

Cost-effectiveness of internet-based guided self-help for depressive disorders in specialized mental health care: A randomized controlled trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON35949

Source

ToetsingOnline

Brief title

Cost-effectiveness of guided internet self-help for depression

Condition

- Mood disorders and disturbances NEC

Synonym

depression, depressive disorders

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: ZonMw (dossiernummer: 80-82310-97-11047)

Intervention

Keyword: cost-effectiveness, depression, depressive disorders, e-mental health

Outcome measures

Primary outcome

Primary clinical outcome measure is the degree of depressive symptoms (as measured with the Center for Epidemiological Studies * depression scale (CES-D).

Secondary outcome

Secondary outcomes include remittance (whether or not the patient meets criteria for a depressive disorder according to the DSM-IV). the level of anxiety, as measured with the HADS, satisfaction with the intervention (CSQ-8), and the use of alcohol and or drugs (CAGE). By use of a diagnostic interview (the CIDI), the clinical diagnostic status after treatment will be measured as well as the time to recovery. Quality of life will be measured with the EQ-5D at baseline and all follow-up measurements. All questionnaires will be completed via the internet.

Health care consumption and absenteeism will be measured using the TiC-P. This instrument is used for economic analyses. Information on which care was received by the patients will be retrieved retrospectively from electronic health records.

Study description

Background summary

Depressive disorders are the fourth burden of disease in the Netherlands , and are expected to be the first in 2030 in developed countries. The loss of quality of life for these patients is enormous and is accompanied by high health care costs.

Fifteen percent of the Dutch population suffers from a major depressive disorder of which 5.8% in the past year.

The impact of depressive disorder on the patient*s life is enormous. Depression is associated with serious functional impairments in the educational, social and occupational domains, together with losses in quality of life, considerable economic costs and high levels of service use. Depressive disorders are commonly treated with pharmacotherapy and/or cognitive behavioural therapy, as prescribed by the multidisciplinary guideline for depressive disorders in the Netherlands.

A considerable number of patients who seek treatment are frequently confronted with long waiting lists and are often not provided with evidence-based treatments.

Although several studies have shown that web-based guided self-help for depression has comparable effect sizes as face-to-face treatment, this is still not a very commonly used treatment mode in daily usual care and the cost-effectiveness in specialized mental health care has not been studied yet. Research shows that the health care costs of depressed patients are high. Faster access to adequate treatment has the potential to speed up recovery and to result in cost savings. Because patients are treated earlier, indirect costs like presenteeism can be reduced and expensive therapists replaced by internet-coaches.

Study objective

The goal of the current project is to examine the cost-effectiveness of an internet-based guided self-help intervention (Allesondercontrole.nu) for depression, in mental health care in comparison with usual care. This intervention has been developed by the applicants with financial support from the VU University and ZonMw. This intervention has been examined and found to be effective in two earlier randomized controlled trials in depressed patients recruited from the community. The cost-effectiveness of internet-based guided self-help has not yet been

examined. Considering the high prevalence of and the high health care costs associated with depression it is important to have information on the cost-effectiveness of this intervention.

Study design

In this study, we will use a non-inferiority design in which we will test the assumption that internet-based guided self-help is clinically not inferior to care-as-usual in this population, and not more expensive than usual care for patients with depression,. After the patient has contacted the mental health care institute by telephone or email (aanmelding), a research assistant will contact the patient within two days, conduct a diagnostic interview by telephone and will screen for in- and exclusion criteria. Patients who are considered eligible and willing to participate (after informed consent) are randomly assigned internet-based guided self-help or care-as-usual.

Intervention

The intervention we examine is the website **Allesondercontrole**, a brief problem-solving intervention based on cognitive behaviour therapy. This webbased intervention is available (for research purposes) and has been examined in two randomized controlled trials. The intervention takes 5 weeks. During that period the respondents indicate what they think is important in their lives, they make a list of their **problems and worries** and they categorize their problems into three groups: unimportant (not related to what they think is important in their lives), important and solvable (these problems are solved by a systematic problem-solving approach consisting of 6 steps), or important but unsolvable (for example having lost someone by death, having a chronic general medical disease; for these problems they make a plan how to live with it). The participants are supported by a coach, who gives feedback to the homework assignments of the participants in brief, weekly emails. The total amount of time spent on each patient is about one and a half hour (estimate based on our earlier trials). The writing of these emails costs about 15 or 20 minutes per week, and will be done by a coach (nurse or social worker) of the participating institute. The coaches will be trained by the psychologists who have developed the intervention. An independent psychologist will verify whether the coaches have followed the protocol sufficiently by reading a random selection of the emails. The coach will be

trained to be a coach, not a psychotherapist. This implies that they only verify whether the patient has done the homework assignments correctly. They do not have any therapeutic contact or general supportive role.

Study burden and risks

N/A

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

- 1) Diagnosis of depression according to DSM-IV criteria
- 2) Patients are enrolled in specialized mental health care

- 3) Patients are 18 years or older
- 4) Patients have access to the Internet
- 5) Patients are motivated for self-help

Exclusion criteria

- 1) Psychotic or bipolar disorder
- 2) Increased risk of suicide

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	07-12-2011
Enrollment:	263
Type:	Actual

Ethics review

Approved WMO	
Date:	13-10-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL36353.029.11