

# Reducing challenging behaviours in people with dementia through a nurse-led intervention

<b>Submission date</b> 29/07/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 11/06/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
LT-Demenz 44-083

## Study information

**Scientific Title**  
Effectiveness of the German version of the Serial Trial Intervention for the reduction of challenging behaviours in people with Dementia

**Acronym**

STI-D

**Study objectives**

Application of the Serial Trial Intervention for Dementia (STI-D) reduces challenging behaviours in nursing home patients with dementia to a significantly greater extent than standard care.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval received from the Ethikkommission der Charite - Universitätsmedizin Berlin on the 12th June 2008 (ref: EA1/094/08)

**Study design**

Multicentre cluster-randomised single-blinded placebo-controlled study

**Primary study design**

Interventional

**Study type(s)**

Quality of life

**Health condition(s) or problem(s) studied**

Dementia

**Interventions**

German version of the Serial Trial Intervention (STI-D). The Serial Trial Intervention constitutes a structured framework for the process of assessment and intervention when challenging behaviours occur. It is carried out by skilled nurses in the nursing home setting. A detailed manual exists.

Nurses from nursing homes assigned to the intervention group are trained to implement the STI-D in their daily clinical care. This is included in a seminar on challenging behaviours in persons with dementia and appropriate care approaches in general.

Nurses from nursing homes assigned to the control group receive a seminar about challenging behaviours in persons with dementia and appropriate care approaches in general that does not include a STI-D training.

Both seminars include two days of classroom session for the registered nurses as well as clinical visits from instructors. Duration of treatment as well as follow-up will both last for six months after nurses have completed training. This applies for both study arms.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Challenging behaviours, measured using the Neuropsychiatric Inventory Nursing Home Version (NPI-NH).

Time points:

Before staff trainings are initiated, four weeks after training is completed, six months after training is completed.

**Key secondary outcome(s)**

1. Quality of life, measured using the Qualidem questionnaire
2. Pain, measured either using a Verbal Descriptor Scale oder BISAD (Beobachtungsinstrument für das Schmerzassessment bei alten Menschen mit Demenz), a tool for behavioural pain measurement, depending on the cognitive capacity of the patient
3. Analgesics and psychotropics prescribed, taken from patient records and converted to Defined Daily Doses

Time points:

Before staff trainings are initiated, four weeks after training is completed, six months after training is completed.

**Completion date**

30/09/2009

## **Eligibility**

**Key inclusion criteria**

1. Nursing home resident
2. Dementia
3. Mini-Mental State Examination (MMSE) less than 24
4. Aged 65 years and older, male and female

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Key exclusion criteria**

1. Psychotic disorders
2. Residency in nursing home less than four weeks

**Date of first enrolment**

01/09/2008

**Date of final enrolment**

30/09/2009

## Locations

### Countries of recruitment

Germany

### Study participating centre

Charité - Universitätsmedizin Berlin

Berlin

Germany

14195

## Sponsor information

### Organisation

Charite - University Medicine Berlin (Charite - Universitatsmedizin Berlin) (Germany)

### ROR

<https://ror.org/001w7jn25>

## Funder(s)

### Funder type

Government

### Funder Name

German Federal Ministry of Health (Bundesministerium für Gesundheit [BMG]) (Germany) (ref: LT Demenz 44-083)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Protocol article](#)

protocol

01/09/2008

11/06/2019

Yes

No