

Evaluation of a person-centred multidimensional interdisciplinary rehabilitation program for community dwelling older people with dementia and their informal primary caregivers

Submission date 03/11/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/11/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/09/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

Dementia causes great suffering as the disease significantly affects all aspects of life for the affected person and the informal primary caregivers (for example, family members). As the number of people with dementia will increase dramatically in the future, the World Health Organization (WHO) advocates that dementia should be a public health priority. The effects of dementia are many and complex. They include memory loss, difficulties with thinking and problem solving (reduced cognitive function), difficulties in walking and balance, physical inactivity, falls and fractures, malnutrition, drug related problems, social isolation and caregiver burden. It may be possible to alleviate these effects via a person-centred multidimensional interdisciplinary rehabilitation program for older people with dementia still living in the community and education and counselling to the people looking after them. However, it is not known whether this approach would work. The primary aim of this study is therefore to look at whether such a program can lead to an increase in the number of people with dementia still living at home after two and three years, rather than, for example, a residual care facility.

Who can participate?

Adults aged at least 60 years, suffering from dementia and is living in ordinary housing. Informal caregivers of the person with dementia are also invited to participate.

What does the study involve?

Participants are randomly allocated into the treatment group, or the control group. The control group continue their usual care. Those in the treatment group participate in a rehabilitation program at the Geriatric Centre, Umeå University Hospital, which includes education and support to primary caregivers. The interdisciplinary team includes physicians, nurses, physiotherapists, occupational therapists, social workers, dieticians, neuropsychologists, dental hygienists, and pharmacists, all experienced in working with rehabilitation of older people with

cognitive and physical impairment. The person with dementia is assessed to identify their problems and needs and tailored rehabilitation goals are set up along with specific interventions (treatments) based on these goals. The social worker assesses the need for support and counselling through interviews with primary caregivers. The persons with dementia are offered a rehabilitation programme for 16 weeks including physical exercise twice a week and other individually tailored goal oriented interventions based on the identified problems and the rehabilitation goals for the individual. The informal primary caregivers are offered six group sessions on education and discussions about dementia to improve self-management skills. The caregivers have the opportunity to choose the topics. In addition, the sessions aim to facilitate social networking among caregivers in the group. Support and Counselling is also offered where needed for up to 6 sessions. All participants will be followed up 5 months and then 14 months after receiving the rehabilitation program.

What are the possible benefits and risks of participating?

Participation in the intervention will hopefully contribute to improved health and quality of life for people with dementia and their informal primary caregivers. The advantages of the study are expected to be greater than the risks that participation might mean. The intervention will include physical activity, including high-intensity functional exercises, which implies that there might be a risk of adverse events. However, the research group has experience of two clinical interventions in residential care homes with similar exercises. In neither of these studies, did any severe complications or side effects occur. In addition, no serious side effects in high-intensity exercise programmes among older people who are healthy and those with moderate impairments have been reported in the literature.

Where is the study run from?

The project is run in collaboration between the units of Geriatric Medicine, Physiotherapy, and Occupational Therapy at the Department of Community Medicine and Rehabilitation, Umeå University, the Department of Nursing, Umeå University, and the County Council of Västerbotten, Sweden.

When is study starting and how long is it expected to run for?

January 2014 to February 2019

Who is funding the study?

1. Forte – Swedish Research Council for Health, Working Life and Welfare (Forskningsrådet om Hälsa, Arbetsliv och Välfärd)
2. The Swedish Dementia Association
3. The County Council of Västerbotten (local ALF)
4. Umeå University

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A person-centred Multidimensional InterDisciplinary REhabilitation program for community dwelling older people with Dementia and their informal primary caregivers: a randomised controlled trial

Acronym

MIDRED

Study objectives

1. Primary hypothesis:

A person-centred multidimensional interdisciplinary rehabilitation program for community dwelling older people with dementia, that includes education and counselling to informal primary caregivers will increase the proportion of people with dementia living at home at the 24- and 36-month follow-up assessment

2. Secondary hypotheses:

2.1. The rehabilitation program decreases burden, and counteracts depression and reduced health related quality of life among informal primary caregivers

2.2. The rehabilitation program increases participation in the society, and counteracts depression and reduced psychological well-being in people with dementia

2.3. The rehabilitation program counteracts physical inactivity, slows decline in cognitive ability, functional ability and in activities of daily living (ADL) performance, reduces behavioural and psychological symptoms of dementia (BPSD), improves nutritional status and oral health, and reduces the use of inappropriate drugs in people with dementia

2.4. The rehabilitation program is feasible in terms of positive experiences among the persons

with dementia and their informal primary caregivers, and in terms of satisfactory attendance and no serious adverse events related to the intervention

2.5. The rehabilitation program is cost-effective

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethical Review Board in Umeå (Sweden), 20/10/2015, ref: 2015-292-31M

Study design

Single-centre randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Dementia

Interventions

The person with dementia and informal primary caregivers are randomised, with a 1:1 allocation, to a control group (usual care) or a person-centred multidimensional interdisciplinary rehabilitation program for the person with dementia, including education and support to informal primary caregivers.

Interventions in the rehabilitation program are conducted in appropriate rehabilitation facilities at the Geriatric Centre, University Hospital of Umeå and, when necessary, activities are conducted in the home of the person with dementia and in the community. The interdisciplinary team includes physicians, nurses, physiotherapists, occupational therapists, social workers, dieticians, neuropsychologists, dental hygienists, and pharmacists. The person with dementia is assessed to identify problems and needs within the following 10 potential problem areas:

1. Functional capacity
2. Cognitive function
3. ADL performance
4. Falls
5. Participation in the society
6. Physical activity
7. Nutrition

8. Medical conditions

9. Behavioral and psychological symptoms in dementia

10. Drugs

Based on the findings/problem areas, needs as well as resources and strengths of each individual, the team is composed. The team members, together with the person with dementia and informal primary caregivers, set up individual rehabilitation goals, including specific interventions based on the goals.

The social worker assesses the need for support and counselling through interviews with primary caregivers.

The persons with dementia are offered a rehabilitation period of 16 weeks containing:

1. Physical activity interventions: individual physical exercise twice a week for approximately 45 minutes, supervised by a physiotherapist, with the goal to improve muscle strength, balance and gait ability, as well as, individual recommendations to reach physical activity of at least moderate intensity at least 150 minutes per week (health promotion recommendations). The individual exercises are based on the High-Intensity Functional Exercise Program (HIFE Program)
2. Other individually tailored goal oriented interventions based on the identified problems and the rehabilitation goals for the individual, performed by any profession in the team

The informal primary caregivers are offered a period of 16 weeks containing:

1. Group sessions: six occasions containing education and discussions about dementia to improve self-management skills. The caregivers have the opportunity to choose the topics. In addition, the sessions aim to facilitate social networking among caregivers in the group
2. Support and counselling when needed up to six occasions by a social worker

Five and 14 months after the rehabilitation period, the intervention will be followed-up. For the persons with dementia, follow-up is made by the team. For the primary caregivers, follow-up is made by the social worker.

Intervention Type

Behavioural

Primary outcome measure

Proportion of people with dementia who are still living at home, which is the inverse of death or institutionalisation combined (describes the odds of someone being alive and in their home at a point in time), at the 24 and 36 month follow-up assessment.

Secondary outcome measures

Persons with dementia:

1. Depressive symptoms measured using the Geriatric Depression Scale (GDS-15) at 4, 12, 24 and 36 months
2. Psychological well-being measured using the Philadelphia Geriatric Center Morale Scale (PGCMS) at 4, 12, 24 and 36 months
3. Participation in society determined using questions concerning number of visits in the home, number of visits made to others and contacts with relatives and friends using telephone or other media at 4, 12, 24 and 36 months
4. Physical activity measured using the International Physical Activity Questionnaire–Elderly (IPAQ-E) including questions added by the project members at 4, 12, 24 and 36 months
5. Cognitive function measured using the Mini-Mental State Examination (MMSE) and Verbal fluency questionnaire at 4, 12, 24 and 36 months
6. Functional capacity measured using the Berg Balance Scale, chair-stand test, and gait speed

test over 2.4 meters at 4, 12, 24 and 36 months

7. ADL performance measured using Functional Independence Measure (FIM), Lawton and Brody's Physical Self-Maintenance Scale (P- and I-ADL) at 4, 12, 24 and 36 months

8. BPSD measured using the Neuropsychiatric Inventory (NPI) at 4, 12, 24 and 36 months

9. Nutritional status measured using the Mini Nutritional Assessment (MNA) at 4, 12, 24 and 36 months

10. Inappropriate drugs including interactions determined using recommendations by The National Board of Health and Welfare in Sweden at 4, 12, 24 and 36 months

11. Feasibility of the intervention by qualitative interviews at the end of the rehabilitation period of people with dementia and informal primary caregivers concerning the experiences of participating in the intervention, and by registering the attendance during the rehabilitation period and adverse events

12. Cost-effectiveness using health related quality of life assessed with the EQ-5D, as well as calculations based on costs of the intervention and consumption of health and social services

13. Explanatory analyses of the feasibility and effects of the intervention. Independent variables: sex, age, access to spousal caregiver, cognitive function, ADL performance, presence of BPSD, nutritional status, and drug use

14. Oral health measured using The Geriatric Oral Health Assessment Index (GOHAI) and Revised Oral Assessment Guide (ROAG) at 4, 12, 24 and 36 months (added 02/02/2016)

Informal primary caregivers:

1. Caregiver burden measured using the Caregiver Burden Scale at 4, 12, 24 and 36 months

2. Depressive symptoms measured using the Geriatric Depression Scale (GDS-15) at 4, 12, 24 and 36 months

3. Health related quality of life assessed measured using the Short Form (36) Health Survey at 4, 12, 24 and 36 months

Overall study start date

01/01/2014

Completion date

25/02/2019

Eligibility

Key inclusion criteria

Inclusion criteria for participants with dementia:

1. Diagnosis of dementia according to ICD-10

2. 60 years and older

3. Living in independent housing

4. Expected survival time more than 6 months

5. A Mini-Mental State Examination score of 10 or more

6. Ability to stand up from a chair with armrests with help of no more than one person

7. Able to hear and understand Swedish language sufficiently well to participate in the assessments

8. Move to residential care facilities are not initiated

9. Approval from the participants physician

Inclusion criteria for informal primary caregivers:

Individuals responsible for the care and support of the participant with dementia. A maximum of two people responsible for the care and support of each participant with dementia will be

offered to participate in the study. Informal primary caregivers can be people within the family or relatives and other people such as neighbors or friends who help the participant with dementia.

Participant type(s)

Mixed

Age group

Mixed

Sex

Both

Target number of participants

179 individuals with dementia

Total final enrolment

128

Key exclusion criteria

Failure to meet inclusion criteria

Date of first enrolment

04/11/2015

Date of final enrolment

30/11/2017

Locations**Countries of recruitment**

Sweden

Study participating centre

University Hospital of Umeå

Geriatric Centre

Umeå

Sweden

901 85

Sponsor information**Organisation**

Umeå University

Sponsor details

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Sponsor type

University/education

ROR

<https://ror.org/05kb8h459>

Funder(s)**Funder type**

Research council

Funder Name

Forte – Swedish Research Council for Health, Working Life and Welfare (Forskningsrådet om Hälsa, Arbetsliv och Välfärd)

Alternative Name(s)

Swedish Research Council for Health, Working Life and Welfare, FORTE

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Funder Name

The Swedish Dementia Association

Funder Name

The County Council of Västerbotten (local ALF)

Funder Name

Umeå University (Umeå Universitet)

Alternative Name(s)

Umeå University, Umeje universitiähta, Universitas Umensis

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Sweden

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results	Non-peer-reviewed qualitative results in preprint	22/10/2020	13/05/2021	No	No
Other publications	Qualitative results	02/06/2021	30/11/2022	Yes	No
Other publications	Focus groups included staff who had shared experiences from the MIDRED study)	18/12/2023	08/01/2024	Yes	No
Results article		28/09/2024	30/09/2024	Yes	No