# Collaborative Care: Depression Initiative in Primary care.

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27843

**Source**
NTR

**Brief title**
CC: DIP

**Health condition**

The collaborative care approach is compared with well documented Care as Usual (CAU) as provided by General Practitioners (GPs).

### Sponsors and support

**Primary sponsor:** Trimbos-instituut// Netherlands institute of Mental Health and Addiction
PO Box 725
3500 AS Utrecht
The Netherlands
**Source(s) of monetary or material Support:** The Foundation Central Funds RVVZ (Reserves Formally Voluntary National Health Service insurances), the Netherlands.

### Intervention

### Outcome measures

**Primary outcome**

The primary outcome measure is response. Secondary outcome measures are remission as measured by the PHQ9 and IDS-SR, effect of chronic physical illness as an effect modifier, and cost-effectiveness as measured with the TiC-P, EQ-5D and the SF-36.

### Secondary outcome

Secondary outcome measures are remission, effect of chronic physical illness and cost-effectiveness.

## Study description

### Background summary

Background:
Depressive disorder is today one of the two most burdensome disorders. Evidence-based treatments of depressive disorder are already available, but are used insufficiently and with less results than possible. Prior research in the USA has shown good results in the treatment of depressive disorder by using a collaborative care approach with Problem Solving Treatment (PST) and an antidepressant treatment algorithm, and prior research in the UK has also shown good results with PST. These treatment strategies may very well work in the Netherlands too, even though health care systems differ between countries.

Methods/design:
The present study is a two armed cluster-randomized clinical trial, with randomization between general practitioner (GP) practices. The aim of the trial is an evaluation of the treatment of depressive disorder in primary care in the Netherlands by means of an adapted collaborative care framework including contracting and adherence improving strategies, and combined with the option of PST and/or an antidepressant medication following a treatment algorithm. Forty GP practices will be randomised between the intervention group or control group. Patients are included who are diagnosed with moderate to severe depression based on DSM-IV criteria. The intervention group receives treatment based on the collaborative care approach, the control group receives care as usual (CAU). Baseline measures and follow up measures (3, 6 and 12 months) are assessed using questionnaires and interview. The primary outcome measure is response as measured by the PHQ9 and IDS-SR. Secondary outcome measures are remission as measured by the PHQ9 and IDS-SR, effect of chronic physical illness as key effect modifier, and cost-effectiveness as measured with the TiC-P, EQ-5D and the SF-36.

Discussion:
In the current study, an American model to enhance care for depressive patients, the collaborative care model, will be evaluated for effectiveness in the primary care setting. If effective across the Atlantic and across different health care systems, it is likely to be a good strategy to implement in the treatment of major depressive disorder in the Netherlands.

### Study objective

The aim of the current randomized clinical trial (RCT) is a cost-effectiveness analyses of a collaborative care approach compared to Care as Usual (CAU). The collaborative care approach is expected to be more effective and cost-effective than CAU.

### Intervention

The collaborative care approach includes care management, contracting, adherence improving strategies, manual guided self help and lifestyle interventions, Problem Solving Treatment, and an antidepressant treatment algorithm; the treatment plan is set based on patient preferences.

## Contacts

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## Eligibility criteria

### Inclusion criteria

The aim is to include patients who are diagnosed with major depressive disorder and who dysfunction due to the depressive disorder (i.e. loss of role in daily life).

### Exclusion criteria

Patients are excluded from the study if they are suicidal, psychotic or suffering from dementia, have insufficient knowledge of Dutch to fill in the questionnaires, are addicted to drugs or alcohol, already receive psychiatric treatment and/or are less than 18 years old.

## Study design

### Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Masking: | Single blinded (masking used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-12-2006 |
| Enrollment: | 240 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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| Date: | 21-11-2006 |
| 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 | NL807 |
| NTR-old | NTR820 |
| Other | : N/A |
| ISRCTN | ISRCTN15266438 |

# Study results

**Summary results**
Marjoliek Ijff, Klaas Huijbregts, Harm WJ van Marwijk, Aartjan TF Beekman, Leona Hakkaart-Van Rooijen, Frans F Rutten, Jurgen Unutzer, Christina M van der Feltz-Cornelis. Cost-effectiveness of collaborative care including PST and an antidepressant treatment algorithm for the treatment of major depressive disorder in primary care; a randomised clinical trial BMC Health Services Research 2007;7:34