

# effect of passive movement on severity of paratonia

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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?

|                              |                  |
|------------------------------|------------------|
| <b>Ethical review</b>        | Approved WMO     |
| <b>Status</b>                | Pending          |
| <b>Health condition type</b> | Muscle disorders |
| <b>Study type</b>            | Interventional   |

## Summary

### ID

NL-OMON29871

### Source

ToetsingOnline

### Brief title

passive movement and paratonia

### Condition

- Muscle disorders
- Dementia and amnestic conditions

### Synonym

counterpull, Gegenhalten

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** Vitalis Zorg Groep Eindhoven financiert promotie traject drs. J.S.M. Hobbelen

## Intervention

**Keyword:** Dementia, paratonia, Passive movement therapy, physical therapy

## Outcome measures

### Primary outcome

Modified Ashworth scale. The modified Ashworth scale is a 5 point scale from 0 to 4, in which 0 = no resistance to passive movement, 1= slight resistance during passive movement, 2= more marked resistance to passive movement, 3 = considerable resistance to passive movement, 4= severe resistance, passive movement is impossible. To assess the severity of paratonia all four limbs will be passively moved in flexion and extension with the participant in a comfortable position in bed.

### Secondary outcome

The Pain Assessment Checklist for Seniors with Limited Ability to Communicate (PACSLAC)[Fuchs et al 2004, Zwakhalen et al 2006].

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 3 most difficult items in daily care and rate these items on a 10 point rating scale.

Global Deterioration Scale (GDS) to assess the severity of the dementia.

## Study description

### Background summary

Paratonia is associated, especially in the late stages of the dementia, with a loss of mobility and with the development of contractures [Souren et al., 1997,

Franssen et al., 1993]. Practical consequences for carers and nurses hold difficulties to wash and dress patients with paratonia. Passive movement therapy, to decrease the high muscle tone and to sustain the range of motion of the affected joints, is the main therapy applied by physiotherapists in Dutch nursing homes. Carers and nurses claim that this therapy, if given shortly before their interaction with the patient, reduces the difficulties they encounter. In a pilot study [Hobbelen et al., 2003], we found that their claims hold some truth; passive movement therapy had a positive short term effect yet worsened the joint and limb stiffness after 3 weeks. Unfortunately, the study was underpowered, and the lack of a clear operational definition of paratonia meant that the study population was heterogeneous.

## **Study objective**

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?

## **Study design**

randomised partially blinded clinical trial with 1 intervention group and 1 control group.

## **Intervention**

passive movement therapy

## **Study burden and risks**

The aim of this study is to analyse the effect of passive movement therapy in 4 weeks time with a frequency of 3 times a week. A trend analysis of our pilot study (n=15) showed a slight negative effect in the treatment group (n=5) compared with stabilising cushions and a control group. However afterwards no negative effect were observed with the participants

## **Contacts**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

patients with dementia (according to the DSM-IV-TR Criteria) and paratonia with a score on the modified Ashworth scale of 2 or more in one of the limbs are included in the study. They are recruited out of the psycho-geriatric population in one of the participating nursing homes. Patients are only included after Proxy consent

### **Exclusion criteria**

Patients with an unstable disease like progressive malignant cancer or other disease with an obvious progressive negative effect on the motor function will be excluded. Patients who receive passive movement therapy prior to admission or use neuroleptic drug will also be excluded. participants who refuse to collaborate during the assessment

## **Study design**

## Design

|                     |                               |
|---------------------|-------------------------------|
| Study type:         | Interventional                |
| Intervention model: | Parallel                      |
| Allocation:         | Randomized controlled trial   |
| Masking:            | Single blinded (masking used) |

**Primary purpose:** Treatment

## Recruitment

|                           |             |
|---------------------------|-------------|
| NL                        |             |
| Recruitment status:       | Pending     |
| Start date (anticipated): | 01-10-2006  |
| Enrollment:               | 90          |
| Type:                     | Anticipated |

## Ethics review

|                    |                                      |
|--------------------|--------------------------------------|
| Approved WMO       |                                      |
| 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     | NL13777.091.06 |