

# The proper chord with music: Treatment of behavioral problems in dementia with individual music therapy.

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Structural brain disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON45298

### Source

ToetsingOnline

### Brief title

Individual music therapy in dementia care

### Condition

- Structural brain disorders

### Synonym

behavioral symptoms, Dementia

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Zuyd Hogeschool, faculteit Gezondheidszorg, lectoraat kennisontwikkeling vak therapieën

**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** Behavioral Symptoms, Dementia, Music therapy, Person-centred care

## Outcome measures

### Primary outcome

Primary outcome will be the difference in symptom reduction and the score on a quality-of-life standard inventory for the three intervention groups.

Besides the result of a time-series analysis of communication and engagement parameters, as can be graphically shown for individual cases, following a person-centred care model.

### Secondary outcome

1. To show if music therapy intervention is particularly effective in any of the clusters of BPSD symptoms: Hyperactivity, psychosis, affective disturbances or apathy.
2. The effect of the interventions on care giver burden and family members, based on the NPI-Q sub scale
3. To show if the therapist for the music therapy intervention can make a correct calculation of the expected effect of the intervention, based on a simple visual analogue scale measurement (Cantril's ladder) at the onset of the therapy (anticipating on further cost effectiveness studies).
4. To show a correlation between the (patient-centred) evolution of well-being and engagement in the time-series analysis, with the scores on NPI and Qualidem in the RCT part of the study.

# Study description

## Background summary

Behavioral and psychological symptoms in dementia (BPSD) are core clinical features that worsen functional decline and quality of life for patients in health care settings and their caregivers. Concerns have been raised about the efficacy and safety of pharmacological interventions. Moreover such interventions pass over the unmet needs of patients who develop some behavioral symptoms. Music therapy might be a suitable alternative, particularly also because the patient is invited to participate and communicate possible needs in a non-verbal way. Studies of music therapy interventions are often small, loosely designed and poorly reported. We designed a single blind randomized controlled study in which individual music therapy intervention is compared with the possible effect of music only (by sound source) and the psychosocial care as usual, where special attention is paid during activities. In a parallel investigation the development of individual well-being and engagement can be observed in a standardised longitudinal way, during the interventions, because this might be a prerequisite for recovery of discomfort that might be the cause of BPSD symptoms. Only tentative experience with such an approach is available and a "time-series analysis" for the implementation of person-centred care principles in the study outcome might be considered as a proof of concept.

## Study objective

The hypothesis is that individual music therapy intervention, according to professional standards, will lead to more symptom reduction of BPSD and a better quality of life based on parameters observed by care givers, compared with listening to music with a sound resource or the psychosocial interventions as usual in a particular care setting.

It is further expected that well-being and engagement, according to patient-centred care standards, will show a positive development during the music therapy interventions, which might be shown by longitudinal registration of communication and participation scales (CODEM and PRS, respectively). To demonstrate this a time-series analysis method is introduced, partly as a proof of concept for further studies on this subject.

## Study design

172 people with dementia and any kind of behavioral problem (BPSD) for which an intervention is warranted, will be recruited from about 20 psychogeriatric departments. Participants will be randomized after informed consent to get any of the three following interventions: Individual music therapy, music listening by sound resource or psychosocial intervention as usual.

Interventions will take place during 3 weeks, every week 3 interventions of 45 minutes. Before the start NPI and Qualidem are scored by a blinded test assistant. During the 3 weeks of the intervention NPI and Qualidem will be scored again. Three weeks after ending of the treatment period a further score of NPI and Qualidem will be performed in order to show a carry-over effect after the treatment period.

During the intervention period video registrations of 9 participants in each treatment arm will be recorded 2 times during the intervention. Based on standardized longitudinal observation methods scales for communication (CODEM) and engagement (PRS) will be scored by a trained observer. The evolution of well-being and engagement will be registered in a standardized way, according to a Time-series analysis method.

## **Intervention**

The interventions (music therapy, passive listening to music and psychosocial activities) are already in use in dementia care settings.

## **Study burden and risks**

We don't expect any particular burden or risk for the participants, apart from the burden they already have from their behavioral symptoms in the institutionalized care setting.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- a. Dementia according to international guidelines (any etiology)
- b. Behavioral or psychological symptoms (BPSD) for which additional care or intervention is needed (according to treating specialist)
- c. Agreement and informed consent from patient or formal family/care givers for participation
- d. Practical feasibility of professional music therapy, during 3 joined weeks, 3 days a week
- e. Availability of activity coaches or care professionals who can adjust the passive music (GDI) or activities (PSI) based on instructions during introductory course.
- f. Availability of some room and the time needed for a test assistant (TA) for the administration of psychometric scales.
- g. The participant has no limitations of hearing or sensory disturbance which seriously interfere with any of the interventions.

### Exclusion criteria

- a. Exclusion of causes (somatic or contextual) for which pharmacological or other treatment is needed first
- b. Refusal of patient or formal caregivers (particularly also in the case of incompetence of will)
- c. Delirium
- d. New psychopharmacological treatment in past 2 weeks
- e. Hearing loss or disturbance of consciousness
- f. Palliative care setting or life expectancy < 2 months
- g. No guarantee that care or intervention can be continued
- h. Sensory disturbances that seriously interfere with any of the interventions

## 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):	05-07-2017
Enrollment:	172
Type:	Actual

## Ethics review

Approved WMO	
Date:	27-03-2017
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

## 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: 21011  
Source: Nationaal Trial Register  
Title:

## In other registers

Register	ID
CCMO	NL60766.096.17
OMON	NL-OMON21011