

Supported employment adapted for people with affective disorders

Submission date 09/12/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/12/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 10/01/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Depression is one of the most common mental health conditions worldwide. Periods of depression (depressive episodes) are a common feature of other affective disorders (conditions which affect the mood), such as bipolar disorder. The characteristics of a depressive episode can vary greatly from person to person, but they generally include low mood, problems with sleeping and/or eating, and a general loss of interest in life. In many people, their ability to work is affected by their low mood, and so unemployment is not uncommon. Currently, there are a number of effective strategies designed to help people with schizophrenia and similar conditions get back into work, however this is not the case for people suffering from affective disorders. Currently, there are general schemes in place with local municipalities which are designed to try and get people back into employment. The aim of this study is to find out whether a programme more focused on people as individuals would be more effective at getting people who have experienced depressive episodes back into employment.

Who can participate?

Unemployed adults suffering from depressive episodes.

What does the study involve?

Participants are randomly allocated to one of two groups. Participants in the first group receive the individual enabling and support (IES) programme for 12 months, delivered by a specially trained IES-employment specialist. The participants then attend individual appointments designed to help with their motivation, thinking processes and lifestyle, followed by sessions designed to make a plan for their future career. Following this, participants begin looking for work and when they find a job, are given sessions with the IES employment specialist to provide them with extra support. Participants in the second group receive the traditional vocational rehabilitation (TVR) programme, which provides rehabilitation in a series of stages, starting with weekly cognitive behavioural therapy (a type of talking therapy) and support from the mental health service, followed by a "work ability assessment" by the Social Insurance Agency and Public Employment Service jointly. Participants considered to have at least 50% work capacity (ability to work) are given 20-40 hours vocational training a week, and those considered to have less than 50% work capacity are given 5-20 hours of pre-vocational training (a more general programme) at the Municipality services. Throughout the study, participants in both groups fill

out weekly log books which they are asked to submit every three months in order to monitor their employment status. Participants also complete a number of questionnaires at the start of the study, and after 6 and 12 months, to assess their mood and general health.

What are the possible benefits and risks of participating?

Participants could benefit from being able to successfully get back into employment. There is a risk however that participants will remain unemployed.

Where is the study run from?

Four Mental Health Service Outpatient Centres in Sweden.

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

November 2015 to October 2016

Who is funding the study?

RESHAM - Rehabilitation and Cooperation national research program (Sweden)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Supported employment adapted for people with affective disorders - a randomized controlled trial

Study objectives

Participants given individual enabling and support (IES) reach employment at a higher rate after 12 months as compared to traditional vocational rehabilitation (TVR) participants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Lund University Ethics Committee, ref: 2011-544

Study design

Single-blind randomised parallel trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Other

Study type(s)

Other

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

Affective disorder

Interventions

Participants are randomly allocated to one of two groups:

Group 1: The individual enabling and support (IES) programme is delivered by an IES-employment specialist. The 12 month programme involves four phases. In the first phase (enabling phase) participants attend hour-long weekly appointments in which they facilitate their own motivational, cognitive, and lifestyle strategies. In the second phase (assessment phase), participants attend hour-long appointments for three weeks in which they work with the IES employment specialist to complete a vocational profile and plan. In the third phase,

participants begin job seeking and in the final phase (supported employment phase) participants undergo 1 hour sessions once every third week so that they can be provided with further support to help them maintain employment based on their individual needs.

Group 2: The traditional vocational rehabilitation (TVR) programme is a general programme that is delivered by various professionals in several settings and organisations and is regulated by the social benefit and unemployment security system. The programme involves stepwise rehabilitation starting with weekly appointments of cognitive behavioural therapy (CBT) and rehabilitation support from the mental health service. The next step involves a work ability assessment period performed by the Social Insurance Agency and Public Employment Service jointly, about 10-20 hours a week. If the participants have 50% work capacity the next step regards vocational training of 20-40 hours a week. Participants with less work capacity will enter a step of prevocational training at the Municipality services regulated to 5-20 hours a week.

Throughout the study, participants in both groups fill out weekly log books regarding their employment status. Participants complete questionnaires assessing health related outcomes at baseline, 6 and 12 months.

Intervention Type

Behavioural

Primary outcome measure

Employment rate is determined using weekly log books filled in by participants and professionals at baseline, 6 and 12 months.

Secondary outcome measures

1. Number of hours and weeks in employment are determined using weekly log books filled in by participants and professionals at baseline, 6 and 12 months
2. Income is determined using weekly log books filled in by participants and professionals at baseline, 6 and 12 months
3. Speed to first employment is determined using weekly log books filled in by participants and professionals at baseline, 6 and 12 months
4. Rate of internship or education is determined using weekly log books filled in by participants and professionals at baseline, 6 and 12 months
5. Health related outcomes are measured at baseline, 6 and 12 months using the following:
 - 5.1. Depression is measured using the Montgomery-Åsberg Depression Self rating Scale (MADRS-S)
 - 5.2. Quality of Life is determined using the Manchester Short Assessment of Quality of Life Scale (MANSA)
 - 5.3. Global health status is determined using the EQ-5D health questionnaire
 - 5.4. Empowerment is determined using the Empowerment scale (ES)
 - 5.5 Social and Community Participation is determined using the Profiles of Occupational Engagement Scale (POES)
 - 5.6. Psychological and Social functioning is determined using the Global Assessment of Functioning Scale (GAF)
6. Cost effectiveness is determined by calculating the QALY index measured using the EQ-5D questionnaire at 12 months

Overall study start date

01/12/2011

Completion date

01/12/2014

Eligibility

Key inclusion criteria

1. Aged between 18 and 63
2. Depressive episode F32, recurrent depression F33, and bipolar disorder F31, F30 (includes depressive episodes) as diagnosed by the team psychiatrist according to the International Classification of Diseases the 10th edition (REF)
3. Able to read and understand Swedish
4. Expresses interest in working
5. Unemployed for past year
6. Receiving mental health services at an outpatient team for persons with affective disorders /attending an IES-information meeting

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

120

Key exclusion criteria

1. Severe conditions of drug or alcohol abuse
2. Somatic illness or physical disability

Date of first enrolment

15/08/2011

Date of final enrolment

15/11/2013

Locations

Countries of recruitment

Sweden

Study participating centre

Ängelholm Mental Health Service Outpatient Centre
Västersjögatan 12
Ängelholm
Sweden
265 53

Study participating centre
Landskrona Mental Health Service Outpatient Centre
Vattenverksallén Landskrona lasarett
Landskrona
Sweden
261 36

Study participating centre
Eslöv Mental Health Service Outpatient Centre
Storgatan 1
Eslöv
Sweden
241 30

Study participating centre
Burlöv Mental Health Service Outpatient Centre
Elisetorpsvägen 11
Arlöv
Sweden
232 33

Sponsor information

Organisation
Lund University

Sponsor details
Medical Faculty
Department of Health Sciences
P.O Box 157
Lund
Sweden
221 00

Sponsor type

University/education

ROR

<https://ror.org/012a77v79>

Funder(s)

Funder type

Research organisation

Funder Name

RESHAM - Rehabilitering och Samordning nationallt forskningsprogram (Rehabilitaton and Cooperation national research program)

Results and Publications

Publication and dissemination plan

Planned publications of papers discussing vocational variables, cost-benefit analysis (brief report) and health-related variables.

Intention to publish date

30/06/2016

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Employment results	01/01/2017		Yes	No
Results article	Depression and empowerment results	01/05/2018	10/01/2023	Yes	No