Cross-trial about the effects of therapeutic touch/massage in nursing home patients with dementia

Published: 27-10-2009
Last updated: 05-05-2024

Direct effects:- Measuring the impact of therapeutich touch/massage at patients with dementie and agitation. Indirectly:- The promotion of the non-verbal communication with the demented elderly in the nursing home. - Offering extra attention as a...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32434

Source
ToetsingOnline

Brief title
Therapeutic touch/massage in nursing homes.

Condition

- Other condition

Synonym
alzheimer disease., dementia

Health condition

dementie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Een deel wordt vergoed door het verpleeghuis waar het onderzoek plaatsvindt en een deel wordt op vrijwilligerbasis gedaan.

Intervention

Keyword: dementia, massage, therapeutic touch

Outcome measures

Primary outcome

? Cohen-Mansfield agitation questionnaire (CMAI)

? neuropsychiatric questionnaire

? nursing home version (NPI-NH) ? 4 measurings (NPI-NH and CMAI):

Baseline at end first therapy (massage or friendly visit), after washout period

= beginning second therapy and at the end of second therapy (friendly visit or

massage).

Secondary outcome

There are not secundary parameters / outcoms of this study

Study description

Background summary

Therapeutic touch or massage is a treatment which is sometimes applied within the framework of palliatory care at cancer patients or at patients with dementia. This therapy has not been yet sufficiently scientifically founded at dementia patients , but is applied because care workers expect that this treatment is effective. Differently than farmacological treatment for disorder or agitation, this treatment has according to the expectations not hardly side effects.

Study objective

Direct effects:
- Measuring the impact of therapeutich touch/massage at patients with dementie and agitation.
Indirectly:
- The promotion of the non-verbal communication with the demented elderly in the nursing home.
- Offering extra attention as a result of which the quality of life of patients with dementia in the nursing home improves.

Study design

? Cross-over trial with intervention duration (massage or friendly visit) of 4 weeks
? Washout period between both interventions of 2 weeks
? massage session are carried out by 2 trained care workers (20-25 minutes, 2 times a week, during 4 weeks) and take place on the chamber of the patient or in another availabel room.
? Friendly visit consistis on a chat and drink coffee on the room of the patient by the same care worker
? 2 time 42 dementia patients
? Researcher is not aware about the intervention (is not informed about who gets the massage or the friendly visit)

Poweranalyse: Given alpha of 0.05, a beta of 0.8, an expected impact size (change in CMAI of total 4 points), SD (of the change in CMAI) of 13 and a correlation between two measurings of r = 0.54 are there 2 time 39 people necessary. Taking into account outburst negative of 5% will be started with 2 time 42 people.

Intervention

Massage/TT session carried out 2 care workers trained by (20-25 minutes, 2 time per week, during 4 weeks).
Massage/TT session take place on the room of the patient or in another available room.

Study burden and risks

Therapeutic touch/massage have none risico' s. There are possibly patients who not appreciate this intervention. When the patient gives up verbally or non-verbally that he/she doesn't want the treatment, the caregiver stop the treatment (massage). When this happens a second time the treatment stops definitely and the patient is taken out of the reaserch(dropout in intention-to-treat the analysis).

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Dongepark 1
5102 DB
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

Dongepark 1
5102 DB
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Dementia (acoording to DSM-IV criteria)
- Agitation (according to the CMAI score above 44 points).

Exclusion criteria

- No agitation
- Recent diseases (for example;urinary tract infections, pneumonia, etc).
- Recent changes in the medication (not longer than 7 days before starting with the trial).
- Terminal patients.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2009
Enrollment:	42
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	27-10-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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

Register	ID
CCMO	NL25358.091.08