

Internet-based Cognitive Behavior Therapy for Loneliness:

A Pilot Randomized Controlled Trial

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Abstract

Loneliness has been described as a common source of discomfort based on a subjective discrepancy between the actual and desired social situation. For some people this feeling may become a sustained state that is associated with a wide range of psychiatric and psychosocial problems. While there are few existing treatment protocols, interventions based on Cognitive Behavioral Therapy (CBT) have shown positive effects. The current study investigated the efficacy of an eight-week internet-based treatment containing CBT components aimed at reducing feelings of loneliness. Seventy-three participants were recruited from the general public and randomly allocated to treatment or a wait-list control condition. Participants were assessed with standardized self-report measures of loneliness, depression, social anxiety, worry, and quality of life at pre-treatment and post-treatment. Robust linear regression analysis of all randomized participants showed significant treatment effects on the primary outcome measure of loneliness (between group Cohen's $d = 0.77$), and on secondary outcomes measuring quality of life and social anxiety relative to control at post-assessment. The results suggest the potential utility of internet-based CBT in alleviating loneliness but more research on the long-term effects and the mechanisms underlying the effects is needed.

Keywords: Internet-based cognitive behavior therapy, loneliness, CBT, guided self-help, digital intervention

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Loneliness has been conceptualized as a subjective, aversive experience stemming from a perceived discrepancy between the desired and the actual social situation (Peplau & Perlman, 1982). This definition differentiates loneliness from similar concepts, such as social isolation, by taking personal preferences into account. Hence it is possible to feel lonely while in a relationship, but also to feel satisfied with one's own social life when lacking frequent social interactions. Though often transient, the feeling of loneliness can be enduring (Cacioppo, Hughes, Waite, Hawkley & Thisted, 2006). Estimates of the proportion of the population who experience loneliness have varied based on the definition of the concept and demographic characteristics of the samples studied (Pinquart & Sorensen, 2001). Older adults have been regarded as particularly prone to feeling lonely, with the proportion of people age 65 years or older who have experienced frequent feelings of loneliness being reported at 12% within a European sample (Sundström, Fransson, Malmberg & Davey, 2009). The corresponding proportion of young adults (15 - 30 years) and adults (30 - 59 years) reporting significant loneliness in the United Kingdom was 6.3% and 5.5%, respectively, suggesting that the problem also manifests itself for a sizable proportion of the non-elderly population (Victor & Yang, 2012).

Frequent feelings of loneliness have been linked to a broad range of psychosocial problems and the experience has been found to have a major influence on mental health and physical well-being (Heinrich & Gullone, 2006). For example, Cacioppo, Hughes et al. (2006) found a bidirectional link between depressive symptoms and loneliness using a longitudinal design, suggesting that depressive symptoms can both be the cause and consequence of loneliness. A later study primarily found an influence of loneliness on depressive symptomology rather than a bidirectional association (Cacioppo, Hawkley &

Thisted, 2010). In relation to other forms of psychopathology, a study investigating the longitudinal relationship with social anxiety found a reciprocal link with loneliness over a six-month period (Lim, Rodebaugh, Zyphur & Gleeson, 2016). Moreover, a link between loneliness and negative affect, such as depression and anxiety, has been found in cross-sectional studies (e.g., Muyan et al., 2015). Loneliness has also been linked to generalized anxiety and worry among older adults (Beutel et al., 2017), and in a student population (Richardson, Elliot & Roberts, 2017), while rumination has been shown to partially mediate the aforementioned relationship between loneliness and depressive symptoms (Vanhalst, Luyckx, Raes & Goossens, 2012). Loneliness has also been linked to suicidal behavior, including an increased risk of lifetime suicide attempts and suicidal behavior in the last 12 months (Stickley & Koyanagi, 2016). This association remained significant after adjusting for the prevalence of common mental disorders, suggesting that loneliness specifically increases the risk of suicidal behavior beyond the rise that is attributed to common forms of psychopathology (Stickley & Koyanagi, 2016). Individuals with frequent feelings of loneliness can also have worse sleep and spend more time awake after bedtime than non-lonely individuals (Cacioppo, Hawkley, Berntson et al., 2002). In addition to these findings, loneliness has been associated with a reduced quality of life (Ekwall, Sivberg & Hallberg, 2005). Taken together, these findings suggest that loneliness is a transdiagnostic phenomenon that can be found within populations with clinical or sub-clinical symptoms of psychopathology.

In light of the studies mentioned above, it could be inferred that loneliness is best conceptualized as a common symptom within a broad spectrum of psychopathology based on internalizing symptoms. However, while prevalent within this category, data suggest that loneliness is best regarded as a separate entity. Based on empirical studies of the affective and emotional properties of the phenomenon, Cacioppo, Hawkley et al. (2006) argued that

Loneliness should be regarded as distinct from depressive symptoms as loneliness draws more heavily on processes linked to increased stress and perceptual vigilance, while also showing a stronger link to affective responses such as anger. A recent factor analysis seeking to untangle the relationship between loneliness, social anxiety, and depression (Fung, Paterson, & Alden, 2017) pointed to the fact that questionnaires for each of these three constructs seem to fall into distinct entities. Thus, while the causal influence between loneliness and established forms of psychopathology remains to be established, it is important to address loneliness in its own right.

The efficacy of specific interventions targeting loneliness, rather than the associated symptoms (e.g., depression), has been estimated in a meta-analysis that included a total of 50 studies (Masi, Chen, Hawkey, & Cacioppo, 2011). The authors divided the interventions into four broad categories based on their focus and implementation. Their taxonomy consisted of interventions that focused on (a) enhancing social support, (b) improving social skills, (c) providing opportunities for social interaction, and (d) maladaptive cognitions. The most effective interventions according to the meta-analysis were those that focused on maladaptive cognitions about social situations (Masi et al., 2011). The results showed an average between-group effect size of Cohens $d = 0.60$ across the four randomized controlled trials in this category (Masi et al., 2011). The efficacy of these interventions has been hypothesized to stem from the fact that loneliness has been linked to a heightened level of social threat and sensitivity to rejection (Cacioppo, Grippo, London, Goossens & Cacioppo, 2015). The observation that stimuli that involve social rejection and exclusion evoke a faster visual fixation reaction towards the perceived threat in lonely, as compared to non-lonely people, has been shown in experimental studies (e.g., Cacioppo, Bangee, Balogh, Cardenas-Iniguez, Qualter & Cacioppo, 2016). Data also suggest that lonely people exhibit a difficulty in disengaging from socially threatening stimuli (Qualter et al., 2013). Cacioppo et al. (2015)

argued that interventions based on cognitive behavioral therapy (CBT), such as identification of automatic negative thoughts and behavioral experiments, may work via the reduction of the perceptual changes that accompany the feeling of loneliness. Cacioppo et al. (2015) also noted that increased isolation and behavioral withdrawal may play a part in the perpetuation of loneliness. The role of behavioral strategies aimed at avoiding potentially aversive situations was investigated in a longitudinal study in which withdrawal from social contexts acted as an antecedent for increased loneliness (Nurmi, Toivonen, Salmela-Aro, & Eronen 1997). Social withdrawal has also been found to mediate the link between rejection sensitivity and loneliness (Watson & Nesdale, 2012) suggesting that interventions aimed at alleviating loneliness may benefit from an explicit focus on reducing withdrawal from social contexts and increasing the level of social participation.

The notion of applying CBT for loneliness is not new, although few empirical studies have been conducted. Young (1982) proposed applying a theoretical framework based on Beck's theory of cognitive therapy for depression, hypothesizing that people that remain lonely over time have beliefs and appraisals that are fundamentally unhelpful in the quest for meaningful social connection. This argument implies that the cognitive distortions should be addressed by means of cognitive interventions such as cognitive restructuring. These maladaptive beliefs are proposed to be related to the lonely person's perceived inability to realize fruitful interpersonal relationships, such as a fear of being rejected or feeling unworthy of love (Young, 1982). Similarly, with support from the literature on cognitive and behavioral abnormalities among the lonely, Rook (1984) recommended that modifying dysfunctional beliefs about oneself and social situations would be helpful for people who experience problematic loneliness. Of the studies included in the aforementioned meta-analysis on interventions targeting loneliness (Masi et al., 2011), some employed a CBT paradigm. In a randomized controlled trial, McWhirter and Horan (1996) investigated the efficacy of three

structured CBT conditions. The results showed that the conditions containing role play, modification of cognitive attributional styles, and homework assignments targeting the participant's social skills were shown to reduce loneliness across measures aimed at both the experience of lacking an emotional confidant and a general feeling of subjective social isolation. Hopps, Boisvert, and Pepin (2003) found that chat-administered and individualized CBT containing cognitive restructuring and exposure interventions led to a large decrease of loneliness for a sample of people with physical disabilities in a small randomized trial. Taken together, these findings suggest that CBT has the potential to be an efficacious way of dealing with loneliness although there is a need for more controlled trials.

CBT has been found to be effective in the treatment of a wide range of psychiatric problems (Hofmann, Asnaani, Vonk, Sawyer, & Fang, 2012), and is also known to be effective when administered via the internet (Andersson, 2016). This treatment format is sometimes used in a pure self-help format without the help of a mental health professional, but the inclusion of therapist-support has been noted to increase the efficacy and reduce attrition (Baumeister, Reichler, Munzinger, & Lin, 2014). Some of the advantages of delivering CBT via the internet (ICBT) include increased cost-effectiveness and availability (Andersson, 2016), and some studies suggest that therapist-supported ICBT can be as effective as face-to-face CBT (Carlbring, Andersson, Cuijpers, Riper, & Hedman-Lagerlöf, 2018). Thus, one way to investigate if CBT reduces loneliness could be to test the intervention using the internet. ICBT may also be viewed as more acceptable by a group that exhibits a high degree of avoidance and withdrawal as this mode of administration has been suggested to reduce the anxiety of social interaction with a therapist (Soucy & Hadjistavropoulos, 2017).

The aim of the study was to examine if individuals who experience frequent loneliness can be treated by means of therapist-supported ICBT. While treatment of loneliness using

computer-mediated-communication has been tested in one study on a specific population of people with physical disabilities (Hopps et al., 2003), the present study is the first to investigate the efficacy of a structured, manualized self-help treatment administered via the internet. As this work is at such an early stage of development, the study was a pilot test for the feasibility of such an approach. The primary objective was to examine whether the treatment would lead to a decrease in loneliness, as measured with the revised UCLA Loneliness Scale (UCLA-LS-3; Russell, 1996). Due to the relationship between loneliness and symptoms of depression (e.g. Cacioppo et al., 2010) and anxiety disorders (e.g. Lim et al., 2016), a secondary aim was to examine if the treatment had an effect on the adverse symptoms linked to loneliness, including depression, social anxiety, worry, and reduced quality of life. We hypothesized that the group receiving the treatment, which contained interventions aimed at reducing the influence of maladaptive social cognitions along with components directed at the potential patterns of avoidance and inactivity, would exhibit significantly lower scores on the UCLA-LS-3 as compared to a wait-list control group.

Methods

The study was a randomized controlled trial with a between-group design in which participants were randomly assigned to ICBT or a control condition. The regional ethics committee approved the study. The study is reported in accordance with the CONSORT statement for non-pharmacological trials (Boutron, Moher, Altman, Schulz, & Rayoud, 2008).

Recruitment and Sample

Inclusion criteria and exclusion criteria. Participants had to be at least 18 years old, experience suffering as a result of loneliness (as assessed by the participant), have a score above the reported mean of 40 on the UCLA-LS-3 (a cut-off used in a previous study by Theeke et al., 2016), able to speak, read and write Swedish, have access to a computer with an internet connection, and, if taking psychopharmaceutic medication, remain on a stable dose

for the duration of the study. A score above the mean for the loneliness measure in question was an attempt to identify people suffering as a result of loneliness to complement the individual assessment. Psychiatric comorbidity was allowed as long as the participant reported that loneliness was their primary concern and none of the exclusion criteria were met.

Persons were excluded from the study if they reported that they had a previously diagnosed personality disorder (as diagnosed by a mental health professional in a regular care setting and indicated by the participant on an item in the initial demographic questions), reported that they were currently receiving psychotherapy, had an ongoing problem with substance abuse (as diagnosed by a mental health professional in a regular care setting and indicated by the participant on an item in the initial demographic questions), suicidal plans (as indicated by the section on suicidality of the structured M.I.N.I. Neuropsychiatric Interview 7.0; Sheehan et al., 1998), or a more acute need for treatment for other conditions (including psychiatric problems requiring specialist care such as anorexia nervosa). The final decision whether to exclude a person or not was based on a structured assessment using the M.I.N.I. Neuropsychiatric Interview 7.0, the scores from the screening procedure and, when needed, a clinical evaluation by the interviewer and the Principal Investigator.

Procedure

All communication between the therapists and patients, distribution of modules, and administration of self-report measures were executed through a secure online interface connected to the website of the current study. In order to log on, the patients had to use an auto generated identification code generated during the screening process, e.g., 1234abcd, a strong personal password, and a six-letter code sent via a SMS message. This type of electronic identification, i.e., SSL certificate, and two-step verification is similar to the

systems used by many governmental agencies, ensuring anonymity and safety throughout the treatment period (Bennett, Bennett, & Griffiths, 2010).

Recruitment began in January 2016. Participants were recruited by means of an advert in a national newspaper. Information regarding the study was also published in an article in a local newspaper, a radio report on a regional radio station and posters in two medium-sized Swedish cities. Participants registered on a secure website (Vlasecu, Alasjö, Miloff, Carlbring, & Andersson, 2016), where they received information and were instructed to send in a consent form by post. They subsequently completed an online screening where it was confirmed that their primary concern was loneliness. A number of questionnaires were then administered at this point assessing loneliness and psychiatric problems such as depression. The screening also included questions regarding demographic factors and contact information. The participants who were excluded at this stage received personalized information about the exclusion and, if needed, advice on how to get in touch with health care facilities (in Sweden all citizens are covered by national health insurance).

Those who passed the initial online screening were contacted for a structured telephone interview. The interview was primarily based on a structured psychiatric assessment using the M.I.N.I. 7.0 (Sheehan et al., 1998) conducted by five final year-students from the clinical psychologist programme at Linköping University. The students had training and previous experience of psychopathology assessment. All assessors underwent a training session for the instrument in question supervised by a licensed clinical psychologist. The M.I.N.I. 7.0 evaluation was used for descriptive purposes and as a clinical guideline for inclusion. The interview also included questions to assess the participants' motivation and ability to complete the treatment. The information provided during the screening and telephone interview was reviewed in a meeting with the clinicians and the Principal Investigator.

Randomization. The 1:1 randomization was conducted independently by researchers who were not involved in other aspects of the study and used a true random number service (www.random.org). A list of anonymous participant identification numbers was used to randomly allocate participants to treatment or control without any restrictions.

Assessment. All outcome measures were collected prior to and after the treatment in both conditions. The assessment forms were administered via the same internet platform that contained the treatment modules (Vlaescu et al., 2016). Two process measures, which were not part of this report, were administered fortnightly during the treatment to be able to investigate mediation: a version of the Adult Rejection Sensitivity Questionnaire adapted by Berenson et al. (2009) and a measure consisting of two subscales from the Behavioral Activation for Depression Scale (the activation subscale and the social impairment subscale, Kanter, Mulick, Busch, Berlin, & Martell, 2007).

Outcome Measures

Primary Outcome.

Loneliness. To measure the subjective experience of loneliness, participants completed the UCLA-LS-3 (Russell, 1996). The measure conceptualizes loneliness as a unitary factor. Items include questions such as “How often do you feel that you lack companionship?” and “How often do you feel close to people?”. The instrument was translated to Swedish in accordance with Gudmundsson’s (2009) guidelines, which included a translation/reverse translation-procedure. The instrument consists of 20 items measured on a four-point scale where the respondents are asked to indicate how frequently the statement is descriptive of them with the alternatives being never, rarely, sometimes, and often. This implies the measurement of loneliness as a trait as no time frame on which the respondents are to make their choice is specified. The word lonely is never used in the original version. As the Swedish language uses the same word for lonely and alone, the translated questionnaire

did contain this word in one of the items. The UCLA-LS-3 has been used extensively in loneliness research (including treatment studies such as Hopps et al., 2003, and McWhirter & Horan, 1996). The psychometric properties include a very high internal consistency (Cronbach's α 's ranging from .89 to .94) and a good test-retest-reliability (.73 over a one year-period; Russell, 1996). In the same study the reported mean and standard deviation was reported at 40.08 (SD = 9.50) in a population of college students and 40.14 (SD = 9.52) in a population of nurses. Additionally, a factor analysis in which the questionnaire was included has shown that the measured construct is distinct from interrelated constructs such as social anxiety and depressive symptoms (Fung et al., 2017). The internal consistency in the present sample at pretreatment was Cronbach's $\alpha = .85$.

Secondary Outcomes.

Quality of Life. Quality of life was measured using the Brunnsviken Brief Quality of Life Inventory (BBQ) (Lindner et al., 2016). This instrument consists of 12 items regarding satisfaction with six areas of life where each item is paired with a follow-up question regarding the importance of the area to the respondent's quality of life. The convergent validity with the Quality of Life Inventory (Frisch, Cornell, Villanueva, & Retzlaff, 1992) has been reported to be satisfactory (Lindner et al., 2016). Other psychometric properties include an internal consistency of Cronbach's $\alpha = .76$, and a high test-retest-reliability (ICC = .86). The mean within a student population has been reported at 60, with a score of 48 and 70 corresponding to the 25th and 75th percentile, respectively (Lindner et al., 2016). The internal consistency was found to be adequate in the current sample at baseline (Cronbach's $\alpha = .82$).

Depression. Depressive symptoms were measured using the Patient Health Questionnaire-9 (PHQ-9), a validated and psychometrically sound instrument for measuring the symptoms of major depressive disorder (Kroenke, Spitzer & Williams, 2001). Severity ratings have been reported at 0 - 4 (minimal), 5 - 9 (mild), 10 - 14 (moderate) and 15 - 19

(moderately severe). The internal consistency at baseline in the current sample was in line with previous studies (Cronbach's $\alpha = .78$).

Social Interaction Anxiety. The Social Interaction Anxiety Questionnaire (SIAS; Mattick & Clarke, 1998) was used as a measure for symptoms related to social anxiety. The instrument has been thoroughly validated and has good psychometric properties, including excellent internal consistency (Cronbach's $\alpha = .93$) and good test-retest reliability ($r = .92$ over a twelve-week period) (Mattick & Clarke, 1998). A score above 36 indicates probable social anxiety disorder. In the current sample, the internal consistency was found to be excellent, Cronbach's $\alpha = .92$.

Worry. Symptoms of generalized anxiety and worry were assessed with the Generalized Anxiety Disorder 7-item scale (Spitzer, Kroenke, Williams & Löwe, 2006). The questionnaire has been extensively used for screening and research purposes. Psychometric properties include an internal consistency of Cronbach's $\alpha = .92$, a test-retest-reliability of .82 along with good specificity and sensitivity (Spitzer et al, 2006). Severity ratings are reported at 0 - 4 (minimal), 5 - 9 (mild), 10 - 14 (moderate), and 15 - 21 (severe). In the current study, the internal consistency at baseline was good, as indicated by a Cronbach's α of .82.

Satisfaction with Treatment. At post-assessment the treatment group completed an additional eight-question form regarding their satisfaction with the different aspects of the treatment including the quality of the treatment, the relevance of the modules and the usefulness of the techniques and interventions using a modified version of the Client Satisfaction Questionnaire-8 (CSQ-8; Attkisson & Zwick, 1982). The original questionnaire consists of 18 questions which aim to measure the client's satisfaction of a psychotherapy. The psychometric properties include an internal consistency of Cronbach's $\alpha = .91$ and a correlation with reductions of client-reported symptoms of $r = .35$. All questions are answered on a four-point scale. Attkisson and Zwick (1982) concluded that the eight-question version

of the original had sufficient psychometric properties to warrant use when a brief measure of satisfaction is needed. We used this abbreviated version as a template for the questionnaire administered in the current study. To provide a better fit in the context of ICBT, questions were modified to align with the framework of internet-administered treatment (e.g. questions referred to the content of the treatment as modules, the participants were asked about the feedback they received from the therapist). Questions two to five were modified for content, and the phrasing was slightly altered on other items to provide a better fit with the Swedish language. The questions and the available alternatives for answering on each question can be found in Appendix 1. The internal consistency for the modified version used in the study was found to be excellent (Cronbach's $\alpha = .93$). The answers to each question were interpreted separately to provide information on how the participants evaluated different aspects of the treatment. Of primary interest was the perceived relevance, quality, usefulness, and overall satisfaction with the treatment and its content (question one, two, six, and seven of the questionnaire). In addition to this, a score of one to four on each question was used to provide an estimate of the average satisfaction across the different aspects with the sum ranging from 0 to 32. This was done to allow for investigation of a potential relationship between satisfaction and outcome on the primary outcome measure.

Conditions

ICBT. The treatment group took part of an eight-week ICBT program administered via an online site. The treatment consisted of eight separate modules, one for each week of the treatment. The modules were created by the authors for the present study but were informed by earlier ICBT modules from our group (Andersson, 2016). Each module contained psychoeducation and assignments linked to a general theme centered around the participant's experience of loneliness. The treatment spanned 118 pages of text in total, with individual modules being between 10 and 19 pages long. The modules were administered on a fixed day

each week, regardless of whether the participant had completed the previous assignments or not. Access without the need for completion of previous modules was given because of the lack of certainty of what constitutes effective and essential techniques and assignments for this population. As it was hypothesized that some participants might benefit more from later modules while some show a greater reduction owing to the content of the first modules, it was deemed clinically and ethically responsible to allow participants access to the entire programme. The participants received feedback and guidance on each of the homework assignments and could also ask questions via the treatment platform. Feedback and answers were given within 24 hours on weekdays. The content of the modules along with rates of access and completion is presented in Table 1.

The functional behavioral model introduced in the first module sought to give the participant a model through which their behaviors could be understood and analyzed throughout the treatment. Modules two to four included interventions based on the principles of cognitive restructuring and behavioral experiments. The primary focus of these modules was identifying and dealing with the maladaptive cognitions that have been hypothesized to perpetuate the state of loneliness (Young, 1982; Cacioppo et al., 2015). Modules five through seven placed an emphasis on behavioral change using behavioral activation (Martell, Dimidjian, & Herman-Dunn, 2011). The interventions sought to increase the overall participation in social contexts as well as elevate the perceived quality in existing relationships by increasing behaviors aimed at help-seeking and expressing vulnerability. The aim of these interventions was to reduce the tendency of social withdrawal that has been linked to loneliness in the literature (e.g. Nurmi et al., 1997; Watson & Nesdale, 2012). The modules also contained psychoeducation about avoidance and anxiety as well as a rationale for exposure with reductions of possible safety behaviors for the participants who identified

anxiety as an obstacle. A PDF-version of the modules/manual is available on request for interested readers (currently only available in Swedish).

The participants were treated by final-year students ($n = 5$) enrolled at the five-year clinical psychologist programme at Linköping University (the same students in charge of the assessment). All students had at least 18 months of prior theoretical and practical experience of CBT and received group supervision by two licensed psychologists during both the assessment and treatment phase. The therapists were responsible for providing feedback and corrections for the participant's work with the homework assignments and answered questions related to both the treatment content and the overall framework of the study via the messaging function on the platform. All of this contact was conducted via text and was asynchronous. The feedback was generally grounded in communicative aspects that Paxling et al. (2013) referred to as task-reinforcement (providing verbal reinforcement for strategies and behaviors in line with the rationale for the module), empathetic utterance (conveying empathy regarding hardships and suffering), and self-efficacy shaping (pointing out and reinforcing spontaneous actions and behaviors that suggest that the participants had expanded their behavioral repertoire in line with the goals of the treatment). At the beginning of each week the therapists sent an introductory message with information about the content of the module and how it related to the work that had been done previously. They also provided technical support when needed (e.g. when a participant had a problem logging in to the platform) and provided reminders by phone if the participant had not logged in during the previous week. The therapists had access to an online discussion forum on the platform between the supervision sessions (which were conducted face-to-face) for internal discussions on the content and structure of the homework feedback.

Control group. The participants in the control condition received a login on the online site but had no access to the treatment modules during the treatment period. They were

instructed, via the message service included on the site, that they were to begin their treatment once the initial treatment period had ended. The control group's use of the platform was restricted to filling in the assessments and, if needed, asking questions regarding the study (questions could also be asked to a public email address). The therapists in charge of contact with the control group were the same people that handled the treatment group during the study. Communication with the control group was kept to a minimum and only related to aspects of a non-clinical nature (i.e. questions regarding the time-frame of the first treatment period or wanting to discontinue their participation). No monitoring took place during the initial treatment period for the control group. After the initial treatment period they received access to the treatment with therapist guidance on-demand (i.e. they could ask a therapist questions and receive feedback if they needed guidance in their work with the modules). Results are presented in the online supplement (Tables 4 and 5).

Statistical Analysis and Power

All analyses were conducted using SPSS Version 23 or Mplus Version 7.3. Throughout, comparisons were two-tailed and treated as statistically significant at the level of $p < .05$, and confidence intervals are given with 95% margin. Baseline characteristics were investigated using ANOVA or t -tests for continuous distributed variables and chi-square test of independence for categorical variables. Non-normality robust regression with maximum likelihood estimation for continuous variables (returned by the MLR option in Mplus) was used as the primary analytic model to test for difference between treatment and control (treatment variable: 0.5 = treatment, -0.5 = control) at post-treatment, using pre-treatment values of the outcome variable as a covariate (similar to analysis of covariance, ANCOVA). We calculated a standardized mean difference between-group effect size measure for continuous distributed variables (Cohen's d) using the standard deviation at pretreatment. Estimated means (and variances) were obtained from the model and unstandardized and

standardized between-group effect sizes (i.e., mean difference divided by the baseline standard deviation) were calculated at post-assessment using the model-implied mean difference and standard deviation. Following the intention-to-treat principle, all participants who were randomized were included in the primary analyses. Full information maximum likelihood (FIML) was used to retain data from participants who had missing values on one or more outcomes in the models. FIML is one of two recommended methods for analysis with incomplete data (Schafer & Graham, 2002), and produces unbiased estimates and standard errors under a less restrictive missing data assumption (so called missing at random assumption, MAR; Enders, 2010). Assuming a moderate standardized mean difference effect size at endpoint ($d = 0.68$), 70 participants would be required to obtain 80% power with a two-sided alpha-level of .05.

Results

Enrollment and Baseline Characteristics

Figure 1 depicts the flow of participants through the study. Of the 98 who expressed an interest in taking part in the study and who were assessed for eligibility, 73 were found eligible and were randomized to treatment ($n = 36$) or control ($n = 37$). Of the excluded participants, the majority were excluded either due to other medical or psychiatric problems (e.g., suicidality) that required special attention. Other reasons for exclusion can be found in Figure 1. No significant differences between conditions were found between the groups in regards to demographics (Table 2; all $p > 0.13$) and outcome measures (Table 3; all $p > 0.46$) at baseline.

Attrition, Treatment Adherence, and Missing Data

Overall attrition was low ($n = 7$); four participants (8%) wished to discontinue treatment during the active treatment phase, whereas three participants (11%) randomized to control reported that they wished to drop out from the study during the same time period.

Table 1 shows percentage of completers for each module. In the treatment condition, participants completed on average 4.89 (SD = 3.03) of the eight modules during the active treatment phase with completion rates of individual modules ranging from 83% (module 1) to 39% (module 8). In total, 18 participants (50%) in the treatment condition completed five or more modules, and 12 participants (33%) participants included in this group completed all eight modules during the active treatment phase.

There was no significant partial correlation between the number of modules completed and the participants' post-treatment score on the loneliness measure controlling for participants level of loneliness at pretreatment assessment ($r = .11, p = .61$). The therapists had an average treatment time of 12.52 minutes (SD = 7.28) per participant per week. The partial correlation between the average total treatment time and post-treatment outcome on the primary measure, whilst controlling for participants level of loneliness at pretreatment assessment, was not statistically significant ($r = .22, p = .29$).

Across conditions 61 participants (84%) completed the outcomes measures at post-treatment. Of those randomized to the treatment condition, 27 participants (75%) completed the post-assessment and of those randomized to the control condition 34 participants (92%) completed the outcome measures at post-assessment. Two participants, one in each condition, reported having started other psychotherapeutic interventions during the treatment period. Across conditions, there were no statistically significant differences with regards to demographic variables or primary and secondary outcome measures at pre-treatment assessment between those who completed the assessment at post-treatment and those who did not (all p 's > .22).

Continuous Outcomes

Table 3 provides observed means and standard deviations for outcome variables at each assessment point by condition. Non-normality robust regression for continuous

outcomes (co-varying pretreatment scores) revealed a statistically significant mean difference between conditions at posttreatment on the primary outcome UCLA-LS-3, $b = -4.65$, $SE = 1.57$, $p = .003$, $d = 0.77$, 95% CI [0.22, 1.33].

Non-normality robust regression for continuous outcomes (co-varying pretreatment scores) revealed a statistically significant mean difference between conditions at posttreatment on the secondary outcome BBQ, $b = 13.95$, $SE = 3.48$, $p < .001$, $d = 0.81$, 95% CI [0.40, 1.22]. Similarly, there was a statistically significant mean difference between conditions on SIAS $b = -5.37$, $SE = 2.38$, $p = .024$, $d = 0.35$, 95% CI [0.04, 0.66]. Although results approached the significance level, no statistically significant difference was detected on secondary outcomes GAD-7, $b = -1.72$, $SE = 0.98$, $p = .077$, $d = 0.39$, 95% CI [0.04, 0.81], and PHQ-9, $b = -2.03$, $SE = 1.09$, $p = .061$, $d = 0.41$, 95% CI [0.02, 0.84].

Satisfaction with the Treatment

Twenty-seven participants in the treatment group filled in the questionnaire regarding satisfaction with different aspects of the treatment. As for the questions of primary interest, 63% of the participants rated the quality of the treatment as *good* ($n = 17$), and 11% ($n = 3$) considered it to be *excellent*. Of the remaining participants, 22% ($n = 6$) rated the quality as *moderate* while 4% ($n = 1$) rated the quality as *poor*. In total, 15 of the 27 participants (55%) regarded the modules as *mostly relevant* for their problems ($n = 15$), 11% as *very relevant* ($n = 3$) while 30% ($n = 8$) felt that the content was *somewhat relevant*. Four percent ($n = 1$) rated the modules as *not at all relevant*, 52% ($n = 14$) answered that the treatment had been *somewhat useful* in helping them deal with their problems, 26% ($n = 7$) rated the treatment had been *very useful*, and the remaining 22% ($n = 6$) rated the usefulness as *not at all useful*. In regards to overall satisfaction 55% ($n = 15$) said that they were *mostly satisfied*, 22% ($n = 6$) choose *very satisfied*, 19% ($n = 5$) considered themselves *indifferent*, and 4% ($n = 1$) rated their satisfaction as *unsatisfied*. The frequencies of answers within each category for the other

four questions can be found in Appendix 2. The mean sum of satisfaction for the entire questionnaire was 23.96 (SD = 4.67). A partial correlation with control for the pretreatment rating on the UCLA-LS-3 indicated that this rating was not significantly related to the outcome on the primary outcome measure ($r = .21, p = .31$).

Discussion

The aim of this pilot study was to investigate the effects of an internet-administered treatment aimed at alleviating feelings of loneliness for a group of people who considered loneliness to be a primary concern. The results showed that the treatment group exhibited a significant reduction in the amount of time they spent feeling lonely, as compared to the control group. The reduction expressed as effect size showed a moderate effect of Cohen's $d = 0.77$. In relation to general population (Russell, 1996), the treatment effect corresponds to a reduction of about one standard deviation on the main outcome measure, which means that the treated participants on average ended up one standard deviation above the average population with regards to experiencing feelings of loneliness (a reduction from being two standard deviations above the average population). The post-treatment mean thus represents a score in between feeling lonely sometimes and feeling lonely rarely. The results also revealed a significant increase in quality of life, Cohen's $d = 0.81$, and a small but statistically significant decrease in symptoms of social anxiety, Cohen's $d = 0.35$, compared to the wait-list condition. For the outcome measures of depressive symptoms and worry the differences between the conditions were non-significant, although the results showed a trend towards fewer reported symptoms in the treatment group than in the control group. Although this is not the first study to include the principles of cognitive restructuring to reduce feelings of loneliness (see Masi et al., 2011), the findings extend the literature by showing that a highly structured programme based on CBT-principles and techniques can be of help for this population. The results also indicate the potential usefulness of behavioral interventions, in

this case behavioral activation and exposure with a reduction in safety behaviors for this population. Additionally, our results lend support to the notion that ICBT can be effective for this client group. This is important as the treatment format has the potential to increase overall access to psychological treatments and reach underserved people in remote areas (Andersson, 2016).

Along with the decrease in loneliness the participants in the ICBT condition experienced a significant increase in quality of life, which could be viewed in light of the previously noted link between loneliness and quality of life, with a higher degree of loneliness being hypothesized to cause a decrease in the quality of life (Ekwall et al., 2005).

The treatment group also showed significantly lower scores on SIAS when compared to the wait-list condition. Although previous research has noted a relationship between loneliness and symptoms of social anxiety (Lim et al., 2016), it is possible that we obtained a secondary impact on social interaction anxiety by treating loneliness. If it is a primary or secondary effect of the intervention cannot be determined here and this question merits further research in larger samples.

A non-significant reduction in worry was found at post-treatment when comparing the two groups, although there was a trend towards significance and a small-medium between-group effect size ($d = 0.39$). Even if the interest in change on GAD-7 was primarily exploratory, loneliness and worry have been linked in the past (e.g. Beutel et al., 2017), and the affective and cognitive features of the loneliness are often thought to closely resemble that of anxiety (Peplau & Perlman, 1982).

Drawing upon the literature linking feelings of loneliness and depression, VanderWeele, Hawkey, Thisted, and Cacioppo (2010) suggested that interventions targeting loneliness may also reduce symptoms of depression in this population over time. We did not find a significant treatment effect on depressive symptoms, although a trend in favor of the

treatment group was observed. One possible area of research would be to study the relationship between loneliness and rumination. Previous research has suggested that the latter construct may mediate the link between loneliness and depressive symptoms (Vanhalst et al., 2012). It could be that our intervention did not target loneliness-specific depressive symptoms (and rumination) well enough, even if we included methods used in depression treatment (like behavioral activation).

Our findings can be viewed from a transdiagnostic standpoint. As mentioned in the introduction, loneliness is most likely common in many psychiatric populations. The ability to alleviate loneliness directly by way of CBT may have implications for how to address psychiatric disorders in cases where loneliness has an impact (e.g., depression and social anxiety disorder). While the causal relationships remain to be investigated and cannot be determined in the present study, viewing loneliness as a transdiagnostic problem may be helpful in case conceptualization work with individual clients (Philippot, Bouvard, Baeyens, & Dethier, 2019).

The results revealed a non-significant relationship between the ratings of loneliness at post-treatment and both number of completed modules and average treatment time devoted by the therapist per module. This is interesting as the number of completed modules were on average 5 out of 8, with a third completing all modules. A lack of a relationship between “dose” of intervention (provided that the number of modules and/or therapist contact can be seen as an adequate proxy for this) and reduction of psychological distress has been observed in other ICBT studies (Andersson, 2016). The idea that a relatively small exposure to psychotherapy is “good enough” to create a significant change is sometimes used to explain findings such as these (Barkham et al., 2006). The finding that the participants showed a reduction in loneliness without exposure to the entire treatment programme could however indicate early gains from the the initial modules focusing on psychoeducation, general CBT-

components such as goal setting and functional analysis, and techniques for cognitive restructuring. Overall, however, more work is needed to investigate which modules are most helpful and which ones are not needed. For example, there may be subgroups of individuals responding to specific elements of the intervention. Indeed, analyses based on any post-assignment variable (e.g., dose variable) could result in biased estimates of the effect of treatment in RCTs. Other data analytic methods (e.g., complier average causal effect analysis; Jo, 2002) would be needed to establish causal effects among different subgroups of participants who have been exposed to the treatment to varying degrees (see Hesser, Hedman, Lindfors, Andersson, & Ljótsson, 2017). Unfortunately, the data in our study did not allow such analyses, and any presence or lack of correlations should be interpreted with caution. Further, the definition of completion used in the study (i.e., completing assignments to a satisfactory degree as judged by the therapist) is not the only way to define treatment completion in ICBT studies. For example, Titov et al. (2013) described completion as when the participant viewed all available text in a module (called lesson), with no restrictions for moving on in the program. This makes it difficult to compare studies as our participants did not have immediate access to all modules.

With regards to overall satisfaction, 77% of the participants rated themselves as mostly satisfied or very satisfied with the treatment. Although a high proportion of participants (78%) found the programme to be relevant for their problem, slightly more than a fifth of the participants did not find the treatment relevant for their situation. What separates these groups in terms of perceived relevance is unknown at this point, but further studies might find more detailed qualitative evaluations useful in order to improve interventions for this population.

The results should be viewed in the light of the limitations of the study. The randomized, controlled design gives strength to the notion that the significant reductions in

loneliness and improved quality of life was caused by the treatment. However, the design does not account for the possibility that non-specific effects, for example contact with the therapist, might have a role in the results. While this contact was fairly standardized throughout the treatment, this may be relevant because of the nature of loneliness. It is possible that the communication between the participant and the therapist touches on principles important in the foundation of a meaningful relationship (e.g. active listening, validation), thus reducing the feeling of loneliness through other means than the CBT-techniques. Later studies should control for the possible role of non-specific treatment effects. The collected data also does not allow conclusions regarding the long-term effects of the treatment on loneliness, or on any of the other constructs. The long-term benefits of the treatment are therefore unknown at this point, and something that should be investigated in future studies.

The fact that the Swedish language uses the same word for lonely and alone does mean that the primary outcome measure had to be phrased in a way that was not consistent with the English original. How this affected the psychometric properties is unknown at this point. Previous research suggests that there may be a slight difference between men and women when asked of feelings of loneliness by direct (i.e. mentioning the word lonely) as compared to indirect means (i.e. not using the word lonely; Borys & Perlman, 1985). However, given the option to exclude the item, we decided to maintain the item as we prioritized keeping the instrument as faithful to the original as possible. Future studies may need to investigate whether the different phrasing results in a meaningful difference in the instrument's properties and ability to measure loneliness across subgroups and cultural contexts.

The observation that approximately 60% of the participants had obtained a university degree is in line with previous research on ICBT indicating that samples for ICBT studies

tend to have a higher education level than is to be expected in a representative sample (Titov, Andrews, Kemp, & Robinson, 2010). This is a threat to the external validity and may be an obstacle when disseminating the treatment into clinical practice. Another factor related to the external validity is the choice of outcome measures. The primary outcome measure, the UCLA-LS-3, is not constructed to measure change from a clinical standpoint as no time-frame is specified and the wording implies a trait conceptualization of loneliness. This might make it hard to detect change over brief periods of time, such as the eight-week treatment period in this study. The fact that a significant reduction was found in spite of this suggests that loneliness can be reduced in a relatively short amount of time. However, with no clear cut-offs or guidelines for interpretation it is difficult to say whether the indicated change is clinically relevant. Also, while a vast majority of the participants had scores one standard deviation above the reported mean (Russell, 1996) before the start of the study, it is not possible to conclude if this group consisted of a representative sample from a population of people suffering from loneliness. Loneliness as a concept is, at this point in time, rather ill-defined from a clinical standpoint. Future research should focus on differentiating what is to be considered abnormal loneliness from the general and transient state, in line with how major depressive disorder is differentiated from a temporary depressed mood state by means of a multitude of diagnostic criteria.

Moreover, as our measure of loneliness arguably has a trait-like character, it is a limitation that no other trait measures were administered to investigate relationships between the trait of perceived social isolation and potentially relevant personality factors such as tendency towards depressive thinking and low emotional stability. While previously diagnosed personality disorders were a reason for exclusion of participants, changes on personality dimensions might be of interest in future studies in order to elucidate the difference between transient, non-problematic forms of loneliness and its chronic counterpart.

Even if cognitive distortions and biases have been implied in the maintenance of loneliness over time (e.g. Cacioppo et al., 2016; Cacioppo et al., 2015), and partly served as a target in the treatment programme, possible changes in these processes were not investigated. This is a limitation as cognitive distortions could be a change mechanism behind the loneliness intervention. Additionally, the study gives us no information about whether targeting biases and distortions more directly, and as the main treatment component, actually would help alleviate loneliness.

Another limitation is the small sample size that limits the statistical power to detect small between group differences and also affects accuracy of estimates. A larger number of participants would improve the ability to detect smaller effects of the treatment on secondary measures. Another caveat is the dropout rate, which reached 14 percent in total. As this subgroup did not provide any data at post-treatment assessment the reasons for dropping out could not be determined. It is important to note however that missing data were handled under the less restrictive missing data assumption, which is formally known as MAR. MAR allows missing data to be a function of observed variables included in the model (e.g., pre-treatment severity score and condition).

Two of the participants reported having started psychological treatment during the study period, which is a threat to the internal validity. However, because of low number of participants for whom this was a problem and the fact that they are equally divided between the conditions, we do not believe that this influenced the results in a meaningful way. Thus, they were included in the ITT-analysis.

Some aspects of the screening process also constitute practices that should be addressed in future studies. These include the lack of data for calculation of inter-rater reliability for the interviewers and adherence to treatment protocol for the therapists. However, as for the former concern, it should be noted that the structured interview only

served as a help for the decision on inclusion/exclusion and did not relate to the outcomes of interest in the present study.

In spite of the limitations, the pilot study adds valuable knowledge about the possibilities of alleviating loneliness by means of cognitive and behavioral interventions delivered via the internet. While more research is needed on the long-term efficacy and processes underlying the reduced feelings of loneliness, the results indicate that ICBT may be an effective way to reduce clinically relevant loneliness and its associated problems.

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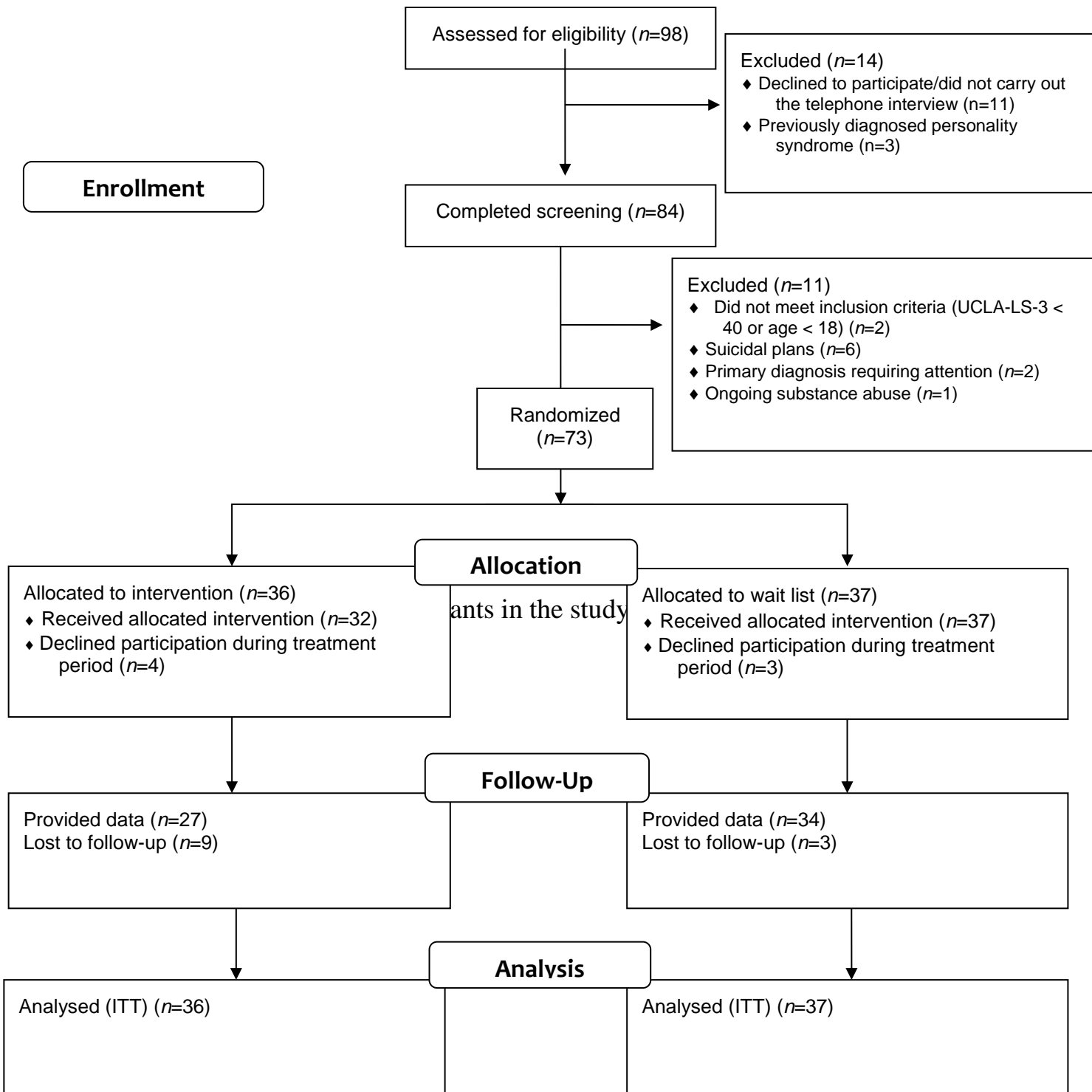


Table 1. Treatment modules

Module	Description	Percentage of participants (<i>n</i> = 36) accessing the module	Percentage of participants (<i>n</i> = 36) rated as completers
1	Psychoeducation regarding loneliness and an introduction to a functional behavioral model used throughout the treatment.	92 %	83 %
2	Identifying goals, values, and an introduction regarding techniques used to challenge dysfunctional thoughts and beliefs	86 %	78 %
3	Continued work with challenging dysfunctional thoughts and beliefs with the addition of strategies to reduce rumination	78 %	78 %
4	Behavioral experiments	67 %	58 %
5	Behavioral activation aimed at increasing the amount of social contact	81 %	61 %
6	Continued behavioral activation and a rationale for exposure with reduction of safety behaviors	78 %	47 %
7	Continued behavioral activation and evaluation of the previous interventions	64 %	44 %
8	Relapse prevention	58 %	39 %

Table 2. *Demographic Characteristics of Participants at Baseline*

Characteristic	Treatment (<i>n</i> = 36)	Control (<i>n</i> = 37)	Total (<i>n</i> = 73)
Age: Mean (SD)	45.6 (16.68)	48.8 (18.40)	47.2 (17.63)
Women: <i>n</i> (%)	26 (72.2)	26 (70.3)	52 (71.2)
Marital Status <i>n</i> (%)			
Single	16 (44.4)	19 (51.4)	34 (46.6)
Partner/Married	12 (33.3)	11 (29.7)	23 (31.5)
Divorced/Widow/Widower	8 (22.2)	7 (18.9)	15 (20.5)
Children: yes <i>n</i> (%)	21 (58.3)	20 (54.1)	41 (56.2)
Highest Educational Degree: <i>n</i> (%)			
Primary school	1 (2.8)	1 (2.7)	2 (2.7)
Secondary school	12 (37.5)	11 (33.3)	23 (35.4)
College/University	20 (62.5)	22 (66.7)	42 (64.6)
Other vocational education	2 (5.6)	3 (8.1)	5 (6.9)
Postgraduate	1 (2.8)	0 (0)	1 (1.4)
Occupational Status: <i>n</i> (%)			
Working/student	27 (75)	21 (56.8)	57 (75.3)
Unemployed	0 (0)	1 (2.7)	1 (1.4)

Retired	7 (19.4)	13 (35.1)	20 (27.4)
Registered sick leave/disability pension	0 (0)	2 (5.4)	2 (2.7)
Other	2 (5.6)	0 (0)	2 (2.7)
Previous treatment for mental illness: Yes <i>n</i> (%)	19 (52.8)	15 (40.5)	34 (46.6)
Use of psychopharmaceutic medication <i>n</i> (%):			
No	21 (58.3)	24 (64.9)	39 (61.6)
Yes, previously	4 (11.1)	5 (13.5)	9 (12.3)
Yes, ongoing	11 (30.6)	8 (21.6)	19 (26.1)
Classes of psychopharmaceutic medication reported:			
	SSRI (<i>n</i> = 4) Stimulants (<i>n</i> = 2) SNRI (<i>n</i> = 4) NaSSA (<i>n</i> = 1) TCA (<i>n</i> = 1)	SSRI (<i>n</i> = 3) Stimulants (<i>n</i> = 1) SNRI (<i>n</i> = 1) Lithium (<i>n</i> = 1) Anticonvulsants (<i>n</i> = 1) Atypical antipsychotics (<i>n</i> = 1)	SSRI (<i>n</i> = 7) Stimulants (<i>n</i> = 3) SNRI (<i>n</i> = 5) NaSSA (<i>n</i> = 1) TCA (<i>n</i> = 1) Lithium (<i>n</i> = 1) Anticonvulsants (<i>n</i> = 1) Atypical anti- psychotics (<i>n</i> = 1)
Probable psychiatric diagnosis (as indicated by MINI 7.0): <i>n</i> (%)			
Major Depressive Disorder	6 (16.7)	7 (18.9)	13 (17.8)
Social Anxiety Disorder	3 (8.3)	2 (5.4)	5 (6.8)
Generalized Anxiety Disorder	1 (2.8)	1 (2.7)	2 (2.7)
Obsessive Compulsive Disorder	1 (2.8)	0 (0)	1 (1.4)
Panic Disorder	0 (0)	1 (2.7)	1 (1.4)

Agoraphobia	0 (0)	1 (2.7)	1 (1.4)
Bipolar disorder I	1 (2.8)	3 (8.1)	4 (5.5)
PTSD	2 (5.6)	1 (2.7)	3 (4.1)
Bulimia Nervosa	2 (5.6)	1 (2.7)	3 (4.1)
Binge Eating Disorder	1 (2.8)	1 (2.7)	2 (2.7)
Alcohol Use Disorder	1 (2.8)	3 (8.1)	4 (5.5)
Antisocial Personality Disorder	2 (5.6)	0 (0)	2 (2.7)

Table 3.
Observed Means, Standard Deviations, and Ns for each Measure by Condition Over Time

<i>M</i>	<u>Pretreatment</u>		<i>M</i>	<i>SD</i>	<u>Posttreatment</u>	
	<i>SD</i>	<i>n</i>			<i>n</i>	
UCLA-LS-3						
Treatment	58.61	4.15	36	50.52	6.95	27
Control	59.62	7.47	37	56.24	9.41	34
BBQ						
Treatment	32.61	17.21	36	45.48	16.95	27
Control	32.14	17.86	37	32.06	18.67	34
SIAS						
Treatment	31.81	14.12	36	25.41	12.20	27
Control	34.39	16.90	37	31.76	16.40	37
PHQ-9						
Treatment	10.14	5.68	36	6.26	4.10	27
Control	9.46	4.30	37	8.09	4.83	34
GAD-7						
Treatment	7.03	4.60	36	4.89	3.64	27
Control	6.76	4.40	37	6.35	4.47	34

Note. UCLA-LS-3 = UCLA Loneliness Scale, Version 3; BBQ = Brunnsviken Brief Quality of Life Questionnaire; SIAS = Social Interaction Anxiety Scale; PHQ-9 = Patient Health Questionnaire-9; GAD-7 = Generalized Anxiety Disorder Screener-7