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Does paying attention to religious themes in therapy influence treatment outcomes?

Submission date
08/02/2024

Recruitment status
No longer recruiting

Registration date
27/02/2024

Overall study status
Completed

Last Edited
26/02/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Cross-sectional studies show positive correlations between psychological wellbeing and religiosity. Most religious patients prefer to discuss religious topics during their therapy. However, it is virtually unknown whether addressing religious issues in psychotherapy increases the effectiveness of psychotherapy of religious patients, as are potential moderating and mediating mechanisms. The main aim of the study is to investigate the influence of discussing religious issues during therapy on treatment outcome, both 6 months after the start of treatment and 1.5 years after the start of treatment. In addition, the study will take possible mediating variables into account, such as cognitive schemas, image of God, and therapeutic alliance. Structural features of personality pathology will be investigated as moderator variables.

Who can participate?
Patients aged from 18 to 65 years who apply for psychotherapy at a mental health institute that is involved in this study and who have been assigned to psychotherapy of 1 to 12 months duration with about 5 to 40 sessions

What does the study involve?
Patients are randomly allocated to:
1. Regular therapy including approximately 15 minutes of talking about religious or spiritual themes each session
2. Regular therapy without talking about religious or spiritual subjects
All patients fill in questionnaires before treatment, 6 months after the start of treatment, and at follow-up 1.5 years after the start of treatment.

What are the possible benefits and risks of participating?
Participants will contribute to expanding and deepening scientific knowledge about the effectiveness of psychological treatments for religious patients. Filling in the questionnaires can make some patients emotionally upset. Clinical experience however shows that these emotional reactions do not frequently occur or are of short duration. Furthermore, there is a risk of disappointment for patients depending on the group they are assigned to.

Where is the study run from?
Vrije Universiteit Amsterdam (Netherlands)

When is the study starting and how long is it expected to run for?
January 2008 to July 2024

Who is funding the study?
Eleos (Netherlands)

Who is the main contact?
Annette Bouwhuis, annettebouwhuis@hotmail.com

Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
NL19473.058.08

Study information

Scientific Title
The influence of attention to religion in psychological therapy in the short- and long-term on the change in psychological functioning, and the contribution of the possible mediating variables: cognitive schemes, the image of God, and therapeutic alliance and the possible moderating variable: structural personality traits

Acronym
R/S therapy

Study objectives
The main aim of the study is to investigate the influence of discussing religious issues during therapy on treatment outcomes, both 0.5 and 1.5 years after starting treatment.

In addition, the study will take possible mediating variables into account, such as cognitive schemas, image of God, and therapeutic alliance. Structural features of personality pathology will be investigated as a moderator variable.

Hypothesis: Treatment where religion/spirituality is part of the therapy is slightly more effective than treatment as usual, especially for depressed patients.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/03/2009, Leiden University Medical Center, METC (Albinusdreef 2, Leiden, 2333 ZA, Netherlands; +31 (0)71 - 5265106; metc-ldd@lumc.nl), ref: P08.107/DT/ib

Study design
Multicentred longitudinal two-arm interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Mental disorders

Interventions
The method of randomisation was per participating institution by order of enrollment. The first subject was assigned to the 'yes group' and the second to the 'no group', and so on.

Patients are randomized into:
1. R/S based therapy. An R/S-based therapy is a regular therapy including approximately 15 minutes of talking about religious or spiritual themes each session.
2. Non-R/S based therapy. A non-R/S-based therapy is a regular therapy without talking about religious or spiritual subjects.

After each session, the therapist records the number of minutes spent on R/S subjects and the type of intervention. (http://geloofintherapie.nl/index.php?option=com_bfsurvey_basictrial&view=onepage&catid=1&Itemid=5)

To measure the influence of desirability, before the start of treatment each patient is asked the question: 'It is possible that religious themes are discussed in your treatment. How desirable do you think that is on a scale of 1 (absolutely not) - 8 (absolutely yes).'

At three times, all patients fill in questionnaires: (T0) before treatment; (T1) 6 months after the start of treatment; and (T3) at follow-up 1.5 years after the start of treatment.

Patients complete the following questionnaires:
1. Brief Symptom Inventory
2. Rand-36
3. Spiritual Well-Being Scale
4. Dutch Abbreviated MMPI (NVM)
5. Young Schema Questionnaire (YSQ)
6. God Image Questionnaire (VGB)
7. Working Alliance Inventory (WAI)

The total duration of interventions depends on the overall duration of treatment. It is tailored to the individual patient and can vary. In the intervention group, the 'intervention' (talking about religion/spirituality) is applied for between 10 and 15 minutes per session and this time is recorded by the psychologist.

Intervention Type
Behavioural

Primary outcome measure
Change in psychological functioning:
1. Self-reported clinical relevant psychological symptoms measured using the Brief Symptom Inventory
2. Overall well-being self-reported using Rand-36

3. Spiritual well-being self-reported using the Spiritual Well-Being Scale
All measured at T0 before treatment; T1 6 months after the start of treatment; and T2 at follow-up 1.5 years after the start of treatment

Secondary outcome measures
Changes in variables that could mediate or moderate changes in psychological functioning after psychotherapy:
1. Personality traits measured using the self-report Dutch Abbreviated MMPI (NVM) at T0 only
2. Self-reported maladaptive schemas that lead to unhealthy life patterns assessed using the Young Schema Questionnaire (YSQ) at T0, T1 and T2
3. Feelings experienced in relation to God and how a person perceives God's actions, self-reported using Dutch VGB (God Image Questionnaire) at T0, T1 and T2
4. Evaluation of the collaborative relationship between the patient and therapist measured by the Working Alliance Inventory (WAI) and completed by both the patient and therapist at T1 only

Overall study start date
01/01/2008

Completion date
01/07/2024

Eligibility

Key inclusion criteria
1. Males and females ranging in age from 18 to 75 years
2. Apply for psychotherapy at the mental health institute that is involved in this study
3. Have been assigned to psychotherapy of 1 month to 12 months duration with approximately 5 to 40 sessions

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
74

Total final enrolment
95

Key exclusion criteria
Patients who consider themselves as non-religious, and patients with (a history of) psychosis

Date of first enrolment
01/09/2010

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Netherlands

Study participating centre
Eleos
Zuiderinslag 4C
Hoevelaken
Netherlands
3871 MR

Study participating centre
Eliagg
Antony Moddermanstraat 188
Amsterdam
Netherlands
1063 LW

Study participating centre
GGZ In de Bres
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Netherlands
9202 PE

Sponsor information

Organisation
Vrije Universiteit Amsterdam

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Sponsor type
University/education

Website
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ROR
https://ror.org/008xxew50

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Eleos

Results and Publications

Publication and dissemination plan
1. Meta-analyses of randomized controlled trials of spiritual-based therapy in mental health care.
2. Therapeutic alliance: What influence does the therapeutic alliance have on the efficacy of R/S therapy and the difference in the effect of a R/S versus non-R/S treatment?
3. Cognitive schemes: The effect of a R/S versus non-R/S treatment on the change of cognitive schemas.
4. God image: The effect of a R/S versus non-R/S treatment on the change of God image.
5. Post-treatment and follow-up efficacy results of R/S therapy compared to non-R/S therapy, including potential moderators.
Optional: differential effect of potential moderator variables on distinguished outcome measures.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date