**Cognitive self-therapy
A contribution to long-term treatment
of depression and anxiety**

RIJKSUNIVERSITEIT GRONINGEN

**Cognitive self-therapy
A contribution to long-term treatment of
depression and anxiety**

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Petrus Cornelis Aloysius Maria den Boer
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Is God Love
Or Love God
Or Death
But Not Science

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Introduction

Self-help groups arise in society when certain needs are not being met by formal health care organisations (Lieberman 1990), and usually exist outside the established mental health care system. Self-help through naturally evolved or specially created 'lay' groups and networks represents the oldest and most widely spread system of care for human ills (Katz 1981). Self-help is a very common phenomenon in a large number of problem areas. A search for 'self-help' results in about 8000 hits for self-help books at a consumer's website, and more then 800 organisations and groups are summed up in a self-help group sourcebook (White & Madara 2002). A well-known example is AA groups for alcoholics, which have been shown to be just as effective as a treatment group at an outpatient clinic, while, moreover, the costs decreased by 45% (Humphreys & Moos 1996). Self-help became a focus of interest for professionals in the 1970s. Manuals were developed for the general support of patients and relatives as a supplement to the regular treatment of somatic or psychiatric disorders. Since the 1980s, cognitive self-therapy (CST) has been developed in the Netherlands, integrating non-professional and professional approaches for the purpose of long-term treatment of psychiatric patients. The large number of participants in self-help (Janssen & Geelen 1996) indicates that these activities meet a need. Doctors have to deal with that phenomenon and need to know which self-help alternatives can be fruitfully combined.

Emotional disorders (depression and anxiety) have been recognised as a main issue in mental health care. In this thesis they are considered jointly given the large degree of co-morbidity between them (Mineka *et al.* 1998), the similar role impairment caused by

these disorders (Kessler *et al.* 1999), and the overlap in therapeutic approaches. In the Netherlands, 13.6% of the adult population under age 65 reported a lifetime diagnosis of mood disorder and 13.8% of an anxiety disorder (Bijl *et al.* 1998). International observational studies indicate that 53.7% of psychiatrists' routine caseloads concern depression disorders and 9.3% anxiety disorders (Pincus *et al.* 1999). Of this joint caseload, 49,8% have a history of hospitalisation. Nearly half (47%) of those meeting lifetime criteria for major depression also meet criteria for a co-morbid anxiety disorder (Regier *et al.* 1998). The World Bank Burden of Disease project reports that mental disorders account for 9.1% of the global burden of disease in the world overall, and 22.4% in established market economies. Anxiety and depression disorders account for almost half (10.9%) (Andrews 1998). The indirect costs of depression to society are estimated at seven times the direct costs for depression management and at one-half of the total costs of all mental illness (Stoudemire *et al.* 1986). Yet strategies for prevention, risk-factor reduction and effective treatment of people with emotional disorders do not seem to have been adequately implemented. A disproportionate amount of treatment effort is spent on people with chronic psychoses compared with those suffering from emotional disorders (Andrews 1998). The Camberwell Needs for Care survey suggests that only 28% of the need for treatment of depression, and only 13% relating to anxiety, is met (Bebbington *et al.* 1997). Among the non-institutionalised civilian population of the United States, most people with psychiatric disorders fail to obtain professional treatment (Kessler *et al.* 1994). In the Netherlands, 28.2% of the Dutch adult population with a mood disorder and 21.6% with an anxiety disorder do not seek help (Van Ginneken & Schoemaker 2005). Care utilisation may differ in the Netherlands, as the provision of mental health care for the Netherlands is high when compared to the prevalence of mental health disorders and the utilisation of mental health services in a variety of settings (Andrews & Henderson 2000). The probability of use among those with a depressive disorder in the USA was half that for the Netherlands. Anyhow, the established mental health care system does not have the resources to meet the extensive need for care for chronic and remittent emotional disorders.

The first choice for treatment of emotional disorders according to national and international guidelines is medication and/or psychotherapy (Multidisciplinaire Richtlijnontwikkeling in de GGZ 2005; American Psychiatric Association 2000). In moderately

severe depression, all established antidepressants, cognitive behavioural therapy (CBT) and interpersonal psychotherapy (IPT) are equally effective (Ellis 2004). However, there is no evidence to support the view that CBT is more effective than other psychological treatments (Wampold *et al.* 2002). In severe depression, antidepressant treatment should precede psychological therapy (Ellis 2004). Despite the availability of high quality economic evaluations of psychological therapies for depression compared with care as usual, there is limited evidence of their cost-effectiveness, particularly when compared directly with pharmacotherapies (Barrett *et al.* 2005). SSRIs and newer antidepressants consistently appear more cost-effective than tricyclic antidepressants. CBT is the most cost-effective treatment for generalised anxiety disorder and panic disorder (Heuzenroeder *et al.* 2004) and superior for social anxiety disorder (Rodebaugh *et al.* 2004). Computer-assisted cognitive therapy for depression reduced therapist contact and was as efficacious as standard cognitive therapy (Wright *et al.* 2005). Bibliotherapy is effective for mild anxiety and depression disorders as well (Gould & Clum 1993; Marrs 1995). Guidelines mention the use of self-help strategies for the treatment of first episode emotional disorders, but do require professional care for remittent and chronic disorders. However, there are no unequivocally evidence-based guidelines for chronic conditions. There is an ongoing need for the development of new programmes to fill the gap between what is provided and what is needed for the treatment of emotional disorders.

The kind of shortfall between what is on offer and what is necessary can be filled by non-professional alternatives in a cost-effective manner (Lovell & Richards 2003), such as self-help strategies and paraprofessionals offering treatment and care traditionally supplied by mental health professionals (Harchik *et al.* 1989). Research on self-help groups and programmes belongs mainly to the field of sociology, and generally concerns case histories based on anecdotal evidence. One meta-analysis (Barlow *et al.* 1999) has examined studies of self-help groups, but no conclusions can be drawn regarding anxiety and depression disorders. Bibliotherapy, as defined by Marrs (Marrs 1995), relies on written texts, computer programs, or audio/video-recorded material for the purpose of understanding or solving problems regarding persons' development or meeting their therapeutic needs. Meta-analyses (Scogin *et al.* 1990; Gould & Clum 1993; Marrs 1995; Cuijpers 1997) have found effectiveness for bibliotherapy for various target problems, ranging from 'minor' problems (assertion

skills, study skills, parental skills, difficulties with sleep, sex, and memory) to disorders that may approach clinical severity (depression, anxiety, habit disorders). Psycho-education, as part of many treatment strategies, might be considered a kind of bibliotherapy. A psycho-education course for unipolar depression (Lewinsohn *et al.* 1986) is effective and useful as part of an active outreach approach for people recruited by the media who might not otherwise seek treatment (Cuijpers 1998). Paraprofessionals, defined as paid unqualified workers as well as volunteers with patient experience, achieve effects that are greater than those obtained under control conditions and comparable to those obtained by professional therapists (Bright *et al.* 1999; Christensen & Jacobson 1994). They may constitute up to 50% of the informal mental health care manpower (Moffic *et al.* 1984). Whether the results of non-professional alternatives will hold true for the treatment of chronic and remittent emotional disorders remains to be seen.

This thesis evaluates the evidence regarding the effectiveness of self-help and paraprofessionals in general, and the effectiveness of the cognitive self-therapy programme in particular, in the treatment of patients with chronic and remittent emotional disorders. With respect to the effectiveness of non-professional alternatives in the treatment of emotional disorders, a meta-analysis has been performed on the effectiveness of self-help strategies (**Chapter 2**) and a second meta-analysis on the effectiveness of paraprofessionals replacing professionals (**Chapter 3**). Next, the background of cognitive self-therapy and a pilot study into the feasibility and effectiveness of cognitive self-therapy are described (**Chapter 4**). The results of the pilot study were promising, and funding could therefore be obtained to perform a multi-centre randomised controlled trial on the cost-effectiveness of cognitive self-therapy. The 18-months results on symptom reduction, social functioning, quality of life and mental health care utilisation (**Chapter 5**) and the cost- analysis of the RCT (**Chapter 6**) are presented. Discussion (**Chapter 7**) and a summary (**Chapter 8**) will conclude the thesis.

The following hypotheses were examined:

Chapter 2   **Why is self-help neglected in the treatment of emotional disorders? A meta-analysis.**

Self-help strategies
a)   are as effective as professional treatment
b)   are more effective than no treatment
c)   the results are modified by the length of treatment or follow-up
d)   the results are modified by the severity of the illness.

Chapter 3   **Paraprofessionals for anxiety and depressive disorders. A meta-analysis.**

Paraprofessionals
a)   are as effective as professionals
b)   are more effective than no treatment
c)   the results are modified by the length of treatment or follow-up
d)   the results are modified by the severity of the illness.

Chapter 4   **Cognitive self-therapy. Results of a pilot study of an alternative treatment for psychiatric patients.**

Cognitive self-therapy
a)   is feasible to apply as a treatment programme for psychiatric patients
b)   leads to symptom reduction
c)   leads to improvement of social functioning.

Chapter 5   **Cognitive self-therapy for chronic depression and anxiety. A multi-centre randomised controlled trial.**

Cognitive self-therapy is more effective than treatment as usual with respect to
a)   symptom reduction
b)   improvement of social functioning and quality of life
c)   reduction of mental care utilisation.

Chapter 6   **Cost-effectiveness of cognitive self-therapy for depression and anxiety disorders.**

Cognitive self-therapy is cost-effective compared with treatment as usual.

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Why is self-help neglected in the treatment of emotional disorders?

A meta-analysis

Peter C.A.M. den Boer, Durk Wiersma & Robert J. van den Bosch

ABSTRACT

Background: Although the burden of emotional disorders is very high, mental health care is available to only a minority of patients. The literature suggests that self-help strategies, both bibliotherapy and self-help groups alike, are effective for various, less serious complaints but it is unclear whether available data support a role for self-help in treatment protocols for patients with clinically significant emotional disorders.

Methods: We searched the literature with a focus on 'anxiety' and/or 'depressive disorder'. Standardised assessment of diagnosis or symptoms and randomised controlled trials were inclusion criteria for a meta-analysis.

Results: The mean effect size of self-help (mainly bibliotherapy) versus control conditions is 0.84, and 0.76 for follow-up; the effect sizes of self-help versus treatment are -0.03 and -0.07 respectively. A longer treatment period is more effective.

Conclusions: Bibliotherapy for clinically significant emotional disorders is more effective than waiting list or no treatment conditions. The dearth of studies on self-help groups for emotional disorders does not permit an evidence-based conclusion concerning the effects of self-help groups. No difference was found between bibliotherapy and psychiatric treatment of relatively short duration.

This study explores the effectiveness of self-help strategies for treatment of patients suffering from remittent and chronic disabling mood and anxiety disorders. Lifetime diagnoses of anxiety and depression show extensive co-morbidity (Mineka *et al.* 1998). Nearly half (47%) of those meeting lifetime criteria for major depression also met criteria for a co-morbid anxiety disorder (Regier *et al.* 1998).

The World Bank has reported that mental disorders account for 9.1% of the world total global disease burden, with 22.4% of that burden residing in established market economies, and half of that due to emotional disorders (Andrews 1998). The indirect costs to society of depression are estimated at seven times the direct costs of depression, half of the total amount attributed to all mental disorders (Stoudemire *et al.* 1986). Yet, strategies for prevention, risk factor reduction and effective treatment of people with emotional disorders do not seem to have been adequately implemented. A disproportionate amount of treatment effort is spent on people with chronic psychoses compared with those suffering from emotional disorders (Andrews 1998). The Camberwell Needs for Care survey concluded that only 28% of the need for depression treatment and only 13% of the need for anxiety treatment is ever met (Bebbington *et al.* 1997). The established mental health care system does not have the resources to meet the extensive need for care of people with mood and anxiety disorders. The kind of shortfall between what is on offer and what is necessary can be filled by alternatives cost-effectively (Lovell & Richards 2003). Such an alternative might include self-help strategies because of their a priori presumed low costs. However, is there any evidence that self-help will be effective as an alternative for the treatment of clinically relevant emotional disorders?

Self-help groups and bibliotherapy are the two main self-help strategies. Each has its own history of development, methodology, research strategy and relationship with professionals. Self-help groups are voluntary associations of persons with similar problems which are controlled by their own members and not by professionals (Humphreys & Rappaport 1994). Professionally led support groups should not be confused with self-help groups. Self-help through naturally evolved or specially created 'lay' groups and networks represents the oldest and most widely spread system of care for 'human ills' (Katz 1981). Self-help groups arise in society when certain needs are not met by formal health care organisations (Lieberman 1990). Well-known examples include the Alcoholics Anonymous groups and self-help programs for eating disorders. Research on these groups and programs is mainly the preserve of the field of sociology and generally concerns case histories based on anecdotal evidence. Only a few studies have contained systematic comparison testing hypotheses (Katz 1981). In the 1980s and 1990s, self-help strategies were developed for the general support of patients and relatives in addition to the regular treatment of somatic or psychiatric disorders. Some controlled trials examined the effectiveness of this kind of supportive self-help groups (Barlow *et al.* 1999). Bibliotherapy, as defined by Marrs (Marrs 1995), relies on written texts, computer programs, or audio/video-recorded material for the purpose of understanding or solving problems concerning a person's development or in meeting their therapeutic needs. It became a focus of interest for professionals in the 1970s. Several meta-analyses were published, including randomised as well as non-randomised controlled effectiveness studies. Our current focus is specifically on bibliotherapy and self-help groups for patients with emotional disorders (depression and anxiety). What do reviews and meta-analyses tell us about the effectiveness of self-help in this patient population?

Four reviews by Glasgow & Rosen (Glasgow & Rosen 1978), Trojan (Trojan 1989), Kurtz (Kurtz 1990) and Lieberman (Lieberman 1990) support self-help as a useful component in the treatment of psychiatric patients. Self-help manuals are reported as being effective for several phobic anxieties (Glasgow & Rosen 1978). Members of self-help groups have reported the reduction of disease-related stress and increased competence and social activation (Trojan 1989). Studies of local peer mutual-aid networks have reported reduced symptomatology and use of professional services (Kurtz 1990). However, from a methodological point of view, the quality of the studies, all published before 1990, is rather

unsatisfactory, at least those reviewed by Trojan (Trojan 1989) and Lieberman (Lieberman 1990).

Five meta-analyses of self-help strategies have been published, four concerning bibliotherapy and one on self-help groups. Mean effect sizes (*ES)* for bibliotherapy (Scogin *et al.* 1990a; Gould & Clum 1993; Marrs 1995; Cuijpers 1997) range from 0.53 to 0.96 for various target problems, ranging from 'minor' problems (assertion skills, study skills, parental skills, difficulties with sleep, sex, and memory) to potentially clinical disorders (depression, anxiety, habit disorders). The effects on mood and anxiety disorders fell within this range (Gould & Clum 1993; Marrs 1995). Differences between self-administered and therapist-administered treatments were non-significant (Marrs 1995; Scogin, Bynum, & Stephens 1990a; Cuijpers 1997). Only one meta-analysis (Barlow, Burlingame, Nebeker, & Anderson 1999) examined studies of self-help groups but no conclusions can be drawn concerning emotional disorders. However, most studies of the meta-analyses included subjects who suffered from relatively 'minor' problems recruited by the media or students, while a few were randomised clinical trials. These reviews and meta-analyses do not permit conclusions on the effectiveness of self-help for patient populations with clinically significant emotional disorders. It was therefore decided to perform a meta-analysis that only included randomised controlled trials concerning emotional disorders which were likely to disturb all areas of social functioning.

METHODS

Objective
To examine whether the reported effectiveness of self-help strategies (bibliotherapy and self-help groups) would hold true for clinically significant emotional disorders by testing the hypothesis that self-help strategies are a) as effective as treatment by professionals, and b) more effective than no treatment, and, if sufficient data are available, whether the results are modified by a) the length of treatment or follow-up, or b) the severity of the illness.

Inclusion criteria
Randomised controlled trials that used symptom measures or a psychiatric diagnosis and compared bibliotherapy or self-help group with placebo or waiting list conditions and usual treatment conditions. Studies of mild emotional disorders were excluded, such as simple phobias which do not affect broad areas of social functioning. The diagnosis was based on a structured clinical

interview for assessment of a DSM or ICD diagnosis or on assessment scales using a cut-off score to establish caseness. Insufficient data to allow meta-analytical pooling was cause for exclusion. Trials exclusively concerning children and adolescents were excluded. Self-help was defined as a therapeutic intervention for self-treatment administered through group meetings (self-help groups) or bibliotherapy, mainly independent of professionals. We restricted the self-help strategies to include those that were found to be relevant in the reviews and meta-analyses referred to because the exclusive objective of this study was whether the reported results would also apply to clinically significant emotional disorders.

Methods of the review
Screening of the studies, quality assessment and data extraction were performed by the first author. Any doubt about inclusion was discussed with the co-authors. Study quality was assessed according to the Delphi criteria list for the quality assessment of randomised controlled trials for conducting systematic reviews (Verhagen *et al.* 1998).

Literature search
In total, the meta-analyses referred to concerned a comprehensive search in electronic databases, databases of dissertation and psychological abstracts, reference lists and hand searches of relevant journals, covering the literature from the 1970s to the 1990s, using the keywords 'self-help', 'self-treatment', 'self-help group' and 'bibliotherapy', including 118 studies on bibliotherapy and 26 on self-help groups. We performed an additional search for the 1990-2000 period in Medline, PsychINFO and the Cochrane Library, not restricting for language, using the same keywords as above and adding 'randomisation' and 'anxiety or depressive disorder' according to the objective of the study, selecting for randomised controlled trials and clinically relevant psychiatric disorders. This resulted in another 28 hits for bibliotherapy and 7 for self-help groups. The total sample encompassed 179 studies, including two studies of German language (Rosner *et al.* 1999). The titles and abstracts of the studies were screened for first orientation on inclusion criteria. Of the 179 studies, 34 studies, all concerning emotional disorders, were selected for detailed examination on the inclusion criteria, 18 of which were subsequently excluded, see the Appendix for excluded studies and exclusion reasons. Only 16 studies met all criteria, including one study of German language . Two studies (Scogin *et al.* 1990b; White

1995) reported on the same population of former studies (Scogin *et al.* 1989; White 1998) and were thus pooled. Therefore, our meta-analysis comprised 14 studies: 13 on bibliotherapy (8 new studies not included in previous meta-analyses) and one on self-help groups (new). Nine concerned mood disorders, four anxiety disorders and one both. The self-help conditions and the treatment conditions were mainly based on cognitive behavioural principles. Patients were adult and elderly persons with mood or anxiety disorders recruited by press announcement (n=9) or from referrals to mental health care facilities (n=5). Nearly two-thirds of the studies concerned patients with chronic conditions or patients with a prior treatment history. Diagnosis was based on a structured clinical interview for assessment of a DSM-III, DSM-III-R or ICD-10 diagnosis (n=9) or on assessment scales using a cut-off score for inclusion (n=5). Details can be found in Table 1 for study characteristics and Table 2 for study conditions and post-treatment and follow-up results.

Quality of included studies
Nine items were assessed in accordance with the Delphi list (Verhagen *et al.* 1998). All studies were randomised controlled trials in concordance with the inclusion criteria. Concealment procedure of treatment allocation was only reported in one study (Tyrer *et al.* 1993). Three studies did not adequately report baseline data (Schelver & Gutsch 1983; Selmi *et al.* 1990; Wollersheim & Wilson 1991). All were active treatment conditions, which are almost impossible to blind for patient and caregiver. Three studies reported assessor blinding (Al-Kubaisy *et al.* 1992; McNamee *et al.* 1989; Tyrer *et al.* 1993). Point estimates and measures of variability were presented for the primary outcome measures. Only three studies included intention-to-treat analyses (Rosner *et al.* 1999; Tyrer *et al.* 1993; White 1995). One study (Tyrer *et al.* 1993) scored the highest possible score for active intervention trials (7 out of 9 items of the Delphi list). Three studies data (Schelver & Gutsch 1983; Selmi *et al.* 1990; Wollersheim & Wilson 1991) scored low (2 or 3 items of the Delphi list), insufficiently describing baseline similarity of the samples of the compared conditions, in contrast with the remaining studies which achieved moderate scores (4 or 5 items of the Delphi list).

Statistics
A meta-analysis aims to integrate a large number of results (Glass *et al.* 1981). Effect sizes are defined as the standardised mean difference (*g*) between a treatment group and a control group in

terms of an outcome variable. Here *'d'* is the corresponding unbiased effect size estimator. We used the computer program META, version 5.3, developed by Schwarzer (Schwarzer 1989). The observed variability in sample estimates of effect size is partly due to variability in the underlying population parameters and partly due to sampling error. Therefore, assuming heterogeneity in the study set, a 'random effects model' (Hedges & Olkin 1985; Schwarzer 1989) was applied. A test of homogeneity serves to examine whether the separate effect sizes can be considered as being samples from a common population of effect sizes. Data are homogeneous if 100% of the observed variance is explained by sampling error, which is desired. When only a percentage can be explained by sampling error, this suggests that the observed differences in the results of individual studies might be caused by factors other than change. Control for moderator variables is then necessary.

Publication bias influences the reliability of population effect sizes. We computed a 'fail safe N' (Orwin 1983) to estimate the number of studies with non-significant results that would be required to convert a significant meta-analytic finding into a non-significant one. Nearly all the studies included reported more than one outcome measure. To avoid disproportionate weighting of the studies with more measures, multiple outcome measures were averaged to obtain one effect size per treatment comparison in each study according to Scogin (Scogin, Bynum, & Stephens 1990a) and Marrs (Marrs 1995). Several studies compared a number of contrast groups. For each of these, the mean effect size was calculated. Post-treatment and follow-up comparisons were made, if available. A sensitivity analysis was performed to control for the influence of self or rater-assessment on the mean effect size estimate.

The analysis included 16 post-treatment comparisons of self-help versus control conditions (placebo/waiting list) and 16 self-help versus contrast treatment conditions. Five follow-up comparisons could be made with placebo conditions, 9 for the contrast treatment conditions. Details can be found in Table 2 for study conditions and post-treatment and follow-up results.

Table 1 *Meta-Analysis on the Effectiveness of Self-help in the Treatment of Emotional Disorders: Study Characteristics*

No	Study	Diagnosis	Inclusion	Recruitment	Illness duration	Age	Measures
1	Al-Kubaisy, 1992	Phobia	ICD-10; FTPQ≥20	Referred patients	> 14 years	18-60	FTPQ avoid / fear; FQ Total
2	Bright, 1999	Major Depression; Dysthymia	SCID	Media	All previously treated	21-72	BDI; HRSD
3	Brown, 1984	Unipolar depression	RDC	Media	± 9 years	16-65	BDI; CES-D
4	Landreville, 1997	Unipolar depression	IDD	Media; Ref. patients	± 10 years disability	≥ 55	GDS; BDI
5	McNamee, 1989	Panic disorder with agoraphobia	SCID	Referred patients	M 12 years (2-40)	29-60	Phobic target; Global phobia
6	Rosner, 1999	Unipolar depression	HRSD > 16	Media	-	22-76	BDI
7	Schelver, 1983	Social anxiety	SADS upper 15%	Students	> 1 year	Students	SADS; FNE; State (STAI)
8	Schmidt, 1983	Unipolar depression	RDC	Media	80% prior treatment	M=42	BDI; SDS; MMPI-D; DACL
9	Scogin, 1987	Unipolar depression	HRSD ≥10	Media	-	≥ 60	HRSD; GDS; BDI
10	Scogin, 1989	Unipolar depression	HRSD ≥10	Media	-	≥ 60	HRSD; GDS
11	Selmi, 1990	Unipolar depression	RDC	Media	> 6 months	Adults	BDI; HRSD; SCL-90-R depr.
12	Tyrer, 1993	Dysthymia; Panic disorder; GAD	SCID	Referred patient	Previously treated	17-76	HADS depression / anxiety

No	Study	Diagnosis	Inclusion	Recruitment	Illness duration	Age	Measures
13	White, 1995	Anxiety disorders	ADIS-R	Referred patient	> 2 years	M=38	HAD-anxiety
14	Wollersheim, 1991	Unipolar depression	DSM-III; MMPI-D T ≥70	Media	50% prev. treated	22-68	BDI; MMPI-D; SDS

No = Research number; *Diagnosis:* GAD = Generalised Anxiety Disorder; *Inclusion:* FTPQ = Four Target Phobia Questionnaire; SCID = Structured Clinical Interview for DSM-III-R; RDC = Research Diagnostic Criteria; IDD = Inventory to Diagnose Depression for DSM-III-R; HRSD = Hamilton Rating Scale for Depression; SADS = Social Avoidance and Distress Scale; ADIS-R = Anxiety Disorder Interview Schedule – Revised; *Age:* in years, unless otherwise indicated

Measures: FTPQ avoid / FTPQ fear = Self-report / observer-rated Four Target Phobias (FTPQ) avoid / fear; FQ = Self-report Fear Questionnaire (FQ); BDI = Self-report Beck Depression Inventory; HRSD= Observer-rated Hamilton Rating Scale for Depression; CES-D = Self-report Centre for Epidemiological Studies Depression Scale; GDS = Self-report Geriatric Depression Scale; Phobic tar / Global ph = Observer-rated phobic target and global phobia; SADS = self-report Social Avoidance and Distress Scale; FNE = Self-report Fear of negative Evaluation Scale; State (STAI) = Self-report State or Trate Anxiety Inventory; SDS = Self-rating Depression Scale; MMPI-D = Self-report Minnesota Multiphasic Personality Inventory Depression scale; DACL = Self-report Depression Adjective Checklist; SCL-90-R d. = Self-report Hopkins symptom Checklist depression scale; HADS anx / depr = Self-report Hospital Anxiety and Depression Scale

Table 2   *Meta-analysis on the Effectiveness of Self-help in the Treatment of Emotional Disorders: Study Conditions, Post-treatment (T1)and Follow- up Period (T2), and Results*

No	Conditions (n)	Comp.	T1	dT1	T2	dT2
1	1) Bibliotherapy (n=26). Behavioural therapy principles, manual: 'Living with Fear', by Marks (1980). Additional 6x 60-minute instruction sessions.	1 vs 2	8	0.92	14	1.00
		1 vs 3	8	-0.28	14	-0.18
	2) Control condition (n=25). Relaxation audiotape. Additional 6x 60-minute instruction sessions.					
	3) Treatment condition (n=25). 6x 60-minute instruction sessions and 9x 90-minute sessions, clinician accompanied exposure plus self-exposure.					
2	1) Self-help group (n=13). Mutual support group, informal exchanges, focussed on interpersonal insight and disclosure.	1 vs 3	10	0.01		
		1 vs 4	10	-0.15		
	2) Self-help group (n=14). Cognitive behavioural principles; 90-minute sessions, weekly, manual: 'Feeling Good', by Burns (1989). No additional contact, except for one peer, who have had training managing the manual.	2 vs 3	10	0.44		
		2 vs 4	10	0.24		
	3) Treatment condition (n=22). Mutual support group, informal exchanges, focussed on interpersonal insight and disclosure, lead by professionals					
	4) Treatment condition (n=18). Group cognitive behavioural therapy; 90-minute sessions, weekly, manual: 'Feeling Good self-help book', by Burns (1989), lead by professionals.					
3	1) Bibliotherapy (n=14). Cognitive behavioural therapy principles, manual: 'Control Your Depression', by Lewinsohn (1978). Additional one session initially, subsequent phone-contact 10-35 minutes, 12 sessions.	1 vs 2	8	0.43		
		1 vs 3	8	-0.00	12	-0.21
		1 vs 4	8	0.11	12	0.36
	2) Control condition (n=11). Delayed treatment control, waiting list.					
	3) Treatment condition (n=25). Cognitive behavioural therapy, manual: 'Control Your Depression', by Lewinsohn (1978); class tutoring, 12 sessions.					

No	Conditions (n)	Comp.	T1	dT1	T2	dT2
	4) Treatment condition (n=13). Cognitive behavioural therapy, manual: 'Control Your Depression', by Lewinsohn (1978); individual tutoring.					
4	1) Bibliotherapy (n=10). Cognitive behavioural principles, manual: 'Feeling Good', by Burns (1989). Additional maximal 15-minute phone-contact once a week. 2) Control condition (n=13). Delayed treatment control, waiting list. Additional maximal 15-minute phone-contact once a week.	1 vs 2	4	0.30		
5	1) Bibliotherapy (n=9). Cognitive behavioural therapy principles, manual: 'Living with Fear', by Marks (1980). Additional 12-minute phone-contact, weekly 8 weeks and 2-weekly for 4 weeks. 2) Control condition (n=9). Relaxation audiotape. Additional 12-minute phone-contact, weekly 8 weeks and 2-weekly for 4 weeks.	1 vs 2	12	1.05	32	1.10
6	1) Bibliotherapy (n=10). Cognitive behavioural therapy principles, manual. Additional 20-minute phone-contact, weekly, non-directive, by non-professionals. 2) Treatment condition (n=18). Cognitive behaviour therapy, manual, weekly. 3) Treatment condition (n=12). Focussed expressive therapy, manual, weekly.	1 vs 2 1 vs 3	20 20	-0.06 0.09		
7	1) Bibliotherapy (n=11). Cognitive therapy principles (Ratio-Emotive Therapy), manual: 'A new Guide of Rational Living', by Ellis & Harper (1961). Additional initial phone-contact, interview and orientation meeting. 2) Control condition (n=12). No-treatment control. Additional initial phone-contact, interview and orientation meeting. 3) Control condition (n=12). Self-administered attention placebo condition: 'Man's search for meaning', by Frankl (1959). Additional initial phone-contact, interview and orientation meeting.	1 vs 2 1 vs 3	5 5	0.94 0.35		
8	1) Bibliotherapy (n=12). Cognitive behavioural therapy principles, manual. Additional initial contact, the first treatment week and a phone-contact in week 4 to offer encouragement and answer client	1 vs 2	8	1.41	18	0.26

No	Conditions (n)	Comp.	T1	dT1	T2	dT2
	questions.					
	tion (n=10). Delayed treatment control, waiting list. No treatment contact.					
	3) Treatment condition (n=11). Cognitive behavioural therapy, individual, manual.	1 vs 3	8	-0.21	18	-0.25
	4) Treatment condition (n=11). Cognitive behavioural therapy, 2 small groups, 90-minute sessions, weekly, manual.	1 vs 4	8	-0.02	18	-0.10
	5) Treatment condition (n=12). Cognitive behavioural therapy, large group, 90-minute sessions, weekly, manual.	1 vs 5	8	0.88	18	0.48
9	1) Bibliotherapy (n=9). Cognitive behavioural therapy principles, manual: 'Feeling Good', by Burns (1989). Additional 10-minute phone-contact, weekly, supportive.	1 vs 2	4	1.34	8	-0.28
		1 vs 3	4	0.83		
	2) Control condition (n=8). Delayed treatment control, waiting list.					
	3) Control condition (n=8). Self-administered attention placebo condition: 'Man's search for meaning', by Frankl (1959). Additional 10-minute phone-contact, weekly, supportive.					
10	1) Bibliotherapy (n=19). Behavioural therapy principles, manual: 'Control Your Depression', by Lewinsohn (1986). Additional phone-contact, weekly.	1 vs 3	4	0.34		
		2 vs 3	4	1.05		
	2) Bibliotherapy (n=21). Cognitive behavioural therapy principles, manual: 'Feeling Good', by Burns (1980). Additional phone-contact, weekly.					
	3) Control condition (n=21). Delayed treatment control, waiting list.					
11	1) Bibliotherapy (n=12). Cognitive behavioural therapy principles, interactive computer program, 6 sessions. Additional initial and at the end of a session; on request while the patient was interacting with the computer.	1 vs 2	10	1.26	18	1.67
		1 vs 3	10	0.14	18	0.12
	2) Control condition (n=12). Delayed treatment control. No treatment.					
	3) Treatment condition (n=12). Cognitive behavioural therapy, 6 sessions, manual.					
12	1) Bibliotherapy (n=40). Psycho-education, self-help treatment package and relaxation tape. Additional 15-minute sessions in week 0, 1, 2, 4, 6.	1 vs 2	10	1.10		

No	Conditions (n)	Comp.	T1	dT1	T2	dT2
	2) Control condition (=26). Placebo pills.	1 vs 3	10	-0.42		
	3) Treatment condition (N=80). Cognitive behavioural therapy, one-hour sessions in week 0, 1, 2, 4, 6.					
13	1) Bibliotherapy (n=21). Cognitive behavioural therapy principles and psycho-education, self-help	1 vs 2	12	0.99		
	anxiety management package (Stresspac) and relaxation tape. Additional 1 30-minute session.	1 vs 3	12	0.70		
	2) Control condition (n=21). Waiting-list control.					
	3) Control condition (n=20). Placebo, 30-minute session, advice on ways of coping with anxiety.					
14	1) Bibliotherapy (n=8). Cognitive behavioural therapy principles, manual: 'Bye Bye Blues:	1 vs 2	11	0.36		
	overcoming depression', by Wollersheim (1980). Additional initial contact in the first treatment	1 vs 3	11	0.36	37	0.05
	week, once midway the treatment, and a final contact.	1 vs 4	11	0.31	37	-0.25
	2) Control condition (n=8). Delayed treatment control.					
	3) Treatment condition (n=8). Cognitive behavioural therapy, weekly 2-hour sessions.					
	4) Treatment condition (n=8). Supportive therapy, weekly 2-hour sessions.					

No = Research number; T1, T2 in weeks; dT1 = d Post-treatment, dT2 = d Follow-up, whereas d = unbiased standardised mean difference,
a positive sign means that the effect size 'd' of the self-help condition is greater than the effect size of the control condition;
a negative sign means that the difference is in the opposite direction;
Manuals:
Burns, D.D. (1980, 1989). Feeling good. New York: Signet / New American Library
Ellis, A. & Harper, R.A. (1961, 1971). A guide to rational living. Englewood Cliffs, J.N: Prentice-Hall
Frankl, V. (1959, 1963). Man's search for meaning. New York: Pocket Books
Lewinsohn, P.M., Munoz, R.F., Youngren, M.A., Zeiss, A.M. (1978). Control your depression. Englewood Cliffs, N.J.: Prentice-Hall
Marks, I.M. (1980). Living with fear. New York: McGraw-Hill
Wollersheim, J.P. (1980). Bye bye blues: overcoming depression. Missoula, MT: Unpublished manuscript, University of Montana

RESULTS

The results are summarised in Table 3. The mean effect size of the self-help versus control conditions comparisons is 0.84 (95% confidence interval=0.65 - 1.02; n=490). A test for homogeneity shows that 100% of the variance can be explained by sampling error, which indicates that differences between samples are absent. A total of 50.8 studies would be necessary in order to reduce the effect size to 0.20 indicating absence of effect (Orwin's fail safe *N*). The mean effect size of the self-help versus contrast treatment conditions comparisons is -0.03 (95% confidence interval=-0.20 - 0.14; n=543). A test for homogeneity shows that 100% of the variance is attributable to sampling error.

The follow-up mean effect size for the self-help versus control conditions comparisons is 0.76 (95% confidence interval=0.09 - 1.42; n=130). The wide confidence interval might include a clinically unimportant advantage to self-help. The test for homogeneity indicates that 35.9% of the variance can be explained by sampling error and 64.1% by population variance. Cluster analysis distinguished two clusters at a 5% level of significance. Therefore, two studies were re-analysed. Study 8 (Schmidt & Miller 1983) revealed an opposite pattern of effects on the DACL (Self-report Social Avoidance and Distress Scale) on the one hand and the three measures of depression on the other. Since depression is a main focus of this study, the DACL could have been excluded giving an increased average mean difference between trial arms. Study 9 (Scogin *et al.* 1987) had several weaknesses: 1) A very small sample size (n=24) was randomised to three conditions; 2) Baseline differences between group characteristics were found, for instance on the GDS (Self-report Geriatric Depression Scale); 3) The contrast 'placebo' manual could have been of therapeutic value; 4) An unusually short treatment and follow-up period (one month) was used. We conclude that the inclusion of the DACL in study 8 and the study characteristics of study 9 may account for the heterogeneity between the studies. Correction for the mean average of study 8 and exclusion of study 9 would increase the mean effect sizes of the meta-analysis of the self-help versus control conditions comparisons, and of the follow-up mean effect sizes as well.

The follow-up comparisons of self-help with contrast treatment conditions revealed a mean effect size of -0.07 (95% confidence interval=-0.33 - 0.19; n=236; where 100% of the variance could be explained by sampling error), implying that there is no difference

between the effect of self-help and contrast treatment during follow-up.

Table 3 *Meta-Analysis on the Effectiveness of Self-help in the Treatment of Emotional*

Disorders: Summary of the results

Comparison conditions	Number of compa- risons	n	Effect size difference	95% confidence interval	Orwin's fail safe N	Test for homo- geneity
Total study sample (14 studies): Clinically significant emotional disorders						
Self-help versus control condition post-treatment	16	490	0.84	0.65 – 1.02	50.8	100%
Self-help versus contrast treatment post-treatment	16	543	-0.03	-0.20 – 0.14		100%
Self-help versus control condition follow-up	5	130	0.76	0.09 – 1.42		35.9%
Self-help versus contrast treatment follow-up	9	236	-0.07	-0.33 – 0.19		100%
Subsample (8 studies): Severity of disease defined as 1) prior treatment, or 2) illness duration > 2 years						
Self-help versus control condition post-treatment	8	288	0.88	0.65 – 1.12	27	100%
Self-help versus contrast treatment post-treatment	9	373	-0.15	-0.36 – 0.06		100%
Self-help versus control condition follow-up	3					
Self-help versus contrast treatment follow-up	6	181	-0.03	-0.32 – 0.27		100%

Does treatment or the follow-up period modify the results? The treatment period varied between 4 and 12 weeks for 16 self-help versus control conditions comparisons with a median of 8 weeks. The average mean difference for comparisons of a short treatment episode (4 weeks: n=5; 5 weeks: n=2) is 0.74; for 8 weeks (n=3) it is 0.92 and for more than 8 weeks (10 weeks: n=2; 11 weeks: n=1; 12 weeks: n=3) it is 0.91. A treatment period of 8 weeks or more seems to be somewhat more effective than a shorter treatment period.

Does severity of illness influence the results? A subset of 8 studies (Al-Kubaisy *et al.* 1992; Bright *et al.* 1999; Brown & Lewinsohn 1984; Landreville & Bissonette 1997; McNamee *et al.* 1989; Schidt & Miller 1983; Tyrer *et al.* 1993; White 1995) reported on referred patients, people who had had prior treatment or whose illness had lasted more than 2 years. Eight post-treatment and only 3 follow-up comparisons were available for self-help versus placebo control conditions, and there were also 9 post-treatment and 6 follow-up comparisons for self-help versus contrast treatment conditions. The mean effect size of the self-help versus placebo control conditions comparisons is 0.88 (95% confidence interval=0.63 - 1.12, n=288). A test for homogeneity indicated that 100% of the variance could be attributable to sampling error. Orwin's fail safe *N* reveals that 27 new studies are needed to reduce the effect to 0.20. Three follow-up comparisons are too few for re-analysis. However, the mean effect sizes are 1.15, 0.28, and 0.43, indicating a positive trend. The post-treatment mean effect size of the self-help versus contrast treatment conditions comparisons is -0.15 (95% reliability interval=-0.36 - 0.06, n=373). A test for homogeneity indicated that 100% of the variance could be attributed to sampling error. The mean effect size of the self-help versus contrast treatment conditions follow-up comparisons is -0.03 (95% reliability interval=-0.32 - 0.27, n=181). A test for homogeneity indicated that 100% of the variance could be attributed to sampling error.

Are the results affected by whether outcomes are self-rated or not? Mood and anxiety affect cognitive functioning and therefore might bias self-assessment. Study 4 (Landreville & Bissonette 1997) found a moderate to high correlation between participants' and significant other persons' ratings. We examined differences in the estimated mean effect sizes for self versus rater-assessed measures by analysing all studies (n=6) using self and rater-assessed measures. Five studies (Al-Kubaisy *et al.* 1992; Schelver & Gutsch 1983; Scogin *et al.* 1987; Scogin *et al.* 1989; Selmi *et al.* 1990) reported a post-treatment self-help versus control conditions comparison and two (Al-Kubaisy *et al.* 1992; Bright *et al.* 1999) a post-treatment self-help versus contrast treatment conditions comparison. We recalculated outcomes for post-treatment self-help versus waiting list (or placebo) conditions. The mean effect size of 6 comparisons (n=197) is 0.69 for self-assessment and 1.40 for rater assessment, a significant difference (T=2.84; *p*<0.005). Exclusion of self-rated assessments would therefore improve the overall results of self-help.

DISCUSSION

This meta-analysis shows a robust effect for bibliotherapy as a self-help treatment for emotional disorders such as depression and anxiety which might be chronic and remitting. Bibliotherapy is significantly more effective than placebos or waiting lists (ES=0.84) and may be as effective as professional treatment of relatively short duration (ES=-0.03). The effect size is remarkably similar to those reported in previous meta-analyses on self-help (ranging from 0.59 to 0.96), all except one concerning miscellaneous targets, mainly minor problems for samples recruited by media advertisements. Our effect size equals the results of cognitive therapy in depressed patients (ES=0.82, Gloaguen *et al.* 1998) and is larger than the effect size of antidepressants (ES=0.50, Joffe *et al.* 1996).

The methodological limitations of our study are the restrictions of the search and the quality of the trials included. We presumed the searches of former meta-analyses to be comprehensive, covering the literature from the 1970s to the 1990s, and performed an additional search for the 1990-2000 period in several electronic databases. However, systematic reviews based on a search of the English language literature accessible in the major bibliographic databases will often produce results that are close to those obtained from reviews based on more comprehensive searches free of language restrictions. The search was not restricted to the English literature, which is important in psychiatry. Controlling for the influence of unpublished trials (Orwen's fail safe *N*), 50.8 studies with non-significant results would need to be found in order to reduce the effect size to absence of effect. It is unlikely that a more comprehensive search would profoundly alter the results. Moreover, hard to locate and unpublished trials may be of lower quality and bias the meta-analysis (Egger *et al.* 2003). In contrast to previous meta-analyses on bibliotherapy, a strong aspect of the study was the restriction to randomised trials. However, trials in which concealment is either inadequate or unclear (lack of information), as was the case in most of the studies included, yield larger estimates of treatment effects compared with trials in which authors report adequately concealed treatment allocation (Schultz *et al.* 1995). Most studies did not blind the assessor or include intention-to-treat analysis, which can bias the results as well. Sensitivity analyses of these aspects were not performed because of the small number of studies. Further limitations included the small sample sizes, the relatively short duration of treatment of 4-20 weeks (the acute phase of treatment only according to APA guidelines) and the restriction to mainly bibliotherapy, usually

based on the principles of cognitive behavioural treatment. Strong aspects of the study include the inclusion criteria and the results of sub-analyses. Inclusion was restricted to populations of adults with established emotional disorders. Disorders such as arachnophobia and acrophobia, which are unlikely to be of clinical significance, were excluded. Referral for psychiatric treatment as a method for recruitment and chronic duration of illness do not seem to have affected the results, as shown by a sub-analysis of eight studies with patient populations with a duration of illness of more than two years and/or previous treatment. This subset produced a similar result (*ES*=0.88). The significantly higher effect size for observer-rated assessments as compared to self-reports adds to the strength of our meta-analytical findings. The five meta-analyses on self-help mentioned earlier concerned patient populations mainly based on media recruitment and all conclude that self-help modalities for these 'pre-clinical' patients are effective. In our sub-analysis of referred patients we found a similar effect size for a specified clinical population. This suggests that any potential bias of recruitment method is of minor importance. Because there is a lack of information about loss of social functioning due to psychiatric disorder, we confined our conclusion to a clinical population of emotional disorders of potentially severe outcome. More trials need to be performed on this subject. Hopefully new trials will perform adequately and report concealment of randomisation. The development of the standardising meta-analysis methodology and quality assessment of trials and the rapidly extending hand-searched database of randomised controlled trials in the Cochrane Library would make it worthwhile starting a meta-analysis on bibliotherapy according to the methodology of the Cochrane Library with periodically performed updates. We found only one study on self-help groups. The effectiveness of self-help groups for emotional disorders still remains under-researched in controlled studies. What is the reason for this? The history of the twentieth century reveals two different developments. Patients who were dissatisfied with mental health care initiated self-help groups. These were studied by sociologists with their own methodology but not explored by controlled studies (Katz 1981). Self-help groups did not enter the field of evidence-based medicine. Bibliotherapy, developed as therapeutic manuals by psychologists and psychiatrists, became a subject of randomised controlled studies as an alternative for professional treatment. It is generally felt to be unethical to refer patients to self-help when treatment by professionals is called for. Nevertheless, self-help groups do have an important role to play in

mental health care. Data from the National Comorbidity Survey reveal that the self-help sector was used in conjunction with other sectors of outpatient mental health care facilities in 63% of cases (Kessler *et al.* 1994). Kessler et al. suggest that the systematic incorporation of self-help groups as part of a comprehensive treatment program could reduce the number of visits to mental health professionals.

Cost-effectiveness was not the object of the studies included in this or earlier meta-analyses. They do, however, suggest that bibliotherapy and self-help groups will be of interest in this respect. Further research in this area is necessary. This also applies to the long-term effects of bibliotherapy. Like other types of treatment, bibliotherapy or self-help groups may not suit or benefit all patients. Therefore, research is needed on patient characteristics predicting outcome.

Two more issues deserve to be mentioned. First, psycho-education is part of many treatment strategies. This may be considered as a kind of bibliotherapy, for example Lewinsohn's 'Coping with Depression' course, containing 12 sessions and 2 booster sessions (Lewinsohn *et al.* 1986). According to Cuijpers (Cuijpers 1998), Lewinsohn's course is an effective treatment for unipolar depression and useful in an active outreach approach for people recruited by media who might not otherwise seek treatment. Second, how effective are trained volunteers or lay workers in using specific treatment models as paraprofessionals? Christensen and Jacobson (Christensen & Jacobson 1994) concluded that paraprofessionals usually produce effects that are greater than those of control conditions and comparable to those of professional therapists. A controlled study (Bright, Baker, & Neimeyer 1999) suggests that paraprofessionals are as effective as professionals in reducing the symptoms of depressed patients by cognitive-behavioural group therapy. It seems a worthwhile avenue to study the effects of courses led by paraprofessionals. Training lay people in giving courses on how to use therapeutic manuals is an interesting field for future exploration.

Is it time for doctors to reconsider their professional role in the treatment of emotional disorders? Do psychiatrists underestimate the value of the acquisition of knowledge by patients? Do psychiatrists and psychotherapists overestimate the importance of the therapeutic relationship and of their own level of experience? The results of our meta-analysis suggest that these are issues that need more attention from researchers.

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*Meta-analysis on the Effectiveness of Self-help in
the Treatment of Emotionaldisorders: Excluded
Studies and Reasons of Exclusion*

	Study	Reason of exclusion by absence of:
1	Becu et al. 1993	Randomised controlled design
2	Jerrell et al. 1994	Anxiety or depression symptom measures
3	Kassinove et al. 1980	Anxiety or depression symptom measures
4	Katon et al. 1995	Self-help comparison condition
5	Keller et al. 1975	Assessment of a diagnosis or cut-off score to establish caseness
6	Kelly et al. 1993	Self-help comparison condition
7	Kuhns 1997	Assessment of a diagnosis or cut-off score to establish caseness
8	Lang et al. 1970	Assessment of a diagnosis or cut-off score to establish caseness
9	McClaskey 1970	Anxiety or depression symptom measures
10	Monti et al. 1979	Anxiety or depression symptom measures
11	Robinson et al. 1997	Self-help comparison condition
12	Salaberria & Echeburua 1998	Self-help comparison condition
13	Schmidt 1980	Assessment of a diagnosis or cut-off score to establish caseness
14	Schmidt & Miller 1983	Self-help comparison condition
15	Schulze et al. 1997	Self-help comparison condition
16	Scogin et al. 1985	Assessment of a diagnosis or cut-off score to establish caseness
17	Telch et al. 1995	Self-help comparison condition
18	Tyrer 1996	Anxiety or depression symptom measures

- **Appendix** - **References**

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Paraprofessionals for anxiety and depressive disorders

A meta-analysis

Peter C.A.M. den Boer, Durk Wiersma, Sacha Russo & Robert J. van den Bosch

Background: The established mental health care system does not have the resources to meet the extensive need for care of those with anxiety and depressive disorders. Paraprofessionals partially replacing professionals may be cost-effective.
Objectives: To investigate the effectiveness of any kind of psychological treatment for anxiety and depressive disorders performed by paraprofessionals. To examine whether the results apply to clinically significant disorders.
Search strategy: CCDANCTR-Studies, EMBASE (ExerptaMedica), MEDLINE, PsycINFO, all years published using the key words: para-/paraprofessional, non-/nonprofessional, rand*, psy*; peer; volunt*; citation lists of articles reviewing the subject and included studies; correspondence with authors of controlled studies and review reports on the subject.
Selection criteria: Randomised controlled trials that used symptom measures, and compared the effects of treatments given by paraprofessionals (paid or voluntary, unqualified with respect to the psychological treatment) with treatments given by professionals, and with waiting list or placebo condition.
Data collection & analysis: The standard mean difference was used to pool continuous data, and odds ratios were used to pool dichotomous data, using a random effects model. The generic inverse variance method was used for combining continuous and dichotomous data. The effect of low quality studies and the use of self-rated versus observer-rated measures were tested. Subgroup analyses were performed for differences between depression and anxiety diagnosis, paraprofessionals with/without professional background, group/individual intervention, length of follow-up and gender (post-hoc subgroup analysis).
Main results: Five studies reported five comparisons of paraprofessionals versus professionals (n=106) and five comparisons of

paraprofessionals versus control condition (n=220). No differences were found between paraprofessionals and professionals (SMD=0.09, 95% CI -0.23 to 0.40, p=0.58), and no significant heterogeneity. Studies comparing paraprofessionals versus control (mixed continuous and dichotomous data) showed a significant effect in favour of paraprofessionals (OR=0.34, 95% CI 0.13 to 0.88, p=0.03), but heterogeneity was indicated (I^2=60.9%, Chi^2= 10.24, df=4, p=0.04). After correction for heterogeneity and removing one study of low quality, the pooling of data from three studies (n=128; mixed gender; women) indicated no significant difference in effect between paraprofessionals and professionals (SMD=0.13, 95% CI -0.39 to 0.64; p=0.63) and a strongly significant pooled effect for three studies (n=188; women) favouring paraprofessionals over the control condition (OR=0.30, 95% CI 0.18 to 0.48, p<0.00001), and homogeneity indicated between studies (I^2=0%, Chi^2=0.47, df=2, p=0.79).

Reviewers' conclusions: The few studies included in the review did not allow conclusions about the effect of paraprofessionals compared to professionals, but three studies (women only) indicated a significant effect for paraprofessionals (all volunteers) compared to no treatment. The evidence to date may justify the development and evaluation of programs incorporating paraprofessionals in treatment programs for anxiety and depressive disorders.

Anxiety and mood disorders have been recognised as a main issue in mental health care. In this review they are considered together given the large degree of co-morbidity between them and the overlap in therapeutic approaches. Observational studies indicate that 53.7% of psychiatrists' routine caseload concern mood disorders and 9.3% anxiety disorders (Pincus *et al.* 1999). Of this joint caseload, 49,8% have a history of hospitalisation. The World Bank Burden of Disease project reports that mental disorder accounts for 9.1% of the global burden of disease in the world overall, and a staggering 22.4% in established market economies. Anxiety and mood disorders account for almost one-half (10.9%) of this (Andrews 1998). The indirect costs of depression to society are being estimated at seven times the direct costs for depression management and at one-half of the total costs of all mental illness (Stoudemire *et al.* 1986). The Camberwell Needs for Care survey suggests that only 28% of the need for treatment of depression, and only 13% relating to anxiety, are met (Bebbington *et al.* 1997). Among the non-institutionalised civilian population of the United States, most people with psychiatric disorders fail to obtain professional treatment (Kessler *et al.* 1994). The established mental health care system does not have the resources to meet the extensive need for care of those with anxiety and depressive disorders. Such gaps between what is on offer and what is needed may be cost-effectively filled by paraprofessionals who could offer treatment and care traditionally delivered by mental health professionals (Harchik *et al.* 1989).

Literature indicates that mental health care may profit from several alternative approaches in the management of anxiety and mood

disorders. (I) Self-help through naturally evolved or specially created 'lay' groups and networks represents the oldest and most widely spread system of care for human ills (Katz 1981). Self-help groups arise in society when certain needs are not being met by formal health care organisations (Lieberman 1990). Well-known examples are the Alcoholic Anonymous groups and self-help programs for eating disorders. Research on these groups and programs belongs mainly to the field of sociology, and generally concerns case histories based on anecdotal evidence. Only one meta-analysis (Barlow *et al.* 1999) has examined studies of self-help groups, but no conclusions can be drawn regarding anxiety disorders. (II) Bibliotherapy, as defined by Marrs (Marrs 1995), relies on written texts, computer programs, or audio/video-recorded material for the purpose of understanding or solving problems regarding persons' development or meeting their therapeutic needs. Meta-analyses (Scogin *et al.* 1990; Gould & Clum 1993; Marrs 1995; Cuijpers 1997) have found mean effect sizes for bibliotherapy from 0.53 to 0.96 for various target problems, ranging from 'minor' problems (assertion skills, study skills, parental skills, difficulties with sleep, sex, and memory) to disorders that may approach clinical severity (depression, anxiety, habit disorders). The effects on anxiety and mood disturbances fell within this range (Gould & Clum 1993; Marrs 1995). Differences between self-administered and therapist-administered treatments were non-significant (Scogin *et al.* 1990; Marrs 1995; Cuijpers 1997). A meta-analysis concerning anxiety and depressive disorders only (Den Boer *et al.* 2004) shows a significant effect as well for bibliotherapy as a self-help treatment for relapsing and chronic anxiety and depressive disorders. (III) Psycho-education, as part of many treatment strategies, might be considered a kind of bibliotherapy, for example Lewinsohn's 'Coping with Depression' course, containing 12 sessions and 2 booster sessions (Lewinsohn *et al.* 1986). According to Cuijpers (Cuijpers 1998), Lewinsohn's course is an effective treatment for unipolar depression, and useful as part of an active outreach approach for people recruited by the media who might not otherwise seek treatment. (IV) Christensen and Jacobson (Christensen & Jacobson 1994) concluded that 'paraprofessionals' usually achieve effects that are larger than those obtained under control conditions and comparable to obtained by professional therapists. A controlled study (Bright *et al.* 1999) suggests that paraprofessionals are as effective as professionals in reducing symptoms of depressed patients by cognitive-behavioural group therapy. The term 'paraprofessional' generally describes a whole category of mental health personnel

who are not qualified as psychiatrists, psychologists, social workers or nurses and who are below the master's-degree level of education (Moffic *et al.* 1984). Alternatively, paraprofessionals may be experienced patients, residents from local catchment areas (Grant *et al.* 1996) or college students (Sherman *et al.* 1998). They may constitute up to 50 percent of the unofficial mental health care manpower (Moffic *et al.* 1984). All have had some degree of training, are connected to professional staff and supervised by professionals in the work they are doing to ensure quality of care and communication skills, and to prevent emotional burn out. On a number of points, the quality of the relationship with clients may differ between paraprofessionals and professionals. Often paraprofessionals ground their therapeutic relationship not so much in established theory or empirical research but in day-to-day experience and common sense (Rohde & Nehls 1996). Paraprofessionals may be paid workers but also volunteers.

Both self-help modalities, self-help groups (I) and bibliotherapy (II), are presumed to be mainly self-supporting without much professional interference. Lewinsohn's psycho-education courses (III) are led by professionals. All alternatives mentioned for professional treatment is meant to reach persons that otherwise might not obtain adequate treatment. By means of bibliotherapy, clients train themselves. By means of a course professionals train clients. Paraprofessionals (IV) are mainly trained or supervised by professionals in order to treat or train clients. If paraprofessionals (like lay people or clients themselves) can perform effective psychological treatment (with or without some initial training but not to a qualification degree) under (or without) supervision by a professional, then this will bring psychological treatment within the range of psycho-education, or even simply education. Bibliotherapy for anxiety and depressive disorders and psycho-education courses for unipolar depression are good examples supporting further development of these modalities in the treatment of anxiety and depressive disorders.

Several RCTs have been published comparing professional and non-professional interventions for anxiety disorder (Barnett & Parker 1985; Falloon *et al.* 1981) and depression (Bright *et al.* 1999; Bedi *et al.* 2000; Kelly *et al.* 1993), but no systematic review exists on these disorders. This review aims to critically examine the common sense notion that professional training/qualification is necessary to deliver effective psychological treatment for anxiety and depressive disorders. With respect to this subject we will define

professionals as being psychiatrists or psychotherapists. Nurses and counsellors are professionals as well, but when performing therapy requiring the skills that are an essential (as opposed to optional) part of the training for a psychiatrist or psychologist, they will be defined as paraprofessionals. We wished to review all RCTs comparing any kind of psychological treatment of anxiety and depression performed by paraprofessionals with professionals or no treatment; and we wanted to know whether the results also would apply to potentially disabling anxiety and depressive disorders. The definition of paraprofessional would be examined on paraprofessionals with versus without a professional background in mental health care.

METHODS

Objectives
1. To systematically review all published and unpublished randomised controlled studies that have compared the effectiveness on symptom outcomes of any kind of psychological treatment of anxiety and depressive disorders for adults, performed by paraprofessionals, with psychological treatment by professionals, or with waiting list or placebo condition.

2. If sufficient data were available, to examine whether this also would apply to those RCTs that focus on clinically significant anxiety and depressive disorders (potentially affecting all aspects of social functioning) of referred patients with a psychiatric history and/or whose illness has lasted two years or more.

Criteria for considering studies for the review

Types of studies
Inclusion criteria
Randomised controlled trials that used symptom measures, and compared the effects of any kind of psychological treatment given by paraprofessionals with psychological treatments given by professionals, or with waiting list or placebo condition.

Exclusion criteria
Quasi-randomised clinical trials.

Types of participants

Adult participants of 18 years and older with a diagnosis within the range of anxiety and depressive disorders, irrespective of gender, race or nationality.

The diagnosis is based on a structured clinical interview for assessment of a DSM or ICD diagnosis, or on assessment scales using cut off scores to establish caseness.

Types of interventions

Any kind of psychological treatment for anxiety and depressive disorders. 'Paraprofessionals' were defined as mental health care workers, paid or voluntary, unqualified with respect to the psychological treatment for anxiety and depressive disorders, and replacing professionals in the treatment of patients with anxiety or depressive disorders. Nurses and counsellors are professionals as well, but when performing therapy requiring the skills that were an essential (as opposed to optional) part of the training for a psychiatrist or psychologist, they were defined as paraprofessionals. For example, behaviourally trained nurses who should have been fully qualified to give behavioural treatment, did not fall within the range of the definition. Nurses or lay people who did not have such qualifications, but had some training in basic principles of behavioural treatment, fell within the range of the definition, whether or not performing their treatments under supervision. The following comparisons were undertaken:
1. Paraprofessionals versus professionals
2. Paraprofessionals versus control (waiting list/placebo).

Types of outcome measures

Depression and/or anxiety symptom scale scores. Validated observer and self-rated measurement scales were accepted.

Search strategy for identification of studies

1. Searching of electronic databases including EMBASE (ExerptaMedica), MEDLINE and PsycINFO, known for their sampling of medical and psychiatric research, all years published. Key words are: para-/paraprofessional, non-/nonprofessional, rand* (randomised trials), respectively psy* limiting the search to psychiatric and psychological treatment.
2. Citation lists of articles reviewing the subject and included studies.
3. Searching the Cochrane Collaboration Depression, Anxiety and Neurosis Controlled Trials Register (CCDANCTR) and The Cochrane Controlled Clinical Trials Register (CCTR) for the

incorporation of hand-searching of specialist journals (additional keywords peer and volunt*).

4. The first author of controlled studies and review reports on the subject were approached requesting for additional unreported data.

Methods of the review

Selection of trials

One author screened all publications, which were obtained by the search strategy on their relevance to this review, based on the criteria for inclusion.

A pilot test on the inclusion criteria was conducted on a sample of six articles, including two that were thought to be certainly eligible, two certainly not eligible and two whose eligibility was questionable, in order to control for and further refine the definition of 'paraprofessional.'

Studies that apparently met the selection criteria, or were likely to be relevant but had to be excluded, were listed, and the relevant reason for exclusion was given.

Assessment of study quality

Two authors independently assessed the study quality by means of Quality Rating Scale (QRS) developed by the Cochrane Collaboration Depression, Anxiety and Neurosis Review Groups. The QRS has been developed in order to standardise the quality assessment of trials, assessing 23 items of quality according to three degrees of adequacy ('0'; '1'; '2'). 'Blinding of subjects' (item 8) cannot be performed for psychological treatments, and 'details on side-effects' (item 15) concerns drug trials, therefore both items were not scored. The maximum score that could be retrieved was 42 for 21 items. Until now, no validation of norms of QRS-assessment exists. Mathematically two groups of quality level were constructed, according to a presumed low level ranging from 0-21, and a moderate to high level from 22-42. Because inter-rater agreement of the QRS has been found to be high for overall scores, but moderate for the individual items (Moncrieff 2001), disagreements on item level were discussed in the research group to define a final quality rating. Sensitivity analysis were performed to address the influence of study quality (low/moderate and high quality), allocation concealment, blinding, post randomisation exclusions, and loss to follow-up.

Data extraction
General information about methods (study duration, type of trial, patient/provider/outcome assessor blinding, anxiety/depression/disabling disorder, drop outs, co-interventions, integrity), participants (inclusion criteria, exclusion criteria, characteristics of setting, number of participants, age, sex, disease stage, race, nationality, baseline characteristic differences between groups), interventions (description of intervention and paraprofessionals, training/supervision, paid/volunteer, client/non-client, professional background, placebo condition, waiting list, frequency of contact, duration of therapy, integrity), outcome characteristics (N, Mean, Standard Deviation / n, N), and allocation concealment were extracted independently by two authors, and entered into Revman 4.2 under Table Characteristics of Included Studies.

Method of analysis
Two comparisons were made to test the review hypotheses: (1) treatment performed by paraprofessionals versus professionals; and (2) treatment performed by paraprofessionals versus waiting list or placebo condition.

Treatment outcome
The main outcome of the review was the post treatment difference between the compared conditions, measured by rating scales.

Statistics
Statistical analysis was performed in accordance with the guidelines for statistical analysis in the Cochrane Reviewers Handbook 4.2.3 (November 2004).

Continuous data
The standard mean difference (SMD) with 95% confidence intervals was used for each comparison to standardise the results of the trials to a uniform scale before pooling. Meta-analysis involves a weighted combination of estimates. Incorporating the assumption that the different studies were estimating different, yet related, treatment effects, assuming heterogeneity in the set of studies, the random effects model was applied.

Dichotomous data
When scales were analysed as dichotomous data, the appropriate continuous data were requested from the authors. If continuous data were not available, dichotomous analysis were found to be

acceptable providing a defensible cut-point to define caseness; odds ratios were used to estimate the pooled effect size. Intention-to-treat (ITT) analyses are preferred as they are unbiased, including all participants randomised into a trial irrespective of what happened subsequently. Data of all patients randomised into the intervention group of available cases were analysed in the review, using as a denominator the total number of people who completed the trial for the particular outcome in question for dichotomous data.

Heterogeneity
A test of heterogeneity examined whether the separate effect sizes could be considered to be samples from a common population of effect sizes. A value greater than 50% may be considered substantial heterogeneity.

Missing data
Very high dropout or difference across treatment groups were considered to be of low quality rating and were removed from pooling. Variation in the degree of missing data was also considered as a potential source of heterogeneity.

Tables
To summarise the data, continuous data were placed in a continuous data table, dichotomous data in a dichotomous data table and all of the data in a third data table using the generic inverse variance method. Odds ratios were re-expressed as standardised mean differences which allow dichotomous and continuous data to be pooled together. Based on the assumption that the underlying distribution of the continuous measurement in each treatment group follows a logistic distribution (which is a symmetrical distribution similar in shape to the normal distribution but with more data in the distributional tails), and that the variability of the outcomes is the same in both treated and control participants, the odds ratios can be re-expressed as a standardised mean difference according to the following formula SMD=v3/p*logOR. The standard error of the log odds ratio can be converted to the standard error of a standardised mean difference by multiplying by the same constant. Alternatively standardised mean differences can be re-expressed as log odds ratios. Log odds ratios and standard errors for all trials in the meta-analysis were combined using the generic inverse variance method in RevMan version 4.2.3.

Sensitivity analyses
Sensitivity analyses has been performed to address the influence of diagnosis or cut-off score as inclusion criterion, study quality (moderate/high), ambiguity concerning studies to include, imputed data, selection of scales (self-/observer rated measures), intention-to-treat analysis, post randomisation exclusions and loss to follow-up.

Publication bias
A funnel plot was produced to examine whether the smaller studies in the meta-analysis tended to show larger treatment effects, which might be due to publication bias.

Subgroup analyses
Subgroup analyses for diagnosis (anxiety/depression), definition of paraprofessionals (with/without professional background), intervention (individual/group) and gender (post-hoc analysis) were performed.

Data synthesis
All respective post treatment follow-up measurements according to the authors' definition were grouped for the main analyses. If post treatment measurement was not reported, the last measurement for studies of short duration (< 3 months) and the first measurement for longer duration of studies were used as the post treatment measurement; the last measurement for longer studies was taken as follow-up measurement. The measurements were also grouped for each three-month time period. The data were synthesised using Review Manager 4.2 software. Data that could not be pooled statistically were described in the results and discussion section.

Comparisons and data

Main comparisons

01   Paraprofessionals versus professionals - post treatment
     01 Continuous data; 02 Dichotomous data; 03 All data;
     generic inverse variance method
02   Paraprofessionals versus control (waiting list/placebo) - post
     treatment
     01 Continuous data; 02 Dichotomous data; 03 All data;
     generic inverse variance method

03   Paraprofessionals versus professionals - follow-up
      01 Continuous data; 02 dichotomous data; 03 all data;
      generic inverse variance method
04   Paraprofessionals versus control (waiting list/placebo) -
      follow-up
      01 continuous data; 02 dichotomous data; 03 all data;
      generic inverse variance method

Sensitivity analyses

05 Study quality (Quality Rating Scale)
06 Allocation concealment
07 Self-report and observer rated scales
08 Intention-to-treat and per protocol analysis
09 One or two and more comparisons with the same control
condition
10 Sample size
11 Diagnosis or cut-off score as inclusion criterion
12 Validity of measures

Subgroup analyses

13 Paraprofessionals (a) with and (b) without professional
background
14 (a) Anxiety and (b) Depressive disorders
15 (a) Individual and (b) Group interventions
16 (a) Same intervention and (b) Different interventions performed
by paraprofessionals and professionals
17 (a) Short term and (b) Moderate to long term post treatment
18 (a) Short term and (b) Moderate to long term follow-up
19 Gender
20 Disabling disorders: paraprofessionals vs professionals post-
treatment
21 Disabling disorders: paraprofessionals vs control (waiting
list/placebo) post treatment
22 Disabling disorders: paraprofessionals vs professionals follow-
up
23 Disabling disorders: paraprofessionals vs control (waiting
list/placebo) follow-up

Description of studies

The electronic search (December 2003) resulted in the
identification of 102 studies, of which one was written in German.

Citation lists of those studies, together with 53 articles reviewing the subject, revealed another 18 studies for examination, of which one further study was German. Suggestions made by eight out of 32 first authors who were approached, did not result in the addition of new studies for examination. Through examination of titles and abstracts of the 120 studies, 32 were identified as falling within the range of the inclusion criteria. Five studies were eligible for inclusion (Barnett 1985, Bright 1999, Dennis 2003, Harris 1999, Russell 1976). Twenty-seven studies were excluded (see reasons for exclusion in Table of Characteristics of Excluded Studies).

Of the five included studies, two studies (Bright 1999; Russell 1976) compared the same intervention performed by paraprofessionals versus professionals. Two interventions, cognitive behavioural therapy and supportive group therapy, were studied in the treatment of depression (Bright 1999). Another two interventions (Russell 1976), systematic desensitisation relaxation and cue-controlled relaxation, were studied in the treatment of speeching anxiety. One further study compared care as usual applied by professionals with a combination of care as usual and a supportive intervention provided by paraprofessionals, which was based on personal experience with the underlying problem of the target population in the treatment of anxious primiparous mothers (Barnett 1985). Another two studies compared peer support and a control condition: experienced mothers to prevent postpartum depression (Dennis 2003); and befriending among women with chronic depression (Harris 1999).

One study presented a diagnosis based on a structured clinical interview for assessment of a DSM-III-R diagnosis (SCID-NP; Spitzer 1990) (major depressive disorder, dysthymia, depression not otherwise specified; Bright 1999). The remaining studies used a cut-off score to establish caseness for anxiety and depressive problems: Personal Report of Confidence as a Speaker (PRCS; Paul 1966) score greater than 15 (Russell 1976); State and Trate Anxiety Inventory (STAI; Spielberger 1970) of 40 or more (retrieved from pilot study: M=33.1 and SD=8.1;Barnett 1985); the Bedford College threshold for 'caseness' (Finlay-Jones 1980) measured with the shortened Present State Examination (PSE-10; Wing 1990) (Harris 1999); and, Edinburgh Postnatal Depression Scale (EPDS; Cox 1987) score of greater than 9 (Dennis 2003).

Three studies involved women only, with a mean age of 28.7 years (Barnett 1985), 18 years or older, but mainly between 25 and 34 years (Dennis 2003), or mainly between 25 and 40 years (Harris 1999). Two studies yielded a gender mixed population with a mean

age of 45.8 years (Bright 1999), and a young population of undergraduates (Russell 1976).

The nationality of patients included was American (Russell 1976, Bright 1999), British (Harris 1999), Canadian (Dennis 2003) and Australian (Barnett 1985). Patients were mainly Caucasian (Bright 1999), or unspecified (Russell 1976, Barnett 1985, Harris 1999, Dennis 2003).

Paraprofessionals were volunteers, non-clients, without professional background comprising: experienced mothers (Barnett 1985); recruited from a community based self-help organisation (Bright 1999); recruited through advertisement (Harris 1999); ex-clients, also recruited by advertisement (Dennis 2003); or advanced undergraduates (Russell 1976), presumed having at least some professional background or experience.

Treatment varied between five sessions over a six week period (Russell 1976), ten weekly 90-minute sessions (Bright 1999); on a regular basis, but not further specified (Barnett 1985); weekly meetings for a minimum of one hour for one year (Harris 1999); and mother-to-mother telephone-based contact as frequently as the individual mother deemed necessary, for eight weeks (Dennis 2003).

Training in the intervention included an initial five training meetings (Russell 1976) or two days' workshop (Bright 1999), with weekly supervision given in both studies; only a set of guidelines and schedule of contact (Barnett 1985), initial training of three days (Harris 1999), or four hours of training, and supervision on request (Dennis 2003) but no control of treatment integrity. See for details of the studies: Table Characteristics of Included Studies.

Two studies did not report baseline characteristic differences between comparison groups (Russell 1976; Bright 1999); two studies found no demographic differences between the groups (Harris 1999; Dennis 2003); and one study concluded that no demographic nor symptom-rated differences existed between the comparison groups (Barnett 1985).

Only one study (Bright 1999) used an observer-rated symptom scale: the revised version of the Hamilton Rating Scale for Depression (HRSD; Rehm 1985) because of the high interrater reliability (coefficient: 0.84 to 0.95 reported on three studies). We preferred uniformity of ratings by using self-report measures for recomputation: Taylor Manifest Anxiety Scale (TMAS; Taylor 1963), validity not reported (Russell 1976); Spielberger State and Trait Anxiety Inventory (STAI; Spielberger 1970), validity not reported (Barnett 1985); Beck Depression Inventory (BDI; Beck 1979), high reliability and documented internal consistency and validity (Beck

1988) (Bright 1999); a shortened version of Present State Examination (PSE-10; Wing 1990), extended by the Bedford College criteria to date onset and offset of episodes of depression and anxiety, as well as to assess the severity of symptoms (Finlay-Jones 1980), the Bedford College threshold for 'caseness' has been found similar to probable major depression according to Research Diagnostic Criteria (RDC) (Dean 1983) (Harris 1999); Edinburgh Postnatal Depression Scale (EPDS; Cox 1987), validated by standardised psychiatric interviews with large samples, has well-documented reliability and validity in multiple languages (Dennis 2003).

Three studies reported one post treatment measurement at eight weeks (Russell 1976), ten weeks (Bright 1999), and one year (Harris 1999); one study reported four measurements at 3, 6, 9, and 12 months (Barnett 1985), and one study 2 measurements at 4 and 8 weeks Dennis 2003), both studies without defining post treatment and follow-up measurements.

For authors' conclusions: changes in self-report indices of speech anxiety showed the cue-controlled relaxation and systematic desensitisation treatments to be significantly more effective than no treatment but not different from each other (Russell 1976). Changes in anxiety levels for mothers not receiving an intervention were minimal in the study by Barnett 1985; in high-anxiety subgroups there was a 19% reduction in state anxiety levels for those receiving a professional intervention; a 12% reduction for those receiving a non-professional intervention; and a 3% reduction in controls. A planned contrast analysis determined that only professional intervention had a significant effect. Bright 1999 concluded that non-professionals were as effective as professionals in reducing depressive symptoms, and that clients in the cognitive behavioural herapy (CBT) and Mutual Support Group (MSG) conditions improved equally; however, more patients in the professionally led CBT group were classified as nondepressed and alleviated of symptoms than in the paraprofessionally led CBT groups, based on BDI scores. A statistically significant effect upon remission was found for befriending (Harris 1999). Dennis 2003 reported that significant group differences were found in probable major depressive symptomatology (EPDS > 12) at the four-week and eight-week assessments in favour of the experimental group; specifically, at the four-week assessment (40.9% of mothers in the control group, compared with 10% in the experimental group), and at the eight-week assessment (52.4% of mothers in the control group, compared with 15% of mothers in the experimental group).

Methodological quality of included studies
According to the Quality Rating Scale (QRS), four studies were of moderate to high quality, ranging from the highest score of 31 (Harris 1999), 30 (Bright 1999) to 27 (Dennis 2003), 23 (Barnett 1985), and one lower quality study scoring 17 (Russell 1976).

Sample size was small (<50 per group) in all studies. Allocation concealment was not reported in two studies (Russell 1976; Bright 1999) and done adequately in three studies (Harris 1999; Barnett 1985; Dennis 2003). Sample demographics were reported in detail by one study (Dennis 2003), basic details were reported by three studies (Barnett 1985; Bright 1999; Harris 1999), and none by one study (Russell 1976).

Objectives and main outcomes were clear in three studies (Bright 1999; Harris 1999; Dennis 2003). Objectives were clear in two studies (Russell 1976; Barnett 1985) but the main outcome was not specified a priori. Planned duration of the trial including follow up was short (< 3 months) in two studies (Russell 1976; Dennis 2003) and adequate (> 6 months) in the remaining studies (Barnett 1985; Bright 1999; Harris 1999). Power calculation was performed adequately in one study (Bright 1999), mentioned without details in one study (Barnett 1985), and not reported in three studies (Russell 1976; Harris 1999; Dennis 2003). Four studies (Barnett 1985; Bright 1999; Harris 1999; Dennis 2003) reported clear inclusion and exclusion criteria; one study reported inclusion and exclusion criteria, but without details about exclusions (Russell 1976).

Blinding of subjects is not possible in treatment intervention trials. One study used an observer-rated symptom measure, but blinding of the assessor was not reported (Bright 1999).

Post randomisation exclusions were not reported in two studies (Russell 1976; Barnett 1985) or did not take place in the remaining studies (Bright 1999; Harris 1999; Dennis 2003). There were no drop-outs (Russell 1976; Bright 1999; Harris 1999;), limited number of drop-outs (Barnett 1985; Dennis 2003), and no cross-overs. Three studies delivered continuous data (Russell 1976; Barnett 1985; Bright 1999), of which one study did not report adequate data for re-analysis (Barnett 1985). Two studies delivered dichotomous data (Harris 1999; Dennis 2003); continuous data were not retrieved on request.

Four studies (Russell 1976; Barnett 1985; Harris 1999; Dennis 2003) recruited representative samples, one study recruited by media advertisements (Bright 1999). Treatment integrity was assessed in three studies (Russell 1976; Bright 1999; Harris 1999).

Only two studies reported a declaration of interest (Harris 1999; Dennis 2003).

In summary, four studies were moderate in quality, and one was low in quality. Caution must be made in interpreting the results because of the small number of studies using small samples, different treatment duration, performance bias (blinding treatments), and rater-bias (use of self-rated and lack of blinding in observer-rated measures). Sensitivity analyses and subgroup analyses were required on various aspects of quality study study characteristics.

RESULTS

Five studies were included in the review, involving 326 participants. For post treatment comparisons, five paraprofessionals versus professionals (n=160) and five paraprofessionals versus control condition (n=220) were included. For follow-up comparisons, one comparison of paraprofessionals versus professionals (n=61) and one comparison of paraprofessionals versus control condition (n=61) were included.The numbers below correspond with the list presented previously in the 'comparisons and data' section. See Table 1 for a summary of the results.

Main objectives
01 Paraprofessionals versus professionals post treatment included five comparisons (Russell 1976 - two comparisons, Barnett 1985, Bright 1999 - two comparisons). The pooled standardised mean difference (SMD) did not indicate a significant difference between the conditions (SMD= 0.09, 95% CI -0.23 to 0.40; p=0.58). No heterogeneity was found between studies (I^2=0.1%; Chi^2= 4.0; df=4; p=0.41). See Forest plot 1a.

02 Paraprofessionals versus control (waiting list/placebo) post treatment included five comparisons, three of which were continuous (Russell 1976 - two comparisons; Barnett 1985) and two of which were dichotomous (Harris 1999, Dennis 2003). The means of one study were in the opposite direction, in favour of the control condition (Barnett 1985). The pooled odds ratio (generic inverse variance method) of re-expressed continuous data (SMD 95% CI) and dichotomous data (OR) indicated a significant result in favour of the paraprofessionals condition (OR=0.34, 95% CI 0.13 to 0.88, p=0.03) but heterogeneity was noted between studies (I^2=60.9%, Chi^2= 10.24, df=4; p=0.04). The Barnett 1985 study,

favouring the control condition, did not specify post treatment measurement and did not supply appropriate data for the continuous outcome (SDs were missing). The study was at least twice the size of each other individual study, while dominating the results. Removing the Barnett 1985 study from this comparison strengthened the significance of the result with a narrower confidence interval (OR=0.25, 95% CI 0.13 to 0.49, p<0.0001) and homogeneity between studies (I^2=0%, Chi^2= 1.72, df=3, p=0.63). See Forest plot 1b.

03 Paraprofessionals versus professionals follow-up included one study (Barnett 1985).
No significant difference was found between conditions at 6, 9 or 12 months.

04 Paraprofessionals versus control (waiting list/placebo) follow-up included one study (Barnett 1985).
No significant difference was found between conditions at 6, 9, ot 12 months.

Sensitivity analyses
05 Study quality (Quality Rating Scale).
Low study quality (1-21: Russell 1976) and moderate to high study quality (22-42: Barnett 1985; Bright 1999; Harris 1999; Dennis 2003) did not interact quantitatively (reversed direction) or qualitatively (size of the effect) with the pooled results of paraprofessionals versus professionals post treatment comparison. With respect to the control conditions, the study of low quality, with two comparisons, increased the size of the effect, with widening of confidence intervals (OR=0.14, 95% CI 0.03 to 0.54; p=0.004). The samples were very small (n=8) and both experimental conditions were compared with the same control condition. However, the moderate to high quality studies (Barnett 1985, Harris 1999, Dennis 2003) reduced the results to nonsignificance (OR=0.14, 95% CI 0.03 to 0.54, p=0.21), again indicating strong heterogeneity between studies. Removing the Barnett 1985 study, the pooled outcome from the remaining studies (Harris 1999, Dennis 2003) was significant in favour of paraprofessionals (OR=0.14, 95% CI 0.03 to 0.54, p=0.004). Low quality dominated the pooled result in favour of paraprofessionals, and the study that was likely to be causing heterogeneity reduced the result to nonsignificance.

Chapter 3

06 Allocation concealment.
Neither adequate or inadequate allocation concealment affected the pooled effect quantitatively or qualitatively for the paraprofessionals versus professionals comparisons. For the paraprofessional versus waiting list/placebo control comparison, containing the same subsets of studies, the results were the same as those for study quality.

07 Self-report and observer-rated scales.
One study with two independent comparisons used both self-report and observer-rated scales (Bright 1999). The SMDs of the individual paraprofessionals versus professionals comparisons measured by self-report scales were in opposite directions, with Cognitive Behavioural Therapy in favour of professionals and Mutual Support Group in favour of paraprofessionals. The results measured by observer-rated scales (blinding not reported) were in the same direction, both interventions in favour of paraprofessionals. Pooling outcome data of observer-rated scales reversed the results in favour of paraprofessionals (SMD=0.35, 95%CI -0.14 to 0.84, p=0.17). Neither the results of individual comparisons nor pooled estimates reached significance. The effect of self-report and observer-rated scales remains a point of controversy.

08 Intention-to-treat and per protocol analysis.
There were no data with which to perform the analysis.

09 One or two and more comparisons with the same control condition.
The same subsets were included as in the sensitivity analysis on study quality. The results correspond with those reported on study quality.

10 Sample size.
There were no data with which to perform the analysis.

11 Diagnosis or cut-off score as inclusion criterion.
One study used a diagnostic assessment for inclusion (Bright 1999) for two independent comparisons with professionals. The remaining studies used a cut-off score for 'caseness'. No interacting effect was found.

Table 1 *Paraprofessionals for anxiety and depressive disorders: summary of results*

Comparison or outcome	Studies	Participants	Statistical method	Effect size
01 Paraprofessionals vs professionals - post treatment				
01 Continuous data (reduction in symptom severity)	5	160	SMD (random), 95% CI	-0.09 [-0.40, 0.23]
02 Dichotomous data (remission versus no remission)	0	0	OR (random), 95% CI	Not estimable
03 All data; generic inverse variance	0	0	OR (random), 95% CI	Not estimable
02 Paraprofessionals vs control (waiting list/placebo) - post treatment				
01 Continuous data (reduction in symptom severity)	3	93	SMD (random), 95% CI	-0.59 [-1.57, 0.39]
02 Dichotomous data (remission versus no remission)	2	127	OR (random), 95% CI	0.30 [0.14, 0.64]
03 All data; generic inverse variance	5	220	OR (random), 95% CI	0.34 [0.13, 0.88]
04 Heterogeneity analysis (Barnett 1985 removed)	4	159	OR (random), 95% CI	0.25 [0.13, 0.49]
03 Paraprofessionals vs professionals - follow-up				
01 Continuous data (reduction in symptom severity)			SMD (random), 95% CI	Subtotals only
02 Dichotomous data (remission versus no remission)	0	0	OR (random), 95% CI	Not estimable
03 All data; generic inverse variance	0	0	OR (random), 95% CI	Not estimable
04 Paraprofessionals vs control (waiting list/placebo) - follow-up				
01 Continuous data (reduction in symptom severity)			SMD (random), 95% CI	Subtotals only
02 Dichotomous data (remission versus no remission)	0	0	SMD (random), 95% CI	Not estimable
03 All data; generic inverse variance	0	0	OR (random), 95% CI	Not estimable
05 Sensitivity analysis: study quality (QRS)				
01 Paraprofessionals vs professionals (post treatment): moderate-high quality (QRS =22-42)	3	128	SMD (random), 95% CI	-0.07 [-0.58, 0.44]
02 Paraprofessionals vs professionals (post treatment): low quality (QRS = 0-21)	2	32	SMD (random), 95% CI	-0.04 [-0.74, 0.65]
03 Paraprofessionals vs control (post treatment): moderate to high quality (QRS=22-42)	3	188	OR (random), 95% CI	0.49 [0.16, 1.49]
04 Paraprofessionals vs control (post treatment): low quality (QRS = 0-21)	2	32	OR (random), 95% CI	0.14 [0.03, 0.54]
06 Sensitivity analysis: allocation concealment				
01 Paraprofessionals vs professionals - post treatment	5	160	SMD (random), 95% CI	-0.09 [-0.40, 0.23]
02 Paraprofessionals vs control (waiting list/placebo) -post treatment	5	220	OR (random), 95% CI	0.34 [0.13, 0.88]

Comparison or outcome	Studies	Participants	Statistical method	Effect size
03 Paraprofessionals vs professionals - follow-up	0	0	SMD (random), 95% CI	Not estimable
04 Paraprofessionals vs control (waiting list/placebo) - follow-up	0	0	OR (random), 95% CI	Not estimable
07 Sensitivity analysis: self-report and observer-rated scales				
01 Paraprofessionals vs professionals - post treatment			SMD (random), 95% CI	Subtotals only
02 Paraprofessionals vs control (waiting list/placebo) - post treatment	0	0	OR (random), 95% CI	Not estimable
03 Paraprofessionals vs professionals - follow-up	0	0	SMD (random), 95% CI	Not estimable
04 Paraprofessionals vs control (waiting list/placebo) - follow-up	0	0	OR (random), 95% CI	Not estimable
08 Sensitivity analysis: intention-to-treat and per protocol analysis				
01 Paraprofessionals vs professionals - post treatment	5	160	SMD (random), 95% CI	-0.09 [-0.40, 0.23]
02 Paraprofessionals vs control (waiting list/placebo) - post treatment	5	220	OR (random), 95% CI	0.34 [0.13, 0.88]
09 Sensitivity analysis: one comparison and two or more comparisons with same control condition				
01 Paraprofessionals vs control (waiting list/placebo) - post treatment	5	220	OR (random), 95% CI	0.34 [0.13, 0.88]
10 Sensitivity analysis: small and moderate/large sample size				
01 Paraprofessionals vs professionals - post treatment	5	160	SMD (random), 95% CI	-0.09 [-0.40, 0.23]
02 Paraprofessionals vs control (waiting list/placebo) - post treatment	5	220	OR (random), 95% CI	0.34 [0.13, 0.88]
11 Sensitivity analysis: diagnosis or cut-off score as inclusion criterion				
01 Paraprofessionals vs professionals - post treatment	5	160	SMD (random), 95% CI	-0.09 [-0.40, 0.23]
02 Paraprofessionals vs control (waiting list/placebo) - post treatment	5	220	OR (random), 95% CI	0.34 [0.13, 0.88]
12 Sensitivity analysis: validity of measures				
01 Paraprofessionals vs professionals - post treatment	0	0	SMD (random), 95% CI	Not estimable
02 Paraprofessionals vs control (waiting list/placebo) - post treatment	0	0	OR (random), 95% CI	Not estimable
13 Subgroup analysis: paraprofessionals (a) with and (b) without professional background				
01 Paraprofessionals vs professionals - post treatment	5	160	SMD (random), 95% CI	-0.09 [-0.40, 0.23]
02 Paraprofessionals vs control (waiting list/placebo) - post treatment	5	220	OR (random), 95% CI	0.34 [0.13, 0.88]
14 Subgroup analysis: (a) anxiety and (b) depressive disorders				
01 Paraprofessionals vs professionals - post treatment	5	160	SMD (random), 95% CI	-0.09 [-0.40, 0.23]

Comparison or outcome	Studies	Participants	Statistical method	Effect size
02 Paraprofessionals vs control (waiting list/placebo) - post treatment	5	220	OR (random), 95% CI	0.34 [0.13, 0.88]
15 Subgroup analysis: (a) individual and (b) group interventions				
01 Paraprofessionals vs professionals - post treatment	5	160	SMD (random), 95% CI	-0.09 [-0.40, 0.23]
02 Paraprofessionals vs control (waiting list/placebo) - post treatment	5	220	OR (random), 95% CI	0.34 [0.13, 0.88]
16 Subgroup analysis: (a) same and (b) different interventions performed by paraprofessionals and professional				
01 Paraprofessionals vs professionals - post treatment	5	160	SMD (random), 95% CI	-0.09 [-0.40, 0.23]
17 Subgroup analysis: (a) short term and (b) moderate to long term post treatment				
01 Paraprofessionals vs professionals - post treatment	5	160	SMD (random), 95% CI	-0.09 [-0.40, 0.23]
02 Paraprofessionals vs control (waiting list/placebo) - post treatment	5	220	OR (random), 95% CI	0.34 [0.13, 0.88]
18 Subgroup analysis: (a) short term and (b) moderate to long term follow-up				
01 Paraprofessionals vs professionals - post treatment	0	0	SMD (random), 95% CI	Not estimable
02 Paraprofessionals vs control (waiting list/placebo) - post treatment	0	0	OR (random), 95% CI	Not estimable
19 Subgroup analysis: gender				
01 Paraprofessionals vs professionals - post treatment	5	160	SMD (random), 95% CI	-0.09 [-0.40, 0.23]
02 Paraprofessionals vs control (waiting list/placebo) - post treatment	5	220	OR (random), 95% CI	0.34 [0.13, 0.88]
20 Subgroup analysis: disabling disorders (paraprofessionals vs professionals - post treatment)				
01 Continuous data	0	0	SMD (random), 95% CI	Not estimable
02 Dichotomous data	0	0	OR (random), 95% CI	Not estimable
03 All data; generic inverse variance	0	0	OR (random), 95% CI	Not estimable
21 Subgroup analysis: disabling disorders (paraprofessionals vs control - post treatment)				
01 Continuous data	0	0	SMD (random), 95% CI	Not estimable
02 Dichotomous data	0	0	OR (random), 95% CI	Not estimable
03 All data; generic inverse variance	0	0	OR (random), 95% CI	Not estimable
22 Subgroup analysis: disabling disorders (paraprofessionals vs professionals - follow-up)				
01 Continuous data	0	0	SMD (random), 95% CI	Not estimable
02 Dichotomous data	0	0	OR (random), 95% CI	Not estimable
03 All data; generic inverse variance	0	0	OR (random), 95% CI	Not estimable
23 Subgroup analysis: disabling disorders (paraprofessionals vs control - follow-up)				
01 Continuous data	0	0	SMD (random), 95% CI	Not estimable
02 Dichotomous data	0	0	OR (random), 95% CI	Not estimable
03 All data; generic inverse variance	0	0	OR (random), 95% CI	Not estimable

Comparison or outcome	Studies	Participants	Statistical method	Effect size
24 Controlling for heterogeneity: paraprofessionals vs control - post treatment				
01 All data; generic inverse variance	4	159	OR (random), 95% CI	0.25 [0.13, 0.49]
25 Controlling for heterogeneity: sensitivity analysis - study quality				
01 Paraprofessionals vs control - post treatment: moderate/high quality (QRS =22-42) (n=3)	3	188	OR (random), 95% CI	0.49 [0.16, 1.49]
02 Paraprofessionals vs control - post treatment: moderate/high quality (QRS=22-42) (n=2)	2	127	OR (random), 95% CI	0.30 [0.14, 0.64]
03 Paraprofessionals vs control - post treatment: low quality (QRS = 0-21)	2	32	OR (random), 95% CI	0.14 [0.03, 0.54]
26 Final analyses				
01 Paraprofessionals vs professionals: post treatment - re-analysis	3	128	SMD (random), 95% CI	0.13 [-0.39, 0.64]
02 Paraprofessionals vs control (waiting list/placebo): post treatment - re-analysis	3	188	OR (random), 95% CI	0.30 [0.18, 0.48]

12 Validity of measures.
All outcome measures used for pooling were reported or known to
be valid.

Subgroup analyses
13 Paraprofessionals (a) with and (b) without professional
background.
One study used paraprofessionals with a possible professional
background (advanced undergraduates; Russell 1976). Containing
the same subsets as included in study quality, the subgroup effects
were the same as reported for the sensitivity analysis of study
quality.

14 (a) Anxiety and (b) depressive disorders.
The results were the same as those reported for the sensitivity
analysis on diagnosis or cut-off score as an inclusion criterion for
the paraprofessionals versus professionals comparisons. With
respect to paraprofessionals versus control condition comparisons,
the pooled OR of two studies examining anxiety disorders (Harris
1999; Dennis 2003) was significantly in favour of paraprofessionals
(OR=030, 95% CI 0.14 to 0.64, p=0.002). Three comparisons of
depressive disorders (Russell 1976, Barnett 1985) did not reach
significance (OR=0.30, 95% CI 0.06 to 2.04, p=0.24). However, both

studies were thought to be controversial because of low study quality (Russell 1976) and causing heterogeneity (Barnett 1985).

15 (a) Individual and (b) group interventions.
No different results for both subgroups comparing paraprofessionals and professionals. The results equalled the sensitivity analysis on study quality for the control condition because of the similar subsets of studies.

16 (a) Same and (b) different interventions performed by paraprofessionals and professionals.
The results equalled those of 15, containing the same study subsets.

17 (a) Short and (b) moderate to long duration post treatment.
There were no data to perform the analysis for the paraprofessionals versus professionals comparison. Concerning the paraprofessionals versus control condition comparison, short duration (= < 3 months) of treatment (Russell 1976, Barnett 1985, Dennis 2003) did not reach a significant level of effect (OR=0.31, 95% CI 0.08 to 1.21, p=0.09), whereas long duration (> 3 months) was significant for one study (Harris 1999) favouring paraprofessionals (OR=0.35, 95% CI 0.15 to 0.83, p=0.02).

18 (a) Short term and (b) moderate to long term follow-up.
There were no data with which to perform the analysis.

19 Gender.
Concerning the paraprofessionals versus professionals comparisons, two studies, both with independent comparisons recruited mixed samples (Russell 1976, Bright 1999) and one study recruited women only (Barnett 1985). No different outcomes were found. With respect to the paraprofessionals versus control condition comparisons, the results equalled those reported in the sensitivity analysis on study quality.

20 - 23 Subgroup disabling anxiety and depressive disorders.
No studies were available to examine whether the results would also apply to clinically significant anxiety and depressive disorders (potentially affecting all aspects of social functioning) of referred patients with a psychiatric history and/or whose illness has lasted two years or more.
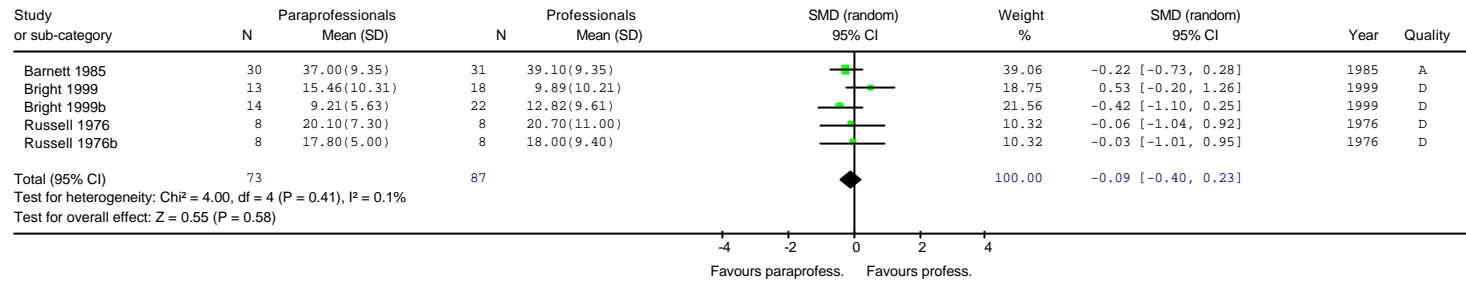
Final analyses

The Russell 1976 study, with two comparisons, showed a number of methodological inadequacies (low quality with inadequate concealment of allocation, comparing two interventions with one control condition, very small sample sizes, use of advanced undergraduate paraprofessionals assumed to have some kind of professional background), all items likely biasing the results in favour of paraprofessionals, and should be removed from pooling.

The Barnett 1985 study, which appeared to cause heterogeneity, was of moderate to high study quality, and performed adequate allocation concealment, while the SMD was in an opposing direction, in comparing the results of the primary outcome of the study with the authors' conclusion. The primary study objective was the state anxiety level (STAI) of high anxiety primiparous mothers at 12 months' duration of follow-up. Post treatment and follow-up were not further specified. We might have been wrong to choose the 3-month assessment as the post treatment measurement according to the review protocol. A second study (Harris 1999) aimed at symptom reduction at 12 months' duration of follow-up for a chronic depressive population, presenting just one post randomisation measurement at 12 months, of which one was used for pooling post treatment data according to the protocol. We decided to take the primary outcome as was described in the original study. We re-analysed the main comparisons of the review, removing the Russell 1976 study from pooling, and choosing 12 months' assessment data from Barnett 1985. Pooling data from two studies (Barnett 1985, Bright 1999; both continuous outcomes) with three independent paraprofessionals versus professionals comparisons (N=128) indicated no significant effect (SMD=0.13; 95% CI -0.39 to 0.64, p=0.63), but also suggested heterogeneity between studies (I^2=49.9%, Chi^2=3.99, df=2, p=0.14), which is difficult to interpret for a very small sample of studies. Pooling data from three studies (Barnett 1985, Harris 1999, Dennis 2003), containing three comparisons (N=188), indicated a very significant result in favour of paraprofessionals (OR=0.30, 95% CI 0.18 to 0.48, p<0.00001) and homogeneity between studies (I^2=0%, Chi^2=0.47, df=2, p=0.79). See Forest plot 2.

Forest plot 1   *Meta-Analysis on the Effectiveness of Paraprofessionals in the Treatment of Emotional Disorders*

1a

Review: Paraprofessionals for anxiety and depressive disorders (Version 03)
Comparison: 01 Paraprofessionals vs professionals - post treatment
Outcome: 01 Continuous data (reduction in symptom severity)

Study or sub-category	Paraprofessionals N	Mean (SD)	Professionals N	Mean (SD)	SMD (random) 95% CI	Weight %	SMD (random) 95% CI	Year	Quality
Barnett 1985	30	37.00(9.35)	31	39.10(9.35)		39.06	−0.22 [−0.73, 0.28]	1985	A
Bright 1999	13	15.46(10.31)	18	9.89(10.21)		18.75	0.53 [−0.20, 1.26]	1999	D
Bright 1999b	14	9.21(5.63)	22	12.82(9.61)		21.56	−0.42 [−1.10, 0.25]	1999	D
Russell 1976	8	20.10(7.30)	8	20.70(11.00)		10.32	−0.06 [−1.04, 0.92]	1976	D
Russell 1976b	8	17.80(5.00)	8	18.00(9.40)		10.32	−0.03 [−1.01, 0.95]	1976	D
Total (95% CI)	73		87			100.00	−0.09 [−0.40, 0.23]		

Test for heterogeneity: Chi² = 4.00, df = 4 (P = 0.41), I² = 0.1%
Test for overall effect: Z = 0.55 (P = 0.58)

```
        -4      -2       0       2       4
        Favours paraprofess.   Favours profess.
```

SMD = Standard Mean Difference; SD = Standard Deviation; Bright 1999: cognitive behavioural therapy comparison; Bright 1999b: mutual supportive group therapy comparison; Russel 1976: group-administered cue-controlled relaxation comparison; Russel 1976b: systematic desensitisation; Quality: Allocation concealment A = Adequate; D = not used

1b

Study or sub-category	Paraprofessionals		Control		SMD (random) 95% CI	Weight %	SMD (random) 95% CI	Year	Quality
	N	Mean (SD)	N	Mean (SD)					
Barnett 1985	30	37.00(9.35)	31	35.50(9.35)		40.98	0.16 [-0.34, 0.66]	1985	A
Russell 1976	8	20.10(7.30)	8	28.30(9.50)		30.14	-0.92 [-1.96, 0.13]	1976	D
Russell 1976b	8	17.80(5.00)	8	28.30(9.50)		28.88	-1.31 [-2.42, -0.20]	1976	D
Total (95% CI)	46		47			100.00	-0.59 [-1.57, 0.39]		

Test for heterogeneity: Chi² = 7.56, df = 2 (P = 0.02), I² = 73.5%
Test for overall effect: Z = 1.18 (P = 0.24)

```
        -4    -2    0     2     4
     Favours paraprofess.  Favours control
```

SMD = Standard Mean Difference; SD = Standard Deviation; Bright 1999: cognitive behavioural therapy comparison; Bright 1999b: mutual supportive group therapy comparison; Russel 1976: group-administered cue-controlled relaxation comparison; Russel 1976b: systematic desensitisation; Quality: Allocation concealment A = Adequate; D = not used

Forest plot 2   *Meta-Analysis on the Effectiveness of Paraprofessionals in the Treatment of Emotional Disorders*

2a

Review: Paraprofessionals for anxiety and depressive disorders (Version 03)
Comparison: 24 Controlling for heterogeneity: paraprofessionals vs control - post treatment
Outcome: 01 All data; generic inverse variance

Study or sub-category	Paraprofessionals N	Control N	log[OR] (SE)	OR (random) 95% CI	Weight %	OR (random) 95% CI	Year	Quality
Dennis 2003	20	21	-1.6607 (0.7856)		18.38	0.19 [0.04, 0.89]	2003	A
Harris 1999	43	43	-1.0498 (0.4394)		58.75	0.35 [0.15, 0.83]	1999	A
Russell 1976	8	8	-1.6689 (0.9671)		12.13	0.19 [0.03, 1.25]	1976	D
Russell 1976b	8	8	-2.3763 (1.0273)		10.75	0.09 [0.01, 0.70]	1976	D
Total (95% CI)	79	80			100.00	0.25 [0.13, 0.49]		

Test for heterogeneity: Chi² = 1.72, df = 3 (P = 0.63), I² = 0%
Test for overall effect: Z = 4.10 (P < 0.0001)

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          0.01   0.1      1    10    100
       Favours paraprofess.   Favours control
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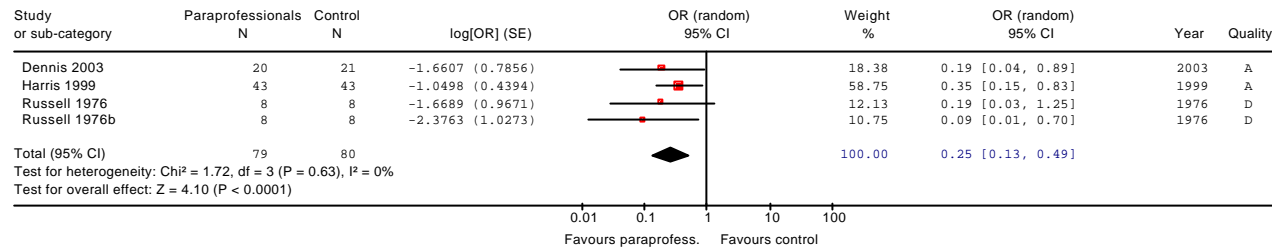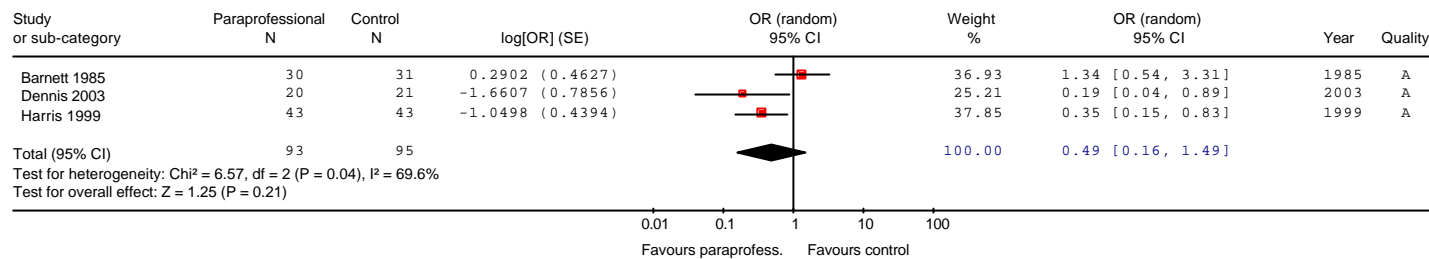
SMD = Standard Mean Difference; SD = Standard Deviation; Bright 1999: cognitive behavioural therapy comparison; Bright 1999b: mutual supportive group therapy comparison; Russel 1976: group-administered cue-controlled relaxation comparison; Russel 1976b: systematic desensitisation; Quality: Allocation concealment A= Adequate; D= not used

2b

Study or sub-category	Paraprofessional N	Control N	log[OR] (SE)	OR (random) 95% CI	Weight %	OR (random) 95% CI	Year	Quality
Barnett 1985	30	31	0.2902 (0.4627)		36.93	1.34 [0.54, 3.31]	1985	A
Dennis 2003	20	21	-1.6607 (0.7856)		25.21	0.19 [0.04, 0.89]	2003	A
Harris 1999	43	43	-1.0498 (0.4394)		37.85	0.35 [0.15, 0.83]	1999	A
Total (95% CI)	93	95			100.00	0.49 [0.16, 1.49]		

Test for heterogeneity: Chi² = 6.57, df = 2 (P = 0.04), I² = 69.6%
Test for overall effect: Z = 1.25 (P = 0.21)

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        0.01    0.1      1      10     100
      Favours paraprofess.   Favours control
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SMD = Standard Mean Difference; SD = Standard Deviation; Bright 1999: cognitive behavioural therapy comparison; Bright 1999b: mutual supportive group therapy comparison; Russel 1976: group-administered cue-controlled relaxation comparison; Russel 1976b: systematic desensitisation; Quality: Allocation concealment A= Adequate; D= not used

DISCUSSION

Summary of the results
This review summarises the results of five studies involving 326 participants, mainly women, including five paraprofessionals versus professionals post treatment comparisons (n=160) and five paraprofessionals versus control condition post treatment comparisons (n=220); and one follow-up comparison of paraprofessionals versus professionals (n=61) and control condition (n=61) respectively. The methodological quality of the studies was, with the exception of one study (Russell 1976), moderate to high with adequate allocation concealment. Paraprofessionals were volunteers without professional background in four studies, and one study used advanced undergraduates in the experimental condition (Russell 1976). Measurements varied between eight weeks and one year.

Both continuous and dichotomous data were used for pooling, where the appropriate data were not received on request (Harris 1999; Dennis 2003). SDs were retrieved from another study for imputation of missing data for one study (Barnett 1985). Using a random effects model, the pooled standard mean difference was calculated for continuous data (paraprofessionals versus professionals comparisons), and for combined data, the pooled odds ratio using the generic inverse variance method (paraprofessionals versus control condition comparisons). Self-report measures were used for pooling data. Interaction on the effect of self- and observer-rated measures was analysed. Furthermore, sensitivity analyses and subanalyses were performed for study and treatment characteristics and for gender.

The individual studies suggested no significant differences between paraprofessionals and professionals, but indicated better results for paraprofessionals compared to the control condition, which was found to be significant in three studies (Russell 1976; Harris 1999; Dennis 2003).

Main results
The pooled results indicated no significant difference between paraprofessionals and professionals at post treatment (Russell 1976, Barnett 1985, Bright 1999) and follow-up (Barnett 1985). A significant difference was found favouring paraprofessionals compared to the control condition, though heterogeneity was found between studies (Russell 1976; Barnett 1985; Harris 1999; Dennis

2003). Removing one study from pooling because of indistinct definition of post treatment measurement (Barnett 1985) resulted in a strongly significant effect and homogeneity. One study reported follow-up data, with no significant differences found between paraprofessionals and professionals, or between paraprofessionals and the control condition (Barnett 1985).

Sensitivity analyses
Low study quality or inadequate allocation concealment (Russell 1976) strengthened the result in favour of paraprofessionals. Both self-report and observer-rated scales were potentially biasing the results, with the self-report scale pointing in the direction of professionals, and with the observer-rated scale pointing to paraprofessionals for one intervention comparison (Bright 1999). No data were available to examine differences between intention-to-treat (all studies) versus per protocol analyses, sample size (all studies: small, <50 per group) and measures (all validated).

Subgroup analyses
Because of the small number of studies, most subgroup analyses could not be performed. The pooled estimate for less than three months' post treatment (post randomisation) measurements did not show a significant difference between paraprofessionals and professionals, whereas for a duration of more than three months, a significant difference was found favouring paraprofessionals compared to the control condition (Harris 1999). No differences were found for mixed samples (Russell 1976; Bright 1999) or women only (Barnett 1985) comparing professionals and paraprofessionals. No studies were available to examine whether the results would also apply to clinically significant anxiety and depressive disorders (potentially affecting all aspects of social functioning) of referred patients with a psychiatric history and/or whose illness has lasted two years or more.

Final analyses
Evaluating the study which appeared to cause heterogeneity (Barnett 1985), the measurement chosen for pooling post treatment outcome (three months' post randomisation) seemed to be inappropriate, while the primary outcome of the study was reduction of anxiety levels at 12 months' post randomisation, according to another study included in the review (Harris 1999). After correction for heterogeneity (taking the 12 months' post randomisation measurement; Barnett 1985) and removing the study of low quality (Russell 1976), pooling of three comparisons

(n=128; mixed gender and women only) indicated no significant effect between paraprofessionals and professionals, and a strongly significant pooled effect for three comparisons (n=188; women only) favouring paraprofessionals over the control condition and homogeneity between studies.

Limitations of the review
Limitations of the review were the small number of studies included, despite the intensive search; the small sample size per study; and a population of mainly women. Potential effect modifiers were dose of support or care provided by paraprofessionals, the choice of comparison treatment, and the distinctive length of treatment and follow-up. Blinding of patient and therapist in active intervention research is impossible (Bower 2001). Participants who are aware of their assignment status report more symptoms, and are probably biased as well (Karlowski 1975). In comparisons of the same interventions provided by professionals and paraprofessionals, blinding could have been performed. Analyses were mainly based on self-report measures. Mood and anxiety were presumed to affect cognitive functioning and therefore might have biased self-assessment. A sensitivity analysis of the biasing effect of self- versus observer-rated measures in a meta-analysis of the effectiveness of self-help methods in the treatment of clinically important anxiety and depressive disorders (den Boer 2004) resulted in a significant difference (T=2.84; p<0.005) between the mean effect size in six comparisons (n=197) for self-assessment (effect size =0.69) versus rater-assessment (effect size =1.40). The use of observer-rated assessments was likely to improve the results favouring self-help. We pointed out that observer rated scales were supposed to be more accurate and objective. The fact that observer rated scales showed a bigger impact than self-rated scales in this review could favour the finding that observer rated scales also suffer from biasing the results, and are like self-rated scales, with the addition of one more layer of bias, at least when observer-rated assessment is not blinded. Studies on the effect of paraprofessionals compared to professionals might be especially sensitive to the occurrence of publication bias, because of the controversial objective caused by the predominant paradigm of professional care.

Comparisons with other studies
In the last decade, evidence of the effectiveness of self-help manuals and courses which could partially replace professionals in treating anxiety and depressive disorders has grown. Meta-analyses

on manuals and courses have concluded that they produce significant results in the treatment of distinctive but mainly minor problems (Scogin 1990, Gould 1993, Marrs 1995, Cuijpers 1997, Cuijpers 1998). A meta-analysis, for anxiety and depressive disorders only, also showed a significant effect for bibliotherapy as a self-help treatment for relapsing and chronic anxiety and depressive disorders (den Boer 2004). In studies included in the review paraprofessionals were trained and used manuals. Three moderate to high quality studies have recently been conducted (Bright 1999, Harris 1999, Dennis 2003), all concerning clinically relevant anxiety or depressive problems. It is hoped that the trend for higher quality RCTs to examine the effectiveness of alternatives to the use of professionals will continue.

Reviewer's conclusions

Implications for practice
The findings of this review are inconclusive on the effect of paraprofessionals partially replacing professionals in the treatment of anxiety and depressive disorders. While there were no significant differences found between paraprofessionals and professionals, the number of included studies was quite small, and the number with follow-up data was even smaller. Studies comparing paraprofessionals and professionals had methodological problems, therefore the possible and acceptable absence of differences leaves an open question about whether the studies were adequately designed and implemented to detect differences. Nevertheless, pooling data from three studies, all involving women only, indicated a strongly significant effect for paraprofessionals (all volunteers) compared to no treatment. Significant questions remain about the conditions under which paraprofessionals can be effective. Most studies mention some selection, training and supervision of paraprofessionals. If paraprofessionals, volunteers or patients, can be effective therapists (with no training or minor initial training), or can offer support because of their personal experience with the underlying problem, this will bring psychological treatment within the scope of psycho-education or education alone. The evidence presented so far may justify the development of new programs incorporating paraprofessionals.
Implications for research
Treatment programs for mood and anxiety disorders incorporating paraprofessionals need further evaluation on their effectiveness and cost-effectiveness. The effect of self-report and observer-rater measures on the results needs more study. Blinding patients for

the paraprofessional versus professional status of the treatment provider and controlling for blinding is likely to reduce pe rformance bias, and needs to be done, but can hardly be performed with psychological or supportive interventions.

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*- **Appendix** - Meta-analysis on the Effectiveness of
Paraprofessionals in the Treatment of Emotional
disorders: Excluded Studies and Reasons of
Exclusion*

	Study	Reason of exclusion by absence of:
1	Alder & Truman 2002	Randomised controlled design
2	Barnett *et al.* 1991	Randomised controlled design
3	Bedi *et al.* 2000	Paraprofessional versus professional comparison
4	Burlingame & Barlow 1996	Assessment of a diagnosis or cut-off score to establish caseness
5	Carey & Burish 1987	Assessment of a diagnosis or cut-off score to establish caseness
6	Clifford *et al.* 1991	Anxiety or depression symptom measures
7	Ebersole *et al.* 1969	Randomised controlled design
8	Falloon *et al.* 1981	Paraprofessional versus professional comparison
9	Johnson *et al.* 1993	Anxiety or depression symptom measures
10	Karlsruher 1976	Anxiety or depression symptom measures
11	Kelly *et al.* 1993	Paraprofessional versus professional comparison
12	Krauthauser & Bassler 1997	Paraprofessional versus professional comparison
13	Lenihan & Kirk 1990	Anxiety or depression symptom measures
14	Lick & Heffler 1977	Paraprofessional versus professional comparison
15	Mann & Rosenthal 1969	Anxiety or depressive disorder
16	Miles *et al.* 1976	Randomised controlled design
17	Miller & DiPilato 1983	Randomised controlled design
18	Mor *et al.* 1983	Anxiety or depression symptom measures
19	Pruitt *et al.* 1989	Randomised controlled design

	Study	Reason of exclusion by absence of:
20	Rehm *et al.* 1981	Paraprofessional versus professional comparison
21	Rosner *et al.* 1999	Paraprofessional versus professional comparison
22	Schinke *et al.* 1979	Randomised controlled design
23	Scott & Freeman 1992	Paraprofessional versus professional comparison
24	Shelton & Madrazo-Peterson 1978	Assessment of a diagnosis or cut-off score to establish caseness
25	Simons *et al.* 2001	Paraprofessional versus professional comparison
26	Taylor 1999	Anxiety or depressive disorder
27	Thomas *et al.* 1987	Paraprofessional versus professional comparison

- Appendix - References

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Cognitive self-therapy

*Results of a pilot study of an alternative treatment
for psychiatric patients*

ABSTRACT

Report on a pilot study of an alternative treatment approach for personal change in psychiatric patients with long-term help needs. Cognitive self-therapy (CST) is offered by the adult outpatient sections of a number of Dutch mental health care facilities to patients who have already undergone several other treatments for depressive or anxiety symptoms or for personality problems. The self-therapy programme comprises an orientation course (1) and a basic course (2), followed by self-therapy meetings (3). A pilot study among 69 patients revealed general satisfaction with the courses. Some 77% of the patients interviewed reported improvement due to CST. The improvement was also reflected in a significant reduction of symptoms as assessed at intake and at the follow-up interview using the Symptom Checklist (SCL-90). A controlled study is now underway to evaluate the effectiveness of the method, the savings which can be expected because of the low level of supervision during the therapy, and its potential tertiary preventive effects.

In 1986 the regional mental health care centre of Breda started an 'integration project' whereby patients of the Social Psychiatry team were given an opportunity to learn Cognitive self-therapy and then to put the method into practice. These patients had already undergone several treatments and had in many cases become dependent on professional aid. Because of the seriousness of their psychiatric disorders, psychotherapy was not considered suitable for them, but they wanted to gain insight into their own functioning and to learn to relate to other people differently. Most of these patients had depressive or anxiety symptoms combined with personality problems which often led to stress, a factor which perpetuated their psychiatric complaints. Where necessary they were already receiving medication, crisis treatment, supportive individual therapy and relationship therapy. In a significant number of patients this combination of self-help and professional treatment led to an improvement in their social functioning: their symptoms were alleviated, crises occurred less frequently or became easier to cope with, and they called in professional help less frequently. If the self-therapy was not effective, the old method of treatment was resumed.

The method was then known as experiential peer counselling (EPC), a name which refers to its principal elements: it is experience-focused, is practised with peers, and consists mainly of 'facilitative listening'. Nowadays it is referred to as cognitive self-therapy (CST), a term which reflects the idea that people's actual emotional, cognitive and behavioural functioning is based on the emotional, cognitive and behavioural response patterns they have learnt since childhood.

In the course of the 1980s and 1990s, CST was also introduced in other institutions, for instance the Stichting Anorexia Nervosa (a Dutch eating disorder association). The psychiatric outpatients' clinic of Groningen University Medical Centre has had good experiences with it since 1995. In order to explore these experiences in more detail, the present authors carried out a pilot study into the feasibility and effectiveness of cognitive self-therapy (Mersch *et al.* 1998).

Self-regulation
Cognitive self-therapy enhances the self-regulatory capacities of patients in the treatment process and their control over it, a role which in other, older forms of psychotherapy was reserved solely for the therapist. CST's starting point is that inadequate expressions of emotion are caused by irrational, negative thoughts and expectations about oneself and others (Ellis 1962; Beck 1976; Beck & Emmery 1985). The treatment is focused on tracking down cognitions of this kind, finding out how the patient learned them, and correcting them. Patients learn to assess their own needs and possibilities in a realistic, rational way, so that they are better able to cope with difficulties in contacts with others. This improves their psychological resilience, so that they become less vulnerable to problems or life events and less susceptible to relapse.

Unlike other forms of self-help or peer contact, CST is a protocolled, structured form of therapy which can be an integral part of regular psychiatric treatment. It has three phases: an orientation course, a basic course and self-therapy meetings. The two courses are supervised by two CST teachers (a psychiatric nurse, social worker, psychologist or psychiatrist); in principle there are no teachers present at the self-therapy sessions. However, for medication advice or crisis intervention the participants can always call on a therapist who is available for the purpose in the background, and if they have any questions about CST they can ask a teacher.

The programme
Patients with depressive or anxiety disorders and personality problems are referred for participation if problems have been observed in their social contacts or in their relationship with their partner. Often these problems prove to be related to their psychological disorders. To be eligible for CST, patients have to be willing to turn up for appointments, to take part in the exercises and to contribute actively to creating a safe atmosphere in the group. They have to be able and willing to talk about their

experiences and emotional reactions, and CST may not interfere with psychotherapy already taking place. Contra-indications for participation include psychosis, mental handicap, pervasive development disorder, insufficient self-control with regard to impulses, suicidal tendencies and aggression, and alcohol or drug abuse.

The orientation course consists of three meetings each lasting a morning, afternoon or evening, spread over three weeks. It introduces six to sixteen patients to the method so that they can make a conscious decision to proceed with it or not. At this stage teachers and therapists have a chance to make a more closely informed judgment as to the likelihood that a patient will succeed – possibly with therapeutic support – in integrating new insights and behaviours into his or her daily life while retaining psychological stability.

In the basic course (five days, spread over the same number of weeks), patients learn the CST method by practising in pairs. The method is described in three manuals (Den Boer & Raes 1997a; Raes & Den Boer 1997b; Den Boer & Raes 1997c)*. Initially the main focus of the exercises is on the quality of interpersonal contact: the importance of confidentiality, giving attention, talking about yourself, equality, respect, etc. If all goes according to plan, the participants will gain enough confidence in each other and in themselves to do exercises in which they learn to cope with actual problems in their everyday lives. Then they do exercises which provide insight into recurrent inappropriate emotional reactions, thoughts and behaviours. To do this they search for similar emotional experiences in the past and with the help of standard questions try to find out if there is a pattern of feeling, thinking and behaviour involved. After exploring the similarities between then and now, they examine how the people and the situations they now have to deal with, as well as their present needs and ability to cope with them, differ from those in the past. In this way they discover new ways of relating to others and themselves. In the next group session they report on their experiences with new behaviour, so that they find out at once if they are able to use the new insights in their daily lives, and therefore whether or not there is any point in continuing with the self-therapy group. The teacher and the therapist also form an opinion on this.

The self-therapy meetings last one morning, afternoon or evening and take place once a week. The participants counsel each other with the help of the programme they have learnt in the basic course. They structure the conversations according to the manuals. Attendance at a meeting is not compulsory. Usually there are six to

twelve participants present. Because they work in pairs, there is no maximum, but the minimum is two participants.

The case described below shows how one patient's autonomy was strengthened in the course of her 'self-therapy process', with a minimum of contact with a teacher and a therapist.

Mrs Q was 42 years old, married with two children and worked part-time. During her intake interview at the clinic she was found to be suffering from a depressive disorder with characteristics of vital depression. It was also found that she had a post-traumatic stress disorder which had existed for a long time and a mixed personality disorder with borderline and dependent tendencies. The depression had arisen after an experience which strongly reminded her of the trauma she had experienced years earlier. Her symptoms were sustained by secrecy and relational problems. Three years before she came to the clinic, the patient had had marital therapy and two years before she came she had been treated for post-traumatic stress disorder. Neither of these treatments had been sufficiently effective. She was now being treated with anti-depressants and anxiolytics, of which she needed more and more. She was maintaining a precarious balance. Her mood varied. She self-mutilated and was suicidal. The patient was aware that she had difficulty tolerating anger, which exacerbated her symptoms. She adapted to her dominant husband. Because of fear of his reactions she did not dare to tell him about the traumatic event, and this burdened her with serious guilt feelings.

She wanted to prevent losing her job or being hospitalized. In order to learn to express herself better and to become more capable of coping with other people's anger (including that of her husband), she took part in the Cognitive self-therapy course and the self-therapy meetings. She learned that her problems were related to the aggression and rejection she had experienced during her childhood. She realized that with the people she now associated with she no longer needed to have this fear. She therefore gradually learnt to express her emotions and to stand up for herself.

She made slow but steady progress in differentiation with respect to other people, integration of her insights and self-control. Nevertheless she had a temporary relapse, showing increased suicidal tendencies, and wanted more therapeutic contact. She considered dropping out of the self-therapy programme and having individual treatment for the post-traumatic stress disorder. In an evaluation session with a CST teacher she saw how much she had progressed and realized that it was due to her own efforts. This motivated her to go on. At a self-therapy meeting she decided to tell her husband about 'her secret'. This decision was a great relief to her. However, it was not enough; she remained unstable and was not sure whether or not to go on with the self-therapy.

The therapist and the course teacher held an evaluation session with the patient and her husband. Her husband was very critical of the treatment

and was concerned about her increased medication, but during this talk he came to understand and acknowledge her development with self-therapy better. Supported by the presence of the therapist and the teacher, the woman was able to formulate her need for attention. Her husband promised to listen to her if she needed him to, for instance when she came home from a self-therapy meeting. Both of them could see the importance of her development, and its importance for their relationship, after which the patient was able to continue, relieved and with renewed strength. She herself suggested reducing the anxiolytics.

Pilot study

Thus far there had been no systematic description of the target group, and no research into patient satisfaction and the effectiveness of CST. This was the reason why we conducted a pilot study among all 139 patients who had been referred to CST at the psychiatric outpatient clinic of Groningen University Medical Centre from 1995 onwards. The goals of the study were

a) to study satisfaction with Cognitive self-therapy (CST)

b) to gain an indication of its effectiveness, and

c) to find ways of improving CST (Mersch *et al.* 1998).

METHOD

We analysed the progress through the programme of the 139 patients (40.3% men, 59.7% women; average age 37.3 years, SD=10.4; range: 21-65 years) who had participated from the beginning. We interviewed a sample of these patients (n=69). Depending on which stage of the programme the respondents were at, the interview varied in length from 37 to 58 questions and lasted half an hour to one and a half hours. The questions were about biographical data, satisfaction with the programme, shortcomings of the programme and suggestions for improvement, and the effectiveness of CST with regard to various aspects of functioning. We also asked the patients in the sample to fill in a self-assessment questionnaire about their symptoms (SCL-90: Derogatis 1977; Arrindell & Ettema 1986). They had previously completed this questionnaire at their intake interview at the clinic.

The patients had a long psychiatric history, on average nearly eight years (although not in treatment during all of that time). Three diagnoses were very common: mood disorders (61% as the first diagnosis; depressive disorder and dysthymic disorder), anxiety disorders (21% as the first diagnosis; generalized panic disorder and social phobia), followed by personality disorder (53% as co-morbidity; mainly from clusters B and C). Many patients

seemed to have a limited social network; 44% were single. It emerged that only 30% of the patients interviewed had paid jobs.

Interviews
It turned out that the 139 patients could be divided into three groups: those who had dropped out after the orientation course (OC) (27%; Group I); those who had dropped out after the basic course (BC) (32%; Group II); and those who had gone on to attend the self-therapy meetings (ST) after the basic course (40%; Group III). To get a good impression of the experiences of the patients who had gone through the whole programme, we decided to interview everyone in Group III (n=56). We also wanted to know why patients had dropped out after the OC or the BC in spite of a positive recommendation. For the interview we took a *randomised* sample of 50% of these patients from Group I and Group II. Of the 90 respondents who were approached, 9 refused to be interviewed, while 12 people could not be reached within the one-and-a-half-month time limit of the study. Most of those who refused were in Group I (n=5).

Eventually 69 of the 139 patients (49.6%) were interviewed. Of these, 8 (42.1%) had only followed an OC although they had been given a positive recommendation to continue, 16 (53.3%) had done both an OC and a BC and had been given a positive recommendation for the self-therapy meetings, and 45 (80.4%) had taken part in the whole programme. The average time between the CST activity (course or self-therapy meeting) and the interview was 10.7 months (SD=8.1; range: 0.5-28 months).

To find out whether there was any difference between the patients who were interviewed and those who were not, we compared the demographics of the two groups. On average, the patients interviewed were a few years older than those not interviewed: 39.1 (SD=9.2) and 35.5 years (SD=11.3) respectively. At intake there were no significant differences between the two groups with regard to general psychopathology, male-female ratio, average number of years in psychiatric treatment or number of diagnoses. It was also found that there were no differences in demographical variables between patients with a negative recommendation after the OC or BC (n=33) and patients with a positive recommendation, nor were there any differences between the groups on the SCL-90 at intake. However, patients who received a negative recommendation did turn out to have had more diagnoses than patients with a positive recommendation ($\chi^2(2)=7.99$; *p*=0.18) and to take psychiatric medication more frequently ($\chi^2(3)=10.16$; *p*=0.017).

RESULTS

Most of the patients (55%) took part in the programme in order to get rid of their symptoms, 46% wanted more insight into their own functioning and about 25% hoped the programme would help them to express themselves better and to improve their social contacts. Eight patients started out on the treatment without any particular goal. A few regarded this treatment as a last resort.

Of the 61 patients interviewed who had gone on to the BC, 90% thought the OC was a fair to good preparation. Of the 61 patients who had gone on to both the BC and the ST after the OC, 84% were satisfied to very satisfied with the programme, while of the eight patients who had stopped after the OC, only 25% were satisfied. The respondents who had stopped after the OC felt the least safe, while those who had stopped after taking part in the self-therapy groups felt the safest (x^2(6)=14.41; p=0.025).

The reason given most frequently for taking part in the self-therapy sessions after a basic course was that patients found the treatment helpful (58%). Other patients wanted to gain more insight into their own functioning (14%), while others were curious and saw it as a challenge (16%). Only two patients mentioned contact with peers as their most important motivation. Between 30 and 45 patients (66%) found the transition from the basic course to the self-therapy groups difficult; for five of them this was the reason why they attended the meetings less frequently than they had originally intended. According to five respondents, the reason the transition was so difficult was the lack of supervision, and according to four others, because it involved working with strangers; eleven people gave both reasons.

On average, the patients took part in the self-therapy meetings 10.7 times (SD=14.2; median 5); at the time of the interview 18 patients (40% of 45) were still participating. Only 44% of the patients received support from a therapist; 20% said they had not received any support, and 29% thought they did not have a therapist. Patient appreciation of CST was also shown by the high percentage of people who said they would recommend the programme: 71%.

Symptom reduction
Of the entire group interviewed (n=69), 73% had fewer symptoms or no more symptoms at all. This was true of 38% and 69% respectively of the respondents who had stopped after the orientation course or the basic course, while the highest percentage was found among those who had also attended self-therapy

meetings: 80%. Twenty-seven patients with fewer or no symptoms were on medication, while 7 patients were receiving some other form of treatment in addition to CST. The patients who had followed the whole programme, including the self-therapy meetings, attributed 60% of their improvement to CST. For the patients who had dropped out after the basic course, this percentage was 47%, and for the 8 patients who had dropped out after the orientation course, only 13%.

The patients' retrospective self-assessment tallied with the results of change on the SCL-90. Across the whole group there was a significant reduction of symptoms as measured by the SCL-90 at the time of the interview compared with the results of the SCL-90 at intake (T-test: 4.31; df-63; p=0.001). The only patients for whom there was no significant difference were those who had done only the orientation course. There was a significant difference for the patients who had also done the basic course (T-test: 2.90; df=13; p=.012) and for those who had then gone on to the self-therapy group (T-test: 41; df=41; p=.002).

Although another treatment (medication in particular) may have contributed to the positive results, this influence seemed likely to be limited. To find out, we first looked at whether the patients who said they had improved most through CST had in fact improved more on the psychopathology scale (the SCL-90) than the patients who reported less improvement. This turned out to be the case. If other treatments played a role, it could be expected that the patients who improved most were mainly those who had received additional treatment. This was not the case. In fact, the patients who attributed the least improvement to CST had received additional treatment or medication more frequently than the patients who said they had benefited the most (55% vs 40% and 65% vs 40% respectively). Possibly, the least improved group had been more seriously ill before starting CST than the most improved group. However, this was not borne out by any variable (SCL-90, number of diagnoses, psychiatric history). There are no indications that other treatments enhanced the improvement. However, although it seems the improvement can be attributed mainly to CST, this still needs to be demonstrated by additional controlled research.

Improvement of social functioning
Of the patients interviewed, 72% said that they could apply what they had learned in CST to their everyday lives. This was particularly true of the patients who had also taken part in the self-therapy meetings – 61% thought they had gained more insight into

their problems. Of those patients who were employed (n=42), 24 (57%) said that they were functioning better, particularly in their contacts with colleagues. Of the 53 respondents who had a partner or a family, 55% said that their relationships with them had improved, especially those with family members. More than half of the patients said that their relationships with their family (54%) and their contacts with friends had improved (57%), 30% had become more self-confident and more independent, 42% thought their social contacts had improved, and 38% had more energy and motivation to undertake things.

The patients who had stopped after the orientation course had done so because CST did not appeal to them or because they did not like working in groups. The patients who had dropped out after the basic course said they did not need any more treatment, that CST was not effective, or that they had practical objections (e.g. time and distance). Most patients who had gone through the whole programme stopped because they no longer needed treatment.

We asked the respondents what they thought were the most important characteristics of CST in comparison with more traditional treatments. Forty-eight percent of the respondents said that more independence and personal responsibility were needed for CST, 23 people (33%) said contact with peers was an important feature, and 7 people (10%) emphasized the intensive character of CST. In general these aspects were highly appreciated.

DISCUSSION

The results of the pilot study show a high degree of satisfaction in the patients who went on to the basic course and the self-therapy meetings (84%). This may be due to the fact that the orientation course acts as a good screening instrument. The percentage of patients who dropped out after the orientation course is relatively high: 27%, which is comparable to the 26% of patients at Dutch regional mental health care centres who terminate contact without the approval of their therapist. The difference in the case of CST is that patients make a motivated choice to stop on the basis of their experience and in consultation with their therapist. Half of the patients who stopped after an orientation course had in fact been advised by the teacher to go on to the basic course. It turned out that in practice several of these patients needed a longer period of preparation and later went on to complete the whole programme.

Due to the limitations inherent to a pilot study, we are not yet able to compare the effectiveness of CST with that of other treatments, but the findings of the study do confirm the clinical

impressions gained up till now. The reduction in symptoms (73%) and patients' ability to integrate what they have learnt into their everyday lives (72%) correspond with the percentage of regional mental health care centre patients who say they have been helped (71%; Van der Sande et al. 1992). However, all of the patients who participated in CST had already undergone several treatments. Patients who completed the basic course did better than the patients who attended only the orientation course. The same is true of patients who went on to the self-therapy meetings in comparison with patients who dropped out after the basic course.

There are a few unfavourable factors which seem to have had little influence on the results. Firstly the seriousness of the psychological disorders: at the commencement of CST the patients had an average psychiatric history of nearly eight years and a high degree of co-morbidity. Moreover, many patients were single and unemployed, and in comparison with most other treatments supervision by professional mental health care workers was much less intensive. The therapy is actually conducted by the patients themselves from the orientation course onwards. Although other treatments (medication in particular) may have contributed to the positive results, their influence appears to be limited and the improvement does in fact seem to be attributable to the CST.

Recommendations
Can the CST programme be improved? The orientation course seems to meet its objectives adequately: patients are able to become acquainted with the method and then decide whether or not to go on to the basic course. A significant proportion of the patients said that the basic course was enough for them. In both the transition phases – from the orientation course to the basic course and from the basic course to the self-therapy meetings – the support given to patients could be improved. At the psychiatric outpatient clinic of University Medical Centre Groningen the policy is to try to make as much use as possible of the patients' own self-regulatory capacities. In the original model of the Breda regional mental health care, the teachers who give the course are also the patients' case managers. This means that a larger group of patients with serious psychiatric problems which have lasted for a long time can take part in the CST programme and reach a reasonable level of stability with little support.

In response to the pilot study, improvements are being sought which can be carried out mainly by the participants themselves. For example, support in the transitional phase from the basic course to the self-therapy meetings was introduced partly on the

initiative of patients who were already taking part in the self-therapy meetings. On the last day of the basic course they come as hosts to meet the potential new participants and answer questions about the self-therapy meetings. After new participants have attended a self-therapy meeting for the first time, experienced participants ask them what they think of the atmosphere in the group, how safe they feel there and if they have any wishes for the next time. To maintain contact with the teachers, every three months a newsletter appears with announcements, information about exercises and contributions from the participants themselves. Each participant also makes an appointment with a teacher for an evaluation after at least three self-therapy meetings.

In short, the CST programme seems to be a valuable supplement to the treatments already on offer. CST may also be important from the point of view of tertiary prevention. Two-thirds of the patients who had taken part in the whole programme said that they were able to apply what they had learnt often and effectively in everyday life, and 40% of those who had already stopped said that they would go to self-therapy meetings again if they needed to. Future research will have to show if this really happens.

For a certain group of patients, CST seems to succeed in placing the responsibility for improvement on the patients themselves. Moreover, the participants experience a high degree of independence. Patients saw this as the biggest difference between CST and other forms of treatment.

There are other arguments for continued research into the effectiveness and practicality of self-help and CST. Mental health care needs to meet practical needs. The demand for extramural mental health care is rising sharply; in ten years' time the number of patients at the regional mental health care centres grew from 169,000 to 419,000 (Mental Health Care annual reports 1996/1997). It has been found that among patients at mental health care centres and psychiatric outpatient clinics the kind of help needed and the treatment offered are not always related to the patients' complaints (Swinkels 1994; Van der Sande 1992). Sixty-seven percent of the patients ask for help with respect to insight into current problems and their relationship with the past (Van der Sande 1992). Insight-providing therapy is time-intensive (once a week, a total of 30 to 60 sessions), while regular psychotherapy is usually contra-indicated for patients with psychiatric symptoms. Moreover, the worse a patient's mental condition or social circumstances are, the less intensive therapy he or she receives. The CST programme has shown good results in patients who would

have been refused regular psychotherapy. It is important for patients to be able to choose their own treatment. The CST appears to meet this requirement well.

The patients who take part in CST belong to the large group of patients with mood or anxiety disorders, with an annual prevalence of 15.9% (Bijl *et al.* 1997), whose treatment cost approximately EUR 775 million in the 1990s (Sytema & Koopmans 1998, extrapolated). At least 20% of the mood and anxiety disorders are chronic. In addition to medication, cognitive behavioural therapy has proved to be successful for anxiety disorders (Van Balkom *et al.* 1997; Mersch 1994), mood disorders (Boelens 1990; Dobson 1989; Dorrepaal *et al.* 1998) and personality disorders (Arntz 1994; Linehan *et al.* 1994; Mersch *et al.* 1995). Nevertheless, some of the patients retain their symptoms or relapse. Forms of self-therapy may be able to contribute to meeting the increasing demand for help. If participation in self-help programmes also helps to reduce the need for treatment contacts, it may also result in considerable savings.

Self-help is a very common phenomenon in a large number of problem areas. It usually takes place outside mental health care. Well-known examples are AA for alcoholics and Weight Watchers for the overweight. Self-help also takes place within patient organisations such as the 'phobia club'. The large number of participants in self-help (Janssen & Geelen 1996) means that these activities meet a need. A few meta-analyses have shown the effectiveness of self-help programmes (bibliotherapy) in comparison to placebo treatments (Cuijpers 1996, 1997; Scogin *et al.* 1990; Gould & Clum 1993; Marrs 1995). Those self-help programmes have proved to be just as effective as the standard treatments for various problems, including mood and anxiety disorders. A study of the effectiveness of an AA group showed this form of self-help to be just as effective as a treatment group at an outpatient clinic, but the costs were 45% lower (Humphreys & Moos 1996).

Thus far there has been no research into the cost-effectiveness of self-help methods for patients with mood or anxiety disorders. A prospective controlled study of the cost-effectiveness of CST in comparison with standard treatment in patients with chronic and recurrent mood or anxiety disorders is currently underway. Five mental health care institutions are taking part in this study, the results of which are expected in late 2004. Then it will be clear whether the result is the same and whether it might be more cost-effective.

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Cognitive self-therapy
for chronic depression and anxiety

A multi-centre randomised controlled study

Peter C.A.M. den Boer, Durk Wiersma, Inge ten Vaarwerk, Mark M. Span, A. Dennis Stant & Robert J. van den Bosch

Abstract

Background: Non-professional treatment programmes are presumed to relieve the extensive need for care of anxiety and depression disorders. This study investigates the effectiveness of cognitive self-therapy (CST) in the treatment of depression or generalised anxiety disorder.

Method: Patients (n=151) were randomised to receive CST or treatment as usual (TAU) in a trial lasting for 18 months, measuring symptoms (SCL-90; main outcome), social functions, quality of life and utilisation of care.

Results: Patients in both conditions improved significantly, but no difference was found between the conditions. Reduction of symptoms, improvement of social functions and medical utilisation were maintained at the end of the 18 months. Medical care utilisation (therapist contact and hospitalisation) was lower for CST than for TAU. No suicides occurred.

Conclusions: Cognitive self-therapy is likely to be effective, can safely be applied, and decreases the need for care of chronic depression and anxiety.

Declaration of interest: None.

Evidence-based treatment strategies for the treatment of chronic and remittent depression and anxiety disorders cannot be recommended unequivocally by applying guidelines. Where no agreed treatment procedures exist, new approaches are necessary. Alternative treatment programmes are presumed to relieve the extensive need for care of these disorders (Andrews *et al,* 1998; Bebbington *et al,* 1997) that are becoming a serious medical condition, as is reflected by the likely worldwide burden of these diseases in the coming decades (Murray, C. J. L. & Lopez, A. D., 1997). Self-help manuals (Den Boer *et al,* 2004), coping with depression course (Cuijpers, 1998), and paraprofessionals (Den Boer *et al,* 2005) are effective in the treatment of depression and anxiety disorders and probably cost-effective. A longitudinal study with before and after symptom measurements found significant symptom reduction for patients who completed the cognitive self-therapy programme (CST) that integrates manuals, course and paraprofessionals, compared to non-completers provided with treatment as usual. The completers were satisfied with CST and appreciated their independence from a therapist. The programme seemed to be cost-effective. The objective of the present study was to investigate the effectiveness of CST in a randomised controlled trial. We expected a significant symptom reduction and a decrease of care utilisation for CST compared to treatment as usual.

METHODS

Study sample
Study participants were recruited and followed from four mental health care centres in the Netherlands between December 2000

and August 2004. Patients were eligible if they met: a) a DSM-IV diagnosis of chronic or recurrent unipolar depressive disorder, dysthymic disorder and/or generalised anxiety disorder; b) previous mental health care related to the assessed diagnosis during more than two years prior to inclusion in the study; and c) age between 18 and 65 years. Exclusion criteria were: a) suicidal behaviour; b) psychotic symptoms, autistic or organic disorders; c) current drug or alcohol dependence; d) mental handicap (IQ score = 85); e) previous participation in the CST programme; f) absence of any awareness of personal vulnerability in social contacts and/or relationships; and g) reluctance to participate in groups.

Recruitment
Referred patients with anxiety or depressive features and a history of disease of longer than two years, were invited to a screening visit for the study at the initial contact, including a psychiatric assessment.

Interventions
Treatment in both conditions took place in outpatient centres. Both conditions involved initial contacts with the patients for the purpose of establishing diagnoses, prescribing medication and in some cases full or partial hospitalisation. The CST programme had been uniformly implemented in all participating centres prior to the study.
Treatment as usual (TAU). TAU consisted of psychological therapy delivered by professionals not according to a study protocol. Interpersonal psychotherapy and cognitive behavioural therapy could be part of the treatment and were provided by a psychologist. In other cases, supportive treatment was given by a psychiatric nurse or social worker focusing on problem-solving and coping strategies. Treatment consisted typically of 10 to 20 visits of 30 to 45 minutes each, throughout the first six to 12 months. Follow-up contacts with therapists were provided if needed.
Cognitive Self-Therapy (CST). CST is a structured method, based on cognitive behavioural and interpersonal therapy principles, that seeks to restructure cognitive schemata by focusing on problems in social functioning and relationships. Patients use a CST manual (den Boer & Raes, 1997) that acquaints them with the treatment principles. The patients' role in the treatment gradually evolves into that of a 'paraprofessional,' such that they finally conduct CST sessions in reciprocal relationships with peers. The CST programme of 12 weeks duration consists of the following phases: 1) a preparatory phase (one to three 45-minute meetings),

providing information and determining the extent to which patients are willing and able to participate in the CST course; 2) an orientation course of three weekly morning meetings to practice with peers before deciding to continue into the next phase; 3) a basic course of five weekly, day-long sessions in which patients learn to manage CST sessions. Those who perform CST sessions adequately with peers are certified to participate in the fourth phase of the CST programme: 4) weekly self-therapy meetings, which are led by peers in accordance with the manual. Certified patients have the option of participating in CST whenever they like. Each CST session lasts between 30 and 40 minutes, is highly structured, and consists of four time-limited steps: exploration of a recent life event (5 minutes); exploration of an associated past life event between childhood and present age (5 minutes); an associated childhood event (5-15 minutes); reflection to gain insight into individual patterns of emotion, cognition, behaviour and needs in relation to others, cognitive restructuring, and planning of new behaviour (15 minutes).

Treatment integrity. The TAU condition did not follow a uniform treatment protocol, but all contacts with therapists were registered. An hour-by-hour structured programme was prescribed for the CST condition. Adherence to the programme and additional contacts with therapists was registered.

Therapists. All therapists in both conditions worked in teams comprising psychiatric nurses, social workers, a psychologist, a psychiatric trainee and a senior psychiatrist. CST teachers included psychiatric nurses, social workers and psychologists who had been trained to perform CST programmes and to teach the CST method to patients. CST teachers provided the CST condition and were not involved in treatment as usual. The remaining therapists provided treatment as usual, but also could be involved in CST when patients stopped with the CST programme and still needed treatment.

Study design
Applying power analysis, based on a 23-point difference on the SCL-90 in the observational study (a difference found between participants who completed the programme and those who dropped out after the orientation course and received treatment as usual), it was estimated that 61 patients were required in each treatment condition to detect such a difference (*SD*=50), with an alpha value of 0.05 and power of 80% (STAT-power) (Bavry, 1991). Anticipating a study drop-out rate of 20%, it was necessary to randomise a

total of 150 patients in order to be assured of having 61 patients in each treatment condition.

We conducted a randomised controlled trial. Informed written consent was obtained from eligible participants (*n*=151). An independent central randomisation telephone service of the University Medical Center Groningen used sealed envelopes to allocate patients randomly to each condition after completion of baseline measurements. Stratified randomisation according to age (< 40 yr. =) and illness duration (< 7 yr. =) within each centre was used. Random permutated blocks of four were used within each stratum. Independent researchers assessed patients using semi-structured interviews and self-report scales.

Data were collected at baseline and at 6, 12 and 18 months after baseline. The main outcome measure was symptom improvement measured by the SCL-90 as it was the outcome measure of the pilot study on which the power analysis was based. Specific measures of anxiety and depression have been used as well.

Measures

The following measures were used:
- A diagnostic computer algorithm delivered DSM-IV diagnoses based on responses to the *Schedules for Clinical Assessment in Neuropsychiatry* - SCAN (World Health Organization, 1992), a semi-structured interview.
- The primary outcome measure was the *Symptom Checklist-90* - SCL-90 (McKinnon & Yodofsky,1986), a multidimensional self-report measure of general psychiatric symptomatology consisting of nine subscales: somatisation, obsessive-compulsivity, interpersonal sensitivity, anxiety, hostility, phobic anxiety, paranoid ideation, psychosis and depression. Total scores range from 90 to 450.
- The *Beck Depression Inventory* - BDI (Beck & Steer, 1993), a self-report inventory for assessing the severity of depressive symptoms. Total scores range from 0 to 63.
- The *State-Trait Anxiety Inventory* - STAI (Spielberger et al, 1970), a self-report instrument measuring state anxiety 'right now' questions) and trait anxiety ('generally' questions). Total scores range *from 20 to 80.*
- *The World Health Organization Quality of Life Assessment –* WHOQoL-Bref (The WHOQOL Group, 1998), a self-report questionnaire, measuring general quality of life, general health evaluation and four additional domains of quality of life (physical, psychological, social and environment). Total scores range from 26 to 130.

- The *Groningen Social Disabilities Schedule* - GSDS (Schutzwohl *et al*, 2003; Wiersma *et al,* 1988), an observer-rated semi-structured interview, to assess social functioning in eight different role domains: self-care, family, kinship, partner, parent, citizen, social and work. The scores range from 0 to 3 and the total score ranges from 0 to 21. The mean social role score was also included. Three raters with university levels of education in psychology or regular health science were specially trained to perform the SCAN and GSDS interviews. Booster sessions were held to prevent a drift in rating. Raters were fully independent from the mental health staff and were regularly supervised.

The SCAN was completed at baseline, before randomisation, and at the follow-up after 18 months. The SCL-90, BDI, STAI and WHOQoL were assessed at baseline, at post-treatment after 6 months and at follow-up after 12 and 18 months. The GSDS was measured at baseline and at follow-up after 12 and 18 months. The number of psychiatric contacts, medication and partial or full hospitalisation was registered at all assessments for the six months prior to the assessment, using information from structured interviews and medical files.

Analysis
Between-group baseline characteristics were analysed with Student's T-tests for continuous variables and Pearson chi-square tests for categorical variables. All symptom measures (SCL-90, BDI and STAI) and the WHO-QoL were analysed using mixed models, a repeated measurement analysis that uses all available data. The model included the main effects of treatment condition and assessment time and their interaction, with a random effect of subject. To account for the difference in baseline scores on the SCL-90, that baseline score was entered into the model as a covariate for each of the symptom measures. The group effect was tested with the Mann-Whitney U-test, and the assessment time effect was tested with the Kruskall-Wallis rank sum test for the categorical variables that were obtained from the GSDS. Between-centre differences were analysed with univariant analysis of variance for continuous variables and Pearson chi-square tests for categorical variables. The main outcome analysis consisted of an 'intention to treat' analysis that included all of the randomised patients. P-values less than 0.05 were considered significant. Data was analysed using the SPSS version 12.0.2 for Windows (SPSS, Inc, Illinois, USA).

RESULTS

Patient baseline characteristics
The sample included 100 women and 51 men, with a mean age of
41.3 (*SD*=9.0) years. One hundred and thirty-five patients (89%)
had a unipolar depressive disorder, 7 patients (5%) had a
dysthymic disorder, and 9 patients (6%) had a generalised anxiety
disorder (Table 1). Over half (52%) of the patients had co-morbid
diagnoses of a depressive or anxiety disorder. The first contact with
mental health care was nearly 13 years before inclusion. Seventy-
two percent used psychiatric medication, significantly more
patients in the TAU group than in the CST group. No significant
between-group differences were found for demographic (gender,
age, living alone, paid employment, level of education) or clinical
(primary diagnosis, co-morbidity, first psychiatric contact, family
psychiatric history) characteristics, nor for symptom level, social
functioning or quality of life, except for the SCL-90 score, which
was significantly higher for the TAU condition than for CST. Except
for level of education, no between-centre differences were found for
demographic and clinical characteristics, and for the SCL-90
scores.

Patient flow and drop out
Eighty-three percent (n=151) of the 182 eligible patients were
motivated to participate in the study; 75 of these patients were
allocated to CST and 76 to TAU (Figure 1). Twenty-four patients
(16%) dropped out of the study, 10 patients in the CST programme
and 14 in the TAU condition. Half of the patients who dropped out
could not be traced, mostly patients in the TAU condition. No
differences were found for gender, living alone, paid employment,
education, nor for psychiatric family history, primary diagnosis,
psychiatric medication, contact with psychiatrists or other
therapists in the six months prior to inclusion, nor for the main
outcome measure (SCL-90) on baseline between those who dropped
out and those who did not. However, patients who dropped out
were about five years younger (T-test: $p<0.05$) and made less use of
a combination of somatic and psychiatric medication ($?^2$=4.810;
$p<0.05$).

Main outcome, symptom level and diagnosis
Means and standard deviations of the symptom measures (SCL-90,
BDI, STAI) are presented in Table 2 and the ANOVA tables in Table
3. The mixed effects analysis showed a significant time effect, but
no significant difference between treatment conditions, neither of

Table 1   *Cognitive Self-Therapy Study: Demographic and clinical patient characteristics at Baseline*

	Total (n=151)	CST (n=75)	TAU (n=76)	P-value
Gender				
Male	51 (34%)	23 (31%)	28 (37%)	0.422
Female	100 (66%)	52 (69%)	48 (63%)	
Age in years[1]	41.3 (9.0)	40.7 (8.9)	41.9 (9.1)	0.393
Living alone				
Yes	39 (26%)	22 (29%)	17 (22%)	0.328
No	112 (74%)	53 (71%)	59 (78%)	
Paid employment				
Yes	67 (44%)	38 (51%)	29 (38%)	0.122
No	84 (56%)	37 (49%)	47 (62%)	
Level of education				
Primary school	75 (50%)	34 (45%)	41 (54%)	0.370
Secondary school	56 (37%)	32 (43%)	24 (32%)	
Higher professional / university	20 (13%)	9 (12%)	11 (15%)	
Primary diagnosis				
Depressive disorder[2]	142 (94%)	68 (91%)	74 (97%)	0.082
Generalized anxiety disorder[3]	9 (6%)	7 (9%)	2 (3%)	
Psychiatric comorbidity				
Yes	78 (52%)	42 (56%)	36 (47%)	0.289
No	73 (48%)	33 (44%)	40 (53%)	
Years since first psychiatric contact[1]	12.7 (8.3)	12.2 (7.6)	13.1 (9.0)	0.535
Psychiatric family history				
Yes	76 (50%)	35 (47%)	41 (54%)	0.371
No	75 (50%)	40 (53%)	35 (46%)	
Use of psychoactive medication				
Yes	108 (72%)	47 (63%)	61 (80%)	0.017
Antidepressants	54 (50%)	24 (51%)	30 (49%)	0.846
Anxiolytics	13 (12%)	6 (13%)	7 (12%)	0.838
Antidepr. + anxiolytics	39 (36%)	15 (32%)	24 (39%)	0.425
Antipsychotics	6 (6%)	3 (6%)	3 (5%)	0.742
No	43 (29%)	28 (37%)	15 (20%)	
Somatic medication				
Yes	77 (51%)	38 (51%)	39 (51%)	0.936
No	74 (49%)	37 (49%)	37 (49%)	
Psychoactive + somatic medication				
Yes	55 (36%)	25 (33%)	30 (40%)	0.433
No	96 (64%)	50 (67%)	46 (61%)	

the main effect nor interaction with time. Later assessments showed lower scores on symptom measures for both treatment conditions. Forty-five (35%) patients still satisfied the criteria for an Axis-I DSM-IV diagnosis at 18 months, as measured with the SCAN (37 patients had a depressive disorder, two a dysthymic disorder, one generalised anxiety disorder and five patients had another anxiety disorder). No difference was found between the conditions (χ^2=1.503; *p*=0.472). Twenty-five (20%) patients had co-morbidity on Axis-I, less in the CST condition than in TAU (Chi-square test: χ^2=4.431; *p*=0.035).

Secondary outcome, social functioning and quality of life
Total GSDS score and the subscale of work role improved significantly in both conditions, without significant differences between the conditions (Tables 3 and 4). The subscales of self-care, family role and kinship role improved significantly in the CST group. Citizen role and partner role improved for TAU.
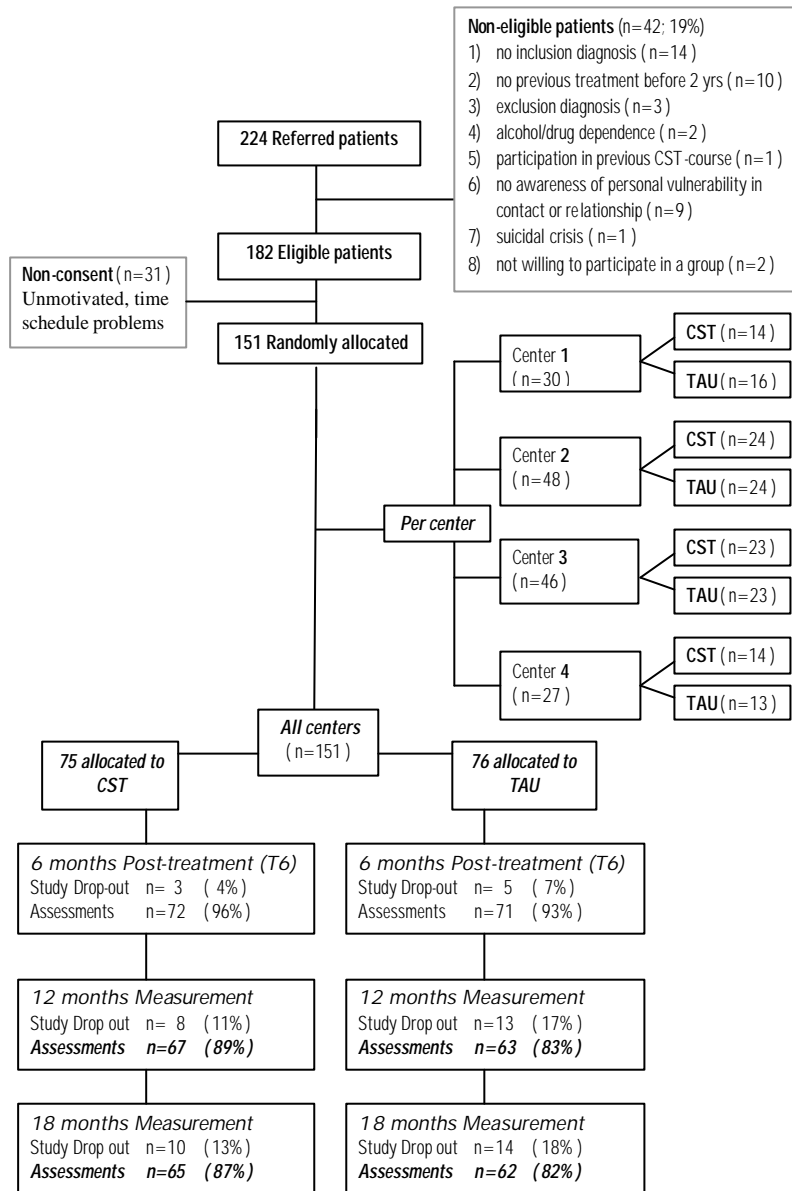Quality of life improved for both conditions, as indicated by WHO-QoL total scores and the subscale of physical health, but no group differences or interactions between treatment and time were found.

Medical care utilisation
Mental health care utilisation related to both treatment conditions was measured using data on medication, full and partial hospitalisation, and the number of contacts with a psychiatrist or other therapist (psychologist, psychiatric nurse, social worker). The use of psychiatric medication was significantly decreased for the TAU condition (McNemar Test: p<0.05),
mainly because of a decrease of the combined use of anxiolytic and anti-depressant medication (McNemar Test: p<0.01), but no differences were found between the conditions nor with respect to the number of contacts with psychiatrists (in the last six months). The mean number of contacts in the last six months with other therapists was significantly lower for CST than for TAU (T= -2.148, df=119, p=0.034).

Figure 1 *Cognitive self-therapy study: Patient flow and study drop-out*

Non-eligible patients (n=42; 19%)
1) no inclusion diagnosis (n=14)
2) no previous treatment before 2 yrs (n=10)
3) exclusion diagnosis (n=3)
4) alcohol/drug dependence (n=2)
5) participation in previous CST-course (n=1)
6) no awareness of personal vulnerability in contact or relationship (n=9)
7) suicidal crisis (n=1)
8) not willing to participate in a group (n=2)

224 Referred patients

182 Eligible patients

Non-consent (n=31)
Unmotivated, time schedule problems

151 Randomly allocated

Per center

Center **1** (n=30) → CST (n=14) / TAU (n=16)
Center **2** (n=48) → CST (n=24) / TAU (n=24)
Center **3** (n=46) → CST (n=23) / TAU (n=23)
Center **4** (n=27) → CST (n=14) / TAU (n=13)

All centers (n=151)

75 allocated to CST

76 allocated to TAU

6 months Post-treatment (T6)
Study Drop-out n= 3 (4%)
Assessments   n=72 (96%)

6 months Post-treatment (T6)
Study Drop-out n= 5 (7%)
Assessments   n=71 (93%)

12 months Measurement
Study Drop out n= 8 (11%)
Assessments   n=67 (89%)

12 months Measurement
Study Drop out n=13 (17%)
Assessments   n=63 (83%)

18 months Measurement
Study Drop out n=10 (13%)
Assessments   n=65 (87%)

18 months Measurement
Study Drop out n=14 (18%)
Assessments   n=62 (82%)

CST = Cognitive Self-Therapy; TAU = Treatment As Usual

Cognitive self-therapy for chronic depression and anxiety   **119**

Table 2   *Symptom ratings – Means and Standard Devations*

	CST			TAU		
	n	M	SD	n	M	SD
SCL-90 total score						
Baseline	75	217.5	(54.2)	76	238.8	(58.6)
6 months	70	184.7	(60.4)	71	211.0	(70.9)
12 months	64	182.9	(68.8)	59	201.2	(79.7)
18 months	62	178.5	(66.9)	59	200.3	(75.6)
SCL-90 subscore depression						
Baseline	75	46.5	(12.1)	76	51.8	(13.0)
6 months	70	37.2	(13.8)	71	43.5	(15.4)
12 months	64	37.0	(15.4)	59	39.4	(17.3)
18 months	62	36.0	(15.3)	59	39.3	(16.2)
SCL-90 subscore anxiety						
Baseline	75	24.4	(8.3)	76	27.1	(9.2)
6 months	70	20.5	(8.0)	71	24.0	(10.3)
12 months	64	19.8	(9.0)	59	22.9	(10.8)
18 months	62	20.0	(8.9)	59	23.0	(10.2)
BDI						
Baseline	75	22.4	(9.1)	76	25.0	(10.1)
6 months	70	17.5	(10.0)	71	19.6	(11.5)
12 months	64	17.4	(11.9)	59	18.4	(12.6)
18 months	62	15.4	(11.2)	59	18.6	(12.9)
STAI - state anxiety						
Baseline	74	53.9	(10.6)	76	56.0	(13.0)
6 months	70	48.2	(12.6)	69	52.0	(13.9)
12 months	64	47.2	(13.7)	52	49.7	(16.7)
18 months	62	46.7	(13.6)	59	50.0	(15.6)
STAI - trait anxiety						
Baseline	74	60.2	(8.0)	76	62.3	(9.8)
6 months	70	52.8	(11.4)	69	56.7	(13.9)
18 months	62	50.1	(13.0)	59	54.3	(15.0)

CST = Cognitive Self-Therapy; TAU = Treatment As Usual

Table 3   *ANOVA tables of mixed effects analysis*

		Treatment Effect			Time Effect			Interaction		
		df	F	p	df	F	p	df	F	p
Symptoms										
SCL-90		(1,148)	0.57	0.45	(3,379)	31.5	< 0.001	(3,379)	0.13	0.90
	Depression	(1,148)	0.63	0.42	(3,379)	41.5	< 0.001	(3,379)	0.33	0.80
	Anxiety	(1,148)	1.17	0.28	(3,379)	21.1	< 0.001	(3,379)	0.14	0.93
BDI		(1,148)	0.183	0.67	(3,379)	26.3	< 0.001	(3,379)	0.38	0.77
STAI	*State Anxiety*	(1,147)	1.86	0.18	(3,375)	15.5	< 0.001	(3,375)	0.47	0.70
	Trait Anxiety	(1,147)	2.18	0.14	(3,375)	35.0	< 0.001	(3,375)	0.93	0.42
Social functioning										
GSDS	Mean total score	(1,148)	0.20	0.66	(2,248)	24.5	< 0.001	(2,248)	0.27	0.76
Quality of Life										
WHO-QoL	Total score	(1,148)	10.5	0.21	(3,379)	18.1	< 0.001	(3,379)	0.43	0.73
	physical health	(1,148)	0.61	0.43	(3,379)	35.3	< 0.001	(3,379)	0.83	0.47
	psychological health	(1,148)	0.02	0.87	(3,379)	15.3	< 0.001	(3,379)	0.54	0.66
	social relationships	(1,148)	1.5	0.21	(3,379)	6.2	< 0.001	(3,379)	0.50	0.21
	environmental	(1,148)	5.3	< 0.05	(3,379)	4.5	< 0.01	(3,379)	1.6	0.19

SCL-90:   Symptom Checklist
BDI: Beck Depression Inventory
STAI: State-Trait Anxiety Inventory
GSDS: Groningen Social Disabilities Schedule
WHOQoL: WHO Quality of Life

Mixed effects analyses of the symptom ratings included a random effect of subject, and were corrected for differences at baseline by means of covariance adjustment.

The difference was still significant at the last six months follow-up (T= -2.020, df=119, p=0.046) when all contacts within the CST programme, including course and self-therapy meetings, were taken into account. During the total study period 11 (15%) patients on TAU and 4 (5%) patients on CST needed full or partial

Table 4   *Social functioning measurements (GSDS):*
Subscales

	Treatment Effect [1]			Time Effect [2]		
	timepoint	*Mann-Whitney U*	*p*	*treatment*	*Kruskal-Wallis* $c^2(df=2)$	*p*
Self-care	12 months	2021	0.88	TAU	5.68	0.06
	18 months	2065	0.36	CST	9.90	< 0.01
Family role	12 months	2151	0.57	TAU	0.33	0.84
	18 months	2296	0.36	CST	11.52	< 0.01
Kinship role	12 months	2217	0.07	TAU	2.20	0.33
	18 months	1982	0.28	CST	9.83	< 0.01
Partner role	12 months	1847	0.35	TAU	6.92	< 0.05
	18 months	1864	0.88	CST	2.39	0.30
Parent role	12 months	779	0.96	TAU	0.79	0.67
	18 months	724	0.58	CST	2.02	0.36
Citizen role	12 months	1719	0.08	TAU	12.30	< 0.01
	18 months	1641	0.12	CST	2.11	0.35
Social role	12 months	2018	0.87	TAU	2.02	0.36
	18 months	1839	0.63	CST	0.49	0.78
Work role	12 months	1716	0.10	TAU	34.7	< 0.001
	18 months	1883	0.84	CST	23.7	< 0.001

GSDS: Groningen Social Disabilities Schedule
[1] Mann-Whitney U-tests of change from baseline scores, testing treatment effects on each separate timepoint.
[2] Kruskal-Wallis tests of change from baseline scores, testing time effects within each treatment condition.

hospitalisation. This was a significant difference (T=2.241; df=149; p<0.05). Four patients on TAU were admitted twice, which increased the total number of hospitalisations to 15 for the TAU group. No suicides occurred in either condition.

Evaluation of the Cognitive Self-Therapy programme
A total of 68 patients (91%) out of 75 that were included in the CST condition entered the preparatory phase of the CST programme. As there are several points at which patients can leave the CST programme, we consider patients to be non-adherent when leaving during the preparatory or orientation phase. If patients do not continue the programme we consider them not trained and competent to perform a CST session with peers. In those patients, no treatment results were supposed to have occurred due to CST. Thirteen patients stopped before and 23 during the orientation

course (considered as non-adherent), including the four patients who needed hospitalisation. Thirty-two patients completed the basic course, with 19 patients attending between one and 24 self-therapy meetings. Attendance on all days of the basic course is conditional before patients are allowed to attend self-therapy meetings. Only patients who have completed the basis course will have sufficiently learned all the techniques that are needed to perform CST sessions safely in a reciprocal relationship with peers during self-supported meetings. If necessary, patients who did not adhere to the programme followed TAU. Adherence to the CST programme was not related to any baseline characteristics.

DISCUSSION

The effectiveness of a highly structured self-therapy programme based on cognitive behavioural and interpersonal therapy principles in terms of symptoms, social functioning and quality of life, was not significantly different from treatment as usual. On the main outcome of anxiety and depression (SCL-90) we expected clinical superiority for CST, based on our experiences with a preceding observational follow-up study among 69 patients, but this effect did not occur. Patients with chronic and remittent depression and anxiety disorders appeared to improve equally and significantly over time in both treatment conditions. However, CST patients had less co-morbid disorders, less medical care utilisation, and the GSDS subscales of self-care, family role and kinship role improved significantly after 18 months. This was in accordance with the aim of the CST programme which is aimed at self-control over the treatment and restructuring cognitive schemata by focusing on problems in social functioning and relationships.

The study had some strong aspects but also limitations. The adherence rate for CST about 50% (left the programme before or at the end of the orientation course) is on top of the range that is generally observed for psychotherapy or medication in the treatment of depression and anxiety disorders (Marks, 2002). However, it was higher than the adherence rate for the observational study (27%). It is unlikely that this was due to patient characteristics measured at baseline. The adherence rate might be explained by the presumed conflicting contrast of the research paradigm of randomisation and the paradigm of self-control and empowerment of self-help groups (Goldklang, 1991; Humphreys & Rappaport, 1994). Moreover, the dependent nature of the patient-therapist relationship in usual treatment and the implicit expectancy of the therapist, reinforce compliance, while

during each phase of the CST programme patients were asked whether they were willing to continue to the next phase. The contrast of research and treatment paradigms may have influenced the results to the disadvantage of the CST condition. Nevertheless, non-adherence occurred mainly in the introduction phase of the programme, indicating that the CST programme resulted in a strong selection procedure within a relatively short time, thus preventing both patients and therapists from making a huge investment in a treatment that probably would not work at that time for those patients. Another limitation was a significant between-group difference at baseline for the main outcome measure (SCL-90) as well as for the use of psychiatric medication, both favouring patients in the CST group. It is possible that baseline differences on the SCL-90 were due to the wide range of psychopathology that is included in the SCL-90, and that also for this reason treatment differences on anxiety and depression were masked. A control condition comparison was not part of the study design. No observer-rated measures were used to assess symptom outcomes with the exception of the assessment of diagnosis (World Health Organization, 1992) and social role functioning (GSDS). The GSDS was not blinded at follow-up assessment. Sensitivity analysis on the results of a meta-analysis of self-help has revealed that the sole use of observer-rated measures for recomputation would have improved the results of self-help (Den Boer et al, 2004), suggesting that self-rater bias might have disadvantaged the CST programme. As the sample concerned a severely ill patient population, standardised treatment was no option. Therefore, specification of the proportion of cognitive behavioural therapy and interpersonal therapy cannot be provided. The first author was one of the developers of CST, but was not involved in patient care neither in the assessments.

Strengths of the study were a moderately sized sample of 151 patients, recruited from four mental health care centres without any between-centre differences or effects, the study duration of 18 months, the relatively low rate of non-eligible cases and the low percentage of drop-outs from the study. Clinically relevant patients who had been referred to the participating mental health care centres, with on average a high mean symptom level, co-morbidity and low social functioning, were included. These aspects, the intention-to-treat analysis and the naturalistic design of the treatment conditions argue in favour of the generalisability of the study results.

Evidence-based treatment strategies for the treatment of chronic and remittent depression and anxiety disorders cannot be

recommended univocally by applying guidelines, although continuous treatment is considered important (American Psychiatric Association, 2000). Many patients with depression and generalised anxiety disorders may experience improvement, but few become asymptomatic after treatment with empirically supported therapies. A substantial number of patients continue to be highly symptomatic. Most treatments for depression in naturalistic samples take between six months for cognitive behavioural therapy and up to two years for other forms of therapy, while treatment length doubles across therapeutic modalities in the presence of co-morbid conditions (Westen *et al*, 2001). After completing the basic course within a six-month CST programme, patients are free to attend CST meetings as long as is necessary. Despite the relatively high non-adherence, the CST programme that integrates manuals, course and paraprofessionals is likely to reduce utilisation of care. Self-administered treatments are mainly used as first order treatment (Scogin *et al*, 2003) in a stepped care model of treatment of depression. Professionals are needed whenever motivation and self-control are lacking. But, as soon as behaviour has come under self-control and the patient acknowledges the need for support or the need to cope with symptoms or dysfunctional cognitions, the appropriate non-professional alternatives may be offered. Guided self-help and coping with symptoms course may be supplied when the primary focus is improvement of coping with depression and/or anxiety. Cognitive self-therapy may be supplied when patients recognise their vulnerability due to cognitive styles that are supposed to underly depression and anxiety. The results of this study may contribute to the discussion of the integration of self-help and paraprofessionals in treatment programmes for patients with chronic and remittent depression and anxiety disorder in all phases of the disease.

CST shares the theoretical basis of treatment as usual when cognitive behavioural therapy was supplied. However, each CST session explicitly seeks to restructure cognitive schemata by focusing on problems in social functioning and relationship, exploring a recent life event and associated past life and childhood event. Patients themselves choose the themes. By means of those sessions, cognitive restructuring becomes part of their psychological skills repertory. Neither professionals nor helping peers actively challenge patient's maladaptive cognitions. As distinctions between childish and mature events are analysed, adaptive cognitions become aware. The treatment process already begins during the training phase and continues as long as

participants attend self-therapy meetings. Meanwhile most think of self-help as being more appropriate for mild to moderate first episode depression and anxiety disorders, a previous longitudinal (unpublished) study and this study show that CST is acceptable and feasible for a moderately to severely ill patient population with chronic depression and anxiety. We think that this is due to patient's self-control over the treatment process. CST shares the principles of self-help and user led groups during the fourth phase of the programme and may use minimal professional contact when needed. CST differs significantly from other non-professional alternatives such that participants are trained to cope with those standardised sessions in a reciprocal relationship with peers.

Implications for research
This study focussed on the more chronically and severely ill patients with emotional disorders. Treatment of mild cases might prevent a substantial proportion of them from becoming more severely ill in the future (Kessler *et al*, 2003). Primary care patients may benefit of alternative treatment programmes including minimal professional contact such as minimal-contact psychotherapy (Willemse *et al*, 2004) and internet-based therapy (Anderson *et al*. 2005). A controlled trial with long-term follow-up is needed to assess the preventive and cost-effective potential of the CST programme in treating first episode non-psychotic depression and anxiety disorders.
The study sample showed high co-morbidity, high symptom levels and low social functioning, none of which was predictive of unfavourable outcomes for the CST programme – even though these factors are generally supposed to predict less favourable outcomes for the treatment of depression and anxiety disorders (Ezquiaga *et al*, 1998; Kersnik *et al*, 2001; Merikangas *et al*, 2003). Comparison of the CST programme with interventions that are already widely accepted as first choice treatments for mild to moderate depressive and anxiety disorders (e.g., cognitive behavioural therapy and interpersonal therapy) in order to examine predictive factors would be worthwhile. Personality factors and cognitive styles are aspects that should be taken into account. Personality disorders are known to predict poor outcomes in depressive disorders (Shea *et al*, 1990; Tyrer *et al*, 1993). A follow-up duration of two years or more would be preferable because both personality and depressive disorders require long-term treatment. Results must be evaluated with blinded observer-rated measures when self-report measures are used.

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Cost-effectiveness of cognitive self-therapy for depression and anxiety disorders

A. Dennis Stant, Els M. ten Vergert, Peter C.A.M. den Boer & Durk Wiersma
Submitted

Abstract

Background: Self-therapy interventions could potentially reduce expenses in the treatment of depression and anxiety disorders, but have rarely been examined in economic evaluations. Aims: To assess the cost-effectiveness of Cognitive Self-therapy (CST) in patients with depression and anxiety disorders.
Methods: 151 patients were randomly assigned to CST or treatment as usual (TAU) and prospectively followed during 18 months. The SCL-90 was the primary outcome measure in the cost-effectiveness analysis. Uncertainty surrounding the economic analyses was addressed by the bootstrap method and related analyses.
Results: Mean costs of patients in the CST group (€4389) were lower than the mean costs of patients who received TAU (€4837). Results of the SCL-90 were slightly in favour of CST. Additional analyses indicated that CST dominated TAU in 44% of the bootstrap replications.
Conclusions: Differences in costs and health outcomes between CST and TAU were modest. Valuing an additional unit of health outcome at €300 will lead to a 74% probability that CST is cost-effective.

INTRODUCTION

Many patients suffering from depression or anxiety disorders can not adequately be treated within current European healthcare systems (Bebbington *et al*, 1997). The number of available therapists is limited and unable to meet the extensive need for care. Unfortunately, the consequences of inadequate treatment of mental illness can be serious, both for the well-being of patients as for national healthcare expenses, especially in case of recurring or chronic mental disorders (Chisholm *et al*, 2004, Barrett *et al*, 2005).

Various studies have indicated that self-help strategies can form an effective alternative for treatment provided by therapists, also in patients with depression or anxiety disorders (Den Boer *et al*, 2004). For policy makers, the potential cost savings associated with such self-help strategies are particularly interesting as well. However, only a limited number of studies analysed both costs and health outcomes of self-help strategies aimed at emotional disorders, and the methodological quality of published studies has been questioned (Bower *et al*, 2001). The study presented in the current paper assessed the cost-effectiveness of cognitive self-therapy (CST) in patients with depression and anxiety disorders.

METHODS

The economic evaluation was part of an 18-month clinical study on the effectiveness of CST in patients with depression and anxiety disorders. Details on the design of the clinical study are provided elsewhere (Chapter 5 this thesis; submitted).

Study population
Recruitment of patients took place between 2000 and 2002 in four outpatient centres located in different parts of The Netherlands. Patients were eligible for the study if they had a diagnosis of depression or generalised anxiety disorder. Additional selection criteria included a history of mental health care utilisation of at least two years, aged between 18 and 65, and an awareness of personal vulnerability in social contacts and/or relationships. Patients were excluded if they displayed suicidal behaviour or psychotic symptoms, had a comorbid diagnosis within the autistic spectrum or an organic disorder, were drug or alcohol dependent, or mentally handicapped (IQ<85).

Randomisation procedure and interventions
Stratified randomisation was applied to ensure the comparability of patient groups. Strata were based on age; <40 years of age or >=40 years of age, and duration of complaints; <7 years or >= 7 years. Patients were randomly assigned to two intervention arms, treatment as usual (TAU) or CST. Both interventions were provided in outpatient centres and included a first contact for diagnostic purposes. During the study, patients received any form of regular care they required in addition to the care provided in the interventions.
TAU consisted of 10-20 contacts with a psychologist, psychiatric nurse or social worker during the first six months after inclusion. During these contacts, therapists mainly focused on problem solving and coping strategies, but they did not follow a prescribed treatment protocol.
CST is a structured method primarily aimed at restructuring cognitive schemata and addressing problems in social functioning and relationships. The CST programme consists of: 1) Preparatory Phase of one to three 45 minute meetings, for informing the patient and for checking whether the patient is able and willing to participate in the CST-course; 2) Orientation Course (OC) of three mornings, once a week, during which the patients practice with peers, before definitely making the choice to continue with the next phase; 3) Basic Course (BC) of 5 days, once a week, in which patients learn to manage a CST-session. Those who perform a CST-session adequately with peers will become certified to participate in the last phase of the CST-programme: 4) Self-Therapy meetings (ST), once a week, led by peers in accordance with the manual as was taught during the BC. All certified patients have the free choice of participation in ST whenever they like and could attend these meetings during the study period. Before the beginning of the

study, the CST programme was uniformly implemented in all participating centres.

Outcome measures and power analysis
The Symptom Checklist 90 (SCL-90; McKinnon *et al*, 1986) was the main outcome measure of the study. The SCL-90 is a multi-dimensional self-report inventory that can identify psychological problems and symptoms of psychopathology. The total score on the SCL-90 is based on nine subscales and can range from 90 – 450, where lower scores indicate better functioning. Power analyses were based on characteristics of this instrument; 61 patients were required in each treatment condition in order to detect a clinically relevant difference of 23 points between groups (SD=50) with an alpha of .05 and a power of 80%. In total 151 patients were included in the study to account for an estimated drop-out rate of 20%. Measurement took place at six-month intervals, starting at the time of inclusion until the end of the follow-up period 18 months later.
Various additional instruments were administered during the clinical study, focusing on depressive symptoms (Beck Depression Inventory; Beck *et al*, 1993), social anxiety (State-Trait Anxiety Inventory; Spielberger *et al*, 1970), social functioning (Groningen Social Disabilities Schedule; Wiersma *et al*, 1988) and quality of life (World Health Organization Quality of Life Assessment-bref; WHOQoL group, 1998). Results of these additional instruments could not directly be included in the economic evaluation due to the theoretical framework of cost-effectiveness analysis, which requires the inclusion of one outcome measure.

Costs and unit prices
The economic evaluation was conducted from a societal perspective, costs were assessed both within and outside the healthcare sector. Table 1 shows the various types of costs that were registered during the 18 months of the study.
Costs of CST included costs of therapists who were training, educating and supporting patients during the various stages of the CST programme. Furthermore, therapists had to be trained in CST and supervised themselves as well. Since therapists involved in the study also treated patients outside the study with CST, costs of training and supervising therapists were corrected accordingly (25% of total training and supervision costs were included in the current study). Costs of travelling and invested time related to the CST meetings were registered during the study. Costs of invested time were valued in monetary terms based on the net income of a

Table 1 *Registered medical and non-medical costs*

Direct medical costs	Direct non-medical costs	Indirect non-medical costs
CST [1]	Travel costs	Productivity losses with and without absence from work
Inpatient and semi-inpatient care	Time costs	
Outpatient and community care	Informal care	
General health care	Out-of-pocket costs	
Day activity institutions		
Medication		

[1] Cognitive self-therapy (training/supervision therapists, therapy/training patients)

patient during that time. Costs of informal care were based on the monetary valuation of the time invested by relatives or acquaintances in helping or assisting the patient. Additional costs related to the illness, like costs of non-prescribed medication, are combined under the heading out-of-pocket costs. The friction cost method (Koopmanschap *et al*, 1995) was applied for estimating costs associated with productivity losses, both for sickness-related absence from work and decreased productivity without absence. Productivity costs were based on the net income of the patient during the time of absence or duration of decreased productivity. Quantities of used resources were registered for all the patients available at the various times of measurement. The information on costs was primarily collected by means of a questionnaire frequently used in economic evaluations in mental health care, which was slightly adjusted to the current situation. This questionnaire assessed, among others, number of admissions to psychiatric hospitals, contacts with psychiatrists and psychologists, and sick leave days of patients. Additional information, like medication use, was collected through various healthcare professionals. In order to facilitate comparisons with other economic evaluations, unit prices, i.e. the price of one unit of each included cost type (available on request), were mainly based on Dutch standard prices (Oostenbrink *et al*, 2000). True costs of used resources were estimated when standard prices were not

available. All unit prices were based on the price level of the Euro in the year 2003. Reference prices established for previous years were adjusted to prices of 2003 by applying the consumer price index.

Cost-effectiveness analysis

In cost-effectiveness analysis, costs and the primary health outcome associated with an intervention are used to calculate the incremental cost-effectiveness ratio relative to one or more alternatives (Drummond *et al.* 1997). In the present study, costs and health outcomes of patients who received CST were compared with those of patients in the TAU condition. Primary outcome measure in the cost-effectiveness analysis was the SCL-90, the instrument on which power analyses of the clinical study were based.

Costs per point improvement on the SCL-90 were expressed by the incremental cost-effectiveness ratio (ICER):

$$ICER = \frac{(C_{CST} - C_{TAU})}{(SCL90_{CST} - SCL90_{TAU})}$$

Where
C_{CST} = mean costs per patient in the CST-group
C_{TAU} = mean costs per patient in the TAU-group
$SCL90_{CST}$ = mean SCL-90 difference score in the CST-group
$SCL90_{TAU}$ = mean SCL-90 difference score in the TAU-group

Costs and health outcomes were not discounted in the current study, since discounting would have had a minor influence on differences between groups in the present study of 18 months. Uncertainty surrounding the calculated ICER was examined by the bootstrap method (Efron *et al*, 1993). Bootstrapping is an iterative method that consists of randomly selecting patient data (with replacement) from the observed population to create a simulated distribution of data. ICERs were calculated for each of the bootstrap iterations (2000 in the present study), simulated values of the mean estimates for the cost and outcome differences were added to the cost-effectiveness plane (Black, 1990). Finally, cost-effectiveness acceptability curves (CEACs) (Van Hout *et al.* 1994; Fenwick *et al.* 2004) were calculated. CEACs inform policy makers on the probability that an intervention will be cost-effective for

various monetary values placed by decision-makers (or society) on an additional unit of health outcome.

Sensitivity analysis
Various sensitivity analyses were performed in order to provide information on the robustness of the results of the economic evaluation. Cost variables with a considerable contribution to total costs were identified (at least 5% of total costs in both groups). These identified costs were increased with 20% in one of the intervention arms, while at the same time being decreased with 20% in the other. Subsequently, consequences for differences in total costs between groups were analysed. Additional sensitivity analyses focused on variations in cost components of the CST intervention.

Missing data and statistical analysis
Results of longitudinal studies can be biased by missing data due to patients who drop out or are lost to follow-up, especially if their missingness is not completely at random (Little & Rubin, 1987). Recently, the potential impact of missing data has also been acknowledged in the area of economic evaluation (Briggs *et al*, 2003). In the current study, the influence of missing data was examined by comparing the results of two different methods. Standard analyses were based on complete cases: patients for whom all the cost and effectiveness data could be registered at the various times of measurement. In addition, the expectation maximisation (EM) algorithm with a bootstrap approach (Oostenbrink & Al, in press) was applied as an alternative method of analysis to include patients for whom not all the data were available at the various assessments. In this alternative method of analysis, the bootstrap method was used to create 2000 simulated patient populations, including patients with missing data. Subsequently, the EM-algorithm was applied for each of these 2000 data sets. The EM algorithm consists of an iterative process, estimating values for missing data based on the observed data. Finally, outcomes of these 2000 derived data sets were combined to estimate overall parameters, for instance overall means and confidence intervals.
Standard statistical analyses were conducted with SPSS for Windows (version 12.0.2, SPSS Inc, Illinois, USA). Significance tests for the differences in mean total costs between groups were conducted by means of 95% confidence intervals generated by the bootstrap method, due to the (expected) non-normality of the cost

data. The Student's t-test for independent samples was used for testing differences and difference scores on the SCL-90.

RESULTS

Results of the economic evaluation are mainly based on 120 patients for whom all relevant data could be registered (79% of 151 included patients), 61 in the CST group (81% of 75 included patients) and 59 in the TAU group (78% of 76 included patients). Details on drop-outs and their influence on the results are described in the section on missing data.

Patients
The CST group consisted of 45 women and 16 men with a mean age of 42.0 years (SD=8.9). The TAU group consisted of 37 women and 22 men with a mean age of 42.8 years (SD=8.6). Main diagnoses in both groups were unipolar depressive disorder (86.9% in CST, 93.2% in TAU), generalised anxiety disorder (9.8% in CST, 1.7% in TAU), and dysthymic disorder (3.3% in CST, 5.1% in TAU). Approximately half of the patients had a comorbid diagnosis of generalised anxiety disorder (18.0% in CST, 30.5% in TAU) or another anxiety disorder (23.0% in CST, 20.3% in TAU). The number of years since first contact with mental health care was 11.4 years (SD = 8.3) in the CST group and 11.6 years (SD = 8.1) in the TAU group. At the time of inclusion, there were no statistically significant differences between groups on the described demographic and clinical characteristics.

Service use and costs
Table 2 shows information on service use and medical costs. Means of each cost type are based on all patients in both groups. If a patient did not make use of a specific cost type, costs of €0 were applied when calculating group means. In addition, mean costs and number of patients who actually used the health services are presented as well.
Medical costs of the CST intervention were € 684 per patient and consisted of costs associated with therapy and support provided to patients, as well as initial costs of training and supervising therapists. Costs of psychiatric hospital admissions, medication use and 'other out-patient care' contributed substantially to total medical costs in both groups. 'Other out-patient care' consisted of various types of treatment, including group therapy and social skills training. Costs outside the health care sector are displayed in Table 3.

Travel costs and costs of invested time were only assessed when directly related to the CST intervention. The estimated costs of invested time by patients in the CST group were substantial. Time costs will be further addressed in sensitivity analyses, since the applied method (net income of the patient during the time spent in CST meetings) may have overestimated actual time costs. Costs related to productivity losses, with and without absence from work, were high in both groups.

An overview of total costs during each measurement period and total costs during the 18 months of the study is presented in Table 4.

Costs during T0-T6 were relatively high in the CST condition due to the initial costs of CST, which included the training of therapists. During T6-T12, total costs in the CST group were significantly lower, partially related to a decreased use of health care services. In the last six months of the study, total costs slowly increased again for patients in the CST group. For patients in the TAU group, there was little variation in total costs during the study.

Mean total costs during the entire study period were €4389 per patient in de CST group (median costs €2615) and €4837 per patient in de TAU group (median costs €2511). Differences in mean total costs between groups were tested by 95% confidence intervals (CI) generated by the bootstrap method. Differences in mean total costs during the 18 months of the study were not statistically significant (95% CI lower boundary: -€3294; upper boundary: +€1886). The fact that no significant differences in total costs between groups were found should be interpreted with caution, since the study was powered (as most economic evaluations) to demonstrate differences in health outcomes and not costs.

Primary health outcome
T0 and T18 results of the SCL-90, the primary outcome measure, are displayed in Table 5.
Lower scores on this instrument represent better functioning. Differences between groups were not statistically significant at the various times of measurement. Difference scores were calculated by subtracting T18 results from T0 results in both groups. Differences in these calculated difference scores were not statistically significant (t=.59, p=.56). More extensive outcome analyses are described elsewhere (Den Boer *et al, this issue of BJP*).

Table 2   *Medical costs (€) during T0-T18*

Health care services and cost types	CST group (n=61)		TAU group (n=59)	
	Mean costs whole group (SD)	Mean costs[1] (<u>N</u>)	Mean costs whole group (SD)	Mean costs[1] (<u>N</u>)
CST				
Training/supervision therapists	361 (-)	361 (61)	-	-
Therapy/training patients	323 (245)	352 (56)	-	-
In-patient and semi-inpatient care				
Psychiatric hospital admission	671 (3717)	20474 (2)	1546 (7445)	18247 (5)
Day care	1 (11)	88 (1)	84 (353)	1236 (4)
Outpatient and community care				
Psychiatrist	70 (129)	157 (27)	82 (139)	194 (25)
Psychologist	143 (212)	265 (33)	186 (324)	422 (26)
Social psychiatric nurse	57 (117)	175 (20)	134 (240)	343 (23)
Social worker	22 (73)	133 (10)	56 (134)	220 (15)
Crisis intervention	2 (18)	139 (1)	5 (25)	139 (2)
Psychiatric home care	9 (67)	523 (1)	33 (253)	1944 (1)
CAD[2]	0 (-)	0 (0)	0 (-)	0 (0)
Other out-patient care	249 (641)	893 (17)	813 (995)	1263 (38)
General health care				
General practitioner	76 (182)	111 (42)	44 (97)	89 (29)
Alternative health care	22 (68)	190 (7)	27 (123)	319 (5)
Home care	3 (13)	51 (3)	3 (13)	46 (4)
Emergency care	0 (-)	0 (0)	0 (-)	0 (0)
Other general health care	23 (109)	205 (7)	18 (68)	155 (7)
Day activity institutions				
Day activity center	29 (171)	894 (2)	0 (-)	0 (0)
Other day activity institutions	0 (-)	0 (0)	0 (-)	0 (0)
Medication				
Prescribed medication	256 (312)	363 (43)	437 (467)	537 (48)

CST = Cognitive Self-Therapy; TAU = Treatment As Usual

[1] Mean costs of persons using the health services and cost types involved (number of patients using these services between brackets)

[2] Consultation office for alcohol and drugs addiction

Table 3   *Direct and indirect non-medical costs (€) during T0-T18*

Services and cost types	CST group (n=61)		TAU group (n=59)	
	Mean costs whole group (SD)	Mean costs[1] (<u>N</u>)	Mean costs whole group (SD)	Mean costs[1] (<u>N</u>)
Direct non-medical costs				
Travel costs	17 (24)	25 (42)	-	-
Time costs	420 (403)	458 (56)	-	-
Informal care	16 (40)	97 (10)	7 (22)	53 (8)
Out-of-pocket costs	53 (157)	248 (13)	42 (136)	191 (13)
Indirect non-medical costs				
Productivity losses with absence from work	1335 (2849)	4073 (20)	935 (1721)	2509 (22)
Productivity losses without absence from work	229 (1613)	4662 (3)	384 (1691)	2519 (9)

CST = Cognitive Self-Therapy; TAU = Treatment As Usual

[1] Mean costs of persons using the health services and cost types involved (number of patients using these services between brackets)

Cost-effectiveness analysis
The point esti mate of the ICER and the results of the bootstrap analyses are graphically presented in the cost-effectiveness plane (CEP) in Figure 1. The calculated value of the ICER was –€80 per point improvement on the SCL-90. Here, the negative value indicates that CST was associated with lower mean costs (- €448) and better health outcomes (mean positive difference of 5.6 points on the SCL-90).
For each quadrant of the CEP, information is provided on the percentage of bootstrap simulations located in that quadrant. Approximately 44% of the ICERs simulated by the bootstrap method are located in the southeast quadrant. In other words, CST dominates TAU in 44% of the cases. Interpretation of outcomes in the northeast and southwest quadrants depends on how much

decision-makers are willing to pay for an additional unit of health outcome in the observed patient population.

Table 4   *Total costs (€) during the study*

Time interval	CST group (n=61)		TAU group (n=59)		95% CI[1]
	Mean	Median	Mean	Median	
T0-T6	2460	1558	1652	1021	-€58, +1834
T6-T12	789	524	1470	729	-€1396, -€64
T12-T18	1139	356	1714	411	-€2561, +€925
T0-T18	4389	2615	4837	2511	-€3294, +€1886

CST = Cognitive Self-Therapy; TAU = Treatment As Usual

[1] 95% confidence interval of the mean cost differences between groups, generated by the bootstrap method. Lower and upper boundaries are presented

Table 5   *Results of the SCL-90*

Assessment	CST group (n=61)	TAU group (n=59)	T-test
T0	220	236	p=.10
T18	178	200	p=.09
Difference score [1]	41	36	p=.56

CST = Cognitive Self-Therapy; TAU = Treatment As Usual

[1] Calculated difference scores on the SCL-90 were multiplied with −1 to represent improved functioning by positive difference scores, which enhances interpretation of the outcomes

Figure 1 *Point estimate of the ICER and bootstrap results*
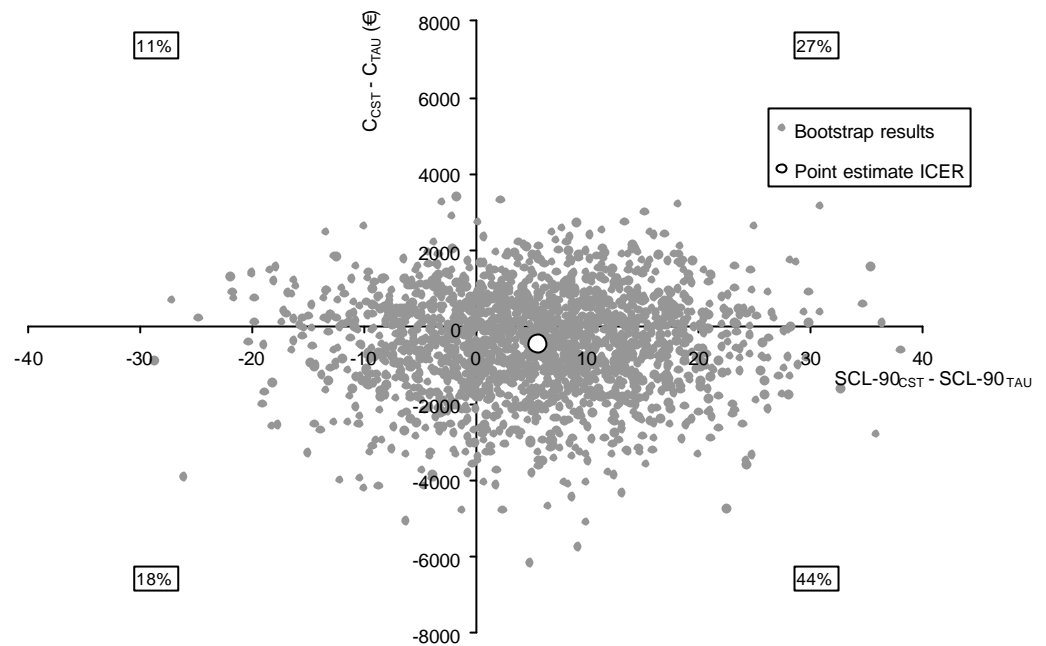
Figure 2 shows the probability that CST will be cost-effective for increasing monetary values placed on an additional unit of health outcome. When decision-makers are willing to pay €300 per point improvement on the SCL-90, the probability that CST will be cost-effective increases up to 74%, and subsequently slowly decreases.

Sensitivity analyses
Cost types that contributed considerably to the total amount of costs were first identified (at least 5% of total costs). These consisted of costs associated with psychiatric hospital admissions, medication use, 'other outpatient care' and productivity losses (with and without absence from work). The identified cost types were increased with 20% in one of the groups, while at the same time being decreased with 20% in the other group. Subsequently, the consequences of these variations for differences in total costs between groups were analysed. A significant difference in favour of TAU was found when the identified costs in the CST group were increased while these costs were at the same time decreased in the TAU condition. This finding could be explained by the fact that the

Figure 2   *Cost-effectiveness acceptability curve*
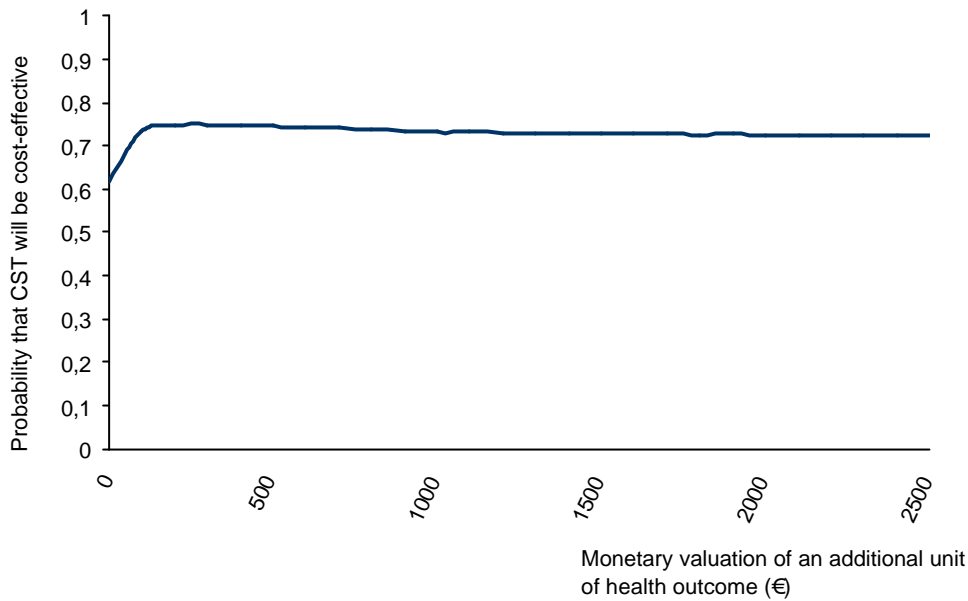
identified cost types in the TAU condition contributed more strongly to the total amount of costs than in the CST group. Additional sensitivity analyses focused on variations of cost components of the CST intervention. In these analyses, 50% of the originally estimated time and travel costs were included. Furthermore, the influence of including 10% instead of 25% of total training and supervision costs in the economic analysis was examined. This lower percentage might better reflect true costs of training and supervising therapists when CST would have been fully implemented in the health care system. In these sensitivity analyses, medical costs of the CST intervention per patient were €467 instead of €684. Travel and time costs associated with CST were €219 instead of €437. Consequently, mean total costs in the CST group were €3954, which did not differ significantly from unchanged mean total costs in the TAU condition.

Missing data
The results presented in the economic evaluation were based on patients for whom all the cost and effectiveness data could be registered (81% of included patients in the CST, 78% of included

patients in the TAU group). Alternatively, the EM algorithm with a bootstrap approach was applied to examine the influence of patients who were lost to follow-up. These analyses were based on patients for whom cost and health outcomes were available for at least one of the times of measurement, which was the case for 70 patients in both groups (93% and 92% of included patients in the CST and TAU group, respectively). Outcomes of the standard analyses and the EM algorithm with bootstrap approach are presented as point estimates of ICERs and 95% confidence ellipses in Figure 3.

Figure 3   *95% confidence ellipses (CE) of the 'standard analyses' and the 'EM algorithm with bootstrap approach' together with the calculated point estimates of the ICERs*
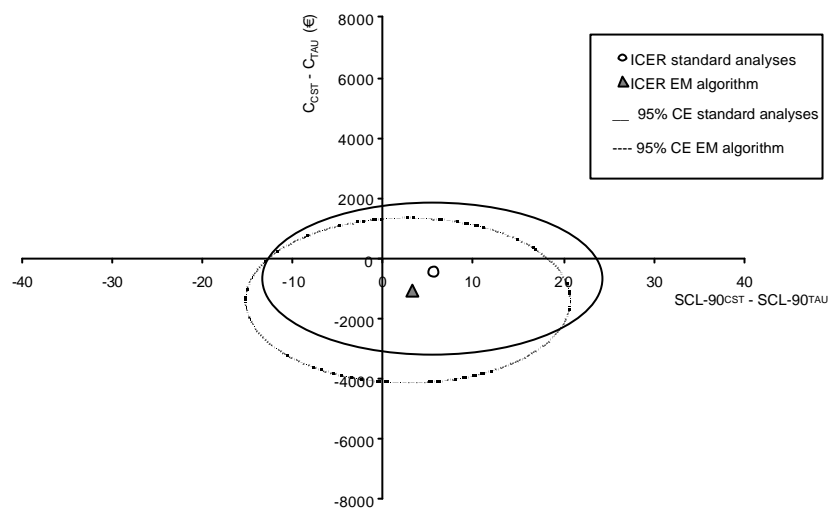
There appear to be some differences between these methods of analysis. When including patients who were lost to follow-up in the alternative analyses, costs are more in favour of CST (a mean difference between groups of -€1058 instead of -€448), while differences in SCL-90 scores somewhat decrease (a mean difference of 3.3 of instead of 5.6).

DISCUSSION

The current paper presented the results of the cost-effectiveness analysis that was part of an 18-month clinical study focusing on CST in patients with depression and anxiety disorders. A

comparison was made between costs and health outcomes of patients who were randomly assigned to one of two treatment conditions, CST or TAU. Overall results indicated that there were modest differences in costs and health outcomes between CST and TAU.

Costs in and outside the health care sector were registered and included in the cost analysis. Mean total costs of patients in the CST group were €4389 versus €4837 in the TAU group.

Costs of providing the CST intervention were estimated at €1121 per patient (included in the total costs of €4389), consisting of initial costs of training therapists and providing therapy to patients (€684), as well as travel and time costs of patients directly related to the CST meetings (€437). Cost types that contributed considerably to the total amount of costs were costs of hospital admissions, medication use, and 'other out-patient care'. Furthermore, costs related to productivity losses with or without absence from work were particularly high, which is in line with the results of previous studies examining (societal) costs of patients with depression or anxiety disorders (Simon *et al*, 1995; Wittchen, 2002).

The primary outcome measure of the cost-effectiveness analysis was the SCL-90. Difference scores were calculated in both groups based on measurements at the time of randomisation and the end of the follow-up period. Differences between groups on the SCL-90 were much smaller than the assumed clinically relevant difference on which power analyses during the design phase of the study were based. The various instruments administered in addition to the SCL-90 showed results comparable with the primary outcome measure (Den Boer *et al, this issue of BJP*). The overall outcomes of these instruments, which measured depressive symptoms, social anxiety, social functioning and quality of life, demonstrated that there were no statistically significant differences between groups on these aspects of health. As indicated by a recent literature overview (Den Boer *et al*, 2004), self-help strategies are commonly associated with results that seem comparable to those of other treatments. Therefore, it may be more appropriate to design studies on self-help strategies, including economic evaluations, as non-inferiority or equivalence studies instead of superiority trials.

Although differences on the SCL-90 were not statistically significant at the time of inclusion for patients included in the economic analyses, patients in the TAU group did seem to be functioning worse despite the applied randomisation procedure (differences were statistically significant for patients initially included in the clinical analyses). It seems likely that these

differences between groups at the time of inclusion did not have direct consequences for the calculated effect differences, since health outcomes during the 18 months of the study were expressed by difference scores (T18-T0). Nevertheless, it may have affected bootstrap analyses, since patient groups included in bootstrap analyses are implicitly assumed to adequately represent the underlying patient population and should therefore be comparable at the beginning of a study.

Recent literature has questioned the relevance of applying standard statistical methods in economic evaluations to asses uncertainty (Hoch *et al*, 2002). In the current paper, the bootstrap method (Efron *et al*, 1993) was used to examine the uncertainty surrounding the economic analysis. Results of the 'EM algorithm with bootstrap approach', suggested that the applied complete case analysis may have underestimated cost differences between groups. It seems that economic analyses with a high percentage of patients dropping out of the study should more closely consider probable bias related to missingness. Cost-effectiveness acceptability curves were used to estimate the probability that CST will be cost-effective for increasing monetary investments per unit of health outcome gained, which is considered to be relevant information for decision-makers. Unfortunately, there is currently no consensus on acceptable benchmarks for an additional unit of health outcome, neither for generic outcomes as the QALY (Quality Adjusted Life Years) nor for more specific outcomes like the SCL-90 applied in the current study. Decision-makers will therefore have to judge whether the indicated prices per additional unit of health outcome seem acceptable or not.

Comparing the overall outcomes of the current cost-effectiveness analysis with other economic studies on self-help treatments is complicated because of the limited follow-up period of published studies. The time horizon of available studies typically ranges from 3 to 6 months (Bower, 2001). Conclusions based on such short study periods should be interpreted with caution. Especially since initial positive consequences of psychiatric interventions may diminish over time (Cooper *et al*, 2003). In order to adequately inform decision-makers, study periods of at least 12 to 18 months seem essential for economic studies, also in the field of mental health care.

To conclude, CST does not lead to clear differences in terms of costs or health outcomes in comparison with TAU in the current study population. The actual cost-effectiveness ratio was - €80 per point improvement on the SCL-90. Additional analyses indicated that if decision-makers are willing to pay €300 per point

improvement on the SCL-90, the probability that CST will be cost-effective increases to 74%. While the advantages of self-help strategies seem obvious, results of available economic studies, including the prese nt one, do not unambiguously confirm its potential benefits for the healthcare system in general, or healthcare expenses in particular. In terms of health outcomes, self-help strategies generally appear to be comparable with treatment provided by therapists. Interventions like CST could therefore be applied to relieve the burden of many patients with depression or anxiety disorders who currently do not receive the necessary care due to a limited number of available therapists. Future economic studies focusing on self-help strategies (for instance in patients with a first episode of depression) may profit from the suggestions made in the present paper, including the use of a non-inferiority design and a follow-up period of at least 12 to 18 months.

Clinical implications
- Differences between CST and TAU in terms of costs and health outcomes (SCL-90) were modest in the current study population.
- The calculated cost-effectiveness ratio was -€ 80 per point improvement on the SCL-90.
- The probability that CST will be cost-effective increases to approximately 74% when decision-makers are willing to pay €300 for an additional unit of health outcome.

Limitations
- The effectiveness of CST may have been overestimated when designing the study, a non-inferiority or equivalence design would have been more appropriate.
- Differences between groups on the SCL-90 at the time of inclusion were not statistically significant for patients included in the economic analyses, in contrast to patients included in the clinical analyses. Differences between groups at the time of inclusion may have affected bootstrap results.
- There is no consensus on acceptable benchmarks for an additional unit of health outcome, decision-makers will have to interpret and judge the information provided by the cost-effectiveness acceptability curve.

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Discussion

The hypotheses that have been examined and the results:

Chapter 2 **Why is self-help neglected in the treatment of emotional disorders? A meta-analysis.**

Hypotheses
Self-help strategies
e)   are as effective as professional treatment
f)   are more effective than no treatment
g)   the results are modified by the length of treatment or follow-up
h)   the results are modified by the severity of the illness.

Results
a)   Bibliotherapy may be as effective as professional treatment of relatively short duration (*ES*= -0.03)
b)   bibliotherapy is significantly more effective than placebo or waiting list (*ES*=0.84); exclusion of self-rated assessments improves the overall results of self-help
c)   a treatment period of 8 weeks or more seems to be somewhat more effective than a shorter treatment period
d)   severity of illness does not affect the results.

Chapter 3   Paraprofessionals for anxiety and depressive disorders. A meta-analysis.

Hypotheses
Paraprofessionals
e) are as effective as professionals
f) are more effective than no treatment
g) the results are modified by the length of treatment or follow-up
h) the results are modified by the severity of the illness.

Results
a) The few studies included in the review on paraprofessionals for anxiety and depressive disorders do not allow conclusions about the effect of paraprofessionals compared with professionals
b) three studies (women only) of moderate to high study quality show a significant effect for paraprofessionals (all volunteers) compared with no treatment (OR=0.30)
c) insufficient data is available for analysis
d) insufficient data is available for analysis.

Chapter 4   Cognitive self-therapy. Results of a pilot study of an alternative treatment for psychiatric patients.

Hypotheses
Cognitive self-therapy
d) is feasible to apply as a treatment programme for psychiatric patients
e) leads to symptom reduction
f) leads to improvement of social functioning.

Results
a) Patients, who attend the basic course and the self-therapy meetings, show a high degree of satisfaction (84%); 27% of patients drops out after the orientation course; in comparison with more traditional treatments, respondents say that more independence and personal responsibility is needed which in general has been highly appreciated
b) while symptom reduction is significant for the patients who have attended the basic course and for those who have then progressed to the self-therapy group, there is no significant symptom reduction in those patients who have only attended the orientation course

c) 72% tells that they can apply what they have learned in CST to their everyday lives; this is particularly true of the patients who have also taken part in the self-therapy meetings.

Chapter 5   **Cognitive self-therapy for chronic depression and anxiety. A multi-centre randomised controlled trial.**

Hypotheses
Cognitive self-therapy is more e ffective than treatment as usual with respect to
d) symptom reduction
e) improvement of social functioning and quality of life
f) reduction of mental care utilisation.

Results
a) All symptom measures (SCL-90, BDI, STAI) show a significant assessment time effect, but there are no differences between the treatment conditions; all these effects are favourable: later assessment times show lower scores for symptom measures
b) total social role functioning (GSDS) and the sub-scale 'work-role' reveal significant within-group improvement for both conditions, but there are no differences between the conditions; in the cognitive self-therapy group, the sub-scales 'self-care', 'family-role', and 'kinship-role' improve significantly; 'citizen-role' and 'partner role' improve for treatment as usual; quality of life (WHOQol) improves for both conditions, but no group differences nor interactions between treatment group and assessment time are found
c) cognitive self-therapy reduces mental health care utilisation (therapist contact and hospitalisation) when compared with treatment as usual.

Chapter 6   **Cost-effectiveness of cognitive self-therapy for depression and anxiety disorders.**

Hypothesis
Cognitive self-therapy is cost-effective compared with treatment as usual.
Results
Mean costs of patients in the cognitive self-therapy group (EUR 4389) are lower than the mean costs of patients who received treatment as usual (EUR 4837). Results of the SCL-90 are slightly

in favour of CST. Cognitive self-therapy has a high probability of being cost-effective for chronic emotional disorders.

DISCUSSION

The aim of the thesis was to evaluate the evidence regarding the effectiveness of self-help and paraprofessionals in general, and the effectiveness of a new cognitive self-therapy programme in particular, in the treatment of patients with chronic and remittent anxiety and depression disorders.

The evidence presented in two meta-analyses indicate that self-help oriented approaches are remarkably effective in patients with chronic and remittent disorders. Limitations of the meta-analysis were the varying quality of the included studies, the mainly small study samples and small to moderate numbers of included studies. On average, the duration of treatment and follow-up was short (<3 months), except for two studies on paraprofessionals (12 months). Mainly self-report measures were used, while blinded observer-rating scales are supposed to provide the least bias rating depressed patients (Möller 2000). Cost-analysis was not the aim of the meta-analyses. Moderate evidence (level 2: generally consistent findings in multiple low quality RCTs; (van Tulder *et al.* 2000)) exists for bibliotherapy and strong evidence (level 1: consistent findings in multiple high quality RCTs) for paraprofessionals that they are more effective than non-treatment. Studies on the effect of non-professional interventions compared to professional interventions might be especially sensitive to the occurrence of publication bias, because of the controversial objective caused by the predominant paradigm of professional care. If this means that studies, without positive outcome for the non-professional condition, were not published, than the results of our meta-analyses must be treated with more caution. Nevertheless, the results are promising for the range of sub-threshold to chronic emotional disorders. The results also indicate that more high quality research is desirable, with a long-term follow-up and the use of self-report and observer-rated measures to examine the (cost-) effectiveness of non-professional alternatives in the treatment of depressive and anxiety disorders.
The cognitive self-therapy programme is feasible to apply as a treatment programme for chronic depressive and (generalised) anxiety disorders, with a high probability that the programme will be cost-effective after 18 months treatment duration. It is hard to

say what kind of consequence the baseline difference, found between the conditions of the cognitive self-therapy trial, has had for the final results of the study. We did not expect to find no differences between cognitive self-therapy and treatment as usual on the main outcome measure (SCL-90). Nor did we expect such a moderately to severely ill patient population. The sample of the complete case analysis (n=120) of the cost-evaluation may differ from the intention-to-treat sample of all cases (n=151) in the clinical evaluation of the cognitive self-therapy trial. The use of an algorithm with a bootstrap approach to the cost-analysis in order to cope with extreme costs such as hospitalisation may have flattened the results. Moreover, cost-analysis studies in general do not yet reach an equivalent standard of methodology, internationally speaking (Donaldson *et al.* 2002), which makes cost-analyses difficult to interpret and hardly comparable. Indeed, the current cost-analysis would require a greater study sample in order to gain more significance. While the multi-centre design, the intention-to-treat analysis and the naturalistic design of the treatment conditions argue in favour of the generalisability of the study results in the Netherlands, the results cannot be generalised to other countries.

A major problem is the adherence rate of about 50% for the cognitive self-therapy programme. Also, we don't know what the adherence rate exactly means to new developments combining professional and non-professional strategies. It is on top of the range that is generally observed for psychotherapy or medication in the treatment of depression and anxiety disorders (Marks 2002). Participants of an internet-based self-help programme for depression completed 65% of all modules (Andersson *et al.* 2005). In total 59% of the participants randomised to minimal-contact psychotherapy refused or failed to start the intervention (22%) or discontinued it (37%) of whom about a half withdrew before the third telephone call (Willemse *et al.* 2004). A remarkable 5.5% did not complete a 16 weeks trial of telephone-administered psychotherapy for depression (Mohr *et al.* 2005). Research design, target population and treatment programme might affect adherence to the intervention. The cognitive self-therapy study randomised 151 participants out of 224 referred patients; the internet-based self-help study randomised 117 out of 343 interested participants; the minimal contact psychotherapy study randomised 216 participants out of 3825 approached and screened patients; the telephone-administered psychotherapy study randomised127 participants out of 748 screened patients. Motivational problems and lack of time are frequently reported as patient characteristics

in case of non-adherence. The four studies varied greatly in the selection and inclusion procedure, which might affect participant's motivation. Also the study samples varied from sub-threshold disorders retrieved from primary care to patients referred with chronic disorders as it was in our study. Further, a main distinction between the cognitive self-therapy programme and the above mentioned new treatment strategies is that during the cognitive self-therapy programme, participants are invited to choose whether they want to continue the programme. This is concordant to the self-help paradigm, but in contrast with the professional paradigm using motivational techniques to improve adherence in pharmacological and psychological treatments. What we safely can say is that one out of two patients with chronic depressive and anxiety disorder will profit from the cognitive self-therapy programme. While the selection occurs in the orientation phase, the cognitive self-therapy programme selects patients on the principles of self-selection, thus preventing both patients and therapists from making a huge investment in a treatment that probably would not work at that time for those patients. More research must be done to understand the patient characteristics that affect self-selection and adherence towards treatment programmes.

Comparison with other studies
Concerning professional approaches, there is a paucity of studies on cost-utility of depression management (9 out of 539)(Pirraglia *et al.* 2004). It is not possible to identify the most cost-effective strategy for alleviating the symptoms of depression (Barrett *et al.* 2005). The small number of relevant articles shows that psychotherapy, care management alone, and psychotherapy in combination with care management all have lower costs per quality-adjusted life year than care as usual. Furthermore, pharmacologic treatment, either alone or in combination with psychotherapy, has a lower cost per quality-adjusted life year than psychotherapy alone.

With respect to non-professional approaches, self-help treatments (mainly cognitive behaviourally based) may have the potential to improve the overall cost-effectiveness of mental health service provision; however, the available evidence is limited in quantity and quality and there is no data concerning the long-term clinical benefits or cost-effectiveness (Bower *et al.* 2001). Computer-based treatments are being developed and appear promising for depressions as well (McKendree-Smith *et al.* 2003). Computer-delivered cognitive behavioural therapy has a high probability of

being cost-effective for anxiety and depression in primary care (McCrone *et al.* 2004), while reducing therapist time (Marks *et al.* 2003; Wright *et al.* 2005). Finally, Lewinsohn's 'Coping with Depression' course (Lewinsohn *et al.* 1986) is an effective treatment for unipolar depression, and useful as part of an active outreach approach for people recruited by the media who might not otherwise seek treatment (Cuijpers 1998).

Professional and non-professional approaches are often intertwined and both benefit patients with a chronic emotional disorder. Self-help is frequently (63%) used in conjunction with other forms of outpatient mental health care (Kessler *et al.* 1994). The thesis and recently published studies indicate that the systematic incorporation of non-professional alternatives as part of a comprehensive treatment programme may reduce the number of visits to mental health professionals and be cost-effective.

Guidelines
The first choice for treatment of depression and generalised anxiety disorder is medication and/or psychotherapy according to national and international guidelines (American Psychiatric Association 2000; Multidisciplinaire Richtlijnontwikkeling in de GGZ 2005; Australian and New Zealand clinical practice guidelines for the treatment of depression, Ellis 2004). Guidelines mention the use of self-help strategies for the treatment of first episode depression disorders, but recommend professional care for remittent and chronic disorders. However, there are no evidence-based guidelines for chronic conditions. Treatment choice depends on the clinician's skills and the patient's circumstances and preferences, and should be guided but not determined by guidelines (Ellis 2004).

Chronic disorders require a combination of pharmacological and psychological treatment. Psychotherapy usually involves 12-20 sessions, but in case of recurrence, chronic duration, and co-morbidity, duration of treatment is much longer resulting in weekly or fortnightly sessions over a one or two-years period. When ongoing sub-threshold symptoms continue after major depressive episodes, the illness is still active, and continued treatment is strongly recommended (Judd *et al.* 2000). While hardly any research has been done on the cost-effectiveness of long-term psychotherapy (Gezondheidsraad 2001), the results described in this thesis indicate that non-professional alternatives deserve a place in the management of chronic emotional disorders when adequate patient motivation is to be expected.

In case of lack of motivation and inadequate self-control of (destructive) behaviour, self-help strategies may not be the first

choice. When behaviour is the main psychiatric problem and patients do not show a genuine motivation for change, then traditional therapy programs should be recommended. Therapist competence becomes the tool whenever motivation and self-control are lacking. But, as soon as behaviour has become under self-control and the patient acknowledges the need for support or the need to cope with symptoms or dysfunctional cognitions, the appropriate non-professional alternatives may be offered again.

Sub-threshold and first episode depression disorders
Subjects with emotional disorders have been shown to be symptomatic 60% of the time, mainly at the minor, dysthymic or sub-threshold level, for both clinical cohorts and community-based epidemiological samples (Judd *et al.* 2002). Sub-threshold symptoms are associated with a high risk for early episode relapse and a significantly more chronic course of illness. Treatment, even at deceptively mild levels of symptoms, should be initiated or maintained (Judd *et al.* 2002). Significantly more people with sub-threshold depressive symptoms report impairment in daily functioning (high levels of household strain, social irritability, financial strain as well as limitations in physical or job functioning, restricted activity days, bed days, and poor health status) than do subjects with no disorder. Subjects with minor depression make less use of professional services than subjects with major depression, but because minor depression is more prevalent than major depression, the absolute number of subjects with minor depression receiving professional help is considerable (Cuijpers *et al.* 2004). Professional mental health care does not meet the need for care of chronic and remittent emotional disorders, while use of outpatient services for psychiatric problems is on the increase. The World Bank has reported that mental disorders account for 9.1% of the world total global disease burden, with 22.4% of that burden residing in established market economies, and half of that due to emotional disorders (Andrews 1998). By the year 2020, depression is expected to be one of the most serious medical conditions as reflected by the global burden of disease (Murray & Lopez 1997). Treatment of sub-threshold symptoms and first episode depression has become a major concern, as treatment of mild cases will prevent a substantial proportion of future serious cases (Kessler *et al.* 2003).

In the Netherlands, mental health care costs increased by 10.3% in 2003 to about 3.6 Billion Euro (Centraal Bureau voor Statistiek 2004). The 12-month prevalence of mood disorders is 5.7% and for generalised anxiety disorder 0.8% (Nemesis study, Bijl

et al. 1998); 20% will become chronic. Data retrieved from Casus Register Drenthe (S. Sytema, personal communication) revealed that adult patients, who suffered sub-threshold anxiety or depressive symptoms, and those who met the diagnosis of depression, all needed on average 25.5 contacts with a therapist during the first year, and during the second year 71% needed on average 12.4 contacts. The number of patients that needed treatment gradually decreased to 14% in 10 years, but the remaining patients still needed on average 12 contacts each year. Over a period of 10 years, the year prevalence of patients with outpatient care longer than one year increased by 53%. If this pattern continues, than more patients will need longer treatment.

First lifetime episodes of depression are typically more strongly associated with major life stress than are successive recurrences (Monroe & Harkness 2005). The stress generation hypothesis proposes that formerly depressed persons generate stressful conditions and events, which in turn cause additional symptoms. Formerly depressed people are at higher risk of experiencing new stress over time, and recurrences and severity of stress are correlated. Whether recurrent episodes become independent of stress (kindling hypothesis), such that stress is no longer an etiological mechanism in the precipitation of recurrence, or individuals become sensitised to stress, such that ever more minor forms of adversity are capable of precipitating recurrence, both hypotheses underscore the urge for prevention strategies and the importance of first episode psychotherapy to improve coping with stress.

The cognitive self-therapy programme aims at correcting interpersonal dysfunctional schemas, which is likely to decrease personal vulnerability and strengthens coping with stress. Conceptually, this approach agrees well with the widely proven effectiveness of interpersonal therapy and cognitive behavioural therapy for depression. Cognitive self-therapy may be of interest for further research on treatment of sub-threshold and first episode depression.

Self-regulation
In sum, strong evidence exists that non-professional approaches are effective for chronic emotional disorders. Meanwhile most think of self-help as being more appropriate for mild to moderate first episode depression and anxiety disorders. However, cognitive self-therapy shows to be acceptable and feasible for a moderately to severely ill patient population with chronic depression and anxiety. We think that this is due to patient's self-control over the treatment

process. Cognitive self-therapy shares the principles of self-help and user led groups during the fourth phase of the programme (self-therapy meetings) and may use minimal professional contact when needed. Cognitive self-therapy differs significantly from other non-professional alternatives such that participants are trained to cope with those standardised sessions in a reciprocal relationship with peers. Patients are satisfied by thus becoming less dependent on professional therapy. Besides a yearly evaluation, occasionally the patient asks the therapist for evaluation of their (self-) therapy process. What has been left to do for professionals, is establishing a diagnosis, providing medication, crisis management, the use of motivation techniques and guiding patients in the treatment process when support is needed. Non-professional approaches re-enforce independence.

In self-therapy, the relationship with therapists is different from the traditional patient-therapist relationship in which 'the therapist knows what is best for the patient' and 'the best therapist has the best results.' It sounds contradictory that traditional therapy supports patients to become independent by means of a dependent relationship. We are so used to the therapist paradigm that we can hardly say to patients: 'it is not me who knows what is best for you,' and 'you better do it yourself'. The role of a therapist using non-professional alternatives becomes more that of a teacher, who supports the self-learning capacity of the trainees and guides them where questions arise in order to find the right answers themselves. The intensity of the therapist-patient relationship, the meetings on a regular basis, the implicit expectations with respect to the superiority of the therapist versus the inferiority of the patient, shift towards an infrequent supportive contact with the assumption that both therapist and patient are qualified, all stimulating self-regulation. In the Netherlands, a law has been established to protect patient's right of self-regulation in the therapist-patient relationship, so called the Medical Treatment Agreements Act (*Geneeskundige behandeloverkomst: WGBO*, 1995). Independence of patients cannot be the economic interest of mental health care institutions. Evidence based treatment has become the modern excuse for therapists for not allowing patients to participate in non-professional approaches. Advancing patient's self-regulation is seemingly not or not yet the competence of therapists and the mental health care system.
It is time for doctors to reconsider their professional role in the treatment of emotional disorders. Psychiatrists and psychotherapists seem to underestimate the value of the acquisition of knowledge by patients and to overestimate the

importance of the therapeutic relationship and of their own level of experience. The results of the thesis indicate that these issues need more attention from researchers. Significant questions remain about the conditions under which self-help and paraprofessionals can be effective. If self-help strategies, paraprofessionals and course are effective, this will bring psychological treatment within the scope of psycho-education or education alone. The evidence presented so far may justify the development of new programs incorporating non-professional strategies.

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Summary

Chapter 1   Introduction

Self-help networks represent the oldest and most widely spread system of care for human ills. Self-help groups arise in society when certain needs are not being met by formal health care organisations. Since the 1970s, manuals have been developed by professionals for the general support of patients and relatives as a supplement to the regular treatment of somatic or psychiatric disorders. Since the 1980s, cognitive self-therapy (CST) has been developed in the Netherlands, integrating non-professional (manual, course and paraprofessionals) and professional approaches for the purpose of long-term treatment of psychiatric patients. Doctors have to deal with the phenomenon of self-help, as the established mental health care system does not have the resources to meet the extensive need for care for chronic emotional disorders.

The first choice for treatment of emotional disorders according to national and international guidelines is medication and/or psychotherapy. In moderately severe depression, all recognised antidepressants, cognitive behavioural therapy (CBT), interpersonal psychotherapy (IPT) and other psychological treatments are effective. There are no evidence-based guidelines for chronic conditions. Bibliotherapy (manuals) is also effective for treatment of first episode emotional disorders, and paraprofessionals may replace treatment otherwise provided by professionals.

This thesis evaluates the effectiveness of self-help and paraprofessionals in general, and the effectiveness of a new cognitive self-therapy programme in particular, in the treatment of patients with chronic and remittent emotional disorders.

Chapter 2   Why is self-help neglected in the treatment of emotional disorders? A meta-analysis.

Although the burden of emotional disorders is very high, mental health care is available to only a minority of patients. Previous meta-analyses concluded that self-help strategies are effective for various, less serious complaints but it is unclear whether available data supports a role for self-help in treatment protocols for patients with clinically significant emotional disorders. We selected studies of the previous meta-analyses and conducted an additional search. Standardised assessment of diagnosis or symptoms and randomised controlled trials were inclusion criteria. Thirteen studies were included. Most studies did not report concealment of treatment allocation, used small samples and had a short study duration. The standard mean difference was used to pool the data, using a random effects model. Publication bias ('fail safe N) was estimated.

This meta-analysis shows a robust effect for bibliotherapy as a self-help treatment for chronic emotional disorders when compared with non-treatment. A total of 50.8 studies would be necessary in order to reduce the effect size to absence of effect. The effect size was even greater when only observer-rated measures were taken. A longer treatment period is more effective. A subset of studies showed that bibliotherapy, too, is more effective than no treatment for referred patients with chronic emotional disorders. No evidence-based conclusion can be made concerning self-help groups. The effect size for bibliotherapy is remarkably similar to that reported in previous meta-analyses on self-help. Our effect size equals the results of cognitive therapy in depressed patients and is larger than the effect size of antidepressants. Further research is necessary on the long-term effects of bibliotherapy and the cost-effectiveness.

Chapter 3   Paraprofessionals for anxiety and depressive disorders. A meta-analysis.

Like bibliotherapy, paraprofessionals partially replacing professionals may be employed cost-effectively to solve the extensive need for care of those with emotional disorders. This study investigates the effectiveness of any kind of psychological treatment for emotional disorders performed by paraprofessionals. An intensive search was performed through electronic data bases including the Cochrane CCDANCTR-Studies of published and

unpublished trials, citation lists of articles and correspondence with authors. Randomised controlled trials that used symptom measures, and compared the effects of treatments given by paraprofessionals (paid or voluntary, unqualified with respect to the psychological treatment) and professionals and no treatment, were included. The standard mean difference, odds ratio, or the generic inverse variance method was used when appropriate, using a random effects model. The five studies included in the review were of moderate to high study quality except one study of low quality. No data were available to perform sensitivity or subgroup analyses.

The studies did not allow conclusions about the effect of paraprofessionals compared with professionals. However, after excluding one low-quality study and another study that was causing heterogeneity between the studies, three studies (women only) indicated a strongly significant effect for paraprofessionals (all volunteers) when compared with no treatment. Two out of three studies evaluated 12 months of care. The evidence to date may justify the development and evaluation of programmes incorporating paraprofessionals in treatment programmes for emotional disorders.

| Chapter 4 | **Cognitive self-therapy. Results of a pilot study of an alternative treatment for psychiatric patients.** |

A new cognitive self-therapy (CST) programme is being offered by the adult outpatient departments of a number of Dutch mental health care facilities to patients who have already undergone several other treatments for emotional disorders or for personality problems, and have become dependent on professional care. Cognitive self-therapy aims to enhance self-control over the treatment process. Unlike other forms of self-help or peer contact, CST is a structured form of therapy which can be an integral part of regular psychiatric treatment. The self-therapy programme comprises an orientation course and a basic course, followed by self-therapy meetings. We analysed the progress through the CST programme of the patients of the outpatient department of the University Medical Center Groningen who had participated from the beginning. Patients filled in a self-report questionnaire about their symptoms (SCL-90), which also was completed at their intake interview at the clinic. The patients (men<women; on average 37.3 years) had a psychiatric history of about 8 years, suffering mainly

depression, anxiety and personality disorders (half as co-morbidity). Many patients had a limited social network, were single and without paid employments.

A high degree of satisfaction was reported by the patients who attended the basic course and the self-therapy meetings. Three-quarters of the patients could apply what they had learned in CST to their everyday lives, and reported improvement due to CST, which was also reflected in a significant reduction of symptoms. About a quarter of the patients dropped out after the orientation course, which is comparable to the rate found in Dutch regional mental health care centres for patients who terminate contact without the approval of their therapist. The CST programme seemed to be a valuable supplement to the treatments already on offer.

Chapter 5   **Cognitive self-therapy for chronic depression and anxiety. A multi-centre randomised controlled trial.**

There are no evidence-based guidelines for chronic emotional disorders, while an extensive need for care of these disorders is becoming a serious medical problem, as is reflected by the projected world-wide burden of these diseases in the coming decades. This study aims to investigate the effectiveness of cognitive self-therapy (CST) in the treatment of emotional disorders. A randomised controlled trial with assessments at baseline, six, twelve and eighteen months was conducted in four outpatient departments of mental health care centres in the Netherlands, using intention-to-treat analysis. Patients (n=151; 100 women / 51 men) were randomised to receive CST or treatment as usual (TAU). Symptoms (SCL-90: main outcome measure; BDI; STAI), social functions (GSDS), quality of life (WHO-Qol) and utilisation of care were outcomes of the study. Included were patients between 18 and 65 years of age (on average: 41.3 years) who had a DSM-IV diagnosis of chronic or recurrent unipolar depressive disorder (90%), dysthymic disorder and/or generalised anxiety disorder, and who previously needed mental health care. Half of them had a co-morbid disorder. The first contact with mental health care was nearly 13 years before inclusion; three-quarters of them used psychiatric medication (TAU>CST). No significant between-group differences were found except for the SCL-90 score (TAU>CST). No relevant between-centre differences were found, nor between those who did or did not drop out.

Symptoms, social functioning and quality of life improved equally in both groups, and were still improved at follow-up. CST significantly reduced medical care utilisation when compared with treatment as usual with respect to the number of therapist contacts and hospitalisation. No differences were found with respect to medication use and the number of contacts with psychiatrists. Adherence to the CST programme was not related to any baseline characteristics. No suicides occurred. The adherence rate for CST (about 50%), which is at the top of the range generally observed in the treatment of emotional disorders, might be explained by the conflicting contrast of the research paradigm of randomisation and the paradigm of self-control and empowerment of self-help groups. Nevertheless, non-adherence occurred mainly in the introduction phase of the programme, indicating that the CST programme resulted in a strong selection procedure within a relatively short time period. Another limitation was a significant between-group difference for the main outcome measure (SCL-90) as well as for the use of psychiatric medication. No observer-rated measures were used to assess symptom outcome. The study design and low study drop-outs argue in favour of the generalisability of the results. As this study is the first trial on the effectiveness of the cognitive self-therapy programme, the trial needs to be replicated.

Chapter 6   Cost-effectiveness of cognitive self-therapy for depression and anxiety disorders.

The current study presents the results of the cost-analysis concerning the cognitive self-therapy trial. Complete case analyses were performed (n=120). The SCL-90 was the primary outcome measure in the cost-effectiveness analysis, and showed no difference between the conditions at baseline. The economic evaluation was conducted from a societal perspective, costs were assessed both within and outside the healthcare sector. The information on costs was collected by means of a questionnaire and through various healthcare professionals. Costs and the primary health outcome associated with an intervention were used to calculate the incremental cost-effectiveness ratio relative to one or more alternatives. Costs per point improvement on the SCL-90 were expressed by the incremental cost-effectiveness ratio. Uncertainty surrounding this ratio was examined by the bootstrap method. Finally, cost-effectiveness acceptability curves were calculated, which provide information on the probability that an intervention will be cost-effective. Sensitivity analyses were planned

in order to provide information on the robustness of the results of the economic evaluation.

Differences in costs and health outcomes between CST and TAU were modest. Mean costs of patients in the CST group (EUR 4389; when fully implemented EUR 3954) were lower than the mean costs of patients who received TAU (EUR 4837). Results of the SCL-90 were slightly in favour of CST. Additional analyses indicated that CST dominated TAU in 44% of the bootstrap replications. Valuing an additional unit of health outcome at EUR 300 will lead to a 74% probability that CST is cost-effective. The applied complete case analyses might have underestimated cost differences between groups.

Chapter 7   Discussion

The aim of the thesis was to evaluate the evidence regarding the effectiveness of self-help and paraprofessionals in general, and the effectiveness of a new cognitive self-therapy programme in particular, in the treatment of patients with chronic and remittent emotional disorders. The evidence presented in two meta-analyses and the results of our multi-centre randomised controlled trial on the effectiveness of cognitive self-therapy indicate that self-help oriented approaches are remarkably effective in patients with chronic and remittent anxiety and depression disorders. Our results show that the cognitive self-therapy programme is feasible to apply as a treatment programme for psychiatric patients, with a high probability that the programme will be cost-effective.

It is not possible to identify the most cost-effective professional strategy for alleviating the symptoms of depression. Self-help treatments may have the potential to improve the overall cost-effectiveness of mental health service provision; however, the available evidence is limited. Professional and non-professional approaches are often intertwined and both benefit patients with a chronic emotional disorder. Systematic incorporation of non-professional alternatives as part of a comprehensive treatment programme may reduce the number of visits to mental health professionals and be cost-effective.

Guidelines mention both professional treatments and the use of self-help strategies for the treatment of first episode depression disorders, but recommend professional care for remittent and chronic disorders. While no evidence-based guidelines for chronic conditions exist, this thesis indicates that non-professional

alternatives deserve a place in the management of chronic emotional disorders when adequate patient's motivation is to be expected. In cases of lack of motivation and inadequate self-control over (destructive) behaviour, self-help strategies may not be the first choice. But, as soon as behaviour has become under self-control and the patient acknowledges the need for support or the need to cope with symptoms or dysfunctional cognitions, the appropriate non-professional alternatives may be offered again.

Significant questions remain about the conditions under which self-help and paraprofessionals can be effective. The evidence presented so far may justify the development of new programs incorporating non-professional strategies.

Summary in Dutch / Samenvatting

Cognitieve zelftherapie
Een bijdrage voor langdurende behandeling
van depressie en angst

Hoofdstuk 1 **Introductie**

Zelfhulp netwerken vertegenwoordigen de oudste en meest
verspreide systemen van zorg voor de zieke mens. Zelfhulpgroepen
ontstaan in de maatschappij als er aan een bepaalde behoefte aan
zorg niet wordt voldaan door de gevestigde instellingen in de
gezondheidszorg. Sinds de jaren zeventig worden er boeken
ontwikkeld door professionals voor algemene ondersteuning van
patiënten en familie aanvullend op de reguliere behandeling van
lichamelijke of psychiatrische ziekten. Sinds de jaren tachtig is er
in Nederland cognitieve zelftherapie (CZT) ontwikkeld waarin niet-
professionele methoden – boek, cursus en paraprofessionals – en
gebruikelijke professionele behandeling geïntegreerd zijn voor
langdurende behandeling van psychiatrische patiënten. Dokters
zullen moeten leren omgaan met het fenomeen van zelfhulp omdat
de gevestigde instellingen van geestelijke gezondheidszorg niet de
hulpmiddelen hebben om tegemoet te komen aan de extensieve
behoefte aan hulp voor chronisch emotionele (angst- en
depressieve) stoornissen.
De eerste keus voor de behandeling van emotionele stoornissen
is volgens landelijke en internationale richtlijnen medicatie en/of
psychotherapie. Voor een matig ernstige depressie zijn alle bekende

antidepressiva, cognitieve gedragstherapie, interpersoonlijke therapie en andere psychologische behandelingen effectief. Er bestaan geen evidence based richtlijnen voor chronische condities. Bibliotherapie (boeken) is eveneens effectief voor de behandeling van eerste episode emotionele stoornissen, en paraprofessionals zouden behandeling kunnen geven die anders door professionals wordt uitgevoerd.

In dit proefschrift wordt de effectiviteit geëvalueerd van zelfhulp en paraprofessionals in het algemeen, en de doelmatigheid van cognitieve zelftherapie in het bijzonder, in de behandeling van patiënten met recidiverende en chronische emotionele stoornissen.

Hoofdstuk 2   **Waarom wordt zelfhulp verwaarloosd in de behandeling van emotionele stoornissen? Een meta-analyse.**

Terwijl de economische en maatschappelijke last van emotionele stoornissen erg hoog is, is geestelijke gezondheidszorg slechts beschikbaar voor een minderheid van de patiënten. Voorgaande meta-analyses toonden aan dat zelfhulp strategieën effectief zijn voor verschillende en matig ernstige klachten maar het was onduidelijk of de beschikbare gegevens tot dezelfde conclusie zouden leiden voor de rol van zelfhulp in behandelprotocols voor patiënten met een klinisch belangrijke emotionele stoornis. We selecteerden studies uit de voorgaande meta-analyses en deden een aanvullende search. Diagnoses of symptomen die op een gestandaardiseerde manier waren gemeten en gerandomiseerde gecontroleerde studies waren inclusiecriteria. Dertien studies werden geïncludeerd. Het waren kleine studies van korte duur en bij de meeste studies was niet vermeld of de toewijzing aan de behandelcondities verzegeld was gebeurd. Het standaard gemiddeld verschil werd gebruikt om de data gezamenlijk te berekenen volgens het 'random effects' model. Publicatie bias ('fail safe N) werd onderzocht.

Deze meta-analyse laat een robuust effect zien voor bibliotherapie als zelfhulp behandeling voor chronische emotionele stoornissen vergeleken met geen behandeling. Er zouden in totaal 50.8 studies nodig zijn om het effect tot niet significant te reduceren. Het effect is zelfs groter als er alleen vragenlijsten werden genomen die door anderen waren ingevuld. Een langere behandelduur is effectiever. Een deel van de studies laat zien dat bibliotherapie ook effectiever is dan geen behandeling voor patiënten met een chronische emotionele stoornis die verwezen

waren. Er kan geen evidence based conclusie getrokken worden voor zelfhulp groepen. De grootte van het effect voor bibliotherapie is opmerkelijk hetzelfde als de effecten die genoemd zijn in voorgaande meta-analyses over zelfhulp. Onze effectmaat evenaart de resultaten van die van cognitieve therapie voor depressieve patiënten en is groter dan het effect van antidepressiva. Verder onderzoek is nodig naar de effecten van bibliotherapie op lange termijn en naar de kosteneffectiviteit.

Hoofdstuk 3   **Paraprofessionals voor angst- en depressieve stoornissen. Een meta-analyse.**

Evenals dat voor bibliotherapie geldt, zou het gebruik van paraprofessionals, die professionals gedeeltelijk vervangen, kosteneffectief kunnen zijn en mogelijk bijdragen aan een oplossing voor de extensieve behoefte aan zorg voor hen met een emotionele stoornis. Deze studie onderzoekt de effectiviteit van elke mogelijke vorm van psychotherapeutische behandeling die door paraprofessionals wordt gegeven. Een intensieve search werd verricht in electronische databanken, waaronder die van de Cochrane CCDANCTR-Studies voor gepubliceerde en ongepubliceerde studies, in referentielijsten van artikelen en door middel van correspondentie met auteurs. Gerandomiseerde gecontroleerde studies werden geïncludeerd die meetinstrumenten voor symptomen gebruikten en de effecten vergeleken tussen behandeling die door paraprofessionals (betaald of vrijwillig, ongekwalificeerd met betrekking tot de psychologische behandeling) en door professionals werd gegeven, en geen behandeling. Het standaard gemiddelde verschil, odds ratio, of de 'generic inverse variance' methode werd gebruikt waar dat nodig was, volgens het 'random effects' model. De vijf geïncludeerde studies van de review waren van matige tot hoge studiekwaliteit behalve een studie van lage kwaliteit. Er waren geen data beschikbaar om sensitiviteits- of subanalyses te verrichten.

Uit de studies konden geen conclusies getrokken worden over het effect van paraprofessionals vergeleken met professionals. Echter, na het verwijderen van een studie met lage kwaliteit en een andere studie die heterogeneiteit veroorzaakte tussen de studies, bleek uit drie studies (alleen vrouwen) een sterk signifcant effect voor paraprofessionals (allen vrijwilligers) vergeleken met geen behandeling. Twee van de drie studies hadden zorg onderzocht die 12 maanden duurde. Het huidige bewijs rechtvaardigt de

ontwikkeling en evaluatie van programma's die paraprofessionals integreren in behandelprogramma's voor emotionele stoornissen.

Hoofdstuk 4 **Cognitieve zelftherapie. Resultaten van een pilot studie van een alternatieve behandeling voor psychiatrische patiënten.**

Een nieuw cognitieve zelftherapie programma (CZT) wordt aangeboden op afdelingen voor ambulante volwassenenzorg van een aantal Nederlandse instellingen voor geestelijke gezondheidszorg, aan patiënten die al verschillende behandelingen hadden ondergaan voor emotionele stoornissen of voor persoonlijkheidsproblematiek, en afhankelijk waren geworden van professionele zorg. Cognitieve zelftherapie heeft als doel zelfcontrole over het behandelproces te vergroten. Verschillend met andere vormen van zelfhulp of lotgenotencontact is CZT een gestructureerde vorm van therapie welke een integraal onderdeel kan zijn van een reguliere psychiatrische behandeling. Het zelftherapie programma bevat een oriëntatie cursus en een basis cursus gevolgd door zelftherapie bijeenkomsten. We analyseerden de voortgang met het CZT programma van de patiënten van de polikliniek van het Universi tair Medisch Centrum Groningen. Patiënten vulden een zelfrapportage vragenlijst in over hun klachten (SCL-90), die ook was ingevuld tijdens de intake op de polikliniek. De patiënten (man<vrouw; gemiddeld 37.3 jaar oud) hadden een gemiddelde psychiatrische voorgeschiedenis van ongeveer 8 jaar, leden hoofdzakelijk aan depressie, angst en persoonlijkheidsstoornis (voor de helft als nevendiagnose). Vele patiënten hadden een beperkt sociaal netwerk, waren alleenstaand en hadden geen betaald werk.

Een hoge mate van tevredenheid was gerapporteerd door hen die naar de basis cursus en de zelftherapie bijeenkomsten waren gegaan. Driekwart van de patiënten kon toepassen in het dagelijks leven wat zij hadden geleerd met CZT en rapporteerden verbetering dank zij CZT, wat ook te zien was in een significante vermindering van de klachten. Ongeveer een kwart van de patiënten viel uit na de oriëntatie cursus, wat vergelijkbaar is met het percentage patiënten, dat gevonden werd in Nederlandse regionale instellingen voor geestelijke gezondheidszorg, die de behandeling afsluiten zonder de instemming van de therapeut. Het CZT programma leek een waardevolle aanvulling te zijn op het aanbod van bestaande behandelingen.

Hoofdstuk 5   Cognitieve zelftherapie voor chronische depressie en angst. Een multi-centrum gerandomiseerde gecontroleerde studie.

Er bestaan geen evidence based richtlijnen voor chronisch emotionele stoornissen, terwijl de extensieve behoefte aan zorg voor deze stoornissen een ernstig medisch probleem aan het worden is, zoals het weerspiegeld wordt in de wereldwijde economische en maatschappelijke last van deze ziekten in de komende decennia. Deze studie heeft als doel de doelmatigheid van cognitieve zelftherapie (CZT) te onderzoeken voor de behandeling van emotionele stoornissen. Er werd een gerandomiseerde gecontroleerde studie gedaan met een voormeting en metingen op zes, 12 en 18 maanden, in vier ambulante afdelingen van instellingen voor geestelijke gezondheidszorg in Nederland, met behulp van een intention-to-treat analyse. Patiënten (151;100 vrouwen / 51 mannen) werden gerandomiseerd toegewezen aan CZT of gebruikelijke behandeling (GB). De uitkomst van de studie betrof klachten (SCL-90: primaire uitkomstmaat; BDI; STAI), sociaal functioneren (GSDS), kwalitiet van leven (WHO-Qol) en zorgconsumptie. De patiënten die in de studie waren geïncludeerd waren tussen de 18 en 65 jaar oud (gemiddeld: 41,3 jaar), hadden een DSM-IV diagnose van een chronische of recidiverende unipolaire depressieve stoornis (90%), een dysthyme stoornis en/of een gegeneraliseerde angststoornis, en hadden eerder psychiatrische hulp nodig gehad. De helft van hen had een nevendiagnose. Het eerste contact met geestelijke gezondheidszorg was ongeveer 13 jaar voor de inclusie. Driekwart van de patiënten gebruikte psychiatrische medicatie (GB>CZT). Er waren geen significante verschillen tussen de condities behalve voor de SCL-90 score (TAU>CST). Er waren geen relevante verschillen gevonden tussen de centra, en ook niet tussen hen die uit de studie vielen en hen die volledig aan de studie meededen.

Klachten, sociaal functioneren en kwaliteit van leven verbeterden evenveel in beide condities, en waren nog verbeterd bij het vervolg van de studie. CZT verminderde significant de zorgconsumptie in vergelijking met gebruikelijke behandeling met betrekking tot het aantal contacten met therapeuten en opnames. Er werd geen verschil gevonden met betrekking tot het gebruik van medicatie en het aantal contacten met een psychiater. Therapietrouw bij het CZT programma was niet gerelateerd aan kenmerkende gegevens van de voormeting. Er kwamen geen suïcides voor. De relatief lage therapietrouw bij CZT (ongeveer 50%), wat aan de bovenrand is van wat in het algemeen gezien

wordt bij de behandeling van emotionele stoornissen, zou verklaard kunnen worden door het strijdigheid tussen het research paradigma van blind toewijzen aan behandeling en het paradigma van zelfcontrole en empowerment van zelfhulp groepen. Desalniettemin stopte men met deze behandeling hoofdzakelijk in de voorbereidingsfase van het programma, hetgeen betekent dat het CZT programma een sterke selectie procedure heeft binnen een betrekkelijke korte tijd van de behandeling. Een andere beperking van de studie was het significante verschil tussen de condities met betrekking tot de belangrijkste uitkomstmaat (SCL-90) en voor het gebruik van psychiatrische medicatie. Er werden geen meetinstrumenten afgenomen die door anderen werden ingevuld om de klachten te meten. Het studie design en het gering aantal deelnemers dat de studie niet voltooiden zijn argumenten die pleiten voor de generaliseerbaarheid van de resultaten. Omdat dit de eerste studie is naar de doelmatigheid van het cognitieve zelftherapie programma is het nodig dat de studie wordt herhaald.

Hoofdstuk 6   Kostenanalyse van cognitieve zelftherapie in de behandeling van depressieve en angststoornissen.

In de huidige studie worden de resultaten gepresenteerd van de kostenanalyse betreffende de studie van cognitieve zelftherapie. De analyses werden verricht van de patiënten die de studie volledig hadden meegedaan (120). De SCL-90, die de primaire uitkomstmaat was in de kostenanalyse, toonde geen verschil tussen de condities bij de voormeting. De economische evaluatie werd gedaan met een maatschappelijk perspectief, waarbij zowel de kosten binnen als buiten de gezondheidssector werden gemeten. De informatie over de kosten werd verzameld door middel van een vragenlijst en werd verkregen bij verschillende professionals in de gezondheidszorg. De kosten en de primaire uitkomstmaat van elke conditie werden gebruikt om de incrementele kosteneffectiviteitsratio te berekenen in relatie tot een of meer alternatieven. De kosten per punt verbetering op de SCL-90 werden met de incrementele kosteneffectiviteitsratio uitgedrukt. Onzekerheid omtrent de kosteneffectiviteitsanalyse werd geanalyseerd door middel van de bootstrap methode. Aanvullend werden curves berekend die de aanvaardbaarheid van de kosteneffectiviteit aangeven, welke informatie geven over de waarschijnlijkheid dat een interventie kosteneffectief zal zijn. Sensitiviteitsanalyses werden voorgenomen om informatie te geven

over de robuustheid van de resultaten van de economische evaluatie.

Er waren matige verschillen betreffende de kosten en de uitkomstmaat van gezondheid tussen cognitieve zelftherapie en de gebruikelijke behandeling. De gemiddelde kosten van patiënten in de cognitieve zelftherapie conditie (€4389; na volledige implementatie €3954) waren lager dan de gemiddelde kosten van patiënten die de gebruikelijke behandeling ontvingen (€4837). De resultaten op de SCL-90 waren licht in het voordeel van cognitieve zelftherapie. Aanvullende analyses gaven aan dat cognitieve zelftherapie in 44% van de herhalingen van de bootstrap de gebruikelijke behandeling domineert. Met een extra investering van €300 zal met een waarschijnlijkheid van 74% cognitieve zelftherapie kosteneffectief zijn. De toepassing van de analyse van deelnemers die volledig meegedaan hebben aan de studie, kan hebben geleid tot onderschatting van de verschillen tussen de groepen.

Hoofdstuk 7   Discussie

Het doel van het proefschrift was om het de effectiviteit van zelfhulp en paraprofessionals in het algemeen, en de doelmatigheid van een nieuw cognitieve zelftherapie programma in het bijzonder, te evalueren voor de behandeling van patiënten met chronische en recidiverende emotionele stoornissen. Het bevindingen van twee meta-analyses en de resultaten van onze multi-centrum gerandomiseerde gecontroleerde studie naar de doelmatigheid van cognitieve zelftherapie tonen aan dat zelfhulp georiënteerde benaderingen opmerkelijk effectief zijn voor patiënten met chronische en recidiverende angst- en depressieve stoornissen. Onze resultaten laten zien dat het cognitieve zelftherapie programma geschikt is voor toepassing als behandelprogramma voor psychiatrische patiënten, met een hoge waarschijnlijkheid dat het programma kosteneffectief is.

Het is niet mogelijk de meest kosteneffectieve professionele strategie te identificeren om symptomen van depressie te verminderen. Zelfhulp behandelingen zouden potentieel de totale kosteneffectiviteit van het aanbod van geestelijke gezondheidszorg kunnen verbeteren, echter de aanwijzingen hiervoor zijn beperkt. Professionele en niet-professionele benaderingen zijn vaak gemengd en patiënten met emotionele stoornissen hebben baat bij allebei. Systematische incorporatie van niet-professionele alternatieven als

onderdeel van een omvattend behandelprogramma zou het aantal bezoeken aan professionals in de geestelijke gezondheidszorg kunnen verminderen en dat zou kosteneffectief kunnen zijn.

In richtlijnen worden zowel professionele behandelingen als het gebruik van zelfhulp strategieën voor de behandeling van een eerste episode van een depressieve stoornis genoemd, maar alleen professionele zorg wordt aanbevolen voor recidiverende en chronische stoornissen. Terwijl er geen evidence based richtlijnen zijn voor chronische condities, wordt door dit proefschrift duidelijk dat niet-professionele alternatieven een plaats verdienen in de behandeling van chronische emotionele stoornissen als verwacht kan worden dat de patiënt adequaat is gemotiveerd. In het geval van een gebrek aan motivatie en inadequate zelfcontrole over (destructief) gedrag, zijn zelfhulp strategieën niet de eerste keus. Maar, zodra er zelfcontrole is over het gedrag en de patiënt herkent de behoefte aan ondersteuning of de behoefte om met symptomen of disfunctionele cognities om te kunnen gaan, dan kunnen de gepaste niet-professionele alternatieven al dan niet opnieuw worden aangeboden.

Belangrijke vragen blijven bestaan betreffende de condities waaronder zelfhulp en paraprofessionals effectief kunnen zijn. De resultaten van onderzoek tot dusverre zouden de ontwikkeling van nieuwe programma's met niet-professionele strategieën kunnen rechtvaardigen.

ABOUT THE AUTHOR

PUBLICATIONS

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ABOUT THE AUTHOR

Peter C.A.M. den Boer, married and two children, was born the 25th of April 1951 in Bergen op Zoom, Noord Brabant, the Netherlands. He studied medicine at the Vrije Universiteit of Amsterdam and graduated in 1977. He completed his studies in psychiatry in 1984 at the University Medical Centre of Amsterdam.

His interest in self-help methods for adults with psychological problems date from early on in his medical study. He was involved in the political and ideological empowerment movements of the seventies and eighties such as radical therapy and re-evaluation counseling or co-counseling. He followed education programs in the United Kingdom and the Netherlands and became a degreed teacher in co-counseling. Co-counseling was an education program for adults aiming to solve problems by self-help strategy.

As a resident-psychiatrist, he observed problems among psychiatric patients which did not differ from the problems of participants he met in self-help groups, and was wondering whether psychiatric patients would profit from self-help strategies as well. As a certified psychiatrist, he worked in a community psychiatry team, part of the regional mental health care centre of Breda (GGz Regio Breda), from 1984 to 1993. Most patients already had a history of chronic and remittent psychiatric symptoms and moderate to severe maladaptive psychological an social functioning. Despite several psychotherapy methods and psychiatric treatments, those patients still expressed a need to better understand themselves. They wanted that something had to be changed by therapy with respect to their psychological vulnerability to stress in order to increase their quality of life. The psychological vulnerability seemed to them to be one of the factors that at least partly caused the ongoing psychiatric problems and concurrent bad social functioning.

In collaboration with Carla Raes, social worker, the author's partner, the self-help methods of the empowerment movement became a highly structured method, and now properly adepted for

psychiatric patients. Together they wrote the manuals Contact & Relationship, and founded Stichting Inde Granaetappel 1671, aiming to facilitate the use of self-help strategies not connected with mental health care institutions. Supported by staff and management of the GGz Regio Breda, the structured self-therapy method became integrated with usual patient care, then called Experiential Peer Counselling. The self-therapy programme seemed to supply a need for care additional to contemporary psychotherapy and psychiatric treatments.

The first education programme for mental health care workers started in 1991. The Dutch Society of Integration of Self-help and Psychiatry (Nederlandse Vereniging tot Integratie van Zelfhulp en Psychiatrie, the N.V.I.Z.P) has been founded in 1996. Since 1993 the author has facilitated implementation of the now called Cognitive Self-Therapy programme (CST) at the outpatient clinic of the department of psychiatry of the University Medical Center Groningen. In the meantime the integration model of CST and psychiatry had been implemented in several mental health care facilities throughout the Netherlands.

The results of a pilot study among the participants of CST at the University Medical Centre Groningen were such that a multi-centre randomised controlled trial was started in 2000 with a grant from the Health Care Insurance Board (*College voor Zorgverzekeringen; CVZ*). The results of the study are subject of the present dissertation.

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Vele vele personen, privé en vakmatig, hebben een rol gespeeld in de ontwikkeling van cognitieve zelftherapie dat begon als een privé onderneming, een behandelprogramma werd in de geestelijke gezondheidszorg en resulteerde in onderzoek naar de effectiviteit van het programma.

I wouldn't have the slightest idea what self-help and paraprofessionals could mean in problem solving if I hadn't needed a kind of support myself. In that way people to whom I was close were very important in the first steps of my personal growth and professional education.

Ik zou niet het minste idee hebben wat zelfhulp en paraprofessionals kon betekenen in het oplossen van problemen als ik niet zelf enige steun daarvoor nodig had gehad. Daarom waren mensen die mij nabij waren erg belangrijk in de eerste stappen van mijn persoonlijke groei en professionele vorming.

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My beloved wife Carla, I am sure that cognitive self-therapy would never have been applicable to potentially serious suffering patients without solutions she gave enhancing self-control of participants. But also, she knows when professionals are making interventions supporting patients' need of dependency in stead of their empowerment.

Despite the fact that I did not have the opportunity to professionally examine the effectiveness of self-therapy for children, I will thank my beloved children Duncan and Shannon who showed me that school kids are capable of handling self-therapy creatively and can internalise very easily the skills of empathy and problem solving in relationships.

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Mijn liefhebbende vrouw Carla, ik weet zeker dat cognitieve zelftherapie nooit toepasbaar zou zijn geweest voor potentieel ernstig lijdende patiënten zonder haar oplossingen om de zelfcontrole van patiënten te vergroten. Maar ook is zij degene die weet wanneer een professional interventies maakt die de behoefte aan afhankelijkheid van patiënten in plaats van hun empowerment stimuleren.

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therapy.

basis voor zelftherapie hebben vergroot.

Research became the final step of the development of cognitive self-therapy but was also the beginning of evidence as needed for discussion of the right position of self-therapy between other evidence based treatment programmes.

Onderzoek werd de laatste stap in de ontwikkeling van cognitieve zelftherapie, maar was ook het begin van bewijs, nodig om de discussie aan te gaan voor de juiste plek van zelftherapie tussen andere 'evidence based' behandelprogramma's.

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Ik weet dat meer mensen de ontwikkeling van cognitieve zelftherapie hebben ondersteund. Het zou kunnen dat sommigen hier genoemd hadden moeten worden. Mijn excuses aan hen. Neem a.u.b. contact met me op en ik zal mijn proefschrift toezenden om u persoonlijk te bedanken.