The implementation of the Dutch Serial Trial Intervention (STA OP!).

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26483

Source
Nationaal Trial Register

Brief title
STA OP

Health condition

Dementia-patients (Reisberg GDS, 5, 6 or 7) with symptoms of pain and/or challenging behavior (measured with MDS-pain, PACSLAC-D, NPI-NH and CMAI).

Sponsors and support

Primary sponsor: - VU University Medical Center (Department of Nursing home medicine)
- EMGO+ Institute of Health and Care Research
Source(s) of monetary or material Support: Innovatiefonds Zorgverzekeraars

Intervention

Outcome measures

Primary outcome

Pain: measured with painscale of the Dutch version of the MDS-RAI and PACSLAC-D Behavior: CMAI, NPI-NH.

Secondary outcome

1. Depression: Cornell-depression and MDS-DRS;

2. Quality of Life: Qualidem;

3. Use of anti-psychotic medication.

Study description

Background summary

Pain (physical discomfort) and challenging behavior 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, allthoug effective, not adequately implemented. Too often psychoactive medication is used to control these behaviors. A stepwise protocol (the Serial Trail Intervention, STI) has been shown to be effective in US nursing homes in controlling pain and challenging behavior. This protocol has been translated and adapted for the Dutch nursing homes.

In 5 meetings of 4 hrs each, nurses and nursing home physicians of all experimental wards are trained in the use of the steps in the protocol. The training is given by two collaborating, experienced trainers: one is an advanced practice nurse and the other has a medical background, while both have specific expertise regarding dementia, pain and discomfort. In the sessions it will be discussed how nurses and nursing home physicians can recognize symptoms related to pain and affective discomfort, and how nurses and physicians can communicate with each other about these symptoms. It is also discussed in general, when a subsequent protocol step is needed when targeted assessments are negative or when the symptoms related to pain or affective discomfort have not been reduced sufficiently by targeted interventions. These targeted interventions will include non-pharmaclogical (e.g. snoezelen, psychosocial interventions, movement) and pharmacological interventions in a stepwise manner.

The STI-protocol consists of five steps:

1. The FIRST step is to perform a physical needs assessment that focuses on probable causes of behavioural symptoms related to pain or affective discomfort;

2. The SECOND step is to perform a needs assessment that focuses on affective needs of people with dementia;

3. The THIRD step concerns a trial of non-pharmacological comfort interventions;

4. The FOURTH step is a trial of analgesics;

5. STEP FIVE refers to consultation of other health care professionals or practitioners, or a trial of psychotropic drugs.

Study objective

Pain (physical discomfort) and challenging behavior 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 to control these behaviors. A stepwise protocol (the Serial Trail Intervention, STI) has been shown to be effective in US nursing homes in controlling pain and challenging behavior. This protocol has been translated and adapted for the Dutch nursing homes.

To 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 behavior 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 STI-protocol lead to change of use in analgesics and psychotropic drugs?

4. Does the use of the STI-protocol lead to a more frequent use of comfort interventions?

Study design

Measurements take place at baseline and after 3 and 6 months after baseline.

Intervention

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Contacts

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Eligibility criteria

Inclusion criteria

1. Global Detoriation Scale (Reisberg 1983), (GDS) > 5;

2. No chronic psychiatric diagnosis other than dementia;

3. CMAI > 44, NPI > 4, MDS-pain = pain.

In all included residents:

1. PACSLAC-D (pain observations);

2. Depression (Cornell and MDS-depression);

3. Quality of Life (Qualidem);

4. ADL (Katz);

5. Co-morbidity (ICD-10);

6. Demographics;

7. Apo-E4 (Buccal mucosa swab).

Exclusion criteria

1. GDS-score < 5;

2. Chronic psychiatric diagnosis other than dementia.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2009
Enrollment:	168
Type:	Actual

Ethics review

Positive opinion

Date:	26-08-2009
Application type:	First submission

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
NTR-new	NL1855

Register	ID
NTR-old	NTR1967
Other	METc, VU Medical Center : 2009/119
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A