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Study protocol for a randomised controlled trial of an e-health stepped care approach for the treatment of internet use disorders versus a placebo condition: the SCAPIT study

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ABSTRACT

Introduction Excessive internet use can lead to problems for some individuals. The WHO has introduced Gaming Disorder in the International Classification of Diseases-11 (ICD-11). Previous research has shown that other internet applications can cause serious mental health problems as well. It is important to provide measures of prevention, early intervention and therapy for internet use disorders (IUDs).

Methods and analysis The study 'Stepped Care Approach for Problematic Internet use Treatment' is a randomised, two-arm, parallel-group, observer-blind trial. The aim of the study is to investigate if a stepped care approach is effective to reduce symptom severity for IUD. The sample is primarily recruited online with a focus on employees in companies with support of health insurances. After screening, the stepped care approach depends on the success of the previous step—that is, the successful reduction of criteria—and comprise: (1) app-intervention with questionnaires and feedback, (2) two telephone counsellings (duration: 50 min) based on motivational interviewing, (3) online therapy over 17 weeks (15 weekly group sessions, eight individual sessions) based on cognitive–behavioural therapy. A follow-up is conducted after 6 months. A total of 860 participants will be randomised. Hierarchical testing procedure is used to test the coprimary endpoints number of Diagnostic and Statistical Manual of Mental Disorders, fifth edition and ICD-11 criteria. Primary analysis will be performed with a sequential logit model.

Ethics and dissemination The study has been approved by the Ethics Committees of the Universities of Lübeck (file number: 21-068), Mainz (file number: 2021-15907) and Berlin (file number: 015.2021). Results will be reported in accordance to the CONSORT statement. If the approach is superior to the control condition, it may serve as part of treatment for IUD.

Trial registration number DRKS00025994.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study is a randomised controlled trial evaluating an e-health-based stepped care approach for internet use disorders, addressing the full spectrum of problematic internet use (PIU).
⇒ The comprehensive approach represents an economic low-threshold tool and provides tailored treatment for individuals with PIU.
⇒ All elements of the interventions are derived from evidence-based approaches from the field of substance use disorders.
⇒ Reaching the participants and subsequent recruitment may be limited due to the COVID-19 pandemic.

INTRODUCTION

The use of smartphones and the internet is widespread, opens up new possibilities and will continue to be of high significance in all areas of our society in the future. In addition to the potential of this medium with its many channels for innovation and development, it must be considered that internet use disorders (IUD) can occur for some users.[1] Essentially, the problematic internet-related behavioural patterns relate to computer games, social network use, pathological consumption of pornography and disordered buying/shopping.[2 3] In the 11th revision of the International Classification of Diseases (ICD-11), the WHO introduced Gaming Disorder as a disorder due to addictive behaviour[4] and provided another ICD-code for other specific behavioural addictions. A recent meta-analysis based on 133 studies worldwide found a pooled prevalence of 'Generalised Internet Addiction' of 7%.[5] For the German general population, a prevalence of about 1%–2.5% of IUD can be assumed, with significantly higher prevalence rates in younger age groups, and the proportion of individuals
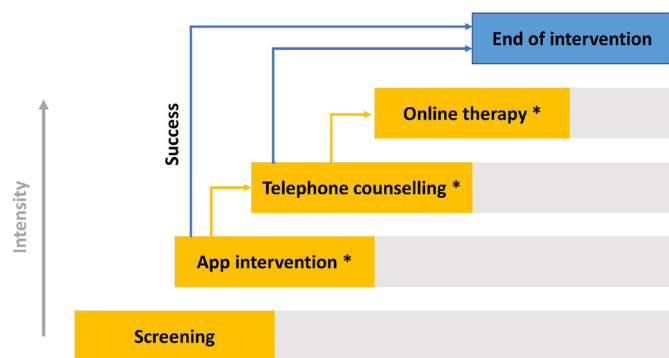
* The description of character and duration of the interventions can be found in the text

Figure 1 Stepped care approach in the SCAPIT trial. SCAPIT, Stepped Care Approach for Problematic Internet use Treatment.*The description of character and duration of the intervention can be found in the text.

with harmful or risky behaviours being about three times higher among younger people,[6 7] making adolescents a crucial target group for early intervention. Furthermore, research among adolescents and young adults indicates a significant increase in problematic internet-related behavioural patterns, especially among women.[8]

Problematic internet-related behavioural patterns are a relatively new phenomenon that requires evidence-based measures of prevention, early intervention and therapy. A group of experts of the Drug and Addiction Council of the Federal Government in Germany has come to the conclusion that there are currently hardly any evidence-based measures of universal and selective prevention for IUDs.[9] In particular, there is a lack of concepts for early intervention and the broad implementation of measures for the care of this new patient group, whose importance will increase in the future. As with all addiction-related behaviours, only a few affected individuals with problematic internet use (PIU) actively seek help, therefore, proactive and low-threshold measures are of particular importance.[10] Proactive—that is, approaching the person affected—action can be implemented feasibly wherever the target group is easily accessible. In addition to places such as basic medical care or school education, the workplace is of great importance here. In terms of effectiveness in changing health behaviour, the workplace is one of the most effective settings.[11]

Aims and objectives

For the group of participants with PIU, a comprehensive and economic care system based on a stepped care approach was developed and will be evaluated (figure 1). The approach also includes a primary prevention module (universal prevention), which is aimed at all participants,
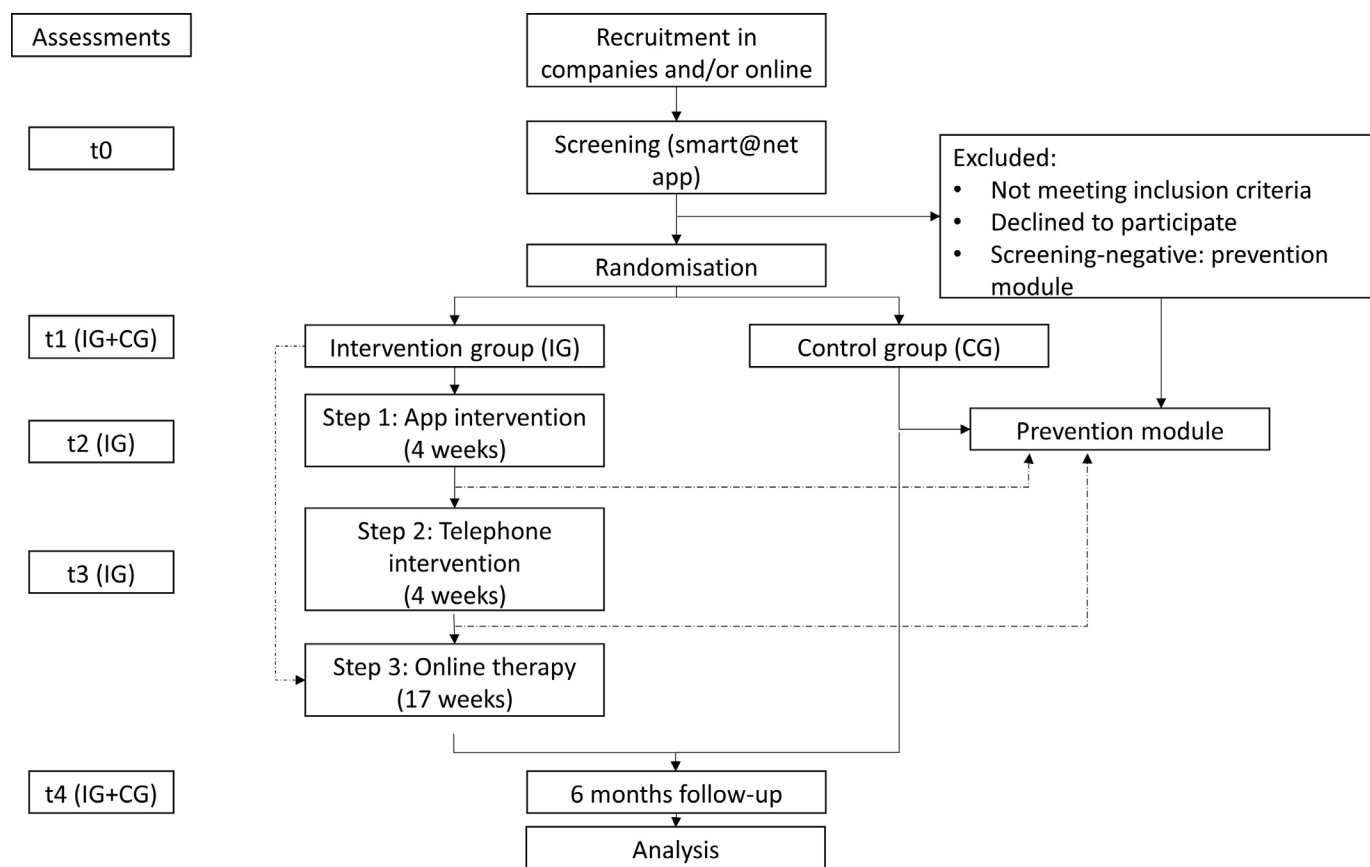
CONSORT: Consolidated Standards of Reporting Trials. t0-t4: time0, time2, etc.; IG = intervention group, CG = control group

Figure 2 CONSORT flow diagram SCAPIT. SCAPIT, Stepped Care Approach for Problematic Internet use Treatment. t0-t4: time0, time2, etc.; IG=intervention group,CG=control group. *The description of character and duration of the interventions can be found in the text.

Table 1 Assessment during screening

Questionnaire	Source	Optional	Feedback
Sociodemographics	Standard, adapted to the setting in companies		
Internet activity	self-developed		
Use of the Internet more than is good for oneself (Act-More)	self-developed		
Compulsive Internet Use Scale	Meerkerk et al[14]		x
Gaming Engagement Screener	Higuchi et al[19]		
Sofalising Scale	Tosuntas et al[20]		
Satisfaction with Life Scale	Diener[21]		x
Mental Health Index-5	Berwick et al[22]		
Perceived Stress-4	Warttig et al[23]		
Burn-out (single item)	Rohland et al[24]		
Smartphone use at the workplace	self-developed		
Use of time indicators	Montag et al[25]		
Health status	Manning et al[26]		
Alcohol Use Disorders Test-Consumption	Bradley et al[27]		
Smoking behaviour	Heaviness of Smoking Index+Shisha use + E-Cigarette use		
Stress caused by the COVID-19 pandemic	self-developed		
Utilisation of psychological treatment	self-developed		
Questions on the work situation during COVID-19 pandemic and working from home	self-developed and questions from https://www.uni-mannheim.de/gip/corona-studie/	x	x
Big Five-International Personality Item Pool	Donnellan *et al*[28]	x	x
Fear of Missing Out	Przybylski *et al*[29]	x	x

including those who do not yet suffer from PIU. This should increase the acceptance of the programme and avoid a division into participants with/without problems.

We hypothesise that the intervention according to the stepped care approach is superior to the prevention module (control condition) with respect to a decrease in symptom severity of IUD according to the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5)[12] or the ICD-11 in 6 months after randomisation. Furthermore, we hypothesise that the intervention leads to less online time, less impairment and more satisfaction with life.

METHODS AND ANALYSIS
Study design and sample collection
The study is a randomised, two-arm, parallel-group, observer-blind trial. Participants are recruited online via various companies, occupational schools, universities and with the support of cooperating health insurances, predominantly—due to the ongoing pandemic—via a web page and social media. Potential participants are either personally invited by study staff or health insurance staff or invited via social media to download the smart@net app onto their smartphones. A QR code is provided for this purpose. The smart@net app was developed

exclusively for the study and is a further development of the Insights app.[13] The smart@net app includes a screening part, as well as a prevention and an intervention module. The contents of the app were developed by the research team and implemented by a software engineer. The stepped care approach (described in detail below) consists of screening and subsequent assignment to an app-based intervention (step 1), brief telephone counselling sessions based on motivational interviewing carried out by psychotherapists or trained health scientists (step 2) and online therapy carried out by psychotherapists (step 3). Defined success criteria determine the end of therapy or the next stage. All interventions are e-health based to lower the threshold to treatment. After an initial screening within the smart@net app, the screening-positive group (defined below) is randomly assigned to the stepped-care condition or a control condition that is invited to use the prevention module. There will be a blinded follow-up after 6 months. The study procedure is depicted in figure 2.

Inclusion criterion for the whole study is based on age: specifically, study participation is limited to individuals between ages 16 and 67. Another inclusion criterion was that the participants have to have a mobile phone. For the three intervention steps, different inclusion criteria

are set: step 1 requires at least 21 points in the Compulsive Internet Use Scale (CIUS).[14] Step 2 includes participants without success in step 1 (ie, CIUS score >20) and/or three criteria according to DSM-5 or one criterion according to ICD-11. For step 3, a lack of success in step 2 (ie, CIUS score >20 and three criteria according to DSM-5 or one criterion according to ICD-11) and an additional clinical diagnosis that requires treatment (more than four criteria according to DSM-5 or three criteria according to ICD-11). If participants have more than six DSM-5 criteria in the first assessment, they are offered immediate access to the online therapy. All participants have to give informed consent (digitally, within the app). Exclusion criteria are psychotherapy within the past 4 weeks (to prevent an influence on the outcome of the interventions) and insufficient knowledge of the German language. All participants can withdraw their consent at any time at their own request without giving reasons and without incurring any disadvantage.

Interventions
Step 1: Over 28 days, participants receive daily questionnaires and weekly feedback via the smart@net app addressing Internet use based on motivation and self-efficacy, the development of goals and the reinforcement of successes. Participants get reminders via push notifications. In addition, the time of smartphone use and the time spent with different apps will be tracked if participants agree to this.

Step 2: Aim of the telephone-based brief intervention is to motivate a change in behaviour in Internet use patterns. Therefore, two telephone counselling sessions based on motivational interviewing[15] and principles of cognitive–behavioural therapy are conducted within 4 weeks, with each session lasting up to 50 min. In collaboration with the participants, individual expectations regarding the use of digital media are explored and unpleasant or stressful negative aspects of media use are identified. In addition to promoting motivation, the aim is to improve self-efficacy for behavioural change and to develop respective goals.

Step 3: The online treatment is based on a standardised behavioural treatment manual, which is based on cognitive–behavioural therapy[16] and proved efficacy in a randomised controlled trial where the treatment was superior to the control group in reducing dependent behaviour patterns in various forms of internet-related disorders.[17] The online therapy includes 15 weekly group sessions (duration: 100 min) with 4–6 participants and eight individual sessions, both provided by one psychotherapist over 17 weeks. The programme comprises various interventions to support abstinence related to the problematic behaviour (eg, excessive use of computer games, pornography or social networking sites). This includes motivational techniques, the development of a daily structure, the establishment of an individual online time management and the improvement of social relationships and partnership. Other key elements include protocols of the online behaviour, a behavioural analysis, a 6-week abstinence trial and strategies for maintaining abstinence. The goal of the online therapy is to achieve abstinence from the problematic behaviour.

For step 2 as well as for step 3, the therapists in charge receive the encrypted contact data of the participants. They are blinded to the information from the survey.

Universal prevention module
The prevention concept aims at increasing awareness via an educational approach. This includes a module on internet addiction (IUDs), as well as various other topics such as cyberbullying. For this purpose, updated information is provided via app. This module serves as a control condition. In addition, information for parents in dealing with their children's use of smartphones is provided via the website of the study (https://www.scavis.net).

Sample size calculation
Given an estimated prevalence of 6% for PIU, we estimate a screening of 24 000 participants and a sample of 1440 participants eligible for the study. Assuming that the participation rate is around 60%, 864 participants could be enrolled in the study. With random assignment of 860 individuals to the intervention or control group, this sample size would ensure that a small effect (d=0.20) could be identified with a power of 80% and a 5% probability of error with two-sided testing for differences in means with a nonparametric test. Thus, a target size of 430 participants per group will be established. Approximately 250 participants are expected for the subsequent brief telephone intervention and 120 for the online therapy.

Randomisation
A stratified block randomisation is used. Age and gender are used as strata. Randomisation will be carried out at the Institute for Medical Biometry and Statistics (IMBS) at the University of Lübeck. Randomisation lists for each stratum will be implemented into the app. After a positive screening and consent for further participation, the app assigns the next free randomisation outcome option to the study participant based on the lists stored on the server. The randomised allocation is then executed on the associated smartphone in the app. The randomisation procedure is based on IMBS internal standard operating procedures.

Assessment and data collection
Assessment during screening (smart@net app)
Table 1 lists the questionnaires used in the screening within the app. For some of the measures, the participants receive a short normative feedback. Furthermore, some measures are offered optionally that also include feedback (introduced with: 'Would you like to learn more about yourself?'). The feedbacks are presented in the form of graphs and short explanatory texts.

Table 2 Assessment during step 1

Questionnaire	Source	Feedback	Intervention
Diagnostic criteria sensu DSM-5 (I-CAT)	Internet-related disorders-Clinical Assessment Tool (c.f.)[30 31]; self-developed based on the principles of the Composite International Diagnostic Interview[32]	x	
Internet Use Expectancies Scale	Brand et al[33]	x	x
WHO Disability Scale	Janca et al[18]	x	x
Fear of Missing Out (single item)	Riordan et al[34]	x	
Readiness ruler+self-efficacy ruler	Heather et al[35]	x	x
Specific self-efficacy	self-developed	x	x
Impact of Internet use and Decisional Balance	Bischof et al[36]	x	x
Need to belong (single litem)	Nichols et al[37]		
Perceived Social Support Questionnaire, short form (F-SozU K-6)	Kliem et al[38]		
University of California, Los Angeles Loneliness Scale	Montag et al[39]		
Bergen Work Addiction Scale	Andreassen et al[40]		
Trierer short scale for Work-Life-Balance	Syrek et al[41]	x	x
Mood-Barometer	self-developed	x	
Compulsive Internet Use Scale	Meerkerk et al[14]		

I-CAT, Internet-related disorders - Clinical Assessment Tool.

Assessment during step 1

Table 2 lists the questionnaires used as part of the 4-week app intervention.

The questionnaires are assessed over 4 weeks and some of them are filled out several times. The feedbacks are ipsative. Based on the collected data, interactive and tailored interventions are implemented, which are communicated in the form of messages and suggestions for reducing PIU based on motivational interviewing principles.[15]

In addition, the tracking function of the app can be voluntarily activated. In this case, the internet behaviour with the smartphone is recorded over a period of 4 weeks for the intervention group and control group through tracking.[13] On a meta-level, it maps the duration (eg, in minutes) and frequency (eg, the number of activation) of the smartphone as well as the specific application use on the smartphone. Basically, the app immediately produces statistics on each smartphone and forwards these statistics to the server. The app is able to record screen locks and screen-ons. 'Screen-ons' are defined as when the phone is only 'tapped' (eg, to check the time), while a 'screen unlock' (entering the password, unlocking the smartphone screen via biometric input (eg, fingerprint)) of the smartphone results in applications (eg, social media or games) being able to run. Other variables to be recorded via tracking are:

► User sessions (screen on/off, screen unlock, session duration, elapsed time since last session).
► App sessions (app title, app package name, duration of use).
► App usage statistics (daily, weekly or monthly aggregated data, app title, app package name, total duration of usage).

Assessment during step 2

At the end of the 4 weeks of step 2, during which two brief telephone interventions are conducted, the CIUS and the diagnostic questionnaire (Internet-related disorders - Clinical Assessment Tool, I-CAT) are assessed again to determine the number of criteria according to DSM-5 and/or ICD-11. Based on the results, participants are assigned to online treatment, if eligible.

Assessment during step 3

At the beginning of the online therapy (t3a), a comprehensive diagnostic assessment is conducted with the participants in order to check possible exclusion criteria and to be able to refer to inpatient treatment in case of severe comorbidities. A part of the questionnaires is administered again about halfway through the online therapy (t3b) and at the end (t3c). Table 3 provides an overview of the data collected.

A telemedical video platform will be established to implement end-to-end encrypted communication between therapists and participants in compliance with data protection regulations. An electronic case report form will be implemented within this telemedical video platform. In this form, the study data for the online therapy module will be collected and stored at the measurement points defined in the study protocol in a data protection compliant manner and in accordance with the course of the study. In order to guarantee the security of the personally reported data within the telemedically end-to-end encrypted group communication during the group sessions, a dedicated confidentiality agreement is signed in advance by all participants of the online therapy.

Table 3 Assessment during step 3

Questionnaire		t3a	t3b	t3c
Internet use disorders	AICA-SKI:IBS; Müller et al[42]	x		x
	CIUS; Meerkerk et al[14]	x	x	x
Depressive symptoms	PHQ-9; Kroenke et al[43]	x		x
	BDI-II; Hautzinger et al[44]	x		x
Anxiety symptoms	LSAS; Stangier et al[45]	x		x
Compulsiveness	SCL-90-R Subscale Compulsiveness; Derogatis[46]	x		x
Self-efficacy	SWE; Schwarzer et al[47]	x	x	x
ADHD	WURS-k; Retz-Junginger et al[48]	x		x
Affect	PANAS; Breyer et al[49]	x		x
Depersonalisation	CDS-2; Michal et al[50]	x	x	x
Patient health	PHQ; Kroenke et al[51]	x	x	x
Global assessment of functioning	GAS; Endicott et al[52]	x	x	x
Medical history of somatic and psychological diseases and treatments, medication		x		
Sociodemographics		x		

t3a: beginning of online therapy, t3b: halfway through online therapy, t3c: end of online therapy.
ADHD, Attention Deficit Hyperactivity Disorder; AICA-SKI, Assessment of Internet and Computer Game Addiction - Structured Clinical Interview; BDI-II, Beck's Depression Inventory; CDS-2, Cambridge Depersonalization Scale; CIUS, Compulsive Internet Use Scale; GAS, Global Assessment Scale; LSAS, Liebowitz Social Anxiety Scale; PANAS, Positive And Negative Affect Scale; PHQ-9, Patient Health Questionnaire; SCL-90_R, Symptom Check-List-90-R; SWE, Skala zur Allgemeinen Selbstwirksamkeitserwartung [Scale for the General Self-Efficacy]; WURS-k, Wender Utah Rating Scale [short form].

Follow-up after 6 months

In the follow-up 6 months after study inclusion, the questionnaires of the screening will be used again and the diagnostic criteria will be assessed via the I-CAT to measure a change in PIU and thus to check the effectiveness of the stepped care approach. The follow-up survey will be conducted via an online questionnaire. The corresponding link will be sent via the contact details provided by the participants. If no valid email addresses of the participants are available, they will be contacted by telephone or, if necessary, by standard mail.

Outcomes

Primary outcome is the number of criteria for PIU according to the adapted Gaming Disorder criteria in DSM-5 and according to the adapted Gaming Disorder criteria in ICD-11 at 6 months after randomisation, both assessed with the I-CAT and adjusted for baseline data. Secondary outcomes are impairments in everyday life (measured with items from the WHODAS,[18]) and time spent online, both at 6 months after randomisation.

Statistical analysis

Analyses will be performed after the data collection is finished (see figure 2). Types of descriptive statistics are shown in table 4.

In a hierarchical testing procedure, using a multiple significance level of 5%, the first primary endpoint defined as the number of criteria for PIU according to the adapted Gaming Disorder criteria in DSM-5/ICD-11 will be tested.

The hypotheses are of the following:

Table 4 Descriptive statistics

Type	Description
Measurement	Median and range with 95% CI Hodges-Lehmann intervals for the difference of medians.
Normal	Means and SD for each treatment group and 95% CI for the difference of means.
Log-normal	Type normal statistics are computed for logarithms and converted back to geometric means, ratio of geometric means and coefficients of variation.
Ordinal	Absolute and relative frequency distributions and 95% CI Wald interval for the OR from an ordinal logistic regression on allocated treatment.
Proportion	Absolute and relative frequencies together with 95% CI score for the difference of proportions.
Time to event	Kaplan-Meier curves and HR with 95% CI estimated from Cox-regression, with competing risks where needed.

1. Primary efficacy: The number of criteria for PIU according to the adapted Gaming Disorder criteria in DSM-5 at 6 months after randomisation.

   Primary null hypothesis: H!: βIntervention versus control=1, that is, the chance to achieve a greater number of criteria for PIU according to the adapted gaming disorder criteria in DSM-5 at 6 months after randomisation is identical between control and intervention group.

   Alternative hypothesis: H/: βIntervention versus control 1.

2. Second coprimary efficacy variable: the number of criteria for PIU according to the adapted gaming disorder criteria in ICD-11 at 6 months after randomisation

   Primary null hypothesis: H!: βIntervention versus control=1, that is, the chance to achieve a greater number of criteria for PIU according to the adapted gaming disorder criteria in ICD-11 at 6 months after randomisation is identical between control and intervention group.

   Alternative hypothesis: H/: βIntervention versus control 1.

A sequential logit model will be used for analysis of the coprimary endpoints. In each model, gender will be used as factor because of stratified randomisation and age will be used as continuous stratification variable. Each endpoint will be adjusted by its baseline. ORs and corresponding 95% CIs will be estimated.

Analyses will be performed on intention-to-treat data. For sensitivity analyses, analyses will be performed on per-protocol population. Missing data in primary endpoints, confounding and subgroup variables as well as baseline values used in primary analysis, will be imputed using multiple imputation.

Patient and public involvement

In the development of the research question, study design and outcome measures, health insurance companies were involved. The health insurance companies also support the recruitment of study participants in associated companies via the company health and safety management and company physicians. A focus group consisting of employees from a local company tested the app for manageability, comprehensibility and presentation. In a discussion meeting, the focus group made suggestions for improvement, which were subsequently implemented in the app. In other parts of the study development, patients/participants were not involved. Participants will be offered the opportunity to be informed of the study results after the trial.

Ethics and dissemination

The study is approved by the Ethics Committee at the Universities of Lübeck (file number: 21-068), Mainz (file number: 2021-15907) and Berlin (file number: 015.2021). The study has a data protection concept which is approved by the data protection officer at the University of Lübeck. All questionnaire and tracking data collected during the screening and during step 1 within the app are transferred in an encrypted form to a secure server.

The monitoring of the study is carried out by the monitors of the Center for Clinical Studies Lübeck (CCS). The monitoring is based on the requirements of Good Clinical Practice and the CCS's own standard operating procedures.

As part of the monitoring, visits will take place before (initiations), during (regular monitoring visits) and after (closeout visits) the survey. To ensure the quality of the study, the following points will be monitored on an ongoing basis during regular visits: Adherence to the recruitment rate, adherence to inclusion criteria, adherence to treatment procedures and completeness of study documents.

For safety aspects, serious adverse events are documented in a case report form during step 2 and step 3 (intervention group) as well as during the follow-up assessment (intervention group and control group) and are reported to the principal investigator.

Study results will be reported in accordance to the CONSORT (Consolidated Standard of Reporting Trials) statement. Data analysis is carried out by the participating universities in Lübeck, Ulm and Mainz. The results will be published in peer-reviewed academic journals. The anonymous data will be uploaded to an online repository of the Open Science Framework. If the stepped care approach is superior to the control condition, the approach can be offered as part of treatment approaches for IUD.

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