BMJ Open

Effects of an online-based motivational intervention to reduce problematic internet use and promote treatment motivation in internet gaming disorder and internet use disorder (OMPRIS): study protocol for a randomised controlled trial

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To cite: Dieris-Hirche J, Bottel L, Pape M, *et al*. Effects of an online-based motivational intervention to reduce problematic internet use and promote treatment motivation in internet gaming disorder and internet use disorder (OMPRIS): study protocol for a randomised controlled trial. *BMJ Open* 2021;**11**:e045840. doi:10.1136/bmjopen-2020-045840

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2020-045840).

Received 14 October 2020
Accepted 22 June 2021

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ABSTRACT

Introduction In May 2019, the WHO classified internet gaming disorder (IGD) as a mental disorder in the upcoming International Classification of Diseases 11th Revision. However, individuals affected by IGD or internet use disorders (IUDs) are often not provided with adequate therapy due to a lack of motivation or absence of adequate local treatment options. To close the gap between individuals with IUDs and the care system, we conduct an online-based motivational intervention to reduce problematic internet use and promote treatment motivation in internet gaming disorder and internet use disorder (OMPRIS).

Methods and analysis Within the randomised controlled trial, a total of n=162 participants will be allocated by sequential balancing randomisation to the OMPRIS intervention or a waitlist control group. The study includes an extensive diagnostic, followed by a 4-week psychological intervention based on motivational interviewing, (internet-related) addiction therapy, behavioural therapy techniques and additional social counselling. The primary outcome is the reduction of problematic internet use measured by the Assessment of Internet and Computer Game Addiction Scale. Secondary outcomes include time spent on the internet, motivation for change (Stages of Change Readiness and Treatment Eagerness Scale for Internet Use Disorder), comorbid mental symptoms (Patient Health Questionnaire-9, Generalized Anxiety Disorder Screener-7), quality of life (EuroQoL Standardised Measure of Health-related Quality of Life–5 Dimensions, General Life Satisfaction-1), self-efficacy (General Self-Efficacy Scale), personality traits (Big Five Inventory-10), therapeutic alliance (Helping Alliance Questionnaire) and health economic costs. The diagnosis of (comorbid) mental disorders is carried out with standardised clinical interviews. The measurement will be assessed before (T0), at midpoint (T1) and after the OMPRIS intervention (T2), representing the primary endpoint. Two follow-up assessments will be conducted after 6 weeks (T3) and 6 months (T4) after the intervention. The outcomes will be analysed primarily via analysis of covariance. Both intention-to-treat and per-protocol analyses will be conducted.

Ethics and dissemination Participants will provide written informed consent. The trial has been approved by the Ethics Committee of the Faculty of Medicine, Ruhr University Bochum (approval number 19-6779). Findings will be disseminated through presentations, peer-reviewed journals and conferences.

Trial registration number DRKS00019925.

Strengths and limitations of this study

- ► The study uses a multicentre randomised design with a waitlist control group.
- ► Follow-up time points of 6 weeks and 6 months allow for a robust evaluation of the effect of the online-based motivational intervention (OMPRIS) on internet use disorder-affected persons' outcomes.
- ► Diagnosticians, therapists and outcome assessors are blind to participants' allocation.
- ► In addition to the clinical efficacy of the OMPRIS intervention, a cost-effectiveness and a cost-utility analysis will also be performed.
- ► Participants cannot be blinded to receiving the intervention.

INTRODUCTION

In 2019, approximately 90% of all German households had access to the World Wide

Web. Families with at least one child have almost 100% internet supply.[1] A current representative study carried out with German adolescents reported an increased time spent on internet applications with a particular increase due to the COVID-19 pandemic in 2020. The average time spent playing video games was 139 min on weekdays and 193 min on weekends.[2] Moreover, there is further evidence from other countries indicating an increase of gaming behaviour (eg, gaming hours) in college students and adolescents, especially due to the COVID-19 pandemic in 2020.[3–5]

Internet use disorder and internet gaming disorder

Internet use disorder (IUD) is an umbrella term defined as the excessive and uncontrolled use of internet applications in terms of a predominantly online behavioural addiction. It includes both excessive gaming (as the largest category) and non-gaming internet activities, for example, online shopping, pornography use, social network use and other internet uses.[6] Consistent with the inclusion of (internet) gaming disorder (IGD) as the first IUD in International Classification of Diseases 11th Revision (ICD-11),[7] many researchers switched from using the term internet addiction to IUD to be in accordance with the terminology used in the upcoming ICD-11.[6]

In the last decades, IUD has increased dramatically worldwide with prevalence rates ranging from 2.6% in northern and western Europe to 10.9% in the Middle East with a global average prevalence of 6.0%.[8] In German-speaking countries, the prevalence rates of IUD range from 1.2% to 3.0% in German[9–11] and Austrian adolescents,[12] respectively. With regard to IGD (as the most frequent IUD), the global prevalence was recently reported to be 3.05%.[13]

Individuals with IUD show a persistent or recurrent pattern of internet use that is characterised by impaired control regarding the onset, intensity and duration of usage.[7] The increased priority given to internet activities leads to neglect of daily activities and life interests, and IUD is associated with social, physical and mental burden.[14 15] In addition, high comorbidity with psychiatric disorder has been reported, especially depressive disorders, anxiety disorders, attention-deficit hyperactive disorder, substance use disorders and impulse control disorders.[16–21]

Evidence of treatment for IUDs

Currently, there are only a few empirical studies investigating IUD and IGD therapy approaches using the scientific standard of a randomised controlled trial (RCT) design.[22–24] A recent meta-analysis demonstrated high efficacy (12 studies with a total of 580 patients) for cognitive–behavioural therapy (CBT) in reducing IGD symptoms (g=0.92 (0.50, 1.34)), depression (g=0.80 (0.21, 1.38)) and anxiety (g=0.55 (0.17, 0.93)).[23] Moreover, interventions based on the motivational interviewing (MI) approach have already been examined in many areas of medicine.[25] The effectiveness of MI has been reported in particular for substance-related addictions and pathological gambling.[25 26] For IUDs, there are only few studies that have systematically examined MI approaches, but it has been widely discussed as a therapeutic option for patients with IUD.[27–31]

eHealth interventions in addictive disorders

Internet-based and eHealth interventions (eg, for depression and anxiety disorders) have been reported as effective treatment options with medium to large effect sizes.[32 33] Also, internet-based and eHealth interventions have been examined in the areas of (mainly substance) addiction.[34 35] A systematic review in 2016 found a total of 16 studies testing internet-related interventions in substance addiction (11 studies in smoking, drinking and opioid abuse) and behavioural addictions (five studies in pathological gambling). Although only five of the 16 studies mentioned effect sizes (d=0.83–1.72), all studies reported positive treatment outcomes for their respective addictive behaviour.[36] To date, only a few studies have examined general eHealth interventions for IUD and IGD.[37] A Chinese pilot study using an online self-help approach on 65 university students with high scores for problematic internet use, divided into four experimental arms, showed significant differences at the follow-up measurement, but no differences were detected between the four intervention groups (IG). This study used MI techniques as main intervention.[29] Furthermore, a recent study protocol presenting an ongoing RCT of an eCoach-guided internet-based intervention for IUD has recently been published.[27]

Our research group performed a preliminary uncontrolled study between 2016 and 2018 exploring an online outpatient service for internet addiction (OASIS) with only two offered webcam sessions.[38] The aim was to test whether individuals with IUD can generally be reached via the internet and to refer them to conventional medical treatment close to their place of residence. Finally, 140 individuals with a minimal level of problematic internet use participated in one or two offered consulting sessions with a moderate referral quote of 30%. The referral was, however, more successful when participants were referred to the clinic or therapists they knew from online consulting (referral rate 93%) underlining the importance of relationship constancy in (online-based) therapy. Despite the low number of only two offered sessions, the intervention showed a small to medium significant reduction of time spent online (−1.23 hours/day; d=0.3) and IUD symptoms (d=0.5) measured by self-reporting questionnaires in post-tests. However, this preliminary study omitted a control group and follow-up.[38]

To the best of our knowledge, the results of evidence-based randomised controlled studies investigating webcam-based intervention for IGD or IUD have not been published yet.

Aims of the study

The aim of this study is to measure the efficacy and the utilisation of a new and innovative online-based intervention for reducing IUD and IGD symptoms and increasing treatment motivation (OMPRIS) compared with a waiting control group. It is hypothesised that the OMPRIS intervention will reduce symptoms of IUD and IGD, and will heighten the motivation for behaviour modification concerning media use. OMPRIS is also intended to help patients with IUD and IGD access conventional treatments. It is hypothesised that the OMPRIS intervention will increase the referral rate to (specialised) mental healthcare.

METHODS AND ANALYSIS

Trial design

The design is a single-blind RCT with two parallel arms, comparing the OMPRIS intervention to a waitlist control (WLC) group. Therapists and the observer will be blinded in this trial. Participants will be scheduled to complete either immediately a 4-week-long webcam-based intervention or a 4-week waiting period. Notably, WLC group participants will be offered the OMPRIS intervention after the expired waiting period. The study is funded by the German Innovation Fund of Germany's Federal Joint Committee and is therefore primarily a healthcare research study that is intended to investigate an innovative form of telemedical eHealth care.

Study setting

This multicentre study is coordinated by the Department of Psychosomatic Medicine and Psychotherapy, LWL-University Hospital of Ruhr University Bochum, Germany (principal investigator (PI): JDH). The OMPRIS intervention will be carried out by four German medical centres specialised in the treatment of IUD and IGD: the Department of Psychosomatic Medicine and Psychotherapy of the LWL-University Hospital Bochum, the Department of Psychosomatic Medicine and Psychotherapy of the University Medical Center Mainz, the Psychosomatic Hospital at Diessen Monastery and the Department of Psychosomatic Medicine and Psychotherapy of the University Hospital Rechts der Isar Munich. Investigators in all centres are experienced psychotherapists, psychologists or experts in related disciplines with experience in the treatment of IUD and IGD.

OMPRIS is an online webcam-based intervention at which affected people throughout Germany can participate. Participation will be managed via a newly developed online study platform that offers user accounts, video chat, appointment management, a psychological test battery and teaching aids. The platform was developed per requirements of current protection of data privacy. Participation in OMPRIS is browser based, requires no software download and is complimentary. Participants can register at www.onlinesucht-hilfe.com.

Participants and recruitment

In total, 162 individuals suffering from problematic or addictive use of internet applications and video games, who meet the eligibility criteria and will consent to participate in the study, will be recruited. The calculation of the sample size is reported in the Sample size section. Inclusion criteria are as follows: problematic or addictive use of internet applications according to the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5) criteria and the ICD-11 criteria for IGD as assessed via a self-report scale (Assessment of Internet and Computer Game Addiction Scale, AICA-S[39 40]) and a structured clinical expert rating (Assessment of Internet and Computer Game Addiction–Structured Clinical Interview, AICA-SKI:IBS[41]); legal age of at least 16 years old (with the informed consent of parents); constant access to the internet via webcam, microphone and email address; sufficient knowledge of the German language; informed consent to dissolve pseudonymisation in case of emergency (ie, concrete suicidal tendency). Exclusion criteria are psychotic disorders (past or present); learning disabilities/intellectual impairment; substance abuse within the past 6 months; active suicidal thoughts or intentions; a comorbid somatic disease with endocrinological medication causing impulsive behaviours (eg, Morbus Parkinson with dopaminergic medication); recent psychiatric or psychotherapeutic treatment focusing primarily on IUD or IGD.

All subjects will be recruited online (www.onlinesucht-hilfe.com) by completing the AICA-S[39 40] questionnaire indicating problematic internet use or video gaming behaviour. All subjects with positive screening results or interest in participation will be provided with initial information about the study via a webcam call with experienced psychologists. During the online eligibility appointment, the inclusion and exclusion criteria will be checked.

Furthermore, the researchers will provide additional written (via electronic download) and verbal information as well as informed consent. In the case of underage persons, the eligibility appointment will be conducted in the parents' presence. Trained psychologists (master's degree and in qualification as psychotherapists) will diagnose all participants via structured clinical interviews for IUD and IGD (AICA-SKI:IBS[41]) as well as psychiatric disorders (Mini-International Neuropsychiatric Interview, MINI 7.0[42]).

Inclusion criteria will be established during the eligibility assessment: pathological internet and video game use via the AICA-SKI:IBS, psychotic disorders, acute suicidality, learning disabilities/intellectual impairments via the MINI, sufficient knowledge of the German language via the ability to complete questionnaires and follow the webcam-based informed consent procedure and a comorbid somatic disease with dopaminergic medication as well as recent psychotherapeutic treatment focusing on IUD by self-report. Motivation and willingness to attend the study will be assessed via self-report during the informed consent procedure, emphasising

the demands of the study in terms of effort and time. The informed consent procedure will end by asking the participants whether they still wish to participate in the study.

Randomisation

Sequential balancing randomisation, according to Borm *et al*,[43] will be used as a method that balances prognostic relevant factors in consecutive order.[43] In this method, each factor is dealt with sequentially, and when new subjects enter the OMPRIS intervention, they are allocated to a specific condition–the IG or the WLC group—that leads to improved balance of the first factor over the arms. For example, if the balance of the first factor is satisfactory, then the arm is allocated that leads to the improved balance of the second factor. If all factors are balanced according to predefined imbalance levels, the new subject is randomly assigned.

Four factors have a relevant prognostic value, with each one divided into three classes based on data gathering from a former study[38 44] and the AICA-S questionnaire[39 40]: (1) gender (women, men, diverse); (2) the severity of internet-related addiction symptoms (AICA-S score <7, 7–13; >13); (3) age (16–17, 18–30, >30 years); and (4) the type of IUD (gaming, pornography/cybersex, all other genres). Imbalance levels for each of the four factors were predefined by a researcher (NT) of the Department of Medical Informatics, Biometry and Epidemiology in Bochum who is not involved in the OMPRIS enrolment or assessment.

The OMPRIS participants will be assigned either to the IG or the WLC group immediately before the first therapeutic OMPRIS session. The randomisation will be conducted automatically via the OMPRIS platform and its results will remain unpredictable to research staff involved in the participant's enrolment as well as the OMPRIS intervention. The study will be administered by the Department of Medical Informatics, Biometry and Epidemiology in Bochum.

Intervention

The manualised OMPRIS intervention is a combined treatment programme mainly based on the MI approach that has been shown as sufficient to improve health behaviour in various medical diseases including addictive disorders.[25 45–48] Furthermore, OMPRIS contains treatment elements from CBT, (internet-related) addiction therapy,[49] media education and social counselling. The primary outcome will be measured constantly after 4 weeks of intervention (measurement points: T0 baseline, T1 mid-intervention and T2 postintervention, see figure 1 and table 1). During these 4 weeks, the participants will be offered up to eight webcam-based psychological treatment sessions and one or two social support sessions. In addition, a detailed diagnostic webcam session will be offered 1 week before and 1 week after the intervention. In total, a participant can thus attend up to 12 webcam sessions. The number of attended sessions will be assessed. Two follow-up measurements will be conducted 6 weeks (T3) and 6 months (T4) after intervention. The 50 min long webcam-based psychological sessions will be implemented twice a week (eight sessions in 4 weeks) via our study platform. Table 2 shows the treatment phases and strategies during the early, middle and termination phases.

Based on self-monitoring and awareness of media use participants will be encouraged to develop an individual behavioural model and goal settings. Furthermore, changing in problematic internet use will be stimulated using different CBT techniques (eg, habit reversal, behavioural rehearsals, practices, restructuring the environment, self-assessment and anticipation of social and health consequences, problem solving, regulation of negative emotions, see table 2). A special focus is placed on the strengthening of existing positive resources and successfully changed behaviour using MI skills. In addition, practical social counselling will be offered (eg, application for housing benefit, information on debt counselling, assisted living) by a professional social worker. In the termination phase, strategies for relapse prevention will be discussed. If required, referrals to further treatment options will be reviewed.

Psychological sessions will be carried out by clinically experienced psychotherapists, psychologists or experts in related disciplines with experience in the treatment of IUD and IGD, who work at the cooperating study centres (Bochum, Mainz, München/Dießen). Social counselling will be carried out by trained social workers. Fidelity checks will be carried out using therapist feedback after each session with classification of the main topics and interventions. A guiding manual is used by the therapists.

Blinding

Participants will be informed that they will be randomly allocated either to the IG or the WLC group after the initial introduction session. The therapists conducting the introduction and diagnostic sessions will be blind to the participants' allocation. Moreover, the staff conducting the OMPRIS intervention will not be informed about participants' allocated conditions. Outcome assessor blinding will be achieved via a software-based measurement of outcomes that offers and evaluates outcome parameters automatically. The participants will receive a short, automatically generated personal feedback report via email after their last session of the OMPRIS intervention including a short description of OMPRIS programme, a confirmation of participation, the IUD diagnosis and (if relevant) personalised recommendation for further treatment. The trial database will be maintained as blind before conducting analyses.

Outcome assessment

Figure 1 shows a flow chart of the time points of assessment: assessment for eligibility (T0a), baseline (T0), mid-intervention (T1; after 2 weeks), postintervention (T2; after 4 weeks, primary endpoint) and two follow-ups (T3; 6 weeks after intervention, T4; 6 months

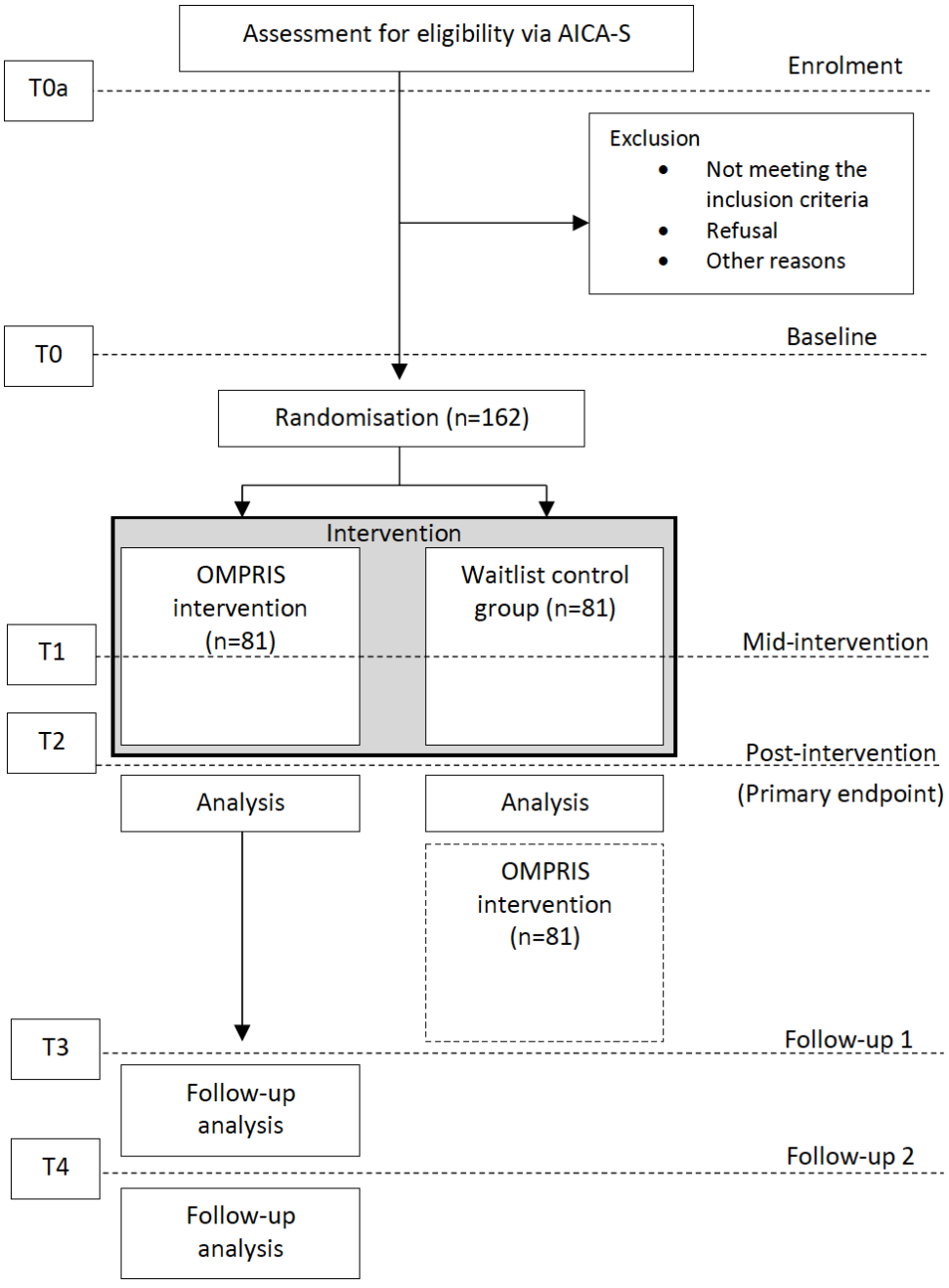

Figure 1 A flow chart of the study. Participants of the waitlist control (WLC) group will be offered the OMPRIS intervention after a 4-week-long waiting period. The follow-up analysis will be performed separately for the WLC group. AICA-S, Assessment of Internet and Computer Game Addiction Scale.

after intervention). All assessments will be automatically offered to the participants at the correct times via the OMPRIS software following the study protocol (see table 1 for the study's schedule). If assessments are not applied within the scheduled timeframe, participants will receive reminders via email and telephone.

Primary outcome: problematic internet use

AICA-S.[39 40] The primary outcome is defined as reduction of current IUD symptoms measured by AICA-S whose items are related to the DSM criteria of substance use disorders and gambling disorder. Fourteen items (5-point Likert scale) are relevant for clinical classification of internet use, including craving, a loss of control, tolerance, unsuccessful attempts to spend less and withdrawal. Negative consequences are relevant according to areas of life, including problems with school, work, health and social partners. Moreover, time spent online, the preferred online activities and the preferred type of problematic internet use are requested. The timeframe of the questionnaire can be adjusted according to the research question. In our study, the timeframe 'during the past 4 weeks' was chosen (duration of the intervention). A cut-off is defined by statistical means based on epidemiological survey analyses.[50] A score of 7 points (three to

Table 1 Study schedule of measurement and testing

	T0a Eligibility	T0 Baseline	Each session	T1 Mid-intervention	T2 Postintervention	T3 and T4 Follow-up	
Approximate time	**1 week**			**After 2 weeks**	**After 4 weeks**	**6 weeks after T2**	**6 months after T2**
Consent	X						
AICA-S (primary outcome)	X	X		X	X	X	X
Demographics	X						
Lifestyle parameter		X			X	X	X
MINI		X					
AICA-SKI:IBS		X			X		
Treatment information		X					
iSOCRATES		X		X	X	X	X
CIUS		X		X	X	X	X
EQ-5D-5L		X			X	X	X
PHQ-9		X			X	X	X
GAD-7		X			X	X	X
L-1		X			X	X	X
SWE		X			X	X	X
BFI-10		X					
Resource use		X			X	X	X
Satisfaction			X		X		
Mood			X				
HAQ				X	X		
SUS					X		

AICA-S, Assessment of Internet and Computer Game Addiction Scale; AICA-SKI:IBS, Assessment of Internet and Computer Game Addiction–Structured Clinical Interview; BFI-10, Big Five Inventory 10-item version; CIUS, Compulsive Internet Use Scale; EQ-5D-5L, EuroQoL Standardised Measure of Health-related Quality of Life–5 Dimensions, 5-Level version; GAD-7, Generalized Anxiety Disorder Screener 7-item version; HAQ, Helping Alliance Questionnaire; iSOCRATES, Stages of Change Readiness and Treatment Eagerness Scale for Internet–Addiction; L-1, General Life Satisfaction 1-item version; MINI, Mini-International Neuropsychiatric Interview; PHQ-9, Patient Health Questionnaire 9-item version; SUS, System Usability Scale; SWE, Self-Efficacy Scale.

four criteria fulfilled) can be interpreted as addictive use. Based on the clinical cut-off values of 7 points, the sensitivity was 80.5% and the specificity was 82.4%.[51] Reliability of AICA-S (internal consistency of α=0.89) and validity are determined in clinical and epidemiological surveys.[50 52 53] The AICA-S was successfully used in a recently published German RCT on the effectiveness of outpatient group therapy for IUDs.[49] This study also showed good sensitivity to change after therapeutic intervention using self-assessment and assessment by experts.[49] It is conducted at baseline, mid-intervention, postintervention and at follow-up.

Secondary outcomes

Stages of Change Readiness and Treatment Eagerness Scale for Internet Use Disorder (iSOCRATES).[38] The iSOCRATES is a self-report measure assessing the stage of readiness and treatment eagerness for IUD. It was adapted from the German SOCRATES for alcohol addiction consisting of 19 motivation-relevant statements whereon participants give their agreement on a 5-point Likert scale.[54 55] Cronbach's alpha of the measure has shown to be α=0.60 for the scale 'ambivalence', α=0.83 for 'taking steps' and α=0.85 for 'recognition'.[55] It will be conducted at baseline, mid-intervention, postintervention and at follow-up.

Compulsive Internet Use Scale (CIUS).[56] The CIUS contains 14 items rateable on a 5-point Likert scale and measures symptoms of internet-related disorders. The instrument has shown a good internal consistency (α=0.89).[57] It will be conducted at baseline, mid-intervention, postintervention and at follow-up.

Patient Health Questionnaire-9[58] (PHQ-9, German translation[59]). This nine-item patient questionnaire is a self-report version of the Primary Care Evaluation of Mental Disorders (PRIME-MD) screening instrument for

Table 2 OMPRIS intervention strategies

Treatment strategies	Treatment phase	Key interventions
Motivational interviewing (MI)	All phases	Client-centred approach with empathy and openness Open questions Affirmation Reflective listening Summarising
Cognitive–behavioural therapy (CBT)	All phases	Psychoeducation on addiction mechanisms Self-monitoring of IUD behaviour and assessment of triggers, goal setting, pros and cons, reward mechanisms Individual model of addiction Awareness on internet use Behavioural practices Strategies to reduce procrastination tendencies Regulating negative emotions (eg, aversion and listlessness) Avoidance changing exposure to cues for IUD behaviour Self-affirmation Action planning Reducing social anxiety Relapse prevention Interpersonal skills training
Media education	Early and middle phases	Development of media rules and limitations
Structuring everyday life	Middle and termination phases	Restructuring of daily routines, sleep hygiene, mealtimes, working hours
Social counselling	Middle and termination phases	Help on individual social problems (eg, unemployment, debt management, housing benefits, assistant living, complying with formalities)

IUD, internet use disorder.

common mental disorders.[60] The PHQ-9 is a depression module, which scores each of nine DSM-IV criteria as '0' (not at all) to '3' (nearly every day). The internal consistency has been found to be excellent (α=0.83–0.92).[61] It will be conducted at baseline, postintervention and at follow-up.

Generalized Anxiety Disorder Screener[62] (GAD-7, German translation[63]). The GAD-7 scale is a self-report measure assessing general anxiety symptoms related to DSM-IV criteria on a 4-point Likert scale. The internal consistency has shown to be excellent (α=0.89).[62] It will be conducted at baseline, postintervention and at follow-up.

General Life Satisfaction (L-1).[64] The short L-1 scale for recording general life satisfaction consists of only one item with the following wording: 'How satisfied are you at present, all in all, with your life?' The 11 answer categories of the L-1 range from 'not satisfied at all' to 'completely satisfied'. The reliability has been tested by test–retest reliability, which has reported to be r_{tt}=0.67.[64] It will be conducted at baseline, postintervention and at follow-up.

General Self-Efficacy Scale[65] (GSE, German translation SWE[66]). The GSE measures self-perceived self-efficacy and consists of 10 items assessing the respondent's belief in the ability to respond to novel or difficult situations adequately and to cope with a large variety of stressors. It is scored on a 4-point scale from '1' (not at all true) to '4' (exactly true). A comparison of the GSE in 23 countries shows a generally good to excellent internal consistency, which varies between α=0.76 and 0.90. In German samples, Cronbach's alpha varies between 0.80 and 0.90.[67] It will be conducted at baseline, postintervention and at follow-up.

Big Five Inventory[68] (BFI-10). The BFI-10 is a self-report measure containing 10 items to assess Big Five personality traits. It has five subscales with two bidirectional items for each of the personality factors. The 10 items are rated on a 5-point Likert scale where the subjects choose from responses ranging from 'strongly disagree' to 'strongly agree'. The reliability has been tested by test–retest reliability, which has been found to be good (r_{tt}=0.58–0.84).[68] The BFI-10 will be conducted only once at baseline.

Helping Alliance Questionnaire[69] (HAQ, German translation[70]). The HAQ is a highly relevant instrument to assess the therapeutic alliance and can be used both as the patient's version (HAQ-P) and, in a slightly modified form, as the therapist's version (HAQ-T). All items are rated on a 6-point Likert scale from 'strongly agree' to 'strongly disagree'. The HAQ has two factors called

'satisfaction with therapeutic outcome' and 'relation to the therapist'. It will be conducted at mid-intervention and postintervention. Cronbach's alpha of the two scales has been reported as good (α=0.75–0.89 on the HAQ-P and α=0.63–0.85 on the HAQ-T).[71]

EuroQoL Standardised Measure of Health-related Quality of Life–5 Dimensions, 5-Level version[72] (EQ-5D-5L, German translation[73]). The EQ-5D-5L is a standardised instrument for measuring generic health status in terms of quality of life. It essentially consists of five items measuring dimensions of impairment (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) on a 5-point Likert scale from 'no problems' to 'extreme problems'. Furthermore, a visual analogue scale (VAS) records the patient's self-rated health on a vertical VAS, where the endpoints are labelled 'The best health you can imagine' and 'The worst health you can imagine'. Interobserver reliability (0.49 vs 0.57) and test–retest reliability (0.52 vs 0.69) have been reported to be good.[74] It will be conducted at baseline, postintervention and at follow-up.

Additional measures

The *AICA-SKI:IBS*[41] is a structured interview that determines the nine DSM-5 criteria for IGD. Moreover, the symptom of craving is examined. The interview is also applicable to other IUDs. The evaluation is carried out according to standardised specifications, which result from the evaluation sheet at the end of the interview. Core criteria are individually assessed on a scale from '0' (not fulfilled) to '5' (certainly fulfilled). A total score (0–30 points) is tallied, and a total score >13 points indicates an IUD. The AICA-SKI:IBS takes approximately 20–30 min and will be conducted at baseline and postintervention.

The MINI V7.0[42] is a short structured diagnostic interview developed for DSM-5 and ICD-10 psychiatric disorders. With an administration time of approximately 15–20 min, it was designed to meet the need for a short but accurate structured psychiatric interview for multicentre clinical trials and epidemiology studies. The MINI will be conducted only once at baseline to detect psychiatric comorbidities.

The *System Usability Scale*[75] is a short, reliable tool for measuring usability in a wide variety of services, including software, websites and applications. It consists of 10 items on a 5-point Likert scale from 'strongly agree' to 'strongly disagree'. It will be conducted at postintervention.

Satisfaction with OMPRIS intervention is measured by 10 items on a 5-point Likert scale from 'strongly disagree' to 'strongly agree' (eg, 'OMPRIS helped me to accept support for the first time because of my (problematic) Internet use' or 'I would recommend OMPRIS to my friends'). It will be conducted at postintervention.

Health economics information is determined by a self-report questionnaire asking for the resource use of current and past medical and psychotherapeutic inpatient and outpatient treatments, medication, rehabilitation treatments and assisted living services. Additionally, data on earning capacity, social security system data (eg, incapacity for work, unemployability, etc), the delay of vocational education and housing situation will be collected. In order to determine the intervention costs, information is collected on one-time intervention costs (eg, software, conceptual design, implementation costs, etc) and ongoing intervention costs (eg, material and personnel costs for therapy sessions, software maintenance, etc).

Referral to other organisations and further treatments is assessed by three items at postintervention and follow-up.

Sample size

The sample size was calculated by a power calculation to find a between-group effect (two-sided t-test) with 80% power at p=0.05. A current RCT treatment study (short-term treatment of internet and computer game addiction (STICA) study) found an effect size of d=1.19 for the effect of analogue CBT treatment on the reduction of IUD symptoms (SD=3.92) using the same outcome measurement AICA-S.[49] We took a conservative estimate of effect size d=0.51 (approximately 43% of the STICA study) for our OMPRIS intervention determining a significant detection of a 2-point difference in the primary outcome measure. Based on these assumptions, 62 participants are required per group. Notably, 81 participants per group are planned to recruit to allow for a dropout rate of 30% according to data from young adults' addiction treatment.[49 76]

Patient and public involvement

The development of the research question and the outcome measures was influenced by previous experience from a previous pilot study on subjects with IUD.[38] Patient feedback was considered in the planning of the study and design. The patients' previous experiences and feedback were particularly important in designing the low-threshold OMPRIS intervention. The main results will be published in a final report, according to the German Innovation Funds directive. The report will be publicly available and free of charge on the internet. Furthermore, the scientific results will be disseminated via publications submitted to peer-reviewed scientific journals. All participants will receive a short final report with their (pre/post) results of the 4-week online intervention. The OMPRIS study is planned and will be conducted in cooperation with the German Fachverband Medienabhängigkeit e.V. that is committed to creating a network of researchers and practitioners in the German-speaking countries who are working on IUD and IGD within the framework of a large-scale cooperation.

Data collection and management

Data collection will be performed online via the OMPRIS software environment (www.onlinesucht-hilfe.com). All data will be stored on protected servers in Germany. Data will be entered into an electronic database on an ongoing basis, and the database and outputs will be regularly backed up to a remote server. The computer databases will not contain information about the participants'

allocation, which will be added as required before the analysis.

Data completeness will be automatically monitored by the OMPRIS software environment. Sensitive participant's data will be stored separately from research data in a second database and will be accessible only to members (admin) of the principal research team. The PI (JDH) will have the primary responsibility for verifying the integrity of the databases and will be responsible for managing and archiving the databases after analysis.

Trial management and monitoring

The PI (JDH) has the primary responsibility for the conduct of the trial. The management of processes will be monitored and discussed in regular meetings with the researchers involved in data collection. The trial management group is composed of LB, MP, NT and JDH and will be in regular contact with all partners of the study.

Adverse event monitoring

Adverse events (AEs) will be monitored by trial researchers conducting the OMPRIS intervention on an ongoing basis and postintervention, recorded via an 'adverse event comment function' in the OMPRIS software environment. The severity of all reported AEs will be classified by an external investigator as '1=mild' to '5=death related to AE' according to the NCI Common Terminology Criteria for Adverse Events.[77] Severe adverse events (SAEs) will be forwarded to an external Data and Safety Monitoring Board (DSMB), which consists of independent experts in the field of statistics and behavioural addiction. The DSMB will examine possible causal relations to the study and identify serious study-related events (SSREs). Possible SAEs for the OMPRIS study were defined as emerging suicidal ideation and tendency; self-destructive behaviour such as self-harm; worsening of general well-being; and psychiatric comorbidity with an indication for inpatient admission (hospitalisation) to a clinic. Both SAEs and SSREs will be reported to the responsible ethics committee.

Data analysis

Method of clinical evaluation

The primary analysis will be conducted as an intention-to-treat analysis; thus, all participants randomised will be included in the analysis regardless of the completion of the OMPRIS programme or the outcome measurement. Missing data will be replaced via imputation with interim values. Secondary analyses will be conducted both as intention to treat and per protocol. Per protocol was defined as participation in at least two online sessions, termination by agreement and completion of the T2 assessment. Primary and secondary outcomes will be analysed via analysis of covariance between T0b and T2 outcome scores. Between-group differences will be calculated via analysis of covariance for IUD symptoms with the covariables of baseline value, gender, age and type of IUD.

It is expected that missing data will not be 'missing-at-random' based on the assumption that the occurrence of the missing value in a variable can be fully explained by the characteristics of the remaining variables. Therefore, diverse sensitivity analyses will be calculated with different strategies for missing data replacement. Details of statistical analyses will be defined in a statistical analysis plan. Potential group imbalances in spite of randomisation will be tested via t-tests for continuous variables and Pearson's χ^2 test. Exploratory analyses will evaluate potential predictors for therapeutic success via linear and logistic regression models. The statistical analyses will be carried out with R Project[78] and IBM SPSS V.27.0 Statistics.

Method of health economic evaluation

The health economic evaluation of OMPRIS contains both a cost-effectiveness and a cost-utility analysis. Additionally, a cost-of-illness study regarding persons with IGD and IUD will be done. The evaluation will include both direct and indirect costs, which will be calculated from statutory health insurance perspective as well as from a societal perspective. The analyses will be using a bottom-up approach. Data on the resource use will be collected at baseline T0b, 4 weeks later at T2 and, again, 6 weeks later at T3 for both groups.

A standardised health economic questionnaire has been developed, which includes questions concerning healthcare resource use, such as outpatient physician contacts, hospitalisation, inpatient and outpatient rehabilitation, occupational therapy, reduction in/loss of earning capacity and disability. Moreover, participants will be asked about sociodemographic data, such as age, gender, graduation, on-the-job training and cash benefits from different sources. Prices for all resource use will be collected using different sources.

The Lauer Taxe® will be used to determine the medication selling prices for the German market. For inpatient and outpatient care, hospitalisation and rehabilitation recommendations will be obeyed according to published standardised procedures in health economic evaluation and standardised prices.[79–82] Costs will be calculated as the product of the number of consumed resources and estimated prices and summarised to compute the overall costs. The analyses will be based on the calculation of mean values and the SDs of resource use and healthcare costs. According to the method of difference in difference, healthcare costs of the two study arms will be analysed in terms of statistically significant differences using the Mann-Whitney U test. To consider uncertainty, sensitivity analyses will be performed.

DISCUSSION

The COVID-19 pandemic has massively increased the acceptance of webcam-based communications in professional and medical contexts. There are strong arguments to support the use of online-based treatment for patients with IUD: (1) Individuals affected by IUD are

used to spending a lot of time on the internet. Their resistance or rejection to use digital applications can thus be considered low. (2) Since motivation, conscientiousness and impulse to change internet use behaviour have been reported as low in IUD,[83 84] an easily accessible and low-threshold approach is essential in IUD or IGD. (3) The psychotherapeutic care situation, especially in the outpatient sector, is currently insufficient, often leading to long waiting periods for an initial consultation.[85] This latency might increase an additional loss of motivation. A quick and uncomplicated initial offer might be important to restructure IUD behaviour. (4) Comorbid disorders, like depressive or anxiety disorders, make it challenging for individuals with IUD or IGD to get into conventional outpatient therapy. Internet-based interventions have already shown good therapeutic effects in many areas of mental disorders and addiction medicine.[32–35] In addition, telemedicine can make evidence-based treatment strategies accessible to a broad patient population no matter where they live. Therefore, internet-based interventions such as OMPRIS can be seen as an innovative way to reach individuals with IUDs and IGD more effectively and quickly than conventional approaches.

OMPRIS is a healthcare research project, which offers a standardised therapeutic internet-based intervention to all interested people aged 16 or older from all over Germany. We expect participation from individuals who want to make positive changes in their media use and use professional help to do so. Due to the low barriers, we hypothesise that OMPRIS will nearly represent the general population of individuals suffering from IUD and IGD (eg, in terms of gender distribution), and will therefore correspond more closely to representative epidemiological studies[9 11] rather than to clinical experiences from specialised IUD outpatient clinics where mainly men are in treatment.[51 86]

ETHICS AND DISSEMINATION

Ethical issues

Clinical protocol and written informed consent were approved by the Ethics Committee for the Faculty of Medicine, Ruhr University Bochum (approval number 19-6779). Furthermore, the main ethical approval was confirmed by the ethics committees of all cooperating centres. All procedures described in the clinical trial protocol follow the Good Clinical Practice guidelines and the ethical principles described in the current revision of the Declaration of Helsinki. The study will be carried out in keeping with local legal and regulatory requirements. The main ethical issues are informed consent, the use of OMPRIS intervention, the use of an online-based intervention, and protection of data privacy, the inclusion of underage persons with parental consent, technical procedures of online participation and online declaration of consent and the WLC group design.

Before being admitted to the OMPRIS trial, subjects (and for underage participants, their parents) will receive detailed information and explanation of the nature, scope and possible side effects of the trial in an understandable form. All participants (and for underage participants, at least one parent) must give consent with active confirmation via an online procedure. Each participant will receive digital study documents that will also be available via the OMPRIS homepage.

Moreover, contact addresses will be given for further questions on OMPRIS participation or in the case of psychological crisis during OMPRIS participation. In this trial, all participants, including the WLC group, will receive the full OMPRIS intervention. The WLC group members will begin their intervention after a short waiting period of 4 weeks.

Dissemination plan

The main results will be published in a final report, according to the German Innovation Funds directive. Furthermore, the scientific results will be disseminated via a publication submitted to peer-reviewed scientific journals following the International Committee of Medical Journal Editors authorship eligibility guidelines and via presentations at national and international scientific conferences. The OMPRIS manual will be published in detail at the end of the project to offer novel treatment strategies for the (online-based) treatment of patients suffering from IUD and IGD.

Trial status

The trial currently is at the beginning of the recruitment phase. The first participant was assessed to OMPRIS study on 1 September 2020. Follow-up measurements for the last participants are expected in July 2022. Substantial protocol amendments will be reported in publications.

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Acknowledgements We thank the whole OMPRIS group, notably Michael Dreier, Nehle Penning, Julia Weretecki, Lorraine Cornelsen, Linny Geisler, Anja Niemann, Christian Suelmann, Dennis Lowin, and the German Fachverband Medienabhängigkeit eV. We acknowledge the support of the Open Access Publication Funds of the Ruhr-Universität Bochum.

Contributors JDH, LB and MP conceived the study. JDH is the principal investigator, acquired funding and drafted the initial study protocol. AN, SN and NT were responsible in the OMPRIS project for data evaluation and statistical analyses, drafted the data analysis of the initial study protocol and revised the method part of

the study protocol. BtW, KW, PH, RB and SH are leaders of the local study centres and contributed to the study design, gave critical feedback and each made a revision of the manuscript.

Funding This publication was created by a project funded by the German Innovation Fund of Germany's Federal Joint Committee (G-BA) under grant number 01VSF18043, awarded to JDH. The recipient is Ruhr University Bochum, Germany.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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