

Stepped Care in patients with common mental disorders: a randomized controlled trial

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24281

Source

NTR

Brief title

Stepped care

Health condition

Stepped Care

Anxiety Disorders; Angststoornissen

Depressive Disorder; Stemmingsstoornissen; Depressie

Primary Care, General Practitioner; Eerste Lijn, Huisarts

Mental Specialist Care; Tweede lijn, GGZ

Treatment as Usual; Gewone Behandeling

Randomised Controlled Trial; Vergelijkende Behandelstudie

Sponsors and support

Primary sponsor: Adhesie, Deventer and Dept of Psychiatry Vu-University Medical Center, Amsterdam

Source(s) of monetary or material Support: Fonds Psychische Gezondheid, Utrecht
Adhesie, Deventer

Intervention

Outcome measures

Primary outcome

1. Percentage of patients responding to treatment, defined as a score of 1 ("very much improved") or 2 ("much improved") on the clinical global improvement rating (CGI).
2. Percentage of patients achieving remission, defined as a score of 1 ("normal, not at all ill") or 2 ("borderline mentally ill") on the clinical global rating of severity (CGS).

CGI and CGS were measured by independent raters.

Secondary outcome

Assessor-rated (independent, blind rater):

1. HAM-Anxiety
2. Criteria for index diagnosis were checked with the MINI during telephone interview by an independent rater.
3. Medical consumption.

Self-rated:

1. CES-D
2. Fear Questionnaire
3. SCL-90
4. 4-DSQ
5. Whiteley Index
6. SF-36
7. MALC
8. SSI
9. PDQ-R (B-cluster)

Study description

Background summary

This practice-based study was designed to evaluate the clinical outcomes and costs of a Stepped Care (SC) treatment algorithm as compared to treatment as usual (TAU). The stepped care algorithm included both pharmacotherapeutic and psychological stepwise interventions for treatment of patients with common psychiatric disorders in both primary and mental specialist care.

Both practices of general practitioners and caregivers in the community mental health center were randomly assigned to either Stepped Care or Treatment as Usual. The settings for this study were 14 primary care clinics with 20 general practitioners (GP's) and a community mental health center in Twente, a semi-rural area in The Netherlands. Written informed consent was obtained from all participants prior to enrollment, and institutional review board approval was obtained for this study.

Study objective

A stepped care intervention in primary and mental specialist care is superior to treatment as usual in patients with anxiety, mood and stress disorders.

Study design

Patients were assessed at baseline, 4 months (midtest), 8 months (posttest), 12 months (follow-up I). 2,5 years (follow-up II)

Intervention

Stepped Care: The first step intervention was provided in primary care. These patients were offered a selfhelp course, guided by five forty-five minute sessions with a psychiatric nurse at the office of the GP or at home. Duration of the course was 3,5 month. In addition, patients with moderately severe disorder episodes were offered antidepressant medication according to disorder specific algorithms shared by GP and psychiatrist and based on national guidelines in the Netherlands.

Treatment offered in step 2 consisted of cognitive behaviour therapy in combination with antidepressants administered at the outpatient department.

To sustain adherence of the therapists to the algorithms multiple tools were provided. GP's got one educational session to clarify the medication algorithm and advise on enhancing medication compliance. During the study there was an opportunity for direct consultation with a psychiatrist. Psychiatric nurses participated in a training in basic CBT strategies. They

had a detailed session-to-session structured manual to guide the selfhelp course. In addition, group-supervision for feedback and adherence to the manual took place every two weeks with an experienced behaviour therapist.

Psychologist used CBT session by session protocols commonly used in the Netherlands which are mostly proven efficacious in clinical studies. Psychologists discussed treatment progress in a multidisciplinary team at least one time during treatment.

In addition to the treatments offered in the first step, the following treatments and services could be provided: social work, addiction care and a short intervention of the psychiatric nurse to advise on work resumption. In addition to the second step intervention at the outpatient department the following modules could be offered: social work, addiction care, intensive psychiatric home care, family therapy and a structuring day-time clinic programme.

Treatment as Usual: The patients could obtain any of the services normally available in the Netherlands. Every GP in this condition could use assistance of a psychiatric nurse at the location of the office. In the Netherlands, national guidelines for treatment of depression and anxiety disorders are available for GP's and psychiatrists. However compliance to these guidelines is relatively low.

The main differences between the national guidelines and the stepped care guideline in this study are the explicit use of minimal interventions and the stepwise intensifying of interventions in the latter.

Contacts

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Eligibility criteria

Inclusion criteria

1. Primary Care patients with the following ICPC codes:

- Feeling Anxious/Nervous/Tense (P01)
- Feeling Depressed (P03)
- Feeling/Behaving Irritable/Angry (P04)
- Anxiety Disorder/Anxiety State (P74)
- Hypochondriasis (P79)
- Depressive Disorder (P76)
- Neurasthenia (P78)
- Other Neurosis (P79)

2. 18 years and older.

Exclusion criteria

1. Obsessive Compulsive Disorder
2. Posttraumatic Stress Disorder
3. Alcohol or Drug Dependence
4. Dementia
5. Psychotic Disorder
6. Bipolar Disorder
7. Terminal Illness

8. Language Barrier

9. Treatment with psychotropic drugs (except for benzodiazepines)

10. Cognitive Behavioural Therapy or InterPersonal Therapy in the present episode of the psychiatric disorder

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Suspended
Start date (anticipated):	01-01-2003
Enrollment:	163
Type:	Anticipated

Ethics review

Positive opinion	
Date:	17-03-2008
Application type:	First submission

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
NTR-new	NL1179
NTR-old	NTR1224
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A