

DARE Progress Report Year 1

Project Title Effectiveness of Mindfulness Based Cognitive Therapy for Preventing Depressive Relapse in Subjects at Very High Risk

Grant Type : Project Grant

NHMRC Application ID: 436897

Administering Institution: Monash University

Chief Investigator A: Prof. Graham Meadows

Year Funding Commenced: 2007

Date of report: 1 February 2008

Overview: This is primarily a multisite pragmatic RCT while secondarily the project will examine therapeutic mechanisms for how a mindfulness based therapy may prevent relapse of Major Depressive Disorder (MDD). Patients are people who have had at least three prior episodes of MDD and who are currently in remission. The intervention is the 8-week group treatment course of Mindfulness Based Cognitive Therapy (MBCT) as practiced by locally recruited and trained clinicians within Australian settings. Control condition is treatment as usual (TAU) with the addition of regular self monitoring for depressive symptoms. Outcomes include time to MDD relapse, time in depressive episodes, and healthcare costs. Candidate intermediary variables monitored include medication compliance and time spent in meditation.

Progress: The project is running on time to the project plan. In the first year we have established a project identity, prepared necessary materials, trained the project workforce, refined design based on NHMRC feedback and further outcomes from pilot work, enrolled a first randomised study group and completed treatment for a first MBCT group. Specific aspects of progress as follows:

- A clear project identity is important for recruitment and retention: The project name is now 'DARE' –for 'Depression Awareness Recovery Effectiveness' with a recognisable project logo.
- Three-year approval to conduct the trial was received from the Standing Committee on Ethics in Research involving Humans at Monash University, from the Human Research Ethics Committee (HREC) B at Southern Health, and subsequently from Peninsula Health HREC. Approval processes are well advanced with Barwon Health HREC and The Alfred HREC
- With consideration of comments from NHMRC reviewers and findings from pilot work that progressed following the submission, we have refined the design better to deal with threats to validity such as selection bias and resentful demoralisation in TAU groups, and to ethically optimise the design. The TAU group is now described as a "Depressive Relapse – Active Monitoring" (DRAM) group. The design specified regular collection of self report of depressive symptoms from all participants, which represents an augmentation over TAU. We have made no change in randomisation protocols or data collected, but simply have placed emphasis on early monitoring as a self management strategy, something that has an associated evidence base. This change has brought the following benefits for the project: We can now fairly present the project as having a discernible 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 TAU/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
- We have set up a website (www.dare.org.au) and developed necessary on-line questionnaires.
- We recruited and trained 8 casual research interviewers, all attending a two day training course during September. In November we completed a practitioner training cycle for 10 new MBCT therapists and a refresher MBCT course for 6 established MBCT practitioners
- Broad and active recruitment commenced in July 2007. 51 inquires have led to 40 phone screenings with 24 candidates proceeding to a face-to-face intake assessment interview.
- Eighteen participants are currently enrolled in the trial with 13 randomised, 5 awaiting randomisation and no withdrawals. Our first MBCT research group concluded on December 18

We are continuing local recruitment efforts and expanding recruitment to our other health care sites

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