Testing an e-supported Illness Management & Recovery Program for People with Severe Mental Illness

Published: 01-12-2014
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The objective of this study is to evaluate the potential effectiveness, effect size, and added value of the e-IMR.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON42273

Source
ToetsingOnline

Brief title
e-IMR

Condition

- Psychiatric disorders NEC

Synonym
Serious Mental illness, Severe Mental Illness

Research involving
Human

Sponsors and support

Primary sponsor: IQ healthcare
Source(s) of monetary or material Support: ZonMW (nr. 520001001)

Intervention

Keyword: e-health, Illness Management & Recovery, Nursing Science, Severe Mental Illness

Outcome measures

Primary outcome

The participant outcome measures of the early trial are: illness management, recovery, psychiatric symptoms severity, self-management, quality of life, and general health.

Secondary outcome

The process of the IMR program and will be evaluated on fidelity and feasibility using the IMR Fidelity Scales and semi-structured interviews with participants and trainers.

Study description

Background summary

Consumers with SMI in the contemplation phase of recovery are referred to the IMR-program. E-health interventions are expected to be more efficient, but overall conclusion on e-mental health cannot be drawn. A blended e-health application to the IMR-program is developed to contribute to the consumers* recovery process and is supposed to be equally effective as face-to-face delivery of the IMR-program.

Study objective

The objective of this study is to evaluate the potential effectiveness, effect size, and added value of the e-IMR.

Study design

The e-IMR intervention will be tested in an early cluster randomized controlled trial with an approximately twelve month follow-up from baseline. Early* reflects the exploratory nature of the trial.

Intervention

Participants in the care as usual group receive guideline-based treatment combined with the IMR-program. On top of this usual care participants in the intervention group receive e-IMR, which adds an e-health application to the IMR-program. On the e-health platform participants can execute home assignments and view illustrative videos and texts showing peer-testimonials, and join group discussions.

Study burden and risks

All participants in this early trial could benefit from the IMR program, which have shown positive outcomes in earlier studies. This early trial could determine whether e-health intervention for consumers with SMI contribute to treatment. In the future consumers with SMI could get more possible treatment options to choose from. The risks that participants in the intervention group might face are estimated as small. Comparable studies have shown usability of e-health and its potential to improve participants* well being. A possible burden for participants might be to fill in the questionnaires and participate in an interview.

Contacts

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Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Participants meet the criteria for having an SMI: having a DSM-IV-TR diagnoses, with a duration of one year since onset, and a disability that is sufficiently severe to cause serious impairment of functioning
Participants are referred to the IMR by their clinician, which means the consumer acknowledges the illness and having a desire and motivation to change.

Exclusion criteria

Excluded are consumers with SMI who are overwhelmed by disability including dependence, denial, confusion, anger, or despair.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-01-2015
Enrollment:	95
Type:	Actual

Ethics review

Approved WMO Date:	01-12-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-08-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-03-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-07-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 24478
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL49693.091.14
OMON	NL-OMON24478