

## Original Research Article

# Feasibility study protocol to examine the role of mantra meditation at reducing psychological distress in emergency department staff

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## ABSTRACT

**Background:** Work in a healthcare setting can affect the psychological wellbeing of healthcare professionals (HCPs). Emotional exhaustion among HCPs can have a significant negative impact on the quality of healthcare provided to patients in terms of increased medical errors and decreased patient satisfaction. There is a need for an effective stress-reducing intervention, such as mantra meditation. This feasibility study will examine the suitability of random controlled trial (RCT) methodology to assess the efficacy of mantra meditation at reducing emotional exhaustion among emergency department (ED) staff.

**Methods:** This is a mixed methods, stratified feasibility study with intent-to-treat protocol, using two study arms (passive control and intervention), the purpose of which is to examine (1) recruitment, retention, and adherence; (2) outcome measures (psychological wellbeing and stress-related biological parameters such as blood pressure, heart rate variability and salivary cortisol); and (3) data management, control, and dissemination prior to conducting a full RCT.

**Results** Eligible ED staff allocated to the intervention group ( $n = 30$ ) will be taught mantra meditation and discuss prescribed texts (4 x 4 hour session over 6 weeks), as well as engage in 20 minutes of twice-daily mantra meditation practice. Participants in the passive control group ( $n = 30$ ) will work as usual. Data will be collected pre (T1), post (week 11; T2) and at follow-up (week 19; T3).

**Conclusions:** This study will pave the way for a larger RCT that will investigate mantra meditation as a definitive intervention to reduce emotional exhaustion among ED staff.

**Keywords:** Health care, Psychological, Stress, Emotional exhaustion, Meditation

## INTRODUCTION

The practice of medicine by health care professionals (HCPs), while often meaningful and rewarding, can have a detrimental impact on psychological and physical wellbeing, leading to emotional exhaustion<sup>1</sup>. Alongside the impact of exposure to environmental hazards, HCPs are at above-average risk of developing stress-related

psychological morbidities, substance abuse, and dysfunctional interpersonal relationships.<sup>2</sup> In particular, the profession of emergency medicine, with its proclivity for complex caseloads, high personal responsibility, and a high-stress environment, can be emotionally and physically arduous.<sup>3</sup> Emotional exhaustion suffered by HCPs, can have significant implications for the quality of healthcare provided to patients<sup>1,4</sup>. Indeed, research

demonstrates an association between HCP emotional exhaustion and reduced compassion and empathy, increased medical errors, and decreased patient satisfaction.<sup>5</sup> There exists a clear and present need from some kind of intervention to address this problem.

Growing evidence points toward the psychological and physiological benefits of meditation practice on the general population.<sup>6</sup> While less attention has been afforded to the potential gains for HCPs, a limited body of research demonstrates the efficacy of meditation (including mindfulness and mantra meditation) at improving wellbeing among this cohort.

Common mindfulness courses promote non-judgemental awareness of each thought, feeling and sensation on a moment by moment basis.<sup>7,8</sup> Mindfulness-based cognitive therapy (MBCT) programmes have been well characterised in the literature and usually involve 8 two-hour sessions during which participants are taught a number of different types of meditations that include walking and sitting practices.<sup>8</sup> The enhanced insight and awareness gleaned from mindfulness meditation practices can translate into considerable gains for HCPs, patients, and the health service. This has been corroborated by Beach et al, who found that patients were more likely to give high ratings on clinical communication and to report increased overall satisfaction with clinicians who practice mindfulness meditation.<sup>9</sup> Specifically, encounters with such clinicians were more likely to be characterised by a patient-centred pattern of communication and conversation about psychosocial issues.<sup>9</sup>

On the other hand, mantra meditation usually involves the repeated saying (internally or externally) of a prescribed word, phrase or set of syllables, in a quiet setting, for a set period of time each day.<sup>10</sup> The practitioner is urged to disengage from all internal and external distractions, while focusing gently and repeatedly on the mantra. Transcendental Meditation (TM) is probably the best described type of mantra meditation practice, however, many religious and non-religious traditions have used mantra meditation as a simple but effective means to calm the mind and promote general wellbeing.<sup>10,11</sup>

Mantra meditation has also been evaluated scientifically and found to improve health and wellbeing, albeit in fewer studies. Elder and colleagues noted that a TM programme reduced depression, anxiety and burnout in 20 secondary school teachers, while Anderson et al, concluded that TM might induce clinically meaningful reductions in systolic and diastolic blood pressure measurements, based on a meta-analytic review of 9 clinical trials.<sup>12,13</sup> In terms of health care practitioners, Bormann reported in 2006 that mantra meditation reduced stress, state anger and anxiety, while it increased quality of life in 42 American health care workers. Furthermore, preliminary, unpublished data from the Royal College of Physicians of Ireland (RCPI), demonstrated that mantra

meditation significantly reduced emotional exhaustion in 19 out of 26 HCP study participants. Despite these studies, a significant knowledge gap exists regarding the impact of mantra meditation on stress-related biological parameters, including pro-inflammatory markers such as interleukin (IL)-6 and Tumour Necrosis Factor (TNF)- $\alpha$ . Larger and more robust RCTs are required to confirm the positive impacts of mantra meditation on health, especially the wellbeing of HCPs.

We have chosen mantra meditation in this study because it represents a cost-effective, flexible, portable, simple and focused strategy for reducing stress and improving well-being.<sup>14,15</sup>

### *Study aims and outcome measures*

The aim of this feasibility study is to assess recruitment, retention, adherence, physical resources, service access, survey instruments, qualitative methodology and managerial issues pertaining to this intervention (mantra meditation to improve wellbeing in HCPs). The target population will be HCPs working in a busy ED. It is hoped that this feasibility study will provide a sound basis for a larger RCT with the principle aim of using mantra meditation to reduce psychological distress among HCPs. Secondly, should the intervention prove successful, the ultimate goal will be to engage with hospitals across Ireland to provide rolling mantra meditation programmes, dedicated to improving the wellbeing of this group of professionals. We aim to develop a sound, evidence-based programme that can be replicated throughout Ireland, using mantra meditation manuals produced as a result of this study. In the long-term, we will also examine the biological mechanisms behind HCP distress and how mantra meditation might impact on the immune system, brain structure and epigenetic control of pro-inflammation.

### *Primary outcome measure*

- Change from baseline in ED staff emotional exhaustion using the Maslach Burnout Inventory (MBI), examined on weeks 11 and 19.

### *Secondary outcome measures*

- Change from baseline in retention and adherence of study participants from both arms, when examined on weeks 11 and 19.
- Change from baseline in ED staff anxiety and depression scores, as measured by the Depression, Anxiety and Stress Scale (DASS) on weeks 11 and 19.
- Change from baseline in levels of mindfulness among ED staff, as measured by the Five Facet Mindfulness Scale (FFMS) at weeks 11 and 19.
- Enhanced Professional Quality of Life Scale (PQoLS) scores on weeks 11 and 19, compared with baseline for participants in the intervention arm.

- Changes in safety attitudes related to teamwork, safety climate, job satisfaction, perceptions of management, stress recognition and working conditions, as measured by the Safety Attitudes Questionnaire (SAQ) on weeks 11 and 19.
- Reduced 24 hour ambulatory blood pressure (ABP) compared with baseline when measured on week 11 for participants in the intervention arm.
- Change from baseline of heart rate variability as measured daily by individual Fitbit wearable devices, with final measures on week 11.
- Change from baseline in the number of participants from the intervention arm, adhering to daily meditation practice, as measured by a bespoke application (app) linked to an individual Fitbit device.
- Change from baseline in participant salivary cortisol using Enzyme-linked Immunosorbent Assay (ELISA) on week 11.
- Store blood samples for subsequent immunological and epigenetic analysis.

Impact on participants in the intervention arm, measured through qualitative interviewing and logbooks on week 19.

## METHODS

### Study design

The design of this feasibility study is based on the guidelines for non-pharmacological clinical trials by the Consolidated Standards of Reporting Trials (CONSORT) group.<sup>16</sup> This is a stratified feasibility RCT with an intent-to-treat protocol, using two study arms (passive control and intervention) with single blind outcome assessors, based at a single centre (St. James's Hospital, Dublin). Once ethical approval was obtained, eligible, consenting ED staff was randomised into two experimental groups: passive control group and mantra intervention group (Fig. 1).

Stratified randomisation allowed firstly for equal gender ratios in each group and secondly, equal distribution of individuals from different ED roles (nursing, other health care professionals, allied health care staff, administrative staff and medical). A comprehensive list of inclusion and exclusion criteria can be found in Tables 1 and 2.

**Table 1: Inclusion criteria**

Inclusion criteria
• Staff member (nurse or doctor) of the ED department of St. James's hospital, Dublin
• Preference to participate in the study
• Over the age of 18 years

**Table 2: Exclusion criteria.**

Exclusion criteria
• Alcohol or substance abuse within the past 6 months
• Are currently using (at the time of enrolment) anti-psychotic medication or recently started on anti-depressant medication (less than 3 months at the time of enrolment). Participants on a stable dose of anti-depressant medication (for more than 3 months) will be permitted but advised to consult with their GP or psychiatrist prior to enrolment
• A diagnosis of schizophrenia
• More than 4 consecutive classes of meditation training or mind-body practices (including yoga and tai-chi) in the past 2 years
• Not available to attend all programme dates

Participants allocated to the intervention group ( $n = 30$ ) will discuss prescribed texts (related to meditation practice and the meaning of healthcare) and learn mantra meditation over a 6-week period (4 x 4 hour sessions), accompanied by 20 minutes of twice-daily mantra meditation practice. Participants in the passive control group ( $n = 30$ ) will work as usual and will not attend regular meetings. Data will be collected at 3 time points (T1-3): pre- (two weeks before intervention; week 1), post- (three weeks after intervention ends; week 11), and at a two month follow-up (week 19). Participant feedback on the intervention and the research study as well as experiences of learning meditation will also be sought through qualitative interviews (week 19). Intervention fidelity will be ensured through a syllabus checklist, which will be marked after each session by facilitators and independent observers.

### Recruitment

Staff at the Health Research Board of Ireland (HRB) Wellcome – Clinical Research Facility (CRF) based at St. James's Hospital will act as data controllers and recruiters of study participants. A presentation of the study aims and objectives was provided to all ED staff, after which, study recruitment posters and information booklets were distributed. Interested staff members contacted the CRF directly by email or telephone to express interest in participating in the study. Volunteers who passed the inclusion and exclusion criteria (Tables 1 and 2) were asked to join the study and allocated a unique identification code (P001 to P060) post randomisation. Eligible participants were taken through a detailed pre-approved consent form by CRF staff, prior to enrolment. This process ensured no interference in the recruitment process by the trial organisers; all outcome assessors will be blind to individual participant identification throughout the study.

### Randomisation

The participants were stratified by work role and gender. Computer generated random numbers were generated to allocate to treatment or control group by an independent statistician. Researchers remained blinded to treatment allocation.

### Mantra meditation intervention programme

Four mantra meditation contact sessions will take place over two consecutive weeks followed by two fortnightly sessions (total of 6 weeks). Each session will be four hours, inclusive of two 10 minute break periods. Two experts in the area of mantra meditation and healthcare provision will co-deliver each session, which will be delivered in line with a structured manual. The objectives of the programme are to teach participants the basic principles and practice of mantra meditation, to support the embedding of the practice of mantra meditation in the daily life of participants, and to facilitate the development of an increased level of awareness. A number of key tools will be used to achieve these objectives, including: the provision of structured talks within a classroom setting (the same talks will be uploaded onto the bespoke study application each week), meditation practice during the class, Q and A sessions with teachers, and online support throughout the programme. Specific texts were chosen to support the themes of each session, which include: how to meditate, distractions, developing the practice, being versus doing, attention, stages of meditation and the meaning of health, suffering and death. The mantra used in this study will be the Aramaic word maranatha, which is usually broken into four syllables: ma-ra-na-tha.

Retention and adherence of the study participants will be carefully monitored throughout the programme.

### Bespoke application linked to a wearable Fitbit® device

A bespoke application, linked to a wearable Fitbit® device will be used to promote adherence to daily meditation (Figure 2). The app will record heart rate variability, movement and sleep via a Fitbit® device when the participant utilises the app timer. The app will also record the duration and frequency of meditation practice on a daily basis. Participants from both control and intervention groups will wear an individual Fitbit® device that will record heart rate variability and sleep patterns for the duration of the programme (6 weeks). However, only recruits from the intervention group will download a bespoke app to their smartphone (Android and Apple devices), which will link to the Fitbit® device. All data will be anonymised and gathered for analysis at the end of the 6 week programme period.

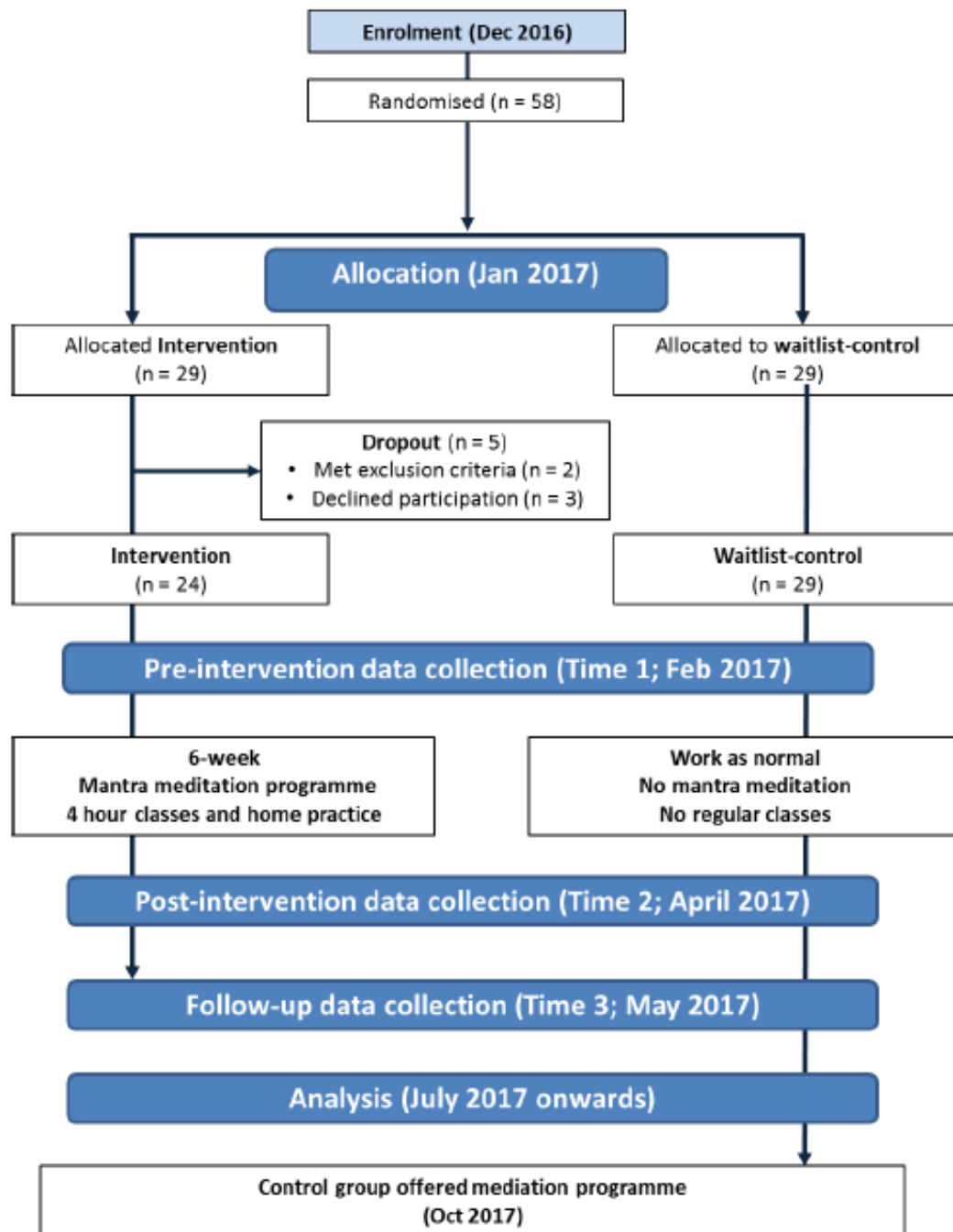
### Sampling and time points

All study participants (passive control and intervention group) will be invited to complete questionnaires (Table 3), on one of the following days at each time point: Time 1 (two weeks before session 1); Time 2 (three weeks after session 4); Time 3 (two months after the end of the programme) (Figure 1). Blood and saliva samples will be gathered on Times 1 and 2 only and will be processed for long-term storage at -80°C in monitored freezers. Analysis of these biological samples will be subject to additional funding.



**Figure 2: Bespoke application and wearable Fitbit® device.**

A bespoke application designed specifically for this project (includes a meditation timer and programme audio files) will be used to promote adherence to daily meditation practice. Heart rate variability measurements will be taken by a wearable Fitbit® device during meditation practice; heart rate variability data will subsequently be downloaded by the study application, which can be accessed by the data controller.



**Figure 1: Participant flow during the study, including time points for questionnaires and biological sampling.**

**Table 3: Biological samples and planned future investigations.**

Sample	Investigation
3 ml whole blood (EDTA)	Serum pro-inflammatory cytokines (Interleukin [IL-6], Tumour Necrosis Factor[TNF]- $\alpha$ )
8.5 ml whole blood (PaxGene DNA)	Epigenetic modification of DNA
2.5 ml whole blood (PaxGene mRNA)	Pro-inflammatory cytokine mRNA (IL-6, TNF- $\alpha$ )
1 ml saliva	Salivary cortisol

#### **Data collection and management**

All participants will complete questionnaires at pre-intervention (T1), post-intervention (T2) and at two month follow-up (T3). Participants will be asked to complete questionnaires at the CRF. All data will be pseudo-anonymised and stored on password-protected computers in locked locations by the data controller. Statistical analysis and appropriate collation of data will be under the supervision of a study statistician and the CRF data controller. All outcome assessors will be blinded. All personal data will be stored in a secure

environment on encrypted computers, in accordance with the Irish Data Protection Act (1998).

### **24-hour ambulatory blood pressure (ABP) measurements**

Participants from both study groups will wear a 24 hour ABP monitor for a 24 hour period at time points 1 and 2 (weeks 1 and 11). Blood pressure readouts will be analysed by blind outcome assessors at the end of the study programme.

### **Study questionnaires**

#### *Maslach Burnout Inventory (MBI; Maslach et al, 1986)*

The MBI is a 22-item scale designed to measure burnout in human services professionals. It comprises three subscales which examine emotional exhaustion, depersonalisation and personal accomplishment. It has since been validated as a reliable and reproducible survey instrument by numerous studies<sup>17</sup>.

#### *Depression, Anxiety and Stress Scale (DASS; Lovibond et al, 1995)*

The DASS represents a widely used, valid and reproducible screening tool to assess symptoms of depression, anxiety, and stress in different community settings, including hospitals<sup>18</sup>. It is a 21-item inventory comprising three sub-scales: (a) the depression sub-scale which measures hopelessness, low self-esteem, and low positive affect; (b) the anxiety scale which assesses autonomic arousal, musculo-skeletal symptoms, situational anxiety and subjective experience of anxious arousal; and (c) the stress scale which assesses tension, agitation, and negative affect.

#### *Professional quality of life scale for compassion satisfaction and compassion fatigue version 5 (Pro-QOL; Stamm et al, 2005)*

The ProQOL scale to addresses compassion levels in HCPs. It comprises three subscales: compassion satisfaction (pleasure derived from helping others), burnout, and compassion fatigue. It is widely regarded as a reliably valid instrument for measuring compassion levels in HCPs<sup>17</sup>.

#### *Five Facet Mindfulness Questionnaire (FFMQ;)<sup>19</sup>*

The FFMQ is a reliable and validated 39-point questionnaire that measures an individual's level of mindfulness. The five subsets examined by this survey instrument include: observing (watching internal experiences both physical and mental), describing (labelling internal experiences), acting with awareness, non-judgement and non-reactivity (to internal and external stimuli). Although this study will not apply mindfulness-based techniques, mantra meditation

practice, cultivates the trait or state of mindfulness; therefore, we expect the FFMQ responses to change in individuals randomised to the mantra meditation group.

#### *Safety Attitudes Questionnaire (SAQ; 30-item inventory)*

Safety culture will be measured by the SAQ, a tool which is widely used, has good psychometric properties and is associated with clinical outcomes<sup>20</sup>. The SAQ comprises six domains; teamwork climate, safety climate, job satisfaction, perceptions of management, stress recognition, and working conditions. Each item on the SAQ is rated on a 5 point Likert scale.

#### *Qualitative Methodology (semi-structured interviews and logbooks)*

Semi-structured interviews, lasting approximately 30 minutes, will be conducted with a subsample of participants who received the intervention (target  $n = 10$ ). Potential consenting participants will be emailed a study information sheet (on T3) outlining the broad topics to be explored: benefits and risks associated with participating, confidentiality, use of data, and the time commitment required. During the interview, questions will focus on gaining participants' insights into the following: delivery of the intervention, perceived barriers, facilitators, daily meditation practice as well as any experienced benefits or negative impacts of meditation. In addition, the interview will explore the effect of meditation on their work performance and on perceived impact on their patients, colleagues, and the healthcare organisation. The interview topic guide will be developed in the context of an appropriate health psychology model of coping and wellbeing. Interviews will be audio-recorded and transcripts will be thematically analysed taking a realist, phenomenological approach.

#### **Participant logbooks**

Participants will be encouraged to add entries to their logbooks on a weekly basis, in response to three basic questions. These questions will be designed to gather information related to their thoughts and feelings on their meditation practice, impact on personal and work life balance and any other relevant topics.

#### **Statistical assessment**

Statistical analysis will be carried out by statistician (blind outcome assessor) using R statistical software, supported with SPSS v23. Data will be analysed using simple descriptive and inferential statistics ( $t$ -test and analysis of variance methods; longitudinal analysis will be employed using repeated measures and analysis of covariance methods). Methods to integrate all the data will be developed and operationalised to allow for full assessment of the effectiveness of the intervention. The level of significance for all tests will be set at  $p < 0.05$ .



### **Power calculations**

The number of participants has been selected for a study of a continuous response variable from independent control and experimental subjects with 1 control per 1 experimental subject (30 versus 30). In a pilot study by RCPI, which assessed the impact of mantra meditation on work-related stress using the MBI (among others, it was found that the response within each subject group for emotional exhaustion was normally distributed with a mean score of 26.8 pre- and 22 post-intervention for all subjects (n=19). We are planning a study of a continuous response variable from matched pairs of study subjects. Prior data indicate that the difference in the response of matched pairs is normally distributed with standard deviation 12.3. If the true difference in the mean response of matched pairs is 3.8, we will need to study 84 pairs of subjects to be able to reject the null hypothesis that this response difference is zero with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. However, power calculation requirements will not be met in this instance, as this is a feasibility study, the sole purpose of which is to determine whether it is feasible to conduct such a study on a larger scale. The results of this power calculation will be applied in the subsequent larger RCT. (calculations were made using PS software; <http://biostat.mc.vanderbilt.edu/wiki/Main/PowerSampleSize>).

### **Ethics**

Ethical approval for access to consenting ED staff has been approved by the Joint Ethics Committee (JAC) of St. James's and Tallaght Hospitals, prior to commencing recruitment (2016-07). Participants received short information booklets to explain the study outline as well as a clear and concise pre-approved consent forms.

### **Risk associated with the project design**

- Time taken and inconvenience for study participants (medium risk)
- Potential identification of interviewees from audio files (medium risk)
- Poor recruitment rates (medium risk)
- High dropout rate (medium risk)
- Poor meditation homework adherence (high risk)

### **Methods for protecting against bias**

The following categories of bias will be addressed in the study design and throughout the project:

#### **Selection bias**

Consenting volunteers will come from the same ED department, located in St. James' hospital. Furthermore, recruits will be processed through a stratified randomisation design that will ensure equal gender ratios

in each group, as well as even distribution of different ED roles. Strict exclusion and inclusion criteria were applied for potential participants (Tables 2 and 3).

#### **Performance bias**

Since participants will all come from the same ED, contamination between groups is a possibility. Members of the intervention group will be encouraged not to discuss meditation or the intervention with colleagues in the passive control group. Since homework adherence remains an issue with interventions that require daily meditation practice, we will use a bespoke application coupled with a wearable Fitbit® device to monitor heart rate variability during daily meditation practice.

#### **Attrition bias**

A 24% (6 out of 25) attrition rate was observed in the recent RCPI pilot study (unpublished). As a result, we might assume similar attrition rates in this study. Drop-out might also become an issue for the two-month follow-up time point.

#### **Detection bias**

We will ensure that the length of follow-up will be the same in both groups (two months from the last session for either group). Outcome assessors responsible for collating and processing survey material will be blinded as to the group status of study participants. Furthermore, the intervention survey instruments represent valid, reliable measures for HCPs that will be applied across both groups.

### **Adverse event reporting**

Based on previous studies as well as the nature of the intervention, we expect that participants will not experience any side effects of the intervention. Yet, in the unlikely scenario, adverse events will be recorded and reported to the JAC of St. James's and Tallaght Hospitals. The CRF data controller will report any adverse effects to the PI who will generate an incident report for the trial oversight committee. Consenting participants in need of psychological or medical assistance will be referred on for assistance.

#### **Trial status**

Participants have been recruited and randomised as of January 31<sup>st</sup> 2017.

## **DISCUSSION**

This feasibility pilot study will pave the way for an efficient, effective and larger RCT that will test whether or not mantra meditation can reduce emotional exhaustion in staff working in large hospital departments. In the long term, we hope to provide a manual of stress

reduction using mantra meditation for HCPs that will advise hospital departments in the set-up and maintenance of an ongoing mantra meditation programme. It is envisioned that this manual will subsequently help guide advances in HCP self-care leading to improved well-being, reduced costs and improved patient satisfaction and safety.

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