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Patients for patients – qualified peer-counselling and self-management for patients with rare chronic diseases

Submission date
27/09/2017

Recruitment status
No longer recruiting

Registration date
20/10/2017

Overall study status
Completed

Last Edited
05/07/2021

Condition category
Genetic Diseases

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

Plain English summary of protocol

Background and study aims
The aim of this study is to assess a brief, peer-delivered self-management intervention for patients with rare chronic diseases. Patients affected by four rare diseases are included in the study: neurofibromatosis type 1 (a genetic condition where tumours grow along the nerves), Marfan syndrome (a disorder of the body's connective tissues), primary sclerosing cholangitis (a chronic liver disease) and pulmonary arterial hypertension (high blood pressure in the arteries that go from the heart to the lungs).

Who can participate?
Patients aged over 16 with either neurofibromatosis type 1, Marfan syndrome, primary sclerosing cholangitis, or pulmonary arterial hypertension

What does the study involve?
Participants are randomly allocated to either an intervention group or a control group. The control group receives care as usual during the study and receives the intervention after the study has ended. The intervention group receives an intervention comprised of two components: a self-management manual and peer-counselling. For 6 weeks, participants complete the self-management manual at home. The first session includes a disease-specific information module. The manual follows an approach based on Acceptance and Commitment Therapy (ACT). ACT supports acceptance of negative conditions, feelings and thoughts rather than fighting against them and targets the question on how to live in line with one’s values. While working on the manual, participants are supported by weekly telephone conversations (max. 30 minutes) with a peer-counsellor who also has one of the four rare diseases named above. Participants’ acceptance of their illness is assessed before, directly after and 6 months after the intervention has ended.

What are the possible benefits and risks of participating?
Participating in the intervention may lead to improved disease management 6 months later compared to care as usual.

Where is the study run from?
University Medical Center Hamburg-Eppendorf (Germany)

When is the study starting and how long is it expected to run for?
November 2014 to October 2018

Who is funding the study?
Robert Bosch Foundation (Germany)

Who is the main contact?
1. Prof. Bernd Löwe
2. Dr Miriam Depping

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Patients for patients RCT

Study information

Scientific Title
Patients for patients – qualified peer-counselling and self-management for patients with rare chronic diseases

Study objectives
Primary hypothesis of the study is that participating in the intervention (consisting of self-management and peer-counselling) leads to a significantly stronger improvement in coping with the disease (indexed by acceptance) after the intervention compared to care as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Hamburg Medical Council, 03/08/2017, ref: PV5088

Study design
Single-center unmasked randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Neurofibromatosis type 1, Marfan Syndrome, primary sclerosing cholangitis (PSC), pulmonary arterial hypertension (PAH)

Interventions
Study coordination is single centered, participants receive their Intervention at home and by phone and will be recruited from all over Germany. Participants are randomly assigned to either condition after providing informed consent. Unmasked random assignment to intervention or waiting-control group.

The 6-week intervention combines self-management and peer-counselling. Participants receive a self-management manual including 6 modules on the following topics: Disease-specific information, dealing with negative emotions, accepting negative thoughts and emotions, values and value-based goals. The information module is the only disease-specific module. All other chapters are generic and do not address a specific condition. Additionally to the manual, participants receive weekly telephone support by a peer counsellor (max. 30 minutes). During the phone calls the recipients of the questions are asked whether working on the current chapter worked and which difficulties arose. The recipients have the opportunity to ask questions regarding the content and process. Peer-counsellors are trained before the intervention starts. They further receive supervision provided by a medical psychotherapist in order to be sufficiently supported during their work. Peer-counsellors further receive consulting guidelines.

The control group receives care as usual during the study. As a waiting control group participants receive the intervention after the trial has ended.

Data assessment will take place before, directly after as well as six months after the intervention has ended. Assessed variables include patient global impression of change, coping mechanisms, quality of life, illness-perception, illness-related fears and illness-related cognitions, psychopathology, social support and optimism. Further, acceptance and subjective usefulness of the intervention will be assessed after the intervention.

Intervention Type
Other

Primary outcome measure
Subscale "Acceptance" of the Illness Cognition Questionaire (ICQ; Evers, Kraaimaat et al. 2001). The instrument assesses ways of cognitively evaluating the aversive character of a chronic illness on the scales helplessness, acceptance, and perceived benefits. Timepoints: pre-assessment (before the intervention), post-assessment (directly after the intervention) and follow-up assessment (6 months after the intervention)

Secondary outcome measures
1. Patient's belief about the efficacy of treatment, assessed using Patient Global Impression of Change (PGIC) at post and follow-up assessment
2. Coping mechanisms, assessed using the Health Education Impact Questionnaire (HeiQ; Schuler, Musekamp et al., 2013) at pre, post and follow-up assessment
3. Illness perceptions, assessed using the Illness Perception Questionnaire (IPQ-R; Glattacker, Bengel et al., 2009) at pre, post and follow-up assessment
4. Health-related quality of life, assessed using the 12-Item Short-Form Health Survey (SF-12; Ware, Kosinski et al., 1996) at pre, post and follow-up assessment
5. Presence and severity of symptoms of depression, assessed using the Patient Health Questionnaire 9-item depression scale (PHQ-9; Kroenke, Spitzer et al., 2001) at pre, post and follow-up assessment
6. Somatic symptom severity, assessed using Patient Health Questionnaire 15-item somatic scale (PHQ-15; Kroenke, Spitzer et al., 2002) at pre, post and follow-up assessment
7. The presence and severity of anxiety symptoms, assessed using the Patient Health Questionnaire 7-item anxiety scale (GAD-7; Löwe, Decker et al., 2008) at pre, post and follow-up assessment

8. Perceived social support, assessed using Social Support Questionnaire – Fragebogen zur sozialen Unterstützung (F-Sozu; Fydrich, Sommer et al., 2009) at pre, post and follow-up assessment

Other measures:
1. Client Sociodemographic and Service Receipt Inventory (CSSRI) – adapted version, used at pre assessment
2. Acceptance and perceived usefulness of the intervention and the specific modules, assessed using self-generated measure at post assessment
3. The perceived relationship with the peer consultant, assessed using self-generated measure at post assessment
4. Subjectively perceived goal achievement, assessed using self-generated measure at post assessment
5. The perceived quality of the peer-counselling sessions from the perspective of the peer-counsellor, assessed using self-generated measure at post assessment
6. Whether expectations of peer-counsellors regarding the intervention have been met, assessed using self-generated measure at post assessment
7. Sociodemographic variables, assessed at pre assessment
8. Helplessness and perceived benefits, assessed using the Illness Cognition Questionnaire (ICQ; Evers, Kraaimaat et al. 2001) at pre, post and follow-up assessment
9. Fear of the progression of the illness and future worries concerning the illness, assessed using Fear of Progression Questionnaire - Short-Form (PA-F-KF; Mehnert, Herschbach et al, 2006) at pre, post and follow-up assessment
10. Optimism and pessimism, assessed using LOT-R (Glaesmer, Hoyer et al., 2008) at pre, post and follow-up assessment
11. General self-efficacy, assessed using Self-efficacy Scale – Allgemeine Selbstwirksamkeitserwartung (SWE; Jerusalem & Schwarzer, 1999) at pre, post and follow-up assessment

Overall study start date
10/11/2014

Completion date
31/10/2018

Eligibility

Key inclusion criteria
1. Diagnosis of one of four specific rare chronic conditions (Neurofibromatosis type 1, Marfan syndrome, primary sclerosing cholangitis, pulmonary arterial hypertension) given by a clinician
2. Limited functionality caused by the disease
3. Minimum age of 16 years
4. Willingness to participate in all parts of the intervention including the self-management manual, the peer counselling as well as willingness to answer to questionnaires
5. Sufficient German language skills

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
128

Total final enrolment
89

Key exclusion criteria
1. Life threatening state of health
2. Acute mental or physical burden requiring an immediate treatment
3. Acute suicidality
4. Current psychotherapeutic, psychosomatic or psychiatric treatment
5. Severe cognitive, auditory or visual impairment
6. Inability to answer study questionnaires

Date of first enrolment
05/10/2017

Date of final enrolment
28/02/2018

Locations

Countries of recruitment
Germany

Study participating centre
Psychosomatic Medicine and Psychotherapy, University Medical Center Hamburg-Eppendorf
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Sponsor information

Organisation
University Medical Center Hamburg- Eppendorf | UKE

Sponsor details

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Sponsor type
University/education

ROR
https://ror.org/01zgy1s35

Funder(s)

Funder type
Charity

Funder Name
Robert Bosch Stiftung

Alternative Name(s)
Robert Bosch Foundation, Robert Bosch Stiftung GmbH, RBS

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Germany

Results and Publications

Publication and dissemination plan
A study protocol is currently being prepared for submission to be published. Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/10/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

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	results	24/02/2021	25/02/2021	Yes	No
Other publications	intervention development	02/07/2021	05/07/2021	Yes	No