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Cost effectiveness of psychiatric rehabilitation

Submission date
14/10/2013

Recruitment status
No longer recruiting

Registration date
13/05/2014

Overall study status
Completed

Last Edited
05/03/2021

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
People suffering from Severe Mental Illness (SMI) require rehabilitation in many areas of life. The Boston University approach to Psychiatric Rehabilitation (BPR) has been developed to help people with Severe Mental Illness reach their goals in the areas of living independently, social contacts, work and meaningful activities in society. Previous research showed partially positive results of BPR. The BPR approach led to increases in participation in work, schooling and independent living and to improved functioning and a better quality of life. In this study, we will compare BPR to usual care in the area of societal participation (work, study, daily activities). We will also find out about if it is financially viable.

Who can participate?
We aim to recruit 250 patients with severe mental illness between 18 and 60 years of age with a wish for a positive change in the area of societal participation.

What does the study involve?
Participants will be randomly allocated to two groups. One group will receive usual care and the other group will receive support according to the BPR. In each group, patients will be offered individual sessions at least once every 2 weeks. At 6 and 12 months, we will assess societal participation in both groups by means of structured interviews and questionnaires. Also, information will be gathered on social functioning, psychiatric symptoms, quality of life and care consumption. This information is used to decide if the BPR approach is more cost effective than usual care.

What are the possible benefits and risks of participating?
All participants will receive additional support to help them achieve their rehabilitation goals. If the participant wishes, the sessions may be continued after the study is completed. The risks of the study are evaluated as 'very low'. By taking part in the study, participants will not experience risks other than those normally involved in clinical psychiatric treatment.

Where is the study run from?
The study will take place in two large mental health care centers in the Netherlands, 'Altrecht Mental Health Care' and 'Dijk en Duin' and an organization for sheltered and supported living 'Promens Care'.

When is the study starting and how long is it expected to run for?
The study started in January 2014 and will run for 3 years. Patients will be recruited over the first 2 years and will participate in the study for 1 year.

Who is funding the study?
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
80-83700-98-132069

Study information

Scientific Title
Societal participation with Boston Psychiatric Rehabilitation for patients with severe mental illness: a cost effectiveness study

Study objectives
Boston Psychiatric Rehabilitation is expected to be effective and cost-effective compared to care as usual in realising patients' goals regarding societal participation. Attending effectively to severe mental illness (SMI) patients' participation needs is expected to promote greater independence of care and so reduce health costs.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of the University Medical Center Groningen (UMCG); 29/11/2013; ref.: 2013/70

Study design
Multicenter randomized clinical trial

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
Severe Mental Illness

Interventions
Participants will receive BPR or care-as-usual for 1 year.

Boston Psychiatric Rehabilitation (BPR) uses a methodology that helps patients to explore, choose and realize their rehabilitation goals in the areas of working, learning, social contacts and living environment. The approach has three phases:

1. Setting a goal: helping patients gain insight into their goals in the areas of work and study, social contacts and living environment and into the skills and resources needed to attain these goals
2. Planning: describing necessary interventions (skills training, support) to achieve these goals
3. Carry out these interventions.

MHC workers receive training and gather practical experience with BPR under the supervision of experts of the Dutch BPR foundation. BPR is a comprehensive approach that can be used in different contexts such as inpatient settings, assertive outreach teams [(F)ACT teams], and in combination with more specific rehabilitation interventions (f.i. social skills training) and support systems.

In this study, BPR will be compared to care-as-usual. In both conditions, patients will be offered individual sessions at least once every 2 weeks to address their rehabilitation needs on the areas of societal participation. The professionals in the control condition offer support to patients in

clarifying and realizing their goals on the basis of generic MHC models; generic mental health nurse care, social work and generic vocational rehabilitation programmes.

Measurements will take place at baseline, 6 months and 12 months after enrollment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Increase in societal participation (getting paid work, voluntary work, and schooling (yes/no; after 6 and 12 months), measured with the Birchwood Social Functioning Scale (Birchwood et al., 1990)
2. Change in social participation expressed in terms of incremental cost per proportion increase in societal participation
3. A cost-utility analysis in terms of Quality Adjusted Life Years (QUALY)

Secondary outcome measures
1. Change in the number of hours of societal participation and in the position of patients on the national societal participation ladder (Divosa, www.participatieladder.nl)
2. Patients' experience of success (yes/no) in achieving societal participation goals in the areas addressed, such as work and schooling. For this purpose we developed an instrument in previous RCTs (Swildens et al., 2011)
3. Change in quality of life measured by the Manchester Quality of life Schedule (MANSA); (Priebe S, 1999)
4. Change in functioning is measured from different perspectives. First, psychosocial functioning is measured by the Birchwood Social Functioning Scale (Birchwood et al., 1990). Further change in psychosocial functioning is measured from the Mental Health Care team's perspective with the Activity and Participation scale (Van Wel et al., 2002). Further change in symptomatic functioning and psychiatric remission is measured with the (remission items) of the Brief Psychiatric Rating Scale (Ventura et al., 1993)
5. Increase of self-esteem with the Recovery Assessment Scale (Corrigan et al., 2004)

Overall study start date
01/01/2014

Completion date
31/01/2017

Eligibility

Key inclusion criteria
1. Having Severe Mental Illness (SMI): a diagnosis according to Diagnostic and Statistical Manual of Mental Disorders (DSM) IV, duration of service contact more than two years; GAF S-D score indicating substantial handicaps in global psychosocial functioning [Global Assessment of Functioning - Symptoms and Disabilities (GAF S-D); score 60 or lower]
2. Expressing a wish for change in societal participation (work, education, daily activities outside

the home)
3. Between 18-60 years of age
4. Willing to participate in a rehabilitation process and in the research

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
250

Total final enrolment
188

Key exclusion criteria
1. Legally incompetent
2. Younger than 18 years
3. Older than 60 years. We decided for the maximum age of 60 years because patients with older age usually have different goals in social participation, notably other than obtaining regular employment.
4. Received Boston Psychiatric Rehabilitation in the 4 months preceding the start of the trial
5. Admitted as inpatient to a Mental Health Care (MHC) centre

Date of first enrolment
06/03/2014

Date of final enrolment
01/01/2016

Locations

Countries of recruitment
Netherlands

Study participating centre

Lange Nieuwstraat 119
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Sponsor information

Organisation
Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

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Sponsor type
Research organisation

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

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	15/09/2015		Yes	No
Results article	results	23/09/2020	05/03/2021	Yes	No