

# Comprehensive Approach to Rehabilitation Evaluation Research

<b>Submission date</b> 11/04/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 05/07/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/11/2016	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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?

Neis Bitter MSc (PhD student)  
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## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

OND1351138

## 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

### **Secondary study design**

Cluster randomised trial

### **Study setting(s)**

Other

### **Study type(s)**

Treatment

### **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**

Severe and persistent 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 measure

1. Recovery: will be measured by use of the Mental Health Recovery Measure (MHRM). The MHRM 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).

#### Secondary outcome measures

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).

**Overall study start date**

01/05/2012

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

320

**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)

### **Sponsor details**

PO Box 31  
Laan van Vollenhove 3213  
Zeist  
Netherlands  
3700 AA

### **Sponsor type**

Other

### **Website**

<http://www.kwintes.nl/>

## **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 Veluwevallis (Netherlands)

### **Funder Name**

Storm Rehabilitation (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?
<a href="#">Protocol article</a>	protocol	22/07/2015		Yes	No
<a href="#">Results article</a>	results	23/11/2016		Yes	No