

Personal music for homeliving people with dementia and their caregivers: MUSIC-DECARE

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55335

Source

ToetsingOnline

Brief title

MUSIC-DECARE

Condition

- Other condition

Synonym

Dementia

Health condition

Dementie

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Foundation Muziek als Medicijn

Intervention

Keyword: Caregivers, Dementia, Music, Quality of Life

Outcome measures

Primary outcome

The endpoint of the study is the difference from baseline to post-intervention in reported scores of problem behaviour (NPI) in people with dementia.

Secondary outcome

Secondary endpoints for people with dementia are positive affect (PANAS), in self-reported mood-score defined with the Geriatric Depression Scale (GDS), quality of life (QoL-AD), 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), and the use of respite care or admission to a nursing home. Furthermore, we will study the effects on physical health (SF-36) and distress in family caregivers (Sense of Competence Questionnaire and distress scale of the NPI) and cost-effectiveness.

Study description

Background summary

This study will investigate the effects of listening to a recorded personal music intervention twice a day in people with dementia and their caregivers. 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 and distress in their caregivers. Listening to individualized music constitutes a promising non/pharmacological intervention for 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.

Study objective

The main objective of this study is to investigate the effects of listening to individualized music two times a day for minimal 20 minutes during 12 weeks on neuropsychiatric symptoms in people with dementia living at home and on distress and physical health of caregivers. Secondary objectives are to study the effects of listening to individualized music on 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. Furthermore, we will study the effects on distress and physical health in the caregiver and the cost-effectiveness of the music intervention.

Study design

This study will be performed as a randomised controlled intervention trial.

Intervention

People with dementia randomised to the intervention group will receive a receptive individualized music intervention two times a day for minimal 20 minutes during 12 weeks, The control group will receive standard care alone.

Study burden and risks

The use of music as intervention has no known deleterious effects on people with dementia. Safety precautions will be taken to limit the volume of the music. Participants in all study arms will receive standard usual care. Burden includes the completion of only two scales: self-reported mood/affect-scores defined with the Geriatric Depression Scale (GDS) and the PANAS. Other measurements are proxy scores completed by the caregiver with assistance of the research assistant during a phone call. A part of the baseline measurements will be collected from normal care data gathered from regular participants* geriatrician visits in Erasmus MC University (Table 1). No extra site visits will be necessary for participation in this study besides the regular check-ups

with their own geriatrician and/or usual care.

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

- * - Adult people diagnosed with dementia (mild to moderate: Global Deterioration Scale score 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
- * - 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:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	23-09-2021
Enrollment:	460
Type:	Actual

Ethics review

Approved WMO	
Date:	18-12-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	29-07-2021

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO	
Date:	25-03-2022
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

ID: 27014
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL73781.078.20
OMON	NL-OMON27014