Worry-specific versus self-tailored internet-based treatments for generalized anxiety disorder, with scheduled support or support on demand: A pilot factorial design trial

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ABSTRACT

Studies suggest that internet-delivered cognitive behaviour therapy (ICBT) can be effective when treating generalized anxiety disorder (GAD). This pilot factorial design study examined the effects of two types of ICBT (worry-specific and self-tailored treatment), and two support types (scheduled weekly support and support on demand), on measures of worry, anxiety, and depressive symptoms. Participants ($N = 85$) were randomized into four treatment groups. Post-treatment measures were completed by 76.5% after eight weeks ($n = 65$). Intention to treat analysis showed significant improvements, with moderate to large within-group effects on the primary outcome measure, Penn State Worry Questionnaire (Cohen's $d = 0.77$–1.43). Minor to large effects on the secondary measures were found in all groups (Cohen's $d = 0.13$–1.66). No significant differences in outcome measures were found between the groups. Receiving scheduled support and self-tailored treatment was rated as more positive than receiving support on demand and the worry-specific program. A limitation is the low number of participants. The pilot results suggest that GAD can be treated with both worry-specific and self-tailored treatments, and that ICBT can be supported both with scheduled and support on demand.

1. Introduction

Generalized anxiety disorder (GAD) is a common anxiety disorder, with an estimated lifetime prevalence of 4.3–5.9% (Tyrer and Baldwin, 2006). In ambulatory and primary care, the prevalence is 8–10%, making GAD one of the most common anxiety disorders in medical settings (Revicki et al., 2012). The disorder is characterized by excessive cognitive worry that is present more days than not and is perceived as difficult to control (American Psychiatric Association, 2013). The worry is accompanied by symptoms such as tension, restlessness, sleep difficulties, and anxiety. GAD affects all areas of life, with high levels of personal suffering and low quality of life (Revicki et al., 2012). It is considered chronic if not treated (Yonkers et al., 2003). Given the frequency of the disorder and its highly negative effects for the individual and society, it is important to develop different evidence-based treatments that can be delivered in a range of settings and in accordance with individual preferences.

Over the past decades, effective internet-delivered treatments have been developed for a range of psychological problems, such as anxiety and depression (Andersson et al., 2019b), as well as somatic conditions, such as headache and tinnitus (Andersson, 2018). Studies suggest that the effects of therapist-guided internet-delivered cognitive behaviour therapy (ICBT) are in line with those of face-to-face treatments based on studies in which participants have been randomized to ICBT of face-to-face treatments (Carlbring et al., 2018). A recent meta-analysis including 20 studies indicated that ICBT for GAD might be effective, with effects sizes of $g = 0.79$ on anxiety measures and $g = 0.75$ on measures of worry compared to control conditions (Eilert et al., 2021). Moderate to large effects were also observed on depressive symptoms, functional impairment and quality of life.

ICBT often focus on a specific diagnosis, with a fixed number of modules given in a specific order. Treatments also often include weekly

support from a clinician (Andersson, 2018). Several previous studies on internet-based treatments for GAD have used this approach resulting in positive effects (Andersson et al., 2012b; Paxling et al., 2011; Robinson et al., 2010; Titov et al., 2009). A possible limitation of treatments that use fixed modules with a focus on one diagnosis is that they may not address comorbid problems (for example insomnia) or suit personal preferences regarding the treatment material. Adapting interventions based on patient preference could have a positive impact on adherence and treatment outcome (Arnkof et al., 2002). In a study on internet-delivered treatments for depression participants were asked to choose between ICBT or internet-delivered psychodynamic therapy (IPDT) and rate how important it was to make this choice as a way to measure the strength of preference (Johansson et al., 2013). In the ICBT group, strength of preference correlated with adherence and outcome, and the authors concluded that strength of preference could have a predictive value in internet-delivered treatments. This is not surprising as there is a literature on treatment preference in randomized trials showing a small but statistically significant effect of getting the preferred treatment (Delevry and Le, 2019).

People with GAD have high rates of comorbid conditions, such as depression and other anxiety disorders (Revicki et al., 2012). These comorbid problems may not be sufficiently targeted in diagnosis-specific treatments even if it known that at least some comorbid problems may decrease when GAD is treated (Newman et al., 2010). Transdiagnostic treatments has been suggested as a possible way to address comorbid concerns by targeting general processes for mental health rather than symptoms associated with a specific diagnosis (Sauer-Zavala et al., 2017). Several studies on transdiagnostic ICBT have included participants with GAD as either the principle or comorbid condition showing positive results (Dear et al., 2015; Johnston et al., 2011; Titov et al., 2010). Another way to address comorbid problems and at the same time incorporate personal preferences is to tailor the treatment. Tailored treatments are based on the assumption that by selecting different treatment materials for different individuals, each treatment can be adapted to suit specific problems and/or preferences and thus improve adherence and outcomes (Carlbring et al., 2011). Treatments can be tailored in two ways: by the psychologists administering them based on the screening results or by the patients themselves based on their own preferences following a description of the treatment component. Another reason to consider choice of treatment components is the observation that some clients may have been in CBT previously, have read self-helps books and may have tried and failed to benefit from a specific CBT technique. Even if they have benefitted they may still prefer to test something different than repeating the same technique again. In an early study by Carlbring et al. (2011) on tailored treatment for anxiety disorders, 54 participants (11 with a GAD diagnosis) were prescribed 6–10 modules over a 10-week treatment period based on a clinical interview and reported preferences. The results showed significant and large within-group effects, as well as moderate between-group effects, compared with the control condition on all measures. In a controlled effectiveness trial including 100 participants (22 had a primary or secondary GAD diagnosis) tailored treatment was tested in a general practice population with anxiety and depressive symptoms (Bergman Nordgren et al., 2014). The treatment was tailored (i.e., type, number, and order of modules) by the researchers based on the initial screening. The mean between-group effect was $d = 0.59$ compared with the control group. Self-tailored treatment (participants were instructed to choose 7 out of 10 possible modules) was evaluated in an open study including 27 participants with mixed anxiety (5 with GAD diagnosis) (Andersson et al., 2011). Large within-group effects were observed on all outcome measures post-treatment. Furthermore, in a meta-analysis including 19 controlled studies on transdiagnostic or tailored ICBT targeting anxiety and depressive symptoms, significant and large combined effects were found on measures of anxiety ($g = 0.82$) and depression ($g = 0.79$) compared with control conditions (Păsărelu et al., 2017). Regarding GAD symptoms, the effects were moderate ($g = 0.58$). There

were no differences between tailored and transdiagnostic treatments.

The addition of clinician support in ICBT has been found improve adherence and outcomes in several studies (see review by Baumeister et al., 2014). However, less is known about the optimal frequency, content, and mode of delivery of the support to have meaningful effects (Hadjistavropoulos et al., 2018). Support on demand has been proposed as a flexible and cost-effective way of delivering support while retaining the positive aspects of a supportive function. In an early controlled trial comparing different support types, participants with social phobia were randomly assigned to treatment with weekly support, support on demand, or pure self-help (Berger et al., 2011). No significant differences in clinical outcomes or dropouts were observed among the three groups. These results are in line with more recent studies (Hadjistavropoulos et al., 2019) indicating that support on demand can be as effective as scheduled support. However, in a study where clients with panic disorder were randomly assigned to a self-help program with scheduled support, support on demand, or a waiting list control group, significant effects on adherence, clinical outcomes, and dropouts were observed in favor of scheduled support Oromendia et al. (2016). In a preference study (Hadjistavropoulos et al., 2019) regarding support type, 78% favored weekly support over support on demand. Clients who preferred weekly support were 2.7 times more likely to have GAD or panic attacks and higher baseline scores. However, no differences in clinical outcomes were observed between the groups.

As a way to further explore the effects of treatment content and support type this pilot randomized factorial design study aimed to compare two types of self-help programs: a worry-specific versus a self-tailored program in which the participants could choose their own treatment components from a range of modules. We also tested the effects of two support types: weekly scheduled support versus support on demand.

2. Methods

2.1. Research design

The research protocol was registered on ClinicalTrials.gov (registration number NCT03807193) and approved by the ethics committee at Linköping University in Sweden (2018/533-31). Informed consent was obtained via an online form that was mandatory in order to gain access to the screening. Since the study aimed to investigate differences between treatments, as well as different support types and possible interaction effects between the variables, a $2 \times 2 \times 2$ factorial design was used with a 1:1:1.1 allocation ratio. A factorial design is an effective way to investigate differences between variables without a traditional waiting list control since each group/contrast has a control condition. Furthermore, the treatments used in the study had already been compared against waiting list controls in previous trials, with positive results. As the trial design would require very large between group effects, or a very large sample for testing interactions, we decided to run the study as a pilot factorial design trial (Eldridge et al., 2016). We did this in order to investigate main effects and test feasibility in terms of treatment outcome based on the two investigated independent variables (treatments and support forms). Results were calculated by comparing pre- and post-measures.

2.2. Recruitment

A site www.iterapi.se/sites/origo/ was created on the treatment platform iterapi.nu (Vlaescu et al., 2016), with information about the study and how to register. Advertisement was done via social media, in a Swedish nationwide newspaper, and on the site studie.nu. After registration, participants were given access to the online questionnaires and the demographic questions for initial screening. Previous studies have shown that it is possible to administer self-report questionnaires online and maintain good psychometric properties (van Ballegooijen et al.,

2016).

Inclusion criteria were: (a) 18 years old or above, (b) screening positive for diagnostic criteria for GAD according to the DSM-5 (not necessarily as the only diagnosis), (c) 45 or more points on Penn State Worry Questionnaire (PSWQ) (Meyer et al., 1990) in order to proceed to the interview, (d) fluent in Swedish, (e) daily access to a computer and the internet, (f) no current substance or alcohol abuse, (g) no active suicide ideation, (h) no current psychotherapeutic treatment, and (i) if using psychiatric medication, a stable dose (no dose adjustments during the previous six weeks or scheduled adjustments in the near future).

After the online screening participants were contacted for further screening through a diagnostic interview or informed that they did not meet the initial criteria for inclusion. The Mini-International Neuropsychiatric Interview (M.I.N.I.) version 7.0.1 (Sheehan et al., 1998) was conducted over telephone by one of six graduate students under the supervision of an experienced clinical psychologist. A final decision regarding inclusion or exclusion was made during the intake meetings. The principal investigator, the first author of this article, and the clinical psychology students involved in the study were present at these meetings. Those excluded were contacted by telephone and informed about the reasons for exclusion and if needed, encouraged to seek help in primary or specialist care. The screening and inclusion period lasted three weeks.

After inclusion, the participants were randomly assigned to one of four groups: I) worry-specific treatment and weekly support, II) worry-specific treatment and support on demand, III) self-tailored treatment and weekly support, or IV) self-tailored treatment and support on demand. An employee at Linköping University who was not involved in the research performed the randomization through an online service.

2.3. Measures

Baseline measures were collected at registration for the study (included in the screening). Post-treatment measures were collected at the end of the treatment after 8 weeks and were similar to the pre-treatment measures. The exception was that we did not administer the alcohol use disorder identification test (AUDIT) (Saunders et al., 1993), added the Negative Effects Questionnaire (NEQ) (Rozental et al., 2016) and questions about experiences of the treatment. A second diagnostic telephone interview was done at post-treatment.

The primary outcome measure was the Penn State Worry Questionnaire (PSWQ) (Meyer et al., 1990). Designed to assess the severity of worry, the questionnaire has shown good psychometric properties and is sensitivity to change, making it the gold standard for evaluating worry. A 45-point cutoff score on the PSWQ was used as an initial inclusion criteria (Behar et al., 2003), based on the rationale that this cutoff gives high sensitivity and specificity in a population seeking help for high levels of worry.

Regarding the secondary outcomes, three additional questionnaires were included to assess GAD symptoms and anxiety. First, we used the Generalized Anxiety Disorder Questionnaire IV (GAD-Q-IV) (Newman et al., 2002) which is designed to capture the presence of a GAD diagnosis according to the Diagnostic and Statistical Manual for Mental Disorders (DSM). Second, the Generalized Anxiety Disorder 7-item scale (GAD-7) is a short questionnaire that assesses worry and anxiety symptoms (Spitzer et al., 2006). Third, the Beck Anxiety Inventory (BAI) assesses the presence of anxiety symptoms (Beck et al., 1988). Two questionnaires targeting depressive symptoms were also included. First, the revised Beck Depression Inventory (BDI-II) which is designed to assess the level of depressive symptoms (Beck et al., 1996). The BAI and the BDI-II are designed to have as little overlap as possible by discriminating between anxiety and depressive symptoms. Second, we used the short Patient Health Questionnaire (PHQ-9) assesses levels of depressive symptoms (Kroenke et al., 2001). In addition to symptom measures, the following questionnaires were used: the Brunnsviken Brief Quality of Life Scale (BBQ) to assess the perceived quality of life (Lindner et al.,

2016), the General Self-Efficacy Scale (GSE) to assess self-efficacy (Löve et al., 2012), and the Acceptance and Action Questionnaire II (AAQ-II) to assess psychological flexibility (Bond et al., 2011). Moreover, the AUDIT was used to initially screen for alcohol consumption (Saunders et al., 1993). Finally, a knowledge test regarding GAD and CBT was created and included (unpublished material), consisting of 22 multiple-choice questions (Cronbach's alpha = 0.65). The following are examples of items: Is anxiety dangerous? Why does a person with GAD worry excessively according to the principles of CBT?

2.4. Participants

Fig. 1 shows a flowchart of the registration, inclusion, randomization, and post-measure completion rates and in Table 1 demographic information is presented. A total of 85 participants were finally included. We were not able to interview all applicants due to limited resources. A majority were female (82.4%) and the mean age was 41.46 years (SD = 14.81). Of the 85 participants, 81 (95.3%) met all the GAD criteria, as a primary or secondary problem, on the M.I.N.I. After the results of the screening measures (PSWQ, GAD-Q-IV, and GAD-7) were evaluated together with the interview, it was decided that four participants who did not meet all criteria in the diagnostic interview would be included as the overall clinical presentation had worry and GAD symptoms as main features. Several participants (65.8%) screened positive for one or more comorbid diagnosis. The most common comorbid diagnosis was a depressive episode (37.6%), followed by social anxiety disorder (27.1%), panic disorder (23.5%), and obsessive-compulsive disorder (11.8%). A majority also had a history of depressive episodes (68.2%).

2.5. Treatments

All materials, measures, and text-based communication were accessed through the study's website (Iterapi.nu). Iterapi.nu is a secure platform that was developed to deliver internet-based questionnaires, treatments, and online communication with a two-factor authentication that has been used for several years in research on internet-based treatments (Vlaescu et al., 2016). Following inclusion, all participants were sent information explaining the treatment and the support type to which they had been randomly assigned. They were instructed to start treatment right away and to work with one of the seven modules per week, with an extra week available if needed.

The two treatments had the same overall structure. They both lasted for eight weeks, comprised seven modules, all accessible from the start, and were accessed through the same treatment platform. The worry-specific treatment is a program (In Swedish called Oroshjälpen), developed to target GAD and high worriers. It is based on acceptance, mindfulness, and valued action strategies. The modules are arranged in a fixed order, building on each other to help the patient get a deeper understanding of worry and how to address the worry trough different techniques. The worry-specific program with weekly support has been evaluated in two previous trials (Dahlin et al., 2016a; Dahlin et al., 2016b), with significant and moderate to large within-group and between-group effects on measures of worry, anxiety, and depressive symptoms. In a small open study the worry-specific program was delivered with support on demand and automated messages. Results showed significant and moderate to large within-group effects at post treatment (Dahlin et al., 2020).

In the self-tailored treatment, the participants were presented with 14 modules, and instructed to select seven modules that they thought would suit them best. The modules were all structured in the same way and included psychoeducation and exercises aimed at the problem that the module addressed. All modules were taken from our research group's previous studies on internet-based treatments. The modules covered topics such as anxiety, worry, depression, sleeping problems, and stress, as well as specific techniques, such as cognitive restructuring,
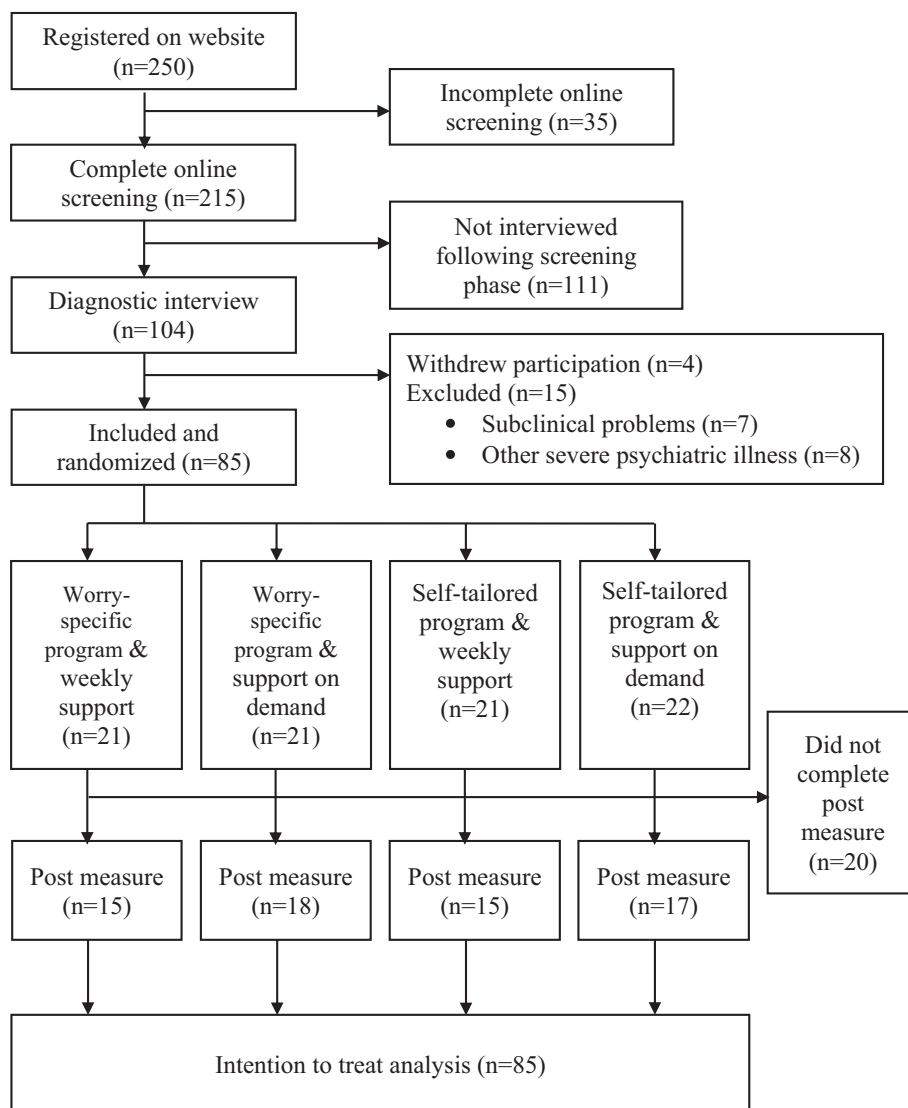
Fig. 1. Flowchart showing registration, inclusion, randomization, post measure, and data analysis.

mindfulness, acceptance, relaxation, and relapse prevention. The participants were encouraged to include the introduction module, as well as the relapse prevention module, but could choose not to do so.

2.6. Support

Four M.Sc. clinical psychology students, in their last term of a five year clinical program, provided the support under the supervision of an experienced clinical psychologist. The team could also contact a psychiatrist if needed. Two support types were included in the study: scheduled weekly and on demand. In the weekly support, participants were instructed to send a report of their work each week and received feedback within 48 h. They could ask questions at other times as well. The supporting psychology students were instructed to keep the work with each patient within 15 min per week and to contact the participant if no report was sent at the end of the week. The participants in the support on demand condition were instructed to go through the treatment on their own and to contact the support if they needed help or clarifications in any way. The support guidelines for both conditions stated that the messages should be short, focused on problem-solving difficulties and questions about the treatment. The supporters were also instructed to use validation and give positive feedback on the work, and when possible, to refer to the information in the treatment modules

rather than to add extra information outside the modules.

2.7. Statistical analyses

One-way ANOVAs were used to examine group differences on the pre-treatment measures. Chi square tests were used to investigate differences in demographic characteristics and post-measure completion. Repeated-measures ANOVAs were used to investigate within-group effects pre-post, as well main effects of treatment condition and the support form. Finally, interaction effects were examined. The study had sufficient statistical power to detect moderate effects ($d = 0.50$) for the main effects/contrasts, given 80% power and a 5% alpha level. However, the power for the interaction effects and for the small between-group effects was limited, which was expected as all four conditions were active. We also did not consider non-inferiority, which would have required a much larger sample. Even if pilot trials can be conducted without considering statistical power and hypothesis testing (Eldridge et al., 2016), treatment outcomes will be presented even if they should be interpreted with caution. In addition, formal hypothesis testing of treatment outcomes can serve as an indicator for future trials. Multiple imputation, as implemented in SPSS, was used to handle missing data. We checked the data and decided that the missing-at-random (MAR) condition would apply. Following Schafer and Graham's (2002)

Table 1
Demographical characteristics of included participants.

		Worry-specific program & weekly support	Worry-specific program & support on demand	Self-tailored program & weekly support	Self-tailored program & support on demand	Total
		(n = 21)	(n = 21)	(n = 21)	(n = 22)	(n = 85)
Gender	Female	18 (85.7%)	17 (81%)	15 (71.4%)	20 (91%)	70 (82.4%)
	Male	3 (14.3%)	4 (19%)	6 (28.6%)	2 (9%)	15 (17.6%)
Age	Mean	41.48	39.19	46.0	39.27	41.46
	SD	17.02	13.55	14.15	14.31	14.81
Marital status	Single	5 (23.8%)	6 (28.6%)	5 (23.8%)	4 (18.2%)	20 (23.5%)
	Married	7 (33.3%)	7 (33.3%)	3 (14.3%)	10 (45.5%)	27 (31.8%)
	Cohabiting	8 (38.1%)	7 (33.3%)	11 (52.4%)	8 (36.4%)	34 (40%)
	Other	1 (4.8%)	1 (4.8%)	2 (9.5%)	0 (0%)	4 (4.7%)
Highest Education	Elementary school	0 (0%)	0 (0%)	1 (4.8%)	1 (4.5%)	2 (2.4%)
	Upper secondary school	5 (23.8%)	3 (14.3%)	3 (14.3%)	2 (9.1%)	13 (15.3%)
	University	15 (71.4%)	17 (80.9%)	14 (66.6%)	18 (81.8%)	64 (75.2%)
	Other	1 (4.8%)	1 (4.8%)	3 (14.3%)	1 (4.5%)	6 (7.1%)
Occupation	Student	4 (19%)	4 (19%)	1 (4.8%)	3 (13.6%)	12 (14.1%)
	Working	12 (57.1%)	14 (66.7%)	14 (66.7%)	13 (59.1%)	53 (62.4%)
	Unemployed	1 (4.8%)	1 (4.8%)	1 (4.8%)	0 (0%)	3 (3.5%)
	Other	4 (19.0%)	2 (9.5%)	5 (23.8%)	6 (27.3%)	17 (20.0%)
Diagnosis	1 diagnosis	6 (28.6%)	7 (33.3%)	7 (33.3%)	9 (40.1%)	29 (34.1%)
	2 diagnoses	8 (38.1%)	7 (33.3%)	7 (33.3%)	10 (45.5%)	32 (37.6%)
	3 diagnoses	6 (28.6%)	6 (28.6%)	4 (19.0%)	3 (13.6%)	19 (22.4%)
	4 diagnoses	1 (4.8%)	0 (0%)	3 (14.3%)	0 (0%)	4 (4.7%)
	5 diagnoses	0 (0%)	1 (4.8%)	0 (0%)	0 (0%)	1 (1.2%)
Psychotropics	Never	15 (71.4%)	14 (66.7%)	13 (61.9%)	9 (40.9%)	51 (60%)
	Previous	1 (4.8%)	3 (14.3%)	3 (14.3%)	5 (22.7%)	12 (14.1%)
	Current	5 (23.8%)	4 (19%)	5 (23.8%)	8 (36.4%)	22 (25.9%)
Previous therapy	No	4 (19%)	6 (28.6%)	7 (33.3%)	8 (36.4%)	25 (29.4%)
	Yes	17 (81%)	15 (71.4%)	14 (66.7%)	14 (63.6%)	60 (70.6%)

recommendation, 20 imputations were made, and the pooled results were used in the repeated-measure ANOVAs. Within-group effect sizes were calculated using Cohen's d by subtracting the average score on the pre-treatment measure from the average score on the post-treatment measure and dividing the result with the pooled standard deviation.

2.8. Clinical significance and reliable change

Clinical significance was assessed using Jacobson and Truax (1991) approach. Based on Fisher's calculation (Fisher, 2006), reliable change was set at seven points or more, and a score of 47 points or less on the PSWQ was required as well.

3. Results

3.1. Enrollment, baseline characteristics and attrition

The study included 85 participants. Demographical data is presented in Table 1. No significant differences on the pre-treatment measures or demographic variables between the groups were observed (all $ps >$ 0.05). Post-treatment measures were answered by 65 participants (76.5%), with no significant difference in completion between the four groups, χ^2 (3, $N = 85$) = 1.60, $p = .66$. However, there was a significant difference on the BAI scores between completers and non-completers, F

(1,83) = 5.31, $p = .024$. The non-completers mean score on the BAI at pre-treatment was 25.95 (SD = 10.85) versus the completers mean score of 21.05 (SD = 7.41). There was also a significant difference in the use of psychotropic medication, χ^2 (2) = 7.94, $p = .019$, with, 50% among the non-completers compared with 18.5% among the completers using psychotropic medication.

3.2. Primary outcome measure

Repeated-measure ANOVA on the PSWQ showed a significant within-group effects of time, $F(1,81) = 127.47$, $p < .0001$, $\eta_p^2 = 0.608$, but no significant effects of treatment format, support type, or any interaction between treatment and support, as seen in Table 2. Within-group effects (Cohen's d) in the four groups were: $d = 1.43$ (CI 95% = 0.99–1.86) for the worry-specific program with weekly support, $d = 0.86$ (CI 95% = 0.51–1.21) for the worry-specific program with support on demand, $d = 0.77$ (CI 95% = 0.42–1.11) for self-tailored treatment with weekly support, and $d = 0.95$ (CI 95% = 0.60–1.31) for the self-tailored program with support on demand. Within-group effects were $d = 1.28$ (CI 95% = 1.08–1.49) for the whole sample ($n = 42$) who received the worry-specific program and $d = 1.00$ (CI 95% = 0.52–1.00) in the self-tailored treatment group ($n = 43$). Within-group effects were $d = 1.22$ (CI 95% = 0.93–1.50) for the whole sample in the weekly support condition (n = 42), and $d = 0.80$ (CI 95% = 0.56–1.04) in the

Table 2
Treatment effects in the whole sample (n = 85).

	Time	Treatment	Support	Treatment * support
PSWQ				
df	1, 81	1, 81	1, 81	1, 81
F	127.47***	0.12*	0.12	0.88
η_p^2	0.608	0.002	0.002	0.010
GAD-7				
df	1, 81	1, 81	1, 81	1, 81
F	80.12***	0.48	0.40	1.21
η_p^2	0.494	0.006	0.012	0.015
GAD-Q-IV				
df	1, 81	1, 81	1, 81	1, 81
F	43.94***	1.54	1.25	1.28
η_p^2	0.350	0.019	0.015	0.016
BAI				
df	1, 81	1, 81	1, 81	1, 81
F	110.31***	2.02	0.04	0.48
η_p^2	0.574	0.043	0.000	0.006
BDI-II				
df	1, 81	1, 81	1, 81	1, 81
F	84.46***	1.05	0.13	4.14
η_p^2	0.507	0.022	0.001	0.067
PHQ-9				
df	1, 81	1, 81	1, 81	1, 81
F	73.15***	1.74	0.43	1.89
η_p^2	0.473	0.021	0.005	0.023
AAQ-II				
df	1, 81	1, 81	1, 81	1, 81
F	20.52***	1.14	0.49	0.24
η_p^2	0.199	0.014	0.006	0.003
BBQ				
df	1, 81	1, 81	1, 81	1,81
F	22.68***	0.11	0.35	0.27
η_p^2	0.217	0.001	0.004	0.003
GSE				
df	1.81	1,81	1,81	1,81
F	12.31**	0.81	0.24	2.55
η_p^2	0.129	0.009	0.003	0.031
Knowledge				
df	1, 81	1, 81	1,81	1,81
F	22.11***	1.92	0.51	0.29
η_p^2	0.213	0.023	0.006	0.003

PSWQ = Penn State Worry Questionnaire; GAD-Q-IV = Generalized Anxiety Disorder Questionnaire-IV; GAD-7 = Generalized Anxiety Disorder 7-item scale; BAI = Beck Anxiety Inventory; BDI-II = Beck Depression Inventory-II; PHQ-9 = Patient Health Questionnaire-9; AAQ-II = Acceptance and Action Questionnaire; BBQ = Brunnsviken Brief Quality of Life Scale.

_* $p \leq 0.05$.
_{**} $p \leq 0.01$.
_{***} $p \leq 0.001$.

support on demand condition (n = 43). The between-group difference for support type was $d = 0.14$, in favor of weekly support over on the support on demand condition. The between-group effect for treatment was small and insignificant $d = 0.10$, in favor of the worry-specific program over the self-tailored treatment. Treatment effects for the whole sample are presented in Table 2 and effect sizes are presented in Table 3.

Reliable change was defined as an improvement or a deterioration of 7 points or more on the PSWQ from pre- to post-treatment. Of the 65

participants who completed the post-treatment 40 (61.5%) demonstrated a reliable change, and no participant showed a deterioration. Considering intention to treat with dropouts regarded as not improving 47% made a reliable change. Recovery was defined as making a reliable change and having a score less than 47 points on the PSWQ. Overall, 17 (26.2%) of the 65 participants met this criterion. It is important to note that initial screening criteria for moving on to the telephone interview was only 45 points. However this was not the only inclusion criteria and was in retrospect too low as none of the included participants had such low entry score with the lowest score being 49 (and 72% having a pretreatment score above 60 points). Considering intention to treat and assuming that the dropouts all were non-responders the corresponding figure would be 20%. There was no significant difference between the two treatments including dropouts as non-improved, χ^2 (1, $N = 85$) = 75, $p = .38$, or the two support types, χ^2 (1, $N = 85$) = 1.98, $p = .16$, in recovery rates. The observed recovery rates were 7/21 in the worry-specific program with weekly support, 4/22 in self-tailored treatment with support on demand, 3/21 in the worry-specific program with support on demand, and 3/21 in self-tailored treatment with weekly support.

3.3. Secondary outcome measures

Repeated-measure ANOVA showed significant within-group effects of time on all secondary measures as seen in Table 2. No significant effects of treatment format, support type, or interactions between treatment and support were observed (see Table 2). Within-group effects (Cohen's d) ranged from very small (0.13) to large (1.66) (See Table 3). Effect sizes were generally largest for the worry-specific program with weekly support, followed by the worry-specific program with support on demand and self-tailored treatment with weekly support. Self-tailored treatment with support on demand showed the smallest effects.

3.4. Clinical interviews

Of the 85 participants, 58 completed the post-treatment diagnostic interview. After treatment, 10 (17.2%) of the 58 participants still met the GAD criteria. Assuming intention to treat with dropouts regarded as still having GAD percentages would increase (44%). Including all participants there was no significant difference between the type of treatment received, χ^2 (1, $N = 85$) = 0.75, $p = .37$, and no difference regarding support type, χ^2 (1, $N = 85$) = 1.98, $p = .16$. Of the 10 participants who still fulfilled the GAD criteria, 5 had gone through a self-tailored treatment with the support-on-demand condition, 3 received the self-tailored treatment with scheduled support, 2 participated in the worry-specific program with support on demand, and none the worry-specific program with scheduled support. Furthermore, 3 participants (5.2%) met the criteria for a current depressive episode, with 2 in the worry-specific program with the support-on-demand condition and 1 in self-tailored treatment with weekly support. A clinical rating of improvement, based on the Clinical Global Impression – Improvement Scale (CGI-I; Guy, 1976) was done in association with the interview. The seven-point scale was later converted into three categories: improved, no change, or worse. Of the 58 participants completing the post treatment interview, 48 (82.7%) were rated as improved, 7 (12.1%) as no change, and 3 (5.2%) as worse. If using intention to treat, and dropouts rated as no change, the ratings are: 56.5% improved, 40% as no change, and 3,5% worse. With dropouts rated as showing no change there was no significant difference between the four groups, $\chi^2(6) = 4.65$, $p = .59$.

3.5. Selection of modules

In the self-tailored treatment participants were asked to select 7 of 14 possible modules. They were strongly encouraged to select the introduction module and the final relapse prevention module. All participants selected the first module, and all but one the relapse prevention

Table 3

Means and standard deviation on pre and post measures (intention to treat analysis, $n = 85$) and within group effects (Cohen's d).

	Worry-specific program & weekly support ($n = 21$)		Worry-specific program & support on demand ($n = 21$)		Self-tailored program & weekly support ($n = 21$)		Self-tailored program & support on demand ($n = 22$)	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
PSWQ								
Mean	63.90	52.57	63.10	56.25	63.90	55.94	62.45	54.64
SD	5.17	8.33	6.43	8.50	6.48	10.80	5.04	9.42
Cohen's d		1.43		0.86		0.77		0.95
GAD-7								
Mean	11.57	4.72	10.76	6.36	10.95	6.04	8.41	6.14
SD	5.25	2.98	4.21	3.97	4.27	4.06	3.67	4.93
Cohen's d		1.66		1.08		1.18		0.53
GAD-Q-IV								
Mean	9.53	6.47	9.26	6.77	8.87	7.02	7.40	6.19
SD	2.52	2.72	2.41	2.98	2.71	2.95	3.05	3.08
Cohen's d		1.17		0.92		0.65		0.39
BAI								
Mean	24.29	11.78	24.10	13.73	21.19	12.75	19.36	12.55
SD	9.33	6.06	8.87	8.09	7.53	6.45	7.87	7.67
Cohen's d		1.63		1.22		1.21		0.88
BDI-II								
Mean	20.62	7.33	21.76	13.18	19.48	11.78	16.09	9.22
SD	11.53	6.23	7.73	8.74	9.32	9.67	5.63	8.45
Cohen's d		1.50		1.04		0.81		0.98
PHQ-9								
Mean	11.14	4.79	12.29	6.86	10.33	5.68	8.77	6.02
SD	5.62	3.17	5.33	5.11	4.29	4.08	4.26	4.04
Cohen's d		1.44		1.04		1.11		0.66
AAQ-II								
Mean	30.95	26.58	30.86	25.94	28.62	27.09	28.18	24.86
SD	6.82	5.44	7.23	8.83	7.20	7.17	7.09	7.49
Cohen's d		0.69		0.61		0.22		0.46
BBQ								
Mean	44.24	51.93	39.48	49.73	40.90	50.55	42.36	48.67
SD	19.81	18.97	19.90	19.17	19.64	19.55	17.11	16.81
Cohen's d		−0.40		−0.52		−0.49		−0.38
GSE								
Mean	25.38	28.11	23.95	26.42	22.38	24.77	25.68	26.51
SD	6.89	5.64	6.05	5.90	7.22	7.05	6.34	6.75
Cohen's d		−0.44		−0.41		−0.33		−0.13
Knowledge								
Mean	15.81	17.29	16.14	17.15	16.10	17.91	16.95	18.17
SD	3.11	2.56	2.57	2.59	3.66	2.39	2.30	1.73
Cohen's d		−0.52		−0.39		−0.60		−0.61

PSWQ = Penn State Worry Questionnaire; GAD-Q-IV = Generalized Anxiety Disorder Questionnaire-IV; GAD-7 = Generalized Anxiety Disorder 7-item scale; BAI = Beck Anxiety Inventory; BDI-II = Beck Depression Inventory-II; PHQ-9 = Patient Health Questionnaire-9; AAQ-II = Acceptance and Action Questionnaire; BBQ = Brunnsviken Brief Quality of Life Scale.

module. Fig. 2 shows the frequency of the selected modules, except for the two recommended ones.

3.6. Adherence to treatment

There was a significant difference in rates of completing the whole treatment, in favor of the worry-specific program with scheduled support, $\chi^2(3) = 9.41$, $p = .024$. In the worry-specific program with scheduled support, 12 (80.0%) of the 15 participants finished all modules compared with 10 (55.6%) of 18 in the worry-specific program with

support on demand 4 (26.7%) of 15 in the self-tailored treatment with scheduled support, and 7 (41.2%) of 17 in the self-tailored treatment with support on demand. The difference in average module completion between the four groups did not reach statistical significance, $F(3,61) = 2.73$, $p = .051$. Post-hoc tests showed a significant difference in the average module completion between the worry-specific program group with weekly support and the self-tailored treatment group with support on demand, in favor of the first ($p = .047$), but not between any other groups. Table 4 presents the percentage of modules completion during treatment period.
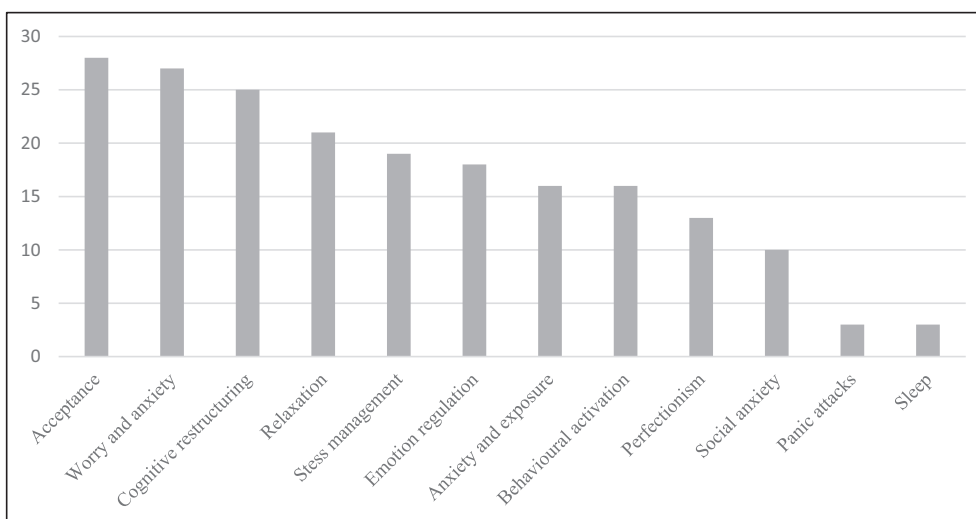
Fig. 2. Frequency of module selection (with the exception of the introduction and relapse prevention modules that were obligatory) in the self-tailored condition (*n* = 43).

Table 4
Overall number and percentage of participants completing treatment modules (*n* = 65).[a]

	n	(Percentage)
Module 1	64	(98.5%)
Module 2	63	(96.9%)
Module 3	57	(87.7%)
Module 4	53	(81.5%)
Module 5	51	(78.5%)
Module 6	41	(63.1%)
Module 7	33	(50.8%)

[a] One completed zero modules.

3.7. Time spent on providing support

The average time spent on providing support to the participants receiving support on demand was 5.6 (SD = 3.54) minutes per participant versus 59.9 (SD = 8.0) minutes in the scheduled support condition.

3.8. Adverse events

No participant showed a reliable deterioration, rated as a negative change of seven or more points on the PSWQ compared with the pre-treatment score. However, some reported negative experiences on the NEQ. In the worry-specific program with weekly support, 10 (66.7%) of the 15 participants who completed the post-treatment measures reported at least one minor negative experiences associated with the treatment, M = 1.53 (range: 1–5, SD = 1.50), compared with 9 (50%) of the 18 participants in the worry-specific program with support on demand group, M = 1.17 (range: 1–6, SD = 1.65), 9 (60%) of the 15 participants of the self-tailored program with weekly support, M = 1.40 (range: 1–5, SD = 1.60), and 10 (41.2%) of the 17 participants of the self-tailored program with support on demand, M = 1.59 (range: 1–4, SD = 2.70). The most frequently reported negative experiences were as follows: 31 occurrences of stress (47.7%), 20 occurrences of unpleasant memories (30.8%), 16 occurrences of more anxiety (24.6%), 16 occurrences of reporting not understanding the treatment (24.6%), and 14 occurrences of and unpleasant feelings (21.5%). There were no significant differences in the frequency or type of negative experiences between the groups (all *ps* > 0.09).

3.9. Participants' evaluation of the treatment

At post-treatment, the participants were asked to rate how satisfied they were with the treatment. Overall, 59 (90.8%) of the 65 completers were satisfied or very satisfied with the treatment. No participant in worry-specific condition with scheduled support was unsatisfied. In the worry-specific program with support on demand, 2 (11.1%) were unsatisfied, compared with 1 (6.7%) in the self-tailored program with weekly support and 3 (17.6%) in the self-tailored program with support on demand. No participant reported being very unsatisfied.

The four groups showed a significant difference in their satisfaction with the treatment as a whole, $F(3,61) = 3.12$, $p = .032$. Further analysis showed that it was an effect of the type of support received, $F(3,61) = 9.56$, $p = .03$, in favor of weekly support, but there was no significant effect of treatment program, $F(3,61) = 0.62.12$, $p = .80$. The four groups showed a significant difference in their satisfaction with the treatment program $F(3,61) = 5.82$, $p = .001$. Further analysis showed that the support type, $F(3,61) = 11.19$, $p = .001$, in favor of weekly support, and the type of treatment program, $F(3,61) = 4.16$, $p = .046$, in favor of self-tailored treatment, had significant effects on the positive evaluation of the treatment program. The four groups showed a significant difference in their satisfaction with support, $F(3,61) = 7.31$, $p = .0001$. Further analysis showed that it was an effect of the support type, $F(3,61) = 22.36$, $p = .0001$, in favor of weekly support, and there was no significant effect of the treatment program, $F(3,61) = 0.003$, $p = .96$.

4. Discussion

The aim of the pilot RCT study was to compare two treatment programs for GAD: worry-specific versus self-tailored, as well as two support types: weekly versus on demand. Of the 85 participants, 65 (76.5%) completed post-treatment measures, and 58 (68.2%) the post-treatment clinical interview. This dropout rate is somewhat larger than in our previous controlled GAD trial on the worry-specific program (Dahlin et al., 2016a), in which 80.8% of the treatment group completed the measures. Overall, the findings are in line with the dropout rate reported in previous ICBT research (Melville et al., 2010). Both treatments resulted in significant within-group effects, with moderate to large effect sizes on the primary measure PSWQ across the four groups (*d* = 0.92–1.69). Significant effects on the secondary measures of GAD, anxiety, and depressive symptoms were also found (range of effect sizes: *d* = 0.39–1.66). These effects are in the same range as effects reported in other trials on ICBT for GAD. No significant between-group effects on

symptoms measures were observed, indicating that worry-specific and self-tailored programs both can be effective, and that scheduled support can be as effective as support on demand (Hadjistavropoulos et al., 2019). However, we do not claim non-inferiority, which would have required a much larger study sample. Bearing in mind the limited sample and consequently, the limited statistical power, it is possible that the worry-specific program with scheduled support would have yielded significantly greater effect sizes on the primary measure and several secondary measures. That group also had a significantly higher completion rate, although the participants evaluated the self-tailored treatment more positively. While not statistically significant the findings indicate that despite the ability to choose treatment components, which was evaluated positively, the addition of optional support might increase the risk of non-adherence. It is also possible that this freedom could trigger more anxiety and worry in a population that is already driven by worry. As mentioned in the introduction, the preference study by (Hadjistavropoulos et al., 2019) indicated that participants with GAD were more likely to choose weekly support over support on demand. While we did not document significant differences between the two treatments, the worry-specific program appeared to work well with support on demand. Likewise, self-tailored treatment with scheduled support also worked. Regarding clinical implications, this could indicate that a pre-determined structure is associated with better outcomes and that self-tailored treatment and support on demand might be too unstructured for persons with GAD. Only a larger study could provide answers to these questions.

Small to medium effects on quality of life, psychological flexibility, and self-efficacy, as well as knowledge about GAD and its treatment, were found in all groups (range: $d = 0.13–0.69$). This indicates that the treatments might lead to improvement in psychological flexibility and self-efficacy which are important aspects for managing problems on your own. Some ICBT studies have found increased knowledge following ICBT (Andersson et al., 2012a; Berg et al., 2019; Strandskov et al., 2017), but as far as we know, no previous study has documented improved knowledge when treating GAD. Some studies have reported improvements in the quality of life but not consistently (Hofmann et al., 2014). Based on the primary outcome measure PSWQ, 61.5% of the completers made a reliable change, and 26.2% were rated as recovered. These findings largely correspond to those of a recent individual patient data meta-analysis on ICBT studies ($N = 2866$), with comparable figures of 65.6% showing reliable change and 35.0% demonstrating recovery (Andersson et al., 2019a). Compared with the other groups, twice as many in the worry-specific program with scheduled support group were rated as recovered. At the post-treatment measure, 17.2% of the sample still met the GAD criteria, with a significant difference between the two treatment types, and in worry-specific program with scheduled support group there were no GAD cases. Significant differences were also noted in rates of treatment completion, in favor of the worry-specific program with scheduled support group. Overall, treatment satisfaction was high (90.8%), with some significant differences in satisfaction in relation to treatment and support type. Receiving weekly support had significant positive effects on the evaluation of the treatment as a whole, the treatment program, and satisfaction with support. Furthermore, self-tailored treatment was evaluated more positively than the worry-specific program. These results support the idea of including patients in decisions about treatment delivery even if it might not affect outcomes.

Several limitations should be considered when interpreting the results. First, the small number of participants resulted in low statistical power when examining possible contrasts among the four groups or the interactions between the two modalities. A related problem concerns measurement points as we only measured pre- to post-differences. This has implications for the imputation model used and also restricted our ability to use alternative ways to analyze the data such as mixed models. The limited number of participants in each condition was partly an effect of the need to stay within the study's time frame and of the research group's limited available staff. Obviously, a much larger sample would have been preferable as we tested two active interventions and included two support forms. However, this pilot study indicates that at least no large differences exist between a worry-specific program and a self-selected tailored program, even if non-inferiority cannot be established. Concerning the support form, more research is needed, and the study is inconclusive regarding the possible interactions between the treatment form and the support form. Second, a majority of the sample had attended university and were working or studying, indicating that they are not representative of a clinical GAD population in terms of education and possibly computer literacy. However, a large proportion had comorbid conditions, suggesting their representativeness at least in terms of clinical presentation. Third, the study did not include a long-term follow-up. Given the nature of GAD, with periods of better functioning, a long-term follow-up could help answer the important question of clinical effect maintenance. In our previous controlled study on the worry-specific program (Dahlin et al., 2016a), clinical effects were maintained in the six-month follow-up, indicating that the worry-specific program can lead to sustained change.

Despite these limitations, the results indicate that internet-based treatments for GAD yield positive effects and both disorder-specific and self-tailored treatment programs might work as well as different support types. Future research could examine the effects in clinically representative settings as it cannot be taken for granted that the treatments and support forms would yield the same outcomes in regular clinics. Previous ICBT research suggests that the results are valid in clinical settings, but this has not been sufficiently documented with regard to self-selected treatment and support on demand, which arguably require more client responsibility.

Declaration of competing interest

The main author (MD) is employed by the private company that has developed the worry-specific treatment program (Oroshjälpen). No other authors have any conflict of interest. To minimize the risk of biased interpretation and reporting of the findings, all results have been analyzed in cooperation between the main author and the professor responsible for the research (GA).

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