


RESEARCH NOTE

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Feasibility study of mindfulness-based cognitive therapy for anxiety disorders in a Japanese setting

Mitsuhiro Sado^{1,2*} , Sunre Park^{3,4}, Akira Ninomiya^{1,2}, Yasuko Sato⁵, Daisuke Fujisawa^{4,6}, Joichiro Shirahase^{1,2} and Masaru Mimura^{1,2}

Abstract

Objective: Mindfulness-based cognitive therapy (MBCT) could be a treatment option for anxiety disorders. Although its effectiveness under conditions of low pharmacotherapy rates has been demonstrated, its effectiveness under condition of high pharmacotherapy rate is still unknown. The aim of the study was to evaluate effectiveness of MBCT under the context of high pharmacotherapy rates.

Results: A single arm with pre-post comparison design was adopted. Those who had any diagnosis of anxiety disorders, between the ages of 20 and 74, were included. Participants attended 8 weekly 2-hour-long sessions followed by 2 monthly boosters. Evaluation was conducted at baseline, in the middle, at end of the intervention, and at follow-up. The State-Trait Anxiety Inventory (STAI)-state was set as the primary outcome. Pre-post analyses with mixed-effect models repeated measures were conducted. Fourteen patients were involved. The mean age was 45.0, and 71.4% were female. The mean change in the STAI-state at every point showed statistically significant improvement. The STAI-trait also showed improvement at a high significance level from the very early stages. The participants showed significant improvement at least one point in some other secondary outcomes.

Trial registration Retrospectively registered at the University Hospital Medical Information Network on 1st August 2013 (ID: UMIN000011347)

Keywords: Mindfulness, Anxiety disorders, Mindfulness-based cognitive behavioral therapy

Introduction

Anxiety disorders are among the most prevalent and long-term mental disorders worldwide. The prevalence rates are estimated to be 18.1% in the US [1], 6.4% in Europe [2], and 5.5% in Japan [3]. The accumulative remission rates within 8 years for social anxiety disorders, panic disorders with agoraphobia, and generalized anxiety disorders remain low, at: 31, 38, and 49%, respectively [4]. The intractable feature of the condition is one of its aspects that boost prevalence.

Such high prevalence considerably burdens the society. The latest disability studies [5, 6] revealed that anxiety disorders represent the 6th leading disease in terms of years of life lived with a disability in 2010. The burden converted into monetary cost manifests the magnitude. The societal cost of anxiety disorders rose to USD 42.3 billion in the US in 1990 [7], GBP 8.9 billion in England in 2007 [8], and JPY 2.4 trillion in Japan in 2008 [9].

Although pharmacotherapy and individualized cognitive behavior therapy (CBT) were recommended as the 1st line treatment among the clinical guidelines [10–12], more patients chose CBT if it was available. However, psychotherapists' scarcity restricts the dissemination of adequate individualized CBT. Therefore, the development of another form of psychotherapy, which is as cost effective and effective as CBT, is necessary.

*Correspondence: mitsusado@keio.jp

¹ Department of Neuropsychiatry, Keio University School of Medicine, Tokyo, Japan

Full list of author information is available at the end of the article



Mindfulness-based cognitive therapy (MBCT) would meet these requirements. It is a form of group psychotherapy combining the essence of CBT and mindfulness-based stress reduction (MBSR) program, which was developed and brought into the healthcare arena by Jon Kabat-Zinn in the 1970s [13]. MBCT aims to cultivate mindfulness and intentional non-judgmental awareness in present-moment experiences [14]. This therapy could be more cost effective than individualized CBT because MBCT is normally provided in a group setting.

The effectiveness of MBCT has been demonstrated in various treatment areas: relapse prevention of depressive episodes [15–18], psychological distress among cancer patients [19–22], chronic pain [23], and so on [24]. Even in the area of anxiety disorder treatment, several studies have already reported significant favorable effects [25–29]. However, because pharmacotherapy rates among the participants in these studies are considerably low (ranging from 0 to 39%), its effectiveness under settings in which the vast majority of patients have already experienced pharmacotherapy (e.g., in Japan the pharmacotherapy rate among patients with anxiety disorders is 86% [30]) is still unknown. Therefore, we aimed to investigate the feasibility and effectiveness of MBCT as a pilot study with a single arm for patients with anxiety disorders.

Main text

Method

Design

A single arm study was used to test MBCT's feasibility and effectiveness with a pre-post comparison. The study was conducted between March 2013 and September 2014.

Ethics approval and consent to participate

This study was approved by the ethical committee at Keio University School of Medicine and registered at the University Hospital Medical Information Network on 1st August 2013 (ID: UMIN000011347).

Participants

Inclusion criteria for this study were: (1) any diagnosis of panic disorder, social anxiety disorder, obsessive compulsive disorder, or generalized anxiety disorder using the Diagnostic and Statistical Manual of Mental Disorders 4th edition; (2) aged between 20 and 74 years; and (3) able to provide consent in writing. The exclusion criteria were: (1) any past history of substance-related disorders/manic or psychotic episode/receiving mindfulness-based intervention, (2) impairment in cognitive function, (3) antisocial personality disorder, (4) severe suicidal ideation, and (5) expected difficulty in following up 4 months after the start of the intervention.

Procedure

The participants were recruited from the Department of Neuropsychiatry, Keio University Hospital. After providing written consent, they attended an 8-week course of MBCT for anxiety, followed by 2 monthly booster sessions. Evaluation was conducted before the intervention (0 weeks) (T0), during it (4 weeks) (T1), at its end (8 weeks) (T2), and during the follow-up periods (1 month (T3) and 2 months after the completion of the program (T4)).

Intervention

Because the original MBCT [13] targets relapse prevention for depression, we made minimal modifications to the original program in order to ensure that it fits with anxiety disorders. Specifically, we revised the psychoeducational part in Session 4 so that it would be relevant to anxiety disorders. The details of the program are shown in Table 1.

This program consists of 8 weekly 2-hour-long sessions. Each session consists of three parts: (1) practicing meditation and yoga, (2) sharing experiences, and (3) psychoeducational portions. The participants were encouraged to practice daily for 30 min to 1 h at home with audio CD instructions and perform other exercises such as monitoring positive or negative feelings.

The program was led by a psychiatrist (MS) and a nurse/clinical psychologist (SP), both of whom had practiced mindful meditation for more than 2 years with experience in attending MBSR and MBCT retreats.

Outcomes

We used the following scales to measure outcomes, all of which had already been validated in Japanese.

Primary We set the State-Trait Anxiety Inventory (STAI)-state as the primary outcome. The STAI is a commonly used measure of state and trait anxiety [31].

Secondary We also used the following scales for secondary outcomes: the STAI-trait, 6-item Kessler Psychological Distress Scale (K-6), Center for Epidemiologic Studies Depression Scale (CES-D), EuroQol 5 Dimension (EQ-5D), Five Facet Mindfulness Questionnaire (FFMQ), 36-Item Short-Form Health Survey (SF-36), Mobility Inventory for Agoraphobia (MIA), and Liebowitz Social Anxiety Scale (LSAS). The details of each scale are as follows.

K-6 The K6 scale was designed to be sensitive to the threshold for the clinically significant range of the distribution of nonspecific distress in an effort to

Table 1 Contents of the program

Session	Theme	Contents
1	Automatic pilot	Psychoeducation: what is mindfulness Exercise: mindfulness eating ("Raisin exercise")/body scan Homework: mindfulness of a routine activity/body scan
2	Dealing with barriers	Psychoeducation: association of mood and thoughts Exercise: thoughts and feelings exercise/body scan/mindful breathing meditation Homework: body scan/breathing meditation/pleasant events calendar
3	Mindfulness of the breath	Psychoeducation: awareness of mind wandering and focusing on the breath Exercise: breathing meditation/gentle yoga/mindful walking Homework: breathing meditation/gentle yoga/mindful walking/unpleasant events calendar
4	Staying present	Psychoeducation: staying present/about anxiety symptoms ^a Exercise: meditation of sounds and thoughts/breathing meditation Homework: meditation of sounds and thoughts/breathing meditation/3-min breathing space
5	Allowing/letting be	Psychoeducation: exploring difficulty Exercise: breathing meditation/meditation of sounds and thoughts/exploring difficulty Homework: breathing meditation/meditation of sounds and thoughts/exploring difficulty/3-min breathing space
6	Thoughts are not facts	Psychoeducation: cognitive biases Exercise: breathing meditation/meditation of sounds and thoughts/exploring difficulty Homework: breathing meditation/meditation of sounds and thoughts/exploring difficulty/3-min breathing space
7	How can I best take care of myself?	Psychoeducation: choosing functional behaviors/behavioral activation/identifying triggers Exercise: mindfulness meditation of sounds and thoughts/breathing meditation Homework: meditation of sounds and thoughts/breathing meditation/3-min breathing space + action plan
8	Using what has been learned to deal with future mood	Personal reflections of course/plans for future practice and strategies for maintaining momentum/farewell Exercise: body scan/breathing meditation

^a The lecture relevant to depression was replaced by that about anxiety in session 4

maximize its ability to discriminate cases of serious mental illness from non-cases [32].

CES-D The CES-D is a short self-report scale designed to measure depressive symptomatology among the general population [33]. The scale contains 20 items that ask how often over the past week the patients experienced symptoms associated with depression.

EQ-5D EQ-5D is a standardized instrument for use as a measure of health outcomes [34]. It provides a simple descriptive profile and a single index value for health status.

FFMQ The FFMQ is based on a factor analytic study of five independently developed mindfulness questionnaires [35]. The five facets are observing, describing, acting with awareness, the non-judging of inner experience, and non-reactivity to inner experience.

SF-36 The SF-36 is a set of generic, coherent, and easily administered quality-of-life measures. These measures rely on patient self-report [36]. It consists of eight sections: vitality, physical functioning, bodily pain, general health perceptions, physical role functioning, emotional

role functioning, social role functioning, and mental health [37, 38].

MIA The MIA is a measurement of self-reported agoraphobic avoidance behavior and frequency of panic attacks [39]. Respondents rate 26 items using Likert-type scales ranging from 1 (never avoid) to 5 (always avoid) to indicate how much they avoid various situations due to anxiety or discomfort when they are accompanied by a trusted companion and when they are alone.

LSAS The LSAS is an instrument used to assess the range of social interactions and performance situations that a patient fears; it assists in the diagnosis of social anxiety disorder [32]. The scale features 24 items, which are divided into two subscales. Of these, 13 questions relate to performance anxiety and 11 to social situations.

Analyses

Changes in mean scores between the baseline and each observational period for each scale were tested with mixed-effect models, repeated-measures, and intention-to-treat analyses. Age, sex, and intervention were

imputed into the model as coefficients. A 5% significance level was adopted for all statistical analyses. STATA ver.15 was used to conduct the statistical analysis.

Results

Basic participant characteristics

Fourteen patients were involved in the research. As shown in Table 2, mean age (standard deviation: sd) was 45.0 (14.1), and 71.4% were female. With respect to primary diagnosis, six participants had panic disorders, while five and three had social anxiety disorder and obsessive compulsive disorder, respectively. Average treatment duration at the start of the intervention was 13.4 years (7.4) and the rate of pharmacotherapy use was 93% (71.4% and 50.0% used antidepressants and benzodiazepine, respectively). All but one of the participants completed the program and the average number of program attendance was 7.4 (1.1). The reason for dropout was the deterioration of respiratory symptoms that were originally comorbid.

Primary outcome

As described in Table 3, the mean change (sd) from baseline in STAI-state at every point showed statistically significant improvements: -6.14 (2.70) at T1, -11.66 (2.78) at T2, -8.12 (2.78) at T3, and -6.58 (2.78) at T4.

Secondary outcome

As shown in Table 3, significant improvements were observed in multifarious scales. For STAI-trait, improvement was observed from the very early stages with high significance levels and continued until 2 months after the completion of the intervention. With respect to K-6, the participants showed significant improvements

post-treatment, but these disappeared during follow-up. Although the total score did not show any change, significant improvements were noted on an FFMQ subscale (i.e., non-judgment) immediately and also at 1 month post-treatment. Moreover, the trend-level improvement in another subscale (i.e., awareness) at 2 months post-treatment was acknowledged.

With regard to the disease-specific scales, the MIA (AAC) score indicated significant improvements at 2 month follow-up, while only improvement trend was detected in MIA (AAL) at the end of the follow-up. No improvement was observed in LSAS, specifically, among the participants with social anxiety disorders.

Discussion

To the best of our knowledge, this is the first study in Japan to evaluate the applicability and feasibility of the MBCT for anxiety disorders. The present results indicate that it would favorably affect the symptoms of anxiety disorders. The quite low attrition rate also demonstrated its feasibility even in settings under which pharmacotherapy had already been provided to the vast majority of participants.

The improvement in STAI-state with a high significance level that was observed even post-treatment indicates that the efficacy of MBCT would be sustained, even after the intervention. Another surprising result was that STAI-trait similarly improved significantly. This means the MBCT has the potential to remedy the trait that would affect the onset and continuity of anxiety symptoms from the very early stages. This might represent the peculiarity of mindfulness, which aims to transform the attitude toward unpleasant events rather than to remove the unpleasant experiences themselves.

We covered only two disease-specific scales: agoraphobia and panic attack (MIA) and social phobia (LSAS) due to the constraints of scale availability. The fact that MIA (AAC) showed significant immediate and 2-month-post-treatment improvements indicates that MBCT has the potential to be effective even for disease-specific symptoms.

Attention should be paid to the interpretation of the results of the FFMQ. The FFMQ is composed of five factors, and is supposed to converge at two higher factors: “self-regulated attention” and “orientation to experience” [40]. Although a previous study showed significant changes in all FFMQ factors pre- and post-intervention in the MBCT group [41], no changes were detected in this study except for “non-judging.” As indicated in previous studies, although numerous validation studies have been conducted to measure mindfulness, the results appear to vary [42]. The discrepancy

Table 2 Baseline characteristics of the participants

Characteristics	Mean/n	sd/%
Age	45.0	14.1
Gender (female)	10	71.4
Diagnosis		
Panic disorder	6	42.9
SAD	5	35.7
OCD	3	21.4
Duration from onset (years)	13.4	7.4
Medication	13	92.9
Antidepressants	10	71.4
Benzodiazepine	7	50.0
Mood stabilizer	2	14.3
Antipsychotics	2	14.3
Frequency of attendance	7.4	1.1

SAD social anxiety disorder, OCD obsessive compulsive disorder

Table 3 Outcomes scores at each assessment point with comparison to baseline

Mean score at baseline and mean differences compared to baseline												
	n	Baseline		4 week		8 week		12 week		16 week		
		Mean	se	Mean difference	se	Mean difference	se	Mean difference	se	Mean difference	se	
STAI-state	14	52.6	2.8	-6.14	2.70	-11.66	2.78	-8.12	2.78	-6.58	2.78	
P value				0.02		<0.001		<0.01		0.02		
STAI-trait	14	55.9	3.0	-3.86	1.85	-6.55	1.90	-4.86	1.90	-3.93	1.90	
P value				0.04		<0.01		0.01		0.04		
K-6	14	8.6	1.6	-1.07	1.17	-2.68	1.20	-1.68	1.20	0.16	1.20	
P value				0.36		0.03		0.16		0.89		
CESD	14	17.7	3.0	-0.71	2.03	-1.46	2.09	-3.85	2.09	1.69	2.09	
P value				0.73		0.48		0.07		0.42		
SF36 PCS	14	54.1	2.8	-0.57	2.02	1.68	2.07	0.52	2.07	1.32	2.07	
P value				0.78		0.42		0.80		0.53		
SF36MCS	14	41.4	3.6	-2.17	2.18	2.11	2.25	2.27	2.25	-1.33	2.25	
P value				0.32		0.35		0.31		0.55		
SF36 RCS	14	42.5	4.3	3.13	2.84	3.03	2.92	4.50	2.92	2.29	2.92	
P value				0.27		0.30		0.12		0.43		
FFMQ (total)	14	110.4	4.9	-1.42	2.25	2.51	2.31	0.96	2.31	-1.17	2.31	
P value				0.53		0.28		0.68		0.61		
FFMQ (observe)	14	22.6	1.5	-0.93	0.99	0.07	1.01	0.14	1.01	0.77	1.01	
P value				0.35		0.94		0.89		0.45		
FFMQ (noreact)	14	16.6	1.7	-0.79	0.84	0.93	0.87	0.81	0.87	0.39	0.87	
P value				0.35		0.28		0.35		0.65		
FFMQ (nonjudgement)	14	23.9	2.0	2.00	1.17	2.62	1.21	2.54	1.21	0.77	1.21	
P value				0.09		0.03		0.04		0.52		
FFMQ (describe)	14	22.9	1.5	-1.18	0.84	0.57	0.87	-0.96	0.87	-1.04	0.87	
P value				0.16		0.51		0.27		0.23		
FFMQ (awareness)	14	24.5	1.6	-0.52	1.11	-1.69	1.15	-1.58	1.15	-2.07	1.15	
P value				0.64		0.14		0.17		0.07		
EQ-5D	14	0.79	0.04	0.01	0.03	0.02	0.03	0.03	0.03	0.04	0.03	
P value				0.79		0.41		0.22		0.09		
MIA (AAC)	6	1.88	0.29	-0.08	0.09	-0.18	0.09	-0.13	0.09	-0.24	0.09	
P value				0.39		0.05		0.14		<0.01		
MIA (AAL)	6	2.24	0.49	-0.02	0.14	-0.15	0.14	-0.05	0.14	-0.25	0.14	
P value				0.87		0.28		0.71		0.07		
MIA (panic attack 1 weeks)	6	2.83	2.44	-0.17	1.19	-1.67	1.19	-2.17	1.19	-1.67	1.19	
P value				0.89		0.16		0.07		0.16		
MIA (panic attack 3 weeks)	6	5.83	4.85	-1.00	1.72	-3.33	1.72	-2.83	1.72	-2.50	1.72	
P value				0.56		0.05		0.10		0.15		
LSAS	5	73.40	13.41	-12.00	6.81	-3.63	7.42	-7.38	7.42	-9.13	7.42	
P value				0.08		0.63		0.32		0.22		

between the previous and current studies possibly represents the nature of this scale. In addition, the discrepancy could be due to the small sample size of the

current study. No, or quite limited, specific measures for anxiety in the CES-D, EQ-5D, and SF-36 would be a reason why no significant changes were observed in scores on these scales.

Limitations

This study has some limitations. The sample size was too small to conduct subgroup analyses between different types of anxiety disorders. This also affected the generalizability of the results. The other limitation was that the study was performed with a single arm pre-post design. Therefore, it is necessary to conduct randomized controlled studies to accurately evaluate its effectiveness in future research.

Abbreviations

AAC: Avoidance Accompanied Scale; AAL: Avoidance Alone Scale; CBT: cognitive behavior therapy; CES-D: Center for Epidemiologic Studies Depression Scale; EQ-5D: EuroQol 5 Dimension; FFMQ: Five Facet Mindfulness Questionnaire; K-6: the 6-item Kessler Psychological Distress Scale; LSAS: the Liebowitz Social Anxiety Scale; MBCT: mindfulness-based cognitive therapy; MBSR: mindfulness-based stress reduction; MIA: the Mobility Inventory for Agoraphobia; sd: standard deviation; SF-36: the 36-Item Short-Form Health Survey; STAI: the State-Trait Anxiety Inventory.

Authors' contributions

MS conceived and designed the study. MS drafted the study protocol. MS and SP organized and supervised the study implementation, and MS drafted the manuscript. SP, AN, JS, and MM refined the study protocol and implementation. MS, SP, and YS intervened with the participants. MS and AN conducted the statistical analyses. MS, AN, DF, JS and MM interpreted the results. MS drafted the grant proposal and was responsible for the study implementation. MS was responsible for the study management. SP, YS, and AN collected data. All authors critically reviewed the manuscript for content and approved the final version. MS and AN had full access to all of the data throughout the study and take responsibility for the integrity of the data and the accuracy of the analysis. All authors read and approved the final manuscript.

Author details

¹ Department of Neuropsychiatry, Keio University School of Medicine, Tokyo, Japan. ² Center for Stress Research, Keio University, Tokyo, Japan. ³ Faculty of Nursing and Medicine Care, Keio University, Tokyo, Japan. ⁴ Palliative Care Center, Keio University Hospital, Tokyo, Japan. ⁵ Department of Nursing, National Hospital Organization Tokyo Medical Center, Tokyo, Japan. ⁶ Division of Patient Safety, Department of Neuropsychiatry, Keio University School of Medicine, Tokyo, Japan.

Acknowledgements

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Consent to publish

Not applicable.

Ethics approval and consent to participate

This study was approved by the ethical committee at Keio University School of Medicine (reference: 2012-440). The identification number of the clinical trial registry system at the University Hospital Medical Information Network was UMIN000011347.

Funding

This research was conducted with the assistance of a fund for the promotion of science from Keio University (H24 KEIO-GAKUSHIN-KOJIN 004163). The fund body was not involved in any of the following processes: the development of

the study design and protocol; data collection, analysis, or interpretation; and the writing of the manuscript.

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Received: 20 July 2018 Accepted: 28 August 2018

Published online: 06 September 2018

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