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SENIORS-D: Person-centred care for people with dementia

Submission date	Recruitment status	[X] Prospectively registered
03/02/2021	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/02/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/01/2025	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Dementia is a general term for loss of memory, language, problem-solving and other thinking abilities that are severe enough to interfere with daily life. Alzheimer's is the most common cause of dementia.

People suffering from dementia (PwD) are often no longer able to express symptoms such as pain due to their illness. In order for these to be recognised and treated, a systematic recording and assessment of these distressing symptoms using a reliable instrument is required. The IPOS-Dem is a robust, high-quality, easy-to-use measurement instrument that was developed in England with the involvement of carers and relatives for the assessment of these distressing symptoms. There is currently no comparable instrument available in Switzerland. For use in Switzerland, the IPOS-Dem was translated and adapted to the Swiss cultural context. In a next step, the validity of the translated IPOS-Dem version will be evaluated in both the acute setting and community care setting in the German-speaking part of Switzerland.

Who can participate?

- Every person with dementia (diagnosed or verified by health care professionals).
- Relatives of the person with dementia, who are directly involved in the care.
- Nurses of any grade, who are directly involved in the care of the person with dementia.

What does the study involve?

Nurses and relatives are asked to complete the IPOS-Dem and additional assessment instruments at two time points. The time required to complete the documents varies between 10 and 30minutes.

What are the possible benefits and risks of participating?

PwD: Immediate overview about most critical symptoms to be addressed.

Relatives: Immediate overview about most critical symptoms to be addressed.

Nurses: Ability to assess symptom burden and -severity systematically and within a short period of time.

Relatives: potential emotional response due to the scale of the symptom burden and -severity

and consequent impact on PwD.
Nurses: potential emotional response due to the scale of the symptom burden and -severity and consequent impact on PwD.

Where is the study run from?
This study is run from 21 (updated 01/04/2022, previously: ten) different sites (acute care ward (hospital) and district nurse services) in the German-speaking part of Switzerland.

When is the study starting and how long is it expected to run for?
July 2020 to February 2023

Who is funding the study?
This project is funded from the Gloria Grathwohl-Palliative-Foundation: https://www.gloria-grathwohl-palliativ-stiftung.ch/ (Switzerland)

Who is the main contact?
Professor Dr Maria Schubert, maria.schubert@zhaw.ch

Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
BASEC-Nr. 2020-01872

Study information

Scientific Title
SENIORS-D Project: PerSon-cENtred care for people with dementIa: Outcome guided palliative caRe through impeccable recognition of relevant Symptoms, neeDs, and care issues.

Acronym
SENIORS-D

Study objectives
For this full psychometric validation, objectives are defined, which are of similar rank and follow a linear alignment and cannot be divided in primary and secondary objective:
To assess the validity and reliability of the Swiss-German IPOS-Dem
To assess interpretability of the Swiss-German IPOS Dem
To assess responsiveness to change of the Swiss-German IPOS Dem
To evaluate the construct validity of the IPOS-DEM with reference to the internal structure, convergent and discriminant validity

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/04/2021, Cantonal Ethics Committee Zurich (Stampfenbachstrasse 121, P8090 Zürich, Switzerland; +41 43 259 79 70; admin.kek@kek.zh.ch), ref: 2020-01872

Study design
Multicenter non-randomized quasi-experimental repeated measures intervention study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Recognition of burdensome symptoms and needs in people with dementia

Interventions
The nature of the intervention is the nurse's or relative's estimation and documentation of possible symptoms, which affect the PwD. The IPOS-Dem (instrument to be validated) is guiding the nurses' and relatives' estimation and documentation. In order to evaluate the psychometric properties of the IPOS-Dem, the intervention will be conducted at one time point (validity) and two time points (reliability, responsiveness to change, and interpretability) by the corresponding participants, who are looking after PwD. The exact same intervention will be conducted for each PwD included into the study.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 01/04/2022:
Burden of physical-, psychological, social-, and spiritual symptoms measured with the Integrated Palliative Care Outcome Scale for People with Dementia (IPOS-Dem), the German version of the Edmonton Symptom Assessment System (revised version) (ESAS-r), and the Nursing Diagnosis according to the NANDA-I Taxonomy. Measured at two-time points with a minimum of three days in between, i.e. at baseline and when the PwDs health status changes or at day 45, whichever comes first

Previous primary outcome measure:
Burden of physical-, psychological, social-, and spiritual symptoms measured with the Integrated Palliative Care Outcome Scale for People with Dementia (IPOS-Dem), the German version of the Edmonton Symptom Assessment Scale (MIDOS2), and the Nursing Diagnosis according to the NANDA-I Taxonomy. Measured at two-time points with a minimum of three days in between, i.e. at baseline and when the PwDs health status changes or at day 45, whichever comes first

Key secondary outcome(s))
Current secondary outcome measures as of 01/04/2022:
Measured at baseline and when the PwDs health status changes or at day 45, whichever comes first:
1. Functional Status measured with the German Version of the Edmonton Symptom Assessment System (revised version) (ESAS-r)
2. Quality of life in Dementia measured with the QUALIDEM
3. Australian Karnofsky Performance Scale (AKPS)
4. Global Rating of Change (GRC)

Previous secondary outcome measures:
Measured at baseline and when the PwDs health status changes or at day 45, whichever comes first:
1. Functional Status measured with the German Version of the Edmonton Symptom Assessment Scale (MIDOS2)
2. Quality of life in Dementia measured with the QUALIDEM

Completion date
28/02/2023

Eligibility

Key inclusion criteria
PwD (patients at home and/or on the acute geriatric ward):
1. PwD with a diagnosis of vascular dementia or Alzheimer disease, which is documented in the patient notes, or
2. PwD with dementia-like symptoms (cognitive impairment measured with the MMSE< 24, and people who are unable to self-report due to cognitive impairment will be included in this study
3. PwD, who have a next of kin or a legal guardian

Nurses and relatives (relatives at home and/or acute geriatric ward and district nurses or ward nurses):
1. Nursing staff and relatives must be at least 18 years of age. Nursing staff must have been employed at least six months
2. Nursing staff and relatives must be able to communicate (speak and understand) in German
3. Relatives, who care for a family member or close friend who is diagnosed with vascular dementia or Alzheimer disease or who presents with dementia-like symptoms

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Sex
All

Total final enrolment
193

Key exclusion criteria
PwD (patients at home and/or on acute geriatric ward):
1. PwD, who are dying when admitted to hospital
2. PwD, who have no next of kin and no legal guardian

Nurses and relatives (relatives at home and/or acute geriatric ward and district nurses or ward nurses):
1. Member of nursing staff or relatives younger than 18 years
2. Relative who is not involved in the daily care of PwD

Date of first enrolment
01/04/2021

Date of final enrolment

31/12/2022

Locations

Countries of recruitment
Switzerland

Study participating centre
pending
Switzerland
8400

Sponsor information

Organisation
Zurich University of Applied Sciences

ROR
https://ror.org/05pmsvm27

Funder(s)

Funder type
Charity

Funder Name
Gloria-Grathwohl Palliativ-Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Study website	21/12/2024	27/01/2025	Yes	No

Study website	11/11/2025	11/11/2025	No	Yes