

The BootStRaP Project: Helping young people to adapt their internet use and promote mental well-being in a rapidly changing world.

Submission date	Recruitment status	<input checked="" type="checkbox"/> Prospectively registered
27/06/2024	No longer recruiting	<input checked="" type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
02/07/2024	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
08/01/2026	Other	<input checked="" type="checkbox"/> Record updated in last year

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 for 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 internet use, and by engaging into 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?

Participants in the will be asked to download 2 apps to their phone. They will be asked to answer some questions on internet use, mental and physical health, how they think and behaviours over a 6 month period. These questions are broken up into blocks that will take approximately 1 hour to complete at the beginning of the study, at 3 months and again at 6 months. Participants will also be asked to play some online games (via the Dragon Game App) when they first start the study and again in 6 months. The games look at how quickly they respond to tasks and take about 12 minutes.

At the beginning of the study and at the end participants will be asked to complete a 7 day diary about their daily internet use, once a month participants will be asked about their internet use in a short 5 minute survey and every 8 days participants will be asked to answer 2 questions about their mood and patience that day.

As you may know, certain information is already collected by phones each day, this is known as Mobile Sensing. The study will collect some of this information while the participant is in the study, but will not be able to see the content of what they are doing on their apps, in their

messages or on their calls. The following information will be collected:
How often and how much time they spend on their phone and what type of phone it is
How many and how much time they spend on which apps and the internet (web browser)
How many, when and how long they spend on phone calls and sending text messages
How many contacts they have and the number of contacts they actively engage with
Number of steps per day, distance covered and physical activity (accelerometer and rotation rate information)

What are the possible benefits and risks of participating?

On completion of the study participants will receive a certificate and shopping e-voucher to download via the BootstrApp.

Participants will also be able to get feedback both on an individual level and compared to other participants about their screen time, app use, game scores and some questionnaire results.

Participation in the study will be helping improve mental health and well-being for young people across Europe and beyond.

Although we do not believe that the questions asked will upset participants, we understand it is difficult for some people to discuss personal things such as mental health.

If a participant becomes distressed during the study, the BootstrApp will have information about where they can find help if they think they need it, from both national organisations and at local levels and from the participant school.

Where is the study run from?

The study will be conducted online via the BootstrApp across 9 European countries (United Kingdom, 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 11 other countries.

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

This study is the 1st phase of a larger project which started on the 1st July 2023 and will run for 5 years. Phase one of the study will run for 1 year and finish in July 2025, this will be followed by an intervention study (running from 2025 - 2026) and a randomised clinical trial (RCT) (running from 2026 - 2027). The result from each phase will be utilised by the next phase of the project.

Who is funding the study?

The study is funded by European Union, European Health and Digital Executive Agency (HADEA), The Research and Innovation Fund, Innovate UK program (UKRI) and 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)

335440

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 335440, CPMS 58987

Study information

Scientific Title

Boosting Societal Adaptation and Mental Health in a Rapidly Digitalizing, Post-Pandemic Europe

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, 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.

Primary Objectives

1. Determine the multifactorial determinants of healthy vs. unhealthy internet usage among European adolescents aged 12-16 years and develop algorithms for quantifying individual risk of PUI. The algorithms will be developed applying both classical and modern machine learning techniques. The primary endpoint quantifying PUI is the short compulsive internet use scale (S-CIUS) (Besser et al., 2017; Pérez-Sáenz et al., 2023). In addition, PUI symptoms will be quantified by the PIUQ (Demetrovics et al., 2008), the ISAAQ (Omrawo et al., 2023) and the ACSID-5 (Müller et al., 2022). (at baseline and t2)
2. Use these algorithms to develop a new, user friendly, digital platform supported on a smartphone app (BootstrApp) that would enable early detection of adolescents 'at risk' of PUI before it is apparent, as a prototype method for early targeted intervention
3. Determine the health economic impact of PUI for European adolescents. Health economic impact will be reported as cost and burden of PUI in European adolescents

Ethics approval required

Ethics approval required

Ethics approval(s)

1. approved 22/05/2024, 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: LMS/SF/UH/05626
2. approved 14/05/2024, The Scientific and Ethical Review Board (VCWE) (De Boelelaan 1105 1081 HV Amsterdam, Amsterdam, 1081, Netherlands; +31 (020) 59 89898; vcwe.fgb@vu.nl), ref: VCWE-2024-089
3. approved 12/05/2024, 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 BRA 2024 1/1
4. approved 17/05/2024, LIETUVOS SVEIKATOS MOKSLŲ UNIVERSITETAS BIOETIKOS CENTRAS (UNIVERSITY OF LITHUANIAN HEALTH SCIENCES CENTER OF BIOETICS) (TilZ.es st. 18, Kaunas, LT-47181, Lithuania; +370 (8 37) 327233; bioetika@lmsu.lt), ref: 2024-BEC3-T-015
5. approved 09/08/2024, Schweizerische Ethikkommissionen für die Forschung am Menschen (Swiss ethics committees for research involving humans) (Haus der Akademien, Laupenstrasse 7, Bern, CH-3008, Switzerland; +41 31 306 93 95; info@swissethics.ch), ref: 2024-00896

6. approved 03/06/2024, COMITÉ DE ÉTICA DE LA INVESTIGACIÓN con MEDICAMENTOS (CEIm) (RESEARCH ETHICS COMMITTEE WITH MEDICINES (CEIm)) (Técnica CEIm HGU Gregorio Anexo al Pabellón de psiquiatría, Madrid, 28007, Spain; +34 91 586 7007; ceim.hgugm@salud.madrid.org), ref: TBC

7. approved 26/07/2024, Research Ethics Committee of the Faculty of Education and Psychology of ELTE Eötvös Loránd University (Kazinczy u. 23-27, Budapest 1075, Budapest, 1075, Hungary; + 36-1 461-4500 / 3885; keb@ppk.elte.hu), ref: 2024/267

8. approved 13/09/2024, Ethics Committee of the Faculty of Psychology and Educational Sciences of the University of Porto (Rua Alfredo Allen, s/n 4200-135 - Porto, Portugal, Porto, 4200-135, Portugal; +351 226 079 700; comissao_etica@fpce.up.pt), ref: 2024-06-02b

9. approved 05/07/2024, 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: RECHMPL24_0103 / UF 8580

Study design

Multicentre naturalistic cohort study

Primary study design

Observational

Study type(s)

Other, Prevention, Quality of life

Health condition(s) or problem(s) studied

Problematic usage of the internet in adolescents

Interventions

For a period of 6 months, participating students will be prospectively assessed by having a specifically developed mobile app – the BootstrApp - installed on their smartphone, which will prompt the students to complete questionnaire assessments regarding their mood, cognitive abilities, and Internet usage.

There will be three survey-based main assessments (T1-T2, 1h per assessment, spaced by 3 Months). Short additional questionnaires will be integrated at defined timepoints throughout the study. This includes four additional assessments of the (S-CIUS) (Besser et al., 2017; Pérez-Sáenz et al., 2023), to provide monthly information on PUI, two 7-day periods (after T1 and T2) of daily information on activities on the internet and affect, and two items on mood and patience that will be queried every eight days. Further passive mobile sensing data will be collected by the smartphone app itself (e.g. actual time and frequency using the smartphone per day).

Intervention Type

Other

Primary outcome(s)

1. Problematic Usage of the Internet is measured using: The Compulsive Internet Use Scale (CIUS); The Problematic Internet Use Questionnaire (PIUQ) ; The Internet Severity and Activities Addiction Questionnaire versions ISAAQ-10, ISAAQ-A and ISAAQ-ED; and A short version of the Assessment of Criteria for Specific Internet-use Disorders (ACSID-11) at Baseline and 6 months. 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 Baseling and 6 months
 3. Self-stigma is measured using the Paediatric Self-Stigmatization Scale (PaedS) at Baseling and 6 months
 4. Obsessive compulsive disorder symptoms are measured using the Short Obsessive Compulsive Disorder Screener (SOCS) at baseline and 6 months
 5. Emotional and behavioural difficulties are measured using the Strengths and Difficulties Questionnaire (SDQ) at baseline and 6 months
 6. Quality of life is measured using the Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) at baseline and 6 months
 7. General health status is measured using the EQ-5D-Y at Baseline and 6 months
 8. Cyberchondria is measured using the Cyberchondria Severity Scale (CSS) at baseline and 6 months. at Baseline and 6 months
 9. In line with the National Institute on Alcohol Abuse and Alcoholism (NIAAA), two items are used to detect early risk in adolescents'. One question asks for the friends' drinking behaviors (e.g., "Do you have any friends who drank beer, wine, or any drink containing alcohol in the past year?") and a second question asks for their own drinking behavior (e.g., "How about you – in the past year, on how many days have you had more than a few sips of beer, wine, or any drink containing alcohol?" at Baseline and 6 months
 10. Cognitive Variables (Affect regulation and Inhibitory executive control). Are 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 and 6 months
 11. Phone usage is monitored throughout the 6 month period using mobile sensing data collected through the app. 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

Key secondary outcome(s)

1. Daily mood, urge to use the internet and interference with everyday tasks is measured using a diary style set of 12 questions every evening for 7 days after baseline and 6 months
2. Personality is measured using the short 10-item version of the Big-Five-Inventory (BFI-10) at 3 months
3. Impulsive behaviour is measured using the Urgency – Premeditation - Perseverance - Sensation Seeking - Positive Urgency (UPPS-P) at 3 months
4. Compulsivity is measured using the Cambridge–Chicago Compulsivity Trait Scale (CHI-T) at 3 months
5. Height (in cm), Weight (in kg) and body mass index (BMI) will be recorded at 3 months
6. Favorite sports or exercise activities will be recorded at 3 months
7. Consequential expectancies of internet usage will be measured using the Internet Use Expectancies Scale (IUES) at 3 months
8. Misinformation will be measured using a visual analog scale asking how much of the information on the internet they believe to be true (0% to 100%) at 3 months
9. Restriction of their online activity will be measured using a standardised set of 3 questions

- asking what the reasons for restricting online activity were and how they did it, at 3 months
10. Gratification and compensation is measured using the Experience of Gratification and Compensation Scale (EGCS) at 3 months
 11. Fear of Missing out is measured using the Fear of Missing Out Scale at 3 months
 12. School performance is measured using means marks from the previous year recorded at 3 months
 13. Family relationship quality and communication are measured using a 5 point likert scale at 3 months
 14. Socioeconomic status is measured using 3 items of the Family affluence scale III (FAS) at 3 months
 15. Vaccine Hesitancy is measured using the Vaccine Hesitancy Scale (VHS) at 3 months

Completion date

12/11/2025

Eligibility

Key inclusion criteria

1. Aged 12 - 16 years
2. Routine access to a mobile phone
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

Total final enrolment

2229

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

23/09/2024

Date of final enrolment

30/04/2025

Locations

Countries of recruitment

United Kingdom

England

France

Germany

Hungary

Netherlands

Portugal

Spain

Switzerland

Study participating centre

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Sponsor information

Organisation

University of Hertfordshire

ROR

<https://ror.org/0267vjk41>

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), ERC

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

Swiss State Secretariat for Education Research and Innovation

Results and Publications

Individual participant data (IPD) sharing plan

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?
<u>Protocol article</u>		19/12/2025	08/01/2026	Yes	No
<u>Participant information sheet</u>	Young person PIS	11/11/2025	11/11/2025	No	Yes
<u>Participant information sheet</u>	Parent PIS		08/01/2026	No	Yes
<u>Protocol file</u>	version 1.1	28/04/2024	11/09/2024	No	No
<u>Protocol file</u>	version 1.2	19/09/2024	25/09/2024	No	No
<u>Study website</u>		11/11/2025	11/11/2025	No	Yes