ISRCTN14218056 https://doi.org/10.1186/ISRCTN14218056

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

Submission date
29/04/2024

Recruitment status
No longer recruiting

Registration date
30/04/2024

Overall study status
Completed

Last Edited
26/02/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[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 caregiver counselling, but could support counsellors in motivating 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 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 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

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Anna Pendergrass

ORCID ID
http://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 9131/85-34142
anna.pendergrass@uk-erlangen.de

Type(s)
Public, Scientific

Contact name
Miss Johanna Schmidt

ORCID ID
https://orcid.org/0009-0005-4099-4235

Contact details
Centre for Health Services Research,
Universitätsklinikum Erlangen, Friedrich-Alexander-Universität Erlangen-Nürnberg
Schwabachanlage 6
Erlangen
Germany
91054
+49 9131/85-34142
schmidt.johanna@uk-erlangen.de

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