ISRCTN61397797 https://doi.org/10.1186/ISRCTN61397797

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/09/2008

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

Age group
Senior

Sex
Both

Target number of participants
n = 465

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)

Sponsor details
Institut für Medizinische Soziologie
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Sponsor type
Hospital/treatment centre

Website
http://www.charite.de/medsoz

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	01/09/2008	11/06/2019	Yes	No