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

Submission date	Recruitment status	[ ] Prospectively registered
19/05/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/06/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/09/2019	Mental and Behavioural Disorders	[ ] 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

Protocol serial number
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 considerate 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

Study type(s)
Treatment

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(s)
1. Hamilton depression rating scale-17 by telephone
2. Patient Heath 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.

Key secondary outcome(s))
Medical Outcomes Study 36- Item Short Form Health Survey, assessed at baseline, 12 and 52 weeks.

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

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes