MSc in Clinical Psychology
Department of Psychology

Improving Adherence to a Web-Based Cognitive-Behavioural Therapy Program for Social Anxiety with Group Sessions: Randomised Control Trial

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Foreword

Growing up as a shy child meant that experiencing anxiety in social settings was a feeling I knew quite well. While shyness was something I eventually grew out of, my interest in social anxiety only increased, most notably once I wrote my bachelor's thesis on questionnaires measuring the effects of social anxiety. Seeing the devastating effects the disorder has on the individuals' lives, motivated me to want to be instrumental in helping this group.

When Dr. Fjóla Helgadóttir came to my university and presented her program, Overcome Social Anxiety, she explained that the web-based treatment program had been proven to greatly decrease users' social anxiety symptoms and, instantly, I was extremely interested. After being told that the main problem at hand with these types of programs was high dropout rates, Dr. Fjóla Helgadóttir and I wanted to see if there was a way to increase treatment adherence and give users/participants a better chance at recovery.

My hope is that this study will spark further interest in other researchers to find ways to make web-based programs – for all different mental disorders – more effective, by increasing adherence to them.

Recently there has been a shift of professional interactions going online, due to COVID restrictions, and I firmly believe that these changes will cause web-based treatment programs to increase in popularity even more. If it is possible to find a way to motivate the users to complete their treatments, the rewards for them (and for therapists) will make the efforts worth it.

This study was done as a part of my master's degree in clinical psychology at Reykjavík University. It was a four-semester project, with the bulk of the dissertation writing done during the first two semesters and the study itself and the statistical analysis during the second two. Since my aim is to submit this dissertation to the Journal of Medical Internet Research, I wrote it in accordance with their instructions for authors.

Dr. Fjóla Helgadóttir and Ross Menzies designed this study, while I executed it. I held the group sessions, analysed the data, and wrote this dissertation. Dr. Fjóla Helgadóttir guided me throughout the writing process and once completed, Magnús Blöndahl made sure the dissertation was in line with the university's standards.

I would like to thank all my co-authors, since without them this dissertation would not have become a reality, my mother-in-law for proofreading the dissertation and my patient partner Nicolas for supporting me when things were not going to plan. Finally, I'm grateful to my parents and brother, for supporting me through everything I do.

Abstract

Background: Untreated social anxiety disorder (SAD) often leads to the development of other serious mental health conditions. Individuals with social anxiety rarely seek treatment and when they do, they commonly receive non-evidence based, and ineffective treatments. Cognitive behaviour therapy (CBT) has been demonstrated to be the best treatment technique to treat social anxiety. Web-based CBT programs can be guaranteed to adhere to evidence-based treatment procedures. The main issue with scalable web-based treatment is low treatment adherence.
Objective: The aim of this study was to test whether adding group sessions to a fully automated web-based CBT program for social anxiety, Overcome Social Anxiety (OSA), would increase treatment adherence.
Method: Potential participants applied to the study by answering an online eligibility questionnaire and SIAS, BFNE and QOLS. 69 participants were accepted, randomly divided into three equally sized groups, and given a four-month access to the OSA program. The program is seven modules in total. There were three different group conditions: experimental condition where participants additionally got three 45-minute online group sessions covering social anxiety specific psychoeducation; placebo condition where participants additionally got three 45 minutes of led progressive muscle relaxation group sessions; and control condition where participants did not get group sessions. Participants in the experimental and placebo conditions were asked to complete a certain amount of treatment modules before each group session. After the study ended, participants were again asked to answer SIAS, BFNE and QOLS. Adherence was measured by modules completed and efficacy by change in pre to post questionnaire scores.
Results: Treatment adherence significantly differed between the conditions $F(2,43)=5.06$, $p=.011$, $\eta^2=.19$ at $p<.05$. On average, participants assigned to the placebo condition completed a significantly bigger portion of the program ($M=4.75$, $SD=2.70$, 95% $CI=3.03 – 6.47$) compared to those in the control condition ($M=1.83$, $SD=2.62$, 95% $CI=0.69 – 2.96$) at $p<.05$. At $p<.05$ there was a significant decrease in BFNE scores for all groups and for total participants there was significant increase in scoring on QOLS. No significant difference was found in treatment efficacy between groups measured by SIAS, BFNE or QOLS at $p<.05$.
Conclusion: Our results indicate that online group relaxation sessions can positively affect treatment adherence to OSA but do not reduce SAD symptoms when compared to doing the program on its own. Due to a small and homogenous sample the results should be generalised with caution.
Trial registration: the study's protocol was approved in full by the Icelandic National Bioethics Committee (clinical study registration number: VSN-20-113).

*Keywords***:** social anxiety; clinical trial; internet; cognitive behavioural therapy; adherence; compliance; group sessions

Introduction

Social anxiety disorder (SAD) is a common and debilitating disorder that often develops early in life (Kessler et al., 2005, 2012). SAD can functionally impair most aspects of an individual's life including romantic relationships (Sparrevohn & Rapee, 2009), social life, friendships and family relations (Schneier et al., 1994). SAD is associated with reduced likelihood of finishing higher education, a decrease in work productivity and lower income (Katzelnick et al., 2001).

To receive a diagnosis of SAD, according to the current Diagnostic Statistical Manual, DSM-5, the individual must, amongst other symptoms, have a fear or anxiety over a social situation where the individual could be scrutinized by others. These individuals fear that they may be judged, embarrassed or humiliated, or show symptoms of anxiety which will be negatively evaluated by others. This fear will cause them to either avoid these situations or endure them with intense anxiety or fear (2013). Due to the nature of SAD symptoms, substance abuse and dependence can develop as individuals try to ease their discomfort in feared social situations (Buckner et al., 2008). Furthermore a SAD diagnosis is related to an increased risk of a subsequent depression diagnosis and suicidal attempts (Beesdo et al., 2007; Katzelnick et al., 2001).

Untreated, only a third of the individuals affected recover on their own (Bruce et al., 2005). Research shows that those dealing with social anxiety report that they do not seek treatment due to fear of the unknown and fear of judgement of others (Olfson et al., 2000). Despite effective treatments being available SAD remains undertreated. The individuals who do seek psychological treatment are at increased risk of receiving ineffective and non-evidence based treatments (Shafran et al., 2009).

Current Treatments of Social Anxiety

There are two main cognitive models in cognitive behavioural therapy (CBT) for SAD. A cognitive model of social phobia by Clark and Wells (1995) and a cognitive behavioural model by Rapee and Heimberg (1997). Clark and Wells' model (1995), provides a hypothesis on how social anxiety is maintained in feared social situations and why the feeling of anxiety does not subside with time. Their theory is that what maintains it, is self-focused attention as well as unhelpful coping mechanisms and safety behaviours, which the individual utilises to combat their anxiety (D. M. Clark & Wells, 1995). Rapee and Heimberg's model (1997) has "the mental representation of the self as seen by others" at the forefront and describes a functionally similar concept to safety behaviours, which they call subtle avoidance.

Studies have shown that CBT can reduce anxiety symptoms, which goes for all anxiety disorders including SAD (e.g. Andersson, 2009). CBT group treatment has been shown to greatly reduce SAD symptoms, both in the short and in the long term (Fogarty et al., 2019). Researcher have not been able to establish greater effectiveness in lessening SAD symptoms in CBT group treatment, compared to individualized CBT treatment (Stangier et al., 2003) However, research has shown that individual cognitive therapy outperforms intensive group therapy when treating social phobia (Hedman et al., 2013; Mörtberg et al., 2007). A meta-analysis showed that treatment of SAD using only two components of CBT; cognitive restructuring and exposure exercises, produced a large effect size on SAD symptom reduction that kept increasing after the treatment ended (Taylor, 1996). In another study, these same two components were shown to be as effective in a natural field setting as in highly controlled research settings (Lincoln et al., 2003). Furthermore, research has shown that CBT as a whole is more effective in treating SAD symptoms than psychodynamic therapy (Leichsenring et al., 2013).

Limited Access to Evidence-Based Treatments

When an anxious person seeks treatment, there is a low chance that they will receive evidence based treatment recommended by international guidelines (Powers & Deacon, 2013). Surveys show that cognitive behavioural therapists are frequently opting for non-evidence based methods and omitting the exposure part of CBT (Hipol & Deacon, 2013). This is an alarming trend since, according to research, exposure is a vital part of an effective intervention as well as being endorsed by NICE guidelines, which are evidence-based recommendations based on independent committees, as a treatment component for anxiety disorders (NICE, 2013). Other studies have shown that in many instances, when therapists claimed to use all components of CBT in their practice, they were not actually doing so (Stobie et al., 2007).

This raises the question of why professionals are not choosing to administer or adhere to evidence-based procedures. According to Shafran et al (2009), there are two main issues. Firstly, some clinicians hold beliefs that go against the proper delivery of CBT and secondly there are gaps in some therapists' knowledge in administering the treatment. There are major issues regarding the usage of CBT practices that need to be resolved. Failure to react to these issues could endanger the integrity of CBT as individuals will receive treatment that they will falsely believe to be CBT, and which may prove to be ineffective. In Iceland, laws regarding obligation to provide evidence-based treatments only apply to licenced clinical psychologists. This mandate does not apply to other types of therapists who are therefore not required by any legal framework to administer evidence-based treatments (Lög um heilbrigðisstarfsmenn, no. 34/20).

Computerised CBT Treatment Programs

When considering the issues regarding lack of access to evidence-based treatments, pre-programmed computerised CBT programs offer a solution, since a computer program can be

guaranteed to adhere to effective evidence-based manuals. This type of treatment can therefore be more transparent compared to traditional therapy and increase opportunity for accountability. This way the patients can be informed on the kind of service they are receiving and can easily find out whether the treatment is evidence based and suitable to their needs. This means less time spent looking for effective, suitable, and attainable treatment, resulting in the patient being able to start recovering from their disorders or problems quicker.

Computerised CBT can be divided into open access and closed access, as well as therapist-guided and unguided or automated programs (Andersson et al., 2009, 2013). In the category of open access, anyone can partake in the program, while closed access requires patients to undergo screening before using the program. Studies show that in most cases, closed access and therapist guided programs have a greater effect compared to unguided and open access programs (Andersson et al., 2009, 2013). Dr. Helgadóttir et al's (2014) study showed that by adding individualistic feedback and case formulation to an unguided program, the program's effectiveness can be increased. Titov et al´s (2008) study showed that despite guided programs outperforming unguided ones, unguided programs produced lasting improvements in life of those affected with social anxiety. Despite their shortcomings, programs using unguided self-help result in persistent improvement in social anxiety symptoms (Furmark et al., 2009).

In modern times, internet access is prevalent, especially in locations like Iceland where over 90% of the population has internet access (Statistics of Iceland, 2016). In the past few years, the use of online services has become extensive. Online therapies date back to the end of the 1990's where they started in the form of email exchanges between therapists and their patients (Barak, 1999) or in the form of a PDF document intended for the patient to download and read (Andersson et al., 2013). In more recent years, computer-based treatments

have evolved to web-based, individualized, interactive programs where users can access help for a variety of psychological problems in the comfort of their own home, at a time and at the pace that suits them. Research has shown that pre-programmed web-based CBT programs can be as effective as traditional in-person CBT (Hedman et al., 2012). These types of treatments do not require guidance and are therefore easily scalable compared to guided or traditional therapy.

According to the NICE guidelines, the recommended treatment for social anxiety is CBT, and if the patient so wishes, they can opt for CBT supported self-help (NICE, 2013). In the United Kingdom, the Improving Access to Psychological Therapies (IAPT) program has approved Internet based CBT, in its stepped care program, as a treatment alternative to low intensity treatment. By providing this option to patients suffering from anxiety, the British National Health System has the possibility of both lowering their financial cost and improving accessibility to their services (Richards et al., 2018).

Web-based CBT programs have, through systematic reviews and meta-analysis of randomised control trials, become well established, having both a large effect size and being highly cost effective (Hedman et al., 2012; Spek et al., 2007).

The Program

Overcoming Social Anxiety (OSA) is a fully automated online CBT program. It is based on a program that was developed for individuals which both stuttered and struggled with anxiety. The original program went through experimental trials and significantly reduced subjects' social anxiety symptoms and improved their speech, when added to speech restructuring. When compared to face-to-face therapy conducted by a clinical psychologist, it was equally effective at reducing stuttering (Menzies et al., 2019). The original program showed a comparable quality of interactions, with regard to therapeutic relationships to face-to-face treatments (Helgadóttir et al., 2009b). In a trial of that program, 78% of those who had a

diagnosis of SAD at the start of treatment, no longer met the diagnostic criteria at the end of treatment and notably the remaining 22% had not completed the program (Helgadóttir et al., 2014).

The OSA program has been empirically tested in a randomised controlled trial (RCT) which showed great efficacy in non-clinical community samples (McCall et al., 2018) and the general community (McCall et al., 2019). When looking at the reduction in social anxiety symptoms, the OSA program's effect size is triple that of the mean effect size of similar programs and compares to therapist guided programs (McCall et al., 2018).

In comparison to other unguided programs, also known as fully automated and open access, OSA's precursor had the highest completion rates in real community settings for computer treatments targeting anxiety, depression or mood enhancements (Fleming et al., 2018). McCall et al. (2019), confirmed that the improved adherence also applied to the program targeting social anxiety in an unguided community sample. Furthermore, participants that complete the OSA show significant reduction in the severity of symptoms exhibited, including symptoms of social anxiety and depression (McCall et al., 2019). What makes OSA stand apart, is that it includes modules that the researchers thought to be crucial but were missing from other similar programs. Notable examples of these added modules are personalized samples of social anxiety symptoms based on answers to questionnaires, as well as explanations of each module provided by a clinical psychologist in either an audio clip or a video recording (Helgadóttir et al., 2014). For more information on the OSA program refer to studies by Dr. Helgadóttir (e.g. Helgadóttir et al., 2009a, 2009b, 2014).

The Main Limitation of Fully Automated Programs

Adherence is an essential factor in the effectiveness of treatment and is therefore immensely important when designing online therapies (Hilvert-Bruce et al., 2012). Additionally, factors that heavily impact the effectiveness of computerised CBT are, for example, user-friendly

treatment programs, inclusion of clear deadlines and access to support (Andersson et al., 2009). Despite OSA having the highest documented completion rate of comparable programs (McCall et al., 2019), it would still benefit from further improvements to its adherence.

Low adherence to web-based treatment is a well-known problem in the field, but a simple solution has yet to emerge. Adherence tends to fluctuate between different computerised CBT programs. These fluctuations can be explained by differences in interactions, including those between patient and counsellor, the dialog support and technological differences (Kelders et al., 2012). Researchers have noticed a relation between depressive symptoms and non-adherence on one hand (DiMatteo et al., 2000) and a positive relationship between therapist encouragement and treatment outcome on the other hand (Paxling et al., 2013).

There is scant data available on how to increase adherence and efficacy of fully automated therapies without adding a costly human-delivered therapy component (McCall et al., 2018). In a meta-analysis on internet therapies, adherence seemed to depend on therapist support (Spek et al., 2007). In a systematic review of adherence in web-based treatment programs, adherence is increased through therapist to client interaction, as well as with shorter sections of intervention at a time, and, furthermore, by informing the users what is expected of them (Kelders et al., 2012). Following these results, the obvious strategy would be to add a therapist element to web-based therapy programs but since their ease of administration and low cost are important components, it is favourable to try to find a middle ground that sacrifices neither.

Goal of This Study

Our goal is to increase adherence to the fully automated web-based CBT program OSA. Our rationale is that if we succeed in increasing adherence to the OSA, which has the highest completion rates of equivalent programs (McCall et al., 2019), similar programs with lower

adherence should be able to utilise our results. Since the program already includes many features that have been shown to increase adherence, we looked for possible ways to further improve its adherence.

Research has shown that in traditional in-person therapy, mutual collaboration can increase both treatment adherence and improve patients' healthcare results (Martin et al., 2005). Perhaps these effects can be mirrored in web-based therapies through online group sessions. Since increasing guidance to web-based treatments translates into higher adherence (Andersson & Cuijpers, 2009), adding therapist contact to an otherwise fully automated program, through online group sessions, could lead to higher adherence. Furthermore, as human support is a determining factor in adherence (Mohr et al., 2011; Spek et al., 2007), the user may have the chance to feel supported by other participants as well as the host through online group sessions. In studies on computerised therapies for psychotic disorders, peer-to-peer interactions and support groups have led to improvements in adherence to evidence based therapies (Biagianti et al., 2017). According to a meta-analysis on patient adherence to medical treatments through social support, all types of social support significantly affect the adherence (DiMatteo, 2004). Psychoeducation is often a large portion of group therapy sessions, where the host explains theories behind psychological problems to increase patients' understanding of how and why the treatment should work. Psychoeducation is effective in improving the clinical course of treatment (Tursi et al., 2013), can reduce psychological distress (Donker et al., 2009), and is linked to increased adherence (Colom & Lam, 2005).

Our primary hypothesis was that by offering psychoeducational online group sessions to the OSA program its treatment adherence would increase. Our secondary hypothesis was that these group sessions would further reduce symptoms of social anxiety and increase life quality for a non-clinical sample.

Method

Participants

132 university students applied to participate in the study, 85 passed the study's inclusion criteria (see in Materials section below) and 69 answered the pre-treatment questionnaires and were accepted into the study. The final group of participants were aged between 19 and 56, with 29.0 years old being the average. All participants were Icelandic speaking Icelanders, 57 identified as female and 12 as male.

Accepted participants were evenly split into three groups using a randomisation formula in Microsoft Excel version 16.46. Each participant was given a random number between 0 and 1, generated by the randomisation formula. The numbers were then organized in an ascending order and participants with the lowest numbers were assigned to the control group, the second lowest to the experimental group and the highest to the placebo group.

Materials

The materials included in this study were four questionnaires, three lectures covering social anxiety psychoeducation, presented on slides, a relaxation script, and OSA program.

The eligibility questionnaire, used to determine the eligibility of potential participants, included three items from the Mini-Social Phobia Inventory (Mini-SPIN), a brief self-rated screening instrument for generalised SAD (K. M. Connor et al., 2001) and four social anxiety assessment items from the 5th edition of the Diagnostic and Statistical Manual of Mental Disorders (2013). Its items assessed the respondent's symptoms of social anxiety in the week prior to filling out the questionnaire. Potential participants answered 1=*not at all*, 2=*a little bit*, 3=*somewhat*, 4=*very much*, 5=e*xtremely*, to each item. To pass the inclusion criteria and be deemed eligible for the study, participants had to score 4 or higher on at least one item of the questionnaire. This criteria is based on McCall et al's study which investigated the effectiveness of the OSA program on reducing users' symptoms of social anxiety (2018). The

combination of questions has shown good internal consistency in English (McCall et al., 2018). On its own the Mini-SPIN's internal consistency, convergent validity and discriminant validity is good (Weeks et al., 2007). When using the cut of score of six or higher, its sensitivity is 88.7% and specificity is 90.0% in identifying individuals with SAD (Kathryn M. Connor et al., 2001). The translation of the Mini-SPIN and DSM 5 SAD items to Icelandic was made by two Icelandic graduate students in clinical psychology, S. Sigurðardóttir and B. K. Ingvarsdóttir, by translating and back translating it in accordance with E. Guðmundsson's instructions on how to translate psychometric questionnaires (2006).

The three pre- and post-treatment questionnaires, Social Interaction Anxiety Scale (SIAS), Brief Fear of Negative Evaluation (BFNE) and Quality of Life scale (QOLS), were used for participant baseline and follow-up measures. These questionnaires were selected in accordance with previous studies on OSA efficiency.

SIAS is a 20 item self-report questionnaire which measures anxiety in social situations (Mattick & Clarke, 1998). The questionnaire's validity and reliability have been demonstrated in English (Mattick & Clarke, 1998) as well as in an Icelandic translation (Ólafsdóttir, 2012).

BFNE is a 12 item self-report questionnaire that measures an individual's fear of the negative evaluation of others (Leary, 1983). The scale's validity and reliability has been demonstrated in English (Rodebaugh et al., 2004) but no psychometric evaluation has been done on its Icelandic translation yet.

QOLS is a 16 item self-report questionnaire that measures contentment with one's life (Burckhardt & Anderson, 2003). The scale has proven to be both reliable and valid in English (Burckhardt & Anderson, 2003). The psychometric properties of the Icelandic translation have been tested on a clinical Icelandic sample, and both its validity and reliability have been demonstrated (Björnsson et al., 2019).

A more detailed description of the questionnaires as well as the rationale behind their selection, apart from QOLS, has been depicted in detail in a prior study on the OSA program's effectiveness (McCall et al., 2018).

For the psychoeducation group, which was subjected to the experimental condition, three lectures covering the same psychoeducational content as the OSA were delivered. The first session covered causal thoughts and cognitive errors, and why and how to challenge them; the second session covered the maintaining factors of SAD and behavioural experiments; and the third and last session covered unhelpful thoughts, attention training, image rescripting, post-event processing and relapse prevention. Each lecture included 8-10 slides, shared through Zoom, designed to last around 45 minutes. During the lecture, participants were asked questions to check their understanding, which they could answer through a chat function or by speaking.

For the relaxation group, which was subjected to the placebo condition, a script for progressive muscle relaxation was used. The script was adapted from The Relaxation and Stress Reduction Workbook by Davis et al. (2008) and translated to Icelandic by S. Sigurðardóttir, a graduate student in clinical psychology, with the assistance of her partner, N. R. Muteau. The original script aims for 20 to 30-minute-long relaxation sessions. The length was extended to 45 minutes, by stretching the pauses between sections, to match the length of the other group's condition. This type of relaxation is often used as a control condition since it has been shown to have minimal effect on social anxiety symptoms (Al-Kubaisy et al., 1992) but is generally not considered a sufficient treatment for SAD on its own (Rodebaugh et al., 2004).

The Overcome Social Anxiety program, OSA, which this study was designed to increase adherence to, is in brief, a web-based computerised cognitive behavioural therapy program designed for individuals that struggle with anxieties related to social situations. The

program has shown great efficacy in non-clinical community samples and in the general community (McCall et al., 2019). A detailed information on the design of the program has been described in detail in previous publications (e.g. Helgadóttir et al., 2009a; Helgadóttir et al., 2009b; Helgadóttir et al., 2014).

Design and procedure

Information about the study and a link to apply was sent by email to all students of two Icelandic universities and selected faculties of one more university. Potential participants were informed that the study's goal was to increase adherence to Overcome Social Anxiety, a fully automated web-based cognitive behavioural therapy program treating social anxiety symptoms, through the addition of relaxation and psychoeducational group sessions. To apply to participate in the study, potential participants had to answer an eligibility questionnaire, which assessed whether they passed the study's inclusion criteria, and three pre-treatment questionnaires. A link to the eligibility questionnaire was attached to the application email, but to receive an email with a link to the pre-treatment questionnaires, potential participants first had to pass the study's inclusion criteria. Links to the questionnaires were open for two weeks after the emails were sent out. Potential participants who had been sent a link to the pre-treatment questionnaires, but had not answered a week later, were reminded once by email.

This study was a three-arm randomised controlled trial, testing the effectiveness of three conditions regarding treatment adherence. Eligible participants were randomly assigned to three groups. An experimental group, where participants got access to the OSA program and an invitation to three online group sessions, covering the social anxiety specific psychoeducation also provided in the OSA program; a placebo group, where participants got access to the OSA program and three online relaxation group sessions; and a control group, where participants simply got access to the OSA program. The rationale for the placebo

group was to control for the extra time given to the experimental group in comparison to the control group without greatly affecting participants' anxiety levels (Al-Kubaisy et al., 1992). Participants were not told whether their intervention was control, experimental or placebo, but they were informed of what intervention was being offered. All group sessions were around 45 minutes long, held on the video telephony software program Zoom pro, prepared, and hosted by S. Sigurðardóttir, a graduate student in clinical psychology, and overseen by Dr. Helgadóttir, a clinical psychologist and co-author of the OSA program.

All accepted participants were sent a welcome email with information on which group they had been assigned to and a code giving them a four-month access to the OSA program. The email sent to participants in the experimental and relaxation groups also included information on which modules they were to finish for each session and a link to a document to sign up for a time slot for the group sessions. For the first session, they were asked to finish the first two modules of the program, for the second the next two modules, and for the third session the last three modules. Two weeks after receiving the welcome email, after being reminded once – a week later – to sign up for a time slot, the participants who had chosen a time slot were sent a confirmation email with a Zoom link for the sessions. A week before each session, participants were sent an email reminding them of their session and of which modules to finish. The sessions were held four, 10 and 16 weeks after the access codes were sent out.

The social anxiety psychoeducation provided in the experimental group's sessions was based on the materials of the OSA program. Each session included material corresponding to the modules of the program which the participants had been asked to complete prior to the session. Participants were encouraged to participate in the discussions and ask questions but assured that it was not mandatory. In the relaxation group's session, participants were led through a 45-minute progressive muscle relaxation.

During the four-month period, all participants of all three groups received the same automatic email notifications, reminding them to log back in, when three, seven, 10, 14, 21 and 28 days had passed since the last log in, as well as emails congratulating them on completing a module. Four months after the welcome email with the access code was sent, all accepted participants who had not withdrawn from the study were sent a link to the post-treatment questionnaires: SIAS, BFNE and QOLS.

The study's protocol was approved in full by the Icelandic National Bioethics Committee, (clinical study registration number: VSN-20-113).

Statistical analysis

Power

A power analysis indicated that the total sample size required for a power level of 0.80 at the $p<.05$ level of significance, 1-tailed, assuming a large effect size $f=0.5$ ($\eta^2=0.2$) was 42 participants divided across three groups. Since a previous study on the OSA program among university users had a 40% drop-out rate (McCall et al., 2018) this study's researchers aimed for doubling the needed participants to increase the likelihood of adequate power level after anticipated dropout.

Adherence

The primary dependent variable was adherence, measured by the number of modules completed in the program by each participant. A one-way between groups ANOVA was conducted to compare differences in adherence among the three conditions, control, experimental and placebo. The data sample did not have any outliers but was skewed and therefore not normally distributed, assessed by box plots and confirmed by the Shapiro-Wilk test of normality, and there was homogeneity of variance, assessed by Levene's test of homogeneity of variances ($p=.519$). Since the groups were similarly skewed and ANOVA is robust for violation of normality in regards to Type I error (Blanca et al., 2017), the violation

was noted and the test was performed. To identify which group differed from another, a post-hoc Tukey's Test was performed. The test was performed using data from all participants assigned to the control group and those who had attended at least one group session in the other two groups.

Efficacy

The secondary dependent variable was the effectiveness of the treatment, measured in changes in SIAS, BFNE and QOLS scores. As when testing differences in adherence, only data from participants in the control group and from the participants that attended at least one group session in the experimental group and the placebo group were used. A paired-samples *t*-test was performed for each group to determine whether the pre-treatment scores differed significantly from the post-treatment scores. Using box plots, the data was determined to be normally distributed apart from scores on QOLS for the placebo group, and no extreme outliers were detected. Due to this violation, the power of the test is affected, while the test is still robust to Type I error (Wiedermann & von Eye, 2013). A one-way ANCOVA was then used to see if there was a significant difference in effectivity of the treatment depending on the group condition. All assumptions were met except for standardised residuals for the overall model for scores on SIAS for the relaxation group, which were not normally distributed, assessed by Shapiro-Wilk's test ($p<.05$). This violation does not affect Type I error substantially (Olejnik & Algina, 1984). One of the most important assumptions for one-way ANCOVA is that the pre-treatment scores between the groups are not significantly different. This was assessed using one-way between groups ANOVA for each scale; pre-treatment scores for all three scales did not significantly differ between the groups ($p>.05$).

Results

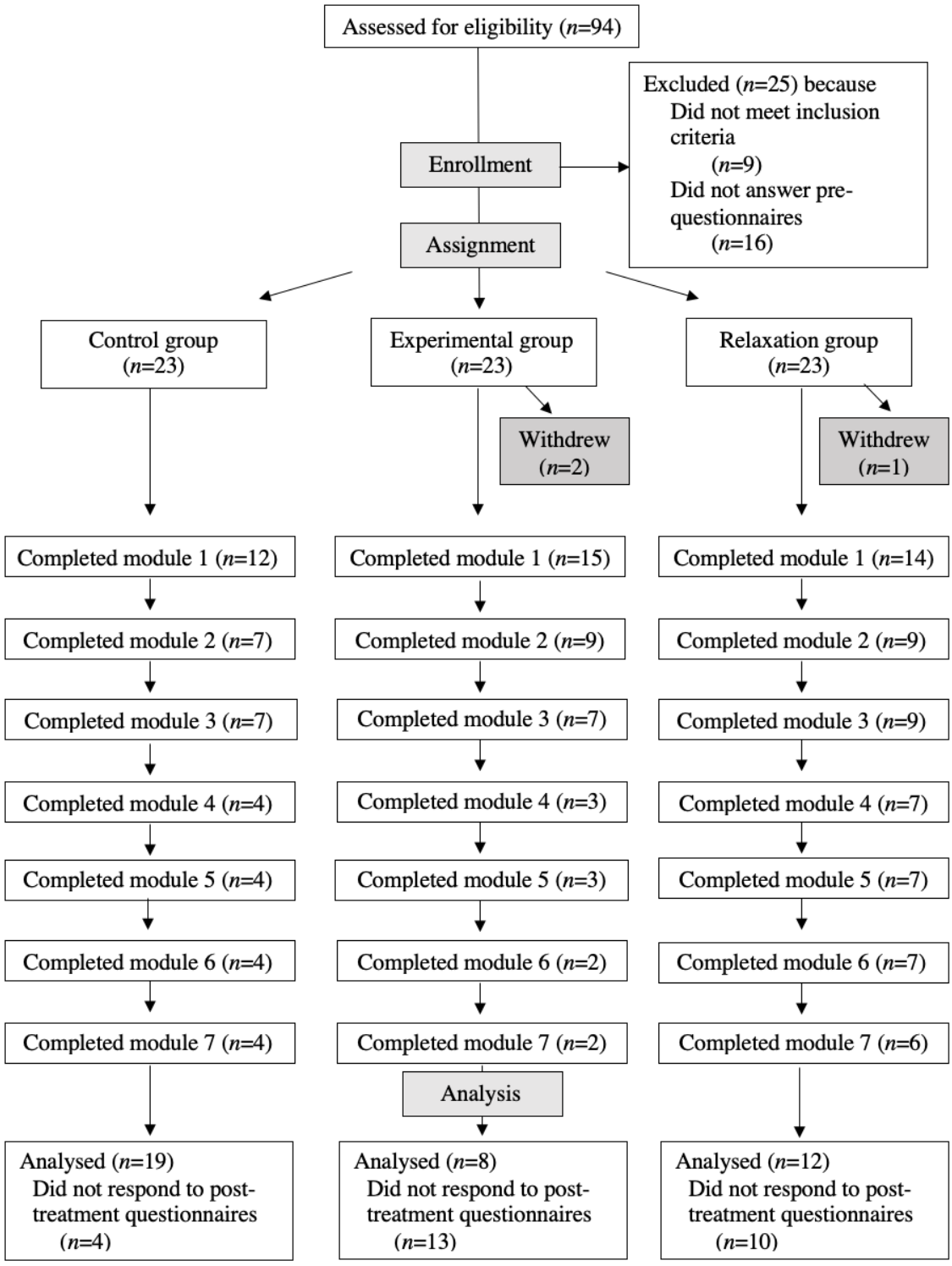
Adherence

Participants in the experimental group attended on average 1.00 group sessions (*SD*=1.14) and 52.38% (*n*=11) attended at least one session. Participants in the relaxation group attended on average 1.18 group sessions (*SD*=1.26) and 54.54% (*n*=12) attended at least one session. Completion rates for total participants were 18.18% (*n*=66), highest for the placebo group 27.27% (*n*=22), second highest for the control group 17.39% (*n*=23) and lowest for the experimental group 9.52% (*n*=21).

Participant's flow through the OSA modules and the study itself can be seen in figure 1.

Figure 1

Flowchart of Participants Through Each Stage of the Study and Modules of the OSA



Note: n=number of participants. Analysed data refers to effectivity calculations, not adherence

The study's primary outcome was adherence; the results demonstrated a statistically significant difference between the groups in average module completion, $F(2,43)=5.06$, $p=.011$, $\eta^2=.19$, 95% *CI*=0.12-.036. The mean increase in adherence was from the control (*M*=1.83, *SD*=2.62, 95% *CI*=0.69 – 2.96) to the relaxation group (*M*=4.75, *SD*=2.70, 95% *CI*=3.03 – 6.47) and it was statistically significant ($p=.008$). The experimental group (*M*=3.00, *SD*=2.37, 95% *CI*=1.41 – 4.59) did not statistically differ from either.

Efficacy

The secondary outcome was the effectiveness of the program depending on the groups; the results demonstrated that there was not a statistically significant difference in post-treatment scores between the groups. SIAS: $F(2,35)=1.1823$, $p=.319$, partial $\eta^2=0.063$; BFNE: $F(2,35)=1.19$, $p=.318$, partial $\eta^2=0.063$; QOLS: $F(2,35)=0.843$, $p=.439$, partial $\eta^2=.046$. Descriptive statistics for participants' scores and statistical tests for change in pre- to post-treatment scores can be seen in table 1.

Table 1

Descriptive Statistics for Pre- and Post-Treatment Scores

Condition (n)	Control (19)	Experimental (8)	Relaxation (12)	Total (39)
SIAS				
Pre-treatment *M* (*SD*)	31.21 (9.11)	32.35 (11.96)	27.25 (8.66)	30.21 (9.57)
Post-treatment *M* (*SD*)	30.37 (10.28)	26.38 (11.17)	23.83 (10.00)	27.54 (10.52)
Change				
M (*SD*)	0.84 (8.11)	5.88 (12.94)	3.42 (9.39)	2.67 (9.57)
Paired *t* test (*df*)	0.45 (18)	1.28 (7)	1.26 (11)	1.74 (38)
P value	.66	.240	.233	.090
Cohen *d*	0.10	0.45	0.36	0.28
BFNE				
Pre-treatment *M* (*SD*)	38.21 (6.20)	40.63 (5.26)	39.33 (4.68)	39.05 (5.53)
Post-treatment *M* (*SD*)	33.47 (7.57)	32.00 (5.40)	30.75 (6.58)	32.33 (6.82)
Change				
M (*SD*)	4.74 (7.44)	8.63 (4.75)	8.58 (6.53)	6.72 (6.82)
Paired *t* test (*df*)	2.78 (18)	5.14 (7)	4.55 (11)	6.15 (38)
P value	.012*	.001*	<.001*	<.001*
Cohen *d*	0.64	1.72	1.32	0.99

QOLS				
Pre-treatment *M* (*SD*)	75.74 (9.31)	68.25 (13.41)	72.50 (9.86)	73.21 (10.53)
Post-treatment *M* (*SD*)	77.89 (13.70)	77.75 (16.90)	77.58 (12.32)	77.77 (13.62)
Change				
M (*SD*)	-2.16 (11.43)	-9.50 (4.68)	-5.08 (8.22)	-4.56 (11.04)
Paired *t* test (*df*)	-0.82 (18)	-2.03 (7)	-2.14 (11)	-2.58 (38)
P value	.421	.082	.055	.014*
Cohen *d*	-0.19	-0.72	-0.62	-0.41

Note. *M*=mean, *SD*=standard deviation, *df*=degrees of freedom, Cohen *d*=effect size, *p*=significance value, *=significant at $p<.05$

At $p<.05$ there was only a significant difference in pre- to post-treatment scores on BFNE for participants in all three groups individually as well as in total, and only for total participants on QOLS.

Discussion

Principal Results

Our primary hypothesis that online group sessions covering social anxiety psychoeducation added to a fully automated web-based CBT program for social anxiety would increase adherence to it, was not supported by our data. Surprisingly, the condition designed to serve as a placebo condition, where the online group sessions consisted of participants listening to a reading of a progressive muscle relaxation script, had the highest adherence of the groups and significantly differed from the control group. Completion rates were also highest for this group, second highest for the control and lowest for the experimental group.

Our secondary outcome showed that on average, participants lowered their social anxiety severity measured by BFNE and increased their life quality post- treatment measured by QOLS. Participants in the experimental group showed the biggest difference in scores on SIAS, BFNE and QOLS despite the difference not always being significant. Post-treatment scores between groups were compared to judge the program's efficacy. This was possible since pre-treatment scores did not significantly differ, making the randomisation process

successful. Contrary to our secondary hypothesis, no significant difference in treatment efficacy was detected in treatment efficacy between the groups.

These results build on previous research that shows that increased support can lead to greater adherence (Kelders et al., 2012; Spek et al., 2007), but the fact that progressive muscle relaxation, rather than additional SAD psychoeducation, had a bigger effect on adherence was not in line with what we previously thought. Lecturing participants on the importance of challenging causal thoughts, cognitive errors and performing behavioural experiments, explaining how SAD is maintained and how it is possible to break the maintenance cycle did not have a significant effect on treatment adherence. These results should be considered when support is added to an otherwise fully automated web-based CBT treatment program since these results indicate that the type of interaction provided matters regarding adherence and possibly treatment effectiveness.

Limitations

This study had a few limitations, despite the study starting out with an adequate sample size the final sample, due to poor group session attendance, ended up being rather small. Lack of significance when comparing post treatment scores might be explained by small groups and high variance in participants' scoring, which could be due to the inclusion criteria being too easy to pass or the sample being non-clinical.

Another limitation is that our study took place doing the COVID-19 pandemic, which may have affected the study in various ways. Due to the sample consisting of only university students, their inboxes were being flooded by university administration emails with COVID-19 updates, which may have caused OSA program emails and group session reminder emails to go unnoticed. Icelandic universities had to shift almost exclusively to online classes, so attending an online group session after a whole day of online university lectures may have been less appealing than we had hoped. Intense social restrictions may also have affected the

users' motivation to continue with their treatments, since anxiety provoking social situations were far fewer.

An important limitation of the study was the large difference in completion rates for our control group compared to what had previously been reported for the OSA program. Recent study evaluating the OSA program reported its completion rate to be 27% in a non-clinical community sample (McCall et al., 2019). The completion rate for our control group was only 17%. Why there was such a large difference is unclear since the treatment given was very comparable between the studies. The main difference between the studies was their sample sizes, the previous study's sample being ten times the size of our control group, meaning the difference could be due to chance. There was also an obvious difference in environmental factors due to our study taking place during the height of the COVID-19 pandemic. The only difference in the treatment itself was that the community sample had to pay for their access and their access was six months, while our university students did not pay and got a four-month access. Despite the commonly held belief that paying for treatment produces better outcomes, recent research does not support it, since paying for treatment does not seem to have an effect on therapy attendance or outcomes (P. Clark & Kimberly, 2014). Interestingly we were able to produce the same completion rate as the previous study when relaxation group sessions were added to the program.

Comparison with Prior Work and Future Research

The importance of fully automated computerised CBT programs is clear. This type of treatment can be guaranteed to adhere to effective and evidence-based therapy methods. Through these programs, quality treatment can be administered to individuals who would not otherwise have access to it due to their location, their economic status, or the symptoms of their disorder. The main limitation of these types of treatment programs is low adherence and low completion rates, which means that users only receive a portion of the potential effects of

the programs. Previous studies have identified that therapist's support, shorter sections of intervention at a time and deadlines can increase adherence (Kelders et al., 2012; Spek et al., 2007).

Research has shown that progressive muscle relaxation can be used as supportive intervention that affects adherence to cancer treatment (Pelekasis et al., 2017) and to medical device usage (Wang et al., 2012). However, to our knowledge, a link has not been drawn between increased adherence to fully automated computerised CBT programs and progressive muscle relaxation. A possible reason could be the nature of CBT, whose goal is to increase patient's distress tolerance, while progressive muscle relaxation causes more of an instant gratification through reduction of state anxiety and psychological distress for individuals battling severe mental disorders like schizophrenia (Vancampfort et al., 2013). CBT takes time, while relaxation does not, which may motivate users of the program to go back to it, since they have experienced this momentary lowered anxiety level through relaxation, contrary to users who did not have access to the relaxation. If the relaxation techniques induced a generalisation it may have helped the study's participants to cope with anxiety provoking situations (Öst, 1987), such as in behavioural experiments. More research is needed to fully understand the results of our study.

Conclusion

The study's results were that participants in the placebo group that attended one or more group sessions showed significantly higher treatment adherence to OSA compared to participants in the control group. Participants in the placebo group were offered three 45-minute online progressive muscle relaxation group sessions and asked to finish a certain number of treatment modules before each session. Participants in the control group were not offered group sessions or asked to finish specific parts of the treatment before a certain time. No significance difference was found in adherence between the experimental group and the

placebo or control groups. The experimental group differed from the placebo group only in the type of group sessions offered. The experimental group's sessions covered social anxiety specific psychoeducation.

Despite these results not being in line with previous research or our hypothesis, they might be explained by the relaxation sessions offering participants reinforcement for continuing treatment. Another possible reason is that perhaps the relaxation technique generalised to anxiety provoking situations making it easier for participants to continue the treatment.

There was not a significant difference in treatment efficacy between the groups, measured by difference in social anxiety symptoms or life quality post-treatment. Despite this lack of statistical significance, the participants in the experimental group did show the greatest improvements.

Due to the study's small size these results should be generalised with caution since further additional research is needed.

Conflicts of Interest

Dr. F. D. Helgadóttir and R. G. Menzies are co-authors and owners of OSA.

Abbreviations

SAD: Social anxiety disorder

CBT: Cognitive behavioural therapy

OSA: Overcome Social Anxiety

SIAS: Social Interaction Anxiety scale

BFNE: Brief Fear of Negative Evaluation scale

QOLS: Quality of Life scale

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