Uniklinikum Erlangen

Information and declaration of consent

Progression in home care: Motivational counselling for informal caregivers – Implementation (Phase III)

Dear Madam or Sir,

With this study, we aim to make an important contribution to positively and sustainably influence your work as a care counsellor, the care counselling itself, and also the associated relief for informal caregivers.

We would like to support you in managing difficult counselling situations with motivational interviewing. To this end, the participating care counsellors will receive training on the topic of "Motivational interviewing for care counselling", which consists of a preliminary e-learning course and a two-day on-site training. This is followed by a voluntary follow-up phase. The training will be evaluated by a survey of participants before the training and immediately after the on-site training, after the voluntary follow-up phase, and 4 months after the end of the follow-up phase. In this way, the benefits of the training can be assessed and opportunities for further development can be provided. The aim is to make the training available to all care counsellors once our research project is complete and thus integrate motivational interviewing into the care counselling setting.
The study is being conducted by the Center for Medical Health Services Research (Director: Prof. Dr. med. Elmar Gräßel) at the University Hospital Erlangen. Participation in this study is voluntary on your part. Non-participation will not result in any disadvantages for you.

Procedure

As part of the project, we will provide you with free training on the topic of "Motivational Interviewing for care counselling". This consists of a brief organizational preliminary meeting, a preliminary e-learning module, and an on-site group training program. The training is followed by a six-week online follow-up phase. During the preliminary meeting, there will be an opportunity to ask questions. Additionally, the application of the e-learning module will be presented. The e-learning module conveys the theory of Motivational Interviewing (MI) with initial application examples and exercises in the setting of care counseling, thus laying the foundation for the subsequent on-site part. During this part, the existing theoretical knowledge of MI is further deepened through role-playing, case vignettes, exercises, and discussions. Additionally, sustainable structures are to be established by providing networking opportunities during the training and by offering an optional digital follow-up-support for six weeks after the training. In order to be able to assess and improve the quality and usefulness of the training, we kindly ask you to participate in the surveys associated with the training (further details can be found in the next section "Scientific Monitoring").

Scientific Monitoring

The project "Progression in home care: Motivational counselling for informal caregivers" is conducted by the Center for Medical Health Services Research at the University Hospital Erlangen. Dr. Anna Pendergrass is responsible for the project (Secretary's office phone: +49 9131/85-34142; Monday to Thursday mornings). Scientific monitoring entails that we would like to briefly survey you before and after the training, after the follow-up-support, and four months after the end of the fol-

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low-up-support. Simple questionnaires will be used for this purpose. You will therefore be asked to fill out a questionnaire at the beginning of the e-learning, at the end of the second day of the on-site training, as well as six weeks after the end of the second on-site day. The last survey takes place four months after the end of the follow-up support, i.e. approximately six months after the start of the training. All collected data will be treated confidentially, stored only in pseudonymized form (without names), and used exclusively for scientific purposes. It is therefore not possible at any time to "recognize" an individual person in the stored data.

General Information

It is my concern and motivation as the project manager to scientifically prove the expected positive effects of the training program. This depends on your participation! Only if as many people as possible are willing to take part can we succeed in using the results to create an enriching training for care counsellors and, consequently, for the clients as well, and making it available to all care counsellors. Participating does not pose any professional risks to you.

Participation is open to all individuals who:

- have completed training as a care counsellor
- are currently (at the time of the training) working in a care counselling context
- can attend at least 80% of the training course (equivalent to 20 lessons (1 lesson = 45 minutes) of "Motivational Interviewing for Care Counselling" in 2024
- have given their informed consent to participate in the study and are willing to take part in the evaluation

The collected data will be evaluated exclusively by project staff. All data will be electronically stored without any identifying information (pseudonymized). The evaluation for scientific purposes is therefore carried out without reference to the individual person! All data protection regulations are strictly adhered to. All employees involved in the project are bound to confidentiality.

Participation in the project is voluntary and free of charge for all. Non-participation or cancellation of participation (withdrawal of consent) is possible at any time, without stating reasons and without any disadvantages.

Contact person
PD Dr. Anna Pendergrass
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Psychiatric and Psychotherapeutic Clinic
Center for Medical Health Services Research
Prof. Dr. med. Elmar Gräßel

PD Dr. Anna Pendergrass
Schwabachanlage 6
91054 Erlangen

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Declaration of participation and data protection

- I have been informed that participation in the above-mentioned study is voluntary and that non-participation will not result in any disadvantages regarding my possible future medical care.
- I will participate in the above-mentioned study.
- I hereby confirm that I have received the written information about the study and that I have also been informed verbally.
- I hereby confirm that I had the opportunity to ask questions. All questions were answered satisfactorily.
- I have been informed and agree that my data will be electronically stored in pseudonymized form for the purpose of the above-mentioned research question. The results of the study will only be published in summarized form, ensuring that no conclusions can be drawn about individual persons. Only project staff have access to the key file linking names to data. Individuals outside the project team will not have access to original documents.
- I agree that the research team at the University Hospital Erlangen may contact me regarding this study even after the 6-month evaluation phase.
- I can withdraw this participation and consent statement at any time and without providing reasons, without suffering any disadvantages.

For legal reasons, we are obligated to provide you with the following detailed information on data protection according to the EU General Data Protection Regulation (GDPR) (see attached text in italics on pages 5 to 8). In summary, the information states that:

1) You can end your participation at any time without any disadvantages, and

2) The encrypted (pseudonymized) data collected up to that point will not be deleted.

Important: Your signature is required on the last page.

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Guidelines on Data Protection according to the EU General Data Protection Regulation (GDPR)

A. General information

1. *Legal basis for data processing: Your consent*
2. *Duration of storage: 10 years, in accordance with the storage period prescribed by the German Research Foundation (DFG) or the legally required archiving period for clinical studies.*

If you wish to exercise any of the rights listed below, please contact your study leader or the data protection officer of your study center. Additionally, you have the right to lodge a complaint with the supervisory authority/agencies if you believe that the processing of your personal data violates the GDPR:

1. *Contact details of the data protection officer of the study center*
   University Hospital Erlangen
   Data Protection Officer
   Krankenhausstr. 12
   91054 Erlangen
   Tel.: +49 9131 85 46810
   Email: datenschutz@uk-erlangen.de

2. *Name and contact details of the responsible persons at the study center:*
   University Hospital Erlangen
   Department of Psychiatry and Psychotherapy
   Center for Medical Health Services Research
   Prof. Dr. med. Elmar Gräßel and PD Dr. Anna Pendergrass
   Schwabachanlage 6
   91054 Erlangen
   Tel.: +49 9131 85 34142 (Monday to Thursday mornings)

3. *Contact details of the supervisory authority responsible for the study center and study management:*
   Bavarian State Commissioner for Data Protection
   Wagmüllerstr.18
   80538 München
   Tel. +49 89 2126720
   Email: poststelle@datenschutz-bayern.de

Schmidt J, *et al. BMJ Open* 2025; 15:e090454. doi: 10.1136/bmjopen-2024-090454

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B. General Rights

The right to erasure and to be "forgotten" is restricted insofar as your data is necessary for scientific research.

Further details can be found here:

1. ***Right to erasure ('right to be forgotten')***

   The data subject shall have the right to obtain from the controller the erasure of personal data concerning him or her without undue delay and the controller shall have the obligation to erase personal data without undue delay where one of the following grounds applies:

   a) the personal data are no longer necessary in relation to the purposes for which they were collected or otherwise processed;

   b) the data subject withdraws consent on which the processing is based and where there is no other legal ground for the processing;

   c) the personal data have been unlawfully processed.

   You have no right to erasure if your data are necessary for scientific research and erasure is likely to make it impossible or seriously impair the achievement of the objectives of this processing, or if processing is necessary for the establishment, exercise, or defense of legal claims.

2. ***Notification obligation regarding rectification or erasure of personal data or restriction of processing:***

   The controller shall communicate any rectification or erasure of personal data or restriction of processing carried out to each recipient to whom the personal data have been disclosed, unless this proves impossible or involves disproportionate effort. The controller shall inform the data subject about those recipients if the data subject requests it.

The right to data portability is restricted or excluded if the deletion is in the public interest or the data constitutes a business secret. Further information can be found here:

3. ***Right to data portability:***

   a) The data subject shall have the right to receive the personal data concerning him or her, which he or she has provided to a controller, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller without hindrance from the controller to which the personal data have been provided, where the processing is carried out by automated means

   b) In exercising his or her right to data portability, the data subject shall have the right to have the personal data transmitted directly from one controller to another, where technically feasible.

   c) The exercise of the data portability shall be without prejudice. That right shall not apply to processing necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller.

   d) The right referred to in paragraph 2 shall not adversely affect the rights and freedoms of others.

4. ***If personal data is transferred to a third country or to an international organization, you have the right to be informed about the appropriate safeguards pursuant to Article 46 of the GDPR in connection with the transfer.***

Notes on purely academic research:

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The research conducted in this study is in the public interest. Therefore, you cannot exercise the right to data portability.

C. Rights limited by the research purpose

The right to rectification, restriction of processing, and access is excluded if exercising these rights is likely to make it impossible or seriously impair the achievement of the research purpose, and the restriction is necessary for the fulfilment of the research purpose.
Further details can be found here:

As the data subject, you have the following rights, ***provided that exercising these rights is not likely to make it impossible or seriously impair the achievement of the research purpose, and the restriction is necessary for the fulfilment of the research purpose:***

1. ***Recht auf Berichtigung:***
   The data subject shall have the right to obtain from the controller without undue delay the rectification of inaccurate personal data concerning him or her. Taking into account the purposes of the processing, the data subject shall have the right to have incomplete personal data completed, including by means of providing a supplementary statement.

2. ***Right to restriction of processing***
   The data subject shall have the right to obtain from the controller restriction of processing where one of the following applies:
   a) *the accuracy of the personal data is contested by the data subject, for a period enabling the controller to verify the accuracy of the personal data;*
   b) *the processing is unlawful and the data subject opposes the erasure of the personal data and requests the restriction of their use instead;*
   c) *the controller no longer needs the personal data for the purposes of the processing, but they are required by the data subject for the establishment, exercise or defence of legal claims.*

   Where processing has been restricted, such personal data shall, with the exception of storage, only be processed with the data subject's consent or for the establishment, exercise or defence of legal claims or for the protection of the rights of another natural or legal person or for reasons of important public interest of the Union or of a Member State.
   A data subject who has obtained restriction of shall be informed by the controller before the restriction of processing is lifted.

3. ***Right of access by the data subject***
   The data subject shall have the right to obtain from the controller confirmation as to whether or not personal data concerning him or her are being processed, and, where that is the case, access to the personal data and the following information:
   a) *the purposes of the processing;*
   b) *die the categories of personal data concerned;*
   c) *the recipients or categories of recipient to whom the personal data have been or will be disclosed, in particular recipients in third countries or international organizations;*

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d) where possible, the envisaged period for which the personal data will be stored, or, if not possible, the criteria used to determine that period;

e) the right to lodge a complaint with a supervisory authority.

f) The controller shall provide a copy of the personal data undergoing processing. For any further copies requested by the data subject, the controller may charge a reasonable fee based on administrative costs. Where the data subject makes the request by electronic means, and unless otherwise requested by the data subject, the information shall be provided in a commonly used electronic form.
The right to obtain a copy referred to in paragraph 3 shall not adversely affect the rights and freedoms of others.

The right of access by the data subject pursuant to section 3 does not apply if the data is required for scientific research purposes and providing such information would involve disproportionate effort.

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I declare that I am participating in the above-mentioned study.

I have received a copy of the informed consent form.
One copy will remain at the study center.

.....
Name in block letters

.....	.....
Date	Signature of participant

Option to document additional questions or other aspects of the informed consent discussion:

I have conducted the informed consent discussion and obtained consent to participate in the study.

.....
Name of the person responsible for the information session in block letters

.....	.....
Date	Signature of the person responsible for the information session