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Digital Health Interventions in the Treatment of Internet Use Disorder and Insomnia in Students

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Table of Contents

Table of Contents 3
Abstract 5
1. Introduction 7
1.1 General Introduction 7
1.2 Aim of this Dissertation 12
1.3 Digital Health Interventions in the Treatment of Internet Use Disorder 13
1.3.1 Internet Use Disorder—An Emerging Psychological Disorder 13
1.3.2 Treatment Options for Internet Use Disorder 15
1.3.3 Treating Internet Use Disorder via the Internet 18
1.4 Digital Health Interventions in the Treatment of Insomnia in Students 20
1.4.1 Insomnia in Students 20
1.4.2 Insomnia Treatment 20
1.4.3 Treating Insomnia in Students via the Internet 21
2. Methods 24
2.1 Study Design—Randomized Controlled Trials 24
2.2 Recruitment 25
2.3 Digital Health Intervention: GET.ON Offline 26
2.4 Digital Health Intervention: StudiCare GET.Sleep 28
3. Original Publications and Articles 30
3.1 Article 1: Psychological interventions to improve sleep in college students: A meta-analysis of randomized controlled trials 31
3.2 Article 2: Design of a guided internet- and mobile-based intervention for internet use disorder – Study protocol for a two-armed randomized controlled trial 32
3.3 Article 3: Case report for an Internet- and mobile-based intervention for Internet Use Disorder 34
3.4 Article 4: Treating internet use disorder via the internet? Results of two-armed randomized controlled trial 67
3.5 Article 5: Efficacy of an internet intervention for students suffering from primary insomnia – results of a two-armed randomized controlled trial 103
4. Discussion 135
4.1 General Discussion 135
4.2 Discussion of the Results on the GET.ON Offline Intervention 144

4.2.1 Summary of Principal Findings and Relation to Previous Research 144
4.2.2 Strengths and Limitations 146
4.2.3 Clinical Implications and Future Research 146
4.2.4 Conclusion 147
4.3 Discussion of the Results on the StudiCare GET.Sleep Intervention 147
4.3.1 Summary of Principal Findings and Relation to Previous Research 147
4.3.2 Strengths and Limitations 149
4.3.3 Clinical Implications and Future Research 150
4.3.4 Conclusion 150
5. Conclusion 151
References 152

Abstract

This dissertation is based on two projects which consist of the two digital health interventions GET.ON Offline and StudiCare GET.Sleep. GET.ON Offline is a newly developed digital health intervention in the treatment of internet use disorder. Internet use disorder is defined as excessive use of the internet despite negative consequences. It is characterized by a strong cognitive focus on internet use, an excessive behavioral use, being strongly preoccupied with the internet use and by a lack of control over the amount of time spent online as well as by neglecting other areas of life. In scope of this dissertation the GET.ON Offline intervention was developed, and three studies were conducted on the topic of internet use disorder. A study protocol describes the rationale, treatment protocol and study design of the digital health intervention GET.ON Offline. Further, a case report was conducted to present preliminary effects of the intervention at individual level. Finally, a two-armed randomized controlled study reports on the efficacy of the digital health intervention compared to a wait-list control group. The studies reveal that a digital health intervention to overcome internet use disorder proves to be effective. The case report shows an overall reduction of symptoms associated with internet use disorder and a good satisfaction with the treatment. Analyzing a single case report gives valuable insights into an individual treatment course and general feasibility of this newly developed digital health intervention for an under-treated field. The results of the randomized controlled trial yielded a moderate effect indicating that a digital health intervention can be effective in reducing internet addiction symptom severity and associated compulsive internet use. Thus, the study findings show that providing treatment over the internet might be a good way to reach those affected from internet use disorder directly in their familiar online setting. The results of the GET.ON Offline studies enhance the evidence-base for treatment of internet use disorder and provide some of the first guidelines on developing internet-based interventions for this under-treated condition.

The StudiCare GET.Sleep project is represented by two further studies. A meta-analysis was performed to evaluate the efficacy of psychological interventions aimed at improving sleep in college students compared to control conditions showing large overall effects of psychological treatment on sleep-related outcomes. Successfully providing psychological interventions to college students does not only include sufficient dissemination of psychological interventions, but also raising awareness of intervention opportunities and providing interventions that are suited to the needs of students. Therefore, a digital health intervention in the treatment of insomnia was adapted to the population of students and its

efficacy was evaluated in a randomized controlled trial including an active control group. The results show that StudiCare GET.Sleep was not superior to an online sleep hygiene control group. High within-group effects in the primary outcome indicate that both conditions are effective in reducing insomnia so that a stepped-care approach could be considered for a broader range of student population.

1. Introduction

1.1 General Introduction

The present dissertation addresses Internet Use Disorder (IUD) and sleep disturbances. First and foremost, the association between these two disorders will be explored. Both sleep and internet use, or the online behavior of individuals, are ubiquitous aspects of life and integral parts of everyday routines, making both subjects omnipresent. Sleep patterns and internet behavior are important topics in the contemporary lives of almost all individuals. Sleep is not just a part of our nighttime behavior. The sleep behavior has an tremendous influence on daytime constitution, including daily functioning or the impact of sleep on concentration and daytime performance (Pagel et al., 2007). Conversely, daytime structure and routines also influence sleep at night. Factors such as daily rhythms, daytime activities, relaxation rituals, or habits contribute to the ability to fall asleep and sleep quality (Sonnentag, 2012; Trougakos & Hideg, 2009). Further, sleep quality not only affects our physical health but also our psychological well-being (Harvey, Murray, Chandler & Soehner, 2011; Pigeon, Bishop & Krueger, 2017). Likewise, the online behavior follows a similar pattern. Modern technology and the internet have had a vast impact on daily lives in recent decades. While the internet offers many benefits and enriches lives in various ways, it also carries potential negative effects, particularly regarding sleep habits and sleep health (Alimoradi et al., 2019). The following paragraphs examine the relationship between IUD and sleep disorders.

The relevance of IUD and sleep disorders is evident in the high prevalence rates of both disorders. Sleep disorders are highly prevalent in the general population (Morin, LeBlanc, Daley, Gregoire, & Mérette, 2006). However, it is noteworthy that the prevalence of sleep disorders among students is even higher (Gaultney, 2010) compared to the general population. IUD shows prevalence rates of 7% (Pan et al., 2020), with increased prevalences over time. Children and especially adolescents have even higher prevalence rates (Kuss, Griffiths & Binder, 2013). IUD is particularly widespread among adolescents, with a prevalence rate of 14-15% (Kaess et al., 2016; Lindenberg et al., 2018). Compared to the general population, adolescents show two to three times higher prevalence rates (Lindenberg et al., 2018). Thus, one common factor between these two disorders is their epidemiology, as both conditions are more prevalent in childhood and adolescence.

In addition to their relevance in everyday life, both IUD and sleep disorders can be categorized into different subtypes. For IUD, the categorization is usually based on the following subtypes of online activities: online gaming, social media use, online shopping,

online gambling, and online pornography use (Young et al., 1999). Sleep disorders can also be characterized in different ways. Sleep can be impaired by insomnia, sleep apnea, narcolepsy, or parasomnia disorders (American Psychiatric Association, 2013). Further, pathological sleep behavior and online behavior can be found in diagnostic classification systems. While sleep disorders are explicitly listed as a category in the F51 section "Nonorganic sleep disorders" in the International Classification of Diseases-10 (ICD-10) and can be coded accordingly, there is currently no separate diagnostic category for IUD in the ICD-10. IUD can be coded as “impulse control disorder” using the ICD-10 code F63.8. However, there was a change in the ICD-11, combining substance-related and behavioral addictive disorders were into the new classification "Disorders due to substance use or addictive behaviors" in Block L1-6C4, so that IUD can be coded as a separate diagnosis under behavioral addictions in the future (World Health Organization, 2019).

Both IUD and sleep disorders are characterized by various, high, and strong comorbid conditions. IUD is associated with depression, anxiety disorders, substance use disorders, and self-esteem issues (Andreassen, 2015; Bargeron & Hormes, 2017; Brunborg, Mentzoni & Frøyland, 2014). Comorbidities are also common in individuals affected by sleep disorders, such as increased rates of depression (O'Brien & Mindell, 2005), impaired overall health status (Smaldone, Honig & Byrne, 2007), and difficulties in maintaining social relationships (Carney et al., 2006). Additionally, individuals with sleep disorders show increased risk-taking behavior (Cummings et al., 2001), decreased attention levels (Pagel et al., 2007), and poorer academic and cognitive performance (Gaultney, 2010).

Regarding the relationship between IUD and sleep disorders, current research suggests that both disorders influence each other, so that no causal or directional relationship can be proofed. On the one hand, increased use of the internet can lead to poorer sleep, on the other hand, sleep disorders can contribute to increased internet use (Alimoradi et al., 2019). Increased screen time before bedtime, as well as during the day, keeps individuals awake and makes it more difficult to relax and subsequently fall asleep. However, it is also evident that people having problems to fall asleep spend more time on the internet when they are unable to sleep (Tavernier & Willoughby, 2014). Studies have shown that excessive internet use, particularly before bedtime, can lead to various types of sleep disorders (Alimoradi et al., 2019). One major factor is the excessive stimulation that the internet provides. Using computers, smartphones, or other internet-ready devices before bedtime can delay the onset of sleep. The bright light emitted by screens inhibits the production of the sleep hormone melatonin and disrupts the natural sleep-wake cycle (LeBourgeois et al.,

2017). Furthermore, excessive internet use can lead to psychological dependence. Individuals addicted to the internet have difficulty controlling their use and detaching themselves from online activities. This can result in late-night surfing or chatting, which impairs sleep quality, reduces sleep time and thus can contribute to the development of sleep disorders (Tavernier & Willoughby, 2014).

In addition to excessive stimulation, the content of the internet can also have an impact on sleep. Social media and online games are particularly emotionally engaging as content on social media platforms or in online games can evoke strong emotional reactions. The use of social media platforms can therefore lead to excitement, stress, or anxiety, which can impair sleep. Constantly refreshing news feeds or reading comments keeps the brain activated and impedes the ability to fall asleep (Tandon, Kaur, Dhir & Mäntymäki, 2020). Similarly, online gaming or other engaging activities on the internet can stimulate the brain and make it thus difficult to fall asleep. Especially with intense, competitive online games, the heightened excitement and engagement in the virtual world can lead to reduced sleep time and sleep disorders (Weaver, Gradisar, Dohnt, Lovato & Douglas, 2010).

When considering the relationship between IUD and sleep disorders, individual differences and risk factors need to be taken into account. Spending a lot of time on the internet does not necessarily result in sleep disorders. The associations can vary individually. Some individuals may be less susceptible to the negative effects of internet use on sleep, while others may be more sensitive. However, there are certain risk factors that can increase the likelihood of sleep disorders in relation to IUD. These include high intensity and duration of internet use, neglecting other important areas of life such as work, school, social interactions, and physical activities. Individuals experiencing stress, anxiety, or depression are shown to be more vulnerable to developing sleep disorders related to IUD (Alonzo, Hussain, Stranges & Anderson, 2021; Baglioni et al., 2011; Lemola, Perkinson-Gloor, Brand, Dewald-Kaufmann & Grob, 2015). The intensity and duration of internet use are crucial factors that can affect sleep. Individuals spending excessive or highly increased time online, whether through social media, streaming services, online games, or other activities, are at a higher risk of sleep disorders. The continued brain stimulation from the mass of information, visual stimuli, and interactions on the internet can make it difficult to unwind and relax, leading to sleep disorders (Cho et al., 2015). Neglecting other areas of life in favor of the internet can also contribute to sleep disorders. When people neglect their work, school, or social interactions to spend more time online, this can lead to an imbalance and thus affect overall well-being. The feeling of being overwhelmed can result in increased stress, which

in turn negatively impacts sleep (Åkerstedt, 2006; Geurts & Sonnentag, 2006). Stress, anxiety, and depression are additional risk factors that can increase the likelihood of sleep disorders in IUD. These mental states can be both causes and consequences of IUD (Åkerstedt, 2006; Carli et al., 2013; Moo-Estrella et al., 2005). Individuals experiencing chronic stress often show difficulties in relaxing and detaching from daytime activeness, which can cause sleep disorders. Anxiety disorders are often characterized by increased late-night rumination on worries and fears so that relaxing and the ability to fall asleep is highly impaired. Depressive disorders are expressed through lack of energy, lack of motivation, and alike a disrupted sleep-wake regulation (Pigeon, Bishop & Krueger, 2017; Sivertsen et al., 2014). It is important to consider these individual differences and risk factors when assessing the association of IUD and sleep disorders. An increased internet use does not necessarily result in sleep issues, but certain factors can increase the risk.

Prevention and treatment of IUD and sleep disorders are crucial in dealing with these two conditions. There are various approaches to prevent negative effects and help individuals to achieve a healthy balance between online activities and sleep behavior. Prevention of IUD comprises a range of measures and interventions aimed at reducing the risk of excessive internet use. An important preventive approach involves raising awareness about potential risks and consequences of excessive internet use (Janocha, Vonderlin & Lindenberg, 2020) i.e., information on potential negative outcomes and sensitizing on a conscious use of the internet. Such preventive strategies aim at establishing an understanding of the internet as a useful tool that, yet also bears limitations and risks. Further, in preventing IUD, it is important to offer alternatives to the internet and promote the development of healthy offline activities (Wölfling, Bengesser, Beutel & Müller, 2012). This can involve engaging in social interactions, physical activities, or hobbies. Creating media-free offline timeframes and spaces within families and schools is also recommended to provide an environment to recover from a constant presence of digital media and focus on offline activities. Moreover, parents, teachers, and professionals should be sensitized to signs and symptoms of IUD in children and adolescents. Early detection and intervention are crucial in reducing the risk of developing an IUD. Through targeted interventions or counseling, individuals at risk can learn to maintain a healthy relationship with the internet (Lindenberg, Kindt & Szász-Janocha, 2022).

To address sleep disorders and improve sleep quality, various preventive measures are recommended. A healthy sleep environment is crucial, including a quiet, dark, and comfortable sleeping area. Regular sleep and wake times, also on weekends, support the

natural sleep-wake cycle and foster an improved sleep quality. Adhering to sleep hygiene routines is also essential and includes limiting screen exposure before bedtime as blue screen light can negatively affect melatonin production and thus disrupt sleep. Instead, relaxation techniques such as deep breathing exercises, meditation, or reading a book before bedtime should be practiced. Additionally, incorporating physical activity into daily routines is important as it helps regulating a healthy sleep-wake rhythm. Stimulating substances such as caffeine or nicotine should be avoided before bedtime as they can interfere with sleep as well. A conscious diet can also have a positive impact on sleep (Siebern & Manber, 2010).

Regarding therapeutic interventions and treatment approaches for IUD and sleep disorders, various interventions can be indicated. Cognitive behavioral therapy (CBT) is considered as the treatment of choice for both conditions (Morgenthaler et al., 2006; Morin et al., 2006; Müller et al., 2018; Petersen et al., 2009). For both disorders, it is indicated to identify and address negative thoughts and behaviors, as it is inherent to CBT. Self-control and stimulus-control techniques are applied for both disorders as well as interventions on coping with emotional distress and stress in general (Morgenthaler et al., 2006; Wölfling, Bengesser, Beutel & Müller, 2012). Stress management techniques can involve meditation, exercise, or seeking professional help to address stress, anxiety, or depression. By dealing with own mental health states and working on psychological well-being, sleep quality can be improved, and a balanced use of the internet can be promoted. Relaxation techniques also play a crucial role in the treatment of both disorders. Applying relaxation techniques such as progressive muscle relaxation or mindfulness exercises, serves in reducing stress thus promoting better sleep. Further, sleep hygiene rules do not only address sleep specific topics, but explicitly target online behavior by recommending avoiding online activities before bedtime. Additionally, sleep logs can help analyze individual sleep-wake rhythms and derive appropriate measures (Siebern & Manber, 2010). In some cases, medication may also be considered as a treatment option. In the short term, medication can be used to alleviate sleep disorders if non-pharmacological interventions are not sufficiently effective. However, it is important that the use of medication is carefully evaluated and monitored by a qualified specialist (Grobe, Steinmann & Gerr, 2019). Additionally, medication can be used to treat accompanying symptoms such as anxiety or depression. It should be considered, however, that there is pharmacological treatment available to address sleep disorders but no specified medication for the treatment of IUD. Therefore, addressing IUD through psychological treatments is recommended as the preferred approach (Müller et al., 2018; Petersen et al., 2009). Overall, it can be stated that the prevention and treatment of IUD and sleep disorders

require a multidisciplinary approach. Collaboration among various disciplines such as psychology, medicine, and education is crucial to ensure a comprehensive and holistic approach in treating IUD and sleep disorders. Integrated and coordinated care through interdisciplinary teams can enhance treatment effectiveness and ensure that all relevant aspects are considered (Lindenberg, Halasy & Schoenmaekers, 2017). The exchange of knowledge and expertise among different professional fields is important to ensure thorough treatment. Through collaboration and exchange of expertise, valid treatment methods and good practices can be identified, and new treatment approaches can be developed.

Despite severe comorbidities and negative impacts on the lives of those affected, currently, there are few available treatment options, so that affected individuals often do not receive adequate treatment (Boumparis et al., 2022). While there are prevention programs and counseling services for IUD, only scarce specific therapeutic treatment options are provided (Müller et al., 2018; Petersen & Thomasius, 2010; Wölfling et al., 2014). This might be due to an unclear diagnosis of IUD, which however could change with the new option to code IUD as a behavioral addiction in the ICD-11. Yet, the main reasons for the treatment gap can be seen in the lack of validated treatment options. Additionally, individuals affected by these disorders often exhibit low treatment motivation, making them difficult to reach. Moreover, there is fear of stigmatization associated with seeking psychological help or psychotherapy (Lindenberg et al., 2017; Müller et al., 2018; Romanczuk-Seiferth, 2017; Wölfling et al., 2019).

To address these barriers, digital health interventions can provide a suitable solution. The following paragraphs will examine IUD and sleep disorders, and the potential benefits that digital health interventions can offer for these mental illnesses.

1.2 Aim of this Dissertation

The aim of this dissertation was to examine benefits of digital health interventions in the treatment of IUD as well as in the treatment of insomnia in students. To pursue this aim, three scientific studies were conducted on the digital health intervention GET.ON Offline in the treatment of IUD and two studies on insomnia in students.

The GET.ON Offline project aimed to develop a digital health intervention for the treatment of IUD and to evaluate its effectiveness in a randomized controlled trial. Findings on the efficacy of the digital health intervention for IUD serve as a basis for establishing and disseminating specialized psychotherapeutic treatments for this poorly researched disorder. Firstly, a study protocol presented the rationale and treatment protocol of the newly

developed guided digital health intervention GET.ON Offline. Further, a case study was conducted with the aim to provide insights into a digital health intervention for IUD and to illustrate feasibility, symptom reduction, and satisfaction with the treatment on an individual level through a case report. Finally, a RCT was conducted with the aim of investigating the efficacy of the newly developed guided digital health intervention for IUD compared to a WCG. It was hypothesized that the digital health intervention is effective in reducing IUD symptoms compared to a WCG.

This dissertation was integrated in a health insurance-funded research project called "StudiCare". The aim of the project was to develop digital health interventions for the treatment and prevention of mental disorders in students and to investigate their effectiveness. In scope of this dissertation, in a first step, randomized-controlled studies on existing sleep treatments for students were analyzed in a meta-analysis. The goal of the meta-analysis was to generate quantitative information on the effectiveness of sleep interventions in students. Only randomized-controlled trials that specifically evaluate psychological treatments and report sleep-related outcomes were included in the analysis. Subsequently, an RCT was conducted to investigate whether a target group-adapted digital health intervention for sleep disorders can be effective in improving sleep compared to an active control group.

The thesis first introduces the two subject areas of IUD und sleep in students. Further, treatment manuals for the two interventions, as well as the associated studies, are presented. This thesis provides results on the use of digital health interventions in the field of mental health care.

1.3 Digital Health Interventions in the Treatment of Internet Use Disorder

1.3.1 Internet Use Disorder—An Emerging Psychological Disorder

The use of the internet is a natural part of people's lives. Most people know how to use the internet reasonably and in a functional way and can thus benefit from its advantages. However, new diseases emerged with digitalization as well (Kothgassner & Felnhofer, 2018). One important step in distinguishing pathological from an everyday use of the internet includes the publication of the diagnosis of internet gaming disorder (IGD), in the fifth edition of the American Psychiatric Association APA's Diagnostic and Statistical Manual of Mental Disorders DSM-V (DSM-5, American Psychiatric Association, 2013). Based on this diagnosis, IUD is characterized by the following diagnostic criteria: 1) an urge to stay online

with a strong cognitive focus (salience) on the internet. 2) A lack of control over the internet use or a reduced ability to control the beginning, end, and duration of the internet use (loss of control). 3) Withdrawal symptoms as soon as the internet is absent for a longer period or access to the internet is restricted. Withdrawal symptoms may manifest in depression, anxiety, irritability, or sadness. 4) Development of tolerance, which is reflected in an increase in the frequency or intensity of the internet use. To maintain positive feelings from online activities, individuals increase the intensity of their internet use. 5) Neglect of other areas of life. Leisure activities and interests formerly experienced as positive are no longer practiced. Professional or academic duties and social contacts can also be neglected. 6) The excessive use of the internet is persistent and leads to negative consequences, which can arise in various areas. Somatic symptoms, e.g., malnutrition, a disturbed sleep-wake rhythm, and physical issues such as back pain or headaches occur. In social life, there is a risk of neglecting relationships or shortcomings in the development of social skills. Regarding academic or professional life, a decrease in performance and difficulties in concentrating may occur, which can subsequently result in job loss or financial issues (American Psychiatric Association, 2013; Bauernhofer et al., 2016; Mann, 2014; Wölfling, Dreier et al., 2017).

IUD is categorized as a behavioral addiction or non-substance-related addiction (Mann, 2014; Romanczuk-Seiferth, 2017; Wölfling, Dreier et al., 2017). In this context, it is not the internet per se that leads to the development of addictive behaviors, instead individual activity patterns can have an addiction-triggering effect (Müller, 2017). IUD occurs particularly for the following five online activities: 1) online pornography and cybersex 2) online gambling, shopping sites, and auctions 3) use of social networks, chats, and internet forums 4) information overload related to the use of databases (web-surfing type) 5) playing online computer games (gaming type) (Young et al., 1999). The gaming type is the most frequently studied subtype to date (Bauernhofer et al., 2016; Wölfling, Dreier et al., 2017). However, IUD can also be understood as a generally addictive use of the internet, when there is an undifferentiated, very high consumption of the internet among affected individuals who engage in many different online activities (Davis, 2001).

Along with an IUD, symptoms of other mental disorders may occur (Müller, 2017; Müller et al., 2018). Studies on comorbid mental disorders show that a substantial number of adults meeting the diagnostic criteria for IUD also meet diagnostic criteria for other mental disorders (Carli et al., 2013). Among these, depression represents the most common comorbid disorder (Carli et al., 2013). Other comorbidities include anxiety disorders

(generalized anxiety disorder, social phobic disorder), personality disorders, attention deficit hyperactivity disorder (ADHD), and substance-related addictions (Bai et al., 2001; Carli et al., 2013; Ho et al., 2014; Zadra et al., 2016). There is also consensus in previous research that there is a strong association of IUD and sleep disorders (Bener et al., 2019; Lam, 2014). IUD is further correlated with somatic diseases, such headaches, visual impairments, hearing issues, and individuals with IUD have been reported to eat fast food more regularly than those with an unobtrusive internet use (Bener et al., 2019). Moreover, IUD was shown to lead to an increase in psychological distress, and subsequently a decrease in psychological well-being and life satisfaction (Lemmens et al., 2011; Müller et al., 2014). Although the co-occurrence of IUD and other mental disorders has been demonstrated, knowledge on causality is often lacking (Aboujaoude, 2010; Kardefelt-Winther, 2014; Kliche et al., 2018; Starcevic, 2010). Excessive internet use does not necessarily indicate a major IUD but may occur as a concomitant symptom of another mental disorder. Thus, reducing symptoms of the primary disorder, may also result in a reduction of excessive internet use. It has not been conclusively determined whether the reported comorbid mental health symptoms are consequences promoted by an IUD or whether these comorbid symptoms precede IUDs in form of influencing factors. The latter would mean that, e.g., individuals suffering from depressions are more likely to develop an IUD. To explain the interaction of pathological internet use and other mental disorders, there are approaches that view internet use as a behavioral manifestation of preexisting psychopathological symptoms (Starcevic & Aboujaoude, 2017). In this context, the internet use functions primarily as a medium through which a problematic behavior pattern is expressed (Starcevic & Aboujaoude, 2017; Wood, 2008). For example, excessive use of social networking sites could be attributable to underlying social anxiety. In this case, the internet enables an anonymous, perceived safe space for social exchange which manifests social anxiety in real life.

1.3.2 Treatment Options for Internet Use Disorder

Despite a strong disease burden, available specialized treatment options for IUD are very limited (Petersen & Thomasius, 2010). There are few therapy and counselling services for people with IUD in Germany. First specific treatment programs and treatment guidelines for IUD emerged only recently, such as the cognitive-behavioral treatment manual for computer gaming disorder and internet addiction (Wölfling et al., 2014; Wölfling, Müller et al., 2017). Yet, eligible treatment structures are currently still in a formation process (Müller et al., 2018; Wölfling et al., 2014). Further, health insurance funding for treatment was often not available in Germany because IUD was initially not included in the international

diagnostic criteria as a disorder. However, in the updated version of the international classification of diseases (ICD-11) gaming and gambling disorder were incorporated as disorders due to addictive behaviors with a section of “other specified disorders related to addictive behaviors” (World Health Organization, 2019).

Nevertheless, therapeutic services for IUD are lacking. According to a study commissioned by the German Federal Ministry of Health which examined the counselling and treatment services for IUD in Germany, there is still a significant need for improvement in treatment options (Petersen & Thomasius, 2010). A survey from the Outpatient Clinic for Gambling Addiction in Adults in Mainz stated an average period of four years between the first occurrence of IUD symptoms and seeking treatment (Müller et al., 2018). Further aspects that explain gaps in the treatment of mental disorders which can be transferred to IUD are: very long waiting periods up to twelve months, for traditional face-to-face treatment in Germany (Rubeis & Steger, 2019). In addition, the treatment of mental disorders is associated with stigma for patients, so that affected individuals often do not want to use available treatment options due to a fear of stigmatization or shame (Ebert, Zarski et al., 2016). Social phobia may also contribute to an avoidance of seeking a face-to-face therapy. Further, psychotherapeutic treatment is often unavailable due to time or local constraints. (Andersson & Cuijpers, 2009).

CBT is revealing as an accepted method in the treatment of IUD. In comparison to other addiction therapy approaches, abstinence from the internet is not the therapeutic goal, rather the aim is abstinence from specific applications with controlled internet use as a treatment goal (Müller et al., 2018; Petersen et al., 2009). In most cases, affected individuals show a loss of control related only to a specific online activity (e.g., online gaming, social networking), while the use of other online activities is possible without showing symptoms of IUD. It is crucial to identify the individual user type to be able to establish subtype-specific abstinence agreements (e.g., exclusively towards online games). Accordingly, the therapeutic goals can vary greatly depending on the subtype (Müller et al., 2018).

While treating IUD, low levels of treatment motivation should be taken into account (Müller et al., 2018; Romanczuk-Seiferth, 2017). IUD shows a high ego-syntonic character which is typically accompanied by cognitive biases, such as the illusion of being able to control the addictive behavior (Müller et al., 2018). Therefore, establishing a motivation to change is of crucial importance at the beginning of treatment, otherwise risk of low compliance and non-adherence to the therapy is high (Müller et al., 2018). Motivational interviewing techniques (Miller, 1995) have proven effective in establishing treatment

motivation in addictive therapy. These techniques target the ambivalence regarding positive and negative aspects of the addictive behavior as well as the ambiguity of the addictive behavior in achievement of e.g., personal life goals.

An additional aspect that should be considered in IUD treatment is that affected individuals often show very low self-efficacy, low frustration tolerance and therefore often face difficulties in setting realistic goals and initiating behavioral change (Floros & Siomos, 2014; Müller et al., 2018). Therefore, it can be concluded that a structured approach and the promotion of realistic and specific goal setting are particularly important for treatment success. Also, low self-esteem and low self-efficacy, contributing to the maintenance of IUD, should be acknowledged in IUD treatments, e.g., by incorporating additional therapeutic elements, such as social skills training or measures to promote self-esteem (Müller et al., 2018).

In light of the described challenges, in particular denial, low motivation to change, and avoidance in help-seeking due to social insecurity or shame, low-threshold approaches are of particular importance in the treatment of IUD (Lindenberg, Halasy et al., 2017). However, review of current literature indicates that there are no low-threshold approaches in the treatment of IUD so that there is not only a gap in the health care system, but also a research gap. This reveals an acute need for research, specifically in the area of low-threshold therapy for IUD.

Additionally, little is known about the effectiveness of previous psychological treatment for IUD. Currently, there are only few evaluation studies that meet the standards of randomized controlled trials (RCTs). Apart from missing or inappropriate control conditions, available studies have been criticized for providing insufficient information on the therapeutic procedure and lack of adequate operationalization of IUD (King et al., 2011; King et al., 2017; Winkler et al., 2013). Despite the mentioned methodological shortcomings of existing clinical trials, a meta-analysis of 16 studies based on 670 patients examining the efficacy of different psychotherapeutic and pharmacological IUD treatments showed that the employed interventions were effective in reducing IUD symptomatology (d = 1.61) (Winkler et al., 2013). Further, in a comparison of different treatment approaches, CBT was found to have higher average effect size (d = 1.48; 95% confidence interval [CI] [0.84, 2.13]) on symptom reduction than other psychotherapeutic approaches (d = 1.12–2.67) (Winkler et al., 2013).

In conclusion, more research, that accounts for methodological quality criteria such as RCT designs, is needed to increase knowledge about IUD and to evaluate the existing

treatment approaches. In order to close the treatment gap for IUD, existing treatment options need to be extended, in particular by low-threshold treatment approaches. New treatment approaches should address the challenges of low treatment motivation, and comorbid conditions such as low self-esteem and social insecurities.

1.3.3 Treating Internet Use Disorder via the Internet

It may sound contradictive to treat IUD online as the excessive use of the internet represents the problem behavior itself. However, the use of digital health interventions can be seen as especially appropriate because those affected are addressed in their common online setting (Jansky-Denk, 2018). Individuals who use the internet extensively will most likely also prefer to use the internet to seek mental health services and treatment options. According to a survey report on counselling and treatment services for IUD in Germany, the participating institutions reported that 71% of respondents acknowledge internet searches as the most frequently used way for help seeking (Petersen & Thomasius, 2010).

Another reason why digital health interventions might particularly be suitable for the treatment of IUD is the active role of the individual in the treatment process in digital health interventions (Ebert & Erbe, 2012). Digital health interventions encourage individuals to use their own resources for problem solving. This is supposed to have a positive impact on the often poorly developed self-efficacy of those affected by IUD. Due to the co-occurrence of IUD with social phobia and low self-esteem, treatment seeker may be inhibited to approach traditional psychotherapy because of shame or anxiety in face-to-face contacts (Prizant-Passal et al., 2016). By using digital health interventions, affected individuals can experience anonymous treatment online without having to expose themselves to a social situation. This may increase the likelihood that they will seek treatment in the first place and subsequently receive treatment. Individuals with comorbid social phobia or a low self-esteem might therefore benefit from digital health interventions to a considerable extent. Thus, digital health interventions could be a useful addition to existing care services in the treatment of IUD and contribute to lowering treatment barriers (Kothgassner & Felnhofer, 2018; Petersen & Thomasius, 2010). In concordance to the above arguments, Lindenberg, Szász-Janocha et al. (2017) proposed three main characteristics that an intervention for IUD should have in order to overcome the treatment gap and successfully treat the heterogenous group of affected individuals. They elaborated on characteristics that interventions for IUD should have, to efficiently treat IUD. These characteristics fit perfectly to the components that a digital health intervention can provide. According to Lindenberg, Szász-Janocha et al. an intervention should be individualizable to cover a variety of symptoms and comorbidities.

Digital health interventions offer content-tailoring and elective modules, allowing an adaption to the specific comorbidities and symptoms of an individual suffering from IUD. Moreover, in light of low motivation and compliance in the target group, the treatment needs to be comprehensive and easily accessible. In this regard, one of the major advantages of digital health interventions is their implementation irrespective of time and place as well as the low threshold of treatment, which makes them easily accessible. Besides, digital health interventions can be designed in a comprehensive way and are easy to understand. Further, as individuals affected by IUD usually show different levels of impairment, ranging from severe dependence to habituated behavior, an intervention should be able to meet every level of demand. Digital health interventions can differ in their degree of therapeutic contact- from email to video-based live chats and provide option to autonomously choose the number of exercises followed by a possibility to review these as per the desired frequency. Overall, digital health interventions fit the proposed characteristics so that it is plausible to deduce that they might have the potential to overcome the treatment gap for IUD (see Fig. 1).

Figure 1

Digital Health Interventions to Overcome Internet Use Disorder (IUD)

Characteristics needed by an efficient intervention for IUD	Components of digital health interventions
Individualized/tailored to cover a variety of symptoms and comorbidities	✓ Elective modules (covering e.g., typically co-occurring symptoms) ✓ Adaptable content based on the clients input
Comprehensive and easily accessible	✓ Independent of time and place ✓ Accessible via internet; low costs
Adaptable for heterogenous levels of impairment	✓ Adaptable degree of contact with therapist ✓ Autonomously choosing suitable exercises and reviewing them according to individual needs

As per available literature, there are currently no digital health interventions in German-speaking countries that explicitly target the treatment of IUD and are based on CBT methods, so that we developed a digital health intervention called GET.ON Offline. This newly CBT-based psychological digital health intervention represents an outstanding pioneering project. In addition, there are no existing studies on the efficacy of digital health

interventions in the treatment of IUD in adults that meet the methodological standards of RCT design, so that little is known about the efficacy of digital health interventions in the treatment of IUD. This dissertation adds value not only on the treatment gap in IUD but also in conducting and providing studies researching IUD.

1.4 Digital Health Interventions in the Treatment of Insomnia in Students

1.4.1 Insomnia in Students

Sleep disorders are widespread, affecting about 27% of students per year (Gaultney, 2010). University students suffer from a range of sleep issues, such as poor sleep quality, sleep deprivation or delayed bedtimes and wake-up times during weekends (Lund et al., 2010). Moreover, studies have found that students' grades are negatively impacted by their sleep habits (Gaultney, 2010; Kelly et al., 2001). Irregular sleep-wake rhythm can lead to lower academic performance (Medeiros et al., 2001) and lack of sleep is associated with reduced learning capacity, poorer procedural and declarative learning and to generally reduced neurocognitive functioning (Curcio et al., 2006). In addition to academic impairment, there are also high correlations between impaired sleep quality of students and behaviors that pose a risk to physical and mental health, such as suicidal thoughts, smoking and alcohol consumption (Vail-Smith et al., 2009). On the other hand, a positive relationship between sleep length and life satisfaction has been found (Kelly et al., 2001). Furthermore, students with insomnia show a higher prevalence for depression, which leads to the conclusion that addressing sleep as a risk factor could reduce the likelihood for developing depression (Moo-Estrella et al., 2005). Due to the students' scientific perspective on treatment information and the instability of their life circumstances, their expectations and needs concerning treatments can be different from the general population (Fleischmann et al., 2018). The need for more individualized, content-related support, increased background information and better understanding of their situation expressed by students should be considered in treatment option for insomnia in students (Fleischmann et al., 2018). Student-specific topics can further include time management, procrastination, test anxiety, motivation, nutrition, exercise, as well as dealing with writer's block and concentration problems (Fleischmann et al., 2018), and therefore highly emphasize the need for tailored treatment programs for students.

1.4.2 Insomnia Treatment

Pharmacological treatments remain amongst the most commonly used treatment methods for sleep disorders, with small to moderate effect sizes (Sateia et al., 2017).

However, studies have found some serious concerns about pharmacological treatments as they have side effects - can lead to tolerance and subsequent dependence and moreover are not curative (Mitchell et al., 2012). Along with pharmacological treatment, psychological interventions are the predominant approaches for insomnia. Although numerous studies show comparable effects in the short, psychotherapy has better long-term effects and fewer known side effects (Jacobs et al., 2004; Mitchell et al., 2012; Riemann & Perlis, 2009; Seda et al., 2015; Wu et al., 2006). That is why psychological interventions are the first-line treatment recommended for insomnia in adults of any age. Pharmacological treatments should only recommended if psychological treatments are not effective or not available (Riemann et al., 2017). Even though psychological interventions should be prioritized and offered as a first treatment option, medication is still commonly prescribed and widespread (Grobe et al., 2019). One of the empirically validated therapies for insomnia that meet the criteria of the American Psychological Association is cognitive behavioral therapy for insomnia (CBT-I) including stimulus control, sleep restriction, progressive muscle relaxation, and paradoxical intention (Morgenthaler et al., 2006; Morin et al., 1999; Morin et al., 2006).

Studies have found that deficient recovery from stress is an important risk factor for developing insomnia. Thus, recovery from university-related stress can serve as an explanatory mechanism, which depends on three core components. Firstly, restorative sleep is crucial as individuals' basic resources are restored during sleep and therefore fatigue is reduced. Secondly, cognitive detachment from university-related thoughts plays a crucial role for restorative sleep. Lastly, psychological detachment and restorative sleep can be promoted by recreational activities as it draws students' attention away from stressful events. Further, activities during leisure time help to rebuild regulatory and affective resources. CBT-I can be effective in affecting these three core components. Meta-analyses showed that the efficacy of CBT-I with its combination of components aiming to improve sleep outperforms the treatment of insomnia with single therapy components, such as educational, behavioural or cognitive ones and its effect is longer lasting in comparison (Morin et al., 2006; van Straten et al., 2018). Studies revealed large effect sizes (g = 0.63–0.98) for CBT-I's (van Straten et al., 2018), which underscores the importance of availability of non-pharmacological treatments even more.

1.4.3 Treating Insomnia in Students via the Internet

Despite the existence of various interventions, the use of treatment is restricted because students suffering from insomnia often do not seek help due to fear of stigmatization

or the desire to solve problems on their own (Harrer et al., 2018). The fact that students do not receive proper treatment is crucial as it might clear the way for taking sleeping drugs instead of adapting own sleeping habits and learning about essentials of healthy sleep. Therefore, using the internet to provide self-help interventions may encourage students to make use of its benefits that traditional treatments might not offer. Advantages of internet intervention are: (1) they are easily accessible at any time and place; (2) participation is anonymous so stigmatization can be avoided; (3) they can be completed at an individual pace and materials can be reviewed as often as desired; (4) they are flexible and can be adapted to personal needs; (5) they may reach affected students earlier than traditional mental health services, hence preventing chronification or the onset of more severe mental health problems; and (6) they are easily scalable, as only a small increase in therapeutic resources is required to reach a larger number of the affected target group (Buntrock et al., 2014; Ebert et al., 2018; Olthuis et al., 2016).

Internet interventions for various conditions, such as depression, anxiety and sleep disorders have been well studied in both community and clinical samples (Cheng & Dizon, 2012; Cuijpers et al., 2009; Hedman et al., 2012; Johansson & Andersson, 2012; Mayo-Wilson & Montgomery, 2013; Richards & Richardson, 2012). Results of a meta-analysis showed that online CBTs were effective in reducing symptoms of depression, anxiety, stress and eating disorders among university students, with small to moderate effect sizes and was found to be superior to other types of treatment (Harrer et al., 2018). However, it is unclear whether this effectiveness reveals the benefits of the intervention rather than changes due to other effects. Moreover, participants included in most existing studies were healthy students and only a few were having sleep disorders or problems (Friedrich & Schlarb, 2018). Also notable is the lack of objective data as former CBT-Is for students relied on self-reports (Freeman et al., 2017; Gao et al., 2014; Morris et al., 2016; Taylor et al., 2014). The validity of the studies is further limited by a lack of follow-up measurements (Friedrich & Schlarb, 2018; Mitchell et al., 2012). Furthermore, previous studies used wait list control groups (Freeman et al., 2017; Gao et al., 2014; Morris et al., 2016; Taylor et al., 2014). Yet even more important, existing online CBT-Is are not adapted specifically to the needs of students.

To address these limitations of current research we adapted an intervention, previously developed and shown to be highly effective (d = 1.45; 95% CI [1.06, 1.84]) by Thiart et al. (2015) and tailored it to the particular population of students. We adapted this online CBT-I in order to meet the students' expectations and address their needs. Furthermore, to add to previous findings, we applied an active control group to control for

non-specific treatment components, identify the actual agents of change and thereby establish internal validity (Norell-Clarke et al., 2015). The comparison between the intervention group and the active control group is especially beneficial as it can serve to evaluate the actual effectiveness of the core components of CBT-I and whether changes are due to the sleep information that the active control group received or due to expectancy effects. This in turn, can provide reliable evidence for the superiority of the suggested intervention. In addition, diagnostic interviews aim to achieve a more reliable and objective diagnosis and thereby close the gap of possible incorrect assessments.

The StudiCare GET.Sleep intervention was specifically designed to target students with sleep disorders. In a RCT the intervention group was compared to an active control group to ensure a proper comparison between the interventions while controlling for non-specific treatment components.

2. Methods

In the following paragraph the RCT design that was used is presented as both interventions were evaluated in scope of a RCT. Also consistent throughout the dissertation were the recruitment methods. The recruitment measures were consistently conducted for the entire dissertation project and thus the GET.ON Offline and StudiCare GET.Sleep intervention were both advertised in parallel and using the same recruitment channels.

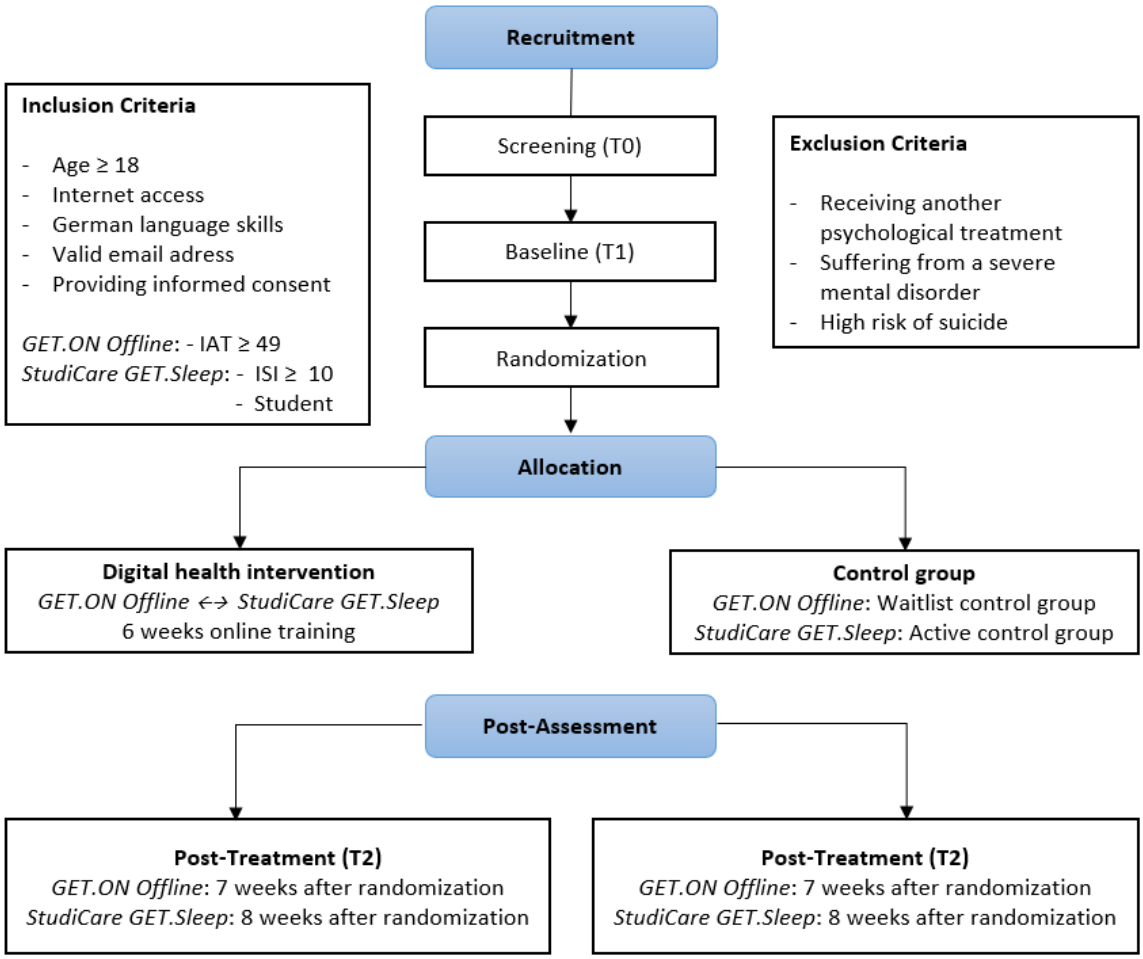
Further, the following chapter provides a brief overview of treatment guidelines and therapy format of the two interventions developed in scope of this dissertation. As the digital health interventions GET.ON Offline and StudiCare GET.Sleep were newly developed or adapted as part of this dissertation, they provide a core and the basis for the subsequent research studies.

2.1 Study Design—Randomized Controlled Trials

Two-armed RCTs were conducted to evaluate the efficacy of the digital health interventions GET.ON Offline and StudiCare GET.Sleep. The GET.ON Offline intervention was compared to a waitlist control group and the sleep intervention to an active control group. Assessments to evaluate the efficacy of the interventions took place at baseline (T1) and at post-treatment (T2: 7 weeks after randomization in the GET.ON Offline trial and 8 weeks after randomization in the sleep trial). See figure 2 for an overview of the study design. All procedures involved in the studies were consistent with the generally accepted standards of ethical practice approved by an ethics committee.

Figure 2

Study Design: Flowchart



2.2 Recruitment

The most important recruitment action was mass e-mailing German universities with information on the StudiCare interventions (https://www.studicare.com). As both disorders affect mainly young adults, this recruitment channel was most useful. Moreover, participants for both trials were recruited in Germany, Austria, and Switzerland via (1) the GET.ON Website (https://geton-training.de) and (2) the StudiCare website. Recruitment took place over (3) social media, discussion forums and self-help groups, (4) publishing articles on Blogs, (5) mass e-mailing with information regarding the studies and interventions to German (non-) psychological counselling centers, medical practices, clinics, health insurances, outpatient clinics and adult education centers. Further, (6) we advertised the interventions in lectures of university classes, (7) spread flyer and posters for example in

university and public buildings and (8) published articles on GET.ON Offline in magazines and newspapers.

For the GET.ON Offline trial recruitment took place from October 2018 to December 2020 and that for the StudiCare GET.Sleep trial from July 2019 to January 2021.

2.3 Digital Health Intervention: GET.ON Offline

To have an overview of the GET.ON Offline intervention and its basic components, see figure 3. To provide the easy access, it is fully internet delivered, contains several elective modules to cover typically co-occurring symptoms. It is a guided intervention with content focused guidance by an eCoach which is based on a treatment manual and guidance is individually adapted for participants according to their input. The intervention further contains tiny tasks delivered via a mobile app, which aims to support the participants in transferring exercises of the intervention into their daily lives.

Figure 3

Components of the GET.ON Offline Intervention

The intervention consists of seven modules: Goal setting and motivational interviewing (module 1), impulse control (module 2), problem solving (module 3), cognitive restructuring (module 4), self-worth (module 5), relapse prevention (module 6), and a booster module four weeks after completion of the core modules (module 7) (see Table 1 for an overview of the main modules).

Table 1

Content of the Training

Intervention content	Module
Goal setting and motivational interviewing: ▪ Introduction to the training ▪ Motivation for behavior change ▪ Setting treatment goals	1
Impulse control: ▪ Self-control and stimulus control techniques ▪ Identifying resources and strengths ▪ Implementation of positive activities	2
Problem solving: ▪ Strategies on how to deal with difficulties ▪ Understanding IUD – Influencing factors, risk factors and vicious circle	3
Cognitive restructuring: ▪ Relationship of cognition, behavior and (negative) emotions ▪ Acceptance and cognitive restructuring	4
Self-worth: ▪ Facilitating positive self-perception ▪ Strengthening self-confidence and self-efficacy	5
Relapse prevention: ▪ Reflection on training progress and personal goals ▪ Identifying mechanisms that helped and planning how to maintain acquired strategies	6
Booster module: ▪ Reflection on training progress and personal goals ▪ Re-definition of treatment goals	7

Note. IUD = internet use disorder.

Moreover, participants can choose between several elective modules based on individual need and preference. The elective modules are directed at personal needs and values, sleep, relaxation, alcohol and affect regulation, appreciation and gratefulness, and procrastination (see table 2 for an overview of the elective modules).

Table 2

Elective Modules

Module
Relaxation
Alcohol & affect regulation
Personal needs & values
Appreciation & gratefulness
Sleep
Procrastination

2.4 Digital Health Intervention: StudiCare GET.Sleep

The StudiCare GET.Sleep intervention is based on the highly effective iCBT-I GET.ON Recovery (Thiart et al., 2015) and tailored to the particular population of students based on prior analyses on specific treatment needs in students using internet interventions (Fleischmann et al., 2018). Tailoring was further achieved by using student testimonials.

The intervention consists of six 1-week modules including well-established CBT-I methods, such as sleep restriction, stimulus control, sleep hygiene, and cognitive interventions (Siebern & Manber, 2010) (see Table 3 for an overview of the modules).

Table 3

Overview of the StudiCare GET.Sleep Intervention

Intervention content	Module
Psychoeducation on recovery and sleep hygiene	1
Stimulus control and sleep restriction	2
Sleep restriction and cognitive detachment	3
Worrying and rumination techniques	4
Detachment mindfulness and attention training (MCT)	5
Relapse prevention/Summary	6

Note. MCT = metacognitive therapy.

The theoretical presumption of StudiCare GET.Sleep is that students' sleep disorders are caused by an impaired recovery from their university-related stress. Thus, insomnia symptoms would improve if their recovery was enhanced (Hahn et al., 2011; Morin et al.,

1994). Based on that, StudiCare GET.Sleep also included interventions on restorative sleep, cognitive detachment, and recreational activities. These interventions were presented on an intellectual level to account for the need for more in-depth information and to provide scientifically validated background information. Moreover, the intervention addressed specifically student-named problems and difficulties that affect sleep, such as an irregular daily structure, increased exposure to distraction stimuli during studies, increased performance pressure, and merging boundaries from university and leisure time. The intervention therefore placed a special focus on the organization of a daily structure and exercises on concentration focusing.

3. Original Publications and Articles

Publications on IUD:

Saruhanjan, K., Zarski, A.-C., Schaub, M.P., Ebert, D.D. (2020). Design of a guided internet- and mobile-based intervention for internet use disorder – Study protocol for a two-armed randomized controlled trial. Frontiers in Psychiatry.

Bernstein, K., Zarski, A.-C., Schaub M.P., Pekarek, E., Berking, M., Baumeister, H. Ebert, D.D. (2023). Case report for an Internet- and mobile-based intervention for Internet Use Disorder. Frontiers in Psychiatry.

Bernstein, K., Schaub, M.P., Baumeister, H., Berking, M., Ebert, D.D.*, Zarski, A.-C.* Treating internet use disorder via the internet? Results of two-armed randomized controlled trial. Journal of Behavioral Addictions. Submitted May 2023 (Currently under review).

*Shared last authorship

Publications on Sleep:

Saruhanjan, K., Zarski, A.-C., Bauer, T., Baumeister, H., Cuijpers, P., Spiegelhalder, K., Auerbauch, R.P., Kessler, R.C., Bruffaerts, R., Karyotaki, E., Berking, M., Ebert, D.D. (2020). Psychological interventions to improve sleep in college students: A meta-analysis of randomized controlled trials. Journal of Sleep Research.

Bernstein, K., Baumeister, H., Ebert, D.D., Zarski, A.-C. Efficacy of an internet intervention for students suffering from primary insomnia – a two-armed randomized controlled trial. In preparation for submission to Sleep.

3.1 Article 1: Psychological interventions to improve sleep in college students: A meta-analysis of randomized controlled trials

Title: Psychological interventions to improve sleep in college students: A meta-analysis of randomized controlled trials

Authors: Karina Saruhanjan, Anna-Carlotta Zarski, Tobias Bauer, Harald Baumeister, Pim Cuijpers, Kai Spiegelhalder, Randy P. Auerbach, Ronald C. Kessler, Ronny Bruffaerts, Eirini Karyotaki, Matthias Berking, David Daniel Ebert

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Summary:

Sleep disturbances and insomnia are common in college students and reduce their quality of life and academic performance. The aim of this meta-analysis was to evaluate the efficacy of psychological interventions aimed at improving sleep in college students. A meta-analysis was conducted with 10 randomized controlled trials with passive control conditions (N = 2,408). The overall mean effect size (Hedges' g) of all sleep-related outcomes within each trial was moderate to large (g = 0.61; 95% confidence interval: 0.41−0.81; numbers-needed-to-treat = 3). Effect sizes for global measures of sleep disturbances were g = 0.79; 95% confidence interval: 0.52−1.06; and for sleep-onset latency g = 0.65; 95% confidence interval: 0.36−0.94. The follow-up analyses revealed an effect size of g = 0.56; 95% confidence interval: 0.45−0.66 for the combined sleep-related outcomes based on three studies. No significant covariates were identified. These results should be interpreted cautiously due to an overall substantial risk of bias, and in particular with regard to blinding of participants and personnel. Nevertheless, they provide evidence that psychological interventions for improving sleep are efficacious among college students. Further research should explore long-term effects and potential moderators of treatment efficacy in college students.

Contribution:

Karina Bernstein was the principal investigator and author of the published article. She conceived and designed the meta-analysis under supervision of David Daniel Ebert and Harald Baumeister. Karina Bernstein analyzed the data and Tobias Bauer analyzed the data as an independent second rater. Karina Bernstein wrote the published article with feedback from Anna-Carlotta Zarski and David Daniel Ebert. The article was approved to be published by all co-authors.

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REVIEW

Journal of Sleep Research

Psychological interventions to improve sleep in college students: A meta-analysis of randomized controlled trials

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Summary

Sleep disturbances and insomnia are common in college students, and reduce their quality of life and academic performance. The aim of this meta-analysis was to evaluate the efficacy of psychological interventions aimed at improving sleep in college students. A meta-analysis was conducted with 10 randomized controlled trials with passive control conditions (N = 2,408). The overall mean effect size (Hedges' g) of all sleep-related outcomes within each trial was moderate to large (g = 0.61; 95% confidence interval: 0.41–0.81; numbers-needed-to-treat = 3). Effect sizes for global measures of sleep disturbances were g = 0.79; 95% confidence interval: 0.52–1.06; and for sleep-onset latency g = 0.65; 95% confidence interval: 0.36–0.94. The follow-up analyses revealed an effect size of g = 0.56; 95% confidence interval: 0.45–0.66 for the combined sleep-related outcomes based on three studies. No significant covariates were identified. These results should be interpreted cautiously due to an overall substantial risk of bias, and in particular with regard to blinding of participants and personnel. Nevertheless, they provide evidence that psychological interventions for improving sleep are efficacious among college students. Further research should explore long-term effects and potential moderators of treatment efficacy in college students.

KEYWORDS

insomnia, meta-analysis, sleep disturbances, students

1 | INTRODUCTION

Impaired sleep is highly prevalent in the general population (Morin, Bootzin, LeBlanc, Daley, Gregoire, & Mérette, 2006; Ohayon, 2002), and is associated with substantial disease burden (Kyle, Morgan, & Espie, 2010; Weinberg, Noble, & Hammond, 2016) and economic costs (Daley, Morin, LeBlanc, Grégoire, & Savard, 2009; Léger & Bayon, 2010). It is a feature of both clinically significant insomnia and non-clinically significant sleep disturbances. Insomnia can be defined as: (a) sleep difficulties concerning quantity and quality; (b) despite adequate opportunity and circumstances for sleep; (c) for at least 1 month; (d) resulting in specific daytime impairment related to the nighttime sleep difficulty (Buysse, Ancoli-Israel, Edinger, Lichstein, & Morin, 2006; Edinger et al., 2004). Sleep

disturbances include cases in which symptoms of insomnia do not reach clinical significance, as well as cases in which there is not enough information present to diagnose insomnia.

College students in particular are at risk for experiencing impaired sleep, in large part due to their high levels of perceived stress; likewise, an epidemiological study found that 60% of college students surveyed reported experiencing sleep disturbances (Lund, Reider, Whiting, & Prichard, 2010). The prevalence of clinical insomnia in college students reaches nearly 10% (Schlarb, Kulessa, & Gulewitsch, 2012; Taylor et al., 2011). As emerging adults trying to earn academic degrees, young college students face numerous new challenges, such as establishing identity and future life goals, reaching momentous life decisions, living independently, handling finances, managing academic demands, and modifying existing and adopting new social roles (Arnett, 2000; Brougham, Zail, Mendoza, & Miller, 2009; Pierceall & Keim, 2007). In contrast to other young adults, college students face a less prestructured everyday life due to self-organized schedules. In this respect, evidence shows that college students often shift to an irregular sleep–wake cycle by short sleep length on weekdays and later wake-up times on weekends (Buboltz, Brown, & Soper, 2001; Machado, Varelle, & Andrade, 1998) due to, for example, long learning hours, parties and noise pollution in student residences.

Given this transition phase in life, there are several reasons to assume that the efficacy of psychological interventions to improve sleep might differ between college students and the general population. Young adults (ages 19–29 years) show especially high strain in their everyday lives due to sleep disturbances and the worst sleep hygiene (SH) behaviour (Rosenberg et al., 2011). More severe sleep disturbances have been shown to be a predictor for larger sleep improvements within the scope of psychological intervention (Espie, Inglis, & Harvey, 2001; van Houdenhove, Buyse, Gabriëls, & van den Bergh, 2011; Murwaski, Wade, Plotnikoff, Lubans, & Duncan, 2018). Furthermore, psychological interventions aimed at changing beliefs and behaviour patterns might be more effective for college students than for other populations. Because cognitive flexibility is correlated with intelligence (Colzato, van Wouwe, Lavender, & Hommel, 2006) – which in turn is fostered by education (Ritchie & Tucker-Drob, 2018) – and decreases with increasing age (Peltz, Gratton, & Fabiani, 2011), college students may have above average cognitive flexibility. This increased cognitive flexibility may lead to improved response to psychological intervention. Finally, research has found increasing evidence that early intervention predicts better treatment outcomes for a variety of psychological disorders (McGorry, Purcell, Goldstone, & Amminger, 2011). Because sleep disturbances and insomnia often begin during the college years, this is an essential time for intervention (Lund et al., 2010).

Insomnia and sleep disturbances have been shown to be a precipitating factor for incidence of mental illness (Harvey, Murray, Chandler, & Soehner, 2011; Pigeon, Bishop, & Krueger, 2017). People suffering from insomnia show a two- to threefold (odds ratio [OR] = 1.98–2.98) increased risk for depression, a significantly greater risk for anxiety disorders (OR = 1.63–2.64), and a significantly greater risk for substance abuse disorders, including alcohol abuse (Baglioni et al., 2011; Pigeon et al., 2017; Sivertsen et al., 2014). Insomnia has also been reported to be a significant risk factor for medical conditions like arthritis (OR = 1.87), whiplash (OR = 1.71), arthrosis (OR = 1.68), headache (OR = 1.50), asthma (OR = 1.47) and myocardial infarction (OR = 1.46; Sivertsen et al., 2014). Studies investigating the mental and physical health consequences of insomnia and sleep disturbances in college students specifically provide results that indicate similar deleterious effects (Hershner & Chervin, 2014; Lund et al., 2010; Taylor & Bramoweth, 2010; Taylor et al., 2011; Wong et al., 2013). Moreover, sleep disturbances and insomnia in college students are associated with personal distress (Meerlo, Sgoifo, & Suchecki, 2008; Rosenberg et al., 2011), lower quality of life, lower academic achievement, and impaired declarative and procedural memory performance (Curcio, Ferrara, & de Gennaro, 2006; Gomes, Tavares, & de Azevedo, 2011; Kelly, Kelly, & Clanton, 2001; Wong et al., 2013). Furthermore, sleep disturbances increase the risk of self- and third-party endangerment. For example, 16% of an undergraduate sample reported having fallen asleep while driving at least once in their lifetime (Hershner & Chervin, 2014; Taylor & Bramoweth, 2010).

Cognitive behaviour therapy for insomnia (CBT-I), including stimulus control, sleep restriction, progressive muscle relaxation, SH and cognitive therapy, meets the American Psychological Association's criteria for empirically validated psychological interventions for insomnia (Morgenthaler et al., 2006; Morin, Bootzin, et al., 2006). CBT-I is recommended for the general population as first-line treatment for insomnia (Qaseem, Kansagara, Forciea, Cooke, & Denberg, 2016; Riemann et al., 2017), as it has been shown to be effective in improving sleep quality (SQ) and quantity in adult samples (van Straten et al., 2018).

Despite this, little is known about the efficacy of psychological interventions among college students, as there are no meta-analyses available referencing this specific population. Thus, investigating treatment response in college students is of particular importance due to their increased vulnerability to sleep disturbances and the negative health outcomes they experience as a result. Given that emerging adulthood – including college years – represents a time of major life transition and the highest risk of developing mental disorders, reaching emerging adults through interventions is of paramount importance (Auerbach et al., 2018; Kessler, Berglund, et al.,

Highlights

- The study shows an improvement of global measures of sleep disturbances in students.
- Interventions reduce SOL and improve daytime functionality.
- Self-help interventions are as effective as F2F interventions.
- The effects persist after the end of treatment.

2005; Kessler, Berglund, et al., 2005). College students experiencing a variety of stressors show an increased onset of mental health problems (Pedrelli, Nyer, Yeung, Zulauf, & Wilens, 2015; Thurber & Walton, 2012), with over 20% of all college students suffering from a mental disorder (Auerbach et al., 2018). This high prevalence depicts the elevated vulnerability for mental disorders at a time of major life transitions, that also influences further life of college students considerably, as this critical time period is substantial for basic life events as, for example, attaining educational levels/degrees (Auerbach et al., 2018; Bruffaerts et al., 2018). The number of affected college students far exceeds the resources of most treatment options at universities, resulting in substantial treatment gaps of mental health issues among college students (Auerbach et al., 2018; Beiter et al., 2015).

Further, college students are a key group in society in terms of human capital (Abel & Deitz, 2012), driving future societal economic growth and innovation. Higher education institutions provide an opportunity to become a key setting for the prevention and early treatment of sleep disturbances and insomnia, with a high reachability of over 50% of emerging adults being enrolled in higher education (Aud et al., 2011; Reavley & Jorm, 2010). Beyond that, because sleep disturbances are a common complaint that lack the stigma associated with other mental health issues, psychological interventions aimed at improving sleep may provide an acceptable low-threshold opportunity for a first step in a care pathway that have the potential to positively affect other co-morbid mental and physical health issues (Freeman et al., 2017; Friedrich & Schlarb, 2017; Wu, Appleman, Salazar, & Ong, 2015).

To the best of our knowledge, there are no meta-analyses available so far, focusing on psychological sleep treatments in college students. To date, two descriptive reviews have synthesized findings on psychological interventions to overcome sleep disturbances in college students. One of these reviews (Dietrich, Francis-Jimenez, Knibbs, Umali, & Truglio-Londrigan, 2016) focuses on education programmes to improve sleep. SH education in varying formats was identified as the main intervention form in the articles included in the review. The interventions on SH education differed in their format with regard to the integration of additional content, delivery strategies, length and duration of the programme. Studies were included that meet the primary outcome measures of SH knowledge, SH behaviour or SQ. However, because such programmes are a poorly explored subsection of psychological sleep interventions (at least among college students), this review includes only three randomized controlled trials (RCTs) and one quasi-experimental study. Significant effects of sleep education on SH knowledge and behaviour, respectively, were found in one of two studies, and effects on SQ were found in one of four studies. Thus, this review only provides preliminary evidence, and does not allow to draw conclusions on the overall effectiveness of sleep education interventions in college students. Furthermore, the review focuses on sleep education only, without targeting and analysing all types of psychological sleep interventions. Friedrich and Schlarb (2017) examined 27 evaluation studies on sleep treatments that included psychological components. The treatments were categorized in SH interventions, CBT-I, relaxation and other treatments (e.g. gestalt therapy or imagery rehearsal therapy). They found small to moderate effect sizes for SH interventions ($d = 0.32–0.61$), large effects for CBT-I ($d = 1.06–1.77$), and moderate effects for other psychological interventions ($d = 0.45–0.61$). Fifteen out of the 27 studies were RCTs, seven studies used a controlled design without randomization, and five trials had no control condition. Because it was the first review on the topic of sleep disturbances in college students, rather broad eligibility criteria were chosen that focused more on sensitivity than specificity (Friedrich & Schlarb, 2017).

Generalizability and interpretability of these two reviews are limited due to the small number of included studies, and the inclusion of studies that were not RCTs. The authors could, therefore, not calculate pooled effect sizes using meta-analytic techniques. Because several RCTs on this issue have recently been published, we performed a meta-analysis to evaluate the efficacy of psychological interventions aimed at improving sleep among college students compared with control conditions. Thus, the aim of the current meta-analysis is to deliver quantitative information on the effectiveness of sleep interventions in college students including RCTs only, focusing on psychological treatment with reported outcomes that are related to sleep.

2 | MATERIALS AND METHODS

This study was carried out as part of the WHO World Mental Health International College Student initiative (WMH-ICS), which aims to: (a) obtain accurate cross-national information on the prevalence, incidence and correlates of mental, substance and behavioural problems among college students worldwide; (b) describe patterns of service use, barriers to treatment and unmet need for treatment; (c) investigate the associations of these disorders with role function in academic and other life domains; (d) evaluate the effects of a wide range of preventive and clinical interventions on student mental health, functioning and academic performance; and (e) develop precision medicine support tools to help select the right interventions for the right students (Cuijpers et al., 2019). The WHM-ICS's meta-analysis initiative, of which the present meta-analysis is a subproject, has been registered with PROSPERO (CRD42017068758). The procedure and results of this systematic review are outlined in accordance to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Liberatio et al., 2009).

2.1 | Study selection

Publications were identified by searching three major electronic databases, starting from database inception on 28 September 2017 up to 20 March 2018: the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and PsycINFO. As part of the WMH-ICS, the search string was compiled on a superordinate level to provide a foundation for investigating a variety of psychological interventions in college students. Thus, the search string did not contain terms that

would restrict the search to the disorders or delivery modes targeted in this analysis; it accepted a high number of references for screening in order to minimize the risk of missing relevant studies. There were no restrictions on publication date or status. The search was based on a string combining terms text words, index, and free terms indicative of RCTs that evaluated psychological interventions in tertiary education settings (see Appendix A). From there, references in identified studies and previous systematic reviews of overlapping topics were checked for earlier publications. The WHO International Clinical Trials Registry Platform was also searched for unpublished trials as a way to identify grey literature. Authors of study protocols without published results were contacted to determine the eligibility of unpublished data for the meta-analysis.

We screened the titles and abstracts of all articles for overall fit for this analysis. Full texts of selected articles were then retrieved and independently assessed for eligibility. Both steps were performed independently by two researchers (KSa, TB). Discussion between researchers was initiated in case of assessor disagreement; two senior researchers (DEE, HB) were consulted when disagreement could not be resolved.

2.2 | Inclusion criteria

We included: (a) RCTs in which (b) individuals enrolled at a tertiary education facility (university, college or comparable postsecondary higher education facility) at the time of randomization, (c) received a sleep-focused psychological intervention, (d) that was compared with a passive control condition, defined as a control condition in which no active manipulation was induced as part of the study (wait-list, treatment as usual). For the purposes of this analysis, "sleep-focused" means: (e) effects on symptoms of sleep disturbances (global measures of sleep disturbances, sleep-onset latency [SOL], fatigue and daytime functionality, pre-sleep behaviour and experiences) were assessed as a (f) target outcome (by declaring a sleep outcome as the primary outcome or by stating the intervention was primarily aimed at this outcome) using (g) standardized symptom measures (objective sleep measures, standardized sleep or fatigue questionnaires, sleep diaries, items recording sleep quantity, quality or hygiene). Only studies (h) published in English or German were considered for inclusion.

Consistent with Cuijpers, van Straten, Warmerdam, and Andersson (2008), psychological interventions were defined as: interventions in which verbal communication between a therapist and a client was the core element; or in which a systematic psychological method was written down in book format or on a website (bibliotherapy), while the client worked through it more or less independently. Psychological interventions consisting of educational elements, cognitive methods, behavioural methods or other CBT-I-related techniques delivered face-to-face (F2F), written, by phone, tape or in computerized form were included. We elected to include all manner of psychological interventions currently practiced in order to provide a representative and overarching depiction of practiced psychological interventions. A subgroup analysis that focused on CBT-I exclusively was also conducted.

Thus, non-psychological interventions like medication, manipulation of light and sound, physical exercise or surgery were excluded. Studies exploring non-specific and hybrid interventions were also excluded, as they did not focus primarily on sleep. Furthermore, studies containing any participants who were not enrolled in higher education institutions were excluded, even if the majority of the sample was. Finally, case studies, cross-sectional studies, non-randomized trials, non-controlled trials, and trials with control groups containing interventions or other active manipulation such as placebo control conditions were also excluded. Our main research question was to analyse non-specific treatment effects of sleep interventions in college students as there was, to date, no evidence whether psychological interventions to treat sleep disturbances were also effective in the vulnerable group of college students (Ohayon & Reynolds, 2009). Thus, active control conditions were excluded as we did not intend to analyse specific effects of treatment in superiority or non-inferiority trials.

2.3 | Data extraction and classification

The following data were extracted for each article, if reported or applicable: (a) bibliographical data (first author, year of publication); (b) sample characteristics (sample size, gender and age distribution, dropout rate, university course[s] of the participants, study subject, compensation for participation, country); (c) participation criteria (inclusion and exclusion criteria)l; (d) intervention characteristics (mode of delivery, frequency and number of contacts, duration of intervention, therapeutic content, type of control group); (e) outcome measures (time points of assessments, outcomes of interest). In addition to sleep-related outcomes, we were also interested in measures of academic performance due to their reported relationship to sleep disturbances.

If relevant information to examine the eligibility of a study was not available, authors were contacted a maximum of two times to attain or clarify information. If the authors did not respond, and the information given in the publication was insufficient to perform a meta-analysis, the article was excluded. Data extraction was conducted independently by two researchers (KSa, TB).

2.4 | Quality assessment

Study validity was evaluated by two researchers (KSa, TB). The risk of bias assessment was carried out according to the updated method guidelines for systematic reviews with RCTs of the Cochrane Collaboration (Furlan, Pennick, Bombardier, & van Tulder, 2009). We examined bias due to: (a) selection (sequence generation, allocation concealment and the similarity of participants in the different conditions); (b) lack of blinding (blinding of participants, personnel and outcome assessors); (c) incomplete outcome data (amount of dropout and the way dropout data were handled [imputation methods]); and (d) four other threats to validity (e.g. selective outcome reporting, presence of parallel interventions to the study intervention, differences in compliance with the interventions across

TABLE 1 List of outcomes reported in at least one of the included studies

Outcome	Outcome type	Abbreviation	Frequency	Specific construct
Sleep diary and objective data				
Sleep quality	Sleep diary	SQ	2	GMoSD
Sleep-onset latency	Sleep diary	SOL	6	SOL
	Actigraphy		1	SOL
	EEG		1	SOL
Difficulties falling asleep	Sleep diary	DFA	1	
Number of awakenings	Sleep diary	NWAK	2	
	Actigraphy		2	
Sleep efficiency	Sleep diary	SE	2	
	Actigraphy		2	
Technology use before and at bedtime	Sleep diary	Techuse	1	
Terminal wakefulness	Sleep diary	TWAK	2	
	Actigraphy		1	
Total sleep time	Sleep diary	TST	2	
	Actigraphy		2	
Wake after sleep onset	Sleep diary	WASO	3	
	Actigraphy		1	
Questionnaires				
Insomnia Severity Index (Bastien, Vallières & Morin, 2001)		ISI	2	GMoSD
Pittsburgh Sleep Quality Index (Buysse, Reynolds, Monk, Berman & Kupfer, 1989)		PSQI	3	GMoSD
Sleep Condition Indicator with 8 items (Espie et al., 2014)		SCI-8	1	GMoSD
Epworth Sleepiness Scale (Johns, 1991)		ESS	2	DFF
Fatigue Severity Scale (Krupp, LaRocca, Muir-Nash & Steinberg, 1989)		FSS	1	DFF
Insomnia Impact Scale (Hoelscher, Ware & Bond, 1993)		IIS	1	DFF
Multidimensional Fatigue Inventory (Smets, Garssen, Bonke & De Haes, 1995)		MFI	1	DFF
Work and Social Adjustment Scale (Mundt, Marks, Shear & Greist,)		WSAS	1	DFF
Dysfunctional Beliefs and Attitudes about Sleep (-Short Form) (Morin, Stone, Trinkle, Mercer, & Remsberg, 1993; Short-form: Morin, Vallières & Ivers, 2007)		DBAS (-SF)	2	PSBE
Sleep Hygiene Index (Mastin, Bryson, & Corwyn, 2006)		SHI	1	PSBE
Disturbing Dreams and Nightmare Severity Index (Krakow et al., 2002)		DDNSI	1	

Abbreviations: DFF, daytime-functionality and fatigue; Frequency, number of comparisons reporting the outcome; GMoSD, global measure of sleep disturbances; PSBE, pre-sleep behaviour and experiences; SOL, sleep-onset latency; Specific constructs, constructs, the outcomes were allocated to, for calculations of effect sizes of specific constructs.

conditions, including intensity, duration, number and frequency of sessions and differences in timing of outcome assessments in the conditions). In addition to the recommendations of Furlan et al. (2009), we reported: (e) researcher allegiance, as it has been shown to be associated to outcome (Munder, Brütsch, Leonhart, Gerger, & Barth, 2013); and (f) whether the sample was a convenience sample chosen due to reachability. The risk of researcher allegiance was considered high if at least one of the authors developed the intervention and: (a) delivered it himself; or (b) did not deliver it himself but trained or supervised those that did (Gaffan, Tsaousis, & Kemp-Wheeler, 1995; Leykin & DeRubeis, 2009). The studies' risk of bias was considered low if: (a) at least six of Furlan et al.'s (2009) 12 suggested risk of bias criteria were rated low; and (b) the risk of researcher allegiance was rated low.

2.5 | Outcome measures

The included studies reported a number of different outcome measures and used different measurement methods (primarily questionnaires or daily sleep diaries, but also actigraphy and electroencephalography [EEG]). Sleep-related outcomes included all measures assessing: (a) direct sleep disturbances (e.g. global measures of sleep disturbances, SQ, sleep duration, SOL, number of awakenings or sleep patterns); (b) pre-sleep behaviour and experiences (e.g. pre-sleep arousal, technology use before sleep); (c) attitudes towards sleep (e.g. dysfunctional beliefs, attribution patterns concerning sleep); (d) fatigue and daytime functioning attributed to SQ and sleep quantity; and (e) behaviour patterns fostering or decreasing SQ and sleep quantity (e.g. SH). The different sleep-related

outcomes reported in the studies and their frequency can be seen in Table 1.

The majority of studies reported more than one outcome assessing sleep, and a primary outcome was not defined. Because of this, we used combined effect sizes for each study. Thus, effect sizes contain effects of the psychological intervention on all obtained sleep-related facets. Effect sizes were calculated by standardizing all sleep-related outcomes within a study and combining them to one effect size. When calculating a combined effect size within a single study, the intercorrelations between included outcomes need to be considered. We assumed a conservative intercorrelation of $r = 1$. To account for the potential distortion of effect size created by this assumption, we added a sensitivity analysis with an intercorrelation estimation of $r = 0$ (Becker, 2000).

2.6 | Meta-analyses

2.6.1 | Power calculation

An *a priori* power analysis (Borenstein, Hedges, Higgins, & Rothstein, 2010) indicated that at least 15 studies with at least 20 participants per condition, respectively, six studies with at least 50 participants per condition, would be needed to detect an effect of $g = 0.3$ (with moderate heterogeneity) with a statistical power of 0.8 and a significance level of $\alpha = .05$.

2.6.2 | Effect size calculations

An effect size for each sleep-related outcome in each study was calculated. These effect sizes compared post-treatment values of intervention groups and control groups. As many included studies had small sample sizes, bias was corrected for by calculating Hedges' *g* as an effect size metric (Hedges & Olkin, 2014). The effect sizes were calculated using reported means and standard deviations or *t*-values (Lipsey & Wilson, 2010). Effect sizes below $g = 0.32$ were rated as small, between $g = 0.33$ and 0.55 as moderate, and above 0.55 as large (Lipsey & Wilson, 1993). To facilitate clinical interpretation of standardized mean difference (Hedges' *g*), we calculated numbers-needed-to-treat (NNT) to generate one additional clinically significant change using the formulae of Kraemer and Kupfer (2006). We applied the random effects model for pooled effect sizes (Borenstein et al., 2010). Effect sizes, measures of heterogeneity (visual forest-plot inspection, *Q* and I^2) and publication bias (visual funnel-plot analysis, Egger's test, Duval and Tweedie's Trim and Fill method) were calculated with the programme CMA (version 3.3.070; Borenstein, Hedges, Higgins, & Rothstein, 2014). For the calculation of effect sizes, we only conducted meta-analyses when there were five or more studies available for pooling. The confidence interval of I^2 was calculated according to Borenstein et al. (2010). I^2 heterogeneity of 25% can be regarded as low, 50% as moderate, and 75% as substantial heterogeneity (Higgins, Thompson, Deeks, & Altman, 2003).

2.6.3 | Subgroup analyses

Subgroup analyses were based on the mixed effects model; a fixed effects model was used to test differences across subgroups, while a random effects model was used within subgroups (Borenstein et al., 2010). Due to the small number of studies included, only three covariates were tested in subgroup analyses: (a) type of psychological intervention; (b) mode of delivery; and (c) risk of bias. Meta-regressions were not conducted for this same reason. (a) Type of psychological intervention could be categorized in behavioural, cognitive, educational, and cognitive behavioural treatment. (b) Mode of delivery was divided into individual F2F therapy, group therapy, and self-help treatment based on the included study; and (c) risk of bias was categorized in high and low risk of bias for the subgroup analysis.

2.6.4 | Specific sleep constructs

In addition to the calculation of the overall effect size, we analysed the effect of the interventions on specific sleep constructs. The construct "*global measures of sleep disturbances*" includes questionnaires assessing the conditions of sleep (Pittsburgh Sleep Quality Index [PSQI], Insomnia Severity Index [ISI], Sleep Condition Indicator with eight items [SCI-8], and the sleep diary item "sleep quality"). To reduce the risk of over-representing single aspects of sleep disturbances, sleep diary items focusing on a single aspect (e.g. "number of awakenings") were excluded. The construct "*fatigue and daytime functionality*" includes all questionnaires assessing fatigue and daytime functionality in connection to SQ, sleep continuity or sleep duration. The construct "*pre-sleep behaviour and experiences*" includes all questionnaires assessing SH or attitudes towards sleep. The construct "*SOL*" includes all measures assessing the duration of time spent trying to fall asleep to actually falling asleep; this includes measures derived from the sleep diary, actigraphy and EEG (Table 1).

2.6.5 | Follow-up analysis

The effect sizes for available follow-up measurements were calculated by comparing the treatment conditions with the control conditions. Follow-up measurements include all measurements declared by the authors of the studies as such and timed after the end of intervention and post-test measurement.

3 | RESULTS

3.1 | Selection of studies

We screened a total of 12,206 studies for titles and abstracts (search string $n = 11{,}936$; secondary search strategies $n = 270$). After this screening, 23 studies of the main search string and 12 studies of the additional secondary search strategies remained to be assessed

on the full text level. The study selection process is described in a PRISMA flowchart (Figure 1). Finally, 10 studies were included in the meta-analysis. The inter-rater reliability concerning study selection was very good ($\kappa = 0.83$).

3.2 | Missing data

With regard to missing data, 14 authors were asked via email to provide the full text. Five of the missing studies were conference abstracts and thus not able to be included. Four studies could be identified as unpublished master theses with no access given. Three authors did not provide full text articles needed, and thus respective studies had to be excluded. Two of the studies received were excluded because they: (a) examined a treatment focusing on headache with sleep disturbances as a co-morbidity; and (b) investigated the effectiveness of booster sessions after the initial treatment only.

3.3 | Study characteristics

Detailed study characteristics can be found in Table 2.

The 10 studies included 2,408 college students in total (treatment conditions: $n = 1,002$; control conditions $n = 1,406$). In the seven studies reporting gender, the majority of participants were female (70.1%). Five studies included only psychology students, while the other five included students from a variety of disciplines. In five of the studies, participants did not receive any incentive for study participation. Conversely, of the remaining five studies, two offered course credit, two offered monetary compensation, and the final study offered both.

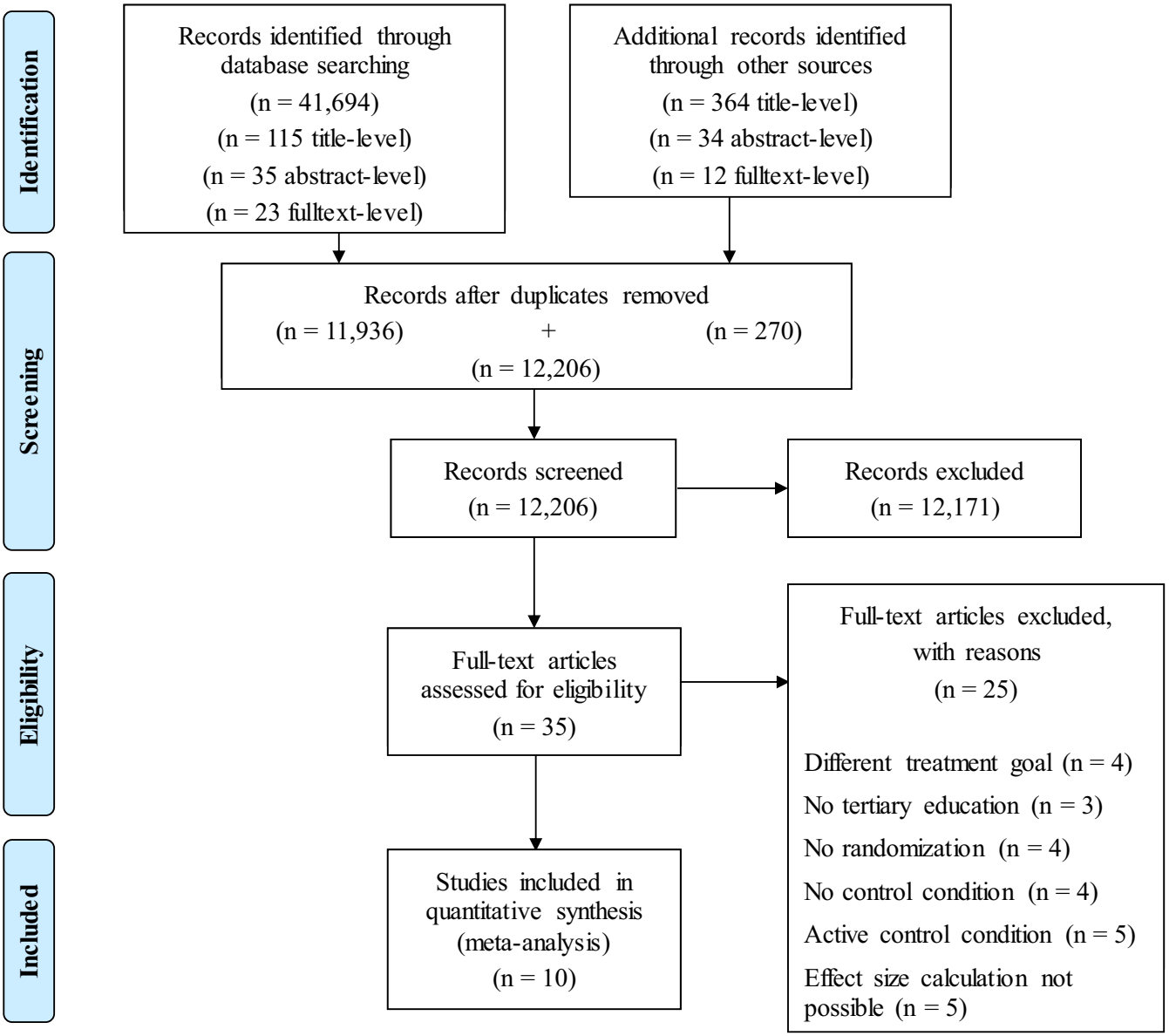


FIGURE 1 PRISMA flowchart of included studies

Seven studies were conducted in the USA, two in the UK and one in China. Two studies did not have any inclusion criteria.

Four studies compared CBT-I with control groups, and one of these studies added music therapy to CBT-I. Freeman et al. (2018) used the unguided web-based CBT-I intervention Sleepio, which is based upon a validated manual (Espie et al., 2001, 2007, 2008) presented by an animated therapist. An initial assessment drove the algorithms used to personalize the programme. Participants completed interactive therapy sessions once a week for 6 weeks; each session lasted 20 min on average. Additionally, participants completed daily sleep diaries. Throughout the intervention, participants had access to a moderated online community and an online library for information about sleep. The psychological intervention included sleep restriction, stimulus control (getting out of bed after 15–20 min not being able to fall asleep) and relaxation as behavioural techniques. The cognitive techniques included paradoxical intention, belief restructuring, mindfulness, imagery, and putting the day to rest. The educational component covered information about SH and the processes of sleep.

Gao et al. (2014) delivered CBT-I components on three consecutive days in 45-min group sessions, including: (a) sleep education; (b) stimulus control; and (c) progressive muscle relaxation (PMR). The first session included sleep education on: (a) proper sleep habits, sleeping process, and sleeping structure; (b) techniques to improve sleep; and (c) instructions to listen to calming music (provided in a music library by the researchers) for 30 min within 1 hr before nighttime sleep. The stimulus control portion of this intervention included six steps participants were required to complete daily (e.g. getting out of bed after 20 min not being able to fall or return to sleep). Finally, for PMR, participants were trained to divide their muscles into 16 groups that were contracted and relaxed successively. Participants were instructed to do PMR daily for 30 min, and were encouraged to combine music therapy with PMR. The process was supervised by researchers visiting students twice a week for 1 month.

Morris et al. (2016) used an unguided web-based CBT-I programme that contained seven modules and monitoring tools that depicted graphical feedback on sleep. Participants received periodic reminders to complete a given module; these reminders included motivational input. In order, the modules contained: (a) psychoeducation; (b) guided imagery; (c) relaxation techniques; (d) SH, stimulus control therapy and sleep restriction; (e) relaxation techniques; (f) PMR; (g) information and tips.

The CBT-I programme delivered by Taylor et al. (2014) was based on two treatment manuals (Morin & Espie, 2004; Perlis, Benson-Jungquist, Posner, & Smith, 2005). The programme included: (a) stimulus control therapy (e.g. getting out of bed after 20 min not being able to fall or return to sleep); (b) sleep restriction; (c) SH information addressing behaviours that may influence SQ and quantity; (d) a relaxation exercise combining deep breathing, PMR and autogenic training to be practiced twice a day; and (e) cognitive restructuring (e.g. eliciting the participants' dysfunctional beliefs and attitudes about sleep, and developing more adaptive ones).

Five studies used standalone behavioural interventions: relaxation ($k = 3$), stimulus control ($k = 1$) and exposition ($k = 1$). The three relaxation interventions contained either group sessions (Borkovec & Weerts, 1976; Steinmark & Borkovec, 1974) or individual sessions (Menas, Lichstein, Epperson, & Johnson, 2000) that trained participants in PMR and instructed them to complete PMR twice daily, including once prior to sleep. The stimulus control intervention (Zwart & Lisman, 1979) required participants to follow stimulus control rules, such as getting up after 10 min of not being able to fall or return to sleep. In the exposition intervention (Carrera & Elenewski, 1980), participants were asked to visualize lying in bed and having difficulties falling asleep. Then, they were encouraged to attend to bodily sensations and interpret them as a strange disease. Finally, they were instructed to imagine their own death.

One study used a sleep education programme (Barber & Cucalon, 2017) in which participants were informed about general SH information and technology boundary management via PowerPoint presentation.

Five of the psychological interventions were self-help programmes, of which four were delivered electronically and two were preceded by F2F training sessions. The other psychological interventions were delivered F2F as group therapy ($k = 3$) and individual therapy ($k = 2$). The group size ranged from two to seven. Considering all 10 studies, the number of contacts ranged from one to 11, and averaged 4.7 contacts (including e-mail contacts). The post-test measurements were conducted on average 4.5 weeks after the baseline measurements (range 1–10 weeks). This duration also reflects the intervention duration.

To measure sleep outcomes, sleep diaries ($k = 6$), objective measures such as actigraphy and overnight EEG ($k = 3$), and questionnaires ($k = 6$) were used. No study evaluated effects on academic functioning. Inter-rater agreement concerning study characteristics was very good ($\kappa = 0.87$).

3.4 | Quality assessments

The complete assessment for each study is presented in Table 3. Overall risk of bias was considerable. Of the 10 studies, five showed a high risk of bias. On average 7.5 of 14 assessments per study were rated unclear or high. Six studies did not report information on sequence generation and allocation concealment. Two studies did not report on demographic and baseline differences between conditions. One study had a high risk of bias in allocation concealment. All studies revealed an unclear or high risk of bias in at least two of the three blinding situations. Five of the studies revealed low risk of bias in the domain of incomplete outcome data. Concerning other threats to validity, most criteria showed on average low risk of bias. Only selective reporting showed on average a higher risk of bias, with nine studies being rated unclear and only one study being rated low. Three studies had an unclear or high risk of compliance differences between the treatment conditions, and three showed a high risk of researcher allegiance. Inter-rater reliability regarding risk of bias assessments was good ($\kappa = 0.76$).

TABLE 2 Selected characteristics of included RCTs (n = 10)

Author (Year)	Participants			Criteria		Outcome measures					
	N	Age M	Subject			MoD			Baseline		Sleep diary
	%Female	Age *SD*	Comp	Inclusion symptoms	Exclusion	Frequency	Treatment condition (*n*)	Control condition (*n*)	Post-test	Questionnaires	Objective measures
	Dropout	Semester	Country			Sessions			Follow-up		
Barber and Cucalon (2017)	78	20.00	all	none	none	SH-E	Sleep education (43)	TAU (35)	0	SHI	
	60.3%	4.84	/			Once			1 week	ICS	Actg (TST, NWAK, SE)
	8	All	US			1 × 23 min			/	Tech	
Borkovec and Weerts (1976)	22	/	psy	SOL > 30 min	CUD	GT (2)	Relaxation (11)	TAU (11)	0	SOL	diary (SOL)
	/	/	cc, mon		CWOPS	weekly			4 weeks		EEG
	3	1	US			4			12 months		
Carrera and Elenewski (1980)	39	/	psy	SOL > 45 min	CWOPS	SH-E	Death-exposure (16)	WLC (23)	- 4 weeks		diary (SOL)
	53.8%	/	/	FNR	PMPEI	once			4 weeks		
	/	1	US			1 × 45 min			/		
Freeman et al. (2017)	1,875	24.70	All	SCI < 16	none	SH-E	CBT-I (733) with sleep education, sleep restriction, stimulus control, relaxation, cognitive restructuring, imagery, mindfulness, paradox, thought stopping, putting day to rest	TAU (1,142)	0	SCI−8	
	71.3%	7.60	/			weekly			10 weeks	ISI	
	1,880	all	GB			6 x 20 min			22 weeks	DDNSI	
										WSAS	
Gao et al. (2014)	84	20.49	all	PSQI > 7	PMPEI	SH-T	CBT-I + *M* (42) with sleep education, stimulus control, relaxation, music therapy	TAU (42)	0	PSQI	
	67.9%	2.46	/	FTS		daily			4 weeks		
	0	all	CN	no job		3 × 45 min			/		

(Continues)

TABLE 2 (Continued)

Author (Year)	Participants: *N* / %Female / Dropout	Participants: Age M / Age *SD* / Semester	Participants: Subject Comp / Country	Criteria: Inclusion symptoms	Criteria: Exclusion	Outcome measures: MoD / Frequency / Sessions	Outcome measures: Treatment condition (*n*)	Outcome measures: Control condition (*n*)	Outcome measures: Baseline / Post-test / Follow-up	Outcome measures: Questionnaires	Outcome measures: Sleep diary / Objective measures
Means et al. (2000)	57	20.59	psy	SOL > 30 min	CUD-S	IT	Relaxation (28)	WLC (29)	0&2 weeks	IIS	diary (SOL, SQ WASO, SE)
	68.5%	4.84	cc	AASO > 30 min	PMPEI	3–7 days			8 weeks	DBAS	
	/	all	US	IDF > 2 months	ASS	3 x 15 min			/	FSS	
										ESS	
Morris et al. (2016)	95	20.48	All	None	none	SH-E	CBT-I (48) with sleep education, sleep restriction, stimulus control, relaxation, guided imagery	WLC (47)	0	PSQI	
	67.4%	2.09	mon			weekly			6 weeks		
	15	all	GB			7 x 20 min			/		
Steinmark et al. (1974)	24	/	psy	SOL > 30 min	CUD	GT (5–7)	Relaxation (12)	WLC (12)	0		diary (SOL, WASO, TWAK, NWAK, DFS)
	/	/	cc	> 6 months	CWOPS-S	weekly			4 weeks		
	4	1	US			4			5 months		
Taylor et al. (2014)	29	19.71	all	SOL > 30 min	CUD	IT	CBT-I (16) with sleep education, sleep restriction, stimulus control, relaxation, cognitive restructuring	WLC (13)	0–1 week	PSQI	diary (SOL, WASO, TWAK, NWAK, SE, SQ, TIB, TST)
	58.8%	2.10	mon	AASO > 30 min	PMPEI	weekly			6 weeks	ISI	
	5	all	US	IDF > 3 months	6			3 months	DBAS		
										ESS	Actg (SOL, WASO, SE, TWAK, NWAK, TST)
										MFI	

(Continues)

TABLE 2 (Continued)

Author (Year)	Participants: N / %Female / Dropout	Age M / Age SD / Semester	Subject / Comp / Country	Criteria: Inclusion symptoms	Exclusion	Outcome measures: MoD / Frequency / Sessions	Treatment condition (n)	Control condition (n)	Baseline / Post-test / Follow-up	Questionnaires	Sleep diary / Objective measures
Zwart and Lisman (1979)	15	/	psy	SOL > 30 min	CUD	GT	Stimulus control (8)	WLC (7)	0–1 week		diary (SOL, WASO, TWAK, NWAK, DFS)
	/	/	/		SDDEN	weekly			4 weeks		
	9	all	US		CWOPS-S	4 × 30 min			8 weeks		

Abbreviations: AASO, awake after sleep onset; Actg (), actigraphy (measures); ASS, atypical sleep schedules (e.g. shift work); CBT-I(+M), cognitive behavioural therapy for insomnia (+ music therapy); cc, course credit; Comp, compensation for participating in the study; CUD, current use of drugs; CWOPS, contact with other professional services/treatment; DBAS, dysfunctional beliefs and attitudes about sleep scale; DDNSI, disturbing dreams and nightmare severity index; DFS, difficulty falling to sleep; diary (), sleep diary (measures); EEG, electroencephalography; ESS, Epworth Sleepiness Scale; FNR, feeling not rested; Frequency, frequency of contacts; FSS, Fatigue Severity Scale; FTS, full-time student; GT, group therapy (group size); ICS, items concerning sleep quantity and sleep quality (in comparison to sleep diary not daily but pre- and posttreatment); IDF, impaired daytime functioning; IIS, Insomnia Impact Scale; ISI, Insomnia Severity Index; IT, individual therapy; MFI, multidimensional fatigue inventory; MoD, mode of delivery; mon, monetary compensation; N, number of participants after dropout included in the comparison; NWAK, number of awakenings; PMPEI, psychological or medical problems except insomnia; PSQI, Pittsburgh Sleep Quality Index; Psy, psychology; -S, concerning sleep; SCI-8, Sleep Condition Indicator; SDDEN, sleep disturbance due to external noise; SE, sleep efficiency; SH(-E)(-T), self-help (-electronic intervention) (-with one to three face-to-face trainings prior to the self-help part); SHI, Sleep Hygiene Index; SOL, sleep-onset latency; SQ, sleep quality; TAU, treatment as usual control condition; Tech, technology use around bedtime; TIB, time in bed; TST, total sleep time; TWAK, terminal wakefulness; WASO, time awake after sleep onset; WLC, waitlist control condition; WSAS, Work and Social Adjustment Scale.

3.5 | Overall effect of psychological intervention

The overall effect size of combined outcomes of the 10 studies was moderate to large (g = 0.61; 95% confidence interval [CI]: 0.41–0.81) with moderate heterogeneity (I^2 = 41; 95% CI: 0–72). Negative effect sizes favour intervention success in the intervention group compared with the control group. The effect size for the combined outcomes equals a NNT of 3.

Visual analysis of the corresponding forest-plot (Figure 2) revealed one potential outlier, not overlapping with the pooled confidence interval. Excluding this study generated a moderate effect size of g = 0.54 (95% CI: 0.46–0.63) corresponding to a NNT of 3.36, with no heterogeneity (I^2 = 0; 95% CI: 0–52). The inter-rater reliability regarding the parameters to calculate effect sizes was excellent (κ = 0.98).

3.6 | Follow-up

Only three studies reported follow-up results. The studies gathered follow-up measures 1 month, 3 months or 12 months, respectively, after the end of psychological intervention. The combined follow-up effect size was g = 0.56 (95% CI: 0.45–0.66) with low heterogeneity of I^2 = 0 (95% CI: 0–95).

3.7 | Subgroup analyses

Subgroup analyses yielded no significant differences between subgroups, indicating that mode of delivery, risk of bias and type of treatment did not affect the effect size (see Appendix B).

3.8 | Sensitivity analyses

Calculating the overall effect size assuming independence of the outcomes (an intercorrelation of r = 0) yielded a slightly smaller effect size (g = 0.57; 95% CI: 0.38–0.75) and a higher heterogeneity (I^2 = 64; 95% CI: 30–82).

3.9 | Specific sleep constructs

For a summary of the effect sizes of specific sleep constructs, see Table 4.

3.9.1 | Global measures of sleep disturbances

Six studies reported at least one global outcome measure of sleep disturbances. Psychological interventions were able to improve the global measure of sleep disturbances compared with passive control conditions (g = 0.79; 95% CI: 0.52–1.06), but also showed moderate

TABLE 3 Risk of bias assessment of included studies (n = 10)

Selection bias			Blinding			Incomplete outcome data		Other threats to validity						
Sequence generation[a]	Allocation concealment[b]	Similar groups[c]	Participants[d]	Personnel[e]	Outcome assessors[f]	Dropout[g]	intention to treat analysis[h]	Selective Reporting[i]	Compliance[j]	Timing[k]	Cointerventions[l]	Researcher allegiance[m]	Convenience sample[n]	Risk of Bias[o]
Barber and Cucalon (2017)														
Low[p]	High	Low	High	High	Low	Low	Low	Unclear	Low	Low	Low	Low	High	Low
Borkovec and Weerts (1976)														
Unclear	Unclear	Unclear	High	High	Unclear	Low	Unclear	Unclear	Low	Low	Low	Low	High	High[q]
Carrera and Elenewski (1980)														
Unclear	Unclear	Low	Unclear	Low	High	Low	Unclear	Unclear	Low	Low	Low	Low	High	Low
Freeman et al. (2017)														
Low	Low	Low	High	Low	High	High	Low	Low	High	Low	Low	Low	High	Low
Gao et al. (2014)														
Unclear	Unclear	Low	High	High	High	Low	Low	Unclear	Low	Low	Low	Low	High	Low
Means et al. (2000)														
Unclear	Unclear	Low	Unclear	Unclear	Unclear	Unclear	High	Unclear	Low	Low	Low	High	High	High[r]
Morris et al. (2016)														
Low	Low	Low	High	High	High	Low	Low	Unclear	Low	Low	Low	High	High	High[s]
Steinmark and Borkovec (1974)														
Unclear	Unclear	Low	High	High	High	Low	Low	Unclear	Low	Low	Low	High	High	High[r]
Taylor et al. (2014)														
Low	Low	Low	High	High	Unclear	Low	High	Unclear	High	Low	Low	Low	High	Low
Zwart and Lisman (1979)														
Unclear	Unclear	Unclear	Unclear	Unclear	High	High	High	Unclear	Unclear	Low	Low	Low	High	High[q]

[a]Risk of selection bias due to inadequate generation of a randomized sequence.

[b]Risk of selection bias due to inadequate concealment of allocations prior to assignment.

[c]Risk of selection bias due to baseline differences between the treatment conditions in outcome measures and demographic measures.

[d]Risk of performance bias due to knowledge of the allocated interventions by participants during the study.

[e]Risk of performance bias due to knowledge of the allocated interventions by personnel during the study.

[f]Risk of detection bias due to knowledge of the allocated interventions by outcome assessors (objective outcomes/subjective outcomes).

[g]Risk of attrition bias due to incomplete outcome data.

[h]Risk of attrition bias due to handling of incomplete outcome data.

[i]Risk of reporting bias due to selective outcome reporting.

[j]Risk of performance bias due to differing compliance between the conditions.

[k]Risk of detection bias due to differences in time of outcome measurement across groups.

[l]Risk of performance bias due to differences in cointerventions across groups.

[m]Risk of detection bias due to researchers' attitudes to the treatments.

[n]Sample chosen for reasons of reachability.

[o]Overall estimated risk of bias.

[p]low, low risk of bias; high, high risk of bias; unclear, not enough information given to estimate the risk of bias.

[q]serious flaw: less than six low risk of bias assessments (researcher's allegiance and convenience sample excluded).

[r]serious flaw: less than six low risk assessments and high risk of researcher's allegiance.

[s]serious flaw: high researcher allegiance.

to high heterogeneity (I^2 = 65; 95% CI: 16–85; see Appendix C). We carried out the same subgroup analyses as in the sensitivity analyses for the overall effect size.

Including only studies using the PSQI (the most frequently reported questionnaire) for a global measurement of sleep disturbances led to even stronger effects (g = 1.09; 95% CI: 0.42–1.77) with high heterogeneity (I^2 = 79; 95% CI: 32–93).

3.9.2 | Sleep-onset latency

Sleep-onset latency was assessed by six studies through sleep diaries, actigraphy and EEG. The effect size of SOL was large (g = 0.65; 95% CI: 0.36–0.94) with very little heterogeneity (I^2 = 0; 95% CI: 0–63; see Appendix D).

3.10 | Publication bias

Both Egger's tests and visual inspection of funnel plots did not show any significant publication bias for all but one analysis. Only the visual inspection of the funnel plot for the effect size distribution of SOL suggested some publication bias. According to Duval and Tweedie's trim and fill procedure, three studies were imputed, resulting in a smaller but still significant effect size of g = 0.46.

4 | DISCUSSION

This meta-analysis suggests that psychological intervention may reduce sleep disturbances in college students, as determined by global measures of sleep disturbances and SOL. Overall risk of bias was substantial, but no indication of larger effects through distortion could be found relating to the risk of bias of a study. Indication for publication bias was only found for the construct SOL, in which adjusting for potential unpublished studies resulted in change. Thus, the present analysis implies psychological intervention to be an appropriate way to help the large number of college students with sleep disturbances.

Our results are in line with previous research among college students. In their review, Friedrich and Schlarb (2017) found comparable medium to high effect sizes regarding SQ (d = 0.61–1.56), a high range of effects regarding SOL (d = 0.38–1.16), and higher effects regarding daytime functioning for CBT-I (d = 1.10). In a meta-analysis, including general and clinical populations, van Straten et al. (2018) found smaller effects for SQ (g = 0.4) and PSQI (g = 0.65), and slightly smaller effects for SOL (g = 0.57), although CIs did overlap. Due to different operationalization of SQ (in our analysis called global measures of sleep disturbances to emphasize the different operationalization) and broad CIs in the present meta-analysis, those differences in effect size need to be interpreted cautiously. Still, they are in line with results found by van Straten et al. (2018) when examining age as a potential moderator. These authors found significant age differences in two (SOL and sleep efficiency [SE]) of the three main outcome variables (young adults: g = 0.7 for SOL, g = 0.99 for SE, g = 1.02 for ISI; all adults: g = 0.42 for SOL, g = 0.55 for SE, g = 0.73 for ISI). Assuming this difference in effect sizes is due to an actual increased benefit for college students compared with older adults (rather than representing methodological or other biases), it might be explained by two factors. First, young adults experience especially high strain from sleep disturbances, and show the worst SH compared with older adults (Rosenberg et al., 2011). Thus, college students (who are, in general, young adults) may have on average more room for improvement regarding their sleep. This assumption is similar to results found in research on depression, showing that higher pre-intervention symptom severity is associated with higher efficacy of psychological intervention (Driessen, Cuijpers, Hollon, & Dekker, 2010). In accordance with these findings, the study by van Straten et al. (2018) found higher effects of psychological treatment on sleep-related outcomes in primary care or specific care settings, in which participants are presumed to have stronger symptoms and psychological distress compared with the general population (care settings: g = −0.64 to −0.93; general population: g = −0.47 to −0.82; van Straten et al., 2018). Second, as outlined above, college students are likely to show above average cognitive flexibility (Colzato et al., 2006), resulting in a higher capacity to change their sleep behaviour and thus a potentially heightened benefit of psychological intervention. Future research is needed to confirm such assumptions.

The present meta-analysis did not find efficacy differences between different types of psychological interventions. This is inconsistent with the suggestion of Friedrich and Schlarb (2017) that CBT-I is the most effective psychological intervention, and SH interventions the least effective, a specification supported by research in the general population (Morin, Culbert, & Schwartz, 1994; Morin et al., 1999; Morin, LeBlanc, et al., 2006; Qaseem et al., 2016). It is noteworthy, though, that the latest and most comprehensive meta-analysis on psychological interventions for sleep disturbances and insomnia in the general population also failed to find this specification. The authors suggested that this may be due to variability within each type of psychological intervention, or a potential correlation of psychological intervention type, study quality and variation in effect size with time of publication; this would result in smaller effects for the types of psychological interventions investigated more recently with higher study quality (van Straten et al., 2018). This explanation might also apply to the results of the present meta-analysis. It is also noteworthy that the small number of trials in our meta-analysis might have reduced power to detect true differences in efficacy between different types of psychological intervention. However, effects of specific psychological intervention techniques could also be overestimated, and the reduction of sleep disturbances might be evoked by generic mechanisms of change common to all types of psychological intervention like therapeutic alliance, empathy, goal consensus and collaboration.

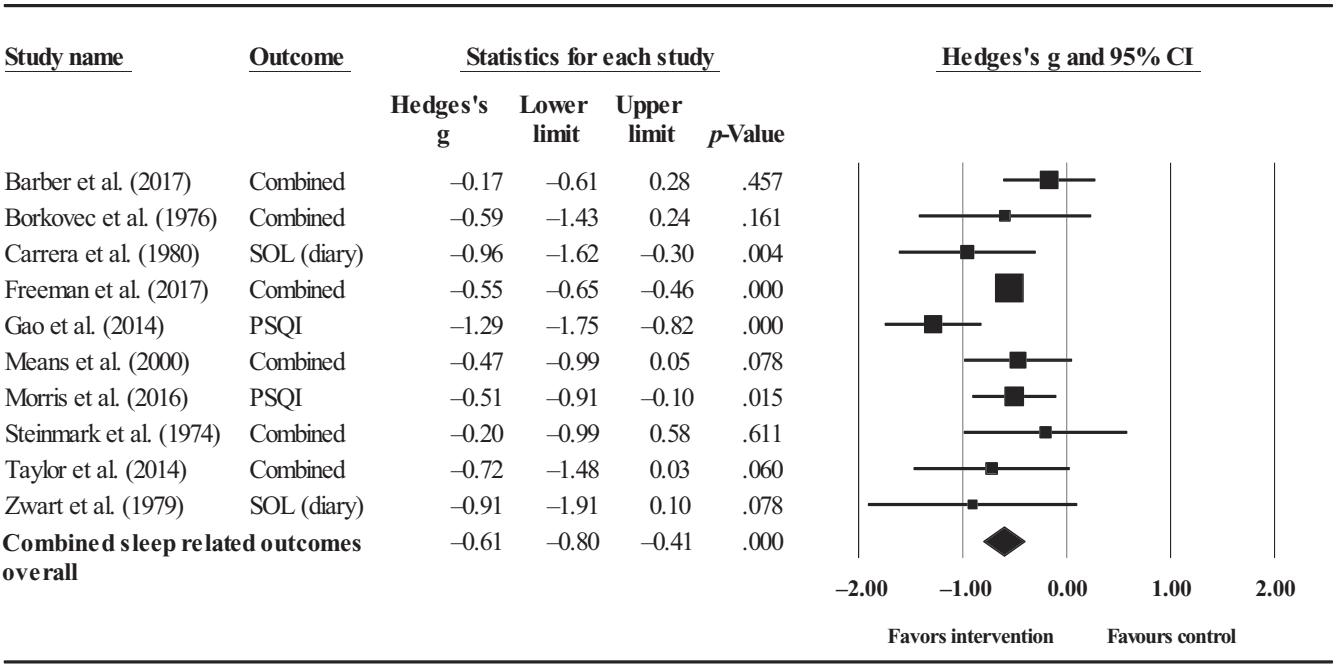
Although a previous study found F2F psychological intervention to be more effective in improving sleep than self-help psychological intervention in the general population (Lancee, van Straten, Morina, Kaldo, & Kamphuis, 2016), the present analysis does not support this

finding. This lack of significant difference in effect size is supported by Blom et al. (2015). Van Straten et al. (2018) found mixed results with F2F psychological intervention being more effective in improving SOL and SE, but not concerning the ISI. If the efficacy of self-help psychological intervention is supported by future studies, it may become the psychological intervention of choice for college students wanting to improve their sleep. Assuming equal efficacy between different modes of delivery, self-help interventions would combine efficacy with superior cost-effectiveness and accessibility compared with F2F psychological intervention.

The current meta-analysis has some limitations. First, the number of included studies was small. However, it is not only the number of studies that makes a meta-analysis reliable, but also the number of participants per study (Borenstein et al., 2010). The 10 studies that were included in this meta-analysis had an average sample size of more than 100 participants per condition, which is sufficient to reliably detect effect sizes of 0.3 and above, even given a small number of trials with high heterogeneity (Borenstein et al., 2010). Yet the small number of studies does enhance the risk of missing true effects due to insufficient power, especially in subgroup analyses. Second, half of the studies showed a high risk of bias, which can increase the chances of inflated effect sizes in comparison to the true effects in the population. However, subgroup analyses (grouped by risk of bias assessment) did not show significant differences in effect size. Finally, this meta-analysis had limited generalizability for the analysis of long-term effects, as only three studies reported usable follow-up data at different time periods.

Despite these limitations, we conclude that psychological interventions aimed at improving sleep among college students are effective, perhaps even more so than in other populations. Thus, extending additional validated psychological interventions to college students suffering from sleep disturbances is likely to be a worthwhile investment for both the individual and society. By improving sleep, psychological interventions reduce the risk of clinical sleep disorders, mental disorders and medical conditions that are triggered or amplified by sleep disturbances and insomnia (along with reducing the associated economic costs). Importantly, these reductions in risk would come during a critical period for the development of mental disorders (Breslau, Roth, Rosenthal, & Andreski, 1996; Daley et al., 2009; Kessler, Berglund, et al., 2005; Kessler, Chiu, et al., 2005; Sivertsen et al., 2014). Above that, such interventions may improve the cognitive performance of college students, who represent a large portion of a society's human capital (Gomes et al., 2011). More RCTs are needed to evaluate the effects and moderators of psychological interventions to improve sleep. It is particularly important to investigate the effects of psychological intervention design (e.g. type of psychological intervention, mode of delivery and number of contacts).

Future research should focus on creating more precise and consistent definitions of constructs (e.g. SQ) in order to differentiate constructs and their operationalization. Doing so may reduce the high number of sleep-related outcomes used in different sleep studies, and improve the comparability and quality of outcomes. It would also contribute to the quality of meta-analyses evaluating psychological sleep interventions. Furthermore, academic performance should be assessed and reported as an outcome in studies examining sleep disturbances in college students. This would help to investigate whether sleep interventions can decrease cognitive impairment



Note. Combined: Mean of all reported sleep related outcomes within a study; PSQI: Pittsburgh Sleep Quality Index; SOL (diary): Sleep onset latency measured via sleep diary

FIGURE 2 Overall effects of psychological treatment on combined sleep-related outcomes compared with passive control groups

TABLE 4 Effects of psychological treatment on specific sleep constructs

Construct specification			Effect size				Heterogeneity	
Construct	Outcomes	Studies (*n*)	Hedges' *g*	95% CI	*p*	NNT	I^2	95% CI
1. Global measures of sleep disturbances	ISI, PSQI, SCI−8, SQ(diary)	6	0.76	0.52 to 1.06	.000	2.36	65	16–85
2. Sleep-onset latency	All SOL measures	6	0.65	0.36 to 1.03	.000	2.82	0	0–63

Note: All SOL measures: sleep-onset latency measured via sleep diary, actigraphy and EEG; CI: confidence interval; ISI: Insomnia Severity Index; NNT: numbers needed to treat; PSQI: Pittsburgh Sleep Quality Index; SCI-8: Sleep Condition Indicator with 8 items; SQ (diary): sleep quality assessed via sleep diary.

induced by sleep disturbances and insomnia, or maybe even improving academic performance independent of former losses.

5 | CONCLUSION

Psychological interventions for improving sleep in college students may improve global measures of sleep disturbances and daytime functionality, and reduce SOL. Providing validated psychological interventions to college students who suffer from sleep disturbances may therefore be a worthwhile investment for both society and the individual. By improving sleep, psychological interventions reduce the risk of clinical sleep disorders, mental disorders and medical conditions triggered or amplified by sleep disturbances and insomnia. This in turn reduces the economic cost associated with these disorders and conditions. Above that, such interventions may improve the cognitive performance of college students, who represent a large portion of a given society's human capital. The task of providing psychological treatment to college students includes not only establishing sufficient provision of psychological interventions, it also includes raising awareness of intervention opportunities and providing psychological interventions that are suited to the needs of college students in particular.

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CONFLICT OF INTEREST

No conflicts of interest declared.

AUTHOR CONTRIBUTIONS

DDE, HB and KSa conceived and designed the meta-analysis. KSa and TB analysed the data. KSa wrote the paper with important contributions from A-CZ and DDE. All authors participated in the review and revision of the manuscript, and have approved the final manuscript to be published.

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APPENDIX A

Search		Query
#77	Add	Search **(#19 AND #33 AND #76)**
#76	Add	Search **(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68 OR #69 OR #70 OR #71 OR #72 OR #73 OR #74 OR #75)**
#75	Add	Search **(anxiety OR fear OR dental anxiety OR panic[MeSH Terms])**
#74	Add	Search **(brain[Text Word] AND doping[Text Word])**
#73	Add	Search **pornography*[Text Word]**
#72	Add	Search **(problematic*[Text Word] AND internet*[Text Word])**
#71	Add	Search **(internet*[Text Word] AND addiction[Text Word])**
#70	Add	Search **(social[Text Word] AND media[Text Word])**
#69	Add	Search **(cognitive AND enhance*)**
#68	Add	Search **neuroenhance*[Text Word]**
#67	Add	Search **nicotine*[Text Word]**
#66	Add	Search **(test*[Text Word] AND anxiety[Text Word])**
#65	Add	Search **self-efficacy[Text Word]**
#64	Add	Search **(time[Text Word] AND management[Text Word])**
#63	Add	Search **time manag*[Text Word]**
#62	Add	Search **(social*[Text Word] AND skill*[Text Word])**
#61	Add	Search **(social[Text Word] AND competence[Text Word])**
#60	Add	Search **stress*[Text Word]**
#59	Add	Search **resilience[Text Word]**
#58	Add	Search **(health[Text Word] AND behaviour[Text Word])**
#57	Add	Search **(health[Text Word] AND behavior)**
#56	Add	Search **(behaviour[Text Word] AND modification[Text Word])**
#55	Add	Search **(behavior[Text Word] AND modification[Text Word])**
#54	Add	Search **(behaviour[Text Word] AND change[Text Word])**
#53	Add	Search **(behavior[Text Word] AND change[Text Word])**
#52	Add	Search **eating*[Text Word]**
#51	Add	Search **weight*[Text Word]**
#50	Add	Search **procrastination*[Text Word]**
#49	Add	Search **rumination*[Text Word]**
#48	Add	Search **fear*[Text Word]**
#47	Add	Search **worry*[Text Word]**
#46	Add	Search **obesity*[Text Word]**
#45	Add	Search **exercise*[Text Word]**
#44	Add	Search **(physical[Text Word] AND activity[Text Word])**
#43	Add	Search **smoking*[Text Word]**
#42	Add	Search **marijuana[Text Word]**
#41	Add	Search **cannabis[Text Word]**
#40	Add	Search **substance*[Text Word]**
#39	Add	Search **drug*[Text Word]**
#38	Add	Search **alcohol*[Text Word]**
#37	Add	Search **HIV[Text Word]**
#36	Add	Search **condom*[Text Word]**
#35	Add	Search **(sexual*[Text Word] AND health[Text Word])**

#34	Add	Search **(mental disorders OR anxiety disorders OR bipolar and related disorders OR disruptive, impulse control, and conduct disorders OR dissociative disorders OR elimination disorders OR feeding and eating disorders OR mood disorders OR motor disorders OR neurocognitive disorders OR neurodevelopmental disorders OR neurotic disorders OR paraphilic disorders OR personality disorders OR schizophrenia spectrum and other psychotic disorders OR sexual dysfuntions, psychological OR sleep wake disorders OR somatoform disorders OR substance-related disorders OR trauma and stressor related disorders[MeSH Terms])**
#33	Add	Search **(#32 NOT #31)**
#32	Add	Search **(#20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #28 OR #29 OR #30)**
#31	Add	Search **(animals [mh] NOT (animals [mh] AND humans [mh]))**
#30	Add	Search **clinical trials as topic [mh]**
#29	Add	Search **trial[Title]**
#28	Add	Search **(#26 AND #27)**
#27	Add	Search **(waitlist*[Title/Abstract] OR wait* list*[Title/Abstract] OR treatment as usual[Title/Abstract] OR TAU[Title/Abstract])**
#26	Add	Search **(control*[Title/Abstract] OR group* 1[Title/Abstract])**
#25	Add	Search **placebo*[Title/Abstract]**
#24	Add	Search **randomly[Title/Abstract]**
#23	Add	Search **randomised[Title/Abstract]**
#22	Add	Search **randomized[Title/Abstract]**
#21	Add	Search **controlled clinical trial[Publication Type]**
#20	Add	Search **randomized controlled trial[Publication Type]**
#19	Add	Search **(#14 OR #15 OR #16 OR #17 OR #18)**
#18	Add	Search **(tertiary*[Title/Abstract] AND education*[Title/Abstract])**
#17	Add	Search **(college*[Title/Abstract] AND student*[Title/Abstract])**
#16	Add	Search **(undergraduate*[Title/Abstract] AND student'[Title/Abstract])**
#15	Add	Search **(university*[Title/Abstract] AND student*[Title/Abstract])**
#14	Add	Search **student*[Text Word]**
#13	Add	Search **internet*[Text Word]**
#12	Add	Search **online*[Text Word]**
#11	Add	Search **web*[Text Word]**
#10	Add	Search **online therap*[Text Word]**
#9	Add	Search **therap*[Text Word]**
#8	Add	Search **psychotherap*[Text Word]**
#7	Add	Search **program*[Text Word]**
#6	Add	Search **psychoeducation*[Text Word]**
#5	Add	Search **course*[Text Word]**
#4	Add	Search **counsel*[Text Word]**
#3	Add	Search **treatment*[Text Word]**
#2	Add	Search **training*[Text Word]**
#1	Add	Search **intervention*[Text Word]**

APPENDIX B

Subgroup analyses of potential moderators between psychological treatment and sleep relevant outcomes

Covariate	Q	df	p
Mode of delivery[a]	0.16870	1	.681
Risk of bias[b]	0.61030	1	.435
Type of treatment[c]	2,53,953	2	.281

[a]Separated in face-to-face treatment and self- help treatment.

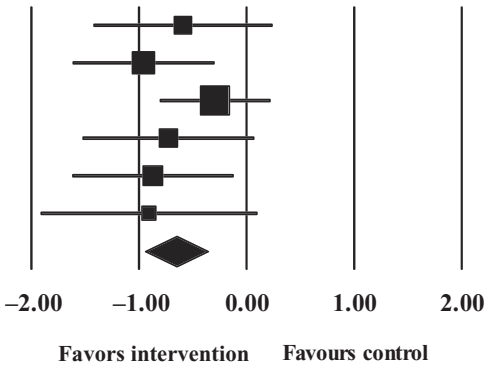
[b]Separated in high and low risk of bias.

[c]Separated in behavioral, cognitive, educational and cognitive behavioral treatment

APPENDIX C

Effects of psychological treatment on global measure of sleep disturbances compared to passive control groups

Study name	Outcome	Hedges's g	Lower limit	Upper limit	*p*-Value
Borkovec et al. (1976)	Combined	–0.59	–1.42	0.24	.164
Carrera et al. (1980)	SOL (diary)	–0.96	–1.62	–0.30	.004
Means et al. (2000)	SOL (diary)	–0.29	–0.81	0.22	.266
Steinmark et al. (1974)	SOL (diary)	–0.73	–1.53	0.07	.075
Taylor et al. (2014)	Combined	–0.87	–1.62	–0.12	.023
Zwart et al. (1979)	SOL (diary)	–0.91	–1.91	0.10	.078
Sleep onset latency overall		–0.65	–0.94	–0.36	.000

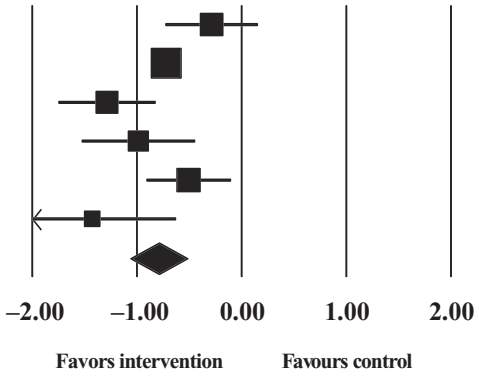


Note. Combined: Mean of all reported sleep onset latency outcomes (via sleep diary, questionnaire, actigraphy and EEG); SOL: Sleep onset latency

APPENDIX D

Effects of psychological treatment on sleep onset latency compared to passive control groups

Study name	Outcome	Statistics for each study				Hedges's g and 95% CI
		Hedges's g	Lower limit	Upper limit	*p*-Value	
Barber et al. (2017)	SQ (diary)	–0.29	–0.73	0.16	.207	
Freeman et al. (2017)	Combined	–0.72	–0.82	–0.62	.000	
Gao et al. (2014)	PSQI	–1.29	–1.75	–0.82	.000	
Means et al. (2000)	SQ (diary)	–0.99	–1.53	–0.44	.000	
Morris et al. (2016)	PSQI	–0.51	–0.91	–0.10	.015	
Taylor et al. (2014)	Combined	–1.43	–2.23	–0.62	.000	
Global measures of sleep disturbances overall		–0.79	–1.06	–0.52	.000	



Note. Combined: Mean of all reported sleep quality outcomes (PSQI, Sleep Condition Indicator – 8 items, Insomnia Severity Index, SQ [diary]); PSQI: Pittsburgh Sleep Quality Index; SQ (diary): Sleep quality reported by sleep diary

3.2 Article 2: Design of a guided internet- and mobile-based intervention for internet use disorder – Study protocol for a two-armed randomized controlled trial

Title: Design of a guided internet- and mobile-based intervention for internet use disorder – Study protocol for a two-armed randomized controlled trial

Authors: Karina Saruhanjan, Anna-Carlotta Zarski, Michael Patrick Schaub, David Daniel Ebert

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Summary:

Context: Internet Use Disorder (IUD), characterized as the inability to control one's internet use, is emerging as an increasing societal concern as it is associated with reduced quality of life and mental health comorbidities. Evidence-based treatment options are, however, scarce due to the novelty of the diagnosis. Internet- and mobile-based interventions may be an effective means to deliver psychological treatment to individuals with IUD as they address individuals affected in their online setting. The aim of the study is to evaluate the efficacy of a newly developed, guided internet- and mobile-based intervention for IUD. Methods: In a two-armed randomized controlled trial ($N = 130$), individuals showing problematic internet use patterns (Internet Addiction Test ≥ 49) will be randomly allocated to the internet- and mobile-based intervention or a waiting control group. Assessments will take place at baseline, 7 weeks, 6- and 12 months after randomization. The primary outcome is internet addiction symptom severity (IAT) at 7 weeks. Secondary outcomes include quality of life, depressive symptoms, anxiety, and other psychosocial variables associated with IUD. Intervention: The intervention consists of seven sessions: Goal setting and motivational interviewing, impulse control, problemsolving, cognitive restructuring, self-worth, relapse prevention, and a booster session. Participants are supported by an eCoach who provides individual feedback after completion of each session. Participants can choose between several elective sessions based on individual need. Conclusions: This is the first study to evaluate an internet- and mobile-based intervention for IUD, which could be a promising first step to reduce individuals' disease burden.

Contribution:

Karina Bernstein was the principal investigator and author of the published article. She wrote the manuscript supervised by Anna-Carlotta Zarski, David Daniel Ebert and Michael

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STUDY PROTOCOL
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Design of a Guided Internet- and Mobile-Based Intervention for Internet Use Disorder—Study Protocol for a Two-Armed Randomized Controlled Trial

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Methods: In a two-armed randomized controlled trial ($N = 130$), individuals showing problematic internet use patterns (Internet Addiction Test ≥ 49) will be randomly allocated to the internet- and mobile-based intervention or a waiting control group. Assessments will take place at baseline, 7 weeks, 6- and 12 months after randomization. The primary outcome is internet addiction symptom severity (IAT) at 7 weeks. Secondary outcomes include quality of life, depressive symptoms, anxiety, and other psychosocial variables associated with IUD.

Intervention: The intervention consists of seven sessions: Goal setting and motivational interviewing, impulse control, problem solving, cognitive restructuring, self-worth, relapse prevention, and a booster session. Participants are supported by an eCoach who provides individual feedback after completion of each session. Participants can choose between several elective sessions based on individual need.

Conclusions: This is the first study to evaluate an internet- and mobile-based intervention for IUD, which could be a promising first step to reduce individuals' disease burden.

Trial Registration: DRKS00015314.
The study is currently ongoing. First participants were enrolled in the study on September 14th 2018. Recruitment will continue approximately through March 2020.

Keywords: internet- and mobile-based intervention, self-help, internet use disorder, randomized controlled trial, study protocol

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INTRODUCTION

Internet Use Disorder (IUD) is characterized by excessive or poorly controlled preoccupations, urges, or behaviors regarding computer use and internet access that lead to social or work-related impairment or distress (1). It includes both excessive gaming and non-gaming internet activities. Non-gaming internet activities can be differentiated in internet gambling, internet pornography, information overload (obsessive research and surfing), internet compulsive buying (2), and excessive social media use. (3, 4). Surveys have indicated that IUD affects 1.5–8.2% of the general population (1, 5). IUD prevalence rates are, however, highly inconsistent due to the varying definitions.

Individuals with IUD show significant social, physical, and mental burdens. IUD may also cause neurological complications, psychological distress, and social problems (6–8). In addition, high comorbidity with psychiatric disorders have been reported, especially affective disorders, anxiety disorders, impulse control disorders, substance use disorders, and attention deficit hyperactivity disorder (1, 9–11). Impairment caused by IUD has also been found to include educational failure, reduced academic perspectives (12, 13), and functional impairment (14).

Despite the severe burden of disease, the range of available specialized evidence-based treatment options for IUD is extremely rare. Treatment accessibility for IUD is impeded as it has only been unsystematically treated so far by selected addiction counseling or educational counseling (15). Currently, there are only very few empirical studies evaluating IUD treatment approaches meeting the scientific standards for randomized controlled trials (16). It has been shown that cognitive-behavioral treatments have large and robust effects on the symptoms of IUD, outperforming other treatments. Among the researched psychological treatments for IUD, none of them measures the effect of an internet-based treatment approach (16). Low utilization of treatment is caused not only by structural but also attitudinal barriers such as fear of stigmatization and low outcome expectancies (17, 18). Internet- and mobile-based interventions can offer a possibility to deliver specialized treatment with a low threshold for uptake.

Treating IUD via the internet may appear contradictive at first. However, there are many arguments supporting this approach: (1) Reaching the target group through their common online setting could be effective as the internet is easily accessible and attractive. (2) Since the target group usually shows low levels of treatment motivation (19), an easily accessible and attractive treatment option is crucial; thus, a low-threshold intervention with interactive audio-visual content may facilitate access and reduce burdens of help-seeking. (3) Due to the individually tailored and adaptable content, a variety of symptoms associated with IUD such as procrastination, bad sleep patterns or alcohol consumption can be addressed. Based on these comorbid symptoms, secondary outcome measures were chosen to assess a reduction in symptoms associated with IUD that were targeted in the intervention. (4) Internet- and mobile-based interventions might be a feasible means to provide evidence-based treatment on a large-scale basis, since they have been shown to be effective in the treatment of numerous mental health disorders (20–23). Therefore, internet- and mobile-based interventions could be a way to reach individuals with IUD better than traditional approach. To the best of our knowledge, this is the first trial evaluating a guided internet- and mobile based intervention for IUD in an RCT design.

AIMS OF THE STUDY

The aim of this study is to evaluate the efficacy of a cognitive-behavioral guided self-help internet- and mobile-based intervention for reducing symptoms of IUD compared to a waiting control group (WCG). Both groups have unlimited access to treatment as usual in routine mental health care. It is hypothesized that the intervention reduces symptoms of IUD.

METHODS

Design

A two-arm randomized controlled trial (RCT) will be conducted to evaluate the internet- and mobile-based intervention compared to a WCG. Assessments will take place at baseline (t1), post-intervention (t2), at 6- (t3) and 12-months follow-up (t4). See **Figure 1** for a detailed overview of the study design. All procedures involved in the study will be consistent with the generally accepted standards of ethical practice approved by the Friedrich-Alexander University of Erlangen-Nuremberg ethics committee (54_18 B).

Participants and Procedures

Inclusion and Exclusion Criteria

We will include individuals who (1) are at minimum 18 years of age, (2) show elevated levels of IUD with scores of $\geq$ 49 on the Internet Addiction Test (IAT) (7), (3) have internet access, (4) have sufficient German language reading and writing skills and (5) are willing to give informed consent. We will exclude subjects who (1) indicate that they have been diagnosed with a psychosis or bipolar disorder, (2) show a notable suicidal risk as indicated by a score greater than 1 on Item 9 of the Beck Depression Inventory (BDI) (24), (3) currently receive or are on a waitlist for psychological treatment regarding any mental disorder.

Recruitment

Participants will be recruited in Germany, Austria and Switzerland via (1) the GET.ON Website, (2) the StudiCare website, (3) recruitment over social media and discussions forums, and (4) mass e-mailing with information regarding the study and intervention sent to German, Swiss and Austrian psychological counseling centers and university students (in Erlangen, Ulm, Bern, Dresden, Hagen and Vienna).

Assessment of Eligibility and Randomization

After registering with a self-chosen email address, applicants will receive an email with detailed information about the study procedure. They will be further informed that it is possible to withdraw from the intervention and/or study at any time without any negative consequences. Applicants are asked to complete an online screening questionnaire and to sign the

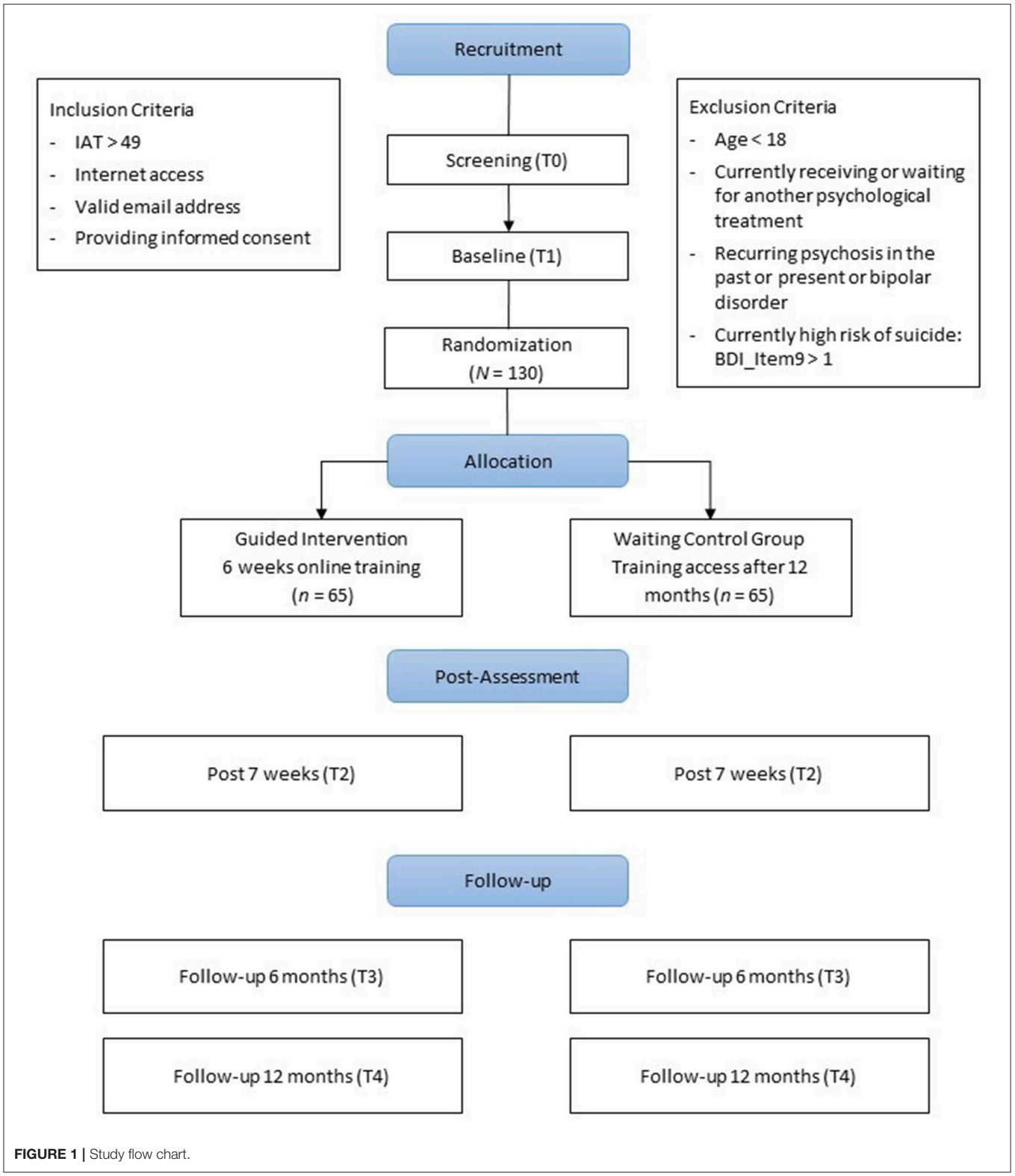

FIGURE 1 | Study flow chart.

informed consent form and return it by post or email. As soon as participants have completed the baseline assessment and meet the inclusion criteria, they will enter the study and will be randomized to one of the two study conditions. Participants are randomized to either the guided intervention group or a WCG in a 1:1 ratio. Randomization is performed by a

TABLE 1 | Content of the training.

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

TABLE 2 | Content of the elective sessions.

Session	Content
Relaxation	Learning the progressive muscle relaxation to reduce tension
Alcohol & affect regulation	Reducing affect regulation related alcohol consumption
Personal needs & values	Reducing personal incongruence in daily life, by achieving balance between personal needs and values
Appreciation & gratefulness	Focusing on the good things and practicing mindfulness strategies
Sleep	Improving sleep hygiene and practicing sleep restriction to enhance sleep quality
Procrastination	Practicing strategies addressing delaying important tasks

research assistant not otherwise involved in the study using block randomization with varying block sizes. Once randomization has been completed, participants in the intervention group receive immediate access while participants in the control group receive access 12 months later.

Intervention

The intervention consists of seven sessions: Goal setting and motivational interviewing (session 1), impulse control (session 2), problem solving (session 3), cognitive restructuring (session 4), self-worth (session 5), relapse prevention (session 6), and a booster session 4 weeks after completion of the core sessions (session 7) (see **Table 1** for an overview of the main sessions). Moreover, participants can choose between several elective sessions based on individual need and preference. The elective sessions are directed at personal needs and values, sleep, relaxation, alcohol and affect regulation, appreciation and gratefulness, and procrastination (see **Table 2** for an overview of the elective sessions). Each session can be completed in ∼30–45 min. We advise participants to do at least one and a maximum of two sessions per week. Further content can only be accessed once previous sessions are completed. Consequently, the training will last about 4–6 weeks plus one additional booster session 4 weeks after completion of the last session. The booster session aims to help participants to refresh and reflect contents and strategies. Sessions consist of texts, testimonials, and include many interactive elements such as quizzes, exercises, and homework, which can be seen in the **Supplementary Material**. At the end of the second session, a plan for behavior change is introduced. This four-step plan aims to help participants to (1) choose specific situations in which they want to change their internet use, (2) set realistic goals, (3) collect ideas on how to realize their goals, and (4) to create a detailed plan for goal acquisition including newly acquired strategies and planning for potential upcoming difficulties. Participants are expected to test their plan for behavior change during the following week and are encouraged to analyze success and difficulties in the training process in the next session. They can also opt to review and adapt their plan in the following session. Participants are encouraged to formulate five plans in total over the course of the training between the second and the sixth session. They are also invited to keep an online diary, which can be accessed via the web interface or an optional smartphone app. The intervention uses content tailoring, thereby engaging the participants by encouraging them to make real-time choices among various response options, and then providing individualized content based on specific needs or preferences. The training is built on responsive web-design and can be completed on any kind on internet-ready device, such as PCs/laptops, smartphones, or tablets. Participants can also opt to receive motivational messages and small exercises referred to as *Tiny Tasks*. These smartphone notifications are sent directly to their mobile device 3 times a day. These notifications will support the participants in transferring the exercises of the training into their daily lives (e.g., giving suggestions on how to implement strategies: "What has influenced your internet usage today?").

Goal Setting and Motivational Interviewing (Session 1)

The first session gives an overview of internet usage in everyday life (e.g., social media, news, online dating), the upcoming sessions, and basic techniques of the intervention. To support participants, three fictional patients are introduced who vary in age, gender and ethnicity, being addicted to online gaming, social media or online dating. One of the main elements of the first session is psychoeducation on the subject of IUD, including the difference between common and problematic internet use, and epidemiology of the disease. Based on that, elements of the motivational interviewing are implemented such as elaborating on personal advantages and disadvantages of using the internet, individual motivation for and confidence in behavior change. Finally, participants are encouraged to create a precise treatment goal using the SMART model.

Impulse Control (Session 2)

The second session introduces the concept of impulse control and self-control in order to help the participants to handle feelings of craving to go online in everyday life. Participants can choose between different exercises, each of them illustrating one strategy [(1) distraction, (2) positive self-instruction, (3) social support, (4) awareness of consequences, (5) stimulus control, (6) mindfulness, and consciousness of the presence]. Afterwards, participants are invited to learn about the benefit of their individual resources (e.g., physically, psychologically, socially) regarding coping of daily hazzles or crisis and implementation

of strategies. Finally, they are presented with a list of positive activities offering alternatives to the internet and can create a detailed plan when and where to implement the activities.

Problem Solving (Session 3)

In the third session, participants are presented with strategies on how to deal with difficulties to stay offline. These strategies address motivational problems, fear of missing out on social situations online, problems in accepting oneself in real life, and loosing social integration online. To enhance their understanding of their problems, participants are introduced to the TRIAS disorder model (25). Based on the TRIAS-Modell participants can then identify individual influencing factors on their internet usage such as their environment (e.g., family, challenging conflict situations), personal dispositions and characteristics (e.g., personality, coping strategies), opportunities of the internet (e.g., self-representation, social contacts) and develop specific strategies such as positive self-instructions with the help of their impulse control and self-control techniques. Participants then learn about psychological, physical, and social maintaining factors of the disorder in combination with specific coping techniques such as strengthening their self and their social relationships offline.

Cognitive Restructuring (Session 4)

In the fourth session, participants are introduced to cognitive restructuring, receiving information on the causal relationship between cognitions, emotions, behavior, and consequences. Participants can then individualize their personal thought records by including personal situations, cognitions, and emotions. After psychoeducation about negative emotions and acceptance, participants create positive and helpful thoughts to contrast their negative thoughts in their thought record. To generally concentrate on and practice positive thinking habits, strategies as taking notes or using cues to remind themselves of helpful thoughts and imagining, how helpful thought would alter the current situation.

Self-Worth (Session 5)

This session aims at highlighting the importance of self-confidence, self-worth and self-efficacy concerning meeting challenges and controlling internet usage. First, participants learn how their internet use can affect their self-worth and vice versa. To strengthen their self-worth, participants are initially invited to state their positive characteristics and skills. After that, the concept of the inner critic, representing self-doubting cognitions, and the benevolent companion, representing self-conductive cognitions, are introduced and participants are encouraged to identify their own self-doubting and negative self-deprecating cognitions, and confront them with their benevolent companion. Lastly, participants plan the upcoming days with activities that foster self-care, such as spending time with friends and family or pursue hobbies.

Relapse Prevention (Session 6)

In the last session, participants can review brief summaries of each session. They are asked to reflect on their progress concerning their intervention goals, and to identify mechanisms of their individual behavior change during the intervention as well as helpful psychological strategies. Subsequently, they are encouraged to make a specific plan of strategies they want to continue exercise in everyday life until the booster session, in order to maintain and generalize acquired strategies.

Booster Session (Session 7)

The participants are invited to complete a booster session 4 weeks after completion of the sixth session. In this session, they can reflect on their learning experience and personal goal attainment. They are asked to consider their current use of the internet, and are provided with additional information on support, if needed. Participants can review the letter they wrote to themselves and set new goals for the upcoming months.

Guidance

During the active intervention phase, participants of the treatment arm receive content-focused guidance (26) by an eCoach who provides individual manualized feedback after completion of each session. eCoaches will have at least a Bachelor's degree in Psychology and have access to supervision when required. Guidance is based on a treatment manual with preformulated standardized text blocks that are prepared for every lesson and individually adapted for participants according to their input and overall progress. As an additional feature, participants have the chance to contact their eCoach through the internal messaging function of the platform. Estimated mean time per feedback is 30 min. eCoaches are advised not to use more than 40 min per individual feedback. Approximately 2.5 h is the total time an eCoach will spend per participant. Session adherence is also monitored, when participants do not complete a session within 7 days, eCoaches will send out email reminders after 7, 14, and 21 days. Additionally, after 28 days a reminder will be sent via text message. Reminders have shown to improve adherence to self-guided behavior change interventions (27, 28). All study participants can contact a support email address in case of any technical difficulties regarding the intervention.

Assessment and Data Management

Self-reports will take place at screening (T0), baseline (T1) prior to randomization, post-intervention (T2) 7 weeks after randomization, at 6- (T3) and 12-month follow-ups (T4; see **Figure 1** for a detailed overview). Self-reported data will be collected using a secure online-based assessment system (AES, 256-bit encrypted).

Outcomes

Primary Outcome

In order to assess the effect of the treatment on symptoms of IUD, the Internet Addiction Test [IAT; (7)] is administered. The IAT is a widely accepted and validated testing instrument that examines a variety of symptoms of internet dependency (29). The 20 items assess, on a 5-point Likert Scale (1 = "rarely," 2 = "occasionally," 3 = "frequently," 4 = "often," 5 = "always") the participant's preoccupation with the internet (e.g., "How often do you block out disturbing thoughts about your life with soothing thoughts of the internet?"), excessive use (e.g., "How often do

you lose sleep due to late-night logins?"), neglection of work and social life (e.g., "How often does your job performance or productivity suffer because of the internet?", "How often do you form new relationships with fellow on-line users?"), anticipation (e.g., "How often do you find yourself anticipating when you will go online again?"), and loss of control (e.g., "How often do you try to cut down the amount of time you spend on-line and fail?"). In several studies, the scale has been shown very good internal consistencies ($\alpha = 0.91$, $\alpha = 0.89$) (30).

Secondary Outcomes

Compulsive internet use

The Compulsive Internet Use Scale (CIUS) (31) consists of 14 items, which refer particularly to the compulsive and impulse control elements of internet use, assessing the severity of symptoms on a 5-point Likert Scale. In several studies, the CIUS has proven to be a valid instrument and has shown good internal consistency ($\alpha = 0.89$) (32). The scales include withdrawal symptoms, loss of control, preoccupation/salience, conflict (referring to social and work life) and coping (using the internet to cope with stressors).

Depressive symptoms

Self-reported depressive symptoms will be measured with the Patient Health Questionnaire (PHQ-9) (33). This frequently used self-report instrument consists of 9 items that are answered on a 4-point Likert scale referring to the previous 2 weeks. Total scores range from 0 to 27. The internal consistency of this measure has been found to be excellent ($\alpha = 0.83$–0.92) (34).

Anxiety

The generalized anxiety disorder measurement (GAD-7) is used to assess symptom severity (35). It consists of 7 items answered from 0 (not at all) to 3 (nearly every day). It possesses excellent internal consistency ($\alpha = 0.92$) and good test-retest reliability (Intraclass Correlation Coefficient = 0.83) (35, 36).

Problematic alcohol consumption

We will use the 3-item version of the Alcohol Use Disorder Identification Test (AUDIT-C) to measure problematic alcohol consumption of the participants on a 5-point Likert Scale (37). The AUDIT-C is a validated and widely used brief screening test for heavy drinking, alcohol abuse, or dependency (38). Even though the internal consistency is only satisfactory ($\alpha = 0.77$–0.80), it is outweighed by the brevity of the AUDIT-C (39).

Insomnia

Insomnia severity will be assessed by the Insomnia Severity Index (ISI) (40), consisting of 7 items to be answered on a 5-point Likert scale. Psychometric properties have been shown to be good ($\alpha = 0.83$) (41).

Worries

In order to evaluate worries, the ultra-brief version of the Penn State Worry Questionnaire (PSWQ-3) (42) is applied. It is a questionnaire that assesses self-reported key aspects of worry, consisting of three items, which are rated on a 5-point Likert Scale. Cronbach's alpha has shown to be 0.74 (43).

Procrastination

The 9-item-version of the General Procrastination Scale (GSP-K) is administered to measure procrastination behavior on a 4-point Likert Scale (44, 45). Overall, the questionnaire shows a very good internal consistency ($\alpha = 0.92$).

Gambling

The German questionnaire Kurzfragebogen zum Glücksspielverhalten (KFG) (46) addresses lifetime gambling behavior and consists of 20 items, each on a 4-point Likert Scale. The threshold for pathological gambling is set at 16 points. The questionnaire shows a satisfactory internal consistency ($\alpha = 0.79$) (47).

Well-being

Well-being will be assessed by the 5-item WHO-5 Well-Being Index (WHO-5) (48) answered on a 6-point Likert Scale with scores ranging from 0 to 30 ($\alpha = 0.82$) (49).

Quality of life

To measure quality of life, we will use the Assessment of Quality of Life Instrument (AQoL-8D) (50, 51), which consists of 35 items with eight dimensions: independent living ($\alpha = 0.9$, ICC = 0.86), pain ($\alpha = 0.85$, ICC = 0.86), senses ($\alpha = 0.69$, ICC = 0.51), mental health ($\alpha = 0.84$, ICC = 0.89), happiness ($\alpha = 0.85$, ICC = 0.90), coping ($\alpha = 0.80$, ICC = 0.79), relationships ($\alpha = 0.73$, ICC = 0.88), self-worth ($\alpha = 0.85$, ICC = 0.81) (51). Psychometrics properties have been shown to be acceptable.

Work limitations

To measure the on-the-job impact of chronic health problems and/or treatment with a focus on assessing limitations while performing specific job demands, the Work Limitations Questionnaire (WLQ) (52) is applied. It consists of 25 items on a 5-point Likert Scale, assessing four dimensions of work limitation. Walker et al. (53) report a Cronbach's alpha range of 0.83–0.88 (53).

Costs associated with psychiatric illness

Other measures related to the intervention include the Trimbos Questionnaire for costs associated with psychiatric illness (TiC-P) (54), including healthcare utilizations and productivity losses, adapted to the German health care system. It consists of 14 yes/no questions to assess contacts with healthcare providers of any kind and five items covering reduced efficiency and/or absence from work due to a psychiatric condition. The TiC-P has been proven to be a feasible and reliable instrument for measuring healthcare utilization and productivity loss (55). The German adaption has been utilized in a substantial number of randomized controlled trials as a basis for health economic outcome evaluations (56–67).

Training and acceptability

User satisfaction will be assessed by a questionnaire based on the Client Satisfaction Questionnaire (CSQ-8) (68), adapted to assess user satisfaction in online interventions (69). Global client satisfaction with the internet- and mobile-based intervention is measured by eight items. Previous research indicated good psychometric properties ($\alpha = 0.84$–0.97) (70).

TABLE 3 | Overview study self-report assessments.

Construct	Questionnaire	T1	T2	T3	T4
Demographics	Socio-Demographic Data	✓	–	–	–
Internet addiction	Internet Addiction Test (IAT)	✓	✓	✓	✓
	Compulsive Internet Use Scale (CIUS)	✓	✓	✓	✓
Depression	Patient Health Questionnaire (PHQ-9)	✓	✓	✓	✓
Anxiety	General Anxiety Disorder Measurement (GAD-7)	✓	✓	✓	✓
Alcohol abuse	The Alcohol Use Disorders Identification Test (AUDIT-C)	✓	✓	✓	✓
Sleep	Insomnia Severity Index (ISI)	✓	✓	✓	✓
Worries	Penn State Worry Questionnaire – Ultra Brief Version (PSWQ-3)	✓	✓	✓	✓
Self-esteem	Rosenberg Self Esteem Scale (RSES)	✓	–	–	–
Social phobia	Social Phobia Inventory (Mini-SPIN)	✓	–	–	–
Procrastination	General Procrastination Scale—Short Version (GPS-K)	✓	✓	✓	✓
Gambling	Kurzfragebogen zum Glücksspielverhalten (KFG)	✓	✓	✓	✓
Wellbeing	WHO-5 Wellbeing Index (WHO-5)	✓	✓	✓	✓
Quality of life	Assessment Quality of Life (AQoL-8D)	✓	✓	✓	✓
Work limitations	Work Limitations Questionnaire (WLQ)	✓	✓	✓	✓
Health economic evaluation	Trimbos Questionnaire for Costs Associated with Psychiatric Illness (TiC-P)	✓	–	✓	✓
Training and acceptability	Client Satisfaction Questionnaire (CSQ-8)	–	✓	–	–

T1, baseline; T2, post-intervention; T3, 6-month follow-up; T4, 12-month follow-up.

Other Assessments

Other assessments include demographics (e.g., age, gender, occupation, level of education) and current and previous experience with psychotherapy, self-esteem via Rosenberg Self-Esteem Scale (RSES) (71) and social phobia via Mini Social Phobia Inventory (Mini-SPIN) (72). For an overview of all outcome measures, see **Table 3**.

Response

To determine the numbers of participants achieving a reliable positive outcome, we will code participants as responders or non-responders according to the widely used reliable change index (RCI) (73) after participation in the intervention. Participants will be considered responders when they display an RCI score of above 1.96.

Statistical Methods

Data will be analyzed on an intention-to-treat basis including all participants who will be randomly assigned to conditions. Additionally, study completer analyses including only participants who filled out the questionnaires and intervention completer analyses including only participants who have completed at least four out of six sessions will be conducted. Missing data will be handled using multiple imputations (MIs) calculated by a Markov Chain Monte Carlo multivariate imputation algorithm of 100 estimations per missing value. MI is especially robust with respect to missing data. We will conduct an ANCOVA to examine differences in the primary outcome. To detect differences between the two study groups, we will conduct univariate analysis of covariance to compare secondary outcomes at post-treatment and 6- and 12-month follow-up adjusting for baseline scores. Predictors and mediators of changes of the primary outcome will be analyzed on exploratory basis using linear regression. For all analyses on continuous measures, Cohen's d (74) will be calculated by standardizing the differences between baseline and follow-up scores by the pooled standard deviation of the baselines scores.

The response rates will be compared across conditions with the help of contingency tables and Chi-Squared tests. For primary analysis, significance levels will be set at 0.05, one-sided. For the explorative analysis of the data, the significance levels will be set to 5%. All analyses will be performed with IBM SPSS v. 24.

Sample Size Calculation

To answer the research question described above, we aim to include 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 test) for an intention-to-treat analysis using G*Power (75). The estimated effect of (Cohen's d) $d = 0.60$ is based on recent meta-analyses on the effects of treatments on internet addiction which shows rather high effect sizes for CBT (16) as well as several other psychological treatments (76).

DISCUSSION

The aim of this two-armed randomized controlled trial is to evaluate the efficacy of a newly developed internet- and mobile-based intervention for IUD in comparison to a WCG. It is hypothesized that the intervention decreases symptoms of IUD in the intervention group as compared to the WCG.

IUD is associated with a high disease burden, a decline in quality of life, and substantial comorbidities. Yet, treatment options are very scarce and unspecialized (15). This study provides some of the first guidelines for the development and efficacy of internet-based treatment for IUD. The intervention is designed as a low-threshold approach and adapted to various internet activities as part of IUD, comorbidities and cultural backgrounds through testimonials. Though treating IUD with the internet appears contradictive at first, it bears great potential because affected individuals are addressed in their online setting. An internet- and mobile-based intervention is easily accessible, anonymous, therefore likely to lower the threshold of treatment utilization and thus can be attractive to the target group which is usually characterized by low treatment motivation. Furthermore, to create an engaging and motivating intervention, adaptable content and multiple elective components of motivating and educative nature are used. The intervention structure is set up easy to follow and individual tailored. Content tailoring allows participants to make real-time choices, which trigger different content based on preference or need. To account for the quality of the intervention, participants are provided guidance by an eCoach. Besides the supportive and engaging function of the eCoach within the treatment process, guidance also has been shown to increase adherence rates in internet- and mobile-based interventions (26). To increase treatment

adherence, eCoaches send participants feedback on completed sessions and are available for consultation. Moreover, we seek to foster the transfer of strategies into daily life, e.g., by sending tiny tasks via app. A strength of our treatment approach is that the intervention aims at reducing internet use and foster a controlled internet usage instead of establishing abstinence. Participants are invited to define their treatment goals on their own and decide about the way they want to change their internet use and how much time they allow themselves to use the internet. Thus, we aim to set up and motivate individuals into a therapeutic process involving participants and fostering self-determination. Further strengths of the study include the strong methodology of a randomized controlled design compromising an appropriate statistical analyses plan with missing data handling with state of the arts methods (77). Thus, this study will contribute significantly to the literature and empirically tested treatment for IUD because, to the best of our knowledge, it is the first study to investigate the efficacy of a guided internet- and mobile-based intervention for the treatment of IUD.

This study also has some limitations. The power analyses was calculated with an estimated effect of $d = 0.60$. It should be taken into account that smaller effects can be clinically relevant as well. We will not include any additional objective measurement of IUD, e.g., tracking of time spent online. To allow a low-threshold approach, only self-reported measurements are used. Future research should consider additional objective measures and independent ratings of internet use and of symptoms associated with IUD. As motivation for treatment is typically low in the target group and guided internet- and mobile-based interventions require high levels of self-regulation, we account for drop-out with a systematic adherence protocol including reminders via email after 7, 14, and 21 days in case participants do not complete a measurement point followed by telephone calls. Moreover, we provide monetary incentives for completing the online questionnaires. With regard to the pitfall of a usually overeducated sample of participants in internet- and mobile-based interventions, we aim to recruit at a broad level in the population, including health insurance companies, counseling centers and local community centers.

CONCLUSION

To conclude, this internet- and mobile-based intervention is a treatment that aims to reduce disease burden of IUD in the general population. To complement research on IUD and to advance evidence-based treatment options, RCTs evaluating treatments for IUD are needed. Internet- and mobile-based interventions might be an appropriate strategy to overcome low treatment availability. This study will contribute to empirical research on IUD and provide information about their acceptability and efficacy. If the efficacy of this intervention can be established, the effectiveness of the intervention needs to be evaluated with regard to large-scale implementation in routine care to make the intervention available to a large number of affected individuals irrespective of place and time.

ETHICS STATEMENT

This study has been approved by the ethics committee of the Friedrich-Alexander University Erlangen Nürnberg (no. 54_18 B). Written informed consent will be obtained from the participants of our study.

AUTHOR CONTRIBUTIONS

KS and DE designed the study. KS drafted the manuscript supervised by A-CZ. DE and MS 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.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpsyt.2020.00190/full#supplementary-material

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Conflict of Interest: DE reports to have received consultancy fees or served in the scientific advisory board of Minddistrict, Sanofi, Novartis, Lantern, Schön Kliniken, and German health insurance companies (BARMER, Techniker Krankenkasse). He is also stakeholder of the Institute for health trainings online (GET.ON), which aims to implement scientific findings related to digital health interventions into routine care.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

3.3 Article 3: Case report for an Internet- and mobile-based intervention for Internet Use Disorder

Title: Case report for an Internet- and mobile-based intervention for Internet Use Disorder

Authors: Karina Bernstein, Anna-Carlotta Zarski, Emilia Pekarek, Michael Patrick Schaub, Matthias Berking, Harald Baumeister, David Daniel Ebert

Status: Accepted 19 June 2023 in Frontiers in Psychiatry

Summary:

Background and aims: Internet Use Disorder (IUD), characterized as the inability to control one's internet use, is associated with reduced quality of life and mental health comorbidities such as depression, substance abuse, or anxiety. Evidence-based treatment options are scarce due to the novelty of the diagnosis. Internet- and mobile-based interventions (IMI) may be an effective means to deliver psychological treatment to individuals with IUD as they address affected individuals in their online setting. This study presents a newly developed IMI for IUD (GET.ON Offline) disclosing treatment satisfaction and preliminary effects by exemplifying with a case report.

Methods: The case of a female participant with IUD, characterized by an excessive use of social media, is analyzed. The case report follows the CARE guidelines and presents qualitative and quantitative outcomes regarding potential symptom reduction measured by the Internet Addiction Test (IAT) and Compulsive Internet Use Scale (CIUS), treatment satisfaction measured by CSQ-8 and feasibility by analyzing participant's written feedback during treatment.

Results: The case report shows that internet- and mobile-based interventions may be feasible in supporting an individual in reducing symptoms of IUD as well as depressive symptoms, anxiety and procrastination behavior. Treatment satisfaction was reported as good.

Discussion and Conclusions: This case report illustrates that IMIs have the potential to be an easily accessible and possibly effective treatment option for IUD. Case studies on IMIs may provide insights into important mechanisms for symptom change. Further studies are needed to expand our understanding of this diverse disorder to provide adequate treatment.

Contribution:

Karina Bernstein was the principal investigator and author of this article. She developed the study design, collected, analyzed and interpreted the data in exchange with Emilia Pekarek. Karina Bernstein drafted the manuscript supervised by Anna-Carlotta Zarski. All

authors participated in the review and revision of the manuscript and have approved the final manuscript to be published.

Case report for an Internet- and mobile-based intervention for Internet Use Disorder

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Authors' contribution: KB and DE designed the study. KB and EP analysed and interpreted the data. KB drafted the manuscript supervised by A-CZ. All authors participated in the review and revision of the manuscript and have approved the final manuscript to be published.

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 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. ACZ reports fees for lectures or

workshops and for expert videos for an internet-based intervention. KB, EP and MPS declare no conflict of interest.

ABSTRACT

Background and aims: Internet Use Disorder (IUD), characterized as the inability to control one's internet use, is associated with reduced quality of life and mental health comorbidities such as depression, substance abuse, or anxiety. Evidence-based treatment options are scarce due to the novelty of the diagnosis. Internet- and mobile-based interventions (IMI) may be an effective means to deliver psychological treatment to individuals with IUD as they address affected individuals in their online setting. This study presents a newly developed IMI for IUD (GET.ON Offline) disclosing treatment satisfaction and preliminary effects by exemplifying with a case report.

Methods: The case of a female participant with IUD, characterized by an excessive use of social media, is analyzed. The case report follows the CARE guidelines and presents qualitative and quantitative outcomes regarding potential symptom reduction measured by the Internet Addiction Test (IAT) and Compulsive Internet Use Scale (CIUS), treatment satisfaction measured by CSQ-8 and feasibility by analyzing participant's written feedback during treatment.

Results: The case report shows that internet- and mobile-based interventions may be feasible in supporting an individual in reducing symptoms of IUD as well as depressive symptoms, anxiety and procrastination behavior. Treatment satisfaction was reported as good.

Discussion and Conclusions: This case report illustrates that IMIs can have the potential to be an easily accessible and possibly effective treatment option for IUD. Case studies on IMIs may provide insights into important mechanisms for symptom change. Further studies are needed to expand our understanding of this diverse disorder to provide adequate treatment.

Trial Registration: DRKS00015314

The randomized controlled study took place from Sept 2018 (first patient in) to Feb 2021 (last patient out). The patient participated in the intervention study from Oct 2018 to Dec 2018.

Keywords: internet- and mobile-based intervention, internet use disorder, case report

List of Abbreviations

Abbreviation	Explanation
IUD	Internet Use Disorder
SV	Scale value
SV_{pre}, SV_{post}	Scale value pre- and post-treatment
T1	Measurement point pre-treatment (baseline)
T2	Measurement point post-treatment
IAT	Internet Addiction Test
CIUS	Compulsive Internet Use Scale
IMI	Internet- and mobile-based intervention
CBT	Cognitive behavioral treatment

BACKGROUND

Internet Use Disorder (IUD) is characterized by excessive or poorly controlled preoccupations, urges, or behaviors regarding computer and internet use that lead to social or work-related impairment or distress (Weinstein & Lejoyeux, 2010). Pathological internet use can be divided into different subtypes related to both gaming and non-gaming internet activities. Non-gaming internet activities include problematic or pathological internet gambling, obsessive research and surfing, compulsive online shopping as well as excessive use of social networks and internet pornography (Young, 2011; Andreassen, 2015; Wölfling, Jo, Bengesser, Beutel & Müller, 2012; Augsburger et al. 2020). There is currently no standard definition of IUD in diagnostic manuals such as the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association, 2013) or the International Statistical Classification of Diseases and Related Health Problems (ICD-10; World Health Organization, 2013). However, in the updated version of the International Statistical Classification of Diseases and Related Health Problems (ICD-11, World Health Organization, 2019), gaming and gambling disorder were incorporated as disorders due to addictive behaviors. Moreover, a section of other specified disorders related to addictive behaviors (6C5Y) was included to code further problematic addictive behaviors beyond gambling and gaming, e.g., social-network-use disorder, pornography-use disorder. Diagnostic criteria provided in the ICD-11 for disorders due to addictive behaviors include functional impairment, loss of control over the problem behavior, neglect of social and work life, and excessive use of the internet despite negative consequences which may be episodic or recurrent (ICD-11; World Health Organization, 2019).In the DSM-5, internet-based gambling, as a part of IUD, 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)."The worldwide IUD prevalence is currently estimated to be at around 7.0% (Pan, Chiu & Lin, 2020). Women have shown to be especially at risk for excessive social network use (Kittinger, Correia, & Irons, 2012). A Social Network Use Disorder in specific is discussed in recent research as a pathological use of social networks, which is more likely to occur among women and presents itself with similar comorbidities as IUD (Bouna-Pyrrou et al., 2018; Bouna-Pyrrou, Mühle, Kornhuber & Lenz, 2015; Brand et al., 2020).

As comorbid symptoms, IUD may cause neurological complications, psychological distress, and social problems (Greenfield, 1999; Young, 1998; Zhou et al., 2011). In addition,

high comorbidities with other mental disorders have been reported, especially affective and anxiety disorders, impulse control disorders, substance use disorders, and attention deficit hyperactivity disorder (Petersen, Weymann, Schelb, Thiel & Thomasius, 2009; Peukert et al., 2010; Shaw & Black, 2008; Weinstein & Lejoyeux, 2010). Impairment caused by IUD has also been found to include educational failure and reduced academic perspectives especially in teenagers and young adults (Beutel, Hoch, Wölfling & Müller, 2011, Rehbein, Kleimann & Mößle, 2009).

Evidence-based treatment for IUD is, however, scarce. The few randomized controlled trials existing have shown large effect sizes of cognitive-behavioral treatment (CBT) on IUD in terms of reducing time spent online and IUD symptoms (Winkler et al., 2013; Wölfling et al., 2019; Stevens, King, Dorstyn & Delfabbro, 2019). Still, in order to adequately approach the heterogeneity of IUD resulting in different impairments depending on preferred online activities, specialized and innovative treatment options have called to be further studied (Starcevic & Billieux, 2017; Andreassen, 2015; DeJong, 2014; Zajac, Ginley & Chang, 2020). Previous case reports on treatment of IUD have focused on internet gaming (Lee, 2011; Torres-Rodríguez et al., 2019)

Treating IUD via the internet may appear contradictive at first, as it seems problematic in terms of additional time spent online. However, internet- and mobile-based interventions (IMIs) can contribute to practice controlled internet use, which is recommended as treatment goal instead of abstinence (Young, 2013; Dau, Hoffmann & Banger, 2015; Andreassen, Pallesen & Griffiths, 2017). IMIs also have the advantage to reach individuals through their common and attractive online setting who may otherwise not consult a therapist due to low treatment motivation and reduced readiness-to-change (O'Brien, Li, Snyder, & Howard, 2016). Thus, IMIs can deliver specialized treatment with a low threshold and easy access for uptake (Carlbring, Andersson, Cuijpers, Riper & Hedman-Lagerlöf, 2018; Ebert et al., 2018). The aim of this study was to give insights into the internet- and mobile-based treatment of IUD with a case report illustrating feasibility, symptom reduction and satisfaction at individual level. As studies on IMIs for IUD are lacking in Germany, the objective of the present work is to present the therapeutic manual of a newly developed IMI for IUD using a detailed case report of a patient who successfully completed the program and describe the course of treatment including treatment effects, potential barriers, and user satisfaction.

Treatment format

The intervention was CBT-based and consisted of the following six weekly core sessions: Goal setting and motivational interviewing (session 1), impulse control (session 2), problem solving (session 3), cognitive restructuring (session 4), self-worth (session 5), and relapse prevention (session 6). Four weeks after completion of the core sessions, a booster session was provided. The aim of the booster session was to support the user in reflecting and refreshing intervention content and strategies. The user could additionally choose between the following elective sessions: personal needs and values, sleep, relaxation, alcohol and affect regulation, appreciation and gratefulness, and procrastination (see Table 1). The core sessions took approximately 45-60 minutes to be completed. The user could continue with the following sessions once the previous session is completed. The intervention was guided self-help provided completely online on an internet-based platform of an eHealth provider. The intervention could be completed on any internet-ready device, i.e., PCs, laptops, smartphones, and tablets. The intervention included interactive elements (exercises, quizzes, testimonials, homework) built on responsive web-design and the user was able to answer questions via text boxes. The answers were then stored within the program and could be viewed by the eCoach and exported in a data format for qualitative evaluation. In addition, to the core intervention content in the treatment sessions, the user could use Tiny Tasks, i.e., small exercises and motivational messages via smartphone three times a day. The aim of the tiny tasks was to help the user to transfer the intervention content into their daily lives. They consisted e.g., of suggestions on how to implement the intervention strategies: "What has influenced your internet usage today?" or "Which features play a key role in contributing to the amount of time you spend online? Are you able to influence those features?"

After completion of each session, the user received content-focused guidance by an eCoach who provided individually manualized feedback (Zarski et al., 2016). The qualification of the eCoaches was at least a bachelor's degree in psychology. The supervised eCoaches used a treatment manual with standardized text blocks which were individually adapted based on the input and overall progress of each user. Further, there was an internal messaging function on the intervention platform through which the user could contact the eCoach. For a detailed description of the IMI see the study protocol (Saruhanjan, Zarski, Schaub & Ebert, 2020).

- (Please insert Table 1 here) -

Design of the case report

A case study was conducted as part of a larger RCT (CARE guidelines; Gagnier et al., 2013) to evaluate the efficacy of the intervention. The case study was conducted to analyze and illustrate an individual course of treatment within the framework of the internet-based program.

The case report follows the Case Reporting (CARE) guidelines (Gagnier et al., 2013). Exemplary symptom reduction and satisfaction of a female student with successful treatment outcome is described. Selection of treatment case considered representativeness of participant characteristics. Case selection followed criteria such as complete treatment course and the transferability of the case through the affiliation to a risk group as a student, as well as through the predominant use of social networks, which has shown to be a represented subtype of IUD among females (Kittinger, Correia, & Irons 2012; Bouna-Pyrrou et al., 2018). As a student of young age, she is part of a target group that has been identified as a risk population for IUD (Kuss, Griffiths & Binder, 2013).

After registering with a self-chosen email address on the study website, the participant received detailed information about the study procedure and was further informed about the possibility to withdraw from the intervention and/or study at any time without any negative consequences. The participant was asked to sign the informed consent together with a data security and confidentiality form. The participant gave informed consent for the participation in the RCT in general and the analysis of her single case in specific. To ensure pseudonymization, we used an individual participant ID number. On the intervention platform, user also registered with a self-chosen anonymous email address. Treatment fidelity was assured as all participants received the same intervention on the online platform ensuring that the intervention has been consistently administered. Randomization and allocation of study participants was performed by an independent employee who was not otherwise involved in the study. All study participants were randomized in 1:1 ratio to the intervention or waitlist-control group. 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, Germany). 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).

To assess feasibility of the IMI, her course of treatment and the number of completed sessions are reported. We qualitatively evaluated the participant's written content in each

session and analyzed quantitative data from the online pre- (T1) and post-treatment assessments (T2) 7 weeks after randomization. Self-reported data was collected using a secure online-based assessment system (UNIPARK, 256-bit encrypted, EFS Survey, 2016). This system allows for data validation to improve data quality.

The Internet Addiction Test (IAT; Young, 2016) and the Compulsive Internet Use Scale (CIUS; Meerkerk, van den Eijnden, Vermulst & Garretsen, 2009) were used to assess IUD symptoms as the primary study efficacy outcome (see Table 2). Other secondary outcomes included depression (PHQ-9; Kroenke, Spitzer & Williams, 2001), insomnia severity (ISI; Morin, 1993), anxiety (GAD-7; Spitzer, Kroenke, Williams & Löwe, 2006), procrastination (GSP-K; Fries & Klingsiek, 2012), alcohol abuse (AUDIT-C; Saunders, Aasland, Babor, de la Fuente & Grant, 1993), worries (PSWQ-3; Berle, Starcevic, Moses, Hannan, Milicevic & Sammut, 2011), work-related impairment (WLQ; Lerner, Amick Ill, Rogers, Malspeis, Bungay & Cynn, 2001), health related quality of life (AQoL-8D; Richardson, Iezzi, Khan & Maxwell, 2013), and psychological wellbeing (WHO-5; Bech, Olsen, Kjoller & Rasmussen, 2003) (for a complete overview, see Table 3). Effectiveness is indicated by reporting change scores. To analyze treatment satisfaction the Client Satisfaction Questionnaire for internet interventions (CSQ; Boß et al., 2016) was used as well as qualitative analysis of the written feedback given by the participant after each session. The written content of the participant was assessed by open format answers to specific question on the intervention platform. The feedback was recorded on the platform and analysed by an inductive approach. The feedback asks about (1) perceived usefulness of the session, (2) completion time, (3) treatment elements that the user liked, (4) exercises that were perceived as helpful, (5) components that were not perceived as helpful, (6) perceived support from the testimonials, and (7) suggestions for improvement.

- (Please insert Table 2 here) -

- (Please insert Table 3 here) -

CASE STUDY

Case history

Emma (pseudonym) is a 21-year-old female university student living with her parents and working part-time as a production assistance. She reported to be in a relationship and to have

no financial issues. Emma is a first-time treatment seeker with no prior experience with internet-based health programs. She signed up for the intervention because of a constant impairing urge to stay "up to date" on the internet, i.e., refreshing the feeds of her preferred websites. This urge to be on the internet has caused severe difficulties for her to master her daily social and professional tasks. She indicated that at work she spent up to 5-6 hours a day on the Internet. The online behavior in her leisure time is primarily characterized by the extensive use of social networks (e.g., Instagram, WhatsApp) and shopping portals in addition to setting up appointments and exchanging email messages. Emma emphasized using the internet as a distraction in stressful situations, which above all leads to problems in her relationship. She also reported efficiency problems and reduced mental well-being due to her excessive internet use. She became aware of the training on the homepage of her university and wanted to participate because the training met her need to cope with her problems on her own.

Diagnostics

Emma met the criteria for IUD with a total score of 65 (Cut-off ≥ 49) on the IAT (Young, 2016) showing high pathological internet use with pronounced symptoms and a score of 49 (Cut-off ≥ 28) on the CIUS (Rooji et al., 2011), indicating problematic compulsive internet use behavior. Her online behavior was characterized by the extensive use of social networks and shopping portals in addition to exchanging email messages corresponding to the subtypes "social networks" and "obsessive research and surfing". Comorbid symptoms of the participant comprised moderately severe symptoms of depression (17 on PHQ-9; Kroenke, Spitzer & Williams, 2001), a moderate level of anxiety (14 on GAD-7; Spitzer, Kroenke, Williams & Löwe, 2006), a tendency to procrastination (31 on GPS-K; Klingsiek & Fries, 2012), and moderate sleep problems (16 on ISI; Morin, 1993). There were no symptoms of an alcohol use disorder (3 on AUDIT-C; Saunders, Aasland, Babor, de la Fuente & Grant, 1993).

Description of the treatment

Emma aimed at reduced, conscious, and deliberate smartphone use as her training goal. In session 1, she came to the conclusion that her high internet usage is maintained by the advantages that the internet dispels boredom, is fun, gives her a sense of belonging, and distracts her from problems. Her motivation for treatment resulted from relationship issues, the impairment with sleep and efficiency, as well as back pain and headaches (see Table 4).

- (Please insert Table 4 here) -

Emma explained that she has realized through psychoeducation that her use of social networks significantly influences her self-esteem (session 3). She stated that she suffers from the perceived pressure to be perfect through social media. She indicated that online advertising gives her an embellished image of women that makes her feel inferior. She tries to alleviate these feelings of insufficiency by uploading edited images of herself on Instagram in order to receive positive feedback by her followers. To strengthen her self-esteem in real life (session 5), she planned mood-promoting self-care activities (e. g. taking a walk) and formulated affirmative statements about herself and her abilities (e.g. “I am open-minded and honest.”; “I am good at cooking and baking.”) during her IMI participation.

As a strategy to overcome strong urges to update her Instagram feed in the morning, she decided on one of the presented strategies in Session 2 and chose to distract herself by reading the newspaper. Planning positive activities with a weekly schedule to specify time and activity, such as doing yoga, reading a book, taking a bath, and scheduling targeted rewards (e.g., listening to music) served as alternatives to her internet use and strengthened her self-control.

In session 4 on cognitive restructuring, Emma identified the underlying vicious circle of her overall tendency to use the internet as an emotion regulation strategy and described these situations in which she tries to influence her feelings through the internet as "escape moments". To regulate her feelings independently of the internet, Emma found the thought record for cognitive restructuring particularly helpful (see Table 5). She reported that the thought record enabled her in unpleasant situations (e.g., her boyfriend gazes after another woman), to identify negative thoughts (“She has prettier eyes than me”) and associated emotions such as feelings of worthlessness and self-doubt. By following the instructions of the thought record, she was able to develop positive and helpful thoughts (“My boyfriend loves me. If I start thinking positively, he will do so as well.”), which lead to more pleasant feelings and a sense of stability and love in her partnership.

- (Please insert Table 5 here) –

In the following sessions, she repeatedly stated her satisfaction with the "new thoughts". Following the “writing a letter to yourself”-exercise, Emma realized, that instead of attempting to distract herself with Instagram and followers complimenting her, she tried to become aware of negative thoughts and to take an appreciative attitude towards herself and her relationship (session 6): "Appreciation is very important and I'm getting it back bit by bit."

To improve her efficiency problems, she chose the elective session on procrastination and tried out different strategies promoting effective time management. She also informed herself about sleep hygiene in another elective session and received strategies on healthy sleep, e. g. not exposing herself to screen light before going to bed. In the sessions "Appreciation & gratefulness" and "Personal needs & values", she identified important values for herself (“I would like to be there for my family more often.”).

Outcome

Regarding feasibility, Emma completed all seven core sessions, four elective sessions and four diary entries. On average, she required 0.5-1 hour to complete one session and an average of three days to go through one core session (range 2-7 days). The participant opted to receive smartphone notifications to accompany the first two sessions.

With regard to symptom reduction, her self-reported symptoms of IUD had decreased from 65 to 44 at post-treatment (7 weeks after randomization) on the IAT corresponding to an improvement to a non-pathological level (cut-off ≥ 49). There was a decrease from 49 to 32 on the CIUS, showing a reduced symptom severity which was however still above the threshold (cut-off ≥ 28) for indicating a compulsive internet use (see Table 2). Reduced loss of control (T1: 12, T2: 8) and excessive usage (T1: 13, T2: 9) together with a decrease in perceived salience of internet-related stimuli (T1: 10, T2: 8) were observed. The participant also reported less conflicts in her social (T1: 7, T2: 4) and work environment (T1: 10, T2: 5). Within the qualitative written statements, Emma described a reduction of internet-related thoughts and reported to spend on average four hours daily online, three hours less than at the beginning of the training. The self-estimated desire to use the internet had decreased between the first and last week of training from 60-70 % to 0 %. With regard to comorbidities, the evaluation resulted in a slight reduction of depressive symptoms (T1: 17, T2: 14), anxiety (T1: 14, T2: 12), and procrastination behavior (T1: 31, T2: 23). There was a slight decrease in insomnia (T1: 16, T2: 19) symptoms (for an overview, see Table 3).

Each of the main sessions was rated as helpful and the support by testimonials in the sessions was used continuously.

Emma rated the quality of the training as good (CSQ: total score = 21; Range 8-32). She stated that she received the kind of treatment she wanted, and the intervention met most of her needs. She was largely satisfied with the level of provided support and the treatment helped her to deal more appropriately with her problems. She would consider the uptake of other online interventions if she needed help in the future and would recommend the intervention to a friend in need.

DISCUSSION

The aim of this case report was to illustrate feasibility, exemplary symptom reduction, and satisfaction of an IMI to treat IUD at individual level. The case study showed that the IMI can successfully support an individual in reducing symptoms of IUD and in achieving self-imposed treatment goals such as improved control over the internet use. Treatment satisfaction was reported as good. In addition to a reported decrease of time spent online and internet-related thoughts, the quantitative data showed a decline of symptoms of IUD, such as feeling less negligent towards work and social life. Furthermore, procrastination behavior tendencies have decreased, as well as the frequency and intensity of depressive symptoms and anxiety symptoms.

In this case report, cognitive restructuring to deal with negative thoughts and emotions and the impulse control strategies were assessed as particularly helpful to control the internet use in everyday life. By showing that IUD is related to many other mental health issues, such as procrastination or depression, it seems important to also address general mental health difficulties to enable comprehensive treatment. The flexibility of the intervention also allowed the participant to complete the intervention in her own pace. The detailed examination of the treatment course provides insight into influencing factors in the emergence and maintenance of IUD. The use of social networks as a coping strategy to regulate emotions in the short term mainly seems to contribute to the maintenance of the disorder but resulting in feelings of self-worthlessness in the long term that cause suffering. By establishing new emotion regulation strategies, such as developing positive and helpful new thoughts, this maintaining factor could be successfully addressed.

According to the merging of behavioral addictions with substance related disorders in the ICD-11 approach under the top level block "Disorders due to substance use or addictive behaviors" (ICD-11, World Health Organization, 2019), IUD can be recently conceptualized as an addictive disorder. Previously, IUD was coded as an impulse control disorder in the ICD-10 (ICD-10; World Health Organization, 2019). Yet, there is also critique on the conceptualization towards disorders due to substance use, stating insufficient empirical evidence for IUD as an addictive disorder (Aarseth et al., 2017; Billieux, Schimmenti, Khazaal, Maurage & Heeren, 2015; Deleuze 2017; Van Rooij & Prause, 2014; Starcevic & Aboujaoude, 2017; Kuss, Griffiths & Pontes 2017; Kardefelt-Winther, 2015). Meta-analytic results show that unpleasant feelings being offline cannot be regarded as equivalent to the state of withdrawal from psychoactive substances (Kaptsis, King, Delfabbro & Gradisar, 2016). However, there is also evidence depicting similarities in brain activation (Ko et al., 2009) as well as underlying learning processes (Romanczuk-Seiferth, 2017) for IUD and disorders due to substance use. Further, the complexity of IUD impedes the definition of a single diagnostic term. There are strong differences in the symptom patterns depending on the use of different online activities and subtypes, e.g., gaming, social network use, and pornography use (Wölfling et al., 2012; Griffiths & Szabo, 2014; Haug et al., 2015). Accordingly, one generic diagnosis might be too inaccurate for the heterogeneity of problem behaviors in IUD and the selection of adequate treatment strategies (Starcevic & Aboujaoude, 2017). In future research, it might be essential to elaborate on the actual problem core rather than focusing on generic diagnoses.

The first limitation of this case report is the selection of a participant with a successful treatment course. Despite this selection bias, Emma's case can be seen as representative due to her online activities and demographic characteristics. To generalize results, RCT data is needed. Second, the participant's self-stated initial motivation to behavior change was rather high. Low motivation for change and ambivalence about internet use represents a common barrier to seeking treatment. Motivational issues should therefore be considered and addressed in the treatment of IUD. Third, complementary diagnostic instruments representing current classification approaches should be used in future studies to assess IUD. Fourth, only self-reported data was used, thus an influence of social desirability cannot be excluded. Fifth, the case report depicts an individual treatment course with individually chosen treatment components and exercises. Future studies should evaluate the use of individual selection of treatment components in a tailored compared to a standard approach. Treating IUD using a digital health intervention may be associated with patients continuing

to spend time and possibly more time on the Internet in the short term as a result of participating in a digital intervention. However, an important goal of the intervention is to help patients gradually build up more activities in the offline setting so that, with the help of strengthened resources and alternative behaviors, they can reduce and control their Internet use in the long term. Moreover, limitations of IMIs in comparison to face-to-face treatments include potential risks in the therapeutic process, e. g. overlooking disease aspects, avoidance of difficult topics on the patient's side, lack of nonverbal signals, or not being able to react appropriately to crises. However, there is evidence that IMIs show an utmost potential to reach burdened individuals which might otherwise not be reached by the health care system because of, i.a., IMIs flexibility in time and place and their low-threshold accessibility (Schuster et al., 2020; O'Brien, Li, Snyder, & Howard, 2016; Carlbring, Andersson, Cuijpers, Riper & Hedman-Lagerlöf, 2018; Ebert et al., 2018).

CONCLUSION

From the case report presented here, it can be concluded that an IMI might be a potentially feasible easy to access and effective treatment approach for IUD. If the available results can be confirmed in the randomized controlled efficacy study, IMIs could serve as a treatment option for people who prefer to achieve more control over their internet use.

Table 1. Overview of content of main sessions and elective sessions of the training

Intervention content – Main sessions	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
Intervention content – Elective sessions	
Sleep	
Alcohol & affect regulation	
Appreciation & gratefulness	
Personal needs & values	
Procrastination	
Relaxation	

Table 2. Overview of subscale values and total scores of IAT and CIUS at T1 and T2

Questionnaire	Subscale	Items	T1	T2
IAT (Young, 2016) Cut-off ≥ 49 Score range: 20 – 100 (higher scores reflect higher IUD)	Salience	5	10	8
	Neglect social life	2	7	4
	Neglect work	3	10	5
	Anticipation of internet use	2	8	6
	Excessive use	5	13	9
	Loss of control	3	12	8
	Total scores	20	65	44
CIUS (Meerkerk et al., 2009) Cut-off ≥ 28 Score range: 14 – 56 (higher scores reflect higher compulsive Internet use behavior)	Salience	3	7	6
	Withdrawal symptoms	1	3	2
	Coping	2	8	6
	Conflict	4	16	8
	Loss of control	4	15	10
	Total scores	14	49	32

Table 3. Overview of sum scores of measured comorbidities at T1 and T2

Construct	Questionnaire	Sum Scores	
		T1	**T2**
Depression	The Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer & Williams, 2001) Score range: 0 – 27 (higher scores reflect higher depressive symptoms)	17	14
Sleep	The Insomnia Severity Index (ISI; Morin, 1993) Score range: 0 – 28 (higher scores reflect higher insomnia symptoms)	16	19
Anxiety	The Generalized Anxiety Disorder Scale (GAD-7; Spitzer, Kroenke, Williams & Löwe, 2006) Score range: 0 – 21 (higher scores reflect higher anxiety)	14	12
Procrastination	The General Procrastination Scale – short version (GSP-K; Fries & Klingsiek, 2012) Score range: 0 – 36 (higher scores reflect higher procrastination behavior)	31	23
Alcohol consumption	The Alcohol Use Disorders Identification Test (AUDIT-C; Saunders, Aasland, Babor, de la Fuente & Grant, 1993)	3	3

	Score range: 0 – 12 (higher scores reflect higher alcohol consumption)		
Worries	The Penn State Worry Questionnaire-Ultra Brief Version (PSWQ-3; Berle, Starcevic, Moses, Hannan, Milicevic & Sammut, 2011) Score range: 0 – 18 (higher scores reflect higher worrying)	11	12
Work limitations	Work Limitations Questionnaire (WLQ; Lerner, Amick Ill, Rogers, Malspeis, Bungay & Cynn, 2001) Score range: 5 – 50 (higher scores reflect higher work limitations)	30	43
Quality of life	The Assessment of Quality of Life Instruments (AQoL-8D; Richardson, Iezzi, Khan & Maxwell, 2013) Score range: 35 – 175 (higher scores reflect lower quality of life)	76	81
Wellbeing	The WHO-Wellbeing Index (WHO-5; Bech, Olsen, Kjoller & Rasmussen, 2003) Score range: 0 – 25 (higher scores reflect higher wellbeing)	18	15

Table 4. Emma's identified personal advantages and disadvantages of her internet use

Advantages of internet use	Disadvantages of internet use
+ The internet dispels boredom	- Poor sleep
+ The internet is fun	- Concentration issues
+ A perceived sense of belonging	- Headaches
+ A distraction from problems	- Back pain
	- Reduced efficiency
	- Forgetfulness

Table 5. Emma's thought record of the instructed cognitive restructuring exercise

Situation	Emotion /Feeling	Negative automatic thoughts	Alternative thoughts	Emotion /Feeling
"My boyfriend gazes after another woman. I distract myself with Instagram and followers complimenting me."	Worthlessness, self-doubt	"She has prettier eyes than me, better lips and skin and a narrower nose."	"My boyfriend loves me. If I start thinking positively, he will do so as well."	More pleasant feelings, a sense of stability and love in the partnership.

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3.4 Article 4: Treating internet use disorder via the internet? Results of two-armed randomized controlled trial

Title: Treating internet use disorder via the internet? Results of two-armed randomized controlled trial

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Summary:

Background and aims: Internet Use Disorder (IUD) is emerging as an increasing societal challenge. Evidence-based treatment options are scarce. Digital health interventions may be a promising way to deliver psychological treatment to individuals with IUD as they address affected individuals in their online setting. The aim of this study was to evaluate the efficacy of a newly developed, digital health intervention for IUD compared to a wait-list control group (WCG).

Methods: In a two-armed randomized controlled trial, N = 130 individuals showing problematic internet use (Internet Addiction Test [IAT] ≥ 49) were randomly allocated to the intervention group (IG; n = 65) or a WCG (n = 65). The intervention consisted of 7 sessions based on cognitive behavioral therapy. The primary outcome was internet addiction symptom severity measured via the IAT at post treatment. Secondary outcomes included quality of life, depressive symptoms, anxiety, and other psychosocial variables associated with Internet Use Disorder.

Results: Participants in the IG (n = 65) showed significantly less internet addiction symptom severity (IAT) (d = 0.54, 95% CI 0.19 – 0.89) as well as less compulsive internet use (d = 0.57, 95% CI 0.22 – 0.92) than the WCG (n = 65) at post-treatment. Effects on all other secondary outcomes were not significant. On average, participants completed 67.5% of the intervention.

Discussion and Conclusions: This is the first randomized controlled trial to evaluate a newly developed digital health intervention for Internet Use Disorder, which could be a promising first step to reduce individuals' disease burden.

Contribution:

Karina Bernstein was the principal investigator and author of this article. She designed the concept and developed the digital health intervention under supervision of Anna-Carlotta Zarski. Karina Bernstein conducted the randomized controlled trial, collected, and analyzed the data and wrote the manuscript with feedback from Anna-Carlotta Zarski and David Daniel Ebert. All authors participated in the review and revision of the manuscript and have approved the final manuscript to be published.

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

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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 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, MPS and ACZ declare no conflict of interest.

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).

Trial registration: German Clinical Trials Register DRKS00015314; Date of registration 29th august 2018.

Submission date: May 11th, 2023

ABSTRACT

Background and aims: Internet Use Disorder (IUD) is emerging as an increasing societal challenge. Evidence-based treatment options are scarce. Digital health interventions may be a promising way to deliver psychological treatment to individuals with IUD as they address affected individuals in their online setting. The aim of this study was to evaluate the efficacy of a newly developed, digital health intervention for IUD compared to a wait-list control group (WCG).

Methods: In a two-armed randomized controlled trial, N = 130 individuals showing problematic internet use (Internet Addiction Test [IAT] ≥ 49) were randomly allocated to the intervention group (IG; n = 65) or a WCG (n = 65). The intervention consisted of 7 sessions based on cognitive behavioral therapy. The primary outcome was internet addiction symptom severity measured via the IAT at post treatment. Secondary outcomes included quality of life, depressive symptoms, anxiety, and other psychosocial variables associated with Internet Use Disorder.

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Discussion and Conclusions: This is the first randomized controlled trial to evaluate a newly developed digital health intervention for Internet Use Disorder, which could be a promising first step to reduce individuals' disease burden.

Keywords: Digital health intervention, internet use disorder, randomized controlled trial, cognitive behavioral therapy for IUD, online CBT, guided self-help

INTRODUCTION

Internet Use Disorder (IUD) is 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). Pathological internet use is an umbrella concept that can be divided into different subtypes related to both gaming and non-gaming internet activities. Non-gaming internet activities can be differentiated in internet gambling (e.g., online-poker, sports betting), obsessive research and surfing, internet compulsive buying, using social networks, and internet pornography (Andreassen, 2015; Wölfling et al., 2012; Young, 2011). Epidemiologic studies have indicated that IUD affects 7% of the general population (Pan et al., 2020), with an increased prevalence rate over time.

IUD may cause neurological complications, psychological distress, and social problems due to the excessive use and extended screen time (Greenfield, 1999; Young, 1998; Zhou et al., 2011). In addition, high comorbidities with other mental disorders have been reported, such as affective and anxiety disorders and substance use disorders (Petersen et al., 2009; Peukert et al., 2010; Shaw & Black, 2008; Weinstein & Lejoyeux, 2010). Impairment caused by IUD can also include educational failure and reduced academic perspectives (Beutel et al., 2011; Rehbein et al., 2009), especially in adolescents and young adults.

Currently, preliminary evidence of uncontrolled pilot studies based on cognitive behavioral therapy (CBT) and motivational interviewing already showed that digital health intervention could be able to reduce IUD symptoms (d = 0.5 – 0.8) (Dieris-Hirche et al., 2021; Su et al., 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 based on dysfunctional coping and internet use expectancies can result in large effects on IUD in face-to-face settings (k = 15,

g = 1.84) (Brand et al., 2014; Goslar et al., 2020; Winkler et al., 2013). Given the numerous and severe negative consequences, available evidence-based treatment options for IUD are rare (Boumparis et al., 2022).

Digital health interventions can offer a possibility to deliver cognitive-behavioral treatment for IUD with a low threshold for uptake (Carlbring et al., 2018). Treating IUD 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 et al., 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 et al., 2021; Zarski et al., 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 IUD 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 et al., 2012). To the best of our knowledge, this is the first trial evaluating a guided digital health intervention for IUD 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 IUD compared to a wait-list control group (WCG). It was

hypothesized that participants assigned to the intervention group (IG) would show reduced internet addiction symptom severity measured via the Internet Addiction Test (IAT) at post-test compared to those in the WCG. 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. Assessments to evaluate the short-term efficacy of the intervention took place at baseline (T1) and 7 weeks after randomization (post-treatment; T2). See figure 1 for an overview of the study design. A detailed description is provided in the study protocol (Saruhanjan et al., 2020).

- Please insert Figure 1 here -

Participants and procedures

Inclusion and exclusion criteria

We included individuals who (1) were at least 18 years of age, (2) showed elevated levels of IUD with IAT scores of ≥ 49 [7], (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, (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 et al., 1996), (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 flyer 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). Once randomization had been completed, participants in the IG

received immediate access to the intervention while participants in the WCG 12 months later.

Intervention

The intervention was CBT-based and consisted of six core sessions and one booster session (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 (Beck et al., 1996). For a detailed description see the study protocol (Saruhanjan et al., 2020).

- Please insert Table 1 here -

- Please insert Table 2 here -

Measures

Baseline assessments

Baseline assessments included demographics, current and previous experience with psychotherapy, self-esteem via Rosenberg Self-Esteem Scale (RSES) (Rosenberg, 1965), and social phobia via Mini Social Phobia Inventory (Mini-SPIN).

Primary outcome

To assess the effect of the treatment on internet addiction symptom severity, the IAT (Young, 1998) was administered (20 items, score range: 20-100; $\alpha = 0.80$) (Widyanto &

McMurran, 2004). Higher items represent higher internet addiction symptom severity (normal range: < 31 points; mild: 31-49 points; moderate: 50-79 points; severe: 80-100 points: Cut-off ≥ 49) (Young, 2017; Young & de Abreu, 2011).

Secondary outcomes

Compulsive internet use: Compulsive internet use was assessed by the Compulsive Internet Use Scale (CIUS; 14 items, score range: 0-56; α = 0.89) (Meerkerk, 2007; Meerkerk et al., 2008). Higher items represent higher compulsive internet use.

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 et al., 2008; Erbe et al., 2016; Kroenke et al., 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 measurement (GAD-7; 7 items, score range: 0-21; α = 0.92) (Löwe et al., 2008; Spitzer et al., 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 et al., 1998; Rumpf et al., 2012; Saunders et al., 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 et al., 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 German questionnaire Kurzfragebogen zum Glücksspielverhalten [short questionnaire on gambling behavior] (KFG; 20 items, score range: 0-60; α = 0.79) (Petry, 1996; Petry et al., 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 et al., 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 et al., 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), 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 = .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 et al., 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: 8-32; 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 et al., 2007). The estimated effect of $d = 0.60$ was based on recent meta-analyses on the effects of treatments on internet addiction 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 et al., 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 et al., 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 compulsive internet use. 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 Figure 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 female (50%), 64 male (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).

- Please insert Table 3 here -

- **Please insert Table 4 here -**

Primary outcome analysis – internet use disorder

Participants in the IG achieved significantly lower internet addiction symptom severity on the IAT than the WCG (IG: $M = 55.47$, $SD = 9.1$; WCG: $M = 60.8$, $SD = 9.29$; $F_{1, 127} = 11.63$, $P < 0.001$) 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 ($\chi^2 = 7.5$, $P = 0.01$). 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 compulsive internet use 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 compulsive internet use significantly more participants in the IG ($n = 36$, 55.4%) than in the WCG ($n = 14$, 21.5%) were classified as responders ($\chi^2 = 15.73$, $P < 0.001$), resulting in an NNT of 2.95 (95% CI 2 – 6). The groups did not differ significantly regarding depressive symptoms, anxiety, alcohol abuse, insomnia, worries, procrastination, gambling, well-being, quality of life, and work limitations (d range = 0.01 to 0.28).

- **Please insert Table 5 here -**

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 $P > .05$). 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 = .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 compulsive internet use at T2 (d = 0.62, 95% CI 0.2 – 0.99) and significantly more participants classified as responders in the IG ($P < .001$). As in the ITT sample, all other secondary outcomes remained with a non-significant result (d range = 0.11 to 0.36). Detailed results can be found in Appendix A.

Intervention completer analysis

The results of the intervention completer analyses (n = 106/130) were similar to the ITT analyses, 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 ($P < .001$). Comparable to the ITT-analyses there was a significant result for compulsive internet use (d = 0.89, 95% CI 0.48 – 1.3) with a reliable improvement in the IG ($P < .001$). 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 to 0.35). The results can be found in Appendix B.

Treatment adherence and satisfaction with the intervention

Almost two third 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%). On average, participants completed 4.05 treatment modules (range = 1-6), which equals 67.5% of the intervention. User satisfaction was 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 IUD in comparison to a WCG. As hypothesized, the participants of the IG showed lower internet addiction symptom severity at post-treatment compared to a WCG with a moderate effect size of d = 0.54. Regarding secondary outcomes, the participants in the IG showed reduced compulsive internet use 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 high.

Uncontrolled pilot studies on digital health interventions for IUD 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 et al., 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 et al., 2016; Sagoe et al., 2021). Yet, evidence on face-to-face treatment for IUD 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 IUD 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 IUD developed subsequently. Nonetheless, an intervention for IUD 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 IUD, 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, a thorough diagnosis 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 IUD might be potentially a beneficial and appropriate approach.

Compared with face-to-face interventions for IUD, either psychotherapy or addiction counselling, (Lindenberg et al., 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 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 gaming activities and thus possibly in IUD 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 et al., 2012). A digital health intervention might seem to be a low-threshold accepted first treatment option, especially for men suffering not only from IUD 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 IUD. This study can make an important contribution to the so far limited research on empirically tested treatment for IUD 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 et al., 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 IUD, 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 internet addiction 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 et al., 2023). Fourth, due to our WCG design, it remains unclear if reported improvements can be achieved when compared to active control groups.

Future research

Future interventions should pay more attention to the high comorbidity of IUD with depression, insomnia and GAD and explore ways of personalizing the intervention to individual needs of individuals with IUD and heightened depressive symptoms. Also, IUD treatment should be considered alongside depression treatment in individuals with both depression and IUD, as e.g., in a blended format. 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 IUD should follow.

CONCLUSION

Given the increasing number of individuals with IUD, it is of prime importance to provide, establish, and disseminate effective IUD treatment. The findings of this study indicate that a digital health intervention can be effective at reducing internet addiction symptom severity and associated compulsive internet use 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 IUD directly in their familiar internet setting.

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FIGURES AND TABLES

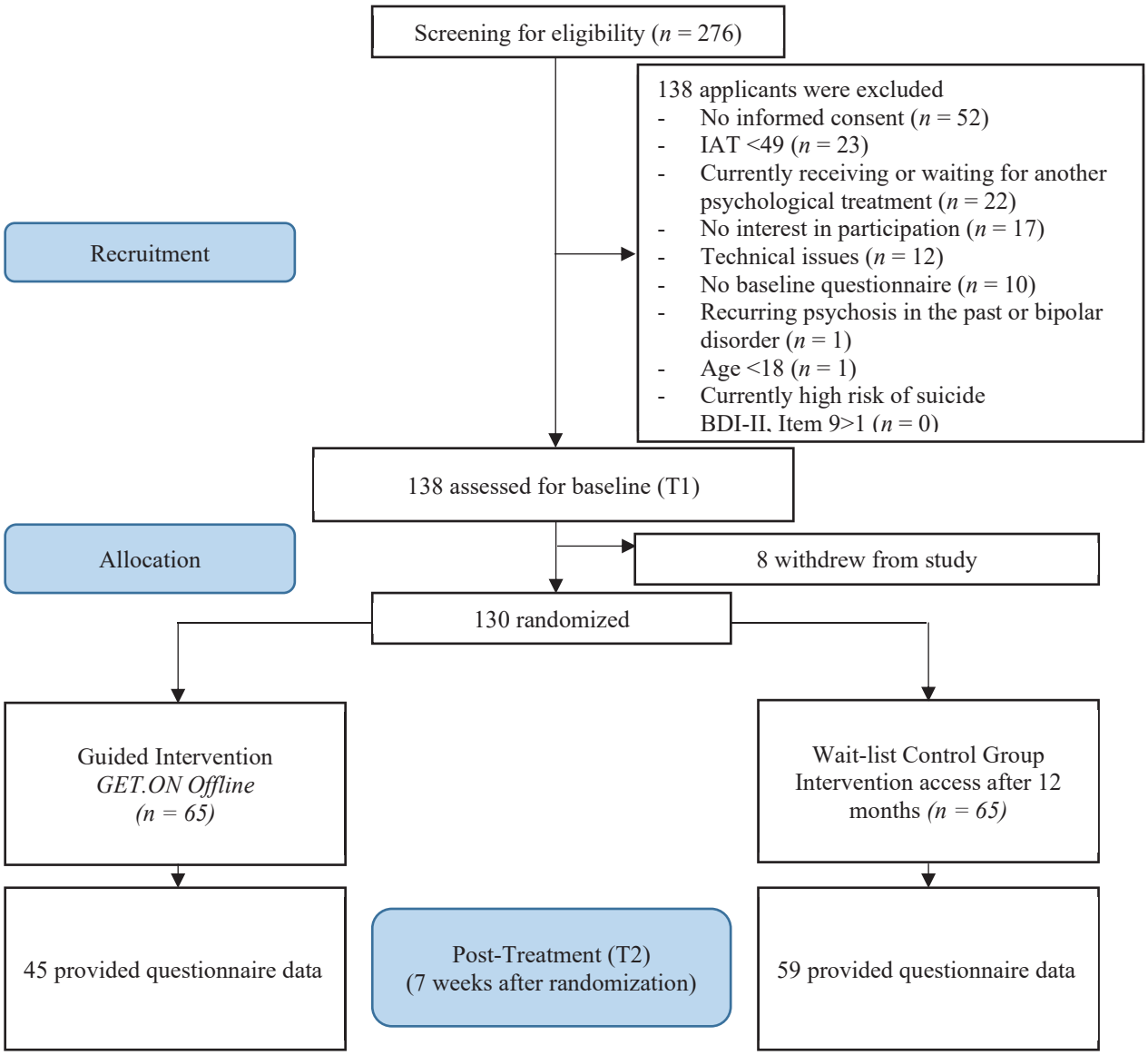

Table 1 Content of the training

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

Table 3 Demographic characteristics

	Total (n=130)	*IG (n=65)*	*WCG (n=65)*
Sociodemographics			
Age in years, mean (SD)	28.45 (10.59)	27.63 (9.27)	29.26 (11.78)
Gender, female *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)

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								
Internet use disorder (IAT)	63.46	9.47	63.89	8.11	55.47	9.1	60.8	9.29
Secondary Outcomes								
Compulsive Internet use (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

[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				
Internet use disorder (IAT)	0.54	0.19 - 0.89	11.63	.00
Secondary outcomes				
Compulsive internet use (CIUS)	0.57	0.22 - 0.92	9.82	.00
Depressive Symptoms (PHQ-9)	0.13	-0.21 - 0.48	0.92	.34
Anxiety (GAD-7)	0.24	-0.11 - 0.58	0.98	.32
Alcohol abuse (AUDIT-C)	0.22	-0.12 - 0.57	0.49	.49
Insomnia (ISI)	0.25	-0.1 - 0.59	2.92	.09
Worries (PSWQ-3)	0.19	-0.16 - 0.53	0.39	.53
Procrastination (GPS-K)	0.27	-0.08 - 0.61	1.46	.23
Gambling (KFG)	0.36	-0.84 – 1.56	0.44	.53
Well-being (WHO-5)	0.07	-0.27 - 0.41	0.98	.32
Quality of Life (AQoL-8D)	0.24	-0.1 - 0.59	1.62	.2
Work Limitations (WLQ)	0.11	-0.23 - 0.46	1.65	.2

APPENDIX A

Table 6 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				
Internet use disorder (IAT)	0.71	0.29 - 1.08	14.81	.00
Secondary outcomes				
Compulsive internet use (CIUS)	0.62	0.2 - 0.99	10.58	.00
Depressive Symptoms (PHQ-9)	0.2	-0.19 - 0.59	1.36	.25
Anxiety (GAD-7)	0.25	-0.14 - 0.64	1.29	.26
Alcohol abuse (AUDIT-C)	0.28	-0.12 - 0.66	1.53	.22
Insomnia (ISI)	0.26	-0.08 - 0.7	2.85	.10
Worries (PSWQ-3)	0.27	-0.12 - 0.66	0.79	.38
Procrastination (GPS-K)	0.29	-0.1 - 0.68	1.89	.17
Gambling (KFG)	0.36	-0.82 – 1.58	0.44	.53
Well-being (WHO-5)	0.16	-0.23 - 0.55	1.30	.26
Quality of Life (AQoL-8D)	0.2	-0.19 - 0.59	1.18	.28
Work Limitations (WLQ)	0.11	-0.28 - 0.49	1.41	.24

APPENDIX B

Table 7 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				
Internet use disorder (IAT)	0.8	0.39 – 1.2	19.64	.00
Secondary outcomes				
Compulsive internet use (CIUS)	0.89	0.48 – 1.3	19.44	.00
Depressive Symptoms (PHQ-9)	0.32	-0.08 – 0.71	4.59	.03
Anxiety (GAD-7)	0.27	-0.12 – 0.66	2.35	.13
Alcohol abuse (AUDIT-C)	0.27	-0.12 – 0.66	0.57	.45
Insomnia (ISI)	0.25	-0.14 – 0.65	3.21	.07
Worries (PSWQ-3)	0.26	-0.14 – 0.65	1.18	.28
Procrastination (GPS-K)	0.35	-0.05 – 0.74	3.27	.07
Gambling (KFG)	0.32	-1.08 – 1.71	0.78	.41
Well-being (WHO-5)	0.14	-0.25 – 0.53	1.53	.22
Quality of Life (AQoL-8D)	0.21	-0.19 – 0.6	1.22	.27
Work Limitations (WLQ)	0.12	-0.28 – 0.51	1.54	.22

3.5 Article 5: Efficacy of an internet intervention for students suffering from primary insomnia – results of a two-armed randomized controlled trial

Title: Efficacy of an internet intervention for students suffering from primary insomnia – results of a two-armed randomized controlled trial

Authors: Karina Bernstein, Harald Baumeister, David Daniel Ebert, Anna-Carlotta Zarski

Status: In preparation for submission to Sleep

Summary:

Study objectives: The aim of the study was to evaluate the efficacy of an internet intervention for students with insomnia in a randomized controlled trial including an active control group.

Methods: In a two-armed randomized controlled trial, N = 90 university students with insomnia (Insomnia Severity Index [ISI] ≥ 10) were randomly allocated to an internet-based cognitive-behavioral-therapy for insomnia (iCBT-I) (n = 45) or to an active control condition receiving online sleep hygiene education n = 45). The intervention consisted of six cognitive-behavioral modules to treat insomnia, involving sleep restriction and stimulus control. Assessment took place at baseline and 8 weeks after randomization. The primary outcome was insomnia severity measured via the Insomnia Severity Index (ISI) at post-treatment (T2). Secondary outcomes included clinician-rated diagnosis of primary insomnia and major depression, sleep quality, sleep efficiency, worrying, recovery experiences, recovery activities, presenteeism, procrastination, cognitive irritation, and recuperation in sleep.

Results: Participants receiving iCBT-I did not achieve significantly lower insomnia severity scores than participants in the active control group at T2 (F1, 87 = 2.57, P = .11) with a d = 0.35 (95% CI -0.06 to 0.77). Within-group analysis showed a significant reduction in insomnia severity with high effect sizes both in the intervention group (t44 = 9.49, p < 0.001; d = 1.31, 95% CI: 0.85-1.77) and the active control group (t44 = 6.11, p < 0.001; d = 1.10, 95% CI: 0.65-1.54).

Conclusions: The iCBT-I did not result in greater insomnia severity reduction compared to online sleep hygiene education. This finding supports the implementation of a stepped care approach in the treatment of insomnia in students with first step online sleep hygiene education. This finding raises the question of effective treatment elements and could suggest online sleep hygiene education as a low first approach in stepped care.

Contribution:

Karina Bernstein was the principal investigator and author of this article. She developed the StudiCare GET.Sleep intervention based on the GET.ON Recovery intervention. She conducted the randomized controlled trial, collected, and analyzed the data and wrote the manuscript under supervision of Anna-Carlotta Zarski.

Efficacy of an internet intervention for students suffering from primary insomnia – results of a two-armed randomized controlled trial

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Abstract

Study objectives: The aim of the study was to evaluate the efficacy of an internet intervention for students with insomnia in a randomized controlled trial including an active control group.

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Results: Participants receiving iCBT-I did not achieve significantly lower insomnia severity scores than participants in the active control group at T2 (F1, 87 = 2.57, P = .11) with a d = 0.35 (95% CI -0.06 to 0.77). Within-group analysis showed a significant reduction in insomnia severity with high effect sizes both in the intervention group (t44 = 9.49, p < 0.001; d = 1.31, 95% CI: 0.85-1.77) and the active control group (t44 = 6.11, p < 0.001; d = 1.10, 95% CI: 0.65-1.54).

Conclusions: The iCBT-I did not result in greater insomnia severity reduction compared to online sleep hygiene education. This finding supports the implementation of a stepped care approach in the treatment of insomnia in students with first step online sleep hygiene education. This finding raises the question of effective treatment elements and could suggest online sleep hygiene education as a low first approach in stepped care.

Keywords: Internet Intervention, Insomnia, Students, Randomized controlled trial, Active control group, CBT-I

INTRODUCTION

University students suffer from a range of sleep issues, such as poor sleep quality, sleep deprivation, or delayed bedtimes and rise times [1]. Sleep disorders, including primary insomnia, affect about 27% of students per year [2]. Primary insomnia is defined as difficulties to fall asleep or sleeping through, early morning awakening or perceived unrestful sleep [3]. Impaired sleep or associated daytime sleepiness causing suffering or impairment in social, professional, or other important functional areas in a clinically significant way is considered as primary insomnia according to the diagnostic criteria of DSM-5 [3].

Insomnia has been found to be a risk factor in particular for developing a depression, in a students with insomnia sample [8]. Further, studies have found that an irregular sleep-wake rhythm negatively impacts students' academic performance [2, 4, 5]. Lack of sleep is associated with reduced learning capacity, poorer procedural and declarative learning, and generally reduced neurocognitive functionality [6]. In addition to academic impairment, there are also high correlations between impaired sleep quality of students and behavior that poses a risk to physical and mental health, including suicidal thoughts, smoking and alcohol consumption [7].

Among the empirically validated psychological therapies for insomnia that meet the criteria of the American Psychological Association is cognitive-behavioral therapy for insomnia (CBT-I). CBT-I includes stimulus control, sleep restriction, progressive muscle relaxation, and paradoxical intention [9–11] aiming at restorative sleep. However, the use of psychological treatment is restricted because students suffering from insomnia often do not seek help due to fear of stigmatization or the desire to solve problems on their own [12]. Using the internet to provide self-help interventions may encourage students to make use of psychological treatment at low-threshold. Internet interventions are easily accessible at any

time and place, participation is anonymous so stigmatization can be avoided. Such interventions can be completed at an individual pace and materials can be reviewed as often as desired, they are flexible and can be adapted to personal needs. Internet interventions may reach affected students earlier than traditional mental health services, hence preventing chronification or the onset of more severe mental health problems. Moreover, they are easily scalable, as only a small increase in therapeutic resources is required to reach a larger number of the affected target group [16–18].

Moreover, most studies used wait-list control groups as comparators [21–24], thus it is unclear to which intervention components the efficacy is attributed to. It is commonly assumed that internet-based interventions have to be interactive and to foster behavioral change in daily life. Studies revealed large effect sizes (g = 0.63 - 0.98) for CBT-I's [25] and meta-analyses further showed that the efficacy of face-to-face CBT-I with its combination of components aiming to improve sleep outperforms and is longer lasting, than the treatment of insomnia with single therapy components, such as educational, behavioral or cognitive ones [10, 25]. Previous research comparing CBT-I to active CGs has shown mixed results with studies revealing significant effects regarding insomnia severity (d = 0.79–0.85) [33, 69] as well as studies with no significant between-group effects (d = 0.44) [70, 71].

The aim of this study was to evaluate the efficacy of the iCBT-I specifically tailored to students needs in comparison to an active CG providing solely online sleep hygiene education in a randomized controlled trial to identify the specific efficacy of behavioral activating treatment components. We hypothesized that the iCBT-I with its interactive components and exercises leads to greater reduction in insomnia severity at T2 compared to an active CG providing online sleep hygiene education. The second objective was to conduct exploratory analyses on the effects of the intervention on secondary outcomes such as clinician-rated diagnosis of primary insomnia and major depression, sleep quality, sleep

efficiency, worrying, recovery experiences, recovery activities, presentism, procrastination, cognitive irritation, and recuperation in sleep.

METHODS

Study Design

A two-armed randomized controlled trial (RCT) was conducted to compare an iCBT-I specifically adapted for students suffering from primary insomnia (IG) to an active CG to assess the efficacy of specific behaviorally activating CBT-I techniques. Outcomes were assessed at baseline prior to randomization (T1) and 8-weeks after randomization (T2) to evaluate the short-term efficacy of the intervention. See figure 1 for the study flow. The study protocol was approved by the Friedrich-Alexander Universität of Erlangen-Nürnberg ethics committee (481_18B). The trial is registered in the German Clinical Trial Register under DRKS00017737.

Participants and Procedures

Inclusion and exclusion criteria

We included self-stated students who 1) were at least 18 years old, 2) had heightened insomnia severity assessed by a score of ≥ 10 on the Insomnia Severity Index (ISI) [34], 3) were Geman-speaking, 4) were willing to give informed consent in study participation, and 5) had internet access to use the intervention. We excluded individuals who 1) reported that they had been diagnosed with a psychosis or bipolar disorder, 2) showed a notable suicidal risk as indicated by a score ≥ 1 on Item 9 of the Beck Depression Inventory (BDI-II) [35], and 3) were currently receiving or on a waitlist for psychological treatment for any mental disorder.

Procedure

Participants were recruited in Germany, Austria and Switzerland via (1) the *StudiCare* website (https://www.studicare.com/), (2) social media and discussion forums, (3) mass e-mailing sent to university students via mail distribution lists of German, Swiss and Austrian universities, (4) flyers and posters distributed, e.g., in university and public buildings. Recruitment took place from July 2019 to January 2021. Participants who scored positive for insomnia on the ISI (≥ 10) were asked to give informed consent, complete the baseline assessment, and participate in a diagnostic interview via telephone (approx. 15 min) to assess primary insomnia and major depressive disorder. After the diagnostic interview, participants were randomized to either the iCBT-I or the active CG in block sizes of 4 and 6 by a person not otherwise affiliated to the project. Once randomization had been completed, participants in the iCBT-I received immediate access to the intervention and participants in the active CG access to online sleep hygiene education. Six months after randomization, participants in the CG were also offered access to iCBT-I.

Intervention

Intervention group

The intervention is based on the iCBT-I *GET.ON Recovery* [32] which has been shown large effects (*d*=1.45; 95%-CI: 1.06–1.84) in reducing insomnia severity via ISI in a sample of teachers in comparison to a WCG [32]. We tailored the iCBT-I *GET.ON Recovery* to the population of students based on prior analyses on specific treatment needs in students using internet interventions [19]. The intervention consisted of six one-week modules including well-established CBT-I methods, such as sleep restriction, stimulus control, sleep hygiene, and cognitive interventions [36]. As the theoretical presumption was that students' insomnia are caused by an impaired recovery from their university-related stress assuming insomnia symptoms would improve if their recovery was enhanced [37, 38], further treatment components were on restorative sleep, cognitive detachment, and recreational

activities. The intervention was presented on an intellectual level to account for the need for more in-depth information and to provide scientifically validated background information. Moreover, the intervention addressed specifically student-named problems and difficulties that affect sleep, such as an irregular daily structure, increased exposure to distraction stimuli during studies, increased performance pressure, and merging boundaries from university and leisure time, placing a special focus on the organization of a daily structure and exercises on concentration focusing.

In the first module, information about recovery and sleep hygiene was given. Participants learned how sleep, cognitive detachment, and recreational activities are interconnected. Also, participants are introduced to the 10-item online recovery diary, covering important sleep items like time in bed and total sleep time, to be able to calculate and monitor their sleep efficiency. In module two, participants were introduced to the stimulus control and sleep restriction techniques and were instructed to reschedule their sleep for the following week. In module three, participants reflected on their progress in the sleep restriction process and adapted their sleep restriction plan according to their sleep efficiency. They also learn about behaviors which help to initiate recovery [39] and thus foster detachment and sleep [40]. Module four used cognitive interventions where participants received psychoeducation on attention and how to apply techniques to deal with worry and rumination. The fifth module was based on Metacognitive Therapy (MCT) [40], teaching participants how continuous attention on ruminating thoughts can further increase its frequency and intensity.

Each module's homework assignments include planning and implementing recreational activities into everyday life, monitoring sleep efficiency, and continuing sleep hygiene and sleep restriction. The intervention concluded with a module aiming at relapse

prevention, e.g., preparing for decreases in sleep quality when facing elevated stress levels, stress management, coping relapse.

Active control group

Participants of the active CG received one module with online sleep hygiene education content via the same online platform as participants of the iCBT-I condition. Online sleep hygiene education was comprised of 1) sleep education informing participants about causes and maintaining factors of insomnia, and 2) rules of sleep hygiene, e.g., stimulus control. Unlike the iCBT-I, the online sleep hygiene education content did not include any exercises and behavioral activities, interactive material, support, or feedback by an eCoach.

Measures

Self-report questionnaires were administered online at baseline prior to randomization (T1), and 8 weeks after randomization (T2). At baseline and T2, trained Bachelor of Science- and Master of Sciene psychologists conducted structured clinical interviews via telephone.

Primary outcome

Insomnia severity

Insomnia severity was assessed by the German version [32] of the Insomnia Severity Index (ISI; 7 items, score range: 0-28; $\alpha = .83$) [34]. Higher items represent higher insomnia symptoms. A web-based measure has been validated as well [41] and is frequently used in iCBT-I research [42]. At screening, we used ISI ≥ 10 as cut-off indicating clinical insomnia [43].

Secondary outcomes

Primary insomnia. A diagnosis of primary insomnia was established via the structured clinical interview for sleep disorders (SCISD-R) conducted over the telephone [44].

Major depression disorder. A current major depression disorder was assessed according to the Diagnostic and Statistical Manual of Mental Disorders Five (DSM-5) by employing the sections of the Clinical Version of the Structured Clinical Interview on major depression (SCID-5-CV) [45] in a telephone interview.

Sleep quality. Sleep quality was measured with one item ("How would you overall describe your sleep quality within the last four weeks?") of the Pittsburgh Sleep Quality Index (PSQI) [46]. A lower score represents better sleep quality.

Sleep efficiency. Participants were asked to record their bedtimes, their rising times, and their total hours of sleep within the past four weeks [47]. Sleep efficiency was computed using the formula total hours of sleep/time spent in bed. A sleep efficiency of ≥ 85% is considered good sleep efficiency [48]. Higher scores reflect higher sleep efficiency.

Worrying. We measured worrying with a short version of the Penn State Worry Questionnaire (PSWQ; 3 items, score range: 0-18; $\alpha = .87$) [49, 50]. We adapted a past-week version of the PSWQ according to the three respective German items of the PSWQ-past week [51]. Higher scores reflect higher worrying.

Recovery experiences. The Recovery Experience Questionnaire (REQ; 16 items, score range: 16-80) [52] includes four factors that represent four different recovery experiences: (i) psychological detachment ($\alpha = 0.89$), (ii) relaxation ($\alpha = 0.77$), (iii) mastery ($\alpha = 0.88$), and (iv) control ($\alpha = 0.87$). Higher scores reflect better recovery experiences.

Recovery activities. The Recreation Experience and Activity Questionnaire (ReaQ; 21 items, score range: 0-84, α = 0.72) [53] rates participants' frequency of recreational activities during the past week (0, 1, 2, 3, or ≥4 times) with items like "Over the last week, I calmly enjoyed a coffee/tee". Higher scores reflect more recovery activities.

Presenteeism. The presenteeism scale for students was used to detect reduced performance due to health problems (10 items, score range: 10-50; α = .81) [54]. The items assess whether health conditions affected the academical work within the past four weeks (e.g., "Were you tired because you lost sleep?"). Higher scores reflect a lower level of presenteeism.

Procrastination. To measure procrastination, we used the procrastination scale for students (7 items, score range: 7-35; α = .94) [55]. Participants indicated to which extent they procrastinated tasks for university in the last two weeks. Higher items represent higher procrastination behavior.

Cognitive Irritation. To measure cognitive irritation, the respective subscale of the irritation scale was used (3 items, score range: 3-21; α = .87) [56]. Higher scores indicate increased cognitive irritation.

Recuperation in Sleep. To measure recuperation in sleep, the respective subscale of the well-validated sleep questionnaire SF-B [57] was used (8 items, score range: 8-40; α = .81). Higher scores represent higher recuperation in sleep.

User Satisfaction. User satisfaction was assessed by a questionnaire based on the Client Satisfaction Questionnaire (CSQ-8; 8 items; score range: 8-32; α = .89) [58, 59],

adapted to assess user satisfaction in online interventions (CSQ-I) [60]. Higher scores reflect higher user satisfaction with the training.

Sample Size

We aim to include 90 participants to statistically detect a minimal clinically relevant effect size of $d = 0.79$, with a power $(1 - \beta)$ of 80% and an alpha of 0.05 (two-tailed test) for an intention-to-treat analysis using G*Power. The design of the study is based on the expected superiority of the IG compared to the active CG on the primary outcome variable at T2.

Statistical analysis

All results are reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement [62]. We presented the results from intention-to-treat analyses, study completer analyses, and intervention completer analyses performed with SPSS, version 26 (IBM Corp. Armonk. NY, USA). Study completer analyses included only participants who filled out the questionnaires at T2 and intervention completer analyses included only participants who have completed at least 4 out of 6 modules. Reported *p*-values are two-sided with a significance level of 0.05. 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 with the multiple imputation functions in IBM SPSS 26; IBM Corp, Amonk, NY, USA. Little's overall test of randomness indicated that data were missing completely at random. All variables were set as predictors for imputation. Imputed datasets were then aggregated to obtain one imputed data set. Separate univariate analyses of covariance (ANCOVA) with T1 scores as covariates were used to compare the IG and CG on all self-report outcome measures at T2 for the primary outcome and the exploratory secondary outcome analyses [63, 64]. Changes within group scores between T1

and T2 were examined with paired sample t-tests. We report P-values and Cohen's d for the between- and within-group effect size [65] and corresponding 95% confidence intervals (95% CI). According to Cohen [66], d = 0.2 can be considered a small effect, d = 0.5 a medium effect and d = 0.8 a large effect. Treatment response with regard to the primary outcome at T2 was assessed in terms of reliable change in improvement according to the reliable change index (RCI) [67], symptom-free status, and diagnose-free status. Symptom-free status in insomnia severity was indicated by a score <8 on the ISI according to Morin [43]. Pearson's chi-squared test was used to compare the IG and active CG in terms of the different treatment response measures. For each of the analyses, the Number Needed to Treat (NNT) and the 95% confidence interval to achieve one additional treatment response was also calculated.

RESULTS

Participants and Descriptive Data

After screening (N = 160), 53 applicants were excluded, mainly due to lack of informed consent (n = 29). A total of 90 participants was randomized to either the IG (n = 45) or the CG (n = 45). Baseline self-report and clinical telephone interview data was available for all participants. The study adherence rate was high at T2 across both groups with 91% (IG: n = 38/45, CG: n = 44/45) completing the online self-assessment questionnaires and 82.2% (IG: n = 34, CG: n = 40) completing the clinical telephone interview. Participants who dropped out of the study, i.e., not providing any data at T2, did not differ significantly from participants who adhered to the protocol on any baseline characteristics (p > .05). Demographic variables are presented in table 1. The data showed an average participant age of 24.97 (SD = 4.51). The majority of participants was female (n = 64/90, 71.1%) and either married or in a relationship (n = 46/90, 51.1%). Sufficient financial resources (n = 39/90, 43.3%) or no financial issues (n = 39/90, 43.3%) were

reported by most of the participants. Wishing to cope with their sleep problems on their own was the most frequently mentioned reason for participating in an internet intervention (*n* = 83/90, 92.2%), followed by being interested in online interventions (*n* = 38/90, 42.2%). Descriptive data for all outcomes at T1 and T2 is depicted in table 2.

- **Please insert Table 1 here** –

- **Please insert Table 2 here** –

Primary Outcome Analysis

Participants in the IG did not achieve a significantly lower insomnia severity score than the CG at T2 (IG: $M = 18.11$, $SD = 4.55$; CG: $M = 19.34$, $SD = 4.06$; $F(1, 87) = 2.57$, $p = .11$) with moderate effect sizes ($d = 0.35$, 95% CI [-0.06, 0.77]). Both study groups showed statistically significant reductions in insomnia severity from T1 to T2 on the ISI. In the IG, there was a mean reduction of 5.40 points on the ISI ($t_{44} = 9.49$, $p < 0.001$), corresponding to a large within-group Cohen's d effect size ($d = 1.31$, 95% CI [0.85, 1.77]). In the CG, the mean reduction on the ISI was 3.95 points ($t_{44} = 6.11$, $p < 0.001$), also showing a large effect size ($d = 1.10$, 95% CI [0.65, 1.54]).

Treatment response and diagnose-free status

Reliable change in improvement according to the RCI was present in 64.4% of the IG (*n* = 29/45) and 37.8% of the CG (*n* = 17/45; ($\chi 2 = 6.4$, p = .011). This finding corresponds to a NNT of 3.76 (95% CI [2, 17]). Neither participants in the IG nor in the CG achieved close to symptom-free status at T2 as indicated by a score of < 8 on the ISI. With regard to diagnose-free status, of the 91.2% (n=31/34) of participants in the IG fulfilling the criteria

for insomnia at T1, 50% of participants (n=17/34) fulfilled the criteria at T2 and of the 95% (38/40) of the CG participants diagnosed with insomnia at T1, 26/40 (65%) fulfilled the criteria at T2. There was no difference in the reduction between the IG and the CG [χ^2 (1, N = 74) = 1.12, p = .29]. This results in a NNT of 8 (95% CI [3, 10]).

Secondary Outcome Analysis

Table 3 summarizes the results of the ITT analyses for the secondary outcomes. There were no significant differences between the IG and the CG regarding sleep quality, sleep efficiency, cognitive irritation, worrying, recovery experiences, recovery activities, recuperation in sleep, presentism, and procrastination (d = 0.02 to 0.44). Statistically significant within-group differences were found in the IG on sleep quality (t_{44} = 6.43; p < 0.001), sleep efficiency (t_{44} = 5.04; p < 0.001), cognitive irritation (t_{44} = 2.34; p = 0.02), recuperation in sleep (t_{44} = 4.41, p <0.001), and procrastination (t_{44} = 3.06; p < 0.005). The CG also showed significant improvement from T1 to T2 on sleep quality (t_{44} = 4.78; p < 0.001), sleep efficiency (t_{44} = 2.17; p = 0.04), cognitive irritation (t_{44} = 2.14; p = 0.04), recovery experiences (relaxation subscale) (t_{44} = 2.51; p = 0.02), recovery activities (t_{44} = 2.64; p = 0.01) and recuperation in sleep (t_{44} = 2.31; p = 0.03). Regarding depression, 34 participants in the IG were free from depression at T1. At T2 there was one participant diagnosed with depression. In the CG diagnosis criteria for depression weren't fulfilled by any of the participants neither at T1 nor at T2.

- **Please insert Table 3 here** –

Study Completer Analysis

Results of the study completer analysis ($N = 82$, IG: $n = 38$, CG: $n = 44$), were similar to those of the ITT analysis, with no significant effect on the primary outcome at T2 between the IG and the CG (IG: $M = 17.97$, $SD = 4.95$; CG: $M = 19.34$, $SD = 4.1$; $F(1, 79) = 1.92$, $p = .17$; $d = 0.28$, 95% CI [-0.16, 0.71]). In contrast to the ITT analysis, sleep efficiency significantly increased in the IG compared to the CG (IG: $M = 0.82$ $SD = 0.13$; CG: $M = 0.79$, $SD = 0.13$; $F(1, 79) = 5.38$, $p = .02$; $d = 0.51$, 95% CI [0.07, 0.95]). The other secondary outcomes remained with a non-significant result for the between-subject analysis ($d = 0.05$–0.51). Detailed results of the study completer analysis can be found in table 4. Comparing the RCI scores, there were 60.5% (23/38) responders in the IG and 38.6% (17/44) responders in the CG. This is comparable to the ITT analysis and results in a NNT of 4.57 (95% CI [2, 84]). There were significantly more responders in the IG than in the CG ($\chi^2 = 3.91$, $p = .048$).

- **Please insert Table 4 here** –

Intervention Completer Analysis

In contrast to the ITT and study completer analysis, the primary outcome showed a significant effect in the intervention completer analysis. Participants in the IG had significantly lower insomnia severity scores than participants in the CG (IG: $M = 16.85$, $SD = 3.96$; CG: $M = 19.34$, $SD = 4.06$; $F(1, 73) = 5.74$, $p = .02$; $d = 0.43$, 95% CI [-0.03, 0.89]). The secondary outcomes remained with a non-significant result for the between-subject analysis (d range = 0.02–0.42). The results can be found in table 5.

- **Please insert Table 5 here** –

Treatment Adherence and Satisfaction with the Intervention

Overall, 51.11% (n = 23/45) of participants completed all six modules of the iCBT-I. The first four core modules of the intervention were completed by 68.89% (n = 31/45) of the participants in the IG. Of the 45 individuals participating in the IG, module 1 was completed by 39 participants (86.67%), module 2 by 37 (82.22%), module 3 by 33 (73.33%), module 4 by 31 (68.89%), module 5 by 27 (60%), module 6 by 23 (51.11%). On average, participants completed 4.22 treatment modules (range = 1–6), which equals 70.33% of the intervention. User satisfaction was high (M = 2.38; SD = 0.74); 79% of the participants (N = 30/38) would recommend the intervention to a friend in need.

DISCUSSION

The present study aimed to evaluate the efficacy of an iCBT-I for university students with insomnia in comparison to an active control group. Contrary to our hypothesis, the results showed that students receiving the iCBT-I did not display significantly lower insomnia severity compared to students receiving one module on online sleep hygiene education. Both IG and CG showed significant within-group improvement in the primary outcome between T1 and T2 with high effect sizes and significant changes to insomnia diagnosis-free status. No significant between-group effects emerged regarding all the secondary outcomes but significant within-group differences from T1 to T2 in both groups regarding sleep quality, sleep efficiency, cognitive irritation, and recuperation in sleep. Thus, the present study showed that receiving online sleep hygiene education only can also result in considerably high reductions of insomnia.

The findings of non-significant differences between CBT-I and an active CG are in line with meta-analytic results showing lower between-group effects of CBT-Is on the ISI when compared to psychoeducational information or minimal intervention groups (g = 0.41) [20]. As also found in our study, CBT-I trials report strong within-group improvements (d

range = 1.1–2.4) in active CGs such as information on sleep hygiene, relaxation, or desensitization [33, 69–71]. The high within-group effects in the primary outcome in both groups in the present study indicate that both, the iCBT-I and online sleep hygiene education, are effective in reducing insomnia. Previous research also shows that brief sleep education programs can have small to moderate effects on sleep duration and sleep onset latency [27, 72]. The study results may suggest that non-specific treatment effects, e.g., expectancy and attention effects, account for the treatment success and thus no specific CBT-I treatment components might be responsible and necessary for improvement in insomnia. It has, however, to be considered also that the majority of the sample was highly educated and wished to cope with their sleeping disorder on their own which might have led to a highly motivated sample especially capable of self-management. Thus, these self-management and planning skills might have facilitated to initiate behavioral change based on online sleep hygiene education only. Additionally, we know that study and intervention context factors can influence outcomes and all participants had personal contact during the diagnostic interviews. But despite high within-group effects, insomnia severity remained moderately severe in both study groups at T2 so that the lack of a significant treatment effect might also be explained by an insufficient treatment dose in general. This argument is supported by the fact that only half of the participants in the IG completed all six modules in contrast to meta-analytic results on iCBT-Is for adults reporting average adherence rates of 78% completing the programs (range: 67%–100%) [21]. Intervention adherence may have been negatively affected due to the high intellectual level of the intervention or high amount of information, providing in-depth and scientifically validated background information which may have resulted in a more demanding and less enjoyable intervention. The intervention completer analysis showed significantly reduced insomnia symptoms in the IG compared to the CG indicating that adherence and working through all the modules may have a positive influence

on the intervention's efficacy. This is also supported by significantly higher rates of responders in the IG.

The present study has several strengths. Applying an active CG receiving online sleep hygiene education in a comparable delivery mode to the intervention informs about the efficacy and therefore aimed to inform on the effects that go beyond the context of delivery via the internet. Another strength is the use of self- and clinician-rated health status. Given that most studies demonstrating the effects of internet interventions have mostly relied on self-ratings, the additional use of clinician-ratings in the present study contributes significantly to the present literature by enhancing the validity of the outcome assessment [21, 73]. The study adherence in the present trial was very high. Further, this study's internal validity can be regarded as high because of the homogeneous student sample.

Also, limitations of this trial must be acknowledged. Firstly, the elaborated study inclusion process typical to an RCT (e.g., completion of self-report assessment and structured interview at baseline) may have led to including more students with above-average motivation than one could not expect outside of a controlled research context. The within-group effects in the CG indicating high efficacy of mere online sleep hygiene education might not be generalizable to less motivated populations. Secondly, regarding generalizability of results, it must be taken into account that the majority of participants was female and are therefore overrepresented as it is commonly found in psychological interventions for insomnia [61]. Thirdly, only participants with elevated symptoms of insomnia (ISI $\geq$10) were included in this study so that no conclusion about any potential effects among students with lower levels of insomnia can be made.

To further investigate and elaborate on the findings, future online brief interventions on sleep hygiene as preventive approaches for individuals should be investigated. Research and dissemination of brief online sleep hygiene education interventions could serve as a first

treatment in a stepped-care approach, which could be especially valuable due to its brevity. Moreover, it would be valuable to investigate who is not benefiting from the intervention and what reasons there might be, e.g., participants may have needed additional support such as continuous guidance. Finally, qualitative interviews could be applied to indicate potential mechanisms that weaken or foster students' adherence to the intervention. These findings raise the question of which components of an intervention actually lead to participants improving.

In conclusion, this study shows that iCBT-I for students was not superior compared to online sleep hygiene education. Both interventions were effective and improved students' insomnia as well as sleep- and student-life related outcomes, such as sleep quality, sleep efficiency, cognitive irritation, recuperation in sleep, and procrastination.

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Conflict of interest: David 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 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 ACZ declare no conflict of interest.

Trial registration: German Clinical Trials Register DRKS00017737.

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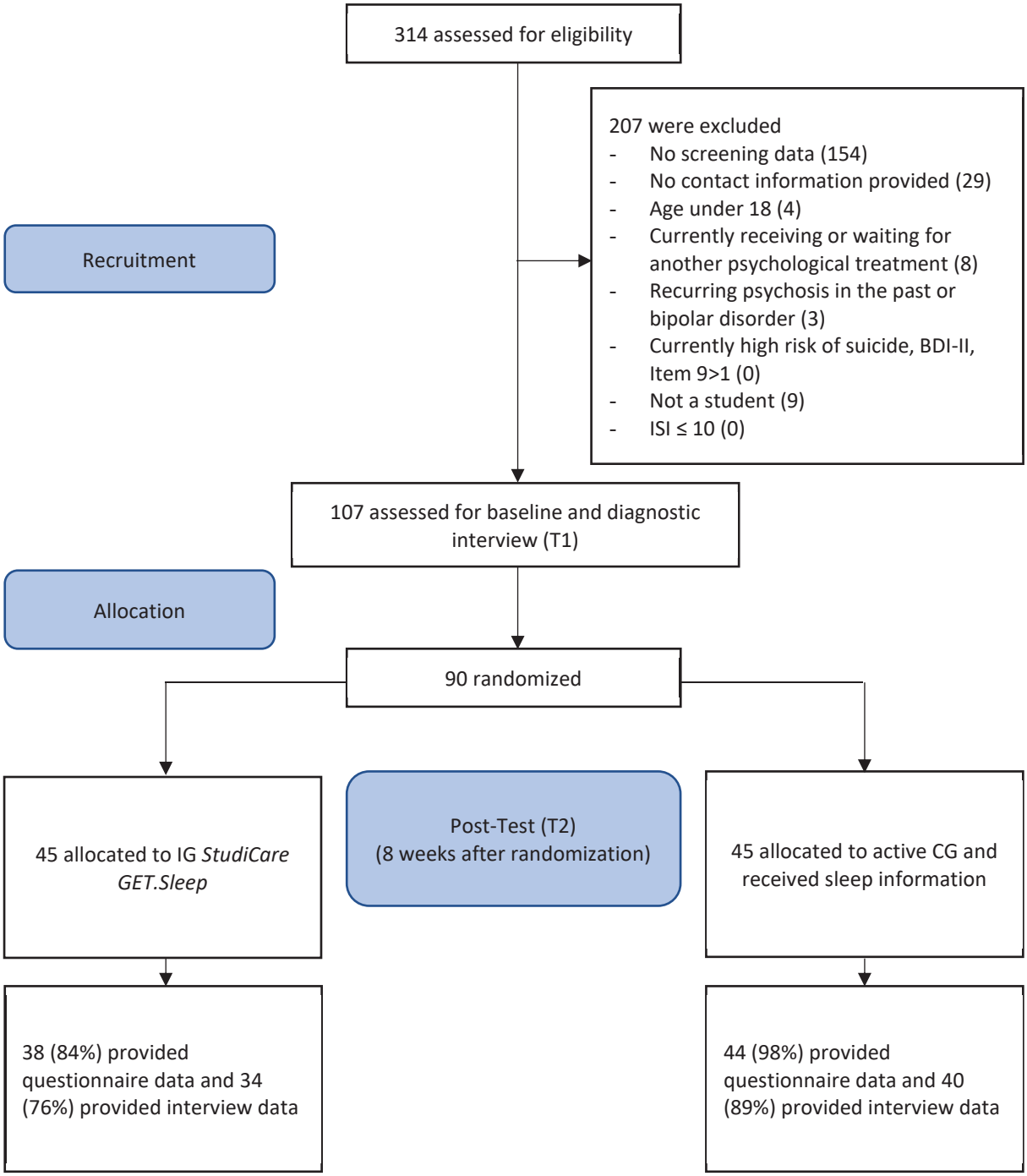
Figures

Figure 1. Study flowchart



Tables

Table 1. Demographic characteristics.

Characteristics	All participants (n=90)	IG (n=45)	CG (n=45)
Sociodemographic characteristics			
Age (years), mean (SD)	24.97 (4.51)	24.86 (4.1)	25.07 (4.93)
Gender, female, n (%)	64 (71.1)	32 (71.1)	32 (71.1)
Married or in a relationship, n (%)	46 (51.1)	25 (55.6)	21 (46.7)
Country of residence, Germany, n (%)	85 (94.4)	42 (93.3)	43 (95.6)
Immigration background, n (%)	19 (21.1)	8 (17.8)	11 (24.4)
German as native language, n (%)	88 (97.8)	45 (100)	43 (95.6)
Children, yes, n (%)	2 (2.2)	1 (2.2)	1 (2.2)
Level of Education, high, n (%)	90 (100)	45 (100)	45 (100)
Academic degree, n (%)			
None	39 (43.3)	22 (48.9)	17 (37.8)
Bachelors	36 (40)	18 (40)	18 (40)
Masters/Diploma	15 (16.7)	5 (11.1)	10 (22.2)
Planned academic degree, n (%)			
Bachelors	23 (25.6)	13 (28.9)	10 (22.2)
Masters	40 (44.4)	18 (40)	22 (48.9)
State examination	20 (22.2)	12 (26.7)	8 (17.8)
Diploma	2 (2.2)	1 (2.2)	1 (2.2)
Other	5 (5.6)	1 (2.2)	4 (8.9)
Work Characteristics, working, n (%)	51 (56.7)	21 (46.7)	30 (66.7)
Financial Situation, n (%)			
No financial issues	80 (88.9)	43 (95.6)	37 (82.2)
Financial issues	10 (11.1)	2 (4.4)	8 (17.8)
Experience with internet-based health programs, n (%)	9 (10)	3 (6.7)	6 (13.3)
Motivation to participate in online intervention, n (%)			
Wish to solve problems on their own/ independently	83 (92.2)	41 (91.1)	42 (93.3)
Interested in online intervention	38 (42.2)	10 (22.2)	28 (62.2)
No prior psychotherapy due to fear of stigmatization	11 (12.2)	8 (17.8)	3 (6.7)
No other treatment option found	9 (10)	5 (11.1)	4 (8.9)
Not able to specify the problem	9 (10)	3 (6.7)	6 (13.3)
No prior psychotherapy due to feeling of embarrassment	9 (10)	6 (13.3)	3 (6.7)
No prior psychotherapy due to too long waiting periods	5 (5.6)	3 (6.7)	2 (4.4)
Prior psychotherapy or other treatment could not help	3 (3.3)	0 (0)	3 (6.7)
No psychotherapy or other treatment offered in respective area	3 (3.3)	3 (6.7)	0 (0)

IG = intervention group; CG = control group

Table 2 Means and SDs of the IG and the CG at T1 and T2 for the intention-to-treat sample.

	T1				T2[a]			
	IG		CG		IG		CG	
Outcome	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
Primary Outcome								
Insomnia severity (ISI)[b]	23.51	3.65	23.29	3.09	18.11	4.55	19.34	4.06
Secondary Outcomes								
Sleep quality (PSQI)[c]	3.02	0.5	2.98	0.45	2.44	0.55	2.57	0.65
Sleep efficiency[d]	0.73	0.15	0.75	0.14	0.82	0.12	0.79	0.12
Cognitive irritation (ISK)[e]	13.51	4.48	12.16	5.06	12.1	3.75	11.03	4.71
Worrying (PSWQ)[f]	12.04	3.92	12.51	4.16	10.84	3.36	11.22	3.63
Recovery experiences (REQ)[g]	48.31	6.9	49.93	8.12	49.6	7.55	50.94	8.15
REQ_psychological Detachment[h]	10.62	3.26	11.71	3.31	11.4	2.9	11.99	3.39
REQ_relaxation	12.71	2.71	12.18	2.83	13.06	2.38	13.18	2.64
REQ_mastery	10.31	3.2	11.2	3.75	10.84	3.09	10.79	3.88
REQ_control	14.67	3.03	14.84	2.66	14.3	2.82	14.97	2.39
Recovery activities (ReaQ)[i]	51.02	10.06	49.11	10.06	52.1	9.87	53.17	12.03
Recuperation in sleep (SFB)[j]	17.82	4.91	17.73	4.17	20.62	5.33	19.31	5.54
Presenteeism (PSS)[k]	28.49	6.3	29.51	5.33	27.08	5.7	27.44	5.66
Procrastination (PFS)[l]	21.58	8.13	21.13	7.07	19.28	6.26	20.51	6.78

Note: M = Mean, SD = Standard deviation

[a]Missing data imputed by multiple imputation

[b]ISI (0-28) higher scores reflect higher insomnia symptoms. [c]PSQI (1-4) lower scores reflect better sleep quality. [d]Sleep efficiency (0-1) higher scores indicate increased sleep efficiency. [e]ISK (3-21) higher scores indicate increased cognitive irritation. [f]PSWQ (0-15) higher scores reflect higher worrying. [g]REQ (16-80) higher scores reflect better recovery experiences. [h]REQ psychological, detachment, relaxation, mastery, control (4-20) higher scores reflect better recovery experiences. [i]ReaQ (0-84) higher scores indicate increased recuperation. [j]SFB (8-40) higher items reflect higher recuperation in sleep. [k]PSS (10-50) higher scores reflect a lower level of presenteeism. [l]PFS (7-35) higher items represent higher procrastination behaviour.

Table 3. Differences between groups at T2 for Intention-to-treat.

	Between-groups effect T2			
	Cohen's d	95% CI	ANCOVA	
Outcome			*F (1, 87)*	*P*
Primary outcome				
Insomnia severity (ISI)	0.35	-0.06 to 0.77	2.57	.11
Secondary outcomes				
Sleep quality (PSQI)	0.29	-0.12 to 0.71	1.33	.25
Sleep efficiency	0.44	0.02 to 0.86	1.88	.17
Cognitive irritation (ISK)	0.08	-0.34 to 0.49	0.16	.69
Worrying (PSWQ)	0.02	-0.39 to 0.43	0.14	.71
Recovery experiences (REQ)	0.04	-0.37 to 0.45	0.08	.79
REQ_psychological detachment	0.17	-0.25 to 0.58	0.04	.84
REQ_relaxation	0.22	-0.19 to 0.64	0.37	.54
REQ_mastery	0.29	-0.12 to 0.71	0.78	.38
REQ_control	0.22	-0.19 to 0.64	1.67	.20
Recovery activities (ReaQ)	0.27	-0.14 to 0.69	0.91	.34
Recuperation in sleep (SFB)	0.27	-0.14 to 0.69	1.77	.18
Procrastination (PFS)	0.35	-0.06 to 0.77	3	.08
Presenteeism (PSS)	0.13	-0.27 to 0.55	0.14	.71

95% CI=95% confidence interval; ANCOVA=analysis of covariance

Table 4. Differences between groups at T2 for study completer.

	Between-groups effect T2			
	Cohen's d	95% CI	ANCOVA	
Outcome			*F (1, 79)*	*P*
Primary outcome				
Insomnia severity (ISI)	0.28	-0.16 to 0.71	1.92	.17
Secondary outcomes				
Sleep quality (PSQI)	0.37	-0.07 to 0.8	2.23	.14
Sleep efficiency	0.51	0.07 to 0.95	5.38	.02
Cognitive irritation (ISK)	0.08	-0.35 to 0.52	0.1	.76
Worrying (PSWQ)	0.05	-0.39 to 0.48	0.12	.73
Recovery experiences (REQ)	0.09	-0.35 to 0.52	0	.96
REQ_psychological detachment	0.29	-0.15 to -0.73	0.15	.70
REQ_relaxation	0.19	-0.24 to 0.63	0.33	.57
REQ_mastery	0.27	-0.17 to 0.7	0.72	.40
REQ_control	0.27	-0.17 to 0.7	2.1	.15
Recovery activities (ReaQ)	0.3	-0.13 to 0.74	1.16	.29
Recuperation in sleep (SFB)	0.2	-0.23 to 0.64	1.08	.30
Procrastination (PFS)	0.4	-0.04 to 0.84	3.63	.06
Presenteeism (PSS)	0.14	-0.3 to 0.57	0	.95

Table 5. Differences between groups at T2 for intervention completer.

	Between-groups effect T2			
	Cohen's d	95% CI	ANCOVA	
Outcome			*F (1, 70)*	*P*
Primary outcome				
Insomnia severity (ISI)	0.43	-0.03 to 0.89	5.74	.02
Secondary outcomes				
Sleep quality (PSQI)	0.42	-0.04 to 0.88	3.21	.07
Sleep efficiency	0.42	-0.05 to 0.88	2.77	.1
Cognitive irritation (ISK)	0.11	-0.35 to 0.57	0.03	.86
Worrying (PSWQ)	0.14	-0.32 to 0.6	1.32	.25
Recovery experiences (REQ)	0.23	-0.23 to 0.69	0.62	.43
REQ_psychological detachment	0.39	-0.07 to 0.85	0.89	.35
REQ_relaxation	0.1	-0.36 to 0.56	0.07	.79
REQ_mastery	0.29	-0.17 to 0.75	0.12	.74
REQ_control	0.11	-0.35 to 0.57	0.04	.85
Recovery activities (ReaQ)	0.02	-0.44 to 0.47	0.09	.76
Recuperation in sleep (SFB)	0.31	-0.15 to 0.77	2.68	.10
Procrastination (PFS)	0.34	-0.12 to 0.8	3.55	.06
Presenteeism (PSS)	0.19	-0.27 to 0.65	0.77	.38

95% CI=95% confidence interval; ANCOVA=analysis of covariance

4. Discussion

4.1 General Discussion

This thesis presents insights compiled from five articles. On one hand, the aim of this dissertation is to address sleep disturbances, which are common among young adults (Gaultney, 2010). On the other hand, young people account for a large proportion of internet users and are therefore particularly susceptible to IUD as well (Alimoradi et al., 2019). For this reason, this work brought both problems into focus. Initially, knowledge was acquired on effective treatment options for sleep disturbances through meta-analytic research. Subsequently, evidence-based digital health interventions for insomnia and IUD were developed incorporating previous research findings. A case study on the IUD intervention provided additional insights. Based on that, the efficacy of the newly developed digital health interventions was evaluated in two RCTs to provide sooner and easily accessible treatment to those affected by IUD or insomnia in the future.

It is noteworthy that the occurrence of insomnia and IUD can be linked. Previous meta-analytic research has already shown that IUD is interrelated with several other mental health issues (Carli et al., 2013), such as sleep disturbances (Alimoradi et al., 2019). A recent meta-analysis, summarizing observational studies on IUD and sleep problems, found significant associations in all of the 23 included studies (Alimoradi et al., 2019). In individuals suffering from IUD, sleep problems were significantly more likely (*OR* = 2.20, 95% CI [1.77, 2.74] and sleep duration was reduced (standardized mean difference [SMD] = -0.24, 95% CI [-0.38, -0.10]) (Alimoradi et al., 2019). Most of the included studies used Young's IAT (Young, 1998), which has also been used in this thesis to assess IUD. The relationship of IUD and sleep disturbances has been researched in a vast number of countries, demonstrating how ubiquitous these mental health issues are in young people (Gupta et al., 2021; Jahan et al., 2019; Masaeli & Farhadi, 2021; Younes et al., 2016; Zafar et al., 2018). However, most studies cannot clarify the direction and causality of the association due to correlational designs. Research on the direction comes from longitudinal and experimental studies on internet and media use. In a three-year longitudinal study (Tavernier & Willoughby, 2014) sleep problems predicted the time university students spent online on social networks or watching movies and shows. Since there was no association in the other direction, this study supports a unidirectional link. The authors concluded using social networks and watching movies as possible coping mechanism for sleep problems (Tavernier & Willoughby, 2014). In an one-year longitudinal study insomnia could be prospectively linked to IUD symptoms in children and adolescents (Chen & Gau, 2016). And it was also

found that symptoms of IUD predicted a disturbed circadian rhythm (Chen & Gau, 2016). Furthermore, an experimental study provides evidence on a causal effect of online gaming on sleep quality (Smyth, 2007). In the study, university students were randomized into one of four groups, each playing some sort of a video game for one month. Results showed that students in the massively multiplayer online role-playing game (MMORPG) group, which differs from the other games by creating a rich online environment, reported significantly longer playing times and worse sleep quality after the study period. Thus, immersive online gaming affected sleep quality negatively (Smyth, 2007). Further, a RCT study showed that sleep quality can be improved by an intervention targeting social media addiction (Hou et al., 2019). To summarize, these findings suggest reciprocal relations of IUD and sleep disturbances. Regarding mechanisms, there are findings suggesting a mediating role of rumination and bedtime procrastination in the relationship of IUD and sleep disturbances (You et al., 2021). Furthermore, a negative correlation for IUD symptoms and time management was found in students (Altiner Yas et al., 2022).

Not only can IUD and insomnia be linked to each other, both of these can have negative consequences on educational and academic achievements (Beutel et al., 2011; Gaultney, 2010; Kelly et al., 2001; Medeiros et al., 2001; Rehbein et al., 2009), which are of significant importance in adolescence and young adulthood. Moreover, IUD and sleep disturbances are found to occur comorbidly with depression (Carli et al., 2013; Moo-Estrella et al., 2005) and suicidal tendencies (Guo et al., 2018; Kim et al., 2017; Vail-Smith et al., 2009), representing the high relevance for treatment options for these conditions especially when occurring in young people. Sleep quality was found to be a mediator for the relationship of IUD and depressive symptoms, as well as IUD symptoms as a mediator for the association of sleep quality and depression in a Nepalese student sample (Bhandari et al., 2017). Yet, the contribution of these findings is limited by the cross-sectional study design. Empirical evidence also relates IUD and sleep disturbances to suicidal tendencies. In a Korean study the risk of suicide plans (adjusted odds ratio [AOR] = 3.83) and attempts (AOR = 3.34) was significantly increased in adults with both IUD and poor sleep quality, whereas the risk of suicide ideation (AOR = 2.17) and suicide plans (AOR = 3.33) was found to be increased in internet addicted adults without sleep disturbances (Kim et al., 2017). Similarly, sleep disturbances and IUD symptoms were found to be associated with an increased risk of suicidal ideation and suicidal attempts among Chinese adolescents (Guo et al., 2018). Moreover, sleep disturbances partially mediated the relationship from IUD symptoms to

suicidal ideation and attempts as well as the relationship from suicidal ideation/attempts to IUD (Guo et al., 2018).

Depressive symptoms and sleep disturbances comorbidity with IUD also characterized the female university student Emma in the case study as part of this thesis. The case study consistently demonstrated that for Emma, her internet use served as an emotion regulation strategy to cope with negative feelings and thoughts. Since depression is linked to IUD and sleep disturbances, depressive symptoms were included as a secondary outcome variable in both, IUD as well as the Sleep trial. Some additional similarities of the efficacy studies on the digital health interventions can be pointed out. Both applied a RCT design to meet scientific standards regarding clinical efficacy trials and analyzed data using ITT data and further conducted study and intervention completer analyses. Participants of both studies were only randomized if meeting predefined inclusion criteria, e.g., elevated levels of IUD or insomnia, no other current psychological treatment, and no significant suicidal risk. Each study included a baseline assessment followed by the intervention and a post-treatment assessment after 7 or 8 weeks.

Both interventions were implemented as a digital health intervention and evaluated whether treatment via the internet can be efficacious for these disorders. This approach is advantageous since interventions via the internet are easily accessible as well as flexible regarding time and place (Ebert et al., 2018). Moreover, they are easily scalable and allow participants to work through the materials at their own pace (Buntrock et al., 2014). They often meet the preference of individuals and might reach affected groups earlier (Andrade et al., 2014; Ebert et al., 2018). Accordingly, coping with her problems on her own was an important reason for Emma to participate in the IUD intervention as stated in the case study. Also, in scope of the RCT analyses, participants of both digital health interventions most frequently reported the wish to work on their problems with a self-help intervention. In the meta-analysis on psychological interventions for sleep disturbances, as part of this thesis, face-to-face interventions did not appear superior to self-help interventions for students. Thus, the meta-analysis also supported the use of a self-help approach for insomnia in students. Moreover, both interventions used similar therapeutic approaches based on CBT. Besides the disorder-specific elements, similarities in the content included goal setting and psychoeducation, behavioral modification, cognitive interventions, and relapse prevention. Regarding structure and duration, the IUD and insomnia intervention each consisted of six core modules. The IUD intervention further offered additional elective modules including one module addressing sleep problems.

Based on the results of both studies, digital health interventions primarily seem to appeal to young people, as the average age of participants in the interventions was 28.45 years for the GET.ON Offline intervention and 24.97 years for the StudiCare GET.Sleep intervention. It should be noted that the latter consisted of a student population exclusively, which further emphasizes that the GET.ON Offline intervention primarily attracted extremely young individuals, as there were no additional inclusion criteria related to age other than being of legal age. Likewise, it is not surprising that digital health interventions are predominantly utilized by young people, as the use of the internet is particularly prevalent among younger age groups, and the prevalence rates for the two disorders examined in this thesis are higher among young individuals (Gaultney, 2010; Kaess et al., 2016; Lindenberg et al., 2018). However, digital health interventions also have the potential to reach older people in the future, as it can be assumed that digital literacy will increase over time due to the widespread use of the internet and digitization.

Comparing the two studies on the gender distribution, the insomnia intervention shows quite typical results, with more than twice as many female participants as male participants. This can be explained by the fact that women are more willing or ready to seek psychological help and are more sensitive to mental distress or have better access to their mental state (Chandra & Minkovitz, 2006; Gonzales, Alegria & Prihoda, 2005). Hence, the equal distribution between male and female participants in the GET.ON Offline intervention is even more noticeable. There was a balanced gender ratio, which may be attributed to the fact that IUD includes gaming addiction, which affects more men (Kittinger et al., 2012). Overall, no consistent conclusions regarding age can be drawn from the study results on both interventions, as the findings are different in this regard. The disorder itself appears to have a greater influence on the gender ratio than the common factor of the intervention, which was administered online for both disorders. There is a different picture regarding the relationship status. In both the GET.ON Offline intervention and the StudiCare GET.Sleep intervention, more than half of the participants were in a relationship. Therefore, no differences due to the disorder are apparent in this regard. Out of the 130 participants in the GET.ON Offline intervention, 58 hold an academic degree. This is characteristic of digital health interventions, as other studies have also shown that higher-educated individuals are more likely to seek for psychotherapeutic help online (Eichenberg, Wolters & Brähler, 2013). In the insomnia intervention, also over half of the participants reported having a bachelor's or master's degree. It should be noted that only students were included in this

study so that even students who already hold an academic degree and were currently pursuing further studies or postgraduate education sought out the intervention.

All participants were asked about their reasons for participating in an online treatment. Across both studies, very similar results were observed. The most common reported reason, mentioned by almost all participants, was the ‘wish to solve problems on their own’. Since multiple responses were allowed for this question, other answer options also received very high scores in both studies. The second most common reason stated in both studies was that an online treatment was perceived as appealing, and the third most common reason was too ashamed to ask for help. These highly consistent results indicate that the desire for self-help is particularly pronounced, and individuals who are willing and capable of working on their symptoms on their own are more inclined to utilize digital health interventions and perceive them as suitable intervention options. This finding aligns well with the self-management approach in CBT (Kanfer, Reinecker & Schmelzer, 2012) so that CBT seems well-suited as therapeutic approach to address the wish for self-help and self-management interventions.

Regarding treatment adherence, similar results were observed for both interventions. In both, the IUD and the Sleep trial, over 60% of participants in the intervention group completed the first four treatment modules, and over 50% completed the entire intervention with all six modules. It can be assumed that half of all individuals who start a digital health intervention will also complete it, and that the completion rate decreases with each additional module. There is also a high level of agreement in user satisfaction in both interventions, as indicated by the results on the CSQ. With 95%, more participants in the StudiCare GET.Sleep intervention would recommend the training to a friend in need compared to the GET.ON Offline intervention (79%). This could be because the student sample in the Sleep trial may have more social contacts or friendships, making a recommendation more likely. Still, the recommendation rate in the GET.ON Offline intervention can also be considered quite high.

When comparing the study adherence rates, both studies show very high rates with over 80%. This pattern suggests that the samples consisted of highly motivated individuals who were not only willing to participate in an intervention and thus receive treatment but also willing to participate in the study itself. Another concordance is the higher study adherence rate in the control groups compared to the intervention groups. The higher adherence in the control groups could be attributed to the fact that the control groups only received access to the core intervention after completing all post-assessments, leading to

higher motivation or extrinsic motivation regarding the completion of post-assessments. It is noticeable that for the insomnia intervention, more than three times as many applicants (N = 314) were assessed for eligibility compared to the intended sample size of N = 90. In contrast, for the IUD intervention, only twice as many applicants (N = 276) had to be screened for eligibility to obtain the 130 participants to be randomized. In the Sleep trial, half of all applicants did not provide screening data and had to be excluded for that reason. This suggests that many students could be reached through the StudiCare advertising and numerous recruitment channels and hence initially registered. Yet, the screening questionnaire obviously posed a crucial barrier in the study process for many applicants. Regarding the entire recruitment period, however, the Sleep trial had a shorter recruitment period with 18 months compared to the IUD trial with more than 2 years to reach the sample size of 130 randomized participants. The most common reason for exclusion was the absence of informed consent. Overall, it can be concluded that students are easier to recruit for intervention and study participation, but they are also less adherent to the study.

The samples examined in this dissertation consistently demonstrated very high baseline scores. In the GET.ON Offline intervention, not only the baseline scores on the questionnaires assessing internet addiction (IAT & CIUS) were remarkably high, but the sample showed very high levels of depression, anxiety disorders, and sleep disturbances as well. The analyzed participant in the case study reported very high scores in various areas of impairment at the beginning of the intervention. In addition to high IAT and CIUS scores, she also stated particularly high levels of depression, anxiety, sleep disturbances, and procrastination, as well as pronounced worrying. The IAT and CIUS scores were notably above the cut-off score in the case report and even after the intervention, the CIUS score did not decrease below the cut-off score. Very similar results could be observed in the RCTs. Although scores on the questionnaires assessing IUD decreased significantly from pre- to post-treatment, they did not decrease below the cut-off scores neither for the IAT or the CIUS at post-treatment. Furthermore, there was no significant improvement on all other secondary outcomes. Concordantly, the baseline scores for the primary outcome were very high in the Sleep trial and although they decreased in both groups at post-treatment, they remained substantially elevated. Similar results were found for the secondary outcome measures. The sample showed poor sleep quality, high levels of worrying, and pronounced procrastination behavior. This not only demonstrates a concordant picture of high initial symptom burden but also displays those high initial scores remained predominantly high even after the intervention. It can be concluded that while significant improvements can be

achieved, strong impairments may persist even after completing a digital health intervention. Therefore, it is recommendable to provide additional treatment options for participants after intervention completion. In both, the IUD and insomnia intervention, information on further treatment options are provided in the final module, which appears highly relevant given the high post-treatment scores observed. Furthermore, it can be concluded that comorbidities should be more actively addressed within future interventions. The causality of associations is not clear, so that e.g., depression might be the primary condition, from which subsequent disorders such as internet addiction or sleep disturbances develop or vice versa. Though, seeking treatment for depression may be more stigmatized, causing individuals to be more receptive to treatment options for comorbid disorders. However, these are only assumptions and no conclusions regarding the direction of causality can be made or derived from the results. Nonetheless, in this regard digital health interventions may be a promising approach by not only being low-threshold in terms of online availability but also by providing an easy and more attractive treatment option for highly burdened individuals with severe symptoms or different comorbidities. Based on these findings, a recommendation for a stepped-care approach can be derived, in which a digital health intervention could be initially offered as a first step, facilitating the initial step towards receiving psychological treatment and thus addressing psychological distress. In a next step, e.g., outpatient psychotherapy for the treatment of comorbidities could be added. By firstly engaging with their own psychological distress and working on symptoms within a digital health intervention, a path can be paved for further psychotherapeutic treatment options that individuals may otherwise not seek. Digital health interventions should, therefore, continue to be presented in a de-pathologizing manner. The low-threshold online access and the interactive, inviting presentation of therapeutic content make digital health interventions an attractive treatment option outside of or in addition to traditional treatments (Hobbs et al., 2019; McKellar et al., 2012). The easy treatment access makes digital health interventions particularly suitable for individuals with low treatment motivation (O'Brien, Li, Snyder, & Howard, 2016). For both, the IUD and the Sleep trial, it can be assumed that motivation for treatment was high, but individuals with low motivation may be even more receptive to an online treatment format.

In terms of the main results of the studies, they differ as in the IUD trial the hypothesis could be confirmed and participants in the intervention group achieved significantly lower scores on the primary outcome after the intervention compared to the control group. Whereas in the Sleep trial the hypothesis could not be confirmed as participants in the intervention group did not achieve a significantly lower insomnia severity score than the control group at

post-treatment. The concordantly high post-treatment scores in both studies may indicate that the treatment was not sufficient for the severity of symptoms. However, it could also be assumed that high initial symptom severity offers more room for improvement through an intervention (Ebert et al., 2016; Harrer et al., 2018).

Despite the differences in the main hypotheses, both studies showed better results in the intervention completer analyses. This could be an argument against an insufficient treatment dose. If participants completed more than half of the intervention, both trials revealed better results compared to the ITT analyses. It can be concluded that actually completing the intervention can make a difference and have a positive impact on the outcomes investigated. Additionally, it should be noted that in the intervention completer analyses, all participants were included who completed at least four modules, not necessarily the complete six modules prescribed for a full intervention. It can be assumed that even better results could be drawn if only those participants who fully completed the intervention and received the complete psychotherapeutic treatment as intended were analyzed. Overall, the intervention completer analyses support the advantages and effectiveness of the interventions. In the future, it is important to ensure that individuals receive the complete intended treatment. In this regard, strengthening treatment motivation is of utmost importance. Treatment motivation is not only crucial at the beginning of a treatment but also, and perhaps to an even greater extent, throughout the intervention as this seems to be an important determinant of successful treatment.

Contrary to the results of the intervention completer analyses, the results of the study completer analyses confirmed the results of the ITT analyses in both trials. Therefore, it can be concluded that completing the questionnaires and adhering to the study is not sufficient to yield better outcomes or effects. It seems to make a difference whether the intervention was completed in its entirety and thus the intended intervention content could be delivered or if there was only motivation to complete the questionnaires. This comparison with the study completer analyses further emphasizes the importance of working through the intervention content.

Due to the initial study design and sample size, moderator analyses were not intended in scope of the trials, and therefore no statements about potential moderators can be drawn based on the available data. In future research it could be examined who benefits the most from the interventions and who does not. Analyzing e.g., age or symptom severity as potential moderator would be of interest in future research. Results on comorbidities could be particularly beneficial. Not only in terms of treatment effectiveness but also in terms of

gaining new insights into specific disorders, the investigation of potential moderating variables would be crucial. For instance, it could be assumed that individuals who primarily suffer from IUD and have few comorbidities may benefit particularly well or poorly from the intervention. It could be hypothesized that individuals with higher levels of e.g., depression may benefit less from the interventions and require more intense treatment with additional components targeting depression. Such assumptions are to examine in future research. Moreover, it would be of interest to investigate other aspects that could influence effectiveness. It is conceivable that participants in a digital health intervention may require more support or guidance. Furthermore, within the framework of dismantling studies, it could be examined which components of the interventions are particularly effective and which are not. This could be expanded to explore which intervention components are particularly relevant for e.g., different levels of symptom severity. In this way, a stronger tailoring and more individualization could be achieved. In further research studies, component analyses could be conducted. Qualitative analyses could also provide valuable insights into these research questions. Interviews with study participants could be conducted as part of future research, and qualitative content analyses could be used to answer more individual and specific research questions, providing a starting point for subsequent quantitative analyses. Optimizing the interventions based on participant feedback can be a reasonable next step, as participant feedback has already been collected within the interventions. Participants rated each module and assessed the intervention usefulness. These data could be analyzed through qualitative content analyses and provide initial indications for further improving the intervention.

Since IUD and sleep disorders are highly comorbid (Alimoradi et al., 2019), it is reasonable to assess both disorders in research studies. In the IUD trial, insomnia was also assessed as a secondary outcome. However, in the Sleep trial, IUD was not assessed in the researched sample. Assessing both disorder in future research could provide not only insights on prevalence rates but also on the intercorrelation of IUD and sleep disorders. The question of whether IUD causes sleep disorders or whether existing sleep disorders are more likely to result in IUD remains unclear. Research on the direction and causality of the association between IUD and sleep disorders would be highly desirable. Since it is already evident that these two disorders frequently occur together (Alimoradi et al., 2019), it can be recommended to provide interventions that address both disorders correspondingly. Combining intervention methods and therapeutic techniques for these two disorders within one single treatment may be considered a practical implication. In the GET.ON Offline

intervention a sleep module was already provided as an elective module. The analysis of the case report revealed that the participant chose the sleep module as additional elective module indicating its relevance for affected individuals. Likewise, treatment for sleep disorders could address IUD in future approaches. Considering the importance of addressing both disorders, it can be concluded that for the future, it is not only important to develop and provide adequate interventions but also to disseminate them widely. This could be achieved through e.g., prevention campaigns or collaboration with health insurance companies to ensure that treatments are made available to as many affected individuals as possible.

Overall, both RCTs showed that digital health interventions for IUD and insomnia can yield significant improvements. Still, options to modify the interventions need to be considered especially regarding severe cases and high comorbidity. In the following, the results of both RCTs are discussed in more detail.

4.2 Discussion of the Results on the GET.ON Offline Intervention

4.2.1 Summary of Principal Findings and Relation to Previous Research

The aim of this RCT was to evaluate the efficacy of a newly developed digital health intervention for IUD in comparison to a WCG. As hypothesized, the participants of the IG showed lower internet addiction symptom severity at post-treatment compared to a WCG with a moderate effect size of $d = 0.54$. Regarding secondary outcomes, the participants in the IG showed reduced compulsive internet use compared to the WCG at T2. There was no significant effect of the intervention on further mental health outcomes, such as depression, anxiety, problematic alcohol consumption, insomnia, worries, procrastination, well-being, quality of life and work limitations. Overall satisfaction with the treatment was high.

The effect of this digital health intervention on internet addiction symptoms is in line with results found in uncontrolled pilot studies on digital health interventions for IUD based on CBT and motivational interviewing, which 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 also yielded a similar medium effect size ($g = 0.67$) (Stevens et al., 2019). Furthermore, the results of this study support previous findings that digital health interventions can be an effective treatment approach for other behavioral addiction behaviors, e.g., gambling (Chebli et al., 2016; Sagoe et al., 2021). Yet, evidence on face-to-face treatment for IUD found higher effect sizes ($k = 15$, $g = 1.84$) (Goslar et al., 2020; Winkler et al., 2013). While face-to-face treatment for IUD has been shown to also reduce depressive and anxiety symptoms (Liu et al., 2017; Winkler et al., 2013), in this 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 IUD developed subsequently. Nonetheless, an intervention for IUD seems to be 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, Heber et al., 2016; Harrer et al., 2018). In case of digital health interventions for IUD, 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, a thorough diagnosis 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 IUD could be an especially beneficial and appropriate approach.

Compared with face-to-face interventions for IUD, either psychotherapy or addiction counselling, (Lindenberg, Szász-Janocha et al., 2017) the present study showed a far 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 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 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 gaming activities and thus possibly in IUD could explain an unusually large number of male participants. On the other hand, women have been shown to display a higher risk for excessive social media use (Kittinger et al., 2012). A digital health intervention might seem to be a low-threshold accepted first treatment option, especially for men suffering not only from IUD but also depressive symptoms.

4.2.2 Strengths and Limitations

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 IUD. This study can make an important contribution to the so far limited research on empirically tested treatment for IUD 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 but is comprehensive for all subtypes of IUD. While women have been overrepresented in most internet-based treatment studies (Brand et al., 2014; Petersen et al., 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 IUD, 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, it should be acknowledged that only participants with elevated symptoms of internet addiction (IAT $\geq$ 49) were included. Therefore, generalizability of results is restricted for people with lower levels of IUD. Fourth, 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 develop digital health interventions for children and adolescents to prevent internet addiction at an early stage.

4.2.3 Clinical Implications and Future Research

Future interventions should pay more attention to the high comorbidity of IUD with depression, insomnia and GAD and explore ways of personalizing the intervention to individual needs of individuals with IUD and heightened depressive symptoms. Also, IUD

treatment should be considered alongside depression treatment, as e.g., in a blended format. Another research question is, despite good adherence rates, how treatment motivation during the study period can be 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 IUD should follow.

4.2.4 Conclusion

Given the increasing number of individuals with IUD, it is of prime importance to provide, establish, and disseminate effective IUD treatment. The findings of this study indicate that a digital health intervention can be effective at reducing internet addiction symptom severity and associated compulsive internet use in comparison to a WCG. Beneficial effects on other associated symptoms like depression, insomnia or procrastination could not be obtained. Thus, the study findings show that providing treatment over the internet might be a good way to reach those affected from IUD directly in their familiar internet setting.

4.3 Discussion of the Results on the StudiCare GET.Sleep Intervention

4.3.1 Summary of Principal Findings and Relation to Previous Research

The present study aimed to evaluate the efficacy of the internet intervention StudiCare GET.Sleep for university students with insomnia. The results showed that students randomized to the IG did not display significantly lower insomnia severity compared to the active CG participants (d = 0.35). Expert-rated primary insomnia did not improve significantly more in the IG compared to the CG as well. Both IG and CG showed significant within-group improvement in the primary outcome between T1 and T2 with high effect sizes (IG: d = 1.31; CG: d = 1.10). The diagnostic interviews also revealed changes to insomnia diagnosis-free status in both groups. With regard to the secondary outcomes, sleep quality, sleep efficiency, cognitive irritation, worrying, recovery experiences, recovery activities, recuperation in sleep, presentism and procrastination, no significant differences between IG and CG could be found (d range = 0.02–0.44). As with the primary outcome,

there were significant within-group differences regarding sleep quality, sleep efficiency, cognitive irritation, and recuperation in sleep within both groups between T1 and T2.

Previous research comparing CBT-I to active CGs shows mixed results with studies revealing significant effects regarding insomnia severity (d = 0.79–0.85) (Kaldo et al., 2015; Norell-Clarke et al., 2015) as well as studies with no significant between-group effects (d = 0.44) (Arnedt et al., 2013; Smith et al., 2015). Further, there are meta-analytic results showing lower between-group effects of CBT-Is on the ISI when compared to information or minimal intervention groups (g = 0.41) (van Straten et al., 2018). However, the high within-group effects in the primary outcome in both groups in the present study indicate that both, the StudiCare GET.Sleep intervention and online psychoeducation, are effective in reducing insomnia. Previous research consistently shows that brief sleep education programs can have small to moderate effects on sleep duration and sleep onset latency (Barber & Cucalon, 2017; Friedrich & Schlarb, 2018). Moreover, CBT-I trials report strong within-group improvements (d = 1.1–2.4) in active CGs such as information on sleep hygiene, relaxation, or desensitization (Arnedt et al., 2013; Kaldo et al., 2015; Norell-Clarke et al., 2015; Smith et al., 2015). Thus, the present study can support previous research in showing that receiving psychoeducation can result in considerably high reductions of insomnia.

The lack of significant between-group effects may be a result of strong within-group changes in the CG. Effects that are not specific to the intervention and treatment, e.g., expectancy and attention effects or statistical regression effects due to severe insomnia symptoms at baseline can contribute to non-significant between-group effects. In general, the results of this study suggest that non-specific treatment effects account for the treatment success and thus no specific CBT-I treatment components might be responsible and necessary for improvement in sleep disturbances. The study result indicates that effective insomnia treatment can be reached by providing sleep psychoeducation online. Further, the wish to work on their problems themselves as the most frequently mentioned reason for participating in the study indicates a highly motivated sample that may have facilitate changes in the CG and, alike, accounts for motivation as a factor for treatment success that is not specific to the intervention. Despite high within-group changes, insomnia severity remained moderately severe in both study groups at post-treatment so that severe sleep problems of the recruited sample might have been addressed insufficiently. Another possible explanation for lacking between-group differences may be the low intervention adherence as only half of the participants in the IG completed all six modules. Meta-analytic results on iCBT-Is for adults reported higher intervention adherence rates (range = 67%–100%) with

78% completing the programs (Cheng & Dizon, 2012). Intervention adherence may have been negatively affected due to the intellectual level of the intervention, providing in-depth and scientifically validated background information. Even though this might correspond to students' needs, it may have resulted in a more demanding and less enjoyable intervention. The intervention completer analysis showed significantly reduced insomnia symptoms in the IG compared to the CG indicating that adherence and working through all the modules may have a positive influence on the intervention's efficacy. This is also supported by significantly higher rates of responders in the IG.

4.3.2 Strengths and Limitations

The present study has several strengths. A particular strength is the application of an active CG. The CG receiving online psychoeducation provided a comparable delivery mode and therefore aimed to inform on the effects that go beyond the context of delivery via the internet. Changes in both groups account for nonspecific effects of treatment. Another strength is the use of self- and clinician-rated health status. Given that most studies demonstrating the effects of internet interventions have mostly relied on self-ratings, the additional use of clinician-ratings in the present study contributes significantly to the present literature by enhancing the validity of the outcome assessment (Cheng & Dizon, 2012; Harrer et al., 2019). The study adherence in the present trial was very high. Personal contact in the diagnostic interviews may have contributed to a high study adherence. Further, this study's internal validity can be regarded as high because of the homogeny student sample. The selected study sample also provides information on the usability and effectiveness of the core intervention *GET.ON Recovery* (Thiart et al., 2015) in a student population.

Despite these strengths, limitations of this trial must be acknowledged. Firstly, the elaborated study inclusion process typical to an RCT (e.g., completion of self-report assessment and structured interview at baseline) may have led to including more students with above-average motivation than one could not expect outside of a controlled research context. The within-group effects in the CG indicating high efficacy of mere psychoeducational information might not be generalizable to less motivated populations. Secondly, regarding generalizability of results it must be taken into account that the majority were females and are therefore overrepresented as it is commonly found in psychological interventions for sleep disturbances (Saruhanjan et al., 2021). Thirdly, only participants with elevated symptoms of insomnia (ISI $\geq$ 10) were included in this study so that no conclusion about any potential effects among students with lower levels of insomnia can be made.

4.3.3 Clinical Implications and Future Research

To further investigate and elaborate on the findings the following should be researched in future studies. Future online brief interventions on sleep hygiene could also serve as preventive approaches for individuals. Research and dissemination of brief sleep education interventions could serve as a first treatment in a stepped-care approach. Moreover, it would be valuable to investigate who is not benefiting from the intervention and what reasons there might be, e.g., participants may have needed additional support such as continuous guidance. Finally, qualitative interviews could be applied to indicate potential mechanisms that weaken or foster students' adherence to the intervention.

4.3.4 Conclusion

In conclusion, this study shows that iCBT-I for students was not superior compared to sleep psychoeducation. Both interventions were effective and improved students' insomnia as well as related health outcomes, such as sleep quality, sleep efficiency, cognitive irritation, recuperation in sleep, and procrastination. Therefore, a stepped care approach with first step psychoeducation could be considered for a broader range of the student population. This could be especially valuable due to its brevity and cost-effectiveness.

5. Conclusion

The overall aim of this dissertation was the development and evaluation of digital health interventions for the treatment of IUD as well as for the treatment of insomnia in students, to provide solutions for closing the health care gap in these areas and to generate a treatment offer adapted to the target group.

The number of individuals burdened by IUD or sleep disorders is rising and most affected do not receive adequate treatment. Contemplating the results of this dissertation on the efficacy of digital health interventions in treating IUD and sleep disorders, digital health interventions reveal high potential in overcoming the challenges of mental health care in these disorders. They showed to be effective in reducing IUD and sleep disorders and, importantly, bear the potential to reach those who do not seek conventional face-to-face treatment. The studies presented in this dissertation contribute to enhancing the evidence-base for treatment of IUD and sleep disorders in students and, even more crucial, provide some of the first guidelines on developing digital health intervention for these target groups. It can be suggested to implement such low-threshold interventions in the health care landscape. Future research should focus on further gaining a deeper understanding of the treatment of the respective disorders and likewise foster dissemination research in these areas.

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