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FULL-LENGTH REPORT

Treating internet use disorders via the internet? Results of a two-armed randomized controlled trial

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ABSTRACT

Background and aims: Internet Use Disorders (IUDs) are emerging as a societal challenge. Evidence-based treatment options are scarce. Digital health interventions may be promising to deliver psychological treatment to individuals with IUDs directly in their online setting. The aim of this study was to evaluate the efficacy of a digital health intervention for IUDs compared to a waitlist control group (WCG). *Methods:* In a two-armed randomized controlled trial, $N = 130$ individuals showing IUDs (Internet Addiction Test; IAT ≥49) were randomly allocated to the intervention group (IG; $n = 65$) or WCG ($n = 65$). The intervention consisted of 7 sessions based on cognitive behavioral therapy. The primary outcome was IUD symptom severity measured via the IAT at post treatment 7 weeks after randomization. Secondary outcomes included IUD symptoms (Compulsive Internet Use Scale; CIUS), quality of life, depressive and anxiety symptoms, and other psychosocial variables associated with IUDs. *Results:* Participants were on average 28.45 years old ($SD = 10.59$) and 50% identified as women, 49% as men, and 1% as non-binary. The IG ($n = 65$) showed significantly less IUD symptom severity (IAT) ($d = 0.54$, 95% CI 0.19–0.89) and symptoms ($d = 0.57$, 95% CI 0.22–0.92) than the WCG ($n = 65$) at post-treatment. Study attrition was 20%. Effects on all other secondary outcomes were not significant. On average, participants completed 67.5% of the intervention. *Discussion and Conclusions:* A digital health intervention could be a promising first step to reduce IUD symptom severity.

KEYWORDS

digital health intervention, internet use disorders, randomized controlled trial, cognitive behavioral therapy for IUDs, online CBT, guided self-help

INTRODUCTION

Internet Use Disorders (IUDs) is an umbrella term for disorders due to addictive behaviors exclusively or predominantly related to Internet use (Brand et al., 2022; Rumpf & Kiefer, 2011). IUDs are characterized by excessive or poorly controlled preoccupations, urges, or behaviors regarding computer use and internet access leading to social or work-related impairment or distress (Weinstein & Lejoyeux, 2010). Both the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association, 2013) and the International Statistical Classification of Diseases and Related Health Problems (ICD-10; World Health Organization, 2019) lack a standardized definition of IUDs. The ICD-11 determines

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gambling and gaming disorders as "disorders due to addictive behaviors" with specifiers for online or offline behavior.

The designation termed "other specified disorders due to addictive behaviors" includes pornography-use disorder, buying-shopping disorder, and social-network-use disorder that are not directly related to gaming or gambling (ICD-11; World Health Organization, 2019). To qualify in the ICD-11 as a disorder due to addictive behaviors, individuals must display: (1) functional impairment, (2) loss of control over the problem behavior, (3) neglect of work and social life, and (4) excessive internet use despite the associated ramifications. Additionally, these symptoms may present in both an episodic manner or in a recurrent one (ICD-11, World Health Organization, 2019). In the DSM-5, internet-based gambling is included in the Gambling Disorder diagnostic criteria (American Psychiatric Association, 2013) and Internet Gaming Disorder is defined as a "Condition for Further Study" (American Psychiatric Association, 2013), while IUDs can be classified as a behavioral addiction.

Epidemiologic studies have indicated that IUDs affect 7% of the general population (Pan, Chiu, & Lin, 2020), with an increased prevalence rate over time. IUDs have been found to cause neurological complications, psychological distress, and social problems due to the excessive use and extended screen time (Fuchs, Riedl, Bock, Rumpold, & Sevecke, 2018; Ioannidis et al., 2019; Poorolajal et al., 2019). In addition, high comorbidities with other mental disorders have been reported, such as affective and anxiety disorders, insomnia, and substance use disorders (Dib et al., 2021; Restrepo et al., 2020). Impairment caused by IUDs can also include educational failure and reduced academic perspectives, especially in adolescents and young adults, and may be associated with worrying about the future (Guo et al., 2021; Kindt, Szász-Janocha, Rehbein, & Lindenberg, 2019). In this context, IUDs have also been found to be associated with overall reduced quality of life and well-being (Dieris-Hirche et al., 2022).

Currently, preliminary evidence of uncontrolled pilot studies based on cognitive behavioral therapy (CBT) and motivational interviewing already have showed that digital health interventions could be able to reduce IUD symptoms (d = 0.5–0.8) (Dieris-Hirche et al., 2021; Su, Fang, Miller, & Wang, 2011). However, based on the recent existing findings, there are no established treatment guidelines yet regarding treatment contents and settings. Previous studies showed that cognitive-behavioral treatments addressing dysfunctional coping and internet use expectancies can result in large effects on IUDs in face-to-face settings (k = 15, g = 1.84) (Brand, Laier, & Young, 2014; Goslar, Leibetseder, Muench, Hofmann, & Laireiter, 2020; Winkler, Dörsing, Rief, Shen, & Glombiewski, 2013). Given the numerous and severe negative consequences, available evidence-based treatment options for IUDs are rare (Boumparis et al., 2022).

Digital health interventions can offer a possibility to deliver cognitive-behavioral treatment for IUDs with a low threshold for uptake (Carlbring, Andersson, Cuijpers, Riper, & Hedman-Lagerlöf, 2018). Treating IUDs via the internet may appear contradictive at first, as it seems problematic to allow participants to spend additional time on the internet. However, digital health interventions can provide treatment to individuals who would not consult a therapist by reaching them through their common online setting. Thus, digital health intervention may help to overcome low levels of treatment motivation and help-seeking (O'Brien, Li, Snyder, & Howard, 2016) as the internet is an easily accessible and attractive environment potentially lowering treatment barriers (Ebert et al., 2018). Digital health interventions have already been shown to be effective in the treatment of numerous mental health disorders (Ebert et al., 2018; Taylor, Graham, Flatt, Waldherr, & Fitzsimmons-Craft, 2021; Zarski, Velten, Knauer, Berking, & Ebert, 2022) including substance use and pathological gambling (Riper et al., 2018; Sagoe et al., 2021) and can be a feasible means to provide evidence-based treatment nationwide due to favorable scalability. They also meet the preference of many individuals for self-help (Andrade et al., 2014; Ebert et al., 2018). Thus, individuals with IUDs might be reached earlier by digital means than with traditional approaches as has been shown in other studies on digital health interventions (Hobbs et al., 2019; McKellar, Austin, & Moos, 2012). To the best of our knowledge, this is the first trial evaluating a guided digital health intervention for IUDs in a randomized controlled trial (RCT).

OBJECTIVE

The aim of this study was to evaluate the efficacy of a cognitive-behavioral digital health intervention for reducing IUDs compared to a waitlist control group (WCG). It was hypothesized that participants assigned to the intervention group (IG) would show reduced IUD severity measured via the Internet Addiction Test (IAT) at post-test compared to those in the WCG. We assumed that a reduction of IUDs could also have potentially positive effects on associated problems such as anxiety and depressive symptoms. Thus, the second objective was to investigate exploratory effects of the intervention on associated mental health outcomes.

METHODS

Design

A two-armed RCT was conducted to evaluate the digital health intervention "GET.ON Offline" compared to a WCG between 17.09.2018 and 15.03.2021. Assessments to evaluate the short-term efficacy of the intervention took place at baseline (T1) and 7 weeks after randomization (post-treatment; T2). See Fig. 1 for an overview of the study design. Monetary incentives were provided for completing the online questionnaires. A detailed description is provided in the study protocol (Saruhanjan, Zarski, Schaub, & Ebert, 2020).

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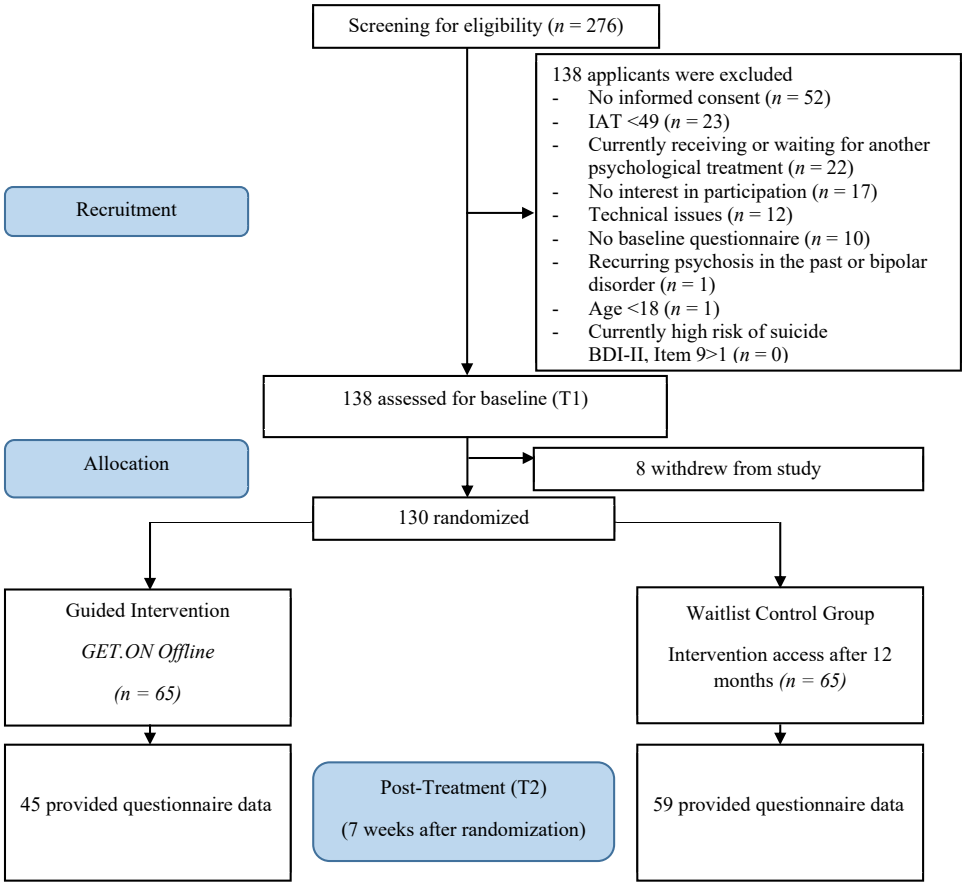

Fig. 1. Flowchart of study design. BDI = Beck Depression Inventory; IAT = Internet Addiction Test

Participants and procedures

Inclusion and exclusion criteria. All applicants were screened for study eligibility via a brief online questionnaire. We included individuals who (1) were at least 18 years of age, (2) showed elevated levels of IUDs applying an IAT cut-off-score of ≥49 indicating the transition from mild to moderate symptoms of IUDs (Young et al., 2011), (3) had internet access, (4) had sufficient German language reading and writing skills, and (5) gave informed consent. We excluded subjects who (1) reported a diagnosed psychosis or bipolar disorder or (2) showed a notable suicidal risk as indicated by a score greater than 1 on Item 9 of the Beck Depression Inventory (BDI-II) (Beck, Steer, & Brown, 1996) to ensure the safe use of the intervention because IMIs are not well-examined for this patient group yet. To avoid confounding effects, individuals were also excluded who (3) currently received or were on a waitlist for psychological treatment regarding any mental disorder.

Recruitment. Participants were recruited through broad online and offline channels in Germany, Austria and Switzerland via (1) the study websites of GET.ON (https://geton-training.de) and (2) StudiCare (https://www.studicare.com/). Recruitment took place through (3) social media, online discussion forums and self-help groups, (4) articles on blogs, (5) mass e-mailing with study information to German (non-) psychological counselling centers, medical practices, clinics, health insurances, outpatient clinics, and adult education centers. Moreover, (6) we published articles on *GET.ON Offline* in magazines and newspapers, (7) advertised in lectures of the FAU and (8) spread flyers and posters for example in university and public buildings.

Assessment of eligibility and randomization. After registering with a self-chosen email address on the study website, applicants received detailed information about the study procedure. They were further informed about the possibility to withdraw from the intervention and/or study at any time without any negative consequences. Applicants were asked to complete an online screening questionnaire and to sign the informed consent form. As soon as participants had completed the baseline assessment and met the inclusion criteria, they were randomized in 1:1 ratio to the IG or WCG. A research assistant not otherwise involved in the study performed block randomization with varying block sizes using an automated computer-based random integer generator (RandList, DatInf GmbH, Tübingen). Once randomization had been completed, participants in the IG received immediate access to the intervention while participants in the WCG received access 12 months later.

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Intervention

The intervention was CBT-based and consisted of six core sessions and one booster session four weeks after completion of the sixth session to maintain intervention effects and prevent relapse (see Table 1). In addition, participants were able to choose between several elective sessions (see Table 2). After completion of each session, participants received content-focused guidance by a trained eCoach and could then continue with the next session (Zarski et al., 2016). It was recommended to work on one session per week and to practice with transfer tasks in everyday life in between.

For a detailed description see the study protocol (Saruhanjan et al., 2020).

Measures

Baseline assessments. Baseline assessments included sociodemographics, current and previous experience with psychotherapy, self-esteem via the Rosenberg Self-Esteem Scale (RSES) (Rosenberg, 1965), and social phobia via the Mini Social Phobia Inventory (Mini-SPIN) (Connor, Kobak, Churchill, Katzelnick, & Davidson, 2001; Wiltink et al., 2017).

Primary outcome. To assess the primary effect of the treatment on IUD symptom severity, the Internet Addiction Test (Young, 1998) was administered (IAT; 20 items, score range: 20–100; α = 0.80) (Widyanto & McMurran, 2004). Higher items represent higher IUD symptom severity (score range: 0–30 points; mild: 31–49 points; moderate: 50–79 points; severe: 80–100 points) (Young, 2017; Young & de Abreu, 2011).

Table 1. Content of the training

Intervention content	Session
Goal setting and motivational interviewing	1
Impulse control	2
Problem solving	3
Cognitive restructuring	4
Strengthening self-worth	5
Relapse prevention	6
Booster session	7

Table 2. Content of the elective sessions

Session	Content
Relaxation	Progressive muscle relaxation
Alcohol & affect regulation	Reducing alcohol consumption by affect regulation
Personal needs & values	Reducing personal incongruence by achieving balance between values
Appreciation & gratefulness	Mindfulness strategies
Sleep	Sleep hygiene and sleep restriction
Procrastination	Working time restrictions, delayed gratification

Secondary outcomes. *IUD symptoms:* Symptoms of IUDs were also assessed by the Compulsive Internet Use Scale (CIUS; 14 items, score range: 0–56; α = 0.89) (Meerkerk, 2007; Meerkerk, Van Den Eijnden, Vermulst, & Garretsen, 2008). Higher items represent higher IUD symptoms. In contrast to the IAT, the CIUS was conceptualized to assess core elements of IUDs instead of related problems and has been found to have a higher correlation with duration of private internet use (Guertler et al., 2014).

Depressive symptoms: Depressive symptoms were measured with the Patient Health Questionnaire (PHQ-9; 9 items, score range: 0–27; α = 0.83–0.92) (Cameron, Crawford, Lawton, & Reid, 2008; Erbe, Eichert, Rietz, & Ebert, 2016; Kroenke, Spitzer, & Williams, 2001). Higher items represent higher depressive symptoms (minimal depression: <5; mild depression: 5–9; moderate depression: 10–14; moderately severe depression: 15–19; severe depression: 20–27).

Anxiety: Anxiety was assessed by the Generalized Anxiety Disorder Scale (GAD-7; 7 items, score range: 0–21; α = 0.92) (Löwe et al., 2008; Spitzer, Kroenke, Williams, & Löwe, 2006). Higher scores reflect higher anxiety.

Problematic alcohol consumption: Problematic alcohol consumption was measured with the Alcohol Use Disorder Identification Test (AUDIT-C; 3 items, score range: 0–12; α = 0.77–0.80) (Bush, Kivlahan, McDonell, Fihn, & Bradley, 1998; Rumpf, Wohlert, Freyer-Adam, Grothues, & Bischof, 2012; Saunders, Aasland, Babor, De La Fuente, & Grant, 1993). Higher scores reflect higher alcohol consumption.

Insomnia: Insomnia severity was assessed by the Insomnia Severity Index (ISI; 7 items, score range: 0–28; α = 0.83) (Dieck, Morin, & Backhaus, 2018; Morin, 1993). Higher items represent higher insomnia symptoms.

Worries: Worries were evaluated by the ultra-brief version of the Penn State Worry Questionnaire (PSWQ-3; 3 items, score range: 0–18; α = 0.74) (Berle et al., 2011; Schuster et al., 2019). Higher scores reflect higher worrying.

Procrastination: Procrastination was measured with the General Procrastination Scale (GSP-K; 9 items, score range: 0–36, α = 0.92) (Klingsieck & Fries, 2012; Lay, 1986). Higher items represent higher procrastination behavior.

Gambling: Lifetime gambling behavior was assessed by the short German version of the Questionnaire on Gambling Behavior (KFG; 20 items, score range: 0–60; α = 0.79) (Petry, 1996; Petry, Peters, & Baulig, 2013). Higher scores reflect higher gambling behavior.

Well-being: Well-being was assessed by the WHO-5 Well-Being Index (WHO-5; 5 items, score range: 0–25, α = 0.82) (de Wit, Pouwer, Gemke, Delemarre-van de Waal, & Snoek, 2007; WHO, 1998). Higher scores reflect higher wellbeing.

Quality of life: To measure quality of life, the Assessment of Quality-of-Life Instrument (AQoL-8D; 35 items, score range: 35–175) (Richardson, Iezzi, Khan, & Maxwell, 2014; Richardson & Rothstein, 2008) was used. The AQoL-8D consists of eight dimensions: independent living (α = 0.90, intraclass correlation coefficient (ICC) = 0.86), pain (α = 0.85, ICC = 0.86), senses (α = 0.69, ICC = 0.51),

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mental health (α = 0.84, ICC = 0.89), happiness (α = 0.85, ICC = 0.90), coping (α = 0.80, ICC = 0.79), relationships (α = 0.73, ICC = 0.88), self-worth (α = 0.85, ICC = 0.81) (Richardson et al., 2014). In the present sample Cronbach's alpha was excellent (α = 0.91). Higher scores represent lower quality of life.

Work limitations: To measure the on-the-job impact of chronic health problems and/or treatment with a focus on limitations while performing specific job demands, the Work Limitations Questionnaire (WLQ; 25 items, score range: 5–50, α = 0.83–0.88) (Lerner et al., 2001; Walker, Michaud, & Wolfe, 2005) was applied. Higher items represent higher work limitations.

Training and acceptability: User satisfaction was assessed by a questionnaire based on the Client Satisfaction Questionnaire (CSQ-8; 8 items; score range: 1–4; α = 0.84–0.97) (Attkisson & Zwick, 1982; Matsubara et al., 2013), adapted to online interventions (Boß et al., 2016). Higher scores reflect higher user satisfaction with the training.

Sample size calculation

To answer the primary research question, we included 130 participants. That is to statistically detect a medium effect of (Cohen's d) d = 0.60, with a power (1- β) of 80% and an α of 0.05 (two-tailed) for an intention-to-treat (ITT) analysis using G*Power (Faul, Erdfelder, Lang, & Buchner, 2007). The estimated effect of d = 0.60 was based on recent meta-analyses on the effects of treatments on IUDs for CBT (Goslar et al., 2020; Winkler et al., 2013) as well as several other treatments such as group counseling programs or sports interventions (Liu, Nie, & Wang, 2017).

Statistical analyses

Data was analyzed on an intention-to-treat basis including all participants who were randomly assigned to conditions. Additionally, study completer analyses including only participants who filled out the questionnaires and intervention completer analyses including only participants who completed at least 4 out of 6 sessions were conducted. We performed univariate analysis of covariance to compare outcomes between groups at post-treatment adjusting for baseline scores. For all analyses on continuous measures, Cohen's d (d = 0.2 small, d = 0.5 medium, and d = 0.8 large effects) (Cohen, 1977) was calculated by standardizing the differences between baseline and post-treatment scores by the pooled standard deviation.

Little's overall test of randomness (Little & Rubin, 2002) indicated that data were missing completely at random. Therefore, missing data in the intention-to-treat and intervention completer analyses were imputed using a Markov chain Monte Carlo multivariate imputation algorithm with 100 estimations per missing and all assessed variables at all time points were set as predictors.

To determine the numbers of participants achieving a reliable positive outcome, we coded participants as responders or non-responders according to the widely used reliable change index (RCI) (Jacobson & Truax, 1991). RCI scores lower than −1.96 indicated responders. To calculate the RCI the change score on the primary outcome and the retest reliability of r = 0.83 (Barke, Nyenhuis, & Kröner-Herwig, 2012) were used. Furthermore, the numbers needed to treat (NNT) to achieve one additional treatment response were calculated (Cook & Sackett, 1995). Following this procedure, reliable positive change was also analyzed for IUD symptoms measured by the CIUS. The response rates were compared across conditions using contingency tables and Chi-Squared tests. Significance levels were set at 0.05 (two-tailed). All analyses were performed with IBM SPSS v. 26 (Corp, 2019).

Ethics

All procedures were consistent with the generally accepted standards of ethical practice approved by the Friedrich-Alexander University of Erlangen-Nuremberg ethics committee (54_18 B). The trial is registered in the German Clinical Trials Register (DRKS00015314). All subjects were informed about the study and all provided informed consent.

RESULTS

Participants and descriptive data

After screening, 138 applicants were excluded mainly due to missing informed consent (n = 52) or an IAT score <49 (n = 23). The study flow is illustrated in Fig. 1. Baseline data was available for all participants. The study adherence rate was 80% at post-treatment (n = 45, 69.2% in IG and n = 59, 90.8% in WCG).

Demographic variables are displayed in Table 3. Participants were on average 28.45 (SD = 10.59) years old. Gender was balanced with 65 women (50%), 64 men (49.2%) and one participant identifying as non-binary (0.8%). Most participants were either married or in a relationship (n = 67, 53.9%). The majority reported a high education level (n = 121, 93.1%) and no financial issues (n = 95, 73.1%). Wishing to work on their problems with self-help was the most frequent reason for participating in the digital health intervention (n = 110, 84.6%). Approximately one third (n = 40, 30.8%) indicated no prior psychotherapy due to feelings of embarrassment.

Descriptive data for all outcomes at T1 and T2 is depicted in Table 4. Besides severe IUD baseline scores, this sample shows at baseline also severe depressive symptoms (IG: M = 20.01, SD = 4.92; WCG: M = 20.26, SD = 4.49), as well as high scores on anxiety (IG: M = 15.25, SD = 4; WCG: M = 14.62, SD = 4.19) and insomnia (IG: M = 17.42, SD = 5.38; WCG: M = 17.49, SD = 5.45).

Primary outcome analysis – IUDs

Participants in the IG achieved significantly lower IUD symptom severity on the IAT than the WCG (IG: M = 55.47, SD = 9.1; WCG: M = 60.8, SD = 9.29;

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Table 3. Sociodemographic characteristics

	Total (n = 130)	IG (n = 65)	WCG (n = 65)
Age in years, mean (*SD*)	28.45 (10.59)	27.63 (9.27)	29.26 (11.78)
Gender, women n (%)	65 (50)	33 (50.8)	32 (49.2)
Married or in a relationship, n (%)	67 (53.9)	35 (58.5)	32 (49.2)
Country of residence, Germany, n (%)	111 (85.4)	52 (80)	59 (90.8)
Immigration background, n (%)	47 (36.2)	22 (33.8)	25 (38.5)
German as native language, n (%)	123 (94.6)	62 (95.4)	61 (93.8)
Level of education, n (%)			
Low	2 (1.5)	0 (0)	2 (3.1)
Middle	7 (5.4)	1 (1.5)	6 (9.2)
High	121 (93.1)	64 (98.5)	57 (87.7)
Academic degree			
Yes (Bachelors, Masters, and Ph.D.)	58 (44.6)	32 (49.2)	26 (40.0)
No	72 (55.4)	33 (50.8)	39 (60.0)
Work status, working, n (%)	32 (24.4)	19 (29.2)	13 (20)
Financial situation n (%)			
No financial issues	95 (73.1)	49 (75.4)	46 (70.8)
Financial issues	35 (26.9)	16 (24.6)	19 (29.2)
Experience with internet-based health programs, n (%)	21 (16.2)	11 (16.9)	10 (15.4)
Motivation to participate in *GET.ON Offline*, n (%)			
Wish to solve problems on their own/ independently	110 (84.6)	53 (81.5)	57 (87.7)
Interested in online intervention	73 (56.2)	44 (67.7)	29 (44.6)
No prior psychotherapy due to feeling of embarrassment	40 (30.8)	17 (26.2)	23 (35.4)
No other treatment option found	20 (15.4)	8 (12.3)	12 (18.5)
No prior psychotherapy due to too long waiting periods	20 (15.4)	10 (15.4)	10 (15.4)
Not able to specify the problem	17 (12.8)	9 (13.8)	8 (12.3)
No prior psychotherapy due to fear of stigmatization	11 (8.5)	3 (4.6)	8 (12.3)
Prior psychotherapy or other treatment could not help	9 (6.9)	2 (3.1)	7 (10.8)
No psychotherapy or other treatment offered in respective area	6 (4.6)	5 (7.7)	1 (1.5)

Note: IG = Intervention group; WCG = Waitlist control group.

$F_{1,\ 127}$ = 11.63, p < 0.001) with moderate effect sizes at T2 (d = 0.54, 95% CI 0.19–0.89). Reliable improvement in the primary outcome was found in 32.3% of the IG (n = 21/65) and 12.3% of the WCG (n = 8/65) at T2 (χ^2 = 7.5, p = 0.01). This finding corresponds to a NNT of 5 (95% CI 3–18).

Secondary outcome analysis

Table 5 summarizes the results of the ITT analyses for the secondary outcomes. Participants in the IG reported significantly less IUD symptoms than WCG participants at T2 (IG: M = 43.06, SD = 8.0; WCG: M = 46.55, SD = 7.15; $F_{1,\ 127}$ = 9.82, p < 0.001, d = 0.57, 95% CI 0.22–0.92). For IUD symptoms, significantly more participants in the IG (n = 36, 55.4%) than in the WCG (n = 14, 21.5%) were classified as responders (χ^2 = 15.73, p < 0.001), resulting in an NNT of 2.95 (95% CI 2–6). The groups did not differ significantly regarding depressive symptoms, anxiety symptoms, alcohol abuse, insomnia, worries, procrastination, gambling, well-being, quality of life, and work limitations (d range = 0.01–0.28).

Study completer analysis

Participants who were lost at T2 did not differ significantly from participants who adhered to the protocol on any baseline characteristics (all p > 0.05). Results of the study completers (n = 104/130) confirmed the robustness of the ITT analysis, with a significant, but larger effect on the primary outcome at T2, (d = 0.71, 95% CI 0.29–1.08) and significantly more responders in the IG (p = 0.01) compared to the ITT analysis. Regarding secondary outcomes, the findings corroborated the results of the ITT analyses with a significant between group difference for IUD symptoms measured by the CIUS at T2 (d = 0.62, 95% CI 0.2–0.99) and significantly more participants classified as responders in the IG (p < 0.001). As in the ITT sample, all other secondary outcomes remained with a non-significant result (d range = 0.11–0.36). Detailed results can be found in Appendix A.

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Table 4. Means and SDs of the IG and the WCG for the intention-to-treat-sample at T1 and T2

	T1				T2[a]			
	IG		WCG		IG		WCG	
Outcome	M	SD	M	SD	M	SD	M	SD
Primary Outcome								
IUD symptom severity (IAT)	63.46	9.47	63.89	8.11	55.47	9.1	60.8	9.29
Secondary Outcomes								
IUD symptoms (CIUS)	50	7.56	49.25	6.56	43.06	8	46.55	7.15
Depressive Symptoms (PHQ-9)	20.1	4.92	20.26	4.49	18	4.69	18.84	4.41
Anxiety (GAD-7)	15.25	4	14.62	4.19	14.16	3.88	14.5	4.17
Alcohol abuse (AUDIT-C)	5.55	1.91	5.92	1.85	5.59	1.61	5.65	1.72
Insomnia (ISI)	17.42	5.38	17.49	5.45	15.46	4.28	16.83	5.27
Worries (PSWQ-3)	11.34	4.49	10.66	4	10.05	3.89	10.22	4.13
Procrastination (GPS-K)	27.72	2.72	27.52	2.54	26.73	2.83	27.29	2.71
Gambling (KFG)	24.74	6.37	23.18	4.71	25.4	9.91	22.29	5.25
Well-being (WHO-5)	15	5.01	14.06	4.48	16.97	4.48	15.7	5.2
Quality of Life (AQoL-8D)	82.74	15.52	81.83	13.76	78.98	14.8	80.7	14.33
Work Limitations (WLQ)	38.82	9.11	39.98	6.92	41.32	6.96	43.46	8.33

Note: M = Mean, *SD* = Standard deviation; T1 = Baseline assessment, T2 = Assessment at post treatment; IG = Intervention group; WCG = Waitlist control group; IAT = Internet Addiction Test, CIUS = Compulsive Internet Use Scale, PHQ-9 = Patient Health Questionnaire, GAD-7 = Generalized Anxiety Disorder measurement, AUDIT-C = Alcohol Use Disorder Identification, ISI = Insomnia Severity Index, PSWQ-3 = Penn State Worry Questionnaire, GPS-K = General Procrastination Scale, KFG = Kurzfragebogen zum Glücksspielverhalten, WHO-5 = WHO-5 Well-Being Index, AQoL-8D = Assessment of Quality of Life instrument, WLQ = Work Limitations Questionnaire
[a]Missing data imputed by multiple imputation

Table 5. Results for analyses of covariance for between-group effects, effect sizes (Cohen's *d*) for primary and secondary outcomes at T2 for the intention-to-treat sample

	Between-groups effect T2			
	Effect size	ANCOVA		
	Cohen's d	95% CI	$F_{1,\ 127}$	*p*
Primary outcome				
IUD symptom severity (IAT)	0.54	0.19–0.89	11.63	<0.001
Secondary outcomes				
IUD symptoms (CIUS)	0.57	0.22–0.92	9.82	<0.001
Depressive Symptoms (PHQ-9)	0.13	−0.21–0.48	0.92	0.34
Anxiety (GAD-7)	0.24	−0.11–0.58	0.98	0.32
Alcohol abuse (AUDIT-C)	0.22	−0.12–0.57	0.49	0.49
Insomnia (ISI)	0.25	−0.1–0.59	2.92	0.09
Worries (PSWQ-3)	0.19	−0.16–0.53	0.39	0.53
Procrastination (GPS-K)	0.27	−0.08–0.61	1.46	0.23
Gambling (KFG)	0.36	−0.84–1.56	0.44	0.53
Well-being (WHO-5)	0.07	−0.27–0.41	0.98	0.32
Quality of Life (AQoL-8D)	0.24	−0.1–0.59	1.62	0.2
Work Limitations (WLQ)	0.11	−0.23–0.46	1.65	0.2

Note: T2 = Assessment at post treatment; CI = Confidence interval, ANCOVA = Analysis of covariance; IAT = Internet Addiction Test, CIUS = Compulsive Internet Use Scale, PHQ-9 = Patient Health Questionnaire, GAD-7 = Generalized Anxiety Disorder measurement, AUDIT-C = Alcohol Use Disorder Identification, ISI = Insomnia Severity Index, PSWQ-3 = Penn State Worry Questionnaire, GPS-K = General Procrastination Scale, KFG = Kurzfragebogen zum Glücksspielverhalten, WHO-5 = WHO-5 Well-Being Index, AQoL-8D = Assessment of Quality of Life instrument, WLQ = Work Limitations Questionnaire

Intervention completer analysis

The results of the intervention completer analyses (n = 106/130) were similar to the ITT results, with large between-group effect sizes for the primary outcome at T2 (d = 0.8, 95% CI 0.39–1.2) and significantly more responders in the IG (p < 0.001). Comparable to the ITT-analyses, there was a significant result for IUD symptoms measured by the CIUS (d = 0.89, 95% CI 0.48–1.3) with a reliable improvement in

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the IG ($p < 0.001$). In contrast to the main analysis, however, depressive symptoms had decreased significantly in the intervention completers compared to the WCG at T2 ($d = 0.32$, 95% CI -0.08–0.71). The other secondary outcomes remained with a non-significant result (d range = 0.12–0.35). The results can be found in Appendix B.

Treatment adherence and satisfaction with the intervention

Almost two thirds of the participants in the IG ($n = 41/65$; 63%) completed the first four modules of the intervention. Overall, 34 (52%) participants completed all six core modules. In the IG ($n = 65$), module 1 was completed by 62 participants (95%), module 2 by 49 (75%), module 3 by 42 (65%), module 4 by 41 (63%), module 5 by 36 (55%), module 6 by 34 (52%) and module 7 by 27 (42%) participants. On average, participants completed 4.05 treatment modules (range = 1–6), which equals 67.5% of the intervention. User satisfaction was medium to high ($M = 2.52$; $SD = 0.26$); 95% stated that they would recommend the training to a friend in need.

DISCUSSION

The aim of this RCT was to evaluate the efficacy of a newly developed digital health intervention for IUDs in comparison to a WCG. As hypothesized, the participants of the IG showed lower IUD symptom severity at post-treatment compared to a WCG with a moderate effect size of $d = 0.54$ as measured with the IAT. The participants in the IG also showed reduced IUD symptoms as measured with the CIUS compared to the WCG at T2. There was no significant effect of the intervention on further mental health outcomes. Overall satisfaction with the treatment was medium to high.

Uncontrolled pilot studies on digital health interventions for IUDs based on CBT and motivational interviewing showed a reduction of IUD symptoms with medium effect sizes ($d = 0.5$–0.8) (Dieris-Hirche et al., 2021; Su et al., 2011). A meta-analysis on CBT for internet gaming disorder yielded a similar medium effect size ($g = 0.67$, 95% CI 0.23–1.11) (Stevens, King, Dorstyn, & Delfabbro, 2019) to the present study. Furthermore, the results of this study support previous findings that digital health interventions can be an effective treatment approach for behavioral addiction behaviors such as gambling (Chebli, Blaszczynski, & Gainsbury, 2016; Sagoe et al., 2021). Yet, evidence on face-to-face treatment for IUDs found higher effect sizes ($k = 15$, $g = 1.84$) (Goslar et al., 2020; Winkler et al., 2013) than the present study. While face-to-face treatment for IUDs has been shown to also reduce depressive and anxiety symptoms (Liu et al., 2017; Winkler et al., 2013), in the present study, only intervention completers showed reduced depressive symptoms in the IG compared to the WCG. No other significant improvements were found on secondary outcomes. This might at least partially be explained by the fact that our sample showed severe depressive symptoms and the intervention did not address depressive symptoms specifically but was mainly focused on IUD reduction. Lack of positive reinforcement and distractibility from reduced internet use coupled with difficulty in establishing satisfying offline activities may have contributed to maintaining depressive symptoms. In the given sample depressive symptoms were especially severe and comorbid with high anxiety and IUD symptoms. This raises the question which disorder initially dominated and whether IUDs developed subsequently. One explanation for the lack of improvement in the other secondary outcomes might also be a lack of or slowed development of alternative behavior to internet use, which would have contributed to the improvement of comorbid symptoms and negative consequences. Internet use could also have masked preoccupation with other problems that tended to follow the reduction in Internet use and then emerge after the intervention ended.

Nonetheless, an intervention for IUDs might be potentially a low threshold and first step treatment opportunity to reach severely burdened individuals who would not seek traditional treatment otherwise. Similarly, digital health interventions aiming at stress reduction have been shown to attract participants with clinically relevant depressive symptoms who have also been profiting from treatment (Ebert et al., 2016; Harrer et al., 2018). In case the digital health interventions for IUDs, given that depression can be effectively treated using digital CBT (Karyotaki et al., 2021), future studies should explore whether a more personalized version of the intervention tailored to depressive symptomatology and behavioral activation in particular might be beneficial for those individuals with comorbid depressive symptoms. Also, comprehensive diagnostics seems essential to identify the initial disorder (e.g., depression) to provide adequate first line treatment on the main disorder. A blended treatment format with e.g., traditional face-to-face therapy for depression and on parallel a digital health intervention for IUDs might be potentially a beneficial and appropriate approach.

Compared with face-to-face interventions for IUDs, either psychotherapy or addiction counselling (Lindenberg, Szász-Janocha, Schoenmaekers, Wehrmann, & Vonderlin, 2017), the present study showed a lower treatment dropout rate, suggesting that individuals who have actively decided for a digital health intervention show a high willingness to adhere. One possible reason for enhanced adherence in the digital health intervention could be a higher motivation justified by the familiar online setting and the medium to high overall satisfaction with the intervention. Additionally, automatic reminders for intervention completion might have been helpful for participants to keep up working on the modules regularly (Ebert et al., 2018). However, a potential selection bias regarding a highly self-help motivated sample must be taken into account.

Another important finding is, that in the current sample around one third of participants did not receive any prior treatment yet as they reported that they were previously too ashamed to seek help. Moreover, gender ratio in our study was balanced. On the one hand, more men being involved in

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gaming activities and thus possibly in IUDs could explain an unusually large number of male participants in the present study compared to other IMI studies. On the other hand, women have been shown to display a higher risk for excessive social media use (Kittinger, Correia, & Irons, 2012). A digital health intervention might seem to be a low-threshold accepted first treatment option, especially for men suffering not only from IUDs but also depressive symptoms.

The present study has several strengths and limitations. To the best of our knowledge, it was the first RCT to investigate the efficacy of a guided digital health intervention for IUDs. This study can make an important contribution to the so far limited research on empirically tested treatment for IUDs through its strong methodology of a RCT design compromising an appropriate statistical analyses plan and missing data handling with state of the arts methods (Schafer & Graham, 2002). In addition, efficacy of the study is not limited to a specific internet use area. While women have been overrepresented in most internet-based treatment studies (Brand et al., 2014; Petersen, Weymann, Schelb, Thiel, & Thomasius, 2009; Winkler et al., 2013) gender ratio in our study was balanced.

The study has the following limitations. First, we did not include any objective measurement of IUDs, e.g., tracking of time spent online. To allow a low-threshold approach, only self-reported measurements were used. Future research should consider additional measures such as applications to monitor screen time, e.g., via smart sensing (Baumeister et al., 2021). Second, the elaborated study inclusion process might have led to more above-average motivated applicants than one could not expect outside of the research context. So, as it is always the case with randomized trials external validity might be limited and real-life effectiveness should be explored under routine care conditions. Third, our intervention refers only to people over the age of 18. Future research should take into account that internet use starts at a very early age (Byrne & Burton, 2017), thus it would be important to evaluate digital health interventions for children and adolescents to prevent IUDs at an early stage. In this context it might be necessary to adapt the intervention to the specific needs of children and adolescents by taking user experience (UX-design) and persuasive design principles into account (Baumeister, Kraft, Baumel, Pryss, & Messner, 2023). Moreover, the sample showed an above-average level of education, which is common in guided self-help internet-based interventions and limits the generalizability of the results.

Future research

Future interventions should pay more attention to the high comorbidity of IUDs with depression, insomnia and GAD and explore ways of personalizing the intervention to individual needs of individuals with IUDs and heightened depressive symptoms. Promising findings emerged with regard to addressing comorbidities such as anxiety and depressive symptoms in IMIs for substance use disorders (Sugarman, Campbell, Iles, & Greenfield, 2017). Also, IUD treatment should be considered alongside depression treatment in individuals with both depression and IUDs, as e.g., in a blended format. Moreover, as disorders due to addictive behaviors are very heterogeneous, it might be promising to tailor interventions for IUDs to specific subtypes, such as pornography-use disorder, to better meet the needs of the subgroup experiencing this disorder (Bőthe, Baumgartner, Schaub, Demetrovics, & Orosz, 2021). Another research question is, despite good adherence rates, how treatment motivation during the intervention period can be further enhanced to help individuals experiencing the full intervention content, implement the exercises in their daily lives, and change their behaviors. This appears especially important in light of significantly reduced depressive symptoms in intervention completers. Identifying for whom the intervention is most effective and how it can further be optimized is also important to explore in the future. Also, motivation issues and ambivalence for behavior change in this target group should be acknowledged and targeted in future research. Moreover, research on the long-term-effects and cost-effectiveness of digital health interventions for IUDs should follow.

CONCLUSION

Given the increasing number of individuals with IUDs, it is of prime importance to provide, establish, and disseminate effective treatment for IUDs. The findings of this study indicate that a digital health intervention can be effective at reducing IUDs in comparison to a WCG. Thus, the study findings show that providing treatment over the internet might be a good way to reach those affected from IUDs directly in their familiar internet setting.

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Authors' contribution: KB, A-CZ and DE designed the study. KB and A-CZ developed the intervention. KB conducted the randomized controlled trial, collected, analyzed and interpreted the data. KB and A-CZ drafted the manuscript. DE and MPS contributed to the further writing of the manuscript. All authors read and agreed to be accountable for all aspects of the work ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of interest: Dr. Ebert has served as a consultant to/on the scientific advisory boards of Sanofi, Novartis, Minddistrict, Lantern, Schoen Kliniken, Ideamed and German health insurance companies (BARMER, Techniker Krankenkasse) and a number of federal chambers for psychotherapy. He is also stakeholder of the Institute for health training online (HelloBetter), which aims to implement scientific findings related to digital health interventions into

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routine care. MB is scientific advisor of GET.ON Institute/HelloBetter and stakeholder of mentalis GmbH. Both companies provide digital aftercare and aim to implement scientific findings related to digital health interventions into routine care. HB reports to have received consultancy fees, fees for lectures or workshops from chambers of psychotherapists and training institutes for psychotherapists and license fees for an Internet-intervention. KB and MPS declare no conflict of interest. ACZ reports to have received fees for lectures or workshops and for expert videos for an internet-based intervention.

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Appendix A

Table A1. Results for analyses of covariance for between-group effects, effect sizes (Cohen's *d*) for primary and secondary outcomes at T2 for study completer

	Between-groups effect T2			
	Effect size	ANCOVA		
	Cohen's d	95% CI	$F_{1,\ 101}$	*p*
Primary outcome				
IUD symptom severity (IAT)	0.71	0.29–1.08	14.81	<0.001
Secondary outcomes				
IUD symptoms (CIUS)	0.62	0.2–0.99	10.58	<0.001
Depressive Symptoms (PHQ-9)	0.2	−0.19–0.59	1.36	0.25
Anxiety (GAD-7)	0.25	−0.14–0.64	1.29	0.26
Alcohol abuse (AUDIT-C)	0.28	−0.12–0.66	1.53	0.22
Insomnia (ISI)	0.26	−0.08–0.7	2.85	0.10
Worries (PSWQ-3)	0.27	−0.12–0.66	0.79	0.38
Procrastination (GPS-K)	0.29	−0.1–0.68	1.89	0.17
Gambling (KFG)	0.36	−0.82–1.58	0.44	0.53
Well-being (WHO-5)	0.16	−0.23–0.55	1.30	0.26
Quality of Life (AQoL-8D)	0.2	−0.19–0.59	1.18	0.28
Work Limitations (WLQ)	0.11	−0.28–0.49	1.41	0.24

Note: T2 = Assessment at post treatment; CI = Confidence interval, ANCOVA = Analysis of covariance; IAT = Internet Addiction Test, CIUS = Compulsive Internet Use Scale, PHQ-9 = Patient Health Questionnaire, GAD-7 = Generalized Anxiety Disorder measurement, AUDIT-C = Alcohol Use Disorder Identification, ISI = Insomnia Severity Index, PSWQ-3 = Penn State Worry Questionnaire, GPS-K = General Procrastination Scale, KFG = Kurzfragebogen zum Glücksspielverhalten, WHO-5 = WHO-5 Well-Being Index, AQoL-8D = Assessment of Quality of Life instrument, WLQ = Work Limitations Questionnaire

Appendix B

Table A2. Results for analyses of covariance for between-group effects, effect sizes (Cohen's *d*) for primary and secondary outcomes at T2 for intervention completer

	Between-groups effect T2			
	Effect size	ANCOVA		
	Cohen's d	95% CI	$F_{1,\ 103}$	*p*
Primary outcome				
IUD symptom severity (IAT)	0.8	0.39–1.2	19.64	<0.001
Secondary outcomes				
IUD symptoms (CIUS)	0.89	0.48–1.3	19.44	<0.001
Depressive Symptoms (PHQ-9)	0.32	−0.08–0.71	4.59	0.03
Anxiety (GAD-7)	0.27	−0.12–0.66	2.35	0.13
Alcohol abuse (AUDIT-C)	0.27	−0.12–0.66	0.57	0.45
Insomnia (ISI)	0.25	−0.14–0.65	3.21	0.07
Worries (PSWQ-3)	0.26	−0.14–0.65	1.18	0.28
Procrastination (GPS-K)	0.35	−0.05–0.74	3.27	0.07
Gambling (KFG)	0.32	−1.08–1.71	0.78	0.41
Well-being (WHO-5)	0.14	−0.25–0.53	1.53	0.22
Quality of Life (AQoL-8D)	0.21	−0.19–0.6	1.22	0.27
Work Limitations (WLQ)	0.12	−0.28–0.51	1.54	0.22

Note: T2 = Assessment at post treatment; CI = Confidence interval, ANCOVA = Analysis of covariance; IAT = Internet Addiction Test, CIUS = Compulsive Internet Use Scale, PHQ-9 = Patient Health Questionnaire, GAD-7 = Generalized Anxiety Disorder measurement, AUDIT-C = Alcohol Use Disorder Identification, ISI = Insomnia Severity Index, PSWQ-3 = Penn State Worry Questionnaire, GPS-K = General Procrastination Scale, KFG = Kurzfragebogen zum Glücksspielverhalten, WHO-5 = WHO-5 Well-Being Index, AQoL-8D = Assessment of Quality of Life instrument, WLQ = Work Limitations Questionnaire

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