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Systematic pain assessment in elderly care: does it make a difference?

Submission date
03/09/2012

Recruitment status
No longer recruiting

Registration date
18/09/2012

Overall study status
Completed

Last Edited
01/03/2017

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Studies have shown that older people in residential living facilities suffer from pain. Pain can lead to reduced daily activities, extended need for nursing care and reduced quality of life. According to some studies, pain is often not identified and not fully treated, which can cause unnecessary suffering and reduce the quality of care. Assessing older people's pain is basic to adequate pain treatment. To date, the use of pain assessment procedures in clinical practice has not been well investigated. The aim of the study is to examine whether a caregiver intervention, including education on pain, and pain assessments increase quality of life among older people in residential living facilities.

Who can participate?
Older people living permanently in one of the 10 residential living facilities

What does the study involve?
Participating residential living facilities are randomly allocated into the intervention or the control group. Staff working at facilities in the intervention group attend a course on pain and pain assessments. The course lasts 3.5 hours together with follow-ups at the respective facilities. The subjects dealt with are: pain among older people, nursing care interventions, pain treatment, and introduction of the pain assessment scales. Data is collected on three occasions (in both groups): at the start of the study followed by repeated assessments one and a half months and five months later. Physical and cognitive (mental) abilities, medication, pain and quality of life are assessed. The caregivers perform the assessments at the intervention group facilities and the corresponding assessments are performed by research nurses at the control group facilities.

What are the possible benefits and risks of participating?
The results of the study could lead to improved knowledge among caregivers and improved pain treatment in elderly care, thus benefiting the older residents. Because the study examines the effect of pain assessments, there are no added risks.

Where is the study run from?
University of Gävle (Sweden)

When is the study starting and how long is it expected to run for?
March to December 2012

Who is funding the study?
1. University of Gävle (Sweden)
2. Swedish Dementia Foundation (Sweden)

Who is the main contact?
Dr Anna-Greta Mamhidir

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Systematic pain assessment in residential living facilities for older people: a cluster-randomized controlled trial

Study objectives
Systematic pain assessment will reduce pain, increase quality of life, reduce signs of discomfort and increase signs of good mood.

The aim of the study is to examine whether a caregiver intervention in residential living facilities, including education on pain, and subsequent pain assessments will increase quality of life and

change pain prevalence among older people (with and without cognitive deficits) compared to a control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethical Review Board in Uppsala, 08/02/2012, ref: 2012/016

Study design
Cluster-randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Patient information material can be found at http://www.hig.se/Ext/Sv/Organisation/Akademier/Akademin-for-halsa-och-arbetsliv/Forskning-vid-akademin/Forskningsprojekt.html (Swedish)

Health condition(s) or problem(s) studied
Residential living facilities for older people.

Interventions
The residential living facilities will be grouped into smaller (n=20-30) and larger facilities (n=40-60). All residential living facilities meeting the inclusion criteria will be randomized into either the intervention or the control group.

The intervention includes two parts carried out within a three-week period, and starts with a course on pain and subsequent administration of pain assessments (Dolpolus 2 scale and Mobid 2 scale). The course for registered nurses, assistant nurses, occupational therapists, physiotherapists, physicians and managers comprises 3.5 hours together with follow-ups at the respective facilities. The subjects dealt with are: pain among older people, nursing care interventions, pain treatment, and introduction of the assessment scales.

Data collection will be performed at three occasions (in both groups) and start with a baseline assessment, followed by repeated assessments after one and a half months and finally five months post-intervention.

The data collection occasions include: patients demographical data, medical diagnoses, medication, physical (Katz-ADL index, Alzheimers Disease Cooperative Study-Activities of Daily Living (ADCS-ADL scale) and cognitive ability (MMSE scale), scores on the Quality of Life in Late-Stage Dementia scale (QUALID) and WHO-5 wellbeing index, as well as patient record reviews

regarding pain and measurement. The pain assessments include visual analog pain assessments (Proxy-VAS), Doloplus 2 and Mobid 2 scales. All pain assessments begin with caregivers making visual analog pain assessments (Proxy-VAS) of the older people followed by the other assessments. At the start of the study, two pain assessments per resident will be conducted (Doloplus 2 and Mobid 2), and thereafter Doloplus 2 will be used once a month during the intervention period. In total about 380 caregivers will participate in the education.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Well-being (OUALID, WHO-5 index)
2. Proxy-VAS

Secondary outcome measures
1. Medication
2. Physical and cognitive ability
3. Documentation about pain

In addition, the psychometric properties of the pain assessment scales will be investigated.

Overall study start date
15/03/2012

Completion date
31/12/2012

Eligibility

Key inclusion criteria
Living permanently in one of the 10 residential living facilities in the municipality

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
A total of 270 older people in residential living facilities will be approached

Key exclusion criteria
1. Newly moved into the residential living facility, i.e., the person has lived there less than one month

2. Short time and respite care
3. Palliative care status

Date of first enrolment
15/03/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Sweden

Study participating centre
University of Gävle
Gävle
Sweden
SE-801 76

Sponsor information

Organisation
University of Gävle (Sweden)

Sponsor details
Kungsbäcksvägen 47
Gävle
Sweden
SE-801 76

Sponsor type
University/education

Website
http://www.hig.se/

ROR
https://ror.org/043fje207

Funder(s)

Funder type

University/education

Funder Name
University of Gävle (Sweden)

Funder Name
Swedish Dementia Foundation (Sweden)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
30/06/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Anna-Greta Mamhidir

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/02/2017		Yes	No