Individual CAReer Management support to improve Education, Employment and Retention for people with anxiety and depression

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

Plain English summary of protocol

Background and study aims

Supported employment refers to services that help people with disabilities, including mental health conditions, to get a job and stay in work. The main aim of this study is to find out whether the Individual Career Management (ICM) intervention is effective at helping people with anxiety and/or depression to get a job and stay in work. We also want to find out whether the ICM intervention is also effective at encouraging participation in education, training or volunteering, reducing severity of anxiety and/or depression, improving quality of life, and increasing self-esteem. A further aim is to find out whether the ICM intervention is more cost-effective in comparison to standard care.

Who can participate?

People aged 18-65 with anxiety and/or depression who have been unemployed or off sick for at least two weeks and are interested in returning to work.

What does the study involve?

Participants are randomly allocated to one of two groups. One group receives standard care - a course of psychological therapy delivered by the Southwark Psychological Therapies Service. The other group receives standard care and also ICM support, which includes career counselling, motivational coaching, education and training support.

What are the possible benefits and risks of participating?

Participants get a 50% chance of receiving the ICM intervention that is currently not available anywhere else in the NHS. They may also feel good about contributing to research that could help improve services for future patients with anxiety or depression. There are few risks involved in this study. It is minimal risk of harm to the participant as the intervention is voluntary and is not designed to put participants under any additional pressure or danger. The main burden for participants will be giving up their time to attend the interviews which will include the completion of questionnaires.

Where is the study run from?

All participants will be recruited from the Southwark Psychological Therapies Service, part of the South London and Maudsley NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for? October 2011 to October 2013.

Who is funding the study? South London and Maudsley NHS Foundation Trust (UK).

Who is the main contact? Claire Price claire.price@slam.nhs.uk

Contact information

Type(s)

Scientific

Contact name

Ms Claire Price

Contact details

South London and Maudsley NHS Foundation Trust Maudsley Hospital Main Entrance Building, 1st Floor Denmark Hill London United Kingdom SE5 8AZ +44 (0)20 3228 3221 claire.price@slam.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT01599481

Secondary identifying numbers

N/A

Study information

Scientific Title

Effectiveness and cost effectiveness of Individual career management for people with anxiety and depression: a randomised controlled trial

Acronym

CAREER

Study objectives

Is the Individual Career Management (ICM) intervention effective in helping people with anxiety and/or depression to obtain and retain in competitive employment?

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Research Ethics Committee Harrow, 12/08/2011, ref: 11/LO/0765

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

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

Anxiety and depression disorders

Interventions

Intervention group: Individual Career Management (ICM) support for a six month period. ICM consists of individually tailored support to help an individual to obtain and retain in employment. ICM follows the seven principles of supported employment (often referred to an Individual Placement and Support), but includes the additional principles of career counselling, motivational coaching, education and training support, and specialist job retention support. The length and frequency of ICM support sessions is determined by the needs of the client.

Control group participants will receive standard care (IAPT therapy) only.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

- 1. The length of competitive employment during the period. The following definition of competitive employment will be used:
- 1. 1. A job paying at least the national minimum wage
- 1. 2. A job located in a mainstream setting not set aside for people with disabilities
- 1. 3. A job that is not owned by the ICM service

Secondary outcome measures

- 1. Job Type: according to occupational codes
- 2. Working Hours: average number of hours worked each week
- 3. Time to Employment: number of days between baseline date and the employment start date
- 4. Salary: average weekly salary over the 6 month period
- 5. Number of Jobs: number of different jobs held during the 6 month period
- 6. Job Terminations: number of job terminations over the 6 month period and the reason for each termination
- 7. Other occupational activity: non-competitive employment (e.g. sheltered work), education, training or volunteering
- 8. Anxiety: Generalised Anxiety Disorder Assessment (GAD 7)
- 9. Depression: Patient Health Questionnaire (PHQ-9)
- 10. Social Functioning: Work and Social Adjustment Scale (WSAS)
- 11. Health-related quality of Life: EQ-5D
- 12. Work-related quality of Life: WRQoL
- 13. Self Esteem: Rosenberg Self Esteem Scale
- 14. Career Search Efficacy: Career Search Efficacy Scale (CSES)
- 15. Return to Work Efficacy: Return to Work Self Efficacy Scale (RTW-SE)
- 16. Productivity: Absenteeism and presenteeism questions from the World Health Organization's Health and Work Performance Questionnaire (HPQ)

Measured 6 months from the date of entry to the study.

Overall study start date

01/10/2011

Completion date

01/10/2013

Eligibility

Key inclusion criteria

- 1. Must be either unemployed or off sick for at least two weeks if employed at the time of entry to the study
- 2. Must be legally allowed to work in the UK
- 3. Must be between the age of 18 65 for men, and 18 60 for women (based on UK retirement age)
- 4. Must have received an Improving Access to Psychological Therpaies (IAPT) assessment and been offered psychological therapy
- 5. Must not have been receiving therapy for more than one month
- 6. Must be interested in obtaining competitive employment
- 7. Must have given full written consent to participate in the study

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

184 (92 in each arm)

Total final enrolment

261

Key exclusion criteria

- 1. People who are employed and attending work or off sick for less than two weeks at the time of entry to the study
- 2. People who do not have the legal right to work in the UK
- 3. People who have not yet received an IAPT assessment
- 4. People who have received an IAPT assessment but not eligible for psychological therapy
- 5. People who have been receiving therapy for more than one month
- 6. People who are not interested in obtaining competitive employment
- 7. People who do not give written consent or who lack mental capacity to give consent at the time of the study

Date of first enrolment

01/10/2011

Date of final enrolment

01/10/2013

Locations

Countries of recruitment

England

United Kingdom

Study participating centre South London and Maudsley NHS Foundation Trust

London United Kingdom SE5 8AZ

Sponsor information

Organisation

Southwark Vocational Service (UK)

Sponsor details

South London and Maudsley NHS Foundation Trust Maudsley Hospital Main Entrance Building, Ground Floor Denmark Hill London England United Kingdom SE5 8AZ +44 (0)20 3228 3221 claire.price@slam.nhs.uk

Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

South London and Maudsley NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

<u>Thesis results</u> 01/01/2018 11/07/2022 No No