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

Submission date	Recruitment status	[X] Prospectively registered		
11/06/2023	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/06/2023	Completed	Results		
Last Edited	Condition category	Individual participant data		
15/12/2023	Mental and Behavioural Disorders	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 personcentred 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 personcentred 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 personcentred 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

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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s))

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: TPO (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).

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

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

65 years

Sex

All

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

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes