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

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The main objective of the study is to gain insight into the cost-effectiveness of BPR compared to care as usual (CAU) for patients withSMI who have a wish for change in their societal participation. Research questions:1. Is BPR (cost-)effective...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41469

Source
ToetsingOnline

Brief title
Cost effectiveness Psychiatric Rehabilitation

Condition

- Other condition
- Schizophrenia and other psychotic disorders

Synonym
Severe Mental Illness (SMI)

Health condition

Doelgroep Ernstige Psychiatrische Aandoeningen (EPA), dat wil zeggen een ernstige DSM IV diagnosis, met een langere ziekteduur (> 2 jaar in zorg bij de GGZ) en beperkingen in het functioneren op meerdere levensterreinen

Research involving
Human

Sponsors and support

Primary sponsor: Altrecht GGZ, Divisie Willem Arntsz
Source(s) of monetary or material Support: ZonMw programma Doelmatigheid

Intervention

Keyword: cost effectiveness, rehabilitation, Severe Mental Illness, societal participation

Outcome measures

Primary outcome

The primary outcome for the effect study will be 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).

The primary outcome measures for the cost-effectiveness study are change in social participation expressed in terms of incremental cost per proportion increase in societal participation, and a cost-utility analysis in terms of Quality Adjusted Life Years (QUALY).

Secondary outcome

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 RCT*s

(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 MHC 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 Assement Scale (Corrigan et al, 2004).

All aforementioned instruments are designed to measure change in patients with SMI and are sensitive to measure change.

Study description

Background summary

Severe mental Illness (SMI) implies having a DSM IV diagnosis, a long duration of the illness (> 2 years in MHC) and having disabilities in multiple life domains. People with SMI need access to a broad array of services. These services do not only entail provision for clinical needs (treatment and crisis response) and humanitarian needs (e.g. physical safety, suitable housing, acceptance as a person), but also rehabilitation needs in the areas of living independently, social contacts, work and meaningful activities in society. It is in these areas that BPR, developed in the US at the Boston University, claims to have its effects.
In recent years the small number of RCT*s into BPR generated partly positive

results: increase of participation in work, schooling, independent living, better functioning, and a better quality of life. From 2004 to 2008 our research group performed a well-powered RCT (n=156) in the Netherlands with support of the ZonMw programme Geestkracht. This research involved SMI patients with care needs in all rehabilitation areas: work, schooling, structured activities, and social contacts, and living independently. The rate of goal attainment was substantially higher in BPR at 12 and 24 months than with CAU. BPR was also more effective in terms of a general measure of societal participation. Though BPR is recommended in the Dutch guidelines for, for instance, schizophrenia, implementation in MCH practice is limited. The lack of insight into the cost-effectiveness structure of BPR seems to be an important obstacle.

Study objective

The main objective of the study is to gain insight into the cost-effectiveness of BPR compared to care as usual (CAU) for patients with SMI who have a wish for change in their societal participation.

Research questions:
1. Is BPR (cost-)effective compared to CAU after 12 months for patients with SMI between 18 and 64 years, living independently and receiving care by a MHC centre or an organization for supported living, who have a wish for change in the rehabilitation area societal participation?
2. Is BPR a (cost-) effective intervention compared to CAU after 6 months for the aforementioned target group?
3. Is BPR an effective intervention in terms of patient satisfaction with regard to reaching their personal rehabilitation goals, subjective quality of life and social functioning after 6 and 12 months for our target group?

Study design

The research will be carried out as a multicentre RCT in which 250 patients with SMI will be included, who have a whish for change in the rehabilitation area social participation. Treatment consists of individual sessions offered at least once every two weeks according to BPR in de experimental group, or CAU in the control group, during one year. Measurements with questionnaires will take place at baseline, 6 months and 12 months. Primary analyses will be conducted according to an 'intention to treat' protocol using multilevel and logistic regression models. Models will be corrected for centre and other confounders.

Intervention

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: a)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; b) planning: describing necessary interventions (skills training,support) to achieve these goals and c) 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 both conditions, patients will be offered individual sessions at least once every two 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.

Study burden and risks

The risks of this study are evaluated as very low because participants will not experience other risks than those normally involved in clinical psychiatric treatment.

The intervention is offered to patients that have a express a wish for change in societal participation (work, education, daily activities outside the home). Patients are offered help in both conditions. Patients are informed by their casemanagers and by the researchers that their decision to participate in the research (yes/no) has no consequences for the careoffer in the centre. This is also stated clearly in the information letter and informed consent form.

Burden of the intervention and questionnaires is also very low. Patients stay in treatment as before but receive extra counseling with respect to their rehabilitation goal minimal once every two weeks, during a year with a worker who is trained in BPR or with a worker who will use a counselings approach that is regularly used in the setting. Since 2012 BPR is registered in the US Substance Abuse and Mental Health Services Administration (SAMSHA).

The questionnaires are frequently used in patients with SMI and are proven to have a small burden. During the reserach period, patients will be measured at 3 moments. Each measurement wiill consist of an interview and questionnaires and will take approximately one hour. Former studies with the same group showed

that this is not too much of burden on the patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The inclusion criteria are:
(a) Having Severe Mental Illness (SMI); a diagnosis according to DSM IV, duration of service contact more than two years; GAF S-D score indicating substantial handicaps in global psychosocial functioning (GAF S-D: Global Assessment of Functioning - Symptoms and Dissabilities; score 60 or lower)
b) Expressing a wish for change in societal participation (work, education, daily activities outside the home).
c) Between 18-64 years of age.

d) Willing to participate in a rehabilitation process and in the research

Exclusion criteria

Excluded are patients that:
a) are legally incompetent
b) are younger than 18 years
c) are older than 64 years. We decided for the maximum age of 64 years because patients with older age usually have different goals in social participation, notably other than obtaining regular employment
d) received Boston Psychiatric Rehabilitation in the four months preceding the start of the trial
e) for all except for patients from Rintveld: are admitted as inpatient to a MHC centre,
f) for patients from Rintveld: inpatient to a MHC centre and NOT in the last phase of inpatient treatment and date of end of admission period is set.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2014
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO Date:	29-11-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-07-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL45706.042.13