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Effectiveness, feasibility, and acceptability of a novel family practice-based integrative care model for family caregivers of dementia patients

Submission date
21/09/2021

Recruitment status
No longer recruiting

Registration date
12/10/2021

Overall study status
Completed

Last Edited
12/10/2022

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Dementia is a major burden for those affected and their family caregivers. The number of patients with dementia is increasing as a result of demographic developments. Involving family caregivers in the care of persons with dementia is essential. Family caregivers of individuals of dementia may be key players, but their multiple tasks often make them overburdened, depressed, and themselves multimorbid.
The aim of this study is to evaluate an integrated care model for family caregivers of individuals with dementia with respect to a) its effect on caregiver burden and b) practicability in Swiss primary care.

Who can participate?
Family caregivers of individuals with cognitive impairment.

What does the study involve?
Participating physicians and practice assistants (German: "Medizinische Praxisfachpersonen"; MPFPs) will be trained in the management of older patients with dementia. Subsequently, key family caregivers of individuals with dementia will be recruited in the setting of primary care. The coaching of these family caregivers will initially be 2-weekly, later 6-weekly - in four visits. In form of a questionnaire, the participating professional groups (MPFPs and physicians) will evaluate the intervention process. The family caregivers will evaluate the intervention process in form of a questionnaire and telephone interview.

What are the possible benefits and risks of participating?
The study intervention does not pose any additional risk to the participants and is expected to increase the participants' quality of life.

Where is the study run from?
The Institute of Primary Care of the University Hospital Zurich runs the study together with the Department of Health Science and Medicine of the University of Lucerne, Switzerland.

When is the study starting and how long is it expected to run for?
January 2021 to June 2024

Who is funding the study?
The study is partly funded by Alzheimer Schweiz (https://www.alzheimer-schweiz.ch) (Switzerland).

Who is the main contact?
1. Prof. Dr. Stefan Neuner-Jehle MPH (stefan.neuner-jehle@usz.ch)
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
AD_HOC_01

Study information

Scientific Title
Alzheimer's disease - HOme visit support for family Caregivers

Acronym
AD HOC-Study

Study objectives
1. Home assistance and support for family caregivers of persons with cognitive impairment leads to a stabilization of the burden or even to a reduced burden of these persons after 6 months (T6) compared to "usual care".
2. The model of care developed in this study integrates well with the primary care outpatient setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health services research not required to be approved. Confirmed by University of Zurich. Req-2021-00280

Study design
Superiority trial with a prospective nonclinical one-group pre-post-design

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Support for family caregivers of people with cognitive impairment in primary care.

Interventions

Family caregivers are coached initially on a 2-weekly basis, later on a 6-weekly basis - in four visits (= outreach) and two telephone calls. In the initial visit, practice assistants (German: "Medizinische Praxisfachperson"; MPFPs) systematically explore the family caregivers' current problems and stresses as well as their priority needs and objectives. On that basis, recommendations are developed and regional care services are selected. During the next visit /telephone call, the results of the exploration and the recommendations are reflected on together with the family caregivers and the specific next steps are defined. The MPFP use an interview guide to ensure the best possible standardization of the intervention.
The intervention phase including the follow-up period will take place between 01 January 2022 to 01 January 2024 (updated 08/08/2022, previously: to 31 December 2022)

Intervention Type
Behavioural

Primary outcome(s)
The burden of care, assessed using the ZBI (Zarit Burden Inventory) at the first home visit at T0 (baseline) and the last home visit at T5 (6 months after T0).

Key secondary outcome(s))
1. Change in the ZBI score of family caregivers between T0 and T6 (9 months after T0).
2. Change in quality of life, assessed using the EQ-5D-5L instrument, of family caregivers between T0 and T5.
3. Changes in quality of life of family caregivers between T0 and T6 (follow-up).
4. Health care utilization by dementia patients under care: Institutionalization, hospitalizations, medical consultations, emergency medical consultations, emergency department visits.

Completion date
01/06/2024

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Family caregiver of individuals with cognitive functional impairment ("Alzheimer's Disease", "Dementia" or "Development of a cognitive disorder")
3. Person who: 1) is perceived by the study physician/MPFP to be the key informal family caregiver of the index patient or, 2) is identified by the index patient as a key informal family caregiver or, 3) is identified by others (professional caregivers, legal representatives, family members) as the key informal family caregiver.

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Key exclusion criteria
1. Presence of cognitive impairment
2. Insufficient language ability in German
3. Moribund case of the family caregiver or the index patient with a remaining life expectancy of <3 months

Date of first enrolment
01/06/2022

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
Switzerland

Study participating centre
Institute of Primary Care
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Sponsor information

Organisation
University and University Hospital of Zurich

Funder(s)

Funder type
Charity

Funder Name
Alzheimer Schweiz (www.alzheimer-schweiz.ch)

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	14/07/2021	06/10/2021	No	Yes