deliver the intervention.

What does the study involve?

Participants who provide informed consent and are identified as eligible in the DigiHero cohort are randomly assigned to either an experimental group (to receive the app in addition to care as usual) or a control group (which does not receive the app but continues to receive care as usual) with equal probability.

Individuals in the experimental condition download the app, complete measures to assess mood

using Ecological Momentary Assessment (EMA), and receive EMI components (personalised feedback and brief momentary psychological interventions) for 40 days. These EMI components are derived from our previous EMIs, cognitive behavioral therapy (CBT) and acceptance and commitment therapy (ACT), including breathing techniques, positive imagery and diary entries to help regulate emotions in daily life.

Outcome: All participants complete outcome assessments using self-report measures, at baseline (prior to randomization), at post-intervention (9 weeks after randomization '9-week post-baseline'), and a follow-up (13-week post-randomization) to assess retention over time, data completeness, satisfaction and usability regarding app use as well as mental well-being, psychological distress, and fatigue (as putative efficacy signals).

What are the possible benefits and risks of participating?

Participants can use a new app designed to support mental well-being. By participating, individuals help generate knowledge on how this training can be effectively used to support individuals living with Long COVID.

This type of digital training is not associated with known harmful effects and the risk of adverse effects or discomfort is considered minimal. While participation requires some time and effort, such as completing questionnaires and app-based exercises, the overall burden is considered low. Smartphone applications for monitoring mood and mental health have been used in research for approximately 20 years and have been shown to be feasible across diverse user groups without evidence of symptom worsening.

Where is the study run from?

The study is coordinated by the Central Institute of Mental Health (ZI) in Mannheim, in collaboration with Charite Berlin and Jena University Hospital (Germany)

When is the study starting and how long is it expected to run for?

June 2026 to August 2026

Who is funding the study?

The project is funded by the German Federal Ministry of Health

Who is the main contact?

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Study information

Scientific Title

Feasibility of trial methodology, intervention delivery, and initial outcome signals of an app-based ecological momentary intervention to promote mental well-being: a feasibility Trial within Cohort study in individuals with Long COVID

Acronym

REMIT

Study objectives

The current feasibility trial aims to:

1. Examine the feasibility of the trial methodology (based on successful recruitment, randomization, retention and data completeness of participants from the DigiHero cohort).
2. Examine the feasibility of delivering the smartphone app (based on participant satisfaction, usability, and adherence to intervention protocol).
3. Evaluate the feasibility of scalability (based on active engagement).
4. Explore signals of efficacy of the EMI on candidate outcomes, i.e., mental well-being, psychological distress and fatigue at post-intervention and follow-up.

Ethics approval required

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Ethics approval(s)

Approved 16/09/2025, Ethics Committee of the Medical Faculty at Friedrich-Schiller University Jena (Bachstraße 18, Jena, 07740, Germany; +49 (0)3641 9391195; ethikkommission@med.uni-jena.de), ref: 2025-3852_1-BO-A

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Mental health promotion in individuals with Long COVID enrolled in a digital cohort

Interventions

Current interventions as of 03/07/2026:

In a two-arm, parallel-group, randomised controlled Trial within Cohort study (TwIC), registered individuals from a digital cohort (DigiHero Study; <https://webszh.uk-halle.de/digihero/en/digi-hero-study/>) with Long COVID identified as eligible in this cohort will be randomly assigned to either the experimental condition, which receives the EMI in addition to Care-As-Usual (CAU), or to the control condition, which comprises CAU only. Participants identified as eligible in the DigiHero cohort will be randomly assigned (1:1) to the experimental or control condition at the

participant level. Block randomization in blocks of 6 will be performed by an independent researcher using a computer-generated sequence.

The training is delivered through a smartphone-based EMI over 40 days. The EMI aims to facilitate the real-time and real-world transfer of intervention content, principles, and techniques into participants' daily lives. The training is grounded in the principles of Cognitive Behavioral Therapy (CBT) and Acceptance and Commitment Therapy (ACT). Key components include breathing exercises, positive imagery, diary entries of joyful moments and gratitude, and self-monitoring through EMA data as well as physiological data tracked by wearables or smartwatches. In addition, the intervention provides personalized feedback and EMI components tailored to person, moment and context based on participants' EMA responses.

The EMI consists of three different EMI delivery schemes and monitoring:

- Enhancing delivery scheme: In the course of the training phase, participants are successively introduced to new EMI components based on CBT and ACT during the first 14 days.
- Consolidating delivery scheme: EMI components that are already known to the participant (i.e., have been practised as enhancing EMI components) will be offered as consolidating EMI components, encouraging practice.
- Adaptive delivery scheme: Participants' responses to short EMA questionnaires on momentary affect provide the basis for delivering adaptive EMI components tailored to person, moment, and context, e.g., when participants score significantly higher or lower on a momentary negative or positive affect item (i.e., moving average + 0.5 standard deviation)
- Self-monitoring: The app offers participants the ability to monitor their mental health, well-being and physiological data, such as steps, hours slept etc., weekly in terms of events, completed training components, activities, and well-being via a datacenter function.

Previous interventions:

In a two-arm, parallel-group, randomised controlled Trial within Cohort study (TwIC), registered individuals from a digital cohort (DigiHero Study; <https://webszh.uk-halle.de/digihero/en/digihero-study/>) with PAIS identified as eligible in this cohort will be randomly assigned to either the experimental condition, which receives the EMI in addition to Care-As-Usual (CAU), or to the control condition, which comprises CAU only. Participants identified as eligible in the DigiHero cohort will be randomly assigned (1:1) to the experimental or control condition at the participant level. Block randomization in blocks of 6 will be performed by an independent researcher using a computer-generated sequence.

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Intervention Type

Behavioural

Primary outcome(s)

1. Recruitment measured using the weekly recruitment rate at the week of the highest recruitment

2. Randomization measured using the number of participants successfully randomized at baseline after informed consent

3. Satisfaction and usability measured using subscales of the mHealth App Usability Questionnaire (MAUQ) at post-intervention

4. Participant adherence measured using the number of completed EMA as well as EMI tasks at intervention as well as whether participants learned three core exercises within 14 days

5. Retention measured using the percentage of retained participants at post-intervention and follow-up

6. Mental well-being measured using the Warwick–Edinburgh Mental Well-being Scale (WEMWBS) at baseline, post-intervention, and follow-up

Key secondary outcome(s)

Completion date

31/08/2026

Eligibility

Key inclusion criteria

Current key inclusion criteria as of 03/07/2026:

1. At least 18 years or older
2. Access to a smartphone running on iOS or Android, which will be continuously available for the duration of the study.
3. Registered in the DigiHero Cohort
4. Presence of Long COVID

Previous key inclusion criteria:

1. At least 18 years or older
2. Access to a smartphone running on iOS or Android, which will be continuously available for the duration of the study.
3. Registered in the DigiHero Cohort
4. Presence of post-acute infection syndrome (PAIS)

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

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

Date of first enrolment

01/08/2026

Date of final enrolment

31/08/2026

Locations**Countries of recruitment**

Germany

Sponsor information**Organisation**

Central Institute of Mental Health

ROR

<https://ror.org/01hynnt93>

Funder(s)

Funder type

Funder Name

Bundesministerium für Gesundheit

Alternative Name(s)

Federal Ministry of Health, Germany, Federal Ministry of Health, BMG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available