ISRCTN33560198 https://doi.org/10.1186/ISRCTN33560198

# Case management to enhance occupational support (CAMEOS)

**Submission date**
24/04/2014

**Recruitment status**
No longer recruiting

**Registration date**
11/09/2014

**Overall study status**
Completed

**Last Edited**
25/06/2020

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 though 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 Occupation 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

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Other

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure
Total recruitment, including rates over time and response rates

## Secondary outcome measures
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

### Overall study start date
01/04/2014

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
100

### 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
England

United Kingdom

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

## Sponsor information

### Organisation
The University of Manchester (UK)

### Sponsor details
c/o Professor Nalin Thakker
Associate Vice-President (Research Integrity)
Oxford Road
Manchester
England
United Kingdom
M13 9PL

### Sponsor type
University/education

### 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

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### 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 |