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Progression in home care: Motivational counselling for informal caregivers – survey (phase I)

Submission date 08/07/2022	**Recruitment status** No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 07/09/2022	**Overall study status** Completed	☐ Statistical analysis plan ☐ Results
Last Edited 14/12/2023	**Condition category** Other	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims
Caring for a relative in the home environment is a great challenge for many informal caregivers, which can be accompanied by physical, psychological and economic risks. In order to support caregivers in this challenging situation, there is a need for systematic relief, e.g. through early counselling. However, current results of previous studies show that only 7% of all caregiving relatives have made use of such counselling "recently". In general, existing professional support services to relieve caregiving relatives are hardly used. In previous research, possible reasons for this low utilisation have rarely been investigated.
The aim is to investigate the reasons for using or not using informal caregiver counselling as well as the needs and individual demands of informal caregivers of relatives suffering from different diseases. The study will focus on care counselling for informal caregivers, which plays a key role in supporting caregivers and has been "underutilized" so far.

Who can participate?
Adult informal caregivers in Germany

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. During the recruitment period, they will be contacted by the care advisors of the MD Bayern in the course of an assessment interview. 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. We expect 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?
Centre for Health Services Research, Universitätsklinikum Erlangen, Friedrich-Alexander-Universität Erlangen-Nürnberg (Germany)

When is the study starting and how long is it expected to run for?
January 2022 to June 2023

Who is funding the study?
Reinhard Frank-Stiftung Foundation (Germany)

Who is the main contact?
1. Dr Anna Pendergrass (Principal investigator; Germany)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
20-220_2-B

Study information

Scientific Title
Progression in home care: Motivational counselling for informal caregivers – survey (phase I) ProCare

Acronym
ProCare

Study objectives
To identify factors related to the use of informal caregiver counselling.
Exploratory objectives include:
1. The needs and individual demands of informal caregivers
2. The detailed reasons for using or not using informal caregiver counselling
3. Other important aspects such as the immigration background of informal caregivers

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/03/2022, Friedrich-Alexander-Universität Erlangen-Nürnberg (FAU) Ethics Committee (Krankenhausstraße 12, 91054 Erlangen, Germany; +49 (0)9131 85-22270; ethikkommission@fau.de), ref: 20-220_2-B

Study design

Observational single-centre cross-sectional study

Primary study design

Observational

Study type(s)

Other

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

25000 questionnaires will be distributed to adult informal caregivers by 500 care assessors of the "Medizinischer Dienst (MD) Bayern". The participants will have made an initial application for a care degree or an application for an increase of the care degree for the person to be cared for and will have their assessment interview with care assessors of the “Medizinischer Dienst Bayern (MD Bayern)” during the recruitment period. After this assessment interview, all informal caregivers will be informed about the study and will receive the questionnaire documents if they are interested in participating. The informal caregivers will be able to decide autonomously whether they want to participate in the study or not. Based on the authors´ experiences in a previous study, it is expected that approximately 5000 of the 25000 persons will fill out the questionnaire (duration of 20 minutes). The questionnaire will be returned within a period of three to six months. The total duration of the study amounts to one year and six months.

Intervention Type

Other

Primary outcome(s)

Reasons for using or not using care counselling are measured by self-report questions at baseline

Key secondary outcome(s))

All measured at baseline:
1. Subjective burden of caregivers measured using the Burden Scale for Family Caregivers -short form (BSFC-s)
2. Quality of life of caregivers measured using a visual analogue scale (VAS) taken from the CarerQol-questionnaire
3. Benefits of being a caregiver measured using the Benefits of Being a Caregiver scale (BBCS)
4. Coping strategies measured using the COPE 6, derived from the Brief COPE questionnaire
5. Loneliness of caregivers measured using the Short Scale for Measuring Loneliness
6. Physical activity of caregivers measured using questions based on the RKI Survey Gesundheit in Deutschland aktuell
7. Sources of information on care-related topics measured using questions based on Gräßel et al

8. Evaluation of the current care situation measured using questions based on the stress appraisal model of Lazarus
9. Utilization of formal support measured using questions based on the Dementia Assessment of Service Needs (DEMAND) questionnaire
10. Relationship quality measured via self-report
11. Physical and mental health of caregivers measured using questions based on the Short-Form-Health-Survey (SF-12)
12. (Sociodemographic) data of caregivers including immigration status measured via self-report
13. Utilization of informal support measured via self-report
14. (Sociodemographic) data of care receivers measured via self-report
15. Activities of daily living, instrumental activities of daily living, and supervision are measured by self-report questions

Completion date
30/06/2023

Eligibility

Key inclusion criteria
Adult informal carers in Germany

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/09/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Germany

Study participating centre

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Sponsor information

Organisation
Reinhardt Frank-Stiftung Foundation

Funder(s)

Funder type
Charity

Funder Name
Reinhardt Frank-Stiftung Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Anna Pendergrass (anna.pendergrass@uk-erlangen.de). Data will be available in the time interval from 12 months until 36 months after publication of the article. The data will be provided for non-commercial research purposes only to researchers with a proposal that was peer-reviewed and approved by an independent review committee. The inquiring researchers have to present an analysis plan and state the research purpose for which the data are needed, e.g. meta-analysis. Data will be available without any additional investigator support. The data that can be provided refer solely to the data underlying the presented results of the manuscript. They will be completely anonymized, linkage to the stored data with personal information will not be possible, thus case-specific additional information/clarification cannot be provided anymore.

IPD sharing plan summary
Available on request