

Brief psychological therapy compared to general practitioners care for depression in primary care: a randomised controlled trial

Submission date 19/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/09/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZonMw: 100.002.021

Study information

Scientific Title

The clinical and functional effectiveness of brief cognitive behavioural therapy compared to general practitioners care for depressive primary care patients: a randomised controlled trial

Acronym

APOLLO

Study objectives

Depressive disorders are highly prevalent in primary care and are associated with considerable functional impairment and increased health care use. Research has shown that many patients prefer psychological treatments to pharmacotherapy, however, it remains unclear which treatment is most optimal for depressive patients in primary care.

The aim of the trial is to compare a brief psychological therapy to general practitioners care for depression in primary care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional ethics review committee of the Academic Medical Centre approved on the 15th of March 2006 (ref: MEC 04/245)

Study design

Multicentre randomised single blind active controlled intervention study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Patient information sheet is available at <https://ives.ruhosting.nl/goms> (username and password required). Please use the contact details below to request further information.

Health condition(s) or problem(s) studied

Depression

Interventions

General Practitioners Care:

The treatment protocol is set up according to The Dutch College of General Practitioners

Practice Guideline (NHG- standard) and composed after reviewing the follow up contacts of colleague GPs with depressive patients.

Before the start of the study we will visit each participating GP and explain the treatment protocol, content of the contacts and offer a ring binder with the protocol. The description of the content of the contacts is meant as a guideline; GPs can adapt the scheme to their own style or to special circumstances. The treatment consists of supportive contacts which can be combined with an antidepressant agent. The duration of the treatment is 12 weeks. The following elements are recommended: psycho-education about depression, life style advices about sleep, alcohol/drugs, nutrition, social activities and physical activities.

The minimum frequency is one contact every two weeks during the first six weeks and one telephonic contact and one face- to- face evaluation contact during the second 6 week period. This can be increased if needed. Reasons for more contacts can be the severity of the complaints and/or lack of social support. After the first six weeks the GP evaluates, together with the patient, the need and frequency for further contacts. If recovery is not sufficient, according to the patient and/or GP, the GP will offer further contacts, during which problem solving will be a key element. If recovery is substantial the GP will provide information on relapse prevention and will offer contacts by telephone during the next month and one face-to- face contact after six weeks.

Brief Cognitive Behavioural Therapy:

The treatment will consist of 8 sessions within 12 weeks, each of fifty minutes duration. At the end of each session patients will receive homework assignments. The treatment will be directed at the role of behaviour and thinking in depressive complaints. Behaviour: patients will obtain insight in the role of pleasant activities in mood and subsequently learn to identify and expand potentially pleasant activities. Thinking: patients will obtain insight in the influence of negative thoughts and beliefs on their feelings/mood and subsequently learn to challenge these thoughts and beliefs thereby reducing the impact on their feelings. The patient learns to formulate alternative (rational) thoughts and beliefs. Eventually, the therapy will result in a personal prevention plan.

All therapists are licensed first line psychologists trained in this form of cognitive behavioural therapy. To guarantee quality, the sessions will be audio taped and the integrity of the intervention will be checked. Also, the therapist performed the intervention under supervision, which means that the therapist will regularly discuss the sessions with colleagues.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Hamilton depression rating scale-17 by telephone
2. Patient Health Questionnaire-9: patient rated. Score: 0 (ie, not at all) and 1 (ie, few days) 2 (ie, more than half the days) and 3 (ie, nearly every day)

All primary outcomes are assessed at baseline, 6, 12 and 52 weeks.

Secondary outcome measures

Medical Outcomes Study 36- Item Short Form Health Survey, assessed at baseline, 12 and 52 weeks.

Overall study start date

01/01/2007

Completion date

01/04/2010

Eligibility

Key inclusion criteria

Patients aged between 18 and 70 years and suffering from major depressive disorder (MDD) determined by an independent researcher with the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

122

Key exclusion criteria

1. Suffering (now and in the past as assessed by the SCID-I) from schizophrenia or bipolar disorder
2. Contra-indication for MDD treatment like mental retardation or terminal illness
3. Having trouble with the Dutch or English language
4. Severe suicidal thoughts
5. Receiving an active MDD treatment. Active treatment is defined as:
 - 5.1. Antidepressive medication (except those who receive this in low dosage for pain complaints: Amitriptyline less than 50 mg, Nortriptyline less than 50 mg, bupropion[Zyban®])
 - 5.2. Psychotherapy
 - 5.3. Supportive visits with the GP or social worker, except for diagnostic visits (less than 2)

Date of first enrolment

01/01/2007

Date of final enrolment

01/04/2010

Locations

Countries of recruitment

Netherlands

Study participating centre
Meibergdreef 5
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Sponsor information

Organisation

Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Sponsor details

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Sponsor type

Government

ROR

<https://ror.org/01yaj9a77>

Funder(s)

Funder type

Government

Funder Name

Netherlands Organization for Health Research and Development (ZonMw) - Mental Health programme (ref: 100.002.021)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/10/2010	19/09/2019	Yes	No