

Solution Focused Brief Therapy in the multicultural memory clinic: a mixed methods study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON49748

Source

ToetsingOnline

Brief title

TULIPA SFBT

Condition

- Dementia and amnestic conditions

Synonym

dementia, mild cognitive impairment

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cross-cultural, Dementia, Psychotherapy [Brief]

Outcome measures

Primary outcome

The main study parameter is the group difference in the trajectories of quality of life from pre-, to directly post- and six months post-treatment.

Secondary outcome

The secondary study parameters are the group differences in the trajectories of depressive symptoms, solution focused skills and caregiver strain from pre-, to directly post- and six months post-treatment.

Furthermore, we will perform a cost-effectiveness study.

Study description

Background summary

Rising numbers of culturally and linguistically diverse (CALD-)patients are visiting memory clinics in the Netherlands, while there are currently no evidence-based psychological therapies available that can help relieve psychological complaints in patients and their caregivers.

Study objective

In this mixed methods study, the main goals are to determine the effect of solution-focused brief therapy (SFBT) on quality of life (quantitative study) and to describe the influence of SFBT on the experiences, emotions and behaviors of the participants (qualitative study). Secondary objectives are to determine the effect on depression, solution focused skills and caregiver strain.

Study design

The study is a combination of a randomized controlled trial (quantitative study) and interpretative group analysis (qualitative study).

Intervention

One group receives five telephone sessions (45-60 minutes) of SFBT, while the other group receives care as usual.

Study burden and risks

The study is associated with a low amount of burden. Patients and their caregivers will be visited at their home for the outcome measurements (or these will be mailed where possible/feasible). In the active treatment arm, participation will entail three study visits and five telephone calls; care as usual entails three study visits. At these three visits (pre-, directly post- and 6 months post-treatment), questionnaires are administered to the patient and caregiver.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- * Patient and caregiver have visited the multicultural memory clinic; all diagnostic assessments (neuropsychological assessment, MRI etc.) have been completed
- * Patient was referred for cognitive complaints
- * Patient and caregiver are willing and able to give informed consent
- * Male or female, aged 18 years or above for caregivers, 30 years or above for patients.

Exclusion criteria

- * If severe psychiatric disorders requiring active treatment are present, as judged during the multidisciplinary meetings of the Alzheimer Center.
- * If the patient is unable to provide informed consent due to severe cognitive impairment, e.g. as shown by an inability to complete the screening measures of the neuropsychological assessment, or floor effects on more than one cognitive domain
- * If the patient is too impaired in speech or language comprehension to participate in the intervention, as judged by the investigator

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-07-2019
Enrollment: 200
Type: Anticipated

Ethics review

Approved WMO
Date: 21-06-2019
Application type: First submission
Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO
Date: 22-06-2020
Application type: Amendment
Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL68385.078.18