The effect of tailoring on the implementation of guideline recommendations for the recognition, diagnosis and allocation of care for anxiety and depression in primary care

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

Summary

ID

NL-OMON35351

Source
ToetsingOnline

Brief title
Effect of tailoring on the implementation of guidelines in primary care

Condition

- Psychiatric disorders NEC

Synonym
Anxiety disorders and Depression

Research involving
Human

Sponsors and support

Primary sponsor: Trimbos-instituut
Source(s) of monetary or material Support: ZonMw aan Trimbos-instituut

Intervention

Keyword: Anxiety disorders, Depressive disorders, Practice guidelines, Tailored strategies

Outcome measures

Primary outcome

Primary outcome measurement at general practitioner level is:

1. Change in the number of patients who have been given the 4DQS as screener.

Secondary outcome

Other secondary outcomes are:

At patient level:

2. Change in the symptoms of anxiety and depression measured with the Four

Dimensional Symptom Questionnaire, the 4DSQ.

3. Change in functioning, measured with the WHO-DASS;

4. Experiences with the care, measured with the Quality Of care Through the

patient's Eyes (QUOTE, CQIndex)

5. Quality-of-life measured with the EuroQol (EQ-5D)

6.Care utilization, illness and work measured with the Trimbos/iMTA

questionnaire for Costs associated with Psychiatric Illness (TiC-P/prodisq).

At general practitioner level

7. Increase in registered diagnoses of anxiety and depression;

8. Change in anti-depressant prescribing, number of references, number of

consultations for anxiety and depression.

Study description

Background summary

Anxiety disorders and depression are are common illnesses that have a negative impact on everyday functioning, cause great suffering, and entail both high care costs and loss of production. Recognition, diagnosis and stepped care allocation of treatment in primary care could be improved. For both disorders national guidelines excist and following guidelines can lead to significant reduction of the burden of disease, significantly greater symptom reduction and improvement of social functioning. Adherence to guidelines should be improved. There can be several barriers which hinder the adherence to guidelines. There is relatively little known about which implementationstrategies are effective in which context. This study is based on the hypothesis that the implementationstrategy offered should be sufficiently aligned with specific characteristics and barriers in the
local context.

Study objective

The objective of this study is to improve the quality of care and outcomes for patients with anxiety disorders and depression and to acquire knowledge and insight into the effect of tailored strategies focused on the implementation of guideline recommendations for the recognition, diagnosis and stepped care allocation in primary care for patients of 18 years and older with a first or new episode of anxiety disorders and/or depression.

The central questions of the study are the following:
1. Does an implementation strategy tailored to address identified barriers to change lead to more guideline-led care with better outcomes for patients with anxiety disorders and/or depression in general practice, as compared with an implementation strategy not tailored to barriers?
2. How can a tailored implementation strategy eliminate the barriers identified in care professionals and in the organization of care?
3. Does implementation with a tailored strategy lead to more efficient care than an implementation strategy that is not tailored?

Study design

A randomised controlled trial (RCT) will be conducted to test the effects of a tailored implementation in mental health primary care. This is a two-arm study with two parallel groups, viz. an intervention group with a tailored implementation strategy and a control group with an implementation strategy that is not tailored, meaning that pre-identified barriers are not taken into consideration. In addition, a process evaluation will take place among the care

professionals and experts involved concerning the manner in which the tailoring was effected, the relevant influencing factors and experiences with the strategy. The implementation costs and yields in both study groups will be calculated and compared in a limited
economic evaluation.

Intervention

The interventions to be implemented in both groups are derived from the national guidelines for anxiety disorders and depression and comprise the phase of recognition, diagnosis and needs assessment for stepped care. The selected interventions are the following:
1. Structural use of a screening instrument, the Four-dimensional Symptom Questionnaire (4DKL), for high-risk patients. Criteria are described in the national guidlines;
2. Making the diagnosis and recording this in the General Practitioner Information System;
3. Discussion of the diagnosis and treatment options with the patient and providing psycho-education to diagnosed patients in accordance with the protocol;
4. Making the distinction between mild/non-complex problems and severe/complex problems and determining suitable initial treatment on this basis (stepped care allocation), in consultation with the patient. This is minimal treatment in the case of mild problems and medication or psychotherapy for people with severe problems.

Tailoring of strategies
In the first months of the project, a list will be prepared of possible barriers to better screening, diagnosis, the provision of information and needs assessment for stepped care in the general practice. The digital barrier list will be used to carry out the analysis of the local context with the general practitioners in the intervention group. Barriers will be coupled directly to concrete strategies, creating combinations of strategies that are geared to the local context.

Study burden and risks

Not applicable.

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 from 18 years and older whose first score on the Dutch version of the extended Kessler-10 (EK-10) is 20 or higher and/or at least once a yes on the added questions 11 till 16

Exclusion criteria

None

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):	26-10-2010
Enrollment:	396
Type:	Actual

Ethics review

Approved WMO Date:	18-11-2009
Application type:	First submission
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)
Approved WMO Date:	15-06-2010
Application type:	Amendment
Review commission:	METIGG: Medisch Ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (Utrecht)

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	NL28350.097.09
Other	TC=1912