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

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Authors' contributions: JDH, LB, and MP conceived the study. JDH acquired funding and drafted the initial study protocol. AN, SN and NT drafted the *data analysis* of the initial study protocol. All other authors contributed to the study design and refinements and approved the final version of the protocol.

Abstract

Introduction: Excessive internet use and computer gaming have increased dramatically in the last decade. In May 2019, the World Health Organisation finally officially classified Internet gaming disorder as a medical illness in the upcoming ICD-11. However, individuals affected by internet addiction and gaming disorder often are not provided with adequate therapy due to a lack of motivation or absence of adequate local treatment options.

Methods and analysis: The randomised controlled trial aims to explore the effect of an online-based motivational treatment programme in gaming disorder and internet addictions (OMPRIS). The OMPRIS intervention is mainly based on motivational interviewing skills and combines treatment strategies from cognitive behavioural therapy, media education, and social counselling with a total duration of four weeks (two sessions per week). Participants will be allocated by sequential balancing randomisation to the OMPRIS intervention or a waitlist control group. The primary outcome is the reduction of problematic internet use measured by self-report and diagnostical expert interview. Secondary outcomes include treatment motivation, co-morbid mental symptoms, quality of life, and costs. All measures will be assessed prior to the beginning, in the middle, at the end, and six weeks after completion of the OMPRIS intervention. Primary endpoint will be the post-intervention measurement. Outcomes will be analysed primarily via analysis of covariance. Both intention-to-treat and per-protocol analyses will be conducted.

Ethics and dissemination: The trial has been approved by the Ethics Committee of the Faculty of Medicine, Ruhr University Bochum (approval no 19-6779). Results will be published as a freely accessible final report suitable for peer-reviewed journals.

Trial registration number: The trial is registered on the German Clinical Trials Register (DRKS), ID: DRKS00019925, Date of registration: 13.03.2020.

Keywords: internet addiction, gaming disorder, randomised controlled trial, treatment, online therapy

Strengths and limitations of the study:

- A new and innovative online-based motivational treatment programme (OMPRIS) is tested in a real-world online setting as a low-threshold intervention to reduce problematic gaming behaviour and promote treatment motivation in internet-addicted subjects.
- Diagnosticians, therapists, and outcome assessors are blind to participants' allocation.
- Outcome measurements include treatment effects, costs and cost-effectiveness.
- Follow-up measurement is limited to six weeks due to the exclusive online design, which makes a higher drop-out rate likely.
- The OMPRIS trial is conducted as a randomised controlled trial (RCT) with a waitlist control group.

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1. Introduction

In 2019, approximately 90% of all German households had access to the World Wide Web. Families with at least one child display a nearly 100% internet supply [1]. A current representative study carried out on 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 videogames was 139 minutes on weekdays and 193 minutes on weekends [2].

Moreover, there is further evidence from other countries indicating an increase of gaming behaviour (e.g. gaming hours) in college students and adolescents, especially due to the COVID-19 pandemic in 2020 [3–5]. In the last decade, internet addiction (IA) has emerged as global issues with a worldwide prevalence estimation of 6.0%, with the highest prevalence in the Middle East (10.9%) and the lowest prevalence in northern and western Europe (2.6%) [6]. Global prevalence of internet gaming disorder (IGD) was recently reported at 3.05% [7].In epidemiological studies conducted in German-speaking countries, prevalence rates of IA and IGD ranged between 1.5% and 3.0% in German [8,9] and Austrian adolescents [10], respectively. In 2013, IGD was included in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) as a condition warranting further research [11]. Because of growing scientific evidence, gaming disorder (GD) was recently introduced as a new diagnosis in the

upcoming *International Classification of Diseases, 11*th *Revision* (ICD-11), in the section 'Disorders Due to Addictive Behaviours' [12].

According to ICD-11, GD is characterised by a persistent or recurrent pattern (lasting at least 12 months) of gaming behaviour that is characterised by (1) impaired control regarding its onset, intensity, duration, frequency, termination, and context; (2) increased priority given to video gaming to the extent that gaming takes precedence over daily activities and life interests; and (3) escalation and continuation despite the occurrence of negative consequences. Furthermore, the pathological behaviour pattern must be sufficiently severe and cause significant impairment in personal, social, educational, occupational, or other relevant areas of functioning [12]. Excessive gaming is related to high health burden and psychiatric comorbidities [13–16].

Despite a slowly increasing number of specific analogue treatment options (e.g. specialised outpatient and inpatient psychotherapy and behavioural addiction counselling centres), individuals affected by IA and IGD often do not find adequate therapy due to a lack of motivation to change or the absence of reachable treatment options close to home [17]. Internet-based interventions are an innovative way of reaching affected patients at a low-threshold level. Guided online interventions (e.g. for depression and anxiety disorders) have been reported as effective treatment options with medium to large effect sizes [18,19]. One meta-analysis even demonstrated that guided self-help might be as effective as face-to-face treatment (for depression and anxiety disorders) with no significant differences in follow-up measurements and even drop-out rates [20].

Furthermore, internet-based interventions have been examined in the field of addictive behaviour. 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 non-

substance addictions (5 studies in pathological gambling) [21]. All studies demonstrated positive treatment outcomes for their respective addictive behaviours.

To the best of our knowledge, no controlled intervention studies have been conducted yet to investigate a guided online-based psychological intervention for patients with problematic internet use and gaming disorder. However, a first preliminary study exploring an online ambulatory service for internet addicts (OASIS) with only two webcam sessions was performed by our research group between 2016 and 2018 to refer addicts to medical treatment close to home [22]. In general, this study showed a high number of participating individuals (N = 27.629 completed an online self-assessment for IA; 45% showed problematic internet use; 9% presented addictive internet use).

Furthermore, over 200 individuals with a minimal level of problematic internet use participated in one to two consulting sessions. In total, the referral of internet-addicted participants to analogue medical treatment was moderate (40% of all cases). It was, however, more successful when participants were referred to online therapists they knew from former online consulting (referral rate 93%). This result underlined the importance of relationship constancy in (online-based) therapy. Despite the low number of only one to two sessions, the online consultation showed small but significant improvements regarding IA symptoms and motivation for change [22].

Given the preliminary results, a new and innovative specific online-based treatment programme (OMPRIS) was developed by our research group to increase treatment motivation and reduce symptoms of IA and IGD. It was essential to create a low-threshold and freely available treatment offer that is independent of the place of residence. As an online-based intervention, OMPRIS is intended to connect IA and IGD patients with a conventional analogue

medical treatment. At best, OMPRIS should interrupt addiction development at an early stage and might avoid the chronic manifestation of IA or IGD.

This study will assess the efficacy of a manualised OMPRIS intervention. The primary aim of the study is to test whether the OMPRIS intervention can successfully reduce problematic internet use and increase the motivation to change in the context of IA or IGD. Furthermore, the impact of co-morbid mental symptoms, personality traits, socio-demographic characteristics, and quality of life will be determined. The study further aims to collect data about acceptability, costs and cost-effectiveness of online-based treatment of IA and IGD to suggest adaption for future research and potential clinical implementation.

2. Methods and analysis

2.1 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 observer are blinded in this trial. Participants will be scheduled to complete either four weeks of an OMPRIS counselling programme or a four-week waiting period. Notably, WLC group participants will be offered the OMPRIS intervention after the expired waiting period.

2.2 Study setting

This multicentre study is coordinated by the Department of Psychosomatic Medicine and Psychotherapy, LWL-University Hospital of Ruhr University Bochum, Germany. The OMPRIS intervention is carried out by four German medical centres specialised in the treatment of IA 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 and counselling of IA and IGD.

The OMPRIS intervention is an online motivational treatment programme, and participants throughout Germany can participate via webcam. Participation is 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.

2.3 Participants and recruitment

Participants will be 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. Inclusion criteria are as follows: problematic or addictive use of internet applications according to the DSM-5 criteria for IGD and the ICD-11 criteria for GD as assessed via a self-report scale (Assessment of Internet and Computer Game Addiction, AICA-S [23,24]) and a structured clinical expert rating (Assessment of Internet and Computer Game Addiction, AICA-SKI:IBS [25]); 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

(i.e. concrete suicidal tendency). Exclusion criteria are psychotic disorders (past or present); learning disabilities/intellectual impairment; substance abuse within the past six months; active suicidal thoughts or intentions; younger than 16 years or missing parental informed consent; insufficient knowledge of the German language; inconstant or no access to the internet via webcam or no email address; a co-morbid somatic disease with endocrinological medication causing impulsive behaviours (e.g. Morbus Parkinson with dopaminergic medication); recent psychiatric or psychotherapeutic treatment focusing primarily on IA or IGD.

All subjects will be recruited online (www.onlinesucht-hilfe.com) by completing the AICA-S [23,24] 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 will diagnose all participants via structured clinical interviews for IA and IGD (AICA-SKI:IBS [25]) as well as psychiatric disorders (Mini-International Neuropsychiatric Interview, MINI 7.0 [26]).

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

Motivation and willingness to attend to study procedures 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.

2.4 Randomisation

Sequential balancing randomisation, according to Borm et al. (2005), will be used as a method that balances prognostic relevant factors in consecutive order [27]. 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 intervention group (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 pre-defined imbalance levels, the new subject is randomly assigned.

Four factors have relevant prognostic value, with each one divided into three classes based on data gathering from a former study [22,28] and the AICA-S questionnaire [23,24]: (1) gender (women, men, diverse); (2) the severity of internet-related addiction symptoms (AICA-S score < 7, 7-13; >13), (3) age (16-17 yrs., 18-30 yrs., >30 yrs.); and (4) the type of internet-related addiction (computer gaming, online pornography/cybersex, all other genres). Imbalance levels for each of the four factors were pre-defined by a researcher (NT) of the Department of Medical Informatics, Biometry & 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 OMPRIS session. The randomisation will be conducted automatically via the online 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.

2.5 Intervention

The manualised OMPRIS intervention is a combined treatment programme mainly based on the motivational interviewing (MI) approach that has been shown as sufficient to improve health behaviour in various medical diseases including addictive disorders [29–33]. Furthermore, OMPRIS contains treatment elements from cognitive behavioural therapy (CBT), (internet-related) addiction therapy [34], media education, and units of social counselling. Within a total duration of five to six weeks (four weeks of intervention plus one or two weeks for pre- and post-diagnostics), OMPRIS comprises approximately 12 webcam sessions with individual therapy, including two diagnostic sessions, eight to nine intervention sessions, and one to two social counselling sessions. The main intervention sessions (50 minutes each) will occur within four weeks, with two sessions per week. Table 1 shows treatment phases and strategies during the early, middle, and termination phases.

Based on the perception of individual ambivalence regarding possible behavioural changes, participants will be encouraged to find an alternative course of action in media use and daily routine. Subjects will be offered MI skills, media use diaries, CBT techniques for understanding individual mechanisms and consequences of problematic internet use, social skill

training, and direct support by professional social counselling. In the termination phase, strategies for relapse prevention will be developed. If required, referrals to further treatment options will be discussed.

Table 1: OMPRIS intervention strategies

Treatment strategies	Treatment phase	Key interventions
Motivational interviewing (MI)	All phases	Client-centred approach with empathy and openness Change talk Confidence talk Commitment talk Reflective listening Affirmation and summarising
Cognitive behavioural therapy (CBT)	All phases	Education on addiction mechanisms Identification of triggers of problematic internet use Individual model of addiction trials Building alternative activities and strategies Strategies to reduce procrastination tendencies Strategies to deal with aversion and listlessness Skills for reducing social anxiety and improving stress-coping Relapse prevention Interpersonal skills training
Media education	Early and middle phase	Upgrowth functional internet use Development of media rules and limitations
Structuring everyday life	Middle and termination phases	Re-structuring of bedtime, meals, working hours
Social counselling	Middle and termination phases	Help on individual social problems, e.g. unemployment, debt management, housing benefits, assistant living, complying with formalities, and etc.

2.6 Blinding

The trial will be conducted as a single-blinded design. Participants will be informed that they will be randomly allocated either to the IG (which immediately starts with the intervention) or the WLC group (which requires a four-week delay to start the intervention) after the initial introduction session. The therapists conducting the introduction and diagnostic sessions will be blind to the participants' allocation.

Moreover, 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. The trial database will be maintained as blind before conducting analyses.

2.7 Outcome assessment

Figure 1 shows a flow chart of the time points of assessment: assessment for eligibility (T0a), baseline pre-intervention (T0b), mid-intervention (T1; ~2 weeks postbaseline), post-intervention (T2; ~4 weeks postbaseline), and follow-up (T3; ~11 weeks postbaseline). The primary endpoint will be assessed at T2 measurement. All assessments will be automatically offered to the patients at the correct times via the OMPRIS software following the study protocol (see Table 2 for the study's schedule). If assessments are not applied within the scheduled time frame, participants will receive reminders via email and telephone. A seven-week follow-up period has been chosen to achieve a high return rate and reduce the risk of drop-outs resulting from the completely online-based design of the intervention.

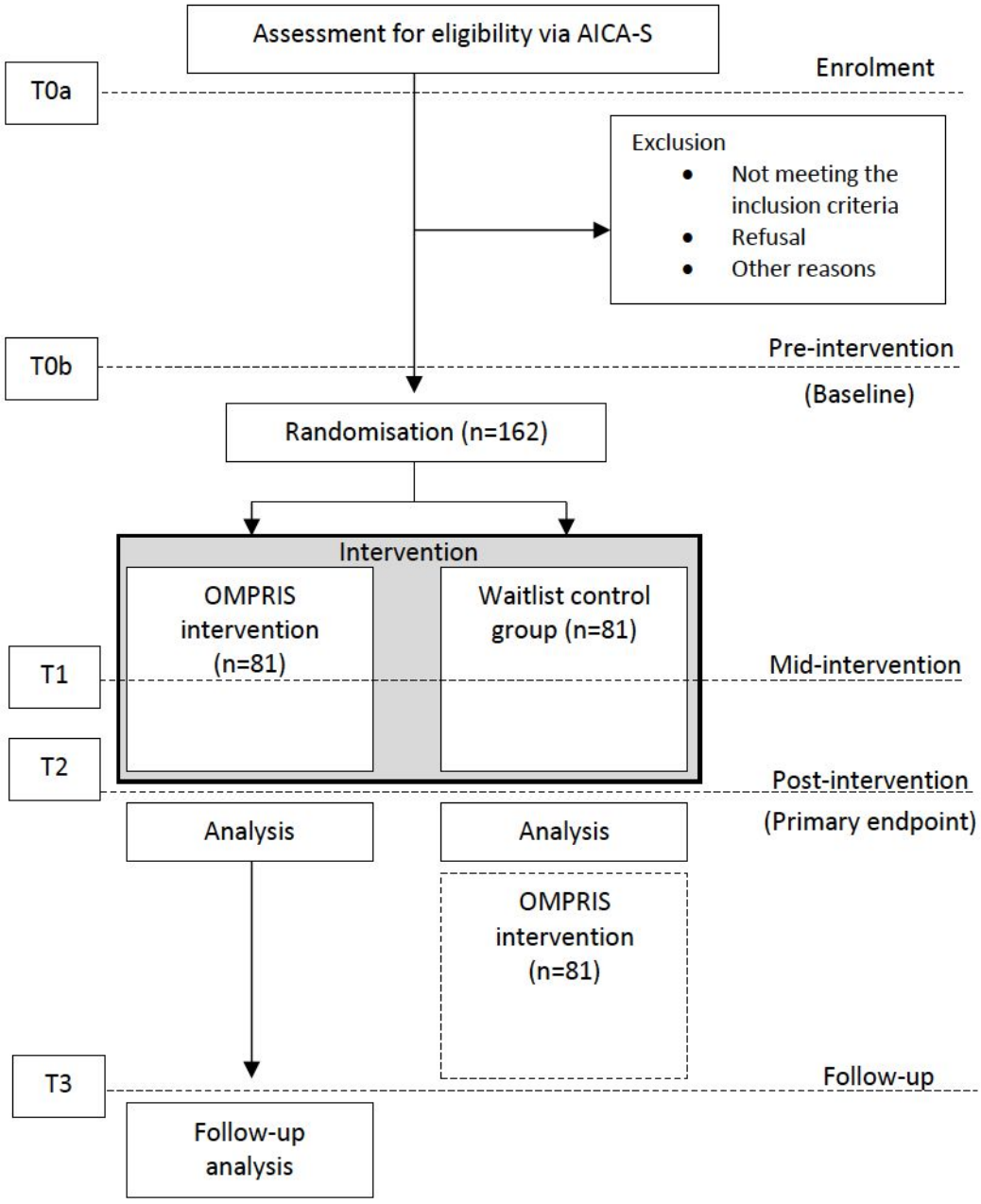

Figure 1: A flow chart of the study. Participants of the WLC group will be offered the OMPRIS intervention after the IG has finished. The follow-up analysis will be performed separately for the WLC group.

Table 2: Study schedule of measurement and testing

	T0a Eligibility	T0b Baseline	Each session	T1 Mid-intervention	T2 Post-intervention	T3 Follow-up
Approximate time since baseline	**- 1 week**	**-**		**2 weeks**	**4 weeks**	**11 weeks**
Consent	X					
AICA-S screening self-test	X					
Demographics	X					
Lifestyle parameter		X			X	X
MINI interview		X				
AICA-SKI:IBS Interview		X			X	
Treatment information		X				
AICA-S		X		X	X	X
iSOCRATES		X		X	X	X
CIUS		X		X	X	X
EQ-5D		X			X	X
PHQ-9		X			X	X
GAD-7		X			X	X
L-1		X			X	X
GSE		X			X	X
BFI-10		X				
Resource use		X			X	X
Satisfaction			X		X	
Mood			X			
HAQ				X	X	
SUS System usability					X	
Referrals				X	X	

AICA-S, Assessment of Internet and Computer game Addiction Scale; MINI, Mini-International Neuropsychiatric Interview; AICA-SKI:IBS, Assessment of Internet and Computer game Addiction - Structured Clinical Interview; iSOCRATES, Stages of Readiness and Treatment Eagerness Scale for Internet Addiction; CIUS, Compulsive Internet Use Scale; EQ-5D, EuroQol standardised measure of health-related quality of life - 5 Dimensions 5 Level Version; PHQ-9, Patient Health Questionnaire 9 Item Version; GAD-7, Generalised Anxiety Disorder Scale 7 Item Version; L-1, General Life Satisfaction 1 Item Version; GSE, General Self-Efficacy Scale; BFI-10, Big Five Inventory 10 Item Version; HAQ, Helping Alliance Questionnaire; SUS, System Usability Scale.

2.8 Primary outcome: Problematic internet use

The primary outcome is defined as an increase of motivation for changing problematic and pathologic internet use measured as a self-reported reduction of IA symptoms in the last four

weeks. The primary outcome measure is the self-report AICA-S scale whose items are related to the DSM-criteria of substance-use disorders and gambling disorder [23,24]. Fourteen items (five-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 activity, and the preferred type of problematic internet use are requested. A cut-off is defined by statistical means based on epidemiological surveys analyses [35]. A score of seven points (three to four criteria fulfilled) can be interpreted as addictive use. Reliability of AICA-S (internal consistency of $\alpha = .89$) and validity are determined in clinical and epidemiological surveys [35–37]. The AICA-S is conducted at baseline, mid-intervention, post-intervention, and a six-week follow-up.

2.9 Secondary outcomes

Stage of Readiness and Treatment Eagerness for Internet Addiction (iSOCRATES) [22]. The iSOCRATES scale is a self-report measure assessing the stage of readiness and treatment eagerness for IA. It was adapted from the German SOCRATES scale for alcohol addiction consisting of 19 motivation-relevant statements whereon participants give their agreement on a five-point Likert scale [38,39]. It will be conducted at baseline, mid-intervention, post-intervention, and a six-week follow-up.

Compulsive Internet Use Scale (CIUS) [40]. The CIUS contains 14 items rateable on a five-point Likert scale and measures symptoms of internet-related disorders. It will be conducted at baseline, mid-intervention, post-intervention, and a six-week follow-up.

Patient Health Questionnaire-9 [41] (PHQ-9, German translation [42]). This nine-item patient questionnaire is a self-report version of the PRIME-MD diagnostic instrument for common mental disorders [43]. 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). It will be conducted at baseline, post-intervention, and a six-week follow-up.

Generalised Anxiety Disorder Screener [44] (GAD-7, German translation [45]). The GAD-7 scale is a self-report measure assessing general anxiety symptoms related to DMS-IV criteria on a four-point Likert scale. It will be conducted at baseline, post-intervention, and a six-week follow-up.

General life satisfaction (L-1) [46]. 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'. It will be conducted at baseline, post-intervention, and a six-week follow-up.

General self-efficacy scale [47] (GSE, German translation SWE [48]). The GSE scale measures self-perceived self-efficacy and consists of ten 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 four-point scale from '1' (not at all true) to '4' (exactly true). It will be conducted at baseline, post-intervention, and a six-week follow-up.

Big Five Inventory [49] (BFI-10). The BFI-10 is a self-report measure containing ten items to assess Big Five personality traits. It has five subscales with two bidirectional items for each of the personality factors. The ten items are rated on a five-point Likert scale wherein the

subjects choose from responses ranging from ‘strongly disagree’ to ‘strongly agree’. It will be conducted only once at baseline.

Helping Alliance Questionnaire [50] (HAQ, German translation [51]). The HAQ is a highly relevant instrument to assess the therapeutic alliance and can be used both as the patient’s version and, in a slightly modified form, as the therapist’s version. All items are rated on a six-point Likert Scale from ‘strongly agree’ to ‘strongly disagree’. It will be conducted at mid-intervention and post-intervention.

EuroQol standardised measure of health-related quality of life - 5 dimensions, 5 level Version [52] (EQ-5D-5L, German translation [53]). 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 five-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’. It will be conducted at baseline, post-intervention, and a six-week follow-up.

2.10 Additional measures

The *AICA-SKI:IBS* [25] 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 internet-related disorders. 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 internet-related disorder.

The AICA-SKI:IBS takes approximately 20-30 minutes and will be conducted at baseline and post-intervention.

The *Mini-International Neuropsychiatric Interview* [26] (MINI, V7.0.) is a short structured diagnostic interview developed for DSM-5 and ICD-10 psychiatric disorders. With an administration time of approximately 15-20 minutes, 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* (SUS) [54] is a short, reliable tool for measuring usability in a wide variety of services, including software, websites, and applications. It consists of ten items on a five-point Likert scale from 'strongly agree' to 'strongly disagree'. It will be conducted at post-intervention.

Satisfaction with OMPRIS intervention is measured by ten items on a five-point Likert scale from 'strongly disagree' to 'strongly agree' (e.g. '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 post-intervention.

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 (e.g. 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 (e.g. software, conceptual design, implementation costs, etc.) and ongoing intervention costs (e.g. material and personnel costs for therapy sessions, software maintenance, etc.).

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

2.11 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 =.05. A current RCT treatment study (STICA study) found an effect size of d = 1.19 for the effect of analogue CBT treatment on the reduction of IA symptoms (SD = 3.92) using the same outcome measurement AICA-S [34]. We took a conservative estimate of effect size d = 0.51 (approx. 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 drop-out rate of 30%.

2.12 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 people with internet addiction [22]. 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 four-

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 IA and GD within the framework of a large-scale cooperation.

2.13 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. Any participants identifiable 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 principal investigator (JDH) will have primary responsibility for verifying the integrity of the databases and will be responsible for managing and archiving the databases post-analysis.

2.14 Trial management and monitoring

The principal investigator (JDH) has 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.

2.15 Adverse event monitoring

Adverse events (AEs) will be monitored by trial researchers conducting the OMPRIS intervention on an ongoing basis and post-intervention, 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 (CTCAE) [55]. 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; psychiatric co-morbidity with an indication for inpatient admission (hospitalisation) to a clinic. Both, SAEs and SSREs will be reported to the responsible ethics committee.

2.16 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. 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 IA symptoms with the co-variables of baseline value, gender, age, and type of internet addiction.

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 chi-squared test. Exploratory analyses will evaluate potential predictors for therapeutic success via linear and logistic regression models.

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 IA 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, four weeks later at T2, and, again, seven weeks later at T3 for both groups.

A standardised health economic questionnaire has been developed, which includes questions concerning health care 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 socio-demographic 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 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 [56–59]. 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 standard deviations of resource use and health care costs. According to the method of difference-in-difference, health care 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.

3. Ethics and dissemination

3.1 Ethical issues

Clinical protocol and written informed consent were approved by the Ethics Committee for the Faculty of Medicine, Ruhr University Bochum, approval no. 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 (GCP) 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 four weeks. The OMPRIS study is funded by the German Innovation Funds of Germany's Federal Joint Committee (G-BA).

3.2 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. If the primary hypothesis is confirmed and the OMPRIS intervention is successful, the OMPRIS manual may be published in detail to offer novel treatment strategies for the (online-based) treatment of patients suffering from IA and IGD.

3.3 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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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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Abstract

Introduction: In May 2019, the World Health Organisation classified Internet gaming disorder as a mental disorder in the upcoming ICD-11. However, individuals affected by Internet gaming disorder (IGD) or Internet use disorders (IUDs) often are 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 intervention, which aims at reducing IUDs symptoms and enhancing the motivation to undergo treatment (OMPRIS).

Methods: 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 intervention includes an extensive diagnostic, followed by a four-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 AICA-S scale. Secondary outcomes include time spent on the Internet, treatment motivation (iSOCRATES), co-morbid mental symptoms (PHQ-9, GAD-7), quality of life (EQ-5D, L-1), self-efficacy (GSE), personality traits (BFI-10), therapeutic alliance (HAQ), and 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 six weeks (T3) and six months (T4) after inclusion. The outcomes will be analysed primarily via analysis of covariance. Both intention-to-treat and per-protocol analyses will be conducted.

Ethics: The trial has been approved by the Ethics Committee of the Faculty of Medicine, Ruhr University Bochum (approval no 19-6779). Results will be published as a freely accessible report suitable for peer-reviewed journals.

Trial registration: German Clinical Trials Register (DRKS), ID: DRKS00019925, Date of registration: 13.03.2020.

Keywords: Internet use disorder, Internet addiction, Internet gaming disorder, randomised controlled trial, treatment, online therapy, eHealth

Strengths and limitations of the study:

- A new and innovative online-based motivational intervention (OMPRIS) is tested in a real-world online setting as a low-threshold intervention to reduce problematic gaming behaviour and promote treatment motivation in Internet gaming disorder and Internet use disorders.
- Diagnosticians, therapists, and outcome assessors are blind to participants' allocation.
- Outcome measurements include treatment effects, costs and cost-effectiveness.
- Follow-up measurements will be 6 weeks and 6 months after inclusion.
- The OMPRIS trial is conducted as a randomised controlled trial (RCT) with a waitlist control group.

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

1. 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 videogames was 139 minutes on weekdays and 193 minutes on weekends [2]. Moreover, there is further evidence from other countries indicating an increase of gaming behaviour (e.g. gaming hours) in college students and adolescents, especially due to the COVID-19 pandemic in 2020 [3–5].

1.1 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, e.g. 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 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 between 2.6% in northern and western Europe and 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 between 1.2% and 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].

1.2 Evidence of treatment for Internet use disorders

The range of available specialised evidence-based treatments for IUD and IGD is still rare. Currently, there are only a few empirical studies investigating IUD and IGD therapy approaches using the scientific standard of a RCT design [22–24]. A recent meta-analysis demonstrated high efficacy (12 studies with a total of 580 patients) for cognitive-behavioral 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 IUD patients [27–31].

1.3 eHealth interventions in addictive disorders

Internet-based and eHealth interventions (e.g. 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 (5 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 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. This study used MI techniques as main intervention [29]. Furthermore, a recent study protocol presenting an ongoing randomised controlled trial 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 h/d; 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, results of evidence-based randomised controlled studies investigating Internet-based intervention for IGD or IUD, especially using face-to-face via webcam, have not yet been published.

1.4 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 (OMPRIS) for reducing IUD and IGD symptoms and increasing treatment motivation compared to 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 IUD and IGD patients access conventional treatments. It is hypothesised that the OMPRIS intervention will increase the referral rate to (specialised) mental health care.

2. Methods and analysis

2.1 Trial design

The design is a single-blind RCT with two parallel arms, comparing the OMPRIS intervention to a waitlist control group (WLC). Therapists and observer will be blinded in this trial. Participants will be scheduled to complete either four weeks of an OMPRIS counselling programme or a four-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 (G-BA) and is therefore primarily a health care research study that is intended to investigate an innovative form of telemedical eHealth care.

2.2 Study setting

This multicentre study is coordinated by the Department of Psychosomatic Medicine and Psychotherapy, LWL-University Hospital of Ruhr University Bochum, Germany (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 and counselling of IUD and IGD.

The OMPRIS intervention will be offered totally online and participants from all over Germany can take part via webcam. 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.

2.3 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 paragraph 2.11. Inclusion criteria are as follows: problematic or addictive use of Internet applications according to the DSM-5 criteria and the ICD-11 criteria for IGD as assessed via a self-report scale (Assessment of Internet and Computer Game Addiction, AICA-S [39,40]) and a structured clinical expert rating (Assessment of Internet and Computer Game Addiction, 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 (i.e. concrete suicidal tendency). Exclusion criteria are psychotic disorders (past or present); learning disabilities/intellectual impairment; substance abuse within the past six months; active suicidal thoughts or intentions; younger than 16 years or missing parental informed consent; insufficient knowledge of the German language; inconstant or no access to the Internet via webcam or no email address; a co-morbid somatic disease with endocrinological medication causing impulsive

behaviours (e.g. 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 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 interview, psychotic disorders, acute suicidality, learning disabilities/intellectual impairments via the MINI interview, sufficient knowledge of the German language via the ability to complete questionnaires and follow the webcam-based informed consent procedure, and a co-morbid 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.

2.4 Randomisation

Sequential balancing randomisation, according to Borm et al. (2005), 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 intervention group (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 pre-defined imbalance levels, the new subject is randomly assigned.

Four factors have 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 yrs., 18-30 yrs., >30 yrs.); and (4) the type of Internet use disorder (gaming, pornography/cybersex, all other genres). Imbalance levels for each of the four factors were pre-defined by a researcher (NT) of the Department of Medical Informatics, Biometry & 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.

2.5 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 cognitive behavioural therapy (CBT), (Internet-related) addiction therapy [49], media education, and social counselling. The primary outcome will be measured constantly after four weeks of intervention (measurement points: T0 baseline, T1 mid-intervention, and T2 post intervention, see Figure 1 & Table 2). During these four weeks, the participants will be offered up to eight psychological treatment sessions and one or two social support sessions. In addition, a detailed diagnostic webcam session will be offered one week before and one 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 enrolment. The psychological intervention sessions (50 minutes each) will take place within four weeks, with two sessions per week. Table 1 shows the treatment phases and strategies during the early, middle, and termination phases.

Based on e.g. 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 (e.g. habit reversal, behavioural rehearsals, practices, restructuring the environment, self-assessment and anticipation

of social and health consequences, problem solving coping panning, pros and cons, regulation of negative emotions, see Table 1). 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 (e.g. 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 and counselling of IUD and IGD, who work at the cooperating study centers (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.

Table 1: 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 (e.g. 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 phase	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, e.g. unemployment, debt management, housing benefits, assistant living, complying with formalities

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2.6 Blinding

The trial will be conducted as a single-blinded design. Participants will be informed that they will be randomly allocated either to the IG (which immediately starts with the intervention) or the WLC group (which requires a four-week delay to start the intervention) after the initial introduction session. The therapists conducting the introduction and diagnostic sessions will be blind to the participants' allocation. Moreover, 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 program, a confirmation of participation, the IUD diagnosis, and (if relevant) personalized recommendation for further treatment. The trial database will be maintained as blind before conducting analyses.

2.7 Outcome assessment

Figure 1 shows a flow chart of the time points of assessment: assessment for eligibility (T0a), baseline pre-intervention (T0b), mid-intervention (T1; ~2 weeks postbaseline), post-intervention (T2; ~4 weeks postbaseline, primary endpoint), and two follow-ups (T3; ~11 weeks postbaseline and T4: ~6 months postbaseline). All assessments will be automatically offered to the participants at the correct times via the OMPRIS software following the study protocol (see Table 2 for the study's schedule). If assessments are not applied within the scheduled time frame, participants will receive reminders via email and telephone.

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Figure 1: A flow chart of the study. Participants of the WLC group will be offered the OMPRIS intervention after the IG has finished. The follow-up analysis will be performed separately for the WLC group.

Table 2: Study schedule of measurement and testing

	T0 Eligibility	T0b Baseline	Each session	T1 Mid-intervention	T2 Post-intervention	T3 & T4 Follow-up	
Approximate time since baseline	**- 1 week**	**-**		**2 weeks**	**4 weeks**	**11 weeks**	**6 months**
Consent	X						
AICA-S (primary outcome)	X	X		X	X	X	X
Demographics	X						
Life style parameter		X			X	X	X
MINI Interview		X					
AICA-SKI:IBS Interview		X			X		
Treatment information		X					
iSOCRATES		X		X	X	X	X
CIUS		X		X	X	X	X
EQ5D-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 System usability					X	-	

Note. AICA-S = Assessment of Internet and Computer game Addiction Scale; MINI = Mini-International Neuropsychiatric Interview; AICA-SKI:IBS = Assessment of Internet and Computer game Addiction - Structured Clinical Interview; iSOCRATES = Stages of Readiness and Treatment Eagerness Scale for Internet-Addiction; CIUS = Compulsive Internet Use Scale; EQ-5D = EuroQoL standarised measure of health-related quality of life; PHQ-9 = Patient Health Questionnaire 9 Item Version; GAD-7 = Generalised Anxiety Disorder Scale 7 Item Version; L-1 = General Life Satisfaction 1 Item Version; SWE = Self-Efficacy Scale; BFI-10 = Big Five Inventory 10 Item Version; HAQ = Helping Alliance Questionnaire; SUS = System Usability Scale.

2.8 Primary outcome: Problematic Internet use

A*ssessment of Internet and Computer game Addiction Scale* (AICA-S) [39,40]. The primary outcome is defined as reduction of current IUD symptoms measured by AICA-S scale whose items are related to the DSM-criteria of substance-use disorders and gambling disorder. Fourteen items (five-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 surveys analyses [50]. A score of seven points (three to 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 82.4 % [51]. Reliability of AICA-S (internal consistency of α =.89) and validity are determined in clinical and epidemiological surveys [50,52,53]. The AICA-S was successfully used in a recent published German randomised controlled trial 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, post-intervention, and at follow-up.

2.9 Secondary outcomes

Stage of Readiness and Treatment Eagerness for Internet use disorder (iSOCRATES) [38]. The iSOCRATES scale is a self-report measure assessing the stage of readiness and treatment eagerness for IUD. It was adapted from the German SOCRATES scale for alcohol addiction consisting of 19 motivation-relevant statements whereon participants give their agreement on a five-point Likert scale [54,55]. Cronbach´s alpha of the measure has shown to be

α = .60 for the scale 'ambivalence', α = .83 for 'taking steps', and α = .85 for 'recognition' [55]. It will be conducted at baseline, mid-intervention, post-intervention, and at follow-up.

Compulsive Internet Use Scale (CIUS) [56]. The CIUS contains 14 items rateable on a five-point Likert scale and measures symptoms of Internet-related disorders. The instrument has shown a good internal consistency (α = .89) [57]. It will be conducted at baseline, mid-intervention, post-intervention, 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 PRIME-MD diagnostic instrument for 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 = .83-.92) [61]. It will be conducted at baseline, post-intervention, and at follow-up.

Generalised Anxiety Disorder Screener [62] (GAD-7, German translation [63]). The GAD-7 scale is a self-report measure assessing general anxiety symptoms related to DMS-IV criteria on a four-point Likert scale. The internal consistency has shown to be excellent (α = .89) [62]. It will be conducted at baseline, post-intervention, 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} = .67 [64]. It will be conducted at baseline, post-intervention, and at follow-up.

General self-efficacy scale [65] (GSE, German translation SWE [66]). The GSE scale measures self-perceived self-efficacy and consists of ten 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 four-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 =.76 to .90. In German samples, Cronbach's alpha varies between .80 and .90 [67]. It will be conducted at baseline, post-intervention, and at follow-up.

Big Five Inventory [68] (BFI-10). The BFI-10 is a self-report measure containing ten items to assess Big Five personality traits. It has five subscales with two bidirectional items for each of the personality factors. The ten items are rated on a five-point Likert scale wherein 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} = .58-.84) [69]. The BFI-10 will be conducted only once at baseline.

Helping Alliance Questionnaire [70] (HAQ, German translation [71]). 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 six-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 post-intervention. Cronbach's α of the two scales has been reported as good (α = .75-.89 on the HAQ-P and α = .63-.85 on the HAQ-T) [72].

EuroQol standardised measure of health-related quality of life - 5 dimensions, 5 level Version [73] (EQ-5D-5L, German translation [74]). 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 five-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 [75]. It will be conducted at baseline, post-intervention, and at follow-up.

2.10 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 Internet use disorders. 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 Internet use disorder. The AICA-SKI:IBS takes approximately 20-30 minutes and will be conducted at baseline and post-intervention.

The *Mini-International Neuropsychiatric Interview* [42] (MINI, V7.0.) is a short structured diagnostic interview developed for DSM-5 and ICD-10 psychiatric disorders. With an administration time of approximately 15-20 minutes, 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* (SUS) [76] is a short, reliable tool for measuring usability in a wide variety of services, including software, websites, and applications. It consists of ten items

on a five-point Likert scale from 'strongly agree' to 'strongly disagree'. It will be conducted at post-intervention.

Satisfaction with OMPRIS intervention is measured by ten items on a five-point Likert scale from 'strongly disagree' to 'strongly agree' (e.g. '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 post-intervention.

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 (e.g. 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 (e.g. software, conceptual design, implementation costs, etc.) and ongoing intervention costs (e.g. material and personnel costs for therapy sessions, software maintenance, etc.).

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

2.11 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 =.05. A current RCT treatment study (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 (approx. 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 drop-out rate of 30% according to data from young adults addiction treatment [49,77].

2.12 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 people with Internet use disorder [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 four-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 GD within the framework of a large-scale cooperation.

2.13 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. Any participants identifiable 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 principal investigator (JDH) will have primary responsibility for verifying the integrity of the databases and will be responsible for managing and archiving the databases post-analysis.

2.14 Trial management and monitoring

The principal investigator (JDH) has 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.

2.15 Adverse event monitoring

Adverse events (AEs) will be monitored by trial researchers conducting the OMPRIS intervention on an ongoing basis and post-intervention, 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 (CTCAE) [78]. 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; psychiatric co-morbidity with an indication for inpatient admission (hospitalisation) to a clinic. Both, SAEs and SSREs will be reported to the responsible ethics committee.

2.16 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 session, termination by agreement, and completion 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 co-variables of baseline value, gender, age, and type of Internet use disorder.

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 chi-squared 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 [79] and IBM SPSS Statistics [80].

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, four weeks later at T2, and, again, seven weeks later at T3 for both groups.

A standardised health economic questionnaire has been developed, which includes questions concerning health care 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 socio-demographic 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 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 [81–84]. 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 standard deviations of resource use and health care costs. According to the method of difference-in-difference, health care 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.

3. Discussion

Treating people with IUD and IGD via the Internet may seem contradictory or paradoxical at first sight. However, the COVID-19 pandemic shows that Internet-based communication via webcam is feasible and may be helpful in many professional and social fields. From our point of view, there strong arguments to support the use of online treatment for IUD patients: (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 [85,86], 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 [87]. This latency might increase an additional loss of motivation. A quick and uncomplicated initial offer might be important to restructure IUD behaviour. (4) Co-morbid disorders, like depressive or anxiety disorders, make it challenging for individuals with IUD or IGD to get into conventional outpatient therapy. Internet-based intervention and telemedicine take the care system to peoples' homes. (5) 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 health care research project, which offers a standardised therapeutic Internet-based intervention to all interested people aged 16 or older from all over Germany. Participation in OMPRIS is guided by individual interests and concerns. We assume that people will come forward who feel that their Internet use might be problematic. Due to the low barriers, we hypothesise that OMPRIS will nearly represent the general population of individuals suffering from IUD and IGD (e.g. 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 [51,88].

4. Ethics and dissemination

4.1 Ethical issues

Clinical protocol and written informed consent were approved by the Ethics Committee for the Faculty of Medicine, Ruhr University Bochum, approval no. 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 (GCP) 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 four weeks.

4.2 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.

4.3 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.

5. Statements

5.1 Authors' contributions: JDH, LB, and MP conceived the study. JDH is the principal investigator, acquired funding and drafted the initial study protocol. AN, SN and NT as those 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.

5.2 Competing interests: The study is funded by the German Innovation Fund of Germany's Federal Joint Committee (G-BA). JDH obtained the funding. The authors declare that they do not receive any financial support from the industry, in particular the computer games industry. The authors declare that there is no conflict of interest with regard to this study protocol.

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5.4 Data sharing statement

In accordance with the ICMJE's data sharing statement individual participants data, that underlies the results reported in the main OMPRIS article, will be shared after de-identification. Data will be shared with investigators whose proposed use of the data has been proven by an independent review committee identified for this purpose at the earliest 9 months following the publication of the main OMPRIS article. As related document, the OMPRIS study protocol will be published. Proposals must be submitted via Email (jan.dieris-hirche@rub.de) up to 36 months following the publication of the main OMPRIS article. Data will be made available for statistical meta-analyses by our research data cloud.

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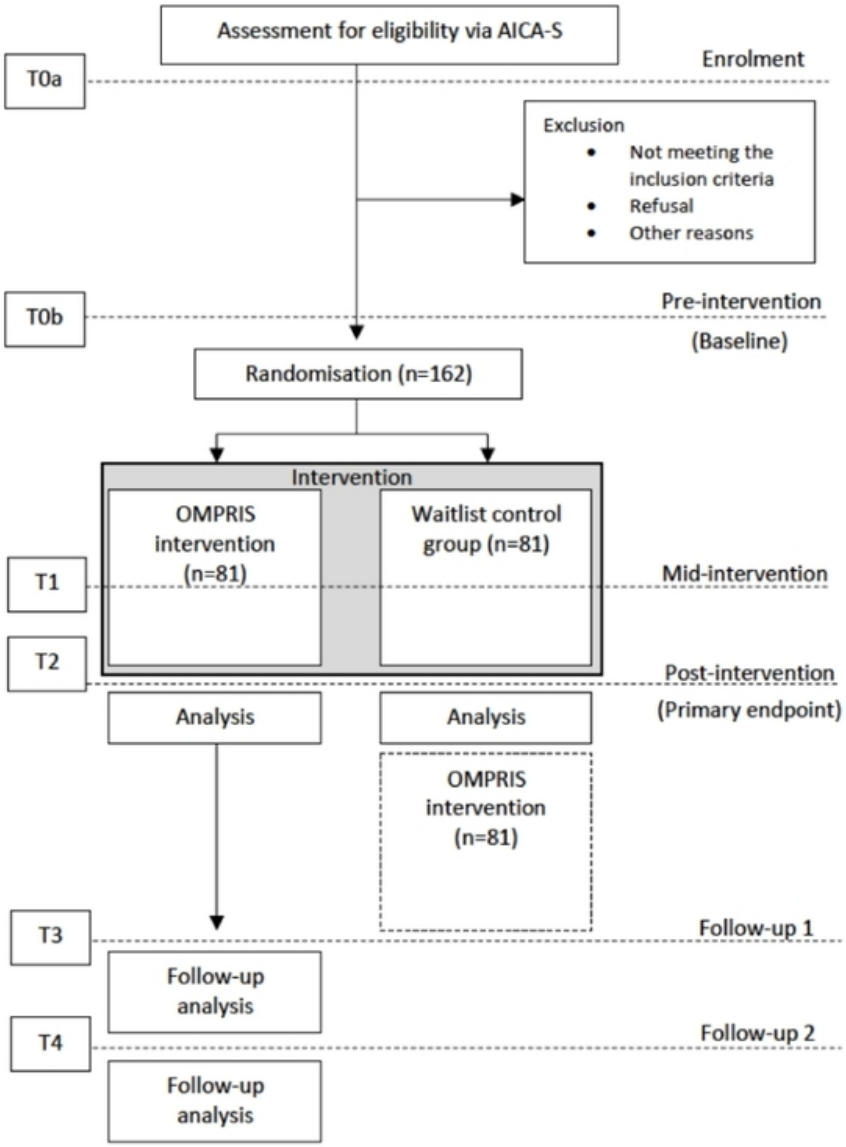

Figure 1: A flow chart of the study. Participants of the WLC group will be offered the OMPRIS intervention after the IG has finished. The follow-up analysis will be performed separately for the WLC group.

49x64mm (300 x 300 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Jan Dieris-Hirche et al. 2021

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym (p. 1)
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry (p.2)
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier (p.2)
Funding	4	Sources and types of financial, material, and other support (p.2)
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors (p.2)
	5b	Name and contact information for the trial sponsor (p.2)
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities (p.2)
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) (p.2)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention (p. 4-7)
	6b	Explanation for choice of comparators (p. 4-7)

Objectives	7	Specific objectives or hypotheses (p.7)
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) (p.8)
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained (p.8)
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) (p.9)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered (p.12-14)
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) (p.12-14)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) (p. 12-14, 24)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial (p. 12-14)
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended (p. 17-21)
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) (p. 16–17)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations (p.22)
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size (p.9-10)
Methods: Assignment of interventions (for controlled trials)		
Allocation:		

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions (p. 10-11)
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned (p. 10-11)
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions (p.11)
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how (p.15 – 16)
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial (p.15)
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol (p.15-22)
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols (p. 25)
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol (p.23-24)
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol (p.25-26)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) (p.26)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) (p.25)

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed (p.24-25)
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial (p.23-24)
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct (p.29)
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor (p.24)

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval (p.28)
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) (p.28-29)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) (p.23-24)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable (p.23)
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial (p.24)
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site (p.2)
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators (p.30)
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation (p.24-25)

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions (p.29)
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code (p.30)
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates (yes, related document pdf)
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable (not applicable)

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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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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Keywords:	Impulse control disorders < PSYCHIATRY, Clinical trials < THERAPEUTICS, Adult psychiatry < PSYCHIATRY

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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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Ethics approval: Ethics Committee for the Faculty of Medicine, Ruhr University Bochum, approval no. 19-6779.

Trial registration number: The trial is registered on the German Clinical Trials Register (DRKS), ID: DRKS00019925, Date of registration: 13.03.2020.

Version: Revised protocol version 3.0, June 02, 2021.

Abstract

Introduction. In May 2019, the World Health Organisation classified Internet gaming disorder as a mental disorder in the upcoming ICD-11. However, individuals affected by Internet gaming disorder (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 intervention, which aims at reducing IUDs symptoms and enhancing the motivation to undergo treatment (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 four-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 AICA-S scale. Secondary outcomes include time spent on the Internet, treatment motivation (iSOCRATES), co-morbid mental symptoms (PHQ-9, GAD-7), quality of life (EQ-5D, L-1), self-efficacy (GSE), personality traits (BFI-10), therapeutic alliance (HAQ), 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 six weeks (T3) and six 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 no 19-6779). Findings will be disseminated through presentations, peer-reviewed journals and conferences.

Trial registration number. DRKS00019925.

Trial registration number: German Clinical Trials Register (DRKS), ID: DRKS00019925, Date of registration: 13.03.2020.

Keywords: Internet use disorder, Internet addiction, Internet gaming disorder, randomised controlled trial, treatment, online therapy, eHealth

Strengths and limitations of the 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 IUD 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.

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

1. 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 videogames was 139 minutes on weekdays and 193 minutes on weekends [2]. Moreover, there is further evidence from other countries indicating an increase of gaming behaviour (e.g., gaming hours) in college students and adolescents, especially due to the COVID-19 pandemic in 2020 [3–5].

1.1 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, e.g. 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 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 between 2.6% in northern and western Europe and 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 between 1.2% and 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].

1.2 Evidence of treatment for Internet use disorders

Currently, there are only a few empirical studies investigating IUD and IGD therapy approaches using the scientific standard of a RCT design [22–24]. A recent meta-analysis demonstrated high efficacy (12 studies with a total of 580 patients) for cognitive-behavioral 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 IUD patients [27–31].

1.3 eHealth interventions in addictive disorders

Internet-based and eHealth interventions (e.g., 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 (5 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 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. This study used MI techniques as main intervention [29]. Furthermore, a recent study protocol presenting an ongoing randomised controlled trial 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 h/d; 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, results of evidence-based randomised controlled studies investigating webcam-based intervention for IGD or IUD have not been published yet.

1.4 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 (OMPRIS) for reducing IUD and IGD symptoms and increasing treatment motivation compared to 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 IUD and IGD patients access conventional treatments. It is hypothesised that the OMPRIS intervention will increase the referral rate to (specialised) mental health care.

2. Methods and analysis

2.1 Trial design

The design is a single-blind RCT with two parallel arms, comparing the OMPRIS intervention to a waitlist control group (WLC). Therapists and observer will be blinded in this trial. Participants will be scheduled to complete either immediately a four-week long webcam-based intervention or a four-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 (G-BA) and is therefore primarily a health care research study that is intended to investigate an innovative form of telemedical eHealth care.

2.2 Study setting

This multicentre study is coordinated by the Department of Psychosomatic Medicine and Psychotherapy, LWL-University Hospital of Ruhr University Bochum, Germany (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.

2.3 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 paragraph 2.11. Inclusion criteria are as follows: problematic or addictive use of Internet applications according to the DSM-5 criteria and the ICD-11 criteria for IGD as assessed via a self-report scale (Assessment of Internet and Computer Game Addiction, AICA-S [39,40]) and a structured clinical expert rating (Assessment of Internet and Computer Game Addiction, 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 (i.e. concrete suicidal tendency). Exclusion criteria are psychotic disorders (past or present); learning disabilities/intellectual impairment; substance abuse within the past six months; active suicidal thoughts or intentions; a co-morbid somatic disease with endocrinological medication causing impulsive behaviours (e.g., 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 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 interview, psychotic disorders, acute suicidality, learning disabilities/intellectual impairments via the MINI interview, sufficient knowledge of the German language via the ability to complete questionnaires and follow the webcam-based informed consent procedure, and a co-morbid 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.

2.4 Randomisation

Sequential balancing randomisation, according to Borm et al. (2005), 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 intervention group (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 pre-defined imbalance levels, the new subject is randomly assigned.

Four factors have 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 yrs., 18-30 yrs., >30 yrs.); and (4) the type of IUD (gaming, pornography/cybersex, all other genres). Imbalance levels for each of the four factors were pre-defined by a researcher (NT) of the Department of Medical Informatics, Biometry & 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.

2.5 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 cognitive behavioural therapy (CBT), (Internet-related) addiction therapy [49], media education, and social counselling. The primary outcome will be measured constantly after four weeks of intervention (measurement points: T0 baseline, T1 mid-intervention, and T2 post intervention, see Figure 1 & Table 2). During these four 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 one week before and one 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-minutes long webcam-based psychological sessions will be implemented twice a week (= eight sessions in four weeks) via our study platform. Table 1 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 (e.g., 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 1). 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 (e.g., 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 centers (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.

Table 1: 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 (e.g., 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 phase	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, (e.g., unemployment, debt management, housing benefits, assistant living, complying with formalities)

2.6 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, 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 program, a confirmation of participation, the IUD diagnosis, and (if relevant) personalized recommendation for further treatment. The trial database will be maintained as blind before conducting analyses.

2.7 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), post-intervention (T2; after 4 weeks, primary endpoint), and two follow-ups (T3; 6 weeks after intervention, T4: 6 months 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 2 for the study's schedule). If assessments are not applied within the scheduled time frame, participants will receive reminders via email and telephone.

<PLEASE INSERT FIGURE 1 HERE>

Figure 1: A flow chart of the study. Participants of the WLC group will be offered the OMPRIS intervention after a four-week long waiting period. The follow-up analysis will be performed separately for the WLC group.

Table 2: Study schedule of measurement and testing

	T0a Eligibility	T0 Baseline	Each session	T1 Mid-intervention	T2 Post-intervention	T3 & 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						
Life style parameter		X			X	X	X
MINI Interview		X					
AICA-SKI:IBS Interview		X			X		
Treatment information		X					
iSOCRATES		X		X	X	X	X
CIUS		X		X	X	X	X
EQ5D-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 System usability					X		

Note. AICA-S = Assessment of Internet and Computer game Addiction Scale; MINI = Mini-International Neuropsychiatric Interview; AICA-SKI:IBS = Assessment of Internet and Computer game Addiction - Structured Clinical Interview; iSOCRATES = Stages of Readiness and Treatment Eagerness Scale for Internet-Addiction; CIUS = Compulsive Internet Use Scale; EQ-5D = EuroQoL standarised measure of health-related quality of life; PHQ-9 = Patient Health Questionnaire 9 Item Version; GAD-7 = Generalised Anxiety Disorder Scale 7 Item Version; L-1 = General Life Satisfaction 1 Item Version; SWE = Self-Efficacy Scale; BFI-10 = Big Five Inventory 10 Item Version; HAQ = Helping Alliance Questionnaire; SUS = System Usability Scale.

2.8 Primary outcome: Problematic Internet use

A*ssessment of Internet and Computer game Addiction Scale* (AICA-S) [39,40]. The primary outcome is defined as reduction of current IUD symptoms measured by AICA-S scale whose items are related to the DSM-criteria of substance-use disorders and gambling disorder. Fourteen items (five-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 surveys analyses [50]. A score of seven points (three to 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 82.4 % [51]. Reliability of AICA-S (internal consistency of α =.89) and validity are determined in clinical and epidemiological surveys [50,52,53]. The AICA-S was successfully used in a recent published German randomised controlled trial 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, post-intervention, and at follow-up.

2.9 Secondary outcomes

Stage of Readiness and Treatment Eagerness for Internet use disorder (iSOCRATES) [38]. The iSOCRATES scale is a self-report measure assessing the stage of readiness and treatment eagerness for IUD. It was adapted from the German SOCRATES scale for alcohol addiction consisting of 19 motivation-relevant statements whereon participants give their agreement on a five-point Likert scale [54,55]. Cronbach´s alpha of the measure has shown to be $\alpha = .60$ for the scale 'ambivalence', $\alpha = .83$ for 'taking steps', and $\alpha = .85$ for 'recognition' [55]. It will be conducted at baseline, mid-intervention, post-intervention, and at follow-up.

Compulsive Internet Use Scale (CIUS) [56]. The CIUS contains 14 items rateable on a five-point Likert scale and measures symptoms of Internet-related disorders. The instrument has shown a good internal consistency ($\alpha = .89$) [57]. It will be conducted at baseline, mid-intervention, post-intervention, 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 PRIME-MD diagnostic instrument for 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 ($\alpha = .83$-$.92$) [61]. It will be conducted at baseline, post-intervention, and at follow-up.

Generalised Anxiety Disorder Screener [62] (GAD-7, German translation [63]). The GAD-7 scale is a self-report measure assessing general anxiety symptoms related to DMS-IV

criteria on a four-point Likert scale. The internal consistency has shown to be excellent (α = .89) [62]. It will be conducted at baseline, post-intervention, 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} = .67 [64]. It will be conducted at baseline, post-intervention, and at follow-up.

General self-efficacy scale [65] (GSE, German translation SWE [66]). The GSE scale measures self-perceived self-efficacy and consists of ten 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 four-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 =.76 to .90. In German samples, Cronbach's alpha varies between .80 and .90 [67]. It will be conducted at baseline, post-intervention, and at follow-up.

Big Five Inventory [68] (BFI-10). The BFI-10 is a self-report measure containing ten items to assess Big Five personality traits. It has five subscales with two bidirectional items for each of the personality factors. The ten items are rated on a five-point Likert scale wherein 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} = .58-.84) [69]. The BFI-10 will be conducted only once at baseline.

Helping Alliance Questionnaire [70] (HAQ, German translation [71]). 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 six-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 post-intervention. Cronbach's α of the two scales has been reported as good (α = .75-.89 on the HAQ-P and α = .63-.85 on the HAQ-T) [72].

EuroQol standardised measure of health-related quality of life - 5 dimensions, 5 level Version [73] (EQ-5D-5L, German translation [74]). 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 five-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 [75]. It will be conducted at baseline, post-intervention, and at follow-up.

2.10 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 minutes and will be conducted at baseline and post-intervention.

The *Mini-International Neuropsychiatric Interview* [42] (MINI, V7.0.) is a short structured diagnostic interview developed for DSM-5 and ICD-10 psychiatric disorders. With an administration time of approximately 15-20 minutes, 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* (SUS) [76] is a short, reliable tool for measuring usability in a wide variety of services, including software, websites, and applications. It consists of ten items on a five-point Likert scale from 'strongly agree' to 'strongly disagree'. It will be conducted at post-intervention.

Satisfaction with OMPRIS intervention is measured by ten items on a five-point Likert scale from 'strongly disagree' to 'strongly agree' (e.g., '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 post-intervention.

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 (e.g., 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 (e.g., software, conceptual design, implementation costs, etc.) and ongoing intervention costs (e.g., material and personnel costs for therapy sessions, software maintenance, etc.).

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

2.11 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 =.05. A current RCT treatment study (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 (approx. 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 drop-out rate of 30% according to data from young adults addiction treatment [49,77].

2.12 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 four-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 GD within the framework of a large-scale cooperation.

2.13 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 principal investigator (JDH) will have primary responsibility for verifying the integrity of the databases and will be responsible for managing and archiving the databases post-analysis.

2.14 Trial management and monitoring

The principal investigator (JDH) has 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.

2.15 Adverse event monitoring

Adverse events (AEs) will be monitored by trial researchers conducting the OMPRIS intervention on an ongoing basis and post-intervention, 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 (CTCAE) [78]. 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; psychiatric co-morbidity with an indication for inpatient admission (hospitalisation) to a clinic. Both, SAEs and SSREs will be reported to the responsible ethics committee.

2.16 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 session, termination by agreement, and completion 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 co-variables 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 chi-squared 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 [79] and IBM SPSS Statistics [80].

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, four weeks later at T2, and, again, seven weeks later at T3 for both groups.

A standardised health economic questionnaire has been developed, which includes questions concerning health care 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 socio-demographic 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 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 [81–84]. 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 standard deviations of resource use and health care costs. According to the method of difference-in-difference, health care 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.

3. 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 IUD patients: (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 [85,86], 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 [87]. This latency might increase an additional loss of motivation. A quick and uncomplicated initial offer might be important to restructure IUD behaviour. (4) Co-morbid 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 health care 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 (e.g., 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 [51,88].

4. Ethics and dissemination

4.1 Ethical issues

Clinical protocol and written informed consent were approved by the Ethics Committee for the Faculty of Medicine, Ruhr University Bochum, approval no. 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 (GCP) 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 four weeks.

4.2 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.

4.3 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.

5. Statements

5.1 Authors' contributions: JDH, LB, and MP conceived the study. JDH is the principal investigator, acquired funding and drafted the initial study protocol. AN, SN and NT as those 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.

5.2 Competing interests: The authors declare that they do not receive any financial support from the industry, in particular the computer games industry. The authors declare that there is no conflict of interest with regard to this study protocol.

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5.4 Data sharing statement

In accordance with the ICMJE's data sharing statement individual participants data, that underlies the results reported in the main OMPRIS article, will be shared after de-identification. Data will be shared with investigators whose proposed use of the data has been proven by an independent review committee identified for this purpose at the earliest 9 months following the publication of the main OMPRIS article. As related document, the OMPRIS study protocol will be published. Proposals must be submitted via Email (jan.dieris-hirche@rub.de) up to 36 months following the publication of the main OMPRIS article. Data will be made available for statistical meta-analyses by our research data cloud.

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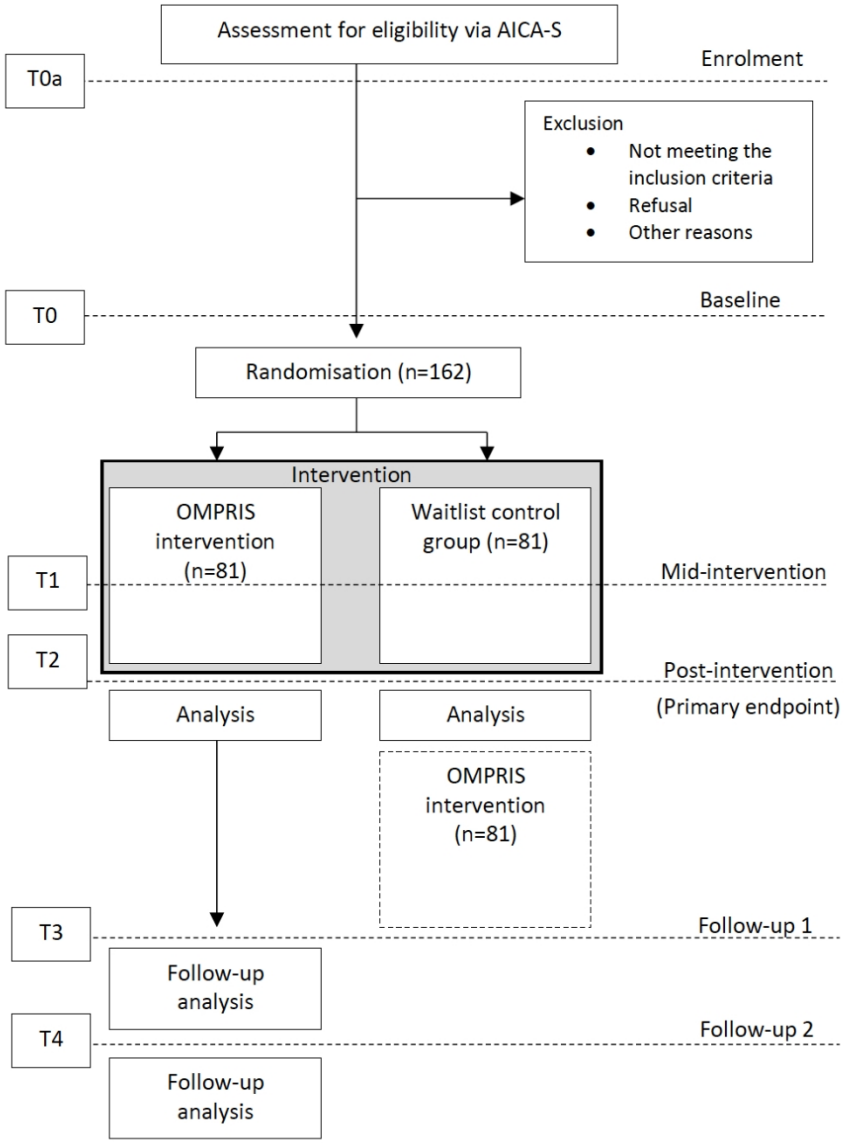

Figure 1: A flow chart of the study. Participants of the WLC group will be offered the OMPRIS intervention after a four-week long waiting period. The follow-up analysis will be performed separately for the WLC group.

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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

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

Jan Dieris-Hirche et al. 2021

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym (p. 1)
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry (p.2)
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier (p.2)
Funding	4	Sources and types of financial, material, and other support (p.2)
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors (p.2)
	5b	Name and contact information for the trial sponsor (p.2)
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities (p.2)
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) (p.2)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention (p. 4-7)
	6b	Explanation for choice of comparators (p. 4-7)

Objectives	7	Specific objectives or hypotheses (p.7)
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) (p.8)
Methods: Participants, interventions, and outcomes		
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained (p.8)
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) (p.9)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered (p.12-14)
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) (p.12-14)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) (p. 12-14, 24)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial (p. 12-14)
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended (p. 17-21)
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) (p. 16–17)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations (p.22)
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size (p.9-10)
Methods: Assignment of interventions (for controlled trials)		
Allocation:		

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions (p. 10-11)
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned (p. 10-11)
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions (p.11)
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how (p.15 – 16)
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial (p.15)
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol (p.15-22)
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols (p. 25)
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol (p.23-24)
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol (p.25-26)
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) (p.26)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) (p.25)

Methods: Monitoring

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed (p.24-25)
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial (p.23-24)
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct (p.29)
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor (p.24)

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval (p.28)
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) (p.28-29)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) (p.23-24)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable (p.23)
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial (p.24)
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site (p.2)
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators (p.30)
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation (p.24-25)

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions (p.29)
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code (p.30)
Appendices		
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates (yes, related document pdf)
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable (not applicable)

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.