Journal of Consulting and Clinical Psychology

Internet-Based CBT for Somatic Symptom Distress (iSOMA) in Emerging Adults: A Randomized Controlled Trial

Severin Hennemann, Katja Böhme, Maria Kleinstäuber, Harald Baumeister, Ann-Marie Küchler, David Daniel Ebert, and Michael Witthöft

Online First Publication, February 17, 2022. http://dx.doi.org/10.1037/ccp0000707

AMERICAN PSYCHOLOGICAL ASSOCIATION

Journal of Consulting and Clinical Psychology

ISSN: 0022-006X

https://doi.org/10.1037/ccp0000707

Internet-Based CBT for Somatic Symptom Distress (iSOMA) in Emerging Adults: A Randomized Controlled Trial

Severin Hennemann[1], Katja Böhme[1], Maria Kleinstäuber[2], Harald Baumeister[3], Ann-Marie Küchler[3], David Daniel Ebert[4], and Michael Witthöft[1]

[1] Department of Clinical Psychology, Psychotherapy and Experimental Psychopathology, Institute of Psychology, University of Mainz
[2] Department of Psychology, Emma Eccles Jones College of Education and Human Services, Utah State University
[3] Department of Clinical Psychology and Psychotherapy, Institute of Psychology and Education, Ulm University
[4] Department of Sport and Health Sciences, Technical University of Munich

Objective: Persistent somatic symptom distress is common in emerging adults and is associated with adverse health outcomes and impairment. Internet-based interventions could help to prevent burden and chronicity. This randomized controlled trial tested the efficacy of a guided, cognitive-behavioral internet intervention for somatic symptom distress (iSOMA) in emerging adults at risk for somatic symptom disorder compared to a waitlist control condition. ***Method:*** 158 participants (N = 156 analyzed; 24.53 years, 83.3% female) with multiple somatic symptoms were recruited among German-speaking universities and randomly allocated to either receive the 8-week iSOMA intervention with psychologist support or the waitlist, both with access to treatment as usual. Primary outcomes were somatic symptom distress Patient Health Questionnaire, somatic symptom scale (PHQ-15) and psychobehavioral features of somatic symptom disorder-12 (SSD-12), assessed at baseline and 8-weeks postrandomization. Secondary outcomes included depression, anxiety, illness worries, functional impairment, and attitudes toward psychological treatment. ***Results:*** Participants in the iSOMA group showed significantly greater improvements ($ps < .001$) in primary outcomes (PHQ-15: $d = 0.70$ [0.36, 1.05], SSD-12: $d = 0.65$ [0.30, 0.99], and secondary outcomes ($ps < .05$; d = 0.41–0.52) compared to the waitlist, except for attitudes toward psychological treatment ($p = .944$). Satisfaction with iSOMA was high (91.0%), most participants (72.8%) completed at least 4 of 7 modules and negative treatment effects were infrequent (14.9%). ***Conclusions:*** Our intervention had a substantial positive impact on somatic symptom distress across a broad range of persistent physical symptoms in a vulnerable target group, opening up promising possibilities for indicative prevention and blended care for somatic symptom disorders.

What is the public health significance of this article?
A guided cognitive-behavioral internet intervention could help to effectively reduce somatic symptom distress as a significant public health problem in emerging adults and provide a low-threshold treatment option to engage first-time help seekers.

Keywords: somatic symptom disorder, internet intervention, cognitive behavioral therapy, emerging adults, randomized controlled trial

Supplemental materials: https://doi.org/10.1037/ccp0000707.supp

Severin Hennemann https://orcid.org/0000-0001-8780-9985
Katja Böhme https://orcid.org/0000-0001-8052-0505
Maria Kleinstäuber https://orcid.org/0000-0002-4453-507X
Harald Baumeister https://orcid.org/0000-0002-2040-661X
Ann-Marie Küchler https://orcid.org/0000-0003-3305-4892
David Daniel Ebert https://orcid.org/0000-0001-6820-0146
Michael Witthöft https://orcid.org/0000-0002-4928-4222

This research received funding from the Johannes Gutenberg-University of Mainz. The associated StudiCare-project received funding from the German health insurance company BARMER. The sponsors had no role in study design, data collection, analyses, decision to publish, or preparation of this manuscript. The clinical trial was preregistered at the German Clinical Trials Register (DRKS00014375, June 20, 2018). We thank E. Bendig, N. Bauerreiß for their help with the intervention platform, K. Krum, D. Huth, and S. Germer as eCoaches in this study, L. Kriston for statistical advice and S. Germer for his invaluable support in the delivery of the intervention and data management.

Severin Hennemann and Harald Baumeister report to have received consultancy fees and fees for lectures/workshops from chambers of psychotherapists and training institutes for psychotherapists in the e-mental-health context. David Daniel Ebert reports having received consultancy fees/served in the scientific advisory board from several companies such as Minddistrict, Lantern, Schoen Kliniken, and German health insurance companies. He is a stakeholder of GET.ON and Hellobetter, which also provide digital health interventions for routine care. Maria Kleinstäuber and Michael Witthöft are the authors of a published treatment manual that iSOMA is based on and receives annual royalty payments from the publisher.

Data from the current trial have not yet been published elsewhere.

Correspondence concerning this article should be addressed to Severin Hennemann, Department of Clinical Psychology, Psychotherapy and Experimental Psychopathology, Institute of Psychology, University of Mainz, Wallstraße 3, 55112 Mainz, Germany. Email: s.hennemann@uni-mainz.de

Persistent somatic symptoms (PSS) such as pain, gastrointestinal dysfunctions, or headache, which can be more or less medically explained, can lead to significant distress and impairment. PSS are a key aspect of various syndrome and disorder classifications (e.g., somatoform disorders, disorders of bodily distress, somatic symptom disorders, functional somatic syndromes). They constitute a significant health problem in emerging adulthood (ages 18–29; Arnett et al., 2014), including university and college students. According to European survey studies, 9.1%–23.5% of university students fulfill criteria for the somatoform syndrome (i.e., multiple, distressing somatic symptoms of unclear etiology), representing the most common psychological syndrome in this group (Bailer et al., 2008; Fischer et al., 2013; Schlarb et al., 2017). Similarly, related functional somatic syndromes such as irritable bowel syndrome are diagnosed in around 10%–20% of university students across various countries (Costanian et al., 2015; Gulewitsch et al., 2011; Hazlett-Stevens et al., 2003). Evidence suggests that emerging adults when compared to other age groups have one of the highest risks functional somatic syndromes and somatoform disorders (Leiknes et al., 2007; Petersen et al., 2020). According to the recent classification in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association, 2013), individuals with somatic symptom disorder (SSD) suffer from at least one or more persistent somatic symptom that is accompanied by excessive and dysfunctional cognitive (e.g., catastrophizing), affective (e.g., health anxiety), or behavioral reactions (e.g., frequent doctor visits). A variety of biopsychosocial risk factors may contribute to the development and persistence of debilitating somatic symptoms and associated somatic symptom disorders (e.g., Rief & Broadbent, 2007). For example, high levels of stress have been associated with the severity of PSS in emerging adults (Gulewitsch et al., 2013; Leppink et al., 2016; Nater et al., 2011).

PSS represent a significant cause of health-care utilization and costs (Barsky et al., 2005) and have a high risk for chronicity (Rief & Rojas, 2007), which can largely affect academic life as an important developmental period. As such, they have been associated with concurrent mental distress (e.g., depression, anxiety), college attrition, or worse functioning even beyond secondary education (Bigal et al., 2001; Breslau et al., 2008; Fischer et al., 2013). At the same time, access to adequate treatment is often difficult and delayed (Herzog et al., 2018) and only a fraction of emerging adults receive psychological treatment (Auerbach et al., 2016; Gulewitsch et al., 2011). Reasons for this treatment gap may include fear of stigmatization or unfavorable attitudes toward psychological treatments (Eisenberg et al., 2009; Schneider et al., 1990), as well as structurally limited treatment resources (Ebert et al., 2019; Xiao et al., 2017). Besides, evidence-based treatments such as cognitive-behavioral therapy (CBT) show only small to medium-sized effects on core clinical outcomes such as symptom severity or impairment across randomized controlled trials (RCTs; Kleinstäuber et al., 2011; van Dessel et al., 2015). Therefore, effective and accessible prevention and treatment options are highly needed.

Internet-based interventions (IBIs) may provide emerging adults with low-threshold, widely accessible, flexible, and stigma-reducing treatment options that seem to be well accepted in this target group and well suited to engage first-time help seekers (Dunbar et al., 2018; Griffiths et al., 2017). Previous studies show that IBIs can be particularly effective in reducing PSS in individuals with completed tertiary education (Vugts et al., 2018) and have repeatedly demonstrated a range of positive effects on PSS across different age groups (Bernardy et al., 2018; Bonnert et al., 2017; Janse et al., 2018; Mehta et al., 2019; Weise et al., 2019). A recent transdiagnostic meta-analysis, which included 30 trials investigating mostly CBT-based internet interventions for various PSS, discovered small to medium-sized effects on somatic symptom severity, catastrophizing, functional impairment, and depression (Vugts et al., 2018), which resemble the range of effects found in face-to-face treatment trials (van Dessel et al., 2015). Furthermore, guided internet-based CBT demonstrated positive effects in trials on patients with SSD with regard to health anxiety or somatic symptom distress (Hedman et al., 2016; Newby et al., 2018).

However, there is a clear lack of research on IBIs targeting PSS in emerging adults. We are aware of one study in Taiwanese nursing students with irritable bowel syndrome in which a 6-week, internet-based CBT with clinician guidance on-demand (contactable online for brief written feedback) was not superior to a waitlist (WL) control group in reducing somatic symptom severity, while a small effect on anxiety and depression was observed (Lee et al., 2019). These findings could be explained by the relatively low intensity of therapeutic guidance (Baumeister et al., 2014) or the focus of the intervention on stress management, in contrast to CBT protocols including exposure-based elements (Ljótsson et al., 2011). Also, the study included a specific, rather homogenous sample, limiting the generalizability to other populations of emerging adults. Furthermore, since previous studies mostly focused on specific symptom clusters (e.g., irritable bowel syndrome, fibromyalgia), much less is known about the transsymptomatic efficacy of IBIs, and particularly for a broader spectrum of concurrent physical complaints and distress criteria.

Therefore, the aim of this randomized controlled trial (RCT) was to investigate the efficacy of a guided, cognitive-behavioral internet intervention for somatic symptom distress (iSOMA) in emerging adults with a broad spectrum of PSS. Our primary hypothesis was that iSOMA would be more efficacious in reducing somatic symptom distress and associated psychobehavioral symptoms of SSD, as assessed at baseline and posttreatment, compared to a WL control group. Furthermore, we assumed that iSOMA would lead to significantly greater improvements in secondary psychological distress outcomes (depression, anxiety, illness worries), functional disability, and attitudes toward traditional psychological treatment. Finally, we aimed to explore the sustained effects, adherence to, and satisfaction with the intervention (acceptability) and assess negative treatment effects (safety).

Materials and Methods

Study Design

This was a prospective, two-armed RCT, comparing a guided, modular internet-based intervention (iSOMA) based on CBT strategies with a WL condition. All participants had unrestricted access to treatment-as-usual (TAU), which could have included, for example, psychological interventions, medication, or physical therapy (Henningsen et al., 2018). Detailed information on the study's procedures can be found in our study protocol (Hennemann et al., 2018). The study was preregistered at the German Clinical Trials Register (DRKS00014375, June 20, 2018) and was approved by the ethics committee of the Department of Psychology at the University of Mainz (Ref. Nr. 2017-JGU-psychEK-012, January 22, 2018). This trial has been conducted within the German-speaking StudiCare framework, which is part of the WHO World Mental Health International College Student (WMH-ICS) Initiative (Cuijpers et al., 2019).

StudiCare features a website that directs users to open access IBIs targeting different mental and behavioral issues [e.g., social anxiety disorder (Kählke et al., 2019); depression (Harrer, Apolinário-Hagen, et al., 2019)] tailored to university students, as part of various research projects.

Participants

Adult university students were recruited over 1.5 years (last-participant-out on August 14, 2020). As the main recruitment strategy, more than 500,000 students from more than 15 universities across Germany, Austria, and Switzerland (as part of the caring universities network: https://www.studicare.com/studicare-universitaeten) received biannual emails with information on accessible IBIs in the context of recruiting trials of the StudiCare framework (including the intervention under study here). At the time of this study, iSOMA was the only IBI for PSS enlisted at the StudiCare website. There was no physical contact between the participants and the study team.

Inclusion criteria were: age ≥18 years, elevated levels of somatic symptom distress as indicated by a score ≥4 in the Patient Health Questionnaire, somatic symptom scale (PHQ-15; Kroenke et al., 2002), enrolled as a university student, internet access, and sufficient knowledge of the German language. We chose a sensitivity-focused cut-off for somatic symptom distress as recommended for the screening of SSD in nonclinical populations by Laferton et al. (2017). No further exclusion criteria were applied to recruit a naturalistic sample.

Procedure

After having indicated interest in participating in the trial, participants were screened for inclusion with an online questionnaire and received detailed information on the study. Participants were informed that neither the study's screening nor the intervention replaced professional medical or therapeutic diagnosis and care, and were advised about specific (local) health-care services, and were therein encouraged to seek care parallel to their study participation as needed. Eligible participants gave written informed consent to participate and were asked to provide an email address for their intervention platform profile. Consequently, participants were invited to fill out the baseline questionnaire. After completion thereof, participants were randomly allocated to either receive iSOMA (the intervention group) or to the WL group and started their respective treatment/waiting time consecutively.

Randomization and Masking

Randomization and allocation were performed by a research assistant not otherwise involved in the study process using automatic concealed randomization software (Sealed Envelope; Sealed Envelope Ltd). The allocation ratio was 1:1 and permuted block sizes (2, 4, 6) were used. Due to the nature of the intervention, neither participants nor clinical personnel could be blinded to the study conditions.

Study Arms

iSOMA

Following a short technical and general introduction, iSOMA included seven consecutive modules, which participants were encouraged to complete on a weekly schedule. Thus, the intervention was intended to be completed in approximately 8 weeks. iSOMA was designed to reduce somatic symptom distress and associated impairment by targeting central maintaining factors such as somatosensory amplification, stress, avoidance or safety behavior, and dysfunctional cognitions according to cognitive-behavioral models of somatoform disorders (Brown, 2004; Rief & Hiller, 2011). The structure and content of the modules were closely adapted from a CBT rationale for medically unexplained physical symptoms (Kleinstäuber et al., 2018), which has proven to effectively reduce somatic symptom distress and further clinical outcomes as short-term CBT in a large-scale RCT (Kleinstäuber et al., 2019). Table 1 gives an overview of the module's objectives and change strategies. All modules featured psychoeducation, exercises, behavioral experiments, and assignments (on average 1–2 per module) via text, audio, or video. The internet-based intervention was delivered via a Secure Sockets Layer (SSL) encrypted digital health platform (https://www.minddistrict.com/). The duration of module completion was estimated to be 45 min; modules consisted of 10 (module 1) to 23 (module 4) browser pages (see Table 1). In the second module, an optional adjunct diary app was introduced, which was also integrated with the web platform. Participants were instructed to monitor somatic symptoms, perceived stress, mood, illness anxiety, and sleep quality using visual analog scales and enter coping strategies for somatic symptom distress daily for at least 1 week. Additionally, participants in the iSOMA group could subscribe to receive prescheduled, standardized text messages, accompanying the intervention content and serving as motivation to the intervention's exercises.

Table 1

Content and Therapeutic Strategies of the iSOMA Modules Based on the CBT Rationale by Kleinstäuber et al. (2018)

Modules	Content and therapeutic strategies (volume in browser pages)
Introduction	Overview of contents, information on procedure and functions of iSOMA (11)
1. Goal setting and illness theories	History of symptom development, influencing factors, realistic treatment goals (10)
2. Stress education and relaxation	Psychoeducation on stress reaction, app-based symptom monitoring, progressive muscle relaxation (21)
3. Attention modification	Selective attention, attention shift techniques (e.g., sensory training), behavioral activation (22)
4. Restructuring illness attitudes	Modification of negative cognitions (e.g., catastrophizing) through cognitive restructuring (e.g., ABC-model) and interoceptive exposure (23)
5. Illness behavior	Reduction of reinsurance (e.g., doctoral visits) and avoidance behavior (e.g., protective posture), graded physical exercise, establishing a continuous model of healthiness (17)
6. Instrumental and cognitive stress management	Transactional stress model, training stress management techniques (e.g., problem-solving) (23)
7. Summary and planning	Composing biopsychosocial explanatory model, summarizing personal coping strategies (15)

Note. iSOMA = Internet intervention for somatic symptom distress; CBT = cognitive-behavioral therapy.

Previous trials have demonstrated an augmenting effect of text messages on the efficacy of and adherence to IBIs (Eckert et al., 2018).

Psychologist Guidance

Across mental disorders and chronic somatic conditions, psychologist-guided IBIs have been associated with higher efficacies compared to unguided IBIs (Baumeister et al., 2014; Vugts et al., 2018). Therefore, participants allocated to the iSOMA condition were guided by eCoaches, that is, clinical psychologists at masters or postgraduate level (i.e., in clinical training). eCoaches provided semistandardized, written therapeutic feedback via the secure internal messaging system of the intervention platform within 48 hr of the completion of each module and activated the next module afterward. The feedback was based on an eCoach manual and aimed to reinforce self-management strategies, promote adherence, and reflect on individual problems, based on the supportive accountability approach (Mohr et al., 2011). eCoaches were trained and supervised by the first author, who is a psychotherapist licensed in CBT. Individual training included a 2-day introduction to iSOMA and the feedback manual and a review of drafts for all therapeutic feedback for the first four participants of each eCoach. Supervision for eCoaches was provided by 4-weekly group sessions, selected reviews of feedback, and individual support as needed. Apart from that, no independent evaluation of fidelity was performed. When a module was not completed within 7 days, eCoaches sent up to three predefined reminders. Participants could contact their eCoach (and vice versa) through the internal messaging system.

Control Condition

Participants in the WL condition completed the same postassessment as the iSOMA group and afterward received access to the iSOMA with eCoach support-on-demand, the results of which will be reported separately.

Assessments and Outcomes

The selection of outcomes and assessment strategies followed the guidelines set out by the European Network on Somatic Symptom Disorders (EURONET-SOMA; Rief et al., 2017). All outcomes were self-assessed through online questionnaires via Unipark (https://www.unipark.com/) at baseline and 8 weeks after randomization (postassessment). In addition to the assessments described in the preregistration, participants in the iSOMA group completed a 6-month follow-up questionnaire postrandomization, allowing for the investigation of medium-term within-group effectiveness. Participants who filled out the follow-up assessment were invited to take part in a voucher draw. Further putative moderating variables of the efficacy of iSOMA were collected at baseline (Hennemann et al., 2018), which will be analyzed and reported separately.

Primary Outcomes

Core features of SSD were evaluated twofold as suggested by Toussaint et al. (2019): Somatic symptom distress was assessed by the PHQ-15 (Kroenke et al., 2002), which covers the most typical somatic complaints in primary care, that are rated regarding the severity to which they had suffered from the presented symptoms in the past 4 weeks (0 = *not bothered at all* to 2 = *bothered a lot*). The total score ranges between 0 and 30 points and scores ≥10 can be considered as a clinically relevant level of somatic symptom distress. The PHQ-15 and has been validated in various clinical and nonclinical populations (Zijlema et al., 2013) and has demonstrated satisfactory internal reliability (α = .82; Hinz et al., 2017). Psychobehavioral features according to the B-criterion of SSD in DSM-5 (i.e., disproportionate thoughts, feelings, and behavior associated with somatic symptoms) with the Somatic Symptom Disorder B-Criteria Scale, 12-item version (SSD-12; Toussaint et al., 2016). Answers are rated on a 5-point scale (0 = *never* to 4 = *very often*). Scores range between 0 and 48 points and a cutpoint of ≥20 indicates clinically relevant symptoms of SSD (Toussaint et al., 2017). The SSD-12 proved to be highly reliable (α = .94; Toussaint et al., 2016), showed high diagnostic accuracy in detecting SSD (Toussaint et al., 2019), and sensitivity to change (Hüsing et al., 2018).

Secondary Outcomes

Secondary outcomes included (a) psychological distress commonly associated with PSS (Petersen et al., 2020). Depression was assessed by the Patient Health Questionnaire, depression scale (PHQ-9; α = .89; Kroenke & Spitzer, 2002), which includes nine symptoms of depression that are rated for the last 2 weeks on a 4-point scale (0 = *not at all* to 3 = *nearly every day*). Scores range between 0 and 27 points, with a proposed cut-off for screening for depression ≥10. Anxiety was assessed by the Generalized Anxiety Disorder Questionnaire (GAD-7; α = .92; Spitzer et al., 2006), which includes seven symptoms of general anxiety which are rated for the last 2 weeks on a 4-point scale (0 = *not at all* to 3 = *nearly every day*). Scores range from 0 to 21 points, with a proposed cut-off for screening for anxiety disorders ≥10. Illness anxiety during the last 8 weeks were assessed by a modified, 14-item version of the Short Health Anxiety Inventory (α = .93; mSHAI; Bailer & Witthöft, 2014). Response categories ranged from 0 (*strongly disagree*) to 4 (*strongly agree*); the total score ranged from 0 to 56. Furthermore, (b) functional disability was assessed by an adapted version (Mewes et al., 2009; α = .93) of the 7-item Pain Disability Index (PDI; Tait et al., 1990). Response categories ranged from 0 (*no disability*) to 10 (*total disability*); the total score from 0 to 70. Attitudes toward psychological treatment (c) as an important determinant of traditional help-seeking (Schneider et al., 1990) were assessed by the 10-item Attitudes Toward Seeking Professional Psychological Help questionnaire (ATSPPH; α = .82; Fischer & Farina, 1995), with response categories from 0 (*disagree*) to 3 (*agree*) and a total score range of 0–30 (higher scores thus represent more positive attitudes toward seeking professional help).

Intervention Usage and Usual Care Consumption

To determine treatment adherence, the number of completed modules was counted. Participant-rated session duration was recorded. Satisfaction with iSOMA was evaluated with the 8-item Client Satisfaction Questionnaire (CSQ-8; α = .90, scale 1–4, range 8–32; Boß et al., 2016). The average time (in minutes) to write individual therapeutic feedback was assessed by eCoaches. The frequency of psychological treatments (psychotherapy, psychological student counseling) and daily medication (according to commonly reported medication by patients with PSS; Weiss et al., 2018) was assessed at baseline (last 4 weeks) and postmeasurement (last 8 weeks).

Negative Effects

Participant-rated negative effects that occurred as a consequence of the intervention were assessed in the iSOMA group at postassessment with a 15-item version of the Inventory for the Assessment of Negative Effects of Psychotherapy (INEP; α = .86; Ladwig et al., 2014), covering effects on symptoms, interpersonal change, stigmatization, patient–therapist relationship, or financial/legal concerns. Furthermore, reliable symptom deterioration in primary outcomes was assessed by the reliable change index (RCI; Jacobson & Truax, 1991), and serious adverse events (e.g., hospital admission, acute suicidality) were recorded by the study team.

Additional Measures

Additional items assessed at baseline included demographic (age, gender, academic year, relationship status) and clinical characteristics (somatic symptom duration, doctor's visits, and self-reported medical conditions in 15 broad categories [e.g., mental disorders, musculoskeletal diseases], adapted from the Workability Index [WAI; Ilmarinen, 2007]).

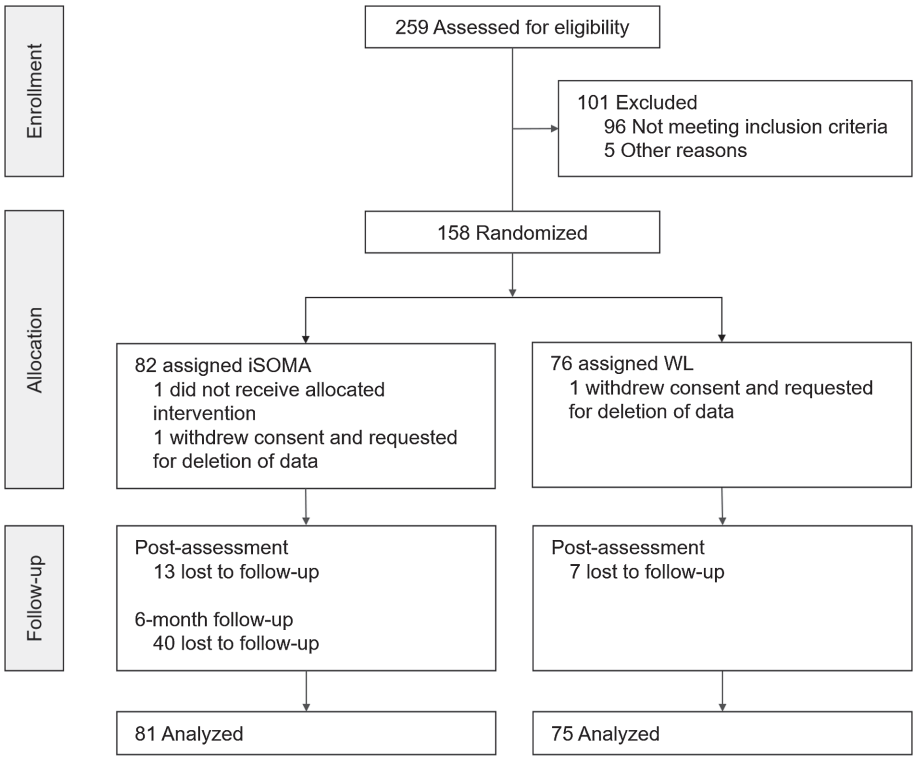
Power Calculation

To detect an expected medium-sized effect ($d \geq 0.50$), based on the range of effects of internet-based self-management interventions in somatic syndromes (e.g., Bernardy et al., 2018; Liegl et al., 2015; Vugts et al., 2018), in an analysis of covariance (ANCOVA) with one covariate, a necessary sample size of $N = 128$ was calculated, assuming a power of 80% and α-level of 5%. To account for an expected dropout rate of 20%, the target sample size was increased to 154. The actual sample size of 156 thus facilitated the detection of effect sizes of $d \geq 0.45$, that is medium to large-sized effects.

Statistical Analyses

All analyses were conducted with IBM SPSS version 23 (SPSS Inc., Chicago, Illinois) and tests were two-sided with a significance level of 0.05. Analyses of primary and secondary outcomes were conducted with the intention-to-treat (ITT) sample, including all participants that were allocated to the trial arms, and gave informed consent for their data to be analyzed (see Figure 1). Other than described in the study protocol (Hennemann et al., 2018) we decided to conduct mixed-model analyses for repeated measures (MMRM) instead of ANCOVA, as MMRM allow to analyze all available data, including partial data at postassessment, without imputation and lead to unbiased estimates under the assumption of data missing at random (Bell & Rabe, 2020). Mixed models included group, time, and the Group × Time interaction as fixed factors, and a random intercept to model interindividual differences, based on diagonal covariance matrices and restricted maximum likelihood estimation (maximum of 100 iterations). Between-group effect sizes were calculated as Cohen's *d* using estimated mean differences, pooled observed standard deviations (*SDs*) at postassessment, and observed sample sizes (see Supplemental

Figure 1
Participant Flow



Note. iSOMA = guided internet-based cognitive-behavioral therapy (CBT) for somatic symptom distress; WL = waitlist control group.

Table E1). Within-group effects were calculated as d_{av} (Lakens, 2013) using estimated mean differences divided by the average (observed) *SDs*. In participants who provided complete data at postassessment, reliable improvement or deterioration in primary outcomes was coded according to the RCI using *SDs* and internal consistencies (Cronbach's α) of the PHQ-15 and SSD-12 from validation studies in the general population (Kocalevent et al., 2013; Toussaint et al., 2017). Additionally, odds ratios (*ORs*) for reliable change in the iSOMA group compared to the WL group are reported. In the iSOMA group, the change in outcomes from baseline to the 6-month follow-up was examined with MMRM including time (baseline, postassessment, follow-up) as a fixed factor and subjects as a random intercept. Estimated mean differences and pairwise comparisons (baseline vs. follow-up) are reported.

We also analyzed participants who were adherent to the intervention per protocol by completing at least four out of seven modules (i.e., >50%), according to the procedures in some of the previous trials in the field (e.g., McCombie et al., 2015). To explore the impact of iSOMA in a potentially clinical population, a subgroup analysis was performed in participants with clinically relevant symptoms of SSD at baseline, according to recommended combined cut-offs (PHQ-15 ≥ 9; SSD-12 ≥ 23) by Toussaint et al. (2019). We explored the association between time spent by eCoaches for providing therapeutic feedback and change scores in primary outcomes from pre- to postassessment using bivariate correlations of observed values.

Results

Participant Characteristics

Between August 28, 2018, and January 31, 2020, 259 adults were screened for eligibility, and 158 were consecutively enrolled in and randomized to one of the study arms (iSOMA: $n = 82$, WL: $n = 76$; see study flow-chart, Figure 1). Two participants, one in each condition, later withdrew their consent and requested their data to be removed completely, so that 156 participants remained to be analyzed. Of these, 13 (16.0%) participants in the iSOMA group and 7 (9.3%) in the WL group did not complete the postassessment. These participants did not differ in their demographic or baseline characteristics from participants who completed the assessment (*ps* > .05). 40 participants (49.4%) in the iSOMA group did not complete the 6-month-follow up.

Table 2 contains detailed information on the baseline characteristics of the total sample and both study groups. 130 participants (83.3%) were female, with an average age of 24.53 (*SD* 5.09) years and a mean symptom duration of 3.25 (*SD* 3.98) years. 36 participants (23.2%) indicated current psychological treatment and 103 (66.5%) were taking daily medication at baseline. 24 participants (15.4%) reported no diagnosed medical condition, 48 (30.8%) reported one, and 84 (53.8%) two or more diagnosed medical conditions, with mental disorders (32.7%) being the most common (see Supplemental Tables A1 and A2 for detailed results). Demographic and clinical characteristics were similar in both groups (*ps* > .05).

Primary Outcomes

In line with our hypothesis, ITT analyses revealed significant Time × Group interactions for the PHQ-15, $F(1, 136.51) = 29.55$, $p < .001$ and SSD-12, $F(1, 137.69) = 18.75$, $p < .001$ in favor of iSOMA, with medium-sized between-group effects at postassessment, PHQ-15: $d = 0.70$ [0.36, 1.05]; SSD-12: $d = 0.65$ [0.30, 0.99]. In participants with complete data ($n = 136$), significantly more participants in the iSOMA group, compared to the WL group, had attained a reliable change in the PHQ-15, 27/68 (39.7%) versus 4/68 (5.9%); $OR = 10.54$ [3.43, 32.32], $Z = 4.19$, $p < .001$, and SSD-12, 47/68 (69.1%) versus 23/68 (33.8%); $OR = 4.38$ [2.13, 8.99], $Z = 4.03$, $p < .001$.

Secondary Outcomes

ITT analyses of secondary outcomes (see Table 3) revealed significant Group × Time interaction effects in favor of iSOMA ($Fs \geq 4.59$, $ps < .05$), with medium-sized between-group effects ($d = 0.41$ [mSHAI] to $d = 0.52$ [GAD-7]) except for attitudes toward traditional psychological treatment, measured with the ATSPPH ($p = .944$).

Table 2
Sample Characteristics at Baseline

Characteristic	Total sample (156)	iSOMA (81)	WL (75)	Test statistic
Gender (female/male), % (*n*)	83.3 (130)/16.7 (26)	84.0 (68)/16.0 (13)	82.7 (62)/17.3 (13)	$\chi^2(1) = 0.05$, $p = .830$
Age, years, *M* (*SD*)	24.53 (5.09)	24.68 (5.72)	24.37 (4.33)	$t(154) = 0.37$, $p = .709$
Relationship status, % (*n*)				$\chi^2(1) = 1.88$, $p = .598$
Married or committed relationship	18.6 (29)	18.5 (15)	18.7 (14)	
Divorced, separated, or widowed	1.2 (2)	2.4 (2)	—	
Single	80.1 (125)	79.0 (64)	81.3 (61)	
Academic year, *M* (*SD*)	4.02 (2.35)	3.97 (2.46)	4.07 (2.24)	$t(154) = -0.26$, $p = .796$
Symptom duration, years, *M* (*SD*)	3.25 (3.98)[a]	3.66 (4.35)	2.80 (3.48)	$t(150) = 1.33$, $p = .184$
Current psychological treatment, % (*n*)	23.2 (36)[b]	22.2 (18)	23.9 (18)	$\chi^2(1) = 0.96$, $p = .757$
Doctor's visits, *M* (*SD*)	1.39 (2.56)[c]	1.39 (2.97)	1.39 (2.00)	$t(139) = -0.002$, $p = .998$
Daily medication, % (*n*)[d]	66.5 (103)	66.7 (54)	65.3 (49)	$\chi^2(1) = 0.004$, $p = .953$
Number of self-reported medical conditions, *M* (*SD*)	1.94 (1.51)	2.00 (1.49)	1.88 (1.53)	$t(154) = 0.50$, $p = .621$

Note. iSOMA = guided internet-based cognitive-behavioral therapy (CBT) for somatic symptom distress; WL = waitlist control group. Data are not available for all randomized participants since two participants withdrew informed consent to add data to analyses (see also Figure 1).
[a] $n = 152$. [b] $n = 155$. [c] $n = 141$ (corrected sample size due to missing values in baseline assessment). [d] Daily medication included any of the following: Analgesic, gastrointestinal-, antihypertensive drugs, antidepressants, thyroid hormones, dietary supplements, herbal medicine, or others.

Table 3

Estimated Means and Observed SDs for Primary and Secondary Outcomes at Baseline and Postassessment and Within- and Between-Group Comparisons for the ITT Sample

Measure (scale range)	Baseline[a]	Post[b]	Effect size *d* [95% CI]	
	M (*SD*)	*M* (*SD*)	Within (pre/post)	Between (post)
Primary outcomes				
PHQ-15 (0–30)		Interaction effect: $F(1, 136.51) = 29.55$, $p < .001$[c]		
iSOMA	12.28 (4.04)	8.46 (3.70)	0.99 [0.65, 1.33]	0.70 [0.36, 1.05]
WL	12.11 (4.63)	11.47 (4.79)	0.14 [−0.19, 0.46]	
SSD-12 (0–48)		Interaction effect: $F(1, 137.69) = 18.75$, $p < .001$[c]		
iSOMA	25.15 (8.73)	17.17 (8.72)	0.91 [0.57, 1.25]	0.65 [0.30, 0.99]
WL	26.27 (8.98)	23.08 (9.53)	0.34 [0.01, 0.67]	
Secondary outcomes				
PHQ-9 (0–27)		Interaction effect: $F(1, 139.72) = 11.01$, $p < .001$		
iSOMA	9.35 (5.14)	6.49 (4.08)	0.62 [0.29, 0.95]	0.43 [0.09, 0.77]
WL	9.16 (4.58)	8.36 (4.61)	0.17 [−0.16, 0.50]	
GAD-7 (0–21)		Interaction effect: $F(1, 142.95) = 4.59$, $p = .034$		
iSOMA	7.53 (4.66)	5.58 (4.30)	0.43 [0.11, 0.76]	0.52 [0.18, 0.86]
WL	8.47 (4.89)	7.98 (4.94)	0.10 [−0.23, 0.43]	
mSHAI (0–56)		Interaction effect: $F(1, 137.30) = 12.03$, $p < .001$		
iSOMA	26.41 (10.66)	21.62 (10.27)	0.46 [0.13, 0.78]	0.41 [0.07, 0.75]
WL	26.91 (12.21)	26.25 (12.19)	0.05 [−0.27, 0.38]	
PDI (0–70)		Interaction effect: $F(1, 141.26) = 9.18$, $p < .001$		
iSOMA	23.53 (12.20)	16.40 (10.23)	0.63 [0.30, 0.96]	0.47 [0.13, 0.81]
WL	24.00 (12.16)	21.76 (12.56)	0.18 [−0.15, 0.51]	
ATSPPH (0–30)		Interaction effect: $F(1, 135.41) = 0.01$, $p = .944$		
iSOMA	22.20 (4.66)	22.48 (4.80)	−0.06 [−0.38, 0.27]	−0.02 [−0.36, 0.32]
WL	22.05 (4.79)	22.37 (5.23)	−0.06 [−0.39, 0.27]	

Note. Interaction effect of group (iSOMA/WL) by time (pre-/post-assessment); ITT = intention-to-treat; iSOMA = guided Internet-based cognitive-behavioral therapy (CBT) for somatic symptom distress; WL = waitlist control group; PHQ-15 = Patient Health Questionnaire, somatic symptom scale (α = .66); SSD-12 = Somatic Symptom Disorder Scale (α = .88); PHQ-9 = Patient Health Questionnaire, depression scale (α = .80); GAD-7 = Generalized Anxiety Disorder Questionnaire (α = .86); mSHAI = modified Short Health Anxiety Inventory (α = .92); PDI = Pain Disability Index (α = .79); ATSPPH = Attitudes Toward Seeking Professional Psychological Help questionnaire (α = .78).

[a] Sample size iSOMA $n = 81$, WL $n = 75$. [b] See Supplemental Table E for observed sample sizes. [c] Significant after alpha correction with the Bonferroni Holm method (only primary outcomes).

Subgroup Analyses

Per protocol analyses of 59 participants (72.8%) who completed ≥4 intervention modules showed significantly greater improvements in the iSOMA group, compared to the WL in primary and secondary outcomes ($Fs \geq 4.28$, $ps < .05$) except in the ATSPPH ($p = .980$), resulting in a pattern comparable to the ITT sample. Between-group effects for primary outcomes were medium-sized (PHQ-15: $d = 0.59$; SSD-12: $d = 0.57$). Subgroup analyses of 83 participants (53.2%) with clinically relevant symptoms of SSD at baseline revealed significantly greater improvements in clinical outcomes in favor of the iSOMA group ($Fs \geq 4.69$, $ps < .05$), except for the GAD-7 ($p = .058$) and ATSPPH ($p = .916$), with medium-sized between-group effects in primary outcomes (PHQ-15: $d = 0.68$; SSD-12: $d = 0.72$). Detailed results of subgroup analyses can be found in Supplemental Tables B1–B2.

Follow-Up Assessment

Participants in the iSOMA group significantly improved from baseline to 6-months postrandomization in both primary, PHQ-15: $F(2, 55.57) = 46.32$, $p < .001$; SSD-12: $F(2, 60.15) = 66.19$, $p < .001$, and secondary outcomes ($Fs \geq 10.40$, $ps < .001$), except for the ATSPPH ($p = .153$), corresponding to significant pairwise comparisons (baseline vs. follow-up, $ps < .001$). Within-group effects were medium to large-sized for primary outcomes, PHQ-15: $d = 0.79$ [0.40, 1.18]; SSD-12: 0.93 [0.54, 1.33]. Detailed results can be found in Supplemental Table C.

Intervention Usage and Usual Care Consumption

Participants in the iSOMA group who completed at least the online introduction to iSOMA ($n = 77$) used the intervention for 3 hr and 38 min (*SD* 2 h 6 m) on average, logged in 18.53 times (*SD* 12.46) and completed 5.49 (*SD* 2.13) out of seven modules (74.6%). Four participants (4.90%) did not complete any module (see Supplemental Table D1 for details). The average duration of module completion was 37.88 min (*SD* 13.03). 59 participants (72.8%) subscribed to receive accompanying SMS. 67 participants (82.7%) provided data in the CSQ-8. Satisfaction with the intervention was high, with a total score of 25.57 (*SD* 4.64) out of 32. 91.0% of participants were satisfied with iSOMA in general and 89.6% would recommend the intervention to a friend (see Supplemental Table D2). eCoaches spent an average of 138.57 min (*SD* 76.74) on providing therapeutic feedback per participant and sent 4.15 (*SD* 2.99) reminders per participant. eCoach time was not correlated with pre–post change in primary outcomes (PHQ-15: $r = 0.21$, $p = .080$; SSD-12: $r = -0.12$, $p = .342$, $n = 68$). 21 participants (25.9%) in the iSOMA group

contacted their eCoaches between modules through the messaging system (37 requests in total). Most requests were related to technical problems (n = 12), treatment content/process (n = 10), or organizational matters (e.g., temporary discontinuation of the treatment, n = 15). At postassessment, 38 of 135 participants (28.1%) with evaluable data reported parallel psychological treatment, iSOMA: 25.4%, WL: 30.9%, $\chi^2(1) = 0.51$, $p = .477$, and 77 of 134 participants (57.5%) daily medication during the intervention phase, iSOMA: 32/66 (48.5%); WL: 45/68 (66.2%), $\chi^2(1) = 4.29$, $p = .038$; most frequent were dietary supplements (44/134, 32.8%), whereas analgesic or antidepressants (6/134, 4.5%, respectively) were infrequent (see Supplemental Table A3). At follow-up, 22 of 41 participants (53.7%) with available data in the iSOMA group reported daily medication use, and 15 participants (36.6%) psychological treatment in the last 4 weeks.

Negative Effects

Sixty seven out of eighty one participants in the iSOMA group filled out the INEP; 14.9% (n = 10) of which reported experiencing at least one unwanted negative treatment effect (Supplemental Table D3). Symptom deterioration was infrequent across groups, PHQ-15: iSOMA: 0%; WL: 4.4%; $OR = 0.14$ [0.01, 2.70], $Z = 1.31$, $p = .191$; SSD-12: iSOMA: 1.5%; WL: 7.4%; $OR = 0.19$ [0.02, 1.65], $Z = 1.51$, $p = .132$. One participant from the WL group indicated being in scheduled inpatient psychotherapeutic treatment at postassessment and two participants at follow-up assessment (for reasons unknown), otherwise no serious adverse events were recorded.

Discussion

Addressing persistent and disabling somatic symptoms in emerging adulthood seems crucial to prevent lifelong burden and chronicity. In a randomized controlled design, this study tested the efficacy of an 8-week guided internet intervention targeting core symptoms of SSD in an at-risk group of emerging adults with diverse physical complaints.

Most importantly, iSOMA led to significant improvements on both somatic symptom distress and associated psychobehavioral features of SSD with medium-sized between-group effects and notable rates of reliable change, confirming our primary hypothesis. In comparison, the effect of iSOMA on core aspects of PSS can be considered higher as in studies investigating IBIs in diagnosed, clinical samples with various PSS (Bernardy et al., 2018; Buhrman et al., 2016; Vugts et al., 2018), albeit lower than the effects reported for specific syndromes such as irritable bowel syndrome (Liegl et al., 2015), chronic fatigue syndrome (Janse et al., 2018) or patients with SSD (Newby et al., 2018). This seems reasonable since we did not tailor our intervention to certain somatic symptom clusters or diagnoses, however, we provide evidence for the transsymptomatic efficacy of guided internet-based CBT across a spectrum of physical symptoms. Furthermore, the effects observed in this study can be considered higher than those previously found in waitlist-controlled trials in the target group of emerging adults with PSS (Lee et al., 2019) as well as mental health issues such as depression, anxiety, or stress (Harrer, Adam, et al., 2019). A broader range of symptom distress and higher intensity of psychologist guidance could have contributed to these differences in effects. Nevertheless, our findings indicate that guided self-help is a promising instrument to reduce general somatic symptom distress in emerging adult populations. Moreover, our data suggest that the effects of iSOMA on symptoms of SSD and other clinical outcomes are sustained in the medium term. This finding, however, needs to be interpreted cautiously as the study design did not allow for a between-group comparison at follow-up and the attrition rate was high, mostly due to technical issues with the provision of the online questionnaire. A lack of adequate follow-up assessments has been criticized for research on the efficacy of IBIs in university students (Becker & Torous, 2019). At the same time, within a population of emerging adults, life transitions and fluctuations in somatic symptom distress (Lieb et al., 2002) can make longer term follow-up challenging.

The second main finding was that iSOMA also showed moderate between-group effects on common mental health problems associated with somatic symptom distress, i.e., depression, general anxiety, and illness anxiety. This contrasts with most previously studied face-to-face and internet-based psychological interventions for chronic somatic conditions, which demonstrated lower effects for psychological distress outcomes, particularly for depression (Hedman et al., 2016; Kleinstäuber et al., 2011; Vugts et al., 2018). Additionally, our intervention yielded significant improvements in functional disability, as one of the central treatment outcomes for chronic somatic conditions (Dworkin et al., 2005), corresponding to a moderate between-group effect. Similarly, an RCT by Hedman et al. (2016) demonstrated a medium-sized between-group effect ($d = 0.77$) of a guided, exposure-focused internet-based CBT on disability in patients with SSD compared to a WL. However, further research across chronic somatic conditions also shows mixed results for the efficacy of IBIs on disability outcomes (Bernardy et al., 2018; Buhrman et al., 2016; Vugts et al., 2018). Contrary to our expectations, attitudes toward psychotherapy itself were not improved by the intervention. An explanation could be that, in comparison to other studies in university students (Elhai et al., 2008), or patient samples (Schneider et al., 1990), in our study, attitudes were already favorable at baseline, indicating a selective sampling of more motivated participants. However, most participants in our study can be considered first-time help seekers concerning psychological treatment and the intervention had no negative effect on professional help-seeking attitudes.

Our findings strongly support the feasibility and acceptance of iSOMA in emerging adults. Satisfaction with the intervention was high and the module completion rate was substantial. Attrition rates were rather low in comparison to previous trials for mental health issues in university students (Becker & Torous, 2019). Our results show a low risk of negative effects and symptom deterioration, comparable to previous trials investigating IBIs for mental disorders (e.g., Boettcher et al., 2014), indicating the safety of the intervention. Adherence and negative effects may have been positively influenced by the regular eCoach support available, as suggested by previous research (Baumeister et al., 2014; Vugts et al., 2018). While the intensity of guidance in this study (i.e., weekly therapeutic feedback, regular reminders) can be generally compared to other trials in the field (Vugts et al., 2018), the time spent for therapeutic feedback (139 min) was higher than in another study investigating an internet-delivered acceptance and commitment therapy for chronic pain (105 min; Lin et al., 2017) but comparable to the average eCoach time across guided IBIs for anxiety disorders (178 min) according to meta-analytic evidence (Domhardt et al., 2020). At the same time, eCoach time to provide therapeutic feedback was not related to greater improvements in the iSOMA

group, which is corroborated by previous studies in the field of chronic somatic conditions that found similar effects for IBIs with regular guidance compared to self-guided (or guidance-on-demand; Hedman et al., 2016; Rheker et al., 2015). However, more research is needed to determine who benefits from which intensity or modality of guidance to help facilitate patient-tailored treatment decisions.

Limitations

When interpreting our findings, certain limitations have to be considered. Since we did not target a clinically diagnosed sample, the generalizability of our findings to clinical populations with SSD or in estimating the potential preventive effect of iSOMA is limited. Particularly, we did not include structured clinical interviews to assess the diagnosis of SSD or comorbid mental disorders or checked medical records for somatic diseases. However, we included validated questionnaires, which have proven diagnostic accuracy and sensitivity to change (Hüsing et al., 2018; Toussaint et al., 2019), and our streamlined assessment strategy aimed to decrease participant burden. Also, iSOMA was introduced as a low-threshold, dimensional health promotion instrument for an at-risk population rather than a stand-alone treatment intervention. Our broad inclusion criteria may have introduced heterogeneity regarding demographic or clinical characteristics and accentuated the self-selection of participants. Then again, we were able to demonstrate substantial effects across varying levels of somatic symptom distress. Low-threshold inclusion criteria are furthermore in line with the aim of the World Mental Health International College Student Initiative to provide prevention and early interventions in mental health problems among students (Cuijpers et al., 2019). While our study sample can be considered largely representative of the German university student population regarding the average age (Middendorff et al., 2017), we included mostly female students, which however is in line with higher prevalence rates of somatic symptom distress in university students (Bailer et al., 2008; Fischer et al., 2013; Schlarb et al., 2017) and in the general population (Hinz et al., 2017) and can be regarded typical for studies investigating IMIs (Harrer, Adam, et al., 2019). Methodologically, a lack of blinding of study participants and personnel can be seen as a limitation to the internal validity of the study results. Also, the waitlist condition may have discouraged participants from beneficial health behavior, and consequently, could have accentuated intergroup effects (Furukawa et al., 2014). To identify mechanisms of action of internet-based CBT, attentional control conditions (e.g., psychoeducation) seem more suitable, as well as testing the effects against other active treatments (e.g., unspecific stress management, unguided internet-delivered intervention, face-to-face CBT). Moreover, the limited number of data points in pre–post treatment designs such as ours averts more fine-grained analyses of individual or nonlinear change mechanisms and has been criticized when using mixed models (Hesser, 2015). These, however, can be considered a statistically powerful and robust approach to ITT analyses, also in the case of high missingness (Xi et al., 2018). Furthermore, since participants had access to TAU through the trial, we cannot fully disentangle effects by iSOMA from parallel treatments. This could also suggest the effectiveness of iSOMA alongside usual care, which, however, needs to be investigated more rigorously (e.g., regarding treatment indication, dose, rationale) in pragmatic trials.

Clinical Implications

Despite these limitations, our study provides the first evidence for the efficacy of a guided internet-delivered CBT in improving symptoms of SSD, mental distress and functionality across a broad range of physical symptoms in a highly relevant target group of emerging adults. As part of an easily accessible, digital health-care hub, a most promising area of clinical application could be indicative prevention, which could also help to engage first-time help seekers and lower treatment barriers. IBIs offer some advantages over traditional support including the ability to self-schedule sessions, ease of use, fewer patient costs (e.g., transportation), and increased accessibility. However, beyond the trial context, the uptake rate and impact of internet-delivered interventions remain to be tested under routine care conditions (Baumel et al., 2019) to obtain robust indicators for effectiveness. Since more than half of our participants were at high risk for SSD at baseline and iSOMA had a substantial impact in this subgroup, our intervention could also be a versatile instrument in other health-care contexts. Optimizing treatments seem particularly important for individuals with multi-organ somatic symptom distress, who are less likely to experience symptom improvement and are often significantly impaired (Budtz-Lilly et al., 2015; Jackson & Kroenke, 2008). Eventually, IBIs could be promising as part of a multimodal treatment strategy (Henningsen et al., 2018), for example, to promote early health-directed behavior change in stepped-care approaches (Worm-Smeitink et al., 2019) or boost the limited effects of psychological treatments by reinforcing self-management strategies (Erbe et al., 2017), which could eventually reduce health-care utilization and costs associated with chronic somatic symptom distress (Barsky et al., 2005).

Conclusion

Since emerging adults are often referred to as the nation's capital and an important investment for the future, improving access to and effectiveness of health-care treatment seems crucial. We conclude that iSOMA has the potential to change the course of persistent somatic symptom distress as one of the most significant and undertreated public health problems among emerging adults and may extend prevention and treatment options.

References

American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders (DSM-5)*.

Arnett, J. J., Žukauskienė, R., & Sugimura, K. (2014). The new life stage of emerging adulthood at ages 18–29 years: Implications for mental health. *The Lancet. Psychiatry*, *1*(7), 569–576. https://doi.org/10.1016/S2215-0366(14)00080-7

Auerbach, R. P., Alonso, J., Axinn, W. G., Cuijpers, P., Ebert, D. D., Green, J. G., Hwang, I., Kessler, R. C., Liu, H., Mortier, P., Nock, M. K., Pinder-Amaker, S., Sampson, N. A., Aguilar-Gaxiola, S., Al-Hamzawi, A., Andrade, L. H., Benjet, C., Caldas-de-Almeida, J. M., Demyttenaere, K., … Bruffaerts, R. (2016). Mental disorders among college students in the world health organization world mental health surveys. *Psychological Medicine*, *46*(14), 2955–2970. https://doi.org/10.1017/S0033291716001665

Bailer, J., Schwarz, D., Witthöft, M., Stübinger, C., & Rist, F. (2008). Prävalenz psychischer Syndrome bei Studierenden einer deutschen Universität. *Psychotherapie· Psychosomatik·Medizinische Psychologie*, *58*(11), 423–429. https://doi.org/10.1055/s-2007-986293

Bailer, J., & Witthöft, M. (2014). Deutsches modifiziertes Health Anxiety Inventory (MK-HAI). *Zusammenstellung Sozialwissenschaftlicher Items Und Skalen*. Advance online publication. https://doi.org/10.6102/zis71

Barsky, A. J., Orav, E. J., & Bates, D. W. (2005). Somatization increases medical utilization and costs independent of psychiatric and medical comorbidity. *Archives of General Psychiatry*, *62*(8), 903–910. https://doi.org/10.1001/archpsyc.62.8.903

Baumeister, H., Reichler, L., Munzinger, M., & Lin, J. (2014). The impact of guidance on Internet-based mental health interventions—A systematic review. *Internet Interventions: The Application of Information Technology in Mental and Behavioural Health*, *1*(4), 205–215. https://doi.org/10.1016/j.invent.2014.08.003

Baumel, A., Edan, S., & Kane, J. M. (2019). Is there a trial bias impacting user engagement with unguided e-mental health interventions? A systematic comparison of published reports and real-world usage of the same programs. *Translational Behavioral Medicine*, *9*(6), 1020–1033. https://doi.org/10.1093/tbm/ibz147

Becker, T. D., & Torous, J. B. (2019). Recent developments in digital mental health interventions for college and university students. *Current Treatment Options in Psychiatry*, *6*(3), 210–220. https://doi.org/10.1007/s40501-019-00178-8

Bell, M. L., & Rabe, B. A. (2020). The mixed model for repeated measures for cluster randomized trials: A simulation study investigating bias and type I error with missing continuous data. *Trials*, *21*(1), Article 148. https://doi.org/10.1186/s13063-020-4114-9

Bernardy, K., Klose, P., Welsch, P., & Häuser, W. (2018). Efficacy, acceptability and safety of Internet-delivered psychological therapies for fibromyalgia syndrome: A systematic review and meta-analysis of randomized controlled trials. *European Journal of Pain*. Advance online publication. https://doi.org/10.1002/ejp.1121

Bigal, M. E., Bigal, J. M., Betti, M., Bordini, C. A., & Speciali, J. G. (2001). Evaluation of the impact of migraine and episodic tension-type headache on the quality of life and performance of a university student population. *Headache*, *41*(7), 710–719. https://doi.org/10.1046/j.1526-4610.2001.041007710.x

Boettcher, J., Rozental, A., Andersson, G., & Carlbring, P. (2014). Side effects in Internet-based interventions for social anxiety disorder. *Internet Interventions: The Application of Information Technology in Mental and Behavioural Health*, *1*(1), 3–11. https://doi.org/10.1016/j.invent.2014.02.002

Bonnert, M., Olén, O., Lalouni, M., Benninga, M. A., Bottai, M., Engelbrektsson, J., Hedman, E., Lenhard, F., Melin, B., Simrén, M., Vigerland, S., Serlachius, E., & Ljótsson, B. (2017). Internet-delivered cognitive behavior therapy for adolescents with irritable bowel syndrome: A randomized controlled trial. *The American Journal of Gastroenterology*, *112*(1), 152–162. https://doi.org/10.1038/ajg.2016.503

Boß, L., Lehr, D., Reis, D., Vis, C., Riper, H., Berking, M., & Ebert, D. D. (2016). Reliability and validity of assessing user satisfaction with web-based health interventions. *Journal of Medical Internet Research*, *18*(8), Article e234. https://doi.org/10.2196/jmir.5952

Breslau, J., Lane, M., Sampson, N., & Kessler, R. C. (2008). Mental disorders and subsequent educational attainment in a U.S. national sample. *Journal of Psychiatric Research*, *42*(9), 708–716. https://doi.org/10.1016/j.jpsychires.2008.01.016

Brown, R. J. (2004). Psychological mechanisms of medically unexplained symptoms: An integrative conceptual model. *Psychological Bulletin*, *130*(5), 793–812. https://doi.org/10.1037/0033-2909.130.5.793

Budtz-Lilly, A., Vestergaard, M., Fink, P., Carlsen, A. H., & Rosendal, M. (2015). The prognosis of bodily distress syndrome: A cohort study in primary care. *General Hospital Psychiatry*, *37*(6), 560–566. https://doi.org/10.1016/j.genhosppsych.2015.08.002

Buhrman, M., Gordh, T., & Andersson, G. (2016). Internet interventions for chronic pain including headache: A systematic review. *Internet Interventions: The Application of Information Technology in Mental and Behavioural Health*, *4*, 17–34. https://doi.org/10.1016/j.invent.2015.12.001

Costanian, C., Tamim, H., & Assaad, S. (2015). Prevalence and factors associated with irritable bowel syndrome among university students in Lebanon: Findings from a cross-sectional study. *World Journal of Gastroenterology*, *21*(12), 3628–3635. https://doi.org/10.3748/wjg.v21.i12.3628

Cuijpers, P., Auerbach, R. P., Benjet, C., Bruffaerts, R., Ebert, D., Karyotaki, E., & Kessler, R. C. (2019). Introduction to the special issue: The WHO world mental health international college student (WMH-ICS) initiative. *International Journal of Methods in Psychiatric Research*, *28*(2), Article e1762. https://doi.org/10.1002/mpr.1762

Domhardt, M., Letsch, J., Kybelka, J., Koenigbauer, J., Doebler, P., & Baumeister, H. (2020). Are Internet- and mobile-based interventions effective in adults with diagnosed panic disorder and/or agoraphobia? A systematic review and meta-analysis. *Journal of Affective Disorders*, *276*, 169–182. https://doi.org/10.1016/j.jad.2020.06.059

Dunbar, M. S., Sontag-Padilla, L., Kase, C. A., Seelam, R., & Stein, B. D. (2018). Unmet mental health treatment need and attitudes toward online mental health services among community college students. *Psychiatric Services*, *69*(5), 597–600. https://doi.org/10.1176/appi.ps.201700402

Dworkin, R. H., Turk, D. C., Farrar, J. T., Haythornthwaite, J. A., Jensen, M. P., Katz, N. P., Kerns, R. D., Stucki, G., Allen, R. R., Bellamy, N., Carr, D. B., Chandler, J., Cowan, P., Dionne, R., Galer, B. S., Hertz, S., Jadad, A. R., Kramer, L. D., Manning, D. C., . . . the IMMPACT. (2005). Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain*, *113*(1–2), 9–19. https://doi.org/10.1016/j.pain.2004.09.012

Ebert, D. D., Mortier, P., Kaehlke, F., Bruffaerts, R., Baumeister, H., Auerbach, R. P., Alonso, J., Vilagut, G., Martínez, K. U., Lochner, C., Cuijpers, P., Kuechler, A.-M., Green, J., Hasking, P., Lapsley, C., Sampson, N. A., Kessler, R. C., & the WHO World Mental Health-International College Student Initiative collaborators. (2019). Barriers of mental health treatment utilization among first-year college students: First cross-national results from the WHO world mental health international college student initiative. *International Journal of Methods in Psychiatric Research*, *28*(2), Article e1782. https://doi.org/10.1002/mpr.1782

Eckert, M., Ebert, D. D., Lehr, D., Sieland, B., & Berking, M. (2018). Does SMS-support make a difference? Effectiveness of a two-week online-training to overcome procrastination: A randomized controlled trial. *Frontiers in Psychology*, *9*, Article 1103. https://doi.org/10.3389/fpsyg.2018.01103

Eisenberg, D., Downs, M. F., Golberstein, E., & Zivin, K. (2009). Stigma and help seeking for mental health among college students. *Medical Care Research and Review*, *66*(5), 522–541. https://doi.org/10.1177/1077558709335173

Elhai, J. D., Schweinle, W., & Anderson, S. M. (2008). Reliability and validity of the attitudes toward seeking professional psychological help scale-short form. *Psychiatry Research*, *159*(3), 320–329. https://doi.org/10.1016/j.psychres.2007.04.020

Erbe, D., Eichert, H.-C., Riper, H., & Ebert, D. D. (2017). Blending face-to-face and internet-based interventions for the treatment of mental disorders in adults: Systematic review. *Journal of Medical Internet Research*, *19*(9), Article e306. https://doi.org/10.2196/jmir.6588

Fischer, E. H., & Farina, A. (1995). Attitudes toward seeking professional psychologial help: A shortened form and considerations for research. *Journal of College Student Development*. Advance online publication. https://doi.org/10.3389/fpsyg.2016.00547

Fischer, S., Gaab, J., Ehlert, U., & Nater, U. M. (2013). Prevalence, overlap, and predictors of functional somatic syndromes in a student sample. *International Journal of Behavioral Medicine*, *20*(2), 184–193. https://doi.org/10.1007/s12529-012-9266-x

Furukawa, T. A., Noma, H., Caldwell, D. M., Honyashiki, M., Shinohara, K., Imai, H., Chen, P., Hunot, V., & Churchill, R. (2014). Waiting list may be a nocebo condition in psychotherapy trials: A contribution from network

meta-analysis. *Acta Psychiatrica Scandinavica*, *130*(3), 181–192. https://doi.org/10.1111/acps.12275

Griffiths, K. M., Walker, J., & Batterham, P. J. (2017). Help seeking for social anxiety: A pilot randomised controlled trial. *Digital Health*, *3*, Article 2055207617712047. https://doi.org/10.1177/2055207617712047

Gulewitsch, M. D., Enck, P., Hautzinger, M., & Schlarb, A. A. (2011). Irritable bowel syndrome symptoms among German students: Prevalence, characteristics, and associations to somatic complaints, sleep, quality of life, and childhood abdominal pain. *European Journal of Gastroenterology & Hepatology*, *23*(4), 311–316. https://doi.org/10.1097/MEG.0b013e3283457b1e

Gulewitsch, M. D., Enck, P., Schwille-Kiuntke, J., Weimer, K., & Schlarb, A. A. (2013). Mental strain and chronic stress among university students with symptoms of irritable bowel syndrome. *Gastroenterology Research and Practice*, *2013*, Article 206574. https://doi.org/10.1155/2013/206574

Harrer, M., Adam, S. H., Baumeister, H., Cuijpers, P., Karyotaki, E., Auerbach, R. P., Kessler, R. C., Bruffaerts, R., Berking, M., & Ebert, D. D. (2019). Internet interventions for mental health in university students: A systematic review and meta-analysis. *International Journal of Methods in Psychiatric Research*, *28*(2), Article e1759. https://doi.org/10.1002/mpr.1759

Harrer, M., Apolinário-Hagen, J., Fritsche, L., Drüge, M., Krings, L., Beck, K., Salewski, C., Zarski, A. C., Lehr, D., Baumeister, H., & Ebert, D. D. (2019). Internet-and app-based stress intervention for distance-learning students with depressive symptoms: Protocol of a randomized controlled trial. *Frontiers in Psychiatry*, *10*, Article 361. https://doi.org/10.3389/fpsyt.2019.00361

Hazlett-Stevens, H., Craske, M. G., Mayer, E. A., Chang, L., & Naliboff, B. D. (2003). Prevalence of irritable bowel syndrome among university students: The roles of worry, neuroticism, anxiety sensitivity and visceral anxiety. *Journal of Psychosomatic Research*, *55*(6), 501–505. https://doi.org/10.1016/S0022-3999(03)00019-9

Hedman, E., Axelsson, E., Andersson, E., Lekander, M., & Ljótsson, B. (2016). Exposure-based cognitive-behavioural therapy via the internet and as bibliotherapy for somatic symptom disorder and illness anxiety disorder: Randomised controlled trial. *The British Journal of Psychiatry*, *209*(5), 407–413. https://doi.org/10.1192/bjp.bp.116.181396

Hennemann, S., Böhme, K., Baumeister, H., Bendig, E., Kleinstäuber, M., Ebert, D. D., & Witthöft, M. (2018). Efficacy of a guided internet-based intervention (iSOMA) for somatic symptoms and related distress in university students: Study protocol of a randomised controlled trial. *BMJ Open*, *8*(12), Article e024929. https://doi.org/10.1136/bmjopen-2018-024929

Henningsen, P., Zipfel, S., Sattel, H., & Creed, F. (2018). Management of functional somatic syndromes and bodily distress. *Psychotherapy and Psychosomatics*, *87*(1), 12–31. https://doi.org/10.1159/000484413

Herzog, A., Shedden-Mora, M. C., Jordan, P., & Löwe, B. (2018). Duration of untreated illness in patients with somatoform disorders. *Journal of Psychosomatic Research*, *107*, 1–6. https://doi.org/10.1016/j.jpsychores.2018.01.011

Hesser, H. (2015). Modeling individual differences in randomized experiments using growth models: Recommendations for design, statistical analysis and reporting of results of internet interventions. *Internet interventions*, *2*(2), 110–120. https://doi.org/10.1016/j.invent.2015.02.003

Hinz, A., Ernst, J., Glaesmer, H., Brähler, E., Rauscher, F. G., Petrowski, K., & Kocalevent, R.-D. (2017). Frequency of somatic symptoms in the general population: Normative values for the Patient Health Questionnaire-15 (PHQ-15). *Journal of Psychosomatic Research*, *96*, 27–31. https://doi.org/10.1016/j.jpsychores.2016.12.017

Hüsing, P., Bassler, M., Löwe, B., Koch, S., & Toussaint, A. (2018). Validity and sensitivity to change of the somatic symptom disorder–B Criteria Scale (SSD-12) in a clinical population. *General hospital psychiatry*, *55*, 20–26. https://doi.org/10.1016/j.genhosppsych.2018.08.006

Ilmarinen, J. (2007). The work ability index (WAI). *Occupational medicine*, *57*(2), 160–160. https://doi.org/10.1093/occmed/kqm008

Jackson, J. L., & Kroenke, K. (2008). Prevalence, impact, and prognosis of multisomatoform disorder in primary care: A 5-year follow-up study. *Psychosomatic Medicine*, *70*(4), 430–434. https://doi.org/10.1097/PSY.0b013e31816aa0ee

Jacobson, N. S., & Truax, P. (1991). Clinical significance: A statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting and Clinical Psychology*, *59*(1), 12–19. https://doi.org/10.1037/0022-006X.59.1.12

Janse, A., Worm-Smeitink, M., Bleijenberg, G., Donders, R., & Knoop, H. (2018). Efficacy of web-based cognitive-behavioural therapy for chronic fatigue syndrome: Randomised controlled trial. *The British Journal of Psychiatry*, *212*(2), 112–118. https://doi.org/10.1192/bjp.2017.22

Kählke, F., Berger, T., Schulz, A., Baumeister, H., Berking, M., Auerbach, R. P., Bruffaerts, R., Cuijpers, P., Kessler, R. C., & Ebert, D. D. (2019). Efficacy of an unguided internet-based self-help intervention for social anxiety disorder in university students: A randomized controlled trial. *International Journal of Methods in Psychiatric Research*, *28*(2), Article e1766. https://doi.org/10.1002/mpr.1766

Kleinstäuber, M., Allwang, C., Bailer, J., Berking, M., Brünahl, C., Erkic, M., Gitzen, H., Gollwitzer, M., Gottschalk, J. M., Heider, J., Hermann, A., Lahmann, C., Löwe, B., Martin, A., Rau, J., Schröder, A., Schwabe, J., Schwarz, J., Stark, R., … Rief, W. (2019). Cognitive behaviour therapy complemented with emotion regulation training for patients with persistent physical symptoms: A randomised clinical trial. *Psychotherapy and Psychosomatics*, *88*(5), 287–299. https://doi.org/10.1159/000501621

Kleinstäuber, M., Thomas, P., Witthöft, M., & Hiller, W. (2018). *Kognitive Verhaltenstherapie bei medizinisch unerklärten Körperbeschwerden und somatoformen Störungen* [Cognitive behavioral therapy for medically unexplained physical symptoms and somatoform disorders]. Springer. https://doi.org/10.1007/978-3-662-54664-2

Kleinstäuber, M., Witthöft, M., & Hiller, W. (2011). Efficacy of short-term psychotherapy for multiple medically unexplained physical symptoms: A meta-analysis. *Clinical Psychology Review*, *31*(1), 146–160. https://doi.org/10.1016/j.cpr.2010.09.001

Kocalevent, R.-D., Hinz, A., & Brähler, E. (2013). Standardization of a screening instrument (PHQ-15) for somatization syndromes in the general population. *BMC Psychiatry*, *13*(1), Article 91. https://doi.org/10.1186/1471-244X-13-91

Kroenke, K., & Spitzer, R. L. (2002). The PHQ-9: A new depression diagnostic and severity measure. *Psychiatric Annals*, *32*(9), 509–515. https://doi.org/10.3928/0048-5713-20020901-06

Kroenke, K., Spitzer, R. L., & Williams, J. B. W. (2002). The PHQ-15: Validity of a new measure for evaluating the severity of somatic symptoms. *Psychosomatic Medicine*, *64*(2), 258–266. https://doi.org/10.1097/00006842-200203000-00008

Ladwig, I., Rief, W., & Nestoriuc, Y. (2014). What are the risks and side effects of psychotherapy? Development of an inventory for the assessment of negative effects of psychotherapy (INEP). *Verhaltenstherapie*, *24*(4), 252–263. https://doi.org/10.1159/000367928

Laferton, J. A. C., Stenzel, N. M., Rief, W., Klaus, K., Brähler, E., & Mewes, R. (2017). Screening for DSM-5 somatic symptom disorder: Diagnostic accuracy of self-report measures within a population sample. *Psychosomatic Medicine*, *79*, 974–981. https://doi.org/10.1097/PSY.0000000000000530

Lakens, D. (2013). Calculating and reporting effect sizes to facilitate cumulative science: A practical primer for t-tests and ANOVAs. *Frontiers in Psychology*, *4*, Article 863. https://doi.org/10.3389/fpsyg.2013.00863

Lee, T.-Y., Hsieh, T.-C., Sung, H.-C., & Chen, W.-L. (2019). Internet-delivered cognitive behavior therapy for young taiwanese female nursing students with irritable bowel syndrome-a cluster randomized controlled trial. *International Journal of Environmental Research and Public Health*, *16*(5), Article 708. https://doi.org/10.3390/ijerph16050708

Leiknes, K. A., Finset, A., Moum, T., & Sandanger, I. (2007). Current somatoform disorders in Norway: Prevalence, risk factors and comorbidity with anxiety, depression and musculoskeletal disorders. *Social Psychiatry and Psychiatric Epidemiology*, *42*(9), 698–710. https://doi.org/10.1007/s00127-007-0218-8

Leppink, E. W., Odlaug, B. L., Lust, K., Christenson, G., & Grant, J. E. (2016). The young and the stressed: Stress, impulse control, and health in college students. *Journal of Nervous and Mental Disease*, *204*(12), 931–938. https://doi.org/10.1097/NMD.0000000000000586

Lieb, R., Zimmermann, P., Friis, R. H., Höfler, M., Tholen, S., & Wittchen, H. U. (2002). The natural course of DSM-IV somatoform disorders and syndromes among adolescents and young adults: A prospective-longitudinal community study. *European Psychiatry*, *17*(6), 321–331. https://doi.org/10.1016/S0924-9338(02)00686-7

Liegl, G., Plessen, C. Y., Leitner, A., Boeckle, M., & Pieh, C. (2015). Guided self-help interventions for irritable bowel syndrome: A systematic review and meta-analysis. *European Journal of Gastroenterology & Hepatology*, *27*(10), 1209–1221. https://doi.org/10.1097/MEG.0000000000000428

Lin, J., Paganini, S., Sander, L., Lüking, M., Ebert, D. D., Buhrman, M., Andersson, G., & Baumeister, H. (2017). An internet-based intervention for chronic pain. *Deutsches Ärzteblatt International*, *114*(41), 681–688. https://doi.org/10.3238/arztebl.2017.0681

Ljótsson, B., Hedman, E., Andersson, E., Hesser, H., Lindfors, P., Hursti, T., Rydh, S., Rück, C., Lindefors, N., & Andersson, G. (2011). Internet-delivered exposure-based treatment vs. stress management for irritable bowel syndrome: A randomized trial. *The American Journal of Gastroenterology*, *106*(8), 1481–1491. https://doi.org/10.1038/ajg.2011.139

McCombie, A., Gearry, R., Andrews, J., Mikocka-Walus, A., & Mulder, R. (2015). Computerised cognitive behavioural therapy for psychological distress in patients with physical illnesses: A systematic review. *Journal of Clinical Psychology in Medical Settings*, *22*(1), 20–44. https://doi.org/10.1007/s10880-015-9420-0

Mehta, S., Peynenburg, V. A., & Hadjistavropoulos, H. D. (2019). Internet-delivered cognitive behaviour therapy for chronic health conditions: A systematic review and meta-analysis. *Journal of Behavioral Medicine*, *42*(2), 169–187. https://doi.org/10.1007/s10865-018-9984-x

Mewes, R., Rief, W., Stenzel, N., Glaesmer, H., Martin, A., & Brähler, E. (2009). What is "normal" disability? An investigation of disability in the general population. *Pain*, *142*(1–2), 36–41. https://doi.org/10.1016/j.pain.2008.11.007

Middendorff, E., Apolinarski, B., Becker, K., Bornkessel, P., Brandt, T., Heißenberg, S., & Poskowsky, J. (2017) *Die wirtschaftliche und soziale Lage der Studierenden in Deutschland 2016. 21 Sozialerhebung des Deutschen Studentenwerks durchgeführt vom Deutschen Zentrum für Hochschul- und Wissenschaftsforschung* [The Economic and Social Situation of Students in Germany 2016. 21 Social Survey of the German Student Union conducted by the German Centre for Higher Education Research and Science Studies]. Bundesministerium für Bildung und Forschung. http://www.sozialerhebung.de/download/21/Soz21_hauptbericht.pdf

Mohr, D. C., Cuijpers, P., & Lehman, K. (2011). Supportive accountability: A model for providing human support to enhance adherence to eHealth interventions. *Journal of Medical Internet Research*, *13*(1), Article e30. https://doi.org/10.2196/jmir.1602

Nater, M., Fischer, U., & Ehlert, S. U. (2011). Stress as a pathophysiological factor in functional somatic syndromes. *Current Psychiatry Reviews*, *7*(2), 152–169. https://doi.org/10.2174/157340011796391184

Newby, J. M., Smith, J., Uppal, S., Mason, E., Mahoney, A. E. J., & Andrews, G. (2018). Internet-based cognitive behavioral therapy versus psychoeducation control for illness anxiety disorder and somatic symptom disorder: A randomized controlled trial. *Journal of Consulting and Clinical Psychology*, *86*(1), 89–98. https://doi.org/10.1037/ccp0000248

Petersen, M. W., Schröder, A., Jørgensen, T., Ørnbøl, E., Dantoft, T. M., Eliasen, M., Carstensen, T. W., Falgaard, E. L., & Fink, P. (2020). Prevalence of functional somatic syndromes and bodily distress syndrome in the Danish population: The DanFunD study. *Scandinavian Journal of Public Health*, *48*(5), 567–576. https://doi.org/10.1177/1403494819868592

Rheker, J., Andersson, G., & Weise, C. (2015). The role of "on demand" therapist guidance vs. no support in the treatment of tinnitus via the internet: A randomized controlled trial. *Internet Interventions: The Application of Information Technology in Mental and Behavioural Health*, *2*(2), 189–199. https://doi.org/10.1016/j.invent.2015.03.007

Rief, W., & Broadbent, E. (2007). Explaining medically unexplained symptoms-models and mechanisms. *Clinical Psychology Review*, *27*(7), 821–841. https://doi.org/10.1016/j.cpr.2007.07.005

Rief, W., Burton, C., Frostholm, L., Henningsen, P., Kleinstäuber, M., Kop, W. J., Löwe, B., Martin, A., Malt, U., Rosmalen, J., Schröder, A., Shedden-Mora, M., Toussaint, A., van der Feltz-Cornelis, C., & the EURONET-SOMA Group. (2017). Core outcome domains for clinical trials on somatic symptom disorder, bodily distress disorder, and functional somatic syndromes: European network on somatic symptom disorders recommendations. *Psychosomatic Medicine*, *79*(9), 1008–1015. https://doi.org/10.1097/PSY.0000000000000502

Rief, W., & Hiller, W. (2011) *Somatisierungsstörung (Fortschritte der Psychotherapie Band 1)* [Somatization disorder]. Hogrefe.

Rief, W., & Rojas, G. (2007). Stability of somatoform symptoms—Implications for classification. *Psychosomatic Medicine*, *69*(9), 864–869. https://doi.org/10.1097/PSY.0b013e31815b006e

Schlarb, A. A., Claßen, M., Hellmann, S. M., Vögele, C., & Gulewitsch, M. D. (2017). Sleep and somatic complaints in university students. *Journal of Pain Research*, *10*, 1189–1199. https://doi.org/10.2147/JPR.S125421

Schneider, W., Beisenherz, B., & Freyberger, H. J. (1990). Therapy expectation in different groups of patients with chronic diseases. *Psychotherapy and Psychosomatics*, *54*(1), 1–7. https://doi.org/10.1159/000288370

Spitzer, R. L., Kroenke, K., Williams, J. B. W., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: The GAD-7. *Archives of Internal Medicine*, *166*(10), 1092–1097. https://doi.org/10.1001/archinte.166.10.1092

Tait, R. C., Chibnall, J. T., & Krause, S. (1990). The pain disability index: Psychometric properties. *Pain*, *40*(2), 171–182. https://doi.org/10.1016/0304-3959(90)90068-O

Toussaint, A., Husing, P., Kohlmann, S., & Lowe, B. (2019). Detecting DSM-5 somatic symptom disorder: Criterion validity of the Patient Health Questionnaire-15 (PHQ-15) and the Somatic Symptom Scale-8 (SSS-8) in combination with the Somatic Symptom Disorder - B Criteria Scale (SSD-12). *Psychological Medicine*, *50*(2), 324–333. https://doi.org/10.1017/S003329171900014X

Toussaint, A., Löwe, B., Brähler, E., & Jordan, P. (2017). The Somatic Symptom Disorder-B Criteria Scale (SSD-12): Factorial structure, validity and population-based norms. *Journal of Psychosomatic Research*, *97*, 9–17. https://doi.org/10.1016/j.jpsychores.2017.03.017

Toussaint, A., Murray, A. M., Voigt, K., Herzog, A., Gierk, B., Kroenke, K., Rief, W., Henningsen, P., & Löwe, B. (2016). Development and Validation of the Somatic Symptom Disorder-B Criteria Scale (SSD-12). *Psychosomatic Medicine*, *78*(1), 5–12. https://doi.org/10.1097/PSY.0000000000000240

van Dessel, N., Den Boeft, M., van der Wouden, J. C., Kleinstäuber, M., Leone, S. S., Terluin, B., Numans, M. E., & van Marwijk, H. W. (2015). Non-pharmacological interventions for somatoform disorders and medically unexplained physical symptoms (MUPS) in adults, a Cochrane systematic review. *Journal of Psychosomatic Research*, *78*(6), Article 628. https://doi.org/10.1016/j.jpsychores.2015.03.132

Vugts, M. A. P., Joosen, M. C. W., van der Geer, J. E., Zedlitz, A. M. E. E., & Vrijhoef, H. J. M. (2018). The effectiveness of various computer-based interventions for patients with chronic pain or functional somatic syndromes: A systematic review and meta-analysis. *PLOS ONE*, *13*(5), Article e0196467. https://doi.org/10.1371/journal.pone.0196467

Weise, C., Kaiser, G., Janda, C., Kues, J. N., Andersson, G., Strahler, J., & Kleinstäuber, M. (2019). Internet-based cognitive-behavioural intervention for women with premenstrual dysphoric disorder: A randomized

controlled trial. *Psychotherapy and Psychosomatics*, *88*(1), 16–29. https://doi.org/10.1159/000496237

Weiss, F. D., Mewes, R., Rief, W., & Kleinstäuber, M. (2018). HCU-Q: Entwicklung eines Fragebogens zur Erfassung der Inanspruchnahme medizinischer Gesundheitsleistungen. *Verhaltenstherapie*, *28*(1), 15–24. https://doi.org/10.1159/000478028

Worm-Smeitink, M., Janse, A., van Dam, A., Evers, A., van der Vaart, R., Wensing, M., & Knoop, H. (2019). Internet-based cognitive behavioral therapy in stepped care for chronic fatigue syndrome: Randomized non-inferiority trial. *Journal of Medical Internet Research*, *21*(3), Article e11276. https://doi.org/10.2196/11276

Xi, W., Pennell, M. L., Andridge, R. R., & Paskett, E. D. (2018). Comparison of intent-to-treat analysis strategies for pre-post studies with loss to follow-up. *Contemporary Clinical Trials Communications*, *11*, 20–29. https://doi.org/10.1016/j.conctc.2018.05.008

Xiao, H., Carney, D. M., Youn, S. J., Janis, R. A., Castonguay, L. G., Hayes, J. A., & Locke, B. D. (2017). Are we in crisis? National mental health and treatment trends in college counseling centers. *Psychological Services*, *14*(4), 407–415. https://doi.org/10.1037/ser0000130

Zijlema, W. L., Stolk, R. P., Löwe, B., Rief, W., White, P. D., Rosmalen, J. G. M., & the BioSHaRE. (2013). How to assess common somatic symptoms in large-scale studies: A systematic review of questionnaires. *Journal of Psychosomatic Research*, *74*(6), 459–468. https://doi.org/10.1016/j.jpsychores.2013.03.093

Received March 31, 2021
Revision received December 1, 2021
Accepted December 16, 2021 ■