DRKS-ID: **DRKS00022339**
Date of Registration in DRKS: **2020/10/05**
Date of Registration in Partner Registry or other Primary Registry: **[---]***

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Trial Description

Title

Burden of disease of people with dementia in nursing homes measured by IPOS-Dem: a stepped-wedge cluster randomised controlled trial

Trial Acronym

IPOS-Dem

URL of the trial

https://www.heds-fr.ch/media/2272/fiche_projet_ako_ipos-dem.pdf

Brief Summary in Lay Language

In this study, we check the IPOS-Dem instrument for its validity (1). Also, we check if there is a long-term effect on the burden of disease when using the IPOS-Dem Instrument in nursing homes. IPOS-Dem should be capable of recognising and prioritising all Symptoms and Needs of people with dementia. Highlighting those symptoms and needs helps to reduce the burden of disease. As far as we know, this is the first study into long-term effects of such a needs and symptom assessment for people with dementia in nursing homes.
GOALS:
***To reduce the burden of disease in people with dementia.**
***To help the family frequently tell their understanding in an orderly way to nursing home staff.**
***To improve the display of value and results from nursing care.**
METHODS:
We include people with dementia, nursing staff of all qualification levels and family members. The study contains two interventions. All nursing homes will receive both interventions. Nurses and family members learn to use IPOS-Dem in the first intervention. During the second intervention, the staff gets coached in symptom management. The interventions inside the nursing homes last 17 months.
BACKGROUND:
People with dementia often suffer from more than one disease and symptoms. Often the symptoms and illnesses are not well treated. In turn, this leads to unnecessary suffering and stress, lowering the quality of life for people with dementia. Diversity among people with dementia and cognitive manifestations (e.g. impaired memory or communication) may lead to misinterpretation or dismissal of needs and symptoms. While swiss nursing homes use routine assessments like RAI or BESA for regular examination, documentation and tariff, only authorised nurses may utilise them. Validated holistic assessment instruments (e.g. IPOS-Dem) may support staff and family to reveal the needs of

Brief Summary in Scientific Language

This study will be conducted as a stepped wedge design (SW-CRT), involving two complex interventions for people with dementia in nursing homes. 13 nursing homes will be randomized in three steps. In three monthly intervals, 4-5 nursing homes will switch from the intervention 1 to the intervention 2 at given periods

**until all nursing homes are applying the intervention.
The study will train family members and nurses in nursing homes in their symptom assessment based on an instrument which is called IPOS-Dem (Integrated Palliative care Outcome Scale for Dementia). The training will include systematic observation training in assessing unmet needs of people with dementia (complex intervention no 1). Nurses will be also trained in symptom management (complex intervention no 2).**

Do you plan to share individual participant data with other researchers?

Yes

Description IPD sharing plan

Dataset: Expected mid 2022, indexed and for download on https://zenodo.org/ (eventually embargoed, dependant on publisher)

Organizational Data

- DRKS-ID: **DRKS00022339**
- Date of Registration in DRKS: **2020/10/05**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2019-01847 , Kantonale Ethikkommission Zürich**
  Stampfenbachstrasse 121
  Postfach
  8090 Zürich

Secondary IDs

- Universal Trial Number (UTN): **U1111-1254-4246**
- Other Secondary-ID: **SNCTP000003941 (SNTCP)**
- Other Secondary-ID: **2019-01847 (BASEC-ID)**

Health condition or Problem studied

- Free text: **Dementia, Alzheimer**
- ICD10: **F00 - Dementia in Alzheimer disease**
- ICD10: **F01 - Vascular dementia**
- ICD10: **F02 - Dementia in other diseases classified elsewhere**
- ICD10: **F03 - Unspecified dementia**

Interventions/Observational Groups

- Arm 1: **The study will train family members and nurses in nursing homes in their symptom assessment based on an instrument which is called IPOS-Dem (Integrated Palliative care Outcome Scale for Dementia). The training will include systematic observation training in assessing unmet needs of people with dementia (complex intervention no 1).**
- Arm 2: **Nurses will be also trained in symptom management (complex intervention no 2).**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Supportive care**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Burden of disease (BOD):
The primary endpoint of this study is the reduction of burden of disease (BOD), measured with the total IPOS-Dem score (sum-score) in PwD compared to before and after the interventions. The primary endpoint will be assessed with the clinically relevant difference of 8 between baseline, and month 1-17.

Secondary Outcome

The secondary endpoint of this study is the improvement (= significant improvement of $p<0.05$) of Quality of life in PwD measured with the QUALIDEM outcome measure. The QUALIDEM will be measured every three months for 17 months. Longitudinal, total domain scores for PwD will be calculated and illustrated to demonstrate the quality of life trajectory.

Countries of recruitment

- CH **Switzerland**

Locations of Recruitment

- other **Zürich**
- other **Aargau**
- other **St. Gallen**
- other **Bern**
- other **Uri**
- other **Wallis**
- other **Luzern**
- other **Basel-Land**
- other **Thurgau**
- other **Solothurn**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/10/01**
- Target Sample Size: **260**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

(1) Nursing Homes (NH): at least 8 People with dementia (PWD), use BESA or RAI for Routine Assessment; (2) PWD: Diagnosed with Alzheimers' disease or vascular dementia OR Symptoms of Dementia documented in NH Records.; (3) Nursing Staff: At least 18 years old, employed in respective NH for at least three months with a quota equivalent to at least 20% (= working one day per week), speak german; (4) Relative: family member OR legal guardian of PWD fullfilling criteria listed above (2)

Exclusion criteria

(1) PwD, who are hospitalised during the recruitment phase and therefore not physically in the nursing home at the time of study start; (2) Relative: family member OR legal guardian of PWD fullfilling criteria listed above (1)

Addresses

- **Primary Sponsor**

  Heds FR, School of Health Professions
  Ms. Professor Andrea Luise Koppitz
  Route des Arsenaux 16a
  1700 Freiburg
  Switzerland

  Telephone: **+41 26 429 60 44**
  Fax: **[---]***
  E-mail: **andrea.koppitz at hefr.ch**
  URL: **https://www.heds-fr.ch/de/forschung/forschungsbereiche/altern/**

- **Contact for Scientific Queries**

  Heds FR, School of Health Professions
  Ms. Professor Andrea Luise Koppitz
  Route des Arsenaux 16a
  1700 Freiburg
  Switzerland

  Telephone: **+41 26 429 60 44**
  Fax: **[---]***
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- **Contact for Public Queries**

  Heds FR, School of Health Professions
  Ms. Professor Andrea Luise Koppitz
  Route des Arsenaux 16a
  1700 Freiburg
  Switzerland

  Telephone: **+41 26 429 60 44**
  Fax: **[---]***
  E-mail: **andrea.koppitz at hefr.ch**
  URL: **https://www.heds-fr.ch/de/forschung/forschungsbereiche/altern/**

- **Collaborator, Other Address**

  Heds FR, School of Health Professions
  Mr. Frank Spichiger
  Route des Arsenaux 16a
  1700 Freiburg CH
  Switzerland

  Telephone: **+41 26 429 60 86**

Collaborator, Other Address

Heds FR, School of Health Professions
Mr. Frank Spichiger
Route des Arsenaux 16a
1700 Freiburg CH
Switzerland

Telephone: **+41 26 429 60 86**
Fax: **[---]***
E-mail: **frank.spichiger at hefr.ch**
URL: **[---]***

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

  Schweizerische Akademie der Medizinischen Wissenschaften
  Haus der Akademien, Laupenstrasse 7
  3001 Bern
  Switzerland

  Telephone: **+41 311 306 92 70**
  Fax: **[---]***
  E-mail: **mail at samw.ch**
  URL: **https://www.samw.ch**
- **Private sponsorship (foundations, study societies, etc.)**

  Gottfried und Julia Bangerter-Rhyner-Stiftung
  Lange Gasse 15, Postfach
  4002 Basel
  Switzerland

  Telephone: **+41 61 277 01 22**
  Fax: **[---]***
  E-mail: **info at bangerter-stiftung.ch**
  URL: **http://www.bangerter-stiftung.ch/bangerter/de/stiftung/portrait.html**

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

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* *This entry means the parameter is not applicable or has not been set.*
*** *This entry means that data is not displayed due to insufficient data privacy clearing.*