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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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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.

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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 diagnostic 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.

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

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

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upcoming *International Classification of Diseases, 11th 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-

1
2
3 substance addictions (5 studies in pathological gambling) [21]. All studies demonstrated positive
4
5 treatment outcomes for their respective addictive behaviours.
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8 To the best of our knowledge, no controlled intervention studies have been conducted yet
9
10 to investigate a guided online-based psychological intervention for patients with problematic
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12 internet use and gaming disorder. However, a first preliminary study exploring an online
13
14 ambulatory service for internet addicts (OASIS) with only two webcam sessions was performed
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16 by our research group between 2016 and 2018 to refer addicts to medical treatment close to
17
18 home [22]. In general, this study showed a high number of participating individuals (N = 27.629
19
20 completed an online self-assessment for IA; 45% showed problematic internet use; 9% presented
21
22 addictive internet use).
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26 Furthermore, over 200 individuals with a minimal level of problematic internet use
27
28 participated in one to two consulting sessions. In total, the referral of internet-addicted
29
30 participants to analogue medical treatment was moderate (40% of all cases). It was, however,
31
32 more successful when participants were referred to online therapists they knew from former
33
34 online consulting (referral rate 93%). This result underlined the importance of relationship
35
36 constancy in (online-based) therapy. Despite the low number of only one to two sessions, the
37
38 online consultation showed small but significant improvements regarding IA symptoms and
39
40 motivation for change [22].
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44
45 Given the preliminary results, a new and innovative specific online-based treatment
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47 programme (OMPRIS) was developed by our research group to increase treatment motivation
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49 and reduce symptoms of IA and IGD. It was essential to create a low-threshold and freely
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51 available treatment offer that is independent of the place of residence. As an online-based
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53 intervention, OMPRIS is intended to connect IA and IGD patients with a conventional analogue
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3 medical treatment. At best, OMPRIS should interrupt addiction development at an early stage
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5 and might avoid the chronic manifestation of IA or IGD.
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8 This study will assess the efficacy of a manualised OMPRIS intervention. The primary
9
10 aim of the study is to test whether the OMPRIS intervention can successfully reduce problematic
11
12 internet use and increase the motivation to change in the context of IA or IGD. Furthermore, the
13
14 impact of co-morbid mental symptoms, personality traits, socio-demographic characteristics, and
15
16 quality of life will be determined. The study further aims to collect data about acceptability, costs
17
18 and cost-effectiveness of online-based treatment of IA and IGD to suggest adaption for future
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20 research and potential clinical implementation.
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23 24 25 26 **2. Methods and analysis**

27 28 **2.1 Trial design**

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30 The design is a single-blind RCT with two parallel arms, comparing the OMPRIS
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32 intervention to a waitlist control (WLC) group. Therapists and observer are blinded in this trial.
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34 Participants will be scheduled to complete either four weeks of an OMPRIS counselling
35
36 programme or a four-week waiting period. Notably, WLC group participants will be offered the
37
38 OMPRIS intervention after the expired waiting period.
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44 45 **2.2 Study setting**

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47 This multicentre study is coordinated by the Department of Psychosomatic Medicine and
48
49 Psychotherapy, LWL-University Hospital of Ruhr University Bochum, Germany. The OMPRIS
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51 intervention is carried out by four German medical centres specialised in the treatment of IA and
52
53 IGD: the Department of Psychosomatic Medicine and Psychotherapy of the LWL-University
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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

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(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.

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3 The OMPRIS participants will be assigned either to the IG or the WLC group
4 immediately before the OMPRIS session. The randomisation will be conducted automatically via
5 the online OMPRIS platform and its results will remain unpredictable to research staff involved
6 in the participant's enrolment as well as the OMPRIS intervention. The study will be
7 administered by the Department of Medical Informatics, Biometry and Epidemiology in
8 Bochum.
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19 **2.5 Intervention**

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21 The manualised OMPRIS intervention is a combined treatment programme mainly based
22 on the motivational interviewing (MI) approach that has been shown as sufficient to improve
23 health behaviour in various medical diseases including addictive disorders [29–33]. Furthermore,
24 OMPRIS contains treatment elements from cognitive behavioural therapy (CBT), (internet-
25 related) addiction therapy [34], media education, and units of social counselling. Within a total
26 duration of five to six weeks (four weeks of intervention plus one or two weeks for pre- and post-
27 diagnostics), OMPRIS comprises approximately 12 webcam sessions with individual therapy,
28 including two diagnostic sessions, eight to nine intervention sessions, and one to two social
29 counselling sessions. The main intervention sessions (50 minutes each) will occur within four
30 weeks, with two sessions per week. Table 1 shows treatment phases and strategies during the
31 early, middle, and termination phases.
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47 Based on the perception of individual ambivalence regarding possible behavioural
48 changes, participants will be encouraged to find an alternative course of action in media use and
49 daily routine. Subjects will be offered MI skills, media use diaries, CBT techniques for
50 understanding individual mechanisms and consequences of problematic internet use, social skill
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3 training, and direct support by professional social counselling. In the termination phase,
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5 strategies for relapse prevention will be developed. If required, referrals to further treatment
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7 options will be discussed.
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Table 1: OMPRIIS 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	Uprgrowth 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.

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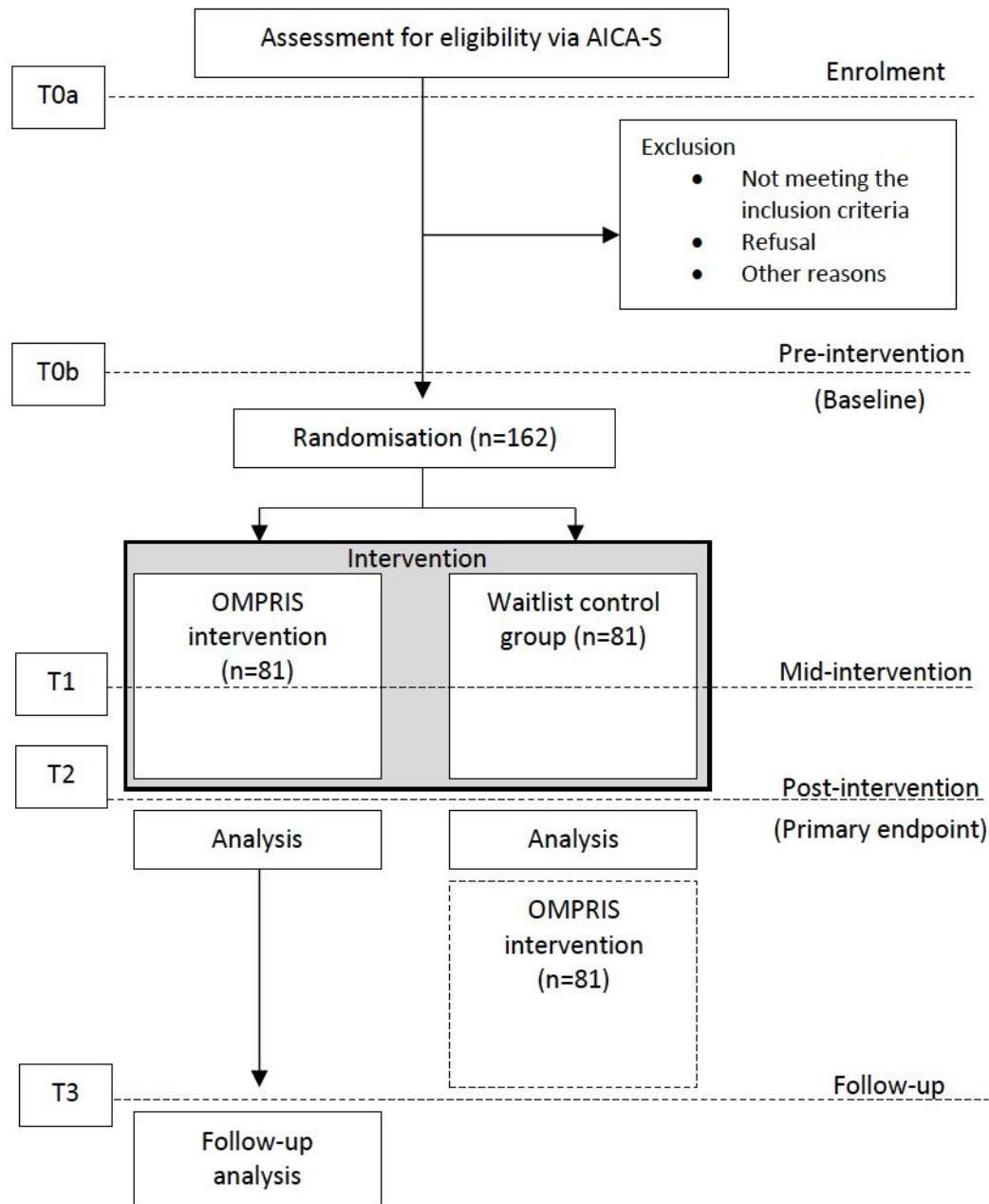


Figure 1: A flow chart of the study. Participants of the WLC group will be offered the OMPRIS intervention after the IG has finished. The follow-up analysis will be performed separately for the WLC group.

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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

1
2
3 weeks. The primary outcome measure is the self-report AICA-S scale whose items are related to
4
5 the DSM-criteria of substance-use disorders and gambling disorder [23,24]. Fourteen items (five-
6
7 point Likert scale) are relevant for clinical classification of internet use, including craving, a loss
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9 of control, tolerance, unsuccessful attempts to spend less, and withdrawal. Negative
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11 consequences are relevant according to areas of life, including problems with school, work,
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13 health, and social partners.
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17 Moreover, time spent online, the preferred online activity, and the preferred type of
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19 problematic internet use are requested. A cut-off is defined by statistical means based on
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21 epidemiological surveys analyses [35]. A score of seven points (three to four criteria fulfilled)
22
23 can be interpreted as addictive use. Reliability of AICA-S (internal consistency of $\alpha = .89$) and
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25 validity are determined in clinical and epidemiological surveys [35–37]. The AICA-S is
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27 conducted at baseline, mid-intervention, post-intervention, and a six-week follow-up.
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33 **2.9 Secondary outcomes**

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35 *Stage of Readiness and Treatment Eagerness for Internet Addiction (iSOCRATES)* [22].
36
37 The iSOCRATES scale is a self-report measure assessing the stage of readiness and treatment
38
39 eagerness for IA. It was adapted from the German SOCRATES scale for alcohol addiction
40
41 consisting of 19 motivation-relevant statements whereon participants give their agreement on a
42
43 five-point Likert scale [38,39]. It will be conducted at baseline, mid-intervention, post-
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45 intervention, and a six-week follow-up.
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50 *Compulsive Internet Use Scale (CIUS)* [40]. The CIUS contains 14 items rateable on a
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52 five-point Likert scale and measures symptoms of internet-related disorders. It will be conducted
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54 at baseline, mid-intervention, post-intervention, and a six-week follow-up.
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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.

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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.

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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.

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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.

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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.

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3 The AICA-SKI:IBS takes approximately 20-30 minutes and will be conducted at baseline and
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5 post-intervention.
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8 The *Mini-International Neuropsychiatric Interview* [26] (MINI, V7.0.) is a short
9
10 structured diagnostic interview developed for DSM-5 and ICD-10 psychiatric disorders. With an
11
12 administration time of approximately 15-20 minutes, it was designed to meet the need for a short
13
14 but accurate structured psychiatric interview for multicentre clinical trials and epidemiology
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16 studies. The MINI will be conducted only once at baseline to detect psychiatric comorbidities.
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20 The *System Usability Scale* (SUS) [54] is a short, reliable tool for measuring usability in a
21
22 wide variety of services, including software, websites, and applications. It consists of ten items
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24 on a five-point Likert scale from 'strongly agree' to 'strongly disagree'. It will be conducted at
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26 post-intervention.
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29 *Satisfaction with OMPRIS intervention* is measured by ten items on a five-point Likert
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31 scale from 'strongly disagree' to 'strongly agree' (e.g. 'OMPRIS helped me to accept support for
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33 the first time because of my (problematic) internet use', or 'I would recommend OMPRIS to my
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35 friends'). It will be conducted at post-intervention.
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39 *Health economics information* is determined by a self-report questionnaire asking for the
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41 resource use of current and past medical and psychotherapeutic inpatient and outpatient
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43 treatments, medication, rehabilitation treatments, and assisted living services. Additionally, data
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45 on earning capacity, social security system data (e.g. incapacity for work, unemployability, etc.),
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47 the delay of vocational education, and housing situation will be collected. In order to determine
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49 the intervention costs, information is collected on one-time intervention costs (e.g. software,
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51 conceptual design, implementation costs, etc.) and ongoing intervention costs (e.g. material and
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53 personnel costs for therapy sessions, software maintenance, etc.).
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6 *Referral to other organisations and further treatments* is assessed by three items at post-
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8 intervention and follow-up.
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12 **2.11 Sample size**

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15 The sample size was calculated by a power calculation to find a between-group effect
16 (two-sided t-test) with 80% power at $p = .05$. A current RCT treatment study (STICA study)
17 found an effect size of $d = 1.19$ for the effect of analogue CBT treatment on the reduction of IA
18 symptoms ($SD = 3.92$) using the same outcome measurement AICA-S [34]. We took a
19 conservative estimate of effect size $d = 0.51$ (approx. 43% of the STICA study) for our OMPRI
20 intervention determining a significant detection of a 2-point difference in the primary outcome
21 measure. Based on these assumptions, 62 participants are required per group. Notably, 81
22 participants per group are planned to recruit to allow for a drop-out rate of 30%.
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35 **2.12 Patient and public involvement**

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38 The development of the research question and the outcome measures was influenced by previous
39 experience from a previous pilot study on people with internet addiction [22]. Patient feedback
40 was considered in the planning of the study and design. The patients' previous experiences and
41 feedback were particularly important in designing the low-threshold OMPRI intervention. The
42 main results will be published in a final report, according to the German Innovation Funds
43 directive. The report will be publicly available and free of charge on the internet. Furthermore,
44 the scientific results will be disseminated via publications submitted to peer-reviewed scientific
45 journals. All participants will receive a short final report with their (pre / post) results of the four-
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3 week online intervention. The OMPRIS study is planned and will be conducted in cooperation
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5 with the German Fachverband Medienabhängigkeit e.V. that is committed to creating a network
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7 of researchers and practitioners in the German-speaking countries who are working on IA and
8
9 GD within the framework of a large-scale cooperation.
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14 15 **2.13 Data collection and management**

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17 Data collection will be performed online via the OMPRIS software environment
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19 (www.onlinesucht-hilfe.com). All data will be stored on protected servers in Germany. Data will
20
21 be entered into an electronic database on an ongoing basis, and the database and outputs will be
22
23 regularly backed up to a remote server. The computer databases will not contain information
24
25 about the participants' allocation, which will be added as required before the analysis.
26
27

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29 Data completeness will be automatically monitored by the OMPRIS software
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31 environment. Any participants identifiable data will be stored separately from research data in a
32
33 second database and will be accessible only to members (admin) of the principal research team.
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35 The principal investigator (JDH) will have primary responsibility for verifying the integrity of
36
37 the databases and will be responsible for managing and archiving the databases post-analysis.
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42 43 **2.14 Trial management and monitoring**

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

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3 covariance for IA symptoms with the co-variables of baseline value, gender, age, and type of
4
5 internet addiction.
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8 It is expected that missing data will not be ‘missing-at-random’ based on the assumption
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10 that the occurrence of the missing value in a variable can be fully explained by the characteristics
11
12 of the remaining variables. Therefore, diverse sensitivity analyses will be calculated with
13
14 different strategies for missing data replacement. Details of statistical analyses will be defined in
15
16 a statistical analysis plan. Potential group imbalances in spite of randomisation will be tested via
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18 t-tests for continuous variables and Pearson’s chi-squared test. Exploratory analyses will
19
20 evaluate potential predictors for therapeutic success via linear and logistic regression models.
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23 24 **Method of health economic evaluation**

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26 The health economic evaluation of OMPRIIS contains both a cost-effectiveness and a
27
28 cost-utility analysis. Additionally, a cost-of-illness study regarding persons with IGD and IA will
29
30 be done. The evaluation will include both direct and indirect costs, which will be calculated from
31
32 statutory health insurance perspective as well as from a societal perspective. The analyses will be
33
34 using a bottom-up approach. Data on the resource use will be collected at baseline T0b, four
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36 weeks later at T2, and, again, seven weeks later at T3 for both groups.
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40 A standardised health economic questionnaire has been developed, which includes
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42 questions concerning health care resource use, such as outpatient physician contacts,
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44 hospitalisation, inpatient and outpatient rehabilitation, occupational therapy, reduction in/loss of
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46 earning capacity, and disability. Moreover, participants will be asked about socio-demographic
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48 data, such as age, gender, graduation, on-the-job training, and cash benefits from different
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50 sources. Prices for all resource use will be collected using different sources.
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3 The Lauer Taxe® will be used to determine medication selling prices for the German
4 market. For inpatient and outpatient care, hospitalisation and rehabilitation recommendations
5 will be obeyed according to published standardised procedures in health economic evaluation
6 and standardised prices [56–59]. Costs will be calculated as the product of the number of
7 consumed resources and estimated prices and summarised to compute the overall costs. The
8 analyses will be based on the calculation of mean values and the standard deviations of resource
9 use and health care costs. According to the method of difference-in-difference, health care costs
10 of the two study arms will be analysed in terms of statistically significant differences using the
11 Mann-Whitney U test. To consider uncertainty, sensitivity analyses will be performed.
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26 **3. Ethics and dissemination**

27 **3.1 Ethical issues**

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31 Clinical protocol and written informed consent were approved by the Ethics Committee
32 for the Faculty of Medicine, Ruhr University Bochum, approval no. 19-6779. Furthermore, the
33 main ethical approval was confirmed by the ethics committees of all cooperating centres. All
34 procedures described in the clinical trial protocol follow the Good Clinical Practice (GCP)
35 guidelines and the ethical principles described in the current revision of the Declaration of
36 Helsinki. The study will be carried out in keeping with local legal and regulatory requirements.
37
38 The main ethical issues are informed consent, the use of OMPRIS intervention, the use of an
39 online-based intervention, and protection of data privacy, the inclusion of underage persons with
40 parental consent, technical procedures of online participation and online declaration of consent,
41 and the WLC group design.
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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

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

References

- 1 Bundesamt für Statistik. Statistisches Jahrbuch Deutschland und Internationales 2019. 2019. https://www.statistischebibliothek.de/mir/receive/DEAusgabe_mods_00004527 (accessed 21 Aug 2020).
- 2 DAK-Gesundheit. Mediensucht 2020 – Gaming und Social Media in Zeiten von Corona. DAK-Längsschnittstudie: Befragung von Kindern, Jugendlichen (12 – 17 Jahre) und deren Eltern. Hamburg: 2020. <https://www.dak.de/dak/bundesthemen/computerspielsucht-2296282.html#/> (accessed 21 Aug 2020).
- 3 Ko CH, Yen JY. Impact of COVID-19 on gaming disorder: Monitoring and prevention. *J Behav Addict* 2020;**9**:187–9. doi:10.1556/2006.2020.00040
- 4 Balhara YPS, Kattula D, Singh S, *et al.* Impact of lockdown following COVID-19 on the gaming behavior of college students. *Indian J Public Health* 2020;**64**:S172–6. doi:10.4103/ijph.IJPH_465_20
- 5 King DL, Delfabbro PH, Billieux J, *et al.* Problematic online gaming and the COVID-19 pandemic. *J Behav Addict* 2020;**9**:184–6. doi:10.1556/2006.2020.00016
- 6 Cheng C, Li AY. Internet addiction prevalence and quality of (real) life: a meta-analysis of 31 nations across seven world regions. *Cyberpsychol Behav Soc Netw* 2014;**17**:755–60. doi:10.1089/cyber.2014.0317
- 7 Stevens MW, Dorstyn D, Delfabbro PH, *et al.* Global prevalence of gaming disorder: A systematic review and meta-analysis. *Aust New Zeal J Psychiatry* 2020;:000486742096285. doi:10.1177/0004867420962851
- 8 Rumpf H-J, Meyer C, Kreuzer A, *et al.* Prävalenz der Internetabhängigkeit (PINTA) Bericht an das Bundesministerium für Gesundheit. 2011.

- 1
2
3 9 Wölfling K, Thalemann R, Grüsser-Sinopoli SM. Computerspielsucht: Ein
4 psychopathologischer Symptomkomplex im Jugendalter. *Psychiatr Prax* 2008;**35**:226–32.
5
6 doi:10.1055/s-2007-986238
7
8
9
10 10 Batthyány D, Müller KW, Benker F, *et al.* Computer game playing: clinical characteristics
11 of dependence and abuse among adolescents. *Wien Klin Wochenschr* 2009;**121**:502–9.
12
13 doi:10.1007/s00508-009-1198-3
14
15
16
17 11 American Psychiatric Association. *Diagnostic and Statistical Manual of Mental*
18 *Disorders, 5th Edition*. 2013. doi:10.1176/appi.books.9780890425596.744053
19
20
21 12 World Health Organization. International classification of diseases for mortality and
22 morbidity statistics (11th Revision). 2018. <https://icd.who.int/en> (accessed 21 Aug 2020).
23
24
25
26 13 González-Bueso V, Santamaría JJ, Fernández D, *et al.* Association between Internet
27 Gaming Disorder or Pathological Video-Game Use and Comorbid Psychopathology: A
28 Comprehensive Review. *Int J Environ Res Public Health* 2018;**15**.
29
30
31
32
33
34
35 14 Carli V, Durkee T, Wasserman D, *et al.* The association between pathological internet use
36 and comorbid psychopathology: a systematic review. *Psychopathology* 2013;**46**:1–13.
37
38
39
40
41
42
43 15 Dieris-Hirche J, Bottel L, Bielefeld M, *et al.* Media use and Internet addiction in adult
44 depression: A case-control study. *Comput Human Behav* 2017;**68**:96–103.
45
46
47
48
49
50
51 16 Steinbuechel TA, Herpertz S, Kuelpmann I, *et al.* Internet Addiction, Suicidality and Non-
52 Suicidal Self-Harming Behavior - A Systematic Review. *Psychother Psychosom*
53
54
55
56
57
58
59
60

- 1
2
3 17 Saunders JB, Hao W, Long J, *et al.* Gaming disorder: Its delineation as an important
4 condition for diagnosis, management, and prevention. *J. Behav. Addict.* 2017;**6**:271–9.
5
6 doi:10.1556/2006.6.2017.039
7
8
9
10 18 Van't Hof E, Cuijpers P, Stein DJ. Self-help and Internet-guided interventions in
11 depression and anxiety disorders: a systematic review of meta-analyses. *CNS Spectr.*
12
13 2009;**14**:34–40. doi:10.1017/s1092852900027279
14
15
16
17 19 Johansson R, Andersson G. Internet-based psychological treatments for depression. *Expert*
18
19 *Rev. Neurother.* 2012;**12**:861–70. doi:10.1586/ern.12.63
20
21
22 20 Cuijpers P, Donker T, Van Straten A, *et al.* Is guided self-help as effective as face-to-face
23 psychotherapy for depression and anxiety disorders? A systematic review and meta-
24 analysis of comparative outcome studies. *Psychol. Med.* 2010;**40**:1943–57.
25
26
27 doi:10.1017/S0033291710000772
28
29
30
31 21 Chebli JL, Blaszczynski A, Gainsbury SM. Internet-Based Interventions for Addictive
32 Behaviours: A Systematic Review. *J. Gambl. Stud.* 2016;**32**:1279–304.
33
34
35
36 doi:10.1007/s10899-016-9599-5
37
38
39 22 te Wildt B. Entwicklung und Evaluation eines Online-Ambulanz-Service zur Diagnostik
40 und Beratung. Abschlussbericht An das Bundesministerium für Gesundheit. 2018.
41
42 https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Drogen_und_Sucht/Berichte/Abschlussbericht/Abschlussbericht_OASIS.pdf (accessed 8 May
43
44
45
46
47
48 2020).
- 49 23 Wölfling K, Müller KW, Beutel M. Reliabilität und Validität der Skala zum
50 Computerspielverhalten (CSV-S). *PPmP Psychother Psychosom Medizinische Psychol*
51
52 2011;**61**:216–24. doi:10.1055/s-0030-1263145
53
54
55
56
57
58
59
60

- 1
2
3 24 Wölfling K, Beutel ME, Müller KW. OSV-S - Skala zum Onlinesuchtverhalten. In: Geue
4 K, Strauß B, Brähler E, eds. *Diagnostische Verfahren in der Psychotherapie*. Göttingen: :
5 Hogrefe 2016. 362–6.
6
7
8
9
10 25 Müller KW, Wölfling K. AICA-SKI:IBS Strukturiertes klinisches Interview zu
11 Internetbezogenen Störungen * Handbuch. Mainz: 2017. [http://www.fv-
14 medienabhaengigkeit.de/fileadmin/images/Dateien/AICA-SKI_IBS/Handbuch_AICA-
15 SKI_IBS.pdf](http://www.fv-
12 medienabhaengigkeit.de/fileadmin/images/Dateien/AICA-SKI_IBS/Handbuch_AICA-
13 SKI_IBS.pdf) (accessed 3 Dec 2019).
16
17
18
19 26 Sheehan D V., Lecrubier Y, Sheehan KH, *et al.* The Mini-International Neuropsychiatric
20 Interview (M.I.N.I.): The development and validation of a structured diagnostic
21 psychiatric interview for DSM-IV and ICD-10. In: *Journal of Clinical Psychiatry*. 1998.
22 22–33.
23
24
25
26
27
28 27 Borm GF, Hoogendoorn EH, Den Heijer M, *et al.* Sequential balancing: A simple method
29 for treatment allocation in clinical trials. *Contemp Clin Trials* 2005;**26**:637–45.
30
31 doi:10.1016/j.cct.2005.09.002
32
33
34
35 28 Bittel L, Bielefeld M, Steinbuechel T, *et al.* Evaluation of an Online Ambulatory Service
36 for Internet Addicts (OASIS). *J Behav Addict* 2018;**7**:45.
37
38
39
40 29 Lawrence P, Fulbrook P, Somerset S, *et al.* Motivational interviewing to enhance
41 treatment attendance in mental health settings: A systematic review and meta-analysis. *J.*
42 *Psychiatr. Ment. Health Nurs.* 2017;**24**:699–718. doi:10.1111/jpm.12420
43
44
45
46
47 30 Palacio A, Garay D, Langer B, *et al.* Motivational Interviewing Improves Medication
48 Adherence: a Systematic Review and Meta-analysis. *J Gen Intern Med* 2016;**31**:929–40.
49
50
51
52
53
54 31 Frost H, Campbell P, Maxwell M, *et al.* Effectiveness of Motivational Interviewing on
55
56
57
58
59
60

- 1
2
3 adult behaviour change in health and social care settings: A systematic review of reviews.
4 PLoS One. 2018;**13**:e0204890. doi:10.1371/journal.pone.0204890
5
6
7
8 32 Garcia-Caballero A, Torrens-Lluch M, Ramírez-Gendrau I, *et al.* The efficacy of
9 motivational intervention and cognitive-behavioral therapy for pathological gambling.
10 *Adicciones* 2018;**30**:217–22. doi:10.20882/adicciones.965
11
12
13
14 33 Petry NM, Ginley MK, Rash CJ. A systematic review of treatments for problem gambling.
15 *Psychol. Addict. Behav.* 2017;**31**:951–61. doi:10.1037/adb0000290
16
17
18
19 34 Wölfling K, Müller KW, Dreier M, *et al.* Efficacy of Short-term Treatment of Internet and
20 Computer Game Addiction: A Randomized Clinical Trial. *JAMA psychiatry* Published
21 Online First: 10 July 2019. doi:10.1001/jamapsychiatry.2019.1676
22
23
24
25 35 Müller KW, Glaesmer H, Brähler E, *et al.* Prevalence of internet addiction in the general
26 population: Results from a German population-based survey. *Behav Inf Technol*
27 2014;**33**:757–66. doi:10.1080/0144929X.2013.810778
28
29
30
31 36 Müller K, Koch A, Beutel M, *et al.* Komorbide Internetsucht unter Patienten der
32 stationären Suchtrehabilitation: Eine explorative Erhebung zur klinischen Prävalenz.
33 *Psychiatr Prax* 2012;**39**:286–92. doi:10.1055/s-0032-1305120
34
35
36
37 37 Kuss DJ, Griffiths MD, Binder JF. Internet addiction in students: Prevalence and risk
38 factors. *Comput Human Behav* 2013;**29**:959–66. doi:10.1016/j.chb.2012.12.024
39
40
41
42 38 Hoyer J, Heidenreich T, Fecht J, *et al.* Stadien der Veränderung in der stationären
43 Alkoholentwöhnungstherapie. *Verhaltenstherapie* 2003;**13**:31–8. doi:10.1159/000070497
44
45
46
47 39 Miller WR, Tonigan JS. Assessing drinkers' motivation for change: The Stages of Change
48 Readiness and Treatment Eagerness Scale (SOCRATES). *Psychol Addict Behav*
49 1996;**10**:81–9. doi:10.1037/0893-164X.10.2.81
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 40 Meerkerk G-J, Van Den Eijnden RJJM, Vermulst AA, *et al.* The Compulsive Internet Use
4 Scale (CIUS): some psychometric properties. *Cyberpsychol Behav* 2009;**12**:1–6.
5
6 doi:10.1089/cpb.2008.0181
7
8
9
10 41 Spitzer RL, Kroenke K, Williams JB. Validation and utility of a self-report version of
11 PRIME-MD: the PHQ primary care study. Primary Care Evaluation of Mental Disorders.
12 Patient Health Questionnaire. *JAMA* 1999;**282**:1737–44.
13
14
15
16
17 42 Löwe B, Spitzer RL, Zipfel S, *et al.* Gesundheitsfragebogen für Patienten (PHQ-D).
18 Komplettversion und Kurzform. 2. Auflage. Karlsruhe: 2002.
19
20
21
22 https://www.psycharchives.org/bitstream/20.500.12034/431/1/PT_9006490_ASKU-
23
24 [Manual_2012.PDF](#) (accessed 18 Oct 2019).
25
26
27 43 Haddad M, Walters P, Phillips R, *et al.* Detecting Depression in Patients with Coronary
28 Heart Disease: A Diagnostic Evaluation of the PHQ-9 and HADS-D in Primary Care,
29 Findings From the UPBEAT-UK Study. *PLoS One* 2013;**8**.
30
31
32
33 doi:10.1371/journal.pone.0078493
34
35
36 44 Spitzer RL, Kroenke K, Williams JBW, *et al.* A brief measure for assessing generalized
37 anxiety disorder: The GAD-7. *Arch Intern Med* 2006;**166**:1092–7.
38
39
40
41 doi:10.1001/archinte.166.10.1092
42
43
44 45 Löwe B, Decker O, Müller S, *et al.* Validation and standardization of the generalized
45 anxiety disorder screener (GAD-7) in the general population. *Med Care* 2008;**46**:266–74.
46
47
48
49
50 46 Beierlein C, Kovaleva A, László Z, *et al.* Eine Single-Item-Skala zur Erfassung der
51 Allgemeinen Lebenszufriedenheit: Die Kurzskala Lebenszufriedenheit-1 (L-1). 2014.
52
53
54 https://www.gesis.org/fileadmin/kurzskalen/working_papers/L1_WorkingPapers_2014-
55
56
57
58
59
60

- 33.pdf (accessed 18 Oct 2019).
- 47 Schwarzer R, Jerusalem M. Generalized Self-Efficacy scale. . In: Weinman J, Wright S, Johnston M, eds. *Measures in health psychology: A user's portfolio. Causal and control beliefs*. . Windsor, England: : NFER-NELSON. 1995. 35–7.
- 48 Schwarzer R, Jerusalem M. Skalen zur Erfassung von Lehrer- und Schülermerkmalen: Dokumentation der psychometrischen Verfahren im Rahmen der Wissenschaftlichen Begleitung des Modellversuchs Selbstwirksame Schulen. . Berlin: 1999.
<http://psychologie.de/schwarzer> (accessed 8 May 2020).
- 49 Rammstedt B, John OP. Measuring personality in one minute or less: A 10-item short version of the Big Five Inventory in English and German. *J Res Pers* 2007;**41**:203–12.
doi:10.1016/j.jrp.2006.02.001
- 50 Alexander L, Luborsky L. The Penn Helping Alliance Scales. In: Greenberg LS, Pinsof WM, eds. *Guilford clinical psychology and psychotherapy series. The psychotherapeutic process: A research handbook*. Guilford Press 1986. 325–
66.<https://psycnet.apa.org/record/1987-97275-009> (accessed 8 May 2020).
- 51 Bassler M, Nübling R. Der ‘Helping Alliance Questionnaire’ (HAQ) von Luborsky. *Psychotherapeut* 1995;**40**:23–
32.https://www.researchgate.net/publication/270645630_Helping_Alliance_Questionnaire
(accessed 8 May 2020).
- 52 Herdman M, Gudex C, Lloyd A, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;**20**:1727–36.
doi:10.1007/s11136-011-9903-x
- 53 Euroqol. EQ-5D-5L . <https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/> (accessed 8

- 1
2
3 May 2020).
- 4
5
6 54 Brooke J. SUS - A Quick and Dirty Usability Scale. In: Jordan P, Thomas B,
7
8 Weerdmeester B, *et al.*, eds. *Usability Evaluation in Industry*. London: : Taylor and
9
10 Francis 1996.
11
12 [https://www.scirp.org/\(S\(351jmbntvnsjt1aadkposzje\)\)/reference/ReferencesPapers.aspx?R](https://www.scirp.org/(S(351jmbntvnsjt1aadkposzje))/reference/ReferencesPapers.aspx?ReferenceID=979187)
13
14 [eferenceID=979187](https://www.scirp.org/(S(351jmbntvnsjt1aadkposzje))/reference/ReferencesPapers.aspx?ReferenceID=979187) (accessed 9 May 2020).
15
16
17 55 NCI Common Terminology Criteria for Adverse Events (CTCAE) - GBG.
18
19 <https://www.gbg.de/de/rechner/ctcae.php> (accessed 9 Oct 2020).
20
21
22 56 Scholz S, Biermann-Stallwitz J, Brettschneider C, *et al.* Standardized cost calculations in
23
24 the German healthcare sector: Report of the working group Standard Costs of the
25
26 committee Economic Evaluation of the dggo. *Gesundheitsökonomie und Qual*
27
28 *2020*;25:52–9. doi:10.1055/a-1107-0665
29
30
31 57 Krauth C, Hessel F, Hansmeier T, *et al.* Empirische bewertungssätze in der
32
33 gesundheitsökonomischen evaluation - Ein vorschlag der AG methoden der
34
35 gesundheitsökonomischen evaluation (AG MEG). *Gesundheitswesen* 2005;67:736–46.
36
37 doi:10.1055/s-2005-858698
38
39
40 58 Bock JO, Brettschneider C, Seidl H, *et al.* Ermittlung standardisierter Bewertungssätze
41
42 aus gesellschaftlicher Perspektive für die gesundheitsökonomische Evaluation.
43
44 *Gesundheitswesen* 2015;77:53–61. doi:10.1055/s-0034-1374621
45
46
47 59 Grupp H, König HH, Konnopka A. Kostensätze zur monetären Bewertung von
48
49 Versorgungsleistungen bei psychischen Erkrankungen. *Gesundheitswesen* 2017;79:48–57.
50
51 doi:10.1055/s-0035-1555950
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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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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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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 2.0, February 26, 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) 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.

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

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

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

32 **Strengths and limitations of the study:**

- 33 - A new and innovative online-based motivational intervention (OMPRIS) is tested in a real-
34 world online setting as a low-threshold intervention to reduce problematic gaming behaviour and
35 promote treatment motivation in Internet gaming disorder and Internet use disorders.
- 36 - Diagnosticians, therapists, and outcome assessors are blind to participants' allocation.
- 37 - Outcome measurements include treatment effects, costs and cost-effectiveness.
- 38 - Follow-up measurements will be 6 weeks and 6 months after inclusion.
- 39 - The OMPRIIS trial is conducted as a randomised controlled trial (RCT) with a waitlist control
40 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].

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

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

80 1.2 Evidence of treatment for Internet use disorders

81 The range of available specialised evidence-based treatments for IUD and IGD is still
82 rare. Currently, there are only a few empirical studies investigating IUD and IGD therapy
83 approaches using the scientific standard of a RCT design [22–24]. A recent meta-analysis
84 demonstrated high efficacy (12 studies with a total of 580 patients) for cognitive-behavioral
85 therapy (CBT) in reducing IGD symptoms ($g = 0.92$; [0.50, 1.34]), depression ($g = 0.80$, [0.21,
86 1.38]), and anxiety ($g = 0.55$, [0.17, 0.93]) [23]. Moreover, interventions based on the
87 motivational interviewing (MI) approach have already been examined in many areas of medicine
88 [25]. The effectiveness of MI has been reported in particular for substance-related addictions and

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3 89 pathological gambling [25,26]. For IUDs, there are only few studies that have systematically
4
5 90 examined MI approaches, but it has been widely discussed as a therapeutic option for IUD
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8 91 patients [27–31].
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11 12 93 **1.3 eHealth interventions in addictive disorders**

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14 94 Internet-based and eHealth interventions (e.g. for depression and anxiety disorders) have
15
16 95 been reported as effective treatment options with medium to large effect sizes [32,33]. Also,
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18 96 Internet-based and eHealth interventions have been examined in the areas of (mainly substance)
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20 97 addiction [34,35]. A systematic review in 2016 found a total of 16 studies testing Internet-related
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22 98 interventions in substance addiction (11 studies in smoking, drinking, and opioid abuse) and
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24 99 behavioural addictions (5 studies in pathological gambling). Although only five of the 16 studies
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26 100 mentioned effect sizes ($d = 0.83 - 1.72$), all studies reported positive treatment outcomes for their
27
28 101 respective addictive behaviour [36]. To date, only few studies have examined general eHealth
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30 102 interventions for IUD and IGD [37]. A Chinese pilot study using an online self-help approach on
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32 103 65 university students with high scores for problematic Internet use, divided into four
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34 104 experimental arms, showed significant differences at the follow-up measurement, but no
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36 105 differences were detected between the four intervention groups. This study used MI techniques
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38 106 as main intervention [29]. Furthermore, a recent study protocol presenting an ongoing
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40 107 randomised controlled trial of an eCoach guided Internet-based intervention for IUD has recently
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42 108 been published [27].
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49 109 Our research group performed a preliminary uncontrolled study between 2016 and 2018
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51 110 exploring an online outpatient service for Internet addiction (OASIS) with only two offered
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54 111 webcam sessions [38]. The aim was to test whether individuals with IUD can generally be
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3 112 reached via the Internet and to refer them to conventional medical treatment close to their place
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5 113 of residence. Finally, 140 individuals with a minimal level of problematic Internet use
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8 114 participated in one or two offered consulting sessions with a moderate referral quote of 30%. The
9
10 115 referral was, however, more successful when participants were referred to the clinic or therapists
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12 116 they knew from online consulting (referral rate 93%) underlining the importance of relationship
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14 117 constancy in (online-based) therapy. Despite the low number of only two offered sessions, the
15
16 118 intervention showed a small to medium significant reduction of time spent online (-1.23 h/d; $d =$
17
18 119 0.3) and IUD symptoms ($d = 0.5$) measured by self-reporting questionnaires in post-tests.
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21 120 However, this preliminary study omitted a control group and follow-up [38].
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24 121 To the best of our knowledge, results of evidence-based randomised controlled studies
25
26 122 investigating Internet-based intervention for IGD or IUD, especially using face-to-face via
27
28 123 webcam, have not yet been published.
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32 125 **1.4 Aims of the study**

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35 126 The aim of this study is to measure the efficacy and the utilisation of a new and
36
37 127 innovative online-based intervention (OMPRIS) for reducing IUD and IGD symptoms and
38
39 128 increasing treatment motivation compared to a waiting control group. It is hypothesised that the
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41 129 OMPRIS intervention will reduce symptoms of IUD and IGD, and will heighten the motivation
42
43 130 for behaviour modification concerning media use. OMPRIS is also intended to help IUD and
44
45 131 IGD patients access conventional treatments. It is hypothesised that the OMPRIS intervention
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47 132 will increase the referral rate to (specialised) mental health care.
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2. Methods and analysis

2.1 Trial design

The design is a single-blind RCT with two parallel arms, comparing the OMPRIIS 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 OMPRIIS counselling programme or a four-week waiting period. Notably, WLC group participants will be offered the OMPRIIS 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 OMPRIIS 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.

157 The OMPRIS intervention will be offered totally online and participants from all over
158 Germany can take part via webcam. Participation will be managed via a newly developed online-
159 study platform that offers user accounts, video chat, appointment management, a psychological
160 test battery, and teaching aids. The platform was developed per requirements of current
161 protection of data privacy. Participation in OMPRIS is browser-based, requires no software
162 download, and is complimentary. Participants can register at www.onlinesucht-hilfe.com.

164 **2.3 Participants and recruitment**

165 In total, 162 individuals suffering from problematic or addictive use of Internet
166 applications and video games, who meet the eligibility criteria and will consent to participate in
167 the study, will be recruited. The calculation of the sample size is reported in paragraph 2.11.
168 Inclusion criteria are as follows: problematic or addictive use of Internet applications according
169 to the DSM-5 criteria and the ICD-11 criteria for IGD as assessed via a self-report scale
170 (Assessment of Internet and Computer Game Addiction, AICA-S [39,40]) and a structured
171 clinical expert rating (Assessment of Internet and Computer Game Addiction, AICA-SKI:IBS
172 [41]); legal age of at least 16 years old (with the informed consent of parents); constant access to
173 the Internet via webcam, microphone, and email address; sufficient knowledge of the German
174 language; informed consent to dissolve pseudonymisation in case of emergency (i.e. concrete
175 suicidal tendency). Exclusion criteria are psychotic disorders (past or present); learning
176 disabilities/intellectual impairment; substance abuse within the past six months; active suicidal
177 thoughts or intentions; younger than 16 years or missing parental informed consent; insufficient
178 knowledge of the German language; inconstant or no access to the Internet via webcam or no
179 email address; a co-morbid somatic disease with endocrinological medication causing impulsive

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180 behaviours (e.g. Morbus Parkinson with dopaminergic medication); recent psychiatric or
181 psychotherapeutic treatment focusing primarily on IUD or IGD.

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

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

193 Inclusion criteria will be established during the eligibility assessment: pathological
194 Internet and video game use via the AICA-SKI:IBS interview, psychotic disorders, acute
195 suicidality, learning disabilities/intellectual impairments via the MINI interview, sufficient
196 knowledge of the German language via the ability to complete questionnaires and follow the
197 webcam-based informed consent procedure, and a co-morbid somatic disease with dopaminergic
198 medication as well as recent psychotherapeutic treatment focusing on IUD by self-report.
199 Motivation and willingness to attend the study will be assessed via self-report during the
200 informed consent procedure, emphasising the demands of the study in terms of effort and time.
201 The informed consent procedure will end by asking the participants whether they still wish to
202 participate in the study.

203

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

225 administered by the Department of Medical Informatics, Biometry and Epidemiology in
226 Bochum.

228 **2.5 Intervention**

229 The manualised OMPRIIS intervention is a combined treatment programme mainly based
230 on the MI approach that has been shown as sufficient to improve health behaviour in various
231 medical diseases including addictive disorders [25,45–48]. Furthermore, OMPRIIS contains
232 treatment elements from cognitive behavioural therapy (CBT), (Internet-related) addiction
233 therapy [49], media education, and social counselling. The primary outcome will be measured
234 constantly after four weeks of intervention (measurement points: T0 baseline, T1 mid-
235 intervention, and T2 post intervention, see Figure 1 & Table 2). During these four weeks, the
236 participants will be offered up to eight psychological treatment sessions and one or two social
237 support sessions. In addition, a detailed diagnostic webcam session will be offered one week
238 before and one week after the intervention. In total, a participant can thus attend up to 12
239 webcam sessions. The number of attended sessions will be assessed. Two follow-up
240 measurements will be conducted 6 weeks (T3) and 6 months (T4) after enrolment. The
241 psychological intervention sessions (50 minutes each) will take place within four weeks, with
242 two sessions per week. Table 1 shows the treatment phases and strategies during the early,
243 middle, and termination phases.

244 Based on e.g. self-monitoring and awareness of media use participants will be
245 encouraged to develop an individual behavioural model and goal settings. Furthermore, changing
246 in problematic Internet use will be stimulated using different CBT techniques (e.g. habit reversal,
247 behavioural rehearsals, practices, restructuring the environment, self-assessment and anticipation

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3 248 of social and health consequences, problem solving coping panning, pros and cons, regulation of
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5 249 negative emotions, see Table 1). A special focus is placed on the strengthening of existing
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8 250 positive resources and successfully changed behaviour using MI skills. In addition, practical
9
10 251 social counselling will be offered (e.g. application for housing benefit, information on debt
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12 252 counselling, assisted living) by a professional social worker. In the termination phase, strategies
13
14 253 for relapse prevention will be discussed. If required, referrals to further treatment options will be
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17 254 reviewed.

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19 255 Psychological sessions will be carried out by clinically experienced psychotherapists,
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21 256 psychologists, or experts in related disciplines with experience in the treatment and counselling
22
23 257 of IUD and IGD, who work at the cooperating study centers (Bochum, Mainz,
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25 258 München/Dießen). Social counselling will be carried out by trained social workers. Fidelity
26
27 259 checks will be carried out using therapist feedback after each session with classification of the
28
29 260 main topics and interventions. A guiding manual is used by the therapists.
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Table 1: OMPRIIS 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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<PLEASE INSERT FIGURE 1 HERE>

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10 298 **Figure 1:** A flow chart of the study. Participants of the WLC group will be offered the OMPRIS
11 299 intervention after the IG has finished. The follow-up analysis will be performed separately for
12 300 the WLC group.
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ONLINE-BASED INTERVENTION FOR INTERNET USE DISORDER

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Table 2: Study schedule of measurement and testing

Approximate time since baseline	T0	T0b	Each	T1 Mid-	T2 Post-	T3 & T4
	Eligibility	Baseline	session	intervention	intervention	Follow-up
	- 1 week	-		2 weeks	4 weeks	11 weeks
						6 months
Consent	X					
AICA-S (primary outcome)	X	X		X	X	X
Demographics	X					
Life style parameter		X			X	X
MINI Interview		X				
AICA-SKI:IBS Interview		X			X	
Treatment information		X				
iSOCRATES		X		X	X	X
CIUS		X		X	X	X
EQ5D-5L		X			X	X
PHQ-9		X			X	X
GAD-7		X			X	X
L-1		X			X	X
SWE		X			X	X
BFI-10		X				
Resource use		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 standardised 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.

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2.8 Primary outcome: Problematic Internet use

339 *Assessment of Internet and Computer game Addiction Scale* (AICA-S) [39,40]. The
 340 primary outcome is defined as reduction of current IUD symptoms measured by AICA-S scale
 341 whose items are related to the DSM-criteria of substance-use disorders and gambling disorder.
 342 Fourteen items (five-point Likert scale) are relevant for clinical classification of Internet use,
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3 344 including craving, a loss of control, tolerance, unsuccessful attempts to spend less, and
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5 345 withdrawal. Negative consequences are relevant according to areas of life, including problems
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7 346 with school, work, health, and social partners. Moreover, time spent online, the preferred online
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9 347 activities, and the preferred type of problematic Internet use are requested. The timeframe of the
10
11 348 questionnaire can be adjusted according to the research question. In our study, the timeframe
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13 349 „during the past 4 weeks" was chosen (duration of the intervention). A cut-off is defined by
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15 350 statistical means based on epidemiological surveys analyses [50]. A score of seven points (three
16
17 351 to four criteria fulfilled) can be interpreted as addictive use. Based on the clinical cut-off values
18
19 352 of 7 points, the sensitivity was 80.5 % and the specificity 82.4 % [51]. Reliability of AICA-S
20
21 353 (internal consistency of $\alpha = .89$) and validity are determined in clinical and epidemiological
22
23 354 surveys [50,52,53]. The AICA-S was successfully used in a recent published German
24
25 355 randomised controlled trial on the effectiveness of outpatient group therapy for IUDs [49]. This
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27 356 study also showed good sensitivity to change after therapeutic intervention using self-assessment
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29 357 and assessment by experts [49]. It is conducted at baseline, mid-intervention, post-intervention,
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31 358 and at follow-up.
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40 360 **2.9 Secondary outcomes**

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42 361 *Stage of Readiness and Treatment Eagerness for Internet use disorder (iSOCRATES)*
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44 362 [38]. The iSOCRATES scale is a self-report measure assessing the stage of readiness and
45
46 363 treatment eagerness for IUD. It was adapted from the German SOCRATES scale for alcohol
47
48 364 addiction consisting of 19 motivation-relevant statements whereon participants give their
49
50 365 agreement on a five-point Likert scale [54,55]. Cronbach's alpha of the measure has shown to be
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ONLINE-BASED INTERVENTION FOR INTERNET USE DISORDER

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3 366 $\alpha = .60$ for the scale ‘ambivalence’, $\alpha = .83$ for ‘taking steps’, and $\alpha = .85$ for ‘recognition’ [55].

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5 367 It will be conducted at baseline, mid-intervention, post-intervention, and at follow-up.

6
7 368 *Compulsive Internet Use Scale* (CIUS) [56]. The CIUS contains 14 items rateable on a
8
9 369 five-point Likert scale and measures symptoms of Internet-related disorders. The instrument has
10
11 370 shown a good internal consistency ($\alpha = .89$) [57]. It will be conducted at baseline, mid-
12
13 371 intervention, post-intervention, and at follow-up.

14
15 372 *Patient Health Questionnaire-9* [58] (PHQ-9, German translation [59]). This nine-item
16
17 373 patient questionnaire is a self-report version of the PRIME-MD diagnostic instrument for
18
19 374 common mental disorders [60]. The PHQ-9 is a depression module, which scores each of nine
20
21 375 DSM-IV criteria as ‘0’ (not at all) to ‘3’ (nearly every day). The internal consistency has been
22
23 376 found to be excellent ($\alpha = .83-.92$) [61]. It will be conducted at baseline, post-intervention, and at
24
25 377 follow-up.

26
27 378 *Generalised Anxiety Disorder Screener* [62] (GAD-7, German translation [63]). The
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29 379 GAD-7 scale is a self-report measure assessing general anxiety symptoms related to DMS-IV
30
31 380 criteria on a four-point Likert scale. The internal consistency has shown to be excellent ($\alpha = .89$)
32
33 381 [62]. It will be conducted at baseline, post-intervention, and at follow-up.

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35 382 *General life satisfaction* (L-1) [64]. The short L-1 scale for recording general life
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37 383 satisfaction consists of only one item with the following wording: ‘How satisfied are you at
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39 384 present, all in all, with your life?’. The 11 answer categories of the L-1 range from ‘not satisfied
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41 385 at all’ to ‘completely satisfied’. The reliability has been tested by test-retest reliability, which has
42
43 386 reported to be $r_{tt} = .67$ [64]. It will be conducted at baseline, post-intervention, and at follow-up.

44
45 387 *General self-efficacy scale* [65] (GSE, German translation SWE [66]). The GSE scale
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47 388 measures self-perceived self-efficacy and consists of ten items assessing the respondent’s belief
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389 in the ability to respond to novel or difficult situations adequately and to cope with a large
390 variety of stressors. It is scored on a four-point scale from '1' (not at all true) to '4' (exactly
391 true). A comparison of the GSE in 23 countries shows a generally good to excellent internal
392 consistency, which varies between $\alpha = .76$ to $.90$. In German samples, Cronbach's alpha varies
393 between $.80$ and $.90$ [67]. It will be conducted at baseline, post-intervention, and at follow-up.

394 *Big Five Inventory* [68] (BFI-10). The BFI-10 is a self-report measure containing ten
395 items to assess Big Five personality traits. It has five subscales with two bidirectional items for
396 each of the personality factors. The ten items are rated on a five-point Likert scale wherein the
397 subjects choose from responses ranging from 'strongly disagree' to 'strongly agree'. The
398 reliability has been tested by test-retest reliability, which has been found to be good ($r_{tt} = .58-.84$)
399 [69]. The BFI-10 will be conducted only once at baseline.

400 *Helping Alliance Questionnaire* [70] (HAQ, German translation [71]). The HAQ is a
401 highly relevant instrument to assess the therapeutic alliance and can be used both as the patient's
402 version (HAQ-P) and, in a slightly modified form, as the therapist's version (HAQ-T). All items
403 are rated on a six-point Likert Scale from 'strongly agree' to 'strongly disagree'. The HAQ has
404 two factors called 'satisfaction with therapeutic outcome' and 'relation to the therapist'. It will be
405 conducted at mid-intervention and post-intervention. Cronbach's α of the two scales has been
406 reported as good ($\alpha = .75-.89$ on the HAQ-P and $\alpha = .63-.85$ on the HAQ-T) [72].

407 *EuroQol standardised measure of health-related quality of life - 5 dimensions, 5 level*
408 *Version* [73] (EQ-5D-5L, German translation [74]). The EQ-5D-5L is a standardised instrument
409 for measuring generic health status in terms of quality of life. It essentially consists of five items
410 measuring dimensions of impairment (mobility, self-care, usual activities, pain/discomfort, and
411 anxiety/depression) on a five-point Likert scale from 'no problems' to 'extreme problems'.

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3 412 Furthermore, a visual analogue scale (VAS) records the patient's self-rated health on a vertical
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5 413 VAS, where the endpoints are labelled 'The best health you can imagine' and 'The worst health
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8 414 you can imagine'. Interobserver reliability (0.49 vs. 0.57) and test-retest reliability (0.52 vs.
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10 415 0.69) have been reported to be good [75]. It will be conducted at baseline, post-intervention, and
11
12 416 at follow-up.
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17 418 **2.10 Additional measures**

19 419 The *AICA-SKI:IBS* [41] is a structured interview that determines the nine DSM-5 criteria
20
21 420 for IGD. Moreover, the symptom of craving is examined. The interview is also applicable to
22
23 421 other Internet use disorders. The evaluation is carried out according to standardised
24
25
26 422 specifications, which result from the evaluation sheet at the end of the interview. Core criteria
27
28 423 are individually assessed on a scale from '0' (not fulfilled) to '5' (certainly fulfilled). A total
29
30 424 score (0-30 points) is tallied, and a total score > 13 points indicates an Internet use disorder. The
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33 425 *AICA-SKI:IBS* takes approximately 20-30 minutes and will be conducted at baseline and post-
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35 426 intervention.
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38 427 The *Mini-International Neuropsychiatric Interview* [42] (MINI, V7.0.) is a short
39
40 428 structured diagnostic interview developed for DSM-5 and ICD-10 psychiatric disorders. With an
41
42 429 administration time of approximately 15-20 minutes, it was designed to meet the need for a short
43
44 430 but accurate structured psychiatric interview for multicentre clinical trials and epidemiology
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47 431 studies. The MINI will be conducted only once at baseline to detect psychiatric comorbidities.
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49 432 The *System Usability Scale* (SUS) [76] is a short, reliable tool for measuring usability in a
50
51 433 wide variety of services, including software, websites, and applications. It consists of ten items
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434 on a five-point Likert scale from 'strongly agree' to 'strongly disagree'. It will be conducted at
435 post-intervention.

436 *Satisfaction with OMPRIS intervention* is measured by ten items on a five-point Likert
437 scale from 'strongly disagree' to 'strongly agree' (e.g. 'OMPRIS helped me to accept support for
438 the first time because of my (problematic) Internet use', or 'I would recommend OMPRIS to my
439 friends'). It will be conducted at post-intervention.

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

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

450

451 **2.11 Sample size**

452 The sample size was calculated by a power calculation to find a between-group effect
453 (two-sided t-test) with 80% power at $p = .05$. A current RCT treatment study (STICA study)
454 found an effect size of $d = 1.19$ for the effect of analogue CBT treatment on the reduction of IUD
455 symptoms ($SD = 3.92$) using the same outcome measurement AICA-S [49]. We took a
456 conservative estimate of effect size $d = 0.51$ (approx. 43% of the STICA study) for our OMPRIS

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3 457 intervention determining a significant detection of a 2-point difference in the primary outcome
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5 458 measure. Based on these assumptions, 62 participants are required per group. Notably, 81
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7 459 participants per group are planned to recruit to allow for a drop-out rate of 30% according to data
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9 460 from young adults addiction treatment [49,77].
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15 462 **2.12 Patient and public involvement**

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17 463 The development of the research question and the outcome measures was influenced by previous
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19 464 experience from a previous pilot study on people with Internet use disorder [38]. Patient
20
21 465 feedback was considered in the planning of the study and design. The patients' previous
22
23 466 experiences and feedback were particularly important in designing the low-threshold OMPRI
24
25 467 intervention. The main results will be published in a final report, according to the German
26
27 468 Innovation Funds directive. The report will be publicly available and free of charge on the
28
29 469 Internet. Furthermore, the scientific results will be disseminated via publications submitted to
30
31 470 peer-reviewed scientific journals. All participants will receive a short final report with their (pre /
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33 471 post) results of the four-week online intervention. The OMPRI study is planned and will be
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35 472 conducted in cooperation with the German Fachverband Medienabhängigkeit e.V. that is
36
37 473 committed to creating a network of researchers and practitioners in the German-speaking
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39 474 countries who are working on IUD and GD within the framework of a large-scale cooperation.
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47 476 **2.13 Data collection and management**

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49 477 Data collection will be performed online via the OMPRI software environment
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51 478 (www.onlinesucht-hilfe.com). All data will be stored on protected servers in Germany. Data will
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53 479 be entered into an electronic database on an ongoing basis, and the database and outputs will be
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1
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3 480 regularly backed up to a remote server. The computer databases will not contain information
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5 481 about the participants' allocation, which will be added as required before the analysis.
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8 482 Data completeness will be automatically monitored by the OMPRIS software
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10 483 environment. Any participants identifiable data will be stored separately from research data in a
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12 484 second database and will be accessible only to members (admin) of the principal research team.
13
14 485 The principal investigator (JDH) will have primary responsibility for verifying the integrity of
15
16 486 the databases and will be responsible for managing and archiving the databases post-analysis.
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21 488 **2.14 Trial management and monitoring**

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24 489 The principal investigator (JDH) has primary responsibility for the conduct of the trial.
25
26 490 The management of processes will be monitored and discussed in regular meetings with the
27
28 491 researchers involved in data collection. The trial management group is composed of LB, MP,
29
30 492 NT, and JDH and will be in regular contact with all partners of the study.
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33 493 34 35 494 **2.15 Adverse event monitoring**

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37 495 Adverse events (AEs) will be monitored by trial researchers conducting the OMPRIS
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39 496 intervention on an ongoing basis and post-intervention, recorded via an 'adverse event comment
40
41 497 function' in the OMPRIS software environment. The severity of all reported AEs will be
42
43 498 classified by an external investigator as '1 = mild' to '5 = death-related to AE' according to the
44
45 499 NCI Common Terminology Criteria for Adverse Events (CTCAE) [78]. Severe adverse events
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47 500 (SAEs) will be forwarded to an external Data and Safety Monitoring Board (DSMB), which
48
49 501 consists of independent experts in the field of statistics and behavioural addiction. The DSMB
50
51 502 will examine possible causal relations to the study and identify serious study related events
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503 (SSREs). Possible SAEs for the OMPRIIS study were defined as emerging suicidal ideation and
504 tendency; self-destructive behaviour such as self-harm; worsening of general well-being;
505 psychiatric co-morbidity with an indication for inpatient admission (hospitalisation) to a clinic.
506 Both, SAEs and SSREs will be reported to the responsible ethics committee.

508 2.16 Data analysis

509 Method of clinical evaluation

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

519 It is expected that missing data will not be ‘missing-at-random’ based on the assumption
520 that the occurrence of the missing value in a variable can be fully explained by the characteristics
521 of the remaining variables. Therefore, diverse sensitivity analyses will be calculated with
522 different strategies for missing data replacement. Details of statistical analyses will be defined in
523 a statistical analysis plan. Potential group imbalances in spite of randomisation will be tested via
524 t-tests for continuous variables and Pearson’s chi-squared test. Exploratory analyses will

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3 525 evaluate potential predictors for therapeutic success via linear and logistic regression models.
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5 526 The statistical analyses will be carried out with R Project [79] and IBM SPSS Statistics [80].
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8 527 **Method of health economic evaluation**

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10 528 The health economic evaluation of OMPRIIS contains both a cost-effectiveness and a
11
12 529 cost-utility analysis. Additionally, a cost-of-illness study regarding persons with IGD and IUD
13
14 530 will be done. The evaluation will include both direct and indirect costs, which will be calculated
15
16 531 from statutory health insurance perspective as well as from a societal perspective. The analyses
17
18 532 will be using a bottom-up approach. Data on the resource use will be collected at baseline T0b,
19
20 533 four weeks later at T2, and, again, seven weeks later at T3 for both groups.
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23
24 534 A standardised health economic questionnaire has been developed, which includes
25
26 535 questions concerning health care resource use, such as outpatient physician contacts,
27
28 536 hospitalisation, inpatient and outpatient rehabilitation, occupational therapy, reduction in/loss of
29
30 537 earning capacity, and disability. Moreover, participants will be asked about socio-demographic
31
32 538 data, such as age, gender, graduation, on-the-job training, and cash benefits from different
33
34 539 sources. Prices for all resource use will be collected using different sources.
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38 540 The Lauer Taxe® will be used to determine medication selling prices for the German
39
40 541 market. For inpatient and outpatient care, hospitalisation and rehabilitation recommendations
41
42 542 will be obeyed according to published standardised procedures in health economic evaluation
43
44 543 and standardised prices [81–84]. Costs will be calculated as the product of the number of
45
46 544 consumed resources and estimated prices and summarised to compute the overall costs. The
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48 545 analyses will be based on the calculation of mean values and the standard deviations of resource
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50 546 use and health care costs. According to the method of difference-in-difference, health care costs
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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

569 to reach individuals with IUDs and IGD more effectively and quickly than conventional
570 approaches.

571 OMPRIS is a health care research project, which offers a standardised therapeutic
572 Internet-based intervention to all interested people aged 16 or older from all over Germany.
573 Participation in OMPRIS is guided by individual interests and concerns. We assume that people
574 will come forward who feel that their Internet use might be problematic. Due to the low barriers,
575 we hypothesise that OMPRIS will nearly represent the general population of individuals
576 suffering from IUD and IGD (e.g. in terms of gender distribution), and will therefore correspond
577 more closely to representative epidemiological studies [9,11] rather than to clinical experiences
578 from specialised IUD outpatient clinics where mainly men are in treatment [51,88].

579

580 **4. Ethics and dissemination**

581 **4.1 Ethical issues**

582 Clinical protocol and written informed consent were approved by the Ethics Committee
583 for the Faculty of Medicine, Ruhr University Bochum, approval no. 19-6779. Furthermore, the
584 main ethical approval was confirmed by the ethics committees of all cooperating centres. All
585 procedures described in the clinical trial protocol follow the Good Clinical Practice (GCP)
586 guidelines and the ethical principles described in the current revision of the Declaration of
587 Helsinki. The study will be carried out in keeping with local legal and regulatory requirements.
588 The main ethical issues are informed consent, the use of OMPRIS intervention, the use of an
589 online-based intervention, and protection of data privacy, the inclusion of underage persons with
590 parental consent, technical procedures of online participation and online declaration of consent,
591 and the WLC group design.

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

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

603 **4.2 Dissemination plan**

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

612 **4.3 Trial status**

613 The trial currently is at the beginning of the recruitment phase. The first participant was
614 assessed to OMPRIS study on 1 September 2020. Follow-up measurements for the last

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3 615 participants are expected in July 2022. Substantial protocol amendments will be reported in
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5 616 publications.
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10 618 **5. Statements**

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15 620 **5.1 Authors' contributions:** JDH, LB, and MP conceived the study. JDH is the principal
16
17 621 investigator, acquired funding and drafted the initial study protocol. AN, SN and NT as those
18
19 622 responsible in the OMPRIS project for data evaluation and statistical analyses, drafted the *data*
20
21 623 *analysis* of the initial study protocol and revised the *method* part of the study protocol. BtW,
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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.

648 **References**

- 649 1 Bundesamt für Statistik. Statistisches Jahrbuch Deutschland und Internationales 2019.
650 2019. https://www.statistischebibliothek.de/mir/receive/DEAusgabe_mods_00004527
651 (accessed 21 Aug 2020).
- 652 2 DAK-Gesundheit. Mediensucht 2020 – Gaming und Social Media in Zeiten von Corona.
653 DAK-Längsschnittstudie: Befragung von Kindern, Jugendlichen (12 – 17 Jahre) und deren
654 Eltern. Hamburg: 2020. [https://www.dak.de/dak/bundesthemen/computerspielsucht-](https://www.dak.de/dak/bundesthemen/computerspielsucht-2296282.html#/)
655 [2296282.html#/](https://www.dak.de/dak/bundesthemen/computerspielsucht-2296282.html#/) (accessed 21 Aug 2020).
- 656 3 Ko CH, Yen JY. Impact of COVID-19 on gaming disorder: Monitoring and prevention. *J*
657 *Behav Addict* 2020;**9**:187–9. doi:10.1556/2006.2020.00040
- 658 4 Balhara YPS, Kattula D, Singh S, *et al.* Impact of lockdown following COVID-19 on the
659 gaming behavior of college students. *Indian J Public Health* 2020;**64**:S172–6.
660 doi:10.4103/ijph.IJPH_465_20
- 661 5 King DL, Delfabbro PH, Billieux J, *et al.* Problematic online gaming and the COVID-19
662 pandemic. *J Behav Addict* 2020;**9**:184–6. doi:10.1556/2006.2020.00016
- 663 6 Montag C, Wegmann E, Sariyska R, *et al.* How to overcome taxonomical problems in the
664 study of Internet use disorders and what to do with “smartphone addiction”? *J Behav*
665 *Addict* 2019;**1**–7. doi:10.1556/2006.8.2019.59
- 666 7 WHO. Gaming disorder, predominantly online. 2019. [https://icd.who.int/browse11/l-](https://icd.who.int/browse11/l-m/en#/http%3A%2F%2Fid.who.int%2Ficd%2Fentity%2F338347362)
667 [m/en#/http%3A%2F%2Fid.who.int%2Ficd%2Fentity%2F338347362](https://icd.who.int/browse11/l-m/en#/http%3A%2F%2Fid.who.int%2Ficd%2Fentity%2F338347362)
- 668 8 Cheng C, Li AY. Internet addiction prevalence and quality of (real) life: a meta-analysis
669 of 31 nations across seven world regions. *Cyberpsychol Behav Soc Netw* 2014;**17**:755–60.
670 doi:10.1089/cyber.2014.0317

- 1
2
3 671 9 Rumpf H-J, Meyer C, Kreuzer A, *et al.* Prävalenz der Internetabhängigkeit (PINTA)
4
5 672 Bericht an das Bundesministerium für Gesundheit. 2011.
6
7
8 673 10 Wölfling K, Thalemann R, Grüsser-Sinopoli SM. Computerspielsucht: Ein
9
10 674 psychopathologischer Symptomkomplex im Jugendalter. *Psychiatr Prax* 2008;**35**:226–32.
11
12 675 doi:10.1055/s-2007-986238
13
14 676 11 Rehbein F, Kliem S, Baier D, *et al.* Prevalence of internet gaming disorder in German
15
16 677 adolescents: diagnostic contribution of the nine DSM-5 criteria in a state-wide
17
18 678 representative sample. *Addiction* 2015;**110**:842–51. doi:10.1111/add.12849
19
20
21 679 12 Batthyány D, Müller KW, Benker F, *et al.* Computer game playing: clinical characteristics
22
23 680 of dependence and abuse among adolescents. *Wien Klin Wochenschr* 2009;**121**:502–9.
24
25 681 doi:10.1007/s00508-009-1198-3
26
27
28 682 13 Stevens MW, Dorstyn D, Delfabbro PH, *et al.* Global prevalence of gaming disorder: A
29
30 683 systematic review and meta-analysis. *Aust New Zeal J Psychiatry*
31
32 684 2020;:000486742096285. doi:10.1177/0004867420962851
33
34
35 685 14 Greenfield DN. Psychological characteristics of compulsive internet use: A preliminary
36
37 686 analysis. *Cyberpsychology Behav* 1999;**2**:403–12. doi:10.1089/cpb.1999.2.403
38
39
40 687 15 Young KS. Internet addiction: The emergence of a new clinical disorder.
41
42 688 *Cyberpsychology Behav* 1998;**1**:237–44. doi:10.1089/cpb.1998.1.237
43
44
45 689 16 González-Bueso V, Santamaría JJ, Fernández D, *et al.* Association between Internet
46
47 690 Gaming Disorder or Pathological Video-Game Use and Comorbid Psychopathology: A
48
49 691 Comprehensive Review. *Int J Environ Res Public Health* 2018;**15**.
50
51 692 doi:10.3390/ijerph15040668
52
53
54 693 17 Carli V, Durkee T, Wasserman D, *et al.* The association between pathological internet use

- 694 and comorbid psychopathology: a systematic review. *Psychopathology* 2013;**46**:1–13.
- 695 doi:10.1159/000337971
- 696 18 Andreassen CS, Billieux J, Griffiths MD, *et al.* The relationship between addictive use of
- 697 social media and video games and symptoms of psychiatric disorders: A large-scale cross-
- 698 sectional study. *Psychol Addict Behav* 2016;**30**:252–62. doi:10.1037/adb0000160
- 699 19 Dieris-Hirche J, Bottel L, Bielefeld M, *et al.* Media use and Internet addiction in adult
- 700 depression: A case-control study. *Comput Human Behav* 2017;**68**.
- 701 doi:10.1016/j.chb.2016.11.016
- 702 20 Bielefeld M, Drews M, Putzig I, *et al.* Comorbidity of Internet use disorder and attention
- 703 deficit hyperactivity disorder: Two adult case-control studies. *J Behav Addict* 2017;**6**:490–
- 704 504. doi:10.1556/2006.6.2017.073
- 705 21 Steinbüchel TA, Herpertz S, Külpmann I, *et al.* Internet Addiction, Suicidality and Non-
- 706 Suicidal Self-Harming Behavior - A Systematic Review. *PPmP Psychother Psychosom*
- 707 *Medizinische Psychol* 2018;**68**:451–61. doi:10.1055/s-0043-120448
- 708 22 King DL, Delfabbro PH, Wu AMS, *et al.* Treatment of Internet gaming disorder: An
- 709 international systematic review and CONSORT evaluation. *Clin Psychol Rev*
- 710 2017;**54**:123–33. doi:10.1016/j.cpr.2017.04.002
- 711 23 Stevens MWR, King DL, Dorstyn D, *et al.* Cognitive-behavioral therapy for Internet
- 712 gaming disorder: A systematic review and meta-analysis. *Clin. Psychol. Psychother.*
- 713 2019;**26**:191–203. doi:10.1002/cpp.2341
- 714 24 Winkler A, Dörsing B, Rief W, *et al.* Treatment of internet addiction: a meta-analysis.
- 715 *Clin Psychol Rev* 2013;**33**:317–29. doi:10.1016/j.cpr.2012.12.005
- 716 25 Frost H, Campbell P, Maxwell M, *et al.* Effectiveness of Motivational Interviewing on

- 1
2
3 717 adult behaviour change in health and social care settings: A systematic review of reviews.
4
5 718 PLoS One. 2018;**13**:e0204890. doi:10.1371/journal.pone.0204890
6
7
8 719 26 Yakovenko I, Quigley L, Hemmelgarn BR, *et al*. The efficacy of motivational
9
10 720 interviewing for disordered gambling: Systematic review and meta-analysis. *Addict Behav*
11
12 721 2015;**43**:72–82. doi:10.1016/j.addbeh.2014.12.011
13
14
15 722 27 Saruhanjan K, Zarski A-C, Schaub MP, *et al*. Design of a Guided Internet- and Mobile-
16
17 723 Based Intervention for Internet Use Disorder—Study Protocol for a Two-Armed
18
19 724 Randomized Controlled Trial. *Front Psychiatry* 2020;**11**:190.
20
21 725 doi:10.3389/fpsyt.2020.00190
22
23
24 726 28 Loton D, Lubman D. Just one more level: Identifying and addressing internet gaming
25
26 727 disorder within primary care. *Aust Fam Physician* 2016;**45**:48–
27
28 728 52.[http://www.racgp.org.au/afp/2016/januaryfebruary/just-one-more-level-identifying-](http://www.racgp.org.au/afp/2016/januaryfebruary/just-one-more-level-identifying-and-addressing-internet-gaming-disorder-within-primary-care/)
29
30 729 [and-addressing-internet-gaming-disorder-within-primary-care/](http://www.racgp.org.au/afp/2016/januaryfebruary/just-one-more-level-identifying-and-addressing-internet-gaming-disorder-within-primary-care/)
31
32
33 730 29 Su W, Fang X, Miller JK, *et al*. Internet-based intervention for the treatment of online
34
35 731 addiction for college students in China: A pilot study of the healthy online self-helping
36
37 732 center. *Cyberpsychology, Behav Soc Netw* 2011;**14**:497–503.
38
39 733 doi:10.1089/cyber.2010.0167
40
41
42 734 30 Kim H. Exercise rehabilitation for smartphone addiction. *J Exerc Rehabil* 2013;**9**:500–5.
43
44 735 doi:10.12965/jer.130080
45
46
47 736 31 van Rooij AJ, Zinn MF, Schoenmakers TM, *et al*. Treating Internet Addiction With
48
49 737 Cognitive-Behavioral Therapy: A Thematic Analysis of the Experiences of Therapists. *Int*
50
51 738 *J Ment Health Addict* 2012;**10**:69–82. doi:10.1007/s11469-010-9295-0
52
53
54 739 32 Van't Hof E, Cuijpers P, Stein DJ. Self-help and Internet-guided interventions in
55
56
57
58
59
60

- 1
2
3 740 depression and anxiety disorders: a systematic review of meta-analyses. *CNS Spectr.*
4
5 741 2009;**14**:34–40. doi:10.1017/s1092852900027279
6
7
8 742 33 Johansson R, Andersson G. Internet-based psychological treatments for depression. *Expert*
9
10 743 *Rev. Neurother.* 2012;**12**:861–70. doi:10.1586/ern.12.63
11
12 744 34 Kruse CS, Lee K, Watson JB, *et al.* Measures of effectiveness, efficiency, and quality of
13
14 745 telemedicine in the management of alcohol abuse, addiction, and rehabilitation:
15
16 746 Systematic review. *J. Med. Internet Res.* 2020;**22**:e13252. doi:10.2196/13252
17
18
19 747 35 Lin L (Allison), Casteel D, Shigekawa E, *et al.* Telemedicine-delivered treatment
20
21 748 interventions for substance use disorders: A systematic review. *J Subst Abuse Treat*
22
23 749 2019;**101**:38–49. doi:10.1016/j.jsat.2019.03.007
24
25
26 750 36 Chebli JL, Blaszczynski A, Gainsbury SM. Internet-Based Interventions for Addictive
27
28 751 Behaviours: A Systematic Review. *J. Gambl. Stud.* 2016;**32**:1279–304.
29
30 752 doi:10.1007/s10899-016-9599-5
31
32
33 753 37 Lam LT, Lam MK. eHealth Intervention for Problematic Internet Use (PIU). *Curr.*
34
35 754 *Psychiatry Rep.* 2016;**18**. doi:10.1007/s11920-016-0747-5
36
37
38 755 38 te Wildt B. Entwicklung und Evaluation eines Online-Ambulanz-Service zur Diagnostik
39
40 756 und Beratung. Abschlussbericht An das Bundesministerium für Gesundheit. 2018.
41
42 757 https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Drogen_und_Sucht/Berichte/Abschlussbericht/Abschlussbericht_OASIS.pdf (accessed 8 May
43
44 758 2020).
45
46
47 759
48
49 760 39 Wölfling K, Müller KW, Beutel M. Reliabilität und Validität der Skala zum
50
51 761 Computerspielverhalten (CSV-S). *PPmP Psychother Psychosom Medizinische Psychol*
52
53 762 2011;**61**:216–24. doi:10.1055/s-0030-1263145
54
55
56
57
58
59
60

- 1
2
3 763 40 Wölfling K, Beutel ME, Müller KW. OSV-S - Skala zum Onlinesuchtverhalten. In: Geue
4
5 764 K, Strauß B, Brähler E, eds. *Diagnostische Verfahren in der Psychotherapie*. Göttingen: :
6
7
8 765 Hogrefe 2016. 362–6.
- 9
10 766 41 Müller KW, Wölfling K. AICA-SKI:IBS Strukturiertes klinisches Interview zu
11
12 767 Internetbezogenen Störungen * Handbuch. Mainz: 2017. [http://www.fv-
17 769 SKI_IBS.pdf](http://www.fv-
13
14 768 medienabhaengigkeit.de/fileadmin/images/Dateien/AICA-SKI_IBS/Handbuch_AICA-
15
16 769 SKI_IBS.pdf) (accessed 3 Dec 2019).
- 18
19 770 42 Sheehan D V., Lecrubier Y, Sheehan KH, *et al.* The Mini-International Neuropsychiatric
20
21 771 Interview (M.I.N.I.): The development and validation of a structured diagnostic
22
23 772 psychiatric interview for DSM-IV and ICD-10. In: *Journal of Clinical Psychiatry*. 1998.
24
25 773 22–33.
- 26
27
28 774 43 Borm GF, Hoogendoorn EH, Den Heijer M, *et al.* Sequential balancing: A simple method
29
30 775 for treatment allocation in clinical trials. *Contemp Clin Trials* 2005;**26**:637–45.
31
32 776 doi:10.1016/j.cct.2005.09.002
- 33
34
35 777 44 Bittel L, Bielefeld M, Steinbuechel T, *et al.* Evaluation of an Online Ambulatory Service
36
37 778 for Internet Addicts (OASIS). *J Behav Addict* 2018;**7**:45.
- 38
39
40 779 45 Lawrence P, Fulbrook P, Somerset S, *et al.* Motivational interviewing to enhance
41
42 780 treatment attendance in mental health settings: A systematic review and meta-analysis. *J.*
43
44 781 *Psychiatr. Ment. Health Nurs*. 2017;**24**:699–718. doi:10.1111/jpm.12420
- 45
46
47 782 46 Palacio A, Garay D, Langer B, *et al.* Motivational Interviewing Improves Medication
48
49 783 Adherence: a Systematic Review and Meta-analysis. *J Gen Intern Med* 2016;**31**:929–40.
50
51 784 doi:10.1007/s11606-016-3685-3
- 52
53
54 785 47 Garcia-Caballero A, Torrens-Lluch M, Ramírez-Gendrau I, *et al.* The efficacy of

- 786 motivational intervention and cognitive-behavioral therapy for pathological gambling.
787 *Adicciones* 2018;**30**:217–22. doi:10.20882/adicciones.965
- 788 48 Petry NM, Ginley MK, Rash CJ. A systematic review of treatments for problem gambling.
789 *Psychol. Addict. Behav.* 2017;**31**:951–61. doi:10.1037/adb0000290
- 790 49 Wölfling K, Müller KW, Dreier M, *et al.* Efficacy of Short-term Treatment of Internet and
791 Computer Game Addiction: A Randomized Clinical Trial. *JAMA psychiatry* Published
792 Online First: 10 July 2019. doi:10.1001/jamapsychiatry.2019.1676
- 793 50 Müller KW, Glaesmer H, Brähler E, *et al.* Prevalence of internet addiction in the general
794 population: Results from a German population-based survey. *Behav Inf Technol*
795 2014;**33**:757–66. doi:10.1080/0144929X.2013.810778
- 796 51 Müller K, Beutel M, Wölfling K. A contribution to the clinical characterization of Internet
797 addiction in a sample of treatment seekers: Validity of assessment, severity of
798 psychopathology and type of co-morbidity. *Compr Psychiatry* 2014;**55**:770–7.
799 doi:10.1016/j.comppsy.2014.01.010
- 800 52 Müller K, Koch A, Beutel M, *et al.* Komorbide Internetsucht unter Patienten der
801 stationären Suchtrehabilitation: Eine explorative Erhebung zur klinischen Prävalenz.
802 *Psychiatr Prax* 2012;**39**:286–92. doi:10.1055/s-0032-1305120
- 803 53 Kuss DJ, Griffiths MD, Binder JF. Internet addiction in students: Prevalence and risk
804 factors. *Comput Human Behav* 2013;**29**:959–66. doi:10.1016/j.chb.2012.12.024
- 805 54 Hoyer J, Heidenreich T, Fecht J, *et al.* Studien der Veränderung in der stationären
806 Alkoholentwöhnungstherapie. *Verhaltenstherapie* 2003;**13**:31–8. doi:10.1159/000070497
- 807 55 Miller WR, Tonigan JS. Assessing drinkers' motivation for change: The Stages of Change
808 Readiness and Treatment Eagerness Scale (SOCRATES). *Psychol Addict Behav*

- 1
2
3 809 1996;**10**:81–9. doi:10.1037/0893-164X.10.2.81
4
5 810 56 Meerkerk G-J, Van Den Eijnden RJM, Vermulst AA, *et al.* The Compulsive Internet Use
6
7 811 Scale (CIUS): some psychometric properties. *Cyberpsychol Behav* 2009;**12**:1–6.
8
9 812 doi:10.1089/cpb.2008.0181
10
11
12 813 57 Meerkerk G, Van den Eijnden R, Vermulst, AA and Garretsen H. The Relationship
13
14 814 between Personality, Psychosocial Wellbeing and Compulsive Internet Use: The Internet
15
16 815 as Cyber Prozac? In: *Pwned* by the Internet*. Rotterdam: : Erasmus Universiteit
17
18 816 Rotterdam 2007. 86–101.
19
20
21 817 58 Spitzer RL, Kroenke K, Williams JB. Validation and utility of a self-report version of
22
23 818 PRIME-MD: the PHQ primary care study. Primary Care Evaluation of Mental Disorders.
24
25 819 Patient Health Questionnaire. *JAMA* 1999;**282**:1737–44.
26
27
28 820 59 Löwe B, Spitzer RL, Zipfel S, *et al.* Gesundheitsfragebogen für Patienten (PHQ-D).
29
30 821 Komplettversion und Kurzform. 2. Auflage. Karlsruhe: 2002.
31
32 822 https://www.psycharchives.org/bitstream/20.500.12034/431/1/PT_9006490_ASKU-
33
34 823 [Manual_2012.PDF](#) (accessed 18 Oct 2019).
35
36
37 824 60 Haddad M, Walters P, Phillips R, *et al.* Detecting Depression in Patients with Coronary
38
39 825 Heart Disease: A Diagnostic Evaluation of the PHQ-9 and HADS-D in Primary Care,
40
41 826 Findings From the UPBEAT-UK Study. *PLoS One* 2013;**8**.
42
43 827 doi:10.1371/journal.pone.0078493
44
45
46 828 61 Cameron IM, Crawford JR, Lawton K, *et al.* Psychometric comparison of PHQ-9 and
47
48 829 HADS for measuring depression severity in primary care. *Br J Gen Pract* 2008;**58**:32–6.
49
50 830 doi:10.3399/bjgp08X263794
51
52
53 831 62 Spitzer RL, Kroenke K, Williams JBW, *et al.* A brief measure for assessing generalized
54
55
56
57
58
59
60

- 1
2
3 832 anxiety disorder: The GAD-7. *Arch Intern Med* 2006;**166**:1092–7.
4
5 833 doi:10.1001/archinte.166.10.1092
6
7
8 834 63 Löwe B, Decker O, Müller S, *et al.* Validation and standardization of the generalized
9
10 835 anxiety disorder screener (GAD-7) in the general population. *Med Care* 2008;**46**:266–74.
11
12 836 doi:10.1097/MLR.0b013e318160d093
13
14
15 837 64 Beierlein C, Kovaleva A, László Z, *et al.* Eine Single-Item-Skala zur Erfassung der
16
17 838 Allgemeinen Lebenszufriedenheit: Die Kurzskala Lebenszufriedenheit-1 (L-1). 2014.
18
19 839 https://www.gesis.org/fileadmin/kurzskalen/working_papers/L1_WorkingPapers_2014-
20
21 840 33.pdf (accessed 18 Oct 2019).
22
23
24 841 65 Schwarzer R, Jerusalem M. Generalized Self-Efficacy scale. . In: Weinman J, Wright S,
25
26 842 Johnston M, eds. *Measures in health psychology: A user's portfolio. Causal and control*
27
28 843 *beliefs*. . Windsor, England: : NFER-NELSON. 1995. 35–7.
29
30
31 844 66 Schwarzer R, Jerusalem M. Skalen zur Erfassung von Lehrer- und Schülermerkmalen:
32
33 845 Dokumentation der psychometrischen Verfahren im Rahmen der Wissenschaftlichen
34
35 846 Begleitung des Modellversuchs Selbstwirksame Schulen. . Berlin: 1999.
36
37 847 <http://psychologie.de/schwarzer> (accessed 8 May 2020).
38
39
40 848 67 Scholz U, Doña BG, Sud S, *et al.* Is general self-efficacy a universal construct?
41
42 849 Psychometric findings from 25 countries. *Eur J Psychol Assess* 2002;**18**:242–51.
43
44 850 doi:10.1027//1015-5759.18.3.242
45
46
47 851 68 Rammstedt B, John OP. Measuring personality in one minute or less: A 10-item short
48
49 852 version of the Big Five Inventory in English and German. *J Res Pers* 2007;**41**:203–12.
50
51 853 doi:10.1016/j.jrp.2006.02.001
52
53
54 854 69 Rammstedt B, John OP. Measuring personality in one minute or less: A 10-item short
55
56
57
58
59

- 1
2
3 855 version of the Big Five Inventory in English and German. *J Res Pers* 2007;**41**:203–12.
4
5 856 doi:10.1016/j.jrp.2006.02.001
6
7
8 857 70 Alexander L, Luborsky L. The Penn Helping Alliance Scales. In: Greenberg LS, Pinosof
9
10 858 WM, eds. *Guilford clinical psychology and psychotherapy series. The psychotherapeutic*
11
12 859 *process: A research handbook*. Guilford Press 1986. 325–
13
14 860 66.<https://psycnet.apa.org/record/1987-97275-009> (accessed 8 May 2020).
15
16
17 861 71 Bassler M, Nübling R. Der ‘Helping Alliance Questionnaire’ (HAQ) von Luborsky.
18
19 862 *Psychotherapeut* 1995;**40**:23–
20
21 863 32.https://www.researchgate.net/publication/270645630_Helping_Alliance_Questionnaire
22
23 864 (accessed 8 May 2020).
24
25
26 865 72 Eich HS, Kriston L, Schramm E, *et al.* The German version of the helping alliance
27
28 866 questionnaire: Psychometric properties in patients with persistent depressive disorder.
29
30 867 *BMC Psychiatry* 2018;**18**:107. doi:10.1186/s12888-018-1697-8
31
32
33 868 73 Herdman M, Gudex C, Lloyd A, *et al.* Development and preliminary testing of the new
34
35 869 five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;**20**:1727–36.
36
37 870 doi:10.1007/s11136-011-9903-x
38
39
40 871 74 Euroqol. EQ-5D-5L . <https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/> (accessed 8
41
42 872 May 2020).
43
44
45 873 75 Janssen MF, Birnie E, Haagsma JA, *et al.* Comparing the standard EQ-5D three-level
46
47 874 system with a five-level version. *Value Heal* 2008;**11**:275–84. doi:10.1111/j.1524-
48
49 875 4733.2007.00230.x
50
51
52 876 76 Brooke J. SUS - A Quick and Dirty Usability Scale. In: Jordan P, Thomas B,
53
54 877 Weerdmeester B, *et al.*, eds. *Usability Evaluation in Industry*. London: : Taylor and

- 1
2
3 878 Francis 1996.
4
5 879 [https://www.scirp.org/\(S\(351jmbntvnsjt1aadkposzje\)\)/reference/ReferencesPapers.aspx?R](https://www.scirp.org/(S(351jmbntvnsjt1aadkposzje))/reference/ReferencesPapers.aspx?R)
6
7
8 880 eferenceID=979187 (accessed 9 May 2020).
9
10 881 77 Brorson HH, Ajo Arnevik E, Rand-Hendriksen K, *et al.* Drop-out from addiction
11
12 882 treatment: a systematic review of risk factors. *Clin Psychol Rev* 2013;**33**:1010–24.
13
14 883 doi:10.1016/j.cpr.2013.07.007
15
16
17 884 78 NCI Common Terminology Criteria for Adverse Events (CTCAE) - GBG.
18
19 885 <https://www.gbg.de/de/rechner/ctcae.php> (accessed 9 Oct 2020).
20
21
22 886 79 R Core Team. R: A language and environment for statistical computing. R Foundation for
23
24 887 Statistical Computing. 2020.<http://www.r-project.org/index.html> (accessed 22 Jan 2021).
25
26 888 80 IBM Corp. IBM SPSS Statistics for Macintosh, Version 27.0. 2020.
27
28 889 81 Scholz S, Biermann-Stallwitz J, Brettschneider C, *et al.* Standardized cost calculations in
29
30 890 the German healthcare sector: Report of the working group Standard Costs of the
31
32 891 committee Economic Evaluation of the dggo. *Gesundheitsökonomie und Qual*
33
34 892 2020;**25**:52–9. doi:10.1055/a-1107-0665
35
36
37 893 82 Krauth C, Hessel F, Hansmeier T, *et al.* Empirische bewertungssätze in der
38
39 894 gesundheitsökonomischen evaluation - Ein vorschlag der AG methoden der
40
41 895 gesundheitsökonomischen evaluation (AG MEG). *Gesundheitswesen* 2005;**67**:736–46.
42
43 896 doi:10.1055/s-2005-858698
44
45
46
47 897 83 Bock JO, Brettschneider C, Seidl H, *et al.* Ermittlung standardisierter Bewertungssätze
48
49 898 aus gesellschaftlicher Perspektive für die gesundheitsökonomische Evaluation.
50
51 899 *Gesundheitswesen* 2015;**77**:53–61. doi:10.1055/s-0034-1374621
52
53
54 900 84 Grupp H, König HH, Konnopka A. Kostensätze zur monetären Bewertung von
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2
3 901 Versorgungleistungen bei psychischen Erkrankungen. *Gesundheitswesen* 2017;**79**:48–57.
4
5 902 doi:10.1055/s-0035-1555950
6
7
8 903 85 O’Brien JE, Li W, Snyder SM, *et al.* Problem internet overuse behaviors in college
9
10 904 students: Readiness-to-change and receptivity to treatment. *J Evidence-Informed Soc*
11
12 905 *Work* 2016;**13**:373–85. doi:10.1080/23761407.2015.1086713
13
14
15 906 86 Dieris-Hirche J, Pape M, Theodor te Wildt B, *et al.* Problematic Gaming Behavior and the
16
17 907 Personality Traits of Video Gamers: A Cross-Sectional Survey. *Comput Human Behav*
18
19 908 2020;:106272. doi:10.1016/j.chb.2020.106272
20
21
22 909 87 Linden M, Zänker I, Solvie J, *et al.* Ambulante Versorgung: Erreichbarkeit von
23
24 910 Psychotherapeuten. *Dtsch Arztebl Int* 2021;**118**:A-252-
25
26 911 .https://www.aerzteblatt.de/int/article.asp?id=217638
27
28 912 88 Müller KW, Dreier M, Duven E, *et al.* Adding clinical validity to the statistical power of
29
30 913 large-scale epidemiological surveys on internet addiction in adolescence: A combined
31
32 914 approach to investigate psychopathology and development-specific personality traits
33
34 915 associated with internet addictio. *J Clin Psychiatry* 2017;**78**:e244–51.
35
36 916 doi:10.4088/JCP.15m10447
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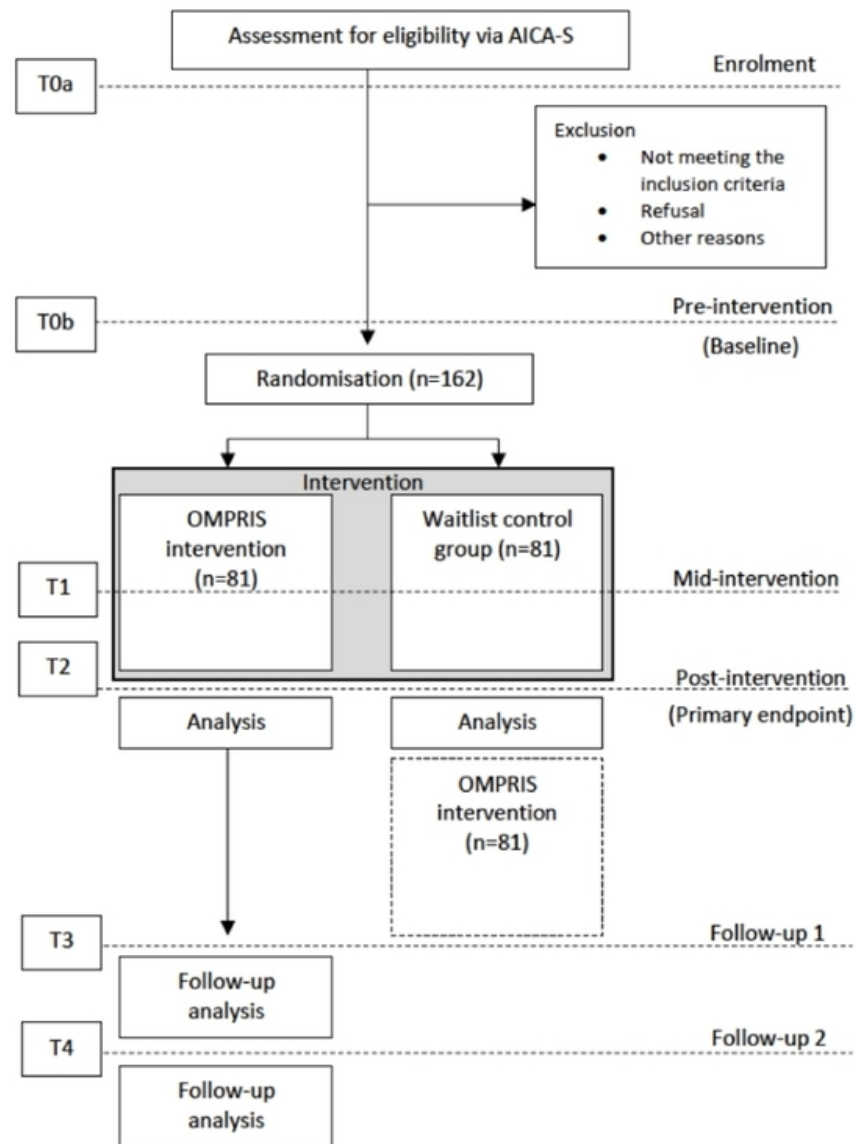


Figure 1: A flow chart of the study. Participants of the WLC group will be offered the OMPRIS intervention after the IG has finished. The follow-up analysis will be performed separately for the WLC group.

49x64mm (300 x 300 DPI)



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)

1			
2	Objectives	7	Specific objectives or hypotheses (p.7)
3			
4	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)
5			
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10	Methods: Participants, interventions, and outcomes		
11			
12	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)
13			
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16	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)
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21	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered (p.12-14)
22			
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24		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)
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29		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) (p. 12-14, 24)
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33		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial (p. 12-14)
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36	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)
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44	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)
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49	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)
50			
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53	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size (p.9-10)
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Methods: Assignment of interventions (for controlled trials)

Allocation:

1			
2	Sequence	16a	Method of generating the allocation sequence (eg, computer-
3	generation		generated random numbers), and list of any factors for stratification.
4			To reduce predictability of a random sequence, details of any planned
5			restriction (eg, blocking) should be provided in a separate document
6			that is unavailable to those who enrol participants or assign
7			interventions (p. 10-11)
8			
9			
10	Allocation	16b	Mechanism of implementing the allocation sequence (eg, central
11	concealment		telephone; sequentially numbered, opaque, sealed envelopes),
12	mechanism		describing any steps to conceal the sequence until interventions are
13			assigned (p. 10-11)
14			
15	Implementation	16c	Who will generate the allocation sequence, who will enrol participants,
16			and who will assign participants to interventions (p.11)
17			
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19	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial
20	(masking)		participants, care providers, outcome assessors, data analysts), and
21			how (p.15 – 16)
22			
23		17b	If blinded, circumstances under which unblinding is permissible, and
24			procedure for revealing a participant's allocated intervention during
25			the trial (p.15)
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Methods: Data collection, management, and analysis

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29			
30	Data collection	18a	Plans for assessment and collection of outcome, baseline, and other
31	methods		trial data, including any related processes to promote data quality (eg,
32			duplicate measurements, training of assessors) and a description of
33			study instruments (eg, questionnaires, laboratory tests) along with
34			their reliability and validity, if known. Reference to where data
35			collection forms can be found, if not in the protocol (p.15-22)
36			
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38		18b	Plans to promote participant retention and complete follow-up,
39			including list of any outcome data to be collected for participants who
40			discontinue or deviate from intervention protocols (p. 25)
41			
42	Data	19	Plans for data entry, coding, security, and storage, including any
43	management		related processes to promote data quality (eg, double data entry;
44			range checks for data values). Reference to where details of data
45			management procedures can be found, if not in the protocol (p.23-24)
46			
47			
48	Statistical	20a	Statistical methods for analysing primary and secondary outcomes.
49	methods		Reference to where other details of the statistical analysis plan can be
50			found, if not in the protocol (p.25-26)
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53		20b	Methods for any additional analyses (eg, subgroup and adjusted
54			analyses) (p.26)
55			
56		20c	Definition of analysis population relating to protocol non-adherence
57			(eg, as randomised analysis), and any statistical methods to handle
58			missing data (eg, multiple imputation) (p.25)
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Methods: Monitoring

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4 Data monitoring 21a Composition of data monitoring committee (DMC); summary of its role
5 and reporting structure; statement of whether it is independent from
6 the sponsor and competing interests; and reference to where further
7 details about its charter can be found, if not in the protocol.
8 Alternatively, an explanation of why a DMC is not needed (p.24-25)
9
10 21b Description of any interim analyses and stopping guidelines, including
11 who will have access to these interim results and make the final
12 decision to terminate the trial (p.23-24)
13
14
15 Harms 22 Plans for collecting, assessing, reporting, and managing solicited and
16 spontaneously reported adverse events and other unintended effects
17 of trial interventions or trial conduct (p.29)
18
19 Auditing 23 Frequency and procedures for auditing trial conduct, if any, and
20 whether the process will be independent from investigators and the
21 sponsor (p.24)
22
23

Ethics and dissemination

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26 Research ethics 24 Plans for seeking research ethics committee/institutional review board
27 approval (REC/IRB) approval (p.28)
28
29 Protocol 25 Plans for communicating important protocol modifications (eg,
30 amendments changes to eligibility criteria, outcomes, analyses) to relevant parties
31 (eg, investigators, REC/IRBs, trial participants, trial registries, journals,
32 regulators) (p.28-29)
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35 Consent or assent 26a Who will obtain informed consent or assent from potential trial
36 participants or authorised surrogates, and how (see Item 32) (p.23-24)
37
38 26b Additional consent provisions for collection and use of participant data
39 and biological specimens in ancillary studies, if applicable (p.23)
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41 Confidentiality 27 How personal information about potential and enrolled participants will
42 be collected, shared, and maintained in order to protect confidentiality
43 before, during, and after the trial (p.24)
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46 Declaration of 28 Financial and other competing interests for principal investigators for
47 interests the overall trial and each study site (p.2)
48
49 Access to data 29 Statement of who will have access to the final trial dataset, and
50 disclosure of contractual agreements that limit such access for
51 investigators (p.30)
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53 Ancillary and 30 Provisions, if any, for ancillary and post-trial care, and for
54 post-trial care compensation to those who suffer harm from trial participation (p.24-
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| 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) |

16 Appendices

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|-------------------------------|----|---|
| 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) |

25 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013
26 Explanation & Elaboration for important clarification on the items. Amendments to the
27 protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT
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BMJ Open

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

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Primary Subject Heading:	Addiction
Secondary Subject Heading:	Public health, Mental health, Addiction
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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 OMPRIIS 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 OMPRIIS 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

ONLINE-BASED INTERVENTION FOR INTERNET USE DISORDER

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24 (approval no 19-6779). Findings will be disseminated through presentations, peer-reviewed
25 journals and conferences.

26 **Trial registration number.** DRKS00019925.

28 **Trial registration number:** German Clinical Trials Register (DRKS), ID: DRKS00019925,

29 Date of registration: 13.03.2020.

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

34 **Strengths and limitations of the study:**

- 35 - The study uses a multicentre randomised design with a waitlist control group.
- 36 - Follow-up time points of 6 weeks and 6 months allow for a robust evaluation of the effect of
37 the online-based motivational intervention (OMPRIS) on IUD affected persons' outcomes.
- 38 - Diagnosticians, therapists, and outcome assessors are blind to participants' allocation.
- 39 - In addition to the clinical efficacy of the OMPRIIS intervention, a cost-effectiveness and a cost-
40 utility analysis will also be performed.
- 41 - 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].

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4 67 In the last decades, IUD has increased dramatically worldwide with prevalence rates
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6 68 ranging between 2.6% in northern and western Europe and 10.9% in the Middle East with a
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8 69 global average prevalence of 6.0% [8]. In German-speaking countries, the prevalence rates of
9
10 70 IUD range between 1.2% and 3.0% in German [9–11] and Austrian adolescents [12],
11
12 71 respectively. With regard to IGD (as the most frequent IUD), the global prevalence was recently
13
14 72 reported to be 3.05% [13].

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16
17 73 Individuals with IUD show a persistent or recurrent pattern of Internet use that is
18
19 74 characterised by impaired control regarding the onset, intensity, and duration of usage [7]. The
20
21 75 increased priority given to Internet activities leads to neglect of daily activities and life interests,
22
23 76 and IUD is associated with social, physical, and mental burden [14,15]. In addition, high
24
25 77 comorbidity with psychiatric disorder has been reported, especially depressive disorders, anxiety
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27 78 disorders, attention deficit hyperactive disorder, substance use disorders, and impulse control
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29 79 disorders [16–21].
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35 81 **1.2 Evidence of treatment for Internet use disorders**

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38 82 Currently, there are only a few empirical studies investigating IUD and IGD therapy
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40 83 approaches using the scientific standard of a RCT design [22–24]. A recent meta-analysis
41
42 84 demonstrated high efficacy (12 studies with a total of 580 patients) for cognitive-behavioral
43
44 85 therapy (CBT) in reducing IGD symptoms ($g = 0.92$; [0.50, 1.34]), depression ($g = 0.80$, [0.21,
45
46 86 1.38]), and anxiety ($g = 0.55$, [0.17, 0.93]) [23]. Moreover, interventions based on the
47
48 87 motivational interviewing (MI) approach have already been examined in many areas of medicine
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50 88 [25]. The effectiveness of MI has been reported in particular for substance-related addictions and
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52 89 pathological gambling [25,26]. For IUDs, there are only few studies that have systematically
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90 examined MI approaches, but it has been widely discussed as a therapeutic option for IUD
91 patients [27–31].

93 **1.3 eHealth interventions in addictive disorders**

94 Internet-based and eHealth interventions (e.g., for depression and anxiety disorders) have
95 been reported as effective treatment options with medium to large effect sizes [32,33]. Also,
96 Internet-based and eHealth interventions have been examined in the areas of (mainly substance)
97 addiction [34,35]. A systematic review in 2016 found a total of 16 studies testing Internet-related
98 interventions in substance addiction (11 studies in smoking, drinking, and opioid abuse) and
99 behavioural addictions (5 studies in pathological gambling). Although only five of the 16 studies
100 mentioned effect sizes ($d = 0.83 - 1.72$), all studies reported positive treatment outcomes for their
101 respective addictive behaviour [36]. To date, only few studies have examined general eHealth
102 interventions for IUD and IGD [37]. A Chinese pilot study using an online self-help approach on
103 65 university students with high scores for problematic Internet use, divided into four
104 experimental arms, showed significant differences at the follow-up measurement, but no
105 differences were detected between the four intervention groups. This study used MI techniques
106 as main intervention [29]. Furthermore, a recent study protocol presenting an ongoing
107 randomised controlled trial of an eCoach guided Internet-based intervention for IUD has recently
108 been published [27].

109 Our research group performed a preliminary uncontrolled study between 2016 and 2018
110 exploring an online outpatient service for Internet addiction (OASIS) with only two offered
111 webcam sessions [38]. The aim was to test whether individuals with IUD can generally be
112 reached via the Internet and to refer them to conventional medical treatment close to their place

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3 113 of residence. Finally, 140 individuals with a minimal level of problematic Internet use
4
5 114 participated in one or two offered consulting sessions with a moderate referral quote of 30%. The
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7
8 115 referral was, however, more successful when participants were referred to the clinic or therapists
9
10 116 they knew from online consulting (referral rate 93%) underlining the importance of relationship
11
12 117 constancy in (online-based) therapy. Despite the low number of only two offered sessions, the
13
14 118 intervention showed a small to medium significant reduction of time spent online (-1.23 h/d; $d =$
15
16 119 0.3) and IUD symptoms ($d = 0.5$) measured by self-reporting questionnaires in post-tests.
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18
19 120 However, this preliminary study omitted a control group and follow-up [38].
20

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22 121 To the best of our knowledge, results of evidence-based randomised controlled studies
23
24 122 investigating webcam-based intervention for IGD or IUD have not been published yet.
25

26 123

27 28 124 **1.4 Aims of the study**

29
30 125 The aim of this study is to measure the efficacy and the utilisation of a new and
31
32 126 innovative online-based intervention (OMPRIS) for reducing IUD and IGD symptoms and
33
34 127 increasing treatment motivation compared to a waiting control group. It is hypothesised that the
35
36 128 OMPRIS intervention will reduce symptoms of IUD and IGD, and will heighten the motivation
37
38 129 for behaviour modification concerning media use. OMPRIS is also intended to help IUD and
39
40 130 IGD patients access conventional treatments. It is hypothesised that the OMPRIS intervention
41
42 131 will increase the referral rate to (specialised) mental health care.
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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

158 platform that offers user accounts, video chat, appointment management, a psychological test
159 battery, and teaching aids. The platform was developed per requirements of current protection of
160 data privacy. Participation in OMPRIS is browser-based, requires no software download, and is
161 complimentary. Participants can register at www.onlinesucht-hilfe.com.

2.3 Participants and recruitment

164 In total, 162 individuals suffering from problematic or addictive use of Internet
165 applications and video games, who meet the eligibility criteria and will consent to participate in
166 the study, will be recruited. The calculation of the sample size is reported in paragraph 2.11.
167 Inclusion criteria are as follows: problematic or addictive use of Internet applications according
168 to the DSM-5 criteria and the ICD-11 criteria for IGD as assessed via a self-report scale
169 (Assessment of Internet and Computer Game Addiction, AICA-S [39,40]) and a structured
170 clinical expert rating (Assessment of Internet and Computer Game Addiction, AICA-SKI:IBS
171 [41]); legal age of at least 16 years old (with the informed consent of parents); constant access to
172 the Internet via webcam, microphone, and email address; sufficient knowledge of the German
173 language; informed consent to dissolve pseudonymisation in case of emergency (i.e. concrete
174 suicidal tendency). Exclusion criteria are psychotic disorders (past or present); learning
175 disabilities/intellectual impairment; substance abuse within the past six months; active suicidal
176 thoughts or intentions; a co-morbid somatic disease with endocrinological medication causing
177 impulsive behaviours (e.g., Morbus Parkinson with dopaminergic medication); recent psychiatric
178 or psychotherapeutic treatment focusing primarily on IUD or IGD.

179 All subjects will be recruited online (www.onlinesucht-hilfe.com) by completing the
180 AICA-S [39,40] questionnaire indicating problematic Internet use or video gaming behaviour.

181 All subjects with positive screening results or interest in participation will be provided with
182 initial information about the study via a webcam call with experienced psychologists. During the
183 online eligibility appointment, the inclusion and exclusion criteria will be checked.

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

190 Inclusion criteria will be established during the eligibility assessment: pathological
191 Internet and video game use via the AICA-SKI:IBS interview, psychotic disorders, acute
192 suicidality, learning disabilities/intellectual impairments via the MINI interview, sufficient
193 knowledge of the German language via the ability to complete questionnaires and follow the
194 webcam-based informed consent procedure, and a co-morbid somatic disease with dopaminergic
195 medication as well as recent psychotherapeutic treatment focusing on IUD by self-report.
196 Motivation and willingness to attend the study will be assessed by self-report during the
197 informed consent procedure, emphasising the demands of the study in terms of effort and time.
198 The informed consent procedure will end by asking the participants whether they still wish to
199 participate in the study.

200

201 **2.4 Randomisation**

202 Sequential balancing randomisation, according to Borm et al. (2005), will be used as a
203 method that balances prognostic relevant factors in consecutive order [43]. In this method, each

204 factor is dealt with sequentially, and when new subjects enter the OMPRIS intervention, they are
205 allocated to a specific condition - the intervention group (IG) or the WLC group - that leads to
206 improved balance of the first factor over the arms. For example, if the balance of the first factor
207 is satisfactory, then the arm is allocated that leads to the improved balance of the second factor.
208 If all factors are balanced according to pre-defined imbalance levels, the new subject is randomly
209 assigned.

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

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

224 2.5 Intervention

225 The manualised OMPRIS intervention is a combined treatment programme mainly based
226 on the MI approach that has been shown as sufficient to improve health behaviour in various

227 medical diseases including addictive disorders [25,45–48]. Furthermore, OMPRIIS contains
228 treatment elements from cognitive behavioural therapy (CBT), (Internet-related) addiction
229 therapy [49], media education, and social counselling. The primary outcome will be measured
230 constantly after four weeks of intervention (measurement points: T0 baseline, T1 mid-
231 intervention, and T2 post intervention, see Figure 1 & Table 2). During these four weeks, the
232 participants will be offered up to eight webcam-based psychological treatment sessions and one
233 or two social support sessions. In addition, a detailed diagnostic webcam session will be offered
234 one week before and one week after the intervention. In total, a participant can thus attend up to
235 12 webcam sessions. The number of attended sessions will be assessed. Two follow-up
236 measurements will be conducted 6 weeks (T3) and 6 months (T4) after intervention. The 50-
237 minutes long webcam-based psychological sessions will be implemented twice a week (= eight
238 sessions in four weeks) via our study platform. Table 1 shows the treatment phases and strategies
239 during the early, middle, and termination phases.

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

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

Table 1: OMPRIIS 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)

257

258 **2.6 Blinding**

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

269

270 **2.7 Outcome assessment**

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

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274 intervention). All assessments will be automatically offered to the participants at the correct
 275 times via the OMPRIS software following the study protocol (see Table 2 for the study's
 276 schedule). If assessments are not applied within the scheduled time frame, participants will
 277 receive reminders via email and telephone.

278

279 <PLEASE INSERT FIGURE 1 HERE>

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

283

284

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 standardised 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.

285

2.8 Primary outcome: Problematic Internet use

Assessment 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 $\alpha = .89$) 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

304 and assessment by experts [49]. It is conducted at baseline, mid-intervention, post-intervention,
305 and at follow-up.

307 **2.9 Secondary outcomes**

308 *Stage of Readiness and Treatment Eagerness for Internet use disorder (iSOCRATES)*

309 [38]. The iSOCRATES scale is a self-report measure assessing the stage of readiness and
310 treatment eagerness for IUD. It was adapted from the German SOCRATES scale for alcohol
311 addiction consisting of 19 motivation-relevant statements whereon participants give their
312 agreement on a five-point Likert scale [54,55]. Cronbach's alpha of the measure has shown to be
313 $\alpha = .60$ for the scale 'ambivalence', $\alpha = .83$ for 'taking steps', and $\alpha = .85$ for 'recognition' [55].
314 It will be conducted at baseline, mid-intervention, post-intervention, and at follow-up.

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

319 *Patient Health Questionnaire-9* [58] (PHQ-9, German translation [59]). This nine-item
320 patient questionnaire is a self-report version of the PRIME-MD diagnostic instrument for
321 common mental disorders [60]. The PHQ-9 is a depression module, which scores each of nine
322 DSM-IV criteria as '0' (not at all) to '3' (nearly every day). The internal consistency has been
323 found to be excellent ($\alpha = .83-.92$) [61]. It will be conducted at baseline, post-intervention, and at
324 follow-up.

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

327 criteria on a four-point Likert scale. The internal consistency has shown to be excellent ($\alpha = .89$)
328 [62]. It will be conducted at baseline, post-intervention, and at follow-up.

329 *General life satisfaction (L-1)* [64]. The short L-1 scale for recording general life
330 satisfaction consists of only one item with the following wording: ‘How satisfied are you at
331 present, all in all, with your life?’. The 11 answer categories of the L-1 range from ‘not satisfied
332 at all’ to ‘completely satisfied’. The reliability has been tested by test-retest reliability, which has
333 reported to be $r_{tt} = .67$ [64]. It will be conducted at baseline, post-intervention, and at follow-up.

334 *General self-efficacy scale* [65] (GSE, German translation SWE [66]). The GSE scale
335 measures self-perceived self-efficacy and consists of ten items assessing the respondent’s belief
336 in the ability to respond to novel or difficult situations adequately and to cope with a large
337 variety of stressors. It is scored on a four-point scale from ‘1’ (not at all true) to ‘4’ (exactly
338 true). A comparison of the GSE in 23 countries shows a generally good to excellent internal
339 consistency, which varies between $\alpha = .76$ to $.90$. In German samples, Cronbach's alpha varies
340 between $.80$ and $.90$ [67]. It will be conducted at baseline, post-intervention, and at follow-up.

341 *Big Five Inventory* [68] (BFI-10). The BFI-10 is a self-report measure containing ten
342 items to assess Big Five personality traits. It has five subscales with two bidirectional items for
343 each of the personality factors. The ten items are rated on a five-point Likert scale wherein the
344 subjects choose from responses ranging from ‘strongly disagree’ to ‘strongly agree’. The
345 reliability has been tested by test-retest reliability, which has been found to be good ($r_{tt} = .58-.84$)
346 [69]. The BFI-10 will be conducted only once at baseline.

347 *Helping Alliance Questionnaire* [70] (HAQ, German translation [71]). The HAQ is a
348 highly relevant instrument to assess the therapeutic alliance and can be used both as the patient’s
349 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 ($\alpha = .75-.89$ on the HAQ-P and $\alpha = .63-.85$ 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.

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3 373 The *Mini-International Neuropsychiatric Interview* [42] (MINI, V7.0.) is a short
4
5 374 structured diagnostic interview developed for DSM-5 and ICD-10 psychiatric disorders. With an
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7 375 administration time of approximately 15-20 minutes, it was designed to meet the need for a short
8
9 376 but accurate structured psychiatric interview for multicentre clinical trials and epidemiology
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11 377 studies. The MINI will be conducted only once at baseline to detect psychiatric comorbidities.
12
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14 378 The *System Usability Scale* (SUS) [76] is a short, reliable tool for measuring usability in a
15
16 379 wide variety of services, including software, websites, and applications. It consists of ten items
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18 380 on a five-point Likert scale from 'strongly agree' to 'strongly disagree'. It will be conducted at
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20 381 post-intervention.
21
22

23 382 *Satisfaction with OMPRIS intervention* is measured by ten items on a five-point Likert
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25 383 scale from 'strongly disagree' to 'strongly agree' (e.g., 'OMPRIS helped me to accept support
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27 384 for the first time because of my (problematic) Internet use', or 'I would recommend OMPRIS to
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29 385 my friends'). It will be conducted at post-intervention.
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32 386 *Health economics information* is determined by a self-report questionnaire asking for the
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34 387 resource use of current and past medical and psychotherapeutic inpatient and outpatient
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36 388 treatments, medication, rehabilitation treatments, and assisted living services. Additionally, data
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38 389 on earning capacity, social security system data (e.g., incapacity for work, unemployability, etc.),
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40 390 the delay of vocational education, and housing situation will be collected. In order to determine
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42 391 the intervention costs, information is collected on one-time intervention costs (e.g., software,
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44 392 conceptual design, implementation costs, etc.) and ongoing intervention costs (e.g., material and
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46 393 personnel costs for therapy sessions, software maintenance, etc.).
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49 394 *Referral to other organisations and further treatments* is assessed by three items at post-
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51 395 intervention and follow-up.
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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].

407

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

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2
3 419 of researchers and practitioners in the German-speaking countries who are working on IUD and
4
5 420 GD within the framework of a large-scale cooperation.
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10 422 **2.13 Data collection and management**

12 423 Data collection will be performed online via the OMPRIS software environment
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14 424 (www.onlinesucht-hilfe.com). All data will be stored on protected servers in Germany. Data will
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16
17 425 be entered into an electronic database on an ongoing basis, and the database and outputs will be
18
19 426 regularly backed up to a remote server. The computer databases will not contain information
20
21 427 about the participants' allocation, which will be added as required before the analysis.
22

23
24 428 Data completeness will be automatically monitored by the OMPRIS software
25
26 429 environment. Sensitive participant's data will be stored separately from research data in a second
27
28 430 database and will be accessible only to members (admin) of the principal research team. The
29
30 431 principal investigator (JDH) will have primary responsibility for verifying the integrity of the
31
32 432 databases and will be responsible for managing and archiving the databases post-analysis.
33
34

35 433

38 434 **2.14 Trial management and monitoring**

40 435 The principal investigator (JDH) has primary responsibility for the conduct of the trial.
41
42 436 The management of processes will be monitored and discussed in regular meetings with the
43
44 437 researchers involved in data collection. The trial management group is composed of LB, MP,
45
46 438 NT, and JDH and will be in regular contact with all partners of the study.
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52 440 **2.15 Adverse event monitoring**

Adverse events (AEs) will be monitored by trial researchers conducting the OMPRIIS intervention on an ongoing basis and post-intervention, recorded via an 'adverse event comment function' in the OMPRIIS 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 OMPRIIS 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 OMPRIIS 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

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3 463 be calculated via analysis of covariance for IUD symptoms with the co-variables of baseline
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5 464 value, gender, age, and type of IUD.
6

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8 465 It is expected that missing data will not be ‘missing-at-random’ based on the assumption
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10 466 that the occurrence of the missing value in a variable can be fully explained by the characteristics
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12 467 of the remaining variables. Therefore, diverse sensitivity analyses will be calculated with
13
14 468 different strategies for missing data replacement. Details of statistical analyses will be defined in
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16 469 a statistical analysis plan. Potential group imbalances in spite of randomisation will be tested via
17
18 470 t-tests for continuous variables and Pearson’s chi-squared test. Exploratory analyses will
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20 471 evaluate potential predictors for therapeutic success via linear and logistic regression models.
21
22 472 The statistical analyses will be carried out with R Project [79] and IBM SPSS Statistics [80].
23

24 473 **Method of health economic evaluation**

25
26 474 The health economic evaluation of OMPRIIS contains both a cost-effectiveness and a
27
28 475 cost-utility analysis. Additionally, a cost-of-illness study regarding persons with IGD and IUD
29
30 476 will be done. The evaluation will include both direct and indirect costs, which will be calculated
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32 477 from statutory health insurance perspective as well as from a societal perspective. The analyses
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34 478 will be using a bottom-up approach. Data on the resource use will be collected at baseline T0b,
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36 479 four weeks later at T2, and, again, seven weeks later at T3 for both groups.
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40 480 A standardised health economic questionnaire has been developed, which includes
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42 481 questions concerning health care resource use, such as outpatient physician contacts,
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44 482 hospitalisation, inpatient and outpatient rehabilitation, occupational therapy, reduction in/loss of
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46 483 earning capacity, and disability. Moreover, participants will be asked about socio-demographic
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48 484 data, such as age, gender, graduation, on-the-job training, and cash benefits from different
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50 485 sources. Prices for all resource use will be collected using different sources.
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3 486 The Lauer Taxe® will be used to determine medication selling prices for the German
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5 487 market. For inpatient and outpatient care, hospitalisation and rehabilitation recommendations
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7 488 will be obeyed according to published standardised procedures in health economic evaluation
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10 489 and standardised prices [81–84]. Costs will be calculated as the product of the number of
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12 490 consumed resources and estimated prices and summarised to compute the overall costs. The
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14 491 analyses will be based on the calculation of mean values and the standard deviations of resource
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16 492 use and health care costs. According to the method of difference-in-difference, health care costs
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18 493 of the two study arms will be analysed in terms of statistically significant differences using the
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20 494 Mann-Whitney U test. To consider uncertainty, sensitivity analyses will be performed.
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27 496 3. Discussion

28 497 The COVID-19 pandemic has massively increased the acceptance of webcam-based
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30 498 communications in professional and medical contexts. There are strong arguments to support the
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32 499 use of online-based treatment for IUD patients: (1) Individuals affected by IUD are used to
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34 500 spending a lot of time on the Internet. Their resistance or rejection to use digital applications can
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36 501 thus be considered low. (2) Since motivation, conscientiousness, and impulse to change Internet
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38 502 use behaviour have been reported as low in IUD [85,86], an easily accessible and low-threshold
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40 503 approach is essential in IUD or IGD. (3) The psychotherapeutic care situation, especially in the
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42 504 outpatient sector, is currently insufficient, often leading to long waiting periods for an initial
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44 505 consultation [87]. This latency might increase an additional loss of motivation. A quick and
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46 506 uncomplicated initial offer might be important to restructure IUD behaviour. (4) Co-morbid
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48 507 disorders, like depressive or anxiety disorders, make it challenging for individuals with IUD or
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50 508 IGD to get into conventional outpatient therapy. Internet-based interventions have already shown
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3 509 good therapeutic effects in many areas of mental disorders and addiction medicine [32–35]. In
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5 510 addition, telemedicine can make evidence-based treatment strategies accessible to a broad patient
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7 511 population no matter where they live. Therefore, Internet-based interventions such as OMPRIS
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10 512 can be seen as an innovative way to reach individuals with IUDs and IGD more effectively and
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12 513 quickly than conventional approaches.

14 514 OMPRIS is a health care research project, which offers a standardised therapeutic
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16 515 Internet-based intervention to all interested people aged 16 or older from all over Germany. We
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18 516 expect participation from individuals who want to make positive changes in their media use and
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20 517 use professional help to do so. Due to the low barriers, we hypothesise that OMPRIS will nearly
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22 518 represent the general population of individuals suffering from IUD and IGD (e.g., in terms of
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24 519 gender distribution), and will therefore correspond more closely to representative
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26 520 epidemiological studies [9,11] rather than to clinical experiences from specialised IUD outpatient
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28 521 clinics where mainly men are in treatment [51,88].
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35 523 **4. Ethics and dissemination**

37 524 **4.1 Ethical issues**

38 525 Clinical protocol and written informed consent were approved by the Ethics Committee
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40 526 for the Faculty of Medicine, Ruhr University Bochum, approval no. 19-6779. Furthermore, the
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42 527 main ethical approval was confirmed by the ethics committees of all cooperating centres. All
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44 528 procedures described in the clinical trial protocol follow the Good Clinical Practice (GCP)
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46 529 guidelines and the ethical principles described in the current revision of the Declaration of
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48 530 Helsinki. The study will be carried out in keeping with local legal and regulatory requirements.
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51 531 The main ethical issues are informed consent, the use of OMPRIS intervention, the use of an
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532 online-based intervention, and protection of data privacy, the inclusion of underage persons with
533 parental consent, technical procedures of online participation and online declaration of consent,
534 and the WLC group design.

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

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

546 **4.2 Dissemination plan**

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

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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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8 **5.4 Data sharing statement**
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10 581 In accordance with the ICMJE's data sharing statement individual participants data, that
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12 582 underlies the results reported in the main OMPRIS article, will be shared after de-identification.
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14 583 Data will be shared with investigators whose proposed use of the data has been proven by an
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16 584 independent review committee identified for this purpose at the earliest 9 months following the
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18 585 publication of the main OMPRIS article. As related document, the OMPRIS study protocol will
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20 586 be published. Proposals must be submitted via Email (jan.dieris-hirche@rub.de) up to 36 months
21
22 587 following the publication of the main OMPRIS article. Data will be made available for statistical
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24 588 meta-analyses by our research data cloud.
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46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

References

- 590
- 591 1 Bundesamt für Statistik. Statistisches Jahrbuch Deutschland und Internationales 2019.
592 2019. https://www.statistischebibliothek.de/mir/receive/DEAusgabe_mods_00004527
593 (accessed 21 Aug 2020).
- 594 2 DAK-Gesundheit. Mediensucht 2020 – Gaming und Social Media in Zeiten von Corona.
595 DAK-Längsschnittstudie: Befragung von Kindern, Jugendlichen (12 – 17 Jahre) und deren
596 Eltern. Hamburg: 2020. [https://www.dak.de/dak/bundesthemen/computerspielsucht-](https://www.dak.de/dak/bundesthemen/computerspielsucht-2296282.html#/)
597 [2296282.html#/](https://www.dak.de/dak/bundesthemen/computerspielsucht-2296282.html#/) (accessed 21 Aug 2020).
- 598 3 Ko CH, Yen JY. Impact of COVID-19 on gaming disorder: Monitoring and prevention. *J*
599 *Behav Addict* 2020;**9**:187–9. doi:10.1556/2006.2020.00040
- 600 4 Balhara YPS, Kattula D, Singh S, *et al.* Impact of lockdown following COVID-19 on the
601 gaming behavior of college students. *Indian J Public Health* 2020;**64**:S172–6.
602 doi:10.4103/ijph.IJPH_465_20
- 603 5 King DL, Delfabbro PH, Billieux J, *et al.* Problematic online gaming and the COVID-19
604 pandemic. *J Behav Addict* 2020;**9**:184–6. doi:10.1556/2006.2020.00016
- 605 6 Montag C, Wegmann E, Sariyska R, *et al.* How to overcome taxonomical problems in the
606 study of Internet use disorders and what to do with “smartphone addiction”? *J Behav*
607 *Addict* 2019;**1**–7. doi:10.1556/2006.8.2019.59
- 608 7 WHO. Gaming disorder, predominantly online. 2019. [https://icd.who.int/browse11/l-](https://icd.who.int/browse11/l-m/en#/http%3A%2F%2Fid.who.int%2Ficd%2Fentity%2F338347362)
609 [m/en#/http%3A%2F%2Fid.who.int%2Ficd%2Fentity%2F338347362](https://icd.who.int/browse11/l-m/en#/http%3A%2F%2Fid.who.int%2Ficd%2Fentity%2F338347362)
- 610 8 Cheng C, Li AY. Internet addiction prevalence and quality of (real) life: a meta-analysis
611 of 31 nations across seven world regions. *Cyberpsychol Behav Soc Netw* 2014;**17**:755–60.
612 doi:10.1089/cyber.2014.0317

- 1
2
3 613 9 Rumpf H-J, Meyer C, Kreuzer A, *et al.* Prävalenz der Internetabhängigkeit (PINTA)
4
5 614 Bericht an das Bundesministerium für Gesundheit. 2011.
6
7
8 615 10 Wölfling K, Thalemann R, Grüsser-Sinopoli SM. Computerspielsucht: Ein
9
10 616 psychopathologischer Symptomkomplex im Jugendalter. *Psychiatr Prax* 2008;**35**:226–32.
11
12 617 doi:10.1055/s-2007-986238
13
14 618 11 Rehbein F, Kliem S, Baier D, *et al.* Prevalence of internet gaming disorder in German
15
16 619 adolescents: diagnostic contribution of the nine DSM-5 criteria in a state-wide
17
18 620 representative sample. *Addiction* 2015;**110**:842–51. doi:10.1111/add.12849
19
20
21 621 12 Batthyány D, Müller KW, Benker F, *et al.* Computer game playing: clinical characteristics
22
23 622 of dependence and abuse among adolescents. *Wien Klin Wochenschr* 2009;**121**:502–9.
24
25 623 doi:10.1007/s00508-009-1198-3
26
27
28 624 13 Stevens MW, Dorstyn D, Delfabbro PH, *et al.* Global prevalence of gaming disorder: A
29
30 625 systematic review and meta-analysis. *Aust New Zeal J Psychiatry*
31
32 626 2020;:000486742096285. doi:10.1177/0004867420962851
33
34
35 627 14 Greenfield DN. Psychological characteristics of compulsive internet use: A preliminary
36
37 628 analysis. *Cyberpsychology Behav* 1999;**2**:403–12. doi:10.1089/cpb.1999.2.403
38
39
40 629 15 Young KS. Internet addiction: The emergence of a new clinical disorder.
41
42 630 *Cyberpsychology Behav* 1998;**1**:237–44. doi:10.1089/cpb.1998.1.237
43
44
45 631 16 González-Bueso V, Santamaría JJ, Fernández D, *et al.* Association between Internet
46
47 632 Gaming Disorder or Pathological Video-Game Use and Comorbid Psychopathology: A
48
49 633 Comprehensive Review. *Int J Environ Res Public Health* 2018;**15**.
50
51 634 doi:10.3390/ijerph15040668
52
53
54 635 17 Carli V, Durkee T, Wasserman D, *et al.* The association between pathological internet use
55
56
57
58
59
60

- 636 and comorbid psychopathology: a systematic review. *Psychopathology* 2013;**46**:1–13.
- 637 doi:10.1159/000337971
- 638 18 Andreassen CS, Billieux J, Griffiths MD, *et al.* The relationship between addictive use of
639 social media and video games and symptoms of psychiatric disorders: A large-scale cross-
640 sectional study. *Psychol Addict Behav* 2016;**30**:252–62. doi:10.1037/adb0000160
- 641 19 Dieris-Hirche J, Bottel L, Bielefeld M, *et al.* Media use and Internet addiction in adult
642 depression: A case-control study. *Comput Human Behav* 2017;**68**.
643 doi:10.1016/j.chb.2016.11.016
- 644 20 Bielefeld M, Drews M, Putzig I, *et al.* Comorbidity of Internet use disorder and attention
645 deficit hyperactivity disorder: Two adult case-control studies. *J Behav Addict* 2017;**6**:490–
646 504. doi:10.1556/2006.6.2017.073
- 647 21 Steinbüchel TA, Herpertz S, Külpmann I, *et al.* Internet Addiction, Suicidality and Non-
648 Suicidal Self-Harming Behavior - A Systematic Review. *PPmP Psychother Psychosom*
649 *Medizinische Psychol* 2018;**68**:451–61. doi:10.1055/s-0043-120448
- 650 22 King DL, Delfabbro PH, Wu AMS, *et al.* Treatment of Internet gaming disorder: An
651 international systematic review and CONSORT evaluation. *Clin Psychol Rev*
652 2017;**54**:123–33. doi:10.1016/j.cpr.2017.04.002
- 653 23 Stevens MWR, King DL, Dorstyn D, *et al.* Cognitive-behavioral therapy for Internet
654 gaming disorder: A systematic review and meta-analysis. *Clin. Psychol. Psychother.*
655 2019;**26**:191–203. doi:10.1002/cpp.2341
- 656 24 Winkler A, Dörsing B, Rief W, *et al.* Treatment of internet addiction: a meta-analysis.
657 *Clin Psychol Rev* 2013;**33**:317–29. doi:10.1016/j.cpr.2012.12.005
- 658 25 Frost H, Campbell P, Maxwell M, *et al.* Effectiveness of Motivational Interviewing on

- 1
2
3 659 adult behaviour change in health and social care settings: A systematic review of reviews.
4
5 660 PLoS One. 2018;**13**:e0204890. doi:10.1371/journal.pone.0204890
6
7
8 661 26 Yakovenko I, Quigley L, Hemmelgarn BR, *et al*. The efficacy of motivational
9
10 662 interviewing for disordered gambling: Systematic review and meta-analysis. *Addict Behav*
11
12 663 2015;**43**:72–82. doi:10.1016/j.addbeh.2014.12.011
13
14
15 664 27 Saruhanjan K, Zarski A-C, Schaub MP, *et al*. Design of a Guided Internet- and Mobile-
16
17 665 Based Intervention for Internet Use Disorder—Study Protocol for a Two-Armed
18
19 666 Randomized Controlled Trial. *Front Psychiatry* 2020;**11**:190.
20
21 667 doi:10.3389/fpsyt.2020.00190
22
23
24 668 28 Loton D, Lubman D. Just one more level: Identifying and addressing internet gaming
25
26 669 disorder within primary care. *Aust Fam Physician* 2016;**45**:48–
27
28 670 52.[http://www.racgp.org.au/afp/2016/januaryfebruary/just-one-more-level-identifying-](http://www.racgp.org.au/afp/2016/januaryfebruary/just-one-more-level-identifying-and-addressing-internet-gaming-disorder-within-primary-care/)
29
30 671 [and-addressing-internet-gaming-disorder-within-primary-care/](http://www.racgp.org.au/afp/2016/januaryfebruary/just-one-more-level-identifying-and-addressing-internet-gaming-disorder-within-primary-care/)
31
32
33 672 29 Su W, Fang X, Miller JK, *et al*. Internet-based intervention for the treatment of online
34
35 673 addiction for college students in China: A pilot study of the healthy online self-helping
36
37 674 center. *Cyberpsychology, Behav Soc Netw* 2011;**14**:497–503.
38
39 675 doi:10.1089/cyber.2010.0167
40
41
42 676 30 Kim H. Exercise rehabilitation for smartphone addiction. *J Exerc Rehabil* 2013;**9**:500–5.
43
44 677 doi:10.12965/jer.130080
45
46
47 678 31 van Rooij AJ, Zinn MF, Schoenmakers TM, *et al*. Treating Internet Addiction With
48
49 679 Cognitive-Behavioral Therapy: A Thematic Analysis of the Experiences of Therapists. *Int*
50
51 680 *J Ment Health Addict* 2012;**10**:69–82. doi:10.1007/s11469-010-9295-0
52
53
54 681 32 Van't Hof E, Cuijpers P, Stein DJ. Self-help and Internet-guided interventions in
55
56
57
58
59
60

- 1
2
3 682 depression and anxiety disorders: a systematic review of meta-analyses. *CNS Spectr.*
4
5 683 2009;**14**:34–40. doi:10.1017/s1092852900027279
6
7
8 684 33 Johansson R, Andersson G. Internet-based psychological treatments for depression. *Expert*
9
10 685 *Rev. Neurother.* 2012;**12**:861–70. doi:10.1586/ern.12.63
11
12 686 34 Kruse CS, Lee K, Watson JB, *et al.* Measures of effectiveness, efficiency, and quality of
13
14 687 telemedicine in the management of alcohol abuse, addiction, and rehabilitation:
15
16 688 Systematic review. *J. Med. Internet Res.* 2020;**22**:e13252. doi:10.2196/13252
17
18
19 689 35 Lin L (Allison), Casteel D, Shigekawa E, *et al.* Telemedicine-delivered treatment
20
21 690 interventions for substance use disorders: A systematic review. *J Subst Abuse Treat*
22
23 691 2019;**101**:38–49. doi:10.1016/j.jsat.2019.03.007
24
25
26 692 36 Chebli JL, Blaszczynski A, Gainsbury SM. Internet-Based Interventions for Addictive
27
28 693 Behaviours: A Systematic Review. *J. Gambl. Stud.* 2016;**32**:1279–304.
29
30 694 doi:10.1007/s10899-016-9599-5
31
32
33 695 37 Lam LT, Lam MK. eHealth Intervention for Problematic Internet Use (PIU). *Curr.*
34
35 696 *Psychiatry Rep.* 2016;**18**. doi:10.1007/s11920-016-0747-5
36
37
38 697 38 te Wildt B. Entwicklung und Evaluation eines Online-Ambulanz-Service zur Diagnostik
39
40 698 und Beratung. Abschlussbericht An das Bundesministerium für Gesundheit. 2018.
41
42 699 https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Drogen_und_Sucht/Berichte/Abschlussbericht/Abschlussbericht_OASIS.pdf (accessed 8 May
43
44 700
45
46 701 2020).
47
48
49 702 39 Wölfling K, Müller KW, Beutel M. Reliabilität und Validität der Skala zum
50
51 703 Computerspielverhalten (CSV-S). *PPmP Psychother Psychosom Medizinische Psychol*
52
53 704 2011;**61**:216–24. doi:10.1055/s-0030-1263145
54
55
56
57
58
59

- 1
2
3 705 40 Wölfling K, Beutel ME, Müller KW. OSV-S - Skala zum Onlinesuchtverhalten. In: Geue
4
5 706 K, Strauß B, Brähler E, eds. *Diagnostische Verfahren in der Psychotherapie*. Göttingen: :
6
7 707 Hogrefe 2016. 362–6.
- 8
9
10 708 41 Müller KW, Wölfling K. AICA-SKI:IBS Strukturiertes klinisches Interview zu
11
12 709 Internetbezogenen Störungen * Handbuch. Mainz: 2017. [http://www.fv-
17 711 SKI_IBS.pdf](http://www.fv-
13
14 710 medienabhaengigkeit.de/fileadmin/images/Dateien/AICA-SKI_IBS/Handbuch_AICA-
15
16 711 SKI_IBS.pdf) (accessed 3 Dec 2019).
- 18
19 712 42 Sheehan D V., Lecrubier Y, Sheehan KH, *et al.* The Mini-International Neuropsychiatric
20
21 713 Interview (M.I.N.I.): The development and validation of a structured diagnostic
22
23 714 psychiatric interview for DSM-IV and ICD-10. In: *Journal of Clinical Psychiatry*. 1998.
24
25 715 22–33.
- 26
27
28 716 43 Borm GF, Hoogendoorn EH, Den Heijer M, *et al.* Sequential balancing: A simple method
29
30 717 for treatment allocation in clinical trials. *Contemp Clin Trials* 2005;**26**:637–45.
31
32 718 doi:10.1016/j.cct.2005.09.002
- 33
34
35 719 44 Böttel L, Bielefeld M, Steinbuechel T, *et al.* Evaluation of an Online Ambulatory Service
36
37 720 for Internet Addicts (OASIS). *J Behav Addict* 2018;**7**:45.
- 38
39
40 721 45 Lawrence P, Fulbrook P, Somerset S, *et al.* Motivational interviewing to enhance
41
42 722 treatment attendance in mental health settings: A systematic review and meta-analysis. *J.*
43
44 723 *Psychiatr. Ment. Health Nurs*. 2017;**24**:699–718. doi:10.1111/jpm.12420
- 45
46
47 724 46 Palacio A, Garay D, Langer B, *et al.* Motivational Interviewing Improves Medication
48
49 725 Adherence: a Systematic Review and Meta-analysis. *J Gen Intern Med* 2016;**31**:929–40.
50
51 726 doi:10.1007/s11606-016-3685-3
- 52
53
54 727 47 Garcia-Caballero A, Torrens-Lluch M, Ramírez-Gendrau I, *et al.* The efficacy of

- 1
2
3 728 motivational intervention and cognitive-behavioral therapy for pathological gambling.
4
5 729 *Adicciones* 2018;**30**:217–22. doi:10.20882/adicciones.965
6
7
8 730 48 Petry NM, Ginley MK, Rash CJ. A systematic review of treatments for problem gambling.
9
10 731 *Psychol. Addict. Behav.* 2017;**31**:951–61. doi:10.1037/adb0000290
11
12 732 49 Wölfling K, Müller KW, Dreier M, *et al.* Efficacy of Short-term Treatment of Internet and
13
14 733 Computer Game Addiction: A Randomized Clinical Trial. *JAMA psychiatry* Published
15
16 734 Online First: 10 July 2019. doi:10.1001/jamapsychiatry.2019.1676
17
18
19 735 50 Müller KW, Glaesmer H, Brähler E, *et al.* Prevalence of internet addiction in the general
20
21 736 population: Results from a German population-based survey. *Behav Inf Technol*
22
23 737 2014;**33**:757–66. doi:10.1080/0144929X.2013.810778
24
25
26 738 51 Müller K, Beutel M, Wölfling K. A contribution to the clinical characterization of Internet
27
28 739 addiction in a sample of treatment seekers: Validity of assessment, severity of
29
30 740 psychopathology and type of co-morbidity. *Compr Psychiatry* 2014;**55**:770–7.
31
32 741 doi:10.1016/j.comppsy.2014.01.010
33
34
35 742 52 Müller K, Koch A, Beutel M, *et al.* Komorbide Internetsucht unter Patienten der
36
37 743 stationären Suchtrehabilitation: Eine explorative Erhebung zur klinischen Prävalenz.
38
39 744 *Psychiatr Prax* 2012;**39**:286–92. doi:10.1055/s-0032-1305120
40
41
42 745 53 Kuss DJ, Griffiths MD, Binder JF. Internet addiction in students: Prevalence and risk
43
44 746 factors. *Comput Human Behav* 2013;**29**:959–66. doi:10.1016/j.chb.2012.12.024
45
46
47 747 54 Hoyer J, Heidenreich T, Fecht J, *et al.* Studien der Veränderung in der stationären
48
49 748 Alkoholentwöhnungstherapie. *Verhaltenstherapie* 2003;**13**:31–8. doi:10.1159/000070497
50
51 749 55 Miller WR, Tonigan JS. Assessing drinkers' motivation for change: The Stages of Change
52
53 750 Readiness and Treatment Eagerness Scale (SOCRATES). *Psychol Addict Behav*

- 1
2
3 751 1996;**10**:81–9. doi:10.1037/0893-164X.10.2.81
- 4
5 752 56 Meerkerk G-J, Van Den Eijnden RJM, Vermulst AA, *et al.* The Compulsive Internet Use
6
7 Scale (CIUS): some psychometric properties. *Cyberpsychol Behav* 2009;**12**:1–6.
8 753
9
10 754 doi:10.1089/cpb.2008.0181
- 11
12 755 57 Meerkerk G, Van den Eijnden R, Vermulst, AA and Garretsen H. The Relationship
13
14 between Personality, Psychosocial Wellbeing and Compulsive Internet Use: The Internet
15 756 as Cyber Prozac? In: *Pwned* by the Internet*. Rotterdam: : Erasmus Universiteit
16
17 757 Rotterdam 2007. 86–101.
18 758
- 19
20 759 58 Spitzer RL, Kroenke K, Williams JB. Validation and utility of a self-report version of
21
22 PRIME-MD: the PHQ primary care study. Primary Care Evaluation of Mental Disorders.
23
24 760 Patient Health Questionnaire. *JAMA* 1999;**282**:1737–44.
25 761
- 26
27 762 59 Löwe B, Spitzer RL, Zipfel S, *et al.* Gesundheitsfragebogen für Patienten (PHQ-D).
28
29 Kompletteversion und Kurzform. 2. Auflage. Karlsruhe: 2002.
30
31 763
32
33 764 https://www.psycharchives.org/bitstream/20.500.12034/431/1/PT_9006490_ASKU-
34
35 765 [Manual_2012.PDF](#) (accessed 18 Oct 2019).
36
37 766 60 Haddad M, Walters P, Phillips R, *et al.* Detecting Depression in Patients with Coronary
38
39 Heart Disease: A Diagnostic Evaluation of the PHQ-9 and HADS-D in Primary Care,
40 767 Findings From the UPBEAT-UK Study. *PLoS One* 2013;**8**.
41
42 768
43
44 769 doi:10.1371/journal.pone.0078493
- 45
46
47 770 61 Cameron IM, Crawford JR, Lawton K, *et al.* Psychometric comparison of PHQ-9 and
48
49 771 HADS for measuring depression severity in primary care. *Br J Gen Pract* 2008;**58**:32–6.
50
51 772
52
53 773 62 Spitzer RL, Kroenke K, Williams JBW, *et al.* A brief measure for assessing generalized

- 1
2
3 774 anxiety disorder: The GAD-7. *Arch Intern Med* 2006;**166**:1092–7.
4
5 775 doi:10.1001/archinte.166.10.1092
6
7
8 776 63 Löwe B, Decker O, Müller S, *et al.* Validation and standardization of the generalized
9
10 777 anxiety disorder screener (GAD-7) in the general population. *Med Care* 2008;**46**:266–74.
11
12 778 doi:10.1097/MLR.0b013e318160d093
13
14
15 779 64 Beierlein C, Kovaleva A, László Z, *et al.* Eine Single-Item-Skala zur Erfassung der
16
17 780 Allgemeinen Lebenszufriedenheit: Die Kurzskala Lebenszufriedenheit-1 (L-1). 2014.
18
19 781 https://www.gesis.org/fileadmin/kurzskalen/working_papers/L1_WorkingPapers_2014-
20
21 782 33.pdf (accessed 18 Oct 2019).
22
23
24 783 65 Schwarzer R, Jerusalem M. Generalized Self-Efficacy scale. . In: Weinman J, Wright S,
25
26 784 Johnston M, eds. *Measures in health psychology: A user's portfolio. Causal and control*
27
28 785 *beliefs*. . Windsor, England: : NFER-NELSON. 1995. 35–7.
29
30
31 786 66 Schwarzer R, Jerusalem M. Skalen zur Erfassung von Lehrer- und Schülermerkmalen:
32
33 787 Dokumentation der psychometrischen Verfahren im Rahmen der Wissenschaftlichen
34
35 788 Begleitung des Modellversuchs Selbstwirksame Schulen. . Berlin: 1999.
36
37 789 <http://psychologie.de/schwarzer> (accessed 8 May 2020).
38
39
40 790 67 Scholz U, Doña BG, Sud S, *et al.* Is general self-efficacy a universal construct?
41
42 791 Psychometric findings from 25 countries. *Eur J Psychol Assess* 2002;**18**:242–51.
43
44 792 doi:10.1027//1015-5759.18.3.242
45
46
47 793 68 Rammstedt B, John OP. Measuring personality in one minute or less: A 10-item short
48
49 794 version of the Big Five Inventory in English and German. *J Res Pers* 2007;**41**:203–12.
50
51 795 doi:10.1016/j.jrp.2006.02.001
52
53
54 796 69 Rammstedt B, John OP. Measuring personality in one minute or less: A 10-item short
55
56
57
58
59

- 1
2
3 797 version of the Big Five Inventory in English and German. *J Res Pers* 2007;**41**:203–12.
4
5 798 doi:10.1016/j.jrp.2006.02.001
6
7
8 799 70 Alexander L, Luborsky L. The Penn Helping Alliance Scales. In: Greenberg LS, Pinosof
9
10 800 WM, eds. *Guilford clinical psychology and psychotherapy series. The psychotherapeutic*
11
12 801 *process: A research handbook*. Guilford Press 1986. 325–
13
14 802 66.<https://psycnet.apa.org/record/1987-97275-009> (accessed 8 May 2020).
15
16
17 803 71 Bassler M, Nübling R. Der ‘Helping Alliance Questionnaire’ (HAQ) von Luborsky.
18
19 804 *Psychotherapeut* 1995;**40**:23–
20
21 805 32.https://www.researchgate.net/publication/270645630_Helping_Alliance_Questionnaire
22
23 806 (accessed 8 May 2020).
24
25
26 807 72 Eich HS, Kriston L, Schramm E, *et al.* The German version of the helping alliance
27
28 808 questionnaire: Psychometric properties in patients with persistent depressive disorder.
29
30 809 *BMC Psychiatry* 2018;**18**:107. doi:10.1186/s12888-018-1697-8
31
32
33 810 73 Herdman M, Gudex C, Lloyd A, *et al.* Development and preliminary testing of the new
34
35 811 five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;**20**:1727–36.
36
37 812 doi:10.1007/s11136-011-9903-x
38
39
40 813 74 Euroqol. EQ-5D-5L . <https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/> (accessed 8
41
42 814 May 2020).
43
44
45 815 75 Janssen MF, Birnie E, Haagsma JA, *et al.* Comparing the standard EQ-5D three-level
46
47 816 system with a five-level version. *Value Heal* 2008;**11**:275–84. doi:10.1111/j.1524-
48
49 817 4733.2007.00230.x
50
51 818 76 Brooke J. SUS - A Quick and Dirty Usability Scale. In: Jordan P, Thomas B,
52
53 819 Weerdmeester B, *et al.*, eds. *Usability Evaluation in Industry*. London: : Taylor and

- 1
2
3 820 Francis 1996.
4
5 821 [https://www.scirp.org/\(S\(351jmbntvnsjt1aadkposzje\)\)/reference/ReferencesPapers.aspx?R](https://www.scirp.org/(S(351jmbntvnsjt1aadkposzje))/reference/ReferencesPapers.aspx?R)
6
7
8 822 eferenceID=979187 (accessed 9 May 2020).
9
10 823 77 Brorson HH, Ajo Arnevik E, Rand-Hendriksen K, *et al.* Drop-out from addiction
11
12 824 treatment: a systematic review of risk factors. *Clin Psychol Rev* 2013;**33**:1010–24.
13
14 825 doi:10.1016/j.cpr.2013.07.007
15
16
17 826 78 NCI Common Terminology Criteria for Adverse Events (CTCAE) - GBG.
18
19 827 <https://www.gbg.de/de/rechner/ctcae.php> (accessed 9 Oct 2020).
20
21
22 828 79 R Core Team. R: A language and environment for statistical computing. R Foundation for
23
24 829 Statistical Computing. 2020.<http://www.r-project.org/index.html> (accessed 22 Jan 2021).
25
26 830 80 IBM Corp. IBM SPSS Statistics for Macintosh, Version 27.0. 2020.
27
28 831 81 Scholz S, Biermann-Stallwitz J, Brettschneider C, *et al.* Standardized cost calculations in
29
30 832 the German healthcare sector: Report of the working group Standard Costs of the
31
32 833 committee Economic Evaluation of the dggo. *Gesundheitsökonomie und Qual*
33
34 834 2020;**25**:52–9. doi:10.1055/a-1107-0665
35
36
37 835 82 Krauth C, Hessel F, Hansmeier T, *et al.* Empirische bewertungssätze in der
38
39 836 gesundheitsökonomischen evaluation - Ein vorschlag der AG methoden der
40
41 837 gesundheitsökonomischen evaluation (AG MEG). *Gesundheitswesen* 2005;**67**:736–46.
42
43 838 doi:10.1055/s-2005-858698
44
45
46
47 839 83 Bock JO, Brettschneider C, Seidl H, *et al.* Ermittlung standardisierter Bewertungssätze
48
49 840 aus gesellschaftlicher Perspektive für die gesundheitsökonomische Evaluation.
50
51 841 *Gesundheitswesen* 2015;**77**:53–61. doi:10.1055/s-0034-1374621
52
53
54 842 84 Grupp H, König HH, Konnopka A. Kostensätze zur monetären Bewertung von
55
56
57
58
59
60

- 1
2
3 843 Versorgungslösungen bei psychischen Erkrankungen. *Gesundheitswesen* 2017;**79**:48–57.
4
5 844 doi:10.1055/s-0035-1555950
6
7
8 845 85 O’Brien JE, Li W, Snyder SM, *et al.* Problem internet overuse behaviors in college
9
10 846 students: Readiness-to-change and receptivity to treatment. *J Evidence-Informed Soc*
11
12 847 *Work* 2016;**13**:373–85. doi:10.1080/23761407.2015.1086713
13
14
15 848 86 Dieris-Hirche J, Pape M, Theodor te Wildt B, *et al.* Problematic Gaming Behavior and the
16
17 849 Personality Traits of Video Gamers: A Cross-Sectional Survey. *Comput Human Behav*
18
19 850 2020;:106272. doi:10.1016/j.chb.2020.106272
20
21
22 851 87 Linden M, Zänker I, Solvie J, *et al.* Ambulante Versorgung: Erreichbarkeit von
23
24 852 Psychotherapeuten. *Dtsch Arztebl Int* 2021;**118**:A-252-
25
26 853 .https://www.aerzteblatt.de/int/article.asp?id=217638
27
28
29 854 88 Müller KW, Dreier M, Duven E, *et al.* Adding clinical validity to the statistical power of
30
31 855 large-scale epidemiological surveys on internet addiction in adolescence: A combined
32
33 856 approach to investigate psychopathology and development-specific personality traits
34
35 857 associated with internet addictio. *J Clin Psychiatry* 2017;**78**:e244–51.
36
37 858 doi:10.4088/JCP.15m10447
38
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40 859
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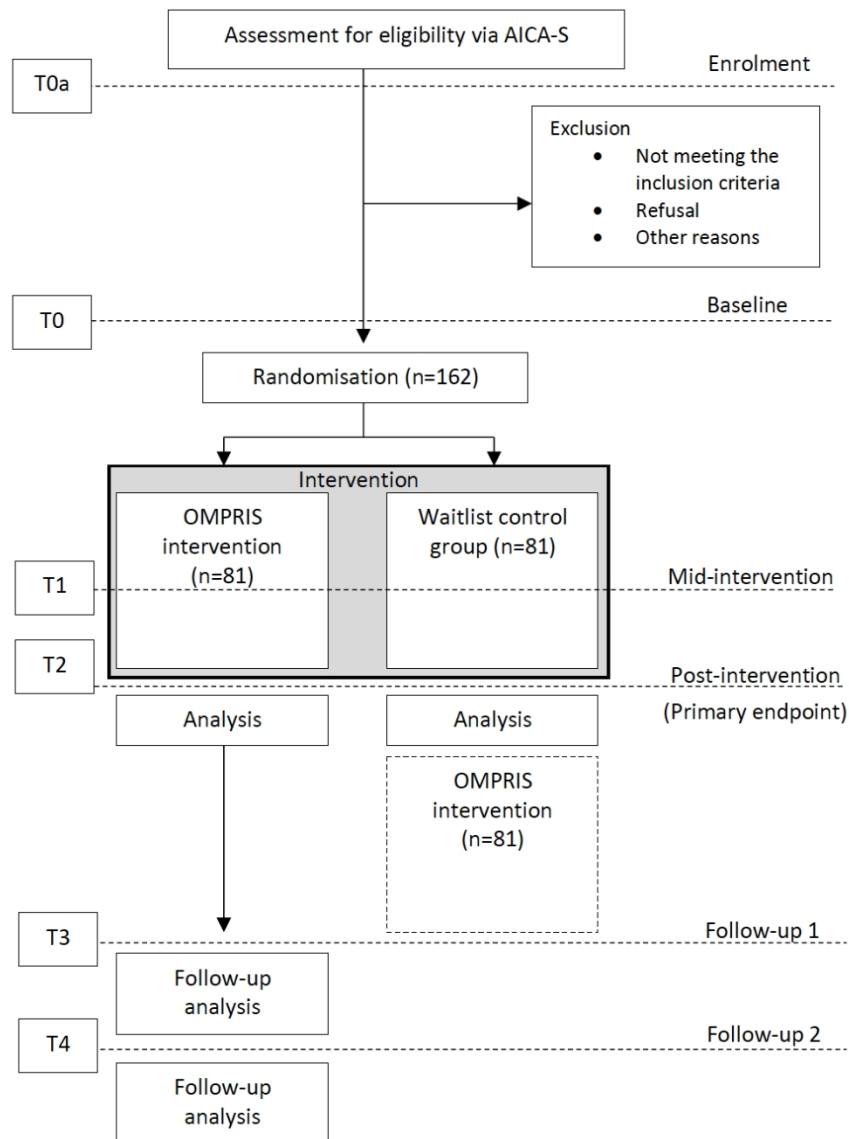


Figure 1: A flow chart of the study. Participants of the WLC group will be offered the OMPRIS intervention after a four-week long waiting period. The follow-up analysis will be performed separately for the WLC group.

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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)

1			
2	Objectives	7	Specific objectives or hypotheses (p.7)
3			
4	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)
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10	Methods: Participants, interventions, and outcomes		
11			
12	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)
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16	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)
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21	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered (p.12-14)
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23			
24		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)
25			
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29		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) (p. 12-14, 24)
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33		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial (p. 12-14)
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36	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)
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44	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)
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49	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)
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53	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size (p.9-10)
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Methods: Assignment of interventions (for controlled trials)

Allocation:

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2	Sequence	16a	Method of generating the allocation sequence (eg, computer-
3	generation		generated random numbers), and list of any factors for stratification.
4			To reduce predictability of a random sequence, details of any planned
5			restriction (eg, blocking) should be provided in a separate document
6			that is unavailable to those who enrol participants or assign
7			interventions (p. 10-11)
8			
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10	Allocation	16b	Mechanism of implementing the allocation sequence (eg, central
11	concealment		telephone; sequentially numbered, opaque, sealed envelopes),
12	mechanism		describing any steps to conceal the sequence until interventions are
13			assigned (p. 10-11)
14			
15	Implementation	16c	Who will generate the allocation sequence, who will enrol participants,
16			and who will assign participants to interventions (p.11)
17			
18			
19	Blinding	17a	Who will be blinded after assignment to interventions (eg, trial
20	(masking)		participants, care providers, outcome assessors, data analysts), and
21			how (p.15 – 16)
22			
23		17b	If blinded, circumstances under which unblinding is permissible, and
24			procedure for revealing a participant's allocated intervention during
25			the trial (p.15)
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Methods: Data collection, management, and analysis

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30	Data collection	18a	Plans for assessment and collection of outcome, baseline, and other
31	methods		trial data, including any related processes to promote data quality (eg,
32			duplicate measurements, training of assessors) and a description of
33			study instruments (eg, questionnaires, laboratory tests) along with
34			their reliability and validity, if known. Reference to where data
35			collection forms can be found, if not in the protocol (p.15-22)
36			
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38		18b	Plans to promote participant retention and complete follow-up,
39			including list of any outcome data to be collected for participants who
40			discontinue or deviate from intervention protocols (p. 25)
41			
42	Data	19	Plans for data entry, coding, security, and storage, including any
43	management		related processes to promote data quality (eg, double data entry;
44			range checks for data values). Reference to where details of data
45			management procedures can be found, if not in the protocol (p.23-24)
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48	Statistical	20a	Statistical methods for analysing primary and secondary outcomes.
49	methods		Reference to where other details of the statistical analysis plan can be
50			found, if not in the protocol (p.25-26)
51			
52		20b	Methods for any additional analyses (eg, subgroup and adjusted
53			analyses) (p.26)
54			
55		20c	Definition of analysis population relating to protocol non-adherence
56			(eg, as randomised analysis), and any statistical methods to handle
57			missing data (eg, multiple imputation) (p.25)
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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)

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| 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) |

16 Appendices

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|----------------------------|----|---|
| 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) |

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