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•ORIGINAL RESEARCH ARTICLE•

Applicability Evaluation of Simplified Cognitive Behavioral Therapy

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Background: We have developed a structured cognitive behavioral therapy manual for anxiety disorder in China, and the present study evaluated the applicability of simplified cognitive behavioral therapy based on our previous research.

Aims: To evaluate the applicability of simplified cognitive behavioral therapy (SCBT) on generalized anxiety disorder (GAD) by conducting a multi-center controlled clinical trial.

Methods: A multi-center controlled clinical trial of SCBT was conducted on patients with GAD, including institutions specializing in mental health and psychiatry units in general hospitals. The participants were divided into 3 groups: SCBT group, SCBT with medication group and medication group. The drop-out rates of these three groups, the therapy satisfaction of patients who received SCBT and the evaluation of SCBT from therapists were compared.

Results: (1) There was no significant difference among the drop-out rates in the three groups. (2) Only the duration and times of therapy were significantly different between the two groups of patients who received the SCBT, and the therapy satisfaction of the SCBT group was higher than that of the SCBT with medication group. (3) Eighteen therapists who conducted the SCBT indicated that the manual was easy to comprehend and operate, and this therapy could achieve the therapy goals.

Conclusion: The applicability of SCBT for patients with GAD is relatively high, and it is hopeful that SCBT can become a psychological treatment which can be applied in medical institutions of various levels.

Key words: simplified cognitive behavioral therapy; generalized anxiety disorder; manual; evaluation

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1. Introduction

The core features of generalized anxiety disorder (GAD) are the chronic and persistent loss of self-control due to worries, and a cognitive evaluation bias towards threats and risks, which causes significant impairments in work, interpersonal social life, physical health, mental health and so forth.[1,2] Currently, the main treatment for GAD is medication with psychotherapy

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as the supplement.[3,4] The most commonly used form of psychotherapy to treat anxiety is cognitive behavioral therapy (CBT), and it has been shown to be more effective for the treatment of mild anxiety than other psychotherapies.[5-7] Brief cognitive behavioral therapy (BCBT) is a short-term psychotherapy which has gained more attention internationally in recent years, and clinical trials have shown it's effectiveness in treating anxiety disorder.[8,9] In the studies done outside of China, the manual for BCBT was gradually developed and applied in primary medical institutions. However, there are few systematic, detailed and structured manuals provided to medical workers for use in China. Previously, we developed a structured simplified cognitive behavioral therapy (SCBT) manual that could be used by medical workers providing services at district level institutions or those who had not received systematic training. We reported on the effectiveness of this treatment which, at the time, was quite early in the provision of psychological services in China.[10-12] The present study was based on this previous research[10,11] to provide further evaluation of the SCBT technique.

2. Methods

2.1 SCBT manual

There are four sections in the manual: (a) instructions, (b) procedure and content, (c) specific treatment content and (d) addendum.[10] Four key steps are emphasized in every treatment session: feedback on the previous homework, treatment content, relaxation technique exercises and homework assignments.

2.2 Participants

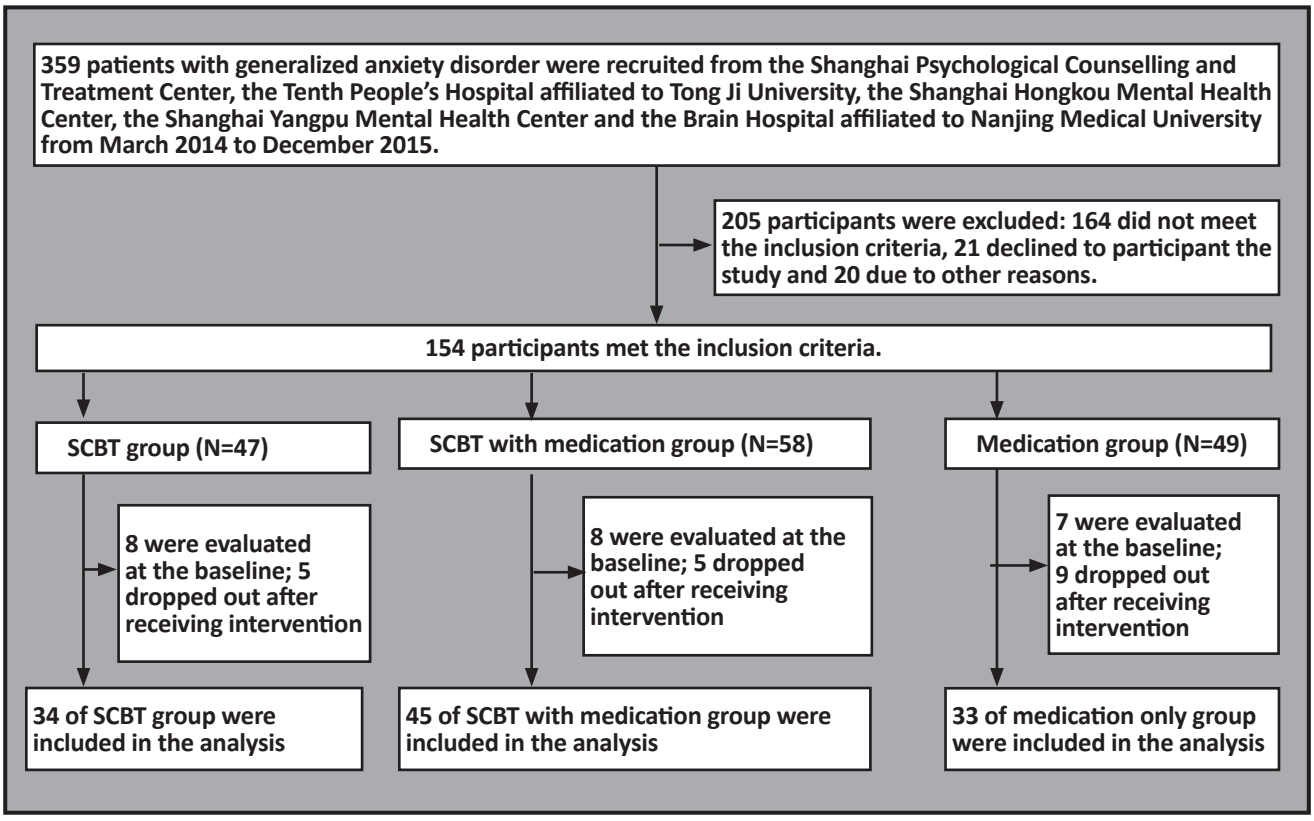
2.2.1 Sample

Participants were recruited through posters, nurse registrations and outpatient doctors' recommendations. The time frame of the recruitment was from March, 2014 to December, 2015. Participants were recruited from the following locations: Shanghai Psychological Counselling and Treatment Center, Tenth People's Hospital of Tongji University, Shanghai Hongkou Mental Health Center, Shanghai Yangpu Mental Health Center and Nanjing Brain Hospital affiliated to Nanjing Medical University.

2.2.2 Inclusion criteria

① Participants who met the diagnostic criteria for GAD according to the DSM-IV; ② participants whose HAMA-14 scores were equal to 14 or above, and equal to 29 or below; and participants whose GAD-7 scores were equal 5 to or above; and participants whose HAMD-17 scores were below 14; ③ females and males between 18 and 65; ④ participants whose education levels were equal to elementary school

Figure 1. The flowchart of the study



or above; ⑤ participants whose visual and audio levels were high enough to complete the assessments required; ⑥ participants who had not received psychological counselling or treatments in any form in the past three months; ⑦ participants who were willing to participate and provided written informed consent.

2.2.3 Exclusion criteria

① Participants who had a current severe medical condition; ② participants who had severe suicidal ideation; ③ females who were pregnant or lactating; ④ participants who had comorbid psychosis or had psychotic symptoms, psychoactive substance dependence or abuse, personality disorder, or mental retardation; ⑤ participants whose symptoms did not improve after receiving medication with sufficient doses and durations and psychotherapies.

2.3 Research tools

① Adapted patient satisfaction questionnaire [8] evaluating the acceptability of SCBT. There are 8 items using a scale of 1 to 5.

② Adapted manual evaluation scale [8] evaluating the applicability of SCBT. There are 3 sub-scales, as stated below:

(a) the treatment feedback scale for therapists after each treatment: therapists evaluate the content, goals, flexibility, effectiveness and other aspects of each treatment. There are 8 items using a scale of 1 to 7. (b) the treatment feedback scale for therapists after each week: therapists evaluate the effectiveness, applicability and other aspects of treatments after each week. There are 8 items using a scale of 1 to 7. (c) the feedback summary scale for therapists: the main focus is for therapists to evaluate SCBT in terms of their general practice and experience. There are 8 items using a scale of 1 to 7.

2.4 Study design

Randomized parallel control and blind evaluation methods were employed in the present study. The present study used a random table generated by computer, and participants were given random numbers according to the order of their enrollment. However, some participants did not cooperate with the group assignment or switched to another group during the study due to worries about the side-effects of drugs, thinking that psychotherapy was useless and being influenced by the information of group assignments, therefore the study was only partially randomized; in fact, the whole randomized design was affected. Participants were divided into three groups: the SCBT group, the SCBT with medication group and the regular medication group. Based on the previous related literature, we planned to recruit 30 participants into each group. Within the sample of 112 participants included in the analysis, 32 (28.6%) of them did not cooperate with the group assignment or switched to another group. Blind evaluation method means that the people who conducted the assessments did not know which group participants were assigned to.

2.5 Study procedure

2.5.1 Simplified cognitive behavioral therapy group (SCBT group)

Participants in this group only received SCBT during the treatment period, and did not receive any other treatment in any form. The treatment duration was 8 weeks with 12 structured sessions. In the first 4 weeks: twice a week; in the latter 4 weeks: once a week. Every individual therapy session lasted for an hour, and the evaluations were conducted at the baseline and the end of the eighth week.

2.5.2 Combined treatment group (SCBT with medication group)

Participants in this group received SCBT with medication during the treatment period. The categories of medications were mainly required to be SSRI, SNRI or benzodiazepines. The evaluation schedule was the same as the SCBT group's.

2.5.3 Regular medication group (medication group)

Participants in this group received routine medication only, and did not receive any SCBT. The categories of medications and evaluation schedule were the same as those of *the* SCBT with medication group.

2.5.4 The applicability evaluation of SCBT

The applicability of SCBT mainly includes acceptability and feasibility.[8] Acceptability is mainly referred to as patients benefitting from the treatment, whether or not they would recommend it to others, their satisfaction towards the treatment and so forth. The adapted patient satisfaction questionnaire was used to evaluate this factor. Feasibility mainly includes the drop-out rate, and the compliance and feedback of therapists to the manual; the adapted manual evaluation scale was employed to assess this factor.[8] The Likert Scale's rating system was employed to rate the patient satisfaction questionnaire and manual evaluation scale.[13]

2.6 Statistical methods

As the acceptability and partial feasibility were evaluated for the whole intervention, only the data of participants who completed the intervention were analyzed. There were participants who dropped out of the study, and their data were excluded from the analysis. Furthermore, missing data were not processed or included in the analysis. Therefore, the

present study employed Per Protocol Set Analysis, which meant only analyzing data of participants who completed the intervention.

SPSS 17.0 was used for statistical analysis. Enumeration data were described with frequencies and rates. Independent sample t tests, multiple tests and X^2 tests were employed. The value of p being smaller than 0.05 indicated that the difference was statistically significant.

3. Results

With Per Protocol Set Analysis being used, there was a total of 112 participants who were included in the final analysis (SCBT group: 34, SCBT with medication group: 45, medication group: 33). The three groups were not significantly different in age, gender, education level or marital status (F=1.88, df=2, p=0.158; X^2=1.16, df=2, p=0.560; X^2=3.50, df=6, p=0.744; X^2=5.08, df=6, p=0.454).

3.1 Acceptability evaluation of SCBT

This part of the analysis only accepted data of participants who received SCBT and completed the eight-week-long intervention (i.e., 34 participants from the SCBT group and 45 participants from the SCBT with medication group).

As stated in Table 1, participants in the SCBT group and SCBT with medication group were not significantly different in satisfaction factors, such as the quality of treatment, the duration and the number of session, or whether their expectations for treatment had been met.

3.2 Feasibility evaluation of SCBT

3.2.1 Drop-out rate

As stated in Table 2, there was no significant difference among the drop-out rates of the three groups (X^2=1.41, df=2, p=0.494) with the drop-out rate of the medication only group being the highest. The summation of drop-out rates of the SCBT group and SCBT with medication group was 24.8%.

3.2.2 Evaluations of the SCBT manual by 18 therapists

Therapist evaluations of each treatment are shown in Table 3. Based on the content and experience of each treatment, therapists conducted evaluations on each item of each participant. All therapists indicated that the flexibility allowed by the manual was medium in each treatment, and the flexibility of the second treatment was the lowest as there was basically no flexibility.

Table 4 shows the therapists' evaluation of each week's treatment. Similarly, therapists evaluated the item for each participant based on the content and experience of each weeks treatment. All therapists indicated that most content of the weekly treatment was useful, that each week's assignment could be used effectively and that the feasibility was good.

Overall evaluation of the program by the therapists is shown in Table 5. Through feedback summary scales of therapists, every participant who completed the eight-week-long intervention was evaluated on every item based on each therapist's insights into the 12 interventions. Therapists suggested that this manual was basically suitable to use on patients.

4. Discussion

4.1 Main findings

SCBT follows the principle of starting simple and gradually becoming more advanced. The main focus of treatment is for patients to identify, analyze and modify maladaptive thoughts and behaviors. In this regard the core technique of CBT (i.e., cognition restructuring and exposing) is included in SCBT, which is consistent with conventional CBT and BCBT.[9,14] The manual for SCBT was edited in a structured way. The duration of treatment is relatively shorter, and the number of sessions is fewer, making it easier for novice therapists to master and conduct. Therefore SCBT can be applied in primary medical centers and is consistent with the lower requirements of therapists conducting BCBT.[8,10]

The drop-out rates for the three groups were not significantly different, but drop out from the medication only group was the highest. This was mainly because that in contrast to the medication only group, participants of in the SCBT group and SCBT with medication group developed good working communities and stable treatment relationships by receiving 12 treatments. The drop-out rate of all participants who received SCBT (SCBT group and SCBT with medication group) was 24.8%, which is comparable to conventional CBT's and BCBT's rates.[8,15]

Therapists considered treatments to be somewhat flexible, and this was mainly because the manual was structured and therapists had little experience. Among the 12 sessions, the flexibility of the second session was rated as the lowest. This was due to the fact that the second treatment session used narrative therapy. In that particular session participants wrote down content and therapists reflected main factors of these depictions back to them.

The evaluation of sessions by the therapists reflected that treatment was rushed to achieve each week's goal. This was also found to be true in other studies of BCBT.[8,16] The reason for this is that therapists are accustomed to conducting conventional CBT and they may feel that 12 simplified treatments are not enough. This suggests that further simplifications and adjustments to SCBT may be needed, and every treatment needs to be organized more reasonably, which can enable participants to master the core technique of CBT within 12 treatments.[17]

Table 1. Patient satisfaction questionnaire

Group/Item	Mean (SD)	Range of actual scores	*t*	*df*	*p*
(1) Do you think the quality of the treatment you received was good?					
1	3.85(0.61)	3—4	0.25	77	0.892
2	3.89(0.65)	3—4			
1+2	3.87(0.63)	3—4			
(2) Do you think you received the help you needed?					
1	3.58(0.61)	3—4	0.43	77	0.892
2	3.64(0.74)	3—4			
1+2	3.62(0.69)	3—4			
(3) Does the current treatment session provide the help you expected to get?					
1	3.74(0.62)	3—4	0.14	77	0.892
2	3.76(0.68)	3—4			
1+2	3.75(0.65)	3—4			
(4) If your friend was in need of this kind of help, would you recommend this treatment to him or her?					
1	3.94(0.95)	3—4	0.99	77	0.872
2	4.11(0.57)	4—5			
1+2	4.04(0.76)	4—5			
(5) Are you satisfied with the duration and number of sessions provided?					
1	4.06(0.69)	4—5	2.38	77	0.160
2	3.58(1.01)	3—4			
1+2	3.78(0.92)	3—4			
(6) Do you think that this treatment solved the problems you faced effectively?					
1	3.91(0.45)	3—4	0.75	77	0.892
2	3.82(0.58)	3—4			
1+2	3.86(0.53)	3—4			
(7) Generally speaking, are you satisfied with the help provided by this treatment?					
1	3.88(0.77)	3—4	0.17	77	0.892
2	3.91(0.73)	3—4			
1+2	3.90(0.74)	3—4			
(8) If you needed this kind of help in the future, would you be willing to join this project again?					
1	3.65(1.20)	3—4	1.70	77	0.372
2	4.02(0.75)	4—5			
1+2	3.86(0.98)	3—4			

Note: 1=SCBT group (34 cases), 2=SCBT with medication group (45 cases), 1+2=SCBT group and SCBT with medication group Item (1): 1=very bad, 2=bad, 3=medium, 4=good, 5=excellent; Item (2): 1=barely any, 2=partially, 3=some, 4=mostly, 5=completely; Item (3): 1=not satisfied, 2=a bit satisfied, 3=basically satisfied, 4=mostly satisfied, 5=completely satisfied; Item (5): Item (4) and (8): 1=highly unlikely, 2=maybe not, 3=not sure, 4=probably will, 5=definitely will; Item (5) and (7): 1=very unsatisfied, 2=a bit unsatisfied, 3=medium, 4=mostly satisfied, 5=completely satisfied; Item (6): 1=mostly unsolved, 2=small portion left unsolved, 3=not sure, 4=basically solved, 5=completely solved.

Table 2. Comparison of the three groups' drop-out rates

	SCBT group (n=47)	SCBT with medication group (n=58)	Medication group (n=49)	X^2	*df*	*p*
Dropped out	27.66%	22.41%	32.65%	1.41	2	0.494

Table 3. The feedback scale of therapists for each session

Group / Item	Session/Mean (SD)											
	First	Second	Third	Fourth	Fifth	Sixth	Seventh	Eighth	Ninth	Tenth	Eleventh	Twelfth
(1) Is the content of this session easy to understand?												
	6.51 (0.55)	6.39 (0.65)	6.16 (0.72)	6.13 (0.74)	6.04 (0.90)	5.86 (0.80)	5.90 (0.92)	5.94 (0.90)	5.90 (1.15)	6.06 (1.04)	6.58 (0.59)	6.69 (0.47)
(2) Is the goal of this session clear?												
	6.42 (0.55)	6.25 (0.69)	6.32 (0.61)	6.22 (0.61)	6.28 (0.62)	6.06 (0.72)	6.32 (0.71)	6.28 (0.62)	6.10 (0.77)	6.17 (0.71)	6.46 (0.60)	6.49 (0.50)
(3) How is the possibility of achieving the goal of this session within the time range set?												
	6.32 (0.69)	5.99 (0.93)	5.80 (0.59)	5.67 (0.76)	5.47 (0.80)	5.28 (0.77)	5.56 (0.85)	5.49 (0.68)	5.47 (0.82)	5.69 (0.71)	6.26 (0.69)	6.27 (0.60)
(4) How is the flexibility allowed by the manual in this session?												
	4.22 (2.32)	3.92 (2.31)	4.20 (2.17)	4.15 (2.33)	4.00 (2.27)	4.00 (2.25)	4.15 (2.30)	4.04 (2.36)	3.96 (2.12)	4.17 (2.41)	4.04 (2.40)	4.29 (2.42)
(5) How is the information volume provided by this manual in this session?												
	5.95 (0.95)	5.82 (1.01)	6.37 (0.75)	6.43 (0.67)	6.14 (0.83)	5.89 (0.96)	5.99 (0.83)	5.81 (0.94)	6.04 (0.81)	5.92 (0.84)	6.18 (0.89)	5.74 (0.90)
(6) How is the contribution made by this individual treatment session to the whole session?												
	6.30 (0.67)	6.41 (0.79)	6.20 (0.82)	6.42 (0.71)	5.89 (0.78)	5.71 (0.83)	6.01 (0.81)	5.71 (0.82)	5.44 (1.03)	5.79 (1.12)	6.00 (1.08)	5.97 (0.99)
(7) Does this session include unnecessary content?												
	1.43 (0.96)	1.61 (1.08)	1.39 (0.97)	1.37 (0.79)	1.46 (0.71)	1.70 (0.91)	1.51 (0.91)	1.92 (1.38)	1.55 (0.78)	1.72 (1.12)	1.85 (1.93)	1.83 (1.93)
(8) Does this session miss any important content?												
	1.30 (0.88)	1.25 (0.87)	1.33 (1.08)	1.25 (0.81)	1.33 (0.89)	1.39 (0.84)	1.26 (0.81)	1.33 (0.89)	1.31 (0.90)	1.31 (0.80)	1.59 (1.28)	1.69 (1.31)

Note: Every item was rated on a scale from 1 to 7: 1=not at all, 2=mostly not, 3=basically not, 4=medium, 5=basically, 6=mostly, 7=completely

Table 4. Feedback scale of therapists on every week's treatment

Group/ Item	Week numbers/Mean (SD)							
	First week	Second week	Third week	Fourth week	Fifth week	Sixth week	Seventh week	Eighth week
(1) Is this week's content useful?								
	6.54(0.66)	6.62(0.61)	6.35(0.75)	6.32(0.70)	6.05(0.85)	6.25(0.73)	6.43(0.75)	6.49(0.68)
(2) Is this week's task feasible?								
	6.44(0.62)	6.27(0.75)	6.09(0.79)	5.83(0.75)	5.64(0.74)	5.96(0.79)	6.26(0.76)	6.38(0.73)
(3) Can patients master the content of this week's session?								
	6.19(0.79)	5.91(0.81)	5.64(0.79)	5.51(0.85)	5.14(0.76)	5.63(0.89)	5.97(0.78)	6.14(0.71)
(4) Is it rushed to achieve this week's goal?								
	2.47(1.91)	2.15(1.74)	2.85(1.58)	2.41(1.55)	3.01(1.21)	2.42(1.54)	2.53(1.69)	2.39(1.78)
(5) Does this week's treatment fit into the whole treatment plan?								
	6.29(0.69)	6.24(0.76)	6.10(0.65)	5.79(0.83)	5.51(1.03)	5.86(1.00)	6.17(0.94)	6.29(0.83)
(6) How is the effectiveness of this week's session?								
	6.26(0.71)	6.03(0.94)	5.77(0.98)	5.62(1.01)	5.49(0.95)	5.71(0.83)	5.76(0.85)	5.66(1.28)

Note: Every item was rated on a scale from 1 to 7: 1=not at all, 2=mostly not, 3=basically not, 4=medium, 5=basically, 6=mostly, 7=completely

Table 5. General feedback scale of therapists		
Group/Item	**Mean (SD)**	**Range of actual scores**
(1) Are the contents of this manual easy to understand?		
	6.12(0.89)	6—7
(2) Are the treatment methods described in the manual easy to conduct?		
	6.15(1.14)	6—7
(3) Are the materials used by this therapy useful?		
	5.90(0.83)	5—6
(4) Is the flexibility allowed by this manual enough?		
	4.09(1.29)	4—5
(5) Do you think twelve sessions long enough to achieve treatment goals?		
	5.68(1.38)	5—6
(6) Does this manual include unnecessary contents?		
	1.72(0.95)	1—2
(7) Does this manual miss any important content?		
	1.54(0.65)	1—2
(8) Do you think this manual is suitable to be applied on patients?		
	5.57(0.86)	5—6
Note: Every item was rated on a scale from 1 to 7: 1=not at all, 2=mostly not, 3=basically not, 4=medium, 5=basically, 6=mostly, 7=completely		

4.2 Limitations

Participants were not assigned randomly, so it is difficult to generalize the conclusion that the applicability of SCBT is high. In addition, not analyzing the data of participants who dropped out may exaggerate the feasibility and acceptability of SCBT.

4.3 Implications

On the basis of previous studies, the present study tested the applicability of SCBT, and provided methodological evidence on treating anxiety disorder for Chinese primary medical workers.

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Conflicts of interest statement

Authors have no conflict of interest related to this manuscript.

Ethical approval

The study was approved by the Ethics Committee of Shanghai Mental Health Center.

Informed consent

All participants provided their written informed consent before they participated in this study.

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Authors' contributions

Li Zhang, Zhipei Zhu, Fang Fang, Yuan Shen and Na Liu were responsible for carrying out the specific steps of the study. Li Zhang wrote the manuscript for the present study. Chunbo Li provided guidance and revision on study design, implementation and paper writing.

简化认知行为治疗的适宜性评价研究

张丽，朱智佩，方芳，申远，柳娜，李春波

背景：我们在国内较早开展并研发了针对焦虑症的结构化认知行为治疗操作手册，本研究在前期研究基础上对简化认知行为治疗的适宜性进行评价。

目的：通过多中心临床对照实验，评价简化认知行为治疗（Simplified Cognitive Behavioral Therapy，SCBT）的适宜性。

方法：通过来自不同级别的精神卫生专科医疗机构和综合医院精神科等多个中心，对广泛性焦虑患者进行SCBT的临床对照研究，分为3组：SCBT组，SCBT＋药物组和药物组。比较三组脱落率，接受SCBT患者对治疗满意度以及治疗师对SCBT评价。

结果：（1）三组脱落率差异没有统计学意义。（2）接受SCBT的两组患者仅在治疗时间和次数上差异有统计学意义，SCBT组比SCBT+药物组患者治疗满意度高。（3）18名SCBT实施人员均认为操作手册内容容易理解、易于操作，并到达治疗目标。

结论：SCBT对广泛性焦虑患者适宜性较强，有望成为在不同级别医疗机构应用推广的心理治疗方法。

关键词：简化认知行为治疗；广泛性焦虑障碍；操作手册；评价

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