Effectiveness of Physio Acoustic Sound (PAS) therapy in demented nursing home residents with nocturnal restlessness: A randomized clinical trial.

Gepubliceerd: 17-01-2012 Laatst bijgewerkt: 13-12-2022

The aim of this study is to test, by means of a randomized controlled trial, the hypothesis that application of PAS therapy with low-frequency acoustic vibrations to demented patients in nursing homes will lead to a significant decrease of nocturnal...

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

Samenvatting

ID

NL-OMON20663

Bron
NTR

Aandoening

Demented nursing home residents with nocturnal restlessness.

Ondersteuning

Primaire sponsor: Maastricht University, PO Box 616, 6200MD Maastricht , the Netherlands
Overige ondersteuning: Funded by Stichting Achmea Gezondheidszorg, Leiden, the Netherlands (projectcode Z333) and by Stichting RCOAK, Amsterdam, the Netherlands (projectnr. 2011.071).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The objectively and subjectively measured difference in nocturnal restlessness between T0-T1-T2.
Objectively: The nocturnal restlessness measured during 6 weeks by means of an actiwatch validated for sleep research with the sleep/wake parameters mentioned above.
Subjectively: Nocturnal restlessness determined on the basis of a sleep diary developed for this study, and filled in by the nursing staff.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Many older people with neuropsychiatric disorders such as Alzheimer's disease and frontotemporal dementia suffer from sleeping problems and often show nocturnal restlessness. Professionals and informal carers face considerable problems in solving these problems. Attempts to diminish these problems with medication in a safe and responsible manner have proven hardly effective or not effective at all. Therefore, nowadays the focus lies more on non-pharmacological solutions for example by influencing environmental factors. There are indications that treatment with low-frequency acoustic vibrations, i.e. Physio Acoustic Sound (PAS) therapy, has a positive effect on sleeping problems. Therefore we study the effectiveness of PAS therapy in demented patients with nocturnal restlessness.

Methods:

In a randomized clinical trial, 66 nursing home patients will be divided into two groups: An intervention group and a control group. For both groups nocturnal restlessness will be measured with actiwatches during a period of six weeks. In addition, a sleep diary will be filled in.

For the intervention group the baseline will be assessed, in the first two weeks, reflecting the existing situation regarding nocturnal restlessness. In the next two weeks, this group will sleep on a bed identical to their own, but with a mattress containing an in-built PAS device. As soon as the patient is lying in bed the computer programme inducing the vibrations will be switched on for the duration of half an hour. In the last two weeks, the wash out period, the measurements of the intervention group are continued, without the PAS intervention.

During the total study period, other relevant data of all the implied patients will be recorded systematically and continuously, e.g. patient characteristics (data from patient files), the type and seriousness of the dementia, occurrence of neuropsychiatric symptoms during the research period and the occurrence of intermittent comorbidity.

Discussion:

If PAS therapy turns out to be effective, it can be of added value to the treatment of nocturnal restlessness in demented patients. Non-pharmacological PAS-therapy is not only safe and patient-friendly, but it can also be widely used in a simple and relatively inexpensive way, both in institutions like nursing homes and residential homes for the elderly, and at home. Ultimately, this may lead to a decrease in the frequent and still common use of psychotropic drugs. In addition, care needs of demented patients also may decrease as well as the number of preventable admissions to care institutions.

Doel van het onderzoek

The aim of this study is to test, by means of a randomized controlled trial, the hypothesis that application of PAS therapy with low-frequency acoustic vibrations to demented patients in nursing homes will lead to a significant decrease of nocturnal restlessness.

Onderzoeksopzet

A validated Neuropsychiatric Inventory assessment (NPI-NH) will be performed in weeks 2, 4 and 6 by a psychologist together with a nursing staff member who knows the patient well. The NPI-NH contains ten behavioural aspects and two types of neuro-vegetative changes, i.e.: delusions, hallucinations, agitation, depression/dysphoria, anxiety, euphoria/elation, apathy/indifference, disinhibition, irritability/lability, aberrant motor behaviour, nighttime disturbances and appetite/eating change. This inventory will provide information on possible coexisting neuropsychiatric symptoms in patients with Alzheimer disease or other dementia syndromes.

Both the frequency and severity of each symptom are rated on a four- (1-4) and three-point (1-3) Likert scale, respectively. A separate score can be calculated for each symptom by multiplying the frequency and severity scores, resulting ranging from 0 to 12 each symptom. A total score can be obtained by summing the 12 frequency and severity scores, yielding total scores that range from 0 to 144.

Onderzoeksproduct en/of interventie

Patients will be randomized over an intervention group and a control group. The patients in the control group will sleep on their own high dependency bed during the three periods of two weeks each. The patients in the intervention group will sleep, after the initial baseline period of two weeks, on a high dependency bed identical to their own for the second period of two weeks. The mattress of this bed, however, contains the same technique as the PAS therapy chair and will be controlled by an external computer. As the intervention can be controlled perfectly and safely via the computer regarding frequency, duration and intensity, the technique is considered suitable for this research. In the third and last (wash out) period of two weeks they sleep again in their own bed.

The computer programme controlling the acoustic vibrations of the mattress will be switched on daily by the nursing staff during a period of two weeks. This will be done as soon as the patient is lying in bed. The programme will switch off automatically after 30 minutes. So as to not contaminate the results by the presence of the staff, the staff member will leave the patient's bedroom as soon as the mattress is switched on. The frequencies used in the programme lie between 27 and 40 Hz en will vary every two or three minutes.

These frequency settings of the intervention have been chosen after advice from Finnish professionals who have many years of experience with this intervention. The design of the programme used in this intervention was originally aimed at reducing pain, and the varying frequencies were based on Melzak and Wall's gate control theory [17].

The other therapeutic applications of PAS therapy described above, whose effectiveness has already been proven, are all based on this design as well.

Contactpersonen

Publiek

Hollewandsweg 17
A.J. Os, van
Zwolle 8014 BE
The Netherlands
+31 (0)38 4687741

Wetenschappelijk

Hollewandsweg 17
A.J. Os, van
Zwolle 8014 BE
The Netherlands
+31 (0)38 4687741

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients are included when diagnosed with the DSM-IV definition of dementia and who have

been residing in the nursing home for a minimum of two months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. The presence of a (high risk of) a pressure sore, i.e. an indication for the preventive use of a different mattress, e.g. an alternative mattress to prevent pressure ulcers;

2. Acute illness, e.g. pneumonia, exacerbation of heart failure, a recent stroke, etc.;

3. A pacemaker, which could possibly interfere with the PAS instruments.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-07-2011
Aantal proefpersonen:	66
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-01-2012
Soort:	Eerste indiening

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	NL3102
NTR-old	NTR3242
Ander register	Stichting RCOAK / Stichting Achmea Gezondheidszorg : 2011.071 / Z333;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A