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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
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?
Matthias Schwannauer, m.schwannauer@ed.ac.uk

Study website
https://www.horizonsmile.eu

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 hypothesis
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

Secondary study design
Cluster randomised trial

Study setting(s)
Community, School

Study type(s)
Treatment, Efficacy

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

Condition
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 measure
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

Secondary outcome measures
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

Overall study start date
01/02/2025

Overall study end date
31/07/2026

Eligibility

Participant 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

Age group
Mixed

Lower age limit
10 Years

Upper age limit
24 Years

Sex
Both

Target number of participants
1438

Participant 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

Recruitment start date
01/05/2025

Recruitment end date
30/06/2026

Locations

Countries of recruitment
Germany

Italy

Poland

Scotland

Slovakia

Spain

United Kingdom

Study participating centre
Universitaet Heidelberg
Heidelberg University Hospital
Im Neuenheimer Feld 130.3 (room 06.322)
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Study participating centre
University of Maribor
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Koroška cesta 46, 2000 Maribor, Slovenija
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Study participating centre
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Study participating centre
SWPS University
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Chodakowska 19/31, 03-815 Warsaw

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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
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Sponsor type
University/education

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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, ERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
The dissemination and communication of SMILE's innovative concepts, research outcomes and results take shape through a wide array of methods and initiatives. Our approach extends beyond reaching our target audience. It focuses on engaging them in a meaningful and collaborative manner. Through these diverse activities, we strive to connect with stakeholders, share valuable insights, and create opportunities for dialogue and collaboration. Each of these methods serves a unique purpose in our overall communication strategy, contributing to the ultimate success of our project. Our commitment to effective communication and dissemination is evident in the variety of activities we employ.

1. Newsletters
The project will produce a newsletter every six months. These newsletters will provide up to date information on the project's progress, achievements, upcoming tasks, and events, in addition to news from similar initiatives and relevant scientific fields.
The newsletters will be prepared by RDIUP, with input from relevant partners regarding the content. The specifics of the content will be determined and agreed upon within the consortium.
A mailing-list will be established to facilitate mass mailing, which will be compiled from contact lists obtained through website registrations, enabling visitors to subscribe to the newsletter in accordance with GDPR rules, and from contact lists gathered during the events. This mailing list will be continuously updated throughout the project.
The newsletters will also be accessible on the project website. Each partner will translate the newsletter into their local language and utilize it.

2. Journalistic articles and Interviews

Press releases are effective for capturing journalists' attention by highlighting newsworthy developments and significant project milestones. To enhance outreach, we are constructing a database of relevant newspaper editors from regional, national, and EU press. This database will facilitate precise targeting of press releases and effective engagement with media partners.

Our inaugural press release marked the official launch of the SMILE project. To maintain regular communication and engagement, a designated partner will oversee a Press Release (PR) every 3 months (Independent.co.uk done by HWU).

To ensure wide visibility, PRs will be available on the project website and widely distributed to external media channels to publicize significant project updates and developments.

For local relevance, each PR will undergo translation and adaptation for specific local contexts. Subsequently, each partner will share these tailored PRs with their respective local media and press offices.

Radio interviews will serve as a powerful medium to convey project updates, news, project results, success stories, and valuable lessons learned. Our partner HWU has engaged with BBC Radio Scotland on their 'Good Morning Scotland' program to showcase the SMILE project and explore how gamification and digital solutions can revolutionize youth mental health support. Furthermore, our partners are in the process of arranging interviews on multiple radio stations. This strategic approach aims to enhance the visibility and recognition of SMILE, thereby further engaging stakeholders and the public.

3. Videos

The consortium has created an engaging animated promotional video on YouTube to provide a general presentation and introduction to the project in English. Recognizing the importance of reaching diverse audiences, this video has also been translated into Spanish, Slovenian, Greek, German, Polish and Italian.

These captivating videos serve as a dynamic tool to convey the project's goals and mission. They will be featured on the project website and relayed through the YouTube platform and social medial accounts, ensuring easy access for all target audiences.

4. Scientific publications

The consortium will publish at least 8 scientific publications and/or articles.

As part of the Extended Open Research Data Pilot, we commit to an Open Access approach for scientific publications, ensuring free, online access to peer-reviewed scientific publications related to our project results, following both green and gold models as defined in article 29.2 of the GA.

These publications will also be available on the project website.

The consortium drafts an indicative list of relevant scientific mental health and AI-related journals and circulates it among partners.

Table 4: List of relevant scientific project-related journals

List of relevant scientific project-related journals

-Journal of Clinical Epidemiology
-eLIFE Sciences
-Plos Medicine
-Plos Digital Health
-The American Journal of Psychiatry
-JMIR Mental Health
-International Journal of Depression and Anxiety
-Digital health Journal
-The Lancet Digital Health
-Computers and Education
-Human-Computer Interaction

-Journal of Artificial Intelligence Research (JAIR)
-International Journal of Computer Games Technology
-International Journal of Serious Games -JMIR (Journal of Medical Internet Research)
-International Journal of Medical Informatics
-New Media and Society
-Journal of Psychosomatic Research
-Neuroscience & Biobehavioural Reviews
-The Child & Adolescent Mental Health (CAMH)
-The international Journal of Artificial Intelligence in Education (IJAIED)
-Children and Youth Services Review
-Journal of Paediatric Psychology
-Journal of Cognitive Enhancement
-Simulation & Gaming
-AI & Society
-Computers in Human Behaviour
-Entertainment Computing

Each partner is responsible for identifying and pursuing publishing opportunities.
The consortium will design a white paper guideline to strengthen our presence within the healthcare sector by documenting the best practices, suggesting policy instructions, and facilitating communication with stakeholders to showcase our partners' high-level expertise.

Intention to publish date
01/09/2026

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