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Expanded nursing roles for person-centred care for people with cognitive impairment in acute care

Submission date
11/06/2023

Recruitment status
No longer recruiting

Registration date
12/06/2023

Overall study status
Completed

Last Edited
15/12/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
People with cognitive impairment often experience hospital stays as negative stress. They feel ignored, helpless, and/or threatened. Hospital staff are often conceptually inadequately prepared for the care of people with cognitive impairment. This can lead to unmet needs, such as unrecognised pain, thirst or itching, resulting in changed behaviour, complications, such as falls, or the occurrence of delirium. Person-centred care is a promising care model to meet the needs of people with cognitive impairment. To successfully implement and establish person-centred care approaches, experienced nurses acting as "change agents" are needed.
The aim of this study is to develop, implement and evaluate a complex intervention on person-centred care for people with cognitive impairment in acute hospitals. Person-centred principles are promoted on the wards by nurses in expanded roles (expanded practice nurses).

Who can participate?
Patients aged 65 years and above with cognitive impairment or at risk for cognitive impairment who are admitted to non-ICU wards at the University Hospital Cologne that care for at least 30 people with cognitive impairment per month

What does the study involve?
The study is conducted at the University Hospital Cologne on six non-ICU wards. The complex intervention is implemented in three intervention wards. The intervention consists of 14 components that reflect the role and tasks of the expanded practice nurses. Each ward receives two expanded practice nurses, who have acquired in-depth knowledge of person-centred care for people with cognitive impairment through 200 hours of training. The intervention is performed over a period of 6 months. Three control wards receive written and oral information on person-centred care. The length of hospital stay of people with cognitive impairment in the intervention and control wards will be compared.

What are the possible benefits and risks of participating?
Participants in the intervention group may benefit from the study as it aims to foster person-centred care for people with cognitive impairment. In addition, the study will extend the

understanding of the effects of the newly developed intervention. There will be no medical risk of participating for people with cognitive impairment and/or staff.

Where is the study run from?
University of Cologne (Germany)

When is the study starting and how long is it expected to run for?
March 2021 to February 2024

Who is funding the study?
Federal Ministry of Education and Research (Germany)

Who is the main contact?
Dr Martin Nikolaus Dichter, martin.dichter@uk-koeln.de

Study website
https://www.enrole-acute.uni-koeln.de/

Contact information

Type(s)
Principal Investigator

Contact name
Dr Martin N. Dichter

ORCID ID
https://orcid.org/0000-0002-5094-3723

Contact details
Gleueler Straße 176-178
Cologne
Germany
50935
+49 (0)221 478 34640
martin.dichter@uk-koeln.de

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
01GY2005

Study information

Scientific Title
Expanded nursing roles for person-centred care for people with cognitive impairment in acute care

Acronym
ENROLE-acute

Study objectives
The study aims to implement a complex intervention for person-centred care of people with cognitive impairment on non-ICU wards by nurses in expanded roles. By introducing person-centred principles, individual needs of people with cognitive impairment can be identified in time and thus complications can be reduced or avoided. This contributes to a reduction in the length of hospital stay.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/06/2023, Ethics Committee of the Medical Faculty of the University of Cologne (Office of the Ethics Committee, University of Cologne, Cologne, 50931, Germany; +49 (0)221 478 87916; ek-med@uni-koeln.de), ref: 23-1009_1

Study design
Single-centre non-randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
People with cognitive impairment in acute hospitals

Interventions
The complex intervention consists of a total of 14 components that reflect the role and tasks of expanded practice nurses in person-centred care:
1. Screening for cognitive impairment

2. Expanded nursing assessment
3. Planning person-centred interventions
4. Conducting person-centred interventions
5. Case conference discharge planning
6. Counselling significant others
7. Initiating consultations
8. Conducting consultations
9. Evaluating person-centred interventions
10. Training staff
11. Monitoring
12. Collaboration
13. Conceptual work
14. Nursing research

The tasks are divided into patient-related (1 - 9) and system-related (10 - 14). In preparation for their role, six expanded practice nurses receive a 200-hour training and a 2-week internship in hospitals with established advanced nursing roles. Two expanded practice nurses are assigned to each intervention ward. During the intervention phase, the expanded practice nurses receive support in the form of bi-monthly coaching sessions. During a kick-off meeting, the members of the interprofessional team of the intervention wards receive information on the study process and principles of person-centred care for people with cognitive impairments as well as on expanded nursing practice.

The control group consists of three non-ICU wards and receives optimised care in the form of an information session for nurses and physicians and written information on person-centred care.

Intervention Type
Behavioural

Primary outcome measure
Length of hospital stay (from study inclusion to hospital discharge), obtained from medical records after patient discharge

Secondary outcome measures
Patient level:
Measured at admission (t1), day 3 of hospital stay (t2), day 7 of hospital stay (t3), day 14 of hospital stay (t4), discharge (t5) and 30 days after discharge (t6):
1. Prevalence of delirium measured using the Confusion Assessment Method (CAM, short form), rated by the research team (t1, t2, t3, t4, t5)
2. Delirium subtype measured using the Delirium Motor Subtype Scale (DMSS-4), rated by nurses (t1, t2, t3, t4, t5)
3. Severity of delirium measured using the Confusion Assessment Method – Severity (CAM-S, short form), rated by the research team (t1, t2, t3, t4, t5)
4. Prevalence of pain measured using the Numeric Rating Scale (NRS), self-rated by patients. If the numeric rating scale is not feasible, the research team rates pain using the Pain Assessment in Advanced Dementia (PAINAD-G) (t1, t2, t3, t4, t5)
5. Undetected pain, defined as a discrepancy between the research team’s rating and nursing documentation of pain or administration of pain medication on demand (t1, t2, t3, t4, t5)
6. Prevalence of agitation measured using Cohen Mansfield Agitation Inventory (CMAI, hospital version), rated by nurses (t3, t4, t5)
7. Quality of sleep measured using Richards-Campbell-Sleep-Questionnaire (RCSQ), self-rated by

patients (t2, t3, t4, t5)
8. Sleep problems measured using single items, obtained from medical records (t2, t3, t4, t5)
9. Anxiety, stress and depression measured using Depression Anxiety Stress Scales (DASS, short form), self-rated by patients (t1, t3, t4, t5)
10. Quality of Life – self-assessment using Bath Assessment of Subjective Quality of Life in Dementia (BASQID), self-rated by patients (t5)
11. Quality of Life – proxy assessment using QUALIDEM, rated by nurses (t5)
12. Person-centred care assessed using Individualised Care Scale (ICS), rated by patients (t5)
13. Falls assessed using single items, obtained from medical records (t5)
14. Physical restraints assessed using single items, reported by nurses (t2, t3, t4, t5)
15. Prescription of psychoactive medication assessed using a list of predefined psychoactive medication, obtained from medical records (t5)
16. Mortality measured using single items, obtained from medical records (t5)
17. Stability of care arrangements assessed using single items, rated by patients or relatives in a telephone interview (t6)

Staff level:
Measured at baseline and 6 months:
1. Burden caused by challenging behaviour of people with cognitive impairment measured using 9-item Residents' Challenging Behaviour-related Distress Index (RCBI)
2. Perceived person-centred climate on wards measured using 59-item Person-Centred Practice Inventory – Staff (PCPI-S)

Cost evaluation:
In the economic evaluation, the mean total costs per group are compared. In addition, subgroup analyses according to gender, age groups, length of hospital stay and relative weight are conducted.

Process-related outcomes:
The accompanying process evaluation has three objectives:
1. To examine the implementation of the intervention components in terms of dose, reach, fidelity, and local adaptations
2. To examine the change processes in expanded practice nurses, interprofessional teams and patients as a result of the implementation of the intervention
3. To examine the contextual factors that influence the success of the implementation
A mixed-methods design will be used, following the MRC guidance for process evaluations of complex interventions and Gant's framework for process evaluations in cluster randomised trials. Process outcome measures will be assessed at five time points: TP0 (before training, internship, and kick-off meeting), TP1 (after training, internship, and kick-off event), TP2 (start of the intervention period), TP3 (after transfer or discharge of patients) and TP4 (6 months after the start of the intervention period).

Overall study start date
01/03/2021

Completion date
29/02/2024

Eligibility

Key inclusion criteria

Ward level:
1. Prevalence of at least 30 people with cognitive impairment per month according to data from hospital controlling
2. Non-ICU wards

Staff level:
1. Nurses, nurse assistants and physicians working on project wards during the intervention period

Patient level:
1. Patients aged 65 years and above
2. Patients with cognitive impairment or a risk for cognitive impairment, identified by:
2.1. Pre-existing diagnosis, defined by the following ICD-10 codes: F00.*, F01.*, F02.3, F02.8, F03, F05*, U51*
2.2. Need for clarification of neurocognitive disorder, assessed by outcome-oriented nursing assessment

AcuteCare (ePA-AC ©)
1. Risk for delirium, defined by a combination of predetermined risk factors

Participant type(s)
Patient, Health professional

Age group
Senior

Lower age limit
65 Years

Sex
Both

Target number of participants
Six project wards (approx. 720 people with cognitive impairment in total)

Key exclusion criteria
Ward level:
1. Intensive care units, intermediate care units, psychiatric wards, palliative care wards, paediatric wards

Staff level:
1. Other healthcare professionals

Patient level:
1. Patients with insufficient German language skills
2. Patients without capacity to give consent and without legal guardianship
3. Patients with a planned hospital stay of <48 hours
4. Patients in the terminal phase (end of life)

Date of first enrolment
13/06/2023

Date of final enrolment
30/11/2023

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Cologne
Kerpener Straße 62
Cologne
Germany
50937

Sponsor information

Organisation
University of Cologne

Sponsor details
Institute of Nursing Science
Gleueler Straße 176-178
Cologne
Germany
50935
+49 (0)221 478 65451
frank.jaeger@uk-koeln.de

Sponsor type
University/education

Website
https://www.uni-koeln.de/

ROR
https://ror.org/00rcxh774

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

Publication and dissemination plan
Planned publications in peer-reviewed journals

Intention to publish date
01/06/2024

Individual participant data (IPD) sharing plan
The datasets generated during the study will be available on reasonable request from Martin Dichter (Martin.Dichter@uk-koeln.de).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		14/12/2023	15/12/2023	Yes	No