An exploratory effectiveness study with MBCT: findings and design issues

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The Mindfulness and Medication Adherence (MiMA) pilot project

Introduction

Major Depressive Disorder is a common condition that tends to recur. At least 60% of people who have had one major depressive episode will have another, mostly within two years of the index episode (Lavori, et. al., 1984). Seventy percent of those who have had two episodes will have a third, and 90% of those with three episodes will have a fourth (Solomon, et. al., 2000). Directly addressing the recurrence of depression is critical to making a substantial difference to the prevalence of this condition in the community.

Mindfulness-Based Cognitive Therapy (MBCT) and Medication Alliance Therapy (MAT) are two interventions that might be useful in maintaining long-term remission from depression in those who have already experienced multiple episodes. MBCT is a manualised group based intervention (Segal, et. al., 2002) that integrates aspects of cognitive therapy with components of a mindfulness-based stress reduction program (MBSR; Kabat-Zinn, 1990). MAT is a therapy designed to promote adherence to medication by 'upskilling' primary care staff in specific adherence strategies, borrowing from cognitive-behavioural principles and motivational interviewing.

The overall aim of this project was to establish and trial the methodology for investigating of the efficacy of MBCT and MAT in the prevention of depressive relapse in people who have had at least three previous episodes of depression.

Method

This study was initially designed as a prospective, randomised controlled trial using a 2 x 2 factorial design with the four cells being: MBCT, MAT, MBCT + MAT, treatment-as-usual (TAU).

However, the study was ultimately restricted to a nested two-arm randomised controlled trial of MBCT against TAU due to:

•Difficulties in recruitment arising from the restrictive selection criteria required for the full factorial study

•Difficulties in recruiting MAT therapists from primary care

Participants were recruited from primary care, public and private mental health services, and from the community. After a baseline assessment, eligible participants were randomised to treatment condition by the independent study statistician. For MBCT participants, therapy was delivered by an instructor in eight weekly 2 hour group training sessions with optional 3 monthly 'booster sessions'. Face-to-face follow up assessments were scheduled every three months for one year.

The primary outcome measure reported here is the Composite International Diagnostic Instrument 2.1 Auto 12 month version (CIDI Auto 2.1 12 month) depression module.

Results

Sixty-four candidates completed the informed consent process and initial interview. Nineteen participants satisfied the selection criteria for the nested study and were randomised to treatment (see Figure 1). The mean age of participants was 46 years (SD: 11.3); 68% were female.

Due to a relatively low completion rate of follow up assessments (43/80: 54%), the focus of analysis was on the follow up time period (months) rather than the number of follow up interviews.

The mean number of months of follow up was 11.9 (SD: 4.4; range 16); the median number of months of follow up was 14. Examination of the CIDI outcome data showed that none of those in the MBCT group had an episode of depression during the follow up period while four of those (50%) in the TAU group had one episode of depression and two (25%) had two episodes of depression. Independent sample *t*-tests showed that there were no differences between the two groups on either number of months of monitoring or number of follow ups. There was, however, a significant difference in number of depressive episodes (see Table 1).

Table 1 Results of *t*-tests comparing MBCT and TAU participants on amount of follow up and number of depressive episodes

	MBCT (n = 8)	TAU (n = 8)	Statistics
Number of months follow up [Mean (SD)]	11.1 (4.7)	12.6 (4.3)	$t(14) = 0.7$; $p = 0.48$
Number of follow ups [Mean (SD)]	2.8 (1.3)	2.6 (1.2)	$t(14) = -0.2$; $p = 0.84$
Number of episodes of depression [Mean (SD)]	0 (0)	1.0 (0.8)	$t(7)^* = 3.7$; $p = 0.007$

*equal variances not assumed

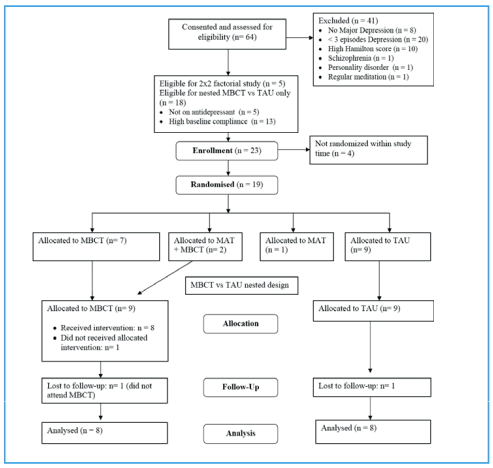

Figure 1: MiMA consort chart

Discussion

The results support previous findings that MBCT is effective in reducing relapse in individuals who have had three or more episodes of depression over a 12 month follow-up period. While none of the MBCT participants relapsed during the follow-up period, 75% TAU participants had at least one episode of depression. The fact that these findings reached significance is particularly striking given the extremely low power of the study.

However, the low sample size and extent of missing data in this pilot does seriously limit the ability to draw inferences about treatment effects. Moreover, participant feedback suggested that the positive results for MBCT may not have been entirely a protective effect of MBCT and raised concerns that the TAU group may have experienced a negative or "nocebo" effect driven by resentful demoralisation. The methodological issues that arose in the course of this study provided essential learning for designing and implementing the subsequent DARE (Depression Awareness Recovery Effectiveness) project.

Depression Awareness Recovery Effectiveness (DARE) project: design considerations

The knowledge and capacity building arising from MiMA contributed towards a successful grant application to the Australian National Health and Medical Research Council to conduct a fully powered two-arm study of MBCT. In this section, we outline the key methodological learnings from MiMA that informed the design and application of this study, called "DARE".

Design and treatment conditions

Given the complexity involved in the 2 x 2 factorial design of MiMA, and the difficulties implementing MAT, a simple MBCT against control was selected as the design for DARE.

The control intervention was developed and presented to candidates with the aim of minimising resentful demoralisation and to ethically optimise the design. In place of the simple TAU control of MiMA, we developed "DRAM" - "Depressive Relapse – Active Monitoring" (DRAM) and explicitly highlighted the fact that all participants would be undertaking supported active monitoring of their symptoms each month in addition to treatment-as-usual. A DRAM manual was written with emphasis placed on the importance of regular monitoring and seeking early intervention as a self management strategy, something that has an associated evidence base. We could now fairly present the project as having a potential benefit for all participants, so reducing selection bias and making recruitment easier.

A project title and marketing name was developed so as to reflect both conditions in an unbiased manner with the aim of balancing treatment expectation and avoiding resentful demoralisation. Marketing materials were carefully worded to ensure balance across the two treatment conditions.

The Expectance/Credibility Questionnaire (CEQ; Devilly & Borkovec, 2000) was used to assess therapy credibility and client expectancy for improvement. Preliminary analysis of the available data following MBCT indicates that although treatment credibility and expectation differed significantly across groups, the differential is consistently contained within an effect size for group (Cohen's D) of <0.5, which means it should be possible to control for this in analysis (see Table 2).

Table 2 Results of *t*-tests comparing MBCT and DRAM participants on treatment credibility and treatment expectation immediately following implementation of MBCT in the treatment group

	MBCT (n = 83)	DRAM (n = 85)	Statistics	Effect size (Cohen's d)
Treatment credibility [Mean (SD)]	6.5 (1.5)	5.7 (1.8)	$t(159)^* = 3.4$; $p = 0.001$	0.29
Treatment expectation [Mean (SD)]	5.6 (1.7)	4.8 (1.9)	$t(166) = 2.9$; $p = 0.004$	0.25

*equal variances not assumed

Assessment

One of the most important changes in DARE was less reliance on face-to-face interviews in order to reduce the rate of missing data. Although the follow-up in DARE is double that of MiMA, being two years, participants only need to attend in person twice. The remainder of assessments are completed by over the internet or by phone or mail. As well, participants are provided with remuneration for completing assessments.

Recruitment and retention

As a result of experience from MiMA, use of the media was emphasised as the most efficient means of recruitment. GP networks and other links developed in MiMA were also accessed. More inclusive selection criteria were adopted compared to MiMA, e.g., including people who were over 65 years of age (up to 75 years). Because most of the exclusions from MiMA were due to failure to meet the inclusion criteria related to the diagnosis of depression (refer to Figure 1), a brief screening questionnaire based on the CIDI 2.1 for lifetime depression was developed and administered to candidates over the phone. Only 18% of DARE candidates who undertook the intake the assessment interview were excluded compared to 64% of MiMA candidates.

More effort was placed on retention strategies by developing a strong project identity including a website, logo, and a wallet-size participant ID card. Participants are sent greeting cards as well as quarterly newsletters providing progress of the project (see www.dare.org.au).

At the close of recruitment for DARE in January 2009, 204 participants were enrolled. As of March 2010, 93% of participants have been retained in the study and our rate of missing data from the continuing participants is running at 9% (see Figure 2 for DARE consort chart).

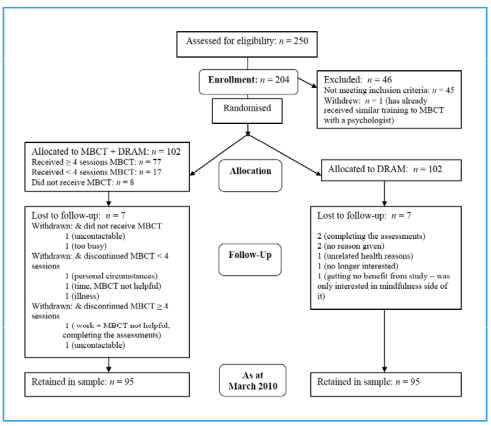

Figure 2: DARE consort chart

Conclusions

The MiMA pilot study adds to the body of data supporting the effectiveness of MBCT. However, lessons from it also raise design considerations in studies of mindfulness-based interventions for depression.

Acknowledgements

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References

Devilly, G. J., & Borkovec, T. D. (2000). Psychometric properties of the credibility/expectancy questionnaire. *Journal of Behavior Therapy & Experimental Psychiatry, 31*(2), 73-86.

Kabat-Zinn, J. (1990). *Full catastrophe living: Using the wisdom of your body and mind to face stress, pain and illness*. New York: Delacorte.

Lavori, P. W., Keller, M. B., & Klerman, G. L. (1984). Relapse in affective disorders: A reanalysis of the literature using life table methods. *Journal of Psychiatric Research, 18*(1), 13-25.

Segal, Z. V., Williams, J. M. G., & Teasdale, J. (2002). *Mindfulness-based cognitive therapy for depression: A new approach to preventing relapse*. New York: Guilford.

Solomon, D. A., Keller, M. B., Leon, A. C., Mueller, T. I., Lavori, P. W., Shea, M. T., et al. (2000). Multiple recurrences of major depressive disorder. *American Journal of Psychiatry, 157*(2), 229-233.