

Muziek voor thuiswonende mensen met dementie en hun mantelzorgers: een gerandomiseerde studie

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27014

Source

Nationaal Trial Register

Brief title

MUSIC-DECARE

Health condition

Dementia

Sponsors and support

Primary sponsor: Pending

Source(s) of monetary or material Support: Pending

Intervention

Outcome measures

Primary outcome

Difference from baseline to post-intervention neuropsychiatric symptoms-score defined with the Neuropsychiatric Inventory (NPI) in people with dementia

Secondary outcome

In people with dementia

- Positive and negative affect (PANAS)
- Dementia quality of life instrument (DQI)
- Cornell Scale for Depression in Dementia (CSDD)
- Independence in activities of daily living (ADL KATZ)
- Independence in instrumental activities of daily living (iADL)
- Medication changes in prescriptions of analgesics and psychotropic drugs (coded as defined daily dosage – DDD)
- Use of respite care or admission to a nursing home
- Total costs, incremental costs per patient with problem behavior successfully reduced, and incremental costs per quality-adjusted life year (QALY) gained

In family caregivers

- Person's 'sense of competence' which is an important factor in their wellbeing (SCQ)-short form
- Distress scale of the NPI
- Physical Health (SF-36)

Study description

Background summary

This study will investigate the effects of a personal music listening intervention on neuropsychiatric symptoms in home living people with dementia. The negative impact of dementia has been widely studied: psychological, behavioural and physical symptoms decrease the quality of life of both people with dementia and their caregivers. There is thus far no cure for dementia. Since most people of dementia live at home with the help of a caregiver for as long as possible, community based interventions are highly needed. Multiple studies have found that music interventions for people with dementia may reduce or delay depression, functional problems and problem behaviour in people with dementia and distress in their caregivers. Listening to personal music by people with dementia constitutes a promising non pharmacological intervention for both people with dementia and their caregivers. However, previous studies contained a number of methodological limitations. Moreover, evidence regarding the effectiveness and cost-effectiveness of such interventions is limited.

The aim of the current study is to assess the efficacy and cost-effectiveness of a personal music listening intervention for people with dementia living at home, using a randomized controlled trial (RCT) design with a large sample size. The primary objective is to evaluate whether the personal music listening intervention improves neuropsychiatric symptoms of home living people with dementia compared to standard usual care.

Study objective

We hypothesize an improvement of neuropsychiatric symptoms in people with dementia randomized to the intervention group compared to the control group. Furthermore, the intervention is expected to enhance mood, quality of life, daily physical and functional functioning, the use of drugs and the use of respite care or admission to a nursing home

Study design

T0 – Baseline

T1 – Intermediate measurement – after 6 weeks

T2 – Post measurement – after 12 weeks, directly after intervention

T3 – First follow-up measurement – after 18 weeks, 6 weeks after intervention

T4 – Second follow-up measurement – 1 year after inclusion

Intervention

Personalized music listening

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

- Adult people diagnosed with dementia (mild to moderate, assessed by the Global Deterioration Scale for assessment of primary degenerative dementia; ≤ 5) by a physician
- Living at home together with a caregiver
- Family caregiver is willing to attend the music intervention twice a day
- Enough knowledge of the Dutch language by patient and caregivers
- Written informed consent by participants (if they are able to) or legally authorized representatives

Exclusion criteria

- Hearing impairments (if the participant is unable to enjoy listening to music due to hearing problems. A hearing aid is not a problem, as long as the participant can listen to music with pleasure)
- Presence of delirium
- Starting using new psychotropic drugs <6 weeks before inclusion
- Life expectancy <6 months

Study design

Design

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

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	23-04-2021
Enrollment:	460
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	23-04-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55335

Bron: ToetsingOnline

Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9412
CCMO	NL73781.078.20
OMON	NL-OMON55335

Study results