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Mindfulness-based psychological interventions for improving mental well-being in medical students and junior doctors (Protocol)

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Mindfulness-based psychological interventions for improving mental well-being in medical students and junior doctors (Protocol).
Cochrane Database of Systematic Reviews 2020, Issue 9. Art. No.: CD013740.
DOI: 10.1002/14651858.CD013740.

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[Intervention Protocol]

Mindfulness-based psychological interventions for improving mental well-being in medical students and junior doctors

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Editorial group: Cochrane Common Mental Disorders Group.
Publication status and date: New, published in Issue 9, 2020.

Citation: Turner T, Tee QX, Hasimoglu G, Hewitt J, Trinh D, Shachar J, Sekhar P, Green S. Mindfulness-based psychological interventions for improving mental well-being in medical students and junior doctors (Protocol). *Cochrane Database of Systematic Reviews* 2020, Issue 9. Art. No.: CD013740. DOI: 10.1002/14651858.CD013740.

ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To assess the impact of psychological interventions with a primary focus on mindfulness on the mental well-being and academic performance of medical students and junior doctors.

BACKGROUND

Description of the condition

The medical profession is recognised for its challenging and demanding nature, which is especially the case for novices such as medical students and junior doctors. This group face substantial personal and professional stressors, which places an enormous strain on their mental well-being.

Compared to age-matched peers, levels of psychological distress and prevalence of depression and anxiety have been found to be consistently higher in medical students, according to a systematic review focused on US and Canadian medical students (Dyrbye 2006). An Australian study found that 48% of medical students were psychologically distressed, more than four times that of age-matched peers (Leahy 2010). Similarly, a US study reported that 47% of students were 'burnt out' and 49% experienced depressive symptoms, with lower scores of Mental QOL (quality of life) compared to aged-matched peers (Dyrbye 2007). The emotional status of students entering medical school appears to be similar to the general population according to depression and anxiety measurements, suggesting that medical education has the potential to significantly influence the mental well-being of medical students (Smith 2007). Similarly, the first National Mental Health Survey of Doctors and Medical Students conducted by Beyond Blue found that medical students and doctors are at greater risk of psychological distress compared to the general community, with medical students and young or female doctors being at greatest risk (Beyond Blue 2019; Gunasingam 2015). Compared to their older counterparts, young doctors were found to work longer hours (an average of 50 hours per week), and suffer from psychological distress and suicidal thoughts to a much greater extent (Beyond Blue 2019).

There are several contributing factors reported by students, which include high expectations, competitiveness, frequent examinations, demanding study load and class content, time pressures, family-related issues and other extracurricular activities (Pereira 2013). In addition, students identified fear of making mistakes or fear of making the incorrect decision about patient care during clinical rotations as stressors (Witt 2019). Burnout is a “state of mental and physical exhaustion” (Ishak 2013), characterised by “emotional exhaustion, depersonalisation and a diminished sense of accomplishment” (Ishak 2009). Lack of time, in combination with a demanding study load, reduces available time to devote to self-care and leisure pursuits, which decreases students’ stress tolerance and makes them prone to burnout. In the same way, burnout is also prevalent among junior doctors, including interns (Gunasingam 2015), and residents as they face many new challenges on entering the medical workforce and learning how to navigate the medical system for the first time. They must learn to manage and communicate with patients as well as other healthcare providers, while also handling an increasingly demanding hospital workload.

In spite of this increased burden, and despite greater knowledge of and access to resources and support services, medical students are less likely to utilise such services due to embarrassment and concern over the lack of privacy and confidentiality, and the potential consequences of having a mental illness on their record (Beyond Blue 2019).

Description of the intervention

In recent years, mindfulness-based interventions have gained in popularity. The concept of mindfulness is ambiguous and difficult to define, with no universally accepted definition. However, Kabat-Zinn described mindfulness as “the awareness that emerges through paying attention on purpose, in the present moment, and non judgmentally to the unfolding of experience” (Kabat-Zinn 2013). This systematic review includes any psychological intervention with a primary focus on teaching the fundamentals of mindfulness: self-regulation of awareness and non-judgemental acceptance of any phenomena entering one’s attention (Baer 2003). This systematic review has been designed to investigate the effects of any of these mindfulness-based psychological interventions on the psychological health and well-being of medical students and junior doctors.

This review will focus on mindfulness interventions delivered to undifferentiated groups of medical students and junior doctors. The focus of the review is on interventions applied for preventative purposes, rather than therapeutic mindfulness interventions to treat individuals with diagnosed mental health conditions. However, we will not exclude studies which include some participants who have mental health conditions at baseline. Mindfulness programs can be conducted through a range of modalities, such as classroom-based teaching, smartphone applications and meditation retreats.

How the intervention might work

Mindfulness has been shown to be beneficial in various populations and contexts, including people suffering from depression, anxiety disorders, chronic pain and cancer, with beneficial impacts shown in medical school and prison life (Grossman 2004; Liu 2018; Schell 2019). According to Keng and colleagues, mindfulness “brings about various positive psychological effects, including increased subjective well-being, reduced psychological symptoms and emotional reactivity, and improved behavioural regulation (Keng 2011)”. Medical students and young doctors may find mindfulness training a useful tool to help improve their ability to cope with stress.

Mindfulness based psychological interventions may equip medical students and junior doctors with the ability to choose where they focus their attention, increasing their productivity and their ability to perform under stress (Kabat-Zinn 2003). Mindfulness may also allow these population to practice more self-compassion, problem-solving and a heightened sense of self awareness (Allen 2010).

Why it is important to do this review

Mental well-being and capacity for resilience are key attributes required by medical students and junior doctors, so that they can optimise patient care. Medical school and the junior years as a postgraduate are important periods of time in the career path of a doctor. This period offers an opportunity to cultivate preventative resilience practices before the accumulation of added responsibility in senior years (Ludwig 2015). Medical students and junior doctors are often time poor, with minimal time for leisure or personal pursuits outside of medicine. Therefore, it is important to establish whether mindfulness is an effective intervention which justifies its time commitment.

Academic performance is highly regarded by medical students and junior doctors. It can therefore be used as an incentive for this population to take up measures to maintain their mental well-being. Thus, in addition to broad measures of mental well-being (such as suicidal ideation and behaviour, depression, anxiety, stress and burnout), it would be worthwhile including academic performance as an outcome measure.

Two Cochrane reviews have examined the value of mindfulness interventions for women with breast cancer, and carers of people with dementia, and reviews are underway of mindfulness interventions for smoking cessation, and substance abuse. One Cochrane review has highlighted the role of mindfulness in fostering resilience amongst healthcare students (Kunzler 2020), however, there is yet to be a review that specifically examines the effect of mindfulness based interventions on mental health in this high-risk population.

OBJECTIVES

To assess the impact of psychological interventions with a primary focus on mindfulness on the mental well-being and academic performance of medical students and junior doctors.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs), including cluster-randomised trials, that compare mindfulness-based psychological interventions to no intervention or waiting-list control will be eligible for inclusion in the review. Randomised cross-over trials will also be eligible, using only data from the first treatment stage to avoid the risk of carry-over effects.

Types of participants

Eligible participants include any student studying any medical course at any year level, and junior doctors in postgraduate years one, two or three. We will exclude studies where all of the participants have pre-existing mental health conditions at baseline and a mindfulness intervention is delivered for treatment; however, we will not exclude studies which include some participants who have mental health conditions and the focus is on mindfulness as a preventative intervention delivered to undifferentiated populations. There will be no other limitations on participant characteristics, such as age, nationality or baseline health measures.

Types of interventions

Experimental intervention

We will include any psychological intervention with a primary focus on teaching the fundamentals of mindfulness as a preventative intervention, including: (i) self-regulation of awareness, and (ii) non-judgemental acceptance of any phenomena entering one's attention (Baer 2003).

This includes any means of treatment delivery. For example, face-to-face, manual-based, individual or group sessions, web-based, CD or phone apps, and retreats.

Comparator intervention

No intervention or waiting-list control.

Types of outcome measures

Changes in mental well-being through any outcome measure listed below.

Primary outcomes

1. Depression, measured using validated scales such as the Depression Anxiety Stress Scale (Antony 1998)
2. Anxiety, measured using validated scales such as the Anxiety Inventory (Beck 1988)

Secondary outcomes

1. Stress, measured using validated scales such as the Perceived Stress Scale (Cohen 1983)
2. Burnout, measured using validated scales such as the Maslach Burnout Inventory (Kristensen 2005)
3. Academic performance, measured using validated scales such as the Fundamentals of Laparoscopic Surgery Skills Test (Peters 2004)
4. Quality of life, measured using validated scales such as the Mental Health Continuum-Short Form (Lamers 2011)
5. Deliberate self-harm, measured using validated scales such as the Self-harm Behaviour Questionnaire (Gutierrez 2001)
6. Suicidal ideation, measured using validated scales such as the Suicidal Ideation Questionnaire (Reynolds 1987)
7. Suicidal behaviour, measured using validated scales such as the Suicide Behaviors Questionnaire-Revised (Osman 2001)

If a study meets the inclusion criteria but does not provide sufficient data necessary to calculate effect estimates, we will still include it in the review for narrative analyses, but will not include it in meta-analyses. For studies where we cannot pool data, we will describe their results in the text of the review, as a narrative synthesis.

Timing of outcome assessment

This review will primarily use outcome assessment immediately postintervention, but we will also extract data on outcomes at up to six months, 6 to 12 months, and over 12 months postintervention.

Hierarchy of outcome measures

We will not give preference to particular outcome measures. Where studies assess the same outcome, but measure it using different scales, we will standardise the results of the studies to a uniform scale before combining them, using standardised mean differences.

Search methods for identification of studies

Electronic searches

We will search the following databases using relevant subject headings (controlled vocabularies) and search syntax, appropriate to each resource:

- Cochrane Central Register of Controlled Trials (CENTRAL; current issue) in the Cochrane Library;
- Ovid MEDLINE (1946 onwards) (Appendix 1);
- Ovid Embase (1974 onwards);

- Ovid PsycINFO (1806 onwards);
- EBSCOhost CINAHL (Cumulative Index to Nursing and Allied Health Literature (1982 onwards);
- EBSCOhost ERIC (Educational Resources Information Center) (1911 onwards);
- Elsevier SCOPUS (all available years);
- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov; all available years);
- World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch; all available years).

We will place no restrictions on date, language or publication status.

Searching other resources

Grey literature

We will search the following sources of grey literature (primarily for dissertations and theses):

- Open Grey (www.opengrey.eu);
- ProQuest Dissertations & Theses Global (www.proquest.com/products-services/pqdtglobal.html);
- DART-Europe E-theses Portal (www.dart-europe.eu);
- British Libraries e-theses online service (EThOS) (ethos.bl.uk);
- Networked Digital Library of Theses and Dissertations (NDLTD) (http://search.ndltd.org);
- Open Access Theses and Dissertations (oatd.org).

Reference lists

We will check the reference lists of all included trials and relevant systematic reviews to identify additional trials missed from the original electronic searches (for example, unpublished or in-press citations).

Correspondence

We will contact trial authors and subject experts for information on unpublished or ongoing trials, or to request additional trial data.

Data collection and analysis

Selection of studies

Two review authors (DT and JH) will independently screen titles and abstracts of all the potential studies we identify as a result of the search, and code them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. If there are any disagreements, a third author will arbitrate (TT). We will retrieve the full-text study reports/publications, which two review authors (DT and JH) will independently screen to identify studies for inclusion. We will identify and record reasons for exclusion of the ineligible studies. We will resolve any disagreement through discussion or, if required, we will consult a third person (TT). We will identify and exclude duplicates and collate multiple reports of the same study, so that each study rather than each report is the unit of interest in the review. We will record the selection process in sufficient detail to complete a PRISMA flow diagram (Liberati 2009), and report information about the excluded studies in the 'Characteristics of excluded studies' table.

Data extraction and management

We will use a data collection form for study characteristics and outcome data, which we will pilot on at least one study in the review. Two review authors will independently extract study characteristics from included studies. We will extract the following study characteristics.

1. Methods: study design, total duration of study, number of study centres and location, study setting, and date of study.
2. Participants: number randomised, number lost to follow-up/withdrawn, number analysed, mean age, age range, gender, inclusion criteria, and exclusion criteria.
3. Interventions: intervention, comparison, concomitant medications, and excluded medications.
4. Outcomes: outcomes specified and collected, and time points reported.
5. Notes: funding for trial, and notable conflicts of interest of trial authors.

Two review authors (to be confirmed) will independently extract outcome data from included studies. We will resolve disagreements by consensus or by involving a third person (TT or SG). One review author (to be confirmed) will transfer data into the Review Manager (Review Manager 2014) file. We will double-check that data are entered correctly by comparing the data presented in the systematic review with the data extraction form.

Main planned comparisons

The main planned comparison will be with waiting-list control or no mindfulness intervention.

Assessment of risk of bias in included studies

Two review authors (JS and one other) will independently assess risk of bias for each study using version two of the Cochrane 'Risk of bias' tool (RoB2), outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019b). We will resolve any disagreements by discussion or by involving another author (TT or SG). We will assess the risk of bias of a specific results of a trial according to the following domains:

1. bias arising from the randomisation process;
2. bias due to deviations from intended interventions;
3. bias due to missing outcome data;
4. bias in measurement of the outcome; and
5. bias in selection of the reported result.

We will assess the risk of bias for the outcomes of the included trials that will be included in our 'Summary of Findings' table. We are interested in quantifying the effect of assignment to the interventions at baseline, regardless of whether the interventions are received as intended (the 'intention-to-treat effect').

Signalling questions in the RoB2 tool will provide the basis for the tool's domain-level judgements about the risk of bias. This risk of bias judgement options will be high, some concerns or low. These algorithm-generated judgements will then be verified by the authors and revised if necessary. This will depend on whether the judgement concerns something likely to affect the ability to draw reliable conclusions from the study. Generally, judging a result to be at a specific level of risk of bias for a specific domain indicates

the result has an overall risk of bias at least this severe. However, if 'Some concerns' arise in multiple domains, authors may decide on an overall judgement of 'High' risk of bias for that outcome.

When considering treatment effects, we will take into account the risk of bias for the studies that contribute to that outcome.

We will assess the risk of bias for cluster-randomised trials using the RoB2 tool with the additional domain 'Bias arising from the timing of identification and recruitment of participants'. We will give additional consideration to the recruitment bias that is unique to cluster-randomised trials. We will also use the RoB2 tool for cross-over RCTs, from which we will only use data from the first period. We will consider the possibility of selective reporting due to isolated analysis of the first data set rather than the complete study timeline.

We will enter and organise our RoB 2 assessments on an Excel spreadsheet (Microsoft Excel RoB2 Macro), and will use the Bridges open access repository to share assessments between authors (Monash University 2020).

Measures of treatment effect

Dichotomous data

We will analyse treatment effects for dichotomous outcomes as risk ratios (RR) with 95% confidence intervals (CI).

Continuous data

For continuous outcomes, we will assess treatment effects using the mean differences (MD) for outcomes measured on the same scale, and the standardised mean difference (SMD) for outcomes measured on different scales. We will calculate all treatment effects with 95% CIs. We will use a P value of 0.05 or less to indicate statistical significance of effects. We will narratively describe skewed data reported as medians and interquartile ranges.

Unit of analysis issues

Participants in RCTs are the unit of analysis.

Cluster-randomised trials

We will include and analyse any identified cluster-randomised trials as long as the trialists undertook proper adjustment for the intracluster correlation, as described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2019c).

Cross-over trials

Due to the risk of carry-over effects, we will only use data from the first phase of cross-over trials.

Studies with multiple treatment groups

Where studies have additional arms that do not meet the inclusion criteria, we will only include data relating to the included intervention and one control arm in the review. If a study has more than two arms that meet the inclusion criteria, we will split the data in the control arm equally to produce two (or more) pairwise comparisons. If one study presents an outcome as dichotomous data and another study presents the outcome as continuous data, we will use an odds ratio (OR) for the dichotomous data and then re-express it as an SMD. This will allow us to pool the continuous and dichotomous data sets.

Dealing with missing data

We will contact investigators or study sponsors in order to verify key study characteristics and obtain missing numerical outcome data where possible (e.g. when a study is identified as abstract only). Where possible, we will use the Revman calculator to calculate missing standard deviations using other data from the trial, such as confidence intervals, based on methods outlined in *The Cochrane Handbook* (Higgins 2019a). Where this is not possible, and the missing data are thought to introduce serious bias, we will explore the impact of including such studies in the overall assessment of results by a sensitivity analysis.

Assessment of heterogeneity

We will assess heterogeneity in two ways. First, we will explore the presence of clinical heterogeneity, by comparing population groups, interventions or outcomes across trials. In the case of clear clinical heterogeneity, we will not pool the results. We will only perform meta-analysis when trials are sufficiently homogeneous in terms of participants, interventions, and outcomes. If there is no obvious clinical heterogeneity, we will use statistical tests to determine the presence and level of statistical heterogeneity for each outcome, namely the Chi^2 test and the I^2 statistic (Higgins 2003). We will interpret the I^2 statistic, accompanied by a statistically significant Chi^2 test, as follows (Deeks 2017):

- 0% to 40% might not be important;
- 30% to 60% may represent moderate heterogeneity;
- 50% to 90% may represent substantial heterogeneity; and
- 75% to 100% may represent considerable heterogeneity.

This assessment will be made with an awareness that the importance of the observed value of I^2 depends on (i) magnitude and direction of effects and (ii) strength of evidence for heterogeneity (e.g. P value from the chi-squared test, or a confidence interval for I^2). If we identify substantial heterogeneity, we will report it and explore possible causes by pre-specified subgroup analysis.

Assessment of reporting biases

If we are able to pool more than 10 trials, we will create and examine a funnel plot to explore possible small study biases for the primary outcomes. We will also perform a formal statistical test for asymmetry (Egger 1997).

Where possible, we will attempt to find protocols or trial registrations for included studies to see whether they reported all planned outcomes.

Data synthesis

We will undertake meta-analyses only where this is meaningful, i.e. if the treatments, participants and the underlying clinical questions are similar enough for pooling to make sense. The random-effects model takes into account the fact that different studies are estimating various, yet related, intervention effects (DerSimonian 1986). We will use this model, owing to the anticipated variability in the intervention and participants of our included studies.

Subgroup analysis and investigation of heterogeneity

We plan to carry out the following subgroup analyses for any outcomes with substantial heterogeneity. We will use the formal

test for subgroup differences in Review Manager (Review Manager 2014), and base our interpretation on this. We plan to undertake subgroup analyses to investigate the impact of the following factors on the magnitude of the treatment effect.

1) Intervention duration: less than three months, three to six months, and 6 to 12 months

2) Proportion of study population meeting study-defined levels of compliance with home meditation: 0 to 50%, over 50%

Given the complexity of ways the intervention may be delivered, we also intend to explore the impact of intervention intensity and report findings narratively.

Sensitivity analysis

We will use sensitivity analyses to assess the robustness of results to key assumptions, such as the impact of imputed data and studies at high risk of bias.

Summary of findings and assessment of the certainty of the evidence

We will create a 'Summary of findings' table using the following outcomes:

1. suicidal ideation;
2. suicidal behaviour;
3. depression;
4. anxiety;
5. stress;
6. burnout; and
7. academic performance.

We will use the five GRADE considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of a body of evidence as it relates to the studies which contribute data to the meta-analyses for the prespecified outcomes. We will incorporate the RoB2 analysis into our GRADE assessment. We will use methods and recommendations described in Chapter 14 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2019), and will generate the table using GRADEpro software (GRADEpro GDT). We will justify all decisions to downgrade the quality of studies using footnotes and we will make comments to aid reader's understanding of the review where necessary.

Two review authors will make judgements about evidence quality independently, resolving disagreements through discussion or by involving a third author (TT or SG). We will justify and document our judgements, and incorporate them into our reporting of each outcome's results.

ACKNOWLEDGEMENTS

We thank the editorial team of the Cochrane Common Mental Disorders Group (CCMD) for providing guidance during protocol development. We developed the search strategies with assistance from Steve McDonald and Sarah Dawson, the CCMD Information Specialist.

The authors and the CCMD Editorial Team, are grateful to the following peer reviewers for their time and comments: Roshan Arjun Ananda, Sanjush Dalmia, Masarat Jilani, Nabihah Malik, Tess Moore, Lindsay Robertson and Trevor Sheldon. They would also like to thank Cochrane Copy Edit Support for the team's help.

CRG funding acknowledgement: the National Institute for Health Research (NIHR) is the largest single funder of the CCMD Group.

Disclaimer: the views and opinions expressed herein are those of the review authors and do not necessarily reflect those of the NIHR, the NHS or the Department of Health and Social Care.

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APPENDICES

Appendix 1. Preliminary MEDLINE (Ovid) search strategy

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations and Daily <1946 onwards>

1 (houseman* or housemen).mp.
2 (house officer*).mp.
3 ((train* or residen* or foundat*) adj3 (doctor* or medic* or physician*)).mp.
4 ((doctor* or physician*) adj7 residen*).mp.
5 (medical school* or (residen* adj2 hospital*)).mp.
6 (medics or (medic* adj1 (undergrad* or graduate* or postgrad* or train*))).mp.
7 ((student* or junior*) adj1 (doctor* or medic* or physician*)).mp.
8 (intern or interns or internship*).mp.
9 Students, Medical/ or exp Education, Medical/ or Schools, Medical/
10 Education, Medical, Graduate/ or Medical Internship/
11 (fy1 or fy2 or pgy1 or pgy2).mp.
12 ((graduat* or undergrad* or postgrad* or train*) adj1 (doctor* or physician*)).mp.
13 or/1-12
14 Relaxation Therapy/ or Mindfulness/ or Meditation/
15 (relax* therap* or mindful* or mind train* or meditat*).mp.
16 (14 or 15)
17 randomized controlled trial.pt.
18 controlled clinical trial.pt.
19 (RCT or randomi?ed).mp.
20 placebo.mp.38895
21 random*.ab.
22 trial.mp.
23 groups.ab.
24 (waitlist* or wait* list* or ((treatment or care) adj2 usual)).mp.
25 exp clinical trial/ or clinical trials as topic/
26 cross-over studies/
27 random allocation/ or single-blind method/ or double-blind method/
28 ((single or double or triple or treble) adj2 (blind* or mask* or dummy)).mp.
29 or/17-28
30 (13 and 16 and 29)

HISTORY

Protocol first published: Issue 9, 2020

CONTRIBUTIONS OF AUTHORS

TT: Oversaw development of methods, drafting and revision of the protocol
QXT: Developed the concept for the review and developed initial methods
GH: Developed methods and drafted the protocol
JH: Reviewed feedback on the protocol
DT: Reviewed feedback on the protocol
JS: Revised the protocol in line with feedback
PS: Revised the protocol in line with feedback
SG: Developed the concept for the review and oversaw the writing of the protocol

DECLARATIONS OF INTEREST

TT: no conflicts of interest
QXT: no conflicts of interest
GH: no conflicts of interest
JH: no conflicts of interest
DT: no conflicts of interest
JS: no conflicts of interest

PS: no conflicts of interest
SG: no conflicts of interest

SOURCES OF SUPPORT

Internal sources

- Cochrane Australia, Australia

  Cochrane Australia supports contributors to Cochrane around Australia, including researchers, editors, authors and review groups.
- School of Public Health and Preventive Medicine, Monash University, Australia

  Support for this review was provided as part of the School of Public Health and Preventive Medicine Scholarly Intensive Program.

External sources

- National Institute for Health Research (NIHR), UK

  Editorial work on this protocol was supported by NIHR Cochrane Infrastructure funding to the Common Mental Disorders Cochrane Review Group.