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

Submission date	Recruitment status	[X] Prospectively registered
29/07/2008	No longer recruiting	[X] Protocol
Registration date	Overall study status	Statistical analysis plan
19/08/2008	Completed	☐ Results
Last Edited	Condition category	Individual participant data
11/06/2019	Mental and Behavioural Disorders	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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 - Universitatsmedizin 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

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 fur 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

Protocol article	protocol	01/09/2008	11/06/2019 Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025 No	Yes