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SMILE: Supporting mental health in young people: integrated methodology for clinical decisions and evidence-based interventions

Submission date
25/04/2025

Recruitment status
Recruiting

Registration date
29/04/2025

Overall study status
Ongoing

Last Edited
29/04/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Adolescence is a time when many young people experience mental health challenges. They might turn to social media for support, but this can sometimes make things worse. The SMILE project aims to help young people build resilience by using a gamified platform with digital cognitive behavioural interventions.

Who can participate?
Young people aged 10-24 years old are invited to participate in the study.

What does the study involve?
Participants will use the SMILE tools for 6 weeks. They will play a serious game and answer questions about their mood and wellbeing. Some participants will receive feedback based on their game performance and wellbeing metrics.

What are the possible benefits and risks of participating?
Participants might benefit from improved mental health and resilience. However, there is a risk that some might not find the interventions helpful or could feel uncomfortable with the feedback.

Where is the study run from?
The study will be conducted in seven countries: Cyprus, Germany, Italy, Poland, Slovenia, Spain, and the UK.

When is the study starting and how long is it expected to run for?
February 2025 to July 2026

Who is funding the study?
The study is funded by the European Union’s Horizon Europe research and innovation programme.

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
24-25CLPS015

Study information

Scientific Title
SMILE: Supporting Mental Health in Young People: Integrated Methodology for cLinical dEcisions and evidence-based interventions

Acronym
SMILE Trial

Study objectives
Primary hypothesis: It is hypothesized that, compared with the control period, anxiety and depression scores (primary outcomes) will be lower in the experimental conditions (i.e., with and without feedback) post-test.
Secondary hypotheses 1: It is hypothesized that, compared with the control period, the secondary outcomes (well-being, resilience, emotion regulation and self-efficacy) will be higher and social anxiety lower in the experimental conditions (i.e., with and without feedback) post-test.

Secondary hypothesis 2: It is hypothesized that feedback will be positively associated with the feasibility, acceptability, and preliminary effectiveness of the SMILE tools.
To meet objective 2, we will test the following hypotheses:
Secondary hypothesis 3: Compared with the control period and the experimental condition without feedback, well-being and resilience will be higher in the experimental condition with feedback post-test.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/02/2025, The University of Edinburgh, School of Health in Social Science, Research Ethics Committee (Medical School, Teviot Place, Edinburgh, EH8 9AG, United Kingdom; +44 1316513954; ethics.hiss@ed.ac.uk), ref: 24-25CLPS015

Study design
Cluster randomized multi-site multi-arm adaptive trial design

Primary study design
Interventional

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Depression and anxiety in children and young people

Interventions
During the SMILE study, participants will be asked to participate in a digital psychosocial intervention in the form of a serious game app and a companion app. Participants will be invited to play a serious game, designed to increase skills like cognitive flexibility, self-efficacy, critical thinking, self-regulation, and self-confidence, and by this prevent symptoms of depression and anxiety. The game will consist of a range of scenarios, divided into five modules, with goal-oriented and story-driven game activities. Throughout the 6 weeks of their participation, young people will also be asked to participate in a companion app. The companion app contains self-report measures, Experience Sampling Methodology (ESM) and invitations to record weekly brief video diary entries.

In clusters allocated to the feedback condition, participants will receive visualisations generated based on these measures and their in-game behaviours. Through interacting with this feedback, they will be invited to reflect on their data. Participants in clusters allocated to the no feedback condition will be asked to participate in the game and companion app, but they will not receive graphical feedback based on their input.

Randomisation will be conducted in blocks (using block randomisation) at the consortium level using REDCap software by a statistician who is not involved in the study. A total of 24 clusters (8 clusters per sequence) will be randomised into two conditions, feedback and no feedback; these will be allocated pragmatically between sites and adjusted in size and distribution if indicated by the interim analyses. There is no randomisation at the individual level. Clusters will be blinded as to which of the two interventions they will receive, i.e., with or without feedback.

Intervention Type
Behavioural

Primary outcome(s)
1. Depression is measured using the Patient Health Questionnaire for Adolescents (PHQ-A) at Weeks 2, 4 and 6
2. Depression is measured using the Patient Health Questionnaire (PHQ-9) at 2, 4 and 6
3. Anxiety is measured using the Penn-State Worry Questionnaire for Children (PSWQ-C) at Weeks 1, 3 and 5
4. Anxiety is measured using the Generalized Anxiety Disorder Scale (GAD-7) at Weeks 1, 3 and 5

Key secondary outcome(s))
1. Well-being is measured using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) at Weeks 1, 3 and 5
2. Resilience is measured using the Child and Youth Resilience Measure (CYRM-12) at Weeks 1, 3 and 5
3. Resilience is measured using the Brief Resilience Scale (BRS) at Weeks 1, 3 and 5
4. Privacy concerns are measured using an adapted online privacy concerns questionnaire at Week 1
5. Emotion regulation is measured using tailored Experience Sampling Methodology (ESM) items, 4 times a day at Weeks 1-6
6. Self-efficacy is measured using tailored ESM items, 4 times a day at Weeks 1-6
8. Social anxiety is measured using tailored ESM items, 4 times a day at Weeks 5 and 6
9. Usage of the SMILE apps is measured using the Unified Theory of Acceptance and Use of Technology Scale (UTAUT2) Post-test
10. User experience of the SMILE apps is measured using the User Experience Questionnaire short version (UEQ_S) Post-test

Completion date
31/07/2026

Eligibility

Key inclusion criteria
1. Adolescents and young adults aged 10-24 years
2. Participants under 16 require consent from a parent or guardian, as well as their own agreement to participate. Informed Consent Forms and their digital equivalents will be tailored to be age-appropriate, ensuring both guardians and participants can make informed decisions. If either the parent or the participant does not agree, the participant will not be included in the study
3. Must complete measures of primary outcome
4. Must have normal or corrected to normal vision

Participant type(s)
Healthy volunteer, Learner/student

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
10 years

Upper age limit
24 years

Sex
All

Key exclusion criteria
1. Unable to consent to participation
2. Have a current confirmed diagnosis or treatment episode for:
2.1. severe mental disorder (schizophrenia, bipolar disorder, severe depression),
2.2. substance use disorder,
2.3. epileptic disorders,
2.4. gaming addiction

Date of first enrolment
01/05/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
United Kingdom

Scotland

Germany

Italy

Poland

Slovakia

Spain

Study participating centre
Universitaet Heidelberg
Heidelberg University Hospital
Im Neuenheimer Feld 130.3 (room 06.322)
69120 Heidelberg

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Germany
69120

Study participating centre
University of Maribor
Fakulteta za elektrotehniko, računalništvo in informatiko
Faculty of Electrical Engineering and Computer Science
Koroška cesta 46, 2000 Maribor, Slovenija
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The University of Edinburgh
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Study participating centre
SWPS University
Institute of Psychology
Chodakowska 19/31, 03-815 Warsaw
Warsaw
Poland
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Study participating centre
IRCCS-AOUBO Policlinico Sant'Orsola
Geriatric Unit and Center for Cognitive Disorders
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Study participating centre
Clínica de Memoria de Valladolid
Martín Santos Romero 1
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Sponsor information

Organisation
University of Edinburgh

ROR
https://ror.org/01nrxwf90

Funder(s)

Funder type
Government

Funder Name
HORIZON EUROPE European Research Council

Alternative Name(s)
European Research Council, Horizon Europe - European Research Council, EU - Horizon Europe - ERC, European Research Council (ERC), Conseil européen de la recherche, Consejo Europeo de Investigación, Det Europæiske Forskningsråd, Europäischer Forschungsrat, ERC, CER, CEI, EFR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The data collected in the study will be anonymised and then used to develop a decision support system (DSS) for researchers in order to carry out an exploratory analysis to 1) recognize and map key factors associated with mood changes, 2) develop transparent algorithms to visualize patterns in mood-change prediction, and 3) support end-user self-monitoring and self-assessment in serious-games. The DSS will be developed within a GDPR compliant software environment.
Participants' personal information will be used to create synthetic data – artificial information

that statistically resembles real data without containing any actual personal details. This process helps the research team develop and test systems while completely protecting individuals' privacy. The synthetic data maintains the patterns and relationships found in the original information but cannot be traced back to any specific person. This approach allows researchers to gain valuable insights while ensuring the highest standards of confidentiality and data protection. Additionally, this methodology helps decrease bias in the resulting algorithms, creating more equitable systems that better represent and serve all populations. Since the information is completely anonymous, this data can be shared among different researchers, even outside the SMILE consortium, without exposing the participants, the owners of the original data, to any risks of re-identification or identification exposure.
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. With participants' consent, anonymised data used in the final analysis will be uploaded to an open science repository after the study in completed in October 2026. The repository name/weblink to this curated dataset are currently unknown and will be made available at a later date.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.5	18/04/2025	29/04/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes