

Case management to enhance occupational support (CAMEOS)

Submission date 24/04/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/09/2014	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/06/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and aims

Common health problems such as back pain, heart problems and depression can cause hardship to people and to their families. Such problems often lead to sick leave (time away from work off sick), which may result in financial problems and long-term effects on employment, health and quality of life. Some employers give some support for workers on long-term sick leave through Occupational Health and employee assistance programmes. However, there is not much evidence that the help currently provided works. This research seeks to develop a simple, low cost treatment (intervention) which will help employees on long-term sick leave, by improving their well-being and hopefully encouraging return to work.

Who can participate?

Employees working for a company who have their Occupational Health services provided by OH Assist or Leicestershire Fit4Work. They must be currently on sick leave for between 4 weeks and up to 12 months.

What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 receive the Collaborative Case Management intervention. This begins with a 60 minute assessment, usually via the telephone, which will include setting goals (agreeing what support is needed) and deciding what treatment choices may help (such as help for depression, for pain or problem solving). Based on this assessment, the case manager (with consent) may contact key health care providers such as the persons GP or nurse. Participants then receive up to 6 further sessions with the case manager over the next 12 weeks. Case managers (with participant agreement) also work with the employer and participant to identify barriers or problems to returning to work. Those in group 2 (the control group) receive their usual care through their employers Occupational Health services. All participants are asked to complete a questionnaire, which will ask about how they are feeling and current health problems, before taking part in any treatment. They are given a £20 gift voucher for the time spent filling in the questionnaire. They are also asked to complete the same questionnaire again 3 months later, to see if there have been any changes in their feelings, for which they receive another £20 gift voucher.

What are the possible benefits/risks to participating?

We are not aware of any side effects, disadvantages or risks to taking part in this research. We hope that those receiving the treatment (Collaborative Case Management) receive improved support, have positive experiences with Occupational Health and that they will experience improved feelings of well-being. Those who do not receive the treatment will still receive the normal support provided by their usual Occupational Health provider.

Where is the study run from?

University of Manchester, working with OH Assist or Leicestershire Fit4Work.

When is the study starting and how long will it run for?

April 2014 to November 2015

Who is funding the study?

National Institute of Health Research- Public Health Research programme (NIHR-PHR) (UK)

Who is the main contact?

Professor Peter Bower

peter.bower@manchester.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Peter Bower

Contact details

Centre for Primary Care:Institute of Population Health

5th Floor Williamson Building

Oxford Road

University of Manchester

Manchester

United Kingdom

M13 9PL

+44 161 275 7638

peter.bower@manchester.ac.uk

Additional identifiers

Protocol serial number

Funder ref: 12/3090/05

Study information

Scientific Title

Collaborative case management to aid return to work after long-term sickness absence (CAMEOS): a pilot study

Acronym

CAMEOS

Study objectives

Objective 1: Is recruitment and randomisation feasible?

This assessment will be based on our ability to meet our pilot recruitment (n=100) and retention targets (75%).

Objective 2: Can we deliver the intervention in an occupational health setting?

This assessment will be based on assessment of uptake rates (defined as initial contact with the case manager) and adherence to the intervention (defined in terms of session attendance and case manager assessments).

Objective 3: Is the intervention feasible and acceptable?

This assessment will be based on the views of participants and providers derived from the CSQ8 scores and the qualitative interviews.

Objective 4: Are the inclusion criteria and outcome measures appropriate?

This assessment will be based on the rates of exclusion of employees, views of the providers concerning the appropriateness of employees for the collaborative case management intervention, and assessment of the responses to the scales (missing data, participant burden, ceiling and floor effects, change over time).

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee North West- Greater Manchester Central, 25/07/2014, ref: 14/NW/1008

Study design

Randomised single-blind multi-centre care as usual-controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Employees with a range of patterns of sickness absence, and a complex mix of mental health and physical health problems, with high proportions suffering from symptoms of depression and anxiety, and musculoskeletal symptoms.

Interventions

Collaborative case management: The intervention will involve core aspects of published collaborative care models, including a 60 minute client-centred assessment, collaborative goal setting, and choice of evidence based low intensity interventions (such as behavioural activation, problem solving, cognitive restructuring), as well as effective liaison and information sharing with key health care personnel such as general practitioners and other primary care providers (where appropriate, and with patient consent). These are elements core to all effective collaborative care interventions and the principles of effective chronic disease management. Employees will receive 5-6 45 minute follow up sessions to assess progress and solve problems that may arise in achieving their goals. To maximise the reach of the intervention, we expect that most sessions will be delivered by telephone, although we will explore the importance of face to

face sessions in the intervention development phase. The intervention will also involve workplace interventions, where the case manager (with client agreement) mediates between employer and employee to identify barriers to return to work. Sharing of information and confidentiality will be crucial and we will ensure that there is agreement between employee and case manager about what information can be shared.

Care as usual: The intervention will be assessed against care as usual in the organisations where we are recruiting. There is likely to be significant variation in care as usual, depending on the type of organisation (large, SME-small and medium sized enterprises, public and private). Although such variation in the trial will reflect usual practice, we will assess the care received by participants in this arm using a structured questionnaire developed in a previous trial of collaborative care in an occupational context. We are unable to control interventions received outside of the occupational context through the NHS. We will collect detailed data on the nature of usual care for description and costing, and of other services accessed via traditional healthcare routes.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Total recruitment, including rates over time and response rates

Key secondary outcome(s)

1. Clinical Outcomes in Routine Evaluation outcome measure (CORE-OM). The CORE-OM is a 34 item measure of psychological distress and comprises four dimensions: subjective well-being, symptoms, functioning, and risk
2. SF12 (version 2) is a brief version of the well-known SF36. The scale uses 12 questions to measure functional health and well-being over the past 4 weeks
3. PHQ 9. This is a nine item scale recording core symptoms of depression
4. Work and Social Adjustment Scale (WSAS) is a short, 5 item measure of impairment in functioning across 5 domains (work, home management, social leisure, private leisure, relationships)
5. Self-reported actual and effective working hours quantified by the World Health Organization Health and Work Performance Questionnaire
6. Client health and social care utilisation will be based on a version of the Client Services Receipt Inventory
7. EQ5D measure of health related quality of life will be included for cost effectiveness calculations. The 5 item scale covers mobility, self-care, usual activities, pain, anxiety and depression, each with three levels of severity and provides a utility value based on a population tariff
8. Client Satisfaction Questionnaire (CSQ8) is an eight item self-administered questionnaire collected at the end of service delivery and scored using a four point Likert scale
9. Bayliss measure of multimorbidity will be used to assess the impact of physical symptoms and associated long-term conditions. The measure assesses the presence and impact of 22 common problems

Completion date

31/12/2016

Eligibility

Key inclusion criteria

1. Employees experiencing or entering long-term sick leave defined as between 4 weeks and 12 months
2. Employees who work for companies who have their Occupational Health services provided by OH Assist or Leicestershire Fit4Work
3. Those who report a minimum level of baseline distress, (defined as a score of 11+ on the CORE-OM measure of general health and well-being: Clinical Outcomes in Routine Evaluation Outcome Measure)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

16

Key exclusion criteria

Employees will be excluded if:

1. They are aged less than 18 years old
2. They refuse consent
3. Score less than 11 on the COREOM
4. Are currently attending any psychotherapy either through NHS counselling services or private services
5. They suffer from a severe and enduring mental disorder or if they are at risk of suicide and require immediate care from a crisis management team

Date of first enrolment

01/04/2014

Date of final enrolment

30/11/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Centre for Primary Care:Institute of Population Health
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation

The University of Manchester (UK)

ROR

<https://ror.org/027m9bs27>

Funder(s)

Funder type

Government

Funder Name

National Institute of Health Research (NIHR) (UK) - Public Health Research programme (NIHR-PHR)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2018	25/06/2020	Yes	No
HRA research summary			28/06/2023	No	No