Protocol

Integrating MEditatioN inTO heaRt disease (The MENTOR study): Phase II randomised controlled feasibility study protocol

Angela Rao [a,*], Michelle DiGiacomo [a], Jane L. Phillips [a,e], Phillip J. Newton [b], Robert Zecchin [c], Alan Robert Denniss [b,c,d], Louise D. Hickman [a]

[a] Improving Palliative, Aged and Chronic Care through Clinical Research and Translation (IMPACCT), Faculty of Health, University of Technology Sydney, Building 10, Level 3; PO Box 123 Ultimo, NSW, 2007 Australia
[b] Western Sydney University, 161-169 Macquarie Street Parramatta, NSW 2150 Australia
[c] Western Sydney Local Health District, Darcy Road, Westmead, NSW 2145 Australia
[d] University of Sydney, Camperdown, NSW 2006, Australia
[e] School of Nursing, Queensland University of Technology, Kelvin Grove, QLD 4059, Australia

ABSTRACT

Background: Additional support services are required to identify and manage poor psychological health symptoms in one in five patients who attend cardiac rehabilitation programs. Meditation has been identified as a low-cost accessible adjunct to conventional therapies and has demonstrated a potential benefit to reducing cardiovascular risk.

Aim: This protocol reports on the design and methods of a study that aims to determine the feasibility, acceptability and preliminary efficacy of integrating a meditation intervention into an existing cardiac rehabilitation program for the reduction of depression and anxiety symptoms in people with cardiovascular disease.

Methods: This is a mixed methods phase II randomised controlled feasibility pilot study. Sixty patients will be randomised to meditation (1 session weekly for six weeks) and usual cardiac rehabilitation (6 week/12 session outpatient cardiac rehabilitation) or to usual cardiac rehabilitation. Measurements will be conducted at baseline, 6 weeks and 3 months. Preliminary outcomes include feasibility and acceptability of meditation (recruitment, screening, randomisation and attrition rates), and depression, anxiety, stress, salivary cortisol, blood pressure and heart rate outcomes. Participants will be invited to attend a semistructured interview at 6 weeks to explore their experiences of participating in meditation. Health professionals will also be interviewed to ascertain their perspectives of integrating meditation into cardiovascular secondary prevention programs.

Discussion: This study will provide preliminary understanding of the feasibility acceptability and preliminary efficacy of meditation as an adjunct therapy for people who may require additional psychological health support. These results may also highlight signals of improvement in psychological health symptoms and inform the development of a future phase III randomised controlled trial.

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Summary of relevance

Problem or issue
- Poor psychological health is associated with reduced participation and completion of cardiac rehabilitation programs, and presents a barrier to health behaviour change.

What is already known
- There is a clear need to strengthen the evidence for meditation as a psychological support strategy for patients who have recently experienced a cardiac event.

What this paper adds

* Corresponding author at: University of Technology Sydney, Improving Palliative, Aged and Chronic Care through Clinical Research and Translation (IMPACCT), Level 3 Jones Street, Ultimo, NSW 2007, Australia, Tel.: +61 414530358; fax: +61 2 9553 3483.

E-mail address: angela.rao@uts.edu.au (A. Rao).

- This protocol describes a mixed methods randomised controlled phase II feasibility pilot study designed to improve psychologi-

cal health in the one in five people with cardiovascular disease who may require additional support.

- The MENTOR Study will contribute to the broader body of knowledge of meditation for patients with cardiovascular disease and will contribute to understanding the feasibility and acceptability of integrating meditation into the cardiac rehabilitation setting.

1. Introduction

Moderate comorbid depressive and anxiety symptoms occur in approximately 15 to 30% of patients who experience a cardiac event globally (Rao, Zecchin, et al., 2019; Sever, Doherty, Golder, & Harrison, 2020; Trajanovska, Kostov, & Perevska, 2019). A preexisting history of depressive symptoms and/or new onset of depressive symptoms after a cardiac event is also linked with increasing cardiac morbidity and mortality (Desveaux et al., 2020). A recent American Heart Association statement has highlighted the need to incorporate a holistic approach to care, including consideration of psychological health and its impact on improving cardiovascular health and reducing CVD risk (Levine et al., 2021). However, targeted strategies to address depression and anxiety symptoms in cardiovascular disease (CVD) patients is minimal during hospitalisation and varies greatly across cardiac rehabilitation (CR) outpatient programs (Ceccarini, Manzoni, & Castelnuovo, 2014).

An integrated approach to care (Anderson et al., 2016) that is inclusive of psychological health is required to ensure that patients with CVD are able to understand and process new information needed to enact necessary lifestyle changes, and reduce the risk of future cardiac events. The current COVID-19 pandemic has highlighted this need, where social isolation and fears of contracting COVID-19 can exacerbate rumination and maladaptive thought patterns and further increase the risk of poor cardiovascular outcomes (O'Neil, Nicholls, Redfern, Brown, & Hare, 2020). Modifiable limitations to CR adherence, including negative beliefs about the perceived risk of exercise or a patient's understanding of their exercise capabilities (Desveaux et al., 2020) can only be addressed with the addition of a psychosocial or psychological component to a tailored CR exercise program that goes beyond an initial CR assessment. Integrating nonpharmacological strategies, such as collaborative, co-ordinated care programs and cognitive behavioural therapies has been demonstrated to assist people with CVD to self-manage their physical and psychological symptoms (Berkman et al., 2003; Huffman Jeff et al., 2011; Morgan et al., 2013). However, none of these therapies have been widely implemented in CR settings, nor is definitive evidence available (Richards et al., 2017).

The American Heart Association (AHA) has also recommended that meditation, in addition to cognitive behaviour therapies, ought to be considered as an additional cardiovascular risk reduction strategy while understanding that the definitive benefits of meditation need to be better established (Levine et al., 2017). Meditation can be described as "…practices that self-regulate the body and mind, thereby affecting mental events by engaging a specific attentional set" (Cahn & Polich, 2006, p. 180). A meta-analysis of meditation across chronic medical conditions, substance abuse, and caregiver stress has demonstrated the efficacy of meditation for anxiety (effect size [ES] 0.40; 95%CI: 0.08-0.71), depression (ES 0.32; 95%CI: -0.01-0.66) and pain (ES, 0.33, 95%CI: 0.03-0.62) at 8 weeks with moderate strength of evidence; while the strength of the evidence for stress or distress, and mental health related quality of life was low (Goyal et al., 2014). Preliminary evidence of meditation's efficacy in cardiovascular secondary prevention programs was found to be of modest quality, yet not definitive of a clinical benefit (Levine et al., 2017; Rao, DiGiacomo, Newton, Phillips, & Hickman, 2019). Successful elements of meditation interventions that have facilitated improvements in depres-

sion and/or anxiety symptoms in cardiovascular secondary prevention programs have included a 'body scan', or guided sequential relaxation of major muscle groups, daily home meditation practice and group meetings (Rao, DiGiacomo, et al., 2019). Mindfulness Based Stress Reduction (MBSR) and/or or adaptations of MBSR have generated statistically significant improvements in depression (Delui, Yari, Khouyinezhad, Amini, & Bayazi, 2013) and/or anxiety, body mass index, blood pressure (Parswani, Sharma, & Iyengar, 2013) heart rate (Delui et al., 2013), and quality of life (Nyklíček, Dijksman, Lenders, Fonteijn, & Koolen, 2014). Transcendental meditation used in addition to CR has demonstrated preliminary efficacy in increasing myocardial flow reserve, which may be clinically significant (moderate effect size of 0.64) (Bokhari et al., 2019), but has not generated significant reductions in depression, trait anxiety or life stress (Paul-Labrador et al., 2006). Similarly qualitative analyses of CR participant experiences of MBCT included improved levels of awareness regarding the causes and triggers of stress, coping and reactivity, anxiety relief related to a shared group experience, awareness of a need for commitment, gaining a sense of awareness and improved mood (Griffiths, Camic, & Hutton, 2009). Patient preference for adjunct meditation use is increasing, with 17.8%, 29.2%, and 21.6% of the general population using it to manage symptoms of depression, anxiety and stress, respectively (Cramer et al., 2016). Similarly, 23.9% of people living with cardiac symptoms or diagnosed cardiovascular disease are using mind-body therapies, with meditation among the top four strategies used for the management of cardiac symptoms (Prasad et al., 2013). Almost half of these people (48.6%) were willing to participate in a clinical trial of an alternative therapy (Prasad et al., 2013). Meditation is also a relatively inexpensive and widely accessible therapy which increases its appeal as an adjunct therapy in cost driven hospital based CR programs (Levine et al., 2017).

The Integrating MEditatioN inTO heaRt disease (MENTOR) Study will be conducted as a smaller version of a future phase III RCT to explore if the components of the intervention can successfully work together (Blatch-Jones, Pek, Kirkpatrick, & Ashton-Key, 2018), and is essentially process oriented, with consideration of recruitment and randomisation retention rates.

1.1. Aims

This protocol reports on design and methods of a study that aims to determine the feasibility, acceptability and preliminary efficacy of integrating a meditation intervention into an existing CR program for the reduction of depression and anxiety symptoms in people with cardiovascular disease.

2. Methods

Reporting of the MENTOR Study protocol adhered to the 2013 SPIRIT Statement (Chan et al., 2013).

2.1. Study design

The MENTOR Study is a mixed methods, open label, parallel group, phase II randomised controlled feasibility pilot study with a qualitative sub-study. This pilot RCT is designed to test the feasibility and acceptability of the proposed methods and procedures to be used in an adequately powered Phase III RCT (Thabane et al., 2010). Feasibility can be defined as the capacity for a new treatment or innovation to be successfully used or carried out within a given setting, and is typically described retrospectively as recruitment, retention or participation rates (Proctor et al., 2011). Whereas acceptability is defined as the perception among implementation stakeholders that a given treatment, practice, service or

innovation is satisfactory or agreeable (Proctor et al., 2011). Using a mixed methods design strengthens the ability of this phase II feasibility pilot RCT to: (i) check adherence to the intervention procedures and factors that may explain variance in adherence, as well as other moderating factors (Klingner & Boardman, 2011); (ii) obtain participant feedback to better understand the outcomes and inform future interventions (Creswell & Plano Clark, 2018); and (iii) counteract publication biases against studies that do not generate statistical significance and are deemed ineffective by clarifying negative results and informing future research (Curry et al., 2013).

Participants will be randomly assigned by an independent statistician in a 1:1 computer generated block randomisation sequence to CR or meditation and CR. There will be no alteration to cardiologist or other outpatient follow up appointments or medications unless advised by the relevant health professional, nor restrictions to the use of other complementary and alternative therapies. Participants will be followed up at 6 weeks and 3 months.

Postintervention interviews of participants allocated to the meditation intervention will be conducted via phone or in small groups after their final group meditation session. Semi-structured interviews will be used to: (i) understand participants' perceptions of the impact of meditation on their psychological health symptoms; and (ii) explore the barriers and enablers to participation in and adherence to group and home practice sessions. Heath professionals will also be interviewed to understand their perspectives on integrating meditation into cardiovascular secondary prevention programs.

2.2. Eligibility criteria

1. Adults $\geq$ 18 years who have been referred to CR following an acute or chronic cardiac event, or for risk factor modification, and attend CR pre-assessment;
2. Have at minimum mild to severe depression as measured by the Depression, Anxiety Stress Scale (DASS- 21) depression subscale score $\geq$ 5, and/or anxiety subscale score $\geq$ 4;
3. Willing to give informed consent; participate in a 6-week group meditation program; adhere to daily home meditation practice using provided resources (CD); and be followed up for 3 months;
4. Basic English literacy to allow completion of study instruments with minimal assistance.

2.3. Exclusion criteria

1. Adults with congenital heart disease
2. Pre-existing severe mental illness (schizophrenia, manic bipolar disorder).

While a more recent study indicates that mindfulness based cognitive therapy may increase self-understanding in people experiencing a psychotic episodes (Randal, Bucci, Morera, Barrett, & Pratt, 2016), this meditation intervention is not considered suitable for use in people with pre-existing psychotic conditions. This intervention does not involve cognitive therapy, and there are possibilities that meditation may trigger a psychotic episode whereby a patient loses their connection with reality, or worsen psychotic symptoms (Dyga & Stupak, 2015). Secondly, clinicians delivering the intervention and caring for patients in the usual CR setting are not psychologists with advanced training in managing or de-escalating patients who are experiencing a psychotic episode beyond providing safety for the patient and those around them.

2.4. Setting

The MENTOR Study will be conducted in one CR program in metropolitan Sydney, Australia. The catchment area of this site reflects the multicultural landscape of Australia, with nearly half (45%) speaking a language other than English at home, and 2.8% of residents identifying as Aboriginal or Torres Strait Islander (Australian Bureau of Statistics, 2016b). The majority (89.6%) of residents are proficient in spoken English (Australian Bureau of Statistics, 2016a).

2.5. Recruitment procedures

Inpatients will be screened and patients entering the CR program will be approached in hospital and/or at pre-assessment to determine interest in participating in a meditation intervention or will be recommended to the researcher by CR nursing staff. Patients will be approached by the researcher in-person and given brief information about the meditation intervention. Interested patients will be given a participant information form with full details of the study, and formal written consent will be obtained.

2.6. Usual care

Participants allocated to the control group will attend the usual outpatient CR program. The CR program includes an initial cardiovascular nursing assessment and 6 weeks/12 sessions of structured supervised exercise and education according to their needs and preferences. Both the meditation intervention group and control group will be able to participate in CR. Participants will remain eligible for the study if they choose to discontinue the usual outpatient CR program. There will be no alteration to cardiologist or other outpatient follow-up appointments or medications unless advised by the relevant health professional nor restrictions to use of other complementary and alternative therapies. These participants will also be offered a meditation CD or USB for home practice at the end of the 3-month trial period.

2.7. Intervention

The facilitator of the meditation sessions will gather participants into a private room at the completion of their exercise session. Lights will be dimmed or turned off and a 'do not disturb' sign will be placed on the door. The facilitator will briefly introduce the purpose of meditation at the first group session, and answer any questions about participants' expectations of meditation. Participants will be reassured that the experiences and sensations are unique to the individual, and that it is normal for chatter to occur in the mind when beginning to establish a meditation practice. In subsequent sessions, the facilitator will hold a brief 2-3 minute 'check in' to address issues with adherence to meditation home practice. The facilitator will then guide participants through a recorded meditation that incudes (i) focused attention to the breath; (ii) a guided 'body scan' or focused attention to major muscle groups; and (iii) peaceful ambient music designed to elicit a meditative state and altered state of consciousness. At the end of the meditation, the facilitator will guide participants back to normal awareness. Further details of the MENTOR Study are described in Fig. 1. The study was informed by a systematic review of the literature (Rao, DiGiacomo, et al., 2019), the researcher's understanding of a variety of meditation practices and informal consultation with meditation experts. The study was underpinned by Bandura's self-efficacy model due to the relationship between self-efficacy (i.e., an individual's perception of their abilities) and health behaviours (Gordon, 2007). Self-efficacy plays a mediating role in successful emotional regulation, defined as the capacity to effectively manage negative affective states (Luberto, Cotton, McLeish, Mingione, & O'Bryan, 2014). Improving perceptions of self-efficacy may be possible by introducing meditation practices designed to

Intervention: An audio CD has been created by the researcher that combines her own voice and a 16 minute breathing meditation by called Seashells by Deuter[4] This meditation will be used to guide participants through the 'concentrative' components of the intervention, including a guided deep breathing practice and a 'body scan' that sequentially drew focused attention to the relaxation of major muscle groups. This will be followed by an open focus that includeds peaceful ambient music designed to calm the mind and facilitate a deeper meditative state or altered state of consciousness. At the end of the meditation, participants will sit in silence with the researcher for 2 to 3 minutes before being gradually guided back to normal awareness. In addition to in-person groups, participants will be asked to practice meditation at home daily, excluding the day of the group meditation session.

At the group meetings, before each meditation session, the researcher will facilitate a short 1-2 minute per person check in' to identify any issues or challenges participants are having with the practice. Prior to the first meditation, a short explanation of the steps involved in the meditation will be explained to participants and participants will have an opportunity to share what they are hoping to gain by using meditation. Participants will be reassured that initially, chatter that occurs within the mind can be difficult quieten, and that this is part of the process, but as practice continues, it becomes easier over time to quiet the mind.

Materials: Digital audio (USB, CD or private YouTube link) for home practice; weekly meditation log sheet; do not disturb sign; comfortable chairs or couches with back support; CD player or laptop to play meditation audio or online link. Pillow or comfortable chair (home practice). You tube account with YouTube analytics (for intervention fidelity - available free online)

Delivery personnel: Group meditation sessions will be facilitated by the researcher, a specialist registered nurse with over 14 years' experience in meditation practice, including completion of a three day silent meditation retreat, an 8 week Mindfulness Based Stress Reduction Course, and 14 years of fortnightly participation in a private meditation group.

Method of communication, intensity and complexity: The intervention was comprised of six face-to face, weekly meditation groups of 16 minutes duration, with 3 additional minutes of introductory and concluding instruction. Participants will be given a copy of the intervention on digital audio. Participants not using the YouTube link for home practice will be given a weekly log sheet to record frequency and duration of mediation sessions for each day of the week.

Home practice: Daily home practice meditation practice consisted of digital audio that was identical to the content and time used in the weekly group meditation sessions, including an introduction and conclusion to each session. The conclusion brought participants back to normal awareness and was recorded in the researcher's voice. Participants will be asked to complete one home practice session daily on the days they are not attending the face-to-face group session.

Environment: Face-to-face group sessions will be held in a private room in close proximity to the participating hospital's cardiac gym. In keeping with usual meditation practice, the lights will be dimmed, doors closed, blinds drawn shut, and a 'do not disturb' sign will be placed on the door to minimise interference. Participants will be seated on couches or padded chairs placed in a circle which will allow for social distancing. Home practice is advised to occur in a quiet space, such as the bedroom or outdoors in a space that was uninterrupted and could be made comfortable with a chair, pillows or a bed.

Fig. 1. Intervention description.

improve emotional regulation (Luberto et al., 2014) and cognitive flexibility (Lee & Orsillo, 2014). While the mechanism of action for meditation and emotional regulation is uncertain, clarity of internal experiences has been identified as partly mediating the relationship between mindfulness states (attention and acceptance) and the regulation of negative affect (Coffey, Hartman, & Fredrickson, 2010). The first meditation session intervention will commence the week following the chronological random assignment of a group of a minimum of 4 and a maximum of 6 participants to the intervention group. Due to the rolling enrolment of participants into CR, and the association of delayed enrolment with reduced participation in CR (Rao et al., 2021), a delay in the start of usual CR until a meditation group is formed is not considered acceptable. The mean number of days before intervention commencement will be described.

2.8. Outcomes

Evaluation of between group differences at 6 weeks and 3 months (where applicable) in:

1 Recruitment rate, screening, randomisation ratio and attrition rate
2 Depression (DASS-21) (Lovibond & Lovibond, 1995) and Hospital Anxiety and Depression (HADS) (Zigmond & Snaith, 1983) depression subscales
3 Anxiety (DASS-21 anxiety subscale; HADS anxiety subscale; self-efficacy (MSES-R) and health status
4 Stress (DASS-21 stress subscale; salivary cortisol)
5 Patterns of attendance at weekly group sessions, adherence to home practice, and mean duration of home practice sessions; qualitative interview responses.
6 Blood pressure (BP), heart rate (HR)

2.9. Sample size

The pilot sample size (n = 60 patients) was determined based on the pragmatics of recruitment and the necessities for examining feasibility (Blatch-Jones et al., 2018).

2.10. Stopping rule

A stopping rule will be employed based on the feasibility of recruitment (refer Fig. 2). The target recruitment rate will be approximately two patients per week, or eight patients per month. The anticipated duration of the trial will be approximately 10 months (between March and December 2018) to reach a recruitment target of 60 patients.

2.11. Study measures

Baseline interview (refer Table 1)
Clinical and socio-demographic data included New York Heart Association (NYHA) classification, clinical history, risk factor profile, medication use, age, marital status, country of birth, living arrangements, number of children, education status, work status, health care utilisation, caregiver status and participation in any current meditation, spiritual practices or other complementary therapies.
Charlson Comorbidity Index (Charlson, Pompei, Ales, & MacKenzie, 1987) will be used to calculate the burden of comorbidity over a period of one year based on the presence of a range of 22 comorbid conditions. Comorbidity burden is calculated based on a weighted score of the number of conditions and the impact of prognosis.
The Social Readjustment Rating Scale (SRRS) is a 43-item scale used to measure additional psycho-social factors found to increase risk for anxiety, depression, stress and heart disease (Scully, Tosi, & Banning, 2000). The SSRS includes yes/no dichotomous answers to questions ascertaining the presence of stressful life events in the past 12 months. New weights assigned to the SRRS items will be used in line with Scully et al. (2000) revisions.
Depression, Anxiety, Stress Scale (DASS-21) is a set of three self-report scales each with seven items designed to measure the negative emotional states of depression, anxiety, and stress (Lovibond & Lovibond, 1995). The depression sub-scale assesses dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest/involvement, anhedonia, and inertia. The anxiety sub-scale assesses autonomic arousal, skeletal muscle effects, situa-

Participant interview guide

1. What was your experience of using meditation in the clinical setting?
2. What aspects of meditation did you enjoy? Was there any part of meditation that you didn't like?
3. What influenced your decision to try meditation?
4. Do you think you will continue to practice meditation at home?
   a) Why or why not? (Prompt - any factors that would support you to continue meditation at home and that would challenge it?)
5. Was anyone else involved in your meditation practice? If so, did they use meditation independently or did you practice meditation together?

Fig. 2. Participant interview guide.

Table 1
Measurement schedule.

Measure	Baseline	6 weeks	3 months
Socio-demographic questionnaire	X		
Charlson Comorbidity Index	X		
Social Readjustment Rating Scale (SRRS)	X		
Depression, Anxiety, Stress Scale (DASS-21)	X	X	X
Hospital Anxiety and Depression Scale (HADS)	X	X	X
Mindfulness Self-Efficacy Scale- Revised (MSES-R)	X	X	X
Health Status	X	X	X
Blood pressure	X	X	
Salivary cortisol	X	X	
Home meditation practice (YouTube Analytics/ weekly written log)		X	

tional anxiety, and subjective experience of anxious affect. The stress sub-scale is sensitive to levels of chronic non-specific arousal. It assesses difficulty relaxing, nervous arousal, and being easily upset/agitated, irritable/over-reactive and impatient. All scales of the DASS-21 have been shown to have high internal consistency and to yield meaningful discriminations in the cardiac rehabilitation setting (Lovibond & Lovibond, 1995). The DASS-21 has also been validated in chronic obstructive pulmonary disease (Yohannes, Dryden, & Hanania, 2018) and older adults with pain (Wood, Nicholas, Blyth, Asghari, & Gibson, 2010).

Hospital Anxiety and Depression Scale (HADS): contains two sub-scales (14 items) that are used to measure depression and anxiety, as well as an overall combined score. Higher scores indicated greater psychological morbidity (Zigmond & Snaith, 1983). A cut-off point of 8 will be used to indicate clinically significant morbidity for the depression and anxiety sub-scales. The HADS will be used in addition to the DASS-21 due to its increased sensitivity to changes in depression and anxiety. Some of the DASS-21 items relating to breathlessness and palpitations could occur as a result of a recent heart event and may be unrelated to emotion.

Mindfulness Self-Efficacy Scale Revised (MSES-R): is a 22 item self-report questionnaire that will assess the change in levels of perceived efficacy before, during and after meditation (Cayoun, Kasellis, & Skilbeck, 2011). It contains subscales of: emotional, equanimity, social, distress tolerance, taking responsibility, and interpersonal effectiveness (Cayoun et al., 2011).

Health status: The first question of the 36-Item Short Form Survey 'in general would you say your health is excellent, very good, good fair or poor' will be used to determine health status (Ware, Snow, Kosinski, & Gandek, 1994). This question is a single item with a 5-point Likert scale that assess the extent to which

participants agreed or disagreed that their overall health status had changed over time, with higher scores indicating better health (Ware et al., 1994). It has been used widely used in cardiovascular patients (Huber, Oldridge, & Höfer, 2016).

Blood pressure: Two blood pressures will be taken at 5 minutely intervals. The mean blood pressure from the two measurements will be used. Where there is >5 mmHg difference between the first and second readings, a third blood pressure will be taken and the average of the three readings will be used.

Salivary cortisol measures: Salivary cortisol measures will be taken after patients are seated comfortably for three minutes at baseline, before the first meditation session and within 10 minutes after the first meditation session. This process will be repeated at 6 weeks after the final group meditation session.

Home practice: Home practice of meditation will be tracked using a weekly log sheet or Google analytics attached to a private YouTube account. Each participant will be assigned a separate YouTube link to the meditation audio.

Postintervention interviews: All participants who have completed the meditation intervention will be invited to complete short semistructured interviews (5-10 minutes) to generate descriptive accounts of their experiences. These interviews will be conducted by an experienced qualitative researcher or members of the research team to avoid response bias associated with the facilitator of the meditation groups. Interview guides, based on identified gaps in the literature, and previous research on barriers and facilitators to meditation in clinical care (Crane & Kuyken, 2013) will be used to ensure consistency in issues explored (refer Fig. 2). Semistructured interviews of 18 health professionals will also be completed to ascertain their perspectives of integrating meditation into routine cardiovascular secondary preventive care (refer Fig. 3).

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Meditation can be described as a variety of practices where the individual trains or regulates the mind, and includes techniques designed to encourage relaxation, well-being and emotional balance. Some examples of meditation practice include mindfulness, guided imagery and transcendental meditation.

1. Have you, or someone that you know, had any experience with meditation?
2. Can you tell me about any situation where you have been involved in the oversight organisation of or delivery of meditation services within a health setting?
   a. If not, do you think that introducing meditation as a part of care could be beneficial?
   b. In what format would you perceive this to be best delivered, for example, as a part of an inpatient care pathway, inpatient cardiac rehabilitation, outpatient follow up care with their clinician or as a part of outpatient rehabilitation services?
   c. Why do you think this format would be best? Are there any other options that have not been considered?
3. What are the organisational behaviours that you perceive facilitate or support a people who may like to use meditation for their health?
   a. What are the organisational behaviours that you perceive facilitate or support a staff member who may like to use meditation for their health?
4. To what level or extent do you think that organisational behaviours or culture may prevent a person from trying meditation?
   a. To what level or extent do you think that organisational behaviours or culture may prevent a staff member from trying meditation?
5. Can you tell me what you think would facilitate or enable meditation to be implemented in clinical settings?
6. What do you see as some of the key challenges to implementing meditation in clinical settings?
   a. What solutions may assist in addressing these challenges?
7. Can you foresee any perceived risks in implementing meditation in clinical settings?
8. Do you think patients or colleagues would be willing to disclose personal use of meditation practices? Why or why not?

Fig. 3. Health professional interview guide.

2.12. Data collection

Baseline demographic, physiological and psychological measures will be collected at cardiac rehabilitation preassessment to ascertain eligibility before randomisation. If preassessment occurs >24 hours before CR program commencement, baseline physiological and questionnaire data will be completed by a member of the research team on the morning of the first CR session. Paper records of patient medical history, personal details, date of entry into CR and number of CR sessions attended will be obtained on-site from discharge summaries and a review of electronic medical records. A record of de-identified screening statistics and key dates (for example, study ID, date of recruitment, allocation, and date of intervention, attendance and completion/noncompletion) will be kept by the research team.

YouTube analytics will automatically tabulate each time the meditation link is accessed and the duration of each session will be recorded in minutes. Participants who are not accessing the YouTube link will be asked to complete a log sheet of the number of home meditation sessions completed, including date, dura-

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tion, and location of their meditation practice. *Weekly log sheets* will contain a column for the date, day of the week, whether they meditated on that day (yes/no) and whether the session was completed (yes/no). Weekly log sheets will be collected and replaced at the weekly group meditation session.

Cortisol sample tubes will be labelled with patient study identifiers and stored in a sealed airtight container for transportation and storage below minus 20 degrees (Garde & Hansen, 2005). Cortisol samples will be centrifuged and analysed using ELIZA assay kits by a laboratory researcher independent to the research team (SR).

Semistructured interviews will be conducted face-to-face at the outpatient CR department or via telephone. Participant interviews will be audio-recorded and field notes will be taken concurrently by the interviewer to ascertain their impressions of each interaction. Data be transcribed by the interviewer and sent to the researcher for coding and analysis. Clinicians will be recruited through purposive and snowball sampling. Clinicians will be identified via publically listed e-mails, such as the Heart Foundation cardiac rehabilitation directory, and national cardiovascular and cardiac rehabilitation websites, and an e-mail invitation of the purpose of the study and involvement will be sent. Interviews will be audio-recorded. Verbatim transcripts will be thematically analysed using the Braun and Clarke (2006) method. Data collection will cease when no new information is elicited and data saturation is reached.

Follow up telephone calls will be made to all participants at 3 months to assess depression, anxiety, stress (DASS-21, HADS), and self-efficacy for mindfulness (MSES-R) outcomes, and whether participants had chosen to continue to use meditation outside of the intervention period.

2.13. Data management

Paper copies of quantitative data will be collected and stored at the hospital. All data will be entered on to REDCap cloud software using a unique participant code. The master log linking the participant data with the identification will be stored separately. Individual interviews will be recorded on a digital recorder, though complete confidentiality will be upheld. The digital file will be stored securely behind password protected servers. A source document will be generated linking the identifiable data to the study code and held separately on a password protected PC in a locked office only accessible by the study team. All records will be kept for 15 years after the completion of the study.

2.14. Data analysis

Data will be analysed using descriptive and inferential statistics. All analyses will be on the basis of intention to treat. Independent t-tests will be used for continuous data and chi squared tests will be used for categorical outcomes in univariate analyses. Scores derived from psychometric measures for depression, anxiety and stress, mindfulness self-efficacy and social readjustment will be measured on continuous scales. Nonparametric tests, such as the Mann Whitney U test and Fishers exact test will be applied for comparing means in non-normally distributed variables. Quantitative data analysis will be completed after consultation with a biostatistician from the participating university, who is blinded to treatment allocation and has no part in the implementation of the intervention or endpoint assessment. Qualitative patient data will be analysed in accordance with Halcomb and Davidson (2006) in a series of six steps to elicit common themes between interactions. This method of analysis was chosen as the interviews will be relatively short in duration and do not require closeness between the researcher and the interview data (Halcomb & Davidson, 2006).

Key points will be noted using reflective journaling immediately after the interview and sent to the researcher for analysis. The summary and field notes will be checked against the audio recording to ensure they accurately reflect the interaction. Data will then be analysed to elicit common themes between interactions, and preliminary findings will be reviewed in an iterative process with the research team. Data will be rechecked to reduce and refine themes and illustrative examples will be used to demonstrate the meaning of each theme from a participant perspective. Semistructured health professional interviews will be audio-recorded and analysed using the Braun and Clarke (2006) method. Verbatim transcripts will be thematically analysed to identify health professionals' acceptability of meditation. Qualitative data will then be integrated with the quantitative data to understand if both forms of data support each other *(complementarity)* and whether participants' experiences shed light on the quantitative findings.

2.15. Ethical considerations

The MENTOR Study conforms to the principles outlined in the Declaration of Helsinki. Human Research Ethics Committee approval was obtained from the Local Health District (AU/RED/HREC/17/WMEAD/495) and the participating university (ETH-18-2337). The MENTOR Study is registered with the Australian and New Zealand Clinical Trials Registry ACTRN12618000844246.

3. Discussion

The MENTOR Study will contribute to the broader body of knowledge of meditation for CVD patients and will contribute to understanding the feasibility and acceptability of integrating meditation into the CR setting. These findings will also inform the design and outcomes for a phase III trial to reduce psychological aspects of cardiovascular risk and improve self-management. Integrating meditation into an outpatient CR program may provide opportunities for CVD patients to shift from focusing on illness in their 'psychological foreground' to maintaining wellness (Lorig & Holman, 2003). It is a small step in addressing the critical need for health professionals to formalise the importance of psychosocial and psychological support within a biomedical model. The MENTOR Study adheres to recommendations from the AHA to consider both evaluation and management of psychological health in CVD patients (Levine et al., 2021) and to consider meditation as a low-cost, low-risk adjunct to conventional CVD reduction strategies while generating definitive evidence to support its implementation (Levine et al., 2017).

Use of a convenience sample from a single hospital introduces the possibility of a selection bias. Despite this limitation, this study will shed light on the demographic, clinical characteristics of participants who may be interested in meditation as a means of providing additional psychological support. The MENTOR Study has the potential to provide signals of improvement in depression and anxiety; and will generate recommendations of the potential to integrate meditation into existing CR programs.

Author statement

AR, LDH, PJN, MD, JLP & RZ conception, methodology, design, planned analysis, writing – review and editing; ARD supervision, writing- review; AR writing- original draft and review.

Declaration of competing interest

The authors declare that there are no conflicts of interest.

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