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A Swiss study on informal care patients and their caregivers

Submission date
14/02/2025

Recruitment status
Recruiting

Registration date
19/02/2025

Overall study status
Ongoing

Last Edited
17/02/2025

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
The Swiss Integrated Care (INCA) study aims to better understand supported family care - a care model where family members receive financial support and professional training to care for loved ones at home. In Switzerland and Europe, family caregiving is a critical part of long-term care, yet it can bring challenges such as stress, financial burden, and physical strain. This study investigates how supported family care affects the health, well-being, and quality of life of both caregivers and care recipients. It will explore: (a) the health and quality of life of patients receiving care, (b) the impact on caregivers, including their stress levels and resilience, and (c) how financial and other types of support influence informal caregiving. By collecting and analyzing data from Pflegewegweiser, a Swiss home care organization, the study aims to create a long-term knowledge base to improve home care policies and support structures.

Who can participate?
The study is open to two groups: (1) adult patients receiving supported family care through Pflegewegweiser in receipt of a Swiss health insurance nursing care prescription, and (2) adult caregivers (family members) who are providing care to a participating patient

What does the study involve?
The study primarily analyzes existing data that Pflegewegweiser already collects, such as (a) health and well-being assessments (e.g., surveys like PROMIS-29) and (b) daily care documentation from caregivers. Participants may be asked to complete additional surveys over time. All data are securely stored and analyzed at the University of Zurich/ETH Zurich. The study is designed to minimize burden—participants continue with their usual caregiving routine, with minor additional data collection.

What are the possible benefits and risks of participating?
Benefits: Participation does not come with direct personal benefits. Yet, participants will help improve our understanding of supported family care, leading to better policies and support for caregivers. The study will also generate evidence-based recommendations for family caregivers and home care providers. Participants will receive summaries of key findings, keeping them informed about the study's progress.

Risks: There are no physical risks since the study only involves data collection. A minor risk exists that personal data could be accessed by unauthorized persons. However, all data is encrypted and stored securely, while only a small team of researchers has access to personal information.

Participation is completely voluntary, and individuals can withdraw at any time.

Where is the study run from?
The study is conducted by the Epidemiology, Biostatistics and Prevention Institute (EBPI) at the University of Zurich (UZH) in collaboration with Pflegewegweiser GmbH, a Swiss home care organization.

When is the study starting, and how long is it expected to run for?
August 2024 to February 2035. The study will start recruiting in February 2025 and is planned to run for at least 10 years.

Who is funding the study?
1. Pflegewegweiser GmbH
2. The UZH EBPI, provide in-kind support (e.g., research resources).
**Future funding may come from additional research grants.

Who is the main contact?
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Additional identifiers

Protocol serial number
202401767

Study information

Scientific Title
The Swiss Integrated Care (INCA) study: establishing a cohort study of patients in reimbursed family care and their caregivers

Acronym
INCA

Study objectives
It is hypothesised that reimbursed (supported) informal care increases the (a) quality of life, (b) physical and mental health, (c) daily functioning, and (d) overall well-being of patients and their caregivers, and mitigates the overall burden on caregivers.

It is also hypothesised that the variability of these outcomes can be predicted by a unique combination of predictors including, for example, the type and amount of supported family care received, and that predictive algorithm based on either (a) traditional statistical methods, (b) machine learning models, or (c) a combination of these, can predict key outcomes, including quality of life and care needs, both as point estimates and trajectories.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/01/2025, Cantonal Ethics Commission, Canton of Zurich (Stampfenbachstrasse 121, Zurich, 8090, Switzerland; +41432597970; admin.kek@kek.zh.ch), ref: 2024-01767

Primary study design
Observational

Study design
National single-centre observational longitudinal cohort study

Study type(s)
Other, Prevention, Quality of life

Health condition(s) or problem(s) studied
Prevention of negative health outcomes and promotion of health-related quality of life among patients in supported informal care in Switzerland.

Interventions
Supported informal care: Financial, emotional, and social support for informal caregivers.

Enrollment will be initiated and supported by trained nurses hired by the home care agency Pflegewegweiser and additionally trained by the study team. During a face-to-face visit at the patient's home, all eligible participants (patients and their caregivers) will receive a printed flyer with summarized study information and QR-codes/links to the study information sheet and an electronic informed consent form via the REDCap data management system.

Enrollment starts with the provision of written, electronic informed consent. After enrollment, participants will initially have no additional tasks to complete. Cohort participation primarily means that the study team can reuse the data routinely generated through the reimbursed informal care contract between patients, caregivers, and the home care agency Pflegewegweiser (see primary and secondary outcomes) for scientific purposes.

Pflegewegweiser staff will perform data downloads of the data of those clients who provided informed consent and prepare the data files according to the Data Sharing Agreement. They will provide the password-protected datasets over a secure access-controlled transfer system to the study team. The study team will store two files of each downloaded dataset: one containing identifiable information only and another with pseudonymized (coded) data used for all analyses. Additional surveys may be introduced at later stages and once new research questions arise and will be voluntary.

The cohort study is initially planned for ten years. Participants will be followed up for as long as they do not withdraw, are alive, and receive reimbursed informal care services from Pflegewegweiser. Participants can withdraw at any time, after which their collected data is anonymized for continued research use.

Intervention Type
Other

Primary outcome(s)
Health-related quality of life of patients will be measured using the PROMIS-29 (Patient-Reported Outcomes Measurement Information System) questionnaire at month 1 and every following month

Key secondary outcome(s)
1. The needs and preferences of patients will be measured using the interRAI HCSchweiz (International Resident Assessment Instrument Home Care Switzerland) questionnaire at baseline and then every six months
2. Caregiver resilience and burden will be measured using the FARBE (“Fragebogen zur Angehörigenresilienz und -belastung”) questionnaire in regular intervals.
3. Provided care will be captured through the daily care documentation of caregivers. Every day, caregivers will be requested to describe one care task (free text). Caregivers will be also asked to rate their sense of security while performing the task on a 10-point scale, ranging from 0 (very insecure) to 10 (very secure). Following this, they evaluate the well-being of the person they are caring for, choosing from the options ‘very good’, ‘good’, ‘normal’, ‘bad’, and ‘very bad’. They will then be asked to provide a reason for the patient's current state of well-being, using either text or the speech transcription function.

Completion date
25/02/2035

Eligibility

Key inclusion criteria
The study is open to two groups:
Patients receiving supported family care through a nursing care prescription from Swiss health insurance and a general practitioner who are:
1. 18 years old and over
2. Registered with the home care agency Pflegewegweiser
3. Fluent in German and cognitively capable of providing written informed consent

Caregivers (family members) who are:
1. 18 years old and over
2. Provide care to a participating patient
3. Understand German and are capable and providing written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Not meeting the participant inclusion criteria

Date of first enrolment
24/02/2025

Date of final enrolment
24/02/2035

Locations

Countries of recruitment
Switzerland

Study participating centre
University of Zurich
Hirschengraben 84
Zurich
Switzerland
8001

Sponsor information

Organisation
University of Zurich

ROR
https://ror.org/02crff812

Funder(s)

Funder type
Industry

Funder Name
Pflegewegweiser GmbH

Funder Name
Universität Zürich

Alternative Name(s)
University of Zurich, University of Zurich, Switzerland, UZH CH, UZH

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly repository of Pflegewegweiser GmbH, the University of Zurich and ETH Zurich.

IPD sharing plan summary
Stored in non-publicly available repository