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Delirium prevention in home dwelling older adults

Submission date
17/02/2016

Recruitment status
No longer recruiting

Registration date
19/02/2016

Overall study status
Completed

Last Edited
16/03/2016

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
Delirium is a state of mental confusion. One third of hospitalized older adults who develop delirium are discharged from hospital while they still have symptoms, or develop symptoms shortly after discharge or an illness. Therefore, strategies for early detection and prevention of delirium at home must be created. The aim of this study is to develop and test the effectiveness, feasibility and acceptability of a nursing intervention to detect and prevent delirium among older adults who were recently hospitalized or had an acute illness.

Who can participate?
People aged 65 or over who have been recently discharged from hospital

What does the study involve?
Participants are randomly allocated into an experimental group or a control group. The control group receives standard home care. The experimental group receives both standard home care and nursing interventions tailored to detect/prevent delirium at five times following discharge (at 48 hours, 72 hours, 7 days, 14 days, and 21 days). Delirium symptoms are assessed at the start of the study and after one month.

What are the possible benefits and risks of participating?
Benefits for participants include five supplementary home visits from an experienced study nurse addressing health care problems , supervision of their medication adherence and monitoring of their health status during the first month of hospital discharge. There are no risks for participants.

Where is the study run from?
Centre Médico-Social de Sion (Switzerland)

When is the study starting and how long is it expected to run for?
February to November 2012

Who is funding the study?
Institut et Haute Ecole de la Santé La Source (Switzerland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect estimation of an innovative nursing intervention to improve delirium among home-dwelling older adults: a randomized controlled pilot trial

Study objectives
The three hypotheses were, compared to older adults who receive usual care, those receiving the nursing preventive intervention over a month period have a significantly larger:
1. Decrease of delirium symptoms as measured by the Confusion Assessment Method (CAM)
2. Decrease of cognitive impairment as measured by the Mini Mental State Examination (MMSE)
3. Increase of functional independency as measured by the Katz and Lawton Index of activities of daily living/instrumental activities of daily living (ADL/IADL)

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethical Committee Valais, Switzerland, 15/11/2011, no CCVEM 030/11

Study design
Pragmatic randomized pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Prevention

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
Delirium among home dwelling older adults

Interventions
Control group
Participants in the control group received only the usual home care but were assessed for delirium symptoms at study entry (M1) after one month (M2) and in patient records during the study period. The amount of usual care depended on the patient's clinical status, the presence of informal caregivers, and the skill mix within the nursing workforce of the home health care center. The community health nurses conducted a total of 484 usual care visits during the study period, with an average of 2.28 (SD= 0.84) visits weekly pro participant.

Intervention group
In addition to the usual care and the delirium symptoms assessment mentioned before, each participant in the EG received five additional patient-centered nursing interventions. The community health nurses conducted a total of 452 usual care visits during the study period, with an average of 2.26 (SD= 1.34) visits weekly pro participant. The construction of the nursing intervention was based on the theoretical framework of prevention strategies from the Neuman System Model and from the Mapping Intervention Model of Bartholomew et al. It was completed with recommendations from different recent evidence-based guidelines as well as from geriatric friendly hospital recommendations.

All nursing interventions were dispensed by the research geriatric clinical nurse during home visits. This research nurse was trained by the PI over three days with the aim to assess delirium symptoms with the CAM and the health status of the participants, and to apply the five person-centered nursing interventions. These five interventions were structured according to six domains (assessment, detection, monitoring, support, dispensed care, health promotion, and education), 15 nursing intervention protocols (Appendices 1) and covered 70 nursing activities. The interventions had been previously judged and accepted by a panel of community nursing experts. Furthermore, the nursing interventions were adapted and standardized after being pre-

tested with five discharged home-dwelling older patients. A user guide was developed with the aim to structure and standardize application by the research GCN. This procedure permitted the interventions to be patient-centered during the home visits by selecting the most appropriate domains, nursing activities, and nursing protocols in relation with the clinical status of the older adults and the presence or not of delirium symptoms or risk factors.

Each intervention started with an assessment of the physical and cognitive status including the CAM, pain and biologic parameters such as blood pressure, temperature, heart rate, glycaemia, oxygen saturation and pain evaluation. In addition, delirium risk factors were also assessed such as constipation/diarrhea, dehydration, infections and additional prescribed/over the counter medications. Subsequently, the nursing interventions provided took into consideration the assessed health status and delirium risk factors. Finally, each intervention was concluded with two or three oral health promotion recommendations to the participant and informal caregiver. The first intervention was made within two days after consent of the participants. Intervention two to five were conducted at 3, 7, 14, and 21 days after their consent. This interval was based on the average duration of a delirium episode, which usually varies between three to seven days. Two assessment visits were planned for all participants at an interval of 30 days (M1 and M2).

Intervention Type
Mixed

Primary outcome measure
Symptoms of delirium assessed with the Confusion Assessment Method (CAM) at M1 and M2

Secondary outcome measures
1. Cognitive impairment measured by the Mini Mental State Examination (MMSE) at M1 and M2
2. Functional status measured by the Katz and Lawton Index of activities of daily living /instrumental activities of daily living (ADL/IADL) at M1 and M2

Overall study start date
01/01/2012

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. Aged 65 years or over
2. Recently discharged from hospital
3. Capable of understanding and answering questions in French

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Minimum 40

Key exclusion criteria
1. Outpatient treatment still going on within the hospital premises
2. A medical prescription for a single intervention of home health care
3. If they were outside the study reach

Date of first enrolment
15/02/2012

Date of final enrolment
01/11/2012

Locations

Countries of recruitment
Switzerland

Study participating centre
Centre Médico-Social de Sion
Avenue de la Gare 24
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Sponsor information

Organisation
Leenaards Foundation (Switzerland)

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Sponsor type
Research organisation

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ROR
https://ror.org/004h88r69

Funder(s)

Funder type
University/education

Funder Name
Institut et Haute Ecole de la Santé La Source (Switzerland)

Results and Publications

Publication and dissemination plan
The feasibility and acceptability publication has been accepted and is currently in press

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/04/2015		Yes	No
Results article	results	18/01/2016		Yes	No
Results article	results	14/03/2016		Yes	No