

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

Submission date 03/02/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/02/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/01/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 30 minutes.

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

Study website

<https://www.zhaw.ch/de/gesundheit/forschung/pflege/projekte/seniors-d/>

Contact information

Type(s)

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/07/2020

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

Age group

Mixed

Lower age limit

18 Years

Sex

Both

Target number of participants

370

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

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Sponsor type

University/education

Website

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ROR

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Funder(s)

Funder type

Charity

Funder Name

Gloria-Grathwohl Palliativ-Foundation

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

01/01/2025

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		21/12/2024	27/01/2025	Yes	No