Clinical effectiveness of metacognitive training as a transdiagnostic program in routine clinical settings: A single-group pre-post study

Hiroki Tanoue
University of Miyazaki
Naoki Yoshinaga (naoki-y@med.miyazaki-u.ac.jp)
University of Miyazaki https://orcid.org/0000-0002-4438-9746
Yuta Hayashi
Kobe University
Ryotaro Ishikawa
Taisho University
Takuma Ishigaki
The University of Tokyo
Yasushi Ishida
University of Miyazaki

Research note

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Abstract

Objective

To evaluate the clinical effectiveness of metacognitive training (MCT) as a transdiagnostic program, on a diverse population with mental disorders in routine day-care settings through a single-group pre-post-design.

Results

Thirty-four participants diagnosed with various mental disorders (schizophrenia = 22, non-schizophrenia = 12) received ten MCT group-sessions. Intent-to-treat analyses revealed significant improvements in quality of life/global functioning during the intervention period, and these improvements were well-maintained during the follow-up (all $p < 0.05$). The baseline to follow-up treatment effect sizes for quality of life and global functioning were middle (Hedge's $g = 0.44$ and 0.47, respectively). Significant improvements were also found in depressive symptoms during both the intervention and follow-up periods (all $p < 0.05$), but not in cognitive insight. Overall, participants were highly satisfied with the MCT content and format. Scores on almost all outcomes (except for depression) at each assessment point were not significantly different between the schizophrenic and non-schizophrenic sub-groups. The findings of this study suggest that MCT for a diverse population with mental disorders is a potentially effective approach in improving quality of life/global functioning and other clinical outcomes in routine day-care settings.

Trial Registration:

UMIN-CTR, UMIN000032393 (registered on April 26, 2018)

Introduction

Diverse non-pharmacological approaches for schizophrenia have been developed as complementary strategies to antipsychotic medication. An example of a novel psychological approach based on cognitive theory is metacognitive training for psychosis (MCT). MCT is theory-driven, standardized, and manualized group training for schizophrenia, targeting common cognitive errors and problem-solving biases [1–3]. Several meta-analyses of existing clinical trials, mostly conducted in Western countries, have demonstrated that MCT reduces the positive schizophrenic symptoms, and is particularly effective in reducing delusions [4, 5]. A Japanese study group has recently conducted a randomized controlled trial, and also demonstrated the efficacy of MCT among patients with schizophrenia [6].

Although MCT is designed mainly for schizophrenia, the program is not limited to schizophrenic patients [1–3, 7]. This is because most of the cognitive errors and problem-solving biases addressed in MCT, are

also common in other mental disorders (e.g. monocausal attributions, jumping to conclusions, etc.) [8]. In fact, in routine clinical settings, especially in psychiatric day-care services in Japan, patients usually attend the same program regardless of disorder [9]. Thus, MCT is provided not only for schizophrenia but also for a wide range of other disorders in clinical settings. Previous studies of MCT only targeted individuals with schizophrenia, but there is no evidence supporting the clinical effectiveness of MCT as a transdiagnostic program.

Therefore, the purpose of this study was to evaluate the effectiveness of MCT as a transdiagnostic program, on a diverse population with mental disorders in routine Japanese day-care settings through a single-group pre-post study.

Methods

Study design

The study employed a single-arm pre-post design, and was carried out from April 2018 to December 2019. Participants were recruited at two psychiatric day-care centers in Miyazaki prefecture, Japan. All participants received up to ten sessions of MCT. Assessments were conducted at baseline (pre-intervention: Pre), 5 weeks (mid-intervention: Mid), 10 weeks (post-intervention: Post), and 14 weeks (follow-up: FU).

This study was conducted according to the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statement.

Participants

In order that the study population reflect routine psychiatric day-care practice in Japan, we set minimal inclusion/exclusion criteria and then recruited a broader, heterogeneous population. The inclusion criteria were: patients diagnosed with any of the mental disorders listed in DSM-IV; aged ≥ 20 years; and patients who were willing to participate. We excluded participants only if their condition was expected to worsen by participating in MCT and/or they posed a threat to group dynamics.

Intervention (MCT)

MCT group sessions were delivered based on the Japanese version of the MCT manual and session materials [7], and consisted of ten 60-minute weekly sessions. Each group had 4–6 participants. More details of MCT programs can be found at the MCT website [7]. All MCT sessions were conducted by one or two mental health care professionals (nurse, occupational therapist, and/or psychiatric social worker) who worked full-time at the study institutions. All therapists had considerable experience as study therapists in a prior randomized controlled trial [6], and were adequately trained via a one day in-person workshop.

Outcomes

For all participants, we set transdiagnostic outcomes to assess quality of life (EuroQoL 5-dimension 5-level: EQ-5D-5L [10, 11]), global functioning (General Assessment of Functioning: GAF [12]), cognitive insight (Beck Cognitive Insight Scale: BCIS [13, 14]), and depressive symptoms (Beck Depression Inventory-Second Edition: BDI-II [15, 16]).

As a specific outcome for schizophrenia patients, we assessed levels of schizophrenic symptoms (Positive and Negative Syndrome Scale: PANSS [17–19]) and cognitive bias (Cognitive Biases Questionnaire for psychosis: CBQp [20, 21]).

At the end of the MCT sessions, we also evaluated patient satisfaction with treatment (MCT Satisfaction Scale [22, 23]). The reliability and validity of the Japanese versions of all measures have been confirmed.

Statistical analysis

The analyses were conducted based on the intention-to-treat (ITT) principle, whereby the last obtained data for dropouts were carried forward until the endpoint assessment. The Pre, Mid, Post, and FU scores for the outcome measures (except for the MCT Satisfaction Scale) were analyzed with single-factor (time) repeated measures analysis of variance (ANOVA). Where the repeated ANOVA indicated significant changes, pairwise Bonferroni corrected t-tests were conducted for post-hoc tests. The magnitude of the within-group treatment effect was determined as the effect size based on Hedges' g. As an additional analysis, we compared the scores for transdiagnostic outcomes (GAF, EQ-5D-5L, BDI-II, and MCT Satisfaction Scale) between sub-groups (schizophrenic group vs. non-schizophrenic group) using Welch's t-test.

All statistical tests were two-tailed, and $\alpha = 0.05$ was employed. Statistical analyses were performed using IBM SPSS Statistics, version 24.0 (IBM, Armonk, New York, USA).

Results

Participants' flow and baseline characteristics

Thirty-eight patients were recruited for the study, of which four patients were excluded. The remaining 34 patients enrolled in the study. The mean number of MCT sessions attended was 8.44 (SD = 2.02), and 26 patients (76%) completed the program (eight dropped out). Please also see Additional file 1: Figure S1 for flow diagram. We observed no serious adverse events during the study. There was no change in prescribed medications during the study.

Of the 34 subjects, 22 (65%) were diagnosed with schizophrenia, and the other 12 non-schizophrenic patients (35%) were diagnosed with either major depressive disorder (n = 4) or bipolar-II disorder (n = 8). The average age was 52.7 (SD = 11.4) years. See Table 1 for more details about baseline clinical characteristics.

Table 1
Baseline characteristics (N = 34)

Variable	Value
Age (years), mean (SD)	52.7 (12.4)
Gender, n (%)	
Female	20 (58.8)
Male	14 (31.2)
Marital status, n (%)	
Single	26 (72.2)
Married/divorced	8 (27.8)
Education background, n (%)	
Junior high school	10 (29.4)
High school	20 (58.8)
University/college	4 (11.8)
Employment, n (%)	
Employed	6 (17.6)
Unemployed	28 (83.4)
Primary diagnosis, n (%)	
Schizophrenia	22 (64.7)
Non-Schizophrenia	12 (35.3)
Duration of primary disorder (years), mean (SD)	19.8 (8.6)
Concomitant medication, n (%)	
Yes	16 (47.1)
No	18 (52.9)
Baseline antipsychotics (chlorpromazine-equivalent, mg/d), mean (SD)	263.8 (231.5)
Baseline antidepressant (imipramine-equivalent, mg/d), mean (SD)	79.0 (84.8)
Baseline anxiolytics (diazepam equivalent, mg/d), mean (SD)	11.3 (10.8)

Outcomes

Table 2 presents changes in all transdiagnostic outcome measures during the study. Within-group treatment effect sizes (Hedges' g) for transdiagnostic outcomes are shown in Table 3. For all subjects, significant improvements were observed in EQ-5D-5L and GAF during the intervention period (Pre–Post)

(p = 0.014 and 0.002, respectively), and further improvements were observed during the follow-up (Post–FU) (p = 0.021 and 0.039, respectively). The Pre–FU treatment effect sizes for EQ-5D-5L and GAF were middle (Hedge's g = 0.44 and 0.47, respectively). As for cognitive insight, there were no significant differences in all BCIS sub-scales. Significant improvements were observed in BDI-II during the intervention period (Pre–Post) (p = 0.006), and further improvements were observed during the follow-up (Post–FU) (p = 0.015). The total scores on the MCT Satisfaction Scale was 45.85 (SD = 7.42). Highly-rated items were “Q6: The training was fun (mean = 4.13 [SD = 0.80])”, “Q2: I was pleased to go to the training regularly (4.08 [0.92])”, “Q10: I found it beneficial that the training was administered in a group (4.04 [0.82])”, and “Q1: The training was useful and sensible (4.04 [0.89])”.

Table 2
Changes in transdiagnostic outcome measures (N = 34)

Measures	Mean (SD)				F value	P value	η^2
	Pre	Mid	Post	FU			
EQ5D-5L	0.74 (0.21)	0.78 (0.23)	0.81 (0.21)†	0.83 (0.20)‡	4.33	0.007	0.12
GAF	57.35 (11.06)	59.76 (10.64)	61.06 (11.27)†	62.68 (11.41)‡	7.65	< 0.001	0.19
BCIS-SR	13.35 (4.01)	13.35 (3.94)	12.58 (3.76)	12.29 (3.82)	1.22	0.306	0.03
BCIS-SC	7.15 (3.31)	7.74 (2.95)	7.82 (3.12)	7.62 (2.72)	0.78	0.510	0.02
BCIS-CI	6.21 (4.80)	5.62 (4.78)	4.76 (4.78)	4.68 (4.83)	1.72	0.168	0.05
BDI-II	12.88 (10.15)	11.09 (8.88)	10.68 (9.13)†	9.12 (7.72)‡	7.64	< 0.001	0.18
MCT Satisfaction Scale	-	-	45.85 (7.42)	-	-	-	-

Notes: † p < 0.05, significant difference in pairwise comparisons with Pre. ‡ p < 0.05, significant difference in pairwise comparisons with both Pre and Post. Time points: Pre (baseline), Mid (5weeks), Post (10 weeks), and FU (14 weeks: follow-up).

Abbreviations: EQ-5D-5L, EuroQOL 5 dimensions 5-level; GAF, Global Assessment of Functioning; BCIS-SR/SC/CI, Beck Cognitive Insight Scale-Self-Reflectiveness/Self-Certainty/Composite Index; BDI-II, Beck Depression Inventory-Second Edition.

Table 3
Difference of transdiagnostic outcomes between the schizophrenic and non-schizophrenic sub-groups

Measures	Mean (SD)		Welch's *t*-test	
	Schizophrenia (n = 22)	Non-schizophrenia (n = 12)	t	p
EQ5D-5L				
Pre	0.74 (0.25)	0.73 (0.10)	0.21	0.837
Mid	0.77 (0.26)	0.78 (0.16)	-0.11	0.910
Post	0.80 (0.23)	0.82 (0.16)	-0.28	0.783
Fu	0.82 (0.22)	0.84 (0.16)	-0.58	0.759
GAF				
Pre	54.77 (9.11)	62.08 (12.66)	-1.70	0.108
Mid	59.64 (10.77)	60.00 (10.41)	-0.09	0.927
Post	59.82 (10.56)	63.33 (12.13)	-0.81	0.426
Fu	61.64 (11.55)	64.58 (10.89)	-0.71	0.483
BCIS-SR				
Pre	13.15 (4.10)	13.00 (3.81)	0.33	0.743
Mid	12.86 (3.95)	14.25 (3.77)	-0.86	0.400
Post	12.86 (4.09)	12.08 (2.98)	0.38	0.709
Fu	11.95 (4.26)	12.92 (2.75)	-1.15	0.262
BCIS-SC				
Pre	7.41 (3.76)	6.67 (2.17)	0.89	0.381
Mid	7.50 (3.06)	8.17 (2.70)	-0.42	0.679
Post	7.41 (2.79)	8.58 (3.52)	-0.95	0.354
Fu	7.32 (2.77)	8.17 (2.54)	-0.87	0.397
BCIS-CI				

Notes: Time points: Pre (baseline), Mid (5weeks), Post (10 weeks), and FU (14 weeks: follow-up).

Abbreviations: EQ-5D-5L, EuroQOL 5 dimensions 5-level; GAF, Global Assessment of Functioning; BCIS-SR/SC/CI, Beck Cognitive Insight Scale-Self-Reflectiveness/Self-Certainty/Composite Index; BDI-II, Beck Depression Inventory-Second Edition.

Measures	Mean (SD)		Welch's *t*-test	
	Schizophrenia (n = 22)	Non-schizophrenia (n = 12)	t	p
Pre	6.14 (5.22)	6.33 (3.92)	-0.26	0.790
Mid	5.36 (5.24)	6.08 (3.75)	-0.49	0.626
Post	5.45 (5.02)	3.50 (4.01)	1.02	0.320
Fu	4.64 (5.09)	4.75 (4.30)	-0.27	0.787
BDI-II				
Pre	9.59 (9.28)	18.92 (8.81)	-2.79	0.010
Mid	8.59 (7.93)	15.67 (8.69)	-2.25	0.035
Post	8.41 (8.58)	14.83 (8.63)	-2.00	0.058
Fu	7.36 (7.07)	12.33 (7.81)	-1.76	0.093
MCT Satisfaction Scale				
Post	44.94 (6.10)	47.29 (5.39)	-0.87	0.403
Notes: Time points: Pre (baseline), Mid (5weeks), Post (10 weeks), and FU (14 weeks: follow-up).				
Abbreviations: EQ-5D-5L, EuroQOL 5 dimensions 5-level; GAF, Global Assessment of Functioning; BCIS-SR/SC/CI, Beck Cognitive Insight Scale-Self-Reflectiveness/Self-Certainty/Composite Index; BDI-II, Beck Depression Inventory-Second Edition.				

In the schizophrenic sub-group, significant differences on PANSS positive scores were observed during both the intervention and follow-up periods ($p = 0.002$ and < 0.001, respectively). As for cognitive bias, there were no significant differences in total scores of CBQp. However significant improvements were observed in JTC sub-scale scores of CBQp during the intervention period ($p = 0.049$), and these improvements were maintained during the follow-up (see Additional file 1: Table S2 for more details).

Table 3 shows means and standard deviations of transdiagnostic outcome scores (EQ5D-5L, GAF, BCIS, BDI-II and MCT Satisfaction Scale) at each assessment point for the schizophrenic and non-schizophrenic sub-groups. Scores on BDI-II at Pre and Mid in the non-schizophrenic group were significantly higher than those in the schizophrenic group ($p = 0.010$ and 0.035, respectively). Scores on other outcome measures (GAF, EQ-5D-5L, and MCT Satisfaction Scale) at each assessment point were not significantly different between sub-groups.

Discussion

This study aimed to examine the clinical effectiveness of MCT on a diverse population with chronic mental disorders in routine Japanese day-care settings. The key finding of this study is that, regardless of primary disorder (schizophrenia or non-schizophrenia), MCT leads to significant improvements in quality of life, global functioning, and depression. Both schizophrenic and non-schizophrenic patients were highly satisfied with the MCT content and format.

This study was designed to recruit patients similar to those seen in routine day-care settings; as a result, 65% had schizophrenia, as is typical (56%) in clinical practice [24]. Also, in this study, patients who had a primary diagnosis of schizophrenia had less severe schizophrenic symptoms at baseline than those observed in our previous randomized controlled trial [6].

Although patients suffering from various mental disorders attended the same MCT program, they obtained significant improvements in their primary psychiatric symptoms, supporting the potential effectiveness of MCT as a transdiagnostic program for a wide range of mental disorders. In the schizophrenic sub-group, positive psychotic symptoms and cognitive biases commonly seen in schizophrenia (i.e. jumping to conclusions) were significantly improved through receiving MCT; though the Pre–FU treatment effect size of 0.47 (Hedge's g) on PANSS was lower than that of 0.71 in our previous trial [6]. In the non-schizophrenic (mood disorder) sub-group, the baseline severity of depressive symptoms was higher than that in the schizophrenic sub-group, but was significantly improved through MCT. As mentioned in the introduction, although MCT was originally developed mainly for schizophrenia [1–3], most of the MCT modules address the cognitive errors and problem-solving biases that are also common in other mental disorders; thus, MCT may also reduce depressive symptoms. These improved psychiatric symptoms/biases, then, might have contributed to improving quality of life and global functioning in this study [1, 25, 26]

Our transdiagnostic MCT program led to considerable improvements in the study population; however, other factors unrelated to MCT-specific effects might also have contributed to this positive outcome. First, the group-format itself might have had a significant treatment effect. Based on the MCT Satisfaction Scale, participants were very satisfied with the MCT, but the highly-rated items (e.g. “The training was fun”, “I was pleased to go to the training regularly”, “I found it beneficial that the training was administered in a group”) may also appear in other well-organized group treatments [27–29]. As far as we are aware, no previous MCT studies have employed group-based active psychological-treatment as a control condition (e.g. wait-list, treatment as usual, supportive counseling, CogPack [computerized cognitive rehabilitation program], or newspaper discussion group) [4, 5]. Further studies should pin down MCT specific-effects by using more MCT-specific questionnaires and/or employing other group-based active treatment controls. Second, the therapists in this study already had experience providing MCT [6], and were practitioners who regularly worked at the institution where the study was conducted. Therefore, each therapist may have already established a good relationship with patients. This factor may have also had a positive impact on treatment effects.

Although treatment satisfaction was higher compared to other studies, the dropout rate (24%) in this study was similar to rates in previous studies4. The main reasons given for dropping out were because of schedule conflicts, and because the therapy was too difficult. Regarding the former reason, participants who did not regularly attend MCT were considered to be non-completers in this study, even though these patients actually continued irregular participation in MCT (i.e. they did not completely drop out from the treatment). This is because the original MCT protocol allows participants to start with any module at any time; so, for the purposes of the study, drop outs due to schedule conflicts do not seem to be a serious problem in a clinical setting. As for patients who said the therapy was too difficult, this may be due to the group-format therapy. In group sessions, therapists sometimes find it difficult to adjust the pace of sessions even when the therapist observes that a patient is struggling (e.g they did not fully understand the therapy contents of the module). For patients who struggle in group therapy, individual-based MCT (known as MCT+ [30]) should be introduced.

In conclusion, the findings of this study indicate the potential efficacy of MCT as a transdiagnostic program in routine clinical settings. Future research should employ active psychological controlled conditions and larger sample sizes in order to replicate the study findings and address the limitations of this study.

Limitations

First, this study employed a single-group design without a control group; therefore, we cannot conclusively state that our MCT was effective. The presence of the Hawthorne effect as well as other non-treatment specific effects, which are typically observed in uncontrolled trials, cannot be ruled out in our study design. Second, our study had a limited number of participants. Third, diagnosis of samples included in the non-schizophrenic group was not uniform; it may be inappropriate to compare the non-schizophrenic group with the schizophrenic group. Fourth, satisfaction feedback was only obtained from patients completed the MCT. Future studies should obtain feedback from dropouts so that we can gather information towards the prevention of patients dropping out.

Abbreviations

BCIS-SR/SC/CI: Beck Cognitive Insight Scale-Self-Reflectiveness/Self-Certainty/Composite Index

BDI-II: Beck Depression Inventory-Second Edition.

CBQp, Cognitive Biases Questionnaire for psychosis

EQ-5D-5L: EuroQOL 5-dimensions 5-level

GAF: Global Assessment of Functioning

JTC: Jumping to Conclusions

MCT: Metacognitive Training

PANSS: Positive and Negative Syndrome Scale

Declarations

Ethics approval and consent to participate:

This study was carried out in accordance with the Declaration of Helsinki. The study protocol was reviewed and approved by the Ethics Committee of the University of Miyazaki (reference number: O-0250). The researchers explained the study aims and objectives to all participants. All participants with adequate decision-making capacity (based on their primary psychiatrist's assessment) voluntarily provided a written informed consent before the participation in the study.

Consent for publication:

Not applicable.

Availability of data and materials:

Data generated from or analyzed in the current study are available from the corresponding author upon request.

Competing interests:

There are no conflicts of interest to declare.

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Authors' contributions:

Conception and design of the study: HT, NY, RI, TI, and YI; Acquisition of data: HT and YH; Analysis and interpretation of data: HT, NY, YH, RI, TI, and YI; Drafting the manuscript: HT, NY, and YI. All authors critically reviewed the manuscript and approved of the final version.

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