ProCare 3: Progression in home care: Motivational counselling for informal caregivers

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered	
29/04/2024		[X] Protocol	
Registration date 30/04/2024	Overall study status Completed	Statistical analysis plan	
		[_] Results	
Last Edited	Condition category	Individual participant data	
26/02/2025	Other	[X] 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. Care counselling thus forms the key to reducing caregiver burden. In this regard, Motivational Interviewing (MI) has the potential to actually achieve positive changes in burdensome home care situations. MI is a technique for guiding conversations in order to strengthen a person's self-motivation and willingness to change. Its effectiveness has been proven internationally in a wide variety of contexts. It has not yet been used in informal caregivers to implement changes (such as seeking support).

The aim of the project is the implementation and evaluation of a training course for informal caregiver counsellors on the topic of "Motivational Interviewing (MI) for informal caregiver counselling". The training is designed to support informal caregiver counsellors in managing difficult counselling situations with motivational interviewing. The evaluation is intended to assess the benefits of the training course and provide opportunities for further development. At the end of the project, the training course can be provided to all informal caregiver counsellors and motivational interviewing can be integrated into the informal caregiver counselling setting.

Who can participate?

The participants are informal caregiver counsellors (completed qualification), who are currently (at the time of the training) working in the informal caregiver counselling context.

What does the study involve?

It involves the training course "MI for informal caregiver counselling", consisting of an infosession (2 units (1 unit = 45 min)), an e-learning course (8 units) and two days of attendance (14 units). After the training course, there will be the possibility to participate in an optional 6-week post-support (via e-mail and a one-time Zoom session). In addition, different questionnaires have to be completed before the start of the training (t0), directly at the end of the training (t1), at the end of the post-support (t2) and 6 months after the training (t6). What are the possible benefits and risks of participating? Due to voluntary participation in the survey, there will be no risks. The participating informal caregiver counsellors receive a training course on the topic "MI for informal caregiver counselling".

We expect to generate empirical data to assess the benefits of the training course, provide opportunities for further development and integrate the training course in the context of informal caregiver counselling focussing on the needs and demands of informal caregivers to strengthen the informal caregiver counselling.

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? August 2023 to March 2025

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

Who is the main contact? Principal investigator: PD Dr. Anna Pendergrass (anna.pendergrass@uk-erlangen.de)

Co-investigator: Johanna Schmidt (Schmidt.johanna@uk-erlangen.de)

Senior advisor: Prof. Dr. med. Elmar Graessel (elmar.graessel@uk-erlangen.de)

Study website

https://www.psychiatrie.uk-erlangen.de/med-psychologie-soziologie/forschung/procare/

Contact information

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers 24-108-B

Study information

Scientific Title

Progression in home care: Motivational counselling for informal caregivers – implementation (phase III)

Acronym ProCare 3

Study objectives Current study hypothesis as of 20/06/2024: Aim: Implementation and evaluation of a training course "Motivational Interviewing for informal caregiver counselling" for informal caregiver counsellors.

Exploratory objectives:

Exploratory objectives are the investigation of the increase (pre to post training) in the participants':

- 1. Knowledge of Motivational Interviewing (MI)
- 2. Social cognitions regarding the use of MI with future clients
- 3. Counseling competence
- 4. Self-efficacy experience

Furthermore, participants' satisfaction with the training and perceived use and impact of MI is investigated.

Hypotheses:

Primary hypothesis

1. Participants' subjective counselling competence is higher after the training than before the training (Level of evaluation according to Kirkpatrick-Model: results (IV)).

Secondary hypotheses

2. Participants' satisfaction with the training is high (Level of evaluation according to Kirkpatrick-Model: reaction (I)).

3. Participants' knowledge of MI is higher after the training than before the training (Level of evaluation according to Kirkpatrick-Model: learning (II)).

4. Participants' perceived use of MI after the training is high (Level of evaluation according to Kirkpatrick-Model: reaction (III)).

5. Participants' experience of self-efficacy regarding their counselling sessions is higher (Level of evaluation according to Kirkpatrick-Model: results (IV)).

6. Participants' level of social cognitions in terms of the Theory of Planned Behaviour regarding the use of MI with future clients is higher after the training than before the training with respect to the dimensions: affective attitudes, instrumental attitudes, perceived behavioural control, subjective norms, intentions (Level of evaluation according to Kirkpatrick-Model: results (IV)).

Previous study hypothesis:

Aim:

Implementation and evaluation of a training course "Motivational Interviewing for informal caregiver counselling" for informal caregiver counsellors.

Exploratory objectives:

Exploratory objectives are the investigation of the increase (pre to post training) in the participants':

1. Knowledge of Motivational Interviewing (MI)

- 2. Social cognitions regarding the use of MI with future clients
- 3. Counseling competence
- 4. Self-efficacy experience

Hypotheses:

1. Participants' knowledge of MI is higher at t1 than at t0.

2. Participants' level of social cognitions regarding the use of MI with future clients is higher at t6 than t0 regarding their

2.1. affective attitudes

- 2.2. instrumental attitudes
- 2.3. perceived behavioural control
- 2.4. subjective norms
- 2.5. intentions
- 3. The participants' counselling competence is higher at t6 than at t0.

4. The participants' experience of self-efficacy regarding their counselling sessions is higher at t6 than at t0.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 23/04/2024, Friedrich-Alexander-Universität Erlangen-Nürnberg (FAU) Ethics Committee (Krankenhausstraße 12, Erlangen, 91054, Germany; +49 (0)9131 85-22270; ethikkommission@fau.de), ref: 24-108-B

Study design

Single-centre interventional longitudinal study without a control group

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Home, Internet/virtual, Training facility/simulation, University/medical school/dental school, Workplace

Study type(s)

Prevention, Treatment, Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

This project focuses on support services for informal caregivers, in particular informal caregiver counselling, by examining a training course for informal caregiver counsellors.

Interventions

Participants attend the training course "MI for informal caregiver counselling", consisting of an info-session (2 units (1 unit = 45 min)), an e-learning course (8 units) and two days of attendance (14 units). After the training course, there will be the possibility to participate in a 6-week post-support (via e-mail and a one-time Zoom session).

In addition, participants complete a questionnaire before the start of the training (t0), directly at the end of the training (t1), at the end of the post-support (t2) and 6 months after the training (t6).

Four training courses are planned, each with 15-20 participants.

Intervention Type

Behavioural

Primary outcome measure

Current primary outcome measure as of 20/06/2024:

Counselling-Competence is measured using the Counselor Activity Self-Efficacy Scale (CASES-R) at t0 (before the start of the training), t1 (upon completion of the on-site workshop), t2 (upon completion of the voluntary follow-up-phase) and t6 (6 months after the start of the training)

Previous primary outcome measure:

MI-knowledge is measured using a test with multiple-choice-questions and open questions before the start of the training (to) and directly at the end of the training (t1)

Secondary outcome measures

Current secondary outcome measures as of 20/06/2024:

1. Satisfaction with the training is measured with a self-report questionnaire at t1 and the Training-Satisfaction-Rating-Scale at t1 and t2

2. MI-knowledge is measured using a test with multiple-choice questions and open questions at t0, t1, t2 and t6

3. Implementation of the acquired knowledge is measured using self-report-questionnaires at t2 and t6

4. Social cognitions regarding the use of MI with future clients are measured using the questionnaire "Social cognitions for using MI with future clients" at t0, t1, t2 and t6 5. Self-Efficay is measured using the "Allgemeine Selbstwirksamkeit Kurzskala (ASKU)" at t0 and t6

Timepoints: before the start of the training (t0), upon completion of the on-site workshop (t1), upon completion of the voluntary follow-up-phase (t2) and 6 months after the training (t6)

Previous secondary outcome measures:

1. Implementation of the acquired knowledge is measured using self-report-questionnaires at t6

2. Impact of the acquired knowledge is measured using self-report-questionnaires at t6

3. Social cognitions regarding the use of MI with future clients are measured using the

questionnaire "Social cognitions for using MI with future clients" at t0 and t6

4. Counselling-Competence is measured using the "Counselor Activity Self-Efficacy Scale (CASES-R)" at t0 and t6

5. Self-efficacy is measured using the "Allgemeine Selbstwirksamkeit Kurzskala (ASKU)" at t0 and t6

6. Participants' satisfaction with the training course is measured using a self-report questionnaire and the "training satisfaction rating scale" at t1 and t2

Timepoints: before the start of the training (t0), directly at the end of the training (t1), at the end of the post-support (t2) and 6 months after the training (t6)

Overall study start date

01/08/2023

Completion date

31/03/2025

Eligibility

Key inclusion criteria

1. Successfully completed training as informal caregiver counsellor

2. Currently (at the time of the training) working in the informal caregiver counselling context

3. Participation of at least 80% of the training (equivalent to 20 units) "MI for informal caregiver counselling" in 2024

4. Given informed consent to participate in the study

Participant type(s)

Health professional, Learner/student, Service user

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

4 training courses are offered for 15-20 people each. In total, 80 people can take part in the study. Based on a pilot project, 15-18 participants are expected per session, i.e. 60-72 participants in total.

Total final enrolment 59

Key exclusion criteria Termination of the training course

Date of first enrolment 14/05/2024

Date of final enrolment 31/07/2024

Locations

Countries of recruitment Germany

Study participating centre Centre for Health Services Research, Universitätsklinikum Erlangen, Friedrich-Alexander-Universität Erlangen-Nürnberg Schwabachanlage 6 Erlangen Germany 91054

Sponsor information

Organisation

Reinhard Frank-Stiftung

Sponsor details

Mönckebergstr. 11 Hamburg Germany 20095 +49 40 2716960 Info@reinhardfrank-stiftung.org

Sponsor type

Charity

Website https://reinhardfrank-stiftung.org/index.html

Funder(s)

Funder type Charity

Funder Name Reinhard-Frank-Stiftung

Results and Publications

Publication and dissemination plan Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2025

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/02/2025	26/02/2025	Yes	No