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[Intervention Protocol]

Organisational level interventions for reducing occupational stress in healthcare workers

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ABSTRACT

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

To evaluate the effectiveness of organisational level interventions aimed at reducing stress in healthcare workers compared to no intervention or alternative interventions.

BACKGROUND

Description of the condition

Work-related stress is the adverse response employees may experience when faced with work demands and pressures that challenge their knowledge and skills, as well as ability to cope (Leka 2004). As the healthcare workforce comprises a range of clinical, allied health, administrative and support roles, the causes of stress can vary between and within occupations. Moreover, research carried out in the healthcare context highlights a broad range of factors related to occupational stress, including work overload (Bilimoria 2017), time pressures (Andersen 2013), shift patterns (Harbeck 2015), patient-related stressors (Weigl 2017), role ambiguity or role conflict (Ben-Itzhak 2015), violence from patients and patients' family members (Bowman 2014), and a risk of exposure to infectious diseases (NIOSH 2008).

For individuals, the psychological, behavioural and physiological effects of occupational stress in this context include lower levels of self-esteem, motivation and job satisfaction (Li 2014), anger and frustration (Lewandowski 2003), and increasing levels of psychological, musculoskeletal and cardiovascular disorders (Bernal 2015; Kivimaki 2012; Kärkkäinen 2013; Levi 1996). The impact of occupational stress on organisations may include lower levels of productivity and performance (Michie 2002), poor relationships and teamwork (Gray-Toft 1981), and increased absenteeism and turnover (Leontaridi 2002).

Organisational level stress interventions, therefore, have the potential to not only improve worker well-being (Fletcher 2005), enhance teamwork and communication (Lown 2010), and patient safety and quality of care (Litvak 2005), but based on evidence

from the broader literature, they can also enhance the efficiency and cost-effectiveness of organisations as a whole (EU-OSHA 2014).

Description of the intervention

According to Ivancevich 1990, stress management interventions in an organisational context comprise any planned activity that focusses on stress prevention or initiatives that support individuals to manage the negative effects of stress when it occurs, or both. Stress management interventions are targeted at the individual, group or organisational level, or a combination of these levels (Giga 2003).

At the individual level, interventions are aimed at enhancing worker coping strategies, with the view to changing their physiological, emotional or behavioural reactions to stressors. At the organisational level, the focus is on adapting the work environment and tackling sources of stress (Naghieh 2015). The literature suggests that interventions aimed at tackling work-related stress should focus primarily on the organisational level, rather than on individuals, due to a number of factors, including maximising the influence, scope, promptness and sustainability of interventions (Karanika-Murray 2015; Michie 2002). This review, therefore, focusses on organisational level interventions.

In order to manage the heterogeneity of study designs, measures and intervention content (Montano 2014), this review categorises organisational interventions to prevent occupational stress in healthcare workers under six broad groupings.

1. Interventions to decrease job demands.
2. Interventions to increase job control.
3. Interventions to improve workplace social support.
4. Interventions to improve clarity in work tasks/roles/organisation.
5. Interventions to enhance task design/work processes.
6. Interventions to improve organisational communication.

How the intervention might work

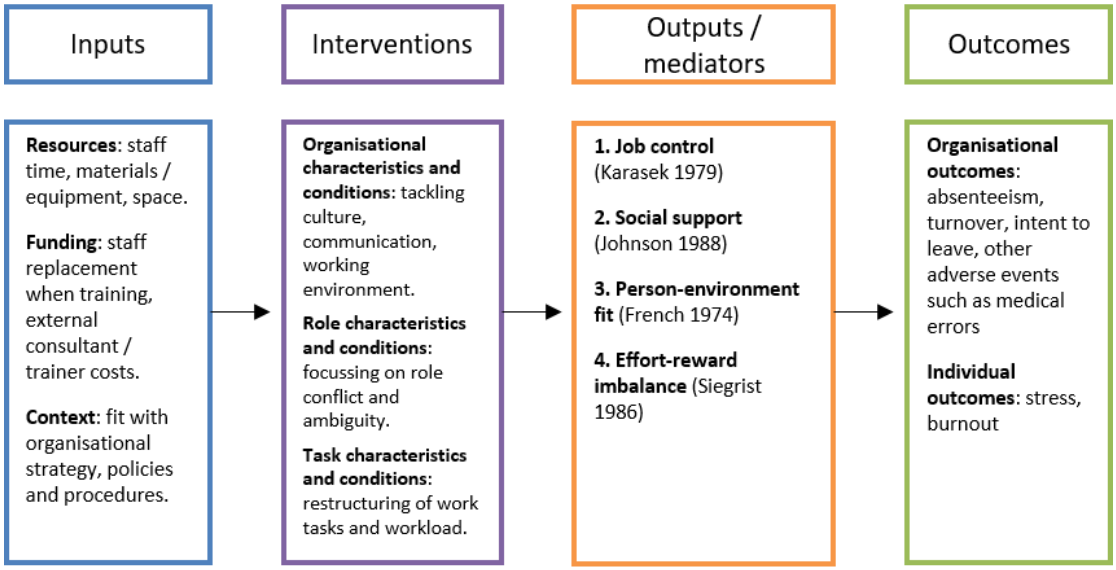
Within a work context, stress research has predominantly focused on aspects around:

1. job control (Karasek 1998);
2. social support (Johnson 1988);
3. person-environment fit (French 1974); and
4. effort-reward imbalance (Siegrist 1986).

The routes by which interventions act to prevent stress will differ depending on their viewpoint and theoretical approach. However, organisational level stress interventions aim to modify the work environment, as opposed to individual level stress interventions, which focus on enhancing worker coping strategies.

Organisational level stress interventions attend to risks associated with physical, psychological and psychosocial factors, including improving conditions relating to environmental hazards, and work flexibility and intensity. This incorporates activities, such as enhancing surveillance of occupational risks, communications and working practices, with the view to improving organisational and workforce outcomes (Montano 2014) (see Figure 1).

Figure 1. Logic model of the intervention



Note: It is possible for some interventions to target more than one output. For example, tackling role ambiguity may lead to higher levels of job control as well as a better person-environment fit.

In reference to the categories described in the previous section, organisational interventions to prevent work-related stress in healthcare workers may thus focus on various initiatives including:

1. decreasing job demands by having more people do the same tasks, giving more time per person to do the same tasks or reducing the number of tasks per person;
2. increasing job control by reducing hierarchy or increasing autonomy;
3. improving workplace social support through enhancing peer to peer or supervisory support;
4. improving clarity in work tasks/roles/organisation by improving role descriptions, responsibilities or supervision;
5. enhancing task design/work processes by developing learning or new care models/paradigms; and
6. improving organisational communication, including feedback, encouraging openness or developing a shared vision.

The interventions highlighted in 1 to 6 above could also include an element of communication, such as clarifying work tasks and roles.

Why it is important to do this review

Given the rising demand on health services internationally, it is not surprising that workers in this environment face unprecedented pressure. Not only does the healthcare sector rank amongst the highest in terms of most stressful of occupations (HSE 2016), but studies also indicate that healthcare workers have higher rates of substance abuse, depression, anxiety and suicide (Pyrek 2011). Although healthcare organisations are actively implementing strategies to prevent and manage employee stress, the evidence supporting the effectiveness of interventions is either of low-quality or does not highlight any effect on stress levels (Ruotsalainen 2015). Not only does this lead to questions of inappropriate support mechanisms for healthcare workers, and the potential negative impacts on patient care, but it also raises concerns about resource wastage on untested interventions at a time when there are increasing efforts to improve organisational efficiency.

There have been a number of reviews published on the effectiveness of interventions for preventing occupational stress or reducing its negative effects (Awa 2010; DeFrank 1987; Giga 2003; Joyce 2016; Lamontagne 1987; Murphy 1996; van der Hek 1997; van der Klink 2001). These reviews have focused on populations that are broader than healthcare populations. Other studies have been restricted to particular healthcare workers, namely nurses (Edwards 2003; Jones 2000; Mimura 2003), and physicians (Regehr 2014; West 2016). A separate review of healthcare workers is needed, as the intervention features designed for this particular occupational group may be different to other occupations (Ruotsalainen 2015).

A Cochrane Review originally published in 2006 and updated most recently in 2015, assessed the effectiveness of work and per-

son-directed interventions for preventing stress at work in healthcare workers (Ruotsalainen 2015). It identified organisational interventions aimed at improving: working conditions, support or mentoring, the content of care, communication skills and work schedules. A new Cochrane Review is required, focusing specifically on the evidence of organisational level interventions (including cohort and randomised controlled trial (RCT) studies not included in the previous review) exploring the possibility of differing intervention effects for different participant groups though subgroup analyses. This Cochrane Review focusses on organisational level interventions for preventing stress in healthcare workers, and is one of two Cochrane Reviews that will supersede the review undertaken by Ruotsalainen 2015.

OBJECTIVES

To evaluate the effectiveness of organisational level interventions aimed at reducing stress in healthcare workers compared to no intervention or alternative interventions.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs). For interventions directed towards organisational change, randomisation at the individual level may not feasible. For such interventions we will also include cluster-RCTs where randomisation is implemented at the group level. We will also include non-randomised controlled trials (NRCTs), in which methods of allocation are not random, for example, by day of the week, and controlled before-after (CBA) trials, as defined by Cochrane Effective Practice and Organisation of Care (EPOC) (EPOC 2017). We will include published and unpublished studies.

Types of participants

We will include studies conducted with adult workers, aged 18 years or above, employed in a healthcare setting, who have not actively sought help for conditions such as stress and burnout. This includes workers, such as nurses and physicians, who are in training and undertaking clinical work. We will exclude studies where workers provide social care such as in nursing homes. If a study involves participants from both healthcare and other settings, we will include the study but only use the data if we can identify outcome data specific to participants in the healthcare setting. We will exclude studies in which participants are simply caregivers and are not employed by a healthcare organisation.

Types of interventions

We will include studies that have evaluated the effectiveness of organisational level interventions aimed at reducing stress. Eligible interventions include the following.

1. Decreasing job demands.
2. Increasing job control.
3. Improving workplace social support.
4. Improving clarity in work tasks/roles/organisation.
5. Enhancing task design.
6. Improving organisational communication.

We will include trials that compare the effectiveness of the active intervention with no intervention or to another active intervention. We will exclude studies that have evaluated the effectiveness of organisational level interventions aimed at preventing bullying or harassment because this is already covered by Gillen 2017.

Types of outcome measures

Primary outcomes

1. We will include studies that have evaluated the effectiveness of interventions on reducing stress using a validated scale which measures stress either alone or as a subscale. Examples of validated instruments include the following.
   - i) Job Content Questionnaire (JCQ) (Karasek 1998).
   - ii) Nursing Stress Scale (NSS) (Gray-Toft 1981).
   - iii) Perceived Stress Scale (PSS) (Cohen 1983).
   - iv) Derogatis Stress Profile (DSP) (Derogatis 1987).
   - v) The Mental Health Professionals Stress Scale (MPHSS) (Cushway 1996).
   - vi) Nurse Stress Checklist (NSC) (Benoliel 1990).
   - vii) Occupational Stress Indicator (OSI) (Cooper 1988).
   - viii) Copenhagen Psychosocial Questionnaire (COPSOQ) (Kristensen 2005).
   - ix) Pressure Management Indicator (PMI) (Williams 1998).
   - x) Effort-Reward Imbalance (ERI) (Siegrist 2004).
   - xi) Depression Anxiety Stress Scale (DASS) (Lovibond 1995).
2. We will include studies that have evaluated the effectiveness of interventions on burnout using a validated scale which measures burnout. Examples of validated instruments include the following.
   - i) Maslach Burnout Inventory (MBI) (comprises three subscales: emotional exhaustion, depersonalisation, personal accomplishment) (Maslach 1982).
   - ii) Oldenburg Burnout Inventory (OBI) (Demerouti 2003).

3. Adverse events, such as medical errors and professional malpractice.

Secondary outcomes

We will include studies that, in addition to measuring one of the above primary outcomes, have evaluated the effectiveness of interventions on one or more of the following detrimental effects of stress.

1. Physiological stress responses. such as:
   i) Fibrinogen (blood) (Hansen 2009).
   ii) Testosterone (anabolic steroid) (Hansen 2009).
   iii) Blood pressure (Hjortskov 2004).
   iv) Heart rate (Hjortskov 2004).
   v) Cortisol (Sluiter 2000).
   vi) Catecholamines (Sluiter 2000).
2. Organisational outcomes, such as absenteeism and turnover, intent to leave and cost-effectiveness data.

We will assess outcomes at:

1. less than one month;
2. from one month to six months;
3. over six months.

Reporting one or more of the outcomes listed here in the study is not an inclusion criterion for the review.

Search methods for identification of studies

Electronic searches

We will conduct a systematic literature search to identify all published trials that can be considered eligible for inclusion in this review. We will adapt the search strategy we developed for MEDLINE for use in the other electronic databases (see Appendix 1). We will impose no restriction on language of publication. We will search the following electronic databases from the date of inception to present.

1. Cochrane Central Register of Controlled Trials (CENTRAL, latest Issue) in the Cochrane Library.
2. MEDLINE (Ovd SP, 1946 onwards).
3. Embase (Ovid SP, 1974 onwards).
4. PsycINFO (Ovid SP, 1806 onwards).
5. NIOSHTIC (OSH UPDATE, 1800s to 1998).
6. NIOSHTIC-2 (OSH UPDATE, 1977 onwards).
7. HSELINE (OSH UPDATE, 1977 onwards).
8. CISDOC (OSH UPDATE, 1974 onwards).

We will also conduct a search of unpublished trials in ClinicalTrials.gov (www.clinicaltrials.gov), and the WHO International Clinical Trials Registry Platform (www.who.int/ictrp/en).

Searching other resources

We will check reference lists of all primary studies and review articles for additional references.

Data collection and analysis

Selection of studies

We will conduct the selection of eligible studies in two stages. First, two review authors (two of SG, IF, GS, BV) will independently screen titles and abstracts of all the potentially relevant studies we find from our search. The review authors will code them as 'include' (eligible or potentially eligible/unclear) or 'exclude'. At this stage we will exclude all references that clearly do not fulfil our inclusion criteria. At the second stage, we will retrieve the full-text study reports and two review authors (two of SG, GS, BV, CM) will independently assess the full-text reports to identify studies for inclusion. At this stage we will include all references that fulfil our inclusion criteria. We will record reasons for exclusion of the ineligible studies assessed as full-texts so that we can report these in a 'Characteristics of excluded studies' table. We will agree on a hierarchy of reasons for study exclusion based on the inclusion criteria and will record the reason for exclusion as the first criterion not met. We will resolve any disagreement through discussion or, if required, we will consult a third review author (IF). We will identify and exclude duplicate records. We will 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 study flow diagram (Liberati 2009).

If we identify studies published in languages in which our author team is not proficient, we will obtain full-text reports and translate these first by using an electronic translator. Should our systematic searches identify studies conducted by authors of this review, we will avoid conflict of interest by having all decisions concerning inclusion and exclusion made by review authors who were not involved with the study.

Data extraction and management

We will use a data collection form to extract study data on characteristics and outcome data. We will pilot the form prior to use. One review author (one of IF, CM, GS, BV) will extract the following study characteristics from included studies.

1. Authors and year of publication.
2. Methods: study design, total duration of study, study location, study setting, withdrawals, and date of study.
3. Participants: N, mean age or age range, sex/gender, severity of stress, inclusion criteria, and exclusion criteria.

4. Interventions: description of intervention, comparison, duration, intensity, content of both intervention and control conditions.

5. Outcomes: description of primary and secondary outcomes specified and collected, and at which time points reported.

6. Notes: funding for trial, and notable conflicts of interest of trial authors.

Two review authors (two of IF, CM, GS, BV) will independently extract outcome data from included studies. We will note in the 'Characteristics of included studies' table if outcome data were not reported in a usable way. We will resolve disagreements by consensus or by discussion with a third review author (SG). One review author (one of SG, CM, GS) will transfer data into the Review Manager 5 file (Review Manager 2014). We will double-check that data are entered correctly by comparing the data presented in the systematic review with the study reports. A second review author (IF) will spot-check study characteristics for accuracy against the trial report. If we identify studies published in languages in which our author team is not proficient, we will arrange for someone sufficiently qualified in each foreign language to complete a data extraction form for us.

Assessment of risk of bias in included studies

Two review authors (two of SG, IF, GS, BV) will independently assess risk of bias for each study. We will resolve any disagreements by discussion or by deferment to a third review author (CM). We will use the RoB 2.0 tool to assess risk of bias for randomised and cluster-randomised trials (Higgins 2016), and we will use ROBINS-I to assess risk of bias for non-randomised studies (Sterne 2016).

We will grade each potential risk of bias as high, low or unclear, and provide a quote from the study report together with a justification for our judgement in the 'Risk of bias' table. We will summarise the risk of bias judgements across different studies for each of the risk of bias domains. We will consider blinding separately for different key outcomes where necessary (e.g. for unblinded outcome assessment, risk of bias for physiological measures of stress, such as fibrinogen, may be very different than for a patient-reported stress scale). Where information on risk of bias relates to unpublished data or correspondence with a trialist, we will note this in the 'Risk of bias' table.

We will consider bias arising from the randomisation process, from deviations from the intended interventions and in measurement of the outcomes to be key domains in RCTs and in cluster-RCTs, and bias due to confounding, in selection of participants into the study, and in measurement of outcomes to be key domains in NRCTs. We will judge a study to have a high-risk of bias overall when we judge one or more key domains to have a high-risk of bias. Conversely, we will judge a study to have a low-risk of bias when we judge low-risk of bias for all key domains.

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

Assesment of bias in conducting the systematic review

We will conduct the review according to this published protocol and report any deviations from it in the 'Differences between protocol and review' section of the systematic review.

Measures of treatment effect

We will enter the outcome data for each study into the data tables in Review Manager 5 to calculate the treatment effects (Review Manager 2014). We will use risk ratios (RRs) and their 95% confidence intervals (CIs) for dichotomous outcomes and mean differences (MDs), or standardised mean differences (SMDs) if outcomes are measured on different scales, and their 95% CI for continuous outcomes. If only effect estimates and their 95% CIs or standard errors are reported in studies, we will enter these data into Review Manager 5 using the generic inverse variance method. We will ensure that higher scores for continuous outcomes have the same meaning for the particular outcome, explain the direction to the reader and report where the directions were reversed, if this was necessary. When we cannot enter the results in either manner, we will describe them in the 'Characteristics of included studies' table, or enter the data into 'Additional' tables.

Unit of analysis issues

For studies that employ a cluster-randomised design and that report sufficient data to be included in the meta-analysis but do not make an allowance for the design effect, we will calculate the design effect based on a fairly large assumed intra-cluster correlation of 0.10. We base this assumption of 0.10 being a realistic estimate by analogy on studies about implementation research (Campbell 2001). We will follow the methods stated in the *Cochrane Handbook for Systematic Reviews of Interventions* for the calculations (Higgins 2011).

Dealing with missing data

We will contact investigators to verify key study characteristics and obtain missing numerical outcome data, where possible (e.g. when a study is identified as abstract only). 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. We will contact study authors and allow them two weeks to respond, if we receive no response we will contact them once more giving them a further two weeks to respond.

Assessment of heterogeneity

We will assess the conceptual similarity of the included studies based on population, interventions and control conditions, outcomes, study design and follow-up. Specifically, we will consider study designs to be similar when they are RCTs and cluster-RCTs. We will also consider controlled before-after studies to be similar when they have assigned intervention and control treatment to one or more concurrent intervention and control group. We will consider populations to be similar when they include participants from the same occupational group; and we consider occupational groups, such as clinicians, nurses, allied health professionals and administrative staff, to be mutually exclusive.

We will consider interventions as similar when focused on either decreasing job demands, such as having more people do the same tasks; increasing job control, such as autonomy; improving workplace social support, such as supervisory support; improving clarity in work tasks/roles/organisation, such as role descriptions; enhancing task design, such as developing new care models; or improving organisational communication, such as encouraging openness.

We will consider all outcome measures of stress as similar, and all measures of burnout as similar. We will report findings of stress and burnout separately from each other. We will consider follow-up times of less than one month as short-term, from one month to six months as medium-term and over six months as long-term outcomes and different.

We will use the I^2 statistic to measure heterogeneity among the trials in each analysis. If we identify substantial heterogeneity we will report it and explore possible causes by prespecified subgroup analysis. We will regard a level of heterogeneity above 50% as substantial, as explained in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011), although we recognise that there is uncertainty in the I^2 measurement when there are few studies in a meta-analysis.

Assessment of reporting biases

If we are able to pool more than 10 trials in any single meta-analysis, we will create and examine a funnel plot to explore possible small study biases.

Data synthesis

We will pool data from studies we judge to be clinically homogeneous using Review Manager 5 software (Review Manager 2014). If more than one study provides usable data in any single comparison, we will a perform meta-analysis. We will use a random-effects model when I^2 is above 50%; otherwise we will use a fixed-effect model. When I^2 is higher than 75% we will not pool results of studies in a meta-analysis (Deeks 2011). We will analyse separately data from studies with different designs.

We will narratively describe skewed data reported as medians and interquartile ranges. We will not include this data in our analyses. Where multiple trial arms are reported in a single trial, we will include only the relevant arms. If two comparisons are combined in the same meta-analysis, we will halve the control group to avoid double-counting. We will report individual and pooled effect sizes to determine the overall effectiveness of organisational level interventions.

'Summary of findings' table

We will create separate 'Summary of findings' tables for each type of intervention and we will use the following outcomes.

1. Stress.
2. Burnout.
3. Adverse events.

According to Cochrane Work Group recommendations we will create our 'Summary of findings' table after we have entered data into Review Manager 5 (Review Manager 2014), written up our results and conducted the 'Risk of bias' assessment, but before we write up our discussion, abstract and conclusions. This will give us the opportunity to think about how the risk of bias in the studies contributing to each outcome affect the mean treatment effect and our confidence in it.

Quality of the evidence

Two reviews authors (two of IF, CM, GS, BV) will independently assess the quality of the evidence for the three outcomes using the GRADE approach as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011), and using the GRADEpro Guideline Development Tool software (GRADEpro GDT 2015). For each outcome we will assess the quality of the body of evidence with reference to the overall risk of bias of each study, directness of the evidence (generalisability), consistency of the results (heterogeneity), precision of effect estimates and risk of publication bias. The GRADE system uses the following criteria for assigning grade of evidence.

1. High: we are very confident that the true effect lies close to that of the estimate of the effect.
2. Moderate: we are moderately confident in the effect estimate and the true effect is likely to be close to the estimate of effect, but there is a possibility that it is substantially different.
3. Low: our confidence in the effect estimate is limited and the true effect may be substantially different from the estimate of the effect.
4. Very low: we have very little confidence in the effect estimate and the true effect is likely to be substantially different from the estimate of effect.

Two review authors (two of IF, CM, GS, BV) will independently rate the quality of the evidence for each outcome as 'high', 'moderate', 'low' or 'very low' and we will justify our decisions to downgrade or upgrade the quality of studies in the footnotes of our 'Summary of findings' tables. We will resolve any disagreement

through discussion or, if required, we will consult a third review author (SG).

We will also compile an additional GRADE table showing all our decisions about the quality of evidence and their justifications.

Subgroup analysis and investigation of heterogeneity

Different occupational groups in health care are likely to face diverse demands in terms of tasks and work environment. Intervention outcomes are therefore likely to vary by occupational group. In this regard, if there are sufficient studies, we plan to evaluate the effect of interventions by occupational group (e.g. clinicians, nurses, allied health professionals, administrative staff). We will use the Chi² test to test for subgroup interactions in Review Manager 5 (Review Manager 2014).

Sensitivity analysis

We will perform a sensitivity analysis to assess the robustness of our conclusions. We will repeat our analyses while excluding studies deemed to be at high risk of bias.

Reaching conclusions

We will base our conclusions only on findings from the quantitative or narrative synthesis of included studies for this review. We will avoid making recommendations for practice based on more than just the evidence, such as values and available resources. Our implications for research will suggest priorities for future research and outline any remaining uncertainties in the area.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 onwards

1. exp Health Personnel/ or "health personnel".mp. or "health care personnel".mp. or "healthcare personnel".mp. or "health care work*".mp. or "healthcare work*".mp. or "health work*".mp. or "health professional*".mp. or "health care professional*".mp. or "healthcare professional*".mp. or "medical care personnel".mp. or "medical personnel".mp. or "medical staff".mp. or "medical professional*".mp. or nurse.mp. or nurses.mp. or nursing.mp. or physician*.mp.
2. exp Burnout, Professional/ or burnout.mp. or "psychological workload*".mp. or (occupation* adj3 stress*).mp.
3. exp Stress, Psychological/ or Anxiety/ or Depression/ or "psychological stress".mp. or "emotional stress".mp. or "work stress".mp. or anxie*.mp. or anxious*.mp. or depress*.mp. or stress*.mp. or distress*.mp. or strain*.mp. or burden*.mp. or "psychological load*".mp.
4. 2 or 3
5. (organi#ation* adj5 (interven* or initiative* or polic* or action* or measure or measures)).mp.
6. (intervention* or initiative*).ti.
7. (stress* adj3 (reduc* or prevent* or decreas*)).mp.
8. ((chang* or modif* or improv* or enhanc* or develop* or ameliorat* or better) adj5 (environment* or work* or condition* or arrang* or hours or shift or shifts or rota or autonom* or method* or policy or policies)).mp.
9. (exp Harassment, Non-Sexual/ or harass*.mp. or bully*.mp.) and (policy or policies or decreas* or reduc* or diminish* or address* or against or action* or measure or measures).mp.
10. 5 or 6 or 7 or 8 or 9
11. (("randomized controlled trial" or "controlled clinical trial").pt. or exp Randomized Controlled Trials as Topic/ or exp Controlled Clinical Trials as Topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or "clinical trial".pt. or exp Clinical Trials as Topic/ or "clinical trial*".mp. or ((singl* or doubl* or trebl* or tripl*) and (mask* or blind*)).mp. or "latin square".mp. or Placebos/ or placebo*.mp. or random*.mp. or "Research Design".sh. or Comparative Study/ or "evaluation studies".pt. or exp Evaluation Studies As Topic/ or Follow-Up Studies/ or Prospective Studies/ or Cross-Over Studies/ or prospectiv*.mp. or volunteer*.mp.) not (exp Animals/ not Humans/)
12. Non-Randomized Controlled Trials as Topic/ or quasi-experiment*.mp. or non-random*.mp. or nonrandom*.mp.
13. Controlled Before-After Studies/ or "controlled before after".mp. or "controlled before and after".mp. or "before and after stud*".mp. or "cba stud*".mp.
14. 11 or 12 or 13
15. 1 and 4 and 10 and 14

CONTRIBUTIONS OF AUTHORS

Conceiving the protocol: SG, IF, GS, CM

Designing the protocol: SG, IF, GS, CM, BV

Co-ordinating the protocol: SG, IF, GS, CM

Writing the protocol: SG, IF, GS, CM, BV

DECLARATIONS OF INTEREST

Sabir Giga: None known.

Ian Fletcher: None known.

Georgios Sgourakis: None known.

Caroline Mulvaney: None known.

Brenda Vrkljan: None known.

NOTES

Parts of the Methods section and Appendix 1 of this protocol are based on a standard template established by Cochrane Work.