Individual music therapy and wellbeing in dementia

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Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25091

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Dementia

Ondersteuning

Primaire sponsor: Alzheimer nederland
Overige ondersteuning: Alzheimer nederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Well-being is measured by a blinded research assistant at baseline, six weeks and twelve weeks, during 5 minutes before and after the intervention session or individual attention

session with the Discomfort Scale - Dementia of Alzheimer Type (DS-DAT).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Neuropsychiatric symptoms (NPS) such as agitation, shouting and wandering, are often associated with distress for the patient with dementia and emotional burden for his/her environment. The symptoms are often treated with psychotropic drugs. However, these frequently cause side effects. Music therapy is a non-pharmacologic treatment that can improve the quality of life in these individuals.
Objective: The main aim of this study is to assess the effects of individual music therapy on well-being controlled for providing individual attention in nursing home residents with dementia. The secondary objective is to assess the effects of individual music therapy on quality of life, NPS, agitation, anxiety, symptoms of depression, pain and quality of sleep.
Study design: The design involves an individual randomized controlled trial employing longitudinal repeated measurements in nursing home residents with dementia and NPS. The research will take place at different facilities of one nursing home organization (Amstelring). All music therapists are trained and credentialed professionals in the service of Amstelring. An independent observer, blinded for the intervention or control condition, will assess wellbeing and pain before and after music therapy sessions. Nurses will assess the other outcomes unblinded. The quality of sleep will be assessed with a wrist device called Actiwatch.
Study population: Nursing home residents with dementia and neuropsychiatric symptoms (NPS) living in an Amstelring health care organization.
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. The participants of the control group receive 30 minutes of individual attention by an attendant twice a week for 12 weeks in their own room.
Main study parameters/endpoints: Well-being is the primary outcome and is measured with the Discomfort Scale – Dementia of Alzheimer type (DS-DAT). The secondary outcomes are: pain (measured with the PAIC-15), quality of life (QUALID), neuropsychiatric symptoms (NPI-NH), anxiety (item of NPI-NH), agitation (CMAI), symptoms of depression (CSDD), quality of sleep and psychotropic drug use. Assessments are at baseline, 6 weeks and 12 weeks.

Doel van het onderzoek

The main purpose of this study is to blindly assess the effects of individual music therapy on well-being controlled for individual attention in nursing home residents with dementia who also have neuropsychiatric symptoms (NPS). The outcomes refer to longitudinal effects, consistent with therapeutic goals of care on alonger term. Further, wellbeing is an important outcome of different care approaches, including palliative care, and therefore is the primary outcome.

Onderzoeksopzet

pre-treatment:T0, after 6 weeks of interventioin (T1) and 12 weeks of intervention (T2)

Onderzoeksproduct en/of interventie

Intervention group (MT) group A: receive 30 minutes of individual music therapy twice a week for 12 weeks in their own room.
Music therapy treatment requires a qualified music therapist and can be defined as the professional use of music experiences and the relationships that developed through them with the aim to promote health. Individual music therapy is one-to-one contact between the music therapist and the patient and uses a person-centered approach. There are two main types of music therapy: receptive and active music therapy. Accredited music therapists deliver the intervention consisting of individual active music therapy sessions with a few receptive techniques.
Control group B: receives 30 minutes of individual attention twice a week for 12 weeks without a therapeutic basis. The individual attention will be given in the resident's room by one attendant, who will have a conversation with the patient and drink coffee without therapeutic aims and without any musical intervention. The attendant will be an informal care support company employee. This is on top of the regular usual care delivered.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1- A chart diagnosis of dementia, which is usually according to Diagnostic and Statistical Manual of Mental Disorders IV criteria (American psychiatric association, 2001).
2-Clinically relevant NPS measured with the Neuropsychiatric Inventory Nursing Home Version (NPI-NH) with the Frequency X Severity item score for at least one individual item ≥ 4

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1- Residents who have received individual music therapy before and residents who have participated in group music therapy in the last 3 months.
2- Major comorbid psychiatric diagnosis (i.e. schizophrenia, psychosis, anxiety disorders). Depression is part of the NPI and patients with a history of depression will not be excluded. Residents with a hearing impairment that considerably impairs hearing, speech or music played at a moderately volume. We will use item 1a of the Severe Dual Sensory Loss in old age screening tool (SDSL)42. SDSL was found a valid and reliable

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2019
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7708
Ander register	METC MCG : METc2019/021

Resultaten