Full Title	**Pilot study of a randomised trial of a guided e-learning health promotion intervention for managers based on management standards for the improvement of employee wellbeing and reduction of sickness absence**
Short Title/Acronym	**Guided e-learning for managers/GEM Study**
Sponsor	Queen Mary University of London Representative of the Sponsor: Gerry Leonard Head of Research Resources Joint Research Management Office 5 Walden Street London E1 2EF Phone: 020 7882 7260 Email: sponsorsrep@bartshealth.nhs.uk
REC Reference	QMREC2013/10
Chief Investigator	Prof. Stephen A Stansfeld Centre for Psychiatry Barts & the London School of Medicine Queen Mary University of London Old Anatomy Building Charterhouse Square London EC1M 6BQ Phone: 020 7882 2021 Email: s.a.stansfeld@qmul.ac.uk
Study site	Chester and Wirral Partnership NHS Foundation Trust The Countess of Chester Health Park Chester CH2 1BQ
Protocol version Incorporating	Version 3.0, 08.10.2013 Amendment 1, 13.05.2013 Amendment 2, 08.10.2013

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1. GLOSSARY OF TERMS AND ABBREVIATIONS

AE	Adverse Events
CI	Chief Investigator
DMC	Data Monitoring Committee
GEM	Guided E-Learning for Managers
GCP	Good Clinical Practice
GHQ	General Health Questionnaire
HR	Human Resources
HSE	Health and Safety Executive
ICER	Incremental cost-effectiveness ratio
NHSBSA	National Health Service Business Services Authority
NIHR	National Institute for Health Research
Participant	An individual who takes part in a clinical trial
PI	Principal Investigator
QALY	Quality-adjusted life year
QMREC	Queen Mary Research Ethics Committee
QMUL	Queen Mary University London
PCTU	Pragmatic Clinical Trials Unit
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
RGF	Research Governance Framework
SME	Small and Medium Sized Enterprises
WEMWBS	Warwick-Edinburgh Mental Well-Being Scale

2. SIGNATURE PAGE

Chief Investigator Agreement

The clinical study as detailed within this research protocol **(Version 3, dated 08.10.2013)**, or any subsequent amendments will be conducted in accordance with the Research Governance Framework for Health & Social Care (2005), the World Medical Association Declaration of Helsinki (1996) and the current applicable regulatory requirements and any subsequent amendments of the appropriate regulations.

Chief Investigator Name: **Stephen A. Stansfeld**

Chief Investigator Site: **Queen Mary University of London**

Signature and Date:

Statistician Agreement

The clinical study as detailed within this research protocol **(Version 3, dated 08.10.2013)**, or any subsequent amendments will be conducted in accordance with the Research Governance Framework for Health & Social Care (2005), the World Medical Association Declaration of Helsinki (1996) and the current applicable regulatory requirements and any subsequent amendments of the appropriate regulations.

Statistician Name: **Sally Kerry**

Site: **Queen Mary University of London**

Signature and Date: Sally Kerry **8th October 2013**

3. SUMMARY/SYNOPSIS

Short Title	Guided e-learning for managers (GEM Study)
Methodology	Cluster randomised pilot trial
Research Sites	Queen Mary University of London in collaboration with Cheshire and Wirral Partnership Trust
Objectives/Aims	To test the acceptability of the trial, feasibility of recruitment, the components of the intervention, adherence and likely effectiveness of the intervention within separate clusters of the same organisation
Number of Participants/Patients	4 clusters with a total of approximately 40 managers and 400 employees
Main Inclusion Criteria	Clusters: organisation receptive to using a CPD approach to adopting management standards that can also provide data on sickness absence and to allow work internet access for managers. Participants: managers and employees who give informed consent, are at least 16 years old, not on long term sick leave, not pregnant, not on a contract due to expire or terminate during the course of the trial
Statistical Methodology and Analysis (if applicable)	Analyses will be largely descriptive: the participation rate, program usage and retention rate for managers completing the intervention; the participation rate and questionnaire response rate for employees, in both intervention and control groups, analysing the characteristics of non-participants and dropouts between baseline and follow up.
Proposed Start Date	01.06.2013 (first participant in)
Proposed End Date	31.03.2014 (last participant, last assessment)
Study Duration	10 months

4. INTRODUCTION

Background

There is empirical evidence including several meta-analyses, which show that the psychosocial work environment impacts on employee wellbeing, mental health and risk of sickness absence (Stansfeld & Candy, 2006; Head et al, 2006; Netterstrom et al, 2008; Bhui et al 2012). Job strain, in terms of high demands and low decision latitude, low social support at work from managers and colleagues, effort-reward imbalance, organisational injustice and job insecurity have been related to increased risk of common mental disorders, depressive disorders and sickness absence. Mental ill-health at work has enormous costs to the economy: in 2007 the Sainsbury Centre for Mental Health estimated that the total cost to UK employers of absenteeism, presenteeism and staff turnover was £25.9bn (Sainsbury Centre, 2007). In the UK 40% of overall sickness absence is due to mental health problems amounting to 70 million working days lost to psychiatric sickness absence per year (Sainsbury Centre, 2007). Recent economic analyses suggest that mental health problems, which account for most sickness absences, in total, cost £105 billion a year, of which only 10 billion are direct NHS costs (Royal College of Psychiatrists position statement, PS4, 2010). Furthermore, unexplained medical complaints cost up to £18.5 billion a year, including stress related problems and physical complaints that appear not to have a medical cause (Royal College of Psychiatrists position statement, PS4, 2010). There is now consensus that employees' health is a public health priority and the responsibility of employers and employees as well as health services (Black, 2008; Boorman, 2009).

Stress management interventions: Stress management interventions in the workplace target either the individual or the organisation, (Cahill, 1996; Cooper, 2001; Marine, 2006) and may act at primary, secondary or tertiary preventive levels. Interventions can also target *both* the individual and the organisation such as workplace policies that promote good work-life balance and peer-support groups. Most interventions to manage stress and mental illness at work have targeted the individual, usually at a secondary or tertiary prevention level, using a clinical intervention such as CBT or treatment of depressive illness with medication (Bhui et al, 2012; Briner, 1997). A meta-analysis of individually targeted health promotion has shown that it is not especially effective, but exercise as an intervention increases overall wellbeing and work ability and reduces sickness absence (Kuoppala et al, 2008). However, the logic of the research findings linking the psychosocial environment to mental health suggests that primary preventive interventions are needed that can be delivered through the workplace.

Organisational interventions: So far, evaluations of organisational interventions for workplace stressors are limited. Three reviews of interventions within organisations (Marine et al, 2006; Richardson & Rothstein, 2008; van der Klink et al, 2001) showed mixed evidence of benefit on health outcomes: van der Klink's meta-analysis of 48 studies of occupational stress interventions showed that the majority of interventions were delivered to individuals rather than targeting the organisation.

Organisational approaches to improving mental health: Examining organisational-level interventions, Egan et al (2007) reviewed action research studies testing Karasek's job strain model. Eight studies reported benefits of the intervention for job control and participation; seven reported significant overall health improvements including for mental health questionnaire scores. Four studies reported decreased job demands post-intervention, accompanied by improved health

outcome in each instance. Improved support was also associated with improved health in the majority of studies in which it was measured. In those studies where control, demand, or support were recorded as unchanged or worsened, health outcomes often remained unchanged (Egan et al, 2007). Furthermore, Bambra et al (2007) reviewed studies of workplace reorganisation involving increasing skill discretion, team working and decision latitude in diverse occupational groups. Nineteen of these studies included a control group, but none were randomised studies (Bambra et al, 2007). Again results were mixed; however, the team working interventions did improve the work environment, by increasing support.

Organisational approaches to reducing sickness absence: Michie & Williams (2003) reviewed six studies and found that training and organisational approaches to increase participation and decision making, increased work support and communication led to reduced sickness absence. The difference between 'healthy' and 'unhealthy' workplaces in terms of the psychosocial as opposed to the physical environment was attributed to the quality of leadership and the competence and awareness of management throughout the organisation (Michie & Williams, 2003). Additionally, one meta-analytic review (Parks & Steelman, 2008) found that participation in organisational wellness programmes was associated with decreased absenteeism and increased job satisfaction.

Methodological problems in organisational interventions: Systematic and meta-analytic reviews conclude that there is a notable scarcity of randomised controlled trials (RCTs) of organisational based interventions. This partly reflects the difficulty in organising RCTs (Gardell & Gustavsen, 1980); insufficient length of follow up (Martin et al., 2009; van de Klink et al., 2001); and difficulties finding similar clusters for randomisation (Kompier, 2003). Nevertheless, these difficulties are not insurmountable, as exemplified by the WellWorks Project which conducted an RCT on cancer prevention strategies in 24 organisations in Massachusetts (Sorensen et al, 1996). In summary, there have been insufficient methodologically robust RCTs to test whether organisational-level psychosocial interventions are effective in improving the wellbeing of employees and reducing sickness absence. In general there is little knowledge of what works at an organizational level to improve employee wellbeing. This study aims to build on the existing research to pilot an organization-level management intervention to test the acceptability of a trial, feasibility of recruitment, the components of the intervention, adherence and likely effectiveness of the intervention before submitting it to a rigorous RCT methodology.

Management Standards: In this study we will use an organisational-level intervention based on the Health and Safety Executive (HSE) management standards (Cousins et al, 2004; Mackay et al, 2004). These psychosocial interventions were the first national approach that sought to reduce incidence of work related stress at source by applying a risk assessment process to triggers of work-related stress. An integral part of that process was the development of the management standards indicator tool (Cousins et al, 2004). This consists of 35 questions designed to assess adherence to the six management standards (demands, control, support, relationships, role and change). The indicator tool provides a way for an organisation to identify potential hotspots where sources of stress exist and each of the six stressor areas is accompanied by a description of the desirable states to be achieved (the Management Standards) which are seen to reflect high levels of health, well-being and organisational performance. The basis of the Management Standards approach is to test or compare the states to be achieved with the actual conditions that currently exist within an organisation. This helps employers identify the underlying causes of workplace stress and think about how

they might be prevented through practical improvements through organisational level interventions (Mackay et al, 2011). We propose to test the benefits of using the management standards as a tool that can promote health in the workplace when used to improve management understanding and development of more effective competencies, rather than only as a method of assessing risk and compliance with standards. As the management standards are concerned with the prevention of work related stress, it is apparent that the application of the six standard areas in the promotion of mental health is useful in the design of packages to improve wellbeing and reduce stress and sickness absence. Donaldson-Feilder et al (2008) found that previous competency frameworks for management did not cover all the six areas of the Management Standards.

Manager competencies: The HSE and the Chartered Institute of Personnel and Development have worked together in a collaborative research programme with input from employers and employees to develop a set of competencies and behaviours perceived as being the most relevant and appropriate for helping managers to be better at managing work-related stress. The Management Competency Framework has four over-arching competencies with an additional twelve sub-competencies. Each competency has associated behaviours, both positive and negative which allow organisations to identify areas of management strengths and development needs around the skills necessary for tackling work related stress. There has been significant interest and uptake of the Management Competency Framework by the Human Resources community enabling new action plans for managers with regards to their current and future training needs. An adapted version of the Management Standards for managers in Small and Medium Sized Enterprises (SME's) has been evaluated by Gaskell et al (2007) who concluded that it offered 'time poor' SME managers a quick and easy method for identifying problems. This study focuses on improving manager competencies to deal with stress at work within the framework of the HSE management standards.

Risks/Benefits

The proposed intervention involves a guided e-learning package for managers supplied as a weekly program. The pilot study provides an opportunity to assess the nature of any risks of the intervention, to assess acceptability and feasibility, and to provide immediate feedback on the program from managers to improve feasibility and efficacy. Potentially, managers could misinterpret the program and adopt maladaptive management strategies, and facilitators could provide unhelpful advice, but it is intended that the intervention will be laid out in such a way that it will be easy to comprehend, is organisationally supported, and is sanctioned as being part of the HR and professional development strategies. We will organise an email/phone based discussion option, as well as an optional review meeting during the intervention, to discuss any issues that arise with the program. Potentially, some managers may be distressed by recognising that their previous management practices have not been ideal or that new techniques may be more time consuming, requiring them to relinquish some control or be involved in more teamwork. However, the majority of SME managers (Gaskell, 2007) reported that conducting the process of management standards risk assessment provided business benefits that outweighed the costs of implementation. Some SMEs were able to pinpoint stress-related problems and identify a mechanism for discussing them. In other cases, where the participants had thought the company was free from problems, issues were identified that may have otherwise remained a source of work-related stress. Some managers may also be currently functioning optimally but we think that most managers would find some new knowledge and techniques from the program. Employees, when completing the

questionnaires on working conditions and wellbeing, may realise that their work situation is adverse and unsatisfactory. Employees may also reveal high levels of psychological distress, in which case the research team would provide relevant sources of support. In the future planned randomised controlled trial the benefits of the intervention will be to improve employees' (and indirectly, managers') levels of wellbeing. It is anticipated that managers will be facilitated to be more effective and supportive and that this will have benefits for the employees in terms of subjective wellbeing and reduced sickness absence. A positive effect in decreasing rates of sickness absence will be to increase productivity and sustain employee confidence, and potentially improve the efficiency, and productivity, of the organisations involved. In general, we expect that the psychosocial work environment will improve in the companies involved with the development of better leadership, more creative work practices and improved employee morale. Investigating perceptions of adverse conditions such as bullying, harassment and discrimination are a first stage of understanding the causes of such perceptions, and addressing unfair work practices. Even in well functioning companies there will be room for an improvement in employee wellbeing.

Rationale

An efficient and potentially cost-effective way of improving the psychosocial work environment is training managers to provide more effective supportive management for employees; this support should make employees feel valued and help managers recognise stressful and unfair conditions in the workplace. When applied to managers at all levels, such interventions can be transmitted through work relationships to change the organisational culture. We plan to test the acceptability, feasibility, risks and effectiveness of an intervention that provides knowledge and skills about management standards and their implementation in terms of managing stress at work and promoting wellbeing. The intervention will be delivered in the form of an e-learning education program provided as part of a continuing professional development process. The advantage of targeting our intervention at managers, who are line managers for numbers of employees, is that this is potentially a cost-effective way of influencing employees' wellbeing. The study will randomise the intervention to 'clusters', who are groups of managers and those employees whom they supervise. We will explore the possibility of carrying out cost-consequence analysis in this study. It has an advantage over approaching employees directly as managers have more power to change working conditions and these changes will apply to a number of employees in specific work groups. We will attempt to match up employees with their managers involved in the study. An e-learning intervention allows managers to access the intervention at the most convenient time for them, and to be supportive and perhaps facilitate alterations in work conditions. It can also be returned to again and again and will be delivered in weekly instalments to make it more manageable within a busy working life. An e-learning package also enables take-up (access, duration, and frequency) to be measured so that the influence of intensity of package use can be assessed; the package is interactive and therefore is more likely to engage the interest of the manager involved. The e-learning package can be applied to the whole cluster simultaneously. Several commercial organisations have developed e-learning programs based on management standards but there is no clear evidence of the effectiveness of such programs. In this pilot study we will test the likely effectiveness of a frequently used e-learning program. We have chosen to adapt as the core element the Anderson Peak Performance e-learning package. We will use the pilot study to test the intervention to ensure maximum take up.

Study Progression
Progression to the main study will be assessed in terms of fulfillment of the pilot study objectives: sufficient trial recruitment; acceptability, use of, adherence to e-learning program by managers; acceptability of the trial to employees and managers; and feasibility of outcome measures and their collections. We estimate that progression to the main study would occur if there is an increase in wellbeing scores of at least 3% amongst those employees whose managers completed the intervention compared to employees from the control cluster whose managers did not complete the intervention. We would aim for 80% recruitment and 80% follow up rate, with at least 60% of managers actively engaging with the intervention. The decision to progress will also take into account whether simple procedures have been identified which are likely to improve rates and taking all measures together rather than in isolation. We will also assess the overall costs and benefits of the pilot to judge whether these would support a full trial.

5. TRIAL OBJECTIVES

Primary Objective
The overall aim of the main study is to evaluate whether an e-learning health promotion intervention using management standards applied by managers will improve employees' wellbeing and reduce sickness absence in clusters selected from an organisation compared to similar clusters in the same organisation where it has not been applied.
In this pilot study we will test the acceptability of the trial, feasibility of recruitment, the components of the intervention, adherence and likely effectiveness of the intervention within separate clusters of the same organisation.

Secondary Objectives
To measure psychological distress in employees, to measure self-report sickness absence, to assess whether the use of the e-learning program by managers alters the perception of the psychosocial work environment for their employees, to measure managers knowledge gained from the intervention, and to pilot the economic evaluation of the intervention.

Endpoints
Adherence to the e-learning intervention will be measured by the number of occasions each manager logs on to the program.
Pre-post changes in levels of **wellbeing** will be assessed using the short version of the Warwick-Edinburgh Mental Wellbeing Scale (Tennant et al, 2007).
Pre-post changes in **sickness absence** will be monitored using the existing reporting system of the organisation recruited.
Self-report sickness absence: short term (< 7 days) and medium-term (7-21 days) sickness absence. This primary outcome will be measured as number of days of sickness absence per 100 person-years excluding absences greater than 21 days. In this pilot study we do not expect to see changes in sickness absence but the pilot will allow us to test the process of data collection.
12-item General Health Questionnaire (GHQ12 – Goldberg & Williams, 1988), which measures **psychological distress**.
Self-report **psychosocial work characteristics** will be assessed using the standardised assessment tools for job strain (control & demands), work social support (Karasek, 2008) and effort-reward imbalance (Siegrist, 2008). We will also assess health behaviours outside work in employees.
Manager's knowledge gained from the program assessed by online quiz.

The **acceptability of the intervention to managers** will be assessed by managers' engagement with the intervention and their attitudes to the intervention using qualitative methods.
The **acceptability of the trial to managers and employees** will be assessed using qualitative methods post-intervention.
The **feasibility of the trial** will be measured for employees and managers by participation and retention rates in the study and the ease of availability of sickness absence and economic data at the cluster level.
Participation for managers will be assessed by consent to take part in the study, attendance at the introductory session and logging on to the program.
Participation for employees will be measured by response rates to baseline and follow up questionnaires.

6. METHODOLOGY

Inclusion Criteria

- Organizational data on sickness absence available
- Internet access at work
- Informed Consent
- Age at least 16 years

Exclusion Criteria

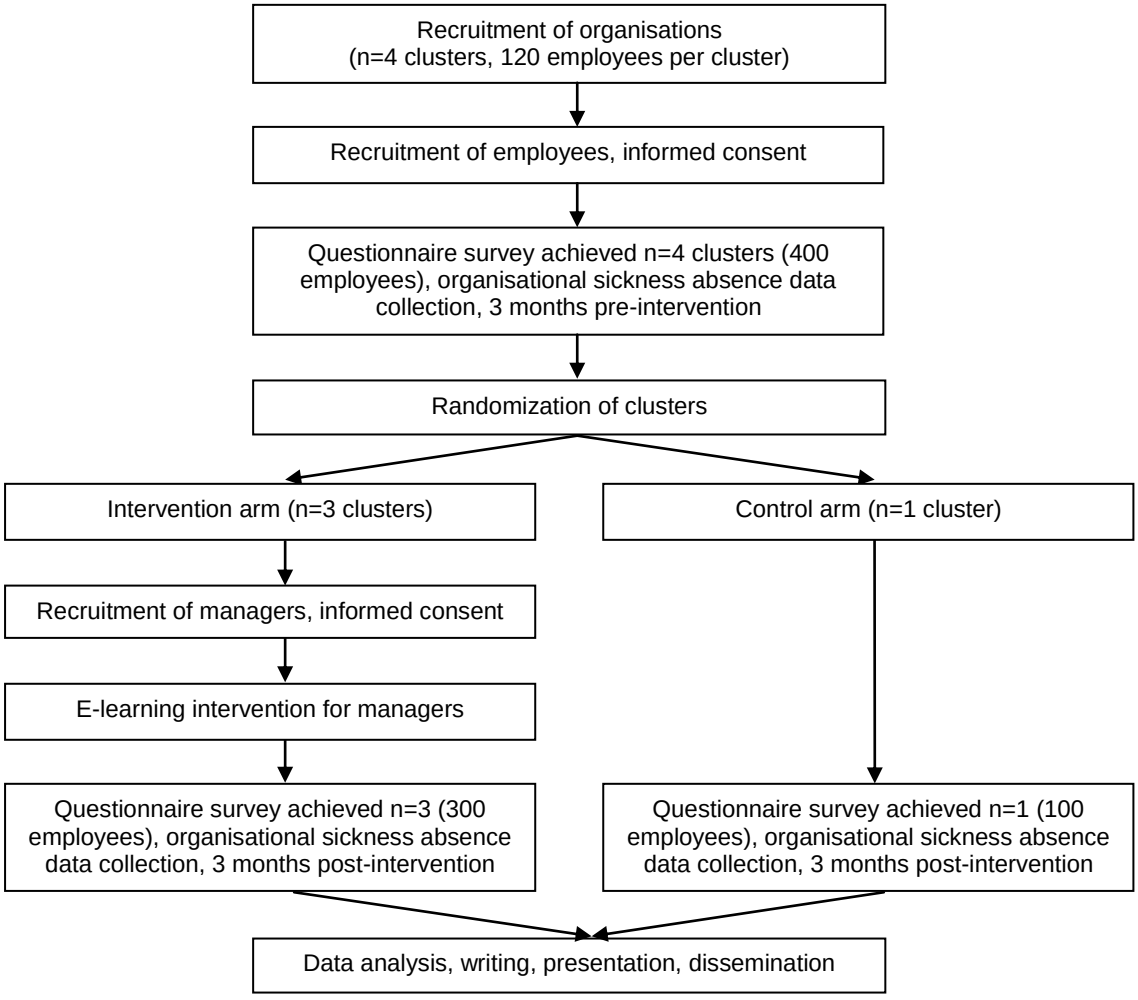
- Employees and managers on long-term sick leave (defined as more than 21 days uninterrupted sick leave)
- Notified pregnancies
- Employees and managers on contracts due to expire or terminate during the course of the trial

Study Plan

This pilot study is the precursor of a cluster randomised single blinded controlled trial of a site level intervention with outcome data measured at the individual level (wellbeing is the primary outcome with common mental disorder being a secondary outcome) and the organisational level (sickness absence is the primary outcome at the site level) and cost-benefit of the intervention.

In this pilot study we have agreement to proceed with the Cheshire and Wirral Partnership NHS Trust. We will select 4 clusters of managers from the Trust staff. We will then select employees relating to the managers in each cluster over a two month period and obtain consent. The study will invite 120 employees per cluster, anticipating that 100 individuals per cluster will consent. Measurements of intervention acceptability can be estimated from those managers who consent to the intervention anticipated to be 40 individuals. We envisage recruiting 30-40 managers, each responsible for 5-20 employees.

Study Scheme Diagram



7. STUDY PROCEDURES

Informed Consent procedures

Written informed consent will be obtained from each participant prior to any participation/study specific procedures. This will follow adequate explanation of the aims, methods, anticipated benefits and potential hazards of the study as laid out in the information sheets for managers and employees. Consent will be taken by trained members of local research staff. The information sheet includes contact information for the CI.

The participant will be given sufficient time (at least 24 hours) to consider giving their consent for the study.

The Investigator (or other qualified person) will explain to the potential participant that they are free to refuse any involvement within the study or alternatively withdraw their consent at any point during the study and for any reason.

Participants approached for the qualitative research part of the study will be asked for consent on the recording and usage of their data, by the qualitative researcher.

Screening, Enrollment

After agreement to participate has been established with the PI, the Queen Mary Research Office will agree the terms of participation with the organisation. We will recruit 4 clusters which will be randomised, three to the intervention and one to the

control after baseline assessment of participants. We will initially make contact with senior managers. We will also be in contact with the Union representatives. We will provide an introductory seminar to the organisation to introduce our approach. We will recruit clusters, consulting with local HR, to ensure we do not select areas likely to have major cuts during the study period.

Randomization Procedures
Clusters will be allocated to the trial groups – 3 to the intervention arm, 1 to the control arm – using the Pragmatic Clinical Trials Unit (PCTU) randomisation service.

Blinding/Unblinding
Employees will be blinded as to whether their managers have been randomised to the intervention or control group. Managers will be instructed not to reveal their randomisation allocation to their employees.
Unblinding procedures are not applicable during this study. We will however inform participants of their randomisation allocation upon completion of the study, via newsletter (see section 18 Dissemination of Research Findings).

Schedule of intervention
Employees will be asked to fill in the questionnaire on their health and wellbeing, while we will ask the Trust to supply anonymized sickness absence data for a period of three months.
All managers in the parts of the organisation randomised to the intervention will receive the e-learning package. Staff will be incentivised to use the intervention, through management 'buy-in', publicity and receiving a certificate of completion as part of continuing professional development. We will also provide a 'certificate of competence' for managers as an added incentive for participating. We will present the program in a way that will incentivise middle managers to participate showing that this can improve their working life.
The e-learning intervention for managers will be conducted in six instalments over the course of two to three months. The developer of the e-learning program will train the study facilitators (who are part of the intervention) who will introduce the program in the intervention clusters in an initial introductory educational session with managers to engage them in the program, followed up by an email or phone conversation with managers, as well as an optional review meeting during the intervention, to discuss any issues that come up. After completion of the intervention managers will complete a quiz to test what they have learnt from the intervention.
Between 1 and 3 months after the intervention, the baseline assessments for employees will be repeated (employee questionnaire and collection of anonymized sickness absence data). Focus groups and in-depth interviews will take place with selected participants during this phase.

Study intervention
The intervention we will use is the Anderson Peak Performance e-learning module for managers, an e-learning health promotion program for managers with a focus on the six management standards domains: Change, Control, Demands, Relationship, Role and Support (www.andersonpeakperformance.co.uk). This psychosocial program aims to help managers identify sources of stress, understand the link with mental and physical illness and improve managers' capacity for helping employees proactively improve their wellbeing and deal with stressful working conditions. The intended focus is on improving social support to employees, improving communication, improving organisational justice, increasing information about job change and making sure that employees' work is valued. We will also include strategies for changing/adjusting/rescheduling workloads and strategies for improving

job autonomy such as working in semi-autonomous teams. The format of the intervention is a series of linked topics with case examples and assessment. It will be presented over a 2 month period. The same intervention will be used for all managers. Use of the program will be monitored to measure uptake of the intervention by managers. The facilitator will also be available after the intervention to receive managers' feedback.

Procedure for Collecting Data

Employee questionnaires will be completed online; each employee will be provided with log-in information (anonymized ID and password) provided by the research team. Only if compliance cannot be achieved after several reminders will paper questionnaires be offered, and data will be entered by the research team at QMUL. Questionnaire data will be submitted directly to the research team at QMUL and will not be made available to the organisation.

Sickness absence data will be collected from the organisation in electronic format and contain employees' age, sex, income band, and information on number of days and duration of sickness absences.

Data on managers' uptake of the e-learning program will be made available by the e-learning service provider based on log-ins allocated to each manager.

Qualitative data will be collected in the form of interviews and focus group discussions with participants.

Health economic data will be collected with dedicated questions on health service use as part of the employee questionnaire.

Demographic details in terms of age-band, sex and salary band will be collected for participants who drop out of the study, and compared to the same demographic details for the overall Trust workforce, in order to characterise the type of non-response from the study.

Follow-up Procedures

There are no follow-up procedures foreseen beyond the post-intervention data collection and focus group interviews mentioned above. We will, however, make the e-learning programme available to managers in the control group upon completion of the study.

Participant withdrawal

Participants will withdraw from the study if they withdraw their consent to continue.

There are no specific criteria for premature withdrawal. If participants wish to withdraw from the study they may do so at any time, and no personalised data will be retained.

Schedule of Assessments

Assessment	Pre-intervention phase	Intervention phase	Post-intervention phase
Informed consent	x		
Employee questionnaire	x		x
Sickness absence data	x		x
Manager E-learning		x	
Focus groups and interviews with participants			x
Interviews with key HR contacts		x	x

End of Study Definition
The study will finish after the final follow-up data collection from the employees is completed.

8. STATISTICAL CONSIDERATIONS

Sample size
The study will recruit 120 individuals from 4 clusters and anticipate 100 individuals will consent. The response rate will be estimated to within 3.8 percentage points e.g. 76.1% to 83.9%. Measurements of intervention acceptability can be estimated from those managers who consent to the intervention anticipated to be 40 individuals. If the take-up is 80% the 95% confidence interval will be 64 to 91%. We envisage recruiting 30-40 managers, each responsible for 5-20 employees. The pilot study will provide evidence for the basic assumptions in our sample size calculations that will strengthen our calculations for the main study. From earlier literature on wellbeing measures the intra cluster correlation coefficient (ICC) is likely to have a value of about 0.07 (Ijzelenberg, 2006). Eldridge & Kerry (2012) show that estimates of ICC from small studies are dependent on the number of individuals and therefore 4 clusters will provide a reasonable estimate. In the pilot study we will estimate the likely effect size with its 95% confidence intervals.

Method of Analysis
Pilot study analyses will be descriptive. Proportions will be estimated with 95% confidence intervals taking into account variability among clusters. If there is considerable variability between clusters in acceptability or take up of outcomes we will present the proportions separately and use qualitative data to explore the reasons for such variability. Change in wellbeing scores for employees of managers who did or did not engage with the intervention will be compared.
We will estimate the participation rate and retention rate for managers completing the intervention. We will also collect and analyse electronic data on managers' usage of the e-learning program. We will also estimate the participation rate and questionnaire response rate for employees, in both intervention and control groups, analysing the characteristics of non-participants, specifically in terms of gender and salary band. We will also examine the baseline sociodemographic data including age, sex, salary bands, manual or non-manual occupation for those who drop out between baseline and follow up.
We will measure both self-reported sickness absence and sickness absence obtained from the organisation as number of days of sickness absence, spells of short term absences (days 1 to 6 of any episode) or medium-term absences (days 7 to 21 of any episode) in the three month period prior to the intervention and the three months post the intervention.

9. ETHICS

Ethical approval for the study has been sought from the Queen Mary Research Ethics Committee (QMREC).
The ethical issues in the study concern the employees involved in the intervention and control groups. We will inform potential study participants initially with an information sheet about the study, including the possible benefits and risks of the study. Informed written consent will be obtained from managers and employees for

participating in the study prior to any intervention, as described in section 7. We will also plan to feedback to employees' findings of the study in the form of a newsletter. In particular, scrupulous care will be taken over maintaining confidentiality of employees' responses on the wellbeing and mental health questionnaires and their report of work characteristics. We will also provide information on how to seek appropriate health services care. We will also have representatives from the organisation involved to comment on the design and implementation of the study and to act as a forum for feedback and dissemination of initial results. We will have a meeting for employees involved in the study to disseminate the results locally.

10. SAFETY CONSIDERATIONS

It is possible that participation in the GEM study will reveal existing psychological distress that requires healthcare. This might arise in managers as a result of taking part in the intervention or in employees as a consequence of completing questionnaires.

The questionnaires for well-being (WEMWBS) and psychological distress (GHQ-12) are too non-specific to identify clinically significant distress reliably within individuals. Nevertheless, psychological distress may be communicated to the research team during the study which needs to be dealt with.

The following guidelines will help to achieve this:

- An initial offer will be made to talk to a member of the research team, who have mental health training (psychiatrist or psychologist) in confidence. If necessary we could notify the organisation's occupational health if that was what participant wanted.

- In the first instance the study participant would be encouraged to see their General Practitioner if they have not already done so.

- The study participant would be offered a list of local sources of help e.g. Samaritans, MIND who could be approached to offer further help

In order to maintain confidentiality, only fully anonymised data on such interventions will be collected.

11. DATA HANDLING AND RECORD KEEPING

Confidentiality

We will take care to maintain the confidentiality of employees' responses on the wellbeing and mental health questionnaires and the report of work characteristics. Research data will be stored in a password protected database held on a secure, encrypted server accessible only to designated research staff. Questionnaire data will not be linked to personally identifiable information in the database. Results reported in papers, reports and newsletters will not include personally identifiable information. Reports will only deal with aggregated data. Data will be managed in accordance with the Data Protection Act 1998, NHS Caldecott Principles, Research Governance Framework for Health and Social Care 2005 and the conditions of the Research Ethics Committee approval.

Record retention and archiving
The records of the study will be kept for 20 years under the Research Governance Framework and will be stored in a secure local long-term repository.

12. PRODUCTS, DEVICES, TECHNIQUES AND TOOLS

Techniques and interventions
The Anderson Peak Performance e-learning module "Managing Employee Pressure at Work" will be used as the main intervention for managers in this study. Prior to the intervention, an introductory training session with a facilitator will take place. Thereafter, managers in the intervention groups will be given individual access to the e-learning programme, which will be delivered in the following instalments over the course of 2 to 3 months:

- Introduction and benchmarking quiz
- Why tackle employee pressure at work? Health, economic and legal issues
- What can a manager do? A management competency topic
- Being proactive – helping your team
- Being proactive – helping employees with individual problems
- A final quiz and confirmation of successful completion

The programme also includes activities for managers to apply to their current work situation. Managers will be able to discuss these with the facilitator. The application allows for access information to be logged and used for calculating uptake.

Qualitative assessments: During the pilot study we will also carry out in-depth interviews with key informants (eg CEO or Head of HR). This will include exploring organisational characteristics and how these might influence the delivery of the program and its effects, and the influence of the economic recession on the organisation and the study. We will also carry out in-depth interviews with managers, as well as focus groups with a sample of managers after the intervention to elicit their views and experience of the intervention and trial. We will carry out in-depth interviews with employees, as well as a focus group with employees in each of the clusters after the intervention to explore their views and experiences of stress and work and its management. We will also assess whether there was any contamination between intervention and control groups. Additional qualitative data will be collected through observation of meetings and other relevant events, and, if possible, shadowing of a sample of managers.

Tools
The following tools will be used in this study:

a) A short version of the Warwick-Edinburgh Mental Wellbeing Scale (Tennant et al, 2007), a brief 14 item scale assessing aspects of positive mental health, including both hedonic and eudaimonic perspectives
b) The 12-item General Health Questionnaire (GHQ12 – Goldberg & Williams, 1988), which measures psychological distress
c) The existing reporting system of the organisation will be used to report sickness absence data.
d) self-report psychosocial work characteristics will be assessed using the standardised assessment tools for job strain (control & demands), work social support (Karasek, 2008) and effort-reward imbalance (Siegrist, 2008). We will also assess health behaviours outside work in employees.
e) A questionnaire on health resource use and the standardised EQ-5D (3L) questionnaire will be used to estimate cost-effectiveness.

f) Uptake by managers will be assessed by monitoring log-on data from the e-learning programme.
g) Interviews and focus groups for managers and employees and one-to-one interviews with representatives of HR and senior management

Economic assessment of the intervention will involve a cost-benefit analysis from the employer's perspective, as well as a cost-effectiveness analysis from the health care payer perspective. In the pilot study we will estimate the cost of the intervention by recording the time spent to deliver and to receive the intervention, including the facilitator's time and will include the up-front costs of the program. We will assess the feasibility of using reduction in duration of sickness absence to measure the benefits of the intervention, assessing the accessibility and reliability of cluster level sickness absence. Sickness absence will be costed using the human capital method.
We will also conduct a cost-effectiveness analysis from the NHS perspective using employees' health-related quality of life (HR-QoL) as effectiveness outcome. HR-QoL data will be collected using the EQ-5D questionnaire. The use of health care services by employees will be collected using the Health Resource Use Questionnaire. National unit costs (DoH, 2012; Curtis, 2012) will be applied to service use frequency data to estimate the cost of service use by employees. The cost of medication will be analysed using the NHS Prescription Cost Analysis database (NHSBSA, 2012).
If data permits, the incremental cost-effectiveness ratios (ICERs) will be estimated as a cost per sickness absence day avoided, and a cost per QALY gained. The uncertainty around the ICER point estimates will be assessed using probabilistic methods (Glick et al, 2007).

13. SAFETY REPORTING

Adverse events (AE) are not expected as reactions to the intervention, and there will be no standardised AE reporting for this study. Possible reports of increased stress and employee dissatisfaction with the manager involved either in the intervention or the control group, as well as any other untoward events, can be documented qualitatively in the planned focus groups with a sample of employees. Negative experiences by managers during the e-learning intervention will be documented as part of the focus groups with a sample of managers. Facilitators will be available by phone or e-mail to discuss the e-learning intervention with managers and gather feedback. We will also compare proportions whose well-being deteriorates at follow up, and we will document sickness absence data per cluster post intervention, including any deterioration in sickness absence. We will also ask our facilitators to report any harms identified.

14. MONITORING & AUDITING

The Pragmatic Clinical Trials Unit (PCTU) at Queen Mary, University of London will conduct a risk assessment of the trial and develop an appropriate monitoring and auditing plan dependent on the level of risk. Trial monitoring and auditing will be conducted as outlined in the monitoring and auditing plan and overseen by the PCTU Quality Assurance Manager. All monitoring and auditing reports will be reviewed by the QA manager and trial sponsor. Triggered audits may be carried out in response to persistent non-compliance or serious breaches of either the protocol, GCP or RGF.
Internal audits may be conducted by a sponsor's or funder representative.

15. TRIAL COMMITTEES

A trial management group comprised of the Chief Investigator and specialist co-researchers and the statistician will be meeting every two months to oversee the study implementation, chaired by the CI. There will also be a regular weekly management committee to carry out the study according to guidelines from the trial management group.
The Study Steering Committee will include experts in occupational, mental and physical health and economics, as well as a union representative and a member of the public. The Study Steering Committee will be convened at the start of the study to inform the research design and implementation, approve the protocol and study questionnaires and the intervention and will then meet face-to-face after one year to advise on the interpretation and dissemination of the results of the study. We do not anticipate having a separate DMC.

16. FINANCE AND FUNDING

The study is entirely funded by NIHR Public Health Board.

17. INDEMNITY

As the trial sponsor, Queen Mary University of London will provide Clinical Trial insurance.

18. DISSEMINATION OF RESEARCH FINDINGS

A peer reviewed paper will be prepared for publication of the results of the study. A newsletter for managers and employees will be written to feedback the results of the study which will also be reported at a local meeting for study participants. We will also have a study website which will contain feedback summaries of our results. We also plan to present the results of the study at one international and one national conference.

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