

A Long-Term Pilot Study of Mindfulness-Based Cognitive Therapy for Subjective Well-Being Among Healthy Individuals in Comparison with Clinical Samples

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Purpose: Mindfulness-based cognitive therapy (MBCT) could be an intervention for improving subjective well-being among healthy individuals (HIs). However, MBCT studies for HIs to improve their subjective well-being are rare. The aim of this study was to report the feasibility, safety and effectiveness of MBCT for HIs in comparison with clinical samples.

Patients and Methods: We conducted a single-arm, pre-post comparison pilot study offering MBCT to both HIs and people with common mental disorders. Twenty-four participants in total were included in the study. Eight weekly two-hour sessions with six monthly boosters were offered to all participants. Assessment was carried out at baseline, week 4, 8, and during follow-up. The 5-item World Health Organization Well-Being Index (WHO-5) was the primary clinical outcome measure.

Results: The results showed the MBCT is sufficiently safe and would be more feasible in HIs compared to in clinical samples (attendance rate: 81.5% vs 61.3%, $p=0.06$). Although Satisfaction with Life Scale, the other scale of subjective well-being used, improved significantly at week 20 ($p=0.01$), no significant improvement was seen in WHO-5. The results of the sub-group analysis revealed WHO-5 improved significantly at week 8 and 32 among the subjects whose baseline scores began in the lower half.

Conclusion: MBCT is sufficiently safe and would be more feasible with HIs compared to the clinical samples. In designing randomized controlled trials, selecting HIs with lower subjective well-being would be reasonable to minimize the “ceiling effect” on outcomes.

Keywords: subjective well-being, mindfulness-based cognitive therapy, feasibility, common mental disorders

Introduction

Numerous studies have endorsed Mindfulness Based Cognitive Therapy's (MBCT's) effectiveness on negative symptoms of clinical populations.¹⁻³ The theoretical model indicates MBCT increases cognitive reappraisal and decreases expressive suppression strategies. This leads to a decrease in depressive and anxiety symptoms and to an increase in psychological well-being. However, whether such a mechanism would also work for healthy individuals (HIs) is not yet known. Subjective well-being for HIs is significant because previous studies revealed that better subjective well-being contributes to better health conditions, including higher

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quality of life, less stress,⁵ and longer life expectancy.^{6–8} However, there is little research examining whether MBCT improves subjective well-being of HIs in the long term. Therefore, in anticipation of future Randomized Controlled Trials (RCTs), we decided to conduct a pilot study for HIs in parallel with clinical samples to assess feasibility, safety, and effectiveness of MBCT, and compare these results with those of clinical samples.

Materials and Methods

Design

The design of the study was a single-arm, pre-post comparison study. The participants consisted of HIs, and people with common mental disorders (CMDs). The same MBCT was offered to all participants in a mixed group.

Ethics Approval and Consent to Participate

The study was approved by the Institutional Review Board of the Keio University School of Medicine and was registered at the University Hospital Medical Information Network Clinical Trials Registry (registry ID: UMIN000022528, URL: https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000025928). The study was conducted and reported in conformance with the STROBE Statement.⁹ This study was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2008.

Procedure

The participants were recruited between May 2016 and February 2017 via the website of the Keio Center for Stress Research for HIs, and at Keio University Hospital for the people with CMDs. After an application from the candidates, one of the research investigators assessed their eligibility for the study. The separate inclusion/exclusion criteria were applied, respectively, as described in Participants section. The groups were not matched (eg age, gender, etc.). After providing written consent, all participants were offered an eight-week MBCT intervention, followed by six monthly follow-up sessions. Assessment was carried out at five time points: before the intervention (T1), at four weeks after the start of the program (T2), at the end of the program (week 8, T3), at three months and six months after completion of the intervention (T4 and T5).

Participants

HIs were included in the study if they (1) had no history of mental illness or had a history of mental illness that was followed by a recovery period of longer than 2 years, (2) had no severe physical illness hindering participation in the study, (3) were aged between 20 and 65, and (4) were able to submit written informed consent. Eligible participants were excluded if they were judged to have (1) difficulty in following up for eight months or (2) a history of previous mindfulness-based intervention (MBI). Patients were included in the comparison group, if they (1) met at least one of any diagnosis based on the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition Axis I Disorders including anxiety disorder (panic disorder with/without agoraphobia, social anxiety disorder, obsessive-compulsive disorder), adaptation disorder, or major depressive disorder (remitted for longer than 6 months); (2) were aged between 20 and 65 years; (3) submitted written informed consent. Candidate participants were excluded when they had (1) difficulty in following up for eight months; (2) a history of previous MBI; (3) severe physical disorders restricting participation in the study; (4) a history of substance use disorder, alcoholism, or anti-social personality disorder; (5) marked suicidal thoughts or self-injurious behavior; or (6) organic cerebral lesions.

Intervention

The intervention used in the study was MBCT, developed by Segal et al.¹⁰ The program consists of psychological education, meditation, yoga, and group discussion. Because MBCT was originally designed to target depression relapse prevention, we added minor modifications to the original program to focus on improving subjective well-being. The program contents and the parts modified are described in Table 1.

As in the original MBCT, we ran eight weekly two-hour-long sessions. Monthly booster sessions were provided during a six-month follow-up period. Between the weekly sessions, the participants were assigned daily homework, such as meditation, yoga, or activity records. We did not assign any regular homework during the follow-up period. Instead, we asked participants to send short essays about their daily practice every two to three months to share their experiences among other participants. The program was mainly run by MS with more than five years' experience of mindfulness practice, with assistance from

Table I Contents of the Program

Session	Theme	Contents
1	Automatic pilot	Psychoeducation: What is mindfulness? Exercise: Mindfulness eating ("Raisin exercise")/body scan Homework: Body scan/mindfulness of a routine activity
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 event calendar/mindfulness in everyday life
3	Mindfulness of the breath	Psychoeducation: Awareness of mind wandering and focusing on the breath Exercise: Breathing meditation/meditation of sounds/gentle yoga/mindful walking Homework: Three-minute breathing space/gentle yoga/mindful walking/unpleasant events calendar
4	Staying present	Psychoeducation: Staying present/exploring difficulty Exercise: Mindfulness meditations (breathing/sounds and thoughts/exploring difficulty) Homework: Mindfulness meditations (breathing/sounds and thoughts/exploring difficulty/three-minute breathing space)/Diary of appreciation and gratitude events
5	Compassion	Psychoeducation: Compassion Exercise: Mindfulness meditations (breathing/sounds and thoughts/exploring difficulty) / Compassion meditation (loving and kindness) Homework: Mindfulness meditations (breathing/sounds and thoughts/exploring difficulty/three-minute breathing space) /compassion meditation/diary of your kind behavior
6	Thoughts are not facts	Psychoeducation: Cognitive biases Exercise: Mindfulness meditations/compassion meditation/watching the movie "Happy" about subjective well-being Homework: Mindfulness meditations (choose what you like/three-minute breathing space)
7	How can I best take care of myself?	Psychoeducation: Choosing functional behaviors/behavioral activation/identifying triggers Exercise: Mindfulness meditations (breathing/sounds and thoughts) Homework: Mindfulness meditations (choose what you like/three-minute breathing space)/diary of activity that nourishes you
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/asking yourself why you are here now and what you became aware of through the program

Notes: The parts modified of Mindfulness-Based Cognitive Therapy were as follows. We skipped the full-day silent retreat, and added a compassion meditation in session 5. We also added homework in the form of an appreciation diary between sessions 4 and 5 and a diary of nourishing activity between sessions 7 and 8. We also watched a short movie related to well-being ("Happy" produced by Roko Belic) at the orientation and in session 6.

AK and TK with three years and one year experience of mindfulness practice, respectively.

Outcomes

Feasibility and Safety

Feasibility and safety of the program was evaluated by the session attendance rate and incident rate of the critical adverse events during the program period.

Clinical Outcomes

The primary clinical outcome was subjective well-being, as measured by the 5-item World Health Organization

Well-Being Index (WHO-5).¹¹ WHO-5 is one of the most widely used questionnaires for assessing affective aspects of subjective well-being. Scores on the scale range between 0 and 25. Higher scores indicate a higher level of affective well-being.

We also assessed 11 scales^{12–25} as the secondary clinical outcomes as shown in [Tables 4](#) and [5](#) and [Tables S1](#) and [S2](#). Due to space restrictions, we only report the results of the WHO-5 (primary outcome), Satisfaction with Life Scale (SWLS), and Five Facet Mindfulness Questionnaire (FFMQ) in [Tables 4](#) and [5](#). We extracted WHO-5 and FFMQ among the secondary outcomes because SWLS is

the other aspect of the subjective well-being and FFMQ is a direct scale to assess mindfulness skills.

Satisfaction with Life Scale (SWLS): The SWLS has 5 questions. The scale focuses on assessing one's life satisfaction, which is cognitive aspect of subjective well-being. Scores on the scale range from 5 to 35.¹²

Five Facet Mindfulness Questionnaire (FFMQ): The FFMQ is a scale to assess an individual's mindfulness skills. It asks respondents to indicate their level of agreement with a series of 39 statements about their general tendency to be mindful during daily life experiences.¹³ Scores are in the range between 39 and 195.

Details of the aforementioned outcomes and other secondary clinical outcomes appear in the [supplementary files](#). (Clinical outcomes reported in the [Tables 4 and 5](#), and 6, Clinical outcomes not reported in the [Tables 4–6](#)). All measures are self-report questionnaires and have been validated in the Japanese population.^{26–36}

Statistical Methods

Statistical data relevant to demographic and feasibility are presented descriptively. The change in mean scores at each scale between baseline and each observational point was analyzed with an intention-to-treat analysis and a mixed-effect model repeat measurement to deal with missing data in longitudinal clinical trials. With respect to the scales of the subjective well-being (ie, WHO-5 and SWLS), we treated each scale individually, rather than integrating them. All analyses were performed using the SPSS Version 24.³⁷

Results

As shown in [Figure 1](#), 24 participants in total (12 HIs and 12 people with CMDs) were included in the study. We originally planned to recruit 30 participants. However, we conducted the study with 24 participants because we judged it was difficult to include all 30 participants by the end of the study period.

Participants' Characteristics

The baseline socio-demographic characteristics are presented in [Table 2](#). In brief, the mean age (SD) of the participants was 45.1 years (SD 9.5), 66.7% were female, all were employed, and 66.7% were married in HIs. The participants in CMDs also showed similarity to the HIs except diagnoses of CMDs (five had anxiety disorder, while four and three participants had adaptive disorder

and major depressive disorder (currently remitted), respectively).

Feasibility and Safety

The mean number of sessions attended in HIs was 7.3 out of 8 compared to 5.9 in CMDs ($p=0.11$) during the weekly sessions, and 4.2 out of 6, while 2.7 in CMDs ($p=0.09$) during the follow-up period ([Table 3](#)). Serious adverse events were not observed in this study.

Clinical Outcomes

Healthy Individuals

The results of the clinical outcomes in HIs are shown in [Table 4](#) and [S1](#). No statistically significant improvement was observed in the primary outcome: WHO-5. However, scores on the SWLS showed significant improvements at week 20. On the FFMQ, one subscale (nonjudgement) score showed a significant improvement at week 4 and 8. Among other secondary outcomes, subscales of Self Compassion Scales (SCS) and Multidimensional Assessment of Interoceptive Awareness (MAIA) improved significantly at week 20 and 32 ([Table S1](#)).

Common Mental Disorders

For the participants with CMDs, WHO-5 showed a significant improvement at week 32. All secondary clinical outcomes, except Connor Davidson Resilience Scale, Perceived Stress Scale, Health and Work Performance Questionnaire (relative presenteeism) and some subscales of SCS and MAIA showed significant improvements during the observational period ([Table 5](#) and [S2](#)).

Subgroup Analysis

We conducted a subgroup analysis by dividing all samples into two subgroups irrespective of health status: the upper and the lower half of the baseline scores of WHO-5. The results revealed that WHO-5 improved significantly at week 8 and 32 among the subjects whose baseline score started in the lower half ([Table 6](#)).

Discussion

To the best of our knowledge, this is the first study to evaluate the safety, feasibility and effectiveness of MBCT for improving the subjective well-being of HIs in long term in comparison with clinical samples. With respect to the program's safety and feasibility, no serious adverse events were observed. The mean attendance rate was higher in HIs compared to that in patients with CMDs

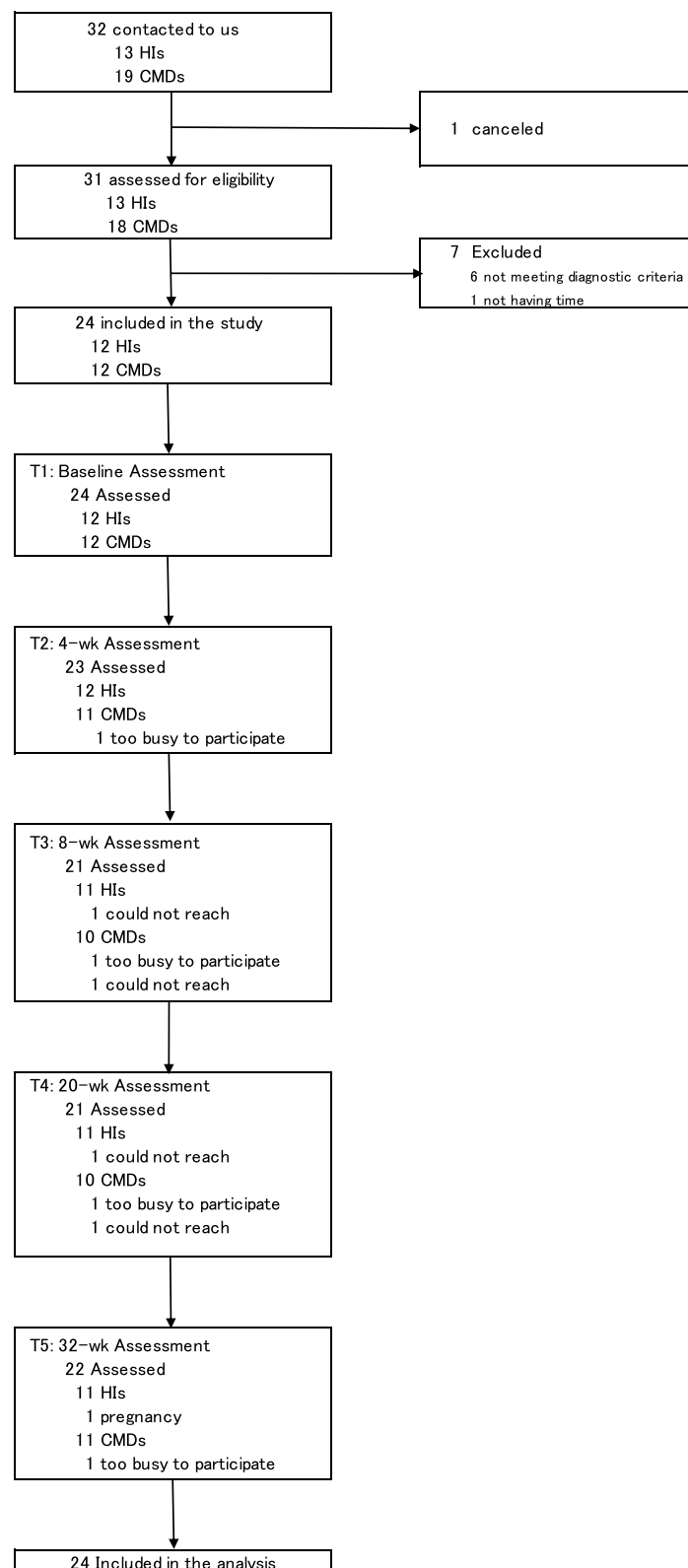


Figure 1 Diagram of the study.

Table 2 Baseline Sociodemographic Characteristics and Diagnosis

	HIIs (n=12)	CMDs (n=12)	p value*
Age, mean (SD), y	45.1 (9.5)	44.3 (10.4)	0.35
Sex (female), n (%)	8 (66.7)	8 (66.7)	1.00
Education, mean (SD), years	16.8 (1.0)	14.6 (2.2)	0.10
Employed, n (%)	12 (100.0)	10 (83.3)	0.15
Marital status, n (%)			
Married	8 (66.7)	8 (66.7)	1.00
Separated, divorced, widowed	1 (8.3)	0 (0.0)	0.33
Single	3 (25.0)	4 (33.3)	0.67
Cohabiting, n (%)	10 (83.3)	11 (91.7)	0.56
Physical complications, n (%)	6 (50.0)	6 (50.0)	1.00
Diagnosis, n (%)			
Panic disorder	N/A	5 (41.7)	N/A
Adjustment disorder	N/A	4 (33.3)	N/A
Major depressive disorders	N/A	3 (25.0)	N/A

Note: *P value is less than 0.05.

Abbreviations: HIIs, healthy individuals; CMDs, people with common mental disorders.

(Table 3). Better health condition might have contributed to higher attendance rate. Considering the fact that the attendance rate of healthy individuals in the study is equivalent enough to the results of previous studies (between 46% and 97%),³⁸ the MBCT for HIIs is sufficiently safe and feasible, and is possibly more acceptable compared to the patients with CMDs.

Table 3 Attendance Frequency to the Sessions

Attendance Frequency	HIIs (n=12)	CMDs (n=12)	p value*
8 week session, n (%) (Weekly, range: 0–8 sessions).	7.3 (90.6)	5.9 (74.0)	0.11
Follow up session, n (%) (Monthly, range: 0–6 sessions).	4.2 (69.4)	2.7 (44.4)	0.09
Total, n (%) Total, n (%) (range: 0–14 sessions).	11.4 (81.5)	8.6 (61.3)	0.06

Note: *P value is less than 0.05.

Abbreviations: HIIs, healthy individuals; CMDs, people with common mental disorders.

Concerning the subjective well-being among HIIs, a statistically significant improvement was detected in SWLS at week 20, following the improvement of one of the FFMQ subscale (nonjudgement) at week 4 and 8. In contrast, no improvement was seen in the primary outcome: WHO-5. Garland et al suggested a mindfulness-to-meaning theory explaining how mindfulness improves peoples' well-being.³⁹ This theory indicates that mindfulness practice improves metacognitive capacity for experience through amelioration of mindfulness skills, resulting in a positive reappraisal of the experience and an increase in positive affect. According to the theory, the order of improvement should be mindfulness skill (FFMQ), followed by the cognitive aspect (SWLS), and the affective aspects (WHO-5) of well-being. This might explain why FFMQ and SWLS improved within the study period, but WHO-5 did not show any significant improvement.

In the people with CMDs, both WHO-5 and SWLS improved significantly at week 32. We judged that this discrepancy possibly occurred due to the following two reasons. The first is the lack of statistical power due to the very limited sample size. The other reason is the “ceiling effect”. As shown in Tables 4 and 5, the baseline scores of any scales were significantly better in HIIs. As the results of the subgroup analysis in Table 6 show, WHO-5 improved significantly at week 8 and 32 if we focused on the subjects whose baseline scores were in the lower half. Considering these facts, in developing a design of RCTs, selecting individuals with lower subjective well-being would be reasonable to minimize the “ceiling effect”.

Limitations

The study had some limitations. The sample size was too small to detect clinically significant difference. Another limitation was that the basic characteristics of the samples in each group were not matched. Furthermore, the study was performed with a pre-post comparison design. Therefore, a well-designed RCT with larger sample sizes is warranted in the next research stage.

Conclusions

MBCT is sufficiently safe and would be more feasible in HIIs compared to the clinical samples. In designing RCTs, selecting HIIs with lower subjective well-being would be reasonable to minimize the “ceiling effect”.

Table 4 Outcomes Score at Each Assessment Point with Comparison to Baseline (Healthy Individuals)

Scales	Mean Score (SD)				
	T1	T2	T3	T4	T5
	Baseline	4 Week	8 Week	20 Week	32 Week
WHO-5 P value	76.0 (7.0)	70.0 (11.9) 0.10	75.6 (12.8) 0.84	73.6 (10.9) 0.63	74.9 (7.2) 0.63
SWLS P value	25.2 (3.9)	24.8 (3.7) 0.70	26.2 (3.1) 0.24	27.6 (3.6) <0.01*	26.0 (3.3) 0.28
FFMQ (total) P value	134.7 (11.8)	135.0 (11.1) 0.74	143.3 (14.8) 0.02	139.2 (16.0) 0.19	143.2 (15.9) 0.07
FFMQ (Observe) P value	26.6 (2.4)	25.8 (4.0) 0.40	28.3 (4.2) 0.14	28.5 (3.3) 0.04	29.7 (3.3) <0.01*
FFMQ (No react) P value	27.0 (4.6)	26.6 (3.7) 0.58	27.0 (4.3) 0.36	27.7 (3.6) 0.36	27.9 (2.5) 0.24
FFMQ (Nonjudgement) P value	26.8 (4.9)	28.8 (5.6) 0.01*	31.3 (5.4) <0.01*	28.3 (6.7) 0.15	29.4 (7.3) 0.19
FFMQ (Describe) P value	28.1 (3.8)	27.4 (4.8) 0.52	28.5 (5.3) 0.41	26.9 (7.0) 0.52	26.7 (6.8) 0.45
FFMQ (Awareness) P value	27.0 (4.1)	27.9 (3.8) 0.24	28.3 (4.2) 0.10	27.8 (4.5) 0.36	29.5 (4.0) 0.049

Notes: All outcomes were analyzed on the basis of intent-to-treat, using a mixed-effects model repeated-measures approach. *P value is less than 0.0125 (set by Bonferroni correction (0.05/4)).

Abbreviations: FFMQ, Five Facet Mindfulness Scale; SWLS, Satisfaction With Life Scale; WHO-5, the World Health Organization-Five Well-Being Index.

Table 5 Outcomes Scores at Each Assessment Point with Comparison to Baseline (People with Common Mental Disorders)

Scales	Mean Score (SD)				
	T1	T2	T3	T4	T5
	Baseline	4 Week	8 Week	20 Week	32 Week
WHO-5 P value	53.3 (16.3)	57.8 (17.2) 0.27	57.2 (13.9) 0.60	56.4 (14.5) 0.64	73.8 (13.2) <0.01*
SWLS P value	23.3 (3.2)	23.9 (3.4) 0.33	25.4 (3.0) 0.06	23.9 (1.9) 0.52	26.6 (2.8) <0.01*
FFMQ (total) P value	119.9 (11.7)	120.8 (10.3) 0.98	131.5 (9.9) 0.07	137.3 (11.7) 0.051	141.2 (13.8) <0.01*
FFMQ (Observe) P value	24.8 (4.8)	27.0 (4.4) 0.20	28.7 (3.3) 0.01*	28.4 (3.7) 0.02	28.6 (4.8) 0.03
FFMQ (No react) P value	22.2 (2.3)	21.0 (3.7) 0.10	23.5 (3.8) 0.67	24.9 (3.2) 0.01*	26.6 (3.7) <0.01*
FFMQ (Nonjudgement) P value	24.3 (4.7)	24.5 (4.2) 0.82	27.4 (4.0) 0.04	26.4 (4.2) 0.21	29.8 (5.2) 0.01*
FFMQ (Describe) P value	26.3 (5.0)	25.1 (4.0) 0.20	26.9 (3.8) 0.93	29.5 (4.7) 0.03	29.0 (4.3) 0.09
FFMQ (Awareness) P value	23.6 (6.0)	23.3 (3.3) 0.70	25.0 (2.5) 0.52	27.2 (4.0) 0.14	27.2 (4.0) 0.13

Notes: All outcomes were analyzed on the basis of intent-to-treat, using a mixed-effects model repeated-measures approach. *P value is less than 0.0125 (set by Bonferroni correction (0.05/4)).

Abbreviations: FFMQ, Five Facet Mindfulness Scale; SWLS, Satisfaction With Life Scale; WHO-5, the World Health Organization-Five Well-Being Index.

Table 6 Subgroup Analysis by Baseline Score (Mean (SD)) of WHO-5 Irrespective of Health Status at Each Assessment Point

Subgroup	Time				
	T1	T2	T3	T4	T5
	Baseline	4 Week	8 Week	20 Week	32 Week
All participants, WHO-5 (n=24) P value	64.7 (16.9)	64.0 (15.6) 0.68	66.9 (16.0) 0.40	65.3 (15.2) 0.68	74.4 (10.4) <0.01*
WHO-5 $\leq$ 69 (n=12) P value	50.7 (12.3)	56.0 (15.9) 0.17	62.2 (13.8) 0.01*	60.4 (14.5) 0.06	73.1 (13.2) <0.01*
WHO-5 $\geq$ 70 (n=12) P value	78.7 (3.9)	71.3 (11.5) 0.048	72.0 (17.5) 0.20	70.8 (14.7) 0.13	75.6 (7.0) 0.15

Notes: All outcomes were analyzed on the basis of intent-to-treat, using a mixed-effects model repeated-measures approach. *P value is less than 0.0125 (set by Bonferroni correction (0.05/4)).

Abbreviation: WHO-5, the World Health Organization-Five Well-Being Index.

Abbreviations

CMDs, people with Common Mental Disorders; FFMQ, Five Facet Mindfulness Questionnaire; His, Healthy Individuals; MBCT, Mindfulness-Based Cognitive Therapy; RCTs, Randomized Controlled Trials; SCS, Self Compassion Scales; SD, Standard Deviation; SE, Standard Error; SWLS, Satisfaction with Life Scale; WHO-5, the 5-item World Health Organization Well-Being Index.

Date Availability

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

Ethics Approval and Informed Consent

This study was approved by the ethical committee at Keio University School of Medicine (reference: 20160009). All participants submitted written informed consent. The identification number of the clinical trial registry system at the University Hospital Medical Information Network was UMIN000022528. This study was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2008.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design,

execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that they have no competing interests.

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