Preventing Relapse in Depression: the Mindfulness-Based Cognitive Therapy and Medication Alliance Therapy Project

FINAL REPORT

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1. Executive Summary

The aim of this project was to establish and trial two therapeutic interventions, Mindfulness-Based Cognitive Therapy (MBCT) and Medication Alliance Therapy (MAT) singly and in combination, for the prevention of depressive relapse in people who have had at least two previous episodes of depression.

MBCT is a group skills-training program that integrates aspects of cognitive therapy with components of a mindfulness-based stress reduction program.

MAT is a treatment derived from Motivational Interviewing to promote compliance with advised treatment regimes, and so far has mainly been used with people who have schizophrenia. The project examined using this approach in the field of depression management, and tailoring the intervention in a way that could be delivered by general care/non-medical staff such as practice nurses.

In this study, people had recurrent major depression and attended either primary care, the private sector or Southern Health Area Mental Health Services, were randomised to one of four conditions:

1. Mindfulness-based cognitive therapy (MBCT)

2. Medication alliance therapy (MAT)

3. MBCT and MAT combined

4. Treatment as usual (TAU).

Prior to recruitment and randomisation, both therapeutic interventions were developed and manualised. Further, therapists were trained to deliver the interventions and a comprehensive recruitment and assessment strategy was developed by the research team.

This report brings together the methodology involved in the practical development of two interventions, their implementation and the design and delivery of a clinical trial to investigate their role in the prevention of depressive relapse.

Key Achievements of the study

Development of Medication Alliance Therapy

Medication Alliance describes a process used to achieve health care goals as they relate to the use of psychotropic medications. It targets the relationship between the clinician and the consumer, seeking to enhance antidepressant-taking behaviour by utilising collaborative problem solving approaches. The team has produced a comprehensive set of manuals and other educational materials to teach MAT. Further, a *Train the Trainer* package has been developed to teach therapists to train MAT. This work resulted in the delivery and subsequent evaluation of a MAT training course to clinicians.

Development and implementation of Mindfulness-Based Cognitive Therapy

MBCT is a manualised group skills-training program that integrates aspects of cognitive therapy with components of a mindfulness-based stress reduction program. It is designed to teach clients to become more aware of, and to relate differently to, their thoughts, feelings and bodily sensations; in particular, to view these thoughts and feelings as passing events in the mind rather than identifying them or treating them as necessarily accurate reflections of reality. The program teaches skills in disengagement from habitual dysfunctional cognitive routines.

A comprehensive manual and teaching package for trainers and therapists was developed and evaluated by the team in the study. This was developed alongside a local training program, now elaborated into a short certificate course available annually through the Monash University School of Psychology, Psychiatry and Psychological Medicine. This course provides a thorough grounding in practice of MBCT for mental health clinicians. It has resulted in the delivery of several clinical MBCT groups, a trained group of MBCT therapists including the therapists who delivered the research therapy in the National Health and Medical Research Council-funded study mentioned below, and further development of the expertise of the team's MBCT practitioners.

Implementation of the fieldwork component of the study

The study developed and trialled in the field a recruitment strategy targeted towards consumers in either primary or specialist care. A substantial suite of instruments was thoughtfully selected to collect efficiently relevant information. The recruitment process resulted in collaborations with many local agencies. Further, the study recruited and trained mental health staff in the theory and practice of research interviewing, to provide a source of trained assessors, for the purpose of assessing potential study particpants.

For a number of reasons, not all arms of the study proved readily deliverable. However, within the study, the team conducted a small randomised controlled pilot of MBCT against TAU in preventing relapse. Though small, the results carried suggestion of positive effects from the intervention.

Ground work laid for a successful grant application to the National Health and Medical Research Council to conduct two-arm study of MBCT.

The knowledge and capacity building arising from the conduct of this study contributed towards a successful NHMRC grant application for a fully powered two-arm study of MBCT, called the DARE (Depression Awareness Recovery Effectiveness) project. The set of strategies and resources developed in MiMA has guided and equipped the implementation of DARE.

Implications for policy and practice

The MAT clinical approach to depression aligns well with principles that would be expected to assist compliance with therapeutic interventions in primary care for depression. An important practical finding from the study was that the intent to involve primary care nurses in this work is limited largely by the lack of a clear funding structure that would make their involvement supportable and sustainable. Further changes in the funding structure for primary care might make the approach more practically useful. In that case, the work invested into the development of this program would be available and could give a head start to mental health work by a large workforce that hitherto has been little involved in this area of clinical practice.

2. Timeframe

Commencement date: 01/03/2003

Completion date: 30/06/2007

3. Summary of Outcomes

The overall aim of this project was to establish and trial the methodology for a thorough investigation of the efficacy of two therapeutic interventions, Mindfulness-Based Cognitive Therapy (MBCT) and Medication Alliance Therapy (MAT), singly and in combination, in the prevention of depressive relapse in people who have had at least three previous episodes of depression. This project has a complex study design (2x2 factorial) in which these two different treatments are delivered singly and in combination, and are compared against a 'treatment as usual' control group.

MBCT is a manualised group skills-training program that integrates aspects of cognitive therapy with components of a mindfulness-based stress reduction program (Kabat-Zinn, 1990). It is designed to teach clients to become more aware of, and to relate differently to, their thoughts, feelings and bodily sensations; in particular, to view these thoughts and feelings as passing events in the mind rather than identifying them or treating them as necessarily accurate reflections of reality.

MAT is a treatment modality derived from Motivational Interviewing to promote compliance with advised treatment regimes, and so far has mainly been used with people who have schizophrenia. We extended this approach into the field of depression management, and tailoring the intervention in a way that it can be delivered by general primary care/ non-medical staff – for example, nurses.

This report describes the outcomes from this project. In summary, outcomes included:

Development and implementation of Mindfulness-Based Cognitive Therapy

- Adaptation of MBCT to the Australian context
- Attendance of a workshop in MBCT in New York, USA
- Conduct of practice MBCT groups
- Conduct of a MBCT group for therapists
- Training of MBCT therapists
- Conduct of a MBCT residential retreat
- Conduct of two research MBCT groups

Development and implementation of Medication Alliance Therapy

- Adaptation of MAT to the management of depression in primary care
- Training of clinicians in MAT
- Training of MAT trainers

Capacity Building

- Training of clinicians in research assessment
- Training of administration staff in data management
- Linkages with other staff members of Monash University
- Liaison with Southern Health and its relevant agencies
- Liaison with Relevant Divisions of General Practice to discuss how best to deliver the project

Conduct of the 2x2 factorial pilot study

- Developed and tested methodology
- Recruitment and assessment of potential research participants
- Completion of a nested two-arm randomised controlled trial of Mindfulness-Based Cognitive Therapy against treatment as usual.
- Data analysis
- Presentation of findings at the World Psychiatric Association International Congress in 2007 with abstract publication.

Awarded a large project grant in 2006 from the National Health and Medical Research Council to run a fully powered two-arm study of MBCT.

4. Issues and Difficulties Encountered

4.1 Initial Delay

There was some delay in initiating the work program with the relocation of the host research unit from the University of Melbourne to Monash University. A Research Fellow (Dr Amanda Favilla) joined the team in May 2004 and undertook the coordinating role for the project.

4.2 Changes to Original Project Protocol

Changes to instrumentation, recruitment source, selection criteria, implementation of Medication Alliance Therapy and randomisation strategy are discussed in Section 11. The most important outcome of some the difficulties encountered was a change to the overall design of the project. Rather than conducting the full 2 x 2 factorial study as originally proposed, the study was restricted to a nested two-arm randomised controlled trial of Mindfulness-Based Cognitive Therapy against treatment as usual.

4.3 Timeline and Costs of Project

The first project participants were assessed and randomised in the latter half of 2005 and the first research MBCT group was conducted in late 2005. A second research MBCT group was undertaken early 2006. MAT was not implemented due to the small sample size together with difficulties recruiting MAT therapists within the context of the current funding model for primary care (see section 7 for further details). The work program here cost substantially more than the allotted funds from the Victorian Centre of Excellence. This shortfall was made up from funds provided from the host research centre, on the basis of the promising nature of the early stages of the work, and the high priority accorded to the project by Southern Synergy. The contribution in kind and cash from the host research centre rather more than matches the initial funds from the VCOE so that the total expenditure made or committed is approximately $230,000.

5. Key Achievements

This section identifies the goals listed in the original proposal and details the outcomes with respect to these goals. The original goals (as they relate to the two interventions) are listed and discussed in detail under relevant headings below.

- Develop and implement MAT and MBCT **[Goal 1]**
    - Development and delivery of manualised MAT course
    - Development and delivery of manualised MBCT course
    - Resources to deliver these
- Develop and implement processes for the training of therapists for both interventions **[Goal 2]**
    - Recruitment
    - Protocol
    - Evaluation
- Educational evaluation of both interventions **[Goal 3]**
- Conduct a study comparing the interventions **[Goal 4]**
    - Recruit and assess potential study participants
    - Development and administration of a clinical assessment package that addresses selection criteria, characterises co morbidities and assesses mediating variables for both therapies
- Anticipated delivery of all of these in a long-term and fully powered study **[Goal 5]**

6. Medication Alliance Therapy Development [Goal 1]

Medication Alliance describes a *process* used to achieve health care goals as they relate to the use of psychotropic medications. Medication Alliance specifically targets the relationship between the clinician and the consumer, seeking to enhance medication-taking behaviour by utilising collaborative problem solving approaches developed from cognitive behavioural therapies and motivational interviewing techniques.

6.1 Develop Manualised Medication Alliance Therapy (MAT)

The package consists of five manuals and is designed to enable any appropriate health professional who has had Medication Alliance train-the-trainer instruction to teach Medication Alliance to other health workers.

1. *Medication Alliance With People Who Have Depressive Disorders Training Manual*
2. *Trainee Resource Book*
3. *Trainee Resource Books, Medication Alliance Package: Engagement, Assessment, Therapy, Evaluation*
4. *Medication Alliance Therapy: Key Concepts*
5. *Train The Trainer Notes*

See Appendix 1 for brief description of contents.

6.2 Development of Train the Trainer

MAT was developed by the team at the University of Wollongong and the Illawarra Institute for Mental Health, chiefly, Mitch Byrne, Danielle Feros, Gordon Lambert and T Coombs, and was further developed to become the training package for MAT in this project. Danielle Feros and Mitch Byrne attended a workshop in Melbourne with Southern Synergy including the educational coordinator (Ms Jill Gray) to develop a train the trainer component, to enable other clinicians to teach the program to others and increase the capacity of these trainers' organisations.

6.3 Delivery of the Medication Alliance Therapy Training Package

(a) MAT training package

- Five manuals
- Case notes
- PowerPoint presentation slides
- Recommended training schedule
- Clinical case vignettes

(b) Training MAT therapists

The training is delivered in a stepped training model, that is, the training is split over several days so that those with primary care knowledge attend days 1 and 2, those with mental health knowledge attend days 2 and 3. Those who intend to go on to learn how to train others in MAT attend days 1, 2 and 3 as well as a fourth day, entitled train the trainer.

Training is divided into three parts:

Part One – Attitudes & Knowledge

Part Two – Core Medication Alliance Skills

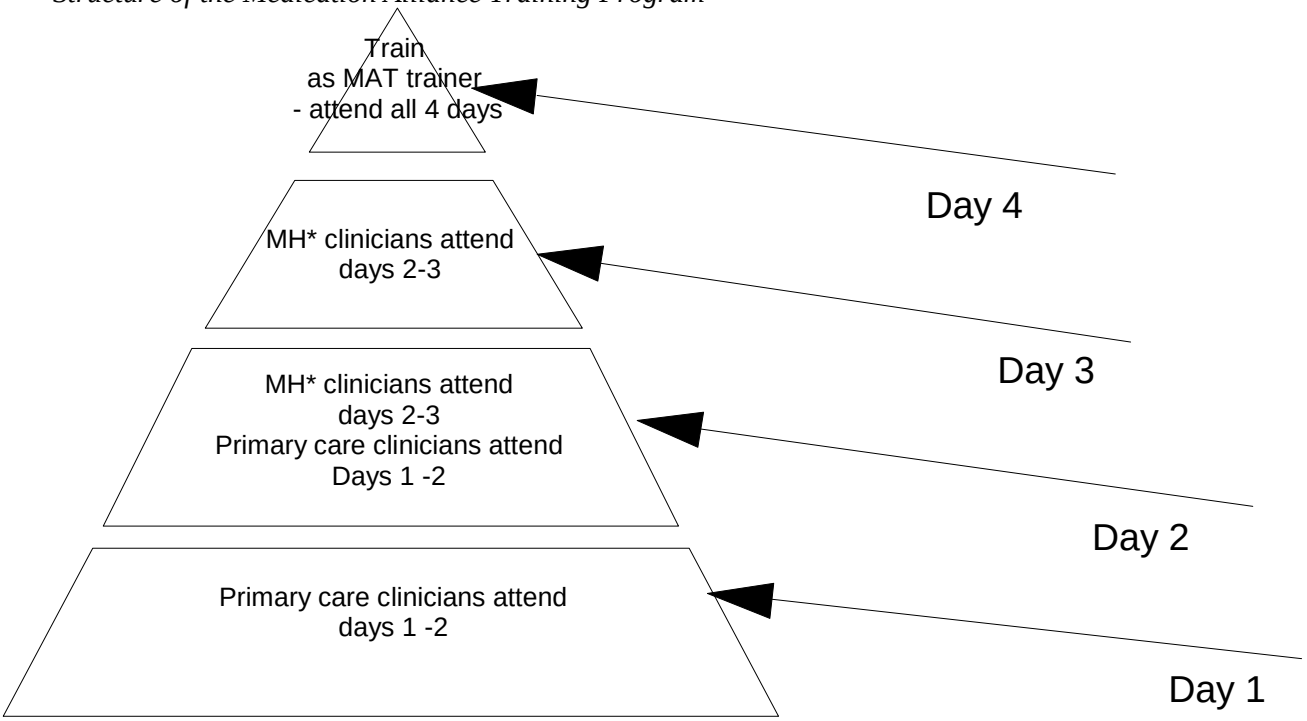
Part Three – Coaching (post-training coaching, for 6 months)

Within this structure, the trainer is provided with a package of resources, including a series of PowerPoint slides, and specific participant exercises and role play activities. The written text is augmented by this resource package. A Train the trainer package is delivered on the final day training day.

(c) Conduct of MAT and train the trainer

MAT training was conducted over four days in February 2005 (14th to the 17th) at the Bayview Conference Centre, Clayton. The promotional flyer is provided in Appendix 2. The training was led by Danielle Feros and Gordon Lambert. The first three days were dedicated to training clinicians in the delivery of MAT. This is the first time that the MAT package was reworked to include a train the trainer component to enable these clinicians to teach medication alliance to other clinicians. The aim is to specifically up skill members of the primary mental health teams and other senior members of the Southern Health staff and provide them with the expertise to conduct their own training and thus substantially add to their skill and capacity of the organisation as a whole.

Structure of the Medication Alliance Training Program



*****MH = Mental Health

DAY 1	DAY 2	DAY 3	DAY 4
Introduction to depression and related disorders • Attitudes and knowledge • core Medication Alliance Therapy skills **Principles of MAT (1)** • Stages of change	**Principles of MAT (2)** • Agenda setting • Normalising techniques • Stress-vulnerability model • Resistance and Motivational Interviewing • Stages of change • Questioning strategies	**Principles of MAT (3)** • Motivational interviewing cont. • Functional analysis • Individualised assessment • Illness Timelines • Cognitive Behavioural Therapy	**Train the Trainer** • Teach backs • Mentored presentations • Learning outcomes of program • small group interactive • dynamic teaching
Primary Care Nurses	**Primary Care Nurses**		
	Mental Health Workers E.g. psychologists, allied health workers contracted to BOIMHC - General Practice Division-based projects.	**Mental Health Workers**	**Southern Health Mental Health Workers**

7. Recruitment of Medication Alliance Therapy Therapist and Trainees [Goal 2]

Promotional material (see Appendix 2) was disseminated through the Southern network, by liaison with nurse educators, senior nurse and a mail out to Southern staff. Staff at the community clinics, wards and Primary Mental Health Teams was notified of the project and opportunity for training.

It was originally intended to recruit Medication Alliance therapists from individuals as close to the integrated primary care context as possible, that is, community health and practice nurses. It was difficult to recruit from this group (this was anticipated in the original protocol proviso). Regular fieldwork meetings involving the team and representatives from nursing, general practice divisions, primary mental health teams revealed that the plan to recruit primary care nurses was unlikely to succeed. Possible reasons mooted were that they are not an autonomous group and receive their direction from their GP employers, that their likely minimal knowledge of and possible disinterest with respect to mental health issues would operate to deter them from wanting to receive training in MAT. We took recourse to community health counsellors, primary mental health team practitioners, and individuals accredited under the Better Outcomes in Mental Health Initiative for the provision of structured psychological strategies. Other factors affecting recruitment include the Christmas/summer holiday break, with many agencies closing or the absence of staff members affecting the recruitment drive.

Recruitment of MAT trainees involved a systematic approach to various relevant agencies, including:

- **Royal District Nursing Service**

The RDNS seem ideally placed for MAT training. They work independently of GP practices and see a wide range of people with significant complexity of clinical problems in the community. Approaches to their individual agencies and Head Office were met with enthusiasm. They agreed to publicize the training and seemed supportive of the concepts and were pleased to be considered. Again pressure of time, relatively short notice and lost working days due to the summer vacation could affect numbers from the RDNS but they are a useful resource and target group for future interventions.

- **Southern Health Network**

Southern is the largest health care network and the complexity of dealing with such a large organisation can complicate learning the hierarchy of management. The managers of the services give the impression that MIMA and the MAT training specifically, is useful and relevant. In particular they thought the training would be very useful because many of their clients are on Community Treatment Orders and relapse in the contest of non-compliance, so any support would be very helpful to both clinicians and clients in their service. Staff members were directed to attend training.

    - ***Primary Mental Health teams***

Middle South Primary Mental Health Team has been involved in the fieldwork meetings and has provided useful support and advice. The team has 5 members and they committed their team manager Shirlene Jayasundera and two other members to undertake training, including Train the Trainer. South East PMHT is also a small team. They have been involved in field work meetings and are helpful in navigating primary care. They provided two members for MAT training, including Train the Trainer, which gives them the ability to train others in MAT

    - ***Senior Nurse Southern Health Network – Dandenong Hospital***

Professor Wendy Cross has shared an enthusiasm for the project and is an invaluable contact with nurses in the network.

- ***Care in Context***

This is a service that manages people who are frequent attendees to the Dandenong Hospital Accident and Emergency Department and are identified as having mental health care needs.

- ***Community Area Mental Health Service community clinics***

Area Mental Health Service clinics and Community Health clinics covering the Casey-Cardinia, Dandenong, Clayton, Moorabbin and Cranbourne Integrated Care, variously provide Crisis Assessment and Treatment Services (CATS), Continuing Care Services, Mobile Support and Treatment Services (MSTS) and residential rehabilitation services were all made aware of the project through visits, flyers and newsletters.

- ***Primary care Managers***

- ***PsyNET – Educational Mental Health Program***

- **General Practice Divisions Victoria**

This is the chief body for the divisions of general practice in Victoria and has access to all the divisions of general practice, and the divisional mental health coordinators.

- ***Local divisions of General Practice***

Contact with their program coordinators has been established. They attend the fieldwork meetings and are very helpful. They publicise our material and are a valuable source of knowledge about the best way to liaise with general practice.

8. Evaluation of Medication Alliance Therapy Training [Goal 3]

This section of the report relating to the evaluation of MAT training is authored by Danielle Feros, University of Wollongong.

8.1 Demographics of MAT Training Attendees

A total of 24 participants were involved in training. Of those, 22 completed demographic information. A summary of the key characteristics of the group based on this *n* of 22 is as follows:

- 68% from allied health
- 8 psychologists, 6 social workers, 1 occupational therapist, 6 nurses, 1 medical practitioner
- 77% female (*n* = 17)
- Mean age 40.7 years (range 23 – 59)
- Length of time working in current profession 13.9 years (range 1 – 40)
- Length of time in working mental health 10.2 years (range 1 – 26)
- 86% active case loads (*n* = 19)
- Of these, all working with individuals with depression, most of whom were taking medication and were variable in adherence
- 18% had previously had training in medication adherence strategies (*n* = 4)

Sixty-eight percent of the total sample was allied health workers. Three quarters were women. The mean age of participants was 40.7 years. Participants had been working in their current profession for an average of 13.9 years, and specifically working in mental health services for an average of 10.2 years.

86% of participants reported active case loads and all of this group were working with individuals with depression, most of whom were taking medication and were also variable in their medication adherence.

Only 4 participants had received previous training specifically related to medication adherence strategies. The type of training included a few hours of lecturing during tertiary education training or workshops.

8.2 Knowledge of Attendees

The pre-training knowledge mean was 6.2 (out of a total of 15). Post-training knowledge mean was 9.3. A significant increase in knowledge was found from pre-training to post-training, $t(23) = -5.91$, $p = .00$.

(*n* = 24)

- Matched samples t-test
- Score range 0 - 15
- Mean pre-test = 6.2 (*SD* = 2.04)
- Mean post test = 9.3 (*SD* = 1.75); $t(23) = -5.91$, $p = .00$, 1-tailed

8.3 Skill

Measure 1: Identify the number of possible influencing variables on adherence

Mean pre-test = 4.8, Mean post test = 5.6

Wilcoxon Signed Ranks Test

No. *possible* variables (pre) – No. *possible* variables (post)

	N	Mean rank	Sum of ranks
Negative ranks	7	7.21	50.50
Positive ranks	11	10.95	120.50
Ties	2		
Total	20		

- z = -1.54, p = .06, 1-tailed

The difference between the first pre-training skill measure (M = 4.8) and post-training skill measure (M = 5.6) was not significant (z = -1.535, p = .06, 1-tailed), although there is movement in the hypothesised direction.

Measure 2: Identify the number of causal variables on adherence

Mean pre-test = .91, Mean post test = 1.23

- Wilcoxon Signed Ranks Test

No. *most likely* variables (pre) – No. *most likely* variables (post)

	N	Mean rank	Sum of ranks
Negative ranks	2	8.5	17.00
Positive ranks	10	6.10	61.00
Ties	8		
Total	20		

- z = -1.81, p = .04, 1-tailed

There was a significant increase in the second pre-training skill measure (M = .91) and post-training skill measure (M = 1.23); z = -1.81, p = .04, 1-tailed.

8.4 Beliefs Regarding Non-Adherence

- Wilcoxon Signed Ranks Test revealed equivalent results to t-test
- Bonferroni $p < .01$, 1-tailed

Scale	Score range	Mean pre (*SD*)	Mean post (*SD*)	*t*	*p*
Adequacy	5 – 30	18.45 (3.93)	24.36 (2.86)	-7.54	.000
Work Satisfaction	3 – 15	10.14 (2.35)	11.59 (1.49)	-3.35	.002
Self Esteem	4 - 20	15.91 (2.95)	17.14 (2.09)	-2.68	.007
Pessimism	3 - 15	13.05 (2.07)	13.68 (1.94)	-1.49	.075
Empathy	3 - 15	11.36 (1.52)	12.27 (2.05)	-2.48	.011

After training, participants demonstrated more positive attitudes in the domains of adequacy ($t = -7.54$, $p = .00$), work satisfaction ($t = -3.35$, $p = .00$), and self esteem ($t = -2.68$, $p = .007$). No significant change was found in the domain of pessimism, however participants scores on this subscale were high to begin with (high scores on pessimism indicate low pessimistic attitudes) suggesting a ceiling effect. The change scores for empathy did not reach significance. It might be noted that the Bonferroni adjustment was used to take into account the effect of multiple comparisons in inflating type 1 error rate. This adjustment may have been overly conservative given the non-independent nature of the comparisons. If it was not applied, the empathy subscale would reach significance. Regardless, participants' scores were also high to begin with on the empathy subscale.

8.5 Beliefs about Medication

- Wilcoxon Signed Ranks Test revealed equivalent results to t-test
- $p < .05$, 2-tailed

Scale	Score range	Mean pre (*SD*)	Mean post (*SD*)	*t*	*p*
Overuse	4 – 20	11.55 (3.07)	12.41 (2.58)	-1.50	.074
Harm	4 - 20	8.14 (2.31)	7.52 (2.33)	1.66	.056

Due to a dearth of research with the Beliefs about Medication on clinicians, no directional hypothesis was applied to this measure. No significant changes occurred as a result of training in any direction. Overall, means on both the overuse and harm subscale suggest that participants had somewhat neutral beliefs about medications.

9. Mindfulness-Based Cognitive Therapy Materials Development [Goal 1]

9.1 Materials for Mindfulness-Based Cognitive Therapy

The following materials were developed by the team and are faithful to the principles of MBCT practised by its creators Segal, Williams and Teasdale.

Equipment

- Multiple sets of 8 CDs and tapes of guided meditation and yoga adapted for the Australian context. See Appendix 4 for titles
- Equipment for the conduct of MBCT groups (mats, blankets, bells, audio visual equipment). See Appendix 5 for list

Manuals

- *MBCT-Oz* Manual for the MBCT leader (see Appendix 6 for cover)
- Individual Handouts for the client participant

Training and educational materials

- Program for booster MBCT classes (see Appendix 7)
- MBCT residential retreat program for trainee therapists (see Appendix 8)
- Educational Materials for residential retreat

9.2 Mindfulness-Based Cognitive Therapy Training Resources

(a) MBCT therapists

Our research team's four experienced MBCT therapists have many years of mindfulness experience and clinical experience with management of people with depressive disorders. They attended a residential workshop delivered by the originators of MBCT in New York, USA in 2004. The MBCT course also requires booster groups to sustain and refine its practice and our group have conducted two of these, designing a program for both.

(b) The conduct of two pilot MBCT groups for lay participants

(c) MBCT group for trainee MBCT therapists

(d) Research group with randomised participants

See Appendix 9 for promotional flyer.

The development and implementation of a training program for MBCT therapists resulted in our teams' already experienced MBCT practitioners developing further expertise in this area. This study has trained 23 therapists in the practice of MBCT so that we now have a resource of trained therapists who can be utilised in future studies, thus providing a highly skilled work force at no extra cost in future applications. Some of these therapists are currently running MBCT groups in the course of their clinical work.

(e) 4-day residential retreat (See Appendix 8)

To complete the training as MBCT therapists, a retreat was designed to provide an intensive experiential approach to increasing skills as a group leader. It included teach backs and further opportunities to practise. 19 of the therapists attended.

The manual and teaching package is now elaborated into a short certificate course available annually through the Monash University School of Psychology, Psychiatry and Psychological Medicine.

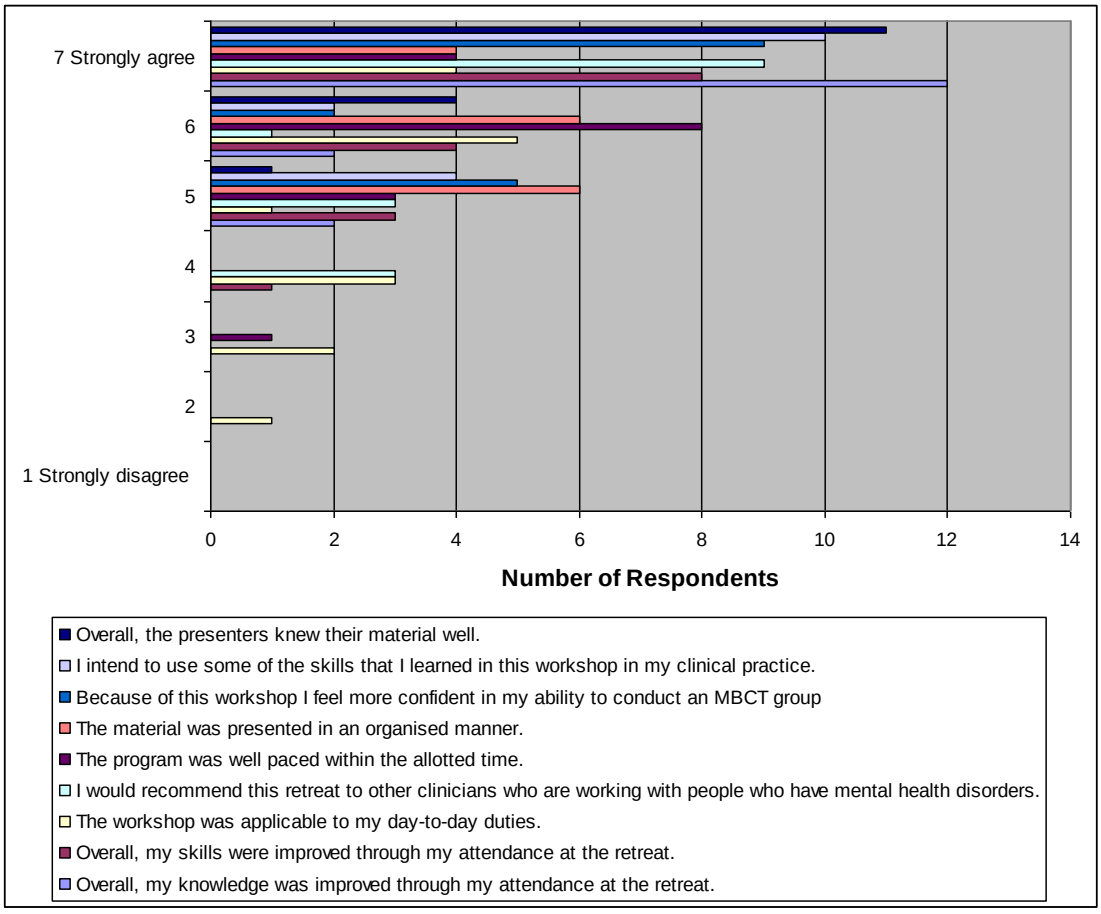
10. Mindfulness-Based Cognitive Therapy Training

10.1 Retreat Evaluation

Nineteen people attended a weekend retreat that was the final component of training in for clinicians in running Mindfulness Based Cognitive Therapy groups. Sixteen of those who attended (84.2%) completed an evaluation relating to this weekend of training. A summary of these evaluations follows.

Initially respondents were requested to show on a 7 point Likert scale their response to the nine positive statements about the weekends training. The figure below serves to summarise both these questions and the responses to these questions. The overall response to the training was very positive (i.e. most of the respondents agreed with the positive statements about the training). The only negative feedback from this section of the evaluation was from three people who disagreed with the statement "*the workshop was applicable to my day-to-day duties*" and one person who disagreed with the statement "*the program was well paced within the allotted time*".

Figure 1 Summary of the responses to nine positive statements about the weekend of training



The respondents were also asked three open ended questions. The responses to these questions are listed in Tables 1-3. In general the responses indicate that those who attended gained a great deal from the retreat.

Table 1 Response to the first open-ended question

Responses to the question: What do you consider to be the most successful, positive and best aspects of this retreat?
• Combination of personal & professional development • Spirit of community, supportiveness & good humour
• Going through the manual as a challenging and supported way • Feedback from the group leader during this process • Gaining an understanding of the role of the instructor in the group • Having my own practice re-enlivened
• Opportunities to practice • Small group work • Supportive environment developed & initiated by group leaders • Friendliness & approachability of group leaders
• Opportunity to "get feet wet" under the supervision of extremely able & experienced clinicians & practitioners of mindfulness • Having the opportunity to deepen my meditation practice
• Role playing leading the sessions and getting feedback • The level of skill in leaders and the transparency of where they were at • The obvious difference in leadership styles that was openly portrayed
* opportunities to experience mindfulness practice whilst we were learning to present the program e.g. morning & evening meditations & day of silence * The small group activities and the teach back very valuable, feedback from instructors & group members
1) Lots of practice and exposure to the techniques and different approaches of the retreat leaders 2) Small groups very good for allowing opportunities for practice in challenging & safe way 3) Lots of open discussions- very good for gaining insight
Bringing together, crystallising the rationale behind the MBCT method
It was great experience the great diversity of the different leaders. It was a very supportive environment and great opportunity to learn heaps -especially the small groups and the small tips given to us
Its structure in terms of melding practice with education of how to run a group
Practice delivering MBCT, practice guiding mediation, discussion of the relationship between different aspects of the program & developing an appreciation of the complexities of MBCT

Responses to the question: What do you consider to be the most successful positive and best aspects of this retreat?
The extent to which the facilitator's were able to generate a learning environment that was honest and extremely safe - as a result of skills that we were learning were applicable to our personal lives as well as our professional ones
The supportive learning environment and wisdom of the presenters
The workshop was very well thought out in terms of material & practice of the 8 week program. Information was clear & relevant. The chance to gain a greater understanding of this complete therapy was fantastic.
Well paced

Table 2 Responses to the second open ended question

Responses to the question: What ways do you think the retreat could have been improved?
• lesser period of silence as it impacted on learning re groups for me • shorter sessions on the Friday night (it was tiring after a week of work & the effort of getting here)
• role play sessions more structured, clearer outlining of participant's tasks. Also clarifications of beginning & end of role play • more specific feedback on tasks, perhaps encouraging "clinicians' to identify their own strengths & weaknesses
• no group hugs please • more awareness prior to the retreat of what the programme might involve over the weekend
• give the participants a schedule • a little more clarity in goals for some sessions • rotate all the group (the 2 big & the smaller 5's) so everyone experiences different leaders & participants.
• instructors should know the lay out a bit clearer as at times it appeared confusing. • not to squeeze session 7 & 8 together
• longer duration?
• (the food less stodgy) • more time to do role plays with feedback from leaders
A plan of proceedings to be sent out prior to the retreat, to enable better preparation for the retreat
accommodation could have been improved slightly e.g. soap in toilet, paper towels available
Allow more time for final day
I can't think of any deficits
In the ideal world: 1) Extend the retreat to another day to include more opportunity for small group work and teach backs. 2) Group some of the small group tasks together, so that "trainee instructors" can follow the teachings point through.
Organising prior to event which person would present which aspect. At least some elements of this with the spontaneous teachings.
The final day felt slightly rushed but I'm sure this will be easily fixed for future retreats
Timing was obviously something of an issue, but difficult to know how to improve this because 3 days was a good length. But even one extra session would have improved the last session!

Table 3 Responses to the third open ended question

Responses to the question: Please add any further comments you may have concerning the retreat
At this stage i.e. prior to final closing session I feel a little uncertain about where to from here with regards to planning and organising a clinical group. My sense is of waiting to run a group according to the manual
Great location as we have space and we were the only group here! Good for mindful practice.
I greatly enjoyed it & learned a lot.
I really enjoyed this weekend, as should be fairly apparent by now! Thank-you all for organising & conducting it.
It has been an immensely rewarding & positive experience. On a personal level it has been wonderful & has made me more motivated than ever to continue my meditation practice
Many thanks for all the hard work, inspirations & integrity in this process.
Thank-you for giving me the opportunity to participate in this retreat. The personal & professional gains have been immense. Central to all of this was the opportunity to work with the four of you and others who practice mindfulness on a daily basis.
Thank-you for running this training it has been really helpful and touching
Thank-you!! This was a wonderful experience for me personally (my first retreat!). I feel confident to continue my learning & practicing of MBCT & look forward to more learning/practice opportunities.
Thank you for organising it & the opportunity to attend.
Thank you, it was a wonderful experience more than anything this will assist my own meditation practice. I also hope to be able to establish opportunities to run MBCT groups. I will definitely incorporate mindfulness practice within my work.
The mindfulness practice was valuable.

10.2 Expertise in Conducting Mindfulness-Based Cognitive Therapy Groups

The primary aim of the proposed project is to conduct a controlled evaluation of MBCT for people who have had at least three prior episodes of depression; a further aim is to assess the role that this treatment may have for treatment of depression. Our group gained invaluable practical experience through the design and conduct of several MBCT classes.

(a) Pilot MBCT groups

Two pilot MBCT groups were conducted in 2004 and 2005. This required recruitment and then assessment of participants by the MBCT practitioners. The participants were registered with Southern Health and the Primary Mental Health Team to provide appropriate medico legal care.

Number of participants: 7 (2 men 5 women)

Referral source: 6 GP, 1 psychiatrist

The first group was conducted at the Noble Park Community Centre on Monday evenings. The group facilitators were Bob Sharples and Ivan Milton. A community centre was selected to avoid the stigma attached to psychiatric settings. All 7 participants were assessed by the MBCT practitioners. Some of these by necessity were done over the telephone. This was not entirely satisfactory and the decision was made that all future assessments be conducted in person.

The second group was conducted at the Monash Medical Centre (MMC). The therapist was Graham Meadows. The MMC is a large tertiary hospital, with an obviously medicalised setting. This was in response to feedback from the first group who had disliked the ambience of the Community Centre's room, describing it as rather small, and" cold". Unfortunately, the community centre was situated near a park where drug dealing was noticed to take place. Participant feedback guides the research conduct and this consumer response is important as MBCT is conducted over many weeks and it is essential for the participants to feel comfortable.

(b) Booster groups

The first was attended by 6 members of the two practice groups, and included a review of participants' experience and experiential exercises. The second booster group consisted of some members of the first two groups and some of the trainee MBCT practitioners.

See Appendix 7 for detailed timetable.

10.3 Mindfulness-Based Cognitive Therapy Training (Trainee Therapists) [Goal 2]

Trainee therapists were recruited by advertising through Southern Health and Monash University. We received responses from about 50 people. Twenty-three trainees were selected based on their professional experience and exposure to mindfulness. These 23 comprised 17 psychologists, 1 psychology student, 2 doctoral (psychology) students, 1 nurse, 1 social worker and 1 general practitioner.

To maintain fidelity with the original MBCT program, the sessions were taped. The camera was focused on the therapist and all participants had agreed to the filming. The tapes were then reviewed by the therapist and another MBCT therapist for fidelity and coaching purposes.

11. Conduct a Study Comparing the Interventions [Goal 4]

11.1 Changes to original protocol

(a) Instrumentation

Experience gained through the conduct of the pilot and expert advice received through wide consultation provided invaluable information about practical modifications to the study design in the form of additional several measures are discussed here. All variations have been submitted to and approved by the relevant Human Research Ethics Committees.

(i) Assessment of Quality of Life measure

The *Assessment of Quality of Life measure* is a brief 15-item measure assesses quality of life according to five domains – illness, independent living, social relationships, physical senses, and psychological wellbeing. The AQOL is currently used as a 'gold standard' for health economists in the costings evaluation of interventions. It permits more detailed examination of the costings of the two therapies.

(ii) A service utilisation measure

We specified the form of this measure and created a variant of the measure utilised in the National Survey for Mental Health and Wellbeing, designed to overcome some of the shortcomings of this measure that have been reported.

(iii) Changes in the diagnostic instrumentation

Role plays of the full instrument suite with a variety of likely response scenarios suggested that the initial interview was unduly burdensome for participants. Cuts were made where these were acceptable on methodological grounds. For example, the somatoform module of the CIDI module was cut because of the intrusive questions of limited gain in context of the pilot.

(b) Recruitment source

We expanded our recruitment sources to include recruiting from the private sector, Southern Mental Health services and the community through advertising in the media. We had interest regarding referring potential participants to the project from clinicians in both the private sector and within Southern Mental Health services. We believe that it has been sensible to open up recruitment of participants to these groups. However, we block randomisation in any analyses to ensure balancing of participants from these referral sources across different study groups.

(c) Selection criteria

The selection criteria required for the initial 2 x 2 factorial design was relatively extensive as a result of having to give consideration to two different treatment conditions. The inclusion criteria included: age 18-65 years; currently prescribed antidepressant medication, with an intention on the part of the prescriber that this be continued for following 12 months; ability to speak and read English fluently; meeting DSM-IV TR criteria for three previous major depressive episodes; at least two of which must have occurred within the past five years, and one within the past two years; at assessment, score on the Hamilton Rating Scale for Depression of less than 10; at assessment, score with respect to antidepressant medication on the Adherence Scale of 5 or less. The exclusion criteria included: history of schizophrenia or schizoaffective disorder, bipolar disorder or cyclothymia; current eating disorder or obsessive-compulsive disorder; organic mental disorder or pervasive developmental delay; current borderline or antisocial personality disorder; current psychotherapy or counselling greater than or equal to once per week; current practice of meditation more than once per week or yoga more than twice per week; active medical illness to which depression is secondary.

The large range of selection criteria resulted in an overly restrictive entry to project with only 8% of candidates found to be eligible to participate in the full factorial design. In particular, 14 of the 19 people who were found to be eligible for the MBCT treatment arm were not eligible for MAT as they were either not prescribed anti-depressant medication are or, if prescribed, were highly compliant. Because MAT is a medication adherence intervention, it is not relevant to people who are not on medication or compliant with their prescription. In response to this emergent problem, a two-arm RCT of MBCT versus TAU was nested into the design and candidates who would have otherwise been excluded on the basis of selection criteria related to MAT were now permitted to take part in the project. The criteria related to the recency of previous depressive episodes and current meditation/yoga practice were also relaxed. Having a diagnosis of antisocial or borderline personality disorder was withdrawn as a formal exclusion criterion due to the complexity involved in establishing diagnosis. In particular, we found that questionnaires used to screen for these disorders either had little or no empirical data to support their use or yield too many false positives while the addition of a formal diagnostic interview would add considerably to participant burden. We considered that altering the selection criteria in this way to be an appropriate response to the realities of primary care and would maximise the chance of obtaining meaningful data.

(d) Randomisation strategy

As a consequence of the above changes to the selection criteria, candidates who were eligible for MBCT but not MAT had their randomisation options restricted to either Mindfulness-Based Cognitive Therapy or Treatment As Usual. Candidates determined as eligible according to the original protocol were randomised to one of the four conditions, that is their randomisation was unchanged.

(e) Implementation of Medication Alliance Therapy

Implementing MAT itself also proved problematic. Though it may well be a useful intervention, the absence of a funding stream to support its implementation meant it generated little interest from primary care nurses to participate. Further changes in the funding structure for primary care might make the approach more practically useful. In that case, the work invested into the development of this program would be available and could give a head start to mental health work by a large workforce that hitherto has been little involved in this area of clinical practice.

(f) Factorial design

The final outcome arising from many of the above difficulties was that the original 2 x 2 factorial design proved to be too complex to administer for the limited resources available. As mentioned, the selection criteria required to administer two treatments was extensive and resulted in an overly restrictive entry to project. In fact, the selection criteria for the two treatments were to some extent oppositional. Participants are most suitable for MAT if they have low levels of motivation and compliance with treatment since these are the direct targets of MAT. On the other hand, participants are most suitable for MBCT if they have high levels of motivation and compliance. Participants who have had three or more episodes of depression would generally be expected to have relatively high motivation to comply with treatment and this may explain the difficulty recruiting participants with poor compliance from this group. Even if we had been successful in recruiting sufficient numbers of participants eligible for both MAT and MBCT, recruiting MAT therapists was found to be an additional obstacle, as discussed in point (e). As a consequence, the decision was made to restrict the study to a nested two-arm randomised controlled trial of Mindfulness-Based Cognitive Therapy against treatment as usual; the results and discussion in sections 11.9 and 11.10 pertain to the outcomes of this substudy.

Given the difficulties we encountered in implementing the full factorial design, we were interested to examine their use in other clinical trials in psychiatry. In June 2009, we conducted a database search of MEDLINE and PsycINFO using the following key terms (mental health or mental disorders or psychiatry or psychiatric or mental illness or depression or major depressive disorder) and (randomised controlled trial or randomized controlled trial or RCT or clinical trial or treatment trial) and (factorial design or factorial designs or factorial). From MEDLINE, 30,565 papers were identified as referring to randomised controlled or clinical trials in mental health; in PsycINFO this figure was 2980. When the search terms (factorial design or factorial designs or factorial) were added, the number of identified papers dropped to 83 and 7 in MEDLINE and PsycINFO respectively. When the titles/abstracts of these papers were examined, only 17

actually involved the use of a factorial design in a mental health-related clinical trial and only seven of these were directly related to the treatment of depression. A separate search using the term "factorial or factorial design" of the 284 trials on the Australian and New Zealand Clinical Trials Registry that had "Mental Health" as their condition category produced a similarly low yield with only one other factorial study identified besides MiMA. Although factorial designs such as that originally proposed for this study are considered efficient and useful, it may be, as we have found, that the resources required and complexity involved may curtail their execution in practice.

11.2 Consultation Structure

Consultation structures developed in the pilot provided valuable guidance and substantial local information. This was particularly important to our group in light of the move from the University of Melbourne to Monash University that occurred. A field work implementation group was established and included local representatives from the General Practice Divisions of Victoria, a source of knowledge about the best way to liaise with general practice; Local Primary Mental Health Teams; and the Senior Nurse, Southern Health Network – Dandenong Hospital. Academic input was also obtained from liaison with the Department of General Practice at Monash University and the Monash Institute of Mental Health Research.

11.3 Recruitment Drive

Contacts were made with, and promotional material (See Appendices 3 and 11) sent to, the following organisations:

- South East Primary Mental Health
- Middle South Primary Mental Health Team
- General Practice Divisions of Victoria
- Primary Mental Health Care Australian Resource Centre
- Royal Australian College of General Practice
- Royal Australian and New Zealand College of Psychiatrists
- Mental health interested practices – as identified by the local Divisions of General Practice
- Community Mental Health Clinics
- Care in Context – Dandenong Hospital
- Private psychiatrists
- Local Newspapers – advertisements placed

11.4 Development and Administration of a Clinical Assessment Package

The assessment package was trialled and revised in the context of practical fieldwork. It was then converted into an Intake Assessment package (see Appendix 10), and a Follow Up package to be administered at 3 monthly intervals. Our suite of instruments was designed to capture demographics, and past history of depressive disorder. It took approximately 2 hours to complete and was administered by trained assessors.

The suite of instruments included:

• Client Demographic Questionnaire	• Hamilton Rating Score of Depression
• Composite International Diagnostic Interview - Auto	• International Personality Disorder Examination – Screen
• Schizophrenia screen question	• Work And Social Adjustment Scale
• Service Utilization Questionnaire	• Assessment of Quality of Life
• Medication and Adherence Information	• Satisfaction Questionnaire
• Drug Attitude Inventory-10	• Mindful Attention Awareness Scale
• Beck Depression Inventory	• Expectancy Questionnaire

11.5 Recruitment and Training of Skilled Assessors

We trained a bank of assessors to provide a cost effective assessment service. As referrals come in at unpredictable rates, the resource of a casual workforce skilled in this area is invaluable.

(a) Train the team

The assessors were recruited from Southern Health inpatient and outpatient services. An Introductory symposium was held to provide an overview and a two day training session conducted in early 2005. The team was trained in the psychometric tests listed above, and the theory and practice of research interviewing.

See Appendix 12 for promotional flyer.

(b) The schedule of training

See Appendix 13.

11.6 Intake Assessment and randomisation

(a) Engagement, consent and intake assessment

Candidates for the project were either self referred or referred by their clinician. Upon referral, the research fellow made contact with them to explain the project and ask a few screening questions such as number of past episodes of depression. Their details were given to a research assistant who contacted them to arrange a mutually suitable time for assessment. The assessment interview took on average 2 hours and was conducted at Southern Synergy. The assessment was then analysed using an eligibility assessment summary form to determine eligibility. The ID numbers of eligible participants were given to a statistician to randomise to treatment.

(b) Randomisation

See Appendix 15 for randomisation procedure.

11.7 Therapeutic Interventions

(a) MBCT

Two MBCT groups were conducted – one late in 2005 and one early 2006. In addition, at the end of the follow up period, all TAU participants were invited to participate in an MBCT group. Three TAU participants accepted and completed an MBCT group during 2007.

(b) MAT

As noted above, MAT was not implemented due to the small sample size together with difficulties recruiting MAT therapists.

11.8 Follow-up assessments

Participants were invited to complete follow up assessments every three months for a year commencing from the end of the MBCT groups for both the MBCT and TAU participants.

11.9 Results

(a) Participant flow

See Figure 2 for consort diagram.

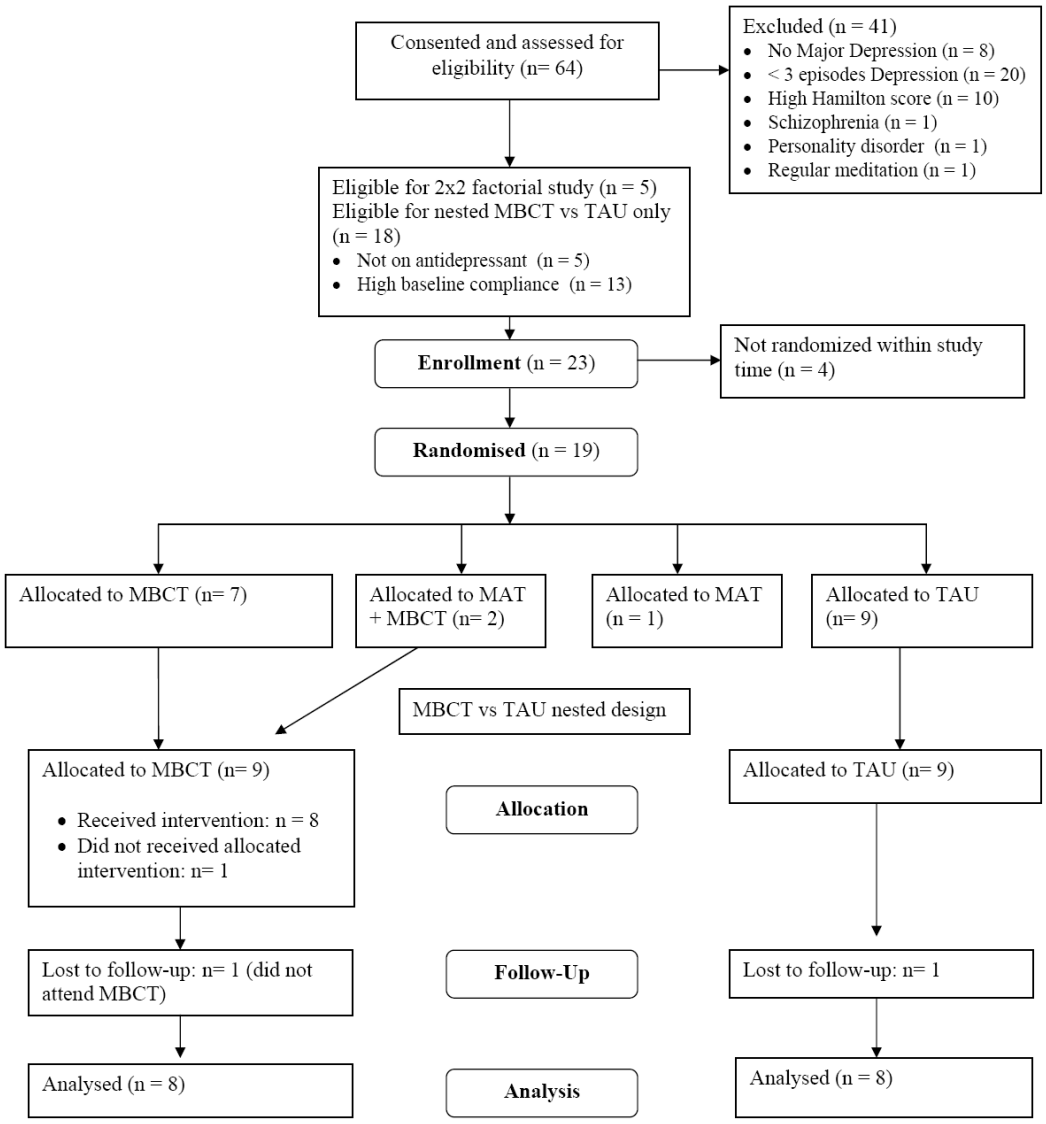


Figure 2 Consort diagram

(b) Participant characteristics

Table 4 shows baseline characteristics of the MBCT and TAU groups.

Table 4 Demographic and clinical characteristics of MBCT and TAU groups at baseline

Variable	MBCT (n = 8)	TAU (n = 8)	Statistics
Age, years [Mean (SD)]	47 (9.8)	45.5 (13.2)	$t(14) = 0.26$; $p = 0.80$
Sex (male/female)	1/7	4/4	
Marital status (n)			
Single	1	5	
Married/defacto	5	2	
Divorced/separated	2	1	
Employment			
Full-time	3	3	
Part-time/casual	4	2	
Unemployed	1	3	
Education			
Year 11-12	3	4	
Diploma/Associate Diploma	0	3	
Bachelor	5	1	
Post graduate	0	0	
Depression			
Age at onset (years) [Mean (SD)]	32.1 (9.8)	32.1 (11.7)	$t(14) = 0.00$; $p = 1.00$
Duration of illness, years [Mean (SD)]	14.9 (10.2)	13.4 (6.7)	$t(14) = 0.35$; $p = 0.73$
HRSD score [Mean (SD)]	3.9 (3.0)	4.0 (2.9)	$t(14) = -0.09$; $p = 0.93$
BDI score [Mean (SD)]	8.8 (6.5)	17.1 (14.1)	$t(9.8) = -1.59$; $p = 0.16$
Time since most recent episode (years) [Mean(SD)]	1.8 (1.4)	0.8 (1.8)	$t(14) = 1.09$; $p = 0.30$
Previous episodes [Median (IQR)]	4 (4)	5.5 (19)	
Longest episode (weeks) [Median (IQR)]	16 (85)	38 (72)	
Psychiatric admission (n)	3	5	
Antidepressant medication (n)	7	6	

Note: HRSD = Hamilton Rating Scale for Depression; BDI = Beck Depression Inventory; IQR = Interquartile range

(c) Outcome analysis: prevention of relapse/recurrence to Major Depression

Although the intention in this pilot project was to conduct 5 follow up interviews with each participant, only 54% of assessments were completed (43/80). It was therefore not feasible to analyse data as originally planned when the study was designed. The decision was made to focus on the period of follow up time (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. The histogram of the frequency distribution for number of months of follow up is provided in Figure 3.

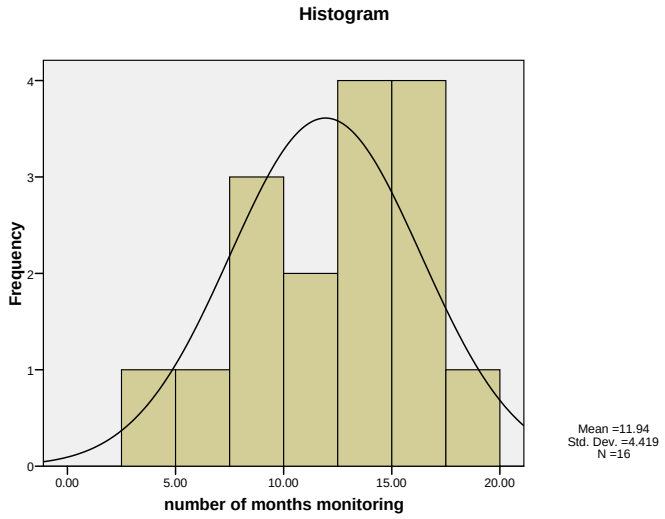


Figure 3 Histogram for number of months of follow

Examination of the outcome data from the CIDI 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 the number of depressive episodes (see Table 5).

Table 5: 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

11.10 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, it is important to note that several methodological aspects of this pilot study seriously limit the ability to draw inferences about treatment effects. These are outlined below.

1. *Sample size*: the small sample size and large number of candidates who were excluded from the study clearly restricts the degree to which the findings can be generalised.
2. *Missing data*: the problem with missing data is that it hinders the ability to detect real relationships and can lead to findings that are unclear or even inaccurate. Unfortunately, missing data proved to be a significant issue in this project with two withdrawals and only around half the follow-up assessments completed. A major contributing cause was the high response burden involved in completing face-to-face interviews every 3 months, which were time consuming, inconveniently located in terms of public transport, and undertaken without any form of remuneration. As noted above, the decision was made to focus on the period of follow up time (months) rather than the number of follow up interviews which went some way to addressing the problem of missing data.
3. *Group allocations*: four participants screened positive for Borderline Personality Disorder and one of these also screened positive for Antisocial Personality Disorder; by chance, all four were randomised to TAU. Although the personality disorder exclusion criteria was abandoned due to low confidence in the use of the screening measure for the purpose of assessing eligibility, this may nevertheless represent some greater vulnerability toward relapse in the TAU group.
4. *Treatment demoralisation*: One of the TAU participants who attended an MBCT group following completion of the project expressed some strong criticism related to completing research assessments at multiple points with no clinical benefit. This criticism was taken very seriously. The literature was reviewed in order to understand better the possible impact of not receiving the active treatment in a clinical trial. We found "resentful demoralisation" to be a well-described bias that may arise in control group participants whereby the belief that they are not receiving a desirable treatment negatively affects their attitude and behaviour, and as a consequence, the outcome results. Indeed, Pilcher (2009) recently highlighted the problem of the "nocebo" effect to describe the opposite of the placebo effect: whereby "dummy pills and negative expectations can produce harmful effects" (p. 2). If such negative expectations are present, the seemingly positive results for the experimental treatment may in fact be accounted for by the negative effects in the control.

Unfortunately, although treatment expectation was measured in 7 of the 8 MBCT participants, only 3 participants in the TAU group completed the relevant instrument and they had widely varying responses. We cannot rule out the possibility that the high rate of relapse in the TAU group relative to the MBCT group may to some extent be explained by resentful demoralisation. Indeed, there is good reason to suppose that our sample, being a group highly vulnerable to depression and therefore negative thinking, would be predisposed to this bias. It is conceivable, for example, that some may even have viewed their allocation to TAU as "another failure" or evidence that they are personally prone to bad luck. They may also have been especially sensitive to negative terminology used in the project. An examination of MiMA publicity materials and correspondence in the light of this possibility suggested that the undesirability of TAU may have been over emphasised. Correspondence sent to TAU participants, although designed to be empathic and conciliatory, may have unintentionally highlighted the undesirability of their group. Thus the TAU participant's allocation was referred to using the phrase "This may be a disappointment to you", and later correspondence noted that "it may be hard to keep up motivation for a project in which you have not been given a therapy". Equally, the desirability of MBCT may have been over emphasised - for example, the headline for the participant flyer and newspaper advertising sounded very hopeful: "New approach to preventing depression. Research participants sought". As noted by Everitt and Wessely (2004), participants entering a trial "are likely to believe that the new therapy is about to solve all their problems. Why else would it be featuring in the trial?" (p. 16). Again, the corollary to this is the likely disappointment when the participant is not provided with a promising new treatment. While obviously some incentive is necessary for recruitment, greater balance is needed where there is a risk of resentful demoralisation. Some effort was made to offset the disappointment of not receiving an active treatment by promising to provide "one of the therapies" at the end of follow up. However, the 12 month wait involved combined with the lack of specificity about the treatment that would be provided may have made this somewhat ineffective.

The methodological issues that arose in the course of conducting this study were extensive but provided essential learning for implementing the subsequent NHMRC-funded "DARE project", a well-designed and fully powered study testing MBCT against TAU which is discussed further in Section 12. We consider MiMA a good example of how a pilot study can lead very productively to effective work on a much larger scale.

11.11 Dissemination of findings

Professor Graham Meadows presented the findings from MiMA at the World Psychiatric Association International Congress in November 2007. The abstract was published as follows:

Meadows, G., Shawyer, F., Martin P., Judd F., Piterman, L., Martin, C., et al. (2007). Developing Evidence Around Mindfulness Based Cognitive Therapy. *Australian and New Zealand Journal of Psychiatry, 41(Supplement 2):A250*.

April 2010: Poster presentation. Meadows, G., Shawyer, F., Graham, A. An exploratory effectiveness study with MBCT: findings and design issues. Investigating and Integrating Mindfulness in Medicine, Health Care and Society. 8th Annual International Scientific Conference. April 7-11, Worcester, Massachusetts, USA

12. Delivery of a Long-Term and Fully Powered Study [Goal 5]

The knowledge and capacity building arising from the conduct of this study contributed towards a successful NHMRC grant application for a fully powered two-arm study of MBCT, called the DARE (Depression Awareness Recovery Effectiveness) project. The set of strategies and resources developed in MiMA has been of enormous benefit in the formulation and practical application of a DARE. In this section, we outline the key methodological learnings from MiMA that informed the design and application of DARE, which to date, has been very successful in its implementation.

12.1 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. As a result of MiMA, all the materials along with trained therapists were available to implement MBCT making this a smooth process and readily transferable to off-site locations.

Considerable thought was put into developing the control intervention and presenting this to candidates so as to minimise 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) group and explicitly highlighted the fact that those not receiving MBCT would be undertaking supported active monitoring of their symptoms each month in addition to treatment-as-usual. The addition of regular monthly monitoring of depressive symptoms will mean that episodes of depression are likely to be picked by and treated earlier than would be the case without such monitoring. Ludman et al., (2003), for example, found that keeping track of depressive symptoms positively predicted improvements in depression symptom scores, controlling for baseline, treatment group and sociodemographic characteristics. 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. Training all participants in the DRAM process, including providing them with an accompanying manual has increased positive treatment expectation in the DRAM group, reducing the threat to validity from resentful demoralisation. This is achieved without affecting the primary endpoint of time to depressive relapse because the DRAM condition does not have any direct action until the person becomes significantly symptomatic; in contrast MBCT is expected to have its effects at a much earlier point in the trajectory towards relapse. Preliminary analysis of the early data suggested we are achieving similar levels of treatment expectancy and treatment credibility across groups (end of treatment means (sd): Expectancy - MBCT: 5.9 (1.0); DRAM: 5.7 (2.8); Credibility – MBCT: 6.8 (1.1) DRAM: 6.5 (2.5); $p > 0.05$).

Careful thought was also put into developing a project title and marketing name so as to reflect both conditions in an unbiased manner with the aim of balancing treatment expectation and avoiding resentful demoralisation. The title was: "A Comparison of Mindfulness-Based Cognitive Therapy with Usual Treatment plus Active Symptom Monitoring for Preventing Relapse in People Who Have Had Recurrent Depression". The marketing name was: "DARE" being an acronym for "Depression Awareness - Recovery Effectiveness". Marketing materials were also carefully worded to ensure balance across the two treatment conditions.

12.2 Recruitment

As a result of experience from MiMA, the use of media was emphasised as the most efficient means of recruiting participants. GP networks and other links developed through MiMA were also accessed.

Exclusion criteria were made more inclusive, e.g., including people with bipolar disorder or a history of schizophrenia, who had their last episode of depression more than 5 years ago, who had a current practice yoga/meditation or who were over 65 years of age (up to 75 years). Although current borderline and antisocial personality disorder was kept as exclusion criteria, no attempt was made to screen for these disorders. Instead, the exclusion criteria were included on the referral form and reliance was placed on referring clinicians to make appropriate judgements in this regard. Given the fact that most of the exclusions from MiMA were due to failure to meet the inclusion criteria related to the diagnosis of depression, a brief screening questionnaire was developed and administered to candidates over the phone. The screening items were base on the CIDI 2.1 for lifetime depression. The screening form was also available on the internet and for use by the referring clinician on the back of the referral form. Where current depression was possible, participants were encouraged to contact their treating clinician to seek assessment of this possible problem. Permission was sought to re-contact the candidate in 6 weeks. Only 18% of candidates who undertook the intake the assessment interview for DARE were excluded compared to 64% of MiMA candidates.

12.3 Assessment

The casual research assessor workforce and workshop-style training worked well in MiMA so we replicated this model for DARE. As referrals come in at unpredictable rates, the resource of a casual workforce skilled in this area is invaluable.

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 phone, mail or over the internet. As well, participants are provided with remuneration for completing face-to-face assessments and the longer remote assessments that occur every 3 months.

The actual instrumentation used in assessments was reviewed based on the experience of MiMA. One of the most important changes involved the administration of the Credibility/Expectancy Questionnaire (CEQ), the instrument for assessing treatment expectation. The instructions for the CEQ were modified so that it was appropriate for participants allocated to DRAM as well as MBCT and all participants were given this questionnaire. We will therefore have the appropriate data to judge whether treatment expectation is reasonably balanced across the two groups. Other changes including replacing the Beck Depression Inventory with the Patient Health Questionnaire-9 as a more directly useful measure of major depression according to DSM-IV criteria and dropping the Hamilton Rating Scale for Depression as this is not a self-report measure and therefore not conducive to assessments completed remotely.

At the close of recruitment for DARE in January 2009, 204 participants were enrolled. The study presently is moving towards completion with anticipation of good retention rates.

13. Summary

The work conducted during 2004-2007 resulted in the following:

• Developed and implemented MBCT-Oz	Full package inc trainer and educational materials with audiovisual material, 60 kits
• Accrued equipment for MBCT groups	
• Attendance of a Conference by the originators of MBCT in New York, USA	
• Conduct of practice MBCT groups	2 MBCT groups conducted
• Conduct of a MBCT group for therapists	1 MBCT groups conducted
• Trained MBCT therapists	23
• Conduct of a MBCT residential retreat	1 conducted
• Conduct of research MBCT groups	2 MBCT groups conducted
• Linkages with other staff members of Monash University	Fieldwork Implementation Group
• Liaison with Southern Health	PsyNET, community clinics and inpatient units
• Liaison with Relevant Divisions of GP to discuss how best to deliver the project	Monash, Dandenong And Central Bayside Divisions
• Developed and implemented MAT	27 therapists trained 1 course inc train the trainer conducted
• Developed Medication Alliance Therapy program	5 manuals produced train the trainer manual
• Trained clinicians in MAT	17
• Trained MAT trainers	10
• Trained clinicians in research assessment	10 trained
• Conducted treatment arms of the study	2 research MBCT groups conducted
• Number of research participants assessed and randomised to treatment	19
• Follow up assessments conducted over a 12 month period	43 assessments completed (54%)
• Data analysis on primary outcome measure	
• Presentation of findings at WPA International congress	
• Success in a 2006 NHMRC grant application to run a clinical trial of MBCT from 2007-2010	

14. References

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

Ludman, E., Katon, W., Bush, T., Rutter, C. et. al., (2003). Behavioural factors associated with symptom outcomes in a primary care-based depression prevention intervention trial. *Psychological Medicine, 33*, 1061-1070.

Pilcher, H. (2009). The science of voodoo: when mind attacks body. *New Scientist, 2708*, 5.

Appendix 1: Medication Alliance Therapy Training Manuals

1. Medication Alliance with people who have depressive disorders Training Manual
Byrne, M. K., Feros, D. L. (2004). Wollongong, NSW: University of Wollongong, Illawarra Institute for Mental Health.
The Training Manual is supported by the Medication Alliance Resource Book for use as a reference tool by Medication Alliance trainees and for other professionals who wish to learn about the particular techniques used in Medication Alliance.

2. Trainee resource book
Byrne, M.K., Feros, D.L. (2004). *Medication alliance with people who have depression: Trainee Resource book*. Wollongong, NSW: University of Wollongong, Illawarra Institute for Mental Health.
The Medication Alliance Resource Book will be of particular value to the trainee while undergoing coaching in Medication Alliance techniques.

3. Trainee Resource Books, Medication Alliance Package: Engagement, Assessment, Therapy, Evaluation
Byrne, M.K., Feros, D.L. (2004). *Medication alliance with people who have depression: Trainee Resource book.* Wollongong, NSW: University of Wollongong, Illawarra Institute for Mental Health.

4. Medication Alliance Therapy: key concepts
Byrne, M.K., Feros, D.L. (2004). *Medication alliance with people who have depression: Trainee Resource book.* Wollongong, NSW: University of Wollongong, Illawarra Institute for Mental Health.

5. Train the Trainer Notes
The manual is designed to enable any appropriate health professional who has had Medication Alliance train-the-trainer instruction to teach Medication Alliance to other health workers.

Appendix 2: Flyer to Recruit Medication Alliance Therapy Therapists

Preventing Relapse in Depression: **Mi**ndfulness-Based Cognitive Therapy and **M**edication **A**lliance Therapy

MONASH University

Southern Health

University of Wollongong

iiMH
ILLAWARRA INSTITUTE FOR MENTAL HEALTH

Free training for Practice Nurses and other Clinicians in: Working with Clients using Medication Alliance Therapy (MAT)

Medication Alliance Therapy specifically targets health workers who are involved in assisting people to become well and to maintain mental health. This training program is for practice nurses and other clinicians of any professional discipline. Medication Alliance describes a process used to achieve health care goals relating to the use of medication and treatment strategies. It specifically targets the relationship between the consumer and the clinician. It aims to enhance medication adherence by utilising problem solving approaches borrowed from cognitive behaviour therapy (CBT) and motivational interviewing. Collaboration and establishing a therapeutic alliance between the consumer and clinician is the basis of Medication Alliance Therapy.

Medication Alliance Therapy Training involves a workshop conducted by the team who designed Medication Alliance Therapy. The workshop is delivered over three days and is divided into sections in order to better meet the training needs of Practice Nurses and other clinicians with different experience in working with people with depression and related disorders. Practice Nurse training will be delivered on days 1 and 2 and clinicians with Better Outcomes in Mental Health Care Initiative training will attend days 2 and 3. Staff from Primary Mental Health Teams interested in completing Train the Trainer will attend a fourth day specifically targeting training skills in Medication Alliance Therapy. Train the Trainer will equip them with the skills to teach Medication Alliance Therapy to other clinicians.

Details Overleaf

When: 14th - 16th Feb 2005 9 am – 4:30 pm

17th Feb 2005 (Train the Trainer) 9 am – 4:30pm

Where: Bayview Conference Centre
1-19 Bayview Avenue, Clayton

Bookings Ms Zoë Dam Zoe.Dam@med.monash.edu.au

Southern Health Adult Psychiatry Research, Training & Evaluation Centre

Dandenong Hospital
Phone: 613 9554 1585
Fax: 613 9554 1955

Monday 14 Feb 2005 Day 1	Tuesday 15 Feb 2005 Day 2	Wednesday 16 Feb 2005 Day 3	Thursday 17 Feb 2005 Day 4
Introduction to depression and related disorders • Attitudes and knowledge • core Medication Alliance Therapy skills • **Principles of MAT (1)** • Stages of change	**Principles of MAT (2)** • Agenda setting • Normalising techniques • Stress-vulnerability model • Resistance and Motivational Interviewing • Stages of change • Questioning strategies	**Principles of MAT (3)** • Motivational interviewing cont. • Functional analysis • Individualised assessment • Illness Timelines • Cognitive Behavioural Therapy	**Train the Trainer** • Teach backs • Mentored presentations • Learning outcomes of program • small group interactive • dynamic teaching
Practice Nurses	**Practice Nurses**		
	BOiMHC workers e.g. psychologists, allied health workers contracted to BOIMHC - General Practice Division-based projects.	**BOiMHC workers**	
Primary Mental Health Team staff	**Primary Mental Health Team staff**	**Primary Mental Health Team staff**	**Primary Mental Health Team staff**

Payment for working as a MAT therapist in the MiMA Project

If you would like to participate in the MiMA project as a Medication Alliance Therapy therapist, you would be allocated to 3-4 clients (with a past history of depression) and asked to implement these skills with them over the following 12 months. You would also be asked to complete questionnaires as part of the project. You will receive supervision for the first six months of the provision of Medication Alliance Therapy.

For further details please contact:

Dr Amanda Favilla | Research Fellow

Southern Health Adult Psychiatry Research, Training, and Evaluation Centre

(03) 9554 1847

Amanda.Favilla@med.monash.edu.au

Appendix 3: Promotional Material

New approach to preventing depression. Research participants sought.

Southern Health Adult Psychiatry Research, Training and Evaluation Centre

Have you had three or more periods of depression but are currently well? Would you like to learn new skills that might help you remain well?

Southern Synergy, The Southern Adult Psychiatry Research, Training and Evaluation Centre

Preventing relapse in depression: the Mindfulness-Based Cognitive Therapy and Medication Alliance Therapy Project.

The project aims to investigate two therapies to see if they reduce the relapse rate of depression. If you take part, you will be assessed and randomly placed (by chance, like tossing a coin) in one of the following four groups:

1. **Mindfulness-based cognitive therapy**
   This therapy aims to help people find new ways to deal with their moods and emotions. It includes meditation, and tuning into thoughts and feelings. It involves attending one group session per week for eight weeks.
2. **Medication alliance therapy**
   The treatment focuses on your views on medication and aims to help people to continue steps they can take to prevent a relapse of depression.
3. **Both therapies**
   You will undertake both of the above therapies.
4. **Treatment as usual**
   You will not receive either of the above treatments. You will continue your usual treatment. At the end of the project you will be offered one of the above therapies.

During the study, we would like to meet with you to see how you are getting on and if the therapy was helpful or not.

At all times you are free to visit any health professional as you see fit.

Participation in this project is entirely voluntary. There is no cost to you and all material is treated as private and confidential.

Please discuss this with your doctor who will be able to refer you to the research team.

For further information, please contact:
Dr Amanda Favilla
Telephone: 03 9554 1847 Fax: 03 9554 1955
Email: amanda.favilla@med.monash.edu.au

www.med.monash.edu.au/psychmed/units/southernsynergy/mima.html

This project is financially supported by beyondblue the national depression initiative and by Southern Health.

MONASH University Medicine, Nursing and Health Sciences

SOUTHERN SYNERGY

beyondblue

Southern Health

Have you had three or more periods of clinical depression in the past but are currently well?

Are you currently prescribed antidepressant medication but have difficulties taking antidepressant medication as prescribed?

Would you like to learn new skills that might help you remain well?

If yes, please ask your GP about our research program.

Southern Health Adult Psychiatry Research, Training and Evaluation Centre

MONASH University
Medicine, Nursing and Health Sciences

beyondblue

Southern Health

Appendix 4: CD Titles

CDs recorded by Bob Sharples for MBCT for Depression: Meadows adaptation.

CD 1

Body Scan Meditation (45 min)

Track 1: Introduction (5 min)

Track 2: Body Scan (45 min)

CD 2

Guided Sitting Meditation Practice (45 min)

CD 3

Three Guided Sitting Meditations

Track 1: Introduction

Track 2: 10 minutes

Track 3: 20 minutes

Track 4: 30 minutes

CD 4

Three Guided Lying Down Meditations

Track 1: Introduction

Track 2: 10 minutes

Track 3: 20 minutes

Track 4: 30 minutes

CD 5

Mountain Meditations and Lake Meditation

Track 1: Introduction

Track 2: Mountain Meditation

Track 3: Lake Meditation

(Both approximately 30 min in duration)

CD 6

Silence with Bells (to mark the passage of time)

Track 1: Introduction

Track 2: 5, 10, 15, 20 minute intervals

Track 3: Random sounds of bells

CD 7`

Mindful Yoga: CD 1: Lying Stretches.

Track 1: Introduction

Track 2: Yoga stretches

CD 8

Mindful Yoga: CD 2: Standing Stretches.

Appendix 5: Equipment for Mindfulness-Based Cognitive Therapy Sessions

Lesson 1 - Automatic Pilot

Name tags, whiteboard, whiteboard markers, Tibetan bells, Raisins, bowl and tongs, Blankets, Small pillows, yoga mats, Homework tape- CD1 (Body Scan), Handout 5 and 6 (pp121-125). Small table and flowers or candle, box of tissues- suggest tissues for every session!

Lesson 2 - Dealing with Barriers

Name tags, whiteboard, whiteboard markers, Tibetan bells, Blankets, yoga mats, handout 7 (pp148-156). Small table and flowers or candle, box of tissues.

Lesson 3 - Mindfulness of Breath

Name tags, whiteboard, whiteboard markers, Tibetan bells, CD 2 - Combined breath Focus & Sitting meditation, Yoga CD 1, Handout 8 + Mindful Stretching/Yoga Stretches handouts. Small table and flowers or candle, box of tissues *(NB this is a very full session and with a large group may need 2 ½ hours.*

Lesson 4 - Staying Present

Name tags, whiteboard, whiteboard markers, Tibetan bells, Automatic Thoughts Questionnaire (p204), Diagnostic Criteria (p206), "Wild Geese" poem, TV/Video, *Healing From Within* video (1st half), DVD/VCR; copies of *Full Catastrophe Living* copies, sheet to record who borrows it to facilitate return, Homework tapes- use CD 2, with Yoga CD1, Handout 9 (pp 214-217). Small table and flowers or candle, box of tissues.

Lesson 5 – Acceptance/Allowing/Letting Be

Name tags, whiteboard, whiteboard markers, Tibetan bells *Healing from Within* video (2nd half), handout 10 (pp 240- 243), "Guest House" poem. Small table and flowers or candle, box of tissues.

Lesson 6 - Thoughts Are Not Facts

Name tags, whiteboard, whiteboard markers, Tibetan bells, Alternative Viewpoints Exercise handout, pens; CD3, 4, 5, 6; Handout 11 (pp 262- 268). Small table and flowers or candle, box of tissues.

Lesson 7 – Taking Care of Myself

Name tags, whiteboard, whiteboard markers, Tibetan bells, Paper & Pens, "A Summer Day" Poem, handout 12 (pp 285- 290), Yoga CD2. Small table and flowers or candle, box of tissues.

Lesson 8 – Linking New Learning to the Future

Name tags, whiteboard, whiteboard markers, Tibetan bells, small rock for each participant for ending ritual, handout 13 (pp306-307), paper and pens for feedback of group/MBCT. Small table and flowers or candle, box of tissues.

Appendix 6: Mindfulness-Based Cognitive Therapy Manual Cover

MBCT-OZ

Lesson Plans for Australia

Additional notes and instruction for the Australian context

Based on the MBCT Manual

By Segal, Williams, and Teasdale, 2002

For use in conjunction with a purchased copy of

Mindfulness-Based Cognitive Therapy for Depression,

Segal, ZV, Williams, JMG and Teasdale, JD.

Authors: Ivan Milton & Bob Sharples

Editor: Graham Meadows

Melbourne, Australia

May 2005

93 David Street, Dandenong
Telephone: + 613 9554 1585
Fax: + 613 9554 1955

www.med.monash.edu.au/psychmed/units/southernsynergy

Table of Contents

Appendix 7: Booster Group Program (Saturday 7 May)

11am-11:30am	Introductions
11:30-12:15	Body scan – GM
12:15-12:30	Mindfulness of sound – GM Stafford poem – CM
12:30-1:15	Lunch in silence
1:15-1:30	Discussion of experience of silence and previous exercises
1:30-2:10	Mindfulness of breath, body, sound, thought - GM
2:10-2:25	Discussion of mindfulness of breath, body, sound, thought
2:25-2:30	Three minute breathing space – CM
2:30-2:45	Afternoon tea
2:45-3:00	Opening to the difficult meditation – CM
3:05-3:30	Mindful walking – CM, Whyte poem – GM
3:30-3:40	Discussion of mindful walking
3:40-4:00	Raisin exercise, close

David Whyte

Enough

Enough. These few words are enough.
If not these words, this breath.
If not this breath, this sitting here. This opening to the life
We have refused
Again and again
Until now.

Until now.

William Stafford

You Reading This, Be Ready

Starting here, what do you want to remember?
How sunlight creeps along a shining floor?
What scent of old wood hovers, what softened sound from outside fills the air?
Will you ever bring a better gift for the world
than the breathing respect that you carry
wherever you go right now? Are you waiting
for time to show you some better thoughts?
When you turn around, starting here, lift this
new glimpse that you found; carry into evening
all that you want from this day. This interval you spent
reading or hearing this, keep it for life--
What can anyone give you greater than now,
starting here, right in this room, when you turn around?

Appendix 8: Mindfulness-Based Cognitive Therapy Retreat Timetable

	Thursday	***Friday***	***Saturday***	***Sunday***
0600 – 0800		Mindfulness practice session Walking, stretching, sitting	Mindfulness practice session Walking, stretching, sitting	Mindfulness practice session Walking, stretching, sitting
0800 – 0900		Breakfast	Breakfast	Breakfast
0900 – 1030		Introduction to initial assessment	Session 3: Mindfulness of Breath *Silence*	Session 6: Thoughts are not Facts
1030 – 1100		Morning tea	Morning tea	Morning tea
1100 – 1230		Session 1: Automatic Pilot	Session 4: Staying Present	Session 7: Taking Care of Oneself Session 8: Using What's Been Learned
1230 – 1400		Lunch	Lunch	Lunch
1400 – 1600		Session 2: Dealing with Barriers	Session 5: Acceptance / Allowing / Letting Be	Wrap-up and ending
1600 – 1630		Afternoon tea	Afternoon tea	
1630 – 1800		Short mindfulness practice and review of day	Short mindfulness practice and review of day	
1800 – 2000	1800 – 1900 dinner?	Dinner	Dinner	
2000 - 2100	1900 – 2100 orientation and introductions	Mindfulness practice *Silence*	Mindfulness practice	

	Thursday	***Friday***	***Saturday***	***Sunday***
0600 – 0800		Mindfulness practice session Walking, stretching, sitting	Mindfulness practice session Walking, stretching, sitting	Mindfulness practice session Walking, stretching, sitting
0800 – 0900		Breakfast	Breakfast	Breakfast
0900 – 1030		Introduction to initial assessment	Session 3: Mindfulness of Breath Key themes: Modelling 'acceptance' and 'curiosity' in handling feedback about frustrations in doing mindfulness practice Highlighting the mindfulness approach is about a way of being with our own experience Learning to take awareness intentionally to the breath, to train in becoming more focused and gathered Practice: Sitting practice (pairs) Leading stretching practice (small groups each person leading a stretch) 3 minute breathing space Unpleasant events h/w	Session 6: Thoughts are not Facts Key themes: Exploring the difference b/w mindfulness and other ways of dealing with negative thought How negative mood and thought restrict our ability to relate differently to experience Working with the notion of reducing identification with thoughts – 'thoughts are just thoughts, even the ones that say they are not' Practice: Extended sitting practice – breath, body, sounds, thoughts, opening to difficult (pairs, diff partner) Alternative viewpoints exercise – moods and thoughts (small groups) 3 minute breathing space as 1st step to working with thoughts Facilitating discussion of ways to see thoughts differently
1030 – 1100		Morning tea	Morning tea	Morning tea

	Thursday	***Friday***	***Saturday***	***Sunday***
1100 – 1230		Session 1: Automatic Pilot Key themes: Creating mood/culture of curiosity / interest in people's experience (modelling acceptance) Establishing a 'not being the expert' stance from very beginning Creating 'safe' space to explore experience Practice: Automatic pilot and how it works in depression (small groups) Body scan (pairs) Sitting with the breath (pairs)	Session 4: Staying Present Key themes: Working with patterns of avoidance (to unpleasant experiences) and attachment (to pleasant experiences) Practising 'being with' pleasant, neutral and boring experiences using mindfulness Practice: Extended sitting – breath, body, sounds, and thoughts (pairs) Territory of depression Three-minute breathing space (poem) Facilitating video feedback (role play)Automatic pilot and how it works in depression (small groups)	Session 7: Taking Care of Oneself Key themes: Exploring the link between mood and activity – the specific things to do when depression threatens – i.e., breathing space then decide what action might be needed Knowing warning signs of relapse – relapse signature Important to be clear about how 'taking action' not the same as avoiding unpleasant experience (potential confusion here) Practice: Extended sitting practice – breath, body, sounds, thoughts, more emphasis on opening to difficult (pairs, diff partner) *Silence* Nourishing/depleting exercise – facilitating discussion of link b/w activity and mood Breathing space – action step (pairs) Discussing why this is not avoidance – i.e., how this fits into acceptance Session 8: Using What's Been Learned Key themes: 'when relapse-related automatic thoughts are triggered, there are skilful ways of responding to them' Exploring how to create a more balanced life Making a commitment to regular mindfulness practice

	Thursday	***Friday***	***Saturday***	***Sunday***
				Important to be clear about how 'taking action' not the same as avoiding unpleasant experience (potential confusion here) Practice: Facilitating discussion of developing a 'relapse action plan' Leading lake or mountain meditation Facilitating discussion on how to keep momentum and discipline in regular practice Ending rituals – other ways of finishing – design your own ritual
1230 – 1400		Lunch	Lunch	Lunch
1400 – 1600		Session 2: Dealing with Barriers Key themes: Willingness to have moment-to-moment experience What does this mean in practice? Practice: Seeing and hearing exercise (pairs) Facilitating feedback from h/w (small group) Thoughts and feeling exercise (small group) Pleasant events h/w – explanation	Session 5: Accepting/Allowing/Letting Be Key themes: 2nd half of MBCT: mindfulness skills to develop more accepting relationship with unpleasant experiences (thoughts, feelings, sensations) Questions explored: What is the flavour of acceptance? Why is it important in preventing relapse? How can acceptance best be developed? Practice: Extended sitting – breath, body, sounds, thoughts (pairs) and opening to difficult (pairs) Facilitating feedback h/w and sitting practice Breathing space – coping (pairs)	Wrap-up and ending

	Thursday	***Friday***	***Saturday***	***Sunday***
1600 – 1630		Afternoon tea	Afternoon tea	
1630 – 1800		Short mindfulness practice and review of day	Short mindfulness practice and review of day	
1800 – 2000	1800 – 1900 dinner? 1900 – 2100 orientation and introductions	Dinner	Dinner	
2000 - 2100		Mindfulness practice	Mindfulness practice *Silence*	

Appendix 9: Flyer to recruit Mindfulness-Based Cognitive Therapy therapists

Preventing Relapse in Depression: the **Mi**ndfulness-Based Cognitive Therapy and **M**edication **A**lliance Therapy Project (**MiMA**)

Seeking clinicians who are interested in participating in a Mindfulness-Based Cognitive Therapy research project

Training in MBCT is provided and preference will be give to those applicants with preparedness to make themselves available to participate in the project

This pilot study - the first of its kind in Australia- aims to compare MBCT and MAT in the prevention of depressive relapse in people with a history of depression.

Mindfulness-Based Cognitive Therapy is a manualised group skills-training program integrating aspects of cognitive therapy with components of a mindfulness-based stress reduction program. It is designed to teach people to become more aware of and to relate differently to their thoughts, feelings and bodily sensations, and to relate to these as passing events in the mind rather than identifying them as accurate reflections of reality.

What is involved in participating as a project therapist?

1. MBCT training

- An introductory group session
- An eight week group (2 hours per week)
- At-home practice involved in group participation (around 45 minutes daily).
- A four-day residential retreat style workshop (28th October to 1st November 2005)

2. Evaluation of Training

- Evaluation of training is part of the project, involving completion of pre and post training questionnaires
- Questionnaires immediately before and after training (takes between 5 and 15 minutes)
- And questionnaires three months after training (takes between 5 and 15 minutes)

You are eligible to participate as a MBCT therapist if you:

- Have experience with assessment and management of people with depressive disorders
- Have seen a range of psychopathology with responsibility for clinical decisions
- Have a well practiced acquaintance with CBT
- Already have a daily mindfulness practice or be committed to developing one
- Have some experience in group work

OR EQUIVALENT

Training is subsidized and you will be paid for your time as a therapist in the project

The first MBCT group for project therapists starts 30th May 2005

Please submit a 2 page CV detailing your professional experience and exposure to mindfulness practice to

Graham Meadows:

Professor of Adult Psychiatry, Monash University,

Director, Southern Health Adult Psychiatry Research, Training and Evaluation Centre.

PO Box 956, Dandenong 3175

Further information Dr Amanda Favilla, Clinical Intervention Coordinator Amanda.favilla@med.monash.edu.au

Appendix 10: The Intake Assessment Interview

See separate booklet.

Appendix 11: Recruiting Newspaper Advertisement

Appendix 12: Flyer to Recruit Research Assessors

MONASH University

EXPRESSION OF INTEREST

RESEARCH ASSISTANTS

Southern Health

Southern Mental Health Adult Research, Training and Evaluation Centre

A randomised controlled pilot of mindfulness-based cognitive therapy and medication alliance therapy for the prevention of relapse and recurrence in depression in primary care

Chief Investigator: Professor Graham Meadows

We are looking for people who would be interested in administering psychopathology measures (eg the CIDI, Hamilton Rating Scale for Depression, Beck Depression Inventory, and the International Personality Disorders Examination ICD-10 screen), and be involved in consenting clients and administration of other questionnaires (eg demographics, medication).

We will train you in the administration of these instruments.

Training is free and you will be paid for your time in the research project.

This training will equip you to participate in this research project and enhance your professional skills and training. For further information, contact

Dr Mandy Favilla 9554 1847 Amanda.Favilla@med.monash.edu.au

✂----------

Please contact me about the administration of research questionnaires.

Name_____

Phone_____

Email_____

Best time to call_____

Appendix 13: Training Agenda for Research Assessors

Day 1: 21 April 2005 Day 2: 22 April 2005

Session	Ref.	Content	Presenter
9.00-9.30	G1	Introductions	
9.30-10.00	G2	Clinical depression: its nature and significance for individuals and the community	Graham Meadows
10.00-11.45	C1	The CIDI-Lifetime. Instructions Session 1. Introducing a structured approach to detection of lifetime histories of psychiatric disorder.	Graham Meadows.
10.45-11.05		Morning tea	
1105-12.00	C2	The CIDI-Lifetime. Instructions Session 2. Role Play	Graham Meadows and John Julian
11.05-1300	H1	Assessment of Depression:– the Hamilton Depression inventory introduced and role play	Graham Meadows and John Julian
1300-1345		Lunch	
13.45-14.15	G3	Relapse prevention in depression – the MiMA Study	Catharine McNab
14.15-15.15	P1	Pencil and paper measures introduced	Catharine McNab
1515-1535		Afternoon tea	
1535-1700	C3	Instructions for the CIDI-Lifetime. Session 2	Graham Meadows

Session **Day 2**	Ref	Content	Presenter
9.00-10.00	G4	Research Data collection and consent procedures	Mandy Favilla and Wendy Cross
9.30-10.00	G5	Interview sequence and time management	Graham Meadows and Mandy Favilla
10.00-11.45	P2	Service Utilisation Measure Instructions	Graham Meadows
10.45-11.05		Morning tea	
11.05-1300	H2	Assessment of Depression:– the Hamilton Depression inventory further exploration and discussion	Graham Meadows
1300-1345		Lunch	
13.45-15.15	G6	Role plays of interviewer administered measures	Graham Meadows
1515-1535		Afternoon tea	
1535-1700	G7	Review Overall discussion, sequencing and time management	Graham Meadows

Appendix 14: Flyer to recruit Mindfulness-Based Cognitive Therapy Therapists

MONASH University Southern Health

Southern Mental Health Adult Research, Training and Evaluation Centre

MiMA PROJECT

Randomised controlled pilot of mindfulness-based cognitive therapy (MBCT) and medication alliance therapy (MAT) for the prevention of relapse and recurrence in depression in primary care.

Chief Investigator: Professor Graham Meadows

CALL FOR APPLICATIONS TO APPLY FOR MBCT TRAINING AND TO PARTICIPATE AS TRAINEE MBCT THERAPISTS.

This pilot study is the first of its kind in Australia and aims to compare **MBCT** and **MAT**, singly and in combination, in the prevention of depressive relapse in people with a history of depression.

Mindfulness-based cognitive therapy

MBCT is a manualised group skills-training program that integrates aspects of cognitive therapy with components of a mindfulness-based stress reduction program. This intervention has been found, in randomised controlled trials, to be effective in reducing relapse among clients recruited from primary care settings. It is designed to teach people to become more aware of and to relate differently to their thoughts, feelings and bodily sensations, in particular, to relate to these thoughts and feelings as passing events in the mind rather than identifying them as necessarily accurate reflections of reality.

You are eligible to participate as a MBCT therapist if you

- have a working familiarity with assessment and management of people with depressive disorders
- have seen a range of psychopathology with responsibility for decision making around the cases,
- Have a well practiced acquaintance with CBT.
- either already have a daily mindfulness practice or to be committed to developing one,
- Have some experience in group work.

OR EQUIVALENT

MBCT Training

The MBCT training involves a three-day workshop and participation in the initial MBCT group along with client-participants (weekly for eight weeks, two hours per session, and then monthly booster sessions for the following four months) that will be run by an experienced mindfulness teacher.

MBCT Trainee involvement in the 'therapist-participant' arm of the study.

As training impact is also of interest in the project, therapists will also be administered a range of measures, and so also come under the rubric of 'therapist-participants'.

- These measures include: Clinician Demographics Questionnaire (5 minutes to complete) and the MAAS A (5 minutes to complete).
- Measures will be administered immediately prior to commencement of the therapist workshop, immediately following the workshop, and three-months after the workshop.
- They will also be administered on two occasions after the completion of the MBCT-Oz group.
- That is, two brief measures on five separate occasions over a period of six months.

Training is free and you will be paid for your time as a therapist in the research project

Submit applications as a two page CV to:

Professor G Meadows, (MBCT Therapist Applications) Southern Mental Health Adult Research, Training & Evaluation Centre, Adult Mental Health Dandenong Hospital, PO Box 956, Dandenong, VIC, 3175.

Appendix 15: Randomisation Procedures

This documents the methods used to generate randomization codes for patients enrolled in MiMA Trials 1 (4-arm trial) and 2 (2-arm trial). Assignment of individual participants to treatment group was undertaken by the study statistician who worked independently of staff involved in the recruitment, assessment and management of participants in the study

Treatment Groups:

MiMA 4-arm Trial: This is a factorial 2x2 trial, with two factors: MBCT (yes/no) and MAT (yes/no). Thus there are to be four groups, with approximately equal numbers in each group. Numeric codes were assigned to the four groups as follows:

0: usual management (neither MBCT Nor MAT);
1: Medication Alliance Therapy (MAT) alone;
2: Mindfulness-based cognitive therapy (MBCT) alone;
3: MAT and MBCT in combination.

MiMA 2-arm trial: For patients ineligible for MiMA4, some may be eligible for MiMA2, which has two arms, testing MBCT against Usual Management alone. Codes as above (0 and 2 only).

Stratification: There is one stratification variable required for MiMA4: source of referral, which is binary – either GP or specialist.

For MiMA2, there are two unequally weighted stratifying factors:

1. Current medication (yes/no), and
2. Source of referral (GP/specialist).

Algorithm: Using the method of minimization to allocate patients to treatment group within stratum, using "MINIM: Minimisation program for allocating patients to treatments in clinical trials", written by Stephen Evans, Simon Day and Patrick Royston, from the Department of Clinical Epidemiology at London Hospital Medical School. The version used on 10 October 2005 was Version 1.5/28-3-90.

Allocation: The program MINIM was used interactively to assign patients to treatment groups.