ISRCTN43916381 https://doi.org/10.1186/ISRCTN43916381

Leben-QD II Strengthening Quality of life for people with dementia through dementia care-mapping

Submission date
10/04/2013

Recruitment status
No longer recruiting

Registration date
15/04/2013

Overall study status
Completed

Last Edited
13/06/2013

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The main objective of caring for people with dementia is to keep up and improve their quality of life (QoL). Many of the residents in nursing homes behave in a challenging (or demanding) manner that strongly affects their QoL. Person-centered care (PCC) aims to achieve the best possible QoL and to reduce this type of behaviour. Dementia Care Mapping (DCM) is a method of carrying out PCC that has been used in Germany for several years. We do not know how well DCM works and we want to find out about the effects of DCM for all concerned: patients and their caregivers.

Who can participate?
People with dementia and their caregivers in nine nursing homes in the St. John of Jerusalem Nursing Home Section West (Germany).

What does the study involve?
The nine nursing groups will be allocated to one of three groups:
Three groups will be set up. Dementia Care Mapping will be performed on group 1 . This group differs from group 2 , in that group 2 has already had experience in the use of DCM. Otherwise group 2 receives the same treatment as group 1. Group 3 will be assessed from time to time to check the Quality of Life. This will be done using a special method called QUALIDEM. In group 3, the QoL of all the people with dementia will be assessed at the start and will be done again if notable changes in the residents needs are noticed later. At least every 6 months, a new QoL assessment must be carried out. If necessary, the staff will discuss each individual case based on the results of the assessments in order to understand the particular needs of that resident /patient.

What are the possible benefits and risks of participating?
There are no risks of injury or harm if you take part in this study. The results of the QoL assessments will be standardized and these, when applied, will help to improve the person-

centered care (PCC) of every person suffering from dementia. The participating caregivers will get additional or new information about person-centered care of people with dementia and will be able to compare it with the previous care offered.

Where is the study being run?
In nine nursing homes in the St. John of Jerusalem Nursing Home Section West.

When will the study start and how long is it expected to run for?
The study started in April 2011 and is expected to run until April 2013.

Who is funding the study?
The Public Welfare Foundation North Rhine-Westphalia (Stiftung Wohlfahrtspflege Nordrhein-Westfalen) and the Knights of St. John Regional Centre West provide the funding for this study.

Who is the main contact person for the study?
Dr Margareta Halek
Margareta.Halek@dzne.de

Contact information

Type(s)
Scientific

Contact name
Dr Margareta Halek

Contact details
Stockumer Str. 12
Witten
Germany
58453
Margareta.Halek@dzne.de

Additional identifiers

Study information

Scientific Title
Leben-QD II Strengthening Quality of life for people with dementia through dementia care-mapping: design of the quasi-experimental study

Acronym
Leben-QD II

Study objectives
The aims of this study are to evaluate the effects of Dementia Care Mapping (DCM) in dementia care in German nursing homes, to explore the implementation of Dementia Care Mapping and to perform a cost-effectiveness analysis.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethics Committee of the German Society of Nursing Science approved on the 19 August 2010.

Primary study design
Interventional

Study design
Quasi-experimental controlled trial

Study type(s)
Quality of life

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

Interventions
The study consists of three study arms.
To measure the effects of Dementia Care Mapping a quasi-experimental design is being used, with 3 measurement points. 9 nursing home units will be assigned to either the DCM intervention group or 1 of 2 comparison groups. The care provider will be responsible for the assignment of a unit to 1 of the 3 groups. The DCM method will be implemented in the 3 units assigned to the intervention group. The first comparison group will consist of 3 nursing units that have at least 3 years of experience in the use of the DCM method. The 3 units in the second comparison group will receive a control intervention based on the use of the dementia-specific Qol-measurement QUALIDEM. The groups will get the following interventions:

Intervention group: Dementia Care Mapping as interventions consists of 6 fixed components: 1) briefing and preparation of care staff and leadership, 2) DCM observation, 3) DCM data analysis and report-writing, 4) feedback of results to care staff and leadership, 5) action-planning by care staff based on the DCM results and 6) realization of the action plan.

Comparison group 1: This group receives the same intervention like the intervention group. The difference to the intervention group is that the 3 included nursing home units are experienced in the use of Dementia Care Mapping. The DCM process has been ongoing since 2009 in the comparison group units.

Comparison group 2: Based on the quality assurance criteria of the German medical advisory service of the statutory health insurance about the well-being of people with dementia and the integration of study results into the care process, it was not possible designate 1 group to care as usual. The dementia-specific measurement QUALIDEM was selected as a comparison intervention because it is known in Germany and, therefore, is a feasible option for assessing Qol in nursing homes. The assumption is that simply measuring Qol leads to a greater awareness of Qol by caregivers and supports the discussion on how to maintain or enhance it. For comparison group 2, the use of the QUALIDEM as a Qol assessment tool is nested in the following intervention components:
1. A short (1.5 hours) training program for staff on the 3 units, including some general information about Qol assessment for people with dementia and the usage of QUALIDEM in particular.
2. QUALIDEM usage as follows

a. An initial Qol-rating will be given to all residents with dementia within 3 months of the training (October December 2012).
b. An additional Qol assessment will be conducted if notable changes in the residents needs are perceived. At least every 6 months, a new Qol assessment must be carried out. The Qol assessments will always be based on the proxy-rating agreements of 2 staff members (nurses or social workers) in relation to a retrospective observation period of 2 weeks.
c. If necessary, staff will initiate case conferences based on the results of the Qol ratings, to understand the individual needs of a particular resident. The care team will participate in these case conferences.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Quality of Life of people with Dementia measured with the Qol-AD proxy-measurement
2. Caregivers attitutes towards dementia meausred with the Attitudes to Dementia Questionnaire

Measured at baseline measure, a first follow up after 6 months and a second follow up after 20 months.

Key secondary outcome(s)
1. Quality of Life of people with Dementia measured with the QUALIDEM proxy-measurement
2. Challenging behavior of people with Dementia measured with the NPI-NH proxy-measurement
3. Caregivers job satisfaction (measured with the COPSOQ) and personal burnout (measured with the CBI)

Measured at baseline measure, a first follow up after 6 months and a second follow up after 20 months.

Completion date
30/04/2013

Eligibility

Key inclusion criteria
1. People with dementia in 9 participating nursing homes units from the Knights of St. John of Jerusalem Nursing Home Section West.
2. People with dementia with a length of stay > 2 weeks on the respective nursing home unit
3. Caregivers from the 9 participating nursing homes units from the Knights of St. John of Jerusalem Nursing Home Section West.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
No informed consent for either patients or caregivers.

Date of first enrolment
15/04/2011

Date of final enrolment
30/04/2013

Locations

Countries of recruitment
Germany

Study participating centre
Stockumer Str. 12
Witten
Germany
58453

Sponsor information

Organisation
St. John Regional Centre West (Johanniter Regionalzentrum West) (Germany)

Funder(s)

Funder type
Government

Funder Name
The funding for this study is provided by Public Welfare Foundation North Rhine-Westphalia (Stiftung Wohlfahrtspflege Nordrhein-Westfalen) and the Knights of St. John Regional Centre West - Germany

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?
Results article	results	01/06/2013		Yes	No