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Efficacy of a group program to support unemployed individuals with mental health problems

Submission date
21/04/2017

Registration date
09/05/2017

Last Edited
24/05/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered

[ ] Protocol

[ ] Statistical analysis plan

[X] Results

[ ] Individual participant data

Plain English summary of protocol

Background and study aims:
People with mental illness often choose not to use mental health services and to limit their job search activities. This leads to productivity losses and poor clinical outcomes. There are few tested interventions to increase mental health service use and job search activities for unemployed people with mental health problems. The aim of this study is to assess the feasibility and effectiveness of a group program to increase help-seeking and job search activities among unemployed people with mental health problems.

Who can participate?
Adults aged 18-64 who are unemployed and have mental health problems

What does the study involve?
Participants are randomly allocated to either take part in the group program or not. Both groups also continue their current mental health service use, if they have any. The group program consists of four sessions of two hours and runs for six weeks. Sessions take place in week 1, 2, 3 and 6. There are about 6 to 10 participants in each group (overall about 100 participants). Using a set of questionnaires, acceptance, sense and purpose of life, disclosure-related distress and help-seeking as well as other outcomes are assessed at three times: at the start of the study, and then again 3 and 6 weeks and 6 months later.

What are possible benefits and risks of participating?
Participants have two possible benefits. First, participants in the treatment group are likely to benefit from the discussions with other participants and with the group facilitators. Second, all participants in both groups fill in questionnaires. Some may find the questionnaires stimulating and helpful, because they raise issues relevant to their current situation with unemployment and mental health. However, some people may find it distressing to think about the questioned issues. Therefore all participants can interrupt or end their participation altogether at any time or find support from group members and facilitators or contact the research team or the department of Psychiatry II at Ulm University, at any time.

Where is the study run from?
Ulm University & BHK Günzburg (Germany)

When is the study starting and how long is it expected to run for?
January 2017 to April 2018

Who is funding the study?
German Research Foundation (DFG)

Who is the main contact?
Dr Nicolas Rüsch

Contact information

Type(s)
Scientific

Contact name
Prof Nicolas Rüsch

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
-

Study information

Scientific Title
Efficacy of a group program to support unemployed individuals with mental health problems: a pilot randomised controlled trial

Acronym
AloHA

Study objectives
1. Participants in the group program report decreased self-stigma, shame, social withdrawal, and secrecy compared to the control group (TAU) after 3 and 6 weeks

2. Participants in the group program report increased self-esteem, empowerment and job search and help-seeking activities for mental health issues, compared to the control group (TAU) after 3 and 6 weeks

Ethics approval required
Old ethics approval format

Ethics approval(s)
The ethics committee of Ulm University, 08/02/2017, ref. 14/17

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Unemployed people with mental health problems

Interventions
Randomization method
Computer-generated random numbers, printed out on paper with one number per page, will be put in closed envelopes, one number/page per envelope. Envelopes will be numbered outside, starting with 1. Randomization will take place following the baseline assessment. Each participant who has completed the baseline assessment will receive the next envelope. Participants with even numbers are assigned to the intervention group, participants with uneven numbers to the control group.

Participants are randomized to one of two groups:

Control group
Control group participants can continue any (mental) health care they may be receiving before the study. No intervention is delivered as part of the study to control group participants. If they wish, they can receive a copy of the program workbook after completing their last assessment.

Intervention group
The group program is about acceptance, help-seeking decisions and support for mental health problems and job search and disclosure. The groups are facilitated by one peer (person with a history of unemployment and mental illness) and one psychotherapist. Each group runs for six weeks and consists of 4 sessions, one session in week 1, 2 and 3 and a booster-session in week 6. Each sessions last about two hours.

1. Acceptance:
In this lesson, participants get an overview about the program and the mindfulness concept. Integral part of all sessions are mindfulness exercises. Acceptance (regarding unemployment and mental health problems) and the motivation of help-seeking is the second part.

2. Own values:
In this session participants get an overview about different values. In a second step participants think about their own values and their implications for behavior and actions. As homework, participants will be encouraged to test a person in their personal surrounding, if he/she is eligible for disclosure.

3. Information about help services:
Intensifying and repeating the topic of values and their implications for participants behavior. Information on help-seeking and availability of help-services for unemployment and mental health problems. As homework, participants are asked to write down, how they would tell their own story to someone else.

4. Committed action and authenticity:
In this session participants learn how to accept thoughts and feelings about their current situation. Participants discuss disclosure of mental health problems to future employers. This session also contains a wrap up of the intervention.

Note that all lessons contain exercises about mindfulness and disclosure and all sessions are accompanied by stories and worksheets in the workbook.

Using a set of questionnaires, acceptance, sense and purpose of life, disclosure-related distress and help-seeking as well as other outcomes are assessed at three times: at baseline, and then again 3 and 6 weeks later.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 21/06/2017:
1. Job search self-efficacy, measured with the Job Search Self-Efficacy questionnaire, 6 Items (van Ryn & Vinokur, 1992)
2. Help-seeking intentions and behaviors, measured with the General Help-Seeking Questionnaire (GHSQ), 10 Items (Wilson et al., 2005)
Measured at baseline (t0), 3 weeks after baseline (t1), 6 weeks after baseline (t2) and 6 months after baseline (t3).

Previous primary outcome measures:
Positive:
1. Psychological inflexibility and experiential avoidance, measured with the Acceptance and Action Questionnaire (AAQ-II), 7 Items (Bond, et al., 2011)
2. Help-seeking intentions and behaviors, measured with the General Help-Seeking Questionnaire (GHSQ), 10 Items (Wilson et al., 2005)
3. Recovery, measured with the Self-Identified Stage of Recovery Scale, 5 Items (Andresen et al., 2010)
4. Job search behaviors and intentions, measured with the Job search behavior and intention questionnaire, 12 Items (Blau, 1994)
5. Job search self-efficacy, measured with the Job Search Self-Efficacy questionnaire, 6 Items (van Ryn & Vinokur, 1992)
6. Job search effort/outcome measured with two previously used items (Rüsch et al, unpublished)
7. Perceived helpfulness of mental health care, measured with one previously used item (Rüsch et al, unpublished)

8. Locus of control, measured with two Items (Lindström, 2011)
9. Perceived need of treatment and presence/outcome of illness, measured with the SAIQ – Self-Appraisal of Illness Questionnaire, 10 Items (Marks et al., 2000)
10. Quality of life, measured with the EUROHIS-QOL, 8 Items (Brähler et al., 2007)
11. Self-esteem, measured with the single item self-esteem measure (SISE; Robins et al., 2001)
12. Empowerment, measured with the self-esteem/self-efficacy subscale of the Empowerment Scale (ES), 9 Items (Roger et al, 1997)

Negative/other:
1. Attitudes to disclosure measured with two previously used items (Rüsch et al., 2011)
2. Social withdrawal and secrecy, measured with the Stigma Coping Orientation Scales, 12 items (Link et al., 1991)
3. Self-stigma associated with help-seeking, measured with Self-Stigma of Seeking Help Scale, 10 Items (Vogel et al., 2006)
4. The cognitive appraisal of stigma as a stressor, measured with the Stigma-Stress-Scale, 8 Items (Rüsch et al., 2009)
5. Shame, measured with one previously used item (Rüsch et al., 2014) – ('Would you feel ashamed about having a mental illness?'; from 1, not at all, to 7, very much)
6. Hopelessness, measured with Beck's Hopelessness Scale – Brief version, 4 Items (Yip & Cheung, 2006)
7. Self-labelling as "mentally ill", measured with one previously used item (Rüsch et al., 2014)
8. Depressive symptoms, measured with the Center for Epidemiologic Studies-Depression Scale (CES-D), German version with 15 Items (Hautzinger & Bailer (1993)
9. Internalized stigma, measured with the Internalized Stigma of Mental Illness Inventory (ISMI), brief version with 10 Items (Boyd et al, 2014)
10. Self-stigma, measured with the Self-Stigma in Mental Illness Scale – Short Form (SSMIS), subscale apply/self-concurrence, 5 Items (Corrigan et al, 2012)
11. Self-reported mental distress, measured with Kessler's K6 Psychological Distress Scale (Kessler, 2003).

Measured at baseline (t0), 3 weeks after baseline (t1) and 6 weeks after baseline (t2)

Key secondary outcome(s))
Moved from primary outcome measures on 21/06/2017:
Positive:
1. Psychological inflexibility and experiential avoidance, measured with the Acceptance and Action Questionnaire (AAQ-II), 7 Items (Bond, et al., 2011)
2. Help-seeking Intentions and Behaviors, measured with the General Help-Seeking Questionnaire (GHSQ), 10 Items (Wilson et al., 2005)
3. Recovery, measured with the Self-Identified Stage of Recovery Scale, 5 Items (Andresen et al., 2010)
4. Job search behaviors and intentions, measured with the Job search behavior and intention questionnaire, 12 Items (Blau, 1994)
5. Job search effort/outcome measured with two previously used items (Rüsch et al, unpublished)
6. Perceived helpfulness of mental health care, measured with one previously used item (Rüsch et al, unpublished)
7. Locus of control, measured with two Items (Lindström, 2011)
8. Perceived need of treatment and presence/outcome of illness, measured with the SAIQ – Self-Appraisal of Illness Questionnaire, 10 Items (Marks et al., 2000)
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11. Self-reported mental distress, measured with Kessler's K6 Psychological Distress Scale (Kessler, 2003)

Measured at baseline (t0), 3 weeks after baseline (t1), 6 weeks after baseline (t2) and 6 months after baseline (t3).

Completion date
01/04/2018

Eligibility

Key inclusion criteria
1. Currently unemployed (working less than 14h/week and receiving less than 451 Euro/months)
2. Psychological distress as indicated by a score ≥13 on Kessler's Psychological Distress Scale (K6)
3. At least moderate level of self-reported stress due to current situation (score 3 or higher in screening item "How mentally distressed do you feel with respect to your current situation?", rated from 1, not at all, to 5, very much)
4. 18 and 64 years of age
5. Ability to provide written informed consent
6. Fluent in German

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
42

Key exclusion criteria
Receiving full disability pension

Date of first enrolment
01/05/2017

Date of final enrolment
01/04/2018

Locations

Countries of recruitment
Germany

Study participating centre
University of Ulm and BKH Günzburg
Ulm
Germany
89069

Sponsor information

Organisation
German Research Foundation (DFG)

ROR
https://ror.org/018mejw64

Funder(s)

Funder type
Research organisation

Funder Name
Deutsche Forschungsgemeinschaft

Alternative Name(s)

German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Germany

Results and Publications

Individual participant data (IPD) sharing plan

The data generated during the current study is not expected to be made available due to the ethics approval that does not permit third party access to the data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2019	24/05/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes