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Needs and demands of informal caregivers [Bedürfnisse und Bedarfe pflegender Angehöriger]

Submission date	Recruitment status	☐ Prospectively registered
07/09/2023	No longer recruiting	☐ Protocol
Registration date	Overall study status	☐ Statistical analysis plan
02/10/2023	Completed	☒ Results
Last Edited	Condition category	☐ Individual participant data
22/01/2026	Other	

Plain English summary of protocol
Background and study aims
Despite the various professional support services that already exist to reduce the burden on informal caregivers, the utilisation of these services is currently low. Apart from the care receivers´ fear of losing their independence, the lack of knowledge about existing services is a possible reason for the low utilisation of these services. In addition, it is essential that professional support services actually meet the needs of informal caregivers (e.g. which specific services are desired or needed by the informal caregivers and to what extent). Preliminary work shows that although there is a high need for various support services, the overall utilisation rate is low. In addition, it is still unclear which group of people specifically uses or can benefit from professional support services and which different needs (i.e. concrete expectations/wishes concerning support services, e.g. spiritual, emotional, etc) exist in informal care.
The overall aim of the study is to investigate the needs as well as the individual demands of informal caregivers who care for people suffering from different illnesses and different stages of illness in the form of a written survey (questionnaire) in all regions of the German federal state of Bavaria (Freistaat Bayern). In addition, some of the respondents will participate in a more in-depth investigation of aspects of their individual quality of life and spiritual needs using qualitative interviews. A second focus of the survey is to determine the reasons for the use or non-use of respite and support services for informal caregivers and their care receivers in Bavaria.

Who can participate?
The participants are adult informal caregivers in the German federal state of Bavaria (Freistaat Bayern) who 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 precursor study ProCare (https://doi.org/10.1186/ISRCTN1339092), 25,000 persons were contacted by the care advisors of the Medizinischer Dienst Bayern (MD Bayern) in the course of an assessment interview from September to December 2022 and received the first questionnaire. Participants of the current study are all persons who filled out the first questionnaire and gave their consent for further

questionnaires. Based on the authors' experience in previous studies, it is expected that about 6,000 of the 25,000 persons will fill out the first questionnaire and that approximately 1,500 will give informed consent for further questionnaires.

What does the study involve?
Based on the in-depth qualitative interviews and the quantitative longitudinal data, important insights into the Bavarian caregiver´s needs and demands will be provided. Furthermore, the researchers will determine what kind of professional support services have a positive effect on the home care situation, in particular on the informal caregivers. In summary with the findings on the reasons for non-use of care counselling and other support and respite services, strategies to improve their utilisation can be developed. This can make an essential contribution to strengthening home care for chronically ill people and to make it more future-proof. After all, informal caregivers will continue to be systemically relevant in the future. For this reason, measures should be taken now to encourage informal caregivers. This includes, quite essentially, that offers to mental and nursing respite are tailored to the needs and demands of family caregivers. Thus, an important contribution can be made to the future of home care in Bavaria.

What are the possible benefits and risks of participating?
Due to voluntary participation in the survey, there will be no risks. The researchers expect to generate empirical longitudinal data focusing on the needs and demands of informal caregivers to strengthen the home care situation in the German federal state of Bavaria (Freistaat Bayern).

Where is the study run from?
1. Centre for Health Services Research, Universitätsklinikum Erlangen, Friedrich-Alexander-Universität Erlangen-Nürnberg (FAU) (Germany)
2. Professur für Spiritual Care und psychosomatische Gesundheit, Klinikum rechts der Isar der Technischen Universität München (TUM) (Germany)

When is the study starting and how long is it expected to run for?
August 2022 to December 2024

Who is funding the study?
Bayerisches Staatsministerium für Gesundheit und Pflege (Germany)

Who is the main contact?
1. Dr Anna Pendergrass, anna.pendergrass@uk-erlangen.de
2. Prof. Dr Eckhard Frick, eckhard.frick@tum.de
3. Dr André Kratzer, andre.kratzer@uk-erlangen.de
4. Prof. Dr Elmar Graessel, elmar.graessel@uk-erlangen.de

Contact information

Type(s)
Principal investigator

Contact name
Dr Anna Pendergrass

ORCID ID
https://orcid.org/0000-0002-2492-0229

Contact details
Centre for Health Services Research
Universitätsklinikum Erlangen
Friedrich-Alexander-Universität Erlangen-Nürnberg
Schwabachanlage 6
Erlangen
Germany
91054
+49 (0)9131 85-34142
anna.pendergrass@uk-erlangen.de

Type(s)
Principal investigator

Contact name
Dr André Kratzer

ORCID ID
https://orcid.org/0000-0001-7906-3079

Contact details
Centre for Health Services Research
Universitätsklinikum Erlangen
Friedrich-Alexander-Universität Erlangen-Nürnberg
Schwabachanlage 6
Erlangen
Germany
91054
+49 (0)9131 85-34142
andre.kratzer@uk-erlangen.de

Type(s)
Principal investigator

Contact name
Prof Eckhard Frick

ORCID ID
https://orcid.org/0000-0002-6753-1004

Contact details
Professur für Spiritual Care und psychosomatische Gesundheit
Klinikum rechts der Isar
Technische Universität München (TUM)
München
Germany
80539
+49 (0)89 23 86 22 30
eckhard.frick@tum.de

Type(s)

Scientific

Contact name
Prof Elmar Graessel

Contact details
Centre for Health Services Research
Universitätsklinikum Erlangen
Friedrich-Alexander-Universität Erlangen-Nürnberg
Schwabachanlage 6
Erlangen
Germany
91054
+49 (0)9131 85-34142
elmar.graessel@uk-erlangen.de

Additional identifiers

Protocol serial number
20-220_3-B

Study information

Scientific Title
Needs and demands of informal caregivers - Longitudinal study to strengthen home care in Bavaria [Bedürfnisse und Bedarfe pflegender Angehöriger - Längsschnittstudie zur Stärkung der häuslichen Pflege in Bayern]

Study objectives
To investigate the needs and individual demands of informal caregivers focusing on two research objectives:
1. Identifying reasons for the use or non-use of caregiver support services and counselling services (questionnaire).
2. Investigation of aspects of the individual quality of life as well as spiritual needs of informal caregivers (qualitative interviews).
In addition, other important aspects such as sociodemographic data, migration background, reasons for care etc. and its relationship with use and non-use of support services and counseling services will be examined.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 08/08/2023, Ethis Committee of the Friedrich-Alexander-Universität Erlangen-Nürnberg (FAU) (Krankenhausstrasse 12, Erlangen, 91054, Germany; +49 (0)9131 85-22270; ethikkommission@fau.de), ref: 20-220_3-B

2. approved 02/09/2022, Ethics Committee of the Technische Universität München (TUM) (Grillparzerstraße 16, München, 81675, Germany; +49 (0)89 4140-7737; ethikkommission@mri.tum.de), ref: 2022-416-S-NP

Study design
Observational multi-centre longitudinal study including two data collection points

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Needs and individual demands of informal caregivers

Interventions
Quantitative data (collected by questionnaires) and qualitative data (collected by qualitative interviews) are collected over different data collection points.

In advance, a questionnaire was distributed for the first time by experts of the Medizinischer Dienst (MD) Bayern to informal caregivers in the German federal state of Bavaria in a separate research project ProCare (https://doi.org/10.1186/ISRCTN13390923). This provided the initial sample.

The present longitudinal study builds on this initial sample and focuses on follow-up measurements, especially on reasons for the use/non-use of central support services and possible positive effects through the use of these. These two quantitative follow-up surveys by means of questionnaires will take place with approx. 1,500 persons 12 months after the distribution of the first questionnaire in the ProCare project and with approx. 1,000 persons 18 months after the distribution of the first questionnaire in the ProCare project. In addition, approx. 50 persons will be interviewed by qualitative interviews; approx. 35 of these will be interviewed again after 12 months.

Intervention Type
Other

Primary outcome(s)
1. Reasons for using or not using support services and care counselling, measured using self-report questionnaires 12 months and 18 months after the distribution of the first questionnaire in the ProCare project (https://doi.org/10.1186/ISRCTN13390923).
2. Aspects of individual quality of life and spiritual needs of informal caregivers, measured using qualitative interviews at baseline and (for approx. 35 of the approx. 50 people to be interviewed) also 12 months later.

Key secondary outcome(s))
All measured 12 months and 18 months after the distribution of the first questionnaire in the ProCare project (https://doi.org/10.1186/ISRCTN13390923):
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. Evaluation of the current care situation measured using questions based on the stress

appraisal model of Lazarus
6. Health complaints measured using the Gießener Beschwerdebogen (GBB-24)
7. Depressiveness measured using the 9-item depression module of the Patient Health Questionnaire (PHQ-9)
8. Physical activity of caregivers measured using questions based on the RKI Survey Gesundheit in Deutschland aktuell
9. Loneliness of caregivers measured using the Short Scale for Measuring Loneliness
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 migration 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, measured by self-report questions

Completion date
31/12/2024

Eligibility

Key inclusion criteria
The participants are adult informal caregivers in the German federal state of Bavaria (Freistaat Bayern) who 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 precursor study ProCare (https://doi.org/10.1186/ISRCTN1339092), 25,000 persons were contacted by the care advisors of the Medizinischer Dienst Bayern (MD Bayern) in the course of an assessment interview from September to December 2022 and received the first questionnaire. Participants of the current study are all persons who filled out the first questionnaire and gave their consent for further questionnaires.

Participant type(s)
Carer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
995

Key exclusion criteria
Does not meet the inclusion critera

Date of first enrolment

01/09/2022

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Germany

Study participating centre
Center for Health Services Research in Medicine, Department of Psychiatry and Psychotherapy, Universitätsklinikum Erlangen, Friedrich-Alexander-Universität Erlangen-Nürnberg (FAU)
Schwabachanlage 6
Erlangen
Germany
91054

Study participating centre
Professur für Spiritual Care und psychosomatische Gesundheit, Klinikum rechts der Isar, Technische Universität München (TUM)
Kaulbachstraße 22a
München
Germany
80539

Sponsor information

Organisation
Bayerisches Staatsministerium für Gesundheit und Pflege (StMGP)

Funder(s)

Funder type
Government

Funder Name
Bayerisches Staatsministerium für Gesundheit und Pflege (StMGP)

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; regarding quantitative data from questionnaires) and from Prof. Dr Eckhard Frick (eckhard.frick@tum.de; regarding qualitative data from qualitative interviews). Data will be available in the time interval from 12 months until 36 months after the 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, and 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/06/2025	22/01/2026	Yes	No
Results article		10/11/2025	22/01/2026	Yes	No
Study website		11/11/2025	11/11/2025	No	Yes