ISRCTN19637698 https://doi.org/10.1186/ISRCTN19637698

Dementia as a living environment

Submission date 28/03/2024	**Recruitment status** No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 13/08/2024	**Overall study status** Ongoing	☐ Statistical analysis plan
		☐ Results
Last Edited 13/08/2024	**Condition category** Other	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

It is estimated that approximately 10,000 people with dementia (PmD) live in South Tyrol, most of whom are cared for at home by their relatives. The irreversible and progressive cognitive changes in the course of the disease are accompanied by an increased need for care on the part of PmD and an increasing need for support on the part of caregivers. As a result of their care activities, primary caregivers themselves are exposed to a significantly increased psychological and physical risk of morbidity, from which both the caregivers themselves, PmD and the healthcare system suffer. Numerous studies confirm that the relief of family caregivers or the improvement of outpatient care has a significant influence on the health and well-being of the caregiver and his or her patient, and thus the long-term continuation in the home environment is ensured by the maintenance of a positive and resource-friendly care situation. Particularly in South Tyrol with its rural and partly structurally weak areas, which are exposed to strong processes of social and economic change, there are longer care paths for PmD with additional multimorbidity and a more difficult guarantee of medical, nursing and social care at home. In the field of dementia, this implies the need for innovative and flexible care pathways, the development and implementation of which require the identification of needs and the currently available relief system. The burden of care is modulated by both disease-related and socio-demographic factors influencing the primary caregiver and PmD. It is also a multifactorial construct further influenced by the structure of available supply (e.g. emergency services). To provide the best possible range of care to reduce the burden of care, it is useful to identify these influencing factors as a guide. In this context, the main objective of the planned study is to generate a comprehensive analysis of the stress and needs of PMD home care in South Tyrol.

Who can participate?

Adult persons living in South Tyrol (family members and 'carers') who care for a PmD in their home environment and act as responsible (lay) caregivers.

What does the study involve?

Participants will have already submitted an initial application for a care degree or an application for an increase in the care degree for the person being cared for. Based on the study results, the goal is to develop optimised counselling and care. Furthermore, the findings will be available to family counsellors and decision-makers in the health care system and politics. The study is expected to generate empirical data focussing on the needs and demands of informal caregivers to strengthen informal caregiver counselling.

What are the possible benefits and risks of participating?
Upon request, the participating caregivers may benefit from feedback on their personal, and individual health risks. Due to voluntary participation in the survey, there will be no risks.

Where is the study run from?
Institute of General Practice and Public Health, Claudiana College of Health Professions

When is the study starting and how long is it expected to run for?
May 2023 to December 2027

Who is funding the study?
Office of the Federal Government of Lower Austria

Who is the main contact?
Dr Barbara Plagg (Principal Investigator), barbara.plagg@am-mg.claudiana.bz.it

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Mrs Barbara Plagg

ORCID ID
https://orcid.org/0000-0002-6116-7504

Contact details
Lorenz Böhler Street 13
Bolzano
Italy
39100
+39 (0)471 067 392
barbara.plagg@am-mg.claudiana.bz.it

Additional identifiers

Protocol serial number
Versione no. 1 del 01.03.2024

Study information

Scientific Title
Factors influencing the care burden and needs analysis of main caregivers of people with dementia in home care in South Tyrol

Acronym
LIFEZ (LEBenswelt DemENZ)

Study objectives

Based on the objectives of the study, the following main questions arise:
1. What is the situation of people with dementia (PmD) care provision in South Tyrol? In which areas do the main PmD caregivers experience the most stress?
2. Which support and relief services do PmD and their main caregivers use, especially in rural South Tyrol?

Secondary questions:
1. Which enabling factors and obstacles in the use of existing health and social services are described by the main caregivers in the South Tyrolean care region? How low are the services offered?
2. What socio-demographic and specific (clinical) characteristics of dementia can be identified for PmD and their primary caregivers, which are understood as predictors of particularly vulnerable care situations with an (imminent) need for intervention?
3. What wishes and suggestions do affected persons and experts have for improving the care situation of PmD to enable PmD to remain in the home environment for as long as possible while easing the burden on the main caregiver?
4. How is communication and coordination between the actors involved (e.g. between service providers)? Which interfaces exist? What points of friction?
5. Is Dementia an issue in the public sphere (e.g. public events, awareness campaigns, social discourse, informal help and stigmatisation, etc.)?

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 13/12/2023, Scientific Ethics Committee of the Autonomous Province of Bolzano, Italy (Comitato etico, c/o Comprensorio Sanitario di Bolzano Italia) (Via Lorenz Böhler 15, Bolzano, 39100, Italy; +39 (0)471438272; comitatoetico.bz@sabes.it), ref: 104-2023

Study design

Mixed-methods study

Primary study design

Observational

Study type(s)

Diagnostic, Screening

Health condition(s) or problem(s) studied

Investigation of the reasons for using or not using informal caregiving counselling and the needs and individual demands of informal caregivers

Interventions

A mixed-methods study is planned to provide quantitative and qualitative data collection that answers the research questions as best as possible. A battery of questionnaires will be used for the main caregiver and the person with dementia, which consists of the following: socio-demographic information, anamnestic data on PmD, a survey on the use or availability of services, validated scales for the assessment of care burden, care intensity/need, support needs and an element for self-rated health. The qualitative part is conceived as a focus group of experts following the quantitative part. The previous analysis from the point of view of the persons concerned should lead to contrasting or comparative information from the point of view of an expert within the focus groups. It is expected that approximately 150 persons will fill out the questionnaires (90 minutes). The total duration of the study amounts to 2.5 years.

Intervention Type
Other

Primary outcome(s)
Reasons for using or not using care counselling are measured using self-report questions at baseline

Key secondary outcome(s))
The following secondary outcome measures are single-time assessments at the time of assessment:
1. Functional impairment in complex activities of daily living of the person with dementia is measured using the Lawton Instrumental Activities of Daily Living Scale (IADL)
2. Behavioral disturbances in the person with dementia are measured using the Neuropsychiatric Inventory (NPI)
3. Caregiver's needs for interventions are assessed using The Carers' Needs Assessment for Dementia (CNA-D)
4. Depression risk in the primary caregiver is measured using the Beck Depression Inventory (BDI)
5. Caregiver burden is measured using the Zarit Burden Interview (ZBI)
6. Self-rated health status of the primary caregiver is assessed using a single Likert-scaled question
7. Functional impairment in personal care activities of the person with dementia is measured using the Barthel Index
8. Cognitive function of the person with dementia is measured using the Montreal Cognitive Assessment (MoCA)

Completion date
31/12/2027

Eligibility

Key inclusion criteria
Adult informal carers in South Tyrol

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

1. Main caregivers who are unable to adequately communicate in the study's language without the need for language mediators or similar assistance.
2. Main caregivers who do not actively provide care for the dementia patient, regardless of their degree of kinship.
3. Main caregivers who are not willing or able to complete the questionnaire under the guidance and support of the study director or psychologist.

Date of first enrolment
01/03/2024

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
Italy

Study participating centre
Institute of General Practice and Public Health Claudiana College of Health Professions
Lorenz Böhler Street 13
Bolzano
Italy
39100

Sponsor information

Organisation
Landesfachhochschule für Gesundheitsberufe Claudiana

ROR
https://ror.org/051nxta34

Funder(s)

Funder type
Government

Funder Name
Amt der NÖ Landesregierung

Alternative Name(s)

Office of the Federal Government of Lower Austria, Office of the Lower Austrian State Government, Office of the Lower Austrian government, Government of Lower Austria, Lower Austria Government, Office of the Government of Lower Austria, Niederösterreichs, Amt der Niederösterreichischen Landesregierung

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Austria

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request at the Secretarial Office, info@am-mg.claudiana.bz.it. The type of data that will be shared includes individual data for patients' baseline characteristics, outcome measures, and study site characteristics. The data will be available for access after the study has been completed and the data has been fully processed and anonymized. Consent from participants was obtained, and all data will be fully anonymized to protect participants' privacy. The data will be fully anonymized, including patients' and GP offices' information, to ensure confidentiality. There are no ethical or legal restrictions on sharing the data as long as proper data anonymization procedures are followed. Additional comments: The research team value data transparency and aim to share the data in a responsible and secure manner to support further research and scientific inquiry.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			15/04/2024	No	Yes
Participant information sheet			15/04/2024	No	Yes