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Effectiveness and public health impact of SELFIE, a blended ecological momentary intervention for improving self-esteem in young people

Submission date
03/12/2025

Recruitment status
Recruiting

Registration date
10/12/2025

Overall study status
Ongoing

Last Edited
09/12/2025

Condition category
Mental and Behavioural Disorders

[X] 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
This study is about helping young people who have faced difficult experiences in childhood and now struggle with low self-esteem and mental health. The aim is to see if a program called SELFIE can boost self-esteem and improve mental well-being over time.

Who can participate?
Young people aged 14 to 25 who have a history of childhood adversity, are currently feeling distressed, and report low self-esteem can take part. Participants will be recruited from Germany, the UK, the Netherlands, Italy, Spain, and Estonia.

What does the study involve?
Participants will fill in questionnaires and keep a digital mood diary at four points over 12 months. Some participants will be randomly chosen to try the SELFIE training, which lasts six weeks. This includes activities on an app and three sessions with a mental health professional. Others will continue with their usual care. Random selection helps make sure results are fair.

What are the possible benefits and risks of participating?
Taking part may help improve mental health, self-esteem, and overall well-being. There are no known health risks linked to the study.

Where is the study run from?
The study is sponsored by the Central Institute of Mental Health in Germany.

When is the study starting and how long is it expected to run for?
Recruitment starts in January 2026 and ends in July 2027.

Who is funding the study?
The study is funded by the Central Institute of Mental Health in Germany.

Who is the main contact?
If you have questions, please contact Anita Schick at anita.schick@zi-mannheim.de.

Contact information

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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
364308

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2025-01-SELFIE

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101156514

Study information

Scientific Title
Effectiveness and public health impact of SELFIE, a transdiagnostic, blended ecological momentary intervention for improving self-esteem in young people exposed to childhood adversity: a hybrid effectiveness-implementation study in 6 European countries

Acronym
European SELFIE trial

Study objectives
The overarching aim of the hybrid effectiveness-implementation study is to assess the 1) effectiveness and 2) public health impact of SELFIE, a transdiagnostic, blended ecological momentary intervention for improving self-esteem, in young people exposed to childhood adversity in a hybrid effectiveness-implementation study in 6 European countries (Estonia, Germany, Italy, the Netherlands, Spain, and UK) and 7 clinical investigation sites.

The trial has two objectives:
1. Translate, adapt and implement SELFIE in a participatory implementation study with stakeholder groups, namely clinicians and young people, in line with prevailing ethical and regulatory requirements in 6 European countries.
2. Examine a) Reach (i.e., user participation, feasibility, acceptability), b) clinical Effectiveness (defined as the interaction of efficacy × implementation in real-world care settings), c) Adoption (proportion of users and clinicians having used SELFIE in routine care settings), d) Implementation (defined as delivery of SELFIE as intended in routine care) and e) Maintenance (defined as intended continuation of intervention usage) in a multi-country RCT, which, consistent with the RE-AIM framework, will provide the basis for establishing the public health impact and sustainability of implementation of SELFIE.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 27/11/2025, Ethics committee II of Heidelberg University (Theodor-Kutzer-Ufer 1-3, Mannheim, 68167, Germany; +49 621 383-71773; ethikkommission-II@medma.uni-heidelberg.de), ref: 2025-430 MF

Study design
Parallel-group assessor- and analyst-blind multi-country interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Mental health problems

Interventions
SELFIE intervention

In this hybrid effectiveness-implementation study, a parallel-group, assessor- and analyst-blind, multi-country RCT will be conducted, in which participants will be randomly allocated using a 1:1 ratio to one of two conditions: (a) the experimental condition, in which participants receive SELFIE in addition to Care-As-Usual (CAU) or (b) the control condition, in which participants are provided with CAU, with a nested process evaluation and an economic evaluation. Participants allocated to the experimental condition will have access to the SELFIE intervention, i.e. a guided self-help intervention and a medical device according to EU MDR 2017/745 consisting of three face-to-face sessions (on-site or online), delivered by trained mental health professionals, three e-mail contacts, and an Ecological Momentary Intervention (EMI) administered through a smartphone-based app for adaptive real-time and real-world transfer of the intervention components to daily life over a course of 6 weeks.

We will assess outcomes at 4 points in time: at baseline, at 3-month follow-up, 6-month follow-up and 12-month follow-up. Thus, the duration of study participation for individual participants is 12 months.

Randomization will be conducted using a concealed sequence generated by the trial statistician with stratification for study site and gender. The allocation list will be implemented in the electronic case report form.

Intervention Type
Behavioural

Primary outcome(s)
General psychopathology at 6-month follow-up assessed by the revised Symptom Checklist (SCL-90-R; Derogatis (1977)). A total score will be calculated.

Key secondary outcome(s))

The following secondary outcomes will be assessed based on self-rated measures (to establish Effectiveness) at 3-month (t1), 6-month (t2), and 12-month follow-up (t3):
1. Well-being assessed with the Mylife tracker (Kwan et al., 2018) and the WEMWEBS (Tennant et al., 2007)
2. Self-esteem assessed with the Rosenberg Self-Esteem Scale (RSES; Schmitt and Allik, 2005) and the Self-Esteem Rating Scale (SERS; Lecomte et al., 2006)
3. Resilience assessed by the CD-RISC (Connor and Davidson, 2003)
4. Social functioning assessed with the WSAS (Jassi et al., 2020)
5. Quality of life assessed with the WHOQOL-BREF (Kwan and Rickwood, 2015; WHOQOL Group, 1998)
6. Psychological distress assessed with CORE-10 (Barkham et al., 2013)
7. Depression assessed by PHQ-9 (Kroenke et al., 2001)
8. Anxiety assessed using the GAD-7 (Spitzer et al., 2006)
9. Service attachment measured with the Service Attachment Questionnaire (SAQ; Goodwin et al., 2003)
10. User-led and co-created outcome measures developed by young people

Secondary outcomes to assess Reach, Adoption, Implementation, and Maintenance:
11. Reach assessed by the number of individuals consenting to, participating in, and dropping out during the intervention period at 3-month follow-up
12. Adoption assessed using a checklist for usage of key components of the SELFIE intervention at 3-month follow-up
13. Implementation assessed by the extent to which SELFIE components are delivered as intended, using a checklist at 3-month follow-up
14. Maintenance assessed by the intended continuation of using the EMI components of SELFIE at 6-month and 12-month follow-up

Completion date
31/07/2028

Eligibility

Key inclusion criteria
1. Aged 14-25 years
2. Presence of clinically meaningful psychological distress opera-tionalized as a score of >10 on the CORE-10 or a GSI score > 0.52 on the SCL-90-R
3. Exposure to childhood adversity, broadly defined (physical, sex-ual or emotional abuse, emotional or physical neglect, peer bullying or parental conflict operationalized (Reininghaus et al. 2024))
4. Self-esteem below average measured with the Rosenberg Self-Esteem Scale (RSES; (Schmitt and Allik 2005))
5. Willingness to participate
6. Ability to give informed consent, and for minors: parental consent

Participant type(s)
Patient, Service user

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
14 years

Upper age limit
25 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Insufficient command of the principal country language: English, Estonian, German, Italian, Spanish or Dutch,
2. Mental health symptoms are due to an organic cause,
3. Meeting criteria for a clinical diagnosis of intellectual disability (ICD-10 F70-F79) or with a disorder of psychological development (ICD-10 F80-89) that are sufficiently severe to impair a person's ability to provide informed consent
4. Inability to use a smartphone
5. Individuals with acute risk to themselves or others.

Date of first enrolment
01/01/2026

Date of final enrolment
31/07/2027

Locations

Countries of recruitment
United Kingdom

England

Estonia

Germany

Italy

Netherlands

Spain

Study participating centre

Birmingham and Solihull Mental Health NHS Foundation Trust
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Study participating centre
Central Institute of Mental Health
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Study participating centre
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MHeNS / FHML
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Netherlands
6226

Study participating centre
Amsterdam UMC
DE BOELELAAN 1117
Amsterdam
Netherlands
1081

Study participating centre
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IRCCS Centro San Giovanni di Dio Fatebenefratelli
Via Pilastroni 4
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Study participating centre
Hospital General Universitario Gregorio Marañón
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Study participating centre
Mittetulundusuhing Peaasjad
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Sponsor information

Organisation
Central Institute of Mental Health

Funder(s)

Funder type
Not defined

Funder Name
European Union

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request