ISRCTN59576080 https://doi.org/10.1186/ISRCTN59576080

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

Submission date 27/06/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 02/07/2024	**Overall study status** Ongoing	
Last Edited 02/09/2025	**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 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 aproximatly 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?
1. Prof. Naomi Fineberg, naomi.fineberg@btinternet.com
2. Prof. Jose Menchon, jmenchon@bellvitgehospital.cat
3. Mrs Natalie Hall, n.hall4@herts.ac.uk

Study website
https://www.internetandme.eu

Contact information

Type(s)
Public, Scientific

Contact name
Mrs Natalie Hall

ORCID ID
https://orcid.org/0000-0002-3635-7699

Contact details
University of Hertfordshire, Health Research Building, College Lane
Hatfield
United Kingdom
AL10 9AB
+44 (0)1707 286290 [xtn 3290]
n.hall4@herts.ac.uk

Type(s)
Principal Investigator

Contact name
Prof Naomi Fineberg

ORCID ID
https://orcid.org/0000-0003-1158-6900

Contact details
HPFT, Rosanne House, Parkway
Welwyn Garden City
United Kingdom
AL86HG
-
bootstrap@herts.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
335440

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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) (TilŽ.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, Laupenstrase 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

Secondary study design
Cohort study

Study setting(s)
Home, School

Study type(s)
Other, Prevention, Quality of life

Participant information sheet
Young person PIS: https://redcap.link/PISyp, Parent PIS: https://redcap.link/PISp.

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 measure
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 moble 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

Secondary outcome measures
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

Overall study start date
01/06/2023

Completion date
25/10/2025

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

Age group
Child

Lower age limit
12 Years

Upper age limit
16 Years

Sex

Both

Target number of participants
Total: 2520 , 280 per 9 recruitment sites.

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
England

France

Germany

Hungary

Netherlands

Portugal

Spain

Switzerland

United Kingdom

Study participating centre
University of Hertfordshire
College Lane
Hatfield
United Kingdom
AL10 9AB

Study participating centre

Eotvos Lorand Tudomanyegyetem
EGYETEM TER 1-3
Budapest
Hungary
1053

Study participating centre
Universidade Do Porto
PRACA GOMES TEIXEIRA
Porto
Portugal
4099-002

Study participating centre
Lietuvos Sveikatos Mokslu Universitetas
A MICKEVICIAUS GATVE 9
Kaunas
Lithuania
44307

Study participating centre
Stichting Vu
DE BOELELAAN 1105
Amsterdam
Netherlands
1081 HV

Study participating centre
Fundacion Para La Investigacion Biomedica Del Hospital Gregorio Maranon
CALLE DOCTOR ESQUERDO 46
Madrid
Spain
28007

Study participating centre
Centre Hospitalier Universitaire Montpellier
AVENUE DU DOYEN GASTON GIRAUD 191
Montpellier
France
34000

Study participating centre
Heidelberg University
Grabengasse 1
Heidelberg
Germany
69117

Study participating centre
Universitat Zurich
RAMISTRASSE 71 null
Zurich
Switzerland
8006

Sponsor information

Organisation
University of Hertfordshire

Sponsor details
Collage Lane
Hatfield
England
United Kingdom
AL10 9AB
+44 (0)1707284983
research-sponsorship@herts.ac.uk

Sponsor type
University/education

Website
http://www.herts.ac.uk/

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, ERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Innovate UK

Alternative Name(s)
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

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
01/06/2026

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?
Protocol file	version 1.1	28/04/2024	11/09/2024	No	No
Protocol file	version 1.2	19/09/2024	25/09/2024	No	No