Psychosocial occupational health management with the focus on Supported Employment. Job maintenance through Supported Employment PLUS: A pilot study to support the mental health of employees.

Submission date 05/06/2014	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 02/07/2014	Overall study status Completed	 Statistical analysis plan Results
Last Edited 02/07/2014	Condition category Mental and Behavioural Disorders	 Individual participant data Record updated in last year

Plain English summary of protocol

Background and study aims

In Germany, the number of days of absence from work caused by mental illness has risen dramatically in the past ten years. Due to lack of qualified staff, it is very important for companies to take care of the physical and mental health of their workers. As a result, the number of people who are unable to work due to mental stress and diseases is extremely high. Supported Employment concepts such as the Individual Placement and Support (IPS) model look at making work a rehabilitative agent itself. Supported Employment Plus (SEplus) uses a modified IPS-approach in order to: maintain the affected employees work ability and performance, re-establish the employees mental well-being in the workplace, preserve the work capacity and productivity for the company; reduce the number of days of absence due to mental health problems.

Who can participate?

Employees of the participating businesses who report psychological distress can take part.

What does the study involve?

Employees are randomly allocated to one of two groups: intervention and control groups. The intervention group receives SEplus the affected workers are specifically and individually coached by experienced job coaches. These job coaches also fulfil an advisory and supportive role for the employer, the colleagues and other stakeholders of the business environment.

What are the possible benefits and risks of participating? Not provided at time of registration.

Where is the study run from?

The study is run from participating business enterprise and service companies in Germany.

When is the study starting and how long is it expected to run for? October 2012 to September 2014.

Who is funding the study? European Regional Development Fund (ERDF) (EU)

Who is the main contact? Prof Wulf Rössler wulf.roessler@uzh.ch

Study website http://www.leuphana.de/partner/regional/gesundheit/vernetzte-versorgung/projekte /supported-employment-plus.html

Contact information

Type(s) Scientific

Contact name Prof Wulf Rössler

Contact details University of Lüneburg Innovation Incubator Rotenbleicher Weg 67 Lüneburg Germany 21335

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title Job maintenance through Supported Employment PLUS

Acronym SEplus

Study objectives

1. Job Coaching according to the approach of Individual Placement and Support (IPS) can contribute to job maintenance of employees under psychological pressure or with mental illnesses. Furthermore, coaching according to IPS enhances job satisfaction and reduces the number of days of sickness absence.

2. In addition we hypothesize the following:

2.1. Improvement of job satisfaction in the intervention group.

2.2. Improvement of global functioning in the intervention group.

2.3. Improvement of the quality of life of the participants of the intervention group.

2.4. Increased self-esteem of the participants of the intervention group.

2.5. Reduction of self-stigma in the intervention group.

2.6. Reduction of cognitive appraisal of stigma as a stressor in the intervention group.

2.7. Enhancement of recovery orientation in the intervention group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Leuphana University of Lüneburg, 25.09.2013, ref. EB-Antrag Rössler201307_SEplus

Study design

Randomised 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

Mental disorders, vocational rehabilitation

Interventions

The intervention lasts from three to six months. The participants should attend to eight to twelve coaching sessions. The job coaches support the participants of the intervention group concerning problems on the job and other psychosocial problems. 50% of the participants are randomized to the intervention group and 50% to the control group.

Several instrument based interviews are conducted every 3 months.

A two-factor analysis of variance with the two factors group affiliation (Intervention- and control group) and outcome (reduction days of illness yes/no) will be conducted to control for the study hypotheses.

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

The primary endpoint is the reduction of days incapacity to work by 40% compared with the control group.

Secondary outcome measures

- 1. Quality of life
- 2. Motivation
- 3. Job satisfaction
- 4. Psychosocial functioning
- 5. Job preferences
- 6. Self-esteem

Overall study start date 01/10/2012

Completion date

30/09/2014

Eligibility

Key inclusion criteria

- 1. Employee of a cooperation partner (e.g. business enterprise or service company) of the study
- 2. Self-reporting of psychological stress or mental disorder
- 3. Psychic distress or mental disorder

4. Voluntariness

- 5. Participant have to give informed consent
- 6. Working age (18-67 years)

Participant type(s)

Patient

Age group Adult

Lower age limit 18 Years

Upper age limit 67 Years **Sex** Both

Target number of participants 120

Key exclusion criteria 1. Persons who need a psychiatric inpatient treatment at the time of the study 2. Persons with an imminent risk of suicide

Date of first enrolment 01/10/2012

Date of final enrolment 30/09/2014

Locations

Countries of recruitment Germany

Study participating centre University of Lüneburg Lüneburg Germany 21335

Sponsor information

Organisation European Regional Development Fund (ERDF), Investitions- und Förderbank Niedersachsen -NBank (Germany)

Sponsor details Günther-Wagner-Allee 12 - 16 Hannover Germany 30177

Sponsor type Government

Funder(s)

Funder type Government

Funder Name European Regional Development Fund (ERDF) (EU)

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