ISRCTN20203855 https://doi.org/10.1186/ISRCTN20203855

Case conference for people with dementia and challenging behavior (FallDem)

Submission date
25/06/2013

Registration date
10/07/2013

Last Edited
17/01/2020

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Case conference is an useful tool for staff to understand the behavior (like aggression) in people with dementia. Understanding their behavior is the basis for staff to begin with targeted interventions to improve quality of care of the people with dementia. Furthermore it may lead to a reduction of the dementia specific burden on the nursing staff.
All together there are two possible ways to conduct a case conference.
A) With help of an assessment instrument which guides the staff to understand the behavior of the resident.
B) In a free narrative way in which the staff has to find the reasons for the behavior of the resident in an unstructured way.
The aim of this study protocol is to study the effectiveness of two dementia-specific case conferences within German nursing homes.

Who can participate?
People with dementia and their caregivers in 12 nursing homes in North-Rhine-Westfalia (NRW), Germany.

What does the study involve?
12 nursing homes take part in the trial. The intervention is rolled-out sequentially every 3 months to two nursing homes over 19 months. Every nursing home will receive the intervention however the order in which the different nursing homes will receive the intervention and the kind of the intervention (Innovative Dementia Orientated Assessment Tool (IdA) or Narrative model of case conference) is determined at random.

What are the possible benefits and risks of participating?
It can be expected that both concepts of case conferences help the nursing staff to understand the residents challenging behavior and thus offers staff the opportunity to initiate interventions that lead to a reduction of residents challenging behavior, the use of psychotropic drugs and increase the quality of life of the residents. Overall they will help to improve the quality of care for the people with dementia living in nursing homes .

Furthermore the expected reduction of the challenging behavior of the residents also leads to a reduction of the dementia specific burden or burnout of the nursing staff.
There are no risks of injury or harm if you take part in this study.

Where is the study run from?
12 Nursing Homes in North-Rhine-Westfalia (NRW), Germany

When is the study starting and how long is it expected to run for?
The study started in May 2013 and will run till October 2015.

Who is funding the study?
The Public Welfare Foundation North Rhine-Westphalia, Germany

Who is the main contact?
Dr. rer. medic. Margareta Halek, MScN
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Study website
http://www.dzne.de/standorte/witten/projekte/falldem.html

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
6227-Z

Study information

Scientific Title

Evaluation of the effects of two dementia-specific case conferences within German nursing homes using a stepped-wedged randomized controlled trial

Acronym
FallDem (Fallbesprechung bei Demenz)

Study objectives
The study is based on the hypothesis that the engagement with challenging behavior within case conferences leads to a greater understanding of residents challenging behavior according to the Need driven dementia compromised behaviour (NDB) Model and thus offers nursing staff the opportunity to initiate purposive interventions that lead to a reduction in the prevalence of residents challenging behavior, the use of psychotropic drugs and increase residents quality of life (QoL).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the German Society of Nursing Science approved on August 2011

Study design
Stepped-wedged randomized controlled trial

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
Training phase (before the start of the intervention): Here all participating nursing staff will receive a one day training in the field of the diagnosis of dementia and challenging behavior and a half day training in handling one of the two models of case conference. Additionally each nursing home have to select two senior nursing staff members who get a two days training to moderate a case conference. The intervention itself starts after the education phase.
In this study two different kinds of interventions will be tested about their effectiveness. Both

concepts of the studies are based on a fixed process and role structure but differ in the content structure. The nursing staff of each ward has to select the people with dementia being discussed in case conferences.

The two different concepts (A/B) of case conferences

A) The model of case conferences with the Innovative Dementia Orientated Assessment Tool (IdA): The staff are guided through the process of understanding the situation with the help of central question in six main topics. The first step is a detailed description and quantification of the challenging behavior. The second step is the search for potential causes of the behavior. For this IdA is divided into five dimensions (state of health, communication, personality, mood emotions and environment influences) with specific guiding questions.

B) Narrative model of case conference: The main topics of understanding the situation takes place in an unstructured way. This means that the nursing staff have to approach the description and understanding of the situation in a free narrative way.

Every cluster will receive the intervention after a control phase. The intervention is rolled-out sequentially every 3 months to two nursing homes over 19 months. The order in which the different nursing homes will receive the intervention and the kind of the intervention (six nursing Homes receive the Case Conferences with IdA and six Narrative case conference) is determined at random.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Challenging behavior of residents with dementia measured with the NPI-NH proxy-measurement. Measured at baseline (T0) and after that every 3 months (T1-T6) over a period of 19 months.

Secondary outcome measures
Patients:
1. Quality of Life of people with Dementia measured with the QUALIDEM proxy- measurement
2. The Defined Daily Dose (DDD) of Psychotropic Drugs

Staff:
1. Burnout of the nursing staff with will be measured with the Copenhagen Burnout Inventory (CBI)
2. The dementia-specific burden on nursing staff will be assessed with the German BelaDem Questionnaire.
3. The vocational action competence of the nursing staff will be measured with the German questionnaire Kompetenz Reflektions Inventar (KRI)

All above outcomes measured at baseline (T0) and after that every 3 months (T1-T6) over a period of 19 months.

Overall study start date

01/05/2013

Completion date
31/10/2015

Eligibility

Key inclusion criteria
The following inclusion criteria were set for institution and patient level of the trial.

Institution Level
1. At least two wards of one nursing home must take part in the study that provide together at least 30 residents with dementia
2. The care of the residents have to take place most of the day in their ward

Patient level
1. Informed consent
2. Diagnosis of dementia
3. Living not less than 14 days in the ward

According to the Federal Statistical Office we expect that most of the patients are > 65 years and around 70% of the patients in our study sample will be women and 30% men.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
12 nursing homes (with 24 wards) and approximately 360 people with dementia and approximately 200 nursing staff)

Total final enrolment
413

Key exclusion criteria
The following exclusion criteria were set for institution and patient level of the trial

Institution level
1. Nursing homes size < 30
2. Some kind of day care is integrated in the institution for people with dementia
3. Reconstruction work on the participated unit and participation in any other research project at the same time that bond personal resources

Patient level
1. Schizophrenia or any other kind of psychiatric diseases (found in the medical documentation)

Date of first enrolment

01/05/2013

Date of final enrolment

31/10/2015

Locations

Countries of recruitment

Germany

Study participating centre
Stockumer Str. 12

Witten
Germany
58453

Sponsor information

Organisation

Stiftung Wohlfahrtspflege Nordrhein-Westfalen [Public Welfare Foundation North Rhine-
Westphalia]

Sponsor details

Horionplatz 1
Düsseldorf
Germany
40213

Sponsor type

Government

Website

http://www.sw-nrw.de/home/

Funder(s)

Funder type

Government

Funder Name

Stiftung Wohlfahrtspflege Nordrhein-Westfalen

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	12/08/2014		Yes	No
Protocol article	protocol	11/12/2014		Yes	No
Other publications	process evaluation	14/01/2019	02/10/2019	Yes	No
Results article	results	25/09/2019	02/10/2019	Yes	No