

# Individual music therapy and wellbeing in nursing home residents with dementia

## A study protocol of a randomized controlled trial

Published: 27-06-2019

Last updated: 21-09-2024

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Dementia and amnestic conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON47943

### Source

ToetsingOnline

### Brief title

Individual music therapie and wellbeing in dementia

### Condition

- Dementia and amnestic conditions

### Synonym

dementia, problem behaviour

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Alzheimer Nederland

## **Intervention**

**Keyword:** dementia, music therapy, problem behaviour, quality of life

## **Outcome measures**

### **Primary outcome**

Well-being is measured with the Discomfort Scale - Dementia of Alzheimer Type (DS-DAT).

### **Secondary outcome**

1. Pain will be assessed with PAIC-15.
2. The Quality of Life in Late-Stage Dementia Scale (QUALID).
3. Neuropsychiatric symptoms are assessed with the Neuropsychiatric Inventory Nursing Home Version (NPI-NH).
4. Anxiety will be derived from the NPI-NH item \*anxiety\*.
5. Agitation and aggression will be assessed using the caregiver-rated questionnaire Cohen-Mansfield Agitation Inventory (CMAI).
6. Symptoms of depression will be recorded using the caregiver-rated Cornell Scale for Depression in Dementia (CSDD).
7. Quality of sleep will be determined using an Actiwatch, which is a small activity monitor. It will be worn on the dominant wrist the week before the intervention started (T0) and the week directly after the last intervention session (T2).
8. Psychotropic drug use. Data on chronic and pro re nata (as needed) use will be derived from the electronic chart. Psychotropics will be categorized into antipsychotics, anxiolytics, hypnotics, antidepressants and anti-dementia drugs

according to the Anatomical Therapeutic Classification (ATC) system.

## Study description

### Background summary

Neuropsychiatric symptoms (NPS), such as agitation, aggression, shouting and wandering, are often associated with a distress for the patient with dementia and emotional burden for his/her environment. The symptoms are often treated with psychotropic drugs. However, these are often associated with side effects. Non-pharmacological treatments are therefore necessary to improve the quality of life in these individuals. Music therapy might be a non-pharmacological treatment for this problem.

### Study objective

The present study aims to address the limitations of earlier research, by employing a large sample size, and investigating the possibility that music therapy has an effect on wellbeing of people with dementia when using blinded outcome assessments and adjustment for individual contact during therapy sessions. The main aim of this study is to assess the effects of individual music therapy on the well-being comparing to individual attention through RCT (randomized controlled trial) research in nursing home residents with dementia and neuropsychiatric symptoms (NPS).

### Study design

The design involves an individual randomized controlled trial employing longitudinal repeated measurements in nursing home residents with dementia and neuropsychiatric symptoms (NPS). The research will take place at different facilities of one nursing home organization (Amstelring). All music therapists are trained and credentialed professionals. An independent observer (blind) will determine the effect of individual music therapy in patients with dementia through music therapy sessions before and after observing.

### Intervention

The participants of the intervention group (MT) receive 30 minutes of individual music therapy twice a week for 12 weeks in their own room. Patients receive an individually tailored session in which the music therapist chooses the means to influence the behavioural problem.

### Study burden and risks

Patients may experience the therapy as unpleasant or tiring. As soon as the music therapist notices that the therapy is too burdensome or not pleasant for the participant, the treatment will be stopped immediately.

## Contacts

### **Public**

Universitair Medisch Centrum Groningen

Huispostcode FA21  
Groningen 9700 AD  
NL

### **Scientific**

Universitair Medisch Centrum Groningen

Huispostcode FA21  
Groningen 9700 AD  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Chart diagnosis of dementia

Clinically relevant neuropsychiatric symptoms

### Exclusion criteria

Never received individual music therapy and received no group music therapy during the last 3 months  
No major comorbid psychiatrist diagnosis (ie schizofrenie, psychosis, anxiety disorders).  
No hearing problems

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	27-08-2019
Enrollment:	80
Type:	Actual

## Ethics review

Approved WMO	
Date:	27-06-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

## 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**

<b>Register</b>	<b>ID</b>
CCMO	NL68639.042.18
Other	NL7708