ISRCTN77355880 https://doi.org/10.1186/ISRCTN77355880

Comprehensive Approach to Rehabilitation Evaluation Research

Submission date
11/04/2013

Recruitment status
No longer recruiting

Registration date
05/07/2013

Overall study status
Completed

Last Edited
25/11/2016

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 with severe mental illnesses (SMI) often have a small social network, lack of resources and a small amount of social roles. Although they do have the same goals in life as other people, it is more difficult for them to realize those goals. Rehabilitation methods support people to choose, achieve and maintain desirable social roles. A well-known and often applied rehabilitation method in The Netherlands is the Comprehensive Approach to Rehabilitation (CARe) methodology. The CARe methodology aims to establish a personal-professional relationship in which the care provider joins the needs and desires of the client. The overall goal of the CARe methodology is to improve the client's quality of life. This is done by helping fulfill the wishes of the client, supporting the client and improving the quality of the social environment. This study aims to investigate the effectiveness of the CARe methodology and assess if support of clients by use of the CARe methodology leads to more recovery compared to clients who receive care as usual.

Who can participate?
The study will be executed in three Regional Institutes for Residential Care (RIRCs; Dutch acronym RIBWs). These institutes provide housing services, as supported housing and supported independent living, to people with long-term severe mental diseases. A minimum of 320 clients (120 per group) will be included in this study.

What does the study involve?
The teams in the intervention group will receive the CARe methodology training, schooling and implementation support to care for their clients. The teams in the control group maintain their usual practice.

What are the possible benefits and risks of participating?
Regarding the guidance of the workers (the intervention) there are no risks, the method has been used for several years. Regarding participating in the study, the only strain is filling in the questionnaires (three times, taking about 1.5 hours).

Where is the study run from?
Tilburg University, Tranzo Scientific Center for Care and Welfare

When is the study starting and how long is it expected to run for?
The study started in May 2012. Inclusion of participants started in November 2012. Data gathering will end February 2015. The study will run until the beginning of 2016.

Who is funding the study?
Funding has been provided by five RIRCs using the CARe methodology: Kwintes, RIBW KA/M, RIBW Gooi- en Vechtstreek, RIBW Arnhem en Veluwevallei and RIBW Fonteynenburg and Storm Rehabilitation.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
ONDI351138

Study information

Scientific Title
Effectiveness of the Comprehensive Approach to Rehabilitation (CARe) methodology: a randomized controlled trial

Acronym
CAREER

Study objectives
Support of clients by use of the CARe methodology leads to more recovery compared to clients who receive care as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Research Ethics Committee of Elisabeth Hospital in Tilburg, 11/10/2012, ref: NL41169.008.12

Study design
Two-armed cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe and persistant mental illness

Interventions
Intervention group: CARe methodology
Teams in the intervention group receive the CARe methodology training. The aims of this training are: training workers in the principles of rehabilitative and recovery-supportive care and to support clients' rehabilitation process in a methodical way. The central principles are: creating a personal-professional relationship with a client aiming to build a cooperative relationship (presence perspective); to map the strengths of a client and his/her environment; determining goals for the future; and to draw up a personal plan and a supporting plan. The training consists of seven meetings (three theoretical and four methodical work support) and is taught by trainers from a specialized training institute (website RINO groep). To enlarge the implementation level team leaders will also take part in the training. Besides that there will be given special attention to the process of implementation and securing of this.
In practice working with the CARe methodology consists of the following 6 steps: (1) building and maintaining a constructive relationship; (2) collecting information and making a personal profile with the client; (3) helping the client with formulating wishes, making choices and setting goals; (4) helping the client making a Personal Plan; (5) helping the client execute the plan and (6) following the process, learn, evaluate and adjust.
After the training program the workers will be supported in working according to the CARe methodology by means of CARe coaching meetings (once every 4-6 weeks) in which practical cases can be discussed. These coaching meetings are guided by a trained CARe coach from the particular organization independent of the team the workers are working in.

Care as usual
The teams in the intervention group do not receive the CARe methodology basis training. The workers in those teams will maintain to work according to the (narrowly implemented) outdated CARe methodology. Teams in the control group will be asked not to implement new recovery /rehabilitation oriented practices as long as they participate in the study.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

1. Recovery: will be measured by use of the Mental Health Recovery Measure (MHRM). The MRHM is a self-report instrument with 30 items. All items are rated using a five-point Likert scale that ranges from 'strongly disagree' to 'strongly agree'.
2. Social Functioning: the Social Functioning Scale (Birchwood) will be used to measure social functioning. The scale consists of 19 items (with different scales) and 4 checklists with activities.
3. Quality of life: will be assessed by the Manchester Short Appraisal (MANSA). The MANSA consists of 12 items with a seven-point Likert scale ('could not be worse' to 'could not be better').
4. Empowerment: for the measurement of empowerment the Dutch Empowerment Scale will be used. This scale consists of 40 items on a five-point Likert scale ranges from 'strongly disagree' to 'strongly agree'.
5. Hope: will be assessed by the Herth Hope Index, consisting of 12 four-point Likert scale items ranging from 'strongly disagree' to 'strongly agree'.
6. Confidence: the Mental Health Confidence Scale (MHCS) will be used to measure confidence . This scale has 16 items with a six-point Likert scale ('totally no confidence' to 'full confidence').
7. Need for care will be measured by use of The Camberwell Assessment of Needs (CANSAS) consisting of 22 items.
8. Goal achievement: the goals of the participating clients will be registered.

All primary outcome measures will be measured at baseline (T0), after 10 months (T1) and 20 months (T2).

Key secondary outcome(s))
1. Psychiatric symptoms: will be measured by use of the Brief Symptom Index (BSI), 52 items with a five-point scale from 'not at all' to 'very much'.
2. Relationship between client and worker: the Recovery Promoting Relationship Scale (RPRS) will be used to measure the way the client experiences the relationship with his or her key worker. This measure has 24 items on a four-point Likert scale ranging from 'disagree' to 'agree' The key workers of the participating clients will be asked to answer questions regarding the diagnosis and care consumption, psychiatric diagnosis (DSM IV) of the client and the amount of contact they have with the client. Besides that, care consumption in general and use of work /recreation facilities will be questioned.
3. Workers' knowledge of recovery will be measured by use of the Recovery Knowledge Inventory (RKI) consisting of 20 items on a five-point Likert scale ranging from 'strongly disagree' to 'strongly agree'.

All secondary outcome measures will be measured at baseline (T0), after 10 months (T1) and 20 months (T2).

Completion date
01/01/2016

Eligibility

Key inclusion criteria
All mature clients of the participating organizations who are able to fill in the questionnaires (with help if necessary)

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

Key exclusion criteria
1. Age below 18 years
2. No personal/key worker
3. Too little knowledge of the Dutch language to fill in the questionnaire
4. An IQ below 50

Date of first enrolment
01/11/2012

Date of final enrolment
01/02/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Warandelaan 2
Tilburg
Netherlands
5000 LE

Sponsor information

Organisation
Kwintes (Netherlands)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Five Regional Institutes for Residential Care (RIRC): Kwintes, RIBW Fonteynenburg, RIBW KA/M, RIBW Gooi- en Vechtstreek, RIBW Arnhem en Veluwevallie (Netherlands)

Funder Name
Storm Rehabilitation (Netherlands)

Results and Publications

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?
Results article	results	23/11/2016		Yes	No
Protocol article	protocol	22/07/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes