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Helping young people to adapt their internet use and promote mental well-being in a rapidly changing world

Submission date 21/10/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 23/10/2025	**Overall study status** Ongoing	
Last Edited 07/11/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Young people are particularly susceptible to digital technology overuse, including in response to the COVID pandemic, and are therefore vulnerable to its potential harmful effects on mental health. Problematic usage of the internet (PUI) is thought to disrupt a person's life, with major consequences for that person, and wider consequences for societal health and well-being. The BootStRaP study brings together a group of researchers from 12 countries, and by working together, they are aiming to change the way that people and governments understand problematic usage of the internet, and by engaging in this study, to reduce the harm that digital devices like phones have on the mental health of young people.

Who can participate?
Students from schools involved in the study, aged between 12 and 16 years, with routine access to a mobile phone.

What does the study involve?
The BootStRaP study involves young people taking part in a digital programme designed to help them reflect on their internet use and build skills to manage it in healthier ways. The study is delivered entirely through two smartphone apps: BootstrApp, which guides participants through tasks and questionnaires, and Dragon Game, which includes fun cognitive games. Before starting, participants complete a 2-week baseline assessment. This includes answering questions about their internet habits, emotional well-being, and personality traits. It also involves some interactive tasks and passive data collection (like screen time and app usage), but no personal content (like messages or photos) is accessed.

After the baseline, participants are randomly assigned to one of three groups:
Emotional Regulation Intervention: This helps young people understand and manage their emotions. It includes games, videos, and exercises that teach emotional awareness, coping strategies, and how emotions influence behaviour.
Inhibitory Control Intervention: This focuses on helping young people manage impulsive behaviours, such as compulsive scrolling or gaming. It teaches self-control strategies, attention-

shifting techniques, and ways to resist urges.
Control Group: This group receives general information about internet use and mental health, but no interactive activities.

Each intervention lasts 4 weeks, with tasks delivered every couple of days via push notifications. These tasks are short and engaging, and participants can complete them at school or at home. Some examples include:
Rating their mood and receiving personalised feedback.
Watching short videos about emotions or impulsivity.
Playing games that help them practise emotional or behavioural skills.
Reflecting on their internet use and setting goals for change.

Participants at higher risk of problematic internet use receive extra support modules, which include more in-depth exercises and personalised feedback.
After the 4-week intervention, participants complete a follow-up assessment to see how things have changed. Depending on the study phase, this happens either 3 months or 6 months later.
Throughout the study, participants are supported by school-based ambassadors (teachers and students) and can access mental health resources through the app if needed. They can also choose to receive feedback on their progress, such as screen time summaries or mood tracking.

What are the possible benefits and risks of participating?
Benefits
Learn practical skills to manage emotions and impulses.
Reflect on internet habits and improve digital well-being.
Receive personalised feedback and support.
Help researchers develop better tools for young people.

Risks
The study is non-clinical and considered low risk.
Some questions may feel personal, but participants can skip any they don't want to answer.
Support links are provided in the app if participants feel distressed.
Participants can withdraw at any time.

Where is the study run from?
The study will be conducted online via the BootstrApp across 9 European countries (UK, France, Germany, Hungary, Lithuania, Netherlands, Portugal, Spain and Switzerland). The study is led by researchers at the University of Hertfordshire in the UK, with researchers from 12 other countries.

When is the study starting and how long is it expected to run for?
These studies are the 2nd phase of a larger project, which started on the 1st July 2023 and will run for 5 years. Phase two of the study will run for 2 years and finish in July 2027.

Who is funding the study?
1. The European Union, European Health and Digital Executive Agency (HADEA)
2. The Innovate UK program (UKRI)
3. The Swiss Confederation, State Secretariat for Education, Research and Innovation (SERI)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
359738

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 69008

Study information

Scientific Title
Boosting societal adaptation and mental health in a rapidly digitalising, post-pandemic Europe (BootStRaP Phase 2)

Acronym
BootStRaP

Study objectives
Extensive use of the internet has given rise to problematic patterns of use, involving loss of control of time spent online, that have adverse effects on the health and well-being of individuals, especially teenagers. Problematic use of the Internet (PUI) is an umbrella term describing a broad range of potentially harmful forms of online behaviour, such as excessive gambling, gaming, and social media use. The EU-funded Bootstrap project aims to mitigate the risks. It will carry out research across Europe to closely monitor the internet usage patterns of young people, to identify patterns of PUI behaviours that result in harm, and devise strategies to tackle these issues.

The aim of this phase of the study, which incorporates both a pilot study (cohort 2) and an RCT (cohort 3), is to investigate two promising theory-informed candidate preventative interventions, targeting A: emotional regulation and B: inhibitory control, for Problematic Use of the Internet (PUI).

For the Pilot study:
The primary objective is to use participants' individual characteristics to build models for predicting outcomes for both novel preventative interventions when compared to a control condition (non-interactive provision of information on PUI).

The secondary objective is to explore the effectiveness of each preventative intervention compared to a control condition when allocated at random.

For the RCT:
The primary objective is to evaluate the effectiveness of the predictive models derived from the pilot. We achieve this by comparing the effectiveness of each intervention (i.e., targeting emotional regulation or inhibitory control) when allocated either according to an algorithm derived from individual baseline outcome predictors (tailored arm), or when allocated at random (random arm) versus a control condition (non-interactive provision of information on PUI).

The secondary objective is to evaluate and compare the cost-effectiveness and cost-utility of both allocation methods (tailored, random), investigating feasibility for large-scale implementation.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 01/10/2025, Health, Science, Engineering and Technology ECDA (University of Hertfordshire, Governance Services, College Lane, Hatfield, AL10 9AB, United Kingdom; +44 (0) 1707 281010; hsetecda@herts.ac.uk), ref: 0635 2025 Jul HSET

2. approved 28/08/2025, Ethics Committee of the Faculty of Behavioral and Empirical Cultural Sciences at the Ruprecht-Karls-University Heidelberg (Ethikkommission der Fakultät für Verhaltens- und Empirische Kulturwissenschaften) (Postfach 10 57 60 69047 Heidelberg, Heidelberg, 69047, Germany; +49 6221 54-2894; dekanat@verkult.uni-heidelberg.de), ref: AZ Lind 2025 1/1

3. approved 07/10/2025, Cantonal Ethics Committee Zurich (Postfach 121, Zurich, 8090, Switzerland; +41 432597970; admin.kek@kek.zh.ch), ref: 2025-01758

4. submitted 30/07/2025, Research Ethics Committee with Medicines (CEIm) (Comité De Ética De La Investigación Con Medicamentos (CEIm)) (Técnica CEIm HGU Gregorio Anexo al Pabellón de psiquiatría, Madrid, 28007, Spain; +34 91 586 7007; ceim.hgugm@salud.madrid.org), ref: TBC

5. submitted 01/09/2025, Ethics Committee of the Faculty of Psychology and Educational Sciences of the University of Porto (Rua Alfredo Allen, s/n 4200-135, Porto, 4200-135, Portugal; +351 226 079 700; comissao_etica@fpce.up.pt), ref: TBC

6. submitted 05/09/2025, CPP Sud-Méditerranéen 1 (Hôpital Sainte Marguerite Pavillon 9, 270, bld Sainte Marguerite, Marseille, 13274, France; +33 4 91 74 42 56; cppsudmed1@gmail.com), ref: TBC

7. submitted 08/09/2025, University of Lithuanian Health Sciences Center of Bioetics (Lietuvos Sveikatos Mokslų Universitetas Bioetikos Centras) (TilŽ.es st. 18, Kaunas, LT-47181, Lithuania; +370 (8 37) 327233; bioetika@lmsu.lt), ref: TBC

8. submitted 13/09/2025, Research Ethics Committee of the Faculty of Education and Psychology of ELTE Eötvös Loránd University (Kazinczy u. 23-27, Budapest, 1075, Hungary; + 36-1 461-4500 / 3885; keb@ppk.elte.hu), ref: TBC

Study design
Multi-centre controlled individually randomized observer-blind parallel-group three-arm trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Problematic usage of the internet in adolescents

Interventions
The two digital interventions developed and refined during the pilot study will be implemented in both the pilot and the RCT. These interventions are underpinned by behavioural change theory. Designed to reduce problematic usage of the internet (PUI) in adolescents, the interventions integrate evidence-based techniques to support emotional regulation and inhibitory control through interactive, personalised, and engaging digital content.
1. Emotional Regulation Intervention
This intervention helps young people understand and manage their emotions better. It starts by encouraging them to reflect on their internet use and emotional habits. Then, it teaches practical skills for handling emotions through interactive games and exercises. The goal is to

build emotional awareness and reduce unhealthy behaviours linked to internet use.
2. Inhibitory Control Intervention
This intervention focuses on helping young people manage impulsive and compulsive behaviours. It begins with self-reflection and confidence-building activities, then teaches strategies to strengthen self-control. Interactive challenges and games help participants practise these skills in everyday life.
Both interventions are personalised based on the level of risk: those at higher risk get more in-depth support, while others receive general guidance.
3. Control Group
Participants in the control group receive a digital educational programme that covers general topics like internet habits and emotional wellbeing. However, it does not include interactive or skill-building activities, components necessary for meaningful behavioural change.

Intervention Type
Behavioural

Primary outcome(s)
Problematic use of the internet (PUI) will be measured using the Problematic Internet Use Questionnaire in its short version (PIUQ-SF-9) at baseline, post-intervention, and 3-month follow-up

Key secondary outcome(s))
1. PUI as measured using The Internet Severity and Activities Addiction Questionnaire versions ISAAQ-part b, and ISAAQ-ED; A short version of the Assessment of Criteria for Specific Internet-use Disorders (ACSID-11) at baseline, post-intervention, and 3-month follow-up
In addition, participants are asked about their Browser Activity: “What do you usually do when you're on the internet using your browser?” in an open-text question format.
2. Depression and anxiety are measured using the 21 Item version (DASS-21) at baseline, post-intervention, and 3-month follow-up
3. Self-stigma is measured using the Paediatric Self-Stigmatization Scale (PaedS) at baseline, post-intervention, and 3-month follow-up
4. Obsessive-compulsive disorder symptoms are measured using the Short Obsessive Compulsive Disorder Screener (SOCS) at baseline, post-intervention, and 3-month follow-up
5. Emotional and behavioural difficulties are measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline, post-intervention, and 3-month follow-up
6. Quality of life is measured using the Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) at baseline, post-intervention, and 3-month follow-up
7. General health status is measured using the EQ-5D-Y and World Health Organisation Disability Assessment Schedule (WHODAS 2.0)(adapted for internet use), at baseline, post-intervention, and 3-month follow-up
8. Cognitive Variables (Affect regulation and Inhibitory executive control) measured using The BrainPAC (Project - The BrainPark Assessment of Cognition (BrainPAC) Project | BrainPark, n.d.) enhanced value-modulated attentional capture (VMAC) task and enhanced Stop Signal task (SST), at baseline, post-intervention, and 3-month follow-up
9. Impulsive behaviour is measured using the Urgency –Premeditation - Perseverance - Sensation Seeking - Positive Urgency (UPPS-P), at baseline, post-intervention, and 3-month follow-up
10. Compulsivity is measured using the Cambridge–Chicago Compulsivity Trait Scale (CHI-T), at baseline, post-intervention, and 3-month follow-up
11. Height (in cm), Weight (in kg) and body mass index (BMI) will be recorded at baseline and 3-month follow-up
12. Favorite sports or exercise activities will be recorded at baseline and 3-month follow-up

13. Consequential expectancies of internet usage will be measured using the Internet Use Expectancies Scale (IUES), at baseline, post-intervention, and 3-month follow-up
14. Misinformation will be measured using a Visual Analog Scale (VAS) asking how much of the information on the internet they believe to be true (0% to 100%) at baseline and 3-month follow-up
15. Gratification and compensation are measured using the Experience of Gratification and Compensation Scale (EGS/ECS), at baseline, post-intervention, and 3-month follow-up
16. Fear of missing out is measured using the Fear of Missing Out Scale, at baseline, post-intervention, and 3-month follow-up
17. School performance is measured using the mean marks from the previous year recorded at baseline and 3-month follow-up
18. Family relationship quality and communication are measured using a 5-point Likert scale at baseline and 3-month follow-up
14. Socioeconomic status is measured using 3 items of the Family Affluence Scale III (FAS), at baseline and 3-month follow-up
15. Vaccine Hesitancy is measured using an adapted version of the Vaccine Hesitancy Scale (VHS), at baseline and 3-month follow-up
16. Habitual nature will be measured using the Self-Report Habit Index (SRHI), at baseline, post-intervention, and 3-month follow-up
17. Phone usage is monitored using mobile sensing data collected through the app throughout the 5 months. Data collected includes: Device sessions (Timestamps, Duration), Contact list (Number of contacts), Calls (Timestamps per Call, Duration, incoming, outgoing, missed), SMS (Timestamps per SMS, Text length, incoming/outgoing), Installed apps (Number of apps), App Sessions (Timestamps per session, duration), App Statistics (Count and Usage time per app), Encrypted GPS / Locations (Timestamps, Anonymized position), Accelerometer (Timestamps and axis data), Rotation Rate (Timestamps and axis data), Pedometer (Count of steps per day)*, Visits (Like GPS but aggregated)*. Device information will also be collected through the app and includes: Screen size, Operating system (OS), OS version, country, language, device, BootstrApp version

Completion date
30/07/2027

Eligibility

Key inclusion criteria
1. Age between 12 and 16 years
2. Routine access to a mobile device
3. Student at a school involved in the study

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit
12 years

Upper age limit
16 years

Sex
All

Key exclusion criteria
1. No exclusive access to a mobile phone
2. Phone operating systems older than 15.6 for iOS or 10 for Android

Date of first enrolment
20/11/2025

Date of final enrolment
30/03/2027

Locations

Countries of recruitment
United Kingdom

England

France

Germany

Hungary

Lithuania

Netherlands

Portugal

Spain

Switzerland

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University of Hertfordshire
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Sponsor information

Organisation
University of Hertfordshire

ROR
https://ror.org/0267vjk41

Funder(s)

Funder type
Not defined

Funder Name
HORIZON EUROPE Framework Programme

Alternative Name(s)
Horizon Europe, Horizon Europe Programme, Framework Programme, Horizon Europe, EU Framework Programme, Horizon

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Innovate UK

Alternative Name(s)
UK Research and Innovation Innovate UK, innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Staatssekretariat für Bildung, Forschung und Innovation

Alternative Name(s)
Segreteria di Stato per la Formazione, la Ricerca e l'Innovazione, State Secretariat for Education, Research and Innovation, Secrétariat d'État à la Formation, à la Recherche et à l'Innovation, SBFI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

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

Protocol file	version 2.0	01/10/2025	07/11/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes