

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

<b>Submission date</b> 18/10/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/12/2006	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 17/08/2012	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

### 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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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

## **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

## **Healthy volunteers allowed**

No

## **Age group**

Senior

## **Sex**

All

## **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)

**ROR**

<https://ror.org/02jz4aj89>

## Funder(s)

**Funder type**

Other

**Funder Name**

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

# Results and Publications

## 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?
<a href="#">Results article</a>	results	01/05/2012		Yes	No
<a href="#">Protocol article</a>	protocol	19/12/2007		Yes	No