An exploratory effectiveness study with MBCT: findings and design issues
Graham Meadows, Fran Shawyer, Annette Graham
Southern Synergy, School of Psychology and Psychiatry, Monash University

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 (Lahtikari 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., 2001). 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 (MATT) 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). MATT is a therapy designed to promote adherence to medication by ‘upsylling’ primary care staff in specific adherence strategies drawn from cognitive-behavioural principles and motivational interviewing.

The overall aim of this project was to establish and trial the methodology for investigating the efficacy of MBCT and MATT 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, MATT, MBCT + MATT, 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 MATT 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. In an MBCT participants, therapy was delivered by an instructor in eight weekly 2 hour group training sessions in addition to treatment-as-usual. A DRAM manual was written with undertaken 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 medication advice if needed.

Due to a relatively low completion rate of follow up assessments (43/50: 86%), 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 depressive episodes or length of follow up period.

Table 1 Results of follow up and number of depressive episodes

<table>
<thead>
<tr>
<th></th>
<th>MBCT</th>
<th>MBCT + MATT</th>
<th>MATT</th>
<th>Treatment-as-usual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD)</td>
<td>11.9</td>
<td>11.9</td>
<td>11.9</td>
<td>11.9</td>
</tr>
<tr>
<td>Median (range)</td>
<td>14</td>
<td>14</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>Number of depressive episodes</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

Note: Not all patients completed the full treatment period.

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 study 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 receipt of a placebo. 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 MBCT, and the difficulties implementing MATT against control was selected as the design for DARE.

The control intervention was developed and presented to candidates with the aim of minimising unhelpful 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 unhelpful demoralisation. Marketing materials were carefully worded to ensure balance across the two treatment conditions.

Acknowledgements
MIMA was funded by Beyond Blue. DARE was funded by the Australian National Health & Medical Research Council.
References


