

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

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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, although...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26483

Bron

Nationaal Trial Register

Verkorte titel

STA OP

Aandoening

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).

Ondersteuning

Primaire sponsor: - VU University Medical Center (Department of Nursing home medicine)
- EMGO+ Institute of Health and Care Research

Overige ondersteuning: Innovatiefonds Zorgverzekeraars

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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, although 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-pharmacological (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.

Doel van het onderzoek

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, although 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?

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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-pharmacological (e.g. snoezelen, psychosocial interventions, movement) and pharmacological interventions in a

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Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. GDS-score < 5;
2. Chronic psychiatric diagnosis other than dementia.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2009
Aantal proefpersonen:	168
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	26-08-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1855

Register

NTR-old

Ander register

ISRCTN

ID

NTR1967

METc, VU Medical Center : 2009/119

ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A