Guy's and St Thomas' NHS
NHS Foundation Trust

Facilitating the return to work of NHS staff with common mental health disorders: a feasibility study.

Sponsor
Research Department (Occupational Health)
Guy's and St Thomas NHS Foundation Trust
Occupational Health Service,
St Thomas' Hospital, Westminster Bridge Rd,
London SE1 7EH
Tele: 020 7188 7188 ext 56228

Chief Investigator
Dr Ira Madan
Reader and occupational physician
Occupational Health Service
Guy's and St Thomas NHS Foundation Trust,
Education centre, 75-79 York Road, LONDON SE1 7NJ
Tel: 020 7188 7188 Ext 56228
Ira.madan@kcl.ac.uk

Project Manager
Dr Vaughan Parsons
OH research manager
Occupational Health Service
Guy's and St Thomas NHS Foundation Trust,
Education centre, 75-79 York Road, LONDON SE1 7NJ
Tel: 020 7188 7188
Vaughan.parsons@gstt.nhs.uk
waysbacktowork@gstt.nhs.uk

Statistician
Dr Georgia Ntani
Tel: 02380764071
gn@mrc.soton.ac.uk

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List of abbreviations

CAU	Care as Usual
CBT	Cognitive Behaviour Therapy
CMHD	Common Mental Health Disorders
EQ-5D	EuroQol standardised instrument for measure of health outcome
ESR	Electronic Staff Record
GAD-7	Generalised Anxiety Scale-7
GP	General Practitioner
HR	Human Resource
HTA	Health Technology Assessment
IAPT	Improving Access to Psychological Therapies
IQRs	Inter-quartile Ranges
MI	Motivational Interviewing
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
OH	Occupational Health
PHQ-9	Patient Health Questionnaire-9
PPI	Public and Patient Involvement
QALYs	Quality-adjusted Life Years
QOF	Quality and Outcomes Framework
RCT	Randomised Control Trial
RTW	Return to Work
SCIN	Skin Care Intervention in Nurses
UK	United Kingdom
UNISON	UK Public Sector Union

NHS National Institute for Health Research

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Version control tracker		
Version Number	**Date**	**Amendments (explanation of changes)**
v1.1	19/09/2016	Adjusting Ethics/HRA submission date and minor comments from Paul Grime (see email 16/9/16)
v1.2	27/09/2016	Table relating to recruitment targets per site added to Phase 3 page 13
v1.3	18/07/2017	1. Measurement of outcomes a. We have agreed with stakeholders that the primary outcome of the definitive trial (if this study shows that a trial is feasible) should be hours until return to work (RTW) (a continuous outcome) rather than time to return to full work as was originally proposed. b. Data on sickness absence would be collected both from the electronic staff records and by self-report via the study questionnaires 2. During the development of the intervention it became apparent that we would not be able to avoid contamination between the intervention and control arms if we tried to run an individual RCT. In consultation with stakeholders we considered testing the feasibility of randomising at departmental level within trusts. Therefore we have changed the protocol to allow for four trusts to receive the intervention in some departmental groups and care as usual in other departmental groups (see protocol for fuller explanation) 3. We have added bipolar disorder to our exclusion criteria. 4. Following the updated systematic review and stakeholder meeting, we agreed that we would put less emphasis on motivational interviewing and more on problem solving therapy and collaborative problem solving. 5. We have developed the intervention using the methodology described on the study protocol and the case management approach will now include: a. Establishment of peer support groups b. Giving workers access to HeadGear (an on-line self-help programme based on CBT principles) c. Development and distribution of an evidence-informed RTW leaflet for the worker and line manager d. More focus on peer support & self-efficacy e. Consideration of work visits (therapeutic RTW) f. Giving line managers – access to HeadCoach (an on-line manager training programme) 6. Referral into the intervention a. We agreed that workers should not self-refer b. We would ask line managers to refer workers directly to case-managers, rather than via occupational health office staff if possible.
v1.4	06/09/2017	Added two updated intervention flowcharts (one for control and one for intervention arm)
v1.5	25/01/2018	To allow for the verbal consent to be taken over the phone
v.1.6	15/02/2018	- To allow workers who self-refer to OH to be eligible for inclusion in the study - To collect contact details from participants (so that follow up questionnaires can be send to participants via email or post)

		- To promote the role of occupational health service in managing workers who are off sick due to common mental health conditions
v1.7	29/06/2018	- Expanding recruitment reach to allow field workers to recruit participants during their first appointments if they are assessed as meeting the inclusion criteria - Providing sites with specific working to promote the role of OH and the WBTW study - Revising timeline dates
V1.8	12/03/2019	- Adjusting study end date in section 9.0 (now mid-October 2019

1.0 Summary of research

Design: A mixed methods study to develop and test the feasibility of an intervention to improve return to work in NHS staff who go on sick leave with a CMHD.
Method: The study is divided into 2 phases:

- *Phase 1* aims to test the feasibility and acceptability of the intervention in the NHS and to assess for contamination if the main trial were to be a randomised controlled trial at departmental level.
- *Phase 2* finalises the manualised intervention and makes recommendations on the best study design for a future trial.

A significant amount of preparatory work was completed prior to phase 1/2 and a full description of this work can be found in the appendix.

We will carry out phase 1 in six OH departments (study centres). At three study centres, study participants will be assigned either to see an OH nurse who has been trained as a case-manager and will receive the intervention or to see an OH nurse who has not been trained as a case-manager and will receive CAU. At two centres, participants will receive CAU only and at one centre, participants will be assigned an OH nurse who has been trained as a case-manager. This design allows us to test for feasibility of the intervention in a NHS setting and to assess the risk of contamination if a cluster RCT were undertaken.

Setting: Six OH departments delivering services to different types of NHS Trusts.
Target population: NHS staff who have recently been issued with a fit note which includes a CMHD.
Inclusion criteria: Staff with a CMHD with or without an associated physical disorder, who have been off sick for more than 7 days and fewer than 90 days. Employee must be off sick when referral made to OH and when completing baseline questionnaire.
Exclusion criteria: Staff with a psychotic disorder, bipolar disorder, substance misuse disorder or dementia. Staff under investigation for misconduct or in the process of formal disciplinary action.
Health technologies being assessed: Standardised case management delivered by OH nurses following training. The intervention is likely to include identifying barriers to RTW, problem solving, peer-support networking, work-focused CBT, optimisation of clinical treatment and goal setting. An agreed written RTW plan with workplace adjustments, based on discussion between participants and their manager and shared with the participants' healthcare professionals. Regular timed reviews.
Outcomes:
***Feasibility*:** Rates of uptake among those eligible to participate; the frequency and nature of protocol violations; completeness of data collection; average consultation times compared to normal and mean number of follow-ups per case; extra line manager and human resource time per consultation compared to normal. Fidelity of the case-manager training.
Acceptability: A summary of qualitative findings representing views on the intervention and its assessment expressed by participants, case-managers, HR and line-managers. Reasons for not completing the intervention and any adverse effects.
Measurements of costs: Costs of delivering the package of interventions including OH nurse time, participant and manager time and cost of training OH nurses in case management.
Manual development: Complete specification of the intervention and standard operating procedures for different settings. A manual for training the case-managers.
Sample size: With a sample size of 60 we will be able to estimate a participation rate of 80% to within a 95% confidence interval of +/- 10%. We have allowed for 77 participants, so we are confident that we will have a good precision around the participation, and completion rates.

2.0 Background and rationale

2.1 *Why is an intervention needed?*
The National Health Service (NHS) is the biggest employer in the United Kingdom (UK) with NHS England alone employing more than one million full time equivalent staff (Taylor 2015). As a whole it performs relatively poorly across many measures of staff health and wellbeing, with sickness absence rates that are 27% higher than the UK public sector average, and 46% higher than the average for all sectors (Chartered Institute of Personnel and Development 2013). Department of Health research has estimated that NHS trusts in England could save

an average of £350,590 per year by reducing sickness absence (Boorman 2009b). Monetary consideration aside, there is an important link between the positive wellbeing of staff and better patient care (Boorman 2009b).

In Britain, common mental health disorders (CMHD), including depression and anxiety are the main causes of sickness absence in the working population (Black 2008) and poor mental health is estimated to account for more than a quarter of staff sickness absence in the NHS (Boorman 2009b, Boorman 2009a). The full cost of mental illness in NHS staff is hard to quantify, since as well as direct financial impacts on the NHS, individual employees and their families incur losses and there is a financial cost to society as a whole. Whilst over 75% of employees who go on sick leave with mental illness do eventually return to work (RTW), (Chartered Institute of Personnel and Development 2011) those who are absent for six months or longer have less than a 50% chance of ever returning to employment (Waddell, Burton 2006).

A recent Cochrane review on workplace interventions to improve capacity for work in people on sick leave found that the quality of evidence on the effectiveness of workplace interventions for workers with mental health problems was low (van Vilsteren et al. 2015). If an intervention in NHS workers who are off work with CMHD could accelerate return to useful work and prevent sickness absence extending to beyond six months, in a way that was cost-effective, there could be major benefits both for the affected worker, their colleagues and for NHS patients.

2.2 *Proposed form of intervention*
Previous work has indicated that interventions to reduce time lost from work due to mental illness are most likely to be effective if multi-faceted (National Institute for Health and Care Excellence 2009, van der Klink et al. 2007, Pomaki et al. 2010). Systematic reviews suggest that an intervention should include identifying barriers to RTW (Waddell, Burton & Kendall 2008), work-focused cognitive behaviour therapy (CBT) (Nieuwenhuijsen et al. 2014), focused problem solving (Arends et al. 2012), optimisation of clinical treatment, goal-setting, a step-wise written RTW plan based on discussion between participants and their manager (Waddell, Burton 2004), workplace adjustments including flexible working and graded RTW, regular timed reviews, and communication of the RTW plan with other healthcare professionals, in particular general practitioners (GPs) who are treating participants (Stern, Madan 2012, Waddell, Burton & Kendall 2008), and maintenance of contact between the line manager and the sick-listed worker (Nieuwenhuijsen,K. 2004). A comprehensive systematic literature search on RTW interventions specifically for workers with CMHD found similar results (Pomaki et al. 2010). That review looked at whether any of the interventions were specific to healthcare, but found that most of the evidence concerned mixed groups of occupations and did not focus on a single sector.

Two important guidelines relevant to the management of workers on sick leave with mental health disorders have been published in the Netherlands and the United Kingdom (UK). The Dutch guideline is specific to mental health conditions (van der Klink et al. 2007). It was first published in 2000, updated in 2007 and the third edition which is currently under development is due to be published in 2016 (Hulshof 2015). The National Institute for Health and Clinical Excellence (NICE) guideline on managing sickness absence applies to all types of illness (National Institute for Health and Care Excellence 2009), and its implementation needs to be tailored to specific conditions and the local context. A few studies have evaluated the use of the Dutch guidelines. A randomised control trial (RCT) comparing the implementation of the first edition (published in 2000) with usual care only showed a decrease in the time to RTW among workers with minor stress disorders, but not in those with other CMHD (Rebergen et al. 2009). An on-going RCT is evaluating the effectiveness of the 2007 Dutch guideline in improving RTW of workers with CMHD by comparing its use by appropriately trained occupational physicians with management by others who have not received such training (van Beurden et al. 2013). In the Netherlands, each employee is required to have a rehabilitation consultation with an occupational physician when they take sick leave beyond a specified period. This is not the case in the UK, where most NHS staff who take sick leave would be seen first by an occupational health (OH) nurse. Therefore, although we will take into account evidence on the Dutch guideline in planning our study, we cannot assume that evidence can necessarily be generalised to NHS workers.

A Norwegian RCT demonstrated that work-focused CBT combined with individual job support for those off work with CMHD led to increased work participation when compared to usual care, especially in those who had been off work for longer than 12 months (Reme et al. 2015). However, the trial was not set in a workplace and the Norwegian Insurance Scheme provides 100% coverage for income lost from mental illness. Thus, the results may not be generalisable to the UK.

Although there have been few studies on this topic in the United Kingdom (UK), one investigation carried out at an English NHS Trust suggested that an intervention could be cost-effective if based on multi-disciplinary case-management delivered by trained OH case managers (who were mainly OH nurses) (Smedley et al. 2013a). Another based in a Scottish health board also used case-management (EASY study). In both studies a bio-psychosocial approach to assessment was a key component of the intervention. The importance of combining workplace and clinical interventions is reinforced by the findings of a recent Cochrane review on interventions to improve RTW in depressed people (Nieuwenhuijsen et al. 2014) and also in a systematic review on characteristics of interventions that facilitate RTW after sickness absence (Hoefsmit, Houkes & Nijhuis 2012).

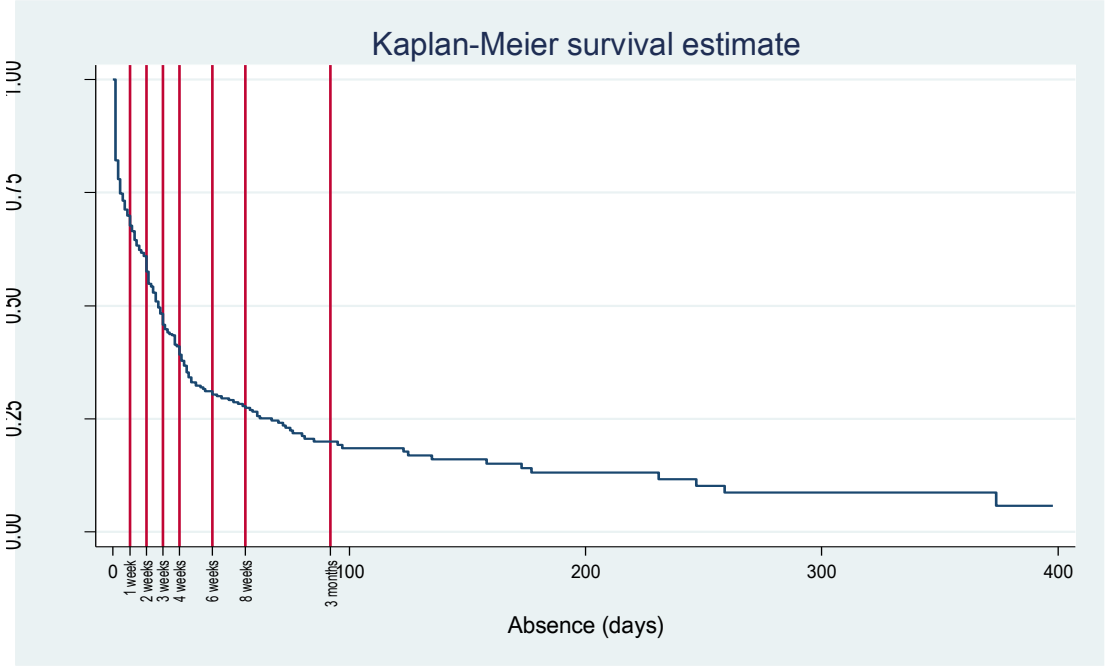
2.3 Proposed timing of the intervention

The NICE guidelines advise that RTW interventions should be delivered between two and six (and a maximum of 12) weeks into a period of sickness absence (National Institute for Health and Care Excellence 2009). Waddell and Black advise that the intervention should be delivered after four weeks of absence (Waddell, Burton 2004, Black, Frost 2011). Previous UK studies on interventions for all causes of sickness absence have intervened after workers have been absent for four weeks, Smedley et al. 2013) and one day (Demou, et al,2015). Smedley's choice was based on the evidence from Waddell (Waddell, Burton 2004) on the pattern of RTW albeit in all cause absence or musculoskeletal disorders.

The EASY study intervention at day one was by telephone and based on the management of sickness absence in 'commercially successful companies' (Demou et al, 2015). The recommendations from Waddell, Black and NICE (Black, Frost 2011, Waddell, Burton 2004, National Institute for Health and Care Excellence 2009) were based on data relating to all causes of sickness absence, with the premise that most workers who take sick leave RTW within four weeks without intervention. In contrast, the Dutch guidelines on RTW after absence due to mental ill health advise that the intervention should take place two weeks into the absence (van der Klink et al. 2007) and on-going trials of interventions to improve RTW after sickness absence due to CMHD are intervening at 'about two weeks' (van Beurden 2013) and before three months of sick leave (Gunnar Bergstrom, personal correspondence).

In considering the timing of the intervention for our study, we looked at two sets of data from NHS workers off sick with mental health problems. The NHS electronic staff record (ESR) has a code (S10) for sickness absence due to anxiety/stress/depression and mental illness. We obtained all staff sickness absence data for code S10 at Guy's and St Thomas' NHS Foundation Trust for 2015 (this included three staff members whose sickness absence for mental illness commenced in 2014). The corresponding Kaplan-Meier survival curve shows that approximately 30% of staff who were on sick leave with mental illness at Guy's and St Thomas' NHS Trust between 1 January- 30 November 2015 returned to work within one week (see: Figure 1). At the Trust, there is currently no policy for intervention until day 27 of sickness absence.

Figure 1



These data suggests that about 25% of the trust staff who were off sick with mental health conditions returned to work within one week of absence and that about half were still absent after three weeks.
We also obtained data from the Health and Social Care Information Centre (Health and Social Care information Centre) (see: Figure 2).

Figure 2 pattern of sickness absence for NHS staff in England July 2015

All sickness absence

	Incidents of sickness absence[1]	Days absent[2]
Absence <7 days	62.56%	5.97%
Absence 7-28 days	18.47%	11.38%
Absence >28 days	18.97%	82.65%

Selected Attendance Reasons[3]

	Incidents of sickness absence[1]	Days absent[2]
Absence <7 days	21.23%	1.10%
Absence 7-28 days	30.86%	9.28%
Absence >28 days	47.91%	89.62%

Notes:

1. Incidents of sickness absence has been calculated by dividing the count of sickness absence days in the specified group by the total count of sickness absence days.
2. Days absent has been calculated by dividing the sum of sickness absence days in the specified group by the total sum of sickness absence days.
3. Includes the following Attendance Reasons as recorded on the Electronic Staff Record : S10 Anxiety/stress/depression/other psychiatric illnesses, Stress.

Source: Health and Social Care Information Centre

These data indicate that some 21% of absences for mental illness lasted < 7 days.
If we deliver an intervention too early we risk expending effort on approximately 20% of workers who are likely to RTW within a few days even in the absence of the intervention, making it less likely that any benefits will be cost-effective. Moreover, evidence from studies on interventions in workers who go off sick with back pain, indicate that very early intervention may obstruct recovery due, in part, to labeling and attention effects, which may encourage illness behaviour (Staal 2003). Absences of one week or less are self-certificated, and fit notes provided by a general practitioner are unlikely to be practically available as a method of case ascertainment within a hospital employment setting until the second week of absence at the earliest. Beyond eight days the survival curve as outlined in figure 1 becomes less steep. Moreover, a fit note with a written diagnosis should become available by day eight of absence. Therefore, delivery of our intervention as soon as possible after eight days seems a suitable and pragmatic choice and aligns with the commissioning brief.

2.4 Proposed data collection tools

In the feasibility study, we will test the acceptability and feasibility of data collection tools that are proposed for use in a full trial and at the same time generate information that can be used to refine the design of the full trial. The measures of interest include clinical and occupational outcomes, prognostic and cost-effectiveness indicators. The data will be obtained largely through self–completed questionnaires and from electronic data collected by ESR at each participating centre. ESR is in use across all NHS Trusts and Health Boards and has a specific code (code S10) for sickness absence due to anxiety/ stress/ depression and mental health.

There is no consensus on what the best tools for collecting data on relevant occupational outcomes are. Indeed, recently published NICE Guidelines (National Institute for Health and Care Excellence 2015) specifically called for more research on how the effectiveness of workplace health policies and programmes can be measured. We have chosen tools that have been used successfully in other studies, and we consider will be feasible to use in this study.

2.4.1 Clinical outcomes

Clinical improvement in CMDs such as reduction in the number or severity of symptoms can be captured with a number of well-established assessment tools. We will use the PHQ-9 and GAD-7 because: they are brief and designed to be completed by the patient; changes in their scores accurately reflect improvement and worsening of symptoms of depression and anxiety: and they are free to use (Kroencke 2001, National Institute for Health and Care Excellence 2011). Furthermore, PHQ-9 is used by GPs and practitioners involved in the Improving Access to Psychological Therapies (IAPT) initiative, giving us an opportunity to compare the outcomes of this study directly with routine care in non-NHS workers. In addition, we will collect information on adherence and change in use of medication.

2.4.2 Occupational outcomes

We will measure full RTW (defined for this study as working the same days or hours per week as before sickness absence in an identical or equivalent role for at least four weeks) and partial RTW (defined as working any number of hours in any role) through the ESR and self-completion questionnaires. A study examining a multi-stakeholder perspective on the definition of RTW after sickness absence due to CMHD found that definitions of RTW based on working days and hours may not accurately reflect the priorities of all stakeholders (Hees et al. 2012). Therefore we will select the most appropriate questions and discuss with our public and patient involvement (PPI) representatives.

A number of instruments have been developed to measure presenteeism, and whilst all have pros and cons we will measure workability by using the Work Ability Index (Ilmarinen, Tuomi 1992). This self-report questionnaire has been used in other sickness absence studies and will allow us to explore the effect of physical co-morbidity on work ability (Ahlstrom et al. 2010) and has shown to be a reliable instrument in this context. We will also use the Work and Social Adjustment Scale (Mundt et al. 2002) as a measure of global functioning. Using both these measures of occupational outcomes will allow us to compare the results from the measures and select which one would be the optimum measure in the full trial.

2.4.3 Prognostic indicators

At baseline, we will include demographic data on personal characteristics such as age, gender, job, previous sickness absence and history of mental and physical ill health. We will enquire about expectations of full RTW and self-efficacy with regard to RTW, as both of these indicators are strongly associated with RTW outcomes (Nieuwenhuijsen et al. 2006, Nieuwenhuijsen et al. 2013). Self-efficacy with regard to RTW will be measured by RTW-SE, a self-report questionnaire, which has shown promising reliability and prediction of actual RTW within three months (Lagerveld et al. 2012).

2.4.4 Cost-effectiveness measures

Assessment of cost-effectiveness of the intervention will require data to be collected on the use of health and social care services that could potentially be used more or less as a result of the intervention.

To this end we will use a short, self-completed version of the Client Service Receipt Inventory (Beecham & Knapp 2001). The objective will be to determine which services are used during

the study follow-up and how often. Although the questionnaire will be relatively short, the list of services will be deliberately comprehensive and this list will be reduced as a result of the feasibility study. The costs of the service use will be determined by combining the above information with data on unit costs. A full trial will involve linking costs for treatment and control groups with clinical outcomes and also quality-adjusted life years (QALYs). The most widely used measure for generating QALYs is the EQ-5D (EuroQol Group 1990). The five-level version of the EQ-5D will be used in the study and the relationship of the utility weights derived from it with the clinical measures will be explored. This will indicate the appropriateness of the measure in a full study. Sensitivity of the utility weights to change in other measures will be assessed using correlations and standardised mean responses. Costs of delivering the package of interventions including OH nurse time, participant and manager time and cost of training OH nurses in case management.

2.4.5 Other measures
In addition to the above we will collect information about rates of recruitment, adherence to the intervention in those allocated to receive it and the management of those who are not. We will also collect information on rates of follow up, and participants' referral to, and uptake of, improving access to psychological therapies services and the Government's Fit for Work Service, in accordance with the commissioning brief.

3.0 Evidence explaining why this research is needed now
It is some time now since the Boorman review recommended pro-active rehabilitation for NHS employees who go on sick leave (Boorman 2009a) and since the Chief Medical Officer called for more interventions to enable workers with mental illness stay at work (Davies 2014). There is increased recognition of the public health implications of sickness absence due to mental ill health (Davies 2014) and in primary care, the 2016 quality and outcomes framework includes financial incentives to GPs for mental health assessment with reviews for patients diagnosed with depression. Moreover, there is now sufficient evidence to formulate and evaluate an intervention that is likely to be cost-effective in reducing the impact of sickness absence due to CMHD in NHS staff.

4.0 Aims and objectives and project outputs
4.1 We will carry out a feasibility study to address the following questions:

1. What is the most up-to-date evidence on the efficacy and cost-effectiveness of interventions to improve RTW in workers who go on sick leave with CMHD?
2. What is the current practice of UK NHS OH departments in managing staff who go on sick leave with CMHD?
3. What form of intervention is most likely to be cost-effective in promoting RTW in NHS staff who go on sick leave with CMHD, and how can this be manualised (written as an instruction manual) to meet individual and organisational needs in different OH settings?
4. What data collection tools should be used to assess changes in clinical state and occupational functioning as a consequence of such an intervention?
5. How feasible and acceptable is it to train the OH nurses as case-managers? What is the impact of the training on skill acquisition during the study period? How much additional training would case-managers need to achieve established competency targets and prevent decay in skills?
6. How feasible and acceptable would it be to deliver such an intervention in different NHS settings? What rate of uptake could be expected, and how good would the adherence by OH staff and study participants be? What would be the resource implications of the intervention? ***(To be assessed in Phase one)***
7. If a trial were conducted to test such an intervention, how well would methods of recruitment and data collection work in practice? What rates of recruitment and follow-up would be expected? What would be the likelihood of 'contamination' if, within the same trust, the intervention were delivered to some staff and not to others? ***(To be assessed in Phase two)***

Note, specific details relating to how questions 1-4 were answered as part of our preparatory work can be found in the appendix. This work was completed prior to the development and implementation of phase 1 and phase 2.

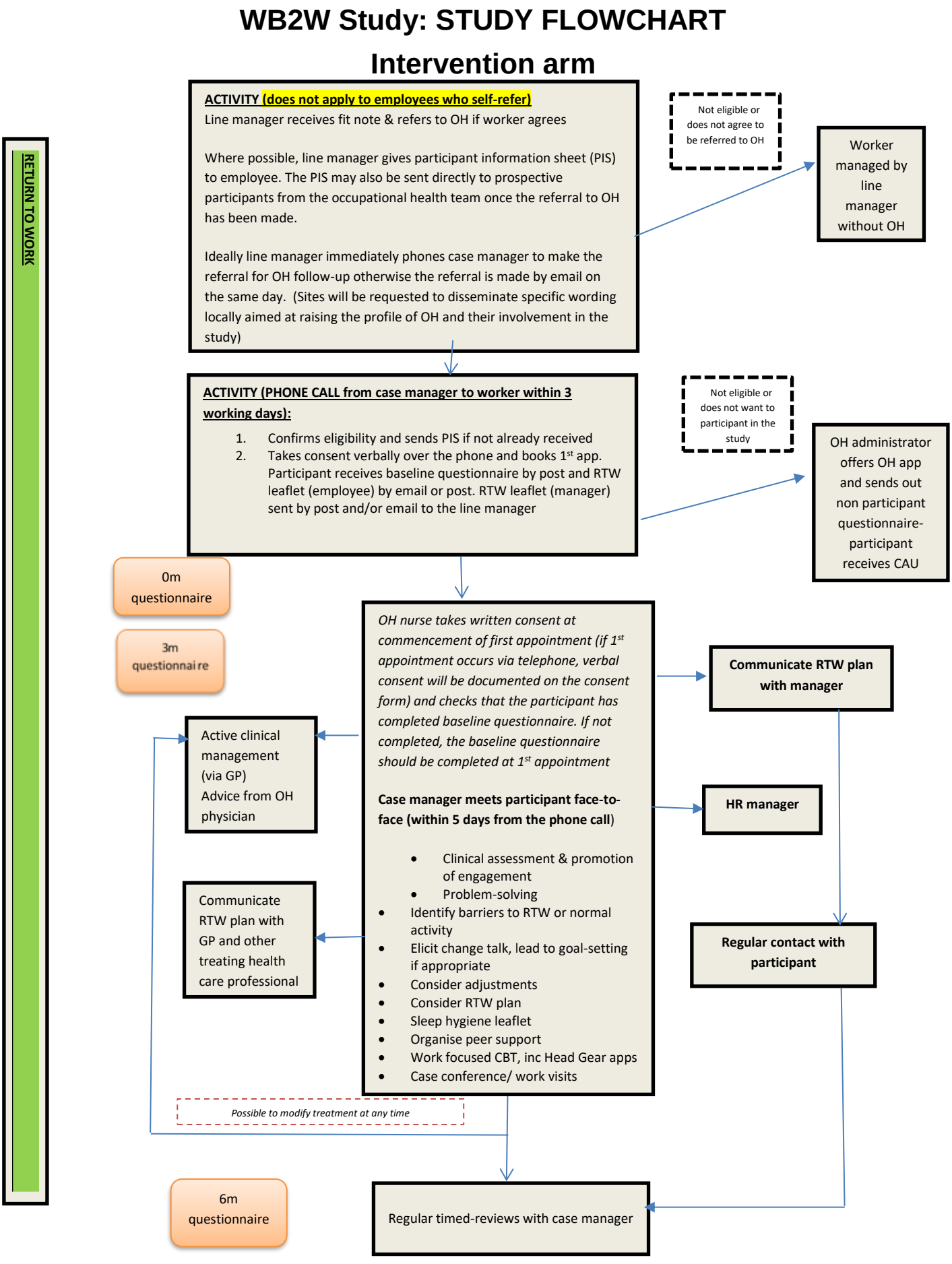
4.2 Study outputs

1. An up-to-date systematic literature review on the efficacy and cost-effectiveness of interventions in primary and secondary care to improve RTW in workers who go on sick leave with CMHD.
2. A comprehensive description of the usual management of NHS staff who go off sick with CMHD (if there is major variation in current management of CMHD, a full RCT might need to stratify accordingly).
3. A manualised intervention, which it is hoped will be cost-effective, and would be practical, acceptable to all stakeholders, and suitable for evaluation in a trial.
4. A report on the optimum data collection tools for an evaluation study
5. A manual for training case-managers in delivery of the intervention. An assessment of the feasibility, acceptability and impact fidelity of the training in strengthening motivation and cognitive behavioural therapy (CBT) directed goal-setting skills.
6. A report on the acceptability of the intervention and of methods to evaluate it, covering:
    - Rates of uptake among those who would be eligible to participate
    - Reasons for non-participation in those who might decline to take part
    - The likely frequency and nature of any protocol violations
    - The potential completeness of data collection for clinical, occupational and cost-effectiveness outcomes
    - Average consultation times compared to normal and the average number of follow-ups per case in the context of a goal-setting approach
    - Extra line manager and human resources (HR) personnel time per consultation needed compared to normal
    - A summary of qualitative findings representing views on the intervention and its assessment expressed by participants, case-managers, HR and line-managers.
7. An assessment of possible “contamination” if as part of a trial, the intervention was delivered to some participants at a trust, but not to others.

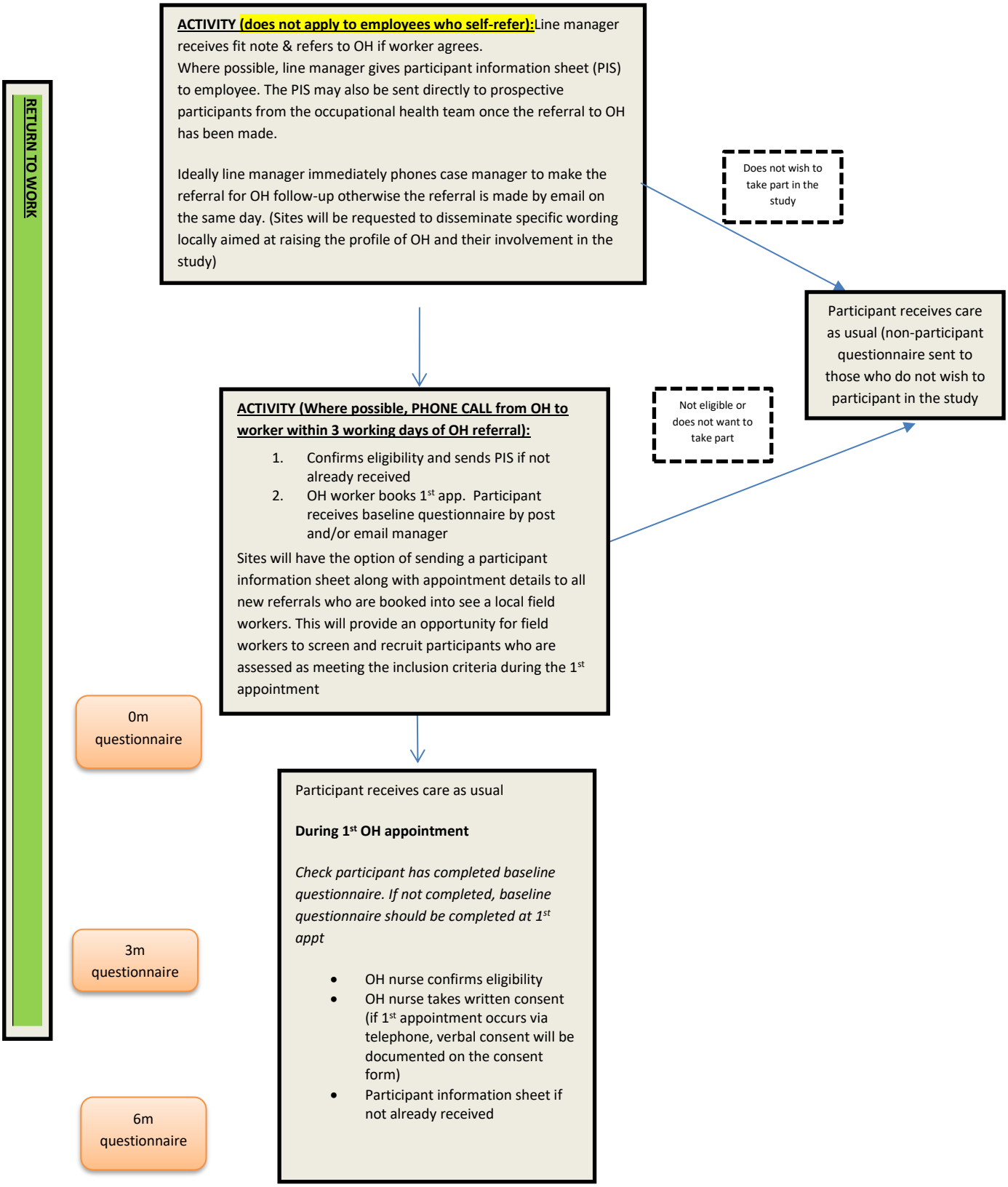
5.0 Health technologies being assessed

The intervention will be based on a case-management approach delivered by an OH nurse (case-manager), trained in CBT based approach to problem solving in the context of CMHD. The assessment of the worker on sick leave will be by a bio-psychosocial approach.
The intervention will include identifying barriers to RTW, problem-solving by participant and manager, work-focused CBT (via on-line programmes i.e. Head Gear smartphone app or face-to-face therapy depending on local access), an evidence informed leaflet on RTW, optimisation of clinical treatment, goal-setting, peer-support networking, a written RTW plan based on discussion between participants and their manager, work-place adjustments including flexible working and graded RTW in discussion with the participant’s manager, maintenance of contact between the line manager and the sick-listed worker, communication of the RTW plan with the treating healthcare professionals including the participant’s general practitioner, regular timed reviews, and referral to an occupational physician or secondary services if required. The intervention will be delivered on receipt of a fit note or soon after. The intervention with be refined during phase 1 of this feasibility study and manualised at the end of phase 2.

Figure 3 Proposed intervention (intervention group) and control group



Care as usual arm



6.0 Research Plan

Design and organisation of the project

The study will be a 32 month mixed methods project with two complementary phases to address the aims and objectives outlined in 4.0.

- Phase 1 will test the feasibility and acceptability of the intervention.
- Phase 2 will inform the preparation for a future multisite trial in the UK.

The project addresses two elements of the development and evaluation process (i.e. developing the evidence base and feasibility) of the MRC Framework for Developing and Evaluating Complex Interventions (Craig 2008). Phase 1 will take account of the MRC guidance *Process evaluation of complex interventions: Medical Research Council guidance* (Moore 2015).

We have used both qualitative and quantitative measures to allow an initial evaluation of process at this feasibility stage, particularly the impact of context (NHS employment setting). We have included both quantitative measures and more detailed qualitative analysis with an iterative loop that will allow the basic assessment and development of fidelity and reach of the intervention during this feasibility stage. We would anticipate that (should the intervention prove to be feasible) further process evaluation, including further work on fidelity, dose and mechanisms of impact would be built in at the full trial stage.

6.1 Phase 1

Design of definitive trial

We think that the impact of an intervention to improve RTW in NHS staff who go on sick leave with CMHD would best be assessed through a cluster randomised controlled trial in a variety of NHS trusts, provided that important "contamination" could be avoided (i.e. delivery of the intervention did not inadvertently modify the management of controls). In PICO format the design of the RCT that is envisaged can be summarised as:

Population: NHS staff, in a variety of NHS Trusts who have been on sick leave because of CMHD (anxiety and depressive disorders) for longer than 7 and less than 90 days.

Intervention: A complex intervention comprising various clinical and workplace provisions, which individually or in combination are thought likely to be effective in this population (either from direct evidence, or because they are known to be effective in other working populations or conditions)

Comparator: Care as usual

Outcomes: Reduction in anxiety/depression, change in use of medication for mental illness; early, part, full and sustained RTW; change in health-related quality of life and wellbeing; relapse rates; and adverse events. We will assess the cost-effectiveness of the intervention both from an NHS and a societal perspective. In addition, the financial implications for employers will be investigated.

The PICO process is a technique used in clinical research to frame and answer clinical or health related questions.

9.1 Before such a trial is mounted we need to answer the following questions, which form the basis of phase 1

Question 5. How feasible and acceptable is to train the OH nurses as case-managers? What is the impact of the training on skill acquisition during the study period? How much additional training support would case-managers need to achieve established competency targets and prevent decay in skills?

Question 6. How feasible and acceptable would it be to deliver such an intervention in different NHS settings? What rate of uptake could be expected, and how good would the adherence by OH staff and study participants be? What would be the resource implications of the intervention?

Question 7. If a trial were conducted to test such an intervention, how well would methods of recruitment and data collection work in practice? What rates of recruitment and follow-up would be expected? What would be the likelihood of 'contamination' if, within the same trust, the intervention were delivered to some staff and not to others?

Study design: To enable us to answer study questions 5, 6 and 7 in an efficient manner, we propose to recruit participants from six NHS trusts, all of which have agreed to help with the study. We plan to see if it is feasible to randomise at departmental group level. We will ask each Trust involved to determine which departments have high incidence of sickness absence due to mental health disorders for more than seven days. We will then group departments together (departmental group) to ensure that we will recruit sufficient participants for the feasibility study.

At three trusts the departmental groups will be assigned either: a) to see an OH nurse who has been trained as a case-manager and receive the intervention; or b) to see an OH nurse who has not been trained as a case-manager and receive care as usual for that trust *(mixed intervention/care as usual sites)*. At two trusts, no OH nurses will have been trained as case managers and all participants from the departmental groups will receive care as usual for that trust *(care as usual sites).* At one trust, participants will see an OH nurse who has been trained as a case-manager and receive the intervention *(intervention only site)*. We will recruit 77 participants. Thus, there will be four groups of participants.

- 21 participants from departmental groups will receive the intervention from study centres delivering the intervention or care as usual (Group A)
- 21 participants from departmental groups will receive care as usual from study centres delivering the intervention or care as usual (Group B)
- 28 Participants from departmental groups will receive care as usual from centres delivering only care as usual (Group C)
- 7 participants from departmental groups will receive the intervention from study the centre delivering the intervention (Group D)

Table 1: Recruitment targets per site

Participating site	**Intervention**	**Care as usual**
Care as usual sites		
Guy's and St Thomas NHS Foundation Trust	N/A	14 (Group C)
West Midlands Ambulance Service	N/A	14 (Group C)
Mixed intervention/ care as usual sites		
The Ipswich Hospital NHS Trust (acute and ambulance)	7 (Group A)	7 (Group B)
Norfolk and Norwich NHS Foundation Trust (acute)	7 (Group A)	7 (Group B)
University Hospitals Leicester NHS Trust (acute)	7 (Group A)	7 (Group B)
Intervention site		
Papworth Hospital NHS Foundation Trust (special)	7 (Group D)	N/A

We will collect the same data on all participants and participating centres. Data from all groups will be used to answer questions about rates of recruitment and follow-up, and the acceptability and performance of methods to assess possible outcome measures. Data from Group A and Group D will provide information about the acceptability and costs of the intervention, and rates of adherence to the intervention. Data from Groups B and C will provide information about the distribution of possible outcome measures in the absence of the intervention (which would help in power calculations for a subsequent trial). Comparison of the management of participants in Groups B and C will give an indication of potential for major "contamination". The follow-up period will be six months from recruitment. Outcomes will be assessed using a mix of qualitative and quantitative methods.

Target population: NHS staff who have recently commenced sick leave because of CMHD

Inclusion criteria: Staff with CMHD with or without an associated physical disorder who have been off sick for a period of more than 7 days (i.e. on receipt of fit note) and less than 90

days. Staff will be screened for eligibility for entry into the study either at the time of referral to OH or during their 1st OH appointment.

Exclusion criteria: Staff with a psychotic disorder, bipolar disorder, substance abuse or dementia. Staff under formal investigation for misconduct or in the formal process of disciplinary action (as this may be an effect modifier).
Six OH departments have been chosen from those confirming that they wished to participate in the feasibility study in response to the questionnaire sent to the current SCIN study centres plus one ambulance trust. We have selected NHS OH departments representative of the range of NHS Trusts in the UK, providing OH services to a mixture of acute, mental health and ambulance trusts. All trusts included have electronic OH data capture systems, do not currently have early (<8 day) intervention for sickness absence or case-management in use and employ more than two OH nurses who advise on RTW in workers with CMHD.

We have allocated the participating trusts to care as usual or mixed intervention/ care as usual centres / intervention centre based on sampling groups with the aim of achieving broad comparability between the types of trust.

Care as usual study centres
Guy's and St Thomas' NHS Foundation Trust (acute)
West Midlands Ambulance Service (ambulance)

Mixed intervention/care as usual centres
The Ipswich Hospital NHS Trust (acute and ambulance)
Norfolk and Norwich NHS Foundation Trust (acute)
University Hospitals Leicester NHS Trust (acute)

Intervention centre
Papworth Hospital NHS Foundation Trust (special)

Reserve centres
Bwrdd Lechyd Hywel Dda Health Board (acute and mental health)

Our experience from the SCIN trial has shown that during the period between OH departments confirming their willingness to participate in a study and the study commencing, internal changes in the trust or the department may mean that the department is no longer able to participate. Therefore we have one reserve trust. Responses from OH departments to the questionnaire administered during the survey of usual care exercise may identify further reserve trusts. We were particularly keen to include OH services which provide OH services to ambulance trusts as these types of trust have the highest incidence of sickness absence in the NHS.

Intervention: W**e** will employ a complex intervention of the type described in section 'health technologies to be assessed'. This was refined and finalised during our initial preparatory work.

6.2 *Case manager training*
Training of the case managers is an important component of the intervention. We have therefore developed a two day bespoke training package. The small groups size of up to eight case managers (a maximum of two per intervention trust) will allow for in-depth training. We will base our training on our experience of running case-manager training days with an emphasis on problem solving and promotion of engagement (JS, RS) (Smedley et al. 2013) and on mental health training days for OH nurses (MH, IM) (Madan et al. 2013). We have previously shown that small group training on mental health for OH nurses results in good knowledge transfer and use of knowledge in practice, plus increased confidence and high levels of satisfaction with the training (Kirkpatrick 1994). The essential skills required of case managers are the capacity to create a supportive, empathic atmosphere in which they explore and make salient the client's own reasons for returning to work, discuss their barriers to RTW and support the client when ready, to identify an acceptable pathway to change by facilitating structured personal goal setting. This goal setting element will be orientated to increasing activities at home and gradually introducing and scaling up engagement with the employer and phased return to work.

Training for case managers will therefore comprise a number of related elements, which will be integrated in the manual and in the training.

1) Clinical assessment of CMHD in the OH context, delivered by a consultant occupational physician and consultant psychiatrist: symptom and functional enquiry, mental state assessment, use of standardised questionnaires (GAD-7, PHQ9), principles of the optimal treatment of CMHDs (counselling, talking therapies, drug treatment, on-line CBT in conjunction with input from a therapist), and availability of these locally, addressing and overcoming barriers to work, problem solving using a specified framework, RTW planning, including the indications for phased hours, minimising shift work, exposure to stressors at work, work volume, and the management of relationships at work.
2) Problem solving and motivational interviewing (MI): Case managers will be taught to deliver problem solving in the spirit of MI to promote participant engagement by RS who is experienced in teaching and delivering MI training in a variety of settings including chronic disease and OH case management.
Training will combine workshop input with follow-up individualised supervision. Case managers will be permitted to consult with the study participants when their problem solving practice has achieved pre-determined competency thresholds.
3) Cognitive Behavioural Therapy (CBT) skills: case managers will be coached in CBT techniques. This will be provided by a psychiatrist, but will stop short of conventional clinical CBT training, focusing instead on the use of CBT approaches (e.g. positive thought cycling) with a workplace focus. For example defusing negative cycling or rumination about problems in the workplace. We will train the case managers in risk assessment of serious self-harm or suicide in the study participants. We will build an escalation procedure into the training, which will take into account the case managers current local procedures.
4) Use of the study protocol and communications with line managers and GPs. Setting up a peer-support network.
5) Safety issues: Procedures for safeguarding vulnerable individuals, which will be dovetailed with the local procedures at the case-manager's trust.

Evaluation

1) We will evaluate the training by using the first three levels of the Kirkpatrick model of educational evaluation: learner satisfaction, learning outcomes and performance improvement (Kirkpatrick 1994), adapting the questionnaire we used in previous evaluation of mental health training for OH nurses (Madan et al. 2013).
2) We will monitor the integrity of case-management delivery through the trial by content analysing a random 40% of consultations undertaken by the case-managers. We will record if and when case-management skill/adherence drops below a pre-determined level. This will allow us to assess how much top-up training and on-going supervision case-managers are likely to require in a full trial.

6.3 Recruitment and sampling:
Before recruitment commences, we will train the centres on how we wish to collect sickness absence data from ESR. We will assist participating OH departments to liaise with their HR departments to ensure that the HR departments accurately record fit notes reporting CMHD onto S10 of the ESR system.

In the study centres where participants receive either the intervention or usual care, two OH nurses will recruit participants at each centre. Up to two OH nurses will be trained in case management and will deliver the intervention and the other will deliver care as usual for that trust. The duration of recruitment will be 6 months. Where possible, all staff who go on sick leave with CMHD during the 6 month recruitment period will be referred to the OH department as soon as their line manager receives a fit note. We will provide sites with wording to further raise the profile of OH and their local site's involvement in the study. The decision on whether to circulate this correspondence will be left to participating sites. The study will also recruit from those who self-refer to Occupation Health departments. All staff who go off sick with CMHD and who are referred to the participating OH departments will be provided with information about the study and invited to participate. Those who wish to participate will be asked to consent and will be screened for eligibility for the study. At the discretion of the participating study centres, participants in the intervention group will continue to receive the

intervention until they RTW or leave their employment, even if they are still on sick leave after the study has finished.

At one study centre (Guy's and St Thomas' NHS Foundation Trust; GSTT) we would like to promote the role of occupational health service in manging workers who are on sick leave due to common mental health conditions. We would like to add a brief message about the role of OH and about the Ways Back to Work study to the Workforce Directorate brief which is correspondence disseminated across the GSTT trust only targeting line managers.

6.4 Data collection and follow up

6.4.1 Quantitative data

Data on sickness absence for CMHD will be collected for six months after the participant enters the study from S10 on the participating centre's ESR and by self-report questionnaire. Study participants will be given a self-administered baseline questionnaire to complete at the time of entry to the study (t=0). They will be sent a follow-up self-administered intermediate questionnaire at three months (T=3) and a final follow-up self-administered questionnaire at six months (t=6) after entry to the study. Note, all participants will complete the same baseline and intermediate questionnaires. Responses provided in the intermediate questionnaire will than determine which version of the final questionnaire will be administered i.e. final questionnaire (version 1) will be administered to those employees who are back at work in any capacity for more than four weeks at the three month time point (T=3); final questionnaire (version 2) will be administered to those who are still off on sick leave at T=3months due to their mental health condition (including those who have not returned to sustained work) or those who did not return the intermediate questionnaire.

Participants will be invited to complete paper-based questionnaires. This will be returned to the central research team using business reply envelopes. A series of reminders will be used to encourage return of the study questionnaires for non-responders. The reminders will include, one email reminder, one telephone reminder and finally a replacement questionnaire will be sent to the participants preferred postal address. To allow to send participants 3 and 6 months questionnaires (and reminders if needed), we will collect contact details from participants (name, surname, mobile phone, email address, home postal address). Contact details will be collected together with the baseline questionnaire.

We will collect information about: rates of recruitment; reasons for non-participation; baseline characteristics of those eligible for inclusion; adherence to the intervention in those allocated to receive it and the management of those who are not; and rates of successful follow-up. Additionally, we will collect data on the distribution of possible outcome measures, including, reduction in anxiety/ depression, health-related quality of life, change in antidepressant use and RTW during the six month study period. Full and partial return to work will be measured by total days of sickness absence before return to work and self-reported number of hours worked. We will collect information about participants' referral to and uptake of improving access to psychological therapies (IAPT) services and the Government's Fit for Work Service We will record any protocol violations, reasons for not completing the intervention and any adverse events.

At the sponsor site (Guy's and St Thomas NHS Foundation), we will conduct further exploratory work to better understand the factors impacting on the identification and referral of employees who are on sick leave with a common mental health disorder. Where appropriate and with relevant permissions, this may include reviewing information on existing management referrals. These insights will be pooled with information obtained from the focus group interviews.

Costs of delivering the package of interventions including OH nurse time, participant and manager time and cost of training OH nurses in case management.

6.4.2 Qualitative data

We will conduct focus groups and in-depth interviews at each site (via telephone or face-to-face) to obtain feedback from participants, line managers, HR and OH staff. Topic guides will

focus on the intervention content and process; how recruitment and delivery methods work in practice; and suggestions for improvement.

Where possible, we will conduct one-to-one in-depth interviews with at least two and a maximum of three study participants per study centre. Where possible, pilot interviews will be carried out prior to the main study to assess comprehension, relevance and appropriateness of the interview schedule. We will conduct two focus groups at each of the six study centres, employing purposes sampling to recruit a group of OH nurses (including those trained in case management), and a group of HR and line managers. There will be a total of 12 focus groups with 5 to 8 members per group. All focus groups and interviews will be audio-taped, last approximately one hour and will take place in a convenient location at each site. The focus groups and interviews will be conducted by one of the research team members (post-doc trained). Sessions will be recorded on an audio-recorder and transcribed verbatim shortly after each session by a fully skilled medical secretary employed by the Guy's and St Thomas' NHS Foundation Trust. Audio recordings will not be deleted after transcription and will be kept for the duration of 20 years. No identifiable information will be included during the transcription process. Transcripts will be stored electronically using password protection.

Distress protocol: The research team members conducting the individual and focus group sessions are qualified psychologists and have experience providing counselling support. In circumstances where a participant in the individual or focus group interviews become upset or distress, the research team will be able to provide them with immediate support in addition to providing the participant with information about local services and resources. In addition, the interviewers are backed up by co-investigators with extensive clinical experience in occupational medicine and occupational psychiatry. Where appropriate we will be able to liaise with participant's GP or alternatively secondary clinical services to facilitate an appointment/referral. We will also take a number of different measures to prevent and minimise upsetting the respondents for example e,g. participants will be given the option to skip questions, should the participant decided that they do not wish to answer. Participants will be informed during the consent stages that they are free to withdraw from the study at any stage without giving a reason.

The end of the study will be the last participant last interview.

6.5 Data analysis

For the purpose of the intention to treat (ITT) analysis, participants will be considered as entered into the study upon completion of the baseline questionnaire.

6.5.1 Quantitative

Rates of recruitment will be calculated from the numbers of eligible participants and of those who agree to participate in the study. Characteristics of eligible participants will be recorded at baseline and will be summarised through means, medians, standard deviations, and inter-quartile ranges (IQRs). Characteristics will be compared between those who agree to participate in the feasibility study and those who do not. Outcome variables, including anxiety/depression score, health related quality of life score, use of antidepressants, will be summarised separately for baseline and follow-up using means and standard deviations if they are normally distributed, or through medians and IQRs otherwise. Number of days before returning to normal working hours will be summarised by medians and IQRs.
For each possible outcome measure, the prevalence of missing data will be quantified. We will calculate the proportion of participants who complete the intervention, and the proportion of completed data sets.

6.5.2 Qualitative

Qualitative analysis of data from focus groups and interviews will involve thematic (i.e. content) analysis, including simple counting and inclusion of deviating accounts. The analysis will follow a six phase structured approach involving: (i) transcription of all interviews by a professional transcriber; (ii) familiarisation with text and creation of an initial list of emerging themes; (iii) coding of transcriptions uploaded to NVivo 8, a qualitative software package that allows data to be annotated as codes, and for the cross-referencing of codes; (iv) categorisation and interpretation through additional coding phases and development of

representative themes and theoretical concepts emerging from analytical induction and cross-checking with an additional researcher on the team; (v) identification of thematic frameworks in additional discussions with the team focused on further refinement through constant comparison within and between the codes to ensure that the framework reflects the data; and (vi) linking findings with existing or newly generated theoretical concepts and models to provide context and confirm the relevance and robustness of the key findings of the study.

6.5.3 Economic

The economic component of the study will assess the feasibility of conducting an economic evaluation of an adequately powered trial. In order to inform the design of an economic evaluation of a full trial, we will identify which services are commonly used so that these can be included in the Client Service Receipt Inventory. We will also assess the feasibility of obtaining economic data and the extent to which questionnaires are completed and return the required information.

6.6 Sample size

We calculated that with a sample size of 60 we will be able to estimate a participation rate of 80% to within a 95% confidence interval of +/- 10%. We have allowed for a maximum of 77 participants so we are confident that we will have a good precision around the participation, and completion rates. All the OH departments who have confirmed that they wish to take part would expect to see more than 20 workers who go on sick leave with CMHD in a six-month period. Therefore, we consider that it is feasible to recruit 14 participants at care as usual and mixed intervention/care as usual centre and 7 participants at the intervention only centre.

Outputs:

- An assessment of the feasibility and acceptability of the intervention to workers who go on sick leave with CMHD, line managers, OH departments and HR managers.
- A manual for training the case-managers.
- An assessment of the feasibility, acceptability and impact fidelity of the training in strengthening motivation and cognitive behavioural therapy (CBT) directed goal-setting skills.

7.0 Phase 2:

Finalisation of the manualised intervention and recommendations for design of a RCT

Method: We will work with our stakeholder group including our PPIs to review the information from the feasibility study and determine whether a cluster RCT could be designed that was free from unacceptable contamination. We will review the findings from qualitative, quantitative and economic analyses. We will pay particular attention to the response rate, and likelihood of contamination to determine if an individual or cluster trial would be the most appropriate method for a definitive trial.

Should a RCT be judged feasible, data from the feasibility study on the distribution of relevant outcome measures in the absence of intervention will help to inform power calculations.

Outputs:

1. Complete specification of the intervention package, standard operating procedures and potential staff and cost implications will be developed for the package.
2. Recommendations for the design of a RCT should it be judged feasible. Feasibility challenges will be reported. If a trial is deemed unfeasible, alternative evaluation methods will be proposed.
3. Practical service information to guide the design and operationalisation of a full study protocol, including length of baseline consultation and duration and number of follow-ups.

8.0 Dissemination and projected outputs:

The research team acknowledges the importance of disseminating research findings. We will dedicate one of the face-to-face research team meetings to discuss the optimum dissemination of the outputs of the study**.**

The major outputs of the study will be

1) An updated systematic review on the efficacy and cost-effectiveness of interventions in primary and secondary care to improve RTW in workers who go on sick leave with CMHD.

2) A training programme and manual on RTW interventions in CMHD and work-focused CBT for case-managers
3) An assessment of the feasibility and acceptability of the intervention to workers who go on sick leave with CMHD.
4) An assessment of the costs of delivering the intervention in a NHS setting
5) A protocol for a RCT, or if a trial is deemed unfeasible, a protocol for an alternative evaluation methods.

The study findings will be:

1) Disseminated to the centres taking part in the feasibility study.
2) Submitted for publication in peer-reviewed journals
3) Submitted for presentation at the Society of Occupational Medicine, annual scientific meeting and at a conference of the International Commission on Occupational Health.
4) Submitted for publication in professional newsletters including, the NHS Health at Work newsletter (sent electronically to over 100 NHS trusts), GP newsletters such as Pulse.
5) We will ask our PPIs to assist in disseminating the results to user groups, including MIND (Tracey West has close links).

9.0 Plan of investigation and timetable:

The timetable will be as follows

Preparatory work: September 2016 – Oct 2017

Systematic literature review; Sponsorship review & approval; Survey of OH departments to establish CAU; Mapping of the evidence onto the intervention; Stakeholder workshop; Finalisation of data collection tools; Secure HRA and R and D approvals; Prepare materials for case-manager training;

Phase 1: July 2017-January 2019

- Case-manager training September 2017
- Standardise study centre recording of CMHD on ESR July –October 2017
- Recruit participants April 2018- September 2018
- Follow up participants September 2018-March 2019
- Sample case-notes to test the fidelity of case-manager training September 2018-March 2019
- Pilot qualitative interviews August 2018 - October 2018
- Qualitative interviews September 2018 - March 2019
- Analysis November 2018 – July 2019 until end of study period.

Phase 2: July 2019 – October 2019

- Finalisation of the manualised intervention and recommendations for design of a RCT. Submission of final report

10.0 Project management:

Dr Madan as chief investigator will have overall management responsibility for the study whilst Guy's and St Thomas' NHS Foundation Trust (GSTFT) will oversee the financial management. We will appoint a full time post doc who will manage the project on a day-to-day basis and will be responsible for the co-ordination of the project and of the case–managers. Dr Ntani (University of Southampton) will manage the quantitative analyses and Professor McCrone (King's College London) will manage the health economics analyses. Dr Hatch (King's College London) will manage the qualitative interviews in phase 2 and their analyses.

Research team meetings will be 4-6 weekly throughout the duration of project. Collaborators based in London will meet face-to-face with other collaborators joining by video or teleconferencing. Many members of the research team meet regularly for other purposes and where possible research team meetings for this study will dovetail with these times. Four face-to-face meetings between members of the research team have been factored in the costings.

A part-time research administrator will be appointed to assist in the co-ordination of the project at Guy's and St Thomas NHS Foundation Trust and the participating centres.

11.0a Governance and legal compliance

) We will apply for Health Research Authority approval study. . We will apply for Research and Development (R&D) approval via the new Health Research Authority's system and R and D approval from each centre via the site specific forms.

Although 49 of the participants will not receive the intervention, they will receive care as usual for their Trust. The participating centre will benefit from help with standardising the data collection of their sickness absence. Our experience from the SCIN trial and other studies in NHS staff has been that NHS staff are keen to participate in research studies which aim to improve the health of NHS staff, provided that questionnaires do not take too long to complete. NHS staff understand the importance of collecting data from participants who may not receive the intervention. Our experience is that NHS staff embrace the concept that 'research is everyone's business.'

Participants who receive the intervention, but have not returned to work after six months, will, at the discretion of the participating centre, continue to receive the intervention until they return to work. Our data on RTW times for NHS staff who go on sick leave with CMHD suggests that most of the participants are likely to have RTW by six months after being recruited into the study.

Approval for the study will be obtained in advance from the management and staff representatives at the participating trusts. Informed consent will be sought from all staff participants before entry into the study. If first occupational health appointment occurs face to face, OH nurse will take written informed consent at the commencement of the first appointment; if first OH appointment occurs by telephone, OH nurse will take informed consent at the commencement of the first telephone consultation and verbal consent will be documented on the consent form..Data collection will be organised such that names and contact details of individuals who take part in the study are held separately from other personal information, which will be identified only by a serial number. No information will be published in a form that could lead to the identification of individuals.

11b Safety assessment and reporting

Lead collaborators at participating sites will be responsible for reporting all SAEs to the chief investigator as soon as they are identified. In the context of this study, SAE are defined as self-harming or attempted or completed suicide by the participants or a serious or significant deterioration in a participant's mental state. The chief investigator will then be responsible for reporting SAEs to the R&D. Reports of related and unexpected SAE will be submitted to the main REC within 15 days of the chief investigator becoming aware of the event.

12.0 Patient and public involvement

Four public/patient representatives informed our application. A NHS human resources (HR) manager who has used an occupational health (OH) service for management of his own depression strongly welcomed the proposal and advised that it was feasible to deliver in the NHS. He suggested that we included HR in the stakeholder group and focus groups. Keith Johnston, Chair of Syngentis (a community interest group providing consultancy for NHS OH services) advised that we include NHS Employers and the NHS Health at Work Network on the panel of stakeholders.

Emer O'Neill, Chief Executive of the charity, Depression Alliance, advised that we add peer-support networking to the health technology to be assessed. Tracey West agreed to join the team as a patient advisor during the development of the full proposal. Ms West has a mental health condition and works full time. She has previously been involved as a PPI for research studies at University College London. She has read the proposal and is fully supportive of the study.

The PPI representatives commented that the lay summary was clear and easy to understand. Having a patient representative's input throughout the study is essential; initially we have included Emer O'Neill as a study collaborator, but she has left her role at Depression Alliance and was unable to continue to contribute to our study. Tracey West agreed to replace her as study collaborator. Tracey attended the stakeholder meeting and has been involved in the development of the intervention and protocol. As a collaborator she will be invited to attend the regular research meetings and we will involve her in the development of the final protocol

as described in phase two. We have included her travel costs and an honorarium for their time in our proposal. We will invite our PPI representative to comment on the participation sheets, consent forms and questionnaires.

13.0 Expertise and justification of support required

We have convened a strong, multidisciplinary team, which has expertise covering all aspects of developing and assessing the feasibility of evaluating this complex intervention. The collaborators have prior successful experience of working together on numerous projects including: the ongoing HTA funded SCIN trial (IM, JS, GN, DC, PM); a MRC/ARC funded programme grant (IM, JS, KWB, GN, DC), National audits on the management of depression in the workplace (IM, JS, MH) and MH, SH and IM have researched into and published several joint papers on various aspects of mental health in the workplace.

The membership of the research team is as follows:
Dr Ira Madan as Chief investigator will bring expertise as an NHS occupational physician with a special interest in mental health disorders in the workplace.

Professor David Coggon OBE will act in a consultancy capacity advising on epidemiological aspects of design, analysis and interpretation.

Professor Amanda Griffiths is an academic occupational psychologist with experience in working on research on stress, and she will be mainly involved in phase one and the qualitative aspects of phase two.

Dr Stephani Hatch is a social epidemiologist with expertise in psychological medicine and qualitative methodology. She will supervise the qualitative interviews in phase two and be responsible for advising on the analysis and interpretation of the results.

Dr Max Henderson is an occupational psychiatrist and epidemiologist. He has worked in as a liaison psychiatrist in a NHS OH service and led the national audits on management of depression in the workplace. He will bring clinical psychiatry expertise and expertise on the training of the case-managers, choice and use of clinical data collection tools.

Professor Paul McCrone is an experienced health economist, who will be responsible for the cost-effectiveness evaluation.

Dr Mariam Molokhia is an academic GP and experienced epidemiologist who will advise on the role of GPs in the management of workers on sick leave with CMHD and how best OH departments can liaise with GPs.

Dr Georgia Ntani will be responsible for the statistical aspects of design, analysis and interpretation of the quantitative aspects of the study.

Ms Tracey West will act as co-ordinator for the PPI representatives on the study and her experience in working with people with depressive disorders will ensure that the sick worker experiential perspective is included in all phases of the study.

Mr Robert Shannon is a chartered psychologist who trained the case-managers in motivational interviewing in Dr Smedley's study (see below). He will facilitate the stakeholder meeting and will be responsible for training the case-managers in motivational interviewing. He will contribute to the development of the training package for case-managers and for advice on measuring the fidelity of the intervention in phase two.

Dr Julia Smedley has been the clinical lead for an NHS OH department for 19 years. She published the first study evaluating the use case-management to improve RTW. She will bring invaluable expertise in the training of the case-managers, collecting data using ESR and OH software and mapping the evidence onto the proposed interventions.

Dr Karen Walker-Bone brings expertise in methodology and co-morbidity with physical disorders. She has experience in clinical trials and the potential barriers to their success. Her expertise will be invaluable in phases one and two.

Appendix

Overview of preparatory work completed

Prior to the commencement of phase 1 and phase 2 of study, we gathered relevant evidence by a systematic review of the literature and established care as usual. In addition, we developed the intervention and data collection tools by an iterative process. Specific details are outlined below

Question 1. What is the most up-to-date evidence available on the efficacy and cost-effectiveness of interventions to improve RTW in workers who go on sick leave with CMHD?
Study design: A systematic review of the literature.
Key questions:

1) Which workplace-based interventions are effective in improving RTW outcomes for workers with CMHD?
2) What are the key elements of effective interventions?
3) Are any interventions specific to the healthcare sector?
4) Are any interventions specific to the UK?

Inclusion and exclusion criteria:

- The inclusion criteria focused on interventions based in the workplace that have return to work or work absence as outcomes.
- We excluded papers in which the results were not presented separately for workers with CMHDs or a specified subset of CMHDs.

Search strategy: A comprehensive systematic review by Pomaki et al (2010) on return to work/stay at work interventions for workers with mental health conditions included studies up to November 2009. We extended that review to cover the seven-year period from 1 November 2009 to the end of September 2016.

Search terms: We combined three groups of terms ('worker', 'mental health', 'intervention') using an AND strategy. We restricted our search to English language papers as papers in other languages are less likely to be relevant to the UK health service setting. We searched for systematic reviews, meta-analyses and primary quantitative and qualitative studies in four electronic databases (MEDLINE, EMBASE, CINAHL, PsychINFO). The electronic database searches were supplemented by including the results of two relevant active reviews that had been identified on PROSPERO (PROSPERO is an international database of prospectively registered systematic reviews in health and social care, welfare, public health, education, crime, justice, and international development, where there is a health related outcome)

(http://www.crd.york.ac.uk/PROSPERO/ accessed 2.12.15):

- Lisa Lyssenko, Christopher Hahn, Nikolaus Kleindienst, Martin Bohus, Miriam Ostermann, Ruben Vonderlin. A systematic review of mindfulness-based interventions in occupational settings. PROSPERO 2015:CRD42015019282 (Due to complete April 2016)
- Alba Fishta, Beate Weikert, Uta Wegewitz. Return-to-work (RTW) interventions for employees with mental disorders: an overview of systematic reviews. PROSPERO 2015:CRD42015023496 (Due to complete June 2016).

In due course, we will obtain and include relevant material from the updated Dutch national guideline (NVAB guideline) on the occupational management of common mental disorders in the workplace. This will be published in due course (Professor Carel Hulshof – NVAB guideline director, personal correspondence 02.12.15). A third active review identified on PROSPERO is not due to complete until March 2017 (Nicole Vogel, Stefan Schandelmaier, Thomas Zumbrunn, Shanil Ebrahim, Wout de Boer, Seyed Mohsen Mousavi, Gordon Guyatt, Jason Busse, Regina Kunz. Return to work coordination programmes for improving return to work in workers on sick leave). We have already contacted the review authors and the results of their review will be taken into consideration in the development of the intervention.
We do not intend to search for full economic evaluations, but we will abstract relevant economic data from identified studies where reported. This will give us some indication of intervention costs.

Data extraction and appraisal:
A data extraction template was developed; focusing on the population to which the intervention was delivered to, the setting of the intervention, the components of the intervention, economic costs, outcome measures and effect sizes. We appraised the papers and guidelines taking into account the methodological quality of each paper, biases and confounders, direction of bias and size of effect of interventions. For randomised controlled trials, we used the Cochrane risk of bias tool to assess the methodological quality of the trial (Cochrane Collaboration). Two reviewers appraised all papers independently. Where agreement was not obtained papers were referred to a third reviewer.
Outputs: We reported the systematic review based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al. 2009).

Question 2.What is the current practice in UK NHS OH departments in managing staff who go on sick leave with CMHD?
Study design: Cross-sectional survey of OH departments providing OH services to NHS trusts and health boards.
Methods: We identified OH departments providing OH services to NHS trusts and health boards from two lists. Firstly, the NHS Health at Work Network (of which the OH department at Guy's and St Thomas' NHS Foundation Trust is a member) had informed us that they had 130 NHS OH departments registered to the network. As a member of the network we had access to the names of the other member OH departments. We contacted each department and obtained a name and email address of the lead of each NHS service registered with the network. We were aware that many NHS Trusts contract their OH services from external commercial OH providers. The Commercial Occupational Health Providers Association lists 116 members and the names of the members are freely available on their website (Commercial Occupational Health Providers Association). We contacted each provider and asked if they delivered OH services to NHS Trusts, and if so which ones and we asked for the name and contact details of the lead person for each NHS OH contract provided. At the end of this process we envisaged that we would have identified the name and contact details of the lead person for the majority of providers of NHS OH services in the UK.

We designed a 12-item electronic questionnaire, enquiring about how OH providers currently manage NHS staff who go on sick leave with CMHD. We included questions on the type(s) of trust to which they provide OH services, who delivers the intervention, the nature of the intervention, how the line manager is involved, whether the workers have rapid access to mental health assessments or treatment, including CBT, and whether the worker's treating healthcare professional is involved.
The questionnaire was piloted amongst the 35 OH departments taking part in the skin care intervention in nurses (SCIN) trial (UK Clinical Research Network 2016). We confirmed that nine OH departments are willing take part in the feasibility study and use electronic OH data collection systems so that we could collect the data required for this study. We have included OH departments, which provide a service to acute and mental health trusts. NHS Staff working in Ambulance Trusts have the highest sickness absence rates of all healthcare workers, and their organisational structure is very different from acute trusts, therefore we are keen to include an ambulance trust in our feasibility study. Since only one of the 35 centres we contacted provides OH care to an ambulance Trust, we contacted one of the largest Ambulance Trusts in England (West Midlands Ambulance Service NHS Foundation Trust). They completed the questionnaire and have confirmed their willingness to participate in the feasibility study. We have selected six OH departments to take part in the feasibility study, with one as a reserve. Our proposed methodology capitalises on one of the stated outputs of the SCIN trial 'to establish a network of NHS OH departments which would be in a good position to deliver future studies'.

Data analysis: We used descriptive statistics to summarise the patterns of management of CMHDs.

Outputs: The information we collected gave us a picture of usual management of NHS staff who go off sick with CMHD.

Development of the intervention
Question 3 What form of intervention is most likely to be cost-effective in promoting RTW in NHS staff who go on sick leave with CMHD, and how can this be manualised to meet individual and organisational needs in different OH settings?

Study design: A two stage iterative consultation based on methodology JS and IM have used in the development of national evidence-based guidelines (Pratt K, Madan I 2006, NHS Plus et al. 2009).

Methods: Stage 1. Four members of the research team, including our OH physicians, occupational psychiatrist and GP in collaboration with our PPI representatives mapped the evidence from onto the proposed interventions as described in section 5.0 (health technology to be assessed) and we added additional interventions found from the literature to be effective in improving RTW in workers off sick with CMHD. The formulation of the provisional intervention model took account of the volume, quality and consistency of the evidence. Well-conducted studies with negative findings and studies that report significant associations were given appropriate weight. Where possible we looked at the size of effect of the intervention and considered the applicability of each intervention to our target population.

Output: A provisional evidence-based model of a complex intervention to improve RTW in NHS staff who go on sick leave with CMHD.

Stage 2. An important component in developing an intervention was to consider processes and involved participants (staff and users) during the design stages. Therefore, we held an intensive all day workshop to harvest the combined knowledge and experience of a group of stakeholders, with expertise in CMDs and NHS systems, from various professional backgrounds. The stakeholder workshop include: at least three members of the research team, including an OH physician, our GP collaborator and psychiatrist collaborator, two OH nurses delivering OH services to the NHS, one NHS HR representative, one matron, one NHS Health at Work Network representative, (volunteers for these will be requested via the NHS Health and Work Network), one representative from NHS Employers, one from UNISON, and our PPI representatives. A particularly important aspect of this engagement was to establish the feasibility and consistency of the HR input to the intervention.

The aims of the workshop were:
i) to refine the map of the intervention, timelines, responsibilities, referral routes, and checks and balances for each component of the intervention
ii) to encourage understanding, buy-in and ownership of the intervention for some of the staff who will operate the asystem.

RS (chartered psychologist) and AG (occupational psychologist) facilitated the stakeholder consultation day. We focused on the evidence for each component of the intervention and the barriers and facilitators (actual and possible) to the success of the provisional model intervention package in the NHS context. Based on participants' advice, we refined the pathways and processes of the intervention to maximise the chances of its success. We took into account service provision, cost-effectiveness and the likelihood of the intervention causing harm to workers. We established a suitable method for identifying workers who might benefit from the intervention. NICE identified the Whooley questions and GAD-2 as the optimal questions for screening for depression and anxiety in adults in primary care (National Institute for Health and Care Excellence 2011). We discussed the suitability of these tools for screening of participants for entry into the feasibility study.

Outputs:
1. A manualised model of the intervention, which we considered would be acceptable and feasible to its intended participants, for testing in the feasibility study.
2. A procedure for recruitment and selection of participants to enter the feasibility study.

Question 4. What data collection tools should be used to assess changes in clinical state and occupational functioning as a consequence of the intervention?

Method: We reviewed the data collection tools and draft questionnaires and participant information sheets. We shared and discussed with our PPI representatives in order to

optimise questions on outcomes (particularly RTW outcomes which are important for workers).

Outputs: the design a protocol for data collection, including suitable questionnaires.

Overall output of phase 2: detailed protocol for phase 1 and phase 2 of the study.

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