

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

Gepubliceerd: 23-04-2021 Laatste bijgewerkt: 15-05-2024

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27014

Bron

NTR

Verkorte titel

MUSIC-DECARE

Aandoening

Dementia

Ondersteuning

Primaire sponsor: Pending

Overige ondersteuning: Pending

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Personalized music listening

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Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	23-04-2021
Aantal proefpersonen:	460
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	23-04-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55335
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten