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...

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