Trial Illness Management and Recovery (IMR)
Effects of IMR on patients with severe mental illness

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The aim of this study is to examine the effectiveness of the IMR program compared to care as usual (CAU) in patients with SMI.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric and behavioural symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON39268

Source
ToetsingOnline

Brief title
Trial IMR

Condition

- Psychiatric and behavioural symptoms NEC
- Lifestyle issues

Synonym
Serious and Persistent Psychiatric Illness / Chronic Psychiatric Problems

Research involving
Human

Sponsors and support

Primary sponsor: Parnassia Bavo Groep (Den Haag)

Source(s) of monetary or material Support: Bavo Europoort en Parnassia Bavo Groep + de firma Janssen-Cilag,Janssen-Cilag

Intervention

Keyword: Illness Management, IMR, Recovery

Outcome measures

Primary outcome

The illness management and recovery scale-patient self score version will be the primary outcome measure. This scale has 15 items and is completed by patients themselves. With this scale the effects of IMR in various domains can be measured (Mueser et al 2004; Salyers 2007; Hasson-Ohayon et al. 2008; Dutch translation De Vries 2011). The consumer and clinician versions of the Illness Management and Recovery (IMR) scales have adequate psychometric properties.

Secondary outcome

a Illness management

- IMR-scale clinician-rated version This scale (15 items) will be used to explore effects. This scale is scored by non-blinded clinicians, who are not involved in the IMR-training.
- Coping is measured with the Coping self-efficacy (CSES) scale (Chesney et al. 2006): *13-items*. This scale has good psychometric properties and provides according to the constructors a measure of a person*s perceived ability to cope effectively with life challenges, as well as a way to assess changes in CSE over time in intervention research.
- Social support is measured with the Multidimensional Scale of Perceived

Social Support MSPSS (Zimet, Dahlem, Zimet & Farley, 1988) (12 items) . This scale has good psychometric properties.

- Medication compliance is measured with the Service Engagement Scale (SES) (Tait et al. 2002) (14-items). This scale has good psychometric properties.
- Insight into own problems is measured with the Insight Scale (IS) (8 self-report items) (Birchwood et al, 1994). The psychometric properties of the scale are called excellent (Tait et al.2003).
- Symptoms are measured with the Brief Symptom Inventory (BSI) (53 items) The authors report good internal consistency reliability, test-retest reliability and validity of the BSI. (Derogatis & Melisaratos 1983; Derogatis 1993; De Beurs, 2008).
- Relapses: The number of relapses (operationalized in the number of hospital admissions) during and after participating in the IMR-training will be compared with the number of relapses in the year before participating in IMR.
- Alcohol & Drugs-use: One item (item 24) of the Addiction Severity Index (ASI), asking how much respondents has been bothered the past 30 days by problems with a. alcohol, b. drugs, (a & b separately scored on a 5-point scale).

b. Recovery

The concept of recovery is complex. We choose to assess general recovery by using a special scale as well as measuring different aspects of recovery

including aspects of what Mueser et al. (2006) call subjective recovery (self esteem, self stigma, quality of life, satisfaction) and objective recovery (functioning).

- General recovery, measured with the Mental Health Recovery Measure (MHRM) (Young & Bullock, 2000); authorised translation in Dutch (Moradi, Brouwers, Van den Bogaard & Van Nieuwenhuizen, 2007). The MHRM is a 30 item self-report measure. This scale has good psychometric properties.
- Self stigma is measured with the Internal Stigma of Mental Illness (Ismi), 29 items (Ritsher 2003). This scale has good psychometric properties.
- Self esteem measured with the Self-Esteem Rating Scale-Short From (SERS-SF), (20 items) (Lecomte et al., 2006). This scale has good psychometric properties.
- Quality of life measured with the EQ-5D (Prieto et al 2003), 5 items. This scale has good psychometric properties.
- Satisfaction, Two questions: **Can you tell me how satisfied you are with your life as a whiole? and *How satisfied are you with the health care services you visited?* These questions are used in the Routine Outcome Monitoring of the Long Stay sector of Parnassia Bavo Group and are supposed to correlate with all other possible satisfaction-questions which were part of satisfaction questionnaires. (see Delespaul et al. 2006)
- Social Functioning is measured with the Social Functioning Scale (19 items and 4 checklists with in total 62 aspects). This Scale is called reliable, valid, sensitive and responsive to change (Birchwood et al. 1990).

c. Cost-effectiveness

- Cost-effectiveness is measured by counting number and duration of contacts (including the IMR-meetings), crisis contacts, (forced) admissions and duration of admissions are calculated in costs in euro*s. These are related with changes in quality of life measured by the EQ-5D (see above), By transforming scores on the EQ-5D in so called *quallies* cost-effectiveness can be calculated.). This scale has good psychometric properties (Lamers et al., 2005), Staring (2010).

Study description

Background summary

In recent years some promising new services for people with serious and persistent psychiatric illnesses (SMI) have emerged, mostly in the USA, but their effectiveness in Dutch Mental Health Care has not yet been proven. Several evidence based psychosocial interventions are at a basic level included in the program of Illness Management and Recovery (IMR).
Illness Management and Recovery (IMR) is a program of care in the form of a training course for patients with severe and persistent psychiatric problems, based on a combination of different types of interventions focused on recovery. The idea underlying the training course is that the patient learns to gain control of his illness (illness management) and to make appropriate choices based on accurate information and skills training.
The total duration of the training program is on average one year if there is a meeting of 1,5 hour each week.
IMR is currently implemented in several countries. In the Netherlands there is much interest in IMR, but implementation of IMR is in about 7 mental health care institutions still at the beginning. In the Netherlands BavoEuropoort has the most experience with IMR.The implementation of IMR at BavoEuropoort has been evaluated with a pilot study.
IMR is named an EBP by the American researchers who have constructed IMR because the ingredients of the program are evidence-based.
In the meantime however three RCT*s on the overall package of IMR have been executed in different countries by Hasson-Ohayon et al (2007), Levitt et al (2009) and Färdig et al. (2011), with positive results for IMR.
Despite these positive studies, IMR is not yet broadly accepted as an EBP in Dutch mental health care. In particular, it is mentioned neither in the Dutch multidisciplinary guidelines on schizophrenia of 2005, nor in the concept guidelines of 2010. More research is needed, especially to investigate whether

IMR is effective in the Dutch context.

Study objective

The aim of this study is to examine the effectiveness of the IMR program compared to care as usual (CAU) in patients with SMI.

Study design

The design is a randomized controlled trial in which patients are assigned to the experimental condition (IMR) or the control group, after providing written informed consent:

- Group 1. IMR program, offered in a group format + care-as-usual (CAU).
- Group 2. Care-as-usual (CAU)

We have planned three moments of measurement. These moments are

1. prior to the randomization, at baseline
2. after the training (the mean duration of the training in the pilot study was 12.6 months).
The second moment of measurement for the control group is 12 months after the first moment of measurement.
3. The follow-up measurement is 6 months after the second measurement.

Intervention

The IMR-training consists of 11 modules that are given weekly, the first module is given individually. During this individual module the patients decide which goals they want to work on during the program.
Then the patients join an IMR group for the other modules. Each module takes about 3 to 4 sessions of one and a half hour each. The IMR group is guided by two trainers (psychiatric nurses). The trainers received a two-day course in IMR and attend supervision once every two weeks.
The modules are described in the IMR-workbooks, translated into Dutch, which the patients received. If necessary, the original American text is adapted to the Dutch context. The modules are:
1. Recovery Strategies, 2. Practical Facts about Mental Illness, 3. Stress-Vulnerability Model, 4. Building Social Support, 5. Using Medication Effectively, 6. Alcohol and Drugs Use, 7. Reducing Relapses, 8. Coping with Stress , 9. Coping with Problems and Persistent Symptoms, 10. Getting Your Needs Met in the Mental Health System, 11. Health for you.
The trainers use techniques from motivational interviewing, psychoeducation and cognitive-behavioral therapy (CBT). Peer group support is part of the IMR-training. Home assignments are provided. Workbooks and homeassignments can be accessed via the internet. There is feedback on homework from trainers on

the Internet.

Study burden and risks

Burden by completing questionnaires and by interviews.
The practical and theoretical relevance of the study justify conducting the research in our opinion.

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

- Patients with serious and persistent psychiatric illnesses. Most of them will be patients who have a psychotic disorder, schizoaffective disorders or bipolar disorders with or without

comorbid disorders (such as substance abuse and personality disorders)
- The patient is treated on an outpatient basis
- Written informed consent

Exclusion criteria

- Having done an IMR-training
- Organic brain syndrome.
- Incompetence regarding the giving of informed consent.
- Patients with severe cognitive impairments who are unable to follow the training
- Insufficient knowledge of the Dutch language (they can not participate in the group)

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-10-2012
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	27-08-2012
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-07-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20008
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL38605.078.12
OMON	NL-OMON20008