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An initial study of an online self-help programme for individuals seeking employment

Submission date
21/07/2014

Recruitment status
No longer recruiting

Registration date
27/08/2014

Overall study status
Completed

Last Edited
16/04/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
We are carrying out a research project looking at low mood and stress in adults seeking employment and attending a disability employment service called Remploy. Low mood is a common mental health problem affecting up to 121 million people worldwide and is more common in unemployed people and those with physical health problems. Although approaches based on the talking therapy cognitive behavioural therapy (CBT) are known to be effective when given one to one by an expert practitioner, this can be expensive, and computerised CBT may be a useful alternative. This project aims to find out whether it is possible to devise an online CBT resource for people who are seeking work and attending Remploy.

Who can participate?
People attending Remploy, aged 16, with no active risk to self can enter the study. Participants must be able read, speak and understand English.

What does the study involve?
Eligible participants will be randomly allocated to begin using a self-help website straight away or after a 3-month delay. All participants will receive the same treatment. This study will help the researchers to compare the groups at 3 and 6 months and find out whether those who have received access to the online modules have greater improvements in mood and job seeking than those who have not yet used the website yet. During the study, participants will be able to access online modules with video and audio that address various aspects of low mood and anxiety. These modules use a cognitive behavioural therapy (CBT) guided self-help approach. They are informal and friendly sessions that aim to teach skills that may help to reduce feelings of stress and improve low mood. Participants will be assigned a support worker to help them progress through the sessions and apply what they have learned.

What are the possible benefits and risks of participating?
Participation within this study will allow people who are out of work and experiencing symptoms of low mood to use CBT-based educational online modules aimed at addressing these and other issues. Since the intervention is a life skills package that will be introduced as part of the Remploy service we do not expect any side effects or emergencies.

Where is the study run from?
Recruitment and delivery of the online package will take place at the Edinburgh and Hamilton Remploy offices in the UK.

When is study starting and how long is it expected to run for?
Recruitment is ongoing and will run until we have the needed number of participants. The study started in November 2012 and is expected to finish in December 2014.

Who is funding the study?
University of Glasgow, UK.

Who is the main contact?
Carrie-Anne McClay
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Study website
http://llttf4remploy.com/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluating an online support package delivered within a disability unemployment service: a randomised controlled feasibility study

Study objectives
Primary question:
Is the study design feasible - is it possible to recruit from Remploy, randomise participants and collect data at baseline, 3 months and 6 months?

Secondary questions:
1. To what extent will participants adhere to the intervention?
2. Is the Living Life (LL) package satisfactory/acceptable to participants?
3. How many participants will be needed for a sufficiently powered future RCT?

Ethics approval required
Old ethics approval format

Ethics approval(s)
College of Medical, Veterinary & Life Sciences Ethics Committee for Non Clinical Research Involving Human Subjects, University of Glasgow; ref. 2012063

Study design
Feasibility study with a pre-post design randomised controlled design with a delayed access control group

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
Low mood, depression and anxiety. Unemployment.

Interventions
Individuals who are suitable for the study will be randomly allocated to begin the online intervention immediately or after a 6-month delay.

Living Life guided CBT self-help online package consisting of modules including:

1. Why do I feel so bad?
2. I can't be bothered doing anything
3. Why does everything always go wrong?
4. I'm not good enough: (low confidence)
5. How to fix almost everything?
6. The things you do that mess you up
7. Are you strong enough to keep your temper?
8. 10 things you can do to help you feel happier straight away.

All participants can continue with treatment as usual during the study. All participants will be asked to complete outcome measures at baseline, 3 months and 6 months.

Intervention Type
Behavioural

Primary outcome measure
The proportion of people taking up and adhering to the LL intervention.

Secondary outcome measures
1. Determine the feasibility of recruiting, delivering the intervention and gathering data from participants via the Remploy service.
2. Describe the difference in proportion of people in work at 12 weeks between the LL group and the TAU control group, or if not in work the number of interviews attended and job submissions made (measuring motivation).
3. Describe the subsequent number (frequency) and total (days) off work over 3 months and 6 months in both arms comparing within group comparisons from baseline, and between-groups at 3 and 6 months.
4. Describe and compare impact on mood, social function and satisfaction at 3 months and 6 months in both arms comparing within group comparisons from baseline, and between-groups at 3 and 6 months.

Overall study start date
19/11/2012

Completion date
15/12/2014

Eligibility

Key inclusion criteria
1. Willing to take up the offer of LL and appropriate for usual Remploy support
2. With no active risk to self at initial Remploy assessment (this is not routinely investigated but if suicidality is disclosed at the initial assessment the individual will not enter the study)
3. Able to register on the website, read and understand the LL resources via the internet or DVD
4. At home or in the Remploy office

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
The aim is to recruit 100 participants in total for this feasibility study, 50 intervention participants and 50 control participants to allow for comparison at the 3-month and 6-month follow-up points

Key exclusion criteria
1. Unwilling or unable to use the LL approach
2. Active risk identified in which case usual care (referral to GP) will occur as is normal Remploy practice

Date of first enrolment
19/11/2012

Date of final enrolment
15/12/2014

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Glasgow
Glasgow
United Kingdom
G12 0XH

Sponsor information

Organisation
University of Glasgow (UK)

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Sponsor type
University/education

Website
http://www.gla.ac.uk/

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
University/education

Funder Name
University of Glasgow (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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?
Protocol article	protocol	01/12/2015		Yes	No