

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

Deliverable D1.5

Phase 2 Protocol

WP1 – Recruitment and Retention

Task 1.1 – Ethics and Legal Issues

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Authors:

Natalie Hall (University of Hertfordshire)

Megan Smith (University of Hertfordshire)

Anita Meinke (University of Zurich)

Lara Zumrode (University of Lübeck)

Giovanni Tardivo (Hertfordshire Partnership University NHS Foundation Trust)

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Contributor(s)	Natalie Hall, Megan Smith, Anita Meinke, Lara Zumrode, Giovanni Tardivo,
Reviewer(s)	David Wellsted (University of Hertfordshire), Simon Foster (University of Zurich), Annika Brandtner (Unversitaet Duisburg-Essen)
Editor(s)	
Partner in charge(s)	University of Hertfordshire
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2.0	1/10/25	Natalie Hall	University of Hertfordshire	Addition of the self-report habit index which should have been included as a new measure to the baseline and follow up batteries.

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This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation, or both.

Moreover, this deliverable reflects only the author's views. The European Community is not liable for any use that might be made of the information contained herein.

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General Information

This document provides details regarding the setting up of, conduct, analysis and dissemination of the European Health and Digital Executive Agency (HADEA) funded study (Project: 10108238; Boosting Societal Adaptation and Mental Health in a Rapidly Digitalizing, Post-Pandemic Europe).

The University of Hertfordshire will sponsor this trial. The below listed organisations are the collaborators of the study. As such, a collaboration agreement will be signed by the parties, specifying responsibilities and financial arrangements.


Chief Investigator	Prof. Naomi Fineberg
Trial Manager	Natalie Hall
Sponsors	University of Hertfordshire
Study committees	Steering Committee General Assembly Data Management Committee Scientific Advisory Board (SAB) Ethics Advisory Board (EAB) Impact Advisory Board (IAB)
Collaborators	Institut Catala De La Salut (Spain) Fundacio Institut Dinvestigacio Biomedica de Bellvitge (IDIBELL, Spain) Universitaet Duisburg-Essen (Germany) Eotvos Lorand Tudomanyegyetem (Hungary) Universidade do Porto (Portugal) Reichman University (Israel) Medical Research Infrastructure Development and Health Services (Israel) Zentrum Fuer Integrative Psychiatrie (Germany) Universitaet zu Lübeck (Germany) Tallinn University (Estonia) Lietuvos Sveikatos Moskslu Universitetas (Lithuania) Universitaet ULM (Germany) Stichting VU (Netherlands) Fundacion Para la Investigacion Biomedica del Hospital Gregorio Maranon (Spain) Centre Hospitalier Universitaire Montpellier (France) Centro di Neurologia Psichiatria e Psicologia Clinica SRL (Italy) Monash University (Australia) Johannes Gutenberg-Universitat Mainz (Germany) Universitat Zurich (Switzerland) University of Gibraltar (Gibraltar) University of Southampton (UK) The Chancellor Masters and Scholars of the University of Cambridge (UK) Euro Youth Mental Health CIC (UK) University of Macau (China)

Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator (CI) agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Good Clinical Practice (GCP) guidelines, the Sponsor's (and any other relevant) Standard Operating Procedures (SOPs), and other regulatory requirements as amended.

We agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

We also confirm that we will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the study will be given; and that any discrepancies and serious breaches of GCP from the study as planned in this protocol will be explained.

Name: Prof. Naomi Fineberg	Role: Chief Investigator	Signature:  Date: 01/10/2025
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Glossary of Abbreviations and Key Terminology

Abbreviations and definitions:

ACSID	Assessment of Criteria for Specific Internet-use Disorders
BootStRaP	Boosting Societal Adaption and Mental Health in a Rapidly Digitalizing, Post-Pandemic Europe
BCW	Behaviour Change Wheel
CHI-T	Cambridge–Chicago Compulsivity Trait Scale
CI	Chief Investigator
COM-B	Capability, Motivation, Opportunity and Behaviour model of behaviour change
CRF	Case Report Form
CSS	Cyberchondria Severity Scale
DASS-21	Depression Anxiety Stress Scale
DEC	dissemination, communication and exploitation
DPA 2018	Data Protection Act 2018
EAB	Ethics Advisory Board
EGCS	Experience of Gratification and Compensation Scale
EQ-5D-Y	European Quality of Life 5 Dimensions
ERQ-CA	Emotion Regulation Questionnaire for Children and Adolescents
EU	European Union
EYMH	Euro Youth Mental Health
FAIR	findable, accessible, interoperable, reusable
FAS	Family affluence scale
FOMO	Fear of Missing Out
GA	General Assembly
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HADEA	European Health and Digital Executive Agency
HRQoL	Health-Related Quality of Life
I-PACE	Interaction of Person-Affect-Cognition-Execution
IAB	Impact Advisory Board
ICF	Informed Consent Form
IDC	Inter Disciplinary Centre
ISAAQ-10, part B	Internet Severity and Activities Addiction Questionnaire – 10 item version part B
ISAAQ- ED	Internet Severity and Activities Addiction Questionnaire – Eating Disorder
IUES	Internet Use Expectancies Scale
NIAAA	National Institute on Alcohol Abuse and Alcoholism
OS	Operating System
PaedS	Paediatric Self-Stigmatization Scale
PI	Principal Investigator
PIUQ	Problematic Internet Use Questionnaire
PPI	patient-public involvement
PQ-LES-Q	Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire
PRIME	Plans, Evaluations, Motives, Impulses and Responses theory of motivation
PUI	Problematic Use of the Internet
QA	Quality Assurance

QALYs	Quality Adjusted Life Years
QC	Quality Control
QMS	Quality Management System
Participant	An individual who takes part in a study
PO	Project Office
REC	Research Ethics Committee
REDCap	Research Electronic Data Capture
S-CIUS	Short-Compulsive Internet Use Scale
SAB	Scientific Advisory Board
SC	Steering Committee
SDQ	Strengths and Difficulties Questionnaire
SERI	Swiss State Secretariat for Education Research and Innovation
SRHI	Self-Report Habit Index
SOCS	Short Obsessive Compulsive Disorder Screener
SOP	Standard Operating Procedure
SST	Stop-Signal-Task
TSC	Trial Steering Committee
UK	United Kingdom
UKRI	Research and Innovation Fund, Innovate UK program
UPPS-P	Urgency – Premeditation - Perseverance - Sensation Seeking - Positive Urgency
WP	Work Package
WHODAS 2.0	World Health Organisation Disability Assessment Schedule

Study Summary

Full title	Boosting Societal Adaption and Mental Health in a Rapidly Digitalizing, Post-Pandemic Europe
Short title/Acronym	BootStRaP
Protocol Version Number and Date	Version 2.0 01/10/2025
Start Date	When approvals have been received (REC)
End Date	01/09/2028
Study Duration	Cohort 2: 12 months + 28-month extension Cohort 3: 12 months
Study Design	A controlled, individual randomised, observer-blinded, three-arm pilot trial followed by a definitive randomised control trial (RCT)
Sponsor/Co-sponsors	The University of Hertfordshire
Chief Investigator(s)	Prof. Naomi Fineberg
Funder	European Union, European Health and Digital Executive Agency (HADEA), Research and Innovation Fund, Innovate UK program (UKRI), Swiss Confederation, State Secretariat for Education Research and Innovation (SERI)
Study Objective(s)	<p>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).</p> <p>For the Pilot study: The primary objective is to use participants' individual characteristics to build models for predicting that predict outcomes for both novel preventative interventions when compared to a control condition (non-interactive provision of information on PUI).</p> <p>The secondary objective is to explore the effectiveness of each preventative intervention compared to a control condition when allocated at random.</p> <p>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).</p> <p>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.</p>
Planned Sample Size	3,600 (approximately 400 young people at each site), per cohort.
Participants	Young adolescents aged 12-16

Intervention	<p>Two 4-week digital self-help preventative interventions have been developed based on two different theoretical underpinnings (emotional regulation and inhibitory control).</p> <p>Pilot study: Participants will be randomly allocated to one of three interventions (emotional regulation; inhibitory control; control condition). The preventative interventions will be stratified into high and low intensity versions and allocated to individuals according to high and low risk of PUI based on a detailed baseline assessment and mobile sensing data.</p> <p>RCT: Participants will receive similar interventions as in the pilot study but allocated in a different way. Participants will be randomised to three separate arms (tailored; random; control), and all will undergo a detailed baseline assessment.</p> <p>For those allocated to the tailored arm, the presence at baseline assessment of risk factors derived from the pilot study will serve as predictors and be used to allocate participants to the intervention (emotional regulation or inhibitory control) most likely to be effective at preventing PUI or reduce problematic behaviour patterns.</p> <p>For those allocated to the random arm, participants will be allocated at random to either of the emotional regulation or inhibitory control interventions.</p>
Follow up duration	<p>Pilot study: The primary endpoint is the post intervention assessment that takes place at the end of the 4-week intervention phase. The secondary endpoint takes place at 3-months following the primary endpoint. Additional assessments will take place 3-monthly during an optional additional 24-month extension phase.</p> <p>RCT: The primary endpoint takes place at the post intervention assessment at the end of the 4-week intervention phase. The secondary endpoint takes place at 6-months following the primary end point.</p>
Outcomes	<p>The primary outcome of both the pilot study and the RCT will be PUI measured using the Problematic Internet Use Questionnaire in its short version (PIUQ-SF-9)(Demetrovics et al., 2008).</p> <p>As a secondary outcome, smartphone behaviour will be monitored using mobile sensing giving insights into variables linked to PUI.</p>

1. Introduction

1.1. Study Background and rationale

Problematic use of the internet (PUI) is a public health concern in an era of digital technology where young people become familiar with computers, mobile devices and the Internet at very early ages. Although young people's internet use has many functional and enriching aspects, some adolescents may develop unhealthy patterns of internet use and may experience associated health issues which develop early in life and once present tend to endure (Brand, 2022; Brand et al., 2019; Gjoneska et al., 2021). Given that the use of Smartphones and the Internet is widespread and plays a significant role in users developing PUI, especially young populations, measures to prevent and reduce the risk of PUI are of special importance (Fineberg et al., 2018).

Research on interventions for Problematic Internet Use (PUI) remains limited (King et al., 2018; Nakayama et al., 2017; Vondráčková & Gabrhelík, 2016) and methodologically weak (King et al., 2011;

King & Delfabbro, 2014; Rumpf et al., 2018, 2019). Nonetheless, reviews highlight promising strategies, including both primary and secondary prevention (King et al., 2018). School-based programs show potential for universal and targeted prevention among adolescents (Throuvala et al., 2019, 2021), though interventions must be accessible across varying risk levels.

Evidence for interventions targeting adolescents with Problematic Usage of the Internet (PUI) remains limited. A review by Throuvala et al., (2019) identified three promising approaches: Cognitive Behavioural Therapy (CBT) (Lindenberg et al., 2017), media literacy (Walther et al., 2014), and interventions aimed at enhancing awareness and protective factors (Bonnaire et al., 2019). However, a systematic review and meta-analysis on primary prevention effectiveness in adolescents found no significant overall effect, despite some positive individual outcomes (Saletti et al., 2021). Similarly, Yeun & Han (Yeun & Han, 2016) reported benefits from school-based psychosocial interventions, though findings were limited to studies conducted in Korea, with only two RCTs included.

Psychological treatments for established internet and smartphone addiction have shown moderate effectiveness (Kim & Noh, 2019; Liu et al., 2017; Malinauskas & Malinauskiene, 2019). Digital interventions, due to their scalability and cost-effectiveness, are increasingly seen as a promising avenue. While evidence supports their use in treating gambling disorder, further research is needed to confirm their efficacy for other internet-related conditions such as gaming and pornography use (Boumparis et al., 2022). Recent studies have shown promising results using Attentional Bias Modification (Nasiry & Noori, 2022) and Emotional Bias Modification in Gaming Disorder (Wu et al., 2022).

CBT-based interventions remain central to treatment, though earlier reviews highlight methodological limitations and a lack of high-quality trials (King et al., 2011; King & Delfabbro, 2014; Stevens et al., 2019; Zajac et al., 2017, 2020). More recent studies (Kaushik et al., 2023; Wölfling et al., 2019) suggest improved outcomes, potentially due to targeting underlying neural mechanisms (Antons et al., 2020).

Crucially, not all participants in preventative or clinic interventional studies of PUI respond equally to specific interventions. Effectiveness is influenced by individual risk factors, additional characteristics and comorbid conditions. For instance, a meta-analysis using machine learning (ML) in CBT research reported an overall predictive accuracy of 74% when integrating clinical, neuroimaging, cognitive, and genetic data, or a combination of these as predictors (Vieira et al., 2022). Researchers recommend leveraging statistical models to enhance interventions specificity in mental health treatment (Cohen & DeRubeis, 2018; Delgadillo & Lutz, 2020). For example, tailored interventions addressing comorbidities have outperformed standard CBT in treating gaming disorder (Torres-Rodríguez et al., 2018).

In summary, while there is growing evidence supporting both preventative and clinical interventions for PUI, high-quality, individualised, and scalable approaches—particularly digital ones—are urgently needed to address this complex and evolving issue.

Based on the reviewed literature, it is evident that the number of high-quality, methodologically rigorous studies remains limited. While systematic reviews and meta-analyses provide some insights, their conclusions are constrained by the small number of available studies and inconsistent findings. According to the Oxford Centre for Evidence-Based Medicine criteria (<http://www.cebm.net/index.aspx?o=5653>),

the current body of evidence falls between levels 2 and 3, highlighting the need for further well-designed research to strengthen the reliability of findings.

The pilot study aims to develop two digital self-help preventative interventions for PUI that will be tested to derive information on tailored interventions based on machine learning (ML). The subsequent RCT aims at testing tailored interventions based on the results of the Pilot Study. The rationale behind this approach is that individuals with PUI will respond differently to the candidate interventions developed in the Pilot Study (emotional regulation intervention: improving emotional regulation and social competence; inhibitory control intervention: improving inhibitory control and cognitive biases). Risk factors and additional characteristics identified in the pilot study will serve as predictors to allocate participants in the RCT to the intervention most likely to prevent PUI or reduce problematic behaviour patterns.

Both the pilot study and RCT follow the assessment study phase of the Bootstrap project, which was the first of the three studies conducted during the whole BootStRaP project. The main aim of the assessment study was to 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.

2. Aims and Objectives

2.1. Study objectives

The second phase of the BootStRaP project aims to evaluate two promising, theory-informed preventative interventions for Problematic Usage of the Internet (PUI). This phase consists of a pilot study and a randomised controlled trial (RCT), designed to refine intervention strategies and optimise participant allocation.

Pilot Study

The primary objective of the pilot study is to identify key predictive characteristics that determine individual responses to the two interventions (emotional regulation and inhibitory control), compared to a control condition (non-interactive provision of psychoeducation on safe and effective use of the internet).

The secondary objective is to assess the overall effectiveness of each intervention relative to the control group under random allocation.

We do not expect one intervention to be superior to the other; rather, both are anticipated to be more effective than the control condition in reducing PUI risk. However, the primary focus is not on comparative effectiveness but on developing algorithms for personalised intervention matching, which will be applied in the subsequent RCT.

Randomised Control Trial

The primary objective of the RCT is to determine whether tailored intervention allocation (matching participants to either the emotional regulation intervention or inhibitory control intervention, using machine learning algorithms developed in the pilot study) leads to better outcomes compared to random allocation to the emotional regulation intervention or inhibitory control intervention or the control arm.

The secondary objective is to evaluate the cost-effectiveness and cost utility of this tailored approach, ensuring feasibility for large-scale implementation.

This structured approach will provide crucial insights into optimising individualised intervention strategies for preventing PUI in adolescents.

3. Methods

3.1. Study Setting

BootStRaP project collaborators in academic organisations across 9 European countries (France, Germany, Hungary, Lithuania, Netherlands Portugal, Spain, Switzerland and United Kingdom) will identify several schools willing to take part. These designated schools will act as the recruitment sites for both the pilot and the RCT studies.

All data collection will be carried out via the BootstrApp and the Dragon Game app on participant's smartphones. Push notifications will guide participants through the data collection.

The sponsor is the University of Hertfordshire (UoH), an academic institution based in the United Kingdom. The study is centrally organised and based on a shared study protocol, but consent and recruitment procedures are adapted to local requirements.

3.1.1. Description of target group

The aim of both studies is to detect early risk for problematic internet use and prevent the development of addictive usage patterns across the whole well-being spectrum, rather than to treat an already developed pathological use. The whole adolescent population is therefore included rather than specific subgroups. The study population will consist of young adolescents of all genders between 12 and 16 years, recruited from schools with different socioeconomic backgrounds and from rural and urban areas. We strive to include young people from low/middle income families who might be especially vulnerable for PUI. The BootStRaP study is designed to evaluate and moderate online behaviour among young people using mobile devices. Therefore, it is a necessary condition, that young people involved have routine and exclusive access to a mobile device to be able to take part in the study.

The eligibility criteria are:

- Age between 12 and 16 years
- Routine access to a mobile device
- Student at a school involved in the study

The exclusion criteria are:

- No exclusive access to a mobile phone
- Phone operating systems older than 15.6 for iOS or 10 for Android

3.2. 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, specifically the Behaviour Change Wheel (BCW) (Michie et al., 2011), the COM-B model (Capability, Motivation, Opportunity and Behaviour), and PRIME (Plans, Evaluations, Motives, Impulses and Responses) Theory of Motivation (West & Michie, 2020). Designed to reduce PUI in adolescents, the interventions integrate evidence-based techniques to support emotional regulation and inhibitory control through interactive, personalised, and engaging digital content.

Alignment with Behaviour Change Frameworks

Behaviour Change Wheel (BCW):

- Education: Modules provide knowledge about PUI, emotional regulation, and impulsivity.
- Persuasion: Personalised feedback and motivational prompts encourage reflection and change.
- Enablement: Exercises and challenges build confidence and reduce psychological barriers.
- Training: Participants practise emotion regulation and inhibitory control strategies.
- Modelling: Examples and scenarios demonstrate adaptive behaviours.

COM-B Model:

- Capability: Built through educational content and skill development.
- Opportunity: Created via structured digital environments and real-life application prompts.
- Motivation: Enhanced through emotionally engaging content, feedback, and goal setting.

PRIME Theory:

- Plans: Participants are guided to set intentions and behavioural goals.
- Responses: Interactive tasks prompt immediate engagement with new behaviours.
- Impulses and Motives: Addressed through content targeting emotional and cognitive drivers of PUI.

Emotional (Affect) Regulation Intervention

This intervention aims to enhance emotional awareness and promote emotional competence in adolescents at risk of PUI. It begins with motivational modules on PUI, encouraging reflection through self-assessment, personalised feedback, and exercises to build confidence and readiness for change. The second phase focuses on developing functional emotion regulation skills using interactive, reflective, and gamified exercises.

Grounded in the BCW (Michie et al., 2011), COM-B model, and PRIME Theory (West & Michie, 2020), the intervention incorporates several mechanisms:

- **Education:** Informative content on emotions and PUI enhances understanding and capability. Educational games have been shown to reduce negative emotional experiences (Ferrari et al., 2022; Reynard et al., 2022).
- **Persuasion:** Personalised feedback and emotionally engaging messages promote motivation and behavioural reflection (Heijde et al., 2015; Yan et al., 2020).

- **Reframing:** Cognitive restructuring and self-monitoring support behavioural change, as shown in CBT-based interventions (Du et al., 2010; Park, S et al., 2016).
- **Enablement:** Confidence-building exercises, such as emotion memory games, reduce psychological barriers and support skill development (David et al., 2024).
- **Gamification:** Therapeutic games encourage the application of emotion regulation strategies in daily life, improving outcomes in PUI and emotional control (Ayub et al., 2023; David et al., 2024).
- **Behavioural Activation:** Participants are encouraged to try alternative, positive behaviours (e.g. reading, social interaction), which reduce maladaptive patterns (Park, S et al., 2016).

The intervention is tailored: those at higher risk receive in-depth modules on emotional regulation, expectations, and the link to PUI, while lower-risk participants receive general guidance on internet use and emotion regulation. The programme aims to foster adaptive emotional functioning and reduce risk behaviours (David & Fodor, 2023; Houck et al., 2022; Smith et al., 2024).

For a detailed week-by-week breakdown and more information on each component of the intervention in relation to behaviour change see Appendix A.

Inhibitory (Executive) control Intervention

This intervention aims to help adolescents understand and manage impulsivity and compulsive behaviours linked PUI. It begins with motivational modules encouraging reflection on internet use, supported by self-assessments, personalised feedback, and confidence-building exercises. The second phase focuses on strengthening inhibitory control through interactive challenges, educational content, and practical strategies.

The intervention is grounded in the BCW (Michie et al., 2011), COM-B model, and PRIME Theory (West & Michie, 2020), and incorporates the following mechanisms:

- **Education:** Informative content on impulsivity and inhibitory control enhances understanding and behavioural capability. Educational approaches have been shown to reduce impulsivity (Santos et al., 2025).
- **Alternative Behaviours:** Participants are encouraged to practise behavioural activation strategies (e.g. attention shifting, seeking support), which reduce maladaptive behaviours like PUI (Park et al., 2016).
- **Persuasion:** Personalised feedback and emotionally engaging messages promote motivation and behavioural reflection (Heijde et al., 2015; Yan et al., 2020).
- **Self-monitoring and Reframing:** Feedback based on self-monitoring supports cognitive restructuring and has been effective in improving self-regulation and reducing internet addiction (Dietvorst et al., 2024; Du et al., 2010; Park, S et al., 2016).
- **Enablement:** Confidence-building tasks (e.g. 3-day impulsivity challenge) help reduce psychological barriers and support change (David et al., 2024).
- **Gamification:** Therapeutic games reinforce inhibitory control strategies and have shown positive effects on PUI and impulsivity (Ayub et al., 2023; Zhan et al., 2024).

The intervention also draws on evidence supporting the use of cognitive behaviour therapy (CBT), motivational interviewing, and cognitive bias modification to reduce impulsivity (Aguilar-Yamuza et al., 2024; Kowalik & Delfabbro, 2025). Participants at high risk receive in-depth modules on impulsivity and its link to PUI, while those at lower risk receive general guidance on inhibitory control and internet use.

For a detailed week-by-week breakdown and more information on each component of the intervention in relation to behaviour change see Appendix B.

Control Condition

Participants in the control condition will receive a structured, digital, non-interactive educational programme. This content will be time-matched to the active interventions, to control for non-specific therapeutic effects associated with time spent engaging in the study. This approach also helps to minimise researcher allegiance bias, which can occur when using waitlist or "treatment as usual" controls.

- The educational material will cover general topics related to:
- Internet use and digital habits
- Emotional well-being
- Dysfunctional behavioural patterns
- Suggestions for alternative, healthier activities

Importantly, this control condition is informational only, with no interactive or skill-building components. This design is grounded in evidence suggesting that while providing information is a necessary foundation, it is not sufficient to produce meaningful behavioural change on its own (Humphreys et al., 2021). Research consistently shows that effective digital health interventions require interactive, motivational, and skill-based elements to facilitate actual behaviour change (Hou et al., 2014).

Thus, the control condition serves as a credible comparator that accounts for participant engagement and time investment, without introducing the active ingredients known to drive behavioural outcomes.

For a week-by-week transcript of the information given to the control participants please see Appendix C.

3.3. Study Design

Pilot Study

The Pilot Study is a controlled, individually randomised, observer-blinded, parallel group, three-arm trial. Participants will be allocated to:

Emotional (Affect) Regulation intervention: Strategies for improving affect regulation (affective responses to triggers, worrying), and increase in social skills see section 3.2 and appendix A.

Inhibitory (Executive) control intervention: Strategies for improving executive (inhibitory) control (boundary setting for internet usage, alternative activities, dealing with urges, habits and cognitive bias modification) see section 3.2 and appendix B.

Control: Manualised digital non-interactive information-provision (education) matched with A and B for time investment see section 3.2 and appendix C.

Each intervention will last for four weeks and will be preceded by a two-week baseline assessment period (see tables 1&2), with a post intervention outcome assessment conducted directly at the end of the four weeks intervention (primary end point), and a follow-up for outcome assessment conducted 3-months later (final end point). Figure 1 shows the flow chart detailing study processes, highlighting the stages leading from participant recruitment to final data analysis. At the end of each assessment and intervention time point participants will be asked to provide feedback about their experience of using the app and elements to evaluate the feasibility and acceptability of the app.

Outcomes: The full list of outcome measure assessments including the period of mobile sensing is shown in table 1 and further details about each assessment and mobile sensing variable can be found in section 6.1.1 The primary main outcome measure assessment for both the pilot study and the RCT will be PUI severity as measured using the PIUQ-SF-9 (Demetrovics et al., 2008). Outcomes will be assessed digitally via a series of self-report questionnaires after sending out push-notifications for invitation as well as reminders in case of non-completion. Additional outcome data is collected via the Dragon Game app, which includes cognitive assessment tasks for affect regulation and inhibitory executive control. As a complementary modality for secondary outcome assessment, smartphone behaviour (data tracking) will also be measured.

The research team are currently seeking funding to include an optional extension to Cohort 2. The optional cohort 2 extension will directly follow on immediately from the original 3-month assessment time point and will last a maximum of 28 months to extend data collection until the end of July 2028. Participants who consent to taking part in the extension phase of Cohort 2 will be followed up during this period, receiving push-notifications to complete assessments derived from the same panel as the original phase, every 3 months until the 31-month final endpoint. Additional data will be collected via the Dragon Game app, which includes the cognitive assessment tasks for affect regulation and inhibitory executive control. Should the research team be successful in obtaining funding, a push-notification will appear asking those who consented to take part in the extension to re-confirm their agreement will appear. Should the research team not be successful, a push-notification will appear thanking them for their consent and time but notifying them that this will be the end of their study involvement (see table 3 for an overview of the extension assessments).

Table 1. Schedule of Assessments outcome measures for both interventions and control.

Assessment/Intervention	Baseline T0 (week 0 to week 2)	Intervention (week 2 to week 6)	Post Intervention T1 (week 6)	Monthly ratings (cohort 2 & 3, week 10 & 14) (cohort 3 only, week 18, 22 & 26)	Follow-up Up T2 (Pilot cohort 2: week 18, RCT; week 30,)
Demographics					
Sex	X				
Gender	X				
Age	X				
Year group at school	X				
Mental Health diagnosis	X				
PUI and clinical variables					
S-CIUS*	X		X	X	X
PIUQ	X		X		X
ISAAQ-10 Part B	X		X		X
ISAAQ-ED	X		X		X
ACSID-5	X		X		X
DASS-21	X		X		X
PaedS	X		X		X
SOCS	X		X		X
SDQ	X		X		X
Browser activity	X		X		X
Inhibitory control					
BrainPac SST	X				X
CHI-T	X		X		X
Question on patience	X				X
Emotional regulation					
BrainPac VMAC	X				X
ERQ-CA	X		X		X
Question on mood	X				X
Persons' characteristics					
UPPS-P	X		X		X
Vaccine hesitancy	X				X
Misinformation	X				X
Physical health					
Height and weight	X				X

Favourite Sports interests	X			X
Internet use expectancies, Internet use experiences, FoMO				
IUES	X		X	X
EGS/ECS	X		X	X
SRHI	X		X	X
FoMO	X		X	X
School performance, family background,				
School marks	X			X
Family background	X			X
Socioeconomic status (FAS)				
Mobile sensing⁺				
Assessment of cost and burden of PUI				
PQ-LES-Q	X			X
EQ-5D-Y	X			X
Alcohol consumption	X			X
WHODAS 2.0	X		X	X
Ambulatory assessment (AmbA)[#]				
AmbA			X	X

Note. # Assessed for 7 continuous days. + Continuous recording, -> denotes the period of continuous recording *Collected monthly between T1 and T2, A number of these assessments will also be used during the Intervention (see table 2)

S-CIUS: Short-Compulsive Internet Use Scale

PIUQ: Problematic Internet Use Questionnaire

ISAAQ-10 Part B: Internet Severity and Activities Addiction Questionnaire - Focus on activities

ISAAQ-ED Internet Severity and Activities Addiction Questionnaire – Eating Disorder

ACSID-5: Assessment of Criteria for Specific Internet-use Disorders

DASS-21: Depression Anxiety Stress Scale

PaedS: Paediatric Self-Stigmatization Scale

BrainPac Stop-Signal-Task (SST)

SOCS: Short Obsessive Compulsive Disorder Screener

SDQ: Strengths and Difficulties Questionnaire

BrainPac-enhanced Value-Modulated Attentional Capture

ERQ-CA: Emotion Regulation Questionnaire for Children and Adolescents

UPPS-P: Urgency – Premeditation - Perseverance - Sensation Seeking - Positive Urgency

CHI-T: Cambridge–Chicago Compulsivity Trait Scale

IUES: Internet Use Expectancies Scale

EGS/ECS: Experience of Gratification Scale and Experience of Compensation Scale

SRHI: Self-Report Habit Index

FoMO: Fear of Missing Out Scale

FAS: Family affluence scale III

PQ-LES-Q: Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire

EQ-5D-Y: European Quality of Life 5 Dimensions

WHODAS 2.0: World Health Organisation Disability Assessment Schedule (adapted for internet use)

Table 2. Schedule of Intervention Assessments and Tasks intrinsic to, for both interventions with high and low PUI.

Assessment/Intervention	Intervention I (4 weeks, weeks 3-6)			
	N3	W4	W5	W6
Both Interventions				
PUI and clinical variables				
S-CIUS	X			
PRISM Internet				
Browser activity	X	X	X	X
Mood-Barometer	X	X	X	X
Self-developed PRISM Internet	X>			
Persons' characteristics				
RR & SER	X			
DBQ-I	X			
Need to belong	X			
UCLA Loneliness Scale	X			
Sofalizing scale	X>			
Internet use expectancies, Internet use experiences, FoMO				
IUES	X>			
FoMO	X>			
FoMO single	X			
Mobile sensing⁺ including App Sessions and Aggregated App usage				
Ambulatory assessment (AmbA)[#]				
AmbA		X>		
Emotional Regulation intervention				
Emotion Memory game		X		
ERQ-CA		X		
Components and functions of emotions video		X		
Pictures with functions of emotions		X		
Emotions and Internet use			X>	
Emotion regulation strategies			X	
Transfer of strategies			X	
Connecting emotion with thoughts (psychoeducation)				X
Connecting Emotion with thoughts (memory game)				X

Transfer to daily life				X>
Emergency plan				X
Inhibitory control intervention				
UUPS-P		X>		
CHI-T		X	X	
Impulsive Behaviour/consequences video		X		
Challenge to observe behaviour		X	X	
Skills for impulse control			X	
Psychoeducation (text) connecting impulsivity with PUI			X>	
Specific alternative behaviours for PUI			X>	
Dealing with problems				X>
Transfer of strategies				X>
Emergency plan				X>
Additional Intervention tasks both intervention A and B				
Breath analyser				
Positive self-instructions				

Note. # Assessed for 7 continuous days, -> denotes the period of continuous recording. + Continuous recording, > High PUI risk group only.

S-CIUS: Short-Compulsive Internet Use Scale

PRISM Internet, self-developed importance activity

RR & SER: Readiness and Self-efficacy Ruler

DBQ-I: Decision Balance Questionnaire

ERQ-CA: Emotion Regulation Questionnaire for Children and Adolescents

UPPS-P: Urgency – Premeditation - Perseverance - Sensation Seeking - Positive Urgency

CHI-T: Cambridge–Chicago Compulsivity Trait Scale

IUES: Internet Use Expectancies Scale

FoMO: Fear of Missing Out Scale

FoMO single: Fear of Missing Out single question

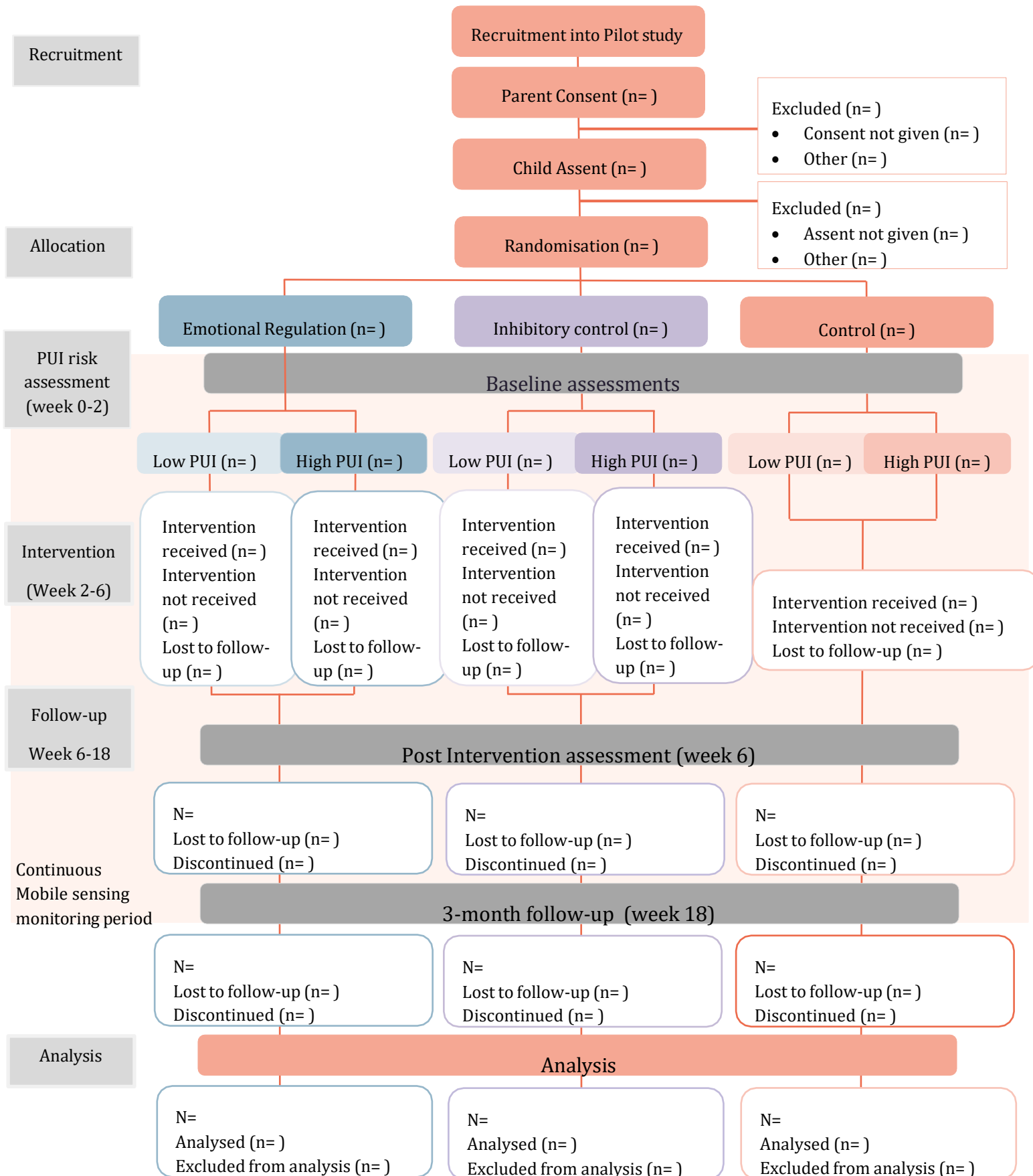


Figure 1. Flow diagram of Pilot study. For the control group, the division into high and low PUI risk will be for analysis purposes only. The two theory driven interventions (emotional regulation; inhibitory control) are delivered as high and low intensity versions, based on assessment of PUI risk at baseline. However, both low and high intensity forms of intervention are analysed collectively within each theoretical interventional model.

Table 3: Schedule of assessments for the optional extension to the pilot cohort (cohort 2). At week 18 of the pilot study, participants receive a push notification to re-confirm agreement to take part in the study extension. Assessments then take place at the indicated time-points.

Variable	Assessment time-point (months after entry to the extension period)																											
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
PUI and clinical variables																												
S-CIUS	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
PIUQ						x						x						x						x				
ISAAQ-10 Part A						x						x						x						x				
ISAAQ-10 Part B						x						x						x						x				
ISAAQ- ED						x						x						x						x				
ACSID-5						x						x						x						x				
DASS-21						x						x						x						x				
Alcohol items						x						x						x						x				
PaedS						x						x						x						x				
Vaccine Hesitancy						x						x						x						x				
Misinformation						x						x						x						x				
Browser activity						x						x						x						x				
Inhibitory control																												
BrainPac SST													%												%			
Emotional regulation																												
BrainPac VMAC													%												%			
Physical health																												
Height and Weight			x						x						x					x							x	
Internet use expectancies, experiences and fear of missing out																												
IUES			x						x						x					x							x	
EGS/ECS			x						x						x					x							x	
FoMO			x						x						x					x							x	
Mobile sensing+																												
Assessment of cost and burden of PUI																												
PQ-LES-Q			x						x						x					x							x	
EQ-5D-Y			x						x						x					x							x	

Note: + Continuous recording, -> denotes the period of continuous recording. % Optional assessment, with additional incentive offered for completion (in countries using incentives, incentive to be determined by individual sites).

PUI: *Problematic Use of the Internet*;
S-CUIS: *Short-Compulsive Internet Use Scale*;
PIUQ: *Problematic Internet Use Questionnaire*;
ISAAQ-10 Part A: *Internet Severity and Activities Addiction Questionnaire* – Focus on symptom severity;
ISAAQ-10 Part B: *Internet Severity and Activities Addiction: Questionnaire* – Focus on activities; ISAAQ-ED: *Internet Severity and Activities Addiction Questionnaire– Eating Disorder*;
ACSID-5: *Assessment of Criteria for Specific Internet-use Disorders*;
DASS: *Depression Anxiety Stress Scale*;

PaedS: *Paediatric Self-Stigmatization Scale*;
BrainPac SST: *BrainPac Stop-Signal-Task*;
BrainPac VMAC: *BrainPac- enhanced Value-Modulated Attentional Capture*;
IUES: *Internet Use Expectancies Scale*;
EGS/ECS: *Experience of Gratification Scale and Experience of Compensation Scale*; FoMO: *Fear Of Missing Out Scale*;
PQ-LES-Q: *Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire*;
EQ-5D-Y: *European Quality of Life 5 Dimensions*.

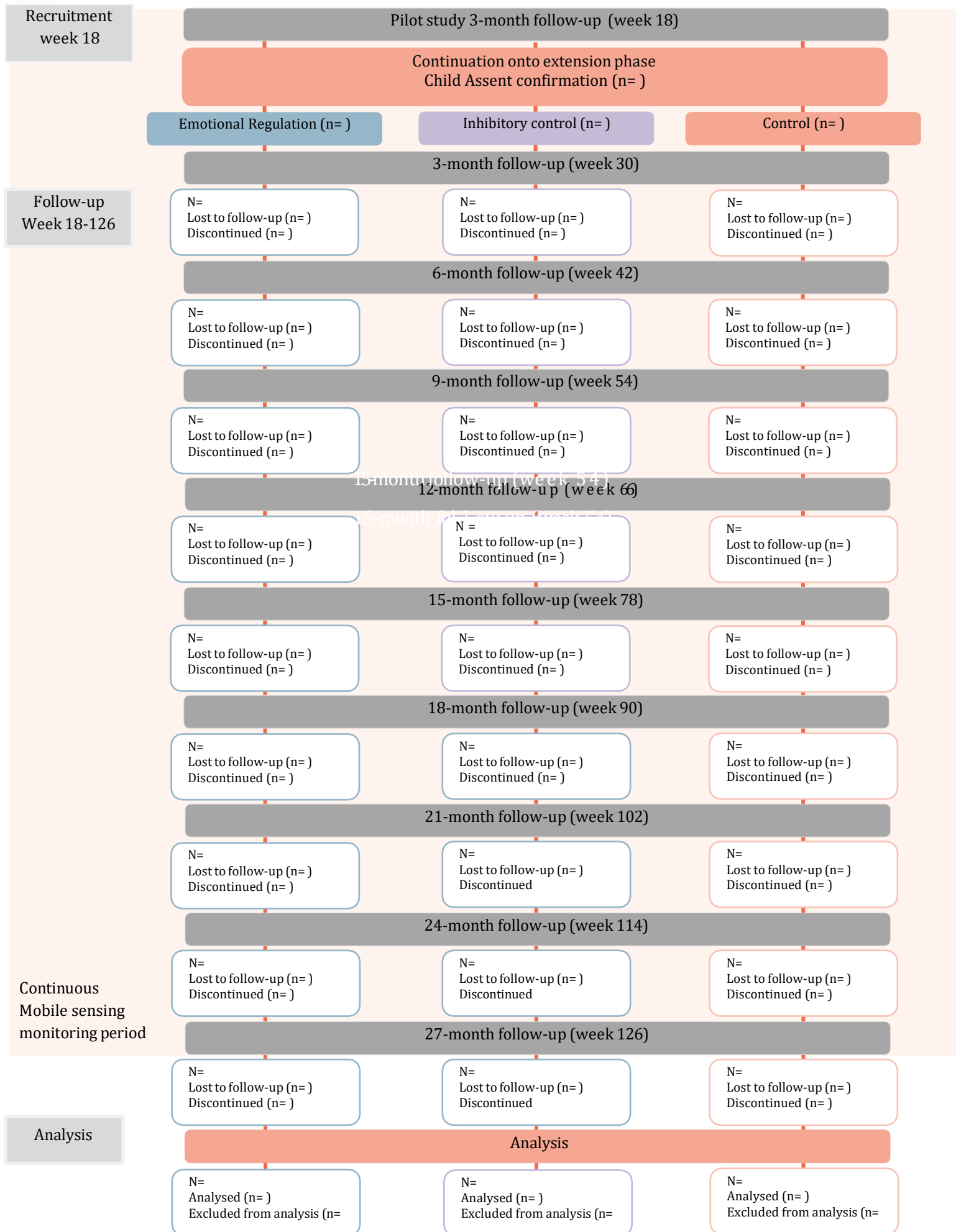


Figure 2. Flow diagram of the optional extension phase. Participant will initially consent to the extension phase during the consent process of the Pilot study. At the 3-month follow-up participants who consented to take part in the extension phase will be sent a push notification through the app to confirm their assent to continue. The 3-month follow-up assessments will be used as a baseline measure for the extension phase.

Randomised Control Trial

The RCT is a controlled, individually randomised, observer-blind, parallel-group, three-arm trial. Participants will be allocated to:

Tailored Arm: Tailored allocation to the Emotional regulation intervention or the Inhibitory control intervention based on prediction of outcome algorithms developed in the Pilot Study.

Random Arm: Random allocation to the Emotional regulation intervention or Inhibitory control intervention.

Control Arm: non-interactive information-provision (education) on safe and effective use of the internet.

Each intervention will last for four weeks, preceded by a two-week baseline assessment (see tables 1&2) period, with a post intervention outcome assessment conducted directly at the end of the four weeks intervention (primary end point), and a follow-up for outcome assessment conducted 6-months later (final end point). Outcomes will be assessed digitally via a series of self-report questionnaires after sending out push-notifications for invitation as well as reminders in case of non-completion. Additional outcome data is collected via the Dragon Game app, which includes cognitive assessment tasks for affect regulation and inhibitory executive control. As a complementary modality for outcome assessment, smartphone behaviour (data tracking) will also be measured. Figure 3 shows the flow chart detailing study processes, highlighting the stages leading from participant recruitment to final data analysis.

Outcomes: The full list of outcome measure assessments including the period of mobile sensing is shown in table 1 and further details about each assessment and mobile sensing variable can be found in section 6.1.1. The primary main outcome measure assessment for both the pilot study and the RCT will be PUI severity as measured using the Problematic Internet Use Questionnaire in its short version (PIUQ-SF-9)(Demetrovics et al., 2008) Outcomes will be assessed digitally via a series of self-report questionnaires after sending out push-notifications for invitation as well as reminders in case of non-completion. Additional outcome data is collected via the Dragon Game app, which includes cognitive assessment tasks for affect regulation and inhibitory executive control. As a complementary modality for secondary outcome assessment, smartphone behaviour (data tracking) will also be measured

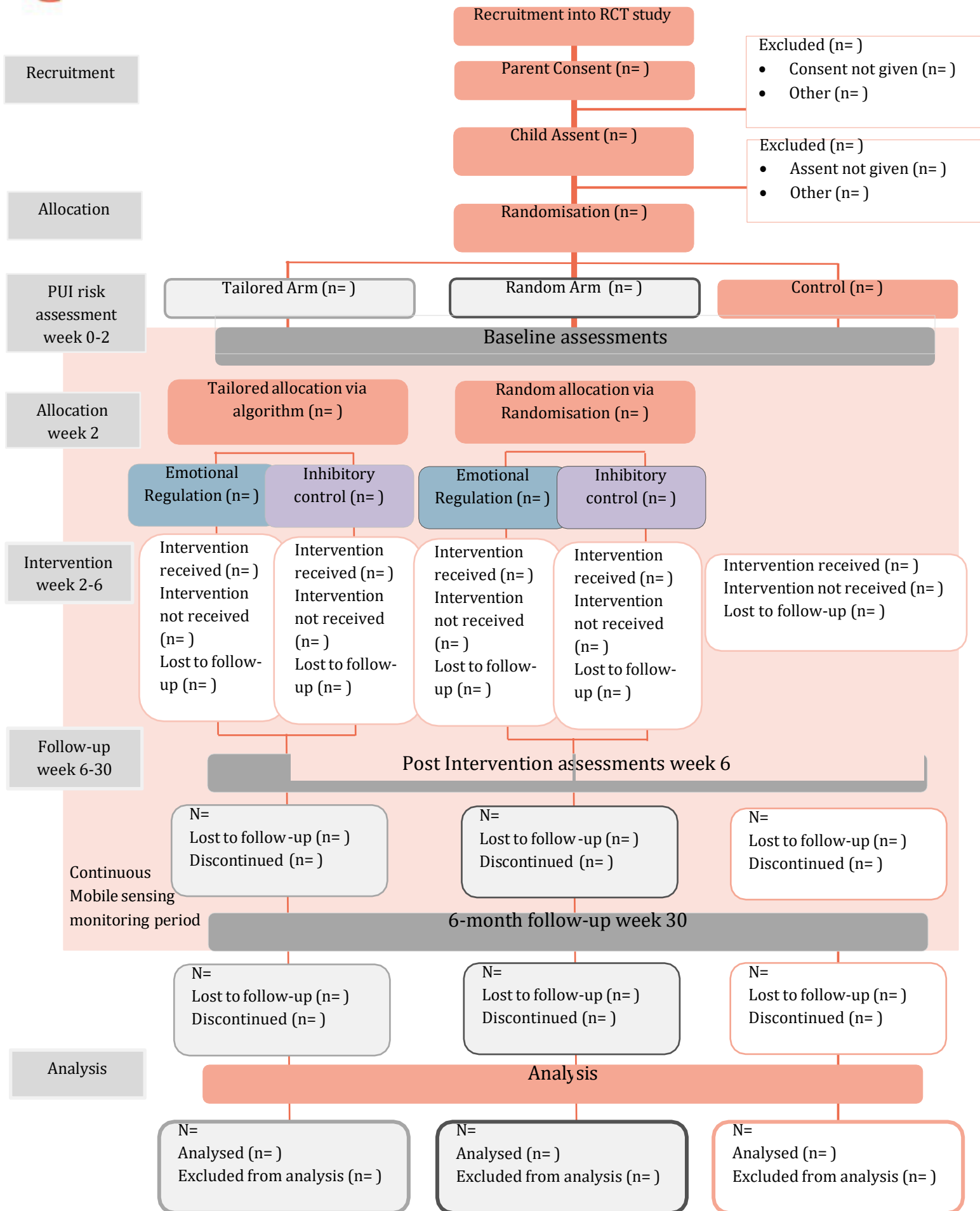


Figure 3. Flow diagram of RCT study. Allocation takes place twice; at week 0 all participants are randomised to either the tailored allocation arm or the random allocation arm or the control arm. At week 2 participants in the tailored allocation arm are allocated to the emotional regulation intervention or the inhibitory control intervention based on prediction of outcome algorithms developed in the Pilot Study. In the random allocation arm participants are randomised to either the emotional regulation arm or the inhibitory control arm. Regardless of the theoretical model of intervention (emotional regulation; Inhibitory control) all participants in either the tailored allocation arm or the randomised allocation arm will be analysed together as we are interested in the effect of the method of allocation on outcomes.

3.4. Study Participants

3.4.1. Approaching study participants

Local research teams have established links with schools involved in the earlier assessment study and have secured interest for participation in the pilot and RCT. Student ambassadors (see Section 9) contributed to the development of study materials and both the assessment and intervention apps. Within participating schools, selected classes are invited to join the study. Parents are informed in advance and asked to provide consent (see Section 4.3). During school hours, local researchers and BootStRaP Ambassadors (teachers or students) introduce the study, answer questions, and obtain student assent. Participation is entirely voluntary, with no pressure from schools.

3.4.2. Sample size, basic assumptions

The pilot study and the RCT study are the second and the third in a series of three studies building upon each other, which will be conducted within the BootStRaP project. Therefore, considerations regarding sample size and power estimates include the prospect of interventions introduced in subsequent studies. As yet, there is little evidence of the effectiveness of this kind of intervention on PUI (specifically as measured by the PIUQ).

For the pilot study we assume $\alpha=0.05$, $1-\beta=0.8$, and a small effect size $d=0.3$, giving a required sample size $n=176$ per group. We assume 70% of randomised young people will complete follow-up. We also assume that 30% of children are high risk. To provide a cohort of 176 high risk children followed up requires a total sample of $n=838$ per group ($n=176/0.3/0.7$). The pilot study assumes 3 groups (random allocation to the Emotional regulation intervention, the Inhibitory control intervention, and a control groups). A 4th group of equivalent size to each study arm is required for validation of the algorithm developed in the machine learning phase; this group will be drawn at random from the sample allocated to each study arm. This giving a total sample size of $4*838= 3352$, or 373 per study site. All other analyses are secondary and will be evaluated using appropriate GLM models.

For the RCT, we assume $\alpha=0.05$, $1-\beta=0.8$, with cluster size=30 and effect size $d=0.3$, requiring $n=176$ per group. To allow for 70% completion, and 30% of children at risk, the total per group $N=838$. For the trial the sample size is $3*N=2514$ or 279 per study site.

4. Study Procedures

4.1. Study Setup

Ethics approvals for both the pilot study and RCT will be obtained from the nine collaborating academic institutions, either through joint or separate applications, depending on local requirements. The

University of Hertfordshire, as lead organisation, will provide standardised study documents (protocol, information sheets, consent/assent forms), which can be locally adapted. The study will be registered on ISRCTN.

BootStRaP Ambassadors (teachers and students) have been recruited at each site, and all participating centres will receive training in study procedures, including Good Clinical Practice (GCP) where needed. Governance is supported by a structured framework comprising a project office, steering committee, general assembly, and advisory boards (scientific, ethics, and impact). An independent reviewer will monitor study procedures and report to the project office and steering committee.

The BootstrApp Intervention app, which will manage questionnaires, mobile usage tracking, randomisation, and intervention delivery, is in development and expected to be ready by mid-2025. The Dragon Game app for BrainPAC tasks will also be completed within this timeframe. A secure data storage system, overseen by UZL, will store all assessment and intervention data.

A dedicated project website, www.internetandme.eu, provides information on this and related BootStRaP studies.

4.2. Recruitment

Each of the nine participating countries has established partnerships with local schools previously involved in the assessment app study, with agreements to continue in the BootStRaP project. At each school, at least one teacher and one student serve as BootStRaP Ambassadors, supporting engagement and retention throughout the pilot and RCT phases. Additional schools will be recruited if needed.

Where available, student organisations will also be engaged to support recruitment. Locally appropriate incentives (e.g. lotteries, competitions, or honoraria) will be used to encourage participation, tailored to each centre's context.

Local researchers and BootStRaP Ambassadors will introduce the study to students, explain its purpose, and demonstrate the BootstrApp Intervention app and Dragon Game app, which will be installed on students' smartphones. Students will have the opportunity to ask questions during these sessions.

Parents or guardians will receive an information pack and be invited to attend at least one session to learn more and ask questions. Participation requires parental consent and student assent. A holding page on the BootstrApp will require a unique code, provided during the information session, to confirm consent, assent, and school affiliation.

4.2.1. Study Campaign

During the assessment app study, national and local publicity campaigns were launched to raise awareness of the BootStRaP project. These included outreach through schools, community groups, local media, and digital platforms to engage students, parents, educators, and policymakers. As the project moves into Phase 2 (pilot and RCT), these efforts will be expanded with support from university press offices and international campaigns.

Delegates from candidate schools in each region will be invited to participate, helping to generate interest and enthusiasm. The research team will maintain regular communication with schools, offering detailed discussions of the study protocol to encourage involvement.

The BootStRaP consortium brings strong experience in media engagement, school collaboration, and adolescent recruitment, which will be leveraged to maximise recruitment, strengthen stakeholder engagement, and support the project's long-term impact across Europe.

4.3. Consent and Assent

For both studies, consent will be obtained prior to participation by parent or guardian for the student's participation and assent from the student. Where needed, the general consent procedure described below is adapted to local requirements.

Although in several countries some of the young people will be old enough to provide informed consent for themselves, as all children will be recruited through schools, we will ask for parental consent for all. Parents or guardians will be asked to provide consent (on behalf of their child), and children will be asked to provide assent to take part. Both parent or guardian consent and student assent will be collected either on paper or electronically outside of the app.

Those who consent to take part in Cohort 2 will also be invited to provide consent to the extension phase. Participants can still take part in Cohort 2 without consenting to take part in the extension phase. Those who consent to take part in both, will receive a push notification before the start of the extension asking them to re-confirm their agreement.

Parent or Guardian Consent

Parents or guardians will receive an information pack including instructions on how to provide consent. Depending on local circumstances, parents or guardians will also have the option to attend an information session if they want to find out more about the study. After being fully informed, they will be asked to give consent for their child's participation by completing an Informed Consent Form (ICF), either on paper or online (dependent on school policies and local requirements). A parent or guardian must give consent before their child can give their assent to take part. If they choose not to allow their child's participation, they can indicate this on the consent form.

Student Assent

Students who wish to participate will give their assent by agreeing to the statements in an assent form, on paper or online or by directly indicating their agreement to the researchers, depending on school policies and local requirements.

Downloading of the BootstrApp Intervention app

The study apps can be downloaded from a smartphone app store. Students who wish to take part will be asked to download the BootstrApp and Dragon Game App to their smartphone, with help from a parent, carer or researcher where needed.

Students can choose their preferred language on the BootstrApp. A holding page will then appear, stopping them from proceeding until consent and assent has been verified by a research team member.

Student Session

Students within the designated age range will be invited to attend an information session hosted by the research team and, possibly, their school ambassadors.

The research team will verify that both the parent or guardian's Informed Consent Form (ICF) and the student's assent has been provided. Once both have been confirmed, a unique code will be assigned to the form(s), and the student will be asked to enter this code into the BootstrApp. Once this code is entered, the student is officially enrolled and will begin the two-week assessment phase. The unique codes will be automatically generated before recruitment begins by the app development team and will consist of 8 alphanumeric characters.

Depending on local circumstances, the above activities may not all take place during a single information session but may be arranged separately.

The unique code ensures that the student's assent can be linked to their parent's authorisation if needed, such as in cases of premature withdrawal, and confirms that parental or guardian consent has been obtained. This code also identifies the time zone to send push notifications at the correct times and the school. For students whose parents have opted out, it will be clearly communicated that they will not be able to participate.

4.4. Baseline

Once enrolled in the pilot or RCT, students will begin automated data collection via the BootstrApp Intervention app. The list of baseline (T0) questionnaires is provided in Table 1.

Depending on local school agreements, assessments may be completed during class or at home. To support retention, students can complete the assessments in one sitting or across multiple days. While the target is to complete baseline assessments within 4 days, the window may be extended to 14 days if needed.

4.5. Randomisation

In both the pilot and RCT studies, randomisation will be carried out using individualised, server-based assignment, based on each participant's access code at registration.

Pilot study: For the pilot study each participant will have an equal probability (33.3%) of being allocated to one of the three groups: Emotional regulation intervention group, Inhibitory control intervention group, or the control group.

RCT: For the RCT, each participant will have an equal probability (33.3%) of being allocated to one of three arms: tailored allocation, random allocation, control. This means that participants will have a 66.6% chance of allocation to an active intervention and 33% chance of allocation to the control arm.

Participants allocated to the random allocation arm will have a 50% chance of receiving the emotional regulation or inhibitory control intervention.

In the tailored allocation arm, participants will receive the intervention (targeting emotional regulation or inhibitory control) predicted as most likely be effective for them by comparing their baseline profile (against the profile of response-predictors developed during the pilot study. .

For both the pilot study and the RCT, both participants and researchers will remain blinded to the group allocation to minimise bias. The statistical analysis will be completed on blinded data (allocation A, B or C), with the blinding only being broken when the primary analysis has been completed.

4.6. Intervention

In both the pilot and RCT study interventions (emotional regulation, inhibitory control and control) as described in section 3.2 will be delivered and completed through the app (see table 2 for a breakdown intervention tasks). On average, participants are asked to complete assigned tasks of the intervention (or for the control group, read presented information) every 2 days over a period of 4 consecutive weeks. The tasks will be delivered through the BootstrApp intervention app with participants being notified of a task to complete via automated push notification.

Within the two intervention arms (targeting emotional regulation or inhibitory control), participants are categorised according to their risk for PUI, using the baseline S-CUIS score with scores of ≥ 9 indicating high risk of PUI. Participants at high risk for PUI are given access to additional intervention elements that either address emotion regulation or inhibitory control in the context of problematic Internet use.

4.7. Follow up Procedures

The BootstrApp Intervention app will guide study participants through assessment and intervention blocks, granting access to information about upcoming tasks directly on its home screen. Automatic push notifications will be sent to prompt completion of upcoming questionnaires/intervention tasks. Automated reminders will be dispatched through the app to ensure timely participation. Depending on individual agreements with schools, the young people can have the possibility to complete their assessments in class and local researchers can arrange visits in class or schools together with school ambassadors, to increase motivation and reinforce awareness of the upcoming assessments/interventions. The complete schedule of assessments and interventions including baseline and subsequent assessments is presented in Table 1 and Table 2. Further detailed information about each assessment can be found in section 6.1.1 and about the interventions in section 6.1.2.

4.8. End of Study

The study will conclude once all participants have completed their assessments and interventions, or when the final assessment window closes. The University of Hertfordshire (UoH) will notify study centres when this point is reached.

End-of-study declarations will be submitted to local ethics committees in accordance with their regulations (e.g. within 90 days, where applicable).

To acknowledge their participation, students who complete the minimum dataset will receive a certificate and compensation at the end of the 3-month (pilot) or 6-month (RCT) follow-up. Additional compensation will be provided for those in the pilot extension. Centres may offer vouchers or prize draws, with formats tailored to local preferences.

Participants will also have the option to receive feedback via the BootstrApp, either during the intervention (where relevant) or after study completion. Feedback may include screen time, app usage, and selected questionnaire results. Participants can choose to view only their own data or compare it with aggregated group data.

4.9. Withdrawal and discontinuation

Participation in both studies is voluntary and study participants who wish to discontinue can opt out at any time without giving a reason. Participants can cancel their study participation in the “Cancel Participation” submenu inside the BootstrApp Intervention app and then deleting both apps. The submenu includes a description of the implications of withdrawing from the study and a designated button to withdraw. Signing off the study results in an immediate stop of all data collection. Due to anonymisation of data for Machine Learning and the data backup strategy, already transmitted data cannot be deleted, and this will be made clear in the participant information. Further processing will either take place pseudonymously (only for BootStRaP partners that have signed the Data Sharing Agreement) or anonymously (everyone else). The young people are informed before consenting on how they can withdraw, and that the deletion of data up to the point of withdrawal will not be possible.

5. Safety

The BootStRaP study involves a community sample of generally healthy young people, not patients, with survey-based assessments primarily using validated questionnaires. These assessments are not expected to cause distress, and participants are informed that they can withdraw at any time without providing a reason. To prioritise participant safety and well-being, the BootstrApp Intervention app includes a dedicated submenu that signposts young people to appropriate school-based, local, or national mental health support services if needed. This signposting content was developed and utilised within Phase 1 of the BootStRaP project and will be reviewed and updated where necessary for use within Cohorts 2 and 3. The participants are advised within their information sheet that as the interventions provided are not clinical treatments, the research team are not able to provide healthcare support or guidance and for any health concerns or support the team recommend consulting with a healthcare professional or using the contacts within the App.

6. Data Collection, Management and Analysis

6.1. Data Collection

Both the pilot study and RCT are controlled, randomised, observer-blind, parallel group, three-arm trials.

Data will be automatically recorded via the BootstrApp Intervention app, which was specifically developed for this study. The Dragon Game app will be used alongside the BootstrApp Intervention app to conduct cognitive assessment tasks focusing on affect regulation and inhibitory executive control.

Participants will primarily interact with the BootstrApp Intervention app, which will seamlessly guide them through all data collection activities, including automatic redirection to the Dragon Game app for cognitive assessments. This streamlined approach ensures a user-friendly experience, with minimal direct interaction required beyond the initial app installation.

To maintain participant anonymity, no names or contact information will be collected within the apps. The questionnaires and cognitive paradigms will be administered in multiple languages (Dutch, English, French, German, Hungarian, Lithuanian, Portuguese, and Spanish). Where translations are not already available, instruments will undergo a rigorous translation process, including double independent translation, back-translation into English, and validation by an expert panel from the UoH with mental health research expertise.

The measured variables are aligned with the key determinants outlined in the logic model (Figure 4). Where required, permissions and licence agreements with copyright holders of the assessment instruments have been secured to ensure compliance and ethical standards.

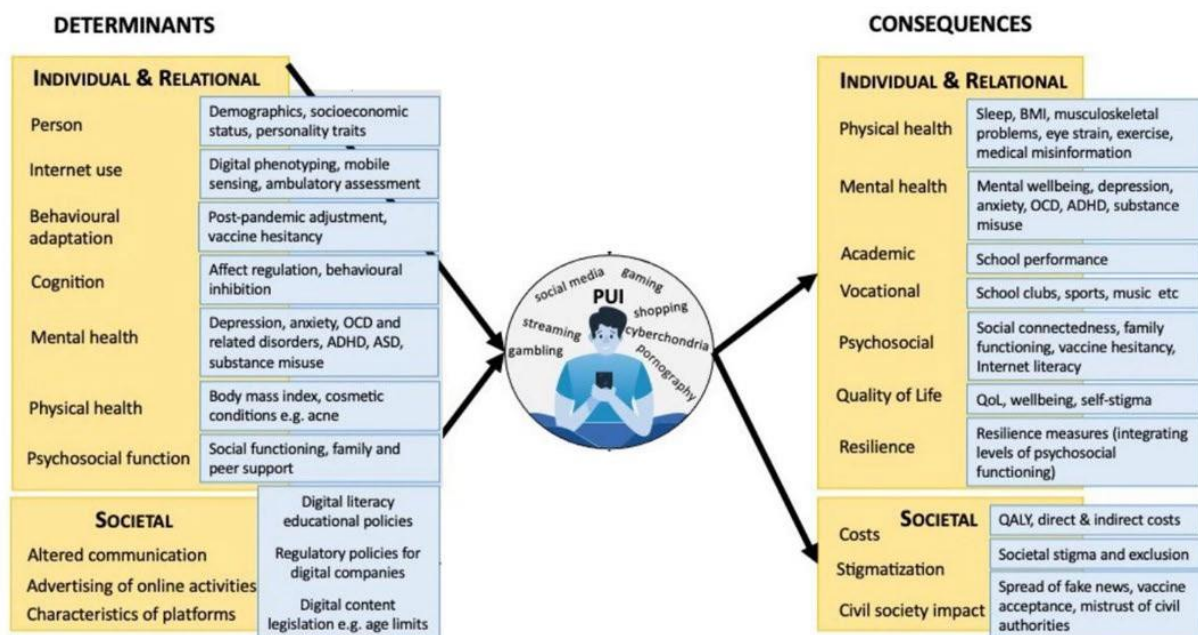


Figure 41. The logic model of PUI (based on (Brand, 2022; Brand et al., 2019).

6.1.1. Assessment tools

Demographic information.

Questions on demographic information at T0 include age, year group at school, sex, gender and any current mental health diagnosis such as ADHD, OCD, Depression etc. The study unique code (see section 4.3) encodes participant's school and country of residence.

Core Determinants and Outcomes

PUI and clinical variables

- The **Compulsive Internet Use Scale** (CIUS) (Meerkerk et al., 2009) will be used in its 5-item short version (S-CIUS) (Besser et al., 2017) and is the primary outcome measure in this study and assesses severity of compulsive internet use. A cut-off of 9 will be used to determine high risk of PUI as identified during the assessment phase.
- The **Problematic Internet Use Questionnaire** (PIUQ) (Demetrovics et al., 2008) will be used in a shorter version (PIUQ-9) (Laconi et al., 2019). The PIUQ-9 assesses three aspects of PUI: obsession, neglect and control disorder.
- The **Internet Severity and Activities Addiction Questionnaire** (ISAAQ-10 (Ioannidis et al., 2023)(Part B) assesses which kinds of activities are done on the internet. Additionally, the ISAAQ-ED (Ioannidis & Chamberlain, 2020) captures internet activities related to eating disorders. Psychometric properties of scales have been evaluated and confirmed (Ioannidis et al., 2023)
- A short version of the **Assessment of Criteria for Specific Internet-use Disorders** (ACSID-11; (Müller et al., 2022)), the ACSID-5 will be used to measure the extent of symptom severity for the most prominent forms of problematic internet use behaviours (i.e., gaming, gambling, social networking, buying-shopping, pornography use) (Müller et al., 2022).
- The 21 Item version (DASS-21) (Lovibond & Lovibond, 1995; Szabó, 2010) of the **Depression Anxiety Stress Scale** (Lovibond & Lovibond, 1995) used to assess symptoms of depression, anxiety, and levels of stress.
- The **Paediatric Self-Stigmatization Scale** (PaedS) (Kaushik et al., 2017) measures self-stigma in children.
- In addition, participants will also be asked about their **Mood** using a mood barometer.
- The Short **Obsessive Compulsive Disorder Screener** (SOCS) (Piqueras et al., 2015; Uher et al., 2007) will be used as self-report measure for obsessive compulsive disorder symptoms.
- The **Strengths and Difficulties Questionnaire** (SDQ) (Goodman, 2001) will be used to assess emotional and behavioural difficulties.
- Participants will be 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.

Inhibitory (Executive) control

- The **Stop-Signal-Task** (SST) (see figure 5) is a well-established measure of response inhibition (Verbruggen et al., 2019). A meta-analysis found moderate deficits in SST performance among individuals with PUI ($g = 0.42$), regardless of subtype (Ioannidis et al., 2019). supporting its use as a general PUI risk indicator.

The **enhanced SST**, developed as part of the **BrainPAC**(Project - The BrainPark Assessment of Cognition (BrainPAC) Project | BrainPark, n.d.) is gamified: players move a character to restock arrows (go trials) and must withhold responses when a dragon appears (stop trials, 30%). A

points-based reward system, progress bar, and sound effects are included to maintain engagement and discourage strategic slowing. The task includes 10 practice and 150 test trials, with stop-signal delay (SSD) staircased from 200ms. The key outcome, Stop Signal Reaction Time (SSRT), is calculated using integration methods (Verbruggen et al., 2019)

- The **Cambridge–Chicago Compulsivity Trait Scale** (CHI-T) (Chamberlain & Grant, 2018) will assess compulsivity traits such as perfectionism, reward seeking, and avoidance of uncertainty.
- Additionally, every eight days, participants will respond to a single-item measure of patience - “How impatient have you been today?” (1 = not at all, 10 = very much)—as a simple, repeated indicator of inhibitory control over time.

Emotional (Affect) regulation.

- The **BrainPAC** (Project - The BrainPark Assessment of Cognition (BrainPAC) Project / BrainPark, n.d.) **enhanced value-modulated attentional capture** (VMAC) task (see Figure 5) assesses reward-related attentional biases, which are linked to addiction vulnerability (Albertella et al., 2017; Le Pelley et al., 2015). In this gamified task, participants search for a target (a teammate) among distractors (opponents), one of whom has brightly coloured hair. The distractor’s hair colour signals the potential reward size—high or low—but is never the target itself. This creates a Pavlovian association, where attention is drawn to reward cues even when they are irrelevant to the task. Participants with stronger attentional capture by high-reward distractors (i.e. ‘sign-trackers’) show slower responses, indicating a susceptibility to maladaptive reward processing, a trait associated with PUI risk (Albertella et al., 2020). In contrast, ‘goal-trackers’ respond faster on high-reward trials, showing more adaptive attentional control.
- **Reversal learning.** We extend the above VMAC task to include a reversal phase (referred to as the VMAC-reversal, or VMAC-R task), where reward associations are switched. This extension measures cognitive flexibility and the persistence of reward-driven biases, offering further insight into compulsivity and risk for addictive behaviours (Albertella et al., 2020).

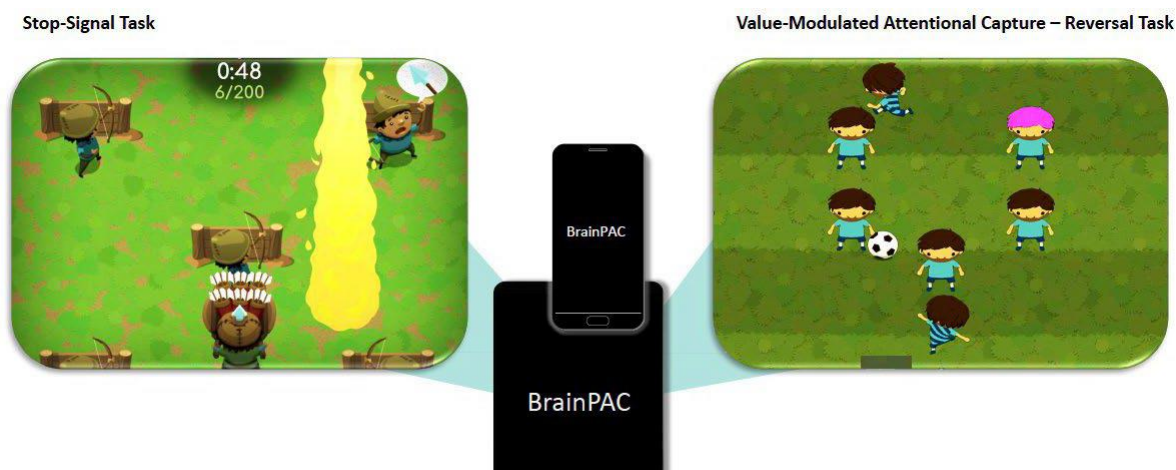


Figure 5. The BrainPAC-enhanced SST and VMAC

- The **Emotion Regulation Questionnaire for Children and Adolescents** (ERQ-CA) (Gullone & Taffe, 2012) will be used to assess two core emotion regulation strategies in a developmentally appropriate manner.

- Additionally, every eight days, participants will respond to a single-item measure of affect regulation: “How was your mood today?” (1 = very stable, 10 = like a yo-yo). The scale anchors reflect the regulation aspect, offering a simple, repeated indicator of emotional stability over time.

Moderating/mediating variables

Person's characteristics

- The **Urgency – Premeditation - Perseverance - Sensation Seeking - Positive Urgency** (UPPS-P) (Geurten et al., 2021; Lynam et al., 2006) will be used to assess five facets of impulsivity: negative urgency, lack of premeditation, lack of perseverance, sensation seeking, and positive urgency (Heather et al., 2008)
- A custom designed 2 item **Vaccine Hesitancy Scale** (VHS) will be used to assess the degree to which individuals would like to receive a vaccination if it was available.
- To assess **Misinformation**, study participants will be asked to rate on a visual analogue scale how much of the information on the internet they believe to be true (0% to 100%).

Physical health

- **Students' height (in cm) and weight (in kg)** will be recorded and used to calculate the *body mass index* (BMI) that will be compared against a national BMI-for-age reference standard since the BMI varies with age and sex (Must & Anderson, 2006).
- Similarly, we will record students' **favourite sport interests** or exercise activities in order to account for physical activity as a protective factor for physical health.

Internet use expectancies, experiences, FoMO

- The **Internet Use Expectancies Scale** (IUES) (Brand et al., 2014) will be used to assess consequential expectancies of internet usage.
- The **Experience of Gratification Scale and Experience of Compensation Scale** (EGS/ECS) (Wegmann et al., 2022) will be used to assess the experiences that individuals have while using the internet.
- The **Self-Report Habit Index** (SRHI) (Verplanken & Orbell, 2003) five items from the index will be used to assess the habitual nature of a participants internet use.
- The **Fear of Missing Out Scale** (Przybylski et al., 2013) will be used in an adapted version (Wegmann et al., 2017) that can assess an online-specific FoMO. Only the online-specific FoMO subscale will used for hypotheses and analyses in this study.

School performance, family background, vaccine hesitancy

- To assess **school performance** of the adolescents, we will ask them in the form of an open text field to type in their mean marks of the last school year.
- To assess the family background, we will ask for the two important family resources among adolescents, namely affect (i.e., “How do you rate the quality of relationships in your family?”) and communication (i.e., “How do you rate the communication in your family?”). Both questions can be answered on 5-point Likert scales ranging from 0 = not good at all to 4 = very good.
- To assess socioeconomic status, three items of the **Family affluence scale III** (FAS)(Torsheim et al., 2016) are used. The three items with the highest factor loadings (the family owning a car, number of bathrooms and presence of a dishwasher) were chosen for this study.

Cost and Burden of PUI variables

- The ***Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire*** (PQ-LES-Q) (Endicott et al., 2006) will be used as a measure for the clinical status of children and adolescents.
- The ***EQ-5D-Y*** (Wille et al., 2010) will be used as a child-friendly measure of general health status and as behavioural risk factor surveillance.
- Following NIAAA guidelines, two brief items will assess **early alcohol risk in adolescents**: one on peer drinking (e.g. “Do you have any friends who drank alcohol in the past year?”) and one on personal use (e.g. “In the past year, on how many days have you had more than a few sips of alcohol?”). Item wording and order vary slightly by school level. Further details are outlined in the YouthGuide (National Institute on Alcohol Abuse and Alcoholism, n.d.).
- The ***World Health Organisation Disability Assessment Schedule*** (WHODAS 2.0) (Janca et al., 1996) has been adapted for Internet use and will be used as a 9-item self-report measure of Health and disability (Janca et al., 1996).

Mobile sensing

Mobile sensing involves the passive collection of behavioural data via smartphone sensors, requiring no active input from users (Montag & Rumpf, 2021). This method helps bridge the gap between self-reports and objective behaviour, addressing time distortion issues common in PUI (Carmi et al., 2022).

Throughout the pilot, extension, and RCT phases, the **BootstrApp** will passively record digital footprints, including screen time, app usage, session duration, and login frequency for the full duration of the study. All data will be time-stamped to support time-based and machine learning analyses.

These patterns offer insights into both technology use and associated psychological traits (Carmi et al., 2022). A full overview of collected data is provided in Table 4, though availability may vary by device. Importantly, no content (e.g. messages, calls, or app interactions) will be accessed. Only behavioural metadata will be collected, ensuring participant privacy and ethical compliance (see Table 4 and Section 6.2).

Table 4. Mobile sensing variables

Data category	Data type	Data format
Mobile sensing data	Device sessions (Timestamps, Duration)	screen_on_timestamp, unlock_timestamp, screen_off_timestamp, locked_duration, unlocked_duration, total_duration
	Contact list (Number of contacts)	count, timestamp
	Calls (Timestamps per Call, Duration, incoming, outgoing, missed)	contact_id, anonymized phone_number type, duration, timestamp
	SMS (Timestamps per SMS, Text length, incoming/outgoing)	contact_id, anonymized phone_number type, duration, timestamp
	Installed apps (Number of apps)	count, timestamp

	App Sessions (Timestamps per session, duration)	package_id, start_timestamp, end_timestamp, duration
	App Statistics (Count and Usage time per app)	package_id, range_start_timestamp, range_end_timestamp, total_usage_duration times
	GPS / Locations (Timestamps, Anonymized position)	anonymised projected lat, lng, alt, speed, accuracy, provider, gps_timestamp
	Accelerometer (Timestamps and axis data)	x, y, z, timestamp
	Rotation Rate (Timestamps and axis data)	x, y, z, timestamp
	Pedometer (Count of steps per day)*	startDate, endDate, numberOfSteps, distance, floorsAscended, floorsDescended, currentPace, currentCadence
	Visits (Like GPS but aggregated)*	arrivalDate, departureDate, locationCategory, distanceFromHome
Mobile sensing - Device information	Screen size	Width, Height
	Operating system (OS)	Android/iOS
	OS version	Version number
	country	Country code
	language	Language code
	device	manufacturer, brand, model, product, version_codename, device
	BootstrApp version	version_release, app_version_code, app_version_name, version_sdk

Note. * Final data format is not known yet; the assumed data format is provided.

Ambulatory Assessment

BootStRaP exploits ambulatory assessment and structured diary approaches for capturing different mental state domains of relevance to self-management of internet use i.e., cognition, affect, perception, behaviour, alongside ‘real time’ contextual information. Participants complete a 5-minute end of day assessment over two 7 consecutive day periods (after T1, T2) including questions about urge, mood, experience of pleasure, compulsive use, and interference with daily activities.

Additional measures used during both interventions to provide individualised feedback.

Both Inhibitory (Executive) control and Emotional (Affect) regulation

- During the 4-week intervention, participants will complete the **S-CIUS**, **FoMO**, and **IUES** (see Section 6.1.1), with individualised feedback provided. Additional measures include:
- The **Readiness and Self-Efficacy Ruler** (RR & SER) (Heather et al., 2008) A brief self-report tool assessing motivation and readiness to change problematic internet use, using Likert scales.
- **Decisional Balance Questionnaire** (DBQ-I) A 12-item self-developed measure assessing perceived pros and cons of private internet use, using a 5-point Likert scale (1='not at all' to 5='totally agree') divided into two subscales that capture the advantages and disadvantages of Internet use.
- **The Sofalizing scale** (Tosuntaş et al., 2024) An 11-item measure assessing online socialising behaviours, covering *Online Displacement* and *Social Compensation*, answered on a five-point Likert scale (0 = 'never' to 4 = 'very often').
- **Need to belong** single item (Nichols & Webster, 2013) Assesses the strength of the participant's desire to belong, a known risk factor for PUI. The item is measuring a strong desire to belong from 1 = 'strongly disagree' to 4 = 'strongly agree'.
- The **UCLA Loneliness Scale** (Montag et al., 2019; Russell, 1996) Measures subjective feelings of loneliness using a five-point Likert scale. Items are answered on a five-point Likert scale (1 = 'Does not apply at all' to 5 = 'Very true').

Inhibitory (Executive) control only

- The **Urgency – Premeditation - Perseverance - Sensation Seeking - Positive Urgency** (UPPS-P) (Geurten et al., 2021; Lynam et al., 2006) impulsive behaviour scale will also be used in its short version as an intervention task with individualised feedback for each participant.
- The **Cambridge-Chicago Compulsivity Trait Scale** (CHI-T) (Chamberlain & Grant, 2018) will also be used as an intervention assessment and challenge over a 3-day period.

Emotional (Affect) regulation only

- The **Emotion Regulation Questionnaire for Children and Adolescents** (ERQ-CA) (Gullone & Taffe, 2012) is a valid age-appropriate measure for investigating the use of 2 specific strategies of ER during the childhood and adolescence developmental periods.

6.1.2. Timing of Assessments

Table 1 shows the timing of the assessments and Table 2 shows the timings of the interventions, for both the pilot study and the RCT. Each Participant will complete a 2-week baseline assessment (T0) followed by a 4-week intervention period (I). After the intervention period has ended each participant will complete a post intervention assessment (T1) and then either a 3-month follow-up (T2: pilot study) or a 6-month follow-up (T2: RCT). The ambulatory assessment will be completed for 7 consecutive days at baseline (T0), in week 2 of the intervention (I), during the post assessment period (T1) and at the 3-month/6-month follow up (T2). The S-CIUS will be completed at baseline (T0), during the post assessment (T1), monthly between T1 and the 3-month/6month follow up (T2) and during T2 follow up. Mobile sensing variables are continuously recorded between baseline and the 3-month/6-month post intervention follow-up.

Table 3 shows the timing of the assessment tools for the extension study. PUI clinical variables are assessed every 3 months (in a staggered schedule: some at months 3 and 9 and some at months 6 and 12). The S-CIUS as an indicator for PUI is assessed every 3 months. Mobile sensing variables are continuously recorded. Cognitive variables are optionally assessed every 12 months.

6.2. Data Management

Work Package 6 (WP6) oversees the coordination and management of all BootStRaP study activities across sites. The Project Office (PO), based at the University of Hertfordshire (UoH), is responsible for implementing quality procedures, managing data collection, resolving conflicts, and ensuring compliance with ethical standards. A dedicated data management group, led by UoH, will oversee data governance and reporting to the European Commission.

The PO will utilise the Clinical Trials Support Network (CTSN) Quality Management System, adapting Standard Operating Procedures (SOPs) as needed. All study documentation will be maintained in a secure, GDPR-compliant electronic Study Management File, hosted behind university firewalls with daily backups. This platform ensures centralised, up-to-date access for all partners, promoting transparency and collaboration.

Data Privacy and Security Measures

The BootStRaP consortium has strong expertise in digital assessments and digital phenotyping, with teams at UZL and UoH experienced in maintaining high privacy standards.

Following 'privacy by design' principles, UZL will implement advanced privacy measures. For example, GPS data will be globally randomised to analyse activity patterns without revealing actual locations. Encryption will protect phone numbers while still allowing analysis of social network size and usage patterns.

The study will follow sandboxing principles, meaning no content from messaging or social media apps will be accessed. Only app installation and usage frequency will be recorded, and all digital phenotyping will remain within the limits set by Android and Apple systems.

Data Governance and Management

Data governance and management will follow ICH Good Documentation Practice (GDP) and EU GDPR standards, as outlined in the University of Hertfordshire's Quality Management System (QMS). A comprehensive Data Management Plan (Deliverable 6.3) will be implemented across all sites, coordinated by the Project Office (PO), with a live Data Sharing Agreement ensuring ongoing compliance and updates.

All sites will receive training on study procedures, with regular monitoring by the PO and steering committee. A Master File will be maintained at UoH, providing access to current processes and locally adapted guidelines. While EU GCP standards apply across the consortium, equivalent governance will be followed in Switzerland and the UK to ensure consistency and oversight.

Adaptation of Quality Management Systems

The UH QMS will be tailored to support study-specific documentation related to:

- Study setup and site initiation (e.g., gSOP-18-01, gSOP-07-01)
- Ethical management and participant safety (e.g., gSOP-20-01, gSOP-38-01, gSOP-02-01)
- Quality management (e.g., gSOP-33-01, gSOP-10-01)
- Data monitoring and integrity (e.g., gSOP-23-01, gSOP-12-01)
- Data management (guided by gSOP-40-01 and led by the data management committee)

Reporting and Communication

The PO will produce a bi-annual progress report, available to all study partners, committees, and the European Commission. These reports will detail progress against all deliverables and milestones, supporting transparent communication and proactive project management.

6.3. Data Analysis

6.3.1. Preparatory steps

Behavioural data of all measures will be combined to specific sum scores or mean scores, as required. Missing data will be evaluated to determine potential estimation bias. If the data is MAR multiple imputation will be used to model the influence of missingness. Where missingness demonstrates other properties, other methods of sensitivity analysis will be considered.

6.3.2. Primary analyses

Pilot Study

The pilot study has one primary research question:

- Can routinely collected data at baseline (passive sensory data, or psychometric measures) predict which intervention will be more effective for an individual (based on baseline assessments and machine learning (ML) algorithms).

A secondary research question is

How effective are each of the active interventions at reducing PUI risk compared to the control group.

The pilot study will include three groups, Emotional Regulation intervention, Inhibitory Control intervention and a control group. A fourth validation group for testing the ML algorithm will be drawn as a random sample of 1/3rd of participants from each study arm, resulting in a total sample size of $4 \times 838 = 3,352$ participants. All other analyses will be secondary and evaluated using General Linear Models (GLM).

Behavioural data from all measures will be aggregated into sum scores or mean scores as appropriate. Efficacy evaluation will be conducted using General Linear Modelling, accounting for demographic and psychological variables. The primary analysis will focus on between-group comparisons, estimating group differences with 95% confidence intervals and calculating effect sizes.

Machine Learning Approach

To predict psychological phenotypes from multisource big data, we will apply a rigorous ML approach underpinned by psychological theory (Montag & Rumpf, 2021). The pilot study data will be used to develop predictive algorithms identifying which individuals are most likely to benefit from the emotional regulation intervention or the inhibitory control intervention.

We will build multivariate predictive models using both classical methods (logistic regression, support vector machines (SVMs), Random Forest, boosted trees (XGBoost)) and advanced techniques (deep neural networks, domain adaptation, deep representations, adversarial training). These models will link assessment data to individual-level outcomes, incorporating risk assessments from the assessment study alongside a range of input dimensions, including:

- Digital behaviour: Repetitive patterns, diurnal variation, app usage types
- Neurological assessments: Reaction time, error ratio
- Personality dimensions: Compliance rate, communication patterns

Learning Representations

We will build upon the representations developed in the assessment study, expanding them to include new data dimensions and integrate predicted risk assessments. Both supervised and unsupervised methods will be utilised, with a focus on model expandability.

Downstream Predictive Modelling

A hybrid approach combining classical and advanced deep learning methods will be applied, following consistent modelling strategies. To address site biases, multi-source domain adaptation will be used, as in the assessment study. Given that treatment outcomes might be influenced by site-specific factors, leave-one-site-out cross-validation will ensure models generalise to new sites while controlling for confounding factors.

To identify actionable variables for interventions, we will apply SHAP (SHapley Additive exPlanations) to evaluate the contribution of individual variables to overall predictions.

Generalisation and Validation

We will use standard methods to assess model generalisation and validation. Once the learning phase is complete and the final predictive performance is established, hypothesis testing will be conducted on the fourth (validation) group. This approach aligns with best practices in eHealth application development, ensuring robustness and practical applicability.

Randomised Control Trial

The RCT has 3 primary research questions:

- Is the intervention (ignoring allocation method) effective (by comparison to control) [2:1 allocation].
- Is tailored allocation more effective than random allocation irrespective of the intervention?
- Is the emotional regulation intervention more effective than the inhibitory control intervention irrespective of allocation method.

These analyses specify 3 groups per analysis, requiring a sample size of $3 \times 838 = 2514$ in total. All other analyses are secondary and will be evaluated using appropriate GLM models.

Behavioural data of all measures will be combined to specific sum scores and/or mean scores, as recommended in the specific previous studies and scale descriptions. Evaluation of efficacy will proceed using General Linear Modelling adjusting for a range of demographic and psychological variables. The primary comparison will be between groups to allow group differences (with 95% confidence intervals) to be estimated along with the effect size (with a confidence interval). Each of the 3 primary questions will be considered in turn.

6.3.3. Secondary analyses

Pilot Study

In the pilot study, secondary analyses will examine group differences, including at-risk versus no-risk participants, gender comparisons, and subtype comparisons among at-risk adolescents, based on PUI symptoms and burden. These analyses will employ multiple-hierarchical (moderated) regression models to explore interactions between predictor and moderator variables in predicting PUI symptoms and clinical outcomes (including burden) at T1.

Structural equation modelling (SEM), covering both manifest and latent variables, will assess relationships and interactions between PUI symptoms, clinical variables, and moderating/mediating factors (T0+3 assessment). The SEM will align with the Bootstrap logic model (Figure 4).

Randomised Control Trial

For the RCT, each factor (allocation method, intervention) will be analysed separately. The same analytical approach as the pilot study will be used, focusing on group differences (at-risk vs. no-risk, gender, subtypes of at-risk adolescents) through multiple-hierarchical regression analyses at T2.

SEM will also be applied to explore symptom interactions and moderating/mediating variables (T0+3 assessment), following the BOOTSTRAP logic model.

Missing data will be assessed for potential estimation bias. If data are missing at random (MAR), multiple imputation will be used. Where missingness is linked to specific demographic or psychological variables, alternative sensitivity analyses will be considered.

Additionally, a health economic analysis within the BootStRaP project will assess both the cost and burden of PUI among adolescents and evaluate the cost-effectiveness and cost-utility of the Emotional regulation intervention and Inhibitory control intervention. These analyses will focus on optimal intervention delivery using the developed risk algorithms.

The economic evaluation will be conducted from both mental health and societal perspectives, considering direct and indirect costs. From a mental health perspective, costs will include expenditures credited to the mental health care budget, aligning with the decision-maker's viewpoint. The societal perspective will encompass direct mental health care costs as well as indirect costs, such as productivity

losses and broader economic impacts. The analysis will incorporate discounting methods for the time horizon used, ensuring a comprehensive view of long-term costs and benefits.

To account for missing data, we will apply multiple imputation techniques, maintaining data integrity and robustness in the economic analysis. Both intent-to-treat and complete case analyses will be conducted, complemented by probabilistic sensitivity analysis to account for variability in economic inputs and costs across different study sites.

A key component of the health economic analysis will be the measurement of Health-Related Quality of Life (HRQoL). We will use two validated scales to provide a balanced assessment of mental health impacts:

- The Paediatric Quality of Life Enjoyment and Satisfaction Questionnaire (PQ-LES-Q) (Endicott et al., 2006) will serve as the primary utility scale. This instrument is particularly suitable for adolescents, as it captures relevant domains and is sensitive to the factors most likely influenced by PUI interventions.
- The EQ-5D-Y (Wille et al., 2010) will be included as a secondary outcome measure. This short (2-minute) and user-friendly tool offers a visual analogue version, which enhances its applicability in diverse settings.

Using both HRQoL measures will enable us to address content validity concerns with existing instruments, especially given that many available quality of life scales favour physical health outcomes over mental health. By leveraging BootStRaP's large, cross-country sample size, we aim to enhance the validity and generalizability of our findings across European contexts.

The economic outcomes will be expressed in terms of societal costs, converted to Quality-Adjusted Life Years (QALYs). We will present the costs of interventions through two primary metrics: incremental costs per QALY gained and incremental costs per adolescent with PUI in full remission. These metrics will provide clear insights into the value for money of the BootStrApp interventions, supporting evidence-based decision-making for policy and practice.

Additionally, we will perform an impact analysis, comparing our effectiveness and cost-effectiveness data with similar disorders where evidence-based interventions are routinely implemented. This benchmarking exercise will include Obsessive-Compulsive Disorder (OCD) (Osborne et al., 2019) and Gambling Disorder (Diaz-Sanahuja et al., 2021), using up-to-date evidence available at the time of analysis. Given the similarities in intervention type, low cost, and scalability of the screening and treatment approaches, we hypothesise a moderate cost-effectiveness ratio for the BootstrApp intervention.

By adopting this comprehensive health economic approach, the BootStRaP project aims to not only demonstrate the clinical effectiveness of its digital interventions but also provide robust economic evidence to support their widespread adoption and sustainability in real-world settings.

7. Ethical Considerations

The BootStRaP study will follow ICH Good Clinical Practice (GCP) principles and all relevant ethics and governance procedures, including HRA approvals. The Project Office (PO) at UoH will provide GCP and GDPR-compliant governance documents, supported by legal and regulatory expertise to ensure alignment with EU standards. An independent Ethics Advisory Board will oversee the project.

The PO, in collaboration with local teams, will supply standardised study materials (e.g. protocol, plain-language information sheets), which can be adapted for local ethics submissions. All documents will be securely stored in the Trial Master File.

No site will begin recruitment until PO approval and site initiation are complete. The study database will remain inaccessible until all documentation is in place, with final sign-off by the Chief Investigator (CI).

The BootStRaP team will submit biannual progress reports and a midterm recruitment report to Horizon Europe. Local reporting and end-of-study declarations will follow national regulations, typically within 90 days of study completion.

8. Quality Assurance and Control

Quality Assurance (QA) involves all planned and systematic actions implemented to ensure that the trial is conducted, and data is generated, documented, recorded, and reported in accordance with Good Clinical Practice (GCP) principles and applicable regulatory requirements. Quality Control (QC) refers to the operational techniques and activities carried out within the QA system to verify that the quality standards for trial-related activities are consistently met.

The UoH Quality Management System (QMS) will be adapted to develop study-specific documents covering study setup, site initiation, ethical management, participant safety, quality management, and data monitoring and integrity. While data management will be led by the Data Management group consisting of members from UZL, IDC, UoH and the Project Office.

8.1. Risk Assessment

QA and QC considerations for the study should be based on the formal risk assessment performed, that acknowledges the risks associated with the conduct of the study and proposals of how to mitigate them through appropriate QA and QC processes. Risks are defined in terms of their impact on the rights and safety of participants; project concept including trial design, reliability of results and institutional risk; project management; and other considerations.

The Project Office (PO) will overview the overall risk management of the project. In case a partner identifies a risk for the project he/she must fill the risk assessment Form. The risk assessment form can be found in the trial master file folder of the BootStRaP Teams channel. All risk assessment forms must be logged as a file note and on the file note log and sent to the Project Office for review.

Risk will be constantly evaluated by the PO and evaluated depending on the severity of consequences and chance of happening through an overall Risk Matrix. All reported risks will be entered into the risk management register and mitigation for these risks identified. Progress and barriers to progress will be

monitored and solutions sought from the SC, and the Advisory Boards as required to enable any issues to be resolved in a timely fashion.

8.1.1. Risk-Benefit Assessment

The pilot study and RCT will build on the findings of the assessment study, offering unprecedented insights into the psychological mechanisms underlying PUI risk, the early detection of at-risk adolescents, and effective preventative interventions. The BootStRaP project aims to develop evidence-based policy recommendations that could significantly contribute to the prevention of problematic internet use across Europe.

The study's robust recruitment strategy, which includes adolescents from nine European countries with diverse genders, socioeconomic backgrounds, and geographical areas (rural and urban), enhances the generalisability of the results.

The risk to participants is expected to be minimal, as the health lifestyle and well-being interventions are designed to prevent PUI, a behavioural issue not a clinical condition, rather than to treat a medical disorder. The study purpose is clearly explained to participants beforehand, including information on the questions asked and potential interventions offered.

Participation is entirely voluntary, and participants can withdraw at any time without providing a reason. If emotional distress arises, the study app includes a dedicated help submenu, guiding participants and, where appropriate, their parents to local mental health support services for children and adolescents.

The study places a strong emphasis on data protection, confidentiality, and anonymity, as detailed in Data Management (Section 6.2) and Data Protection and Participant Confidentiality (Section 11).

The pilot study and RCT are expected to benefit participants by:

- Reducing their risk of PUI.
- Enhancing emotional regulation and inhibitory control strategies, depending on the allocated intervention.

Participating schools have become part of international research on PUI and can influence how the study is conducted (see section 9). They have access to a network of PUI experts and are featured on the project website if they choose. In addition, schools can receive anonymous feedback if they wish. Educational input (e.g. Informative presentations for students or parents) can be offered by the recruitment centres depending on the interest of schools. School ambassadors will be involved in designing feedback and educational inputs for schools. Materials for developing educational input are already available on the BootStRaP website [Net and Me – BOOTSTRAP \(internetandme.eu\)](https://internetandme.eu). Any feedback or educational inputs are only provided after completion of the data collection, to avoid biasing the study results. Schools and educators will gain access to the intervention materials at the end of the project, enabling ongoing use within educational settings. The project's findings will also provide long-term benefits to future individuals at risk of PUI.

Participants will receive a certificate and a monetary voucher as a token of gratitude for their time and effort, promoting engagement and recognising their contribution to the research.

8.2. Monitoring

The UoH QMS will be adapted to provide study specific documents relating to data monitoring and integrity.

The data will be monitored on a weekly basis by the co-ordinator or a delegated individual, and data integrity monitored on a routine basis by an independent monitor. Part of the monitoring process will include identifying systematic data errors either at study sites, or due to systematic structural issues with the data collection process. Where required, a data recovery process will be recorded and specified, and training of all relevant individuals will be undertaken to ensure that ongoing errors are avoided. Serious data breaches will be reported within 48 hours to the sponsor and to the PI at the concerned study site. The breach will be followed up within 7 days to ensure that appropriate action is taken by the study team and by the relevant organisations involved.

Study adherence will be centrally monitored via the mobile app and automated reminders will be sent (based on ethical protocols). Monitoring of data collection is done via the “BootStRaP Analytics” Dashboard (an internal website accessible for recruitment centres). Our recruitment centres are located in 9 different countries, each recruiting around 400 participants per study (Pilot and RCT) from local schools with differing operating policies. The researchers will make themselves available to participants, staff and parents for the duration of the study supporting retention and troubleshooting problems.

The PO will provide a monthly report, which will be available to all study partners, committees and the EU Commission as required specifying progress against all deliverables and milestones

8.3. Study Oversight

The governance structure of the BootStRaP Project is displayed in Figure 6. The study will be continuously supervised by two external committees, the Scientific Advisory Board (SAB) and the Ethics Advisory Board (EAB) to ensure all necessary consultation is available for the duration of the BootStRaP project. The sponsor is the University of Hertfordshire, an academic institution, based in the United Kingdom. The University of Hertfordshire leads on management and coordination of the whole project

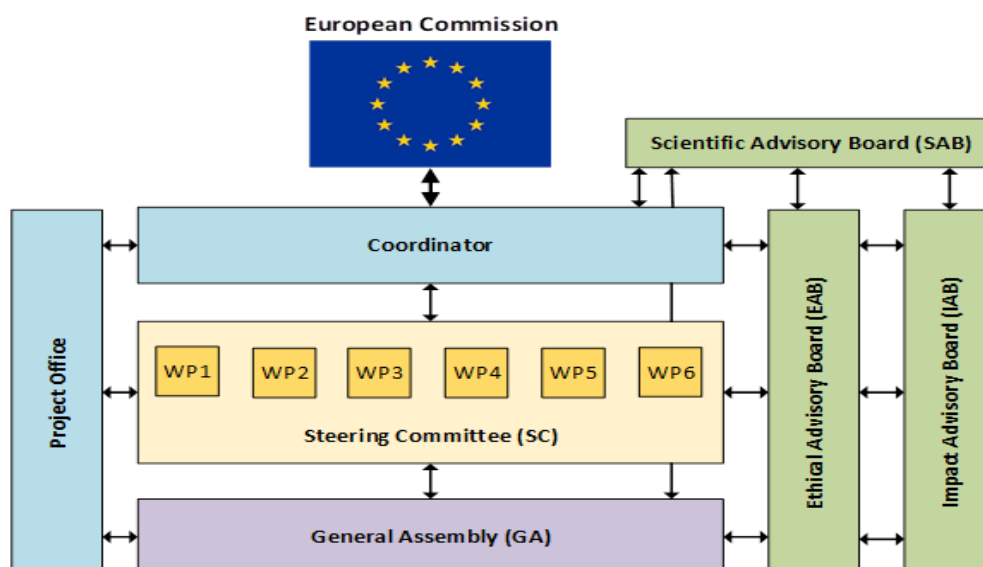


Figure 6: BootStRaP governance structure

including governance, data management, analysis. The Interdisciplinary Centre (IDC) leads on digital data management and analysis. As outlined below, the Project Office is based at the University of Hertfordshire who will provide oversight and coordination for the project (the co-ordinator). The co-ordinator will report directly on a monthly basis to the Steering Committee who will be represented by all the work-package leads (or deputy). The Co-ordinator will also report to the General Assembly and to all the Advisory Boards ensuring seamless coordination and communication between all parties.

8.3.1. Project Office

A Project Office (PO) will be established at UoH, including the co-ordinator, a project manager and support staff. The PO is responsible for central, day-to-day operational management and smooth and timely execution of the project, acting as an accessible helpdesk and consultation and communication point on all matters related to study conduct. In addition, the PO is responsible for assisting the General Assembly (GA), Steering Committee (SC) and the boards of external advisers (Scientific Advisory Board (SAB), Ethics Advisory Board (EAB), Impact Advisory Board (IAB)) on all operational management issues. Data management will be led by the data management committee consisting of the Coordinator, Project Office (UoH), UZL and IDC.

The Project Office (PO) implements standard quality procedures, including meeting procedures, a guide on reporting procedures, standard procedures for data collection and procedures on conflict mediation and corrective actions. The PO will use the CTSN QMS adapting Standard Operating Procedures where necessary.

The Consortium's credentials are enhanced by 3 exceptional Advisory Boards covering all aspects of the project with broad trans-cultural and multidisciplinary expertise, including a Scientific Advisory Board, an Impact Advisory Board, and an Ethics Advisory Board.

8.3.2. General Assembly

The General Assembly (GA), as the strategic and ultimate decision-making body of the project including any aspect affecting the Consortium Agreement and/or Grant Agreement, comprises one representative per beneficiary. The GA is responsible for quality and progress monitoring, financial monitoring, overall risk management, conflict resolution and decisions on any corrective measures in case of (un)anticipated contingencies, including resolving any disputes.

8.3.3. Steering Committee

The Steering Committee (SC), consisting of all WP leaders and chaired by the Co-ordinator, is the central management team and supervisory body for execution of the project. The SC is responsible for overall monitoring of the scientific and financial progress, based on the agreed deliverables and milestones, monitors and facilitates alignment between WPs and organises all management meetings (assisted by the PO).

8.3.4. Data Monitoring and Ethics Committee

The PO will provide a six-monthly report which will be available to all study partners, committees and the EU Commission as required specifying progresses against all deliverables and milestones.

8.3.5. Trial Management Group

The sponsor is the UoH, an academic institution, based in the United Kingdom. BootStRaP engages a whole work package on the project management where the scientific and operational governance will be enacted. WP6 is responsible for management and coordination of all study activities across the different sites. The Project Office (PO), based at UoH (UK), will implement standard quality procedures, standard procedures for data collection and procedures on conflict mediation and corrective actions.

9. Public and Participant Involvement

9.1. BootStRaP Ambassadors

A teacher and 2-3 students in each school participating in the BootStRaP project have been identified to act as a BootStRaP Ambassador for the duration of the project to maximise school community's engagement in the research project. Their role is advisory and as research collaborators in the research process. They are not research participants. Activities planned together with ambassadors include:

- Collaborate with researchers to recruit other students as research participants, maximise retention, and engagement of schools
- Provide feedback to increase the accessibility of the smartphone app used for interventions
- Co-designing how to involve schools and students
- Influence the overall project coordination, by sitting in the management board
- Help reviewing information- and advertisement material
- Help in planning and conducting local dissemination events
- Represent the school and peers in the international research project

These involvement activities are performed in virtual workshops, regular online-meetings, face-to-face meetings with local researchers, and one BootStRaP Bootcamp with ambassadors from included schools. Therefore, to become ambassadors, students need good English skills and need to be able to travel, for attending the Bootcamp.

Youth, Student and Teacher Ambassadors are involved in the process of co-designing the BootstrApp digital tool. This involvement is to ensure that the tools are appropriate to young people's needs and demands, to increase engagement in using the App, to make sure the design is appealing and functional and to ensure usability. Co-creation activities have been used to design the engagement strategy for the project and also to co-create the BootstrApp Intervention app. During online meetings, students, teacher ambassadors and researchers collaborate with members of the research team to identify and prioritise needs regarding the engagement of students in the project.

The youth advisory group (Bootcrew) are involved in providing advice and support to the project at different stages. The Bootcrew was developed by Euro Youth Mental Health ([EYMH](#)), which is a non-profit organisation that works with young people with direct or indirect experience of mental health difficulties across Europe, and has incorporated members of the EU-PUI PPI (patient-public involvement) Reference

Group, which was created in the COST Action European Network of Problematic Internet Usage, known as Internet & Me. The Bootcrew are involved in the planning and conduction of the BootStRaP project and facilitate public and especially youth involvement. Involvement activities will include commenting on study materials, co-designing the project website and advising on the dissemination activities.

10. Protocol Compliance

The CI will ensure that the studies are conducted in compliance with the principles of the Declaration of Helsinki (1996), and in accordance with all applicable regulatory requirements including but not limited to the Research Governance Framework and Research Office policies and procedures and any subsequent amendments.

A log of any non-compliances will be stored to ascertain if there are any trends developing which to be escalated. The sponsor will assess the non-compliances and action a timeframe in which they need to be dealt with. Each action will be given a different timeframe, dependant on the severity. If the actions are not dealt with accordingly, an appropriate action will be agreed, including an on-site audit.

Part of the monitoring process will include identifying systematic data errors either at study sites, or due to systematic structural issues with the data collection process. Where required, a data recovery process will be recorded and specified, and training of all relevant individuals will be undertaken to ensure that ongoing errors are avoided. Serious data breaches will be reported within 48 hours to the Sponsor and to the PI at the concerned study site. The breach will be followed up within 7 days to ensure that appropriate action is taken by the study team and by the relevant organisations involved.

11. Data Protection and Participant Confidentiality

Where necessary, personal data shall be handled in accordance with applicable data protection laws and shall cooperate in order to enable one another to fulfil legal obligations arising under those laws. Fundamental ethical principles outlined under Article 8 (protection of personal data) of the Charter of Fundamental Rights of the European Union, the European Union (EU) Regulation 2016/679 (General Data Protection Regulation (GDPR)), the United Kingdom (UK) Data Protection Act 2018 (DPA 2018) and as outlined in the UoH Quality Management System will be adhered to. The CI will ensure that the trial is conducted in compliance with the principles of the Declaration of Helsinki (1996), and in accordance with all applicable regulatory requirements.

Data management will be led by the Data Management group consisting of University of Lübeck (UZL), IDC, the Coordinator, and the PO (UoH). The team from UZL will follow specific principles such as anonymising data before transmitting them from phones to servers, sandboxing mechanism, and 'privacy by design' to protect the privacy of the study participants, as described in the Data Management section (6.2). The content of the online activities the participants engage in i.e., what participants are doing or saying on their apps, in their messages or in their calls, are not accessed. Within the app no name or contact information is collected. Any named consent and assent forms will be stored separately to any other data collected for the study as these other data will be collected online directly on to the BoostApp Intervention app and the Dragon Game app. Only designated study personnel will have access to the data, to fulfil their roles within the project. The Chief Investigator (Naomi Fineberg) is the 'Custodian' of the

data. All data will be jointly controlled by the BootStRaP partners signing the Data Sharing and Joint Controller Agreement. Institution-specific DPIAs for the BootStRaP project are prepared and approved locally by partner organisations, as required.

11.1. Case Report Form (CRF)

The CRF is electronic and located on the BootstrApp and will be self-completed by the participants as required.

11.2. Archiving and deletion of participant data

All participants can withdraw from the study participation at any time. Due to anonymization of data for Machine Learning and the data backup strategy, already transmitted data cannot be deleted. Further processing will either take place pseudonymously (only for BootStRaP partners that have signed the Data Sharing Agreement) or anonymously (everyone else). After deleting the BootstrApp and the Dragon Game app, no personal data that was collected by the BootstrApp Intervention app, remains on the smartphone of the participants. Participants will be informed in both the participant information and consent process that the deletion of data up to the point of withdrawal will not be possible.

After the completion of the study and reporting of results, all identifying data will be removed from the electronic data collected. Anonymous data will be kept for at least 10 years for use in future research in this area. Anonymous data will be uploaded to a data repository as a requirement of the study funders.

12. Publication and Dissemination

A detailed dissemination, communication and exploitation (DEC) plan for the BootStRaP project (Horizon project including this study) has been created and is continuously updated. Dissemination is the act of spreading research results, findings, scientific knowledge, and discoveries to the scientific community. Exploitation involves practical application of scientific knowledge and research outcomes for societal benefits. Communication encompasses translating aforementioned research findings into language that the public understands and communicating it to various public stakeholders.

DEC activities follow the DEC plan and are monitored by the scientific and impact external advisory boards and steering committee of the BootStRaP project. Dissemination outcomes in the BootStRaP project comprises intellectual products such as open-access publications, digital assessment tool, self-management tool, policy toolkit, etc. All of these outcomes will have a potential to be exploitable. A designated Innovation Manager will be responsible for stimulating and monitoring exploitation throughout the project. A communication lead team has been established and will be in contact with local groups via a designated members (national representatives) to communicate on dissemination activities. All DEC activities will be performed according to Horizon Europe regulations, including acknowledging funding by Horizon Europe, Innovate UK program (UKRI) and Swiss State Secretariat for Education Research and Innovation (SERI). Results will be communicated primarily via the following channels:

- Open access publications in peer reviewed journals
- Presentations at scientific conferences and to stakeholders

- Social media channels (Facebook, LinkedIn, YouTube, etc.)
- Traditional media (e.g. Newspaper, radio, TV or podcast appearances)

Project news, links referencing media articles and publications of the study will be available on the BootStRaP project website Net and Me – BOOTSTRAP (internetandme.eu). We will also run a national and international publicity campaign (supported by university press offices) in which delegates from candidate schools in each recruitment region will be invited to participate, to generate interest and enthusiasm in our European project among local schools. After the main study results have been published, the anonymous data set will be made publicly available on open access repositories.

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Appendix

Appendix A

Emotional (Affect) regulation intervention week-by-week guide and relationship to behaviour change

Week 1

Introduction to the Astronaut Story: Participants are introduced to the story of an astronaut and the rewards for completing intervention modules.

Mood Barometer: Participants are asked to rate their mood three times a week during the four-week intervention phase on a seven-point scale. Based on these ratings, participants receive personalized feedback and the option to explore how their emotions may influence impulsive behaviour further.

1. Intervention phase: Enhance motivation for behavioural change and intervention elements for PUI

Self-assessment of problematic Internet use with the Compulsive Internet Use Scale and Psychoeducation

Participants can reflect on their Internet use and related issues based on the CIUS. The scale consists of 14 items that explore various aspects of online behaviour. Each item is rated on a scale from 0 (never) to 4 (very often), allowing for a total score between 0 and 56. Based on the total score, participants receive individualized feedback categorizing their behaviour as low risk (scores of 0–20 indicate low risk and suggest no major issues with internet use), risky (scores of 21–39 indicate moderate risk and reflect some problematic behaviours), or high risk (scores of 40–56 indicate a very high risk of compulsive internet use associated with impairments). After completing the CIUS, participants receive further information on problematic Internet use (PUI), including its definition and consequences. This module is designed to help participants reflect on their current Internet use and increase their motivation to change potentially problematic behaviours.

Self-assessment of the Readiness and self-efficacy to change behaviour (Heather & Hönekopp, 2008) adapted)

Participants use the Readiness & Self-Efficacy Ruler Scale to rate the importance of changing their behaviour on a scale from 1 to 10, as well as their confidence in making that change. Further, participants select one of five statements that best describes their current attitude toward reducing their Internet use. Based on these responses, personalized feedback is provided, either encouraging further exploration of motivations or offering support for taking steps to change. If participants show readiness or need help beginning to change their behaviour, they are given a list of practical strategies (e.g., starting physical activities, talking to someone, and tracking daily progress). These suggestions are designed to make changes feel manageable and realistic.

Self-assessment with the Decisional Balance Questionnaire (DBQ-I)

Participants rate 12 items about their online activities using a 5-point scale (5 = totally agree to 1 = not at all). The items cover negative consequences of Internet use (e.g., strained relationships or neglecting

responsibilities) and perceived benefits (e.g., entertainment or stress relief). Based on the results, participants receive individualized feedback informing them whether negative or positive consequences dominate. If participants report more negative consequences than benefits, they are asked to identify the three most significant negative effects they experience and to reflect on their motivation to change. If participants report more benefits than negative consequences, they are invited to consider what might motivate them to change and what positive outcomes they would hope to achieve.

Self-assessment and psychoeducation on Need to belong (single Item, Nichols & Webster, 2013) and UCLA Loneliness Scale (Montag et al., 2019)

Feelings of loneliness and the need to belong are assessed using a single-item measure and three items from the UCLA Loneliness Scale. Participants rate their desire to belong (from 1 = strongly disagree to 4 = strongly agree) and their feelings of social isolation or loneliness (from 1 = does not apply at all to 5 = very true). Individualized feedback is provided. High scores indicate loneliness and a lack of social contacts. Participants are informed about the relationship between loneliness and PUI. Those interested receive suggestions for activities that others have found helpful for improving real-life social connections (e.g., joining group activities or accepting invitations). Low scores suggest that users feel socially connected, which is positively reinforced.

Week 2

2. Intervention phase: Emotion regulation and Emotional Awareness:

Emotion Memory and Recognition

Participants can explore a broad range of emotions, such as anxiety, confusion, craving, empathy, joy, and boredom, and associate them with real-life examples and emojis. For example, anger can make you feel mad and frustrated. It can be expressed in many ways, such as crying or shouting. The aim of the emotion memory game is to reinforce emotional literacy. Participants receive immediate positive feedback for engagement.

Self-assessment with the Emotion Regulation Questionnaire for Children and Adolescents (ERQ-CA) (Gullone & Taffe, 2012)

To measure emotion regulation tendencies, such as managing emotions by keeping them to oneself or thinking / doing something else, participants can rate how they typically deal with emotions, whether through reappraisal or suppression. The 10 items can be answered using a five-point Likert scale, ranging from 1 (strongly disagree) to 5 (strongly agree). Based on their responses, personalized feedback is provided to help participants learn more about their emotion regulation tendencies and promote development.

Video to components and function of emotions

To spark curiosity, participants are invited to perform a brief thought experiment to imagine life without emotions. Through an informative video featuring an interactive character, participants learn about the function of emotions. The video defines emotions as functional signals that motivate behaviour. For example, sadness prompts withdrawal, while anger motivates action.

Combining pictures of the astronaut with functions of emotions

The purpose of this game is to reinforce what the participants have learned. Participants have received information about the function of emotions. They can then apply this knowledge by matching emotional expressions with their respective feelings and functions. Through pictures of an astronaut, participants will learn that emotions motivate us to act in different ways.

Week 3

Emotion regulation strategies

Participants can select emotion regulation strategies from a categorized list (Activities, Mindfulness, Cognitive Distraction, and Other) and highlight the options that are the most fun and useful for them. Through a challenge, they are encouraged to apply the selected strategies in real life and provide follow-up feedback on their usefulness. If necessary, adaptations can be made, and the list of strategies will be presented again.

Transfer of strategies

To evaluate the application of previously selected strategies for managing emotions, participants are challenged to apply these strategies to their daily lives over the course of two days. Participants receive personalized feedback based on their experience to encourage reflection and engagement. If necessary, adjustments to the selected strategies can be made.

Week 4

Connection of thoughts, emotions, and behaviour

Through an interactive video with examples, participants can explore how thoughts influence emotions and behaviours. Avatars provide the informative content for identification and promotion of its application to one's own life. After the video, participants are asked to think of an example in which their feelings influenced their thoughts and behaviour.

Matching game of thoughts, emotions, and behaviour

Participants can now match emotions with thoughts and behaviours. They receive feedback once they have completed the game.

Daily Transfer Emergency Planning

To help participants manage their emotions in the future, they can reflect on what they have learned. They will develop an individualized emergency plan using personalised and suggested strategies to prepare for emotional challenges. Participants can now match emotions with thoughts and behaviours. They receive feedback upon completing the game.

Bonus game

The program includes timed mindful breathing exercises and breath analysers to support self-regulation. Participants earn coins daily and for completing challenges, which promotes consistent engagement and motivation.

Bonus game

Additionally, helpful thoughts and self-instructions are provided. Through a fictional story about a clever astronaut, participants learn that their internal self-talk can guide their behaviour and emotional regulation. Participants are encouraged to adopt positive self-statements, such as "I can stay calm" or "I don't have to go online right now," especially when facing situations in which they would normally use

the internet in an unhelpful way. Then, participants choose or create one self-instruction to try and are encouraged to use it over the next few days.

Additional intervention element for high-risk group

Week 1

Self-assessment of importance of Internet use

Internet use. Using the PRISM Internet Assessment, participants visually represent the role of the Internet in their lives. They are asked to place a cross in a square diagram to show how close or distant the Internet feels to them currently, and then again to reflect how they would like it to be after the intervention. The distance between themselves and the cross reflects the perceived importance of Internet use.

Self-assessment and psychoeducation on Sofalizing

The Sofalizing Scale (Tosuntaş et al., 2024) assesses participants' tendency to interact socially online rather than in person. The scale includes 11 items that are rated on a 5-point scale from (0 = never to 4 = very often). The subscales cover two key dimensions: online displacement and social compensation. Based on the scores, personalized feedback about the tendency to interact is provided. Additionally, participants are introduced to the concept of Sofalizing, which refers to social interaction from home via digital platforms. The app encourages users to reflect on their social habits and provides more information for those who are curious while respecting those who decline. This module raises awareness of the differences between online and offline social behaviour. It helps users reflect on the role of digital interaction in their lives and potentially guides them toward a more balanced social life.

Self-assessment with the Fear of Missing Out (FoMO) Questionnaire (Przybylski et al., 2013) and the FoMO single item (Riordan et al., 2020) Scale

The assessment raises awareness and provides information on the relationship between the fear of missing out and problematic online behaviour. The module begins with an intriguing question: "Have you ever felt like you were missing out on something important, or like your friends were doing fun things without you?" Then, the 12 items of the FoMO questionnaire address both general FoMO (trait) and online-specific FoMO (state). Participants rate these items on a 5-point Likert scale from 1 (Not at all) to 5 (Extremely true of me) and cover emotional responses, compulsive behaviour, and social comparison. After completing the self-assessment, participants receive personalized feedback with a visual representation of their results. This feedback validates their experience and suggests appropriate next steps. Participants with high FoMO receive reflective prompts and further information on FoMO and behavioural change. Those with low FoMO are positively reinforced and offered optional educational content. The information section explains the link between FoMO and PUI. It details how FoMO can lead to compulsive checking behaviours due to perceived social exclusion, which can result in decreased emotional well-being and problematic online activities.

Self-assessment with the Internet Use Expectancies Scale (IUES) (Brand et al., 2014)

The scale provides insight into why participants use the Internet, focusing on emotional and psychological expectations. By identifying patterns that may indicate avoidance-based or pleasure-seeking Internet use, the assessment can help determine the relevance to the development of PUI. Participants rate each item on a 6-point Likert scale (1 = completely disagree to 6 = completely agree)

based on how strongly they agree with it. Personalized feedback focuses on the subscale's avoidance-oriented use (indicating that participants use the internet to escape negative emotions or responsibilities) or positive reinforcement use (indicating that participants seek fun, enjoyment, or positive emotions by using the internet). Participants with high scores on one of the two subscales are prompted to reflect on whether this strategy is helpful or if they would prefer to learn healthier emotion regulation techniques (e.g., physical activity or social interaction). Motivational interviewing techniques are used in the personalized feedback to encourage self-reflection and motivate engagement in alternative offline activities for emotional well-being.

Week 2

Self-assessment and categorisation of participants with the Amba

This self-assessment instrument helps participants reflect on the relationship between their emotional state and their tendency to use the Internet in order to provide personalized feedback. First, participants rate their mood (1 = very bad to 10 = very good) and their stress level (1 = not at all stressed to 10 = very stressed). Then, participants are asked to rate their temptation to use the Internet and their primary online activity, as well as other helpful activities. Based on their responses, participants are categorized as low-risk (defined as a good mood, low stress, and minimal internet use) or high-risk (defined as a bad mood, high stress, and frequent internet use). Participants are then provided with individualized feedback to encourage reflection on alternative coping strategies and behavioural changes.

Week 3

Emotions and Internet use

Participants learn to identify specific emotions that prompt their Internet use, creating awareness of the emotional triggers of PUI. Follow-up feedback and push notification encourages participants to observe their online behaviour over the next few days.

Table 5. Emotional regulation intervention content mapped from the COM-B to the theoretical domain, intervention function, and behaviour change techniques (BCT's)

Intervention element	COM-B	Theoretical domain	Intervention function	BCT	Elements
Week 1					
Mood Barometer	-Psychological Capability	-Emotional awareness	-Enablement	-Self-regulation	During the four-week intervention phase, participants can rate their mood three times a week and receive personalized feedback. Through this process, they learn how their emotions influence their impulsive behaviour.
Self-Assessment – Compulsive Internet Use Scale (CIUS) + Psychoeducation	-Psychological Capability -Reflective Motivation	-Knowledge -Beliefs about consequences -Self-reflection	-Education	-Self-monitoring -Feedback on behaviour	Based on the self-assessment, participants can reflect on their Internet usage and its related health consequences. They will receive information on PUI and personalized feedback on their behaviour.
Self-Assessment – Readiness and Self-Efficacy Ruler	-Psychological Capability -Reflective Motivation	-Beliefs about capabilities -Verbal persuasion	-Education -Persuasion	-Goal setting (behaviour) -Action planning	The assessment is used to measure readiness and capacity to change behaviours. Participants rate how important it is for them to change their behaviour and how capable they are of doing so. Participants will receive personalized feedback encouraging them to further explore their motivations or offering support for taking steps to change.
Self-Assessment – Decisional Balance Questionnaire	-Psychological Capability -Reflective Motivation	-Beliefs about consequences -Self-reflection -Intentions	-Education -Persuasion -Enablement	-Pros and cons -Feedback on behaviour -Action planning	Participants reflect on the negative consequences and perceived benefits of Internet use and receive individualized feedback. The three most significant negative effects are assessed to determine helpful steps for motivating change.
Self-Assessment – Need to belong and UCLA Loneliness Scale	-Psychological Capability -Reflective Motivation -Social Opportunity	-Social influences -Emotions -Reinforcement	-Education -Enablement -Persuasion	-Self-monitoring of outcomes of behaviour -Information about social and environmental consequences -Behavioural practice/rehearsal	Feelings of loneliness and the desire for belonging are examined in the context of PUI. Participants learn about the relationship between loneliness and Internet usage. Helpful activities for improving real-life social connections are provided, and positive reinforcement is given to socially connected participants.
Week 2					
Mood Barometer	-Psychological Capability	-Emotional awareness	-Enablement	-Self-regulation	During the four-week intervention phase, participants can rate their mood three times a week and receive personalized feedback. Through this process, they learn how their emotions influence their impulsive behaviour.

Emotion memory and recognition	-Psychological Capability -Automatic Motivation	-Knowledge -Emotion -Memory, Attention and Decision Processes	-Training -Enablement -Education	-Instruction on how to perform the behaviour -Behavioural practice/rehearsal -Prompts/cues -Verbal persuasion about capability	Participants can explore a variety of emotions, such as anxiety, confusion, craving, empathy, joy, and boredom. They can then associate these emotions with real-life examples and emojis. For instance, anger can make you feel mad and frustrated. It can be expressed in many ways, such as crying or shouting. The aim of the emotion memory game is to reinforce emotional literacy. Participants receive immediate positive feedback for engagement.
Self-assessment with the Emotion Regulation Questionnaire for Children and Adolescents	-Psychological Capability -Reflective Motivation	-Self-reflection -Behavioural regulation -Beliefs about consequences	-Education -Enablement -Persuasion	-Self-reflection -Knowledge -Behavioural regulation	To measure emotion regulation tendencies, participants rate how they typically deal with emotions, whether through reappraisal or suppression. Based on their responses, personalized feedback is provided to help participants learn more about their tendencies and promote development.
Video to components and function of emotions	-Psychological Capability -Automatic Motivation	-Knowledge -Emotion	-Education -Persuasion	-Instruction on how to perform the behaviour -Information about health/emotional consequences -Framing/reframing	To stimulate curiosity, participants are invited to perform a brief thought experiment in which they imagine life without emotions. Through an informative video featuring an interactive character, they learn about the purpose of emotions. The video defines emotions as functional signals that motivate behaviour. Sadness, for example, prompts withdrawal, while anger motivates action.
Combining pictures of the astronaut with functions of emotions	-Psychological Capability -Reflective Motivation	-Memory, Attention and Decision Processes	-Training -Reinforcement	-Behavioural practice/rehearsal -Prompts/cues	The purpose of this game is to reinforce what participants have learned. They receive information about the function of emotions. They can apply this knowledge by matching emotional expressions with their corresponding feelings and functions. Through pictures of an astronaut, participants learn that emotions motivate us to act differently.
Week 3					
Mood Barometer	-Psychological Capability	-Emotional awareness	-Enablement	-Self-regulation	During the four-week intervention phase, participants can rate their mood three times a week and receive personalized feedback. Through this process, they learn how their emotions influence their impulsive behaviour.

Emotion regulation strategies	-Psychological Capability -Reflective Motivation -Automatic Motivation	-Skills -Goals -Memory, attention, and decision processes	-Enablement -Persuasion	-Problem solving -Self-monitoring of behaviour -Review behaviour goal(s)	Participants can select emotion regulation strategies from a categorized list of activities, mindfulness practices, cognitive distractions, and other strategies. They can choose the options that are most enjoyable and helpful. Participants are encouraged to apply these strategies in real life and provide feedback on their effectiveness through individualized feedback and prompts. If necessary, the list of strategies will be presented again with adaptations.
Transfer of strategies	-Psychological Capability -Reflective Motivation	-Reflection -Reinforcement -Behavioural regulation	-Enablement -Persuasion	-Behavioural practice/rehearsal -Instruction on how to perform the behaviour -Feedback on behaviour -Verbal persuasion about capability	To evaluate the effectiveness of the previously selected emotion management strategies, participants are challenged to apply them to their daily lives over the course of two days. They receive personalized feedback based on their experience to encourage reflection and engagement. If necessary, adjustments to the strategies can be made.
Week 4					
Mood Barometer	-Psychological Capability	-Emotional awareness	-Enablement	-Self-regulation	During the four-week intervention phase, participants can rate their mood three times a week and receive personalized feedback. Through this process, they learn how their emotions influence their impulsive behaviour.
Connection of thoughts, emotions, and behaviour	-Psychological Capability -Reflective Motivation	-Beliefs about consequences -Knowledge -Emotion	-Education -Persuasion -Training	-Instruction on how to perform the behaviour -Framing/reframing -Behavioural practice	Through an interactive video with examples, participants can explore how thoughts influence emotions and behaviours. Avatars provide informative content for identifying and promoting its application to one's own life. Afterwards, participants are asked to think of an example in which their feelings influenced their thoughts and behaviour.
Matching game of thoughts, emotions, and behaviour	-Psychological Capability	-Cognitive processing -Learning	-Training -Reinforcement	-Behavioural practice/rehearsal -Prompts/cues	To reinforce their understanding of the connection between emotions, thoughts, and behaviours, participants match emotions with thoughts and behaviours. After completing the game, they receive feedback.

Emergency Plan and Relapse Prevention	-Psychological Capability -Reflective Motivation	-Self-reflection -Goals -Intentions -Beliefs about capabilities	-Enablement -Education -Goal setting	-Action planning -Problem solving -Focus on past success -Social reward -Review outcome goal(s)	To help participants manage their emotions in the future, they reflect on what they have learned. They develop an individualized emergency plan with personalized strategies to prepare for emotional challenges.
Bonus game - Mindful Breathing	-Psychological Capability -Reflective Motivation	-Skills -Regulation	-Training -Incentivization	-Reduce negative emotions -Material incentive (behaviour) -Behavioural practice/rehearsal	The game includes timed mindful breathing exercises and breath analysers to promote self-regulation. Participants earn coins daily and for completing challenges, which encourages consistent engagement and motivation.
Bonus Game - Positive Instructions and Helpful Thoughts	-Psychological Capability -Reflective Motivation	-Skills -Regulation -Beliefs about capabilities	-Education -Training -Enablement	-Verbal persuasion about capability -Reduce negative emotions -Habit formation -Framing/reframing	Helpful thoughts and self-instructions are provided. Participants learn that internal self-talk can influence behaviour and emotion. They are encouraged to adopt positive self-statements and use them over the next few days.
Additional intervention elements for the high-risk group					
Visual self-reflection of Internet use with the PRISM self-assessment	-Psychological Capability -Reflective Motivation	-Goals -Self-reflection	-Education -Persuasion	-Self-monitoring of behaviour -Review behaviour goal(s)	Participants visually represented the role of the internet in their lives before and after the intervention. These visual displays promote self-monitoring and goal setting for change.
Self-assessment and psychoeducation on Sofalizing	-Psychological Capability -Reflective Motivation	-Self-reflection -Knowledge	-Education -Enablement	-Self-assessment and psychoeducation on Sofalizing	The participants' tendency to interact socially online rather than in person is assessed, and they are provided with personalized feedback. Participants are introduced to the concept of "Sofalizing" and encouraged to reflect on their social habits. This self-assessment helps users consider the role of digital interaction in their lives and potentially guides them toward a more balanced social life.

Self-assessment with the Fear of Missing Out (FoMO) Questionnaire	-Psychological Capability -Reflective Motivation	-Self-reflection -Knowledge -Social influence	-Education -Persuasion	-Information about social comparison -Reduce negative emotions Feedback on behaviour	Educational elements explain the link between FOMO and FUI. Participants evaluate their own fear of missing out and receive personalized feedback, as well as a visual representation of their results. Those with high FoMO receive reflective prompts and more information about FoMO and behavioural change. Those with low FoMO receive positive reinforcement and are offered optional educational content.
Self-assessment with the Internet Use Expectancies Scale	-Psychological Capability -Reflective Motivation	-Self-reflection -Knowledge -Emotion -Reinforcement	-Education -Persuasion	-Information about emotional consequences -Problem solving -Verbal persuasion about capability	The self-assessment provides insight into why participants use the Internet, with a focus on emotional and psychological expectations. Participants with high sum scores are encouraged to consider whether this strategy is helpful or if they would prefer to learn healthier emotion regulation techniques, such as physical activity or social interaction. Personalized feedback encourages self-reflection and motivates engagement in alternative offline activities that promote emotional well-being.
Self-assessment of mood, stress, temptation, and Internet use	-Psychological Capability -Reflective Motivation	-Self-monitoring -Emotion	-Education -Persuasion	-Self-monitoring of outcomes of behaviour -Information about health consequences -Feedback on behaviour Problem solving	Participants reflect on the relationship between their emotional state and their Internet usage habits. Based on their responses, they are categorized as low- or high-risk users. They are provided with individualized feedback to encourage reflection on alternative coping strategies and behavioural changes.
Emotions and Internet use	-Psychological Capability -Reflective Motivation -Opportunity	-Skills -Regulation -Emotion -Behavioural regulation	-Education -Enablement -Training -Persuasion	-Self-monitoring of behaviour -Information about health consequences -Prompts/cues	Participants learn to identify the specific emotions that prompt their Internet use, raising awareness of the emotional triggers of problematic internet use (PUI). Follow-up feedback and push notifications encourage participants to observe their online behaviour over the next few days.

Inhibitory (Executive) Control intervention week-by-week guide and relationship to behaviour change

Week 1

Introduction to the Astronaut Story: Participants are introduced to the story of an astronaut and the rewards for completing intervention modules.

Mood Barometer: Participants are asked to rate their mood three times a week during the four-week intervention phase on a seven-point scale. Based on these ratings, participants receive personalized feedback and the option to explore how their emotions may influence impulsive behaviour further.

1. Intervention phase: Enhance motivation for behavioural change and intervention elements for PUI

Self-assessment of problematic Internet use with the Compulsive Internet Use Scale and Psychoeducation

Participants can reflect on their Internet use and related issues based on the CIUS. The scale consists of 14 items that explore various aspects of online behaviour. Each item is rated on a scale from 0 (never) to 4 (very often), allowing for a total score between 0 and 56. Based on the total score, participants receive individualized feedback categorizing their behaviour as low risk (scores of 0–20 indicate low risk and suggest no major issues with internet use), risky (scores of 21–39 indicate moderate risk and reflect some problematic behaviours), or high risk (scores of 40–56 indicate a very high risk of compulsive internet use associated with impairments). After completing the CIUS, participants receive further information on problematic Internet use (PUI), including its definition and consequences. This module is designed to help participants reflect on their current Internet use and increase their motivation to change potentially problematic behaviours.

Self-assessment of the Readiness and self-efficacy to change behaviour (Heather et al., 2008 adopted) Participants use the Readiness & Self-Efficacy Ruler Scale to rate the importance of changing their behaviour on a scale from 1 to 10, as well as their confidence in making that change. Also, participants select one of five statements that best describes their current attitude toward reducing their Internet use. Based on these responses, personalized feedback is provided, either encouraging further exploration of motivations or offering support for taking steps to change. If participants show readiness or need help beginning to change their behaviour, they are given a list of practical strategies (e.g., starting physical activities, talking to someone, and tracking daily progress). These suggestions are designed to make changes feel manageable and realistic.

Self-assessment with the Decisional Balance Questionnaire (DBQ-I)

Participants rate 12 items about their online activities using a 5-point scale (5 = totally agree to 1 = not at all). The items cover negative consequences of Internet use (e.g., strained relationships or neglecting responsibilities) and perceived benefits (e.g., entertainment or stress relief). Based on the results, participants receive individualized feedback informing them whether negative or positive consequences dominate. If participants report more negative consequences than benefits, they are

asked to identify the three most significant negative effects they experience and to reflect on their motivation to change. If participants report more benefits than negative consequences, they are invited to consider what might motivate them to change and what positive outcomes they would hope to achieve.

Self-assessment and psychoeducation on Need to belong (single item, Nichols & Webster, 2013) and UCLA Loneliness Scale (Montag et al., 2013)

Feelings of loneliness and the need to belong are assessed using a single-item measure and three items from the UCLA Loneliness Scale. Participants rate their desire to belong (from 1 = strongly disagree to 4 = strongly agree) and their feelings of social isolation or loneliness (from 1 = does not apply at all to 5 = very true). Individualized feedback is provided. High scores indicate loneliness and a lack of social contacts. Participants are informed about the relationship between loneliness and PUI. Those interested receive suggestions for activities that others have found helpful for improving real-life social connections (e.g., joining group activities or accepting invitations). Low scores suggest that users feel socially connected, which is positively reinforced.

Week 2

1. *Intervention phase: Inhibitory control*

Informative video for understanding Impulsivity (Psychoeducation)

An interactive, avatar-based video introduces the concepts of compulsive behaviour and impulsivity. It defines these behaviours and illustrates how they impact one's actions. Participants are encouraged to reflect on their experiences and reassured that they can learn to manage their impulses.

Self-Assessment – Urgency – Premeditation - Perseverance - Sensation Seeking (UPPS-P, Lynam, 2013)

Participants evaluate their impulsive tendencies through 20 items (4 = not at all like to 1 = very much like me). Based on their answers, a sum score is calculated. Their scores help to determine if they struggle with impulse control. Higher scores indicating higher impulsivity and less impulse control. Based on the level of impulsivity identified, personalized feedback is provided to encourage participants to explore their impulsive behaviour and how it may affect them.

Day 1 of the 3-day Challenge to observe behaviour with the Cambridge–Chicago Compulsivity Trait Scale (CHI-T; Chamberlain et al., 2018)

Over three days, participants answer questions from the CHI-T scale to monitor compulsive and habitual behaviours. Daily feedback encourages reflection on personality traits such as perseverance, addiction tendencies, and perfectionism.

Week 3

Day 2 and 3 of the 3-day Challenge to observe behaviour with the Cambridge–Chicago Compulsivity Trait Scale (CHI-T; Chamberlain et al., 2018)

Over three days, participants answer questions from the CHI-T scale to monitor compulsive and habitual behaviours. Daily feedback encourages reflection on personality traits such as perseverance, addiction tendencies, and perfectionism.

Learning and Practicing Impulse Control Strategies

Participants can select and learn various strategies, such as the STOP techniques (saying stop and imagine consequences) and self-regulation skills (meditation, shifting attention, and alternative behaviours), to help them identify and observe an impulse without acting on it or to stop a compulsive behaviour. Participants identify which strategies are enjoyable and useful in daily life. Motivational interviewing techniques are used in personalized feedback to encourage self-reflection and engagement in alternative offline activities that promote emotional well-being.

Transfer of strategies

To evaluate the application of previously selected strategies for inhibitory control, participants are challenged to apply these strategies to their daily lives over the course of two days. Participants receive personalized feedback based on their experience to encourage reflection and engagement. If necessary, adjustments to the selected strategies can be made.

Week 4

Practice use of strategies and transfer into daily life

The interactive challenges simulate situations in which impulsivity may occur, as exemplified by a frustrated astronaut. Participants help the astronaut choose appropriate coping responses. Participants then apply these strategies to real-life situations and earn rewards for doing so. They also receive follow-up reflection prompts.

Emergency plan and relapse prevention

Participants are invited to reflect on what they have learned so far. They can create a personalized emergency plan for managing impulses in high-risk situations in the future. The intervention phase concludes with positive reinforcement and encouragement to continue applying the learned strategies.

Bonus game:

The program includes timed mindful breathing exercises and breath analysers to support self-regulation. Participants earn coins daily and for completing challenges, which promotes consistent engagement and motivation.

Bonus game:

Additionally, helpful thoughts and self-instructions are provided. Through a fictional story about a clever astronaut, participants learn that our internal self-talk can guide our behaviour and impulses. Participants are encouraged to adopt positive self-statements, such as "I can stay calm" or "I don't have to go online right now," especially when facing situations in which they would normally use the internet in an unhelpful way. Then, participants choose or create one self-instruction to try and are encouraged to use it over the next few days.

Additional intervention elements for the high-risk group:

Week 1

Internet use. Using the PRISM Internet Assessment, participants visually represent the role of the Internet in their lives. They are asked to place a cross in a square diagram to show how close or distant the Internet feels to them currently, and then again to reflect how they would like it to be after the intervention. The distance between themselves and the cross reflects the perceived importance of Internet use.

Self-assessment and psychoeducation on Sofalizing

The Sofalizing Scale (Tosuntas, et. al., 2020) assesses participants' tendency to interact socially online rather than in person. The scale includes 11 items that are rated on a 5-point scale from (0 = never to 4 = very often). The subscales cover two key dimensions: online displacement and social compensation. Based on the scores, personalized feedback about the tendency to interact is provided. Additionally, participants are introduced to the concept of Sofalizing, which refers to social interaction from home via digital platforms. The app encourages users to reflect on their social habits and provides more information for those who are curious while respecting those who decline. This module raises awareness of the differences between online and offline social behaviour. It helps users reflect on the role of digital interaction in their lives and potentially guides them toward a more balanced social life.

Self-assessment with the Fear of Missing Out (FoMO) Questionnaire (Przybylski et al., 2013) and the FOMO single item (Riordan et al., 2020) Scale

The assessment raises awareness and provides information on the relationship between the fear of missing out and problematic online behaviour. The module begins with an intriguing question: "Have you ever felt like you were missing out on something important, or like your friends were doing fun things without you?" Then, the 12 items of the FoMO questionnaire address both general FoMO (trait) and online-specific FoMO (state). Participants rate these items on a 5-point Likert scale from 1 (Not at all) to 5 (Extremely true of me) and cover emotional responses, compulsive behaviour, and social comparison. After completing the self-assessment, participants receive personalized feedback with a visual representation of their results. This feedback validates their experience and suggests appropriate next steps. Participants with high FoMO receive reflective prompts and further information on FoMO and behavioural change. Those with low FoMO are positively reinforced and offered optional educational content. The information section explains the link between FoMO and PUI. It details how FoMO can lead to compulsive checking behaviours due to perceived social exclusion, which can result in decreased emotional well-being and problematic online activities.

Self-assessment with the Internet Use Expectancies Scale (IUES) (Brand et al., 2014)

The scale provides insight into why participants use the Internet, focusing on emotional and psychological expectations. By identifying patterns that may indicate avoidance-based or pleasure-seeking Internet use, the assessment can help determine the relevance to the development of PUI. Participants rate each item on a 6-point Likert scale (1 = completely disagree to 6 = completely agree) based on how strongly they agree with it. Personalized feedback focuses on the subscale's avoidance-oriented use (indicating that participants use the internet to escape negative emotions or responsibilities) or positive reinforcement use (indicating that participants seek fun, enjoyment, or positive emotions by using the internet). Participants with high scores on one of the two subscales are prompted to reflect on whether this strategy is helpful or if they would prefer to learn healthier emotion regulation techniques (e.g., physical activity or social interaction). Motivational interviewing techniques are used in the personalized feedback to encourage self-reflection and motivate engagement in alternative offline activities for emotional well-being.

Week 2

Self-assessment and categorisation of participants with the Amba

This self-assessment instrument helps participants reflect on the relationship between their emotional state and their tendency to use the Internet in order to provide personalized feedback. First, participants rate their mood (1 = very bad to 10 = very good) and their stress level (1 = not at all stressed to 10 = very stressed). Then, participants are asked to rate their temptation to use the Internet

and their primary online activity, as well as other helpful activities. Based on their responses, participants are categorized as low-risk (defined as a good mood, low stress, and minimal internet use) or high-risk (defined as a bad mood, high stress, and frequent internet use). Participants are then provided with individualized feedback to encourage reflection on alternative coping strategies and behavioural changes.

Week 4

Impulsivity and Internet use

An informative text explains the connection between impulsivity and PUI. Participants can indicate which online activities they struggle with (e.g., social media or gaming). Based on their responses, participants are asked to choose alternative behaviours and stimulus control techniques tailored to them (e.g., setting screen time limits or deleting apps).

Specific alternative behaviours for PUI

Based on the selection of problematic online behaviours, specific strategies and activities are provided. Participants are encouraged to change PUI and engage in alternative activities through feedback that promotes the use of strategies in their daily life.

Table 6. Inhibitory control intervention content mapped from the COM-B to the theoretical domain, intervention function, and behaviour change techniques (BCT's)

Intervention element	COM-B	Theoretical domain	Intervention function	BCT	Elements
Week 1					
Mood Barometer	-Psychological Capability	-Emotional awareness	-Enablement	-Self-regulation	During the four-week intervention phase, participants can rate their mood three times a week and receive personalized feedback. Through this process, they learn how their emotions influence their impulsive behaviour.
Self-Assessment – Compulsive Internet Use Scale (CIUS) + Psychoeducation	-Psychological Capability -Reflective Motivation	-Knowledge -Beliefs about consequences -Self-reflection	-Education	-Self-monitoring -Feedback on behaviour	Based on the self-assessment, participants can reflect on their Internet usage and its related health consequences. They will receive information on PUI and personalized feedback on their behaviour.
Self-Assessment – Readiness and Self-Efficacy Ruler	-Psychological Capability -Reflective Motivation	-Beliefs about capabilities -Verbal persuasion	-Education -Persuasion	-Goal setting (behaviour) -Action planning	The assessment is used to measure readiness and capacity to change behaviours. Participants rate how important it is for them to change their behavior and how capable they are of doing so. Participants will receive personalized feedback encouraging them to further explore their motivations or offering support for taking steps to change.
Self-Assessment – Decisional Balance Questionnaire	-Psychological Capability -Reflective Motivation	-Beliefs about consequences -Self-reflection -Intentions	-Education -Persuasion -Enablement	-Pros and cons -Feedback on behaviour -Action planning	Participants reflect on the negative consequences and perceived benefits of Internet use and receive individualized feedback. The three most significant negative effects are assessed to determine helpful steps for motivating change.
Self-Assessment – Need to belong and UCLA Loneliness Scale	-Psychological Capability -Reflective Motivation -Social Opportunity	-Social influences -Emotions -Reinforcement	-Education -Enablement -Persuasion	-Self-monitoring of outcomes of behaviour -Information about social and environmental consequences -Behavioural practice/rehearsal	Feelings of loneliness and the desire for belonging are examined in the context of PUI. Participants learn about the relationship between loneliness and Internet usage. Helpful activities for improving real-life social connections are provided, and positive reinforcement is given to socially connected participants.
Week 2					

Mood Barometer	-Psychological Capability	-Emotional awareness	-Enablement	-Self-regulation	During the four-week intervention phase, participants can rate their mood three times a week and receive personalized feedback. Through this process, they learn how their emotions influence their impulsive behaviour.
Informative video for understanding Impulsivity	-Psychological Capability -Reflective Motivation	-Knowledge -Beliefs about capabilities	-Education -Persuasion -Modelling	-Information about health consequences -Framing/reframing -Verbal persuasion about capability	An interactive, avatar-based video introduces the concepts of compulsive behaviour and impulsivity. Participants are encouraged to reflect on their experiences and are reassured that they can learn to manage their impulses.
Self-Assessment – Urgency – Premeditation - Perseverance - Sensation Seeking Scale	-Psychological Capability -Reflective Motivation	-Behavioural regulation -Beliefs about consequences	-Education -Enablement -Persuasion	-Self-monitoring of behaviour -Information about health consequences -Feedback on behaviour	Participants evaluate their impulsive tendencies based on the self-assessment. Then, based on the identified level of impulsivity, personalized feedback is provided to encourage exploration of impulsive behaviour and its potential effects.
3-day Challenge to observe behaviour with the Cambridge–Chicago Compulsivity Trait Scale	-Psychological Capability -Reflective Motivation -Automatic Motivation	-Reinforcement -Goals -Memory, attention, and decision processes	-Enablement -Education -Persuasion	-Self-monitoring of outcomes of behaviour -Feedback on behaviour -Review behaviour goal(s)	Participants spend three days monitoring their compulsive and habitual behaviours. Daily feedback encourages reflection on personality traits, motivating participants to set goals and make changes.
Week 3					
Mood Barometer	-Psychological Capability	Emotional awareness	Enablement	Self-regulation	During the four-week intervention phase, participants can rate their mood three times a week and receive personalized feedback. Through this process, they learn how their emotions influence their impulsive behaviour.
3-day Challenge to observe behaviour with the Cambridge–Chicago Compulsivity Trait Scale	-Psychological Capability -Reflective Motivation -Automatic Motivation	-Reinforcement -Goals -Memory, attention, and decision processes	-Enablement -Education -Persuasion	-Self-monitoring of outcomes of behaviour -Feedback on behaviour -Review behaviour goal(s)	Participants spend three days monitoring their compulsive and habitual behaviours. Daily feedback encourages reflection on personality traits, motivating participants to set goals and make changes.

Learning and Practicing Impulse Control Strategies	<ul style="list-style-type: none"> -Psychological Capability -Reflective Motivation -Automatic Motivation 	<ul style="list-style-type: none"> -Skills -Reinforcement -Beliefs about capabilities 	<ul style="list-style-type: none"> -Training -Enablement -Education -Persuasion 	<ul style="list-style-type: none"> -Problem solving -Behavioural practice/rehearsal -Instruction on how to perform the behaviour -Feedback on behaviour -Verbal persuasion about capability 	<p>Participants select various strategies, such as the STOP technique and self-regulation skills, to help them stop a compulsive behaviour or observe an impulse without acting on it. Personalized feedback using motivational interviewing techniques encourages self-reflection and engagement in alternative offline activities that promote emotional well-being.</p>
Transfer of strategies	<ul style="list-style-type: none"> -Psychological Capability -Reflective Motivation 	<ul style="list-style-type: none"> -Reflection -Reinforcement -Behavioural regulation 	<ul style="list-style-type: none"> -Enablement -Persuasion 	<ul style="list-style-type: none"> -Behavioural practice/rehearsal -Instruction on how to perform the behaviour -Feedback on behaviour -Verbal persuasion about capability 	<p>To evaluate the effectiveness of the previously selected strategies, participants are challenged to apply them to their daily lives over the course of two days. They receive personalized feedback based on their experience to encourage reflection and engagement. If necessary, adjustments to the strategies can be made.</p>
Week 4					
Mood Barometer	<ul style="list-style-type: none"> -Psychological Capability 	<ul style="list-style-type: none"> -Emotional awareness 	<ul style="list-style-type: none"> -Enablement 	<ul style="list-style-type: none"> -Self-regulation 	<p>During the four-week intervention phase, participants can rate their mood three times a week and receive personalized feedback. Through this process, they learn how their emotions influence their impulsive behaviour.</p>
Astronaut challenge-Strategy Use and Application via Interactive Scenarios	<ul style="list-style-type: none"> -Psychological Capability -Reflective Motivation -Automatic Motivation 	<ul style="list-style-type: none"> -Skills -Reinforcement 	<ul style="list-style-type: none"> -Modelling -Training -Reinforcement 	<ul style="list-style-type: none"> -Demonstration of the behaviour -Behavioural practice/rehearsal -Material incentive (behaviour) -Review behaviour goal(s) 	<p>The interactive challenges simulate situations in which impulsivity may arise. Participants help the astronaut select appropriate coping strategies and apply them to real-life situations. Then, they receive follow-up reflection prompts.</p>
Emergency Plan and Relapse Prevention	<ul style="list-style-type: none"> -Psychological Capability -Reflective Motivation 	<ul style="list-style-type: none"> -Self-reflection -Goals -Intentions 	<ul style="list-style-type: none"> -Enablement -Education -Goal setting 	<ul style="list-style-type: none"> -Action planning -Problem solving -Focus on past success 	<p>Participants are invited to reflect on what they learned during the intervention phase. Then, they can create a personalized emergency plan for managing impulses in high-risk situations. The intervention phase concludes with positive reinforcement and encouragement to continue using these strategies.</p>

		-Beliefs about capabilities		-Social reward -Review outcome goal(s)	
Bonus game - Mindful Breathing	-Psychological Capability -Reflective Motivation	-Skills -Regulation	-Training -Incentivization	-Reduce negative emotions -Material incentive (behaviour) -Behavioural practice/rehearsal	The game includes timed mindful breathing exercises and breath analysers to promote self-regulation. Participants earn coins daily and for completing challenges, which encourages consistent engagement and motivation.
Bonus Game - Positive Instructions and Helpful Thoughts	-Psychological Capability -Reflective Motivation	-Skills -Regulation -Beliefs about capabilities	-Education -Training -Enablement	-Verbal persuasion about capability -Reduce negative emotions -Habit formation -Framing/reframing	Helpful thoughts and self-instructions are provided. Participants learn that internal self-talk can influence behaviour and emotion. They are encouraged to adopt positive self-statements and use them over the next few days.
Additional intervention elements for the high-risk group					
Visual self-reflection of Internet use with the PRISM self-assessment	-Psychological Capability -Reflective Motivation	-Goals -Self-reflection	-Education -Persuasion	-Self-monitoring of behaviour -Review behaviour goal(s)	Participants visually represented the role of the internet in their lives before and after the intervention. These visual displays promote self-monitoring and goal setting for change.
Self-assessment and psychoeducation on Sofalizing	-Psychological Capability -Reflective Motivation	-Self-reflection -Knowledge	-Education -Enablement	-Self-assessment and psychoeducation on Sofalizing	The participants' tendency to interact socially online rather than in person is assessed, and they are provided with personalized feedback. Participants are introduced to the concept of "Sofalizing" and encouraged to reflect on their social habits. This self-assessment helps users consider the role of digital interaction in their lives and potentially guides them toward a more balanced social life.
Self-assessment with the Fear of Missing Out (FoMO) Questionnaire	-Psychological Capability -Reflective Motivation	-Self-reflection -Knowledge -Social influence	-Education -Persuasion	-Information about social comparison -Reduce negative emotions Feedback on behaviour	Educational elements explain the link between FoMO and FUI. Participants evaluate their own fear of missing out and receive personalized feedback, as well as a visual representation of their results. Those with high FoMO receive reflective prompts and more information about FoMO and behavioural change. Those with low FoMO receive positive reinforcement and are offered optional educational content.

Self-assessment with the Internet Use Expectancies Scale	-Psychological Capability -Reflective Motivation	-Self-reflection -Knowledge -Emotion -Reinforcement	-Education -Persuasion	-Information about emotional consequences -Problem solving -Verbal persuasion about capability	The self-assessment provides insight into why participants use the Internet, with a focus on emotional and psychological expectations. Participants with high sum scores are encouraged to consider whether this strategy is helpful or if they would prefer to learn healthier emotion regulation techniques, such as physical activity or social interaction. Personalized feedback encourages self-reflection and motivates engagement in alternative offline activities that promote emotional well-being.
Self-assessment of mood, stress, temptation, and Internet use	-Psychological Capability -Reflective Motivation	-Self-monitoring -Emotion	-Education -Persuasion	-Self-monitoring of outcomes of behaviour -Information about health consequences -Feedback on behaviour -Problem solving	Participants reflect on the relationship between their emotional state and their Internet usage habits. Based on their responses, they are categorized as low- or high-risk users. They are provided with individualized feedback to encourage reflection on alternative coping strategies and behavioural changes.
Impulsivity and Internet Use (Education and Alternative Behaviours)	-Psychological Capability -Reflective Motivation -Opportunity	-Skills -Regulation -Beliefs about capabilities	-Education -Training -Persuasion	-Restructuring the physical environment -Problem solving -Instruction on how to perform behaviour -Behavioural practice/rehearsal	An informative text explains the connection between impulsivity and PUI. Participants select the online activities with which they struggle. Then, based on their responses, participants are asked to choose alternative behaviours and stimulus control techniques.
Specific Alternative Behaviours for PUI	-Psychological Capability -Reflective Motivation	-Skills -Regulation -Reinforcement	-Education -Enablement -Persuasion	-Behaviour substitution -Problem solving -Verbal persuasion about capability -Social reward	Specific strategies and activities are provided based on the selection of problematic online behaviours. Participants are encouraged to change their PUI and engage in alternative activities by receiving feedback that promotes the use of these strategies in daily life.

Appendix C.

Control condition transcript

Introduction

Hi! Great to see you here.

Over the next 4 weeks, you will get helpful tips about using the internet and taking care of your mental health. Mental well-being means how you think, feel, and act. It affects your mood, your energy, and how you get along with other people. Just like your body needs care, your mind does too. Good brushing your teeth or eating healthy! You will get a new short post every second day. Take a look and learn more about these interesting topics.

1.1 Problematic and addictive use of the Internet

The internet is part of our daily lives. We use it to listen to music, chat with friends, and have fun. But sometimes, we use it too much, and that can become a problem. Most people think of online games when they hear "internet addiction." But using social media or shopping online too much can also be a problem.

So, when is internet use a problem? It's a problem when it starts to hurt other parts of your life. For example, if you: Stop doing homework or going to hobbies because you're online all the time, or you reduce spending time with family or friends in real life. This can lead to impairments for instance in school or your social life.

1.2 Digital Detox Time

Try to take one hour a day without screens. No phone, computer, or TV. Use this time to do something fun without the internet—like reading, playing outside, or talking with your family. When it gets easier, you can try to spend even more time offline.

2.1 Social media and mental health

Apps like Instagram, TikTok, and Facebook help us feel connected, and entertain us. Watching what friends, influencers, and others share online can help us feel like we belong. Also, social media helps you find people who like the same things as you. But sometimes there are problems related to the use of social media.

Here are some examples:

- You might start comparing your life to others or feel bad about yourself.
- You can feel lonely or left out.
- You might get FOMO (Fear of Missing Out), which means being worried about not knowing what's going on.

If using social media makes you feel stressed or sad, take a break. Set limits, and don't be afraid to talk to someone about it.

2.2 The Real-Life Connection Challenge

Each day, try to swap one thing you do online (like texting or using social media) with something real-life. Call a friend instead of texting. Meet someone in person instead of chatting online. Join a club, play sports, or try a hobby group. So, what are you waiting for? Let's give it a go!

3.1 Hobbies and Social Media

Many teens have hobbies – and that's great! Hobbies are fun and relaxing. They help us feel calm and happy. When we do something we enjoy, it can help us slow down and feel better after a busy day. Today, a lot of people spend their free time in front of screens – watching TV, videos, or scrolling on their phones. But sometimes, they aren't even really interested in what they're watching. Having a personal, active hobby (like drawing, playing music, or cooking) keeps you active and happy. Doing something with your hands or body is often better than just sitting and watching things online. If you already have a hobby, keep doing it! If you don't, maybe it's time to find one you like.

3.2 New Hobby Challenge

Try out a new hobby or spend more time on one you already like. Here are some fun ideas:

Creative: Drawing, painting, taking photos, writing

Musical: Learning an instrument, singing, making music

Active: Sports, dancing, hiking, skateboarding

Techy: Coding, building robots, science fun

Helpful: Cooking, DIY crafts, helping in the house or garden

4.1 Learning patience

Being patient can be hard, especially when things are stressful - at school or at home. But here's the good news: You can practice being patient, just like learning a sport or playing an instrument. Patience is like a muscle - you can make it stronger. One easy way is with a breathing exercise. It helps you calm down and feel more relaxed. When you feel stressed or get impatient, your heart beats faster and you breathe quicker. This simple trick can help your body feel calm again.

4.2 5-breath exercise for more patience

If you feel impatient or stressed, stop for a moment. Notice what's going on in your body. Do you feel jumpy, tense, or like your heart is racing? Now focus on your breathing. Breathe in deeply through your nose, and out slowly through your mouth. Take your time. Imagine each breath making you calmer. You'll start to feel more relaxed. Your heart slows down, and your breathing gets easier. With a bit of practice, you'll find it easier to stay cool in tough situations.

5.1 Coping with stress

Everyone feels stressed sometimes. That's totally normal.

Some healthy ways to deal with stress are:

- Moving your body (exercise)
- Talking to someone you trust
- Trying mindfulness (relaxing your mind)

Talking about your feelings really helps. Keeping everything inside can make problems feel bigger. You don't have to have all the answers—but sharing how you feel can help a lot.

5.2 Move & Reset Challenge

Every day, try to move your body for at least 15 minutes. It helps you feel less stressed and fuller of energy. Try something fun like:

Cardio: Jogging, jumping rope, cycling, **Strength:** Bodyweight exercises (push-ups, squats), **Fun Movement:** Dancing to your favorite music, **Relaxing Exercise:** Yoga or stretching

6.1 Mindfulness

Mindfulness means paying full attention to right now. This means you try to notice how your body feels and what you see, smell and taste. Maybe you even feel emotions in your body, perhaps through a tightness somewhere, or a good sensation.

Mindfulness is also noticing what your mind is doing. It helps you feel calm and focused. If you're feeling nervous about school or stressed by social stuff, mindfulness can help.

6.2 Practice mindfulness

Mindfulness can help you understand your feelings better.

Try this fun exercise using your hand!

The thumb: Lift your thumb once. This thumb represents the beautiful things in your life. In the morning, ask yourself: Who/what am I looking forward to today? In the evening, you can also ask yourself: What/who was I grateful for today?

Since people are often more aware of the negative, this step helps us to focus on the positive.

The Index Finger: We use it to point or interpret. What do I want? In the morning we can set a motto for the day: What do I want today? This makes us aware of our goals and desires. With this focus, we can make targeted decisions and take steps in that direction. In the evening: How did I contribute to the outcome of this day? We become aware of our impact.

The middle finger: It represents our motivation. In the morning: Feel your energy level. How full is it today? In the evening before going to bed: How motivated was I today? What robbed me of energy and what gave me energy? By reflecting, we can identify and possibly increase the actions that give us energy.

The Ring Finger: The ring finger represents the circle of the day. This is where I can simply "be" in order to come to rest. Then I am neither accessible nor inaccessible. In the morning: When will I take time for myself today? In the evening, we reflect on how this moment felt.

The little finger: How is my body? When we pay attention to our body, it serves as an early warning system. In the morning: We pay attention to how our body feels and what it might need. By stopping and being more aware of it, we can give it little nudges that do it good. In the evening, reflect on how your body has been today.

7.1 Sleep and mental health

Sleep is super important! It helps your body grow, your brain learns, and your mood stays balanced. Good sleep helps you focus at school, feel happy, and have energy to play. To get a good night's sleep, try to stick to a regular bedtime, avoid screens before bed, and create a calm, quiet space to rest. Remember, a good night's sleep helps you be your best every day! Try to stick to a regular sleep schedule and avoid screen time right before bed to get the best rest.

7.2 Mini-breaks

Life can feel super busy and stressful sometimes. One helpful trick is to take mini-breaks! These are tiny breaks that last just 2 to 5 minutes. You can stretch, walk, or take a few deep breaths. Even short breaks like this help your brain feel better, reduce stress, and help you focus again. Think of it like pressing a reset button! Try it during your day!

8.1 Building Resilience

Resilience means staying strong when things go wrong. Everyone has hard times - school stress, fights with friends, or feeling scared to try something new. If you're resilient, you don't give up. You keep trying, ask for help, and learn from mistakes. Believe in yourself. Stay positive. Remember: mistakes help you grow!

8.2 Positive Self-talk

"I am good as I am."

Say this sentence out loud during the day - in the morning, when you're stressed, before you go to bed. Focus on what it means. The more you say it, the more it can help you feel calm and strong.

9.1 Importance of friendships

Friends make life better! Good friends: Make you laugh, listen to you, support you. Sometimes you may fight or feel misunderstood—but real friends talk things out, are kind, and respect each other. A true friend likes you for who you are and wants you to be happy.

9.2 The Friendship Boosting Challenge

Try something small to grow a friendship or make a new one such as giving a sincere compliment to a classmate, inviting someone to join you for lunch or a walk, sending a kind note to check on a friend, trying a new activity or hobby with someone else.

10.1 Express emotions

Do you have trouble expressing your feelings? Sometimes it's hard to talk about feelings. You may feel stuck or misunderstood. But sharing your emotions is really important.

Talking about how you feel helps you:

- Feel less stressed
- Understand yourself
- Get closer to others

Hiding emotions can make you feel worse. Let them out in a healthy way!

10.2 Challenge to get to know your emotions

Each day, write a few notes about how you feel. This helps you understand your emotions better. Follow these steps for writing down your emotions:

Naming – How are you feeling (e.g., happy, angry).

Rating: On a scale of 1-10, how strong is your emotion?

11.1 Procrastination

We all know the feeling when we should be doing our homework, but we suddenly get the urge to do something else. Do you ever avoid some exercises by watching videos or doing something else? That's called procrastination - putting things off.

It feels good in the moment, but later it causes stress. Why do we do it? Maybe we're afraid, confused, or trying to be perfect.

11.2 5-Minute Action Challenge

When you feel like avoiding something you should do, try this: Set a timer for 5 minutes and just start the task (like homework or cleaning). After 5 minutes, you can either keep going or take a short break and try again. It's a great way to get started!

12.1 Summary mental health and Internet use

Your mental health is about how you feel, think, and deal with life. When your mental health is good, you can handle stress, feel confident, and enjoy your friendships. To feel your best:

- Balance screen time
- Do fun things offline
- Talk to real friends
- Take care of your body and mind

12.2 Final Challenge

Great job! You've learned a lot about mental health and using the internet in a healthy way.

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