# The implementation of the serial trial intervention for pain and challenging behavior in advanced dementia patients in Dutch nursing homes;*STA OP!*

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Too study the effects of implementation of the Dutch STI on pain and challenging behavior.The RESEARCH QUESTIONS are:1. Is the use of the STI-protocol more effective than usual care in reducing symptoms of pain and challenging behaviours in nursing...

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Dementia and amnestic conditions |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON33837

**Source**
ToetsingOnline

**Brief title**
the implementation of the Dutch Serial Trial Intervention

### Condition

- Dementia and amnestic conditions

**Synonym**
behavioral problems, dementia

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum
**Source(s) of monetary or material Support:** Innovatiefonds zorgverzekeraars

## Intervention

**Keyword:** behavior, dementia, pain

## Outcome measures

### Primary outcome

pain, challenging behavior

### Secondary outcome

depression, quality of life, use of antipsychotic medication

# Study description

### Background summary

Pain (physical discomfort) and challenging behaviour are highly prevalent in nursing home residents with dementia. It has been shown that pain is undertreated in this group, and that psychosocial interventions for behavioral problems are ,allthough effective, not adequately implemented. Too often psychoactive medication is used too control these behaviors.
A stepwise protocol (the serial trial intervention, STI) has been shown too be effective in US nursing homes in controlling pain and challenging behavior. This protocol is translated and adapted for the Dutch nursing homes.

### Study objective

Too study the effects of implementation of the Dutch STI on pain and challenging behavior.
The RESEARCH QUESTIONS are:
1. Is the use of the STI-protocol more effective than usual care in reducing symptoms of pain and challenging behaviours in nursing home residents?
2. Does the use of the STI-protocol lead to less depressive symptoms and a better quality of life in advanced dementia patients?
3. Does the use of the STI-protocol lead to a change in use of analgesics and psychotropic drugs?
4. Does the use of the STI-protocol lead to a more frequent use of

non-pharmacological comfort
interventions?

### Study design

Randomized controlled trial, randomisation at nursing home level.

Staff is trained in working with the STI, and measurements are performed at t0, 4 weeks, 13 weeks and 6 months.

### Study burden and risks

No risks

## 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

stage dementia Reisberg GDS 5,6 and 7

### Exclusion criteria

terminal prognosis
psychiatric illness other than dementia

## Study design

### Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 07-04-2010 |
| Enrollment: | 168 |
| Type: | Actual |

## Ethics review

Approved WMO

| | |
|---|---|
| Date: | 23-07-2009 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

# 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 | NL24520.029.09 |