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A randomised clinical trial of passive movement therapy in patients with moderate to severe paratonia

Submission date	Recruitment status	[X] Prospectively registered
18/10/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/08/2012	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Rob de Bie

Contact details
PO Box 616
Maastricht
Netherlands
6200 MD
+31 (0)43 388 2366
RA.deBie@EPID.unimaas.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
Paratonia

Study objectives
Paratonia is a form of hypertonia with an involuntary variable resistance during passive movement. The nature of paratonia may change with progression of the dementing illness (e.g. active assistance (mitgehen) is more common early in the course of degenerative dementias, whilst active resistance is more common later in the course of the disease). The degree of resistance varies depending on the speed of movement (e.g. a low resistance to slow movement and a high resistance to fast movement). Paratonia increases with progression of dementia. Furthermore, the resistance to passive movement is in any direction and there is no clasp-knife phenomenon. The resistance must be felt in either two directions in one limb or in two different limbs.

The hypotheses of this trial are:
1. Is passive movement therapy an effective intervention on the severity of paratonia in comparison with usual care without passive movement therapy?
2. Is passive movement therapy an effective intervention for improvement of daily care?
3. Is there a difference in side effects of passive movement therapy versus care as usual in patients with moderate to severe paratonia?

Please note the anticipated start and end dates have been altered - the initial start date was 01 /01/2007 and end date was 31/12/07, the target number of participants has also been updated to show the final recruitment number. Inclusion criteria have also been updated

Ethics approval required
Old ethics approval format

Ethics approval(s)
CMO region Arnhem-Nijmegen Radboud University Nijmegen has approved this trial on the 10th April 2007 (CMO nr. 2006/157, ABR dossier number NL13777.091.06).

Study design
Multi-centre interventional randomised single-blind study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Paratonia in dementia

Interventions
We propose a randomised controlled trial with a four week follow-up period. After computerised and concealed block randomisation (block-size of four) patients will be included in one of two groups. The first group will receive Passive Movement Therapy (PMT), the second group will receive usual care without PMT.

PMT will be given three times a week (between 8 a.m. and 10 a.m. shortly before washing and dressing) for four weeks in a row. Usual care (given to both groups) is mainly a combination of good stabilising cushions and a special care protocol called Passivity of Daily Life (PDL).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Modified Ashworth scale - a five-point scale from zero to four, in which:
Zero = no resistance to passive movement
One = slight resistance during passive movement
Two = more marked resistance to passive movement
Three = considerable resistance to passive movement
Four = severe resistance, passive movement is impossible

Secondary outcome measures
1. The Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC)
2. To assess pain as a possible side effect of PMT
3. The Clinical Global Impressions (CGI) to assess the clinical improvement and a derived form of the Patient Specifieke Klacht (PSK) assessment in which the carers are asked to address the three most difficult items in daily care and rate these items on a ten point rating scale

Overall study start date
01/04/2007

Completion date
30/04/2009

Eligibility

Key inclusion criteria

1. Patients with dementia (according to the Diagnostic and Statistical Manual of Mental Disorders fourth edition [DSM-IV-TR] Criteria) and paratonia with a score on the modified Ashworth scale of two or more in one of the limbs are included in the study. Patients are only included after Proxy consent.

Added 28/07/09:
2. Male or female
3. Age range at close of recruitment was 67-98 (mean 84)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
98 patients from 12 different elderly health care institutions (final recruitment 101, 83 female, 18 male)

Key exclusion criteria
1. Patients with an unstable disease like progressive malignant cancer or other diseases with an obvious progressive negative effect on the motor function
2. Patients who receive passive movement therapy prior to admission
3. The nursing home physician can decide to withdraw a participant from the study for urgent medical reasons

Date of first enrolment
01/04/2007

Date of final enrolment
30/04/2009

Locations

Countries of recruitment
Netherlands

Study participating centre
PO Box 616
Maastricht
Netherlands
6200 MD

Sponsor information

Organisation
The Caphri Institute (The Netherlands)

Sponsor details
Maastricht University
Universiteitssingel 40
Maastricht
Netherlands
6200 MD
+31 (0)43 388 2446
D.Moens@CAPHRI.unimaas.nl

Sponsor type
University/education

Website
http://www.caphri.nl/

ROR
https://ror.org/02jz4aj89

Funder(s)

Funder type
Other

Funder Name
The Vitalis Care Group (Vitalis Zorg Groep), Eindhoven (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/12/2007		Yes	No
Results article	results	01/05/2012		Yes	No