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**TITLE:** Efficacy and feasibility of a tele-health intervention for acute coronary syndrome patients with depression: Results of the 'MoodCare' randomized controlled trial

**AUTHOR LIST:** Dr Adrienne O'Neil BA(Hons) PhD[1,2], Professor Barr Taylor MD[3], Dr Kristy Sanderson BSc(Hons) PhD[4], Dr Sheila Cyril MBBS MPH[2], Ms Bianca Chan BSc/BA MPH[5], Associate Professor Anna L Hawkes BSc(Hons) MPH PhD[6], Professor David L Hare MBBS DPM, FRACP FCSANZ[7,8], Professor Michael Jelinek MBBS MD FRACP FACC FCSANZ[9,10], Dr Kamalesh Venugopal PhD[1], Associate Professor John J Atherton PhD, FRACP, FCSANZ[11,12], Associate Professor John Amerena MBBS, FRACP, FCSANZ[13], Associate Professor Leeanne Grigg MBBS(Hons) FRACP FCSANZ[14], Associate Professor Darren L. Walters MBBS MPhil FRACP FCSANZ[15], Professor Brian Oldenburg BSc MPsych PhD[2], on behalf of the MoodCare Investigator Team

1. School of Medicine, Deakin University, Victoria Australia

2. School of Public Health and Preventive Medicine, Monash University, Victoria Australia

3. Department of Psychiatry, Stanford University, California USA

4. Menzies Research Institute Tasmania, University of Tasmania, Australia

5. Institute for Safety, Compensation and Recovery Research, Monash University, Victoria Australia

6. School of Public Health and Social Work, Queensland University of Technology, Queensland Australia

7. Department of Cardiology, Austin Hospital, Victoria Australia

8. Department of Cardiology, University of Melbourne, Victoria Australia

9. Department of Cardiology, St Vincent's Hospital, Victoria Australia

10. Nursing and Midwifery, Australian Catholic University, Victoria Australia

11. Department of Cardiology, The Royal Brisbane and Women's Hospital, Queensland Australia

12. Department of Medicine, University of Queensland, Queensland Australia

13. Department of Cardiology, Barwon Health Victoria Australia

14. Department of Cardiology, Melbourne Health Victoria Australia

15. Department of Cardiology, The Price Charles Hospital, Queensland Australia

**CORRESPONDING AUTHOR:** Dr Adrienne O'Neil, School of Medicine, Deakin University, Po Box 281, Geelong, VIC Australia 3220, AONEIL@barwonhealth.org.au

Phone: +61412927921

***Abstract***

**Background:** Depression is common after a cardiac event, yet there remain few approaches to management that are both effective and scalable.

**Purpose:** To evaluate the 6-months efficacy and feasibility of a tele-health program (MoodCare) that integrates depression management into a cardiovascular disease risk reduction program for Acute Coronary Syndrome patients with low mood.

**Methods:** A two-arm, parallel, randomized design comprising 121 patients admitted to one of six hospitals for Acute Coronary Syndrome.

**Results:** Significant treatment effects were observed for Patient Health Questionnaire 9 (PHQ9) depression (mean difference; change)(-1.8; *p=0.025*; Effect Size: *d*= 0.36) for the overall sample, when compared with usual medical care. Results were more pronounced effects for those with a history of depression (mean difference; change)(-2.7; *p=0.043*; Effect Size: *d*=0.65).

**Conclusions:** MoodCare was effective for improving depression in Acute Coronary Syndrome patients, producing effects sizes exceeding those of some face-to-face psychotherapeutic interventions and pharmacotherapy.

**Keywords:** depression, acute coronary syndrome, tele-health, cognitive behavior therapy, cardiac

**Trial Registration Number**: ACTRN1260900038623

***Introduction***

Depression after a coronary event is associated with impaired health related quality of life (HRQOL) and detrimental clinical and psychological outcomes [1]. However, despite its high prevalence and associated poor outcomes, depression continues to remain under-recognized and poorly treated in cardiac populations. Recent data suggest that all-cause mortality is greatest in acute coronary syndrome patients with depression, specifically those for whom depression is inadequately treated [2]. To date, however, there remains a lack of consensus about scalable, effective approaches to treatment that are realistic to integrate into existing health care delivery.

Randomized controlled trials evaluating the efficacy of anti-depressants have produced only modest effects on depressive symptoms [3]. Psychotherapeutic approaches have yielded some success; problem-solving therapy has been shown to produce reductions in depressive symptoms of a medium effect [4], while cognitive behavior therapy has produced even larger effects in Coronary Artery Bypass Surgery patients [5]. The authors of the latter study concluded that Cognitive Behavior Therapy has "greater and more durable effects" than other approaches. Based on this and other evidence of its benefits in group settings [6], the American Heart Association has endorsed the use of Cognitive Behavior Therapy for cardiac patients [7]. However, there are several key challenges in delivering such intensive, face-to-face counseling programs in this population including limited program reach, uptake and poor adherence. An approach that can overcome these barriers - while still achieving equivalent efficacy- has great potential to improve the way in which depression is currently being managed in cardiac patients.

Tele-health delivery has been shown to be feasible and effective for achieving improvements in cardiovascular disease -related outcomes in coronary disease patients [8, 9]. For example,

this mode of delivery has been employed to administer depression treatment to cardiac patients. Rollman et al delivered an 8-month, collaborative care intervention over the telephone to Coronary Artery Bypass Grafting patients experiencing depression [10]. The program was effective in improving depression, mental health and other health outcomes. However, the generalizability of such an approach has been subject to criticism; it has been argued that this is a resource intensive model to implement, likely to unnecessarily overlap with the delivery of cardiac rehabilitation and other related programs [11]. Moreover, the effect sizes are almost half of that produced by Cognitive Behavior Therapy approaches [2]. The authors subsequently concluded that while a telephone-delivered model of care is both scalable and widely accepted, an approach that can match the efficacy of "more intensive face-to-face counseling strategies"[12], is warranted.

'MoodCare' is a telehealth program which aims to address low mood by integrating a Cognitive Behavior Therapy approach into a broader cardiovascular risk reduction program [13]. The MoodCare program is based on a telehealth program (Proactive Heart) (7) that we have previously developed and trialled for myocardial infarction patients, but which did not have a significant focus on mood management. Indeed, a randomized trial of Proactive Heart demonstrated that it improved HRQOL, physical activity, smoking and alcohol intake of myocardial infarction patients when compared with usual medical care, however, the program was only modestly successful in improving mood [14]. We therefore concluded that the Proactive Heart program had the potential to impact on cardiac depression [and anxiety] of a greater intensity in a clinically meaningful way, should it incorporate a more psychological-specific treatment [14].

Using a two-arm, parallel, randomized design, we aimed to determine the efficacy and feasibility of a telehealth intervention (MoodCare) for ACS patients using primary outcomes (depression and HRQOL) at 6-months, compared with usual care.

***Methods***

The study methods have been described previously [13]. Briefly, 3071 patients admitted after index admission for ACS were screened for depression at six metropolitan hospitals in the states of Victoria (The Austin, St Vincent's, Geelong and Royal Melbourne Hospitals) and Queensland (Royal Brisbane and Women's and The Prince Charles Hospitals), Australia**.** Eligibility criteria included: a clinical diagnosis of ACS (myocardial infarction [ST segment elevation myocardial infarction; STEMI or non-STEMI] or unstable angina confirmed by angiogram), aged between 21-85 years, fluency in English, availability via the telephone for the duration of the study, and a Patient Health Questionnaire (PHQ9) score of 5-19. Patients were excluded if they: were participating in regular psychological therapy with a mental health professional at the time of admission for ACS, had a diagnosed psychiatric condition impacting upon involvement (including bipolar illness, psychotic illness of any type, dementia, acute suicidality, severe personality disorder), cognitive impairment impacting on their ability to participate in the study, diagnosis with a terminal illness, or an inability to participate in a tele-based unsupervised mood and lifestyle intervention as confirmed by the treating clinician. After participants were provided a comprehensive description of the study, written informed consent was obtained. All consenting patients were assessed for depression prior to hospital discharge using a psychometrically robust and valid instrument (PHQ9) [15]. Patients with a PHQ9 score of 5-19 (indicating mild to moderately severe depression) during hospitalization were eligible to participate. This scoring range was selected due to its high sensitivity and specificity, as opposed to the commonly used cut off (≥ 10), which has comparable specificity (92% and 90%, respectively), but poorer sensitivity (39% and 54%, respectively) [16]. Patients with a PHQ9 score <5 were provided with relevant feedback, reassurance and advice. Any persons indicating suicidal thoughts on PHQ9 and/or those with severe depression, as indicated by PHQ9 scores of 20-27, were excluded and referred for assessment by a mental health professional.

Eligible participants were contacted by the research team via telephone within 1-2 weeks of discharge to complete Time 1 data collection. This included secondary assessment of depression to screen for remission since in-hospital screen using the first two PHQ items [16], followed by the lifetime version of the full Composite International Diagnostic Interview assessment (CIDI_Auto 2.1).

Ethics approval was received from Human Research Ethics Committees at Monash University and all participating hospitals.

**Study conditions**

Both Usual Care and intervention participants received a brief National Heart Foundation of Australia education pamphlet on myocardial infarction recovery. Upon enrollment, a letter was sent to all participants' primary care provider/s informing them of the study, the group to which the participant was randomized and other relevant information. A study newsletter based on existing educational materials was sent to participants to enhance study retention.

*Control:* Usual Care participants continued to receive medical care through their health care providers.

*Intervention*: Commencing within 2-weeks of screening, the intervention was delivered by Master's level qualified psychologists (required for specialist registration to practise as a Clinical Psychologist in Australia) with at least 2-years of clinical Cognitive Behavior Therapy experience. The interventionists provided information to participants via the telephone during structured intervention sessions, consisting of short- and long-term goal setting with the view to improve their mental health and cardiovascular risk factor profiles. Techniques included motivational interviewing, goal setting, behavioral activation and

cognitive restructuring. The intervention comprised 10 sessions over a 6-month period, unless target recovery was achieved prior to program completion (in this event, the interventionists reviewed the individual case with the senior clinical consultant, and if the participant produced a PHQ score in the normal range for three consecutive counselling sessions, after completing at least four sessions, the participant was considered to have met target recovery). Cognitive Behavior Therapy has been shown to effectively reduce depressive symptoms when delivered over 10-11 sessions [17].

The sessions were most intensive over the first 3-months when depressive symptoms are most likely to affect Acute Coronary Syndrome patients [18]. Participants received a supplementary handbook containing project specific and general health resources, monitoring forms and recording sheets to be used for tracking mood and thoughts, session activities, cardiovascular risk factor goals and changes (specifically, increasing physical activity, medication adherence, healthy eating, reducing alcohol and tobacco consumption and improving self-management of medical co-morbidities and weight). Sleep hygiene was also promoted and relaxation techniques were provided. Algorithms were in place for those whose condition deteriorated throughout the program: In each session, the interventionists asked the participants to rate their best, worst and average mood since the previous session as well as their highest, lowest and average level of anxiety. Clinical deterioration was thus determined by an increase in reported depression on this measure, an increase in depressive symptoms, particularly suicidality and failure to improve by 50%. If a participant was distressed, interventionists followed the following algorithms: (1) Acknowledge distress, 'How are you feeling since your acute heart event?' (2) Normalize feelings (3) Check mood level, (4) Ask about support - partner, family, friends (5) Ask about current concerns using reflective listening. If suicidality was detected or there was a marked deterioration in mood, interventionists invoked a risk management protocol - i.e. developing a safety plan and

possible referral to other services. Figure 1 displays the web-based, intervention platform containing the various cues and scripts used by the interventionists throughout the course of the program to determine the focus of the program for each individual.

**Study Integrity**

Stratified randomization occurred using a separate block randomization list that was generated for each study group or strata. Randomization was integrated into the web-based database and occurred following the completion of Time 1 data collection. The randomization schedule was stratified by Composite International Diagnostic Interview assessment (current Major Depressive Disorder versus No) to ensure that the distribution of major depression cases between groups was even. The randomization schedule was concealed from investigators. Project staff who administered telephone questionnaires were blinded to participants' study group. Participants were asked not to reveal the group to which they were randomized. Intervention sessions were audio-taped. A standardized inventory was employed for quality assurance and to ensure intervention fidelity and treatment integrity. The overall study conduct was guided by the CONSORT statement [19].

**Data collection and outcome measures**

Primary outcomes were depression (measured by the CDS [20] and PHQ9 [15]) and HRQOL measured by the SF-12 Version 1 [21]. The CDS has demonstrated excellent test-retest reproducibility with responsiveness to change over time [22] and moreover, has excellent sensitivity (97%) at appropriate specificity (85%) for the categorical diagnosis of major depression [23]. The CDS is a 26-item questionnaire which was designed to measure depressed mood in cardiac patients. Participants respond to each item using a scale of 1–7, where 1=disagree strongly and 7=agree strongly. The seven positively-worded items are

reverse scored, where a higher overall score reflects worse symptoms (scores range between is 26–182). The PHQ-9 is a nine-item diagnostic instrument for depressive disorders. It scores each of the nine Diagnostic & Statistics Manual-IV criteria as "0" (not at all) to "3" (nearly every day) and provides indication of symptom related difficulty [15]. The PHQ9 has been recommended as the screening instrument to use to detect depression in cardiac patients [7]. Lifetime history of diagnosed Diagnostic & Statistics Manual-IV depression was confirmed through administration of the diagnostic psychiatric interview performed by our study team, considered the "gold standard" measure of assessment. The SF-12 is a 12-item multipurpose short form survey (derived from the SF-36), the results of which are weighted and summed to provide easily interpretable scales for a participant's physical and mental health. Scores are generated for Physical and Mental HRQOL which are calculated using the scores of the 12-items (range= 0 to 100, where a zero reflects the lowest level of health) [21]. Data were collected at baseline and 6- months. Medication use was collected via self-report (specifically, medications for depression and cardiovascular disease) and cross-referenced with data extracted from medical records at discharge. Measures of feasibility included participant retention and compliance with the intervention.

*Sample Size*

Sample size analysis indicated that 50 subjects per group (intervention and control) or a total of 100 were required to complete the study in order to detect an absolute intervention effect with 80% power and type I error of 5% (two-tailed). Sample size was calculated based on an overall difference between participants in the intervention and control groups in the primary outcome measure of depression scores at 6-months. For example, a sample size of n=100 was sufficient to detect a between-group difference in mean CDS score change of 6.8, assuming a paired score SD of 12 [22]; equating to an ES of d=0.56.

*Statistical analysis*

Differences in the baseline characteristics of intervention and UC participants were identified using independent sample t-tests for continuous variables and Fisher's exact tests for categorical variables. The t-test for matched paired samples was undertaken to test significant within-group mean differences between baseline and 6-months. An Analysis of Covariance was conducted to assess differences in outcome measures between timepoints, across intervention and UC groups. Results were expressed using estimated marginal mean changes in outcomes by group, all with corresponding 95% confidence intervals (CIs). All Effect Sizes were presented as Cohen's *d*,(positive values where the mean difference was in the predicted direction [24]). Interaction terms were included in a separate analysis to explore potential effect modification between treatment group and relevant variables. As a history of clinical depression has been shown to be predictive of both poorer outcomes [25] and differential responsiveness to treatment in this population [26], a subgroup analysis comprising participants with clinical interveiw-assessed depression (major, minor, dysthymia) versus no depression over the lifetime (as measured at baseline) was conducted. As depression is severely under-diagnosed in this population, this independent measure of clinical diagnosis was considered to yield greatest accuracy over other techniques (e.g. chart review). Analyses were based on intention to treat. A variety of imputation methods were used in sensitivity analyses, all of which gave a similar result; the Last Observation Carried Forward approach is reported here for simplicity. All statistical analyses were conducted using SPSS Version 21.

## *Results*

*Recruitment and baseline characteristics*

Figure 2 displays the study recruitment numbers. Initially, 3071 hospitalized Acute Coronary Syndrome patients were identified as potentially eligible by recruitment staff. Three hundred and eighty seven patients completed informed consent and were administered the PHQ9; 177 of these recorded PHQ9 scores between 5 and 19. Of these, 121 participants were enrolled and randomized (n=60 Usual Care; n=61 intervention). The most common reasons for exclusion were as follows: a diagnosis of ACS that could not be confirmed, the patient was not proficient in English or the patient was "missed" (initially identified from chart review but discharged prior to being approached). The rate of acceptance was high (121/177=68%). Fifteen participants (n=7 Usual Care; n=8 intervention) did not complete assessment (lost to follow up/withdrew from the study). The study attrition rate was 12%.

In-hospital PHQ9 depression scores were comparable between groups (Usual Care participants = mean 9.4 95% CI: 8.0 to 10.7; Intervention participants = mean 9.1, 95% CI: 7.8 to 10.4), indicating mild depression.

Table 1 displays the key baseline characteristics of the sample. The mean age of participants was 60 years. The sample comprised majority males (75.2%), who had completed high school education (55.4%) and were without private health cover (69.4%). One third (34.7%) were in full time employment.

According to the CDS, almost half of participants (46.3%) had major depressive disorder (MDD) (mean ± SD 91.2 ± 25.7) (Table 2). According to the PHQ9, 78.5% of participants had depressive symptoms at baseline, with the remaining reporting minimal symptoms (eligibility was based on in hospital PHQ9 score, not baseline assessment). SF12 scores revealed poor baseline physical (33.7 ± 9.6) and mental health (38.9 ± 9.9) functioning.

The majority of participants were self-reported former smokers (58.3%), current drinkers (54.2%) and had doctor-diagnosed hypercholesterolemia (72.7%) or hypertension (66.1%).

One quarter had diabetes. At six months, two thirds (n=71) of the 106 participants for whom follow up data were available at follow up indicated that they had attended a cardiac rehabilitation; of which 39 (55%) were in the intervention group and 32 (45%) were in the control group.

The characteristics of the groups did not differ significantly with two exceptions; a significantly higher proportion of intervention participants was born in Australia (Table 1) and had visited a general practitioner in the past 6-months. The number of participants with clinical interview-diagnosed major depression was comparable across groups. For those indicating prior depressive episodes, average age of onset across the lifetime was also comparable. All participants for whom pharmacological data were available (95%) had been prescribed medication upon hospital discharge. Sixteen percent of the sample (20/121) was taking anti-depressant/anxiety agents upon study enrollment. No between group imbalances were observed (n=10 MoodCare; n=10 Usual Care). The most common agents were: serotonin–norepinephrine reuptake inhibitors (n=4), selective serotonin reuptake inhibitor (n=4), tricyclics (n=3), benzodiazepines (n=2), Monoamine Oxidase Inhibitors (n=1), herbal agents (n=1), unknown (n=5). Because no imbalances were observed in anti-depressant medication usage at baseline, we did not control for this variable in our analyses.

*Intervention exposure and outcome*

More than half (61%) of intervention participants completed 5 or more sessions. The median number of sessions was 8 and average length of the sessions was 48.4 minutes. The mean total length of intervention exposure during the 6-month period was 384 minutes for each participant. Fidelity of the intervention was assessed via independent review of the counselling sessions. A minimum of two sessions were randomly selected by a reviewer, from intervention sessions 2-9. Out of a total of 378 intervention sessions delivered, 327

sessions (86.5%) were reviewed, 17% of sessions were reviewed by an expert (psychiatrist) and 70% by an independent peer reviewer; 13.5% of sessions (51 sessions) were unable to be reviewed (non-completion of intervention sessions, technical difficulties in recording sessions and electronic file transfer). Of those reviewed, results indicated sound fidelity between interventionists; 87**%** of relevant items (mood, lifestyle factors and useful skills comprising of sleep, communication, relaxation and goal setting) were completed in all delivered sessions.

Results for treatment effects (overall sample)

Table 3 shows the comparative changes in CDS, PHQ9 and SF-12 scores (analyzed by paired t-tests) of changes over 6 months, by group. The mean difference in CDS and PHQ9 change scores over time between intervention and Usual Care groups was -2.8 (Standard Error: 3.1) and -1.8 (Standard Error: 0.9), respectively (data not shown). After adjustment for baseline depression, the intervention group demonstrated statistically significant reductions in PHQ9 depression compared with Usual Care at 6-months (mean difference [change] -1.8; *p= 0.025*; ES: *d*=0.36) (Table 4). Similar trends were also observed for mental SF-12 scores after adjustment for baseline mental SF-12 scores; however these did not reach statistical significance (mean difference [change] 3.2; *p= 0.070*; ES: *d*=0.31). No other statistically significant differences were observed. When interaction terms were included in the main effects model (e.g. GP visits and cardiac rehabilitation attendance) none were significant (data not shown).

Results for treatment effects (sub-sample with lifetime history of diagnosed depression)

Sub-group analyses comprising those with depression positively identified by diagnostic interview, the intervention was shown to produce significant improvements in PHQ9 depression (mean difference [change] = -2.7; *p=0.043*; ES: *d*=0.65) and mental SF-12 scores

(mean difference [change] = 5.7; *p=0.041*; (ES: *d*=0.63) for those with depression history, when compared with Usual Care at 6-months (Table 4).

***Discussion***

When compared with usual medical care, a telehealth, depression management and cardiovascular risk reduction program ('MoodCare') produced improvements in PHQ9 depression of a medium to large magnitude for those with a history of depression (ES: *d*=0.65), and more moderate effects (ES: *d*=0.36) for the overall sample [24]. The program was shown to produce medium to large improvements in mental HRQOL for those with a depression history (ES: *d*=0.63). Furthermore, the intervention was shown to be feasible as demonstrated by high retention and sound program compliance.

This study goes some way to addressing previous recommendations for the development and evaluation of new and scalable intervention approaches that address depression in coronary patients, without compromising efficacy and acceptability [12]. The MoodCare program produced effect sizes exceeding a number of the previously published trials in this field. Specifically, MoodCare produced effect sizes exceeding that of pharmacological trials (e.g. SADHART; *d*= 0.15; 95% CIs: -0.05, 0.35) [27], and face-to-face psychotherapeutic interventions that generally have poor adherence (e.g. ENRICHD; *d*: 0.33; 95% CIs 0.24, 0.42) [27]. A recent meta-analysis that pooled and calculated the Cohen's d effect sizes of depression interventions in cardiac populations between 1996 and 2011 concluded an overall medium effect exists for improving depression (*d*=0.29)[27]. When we compared our effect sizes to the magnitude of cognitive behavior-specific therapies observed in this analysis (*d*: 0.44 95% CIs: 0.13, 0.75) [27], the effects from our trial were more modest but still comparable, suggesting only slight degradation in outcome using a telephone-delivered platform. The more pronounced effects observed in those with a depression history also

exceeded the Cohen's d effect sizes for psychotherapeutic programs conducted in both ACS populations (e.g. COPES (*d*: 0.45; 95% CIs: 0.13, 0.77) and Coronary Artery Bypass Grafting populations (e.g. Freedland et al; *d*: 0.53; 95% CIs: 0.17,0.89) presented in this meta-analysis [27].

Our findings provide further support for the feasibility of tele-health delivery in this population, with attrition rates comparable to other studies (16.5%) [10]. The technology platform that was developed as part of this study for intervention delivery likely minimized some of the most important barriers to participation associated with center-based, cardiac rehabilitation and secondary prevention programs.

While the intervention produced significant effects for PHQ9-measured depression, we acknowledge that no significant effects were observed for CDS depression or either domain of the SF-12 (with the exception of the mental health domain in sub group analyses). This finding is consistent with other small-scale, randomized trials of cardiac rehabilitation programs that have used the CDS; for example, Redfern et al (2009) found that, compared with a control group, an individualized, rehabilitation program (CHOICE) delivered post-ACS produced some mental health benefits after 12-months but not CDS-assessed depression [28]. This issue notwithstanding, the average improvements observed in participants who received the intervention (CDS change score, -5.13) are considered to be clinically meaningful [22].

We note some distinction in study samples between the present and other studies; for example, SADHART [29] and ENRICHD [17] included patients with major or minor depression, whereas MoodCare primarily recruited those with depressed mood. As a result, this study comprised a selective sample of Acute Coronary Syndrome patients with predominantly mild to moderate depression. Recent evidence suggests that intervention in

this sub-population is important because mild depression has been shown to predict earlier death in MI patients followed over a 12 year period [30]. Additionally, when trajectories of depressive symptomatology have been studied in patients undergoing surgical intervention, those with initial mild depression were often those at greatest risk of symptom progression; their symptoms were found to worsen in the ensuing six months [31]. In this study, the obtained effect size observed for the overall sample is reasonable given that one fifth of participants reported minimal depressive symptoms at baseline. However, we acknowledge, that this effect size may be an underestimate because of the selective sample. It is possible that MoodCare prevents symptom progression or recurrent depressive episodes in this population, however this warrants further investigation in a larger study.

It is important to note that three-quarters of all enrolled participants in the MoodCare trial were men. Other depression treatment trials in this area have also observed an under-representation of women. While this may reflect the higher prevalence of coronary heart disease in men, it is acknowledged that much of the focus in this area has traditionally been placed on the outcomes of male patients. Potential reasons for lower recruitment, enrollment and retention of women in depression treatment trials, may include: under-diagnosis of Acute Coronary Syndrome, limited free time due to competing demands at work and home; prioritisation of health and wellbeing of family members; lack of responsiveness to help or advice regarding lifestyle and mental health issues [32]. Such factors require further investigation. It is therefore recommended that greater focus be placed on enrolling women into future trials, where evidence suggests that they are often under-represented [33].

In conclusion, our findings provide some support for the use of a telehealth program in Acute Coronary Syndrome patients with depression. Most importantly, the MoodCare program uses a technology platform and means of telehealth delivery that is both novel and scalable;

however, larger implementation trials are required to demonstrate longer term effectiveness and maintenance of outcomes.

**Author Statement of Conflict of Interest and Adherence to Ethical Standards**

Dr O'Neil, Professor Taylor, Dr Sanderson, Dr Cyril, Ms Chan, A/Prof Hawkes, Professor Jelinek, Dr Venugopal, A/Prof Atherton, A/Prof Amerena, A/Prof Grigg, A/Prof Walters, Professor Oldenburg declare that they have no conflict of interest. DLH developed the CDS, and has received research, fellowship and consultancy funds from the National Health and Medical Research Council (NHMRC), the National Heart Foundation of Australia, the Austin Medical Research Foundation, *beyondblue*, and Diabetes Australia for the development and researching of this scale. He has also received payment for research projects, consultancies, travel, advisory board memberships and lectures from industry including Abbott, Amgen, AstraZeneca, Biotronic, Bristol-Myers Squibb, Boehringer Ingelheim, CSL-Biotherapies, Hoffmann-LaRoche, Hospira, Lundbeck (Denmark), Medtronic, Menarini, Merck KA (Germany), Merck (US), MSD, Pfizer, Roche, Sanofi-Aventis, Servier and Wyeth. All procedures, including the informed consent process, were conducted in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000.

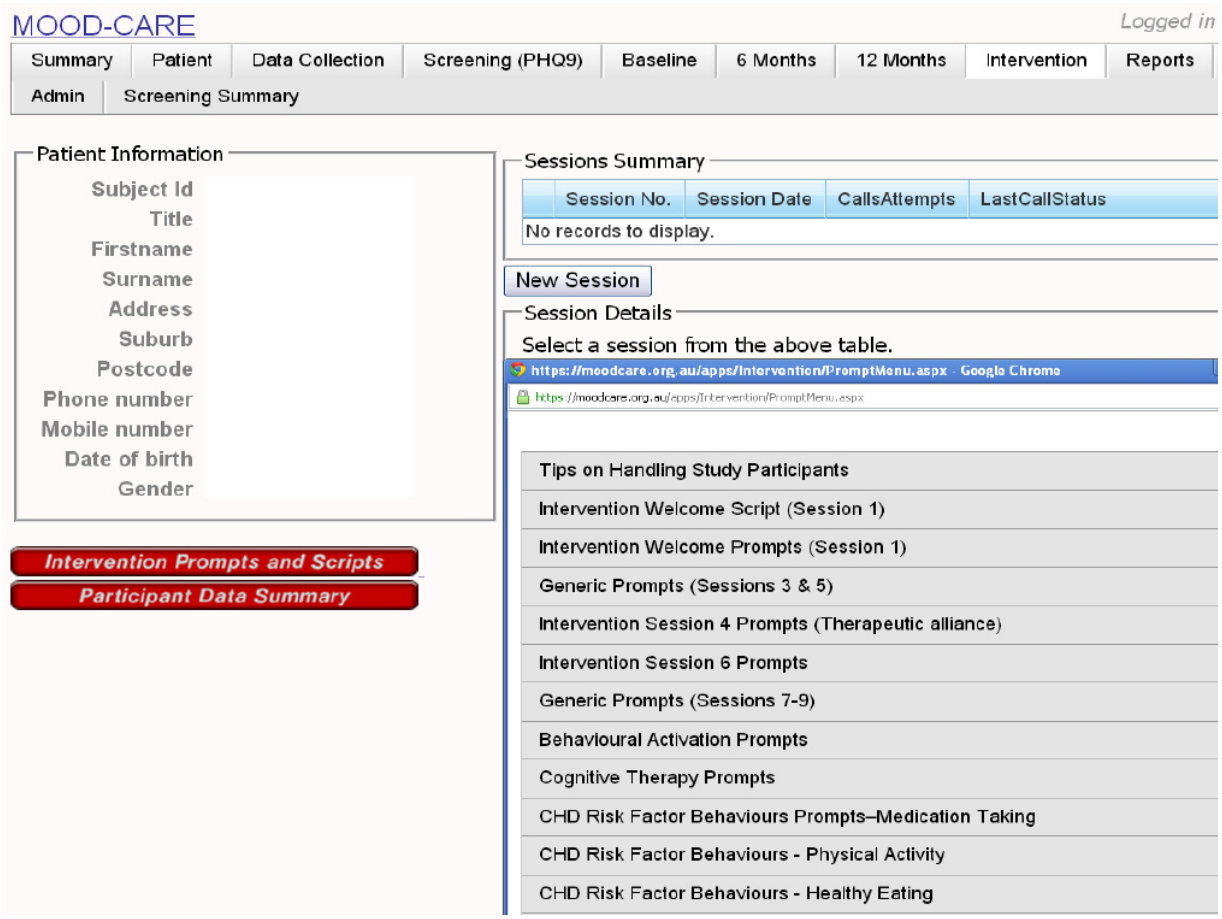


Figure 1. MoodCare web-based platform used by interventionists to guide program orientation

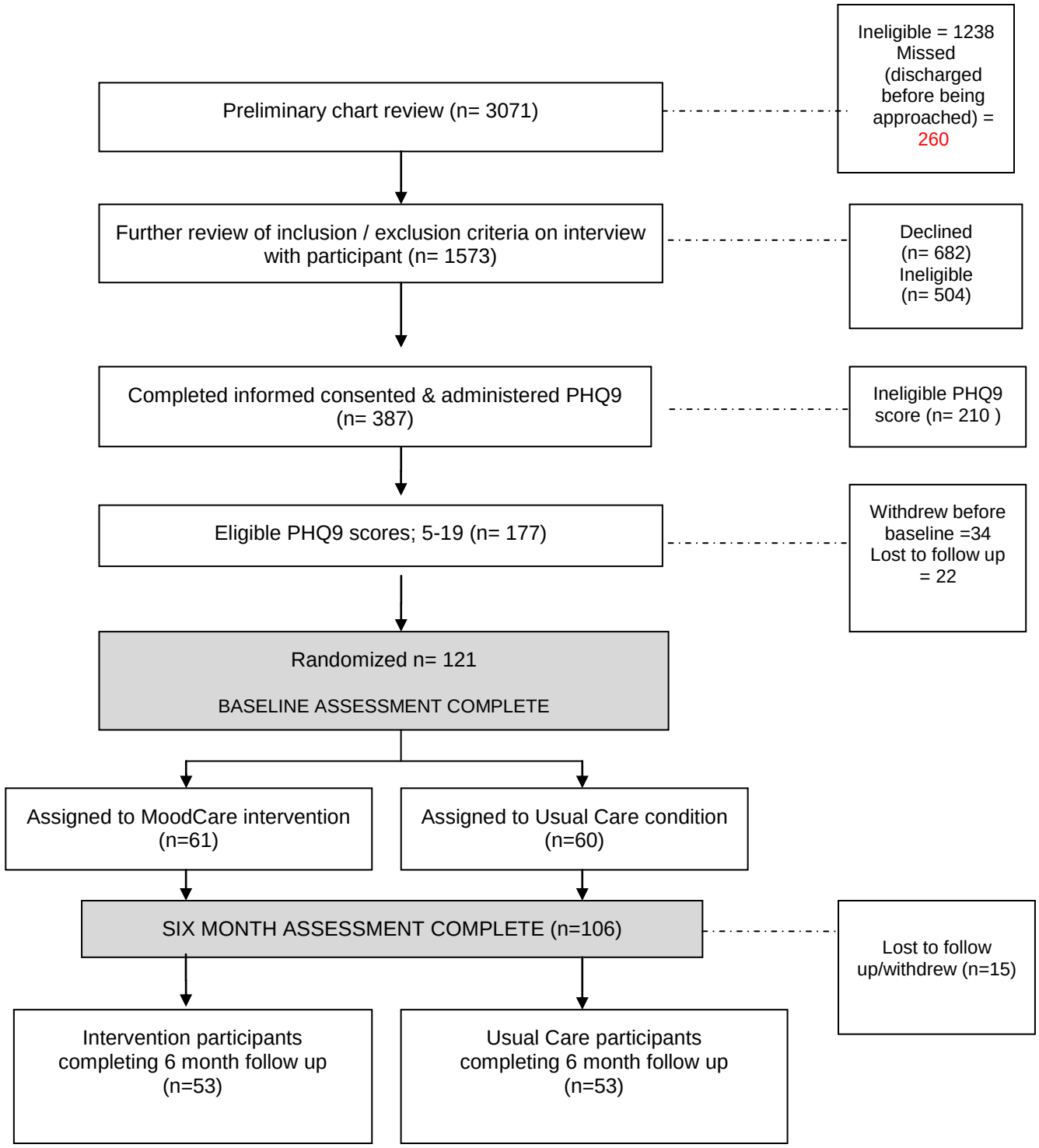


Figure 2. Flowchart of participant recruitment in the MoodCare trial

Table 1. Comparison of baseline demographic characteristics between the intervention and usual care groups

| Characteristics | MoodCare (n=61) | | Usual Care (n=60) | | Total (n=121) | |
|---|---|---|---|---|---|---|
| | n | % | n | % | n | % |
| **Gender** | | | | | | |
| Male | 45 | (73.8) | 46 | (76.7) | 91 | (75.2) |
| Female | 16 | (26.2) | 14 | (23.3) | 30 | (24.8) |
| **Age, years (Mean± Standard Deviation [SD])** | 61.0 ± 10.2 | | 58.9 ± 10.7 | | | |
| **Country of birth** | | | | | | |
| Australia | 51 | (83.6) | 41 | (68.3) | 92 | (76.0) |
| Other | 10 | (16.4) | 19 | (31.7) | 29 | (24.0) |
| **Household income/year** | | | | | | |
| < $30,000 | 21 | (34.4) | 13 | (21.7) | 34 | (28.1) |
| $30,000-$59,999 | 19 | (31.1) | 16 | (26.7) | 35 | (28.9) |
| $60,000-$124,999 | 11 | (18.0) | 23 | (38.3) | 34 | (28.1) |
| ≥ $125,000 | 10 | (16.4) | 8 | (13.3) | 18 | (14.9) |
| **Employment** | | | | | | |
| Full-time | 19 | (31.1) | 23 | (38.3) | 42 | (34.7) |
| Part-time, Casual, home duties | 8 | (13.1) | 13 | (21.7) | 21 | (17.4) |
| Retired | 25 | (41.0) | 14 | (23.3) | 39 | (32.2) |
| Student, unemployed, unable to work | 9 | (14.8) | 10 | (16.7) | 19 | (15.7) |
| **Living arrangement** | | | | | | |
| Single | 18 | (29.5) | 19 | (31.7) | 37 | (30.6) |
| Couple with no children | 28 | (45.9) | 17 | (28.3) | 45 | (37.2) |
| Couple with children | 13 | (21.3) | 20 | (33.3) | 33 | (27.3) |
| **Highest qualification** | | | | | | |
| High School | 37 | (60.7) | 30 | (50.0) | 67 | (55.4) |
| Diploma/trade/apprenticeship | 9 | (14.8) | 14 | (23.3) | 23 | (19.0) |
| Bachelor/Master/PG diploma | 11 | (18.0) | 8 | (13.3) | 19 | (15.7) |
| **Aboriginal or Torres Strait Islander** | | | | | | |
| Yes | 1 | (1.6) | 1 | (1.7) | 2 | (1.7) |
| No | 60 | (98.4) | 59 | (98.3) | 119 | (98.3) |
| **Private health insurance[+]** | | | | | | |
| Yes | 16 | (26.2) | 21 | (35.0) | 37 | (30.6) |
| No | 45 | (73.8) | 39 | (65.0) | 84 | (69.4) |
| **Speak English as 1st language at home** | | | | | | |
| Yes | 55 | (90.2) | 55 | (91.7) | 110 | (90.9) |
| No | 6 | (9.8) | 5 | (8.3) | 11 | (9.1) |
| **Alcohol** | | | | | | |
| Current drinkers | 24 | (48.0) | 28 | (60.9) | 52 | (54.2) |
| Past drinkers | 11 | (22.0) | 8 | (17.4) | 19 | (19.8) |
| Never drank | 15 | (30.0) | 10 | (21.7) | 25 | (26.0) |
| **Smoking** | | | | | | |
| Currently smoke | 6 | (12.0) | 11 | (23.9) | 17 | (17.7) |
| Former smoke | 30 | (60.0) | 26 | (56.5) | 56 | (58.3) |
| Never smoke | 14 | (28.0) | 9 | (19.6) | 23 | (24.0) |

+ = In Australia, can include hospital cover only, ancillaries only (extras such as physiotherapy, dental, elective surgery) or both. This entitles patients to be admitted to a 'public' hospital as a private patient and receive additional services (private room, entertainment, surgery without waiting periods). Patients without insurance can still be admitted to a public hospital and receive subsidized care. All participating hospitals in this study were public hospitals, admitting patients who were with or without private health cover.

Table 2 Participants' baseline health and psychosocial profile

| | MoodCare | | Usual Care | | Total | |
|---|---|---|---|---|---|---|
| | **n** | **%** | **n** | **%** | **n** | **%** |
| **Co-morbidities present** | | | | | | |
| Diabetes | 20 | (32.8) | 12 | (20.0) | 32 | (26.4) |
| High Cholesterol | 40 | (65.6) | 48 | (80.0) | 88 | (72.7) |
| Hypertension | 41 | (67.2) | 39 | (65.0) | 80 | (66.1) |
| Heart disease | 51 | (83.6) | 53 | (88.3) | 104 | (86.0) |
| Stroke | 5 | (8.2) | 5 | (8.3) | 10 | (8.3) |
| Peripheral vascular disease | 20 | (32.8) | 17 | (28.3) | 37 | (30.6) |
| Lung disease | 14 | (23.0) | 11 | (18.3) | 25 | (20.7) |
| Depression/anxiety/nervous disorder | 31 | (50.8) | 21 | (35.0) | 52 | (43.0) |
| Stomach ulcer | 13 | (21.3) | 6 | (10.0) | 19 | (15.7) |
| Arthritis | 29 | (47.5) | 20 | (33.3) | 49 | (40.5) |
| Kidney disease | 4 | (6.6) | 1 | (1.7) | 5 | (4.1) |
| Cancer | 9 | (14.8) | 7 | (11.7) | 16 | (13.2) |
| Other | 12 | (20.3) | 14 | (24.6) | 26 | (22.4) |
| **Lifetime Depression (CIDI diagnosis)[1]** | | | | | | |
| No diagnosis | 28 | (45.9) | 30 | (50.8) | 58 | (48.3) |
| Major depression | 29 | (47.5) | 25 | (42.4) | 54 | (45.0) |
| Mild depression | 1 | (1.6) | 1 | (1.7) | 2 | (1.7) |
| Dysthymia | 3 | (4.9) | 3 | (5.1) | 6 | (5.0) |
| **Generalized Anxiety Disorder GAD-7** | | | | | | |
| None-minimal | 22 | (36.1) | 25 | (41.7) | 47 | (38.8) |
| Mild | 23 | (37.7) | 16 | (26.7) | 39 | (32.2) |
| Moderate | 8 | (13.1) | 13 | (21.7) | 21 | (17.4) |
| Moderately severe | 7 | (11.5) | 4 | (6.7) | 11 | (9.1) |
| Severe | 1 | (1.6) | 2 | (3.3) | 3 | (2.5) |
| **PHQ9** | | | | | | |
| None-minimal | 13 | (21.3) | 13 | (21.7) | 26 | (21.5) |
| Mild | 21 | (34.4) | 17 | (28.3) | 38 | (31.4) |
| Moderate | 18 | (29.5) | 17 | (28.3) | 35 | (28.9) |
| Moderately severe | 6 | (9.8) | 12 | (20.0) | 18 | (14.9) |
| Severe | 3 | (4.9) | 1 | (1.7) | 4 | (3.3) |
| ***PHQ9 score (Mean ± SD)*** | 9.0 ± 5.4 | | 9.4 ± 5.2 | | 9.2 ± 5.3 | |
| **CDS** | | | | | | |
| No diagnosis (< 95) | 33 | (54.1) | 32 | (53.3) | 65 | (53.7) |
| Major depression (≥ 95) | 28 | (45.9) | 28 | (46.7) | 56 | (46.3) |
| ***CDS score (Mean ± SD)*** | 94.2 ± 26.3 | | 88.2 ± 25.0 | | 91.2 ± 25.7 | |
| **Age of depression onset** | 33.8 ± 14.0 | | 37.3 ± 17.3 | | 35.4 ± 15.6 | |
| **Health Related Quality Of Life (SF-** | | | | | | |

**12)**

| | | | |
|---|---|---|---|
| Physical HRQOL (Mean ± SD) | 33.5 ± 9.2 | 33.8 ± 10.1 | 33.7 ± 9.6 |
| Mental HRQOL (Mean ± SD) | 39.2 ± 9.3 | 38.7 ± 10.4 | 38.9 ± 9.9 |

[1] The percentage may not add up to 100% because of missing values from interview non-completion. CIDI= Composite International Diagnostic Interview; PHQ9=Patient Health Questionnaire (PHQ9); CDS=Cardiac Depression Scale

Table 3 Changes from baseline to 6-months by group (Matched pairs[1])

| Outcomes | MoodCare | | | | | | Usual Care | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Baseline | | 6-months | | | | Baseline | | 6-months | | | |
| | Mean | SD | Mean | SD | $\Delta^2$(SD) | p-value[3] | Mean | SD | Mean | SD | $\Delta^2$ (SD) | p-value[3] |
| ***Overall sample*** | | | (n=61) | | | | | | (n=60) | | | |
| CDS score | 94.2 | 26.3 | 89.1 | 28.6 | -5.13 (14.88) | **0.009** | 88.2 | 25.0 | 85.8 | 25.8 | -2.37 (19.18) | 0.343 |
| PHQ9 score | 9.0 | 5.4 | 6.1 | 5.5 | -3.00 (4.30) | **0.000** | 9.4 | 5.2 | 8.1 | 5.8 | -1.27 (5.24) | 0.066 |
| SF12 Physical health | 33.5 | 9.0 | 38.0 | 9.2 | 4.43 (8.67) | **0.000** | 33.8 | 10.1 | 35.9 | 10.4 | 2.09 (8.55) | 0.063 |
| SF12 - Mental health | 39.2 | 9.1 | 44.8 | 11.0 | 5.66 (9.49) | **0.000** | 38.7 | 10.4 | 41.3 | 11.8 | 2.66 (10.85) | 0.062 |
| ***Sub-sample: lifetime diagnosed depression*** | | | (n=33) | | | | | | (n=29) | | | |
| CDS score | 96.1 | 24.4 | 93.1 | 25.8 | -3.03 (15.78) | 0.278 | 99.5 | 18.9 | 97.9 | 22.6 | -1.55 (20.54) | 0.687 |
| PHQ9 score | 9.5 | 5.4 | 6.5 | 5.9 | -3.03 (4.84) | **0.001** | 11.4 | 4.5 | 10.4 | 6.1 | -1.00 (5.90) | 0.369 |
| SF12 Physical health | 34.0 | 9.6 | 38.6 | 10.0 | 4.64 (9.05) | **0.006** | 32.1 | 10.3 | 35.8 | 10.6 | 3.65 (8.73) | **0.032** |
| SF12 - Mental health | 37.4 | 8.8 | 43.6 | 12.3 | 6.15 (10.08) | **0.001** | 35.0 | 6.9 | 36.1 | 11.5 | 1.16 (11.47) | 0.590 |

[1] The missing values for the variables have been imputed using LOCF (at 6-months) and the group mean (at baseline).
[2] $\Delta$ denotes the mean difference (change) from baseline to 6-months
[3] t-test undertaken for matched paired samples for mean difference and significant values are indicated in bold font
PHQ9=Patient Health Questionnaire (PHQ9); CDS=Cardiac Depression Scale

Table 4. Modelling for changes in CDS, PHQ9, SF12 - Physical and Mental health, using ANCOVA at baseline and 6-months, by overall sample and lifetime depression sub-group

| Characteristics | Estimated Marginal Means | | Δ[1] | SE | p-value | 95% CI | |
|---|---|---|---|---|---|---|---|
| | MoodCare | Usual Care | | | | Lower | Upper |
| **Overall sample** | | | | | | | |
| CDS score | 86.6 | 88.4 | -1.8 | 3.06 | 0.558 | -7.8 | 4.3 |
| PHQ9 score | 6.1 | 8.0 | -1.8 | 0.81 | **0.025** | -0.2 | -3.4 |
| SF12 Physical health | 38.0 | 35.8 | 2.2 | 1.42 | 0.117 | -0.6 | 5.1 |
| SF12 - Mental health | 44.7 | 41.5 | 3.2 | 1.74 | 0.070 | -0.3 | 6.6 |
| ***Sub-sample: lifetime diagnosed depression*** | | | | | | | |
| CDS score | 94.3 | 96.5 | -2.2 | 4.49 | 0.620 | -11.2 | 6.8 |
| PHQ9 score | 7.0 | 9.7 | -2.7 | 1.32 | **0.043** | -5.4 | -0.1 |
| SF12 Physical health | 38.1 | 36.4 | 1.7 | 2.10 | 0.432 | -2.5 | 5.9 |
| SF12 Mental health | 42.8 | 37.1 | 5.7 | 2.73 | **0.041** | 0.2 | 11.2 |

CDS=Cardiac Depression Scale; PHQ9=Patient Health Questionnaire (PHQ9); SF12=Short Form-12, ANCOVA=Analysis of Covariance. [1] The mean difference is between the intervention and no intervention group (MoodCare minus Usual Care) and is based on estimated marginal means adjusted for baseline measures of depression and SF-12 scores.

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**Author/s:**
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