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Ways Back to Work: facilitating the return to work of NHS staff with common mental health disorders

Submission date
05/07/2018

Recruitment status
No longer recruiting

Registration date
10/08/2018

Overall study status
Completed

Last Edited
24/08/2022

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Workers in the NHS are more likely to develop mild to moderate anxiety and depression (known as common mental health disorders or CMHD) than the general working population. Having staff off work sick is costly to the NHS. For individuals, being off sick is associated with poor health-related quality of life and social isolation. The longer someone is off sick, the less likely it is that they will get back to work. We know that early, proactive support for NHS staff with CMHD who are on sick leave is beneficial. However there is a lack of UK research to test effective ways to help get workers off sick with CMHD back to work.
We know from previous studies that clinical assessment and treatment of sick-listed workers alone does not result in early return to work. It seems to be better to combine clinical treatment with adjustments to the workplace to help individuals to get back to work. Results of a recent study suggested that a healthcare-trained case-manager is ideal to assess individuals off sick, discuss with their managers and to suggest practical workplace adjustments to support the individual to get back to work. Case managers coordinate the care of individual patients and case management is the process of assessment, planning and evaluation to best meet the needs of the individual.
This study has 5 aims:
1. Developing a way, based on case management, to help NHS staff on sick leave with CMHD get back to work
2. Looking at whether it is feasible to use a case management style return to work service in an NHS setting
3. Assessing the effectiveness of an education program to train occupational health (OH) nurses in case management
4. Looking at whether it is possible to run a full trial to test the case management approach
5. Producing a detailed description of the case management approach and the training program for OH nurses

Who can participate?
NHS staff who have been off work with CMHD for 7-90 days, along with local line managers, representatives from Human Resources departments and nurses trained in/using the case management approach

What does the study involve?
Participants will receive either the intervention or care as usual (CAU).
The intervention involves a case management approach to managing sickness due to CMHD, and involves setting foals, motivational interviewing to solve problems, access to online cognitive behavioural therapy (CBT) and making a plan for return to work (RTW). The case manager, who will be an OH nurse who has received case management training, will discuss with the participant's line manager and develop the RTW plan with the participant and the line manager. The case manager will also communicate with the participant's GP, and can make referrals to other support services as necessary. Participants will also have regular reviews with their case manager.
Participants who receive CAU will see an OH nurse who has not received case management training.
Staff on sick leave who participate in the study, NHS managers, HR representatives and OH nurses who deliver the intervention will be interviewed to find out about their experiences of and opinions about the intervention, in order to get information about it from various points of view. Participants who are in the intervention or CAU groups will also be asked to complete multiple questionnaires relating to their health.
This study also has an economic component, where the cost of this study will be used to evaluate the cost of carrying out a full trial of this case management approach.

Where is the study run from?
The study is run from the Occupational Health Department at Guys and St Thomas' Hospital, London.
The other study centres are:
1. West Midlands Ambulance NHS Foundation Trust, Brierley Hill
2. University Hospitals Of Leicester NHS Trust, Leicester
3. Royal Papworth Hospital NHS Foundation Trust, Cambridge
4. Norfolk and Norwich University Hospitals NHS Foundation Trust, Norwich
5. The Ipswich Hospital NHS Trust, Ipswich

When is the study starting and how long is it expected to run for?
June 2016 to September 2019

What are the possible benefits and risks of participating?
The possible benefit to participants taking part in this study is improved occupational care for their CMHD. The only known risk of participating in this study is that answering questions from questionnaires may cause distress, but we consider this unlikely given the questions participants will be asked.

Who is funding the study?
The National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
n/a

IRAS number

ClinicalTrials.gov number
n/a

Secondary identifying numbers
15/107/02

Study information

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

Acronym
Ways back to Work

Study objectives
This is a feasibility study of an intervention to improve return to work in NHS staff who go on sick leave with a CMHD.

Ethics approval required
Old ethics approval format

Ethics approval(s)

NHS Research Ethical Approval is not required for studies involving NHS staff. NHS staff are protected by other legislation and since there are no other legal or ethical issues or invasive procedures involved in this study, only Health Research Authority assessment is required. Research governance approval for all sites has been secured via local R&D departments

Study design
Interventional non-randomised mixed methods feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Common mental health disorders (depression, anxiety, stress)

Interventions
Allocation of sites to either 'intervention', 'mixed intervention/ care as usual' or 'care as usual only' arm will not be undertaken using a randomisation method. Rather, this will be influenced by whether sites have sufficient OH (occupational health) personnel available to be trained to deliver the new intervention. In addition, we will ask each site to determine which departments have high incidence of sickness absence due to mental health disorders for more than 7 days. In the first instance, we will then group departments together (departmental group) to ensure that we will recruit sufficient participants for the feasibility study. If recruitment is low, then we will extend recruitment to all departments. Participants in this study will be NHS staff who have recently been issued with a fit note which includes a common mental health disorder; who have been off sick from work for more than 7 days and fewer than 90 days. The feasibility of delivering a novel case management approach will be compared to standard care. The case-management approach will be delivered by an OH nurse (case-manager), trained in CBT based approach to problem solving in the context of common mental health disorders (CMHD).
At 3 trusts the departmental groups will be assigned either:
1. To see an OH nurse who has been trained as a case-manager and receive the intervention
2. 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 2 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 1 trust, participants will see an OH nurse who has been trained as a case-manager and receive the intervention (intervention only site). We aim to recruit 77 participants.
The intervention is likely to include identifying barriers to returning to work (RTW), problem solving, peer-support networking, work-focused cognitive behavioural therapy (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. The duration of treatment will not be standardised – participants will continue to receive the intervention until they return to work or leave their employment.
We will employ mixed methods for data collection. We will collect data on:
1. Sickness absence for CMHD for 6 months
2. Information about rates of recruitment
3. Reasons for non-participation
4. Adherence to the intervention in those allocated to receive it
5. The management of those who are not allocated to receive the intervention and rates of follow-up
A series of participant questionnaires will be administered during the study. Participant interviews and focus group sessions (with OH nurses, HR rep and line managers) will be conducted at the end of the study. These will allow us to determine distribution of possible outcome measures.

Intervention Type
Other

Primary outcome measure
1. Feasibility of the intervention, assessed at the end of the study once all data has been analysed:
1.1. Rates of uptake among those eligible to participate
1.2. Frequency and nature of protocol violations, assessed throughout the study period from file note data, feedback from sites and during the qualitative component (e.g. whether there were any difficulties in implementing the protocol)
1.3. Completeness of data collection, assessed through a final report at the end of the study from the trial statistician detailing the extent of missing data
1.4. Average consultation times compared to normal, assessed at the end of the study using the 'care as usual' and 'case management' data collection forms
1.5. Mean number of follow-ups per case, assessed at the end of the study using the 'care as usual' and 'case management; data collection forms
1.6. Extra line manager and human resource time per consultation compared to normal, captured during qualitative data collection
1.7. Fidelity of the case-manager training, assessed using the 'case management' data collection form
1.8. Adherence to the intervention in those allocated to receive it
2. Acceptability of the intervention, assessed during qualitative data collection:
2.1. A summary of qualitative findings representing views on the intervention and its assessment expressed by participants, case-managers, HR and line-managers. All qualitative data will be transcribed and thematic analysis will be undertaken. The findings of this will be outlined in the final study report.
2.2. Reasons for not completing the intervention and any adverse effects, assessed throughout the study using the serious adverse events form, the withdrawal form, participant questionnaire parts C and D, along qualitative interviews.
3. Measurements of costs of delivering the package of interventions including OH nurse time, participant and manager time and cost of training OH nurses in case management. This is assessed using the Client Service Receipt Inventory to determine which services are used during the study follow-up and how often, along with the EuroQol-5D (EQ-5D) as a measure of health-related quality of life to assist with this evaluation.

4. Manual development. This will be a 2 stage process. Stage 1 (initial manual development) will be designed during the feasibility study period and stage 2 (finalisation of the manual) will be completed following data analysis and study completion.
4.1. A complete specification of the intervention and standard operating procedures for different settings
4.2. A manual for training the case-managers
5. Demographic data, including age, gender, job, previous sickness absence and history of mental and physical ill health, assessed at the baseline using the baseline questionnaire
6. Expectations of full RTW and self-efficacy with regard to RTW, assessed using the self-reported Return to Work Self Efficacy (RTWSE) scale at the baseline, after 3 months and after 6 months
7. Common mental health disorders, assessed at the baseline, after 3 months and after 6 months, using:
7.1. Patient Health Questionnaire (PHQ-9)
7.2. General Anxiety Disorder Questionnaire (GAD-7)
8. Return to work, either full (working the same days or hours per week as before sickness absence in an identical or equivalent role for at least 4 weeks) or partial (working any number of hours in any role), determined from data collected from employee staff records and self-report questionnaires at the baseline, after 3 months and after 6 months
9. Work ability, assessed using the Work Ability Index at the baseline, after 3 months and after 6 months

Secondary outcome measures
N/A

Overall study start date
01/06/2016

Completion date
01/09/2019

Eligibility

Key inclusion criteria
1. NHS staff
2. Common mental health disorder (CMHD) with or without an associated physical disorder
3. Off sick from work for more than 7 days and fewer than 90 days
4. Off sick when:
4.1. Referral made to Occupational Health (OH)
4.2. Completing baseline questionnaire

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants

77

Total final enrolment
24

Key exclusion criteria
1. Psychotic disorder
2. Bipolar disorder
3. Substance misuse disorder
4. Dementia
5. Under investigation for misconduct or in the process of formal disciplinary action.

Date of first enrolment
01/02/2018

Date of final enrolment
30/09/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's and St Thomas NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7NJ

Study participating centre
West Midlands Ambulance NHS Foundation Trust
Millennium Point
Waterfront Business Park
Waterfront Way
Brierley Hill
United Kingdom
DY5 1LX

Study participating centre
University Hospitals Of Leicester NHS Trust
Infirmary Square

Leicester
United Kingdom
LE1 5WW

Study participating centre
Royal Papworth Hospital NHS Foundation Trust
Lakeside Crescent
Papworth Everard
Cambridge
United Kingdom
CB23 3RE

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Norfolk and Norwich University Hospital
Colney Lane
Norwich
United Kingdom
NR4 7UY

Study participating centre
The Ipswich Hospital NHS Trust
Heath Road
Ipswich
United Kingdom
IP4 5PD

Sponsor information

Organisation
Guy's and St Thomas NHS Foundation Trust

Sponsor details
Westminster Bridge Road
London
England
United Kingdom
SE1 7EH

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Not defined

Funder Name
National Institute of Health Research

Results and Publications

Publication and dissemination plan
The report on the feasibility study will be sent to funder and we would expect to publish a complete account of the research in the NIHR HTA Journal. We would consider publishing other outputs of the study as papers in the their own right, for instance the assessment of fidelity of the case-manager training and the updated systematic review.

Intention to publish date
01/10/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as the researchers do not have specific consent from the participants to share their data

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2021	02/03/2021	Yes	No
Protocol file	version 1.8	12/03/2019	23/08/2022	No	No