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An online aftercare programme to improve vocational reintegration after inpatient medical rehabilitation

Submission date
15/08/2011

Recruitment status
No longer recruiting

Registration date
27/10/2011

Overall study status
Completed

Last Edited
30/01/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Mental and psychosomatic disorders are the leading reasons for work disability and premature pension in Germany and in most other high-income countries. In our previous studies we showed that job-specific interventions during in-patient rehabilitation, like real workplace training or stress management training, could be helpful to improve treatment satisfaction. Patients taking part in these programmes could also improve their vocational reintegration after inpatient rehabilitation. Currently we dont know how patients could transfer these improvements into their daily work. In most studies the improvements achieved during an inpatient rehabilitation treatment fade over time. Most patients are back to their initial health status 12 months after discharge from inpatient rehabilitation.
Aftercare programmes do exist but are not commonly known or accessible. Therefore, the internet offers new possibilities for special internet-based treatments (e.g. counselling interventions). This is groundbreaking because the internet is widely used, with 73.3% of the German population using the internet on a regular basis. The main aim of our study is to analyse if an internet-based aftercare programme could improve vocational reintegration after inpatient rehabilitation. In particular, we want to show if our aftercare programme could help to stabilise the improvements achieved during inpatient rehabilitation concerning subjective vocational stresses as well as health status of participating patients.

Who can participate?
Patients aged 18 to 59 years who are admitted to the participating rehabilitation units because of psychosomatic, orthopaedic and cardiovascular complaints.

What does the study involve?
Patients will be recruited through information from health professionals at the participating rehabilitation clinics at admission to the inpatient rehabilitation treatment. Those who are interested will receive written information about the study. After giving their informed consent 800 patients who meet the above requirements can participate.

Patients will be randomly allocated into one of two groups: the intervention group or the control group. If you are allocated to the intervention group you will get an internet-based aftercare programme following the inpatient treatment. The internet-based aftercare programme consists of: a section with information material to download, a moderated forum, a self-test, and a weekly blog concerning different situations at your workplace, with a commentary from an online therapist. If you are allocated to the control group you will also get access to an internet-based aftercare programme that consists of information material to download concerning stress management, physical training, health behaviour and relaxation techniques.

What are the possible benefits and risks of participating?
The expected benefits of taking part in this aftercare programme include stabilised improvements concerning stress management, coping with conflicts at work and improved vocational reintegration.
There are no known risks to participants.

Where is the study run from?
There are four participating clinics in Germany and the analysing centre is at the University Medical Centre Mainz, Department of Psychosomatic Medicine and Psychotherapy.

When is the study starting and how long is it expected to run for?
The study is running from November 2010 until October 2013.

Who is funding the study?
German Statutory Pension Insurance.

Who is the main contact?
Dr Rüdiger Zwerenz
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Study website
http://www.online-nachsorge.de/?htmlInformation

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0423/00-40-65-50-25

Study information

Scientific Title
Development and evaluation of an internet-based aftercare programme to improve vocational reintegration after inpatient medical rehabilitation

Study objectives
In this study we develop and evaluate an internet-based aftercare programme after inpatient medical rehabilitation, with hypotheses as follows:
1. We expect that vocationally strained patients taking part at the internet-based aftercare programme could stabilise the improvements achieved during inpatient rehabilitation concerning stress management and coping with conflicts at the workplace more than the "treatment as usual" control group, resulting in an improved vocational reintegration
2. We expect these effects to be evident up to nine months after the end of the internet-based treatment

On 23/08/2013 the anticipated end date was changed from 31/10/2013 to 31/05/2014.

On 03/07/2014 the anticipated end date was changed from 31/05/2014 to 31/08/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical association of Rhineland-Palatinate Ethics Committee, Mainz [Landesärztekammer Rheinland-Pfalz], 12/01/2011, ref: 837.415.10 (7424)

Study design
Multi centered, prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Vocationally strained patients in psychosomatic, orthopaedic and cardiovascular rehabilitation

Interventions
With a cluster randomised controlled intervention study we intend to study overall 800 patients at the beginning (T0) and at the end (T1) of inpatient medical rehabilitation as well as at the end of the aftercare programme (3 months after T1) and 9 months later (12 months after T1).

Patients in the intervention group get the internet-based aftercare intervention, based on a manualised, educational vocational training (Health training stress management at the workplace) they attended during inpatient rehabilitation. Patients of the control group also attend the inpatient training and do not get the special internet-based aftercare programme but obtain access to a placebo internet-based programme (with links to public accessible information about stress management and coping).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Social medical risk index in the screening questionnaire SIBAR (Bürger & Deck, 2009) at follow-up, including subjective prognosis for work, time of sick leave and unemployment as well as wish for pension.

Timepoints:
Screening = T0 = 0 months
Baseline = T1 = after the vocational training (about 3-6 weeks after screening)
End of treatment = T2 = 3 months after baseline diagnostics
Follow-up = T3 = 12 months after baseline diagnostics

Secondary outcome measures
Level of vocational distress, physical and mental health and capability at follow-up.

Timepoints:
Screening = T0 = 0 months
Baseline = T1 = after the vocational training (about 3-6 weeks after screening)
End of treatment = T2 = 3 months after baseline diagnostics
Follow-up = T3 = 12 months after baseline diagnostics

Overall study start date
01/11/2010

Completion date
31/08/2014

Eligibility

Key inclusion criteria
Vocationally strained patients in psychosomatic, orthopaedic and cardiovascular rehabilitation:
1. Private internet-access
2. Aged 18-59 years
2. Current occupation (full time, part time)
3. Vocational distress or high demand for vocational training / therapy according to the screening
4. German-speaking

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
59 Years

Sex
Both

Target number of participants
800

Key exclusion criteria
1. Unemployment, pension or no plans to work (e.g. housekeeping) at the beginning of inpatient rehabilitation
2. Severity of physical or psychological complaints, so that it is not possible to take part at the inpatient stress management training

Date of first enrolment
01/11/2010

Date of final enrolment
31/08/2014

Locations

Countries of recruitment
Germany

Study participating centre
University Medical Center of the Johannes Gutenberg-University Mainz
Mainz
Germany
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Sponsor information

Organisation
German Statutory Pension Insurance (Deutsche Rentenversicherung Bund) (Germany)

Sponsor details
Ruhrstr.2
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Sponsor type
Government

Website
http://www.deutsche-rentenversicherung-bund.de

ROR
https://ror.org/05am9gt90

Funder(s)

Funder type
Government

Funder Name
German Statutory Pension Insurance (Deutsche Rentenversicherung Bund) ref: 0423/00-40-65-50-25

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	25/01/2013		Yes	No
Results article	results	08/05/2017	30/01/2019	Yes	No