

Resourcegroupss: effectiveness, costs and meaning

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23275

Source

Nationaal Trial Register

Health condition

severe mental illnessess; empowerment in mental health care

ernstig psychiatrische aandoeningen; empowerment in de geestelijke gezondheidszorg

Sponsors and support

Primary sponsor: Trimbos Instituut, Erasmus Medical Center, Arkin, Altrecht, GGZ Breburg, GGZ Centraal, GGZ Noord-Holland-Noord, Lentis, GGZ inGeest, BAVO Europoort, Antes.

Source(s) of monetary or material Support: Stichting tot Steun VCVGZ

Intervention

Outcome measures

Primary outcome

Empowerment

Secondary outcome

Quality of Life; General, social and societal functioning; Personal Recovery; Psychopathological symptoms; Attachment Style; Consumer Satisfaction; Use of Health Services;

Study description

Background summary

Background.

Despite a growing awareness in Dutch mental health policy for the importance of involving patients and their significant others in their own care, well designed research on effective interventions to bring this into clinical practice is scarce. Resource Groups (RG) may offer a new structure to systematically engage patients social network into treatment, to improve communication within different support systems and to encourage patients to take responsibility and ownership in their path to recovery. Hereby, the RG method is in line with recent developments around recovery-supporting mental health care, shared decision making and empowerment. The aim of the present study is to investigate the effectiveness, cost-effectiveness, meaning and implementation-process of combining usual Flexible Assertive Community Treatment (FACT) care with Resource Groups (RG) for patients with severe mental illnesses (SMI).

Method. In a multicenter randomized controlled trial with 18 participating FACT teams throughout the Netherlands a minimum of 180 patients entering FACT care will be randomly assigned to one of the groups (FACT + RG or FACT alone; ratio 1:1). An economic evaluation and a qualitative research study on patient, RG members and caregiver perspectives on RG are embedded in this trial. Outcome assessments (both for clinical effectiveness and economic evaluation) take place at baseline and 9 and 18 months after start. Primary outcome is empowerment; secondary measures include quality of life, social functioning and general psychopathological complaints. Data for the cost-effectiveness and cost-utility analyses are collected by using a retrospective cost-interview. Information on patient, RG members and therapist perspectives is gathered using in-depth interviews and focus groups, and focuses on possible helpful and impeding aspects of the RG method as well as on implementation issues.

Discussion. This trial is the first to investigate the direct value of the RG within the context of FACT care for people with SMI. By combining clinical effectiveness data with an economic evaluation and with in-depth, direct information from primary stakeholders, this trial offers a

complete and thorough view on RG as a contribution to the improvement of care for people with SMI.

Study objective

The primary objective of the present study is to investigate the effectiveness of the Resource Groups (RG) on patient outcomes compared to care as usual alone for people with severe mental illnesses. It is hypothesized that participation in the RG is associated with increased empowerment, improved well-being and enhanced social and community functioning, when compared to care as usual.

The secondary objective is to investigate whether care as usual with RG is more cost-effective than care as usual alone. The RG method is hypothesized to be more cost-effective on the long term than care as usual.

The third objective is to explore the implementation process of the RG in Dutch mental health care and the deeper meaning for patients; and to assess potential obstacles, bottlenecks and success factors by using a qualitative case-approach.

Study design

baseline, 9 months, 18 months

Intervention

The central element in the RG is the patient as the director of the group (Nordén et al., 2012b). That is, the patient nominates group-members sets his/her self-recovery treatment goals and decides on the location and time of the meetings, guided and supported by the case manager (CM). The CM and the patient always take part of every RG meeting, and the psychiatrist of the FACT-team attends the RG once a year if possible and necessary. Other RG-members can be significant others (family members, friends or others) as well as (family) experts and professionals from within and outside mental health care. The recovery goals can relate to all aspects of recovery, such as personal recovery (recovery of identity), social rehabilitation (meaningful participation and performance in society) and health (treating and improve physical and mental symptoms). During the meetings, the group decides on the role of each member in accomplishing the intended goal. The RG makes decisions together and takes responsibility for seeing to it that the development plan is followed (Nordén et al., 2012b). All the RG-meetings are clearly and consistently structured over time and follow the agenda that the patient and the CM agreed on. Additionally, an action plan for recognizing early warning signs that indicate an approaching relapse is established so that RG members can provide adequate, adjusted guidance that is designed and approved by the patient. Between the meetings and during evaluation, subjects are motivated to work on these goals and to involve the RG members in this process.

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Eligibility criteria

Inclusion criteria

- Age between 18 – 65 years
- Having a severe mental illness, defined as: (1) a diagnosable mental, behavioral, or emotional disorder according to the diagnostic criteria specified within the DSM-5, (2) that is associated with serious social and/or societal limitations, (3) in which the limitation is the cause and effect of the psychiatric disorder, (4) in which the psychiatric disorder has a chronic course; and (5) for which coordinated care of mental health care professionals in care networks is indicated to realize the treatment plan (Delespaul et al., 2013).
- FACT-care for at least 18 months is indicated

Exclusion criteria

- Unable to give informed consent
- Insufficient knowledge of Dutch language

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-10-2017
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion	
Date:	27-09-2017
Application type:	First submission

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
NTR-new	NL6548

Register

NTR-old

Other

ID

NTR6737

VU-METC : 2017.316

Study results