Nurse-led self-help for recurrent depression in the primary care setting versus usual care; a pragmatic randomised trial and economic evaluation

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To study whether nurse-led self-help is (cost-)effective for persons with recurrent MDD in primary care. Effectiveness is defined as significantly less SCID/DSM-V recurrences in one year follow-up compared to usual care. Cost-effectiveness is...

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

Summary

ID

NL-OMON39338

Source
ToetsingOnline

Brief title
PARADE-study: Prevention of Recurrent Depression in Primary Care

Condition

- Mood disorders and disturbances NEC

Synonym
Recurrent depression

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Depression, Nurse, Prevention, Primary Care

Outcome measures

Primary outcome

- Effectiveness, defined as cumulative incidence of recurrences meeting DSM-IV criteria for a major depressive episode in the intervention group versus the control group

- Cost-effectiveness, defined from a societal perspective meaning that the costs of the intervention, health care uptake, patients' out-of-pocket costs and costs due to productivity losses will be included in the economic evaluation and compared between groups

Secondary outcome

To study whether nurse-led self-help for patients with recurrent MDD versus usual care alone:

A is (cost-)effective in reducing health care utilisation

B is (cost-)effective in reducing co-morbid distress, anxiety and somatisation)

C is satisfying according to patients

D is (cost-)effective in certain subgroups of patients, particularly related to (i.e. modified by):

- the number of previous episodes,

- type of treatment for the last recurrence (AD, psychological intervention,

noting etc).

- the severity of residual depressive symptoms in the remitted phase

- age of onset of the first depressive episode,

- social economic status and

- self-efficacy for managing,depression

- symptoms of pain and/or fatigue

Study description

Background summary

Major Depressive Disorder (MDD) is estimated by the World Health Organization to be a leading cause for loss of disability-adjusted life years and makes a major contribution to disability and healthcare costs.1;2 MDD tends to run a relapsing (symptomatic exacerbation occurring after a response but before achieving sustained remission during the same episode, mostly within 4-6 months after recovery) and recurrent (a new episode of depressive illness, mostly starting 4-6 months after recovery) course.3 Accordingly, interventions to reduce the disabling effects of depression should be aimed at the prevention of depressive relapses/recurrences 4 . Henceforth, *relapse/recurrence* is captured in the term *recurrence*.

Both psychological and pharmacologic therapies are effective in the long-term treatment of patients with depressive disorders and each has its own merits. Maintenance treatment with antidepressants (AD) for several years has been the leading strategy to prevent recurrence in patients with recurrent MDD. However, the quality of the evidence to support such prolonged treatment is poor. 5-7 A majority of the patients are not willing tot take AD for a long period of time. 8;9 Therefore, adherence in AD users is estimated at only 50% at best. 8-10 Besides, AD may be contra-indicated because of somatic illness or side effects. Furthermore, patients* protection from recurrence ceases on discontinuation of AD 7 and patients might develop resistance against the prophylactic properties of AD. 11 Last but not least, the optimal duration of the maintenance treatment has not been studied. Particularly in primary care, recommendations on maintenance treatment with antidepressants cannot be considered evidence-based.

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Only more recently attention has turned to psychotherapy in preventing recurrence in recovered depressed patients. As a rule, persons at risk of becoming depressed prefer psychological treatments over drugs. According to a review by Hollon et al (2010), Cognitive Behavioural Therapy (CBT) is efficacious (*) in the maintenance treatment of recurrent MDD13. A meta-analysis by Vittengl et al of 28 studies including 1,880 adults, demonstrated that among acute-phase treatment responders, CBT substantially reduces the number of recurrences compared to assessment only at the end of continuation treatment. Preventive cognitive therapy (PCT), a particular type of CBT, is also effective in the prevention of recurrence in major depression.14 This preventive cognitive therapy differs from other cognitive therapies as it mainly focuses on identifying and changing dysfunctional attitudes, enhancing specific memories of positive experience by keeping a diary of positive experiences and formulating specific recurrence prevention strategies.
15

Psychological interventions, like PCT, however, have relatively high costs, are less readily accessible16 and integrated treatments lack until recently. Explanations are that psychological interventions are not included in the Diagnose Behandel Combinatie (DBC; Diagnosis Treatment Combination which is foundation of the Dutch healthcare costs system) and that most of the cognitive therapies take place at the specialist level and thus draws on scant resources. The vast majority of depressed patients however, visit - and are treated by their primary care physician (PCP) first.17 Because the long-term outcome of major depression is often unfavourable, and because most cases of depression are managed by PCP*s,18 there is an urgent need for a (cost)effective, psychological intervention for patients with recurrent MDD that is readily accessible at the primary care level. The need for psychological intervention might be especially pronounced in patients who are adverse to using antidepressants either because they have shown no treatment response to pharmaceutical intervention in the past, or have not been very adherent to pharmaceutical intervention. Only few studies have focused on interventions aimed at the prevention of recurrences in primary care patients with depression. 19 This study involves an economic evaluation of nurse-led self-help for patients at high risk for recurrent MDD in primary care.

Casefinding in this trail should not be a problem as these high risk patients are often seen by the PCP and are rather easily diagnosed with recurrent depression in the long term. Hence, inclusion should not be endangered.

The most accessible form of psychological intervention for recurrent depressed primary care patients is bibliotherapy or self-help intervention, which is defined as the use of written, audio, or e-learning materials to provide therapeutic support in mental health service. The patient works the materials

through more or less independently. Research indicates that cognitive bibliotherapy, has a moderate to large effect in reducing symptoms of depression and anxiety. 20-23 PCT is especially feasible to deliver in a led self-help intervention format because of its very structured design.

Self-help interventions can be purely self-administered or can be used as part of a *guided* therapist-led intervention. A disadvantage of guided self-help interventions is that they may impose a time burden on PCP*s. Also, PCP*s may lack the necessary training to administer these interventions. Recent studies have shown that paraprofessionals, like nurses or prevention-workers, can be successfully trained to administer forms of CBT-based self-help interventions, and thus may complement the regular work of the PCP*s. 24;25
In this study, contact with the nurse is mainly supportive or facilitative and includes no active therapeutic engagement.

Studies show that self-help therapies may be sufficient for several anxiety and depressive disorders but that some form of support may be essential for enhancing compliance with the ultimate aim of improving treatment outcomes.23;26-28 Some form of guidance is likely to be important because the motivation in remitted patients to actively participate in self-help might be relatively low and because the therapy might be difficult at certain stages. Hence, some contact between patients and therapist is generally speaking a good idea.

From 2008 onwards, ambulatory psychiatric care is included in Dutch healthcare insurance and PCP*s can employ a mental health nurse in their practices for four hours a week per PCP. For both cost-effectiveness and pragmatic reasons it is therefore attractive to let a nurse play a pivotal and facilitating role.

This study focuses on patients at high risk for recurrence. High risk for recurrence is often defined as having a history of multiple previous depressive episodes. Several subgroup analyses, based on stratified 29,30 and non-stratified 15 subsamples, suggested that PCT is more effective in patients with a history of at least three episodes on a life time basis.
However, recall-bias hampers assessment of the number of previous episodes on a life-time basis. Therefore it is better to select patients on the number of episodes during a shorter time frame of, say, the last five years. Altogether; a high risk for recurrence is established when a patient experienced at least two depressive episodes in the past five years.

Summarizing, this study aims at evaluating the costs and effects of a nurse-led self-help cognitive therapy-based preventive intervention for patients at high risk for recurrent MDD versus usual care alone in the Dutch primary care setting.

Study objective

To study whether nurse-led self-help is (cost-)effective for persons with recurrent MDD in primary care. Effectiveness is defined as significantly less SCID/DSM-V recurrences in one year follow-up compared to usual care. Cost-effectiveness is defined from a societal perspective meaning that the costs of the intervention, health care uptake, patients' out-of-pocket costs and costs due to productivity losses will be included in the economic evaluation.

It is hypothesized that adding nurse-led self-help to usual care is clinically superior to care as usual alone for preventing recurrence in recurrent depressive disorder. In addition, it is expected that the intervention dominates the comparator condition in terms of cost-effectiveness.

Study design

This study is a randomised controlled trial with randomisation at patient level. Randomisation at this level makes it attractive for patients as they are able to receive their care in their own practice. It is also attractive for practices to participate as they deliver both the intervention and care as usual alone. Therefore, the inclusion of patients will be easier. Lastly, the statistical analysis and its outcome is of greater worth because it is more transparent and well replicable. There will be two parallel groups to evaluate the costs and effects of nurse-led self-help + usual care for 134 primary care patients with remitted MDD versus 134 controls (usual care) at 3, 6, 9 and 12 and 15 months follow up. Stratification variables will be the number of previous episodes (cut-off point at 2 or more previous episodes in the last 5 years) and the type of treatment as usual received for the last episode. (psychological intervention / AD / no care).

Nurses will deliver the nurse-led self- help. The face-to-face contacts take place in the primary care practice. The nurses are trained by a professional from Claudi Bockting*s group. All practice nurses are experienced in offering cognitive therapy in depressed patients using the Dutch version of the *Coping with Depression* course (*In de put, uit de put*) 45, based on the work of Peter Lewonsohn. It takes approximately 1 to 1,5 day to train the nurses.

Intervention

The investigational treatment in this trial is *nurse-led self-help* based on PCT; this preventive cognitive therapy has been demonstrated to be protective in recurrent depression for a period of at least 2 to 5,5 years.44
Patients will be offered a detailed treatment manual of the therapy with literature, backgrounds and assignments. This self-help book will enable patients to follow the course of the therapy in their own homes, in their own time.

Prior to the start of the therapy, a face-to-face meeting with the nurse is planned at the primary care practice (at a maximum of 45 minutes). This meeting involves psychoeducation on (the course and treatment of) recurrent depression, and an introduction to the nurse-led self-help therapy on the basis of the treatment manual. Apart from this face to face meeting there is weekly telephone contact (at a maximum of 15 minutes), initiated by the nurse. During these telephone meetings patients are asked several questions based on a rather strict protocol. These questions comprise: 1) what is your Q-IDS-SR score? 2) did you read and understand the literature belonging to that week?, 3) did you make the accompanying assignments? and 4) what difficulties did you experience in your assignments ? After these 3 questions, patients are shortly prepared for next week*s literature and exercises. The contact is of a supportive and facilitating nature and not of a psychotherapeutic nature.
If a nurse notices depressive symptoms during a regular phone-contact or a patient brings up feeling depressed, the nurse emphasizes specific parts of the therapy in order for the patient to cope with these symptoms. Only in the case of a patient expressing suicidal symptoms, the PCP should be notified. These procedures are included in the informed consent papers.

Study burden and risks

This nurse-led self -help psychosocial intervention brings no risks. The burden in time is relatively small as patients can work through the manual in their own homes in their own time.

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

age 18+ year
current remission according to DSM-IV criteria (SCID)
a least 2 confirmed previous MDD episodes with the SCID lifetime
the last episode ended at least 8 weeks ago and no longer than 5 years ago
the last episode lasted at least 2 weeks
fluent in Dutch

Exclusion criteria

current mania or hypomania or history of bipolar illness
any current organic or psychotic disorder
current or previous hospitalisation for alcohol or drug abuse
severe sensory disabilities

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-07-2012
Enrollment:	268
Type:	Actual

Ethics review

Approved WMO Date:	10-01-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-09-2013
Application type:	Amendment
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	NL37685.029.11
Other	NTR volgt nog