

Graduate thesis, PSYPRO4100
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**A randomized controlled trial of
metacognitive therapy vs. cognitive
behavioral therapy vs. waiting list in the
treatment of adults with generalized
anxiety disorder: A preliminary analysis**

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Abstract

Forty two participants with generalized anxiety disorder were treated with either Metacognitive therapy or Cognitive Behavioral Therapy, in a randomized controlled study comparing the relative effect of the two treatments. A wait list condition comprised the control group. Statistical analysis proved MCT superior to CBT, and CBT proved superior to no treatment. Because this is a preliminary study it has some limitations, such as no follow-up data or treatment adherence control. Thus at the current stage the results is to be considered preliminary findings.

Introduction

Generalized Anxiety disorder (GAD) is a common and debilitating mental illness defined by “excessive anxiety and worry (apprehensive expectation), occurring more-days-than-not for at least 6 months, about a number of events or activities” (American Psychiatric Association [*DSM-IV-TR*], 2000, p. 476). GAD has gone from being considered somewhat of a residual diagnosis (DSM-III) to be recognized as one of the most prevalent anxiety disorders. Using DSM-III-R criteria GAD is shown to have a one-year prevalence of 1.9% and a lifetime prevalence of 4.5% in the Norwegian population (Kringlen, Torgersen & Cramer, 2001). In the same study the lifetime prevalence ratio of women was 2.5:1 compared to men (6.1% and 2.4% respectively), while a large US study found the ratio to be 1.9:1 (Vesga-López et al., 2008). There is also a clear gender bias in the general treatment literature, with about 72% of the treatment seeking population being women (Covin, Ouimet, Seed & Dozois, 2007). Using DSM-IV criteria Kessler et al. (2005) found the lifetime prevalence in a large US sample to be 5.7%, which the authors considered to be a conservative estimate. Comorbid diagnoses are very common, with almost 90% of sufferers having a lifetime history of at least one other anxiety disorder (Goisman, Goldenberg, Vasile & Keller 1995). Current comorbidity rates in the

treatment literature typically range from 50% through 80% (e.g.; Dugas et al., 2003; Wells, Welford, King, Wisely & Mendel, 2010; Dugas et al., 2010; Newman, Przeworski, Fisher & Borkovec, 2010).

GAD is generally regarded as the anxiety disorder least responsive to cognitive behavioral therapy (CBT) (Campbell & Brown, 2002), and only about 50% of individuals receiving CBT recover (Fisher & Durham, 1999; Fisher, 2006). Newer, innovative treatments have been developed to address this and the preliminary results are promising. The recovery rates using these newer treatments typically range from 70% to 80% post-treatment (Romer & Orsillo, 2008; Wells et al., 2010; Dugas et al., 2010). There is however no general consensus on what constitutes the best measure of recovery, and different measures are used in all the mentioned trials. Romer & Orsillo (2008), for instance, used three separate measures of recovery rates found by diagnostic status (ADIS-IV), a reduction of 20% or more on at least three of four anxiety measures (GAD severity, PSWQ, DASS-Anxiety, and DASS-Stress), and whether participants fell into the normative range (within 1 standard deviation of published norms or a GAD CSR score ≤ 3) on at least three of the four mentioned measures. Dugas et al. (2010) used a clinician's severity rating of 3 or less for GAD (ADIS-IV) while Wells et al. (2010) used Jacobson & Truax' (1991) criteria for clinically significant change on the "Penn-State worry questionnaire" (PSWQ) and the trait-anxiety subscale of the "State-Trait-anxiety inventory" (STAI-T), as defined by Fisher (Fisher & Durham, 1999; Fisher, 2006), plus diagnostic assessment (SCID).

This lack of common methodology makes treatment comparison across studies difficult. For instance it looks like diagnostic remission alone might not be a very stringent criterion of recovery, as diagnostic recovery rates are usually higher than rates showing meaningful change on central measures of anxiety and worry (e.g.: Wells et al., 2010; Romer & Orsillo, 2008; Ladouceur et al., 2000). In addition diagnostic recovery does not express the extent of the change produced by treatment, thus offering less opportunity for treatment comparison across studies than other measures of recovery. It has been argued that clinically significant change needs to be expressed as the extent to

which therapy moves someone outside the statistical range of the dysfunctional population or within the range of the functional population (Jacobson, Follette & Revenstorf, 1984). Jacobson & Truax (1991) proposed that this can be achieved by defining how great a reduction in test-score on any given statistical measure (e.g.; PSWQ) needs to be to reliably express a change, and whether a given score is more likely to belong to the normal population than the patient population. This is done by defining a cut-off point where the distribution of the normal population and of the patient population meet ($\text{cut-off} = \text{SD}_1 * \text{M}_2 + \text{SD}_2 * \text{M}_1 / \text{SD}_1 + \text{SD}_2$; where SD is the standard deviation and M is the mean of either the normal [1] or the patient [2] population), and a score that is likely to reflect real change rather than variance due to measurement error ($\text{RCI} = \text{M}_2 - \text{M}_1 / \sqrt{2 \{S_e\}^2}$; where S_e is the standard error of measurement). This approach is considered to be the least arbitrary method for defining clinically significant change where normative data for functional and dysfunctional populations is available and in which the two distributions overlap (Jacobson & Truax, 1991; Jacobson, Roberts, Berns & McGlinchey, 1999; Fisher & Durham, 1999). Using this method patients can be divided into four groups; unchanged (pre – post-treatment score $< \pm \text{RCI}$), worse (pre – post score $< -\text{RCI}$), improved (pre – post score $> \text{RCI}$) and recovered (pre – post score $> \text{RCI}$, and post score \leq cut-off) (Fisher & Durham, 1999). This method is a stringent but statistically robust method of defining change and it is used in relevant peer literature (e.g.; Wells et al., 2010). For these reasons the current study will make use of Jacobson & Truax' criteria, with norms as defined by Fisher for the STAI-T (Fisher & Durham, 1999) and the PSWQ (Fisher, 2006).

The aim of the current study was to compare the relative treatment efficacy of Tom Borkovec's established CBT model (Borkovec, 1994) and Adrian Wells' Meta-Cognitive therapy (MCT) model (Wells, 1999) for treatment of GAD, through a randomized controlled trial. Borkovec's model is based on the cognitive avoidance theory of worry while Wells' model is based on his theories of meta-cognition. The cognitive avoidance theory stipulates that GAD sufferers utilize worry as a cognitive means of avoiding fear and anxiety. This becomes a problem for GAD sufferers when the worry

process becomes negatively reinforced through effective avoidance of negative emotions. This in turn prevents normal emotional processing and subsequent modification of anxiety producing stimuli interpretations. Treatment through this model aims to suspend the worry process through traditional cognitive techniques, such as teaching the patients to question the validity of their anxiety inducing thoughts or beliefs (worry-cues) and helping them to develop alternative, less anxiety arousing assumptions or interpretations of said thoughts and beliefs. The method also capitalizes on the treatment efficacy shown by “applied relaxation” (e.g.; Borkovec & Costello 1993; Borkovec, Newman, Pincus & Lytle, 2002), by teaching patients relaxation techniques and diaphragmatic breathing.

Empirical support for this model is mixed. The model asserts that worry inhibits anxiety related somatic and emotional activation. From this we can predict that worry will reduce the amount of physiological arousal experienced by the individual. Borkovec has found apparent support for this prediction in several studies (e.g.; Borkovec & Hu, 1990). Stapinski, Abbott & Rapee (2010) however found that worry increased physiological arousal in GAD patients as measured by skin conductance level (SCL), while Hofmann et al. (2005) found that both SCL and heart rate increased in students as a result of worry. These mixed results might be due to design flaws in the earlier studies supporting the model. For instance the supportive studies have generally not been conducted on GAD patients and less sensitive/suitable measures of arousal might have been employed. If this central hypothesis of the avoidance model is not supported then further clarification of the mechanisms involved in GAD is necessary.

The MCT model stipulates different mechanisms involved in GAD. Here the unhelpful worry process of GAD patients is perpetuated by positive and negative metacognitive beliefs about worry. Positive beliefs are to some extent held by most people, e.g. “Worry helps me avoid danger”, while negative metacognitive beliefs deal with perceived uncontrollability and danger of worry (meta-worry, or “Type 2 worry”). Examples of positive meta-beliefs in GAD patients include “Worrying helps me cope” and “If I worry I can anticipate and avoid problems”, while negative meta-beliefs include “I have no control over worry”, “Worrying will damage my body” and “I could go crazy

with worry'. According to Wells GAD develops when the individual activates negative beliefs about worry (Wells, 2009). The aim of MCT is to identify and challenge these meta-beliefs, through discourse and cognitive experiments (e.g.; thought suppression and trying to lose control of worry). The primary focus is the negative beliefs, followed by the positive beliefs. Once the patient learns that his metacognitive beliefs are wrong/not helpful it is theorized that he/she will be able to break the unhelpful worry pattern that is the defining feature of the illness.

This theoretical framework is somewhat newer than the avoidance model, so only parts of the MCT model have been thoroughly empirically tested. There is convincing evidence that individuals with GAD endorse negative beliefs about worry and engage in meta-worry (Behar, DiMarco, Hekler, Mohlman & Staples, 2009). Furthermore research indicate that GAD sufferers do indeed experience less control of their worry thoughts and endorse several negative beliefs about worry more strongly than matched non-GAD high-worriers (Ruscio & Borkovec, 2004). There is less clear evidence for the notion that meta-worry is specific to GAD however, as there have been found comparable levels of meta-worry in OCD (Cartwright-Hatton & Wells, 1997) and panic disorder patients (Wells & Carter, 2001).

This study did not propose to further investigate the validity of these different constructs, but rather to test the relative efficacy of the therapies derived from the two distinct models. CBT has proved to be effective in treatment of GAD, although not quite en par with treatment of other anxiety disorders. MCT has not been empirically tested with GAD on this level before, but it has shown promising results in two smaller trials (Wells & King, 2006; Wells et al., 2010), where it was produced very high effect sizes for MCT. Based on these results MCT was expected to be more effective than CBT in the current study, while CBT was expected to be more effective than no treatment.

Method

Design

The full research trial is currently being conducted at the outpatient-clinic at the Department of Psychology, Norwegian University of Science and Technology in Trondheim, Norway. The aim of the research trial is to treat a total number of 60 participants suffering from GAD, 30 with MCT and 30 with CBT. 20 of these patients (10 from each treatment condition) will be placed at a 12 weeks waiting list prior to treatment. This group comprises the control condition. All participants were randomly assigned to one of the three treatment conditions (MCT, CBT and WAIT) by blocked randomization, based on SPSS. Once the wait group had finished their 12 week wait they were re-randomized to either of the other two treatment conditions. Two factors are controlled for in the randomization, these being gender and the presence of major depressive disorder. Participants were requested to fill out a battery of self-report instruments before being placed on the waiting list (wait group only), before their first therapy session, after their last therapy session, one and two years after finishing treatment. The research trial is not yet complete so this preliminary study will only use the part of the sample that has completed treatment at the current date (N=42). No follow-up data will be used as the sample size would be too small to allow meaningful analysis.

Participants

Participants were offered to participate in the study if they (1) had GAD as their primary diagnosis, (2) were at least 18 years old, (3) had no known somatic illness, (4) did not have psychosis, (5) did not have any past suicidal attempts and/or current intent, (6) did not have PTSD, (7) did not have cluster A or B personality disorder, (8) did not have a substance dependence, (9) were willing to accept the assigned treatment condition and

(10) were willing to withdraw any psychotropic medication for a period of 4 weeks prior to entry. A total number of 298 people were considered for the study, of which 185 were excluded by phone screening and 55 were excluded by pre-treatment assessment for not meeting admission criteria. A further 16 withdrew from the study after being offered inclusion.

The sample for this study (N=42) consisted of 29 women (69%) and 13 men (31%), which is similar to the gender distribution normally seen in GAD patients (Covin et al., 2007). The average age of the whole sample was 36.51 (SD=13.11), while the CBT and MCT groups had an average age of 35.94 (SD=8.68) and 36.92 (SD=15.69) years respectively. This age difference was not significant ($p=.80$). Six of the participants were single, 22 were married or co-habiting, four had a partner they did not co-habit with, three were separated and seven did not specify. The ethnic composition was primarily Caucasian (95.2%) with only two participants (4.8%) reporting other nationalities (Tunisia and Turkey), one in the CBT group and the other in the MCT group. Including GAD the participants in the study had an average of 2.29 diagnoses at pre-treatment assessment. The CBT and MCT groups had an average of 2.5 and 2.12 diagnoses respectively. 65% of the participants had at least one additional diagnosis. These additional diagnoses (ICD-10) were social phobia (11), Panic disorder (7), specific phobias (5), Major depressive disorder, recurrent, in remission (5), Major depressive disorder, recurrent, mild (5), Major depressive disorder, recurrent, moderate (4), Dysthymic disorder (4), Undifferentiated somatoform disorder (2), Avoidant personality disorder (2), Obsessive-compulsive disorder (1), Hypochondriacal disorder (1), Agoraphobia with panic disorder (1), Major depressive disorder, single episode, moderate (1), Major depressive disorder, single episode, severe without psychotic features (1), Other depressive episodes (1), Overeating associated with other psychological disturbances (1) and Eating disorder, unspecified (1). Twenty four of the participants received MCT treatment and 18 received CBT, which reflects differing progress in the two treatment groups. Twelve of the participants (MCT=6 & CBT=6) were assigned to

the waiting list condition before receiving treatment. A demographic summary can be found in table 1.

Table 1

Participant characteristics of the treatment sample.

Characteristic	All Participants (n=42)	CBT (n=18)	MCT (n=24)
Gender, n			
Female	29 (69%)	12 (67%)	17 (71%)
Male	13 (31%)	6 (33%)	7 (29%)
Age, mean (SD)	36.51 (13.11)	35.94 (8.68)	36.92 (15.69)
Social Status, n			
Single	6 (14%)	2 (11%)	4 (17%)
Partner	4 (10%)	1 (6%)	3 (13%)
Married/cohabiting	22 (52%)	8 (44%)	14 (58%)
Separated	3 (7%)	2 (11%)	1 (4%)
Not specified	7 (17%)	5 (28%)	2 (8%)
Ethnicity, n			
Caucasian	40 (95%)	17 (94%)	23 (96%)
Other	2 (5%)	1 (6%)	1 (4%)
Most common additional diagnoses, n			
Depression (all)	17 (40%)	8 (44%)	9 (38%)
Social Phobia	11 (26%)	5 (28%)	6 (25%)
Panic Disorder	7 (17%)	5 (28%)	2 (8%)
Specific Phobias	5 (12%)	1 (6%)	4 (17%)

Procedure

Participants were recruited to the study through a combination of newspaper advertising and referrals from general practitioners and mental health specialists in the Trondheim area, over a period of four years. A total number of 298 people were considered for inclusion in the study. Of these 251 answered the newspaper ads and the remaining 47 were referred to the project. One of four clinical assessors (advanced clinical graduate students trained in DSM diagnostic interviewing) conducted a brief (about 30 min), semi-structured phone interview with those who responded to the advertisements, to determine likely eligibility. Of the 251 who answered the ads 185 were excluded in this manner. Fifty of the remaining 66 were offered a brief (1 hour), in person, screening interview, through which a further 26 were excluded while the rest were offered a full diagnostic interview. The remaining 16 were offered a full diagnostic interview directly. Those participants who were deemed potentially suitable through this screening process (40), plus all those that were referred from GP's (47), were then administered the full, structured, diagnostic interview, which included the Anxiety Disorders Interview Schedule for DSM-IV (ADIS-IV) and the SCID-I + II, to determine if the participants met all of the inclusion, and none of the exclusion criteria. A diagnosis (ICD-10) was set if the participant met the general criteria of any diagnosis in either ADIS-IV or SCID-I + II. If the assessor deemed a participant suitable for inclusion a videotape of the diagnostic interview was shown to their supervisors, Hans M Nordahl, Ph.D. Professor, NTNU (Principal investigator) and Roger Hagen, Ph.D., Associate professor, NTNU, to ensure diagnostic reliability. If there was consensus between assessor and supervisor at this point the participant were offered inclusion in the study. Of the 87 participants given a diagnostic interview 58 were offered inclusion.

After the completion of treatment the same assessor that did the diagnostic interview reassessed the participant, to see if he or she still met criteria for the diagnoses given before treatment. Assessors were kept unaware of treatment condition and progress to avoid any bias.

Outcome measures

A battery of self-report questionnaires were filled out by the participants 12 weeks before treatment (wait group only), pre-treatment and after their last treatment session. This battery included, among other measures, the “Penn-State worry questionnaire” (PSWQ: Meyer, Miller, Metzger & Borkovec, 1990), the trait-anxiety subscale (STAI-T) of the “State-Trait-anxiety inventory” (STAI: Spielberger, Gorsuch, Lushene, Vagg & Jacobs, 1983), the Beck Anxiety Inventory (BAI: Beck, Epstein, Brown & Steer, 1988) and the Beck Depression Inventory (BDI: Beck, Ward, Mendelson, Mock & Erbaugh, 1961).

The PSWQ is a 16-item general measure of pathological worry and is, perhaps, the most commonly used self-report measure in clinical treatment research on GAD (Covin et al., 2007). It is designed to capture some of the most important features of clinically relevant worry, namely its generality over time and situations, its intensity/excessiveness and its uncontrollability. The PSWQ is a reliable and well validated clinical measure of pathological worry, with high internal consistency ($\alpha = .93$) and high stability (test-retest r 's range from .74 to .93) (Molina & Borkovec, 1994). Each item is scored on a five point Likert scale, from 1 (Not all typical) to 5 (Very typical), with 5 of 16 items reversed (absence of worry), which gives a possible total score of 16-80. Sample items include “I am always worrying about something”; “I find it easy to dismiss worrisome thoughts”; and “When there is nothing more I can do about a concern, I don't worry about it anymore”. The normative mean in a screened, non-anxious, student group ($N=2130$) was found to be 43.81, while a clinical sample of GAD sufferers ($N= 174$, ADIS-R screened) had a comparative mean of 67.66 (Molina & Borkovec, 1994). When the instrument is used for diagnostic purposes 45 is considered the optimal cut-off score for GAD (Behar, Alcaine, Zuellig & Borkovec, 2003). The PSWQ also correlates highly with the STAI-T ($r = .74$) though they only share 50% variance (Molina & Borkovec, 1994). Using Jacobson & Truax' (1991) criteria Fisher (2006) established that the Reliable change index (RCI) for PSWQ was 7, with the cut-off point ≤ 47 .

The trait-anxiety subscale of the State-Trait-anxiety inventory is also a commonly used outcome measure in treatment research on GAD (e.g.; Borkovec et al., 2002; Wells et al., 2010; Dugas et al., 2010). It is designed to measure “relatively stable individual differences in anxiety-proneness” (Spielberger et al., 1983, p. 1), that is; the tendency to perceive stressful situations as threatening and to respond to such situations with elevated levels of current anxiety. The instrument comprises 20 items, scored from 1 (Almost never) to 4 (Almost always), with 9 of 20 items reversed (anxiety-absent items). Sample items include “I lack confidence” and “I feel safe” (reversed). Spielberger et al. (1983) found the STAI-T to have reasonably high stability (test-retest r 's range from .65 to .86) and high internal consistency across populations ($\alpha = .89-.96$). Fisher and Durham (1999) found the mean of a treatment seeking population, across six studies ($N = 404$), to be 57 ($SD = 9.45$) while the mean of a well function population ($N = 1838$) was 34.84 ($SD = 9.19$). Using Jacobson & Truax' (1991) criteria Fisher & Durham (1999) established that the RCI for STAI-T was 8, with the cut-off point ≤ 45 . There has been some controversy as to the construct validity of this instrument. Bados, Gómez-Benito & Balaguer (2010), for instance, found the instrument to be more strongly correlated with negative affect (depression) than with anxiety. This controversy does not make the instrument unsuitable as an outcome measure for the current study however, given the high comorbidity between GAD and MDD. Indeed... MCT has shown potential to produce considerable effect sizes (2.30) on this instrument in a previous study (Wells et al., 2010).

The BAI is an established measure of anxiety and is commonly used in both research and diagnostics. As the name implies the instrument measures the severity of common somatic and cognitive anxiety symptoms, during the past week. Beck et al. (1988) found the BAI to possess high internal consistency ($\alpha = .92$) and stability (one week test-retest $r = .75$) in a psychiatric outpatient population. The instrument comprises 21-items, scored from 0 (Not at all) to 3 (Severely- I could barely stand it), indicating the level of symptom severity. Sample items include “I have felt nervous” and “I have been afraid to die”. Beck et al. (1988) also found the BAI to discriminate successfully between

anxious diagnostic groups (E.g. GAD) and non-anxious diagnostic groups (E.g. MDD) using DSM-III criteria. No norms for Jacobson & Truax' (1991) criteria were found on PsycNET for this instrument.

The BDI is a commonly used measure of depression severity, measuring both symptoms and attitudes. It comprises 21 items scored from 0 (absence of symptom/attitude) to 3 (severe symptom/attitude) with a higher score indicative of depression. Each score is connected to a description and the respondent is asked to select the description that he/she thinks fits them best. Symptoms and attitudes measured include mood, self-dislike and sleep disturbance. In clinical assessment a BDI score of 10-18 is indicative of mild to moderate depression, 19-29 moderate to severe depression and 30-63 is considered severe depression. Beck, Steer & Garbin (1988) found the instrument to possess high internal consistency ($\alpha = .86$, for psychiatric patients) and concurrent validity. BDI is not designed to measure GAD severity and is thus not considered an outcome measure of the primary effect we wish to see in this study. BDI is however well validated and perhaps the most widely used measure of major depressive disorder (MDD), which is a very common comorbid diagnosis with GAD. It is also commonly used in GAD treatment literature, so it is included in the current study as a measure of secondary treatment effects. For the mentioned reasons no Jacobson & Truax analysis will be done with this instrument.

Therapists

There were seven doctoral-level therapists (male) involved in this study, all of them clinical psychologists trained in cognitive therapy of GAD. In the full trial it is intended that six of the therapists will treat an equal number of participants, in both conditions, so as to minimize any therapist bias. The last therapist withdrew from the study after treating one participant (MCT). In the current study the six main therapists have treated

an unequal number of patients, divided unevenly among treatment conditions. Therapist one treated eight of the participants (MCT=5 & CBT=3), therapist two treated five participants (MCT=5), therapist three treated seven participants (MCT=2 & CBT=5), therapist four treated ten participants (MCT=5 & CBT=5), therapist five treated five participants (MCT=2 & CBT=3) and therapist six treated six participants (MCT=4 & CBT=2).

The six main therapists were divided into two teams, each team treating the first half of their patients with either CBT or MCT. After half the patients were treated the teams switched treatment condition. Professor Thomas Borkovec, Penn State University, supervised the Cognitive Behaviour therapists, while Professor Adrian Wells, University of Manchester/Norwegian University of Science and Technology, supervised the Metacognitive therapists. Professor Hans M. Nordahl, Norwegian University of Science and Technology, held supplementary supervision for both groups on a bi-weekly basis.

Treatments

Treatment sessions were normally held once per week for 8-12 sessions. Each session was 45-60 min in duration. Treatment could be terminated at any stage after 8 sessions by mutual agreement between therapist and participant. Treatment with CBT and MCT followed the published treatment protocols of Borkovec and Wells respectively. Session by session checklists (Appendix) were formulated to allow for control of treatment adherence and for any violations of manual (not part of this preliminary study). To avoid overlapping techniques therapists in the CBT condition were specifically instructed not to; focus on the controllability of worry, focus on meta worries or to address positive or negative meta-beliefs. Therapists in the MCT condition were specifically instructed not to; do awareness training of worry cues, use any relaxation techniques or diaphragmatic breathing. The session by session checklists can be found in the appendix.

Statistical Power

The minimum clinically meaningful difference between treatments that we wish to detect in PSWQ will be 12 (Molina & Borkovec, 1994). We have found a difference of 15. With a probability of Type I error of 5 per cent with at least 18 patients included in each of the treatment groups, we have calculated the power of the statistical analysis to detect significant differences to be 0.826. Thus, there is sufficient statistical power to do a between conditions comparison (Lenth, 2001)

Results

Data Analysis

The data is presented in table 2.

Table 2

The pre- and post-treatment N, mean, and Standard Deviation for all four outcome measures.

Measure	Descriptive	CBT		MCT		WAIT	
		Pre	Post	Pre	Post	Pre	Post
BAI	N	18	18	23	22	12	11
	Mean	23.22	11.72	28.30	5.00	28.58	28.18
	SD	10.35	14.73	14.28	6.31	14.31	14.20
PSWQ	N	18	18	23	21	12	11
	Mean	69.72	54.72	65.30	39.95	66.25	65.91
	SD	5.32	12.98	8.37	12.06	8.54	9.63
STAI-T	N	17	18	21	22	12	11
	Mean	59.47	47.94	55.29	40.23	58.08	55.18
	SD	9.74	11.52	10.58	11.828	9.46	9.14
BDI	N	18	18	23	22	12	11
	Mean	17.22	10.33	15.70	4.82	16.42	18.45
	SD	9.82	10.91	9.26	7.00	11.58	12.53

Note: CBT = Cognitive behavioral therapy; MCT = Metacognitive therapy; WAIT = Waiting list (No treatment); BAI = Beck Anxiety Inventory; PSWQ = Penn-State worry questionnaire; STAI-T = trait-anxiety subscale of the State-Trait-anxiety inventory; BDI = Beck Depression Inventory.

Pre-treatment differences

The two groups were controlled for pre-treatment differences using independent sample t-tests. The two groups were not significantly different on BAI ($p=.194$), STAI-T ($p=.217$) or BDI ($p=.613$). The MCT group proved to be better functioning on PSWQ ($p=.047$).

Attrition and number of sessions

Of the 58 participants that were offered inclusion fifteen declined treatment and one were excluded from the MCT group after eight sessions, because she had received treatment for social phobia outside the study. As it is not possible to attribute her treatment gains to the current study, with any degree of certainty, all her data have been removed from the analysis. The remaining participants all received between eight and twelve therapy sessions.

Treatment Outcome

Differences between groups after treatment

Univariate ANCOVAs were run in order to assess the relative treatment efficacy (table 3). Pre-treatment scores were entered as the covariate and the grouping variable was entered as a fixed effect. MCT proved significantly more effective than CBT on BAI, PSWQ and BDI while both MCT and CBT proved significantly more effective than no treatment on all measures. Using independent samples t-tests the MCT group showed significantly better functioning post-treatment than the CBT group on PSWQ ($p=.001$) and STAI-T ($p=.045$), but not on BDI ($p=.060$) or BAI ($p=.085$).

Table 3

Between-group differences at post-treatment adjusting for pre-treatment scores (ANCOVA).

Variable	MCT vs. CBT		MCT vs. WAIT		CBT vs. WAIT	
	F	P	F	P	F	P
BAI	6.330	.016	43.020	.000	5.193	.031
PSWQ	10.851	.002	36.434	.000	11.653	.002
STAI-T	4.025	.053	12.778	.001	5.518	.027
BDI	5.336	.027	32.532	.000	10.345	.003

Within-group change

Using paired samples t-tests on the pre- and post-treatment scores both the CBT and MCT groups showed improvement on all outcome measures at a significance level of $p \leq 0.001$ (Table 4).

Table 4

Within-group change pre- to post-treatment (pre minus post-treatment scores).

Variable	CBT	MCT	WAIT (No-treatment)
BAI	11.50*	23.3*	0.40
PSWQ	15.00*	25.35*	0.34
STAI-T	10.59*	15.06*	2.90
BDI	6.89*	10.88*	-2.03

Note: * $p \leq 0.001$.

Wait List Control

The wait list group was controlled for spontaneous recovery, over their 12 week wait, on all four outcome measures. We can see in table 4 that the group as a whole had a reduction of BAI score by 0.40, of PSWQ score by 0.34 and of STAI-T score by 2.90. On BDI the group increased their score by 2.03. None of these changes were significant however (paired-samples t-tests give: $p=.53$, $p=.58$, $p=.14$ and $p=.50$ respectively). Table 5 shows that none of the participants in this group met Jacobson & Truax' (1991) criteria for recovery on the PSWQ or STAI-T. On the PSWQ two participants improved and one participant got worse, while on the STAI-T two participants improved. All in all there is little evidence of spontaneous recovery or regression to the mean in the control group.

Recovery rates and clinically significant change

Using Jacobson & Truax criteria a participant is defined, post-treatment, as worse if his score has increased by the RCI or more, improved if his score has decreased similarly and recovered if his score has decreased by the RCI and is below the cut-off point. If neither of these criteria is met the participant is considered unchanged. Although I report rates for improvement it is worth mentioning that only recovered patients would be considered by Jacobson et al. (1999) to display clinically significant change.

Table 5 shows the summary of the rates. There were 5 participants with score \leq cut-off on the STAI-T pre-treatment (1 in the CBT group and 4 in the MCT group) that were included in the analysis. These were considered recovered if their pre – post-treatment scores $>$ RCI. All participants had scores above cut-off on the PSWQ pre-treatment. In the MCT group one participant was excluded on both measures due to missing post data (did still meet diagnostic criteria for GAD), two were excluded from just PSWQ due to missing post data (did not meet criteria for GAD) and three were excluded just from the STAI-T condition due to either missing pre or post data (none still met criteria for GAD).

One participant was excluded from the CBT group in the STAI-T condition due to missing pre data (did not meet GAD criteria).

Table 5

Percentage of participants in each condition meeting Jacobson's criteria for recovery and change on the PSWQ and STAI-T.

Treatment	Instrument	N	Worse	Unchanged	Improved	Recovered
CBT	PSWQ	18	0%	22%	39%	39%
MCT	PSWQ	21	0%	19%	10%	71%
WAIT	PSWQ	11	9%	73%	18%	0%
CBT	STAI-T	17	0%	47%	24%	29%
MCT	STAI-T	20	0%	25%	15%	60%
WAIT	STAI-T	11	0%	82%	18%	0%

Reassessment/Diagnosis

Two of the 42 participants (both CBT) failed to be reassessed after completing treatment (for unknown reasons). Neither of these participants met Jacobson & Truax' (1991) criteria for recovery on either the PSWQ or STAI-T (though both met the criteria for improvement on the PSWQ). Of the remaining 16 CBT participants five still met the criteria for GAD, which is a recovery rate of 68.8%. Of the 24 MCT participants only three still met the criteria for GAD, which is a recovery rate of 87.5%. With additional diagnoses the CBT and MCT groups had an average of 0.94 and 0.46 diagnoses respectively after treatment. None of the eight participants who retained their GAD diagnosis at reassessment met Jacobson & Truax' (1991) criteria for recovery on either the PSWQ or STAI-T, which suggests that the real recovery rate of CBT might be somewhat lower than indicated here.

Post-treatment effect sizes

Within-group effect sizes were calculated using Cohen's D ($\{M_1 - M_2\} / \{SD_1 + SD_2\}/2$; Where M is mean and SD is standard deviation before [1] or after [2] treatment). MCT had large effect sizes on all four measures, while CBT had a medium effect size on BDI and large sizes on the other three measures. MCT had consequently greater effect sizes than CBT on all measures. A summary is found in Table 6.

Table 6

Within-group effect sizes for both treatments on all the four outcome measures, using Cohen's D .

Treatment	PSWQ	STAI-T	BAI	BDI
CBT	1,64	1,00	0,92	0,66
MCT	2,48	1,34	2,26	1,34

Discussion

The current study compared the relative efficacy of CBT and MCT in treatment of generalized anxiety disorder. As expected both CBT and MCT proved to be effective treatments of GAD. CBT proved to be significantly more effective than no treatment on all outcome measures ($p < .05$) while MCT proved to be significantly more effective than CBT measured on the PSWQ, BAI and BDI ($p < .05$). The difference in treatment effect as measured by trait anxiety (STAI-T) failed to reach significance ($p = .053$), although the MCT group proved to be significantly better functioning post-treatment ($p = .045$). MCT proved to be more effective than no treatment, on all outcome measures, at a higher significance level than CBT ($p \leq .001$). The control group showed no signs of significant change over their 12 week wait. Following treatment the Jacobson & Truax (1991) recovery rates of MCT were impressive, given the stringent criteria employed. 71% of the participants recovered on the PSWQ measure, which was considerably higher than the 39% of CBT. On the STAI-T the recovery rate of MCT was twice as high as that of

CBT (60% vs. 29%). The diagnostic recovery rate was even more impressive, with 87.5% of the MCT patients in remission at the end of treatment, compared with 68.8% of the CBT patients. Finally the effect sizes produced by MCT were consequently larger than those produced by CBT, and especially those produced on PSWQ (2.48) and BAI (2.26) are considerable. All the effect sizes produced by MCT were very large.

These findings differ somewhat from those found in the two preceding MCT trials done by Adrian Wells and colleagues on GAD (Wells & King, 2006; Wells et al., 2010). In the first trial Wells & King (2006) treated 10 patients without employing any comparison treatment or control group. With this small sample MCT produced very large effect sizes on BAI (1.82), STAI-T (2.78) and BDI (1.41) post-treatment, while the Jacobson & Truax (1991) recovery rate on STAI-T was 87.5%. The pre-treatment scores of this sample closely resembled those found in the current study, with the exception of BAI where Wells & King's sample proved better functioning (21.0 vs. 28.3). In the second trial (Wells et al., 2010) MCT was compared to applied relaxation (AR) and another 10 patients were treated with MCT. This time MCT produced very large effect sizes on BAI (1.38), STAI-T (2.30) and BDI (1.24) again, plus also on the PSWQ (3.41). The diagnostic recovery rate of MCT was 100% while the Jacobson & Truax (1991) recovery rate was 80% on both PSWQ and STAI-T post-treatment. The pre-treatment scores of this sample also closely resembled those found in the current study, again with the exception of BAI (22.2 vs. 28.3).

When we compare these results with the current study we can see that MCT produced considerably smaller effect sizes on the STAI-T and PSWQ, a considerably larger size on BAI, and about the same size on BDI with our sample. The difference in size on BAI is largely due to the fact that our sample had a considerably higher pre-treatment score than that of the two preceding studies. In addition the two Wells studies calculated Cohen's *D* by dividing with pre-treatment standard deviation (SD_1), whereas the current study used mean SD ($(SD_1 + SD_2) / 2$). This will favor the current study if SD_2 is consequently smaller than SD_1 , which appears to be the case with BAI in all the three studies. Calculating effect size with only SD_1 gives an effect size of 1.63 for the BAI,

which is more in line with the results found in the previous studies. The STAI-T effect size was considerably smaller in the current study than the two previous ones, although it was still very large (1.34). A closer look at the data reveals that our sample had both higher standard deviation and higher post-treatment scores than the samples in the other studies. The sample sizes of those studies are rather small however, so it is quite possible that the effect sizes are overestimations. As for the PSWQ the effect size found in the current study is impressive (2.48), but it does not approach that found by Wells et al (3.41) (2010). The reduction in score pre- to post-treatment found by Wells et al (2010) is almost identical to the one found in the current study (25.5 vs. 25.35) so the difference between the effect sizes is exclusively due to differences in SD. Both the SD's found in the current study were larger than the corresponding ones found by Wells et al (2010). In both studies SD_1 was smaller than SD_2 , by several points, which further favor of the preceding study. Using only SD_1 gives an effect size of 3.03 for PSWQ in the current study. Taking all of this, and the small sample size employed into account, it is again likely that the effect size produced by Wells et al (2010) is an overestimation. Excluding the Wells studies, the effect size produced on PSWQ by MCT in the current study is still the largest reported in GAD treatment literature (known to the author) to date.

The recovery rates found in the current study were consequently lower than those found in the Wells studies. The largest difference was found with the STAI-T, on which MCT have previously produced recovery rates of 87.5% (Wells & King, 2006) and 80% (Wells et al., 2010), whereas we only got a rate of 60%. In addition CBT only produced a recovery rate of 29% on the STAI-T in the current study, while Fisher & Durham (1999) found the average recovery rate of individual CBT to be 48% across studies. The pre-treatment score of our sample (CBT=59.47 & MCT=55.29) were not so different from that found by Fisher & Durham (57.0) (1999), which suggests that there might be a bias in our sample on this particular instrument (no validation of the Norwegian translation could be found by the author). The recovery rate on PSWQ and the diagnostic recovery rate did not quite reach the levels found by Wells et al (2010) (71% vs. 80% & 87.5% vs.

100% respectively), but this was likely due to the small sample size employed in that study.

Compared with the other innovative treatments MCT also proved very effective. Dugas et al. (2010) reported lower effect sizes than those found in the current study on the PSWQ (2.38), BAI (0.87) and BDI (1.11) using only SD_1 , while Romer & Orsillo (2008) reported a lower effect size on the PSWQ (1.58) and a higher size on the BDI (1.74). The Dugas et al. (2010) study also reported a lower diagnostic recovery rate (70%).

The treatment efficacy of CBT in the current study did not approach that found by Borkovec & Costello (1993). That particular study did not report effect sizes or recovery rates, but they did report means, SD's and what they termed "high endstate functioning" (a post-treatment score within one SD of the mean of a normative sample, on 6-8 of the employed measures). Calculating Cohen's D using the same method employed by the current study yield effect sizes of 1.64 on the STAI-T, 1.87 on PSWQ and 1.43 on BDI for CBT in Borkovec & Costello's study, to which the respective values of 1.00, 1.64 & 0.66 found in the current study does not compare well. As for clinically significant change Borkovec & Costello (1993) reported a "high endstate functioning" rate of 26.3%, which is not directly comparable with the Jacobson & Truax (1991) rates found by the current study. Accessing the full data Fisher found the Jacobson & Truax recovery rates of the Borkovec & Costello (1993) study to be 71% on the STAI-T (Fisher & Durham, 1999) and 53% on the PSWQ (Fisher, 2006). These rates are the highest found across studies for CBT (Fisher & Durham, 1999; Fisher, 2006), and especially the rate found on STAI-T is considerably higher than treatment average (STAI-T = 48% & PSWQ = 48%). Indeed, replications of the Borkovec & Costello study have generally not been able to reproduce the initial impressive results (Covin et al., 2007). All this suggests that the original findings by Borkovec & Costello (1993) represent an overestimation of CBT's real efficacy in GAD treatment, possibly due to differences in the sample treated (Unlike the current study Borkovec & Costello screened to exclude panic disorder and severe MDD), or some random error.

The current study had several significant strengths and limitations. The main strengths lie in the study's design. Randomized controlled studies are arguably the gold standard of how to conduct efficacy studies, as it limits potential biases. The current study employed independent assessors, blind to treatment group and progress. This should have eliminated the effect of any potential treatment preference bias on the part of the assessors. Therapists might have had preferences for/been more apt at one treatment over the other, but the potential confounding effect this represents should be limited by the number of therapists treating patients in both conditions. A further strength lies in the fact that both treatments were supervised by their respective founders, Professor Thomas Borkovec, Penn State University, for CBT and Professor Adrian Wells, University of Manchester/Norwegian University of Science and Technology, for MCT.

This being a preliminary study it has some considerable limitations. Most prominent of these is the lack of follow-up data and treatment adherence control. Both are planned for the full trial, but at the current date there is not enough follow-up data to allow meaningful analysis, while treatment adherence control will not be conducted until the trial is complete. The consequence of this lack of data is that we don't know if the improvements experienced by the participants are retained for any time after treatment completion. The limited results from the preceding studies (Wells & King, 2006; Wells et al., 2010) suggests that the majority of patients retain their improvements 12 months after treatment, but no such conclusion can be drawn in this preliminary study. No treatment adherence control means that the therapists might have diverted from the treatment protocols, and thus have biased the results found here. The specific formulated treatment checklists (appendix) and the high level of supervision should have eliminated this, but with no control conducted we simply don't know.

Another limitation is the fact that the MCT group proved to have significantly lower levels of pathological worry than the CBT group pre-treatment (PSWQ; $p=.047$). Thus, as the CBT group arguably had more severe symptoms than the MCT group pre-treatment, this might have made them more difficult to treat, contributing to the great between-group differences observed. Granting that this might have reduced the effect of

CBT in the current study MCT nonetheless proved very effective on its own. The effect sizes and recovery rates produced by MCT on PSWQ in the current study are still superior to any produced by CBT in previous studies.

In conclusion, the results of the current study suggest that MCT is a highly effective treatment of GAD, superior to more traditional CBT, and that it is at least as effective as the other, current, innovative treatments of GAD. This was especially true when measuring reductions of pathological worry, where MCT produced the greatest effect size seen in the treatment literature (of any considerable size) to date. The recovery rates were also impressive, with more than 70% recovering from pathological worry, with the most stringent criterion employed, and almost 90% of patients considered to be in remission at the end of treatment. These preliminary results are very promising for the full trial and suggest that MCT might be able to bring GAD treatment on par with CBT treatment of the other anxiety disorders.

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Appendix

Generalized Anxiety Disorder

Checklist: Combined self-control desensitisation and CBT

(Tom D. Borkovec)

SESSION 1

- Description of treatment & Rationale
- SCD Hierarchy Construction
- Diaphragmatic Breathing (DB)
- Homework
- Distribution of inventories and instruments used in the therapy

SESSION 2

- Review of the Client's week
- Cognitive Therapy: Cognitive Monitoring and Identification
 - o Give client the handout on characteristics of maladaptive thoughts, review this in session
- Progressive Relaxation
 - o Focusing on the present moment: Perceive process and learning about the reality with paying attention to experience about reality moment to moment.
 - o Demonstration of 7 muscle group PR
- Homework Assignment
 - o Twice a day PR practice
 - o Focusing on the present moment: Perceive process and learning about the reality with paying attention to experience about reality moment to moment.
 - o Continuing self-monitoring of anxiety levels

SESSION 3

- Review of Week and Homework
- Cognitive Therapy: Challenging Automatic Thoughts and Beliefs
- Continue application training, discussion, questions and problem resolution.
- In Session PR application.
- Imagery training
- 7 Muscle Group PR Training and DB

- RRS
- Discussion of Experience, Resolution of Problems, Practice Reminder.
- Homework Assignment

SESSION 4

- Review of Week and Homework
- Cognitive Therapy: Continue discussion of 15 Styles of Distorted Thinking.
- Continue application training, discussion, questions and problem resolution.
- In Session PR application.
- Introduce SCD and select today's hierarchy scene.
- 7 Muscle Group PR Training
- SCD
 - Introduction of technique and how to apply it
- RRS
- Homework Assignment

SESSION 5

- Review of Week and Homework
- Cognitive Therapy: Logical Analysis Continued
- Continue application training, discussion, questions and problem resolution.
- In Session AR application.
- Self-Statement Training and SCD scene identification.
- 4 Muscle Group PR Training
- SCD
- RRS
- Homework Assignment

SESSION 6

- Review of week and homework
- Cognitive therapy: Continue Logical Analysis
- Continue application training, discussion, questions and problem resolution
- In session PR application
- Self-statement training and SCD scene selection
- 4 Muscle Group PR training
- SCD
- RRS
- Homework Assignment

- o Encouraged to enter anxiety provoking situations and applying newly acquired coping skills and to test belief hypotheses. Decide on specific approach tasks, as before

SESSION 7

- Review of week and homework
- Cognitive therapy: Developing Alternative Thoughts and Beliefs
- Continue application training, discussion, questions and problem resolution
- In session PR application
- Self-statement training and SCD scene selection
- 4 Muscle Group PR training
- SCD
- RRS
- Homework Assignment

SESSION 8

- Review of week and homework
- Cognitive therapy: Continue Alternative Thought and Belief Generation
- Continue application training, discussion, questions and problem resolution
- In session PR application
- Self-statement training and SCD scene selection
- Relaxation by Recall Group PR training
- SCD
- RRS
- Homework Assignment

SESSION 9

- Review of week and homework
- Cognitive therapy: Continue Alternative Thought and Belief Generation
- Continue application training, discussion, questions and problem resolution
- In session PR application
- Self-statement training and SCD scene selection
- Relaxation by recall PR training
- SCD
- RRS
- Homework Assignment

SESSION 10

- Review of week and homework
- Cognitive therapy: Decatastrophizing

- Continue application training, discussion, questions and problem resolution
- In session PR application
- Self-statement training and SCD scene selection
- Relaxation By Recall and Counting Training
- SCD
- RRS
- Homework Assignment

SESSION 11

- Review of Week and Homework
- Cognitive Therapy: Treatment of Underlying Beliefs
- Method
 - o Review the client's history of irrational thinking and anticipate future false beliefs.
 - o Prepare preventive beliefs for each threatening situation the client expects to face or, more generally, for overall client problems
 - o Prepare a master list of situations that most people have to face sometime in their lives, along with irrational thoughts and alternative beliefs
 - o The client needs to practice until they become second nature
- Continue application training, discussion, questions and problem resolution
- In Session PR application – the responsibility for recognizing early cues should have been transferred to the client
- Self-Statement training and SCD scene selection (as in session 5)
- Relaxation-by-counting alone
- SCD (as in session 5)
- RRS
- Homework Assignment

SESSION 12

- Review of Week and Homework
- Cognitive Therapy: Continue Treatment of Underlying Beliefs
- Continue application training, discussion, questions and problem resolution
- In Session PR application – responsibility for recognizing early cues should have been transferred to the client
- Self-Statement training and SCD scene selection
- Relaxation Training: the client is instructed to spend this period flexibly deploying the variety of relaxation methods
- SCD (as in session 5)
- RRS

- Homework Assignment
- Closure

Generalized Anxiety Disorder

Checklist for Meta-cognitive therapy

(adapted from Wells, 1997)

SESSION 1

- Generated a case formulation
- Socialised to the model
- Run suppression experiment
- Focus on verbal challenging uncontrollability belief
- Introduce worry postponement experiment
- Homework: Worry postponement, use WTR if necessary

SESSION 2

- Check homework & GADS, especially uncontrollability beliefs
- Verbal and behavioural reattribution to challenge uncontrollability
- Homework: Continue worry postponement & loss of control experiment

SESSION 3

- Check homework & GADS, especially uncontrollability beliefs
- Continue to challenge uncontrollability
- Run loss of control experiment in session if needed
- Begin to focus on challenging beliefs about danger
- Homework: Continue worry postponement, reverse worry avoidance

SESSION 4

- Check homework & GADS, especially uncontrollability beliefs
- Begin challenging beliefs about danger of worry
- Try to go crazy, damage self with worry experiment
- Homework: Push worry to test dangers

SESSION 5

- Review danger beliefs on GADS
- Continue challenging beliefs about danger
- Homework: behavioural experiments to challenge danger

SESSION 6

- Review danger beliefs on GADS
- Continue challenging beliefs about danger
- Homework: behavioural experiments to challenge danger

SESSION 7

- Review danger beliefs on GADS
- Continue challenging beliefs about danger
- Homework: behavioural experiments to challenge danger

SESSION 8

- Check GADS
- If negative at zero, move to challenge positive beliefs
- Homework: Mismatch strategy, increase/decrease worry strategy

SESSION 9

- Check GADS
- If negative at zero, move to challenge positive beliefs
- Homework: Mismatch strategy, increase/decrease worry strategy

SESSION 10

- Check GADS
- If negative at zero, move to challenge positive beliefs
- Homework: Mismatch strategy, increase/decrease worry strategy

SESSION 11

- Check residual scores on GADS, beliefs and avoidance
- Deal with residual avoidance/beliefs
- Introduce practices of alternative strategies to worry
- Relapse prevention: write therapy blueprint
- Homework: Specify based on above issues

SESSION 12

- Check residual scores on GADS, beliefs and avoidance
- Deal with residual avoidance/beliefs
- Introduce practices of alternative strategies to worry
- Homework: Specify based on above issues