ORIGO: A RANDOMIZED CONTROLLED STUDY

– THE EFFICACY OF A GUIDED SELF-HELP TREATMENT FOR GENERALIZED ANXIETY DISORDER VIA THE INTERNET

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Keywords
Generalized anxiety disorder, computerized cognitive behavior therapy, CBT

Abstract

The aim of this study was to evaluate if a population suffering from generalized anxiety disorder could benefit from an Internet based self-help treatment guided via email contact with a therapist. The treatment was based on established cognitive behavioral principles. It was hypothesized that significant improvements would be found as measured by eight self report questionnaires, absence of a clinical diagnoses and global clinical improvement. A total of 89 participants were included and 44 were randomized to a treatment condition and 45 were assigned to a waitlist control. The controls received similar treatment after the first post treatment assessment, conducted eight weeks after the beginning or treatment of the first group. The results showed statistically significant improvements for the treatment group. No changes were observed in the waiting-list control group, with the exception of a minor decrease in depression scores. Large effect sizes were found both within the treatment group and between the two groups in favor of the treatment. In conclusion, Internet treatment can be an efficacious format for treating generalized anxiety disorder.

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Contents

Origo: A randomized Controlled Study – the Efficacy of Guided Self-help Treatment for Generalized Anxiety Disorder via the Internet

This thesis is a report of the efficacy of an Internet delivered treatment program that targeted generalized anxiety disorder. The name of the study and the treatment program it contained was Origo, and refered to the written materials as well as the entire project. This name was used in contact with the participants and in communication with various speaking partners to the project.

Basic features of Generalized Anxiety Disorder

Anxiety is a common symptom in almost all forms of psychological distress. In order to understand and treat anxiety, much effort has been put into organizing and classifying the different ways in which people can suffer from anxiety. One institution that has generated such a classification is the American Psychiatric Association. In the text-revised fourth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR; American Psychiatric Association, 2000) it is proposed that it is reasonable to establish 12 different anxiety disorders. One of these constructs is termed Generalized Anxiety Disorder, abbreviated GAD, and its most prominent feature is excessive worry. Excessive worry is described as hard or impossible to control and can be centered around past, as well as, future events. Often, the worry generalizes to many topics and becomes a way of approaching most issues and problems that can be encountered in life. Another criteria that has to be met to indicate GAD, is that a person has to have been worrying for more days than not during the last six months. This cognitive inflexibility is often combined with a rigid level of autonomous functioning, that can be detected when measures of vagal nervous activity are monitored (Roemer, Salters, Raffa & Orsillo, 2005). Of course, if the symptoms can be better understood as emanating from some other diagnoses or due to physiological or chemical factors influencing a patient, the diagnosis is not identified to be GAD.

GAD is estimated to be prevalent in 1.6 percent of the population at any given moment, and in these populations as many as 5.8 percent can be expected to contract this disorder in their life time. The disorder is more common among women than men, with women being over-represented with a factor of 2.5 (Breitholtz, 2006).

According to Turk, Mennin, and Heimberg (2004a), historically, GAD has not always been considered an entity in and of itself. It was first in 1980, with the introduction of the DSM-III, that long term duration anxiety was separated from

panic disorder and was thus introduced as an independent construct. However the hierarchical diagnostic system proposed in the DSM-III turned GAD into a sort of last resort to be considered when most other anxiety diagnoses had been considered, which gave GAD a function resembling that of Anxiety NOS (not otherwise specified). This led to a low frequency of GAD diagnoses which might be responsible for why research into the mechanisms and treatment of GAD has been sparse in comparison to other anxiety diagnoses during the last decades. However, due to the research that has been conducted in this field during the last decades, the understanding of the disorder has come to gain a certain amount of momentum and is now better understood than before.

GAD is a problematic disorder in that it is a highly comorbid disorder that often presents itself as an underlying disorder that bears resemblance to axis-II diagnoses in the DSM-IV (Turk, Heimberg & Mennin, 2004b). These writers also describe comorbidity with other axis-I mental disorders and report that sufferers of GAD has been to be found to have at least one additional diagnosis regarding mental ill-health in as many as 60-90% of the cases. Of those who are diagnosed with GAD, 23 to 59% also suffer from social phobia, and 11 to 27% are also diagnosed with panic disorder. Comorbidity with obsessive-compulsive disorder have been reported to be comparatively low (1-11%), whereas mood disorders are highly comorbid with GAD. In GAD-populations, rates as high as 50% has been reported to also suffer from dysthymic disorder and 42% of a sample of individuals impacted by GAD has been reported to simultaneously be diagnosed with at least one previous depressive episode.

Etiology

There are different theories put forth by the academic community in attempts to explain the underlying mechanisms of GAD. These theories are often examined in research settings, and have come to influence the way this disorder is regarded and diagnosed. A few different explanations of the etiology and pathology of GAD is presented below.

GAD as avoidance of distressing emotions and thoughts

According to Borkovec, Alcaine and Behar (2004) the predominant feature of GAD is that worry functions as a means to cognitively avoid negative imagery and the perception of threat. This model of GAD is based on the empirical evidence of Mowrer's two-stage theory of anxiety that posits that anxiety is the result of the acquisition of a classically conditioned fear, followed by operantly conditioned avoidance behavior of cues that are threatening. From this logic it is concluded that the highly functional avoidance behavior that serves as a means for survival in many organisms, also could come in a cognitive shape not visible to the eye. Thus, avoidance, in humans, could be an internal mental behavior as

well as an external visible behavior. This would also have potentially important implications for the understanding of why exposure therapy is sometimes less effective in GAD, even though visible properties of the exposure setting might be similar. According to Roemer, Salters, Raffa and Orsillo (2005) Borkovec and colleagues have in many empirical trials tested the hypotheses of cognitive avoidance and found it to be an important factor in the maintenance worry. They have explained the function of worry as a negatively reinforced reduction of anxiety produced by a mental distance from images that are perceived to be harmful. This theory might seem to be a contradiction in terms, because it would assume that humans actively engage in self-harming behavior. However, the theory is coherent with behavioral theory where all organisms prioritize the avoidance of harmful stimuli in order to survive, even though it might entail negative consequences. In this theory, then, worry is regarded as a mainly verbal activity that has similarities to problem solving. The problem with this activity is that it becomes ineffective as a solution, due to its main focus on avoiding fear-inducing images rather than solving problems. This theory has implications for the treatment of GAD via empirically tested behavioral techniques, such as worry exposure and the response prevention (in certain spaces or time frames) of worry as a means to reduce anxiety. The uses of such techniques in this study are further elaborated in the description of the materials.

GAD as biased information processing

A core feature of this theory, or group of theories, is the operation of selective information processing in the cognitive system with a bias towards negative information (Macleod & Rutherford, 2004). This is a prominent feature of anxiety disorders in general and can also be said to be true for GAD. Intrinsic to this model is a predisposition of anxiety patients to notice and encode threatening information and drawing threatening inferences when presented with ambiguous information, on an automatic cognitive level. Anxiety patients are also more likely to access and retrieve threatening information from memory than non clinical populations. This approach also entails that the underlying and maintaining feature of GAD is a danger schemata. The theoretical construct of schemata, hypothesizes that GAD-patients more easily than others encode and retrieve threatening information. This process is supposedly facilitated by an automatic activation in the semantic memory, where over-active anxiety nodes create an augmented relevance of ambiguous information. The focus of a bias towards selecting and processing threatening information is in this research tradition an important key to the understanding of the development and maintenance of GAD.

According to Macleod and Rutherford (2004) there is an overarching idea in this theoretical paradigm, which focus worry as a form of cognitive processing in which threatening thoughts are over-represented and are accompanied by

experiences of anxiety persistent over time. This is based on reports that worry is highly correlated with state anxiety. Experimental studies have also shown that worry is ubiquitous and that there are no, or few, differences in the nature and content of worry in populations with GAD and non clinical populations. The major difference in GAD-populations is that people experience less conscious control over their worry. Based on these studies researchers have tried to identify basic differences between the perceived ability to control worry in clinical and non clinical populations. Experimental studies indicate that GAD-patients have a selective bias towards threatening information, including ambiguous information interpreted as threatening. According to Roemer, Salters, Raffa and Orsillo (2005) there is less support for the hypothesis that GAD-patients are biased in the retrieval of threatening information. Both non clinical worriers and GAD-populations share the automatic response to threatening information. However, the difference between a GAD-population and a non clinical population is not in the automatic cognitive responses but in the following responses of these initial responses. After the automatic threat processing responses the non clinical population engages in a conscious cognitive process to counter the emotional distress or anxiety that the threatening information can generate. This ability is something that the GAD-population appears to lack, which would explain why they experience a lower level of control of worry. Thus, studies of information processing lend support to the hypothesis that selective patterns of processing negative information have an influence on the development and maintenance of GAD.

GAD as intolerance of uncertainty

Another theory that is based on empirical research on the nature of worry is Dugas's theory of intolerance of uncertainty, which has relevance to the understanding of GAD (Dugas, Buhr & Ladoceur, 2004; Dugas, Marchand & Ladoceur, 2005). A central tenet to this set of ideas is that worry has more in common with low tolerance of uncertainty than it has with depression and anxiety. Furthermore, experimental trials show that worry seems to be more easily elicited in GAD-patients when uncertainty is higher. This process is therefore common in threatening and/or ambiguous situations, where problem solving might be called for. However, due to the avoidant nature of worry, the cognitive activity in GAD-populations rarely becomes efficient. Instead worry is used as a mechanism to distance oneself from threatening information. In GAD-populations it appears that this strategy is more often used, due to their tolerance of uncertainty being lower. Conversely, the frequency by which GAD-patients detect ambiguous and fear-evoking stimuli is elevated.

GAD as worry about worry

The theory of metacognitive beliefs as central to the etiology of GAD is derived from empirical studies on the nature of worry and clinical trials (Wells, 2004,

2005a, 2005b). According to this theory, metacognition is the cognitive process of thinking about thinking, and becomes central to the etiology of GAD due to the tendency of patients with GAD to hold positive beliefs about worry. This bias is often combined with a belief that worrying is helpful in solving problems and in responding to anticipated threats. Metacognitive beliefs about worry are activated when GAD-patients perceive a threat which activates worry as an attempt to remove the threat. This coping strategy works as a behavioral avoidance strategy that frequently follows upon negative imagery. This makes worry a dominant coping strategy, which is easily activated whenever someone who suffers from GAD, perceive a threat or need to solve a problem. This type of worrying is called type 1 worry and can be described as a chain of negative thoughts about the future. Lampe (2004) has describeb this feature of GAD as "whatifitis" (compare to meningitis), since it is common for GAD-patients to construe negative scenarios about the future using questions beginning with the "What if"-operator. Type 1 worry then continues in an ongoing chain of questions in an attempt to find solutions to the problem at hand. This type of worry can be pervasive, and oftentimes hard to stop. Initially, this manner of worrying easily becomes a source of negative emotions and anxiety evoking, but theses negative effects often subside as the person experiences that she or he can cope with the situation as a result of the worry. However, if this cognitive activity is not immediately successful as an anxiety reducer, the process has a tendency to get ever stronger in an attempt to solve the initial problem.

Meta-cognitions in the form of type 1 worry strengthens the frequency of worry, but negative meta-cognitions about this process at same time makes it painful to continue this activity (Wells, 2004, 2005a, 2005b). During a worry episode, negative meta-cognitive beliefs about worry are activated, and there are two domains of negative beliefs about worry that are central in GAD. Beliefs about the uncontrollability of worry are one domain, and the potential threat of mental, physical and social dangers associated with worrying make out the other. The activation of these negative domains of thought, are termed type 2 worry, or meta-worry. This type of worry activates an escalated cycle of negative meta-cognitions, which is often associated with a loss of control, feelings of loosing ones mind and anxiety reactions. A rise of anxiety can therefore be taken as a sign that the coping strategy of worry is not working. More type 1 worry to cope with this situation can then be executed in order to reduce this secondary anxiety. Type 1 worry is in this way initially regarded as a positive coping strategy, but as the worry progresses and activates negative meta-cognitions about the worry the spiral of anxiety progresses. The pervasiveness of worry for people with GAD creates a reluctance to give it up, even though it involves type 2 worry, because it would mean the cessation of coping. The negative beliefs about worry then makes the person prone to suppress distressing thoughts about the same worry. However, the thought suppression is often inefficient, which is

regarded as evidence of loss of control also in this area. This in turn calls for meta-worry about loss of control and further strengthening of the positive beliefs about worry as a coping strategy. A long term effect of meta-worry is that it produces a narrow repertoire of behaving in threatening situations, that makes it difficult to learn new ways of responding to emotions. Thus, this ineffective worry strategy is kept alive.

GAD as neurobiological malfunctioning

When GAD is examined in a medical context attention is first brought to the regions of the brain that are responsible for detecting and responding to threat via a fear response (Sinha, Mohlman & Gorman, 2004). The amygdala, which is a low level structure in the brain, is primarily important as an administrator of emotions and motivational drive as a means of directing the attention of the organism towards relevant stimuli. This entails the activation of anxiety in a direct response to the possibility of threat. Another brain structure that is important in the understanding of anxiety is the hippocampus, which is closely linked to the amygdala. The role of the hippocampus is to relay information recorded into memory, which includes potentially harmful information and fear-accompanied stimuli. These two areas of the brain use several neurotransmitters to communicate with each other and other parts of the brain. For the understanding of GAD the relationship between these structures and the frontal cortex, were cognitive activity is managed, is especially important. One neurotransmitter that is central to the relay of anxious responses in the brain, is gamma-aminobutic acid (GABA). This transmitter has an inhibitory effect on all parts of the brain that have receptors for this agent. Such receptors are abundant in the amygdala, hippocampus and the frontal cortex. Via the functional connection between the GABA-receptors and bensodiazepine receptors, the insertion of bensodiazepines into this system has an anxiolytic effect. For this reason bensodiazepines have been used to reduce anxiety in GAD patients. The role of other neurotransmitters in GAD has also been investigated, but the numbers of studies are few and the results are often inconclusive. Results therefore imply that norepinephrine, serotonin and cholecystokinin might play a role as etiological agents in GAD, however the mechanisms by which these neurotransmitters affect the development of GAD are yet unaccounted for.

According to Sinha, Mohlman and Gorman (2004) research has been conducted in order to understand the role of neuroendocrine factors in GAD. This research area focus on the effects of chemical influence of hormones rather than the electric effects of neurotransmitters. In these investigations the limbic-hypothalamic-pituitary-adrenal axis is a main area of research efforts. Reports suggest that the activity in this axis is closely linked to anxiety and that anxious responses elicit a reaction in this system which leads to an increased production of cortisol. This is a basic function in stress reactions and helps the organism

maintain homeostasis during the highly elevated energy depletion that occurs during the individuals response to threat via freeze, flight or fight. The basic goal of the research in the area of neurobiological factors influencing GAD, is to understand how dysregulation of these neurotransmitters and hormones can result in elevated general anxiety which might cause GAD.

Treatments of Generalized Anxiety Disorder

Cognitive behavioral therapy (CBT)

Cognitive behavioral therapy has a very good level of evidence to support its efficacy in reducing the ailments associated with GAD (Schulz, Gotto & Rapaport, 2005). Oftentimes this approach entails the use of psychoeducation about the nature of GAD and worry, registration of worry behaviors in everyday life and a cooperative stance towards finding new ways to deal with negative emotional and cognitive events. An understanding of how emotions, thoughts and behaviors influence each other is often pointed out, and in many cases relaxation techniques are used to help the client or patient get better acquainted with their bodies and perhaps change their personal style of responding to anxiety evoking stimuli.

A few techniques that are used in order to help a user of CBT to locate repetitive ways of responding to anxiety with worry is to incorporate unusual ways of behaving towards these events (Breitholtz, 2006). This can be done via the use of "worry time" and "worry free zones", which simply means that the client is instructed not to worry except in a certain given time frame and not worry in certain places. This is done to give the client a direct way to observe how worry affects every day life and how it quickly can become a ubiquitous way to handle a wide range of emotions, thoughts, problems and relationships. This is done to detect how common worry can become, in spite of the delay and pain it may cause when applied to these situations, due to its effect of reducing anxiety short term. Other treatment components include worry exposure and cognitive restructuring, which has the advantage of training the client in behaving in ways that are not compatible with worry. This entails thinking, talking and imagining in different ways, that aim to create an exploring stance towards the content of the mind. Instead of instantly averting oneself from anxiety, the idea is to be curious as to why it presents itself in order to more appropriately respond to it.

Pharmacological treatments

Tricyclic antidepressants (TCA:s), serotonin-norepinephrine reuptake inhibitors (SNRI:s) and selective serotonin reuptake inhibitors (SSRI:s) are pharmacological agents that inhibit the reuptake of different neurotransmitters (Schulz, Gotto & Rapaport, 2005; Rang, Dale, Ritter & Moore, 2003). These

substances allows for transmitters to be more abundant in the central nervous system to facilitate positive fluctuations of mood. Benzodiazepines which have a somewhat sedating effect are also effective in the treatment of GAD, but have the disadvantage of being highly addictive. According to SBU (The Swedish Council on Technology Assessment in Health Care, 2005) SSRI's, SNRI's and benzodiazepines are drugs used in treatment of GAD, that are reported to have adequate levels of evidence to support the prescription of them in clinical settings. However, it is also reported that negative side effects of the administration of these drugs are frequent.

Other psychotherapeutic approaches

According to Schulz, Gotto and Rapaport (2005) there is little support provided for the efficacy of other psychotherapeutic approaches to alleviate GAD. This is possibly an effect of the less frequent utilization of DSM-IV diagnoses in research projects investigating other psychotherapy forms than CBT. One study (Crits-Christoph, Gibbons, Narducci, Schamberger, Gallop, 2005) has examined the outcome of interpersonally oriented psychodynamic treatment of GAD. However, no differences from supportive theory were found on the utilized outcome measures.

Self-help treatment

There are several self-help treatment manuals available in English, which utilize CBT-strategies such as relaxation, exposure to threatening imagery, stimulus control and response prevention of worry (Lampe, 2004; Sanderson & Rygh, 2004; White, 1999). These books rely heavily on psycho education due to the format of the written word. In Swedish there are not yet any self-help books adapted for GAD, hence the public is referred to general self-help literature about anxiety disorders.

Internet treatment

At present moment merely one study has investigated the use of computerized interventions for GAD (Jones et al., unpublished). However, there is a substantial number of studies which report that efficacy can be obtained within Internet treatments for other diagnoses such as depression, social phobia and panic disorder (Andersson et al., 2005; Andersson et al., 2006; Carlbring et al., 2005). These studies show that Internet treatment can be as efficient as live treatment and that they are also cost efficient. Another advantage is that geographic distances can be bridged in terms of increased accessibility to treatment and that both client and therapist can work together separated in time.

Cost efficiency

Palmqvist (2006) has provided an elaborate report of the costs of GAD and its treatment. As reviewed by Palmqvist anxiety disorders cost the Swedish society tens of billions per year and that treatment costs make out the main part of these costs. Most treatment of GAD is pharmacological in Sweden, but CBT is reported to be a more cost efficient method of treatment for this group, since it lowers the frequency of the use of wide range treatments sought outside of psychiatric care. This is understood to be a result of reduced worry about health related issues.

Aim of the study

The aim of this study was to experimentally investigate whether it is possible to alleviate symptoms and indeed the whole GAD-construct via guided CBT self-help treatment administered via the Internet. Another goal was to investigate how people suffering from GAD perceive future possibilities and threats and whether cognitive processing of future possible events could be influenced by guided self-help via the Internet. A third research question in the study was whether guided self-help via the Internet was a cost efficient method of treating GAD. In this thesis the focus is on reporting the efficacy of the treatment. The other research questions will be answered in two other theses simultaneously written (see Palmqvist, 2006; and Dahlin, 2006). The following hypotheses are hence put forth and it is the aspiration of this thesis to test them.

1. Participants in the treatment condition will, in comparison to the control group, reduce their levels of GAD symptoms as measured by PSWQ and GAD Q-IV.
2. Participants in the treatment condition will, in comparison to the control group, reduce their degree of anxiety as measured by STAI and BAI.
3. Participants in the treatment condition will, in comparison to the control group, reduce their degree of depression as measured by BDI and MADRS-S.
4. Participants in the treatment condition will, in comparison to the control group, increase their quality of life as measured by QOLI.

Method

Sample

Recruitment

Information about this study was spread trough articles and interviews in the written and televised media. This was done in both national and local media. Information about the study was also available on an online website (www.studie.nu). The participants in this study were then recruited through the website where applicants were offered to sign up on an interest list. In total, 558 applicants registered their interest in the study at this point. Subsequently these people were contacted via email and invited to register their personal information, and also answer four self-rating questionnaires. The information gathered in this process was used to determine whether the applicant might have use of the materials of the study or not. No payment was given to participants in the study, nor were they required to pay any fees to take part in the project. The only costs for the participants were that they had to have access to the Internet on a regular basis and, if they wanted to, had to sustain the costs for printing the text materials they were given access to.

Inclusion criteria

To be included in the study a participant had to meet several criteria. These criteria were set up to ensure that the ethical guidelines given by the Regional Ethical Review Board in Linköping were met and to only include people who plausibly could benefit from the treatment program. Thus, participants had to be 18 years of age or older and be diagnosed with GAD via the SCID-I (Structured Clinical Interview for DSM-IV; First, Gibbon, Spitzer, Williams, & Benjamin, 1999). In order to be eligible for clinical interview participants also had to register responses to four self-report measures. These were then analyzed in order to give indications of whether a GAD diagnosis was present. This was done with the Penn State Worry Questionnaire, abbreviated PSWQ, (Meyer et al, 1990) and the Generalized Anxiety Disorder Questionnaire IV, GAD-Q IV in short (Newman et al, 2002). The self-report measures also inquired into whether a depression diagnoses could be present via the use of the Montgomery Åsberg Depression Rating Scale - Self rated (MADRS-S) (Montgomery & Åsberg, 1979). If an applicant achieved a score that indicated severe depression (a score of 35 or above) they were not included in study, neither were they included if they gave a response indicating suicidal tendencies on the ninth item of the MADRS-S. The self-report instruments were further designed to cover the applicants use of alcohol. For this purpose the AUDIT (The Alcohol Use Disorders Identification Test; Claussen & Aasland, 1993) was used where applicants were included if they reported a score of less than 19, thus not indicating risk behavior associated with drugs or alcohol. Another inclusion

criteria were that participants had to send in a signed copy of a statement of permission to use the participants personal information in the study, according to the regulations of the Swedish Personal Information Law (1998:204, The Swedish Ministry of Justice). The participants also had to maintain pharmacological intake (of medications for mental ill-health) at a constant level, refrain from participating in other psychological treatment and have no other primary psychiatric diagnosis that would better explain the GAD symptoms. Comorbid conditions were however allowed, but GAD should be the primary complaint. Detailed information about the measures is presented below.

Of the 266 applicants who answered the screening questionnaires 158 met the inclusion criteria and were eligible for receiving a diagnostic interview via telephone. In total, 117 applicants were given the SCID, and of these, 89 were included to the study. The mean age for the included participants was 39.3 years (SD = 10.8) and the percentage of women was 79.8%. The 177 applicants that were excluded either through Internet screening, through telephone interview or due to size boundaries of the study were each sent an email message stating the reason for why they had been excluded. They were also informed of that the reason for exclusion was that they probably would not benefit from participating in this study. They were also given a list of self-help books relevant for their condition, as well as information on how to find therapeutic help in other ways. For participant flow through the study, reasons for exclusion and attrition, see Figure 1.

Clinical diagnoses

To validate the results the applicants had given through the self-report questionnaires, a semi-structured clinical interview was conducted to ensure that participants would indeed meet the DSM-IV-R criteria for generalized anxiety disorder. In the diagnostic procedure, two parts of the SCID (First et al., 1999) were chosen to be administered in the interview. These parts were the diagnoses of major depression and generalized anxiety disorder. No other diagnoses were screened for with the SCID, due to time constraints. Including a test for measuring the participants' future directed thinking at both occassions, the interviews lasted between 35 and 90 minutes. All those included in the study were thus diagnosed with GAD through self-report measures and a diagnostic interview. Of those 89 included in the study 16 also had a current episode of depression, and 11 had had a previous episode of depression. Moreover, 25 had, previously to entering the study, had multiple recurring episodes of depression. A more detailed report of the characteristics of the SCID can be found in the descrition of the measures.

Attrition

At the end of the eighth week of treatment, all 89 participants were asked to fill out the post-measurements regardless of how many modules they had completed in the treatment program. The participants were also, once again, given a research version of the SCID-interview, which included the same questionnaires as the interview administered in the beginning of the study. The total number of participants who entered their self-report post-measurement data was 82 (92.1%). This entailed that in the control group, 44 (97.8%) entered their self-report data at post testing, and in the treatment group 38 (86.4%) sent in their self-report data at post-measurement.

Attrition also occurred before to the second round of SCID-interviews which had the effect that 81 (91.0%) of all participants were given a SCID-interview at post-measurement and that 44 (97.8%) participants in the wait list group were given interviews at post-measurement. Summarily, 38 (86.4%) participants in the treatment condition were given interviews at post-measurement. This meant that a total of ten participants failed to report complete post-measurements. Four of these gave no post-measurements at all, three entered their self-report post-measurements but did not receive an SCID-interview and, finally, three were given SCID-interviews but did not enter their self-report data at post-measurement. In the control group one individual did not enter his or her self-report measures and one was not interviewed. In the treatment condition four gave no post measures at all, two entered their self-report data but was not interviewed and, conversely, two did report post measures through self-report but were not given an interview. An elaborate description of the attrition in the study can be found in Figure 1.

Measures

The measures used in this study were self-report questionnaires, a semi-structured interview and a systematic assessment of clinical global improvement. The self-report measures served a double function in that they were used both as screening instruments and as outcome measures, unless otherwise reported.

Structured Clinical Interview for DSM-IV (SCID-I-RV)

The SCID-I-RV (First, et al., 1999) is a semi-structured clinical interview designed to facilitate DSM-IV diagnoses. It entails a hierarchical system through which to conduct the interview and allows for both prerequisite and spontaneous questions to be asked during the assessment. The interviewer is guided by the structure to ensure that all criteria are accounted for and when criteria is not met the interviewer is informed on when to continue the inquiry of certain diagnoses

and when to shift focus and investigate the relevance of other diagnoses. In this manner more diagnoses can be covered and the frequency of reported comorbidity is elevated through the use of the SCID, which can give a more diverse picture of the individual situation of each patient (Zimmerman & Mattia, 1999). The SCID comes in different versions where the basic design differences are for clinical and research uses. The SCID-I-CV is used for clinical settings and the SCID-I-RV is adapted to research uses. The different versions are created for administrative purposes and take into account the different demands of clinical and research settings in recording information. One key aspect of both versions of the SCID-I is that they aspire to include a multi-axial assessment that mimics that of DSM-IV. However, axis-II diagnoses are not covered in the two versions of SCID-I, which instead are covered in a separately designed instrument called SCID-II. In this study two diagnoses were covered using the parts of the SCID-I-RV instrument that cover depression and generalized anxiety disorder.

Penn State Worry Questionnaire (PSWQ)

The Penn State Worry Questionnaire (Meyer et al, 1990) consists of 16 items, which the participant can give a value of 1-5, thus, overall results theoretically range from 16-80. If a participant reports the highest value on an item it indicates that the respondent agrees that the item reflects his or her situation. The lowest value indicates that the participant does not agree that it is true for her or him. Meyer et al. (1990) has shown that the PSWQ has a high validity and reliability. Items 1, 3, 8, 10 and 11 are inverted in order to ensure that a participant does not routinely give high responses. In this study a cut-off value for this measurement was set at 53, which has been reported to be an appropriate cut-off level in order to determine that a person indeed suffers from GAD (Fresco, Heimberg, Mennin & Turk, 2003).

Generalized Anxiety Disorder Questionnaire-IV (GAD-Q-IV)

The GAD-Q-IV (Newman et al, 2002) is an instrument that is an attempt to mimic the structure of the DSM-IV diagnoses of generalized anxiety disorder in its design. Thus, the questionnaire is comprised of a checklist that inquires into whether the participant has had excessive worry during the last 6 months. It also lets the participant register symptoms which are common with GAD-patients via a checklist, and lets the respondent give an account over his or her worry areas or topics. The last question allows for the participant to give an answer as to how severely she or he is impacted by GAD on a Likert type scale. As cut-off for this instrument, a score of 5.7 has been reported to indicate the presence of GAD (Carlbring, 2005). However, due to technical error, ten participants with a lower score than 5.7 were included in the study. The reason for inclusion in the study was that these participants were diagnosed as having GAD via the SCID-interview, which was given priority to the self-report measurement.

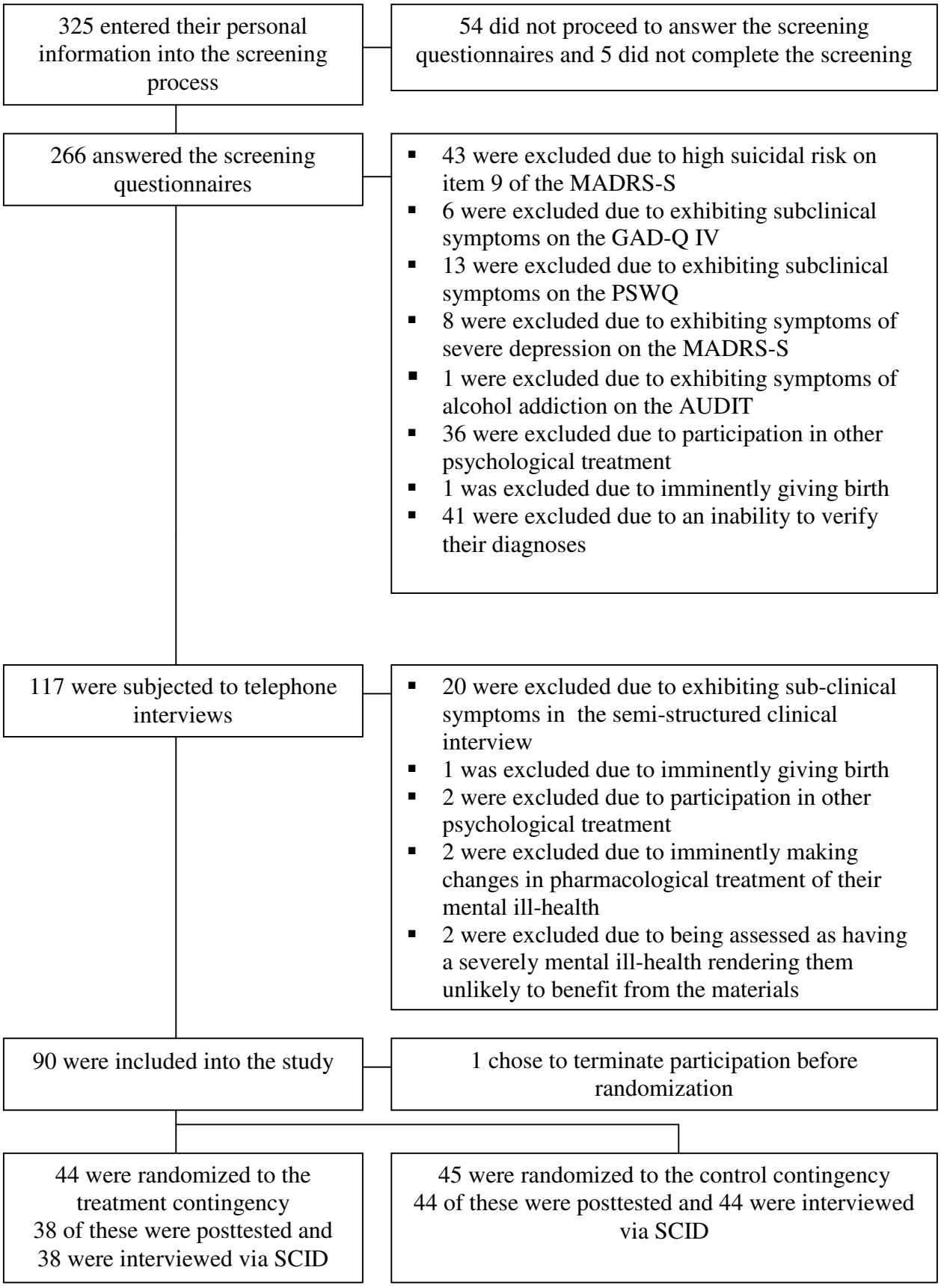

Figure 1. Flowchart of inclusion and attrition.

State-Trait Anxiety Inventory (STAI)

The STAI scales (Spielberger, Gorsuch, Lushene, Vagg & Jacobs, 1983) are divided into two inventories of 20 questions each. These subcategories, named STAI-T and STAI-S, separately measure trait anxiety (defined as anxiety that persists over time and different situations) and state anxiety that refers to the level of anxiety that the respondent has experienced in a recent time period. All questions are answered on a scale from 1-4, where a low score indicates that the statement given in the item is not at all or very little/seldom true for the respondent. The scoring of the STAI is to be interpreted directly in the sense that high scores indicate more anxiety and vice versa. The inventory has been reported to achieve satisfying levels of test-retest reliability on the trait anxiety inventory (.65 to .86) and, expectedly, lower levels of test-retest persistence on the state anxiety inventory (Carlbring, 2005). The STAI entails inverted items to counter routinely high scoring. On the STAI-S items 2, 3, 6, 9, 11, 12, 16, 17, 20 and 21 are inverted and similarly on the STAI-T items 1, 3, 6, 7, 10, 13, 14, 16 and 19 are inverted. This measure was only used as an outcome measure.

Beck Anxiety Inventory (BAI)

The BAI is a self-report questionnaire consisting of 21 items that measure anxiety symptoms over a one week period (Beck, Epstein, Brown & Steer, 1988). Each item can be responded to with replies ranging from 0 to 3, which allows for a total score of 0 to 63. The items refer to inner emotional and bodily states, such as “Scared”, “Faint” and “Terrified”. According to Carlbring, (2005) the inventory has been reported to differentiate anxiety from depression and has been shown to have a solid internal consistency (α = .92) and good test-retest reliability over one week (r = .75). This measure was also used only as an outcome measure and was not a part of the screening process.

Beck Depression Inventory (BDI)

In this study the first Swedish version of the BDI was used (Beck, Ward, Mendelson, Moch & Erbaugh, 1961). The BDI is probably the most widely used instrument to assess degree of depression. This instrument is a self-report questionnaire that includes 21 items which can be responded to with answers ranging from 0 to 3, depending how severely the item is impacting on the respondents’ life. A total score of 63 can thus be obtained and norms indicate that 30 is an appropriate cut-off for severe depression. This measure was also used only as an outcome measure of the study.

Montgomery Åsberg Depression Rating Scale - Self rated (MADRS-S)

The MADRS-S (Montgomery & Åsberg, 1979) is a self-rating inventory of depressive tendencies. It is primarily used to detect changes in depressive behavior and thoughts. The inventory has been reported to have a high correlation with clinical impressions and has a high test-retest reliability (r = .80

to .94) (Carlbring, 2005). The inventory contains 9 items with possible replies ranging from scores of 0 to 6. The scoring of the MADRS-S is uncomplicated with high scores implying high levels of depression. The cut-off score for this measure was set at a score of 35, in order to exclude severely depressed applicants.

Quality of Life Inventory (QOLI)

The QOLI (Frisch, Cornell, Villanueva & Retzlaff, 1992) is an inventory that is designed to measure life satisfaction via 16 items that together is assumed to entail many areas of life that can be considered important in achieving a certain level of quality of life. Each item is first given a score of 0 to 2 which indicates whether the item represents an area that is important to the respondent, then the respondent scores how content she or he is with her or his current situation in regards to this area with responses ranging from not all content (-3) to very content (3). This instrument has been reported to have adequate levels of reliability and validity. This measure was not part of the screening process but was used as an outcome measure

The Alcohol Use Disorders Identification Test (AUDIT)

The AUDIT (Claussen & Aasland, 1993) is a self-report questionnaire that is designed to inquire into respondents use of alcohol. The inventory contains 10 items which is responded on Lickert type scales ranging from 0 to 4. A score of 19 or higher has been reported to indicate severe alcohol problems and was chosen as a cut-off in this study. According to Carlbring, 2005 test-retest reliability has been reported (r = .97), and there is also support to indicate a certain level of internal validity for the test (Cronbach's α = .92 to .62). This measure was not an outcome measure, but was used in the screening process.

Clinical Global Improvement (CGI)

This is a three items method of assessing clinical improvement in its complete form (Guy, 1976). In this study only one item was used to assess the level of clinical improvement at the follow up interview conducted at post-measurement. An assessment on a 4 level scale was rendered using the levels: very much improved, much improved, minimally improved and no change.

Materials

All participants in the study had to have access to an Internet connected computer on a regular basis. It was also recommended that the users had access to a printer in order to be able to read the working material away from the computer screen. Access to a printer was however not a prerequisite, and the participant was free to use the materials in whatever way that suited them. The written text materials that the treatment group was given, were comprised of

eight modules. These text modules correlated to an eight week program, during which, the participants were given email support, education and encouragement to help them digest the text and home assignments presented to them each week. The entire text mass was 170 pages long including home assignments, and the length of the modules varied between 9 and 36 pages. Other self-help texts include similar designs, for example Lampe (2004), Sanderson & Rygh (2004) and White (1999). The technique Applied Relaxation, which was used in the treatment program with permission, was directly adapted from Öst (2006). The design of the materials is presented in Table 1.

Design

The design of this study was a randomized controlled experimental treatment study utilizing both a waitlist control group and an active treatment group. Independent variables were a between group variable (control or treatment group) and a within sample variable (time). As measures of outcome on the dependent variables a total number of eight self-rating questionnaires were used, namely the PSWQ, GAD Q-IV, STAI-S, STAI-T, BAI, BDI, MADRAS-R and QOLI. Alongside of these measures, results of a semi-structured clinical interview (SCID) and a clinical global impression (CGI) was obtained and were also used as indicators of change on the dependent variables.

Procedure

An online site (www.kbt.info/origo) was set up during the spring of 2006 to inform the public that a treatment study on GAD was about to be conducted. On this website members of the public had the opportunity to register their interest in the study and, if they chose to do so, they were given a username containing four digits and four letters (e.g. 0001JoAl). The applicants were then invited to fill out 4 screening instruments (GAD Q-IV, PSWQ, MADRS-S and AUDIT). They were also instructed to send in a signed copy of their consent to let their personal information be processed in the course of the study. The applicants that through the screening process were eligible for participation in the study, were then given a SCID-interview via telephone to verify the diagnoses indicated by the self-rating questionnaires. The first 90 applicants who were found to be fitting participants of the study were then included and emails were sent to all excluded applicants stating the individual reasons for exclusion and where the excluded applicants could turn to find other evidence-based treatment.

Table 1
Design of the treatment program.

Module number	Module content
Module 1	*Introduction to CBT, GAD and Internet treatment.* The first module served as a general introduction to generalized anxiety disorder, cognitive behavioral therapy and Internet treatment. It explained the design of the program, which criteria the diagnosis of GAD consists of, and explanations of the etiology and maintenance of excessive worry. It also contained homework assignments to be completed before access was granted to the following module.
Module 2	*Introduction to Applied Relaxation (AR) and the first step of AR (progressive relaxation).* The second module gave an introduction to Applied Relaxation and contained the instructions for progressive relaxation with a recorded verbal instruction provided on a compact disc, which was sent to all those in the treatment condition. In the first week of the relaxation training the participant was instructed to practice progressive relaxation two times a day during a 23 minute long track on the aforementioned CD. To instill an experience of change from tension to relaxation the participant was first instructed to flex a given muscle and the relax it while noticing the difference between the two states.
Module 3	*Step two (short relaxation) of AR, and worry time.* The third module contained instructions for short relaxation, which is a faster way to reach relaxation (7 minutes) where the participant relaxes every muscle group one by one, this time without first flexing the muscles prior to relaxing them. The participant was also given further information as to how worry manifests itself, and was taught how to limit worry in time and space through a designated worry time and worry free zones. The point of a designated worry time, which could be a given half hour in the evening, was to postpone all worry during the rest of the day to this time, hence giving the participant the option to ease in to worry cessation. Worry free zones were places, for instance in the home, in which worry behavior was forbidden, and should not be executed. These areas were therefore used as stimulus control objects.
Module 4	*Step three (conditioned relaxation) of AR and introduction to flexibility to content of thought.* In the fourth module the participants continued their work in AR with attempts to condition their achieved relaxed bodily states to a spoken word ”Relax” (“Slappna av” in Swedish). They also begun exploring the content of their thoughts and were introduced to the concept that the process of thinking and the contents of thought are not one and the same, and that the presence of a certain thought is not equal to mental ill-health.
Module 5	*Step four (differential relaxation) of AR, working with flexibility to content of thought and problem solving.* In the fifth module the training in AR was directed at differential relaxation, which entailed practicing relaxation of inactive muscle groups, while standing up or walking around. The task was thus to differentiate active from idle muscles and relax muscles that were not actively supporting an upright body position. This module also contained the next step in achieving a flexible position towards the content of thought. The participant was here engaged in working with techniques such as cognitive restructuring and challenging the validity of thoughts. The work was centered around identifying common thought traps and how thoughts can elicit dysfunctional behavior.

Table 1 (continued)
Design of the treatment program.

Module number	Module content
Module 6	*Step five (fast relaxation) of AR and worry exposure.* In this module the participants were instructed to continue their training in Applied Relaxation to reach a relaxed bodily state in a shorter amount of time. The time frame in which the participants were expected to achieve relaxation had now been reduced from 22 minutes to about 30 seconds. Ideally they would also be able to relax in many surroundings and in different positions (both standing up and sitting down, for instance). Module 6 also had an element of exposure in it. Here the participants worked on staying in contact with thought and mental images that usually would evoke worrying. Instead of worrying, which was regarded as avoidant behavior, the participant was instructed to stay in contact with the anxiety evoking stimulus and through exposure learn that a memory or image was in fact not harmful to stay in contact with.
Module 7	*Step six (practicing applicability) of AR, interpersonal problem solving and sleep hygiene.* The seventh module instructed participants to begin applying relaxation to situations where they felt beginning signs of their tension rising. In such situations they were encouraged to use the conditioned word they had chosen, and thereby relaxing their bodies in situations were they normally would be tense and start worrying. This module also contained the application of the previously learnt technique of problem solving on interpersonal problems. The task was here to identify interpersonal problems and try to resolve them by using problem solving on the problem at hand. Finally this module contained a text addressing sleeping problems that participants might have and instructions to use sleep hygiene, in an attempt to rectify dysfunctional sleeping patterns.
Module 8	*Relapse prevention and maintenance of progress.* The last module was centered around the issue of maintaining whatever progress had been made. The participants were guided in the construction of a maintenance program and the risk of relapse was addressed. The participants were in this fashion handed over into their own care, but were also instructed to send in reports on how well they were able to keep to their maintenance program. The purpose of this module was to remind the participants that continued work with the strategies they had learnt, would give them a more robust defense against relapses.
Compact Disc	*Applied Relaxation.* At the start of the treatment each participant that was assigned to get immediate treatment was sent a CD containing instructions for the different steps in Applied Relaxation. The disc contained 8 tracks and began with an introduction and a track that taught a technique for deep stomach breathing. Track 3 contained the instructions to progressive relaxation and track 4 taught the participant to shorten the time it took to relax from the 23 minutes in progressive relaxation to a mere 10 minutes. The fifth track taught the participant to condition a relaxed state to a given word. Track 6 and 7 instructed the listener to relax idle muscles when the she or he was engaged in standing up and walking. Finally, the last track instructed the listener to relax in 30 seconds.

In September 2006 one of the participants stated the she or he no longer wanted to take part in the study. Thus 89 participants were randomized to either the control or treatment condition by an impartial party. This was done via an online website (www.random.org) that utilizes weather fluctuations to render random sequences of number, which were then used in order to randomly assign all participants to each group. Through this process 45 participants were assigned to the waitlist group and 44 to the treatment group. After randomization these 89 participants were invited to fill out the pretests reported in this thesis (STAI, BDI, BAI, QOLI), along with other measures that were to be used in research of cognitive features of this population and the cost effectiveness of the treatment which they were to receive (see Dahlin, 2006; and Palmqvist, 2006). The measurements were collected to be used as baseline measurements for detecting changes in the dependent variables. At this point the 44 participants that were randomized to the treatment group were given notice of the fact that they were assigned to the group that would begin their treatment immediately. They were also given access to the website, where they could retrieve the first module in the treatment program. During the eight following weeks they had access to an Internet therapist who assisted and guided the participant. The therapists in the treatment were psychology students in their last year of psychology program and had completed their basic therapist training. Every week the participants sent in reports of their progress, which could be accompanied by questions. The mean length of time that each therapist spent on email correspondence was 97 minutes per treatment. The email contact was centered on educating, motivating and validating the hardships facing the participants, in order to help them work trough the treatment program. This therapeutic stance was taken in light of that the treatment program sometimes entailed struggle, confusion and even discomfort for the participant. In order to let the email contact be analyzed without interference, no therapist treated any client which he had initially interview via telephone. During the treatment the therapists received clinical supervision every week by an experienced supervisor, who had many years experience of treating GAD-patients in a clinical psychological setting. The remaining 45 participants were given the information that they were assigned to the waitlist control and that they would be contacted again to fill out the control group posttests and that they then would receive the treatment program regardless of their answers in the waitlist posttests. After the duration of eight weeks all 89 participants were again contacted via email and were asked to fill out post-measurements regardless of their progress in the treatment program. This meant that some of the participants in the treatment group had not completed the whole treatment program and that none of the participants in the waitlist control group had begun their treatment before filling out the post-measurements to be compared to baseline data. In the sample attrition occurred and merely 82 (92.1%) people answered the self-report measures and only 82 (92.1%) people were given telephone interviews.

Ethical aspects

The basis for this study was voluntary participation with informed consent regarding the use of participant information in the research setting. Due to the use of a waitlist control and of a relatively new form of treatment, ethical considerations were made where the potential use of the study outcome was juxtaposed to the potential harm of the participants. The following risk factors were identified.

The possibility of inclusion of suicidal applicants

In order to reduce this risk applicants who gave a response of 4 or higher on item 9 on the MADRS-S, which inquires into the respondents will to live, were excluded. Those who were excluded for this reason were encouraged to seek help from their local psychiatric facilities and were informed of a website (www.kbt.nu) where they could find CBT-therapists in their proximity.

The possibility of negative reactions to exclusion

An attempt to reduce this risk factor was made through efforts to explain the individual reasons for exclusion of each applicant, with a focus on the anticipated strain outweighing the potential benefits of the treatment. Emails were sent as soon as exclusion was verified to reduce the time frame in which applicants were waiting for a response. The idea of these email were to relay the narrow span of mechanisms that were targeted in the treatment, and that not all who suffered from mental ill-health were likely to benefit from the program. Information about how to find other psychological treatments was also included in these emails.

The possibility of negative reactions to assignment to the waitlist

When applicants entered their personal information into this study, they were directly informed of the design, and the possibility of delayed entry into the treatment. However, they were also, during the telephone interview, informed of the fact that all included participants would be given treatment, even though a delay of 8 weeks might affect any given applicant. When the treatment of the control group began 44 of 45 participants were still interested and began their treatment. The study protocol was approved by the the Regional Ethical Review Board in Linköping.

Data integrity

In order to ensure the integrity of the collected data and that non-authorized individuals would not be able to access any information gathered in the study, all data were stored on encrypted databases which required passwords to grant access. All email contact was stored on an encrypted web hotel to which access could only be obtained via passwords. All participants were given eight digit

usernames, which were used in all contact during the study. The information linking participants to their usernames was stored separately and could only be accessed through knowledge of yet another password.

Statistical analyses

Statistical analyses were done with SPSS 13.0. In order to test the probability of significant differences between the groups ANOVA was used to investigate whether there were any significant differences between the two groups at pretest and in demographic data. ANOVA was also used to detect differences between pre and post-measurements, and a two-way 2x2 mixed design was utilized. Chi-square testing was used whenever non-parametric data was analyzed in detecting differences between pre treatment and post-treatment tests. Bonferroni corrected *t*-tests were used for post-hoc contrasts yielding a corrected *p*-value of $p < .0125$.

Results

The results of the study are presented through changes in self-report outcome measures, clinical diagnoses and clinical global improvement. The outcomes on eight measurements (PSWQ, GAD-Q IV, STAI-S, STAI-T, BAI, BDI, MADRS-S and QOLI) are presented via means, standard deviations, analyses of variance and effect sizes within and between groups. The percentages of participants still suffering from GAD and clinical significant improvement are presented. Finally the frequencies of modules finished in the treatment condition at post-measurement are presented in. When effect sizes are presented they refer to Cohen's *d* (Cohen, 1988), where an effect size of $d = .20$ can be considered a small effect size, $d = .50$ a medium effect size and $d = .80$ a large one. The results were analyzed on an intention to treat principle with all randomized participants with follow-up measures included. Hence participants who provided measures were included regardless if they had completed the treatment or not. Analyses were also made using the last observation carried forward procedures.

Self-report measures

The outcome effects on the self-report measures are presented in Table 2.

Penn State Worry Questionnaire (PSWQ)

No significant differences between the two groups were detected at pretest. Analyses of variance using repeated measures revealed a significant interaction effect over group and time ($F(2,80) = 30.17$, $p < .0001$). At post-measurement, a significant group difference was detected using an independent *t*-test between them ($t(80) = 5.10$, $p < .0001$). In the treatment group a significant change over time was detected through a paired *t*-test ($t(37) = 5.70$, $p < .0001$). The effect size within the treatment group was $d = 1.08$. Between the two groups at post-measurement the effect size was slightly larger; $d = 1.11$. After applying Bonferroni corrections ($p = .0125$) these results remained significant.

Generalized Anxiety Disorder Questionnaire-IV (GAD-Q-IV)

No significant differences between the two groups were detected at pretest. Analyses of variance using repeated measures revealed a significant interaction effect over group and time ($F(2,80) = 22.52$, $p < .0001$). At post-measurement, a significant group difference was detected using an independent *t*-test between them ($t(80) = 4.89$, $p < .0001$). In the treatment group a significant change over time was detected through a paired *t*-test ($t(37) = 5.53$, $p < .0001$). The effect size within the treatment group was $d = 1.19$. Between the two groups at post-measurement the effect size was slightly smaller; $d = 1.07$. Bonferroni corrections ($p = .0125$) of these results did not alter the significance of the results.

Table 2

Mean (standard deviation). Main effects (F) of group, time and interaction. Effect sizes (d) computed within the treatment group and the control group, and between the two contingencies. Treatment group, n=38. Control group, n= 44. N total=82.

	Treatment group	Control group	Between group effects	
PSWQ				
Pretest	68.74 (5.94)	69.32 (6.55)	Interaction	$F(2,80) = 30.17$***
Posttest	57.82 (13.01)	69.39 (7.06)	Effect size	$d = 1.11$[2]
Change	10.92 (11.81)	-.07 (5.65)		
Effect size (*d*)	1.08[1]	-.01[1]		
GAD-Q IV				
Pretest	10.08 (2.42)	10.34 (2.13)	Interaction	$F(2,80) = 22.52$***
Posttest	6.45 (3.59)	9.89 (2.77)	Effect size	$d = 1.07$[2]
Change	3.63 (4.04)	.44 (1.74)		
Effect size (*d*)	1.19[1]	.18[1]		
STAI-S				
Pretest	57.24 (10.45)	58.07 (10.24)	Interaction	$F(2,80) = 30.12$***
Posttest	43.82 (10.65)	57.61 (9.73)	Effect size	$d = 1.35$[2]
Change	13.42 (10.92)	.45 (10.45)		
Effect size (*d*)	1.27[1]	.05[1]		
STAI-T				
Pretest	58.84 (6.45)	61.57 (6.51)	Interaction	$F(2,80) = 26.80$***
Posttest	50.21 (9.01)	60.61 (7.02)	Effect size	$d = 1.29$[2]
Change	8.63 (8.54)	.95 (4.55)		
Effect size (*d*)	1.10[1]	.14[1]		
BAI				
Pretest	20.61 (10.64)	20.98 (9.66)	Interaction	$F(2,80) = 14.95$***
Posttest	12.37 (7.43)	19.20 (8.56)	Effect size	$d = .85$[2]
Change	8.24 (8.69)	1.77 (6.42)		
Effect size (*d*)	.90[1]	.19[1]		
BDI				
Pretest	17.66 (9.81)	16.93 (7.91)	Interaction	$F(2,80) = 26.06$***
Posttest	10.08 (7.75)	16.70 (7.60)	Effect size	$d = .86$[2]
Change	7.58 (7.56)	.23 (5.43)		
Effect size (*d*)	.86[1]	.03[1]		
MADRS-S				
Pretest	20.24 (7.29)	20.57 (5.99)	Interaction	$F(2,80) = 13.46$***
Posttest	11.84 (6.56)	17.95 (5.94)	Effect size	$d = .98$[2]
Change	8.39 (8.39)	2.61 (5.80)		
Effect size (*d*)	1.21[1]	.44[1]		
QOLI				
Pretest	.38 (1.55)	.24 (1.74)	Interaction	$F(2,80) = 9.13$*
Posttest	1.34 (1.72)	.44 (1.79)	Effect size	$d = .51$[2]
Change	.96 (1.27)	.20 (1.02)		
Effect size (*d*)	.59[1]	.11[1]		

[1] = effect size within group, [2] = effect size between groups at posttest, * = $p < .01$, *** = $p < .0001$.

State-Trait Anxiety Inventory-Trait (STAI-T)

No significant differences between the two groups were detected at pretest. Analyses of variance using repeated measures revealed a significant interaction effect over group and time ($F(2,80) = 26.80$, $p < .0001$). At post-measurement, a significant group difference was detected using an independent *t*-test between them ($t(80) = 5.87$, $p < .0001$). In the treatment group a significant change over time was detected through a paired *t*-test ($t(37) = 6.23$, $p < .0001$). The effect size within the treatment group was $d = 1.10$. Between the two groups at post-measurement the effect size was slightly larger; $d = 1.35$.

Beck Anxiety Inventory (BAI)

No significant differences between the two groups were detected at pretest. Analyses of variance using repeated measures revealed a significant interaction effect over group and time ($F(2,80) = 14.95$, $p < .0001$). At post-measurement, a significant group difference was detected using an independent *t*-test between them ($t(80) = 3.83$, $p < .0001$). In the treatment group a significant change over time was detected through a paired *t*-test ($t(37) = 5.85$, $p < .0001$). The effect size within the treatment group was $d = .90$. Between the two groups at post-measurement the effect size was slightly smaller; $d = .85$.

Beck Depression Inventory (BDI)

No significant differences between the two groups were detected at pretest. Analyses of variance using repeated measures revealed a significant interaction effect over group and time ($F(2,80) = 26.06$, $p < .0001$). At post-measurement, a significant group difference was detected using an independent *t*-test between them ($t(80) = 3.90$, $p < .0001$). In the treatment group a significant change over time was detected through a paired *t*-test ($t(37) = 6.18$, $p < .0001$). The effect size within the treatment group was $d = .90$. Between the two groups at post-measurement the effect size was slightly smaller; $d = .85$.

Montgomery Åsberg Depression Rating Scale - Self rated (MADRS-S)

No significant differences between the two groups were detected at pretest. Analyses of variance using repeated measures revealed a significant interaction effect over group and time ($F(2,80) = 13.46$, $p < .0001$). At post-measurement, a significant group difference was detected using an independent *t*-test between them, $t(80) = 4.43$, $p < .0001$. Both in the control group, $t(43) = 2.99$, $p < .01$, and in the treatment group, $t(37) = 6.17$, $p < .0001$, a significant change was detected over time using paired *t*-tests. The effect size within the control group was $d = .44$. After applying Bonferroni corrections ($p = .0125$) these results remained significant. The effect size within the treatment group was $d = 1.21$. Between the two groups at post-measurement the effect size was $d = .98$.

Quality of Life Inventory (QOLI)

No significant differences between the two groups were detected at pretest. Analyses of variance using repeated measures revealed a significant interaction effect over group and time ($F(2,80) = 9.13$, $p < .01$). At post-measurement, a significant group difference was detected using an independent *t*-test between them ($t(80) = -2.32$, $p < .05$). This outcome did, however, not survive Bonferroni correction ($p = .0125$). In the treatment group a significant change over time was detected through a paired *t*-test ($t(37) = -4.68$, $p < .0001$). The effect size within the treatment group was $d = .59$. Between the two groups at post-measurement the effect size was slightly smaller; $d = .51$.

The effects of last observations carried forward (LOCF)

In an attempt to display the outcome for all the participants the study intended to treat, the last observations of the included participants were carried forward into the post-measurement data. This constructed an analysis of attrition, where missing data was assumed to be unchanged. On the outcome of the eight self-report measures this procedure did not substantially alter the significance of the obtained results (e.g., all interactions remained significant, albeit at a less probable level: $p < .01$).

Summary of self-report outcomes

In all of the outcome measures significant interaction effects were achieved. Furthermore, all post-hoc results survived Bonferroni corrections, revealing that effects were due to changes in the treatment group. On all outcome measures, except the MADRS-S, no significant effects were achieved in the wait list control. However, the decrease in the control group on this inventory of depressive symptoms, remained significant after Bonferroni corrections. All measures indicated a favorable outcome in the treatment group, revealing significant changes and large effect sizes on all measures (except on the QOLI, where the effect size was moderate compared to the control group). Neither did the significant difference between the groups at post-hoc testing of QOLI survive a Bonferroni correction.

Clinically significant improvement

Table 3 presents an analysis of clinically significant improvement, using a two standard deviation difference from pretest data as indication of clinically significant improvement between pre and post-measurement for each participant in the treatment group (Ogles, Lambert & Fields, 2002). This level of required change was a tough test of the data, but did yield results. For example, on the PSWQ this meant a score difference of 13 points. The analyses revealed that 42.1% of the treatment group had decreased their scores with more than two standard deviations and were clinically improved on this measure. In the control group the percentage of clinically improved individuals was 2.3%. The difference between the groups revealed itself to be significant (X^2 = 19.69, p < .0001).

Table 3
N*(%) still diagnosed with GAD at second SCID-interview and n (%) two standard deviation improvement on self-report measures. Effects computed via Pearson's chi-square. Treatment group, n=38. Control group, n= 44. N total=82.*

Improvement	Treatment group	Control group	Between group effects
PSWQ			
2 SD change	16 (42.1%)	1 (2.3%)	X^2 = 19.69, p < .0001
Less change	22 (57.9%)	43 (97.7%)	
GAD-Q IV			
2 SD change	17 (44.7%)	3 (6.8%)	X^2 = 15.90, p < .0001
Less change	21 (55.3%)	41 (93.2%)	
BDI			
2 SD change	6 (15.8%)	0 (0%)	Not eligible for X^2
Less change	32 (84.2%)	44 (100%)	analysis

On the GAD-Q IV, a score difference of 4.5 was regarded as a clinically significant change. Analyses revealed that 44.7% of the treatment group had decreased their scores with more than two standard deviations and were clinically improved on this measure. In the control group the percentage of clinically improved individuals was 6.8%. An analysis of this difference also detected a significant difference (X^2 = 15.90, p < .0001). On the BDI, a score difference of 18 points would result in a two standard deviation change on the measure. Six participants attained this difference in the treatment group, while none of the participants in the control group reached this level of change. The group difference on this measure was not possible to subject to Pearson's chi-square test, due to the limited count number in each cell. Descriptive analyses of the differences obtained on the BDI revealed that 15.8% of those in the treatment group had decreased their scores with more than two standard deviations and were clinically improved on this measure. In the control group the percentage of clinically improved individuals was 0%.

Clinical Global Improvement and remission of diagnoses

At post-testing 82 participants were given SCID-interviews, and Table 4 presents the outcome on the four level scale that was used to assess the degree of clinical global improvement. The levels were: very much improved, much improved, minimally improved and no change. In the treatment group 57.4% were much or very much improved and in the control group these levels of improvement were reached by 6.8%. Overall, the level of improvement significantly differed between the two groups (X^2 = 26.60, p < .0001). This effect was achieved when the first class (very much improved) was assimilated into the second one (much improved) in order to allow a chi-square computation.

Table 4
N(%) Clinical Global Improvement. Effect computed via Pearson's chi-square. Treatment group, n=38. Control group, n= 44. N total=82.

Improvement	Treatment group	Control group	Between group effects
CGI			
Very much improved*	2 (5.3%)	0 (0%)	X^2 = 26.60, p < .0001
Much improved*	16 (42.1%)	3 (6.8%)	
Minimally improved	15 (39.5%)	13 (29.5%)	
No change	5 (13.2%)	28 (63.6%)	
Clinical Diagnoses			
Still GAD	15 (39.5%)	37 (84.1%)	X^2 = 17.50, p < .0001
No GAD	23 (60.5%)	7 (15.9%)	

* = First classes combined in order to achieve zero cells with a count of less than five.

Table 4 also shows the number of participants that were once again diagnosed with GAD. In the control group 37 (84.1%) participants was once again diagnosed with GAD. Among those assigned to the treatment condition the number of people still diagnosed with GAD was 15 (39.5%). This difference between the groups in diagnostic status post treatment was significant (X^2 = 17.50, p < .0001).

Adherence

The adherence to the treatment program was measured by the frequency of modules finished. In the treatment group 7.9% had finished no modules at post-measurement but, conversely, 92.2% had finished at least one module and 63.2% had finished half of the treatment program. A completion of the entire treatment program had been reached by 10.5%. The three participants in the treatment group that hadn't finished any modules at all at post-measurement, were still included in the measures of the treatment group in keeping with the intention to treat procedure. Table 5 describes these findings.

Table 5
Frequency of termination after each module and cumulative frequency of modules finished in the treatment group, n=35. Frequency and cumulative frequency of participants with no completed measures, n=3.

Modules finished[1]	Frequency	%	Cumulative frequency[1]	Cumulative %
Module 1	2	5.3	35	92.2
Module 2	3	7.9	33	86.9
Module 3	6	15.8	30	79
Module 4	6	15.8	24	63.2
Module 5	3	7.9	18	47.4
Module 6	5	13.2	15	39.5
Module 7	6	15.8	10	26.3
Module 8	4	10.5	4	10.5
No finished module	3	7.9	3	7.9
Group total	38	100.0	38	100.0

[1]=Mean and standard deviation for the participants who finished at least one module: 4.8 (2.1).

Discussion

The results in summation

Outcome measures of this study were self-report questionnaires, remission of diagnoses, clinically significant improvement and an assessment of clinical global improvement. Statistical analyses of these measures indicated significant changes with moderate to large effect sizes in the treatment group. In the control group, no changes were found between the two points of measurement, except for a significant, moderately large, decrease on the MADRS-S. A report of how far the participants had come in the treatment program at post-measurement showed that the mean for the participants who had finished at least one module was 4.8 modules.

A discussion of the results

The results of this study quite uniformly indicated that a change had occurred in the treatment group, compared to the wait list controls in regard to the suffering induced by GAD. To further support the notion that the alternative hypothesis was true, all (except for the QOLI) self-report measures indicated large effect sizes between the two groups. This, in turn, suggested that the encouraging results could be seen in a large portion of the participants. This was in keeping with the theoretical framework within which the study was carried out. The focus of the treatment was centered around the intentional cessation of worry and the instilling of a new outlook on the importance and efficiency of worry. It therefore appeared as if though the treatment methods used in the study had sufficiently targeted the processes that induce worry, in order to reduce symptoms and descriptions of GAD. These conclusions were drawn from the results of both self-report by the PSWQ and the GAD-Q IV, and clinical assessment. The first hypothesis, stated in the aim of the study, was therefore considered to be stipulated.

When the second hypothesis in the aim of the study was revisited it became clear that this research question also could be considered answered with a confirmatory response. This conclusion was made based on that the interaction effects of group and time were significant on a $p < .0001$ level on both the STAI measures and on the BAI. The effect sizes could also be considered large. These findings lent further support to the notion that the processes of anxiety and worry were targeted via the treatment program and that they could be remedied to a significant extent. Another encouraging finding was that the participants in the treatment group also appeared to have gained a reduction of symptoms associated with depression as measured by the BDI and the MADRS-S. This was in keeping with the avoidant theory of GAD put forth by Borcovec and colleagues (Borcovec et al., 2004), in which worry is considered an avoidant

behavior that is similar to the avoidance behaviors that are associated with depression. This finding could also be inferred from the significant clinical improvement apparent on the BDI. However, a puzzling result occurred in the treatment group on the follow up measurement of the MADRS-S, where a significant reduction in the scores of the control group had occurred. The effect size of this change was moderate and an interaction effect was obtained over group and time, which still indicated that it was more favorable to have been in the treatment group than in the wait list, but the change in the control group was not anticipated. One possible explanation of this finding was that depressive symptoms might have a more cyclic quality and might therefore have been less persistent over time. Another explanation might be that the knowledge of treatment being imminently forthcoming alleviated feelings of hopelessness and thereby reduced scores on this measure. The third hypothesis stated in the aim of the study was in the light of these results also considered to be stipulated. When research is conducted into whether studied treatments are efficacious, the symptoms that negatively influence a person's life are often the target of any intervention. However, it is also interesting to study more positively oriented outcome measures such as the QOLI. In this light, it was uplifting to find that a significant interaction was visible on this outcome measure. Even though the effect size was more modest on this measure (Cohen's d = .51), it seemed that the quality of life had been significantly improved in the treatment group. In light of this finding, the fourth hypothesis stated in the aim of the study was, as the previous ones, also considered to be confirmed.

A discussion of the chosen method

Due to the effort to maintain all interfering variables at a constant all participants were post-measured after eight weeks. This entailed that participants that kept a lower pace than one module per week, were not allowed to complete the treatment before post-measurement. This, and the fact that some participants chose not finish the entire treatment led to the finding that the mean throughput of participants in the study were 4.8 modules. This gives rise to questions of whether this level of completion should be considered in terms of attrition, adherence or satiation. When considering this finding as a result of attrition a problem arises in the design of the study, where a low level of completion would lead to a smaller improvement of psychological health than desired. However the outcome measures of the study indicate that improvements had occurred in the treatment group in spite of the low level of completers of the last module. This finding is therefore possibly better understood as treatment satiation where participants lower their efforts to complete the program as their mental ill-health decreases as a result of the treatment. It is therefore important to continuously investigate this effect to better understand how adherence to the treatment program can be elevated, but also if this is a necessary goal in order to achieve

good treatment outcome. It might be that the role of the treatment program should be to offer more modules than are necessary for a large part of participants, in order to help those who need the most guidance. In regard to other treatment outcomes reported the results in this study were promising in comparison, and indicated the possibility that this form of treatment can be even more favorable than live face to face treatments of GAD. How was this possible?

There were a few possible answers to the above formulated question. One possible explanation was that the results of this study were skewed by some unexplained variable of variance due to a faulty design. The randomization at the beginning of the study was conducted in order to eliminate such eventualities, and ensure that any differences detected at follow up would be due to treatment effects. However, it is possible to interpret the treatment outcome as due to placebo effects, since the control condition was a wait list which is not likely to entail a similar placebo effect. This, in turn, was balanced by the control group participants knowledge of that their treatment was near in time (eight weeks) and that they, too, might hold positive beliefs and expectations of help being near in time.

Another possible explanation was that the results were not influenced by the treatment materials, but instead was a consequence of the email alliances that was formed in the email contact the treatment group participants received. Another study of Internet treatment of mental ill-health (Lenndin & Wernmark, 2005) found that email contact alone could alleviate symptoms as well as self-help treatment with minimal therapist contact. It is therefore a conclusion in this thesis, that it is likely that both the email contact and the treatment materials played an important part in the treatment and the positive outcome it spawned. This was concluded in the light of that previous self-help treatments, without supplemental support, have been efficacious in the past.

A more positive explanation to the somewhat surprisingly good outcome of the study might be that the treatment simply is as good as, or better than, other psychological treatments available today. In support of this was that the treatment materials were based on methods which have gained support in other settings (self-help books and in live treatment) and that the email contact was performed by therapists who had an adequate knowledge of the treatment program and of the principles it was based on. More support for this explanation might be found in the quality of supervision of the therapists, which was considered to be of high standard. Thus, it might have reduced the risk of ruptures and malpractice. Yet another explanation is that there has been a relatively small amount of research in the field of GAD (Dugas, 2000), which might have led to that there has been a relatively slow development of

knowledge and methods in the field of GAD. This might have lent little support to the methods of the previously carried out research of the treatment of GAD. For example, attrition might have affected other studies to a greater extent and a lack of consistency of measures might have disguised positive outcomes in other studies. Since the method chosen in this study was a two by two comparison between a treatment condition and a wait list control, the choice of method had the advantage of delivering a fairly uncomplicated result. The study therefore communicated a quite uniformly structured outcome, favoring this treatment over a waitlist control. However, this uncomplicated result also raised questions of the risk of oversimplification. For instance, it might be erroneous to conclude that self-report measures portray an accurate description of the gains of the studied treatment. To control for this risk clinical interviews were also conducted and an estimate of clinical global improvement was induced, which allowed for a gain of a more complex understanding of the positive changes in the treatment group.

Other methodological problems that might have occurred were statistical miscalculations and technical error in the digital transformation of the questionnaires. As reported above, one such event was detected and participants who scored to low on the GAD-Q IV to pass screening were in spite of this fact included in the study. This contributed to a wider range of included scores which gave larger standard deviations for this measure. In spite of this fact, a significant interaction effect was obtained on this measure. The risk of statistical miscalculations was reduced via the use of different statistical methods on the same outcome measures. This risk was also reduced through a direct transport of data from the initial collection to the final calculations, since data were collected in digital form and could be directly transferred in to SPSS 13.0.

Another possible explanation for the outcome effects of this study was that the obtained changes were due to an elevation of hope in the participants that were included. In order to control this parameter the design of the study entailed a comparison between a wait list control and a treatment group for two reasons. Firstly it was considered more ethical that all participants would receive treatment and secondly it was to used to control for any expectancy effects achieved in the sample. According to Kendall, Holmbeck and Verduin (2004) the design of wait list controls is preferable to non treatment controls, since participants invest time and effort into the treatment and have knowledge that treatment is imminent. They may therefore anticipate change due to therapy, and a design utilizing a waitlist control can compensate for such effects which otherwise might have been able to explain the outcome of the treatment. A derivation from this logic is that the results in this study were not probable to have emanated from a shift in cognitive perceptions of the future as a result of inclusion, but more likely dependant on the effort spent by the participant in the

treatment program. This study did not directly investigate whether there was a relationship between hope and treatment outcome, but it did appear as if mere awareness of that help was around the corner did not produce a positive outcome.

Limitations of the study

In the diagnostic screening process no other axis-I diagnoses were assessed than GAD and depression. This can be considered a weakness of the study, especially since GAD is the anxiety diagnosis with the highest comorbidity rate. Neither was the presence of any axis-II diagnoses investigated, which limits the clinical assessment to cover the two diagnoses that the outcome measures targeted. One reason that the clinical interviews were not prolonged with additional questions, regarding other diagnoses was to attempt to minimize the strain put on those who would not be included in the study. The telephone interviews lasted for about 45 to 60 minutes, including research questions regarding the cognitive flow and flexibility of the participants (see Dahlin, 2006, for a larger elaboration) and would have been much elongated in time in order to screen for additional diagnoses. Another limitation of the study was that at no time did the research team meet any of the participants, which might question the credibility of the research project. Therefore one might raise concerns about the Internet format and that it could lower the truthfulness of the participants' responses in the contact with their therapists and on the questionnaires. It is of course a possibility that some people did not do any homework assignments at all, or that they felt less inclined to answer truthfully on the self-report measures. However, the motivation for such behavior seems low since the treatment program entailed weekly checkups via email and home work assignments to be carried out each day. Therefore it was considered unlikely that such behavior would be responsible for any substantial part of the variance explained by the treatment outcome. Especially in light of that little reinforcement was given when participants did not actively report and reflect upon their progress in the treatment program.

Future research

The results of this study gave support to the use of Internet based treatments in order to treat GAD. Long term follow up data is however important to collect in order to establish that the effects of the treatment are not short lived. An aspiration is to collect follow up data at six and twelve months post treatment. In order to verify the efficacy of the treatment program, a replication of this study would also be advisable to conduct. Since the results were promising in this study, it could be a way of lending even more support to the Internet as a valid basis for treating GAD. Another way of studying the validity and reliability of this treatment program would be to compare it to live face to face psychological

treatment, in order to investigate whether these modalities are equal or if they differ in any important aspect. A third possibility of pushing the research frontier forward would be to implement the treatment method of this study into primary care in order to conduct a study of the treatment effectiveness in a clinical setting outside of the research community.

Conclusions

The main conclusion drawn from this study was that Internet based self-help treatments which are accompanied by email guidance can be a viable way of treating generalized anxiety disorder. This conclusion was deduced from the findings of reduced scores on self-help measures, assessment of clinical global improvement and from remission of clinical diagnoses of GAD. It was also concluded that Internet treatments carried out in this fashion can achieve low levels of attrition and large effect sizes, which would make them viable in larger settings, for example in primary care. It was also concluded that even if the participants who did not report post-measurements was not positively affected by the treatment, that it is an efficacious form of treatment. Finally, the uplifting results of this study were visible in self-report questionnaires, clinical assessment by group-status blind interviewers and in the clinical judgement of the therapists in the treatment. Hopefully, these results could be used in order further develop this form of treatment, in the hope of giving more people who suffer from mental ill-health better treatment options.

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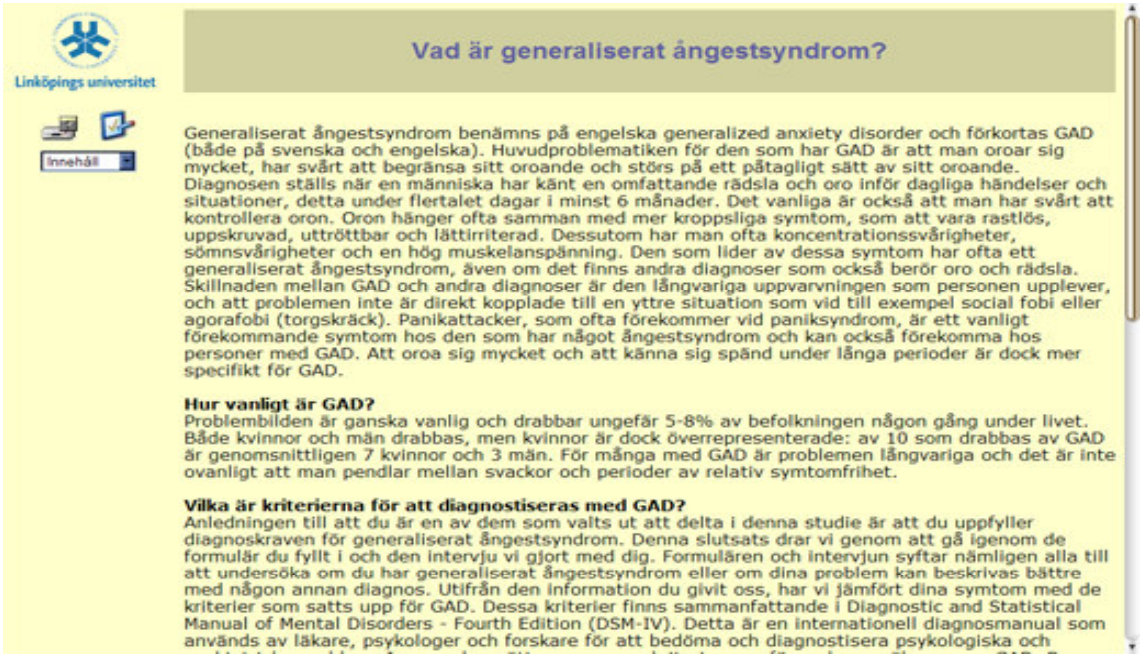
Appendix

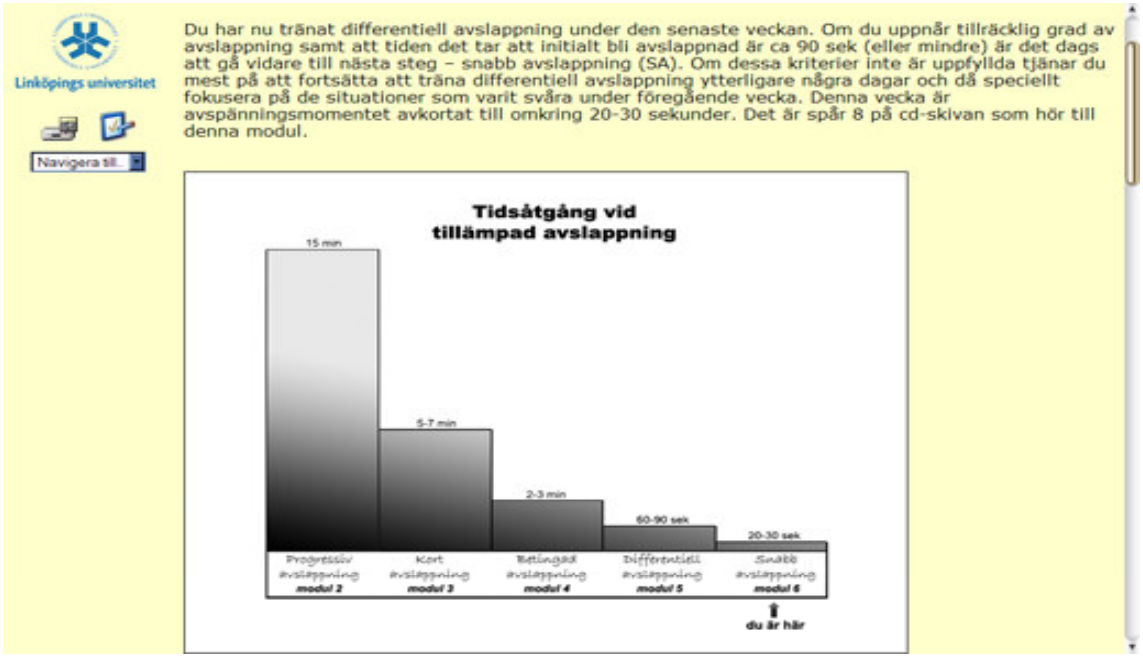
The on screen layout of the treatment program

The example of a question in the STAI-S questionnaire is here shown in its digital form. The client was presented with a statement (I'm tense) and had four alternatives from which to choose a response (Not at all, Somewhat, A great deal, and Very much).

The layout of a module, when logged on, can be seen below. At the left column, the client could click on the disc drive to get to the downloading area for this particular module, or go to the homework section by clicking on the drawing board. Just below these icons a pull-down menu could be found, by which the client could skip back and forth in the module. The right part of the page is the main area, where text and images were presented. On this particular page, the client is presented with a psychoeducative text on the disorder.

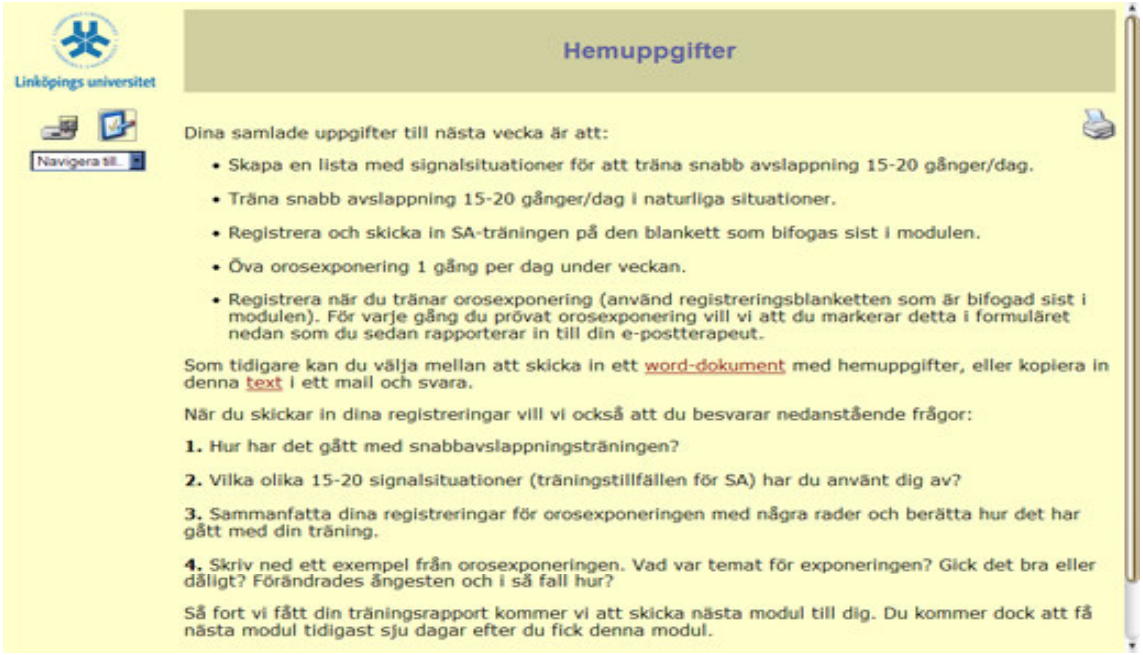


The figure below reveals a graphical model of the steps of the applied relaxation the client was presented with. The time each step of relaxation took to perform can be seen.

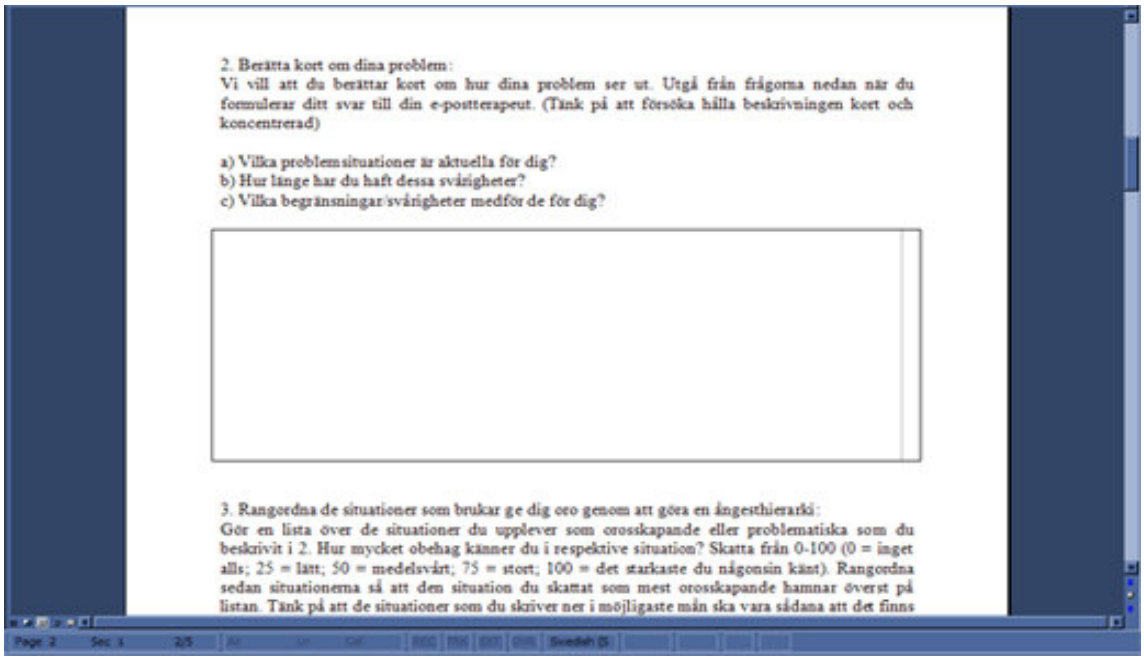


The next figure reveals a drop-down menu on the left, where the client could choose a specific point in each module of interest to go to. On the right main part of the screen, the client is presented with the download page. Here the client could download the entire module as a pdf-file, forms in different file formats for registering their training, the homework section of the module in different file formats, and an mp3 version of the relaxation audio track associated with the current module.

The next figure presents the homework instructions for a specific module. At first, a list of what the client was instructed to do in regards to the training was visible, and then a couple of questions that the client could ponder upon and then reply to and send in to their e-mail therapist in order to gain access to the next module.



The final figure shows a word version of a homework assignment, where the client filled out her or his answers in empty boxes, saved the file and then sent it to the e-mail therapist.



2. Berätta kort om dina problem:
Vi vill att du berättar kort om hur dina problem ser ut. Utgå från frågorna nedan när du formulerar ditt svar till din e-postterapeut. (Tänk på att försöka hålla beskrivningen kort och koncentrerad)

a) Vilka problemsituationer är aktuella för dig?
b) Hur länge har du haft dessa svårigheter?
c) Vilka begränsningar/svårigheter medför de för dig?

3. Rangordna de situationer som brukar ge dig oro genom att göra en ångesthierarki:
Gör en lista över de situationer du upplever som orosskapande eller problematiska som du beskrivit i 2. Hur mycket obehag känner du i respektive situation? Skatta från 0-100 (0 = inget alls; 25 = lätt; 50 = medelsvårt; 75 = stort; 100 = det starkaste du någonsin känt). Rangordna sedan situationerna så att den situation du skattat som mest orosskapande hamnar överst på listan. Tänk på att de situationer som du skriver ner i möjligaste mån ska vara sådana att det finns