

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

<b>Submission date</b> 21/09/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/10/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/10/2022	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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](mailto:stefan.neuner-jehle@usz.ch))

2. Gino Bopp ([gino.bopp@usz.ch](mailto:gino.bopp@usz.ch))

## Contact information

### Type(s)

Scientific

### Contact name

Prof Stefan Neuner-Jehle MPH

### ORCID ID

<http://orcid.org/0000-0002-6260-8148>

### Contact details

Institute of Primary Care  
University and University Hospital of Zurich  
Pestalozzistrasse 24  
Zurich  
Switzerland  
8091  
+41 (0)44 255 98 55  
[stefan.neuner-jehle@usz.ch](mailto:stefan.neuner-jehle@usz.ch)

### Type(s)

Scientific

### Contact name

Mr Gino Bopp

### ORCID ID

<http://orcid.org/0000-0003-2517-0260>

### Contact details

Institute for Primary Care  
University and University Hospital Zurich  
Pestalozzistrasse 24  
Zurich  
Switzerland

8091  
+41 (0)44 255 85 09  
gino.bopp@usz.ch

## **Additional identifiers**

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
AD\_HOC\_01

## **Study information**

**Scientific Title**  
Alzheimer's disease - H0me 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

**Secondary study design**  
Non randomised study

**Study setting(s)**  
Home

## **Study type(s)**

Quality of life

## **Participant information sheet**

See additional files (in German)

## **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 measure**

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).

## **Secondary outcome measures**

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.

## **Overall study start date**

01/01/2021

## **Completion date**

01/06/2024

# **Eligibility**

## **Key inclusion criteria**

1. Age  $\geq 18$  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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

30-40

**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**

University and University Hospital of Zurich

Pestalozzistrasse 24

Zurich

Switzerland

8091

**Sponsor information**

## Organisation

University and University Hospital of Zurich

## Sponsor details

Prof. Dr. Stefan Neuner-Jehle MPH

Institute of Primary Care

Pestalozzistrasse 24

Zurich

Switzerland

8091

+41 44 255 98 55

stefan.neuner-jehle@usz.ch

## Sponsor type

Research organisation

## Website

<http://www.hausarztmedizin.uzh.ch/>

# Funder(s)

## Funder type

Charity

## Funder Name

Alzheimer Schweiz ([www.alzheimer-schweiz.ch](http://www.alzheimer-schweiz.ch))

# Results and Publications

## Publication and dissemination plan

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

## Intention to publish date

01/06/2024

## 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?
<a href="#">Participant information sheet</a>	version 2	14/07/2021	06/10/2021	No	Yes

