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Home-based exercise training following ward-based rehabilitation in geriatric patients with cognitive impairment

Submission date
08/10/2015

Recruitment status
No longer recruiting

Registration date
06/11/2015

Overall study status
Completed

Last Edited
17/01/2024

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Mild or moderate cognitive impairment (MCI) is a common condition which is thought to affect more than 50% of elderly people. It causes problems with memory and thinking, meaning that people suffering from MCI can have difficulties with certain aspects of daily life. Although it is not as noticeable to others as dementia, it can cause the sufferer considerable distress. In many cases, MCI can lead to other problems that require admittance to hospital, such as falls. Physical activity, especially functional training (practising everyday activities such as walking, standing and sitting) is an important part of rehabilitation when a person is hospitalised. Currently, there are only a limited number of rehabilitation programs specifically for people affected by MCI. Supervised, ward-based rehabilitation has been shown to improve strength and balance in patients with MCI, making them less likely to fall and injure themselves. Many patients want to be discharged from hospital as soon as they can, and so completing these rehabilitation exercises at home may be a preferable option. Home-based exercises may also prove to be more cost-effective, as patients are able to go home from hospital earlier. The aim of this study is to find out whether a home-based training program is a successful way of rehabilitating people with MCI after hosptialisation.

Who can participate?
Adults over 65 years of age with mild to moderate cognitive impairment.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group (intervention group) meet with a sports scientist and are given exercises to do at home, designed to improve strength, balance and abilities (functional training) for 12 weeks. Participants are also encouraged to walk regularly, and are given a personalised walking regime to follow by the sports scientist. A pedometer is given to track the number of steps as an extra motivator. Those in the second group (control group) receive newsletters providing general information about the importance of strength training, nutrition and relaxation. Participants in both groups complete physical tests at the beginning of the study, after 3 months and after a further 3 months to find out if their level of physical activity has improved. Participants also complete a

number of questionnaires to find out if the exercise has improved their emotional and mental well-being.

What are the possible benefits and risks of participating?
Potential benefits of participating include improvements to walking ability and balance, making them less likely to fall in the future.. Risks of participating are minimal, however the study does require physical effort which may lead to muscle soreness and tiredness.

Where is the study run from?
Agaplesion Bethanien Krankenhaus Heidelberg gGmbH (Germany)

When is the study starting and how long is it expected to run for?
March 2015 to December 2017

Who is funding the study?
1. Ministry of Labour and Social Affairs, Families, Women and Senior Citizens (Germany)
2. Municipal Association for Youth and Social Affairs Baden-Wuerttemberg (Germany)

Who is the main contact?
Professor Klaus Hauer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Home-based exercise training following ward-based rehabilitation in geriatric patients with cognitive impairment: A randomized controlled trial

Acronym
HeikE

Study objectives
The study aims to provide a feasible and cost-effective home-based exercise program for geriatric patients with mild to moderate cognitive impairment following ward-based rehabilitation.

Primary hypotheses:
1. Twelve weeks of exercise training improves motor performance, as assessed by the Short Physical Performance Battery (i.e., total score)
2. The intervention increases physical activity (e.g., daily walking duration), as assessed by a physical activity monitoring system

Secondary hypotheses:
1. The training program improves gait, balance and sit-to-stand performance, as assessed by electronically measured sub-scores of the Short Physical Performance Battery and the Timed-Up-and-Go test
2. The training program increases the area of activity/life space (e.g., maximum distance from home, maximum distance of each trip), as assessed by Global Positioning System and the UAB Study of Aging Life-Space Assessment questionnaire
3. The training program improves gait performance (i.e., increase number of steps, cadence), as assessed by the physical activity monitoring system
4. The training program decreases the number of falls, fear of falling and the number of activities avoided due to fear of falling
5. The intervention is a cost-effective home-based exercise training, as assessed by the FIMA questionnaire
6. Effects of training are sustainable after the end of intervention period (12 weeks follow-up)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Internal Review Board at the Medical Faculty of the University of Heidelberg, 26/06/2015, ref: S-252/2015

Study design
Randomized controlled trial with blinded assessors

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Moderate cognitive impairment

Interventions
Patients are randomly assigned to one of the two study groups (intervention group and control group):

Intervention group: Patients take part in a standardized 12-weeks home training program, including exercises to promote balance, strength and physical functioning (i.e., walking, stairs, sit-to-stand transfer) and the identification of individually-tailored walking courses. The motivational approach of the study is based on the Theory of Planned Behavior, by providing knowledge about the benefits of physical activity, increasing patients' self-efficacy, setting individual goals, and encouraging patients to translate their intentions into behavioral changes (including the identification of potential barriers). Participants identify their individual abilities and their desire for improvements in:
1. Key motor qualifications (i.e., standing, walking, sit-to-stand transfer)
2. Indoor activities (i.e., bathing, house cleaning)
3. Outdoor activities (i.e., shopping, medical appointments, socializing).
Subsequently, one or two individual goals are defined and implemented into the training intervention. The home training program is specifically-tailored for elderly patients with mild to moderate cognitive impairments. It has been shown to be feasible and effective in multi-morbid, frail older adults and includes six exercises covering balance and strength-related aspects of motor performance. The exercises are explained and regularly reviewed by a sports scientist and illustrated at the patient's home using a large poster. Also, pictures and a brief comprehensive description of key elements for each exercise are provided. Furthermore, participants in the intervention group will be encouraged to walk regularly. The sports scientist specifies a walking trail for each participant, including individual goals (i.e., going to a bakery or a supermarket). Participants and instructor specify when and where the walking exercises take place and who is available to assist (i.e., relatives, friends), thereby encouraging the participant to incorporate walking into his everyday life. To foster motivation and participation, participants in the intervention group use a pedometer to track daily number of steps. Also, participants are asked to record their daily step-counts and training in a physical activity diary to set goals, monitor progress, and provide feedback. The balance and strength training in combination with regular walking trips are expected to lead to improvements in key motor qualifications (i.e., standing, sit-to-stand transfer, climbing stairs, walking).

Control Group: Patients receive newsletter-based information about unspecific strength training, nutrition and relaxation over a period of 12 weeks.

Participants in both groups are called weekly and visited regularly (week 1, 4, 7 and 9) by professional trainers to document and foster participation. Patients in the control group and the intervention group will have the opportunity to join a local sports club after the project is finished.

Intervention Type
Behavioural

Primary outcome measure
1. Physical and functional performance is measured using the Short Physical Performance Battery and Timed Up & Go at baseline, 3 months and 6 months
2. Physical activity (duration, intensity, and frequency of lying, sitting, standing, and walking) is be recorded using tri-axial accelerometers for 48 consecutive hours at baseline, 3 months and 6 months

Secondary outcome measures
1. Life space is measured using a Global Positioning System device recording participants' locations (Qstarz International Co., Ltd., Taiwan) over a period of 48 hours. Data registered include distance and time spent in various activities (i.e., walking, standing, in a vehicle). Subjects' life space will also be measured with the UAB Study of Aging Life-Space Assessment. The LSA will retrospectively assess the frequency of in- and outdoor activities over a period of one week at baseline, 3 months and 6 months
2. Psycho-social parameters are measured at baseline, 3 months and 6 months
2.1. Fear of falling is measured using the short version of the falls efficacy scale (FES-I)
2.2. Fall-related activity avoidance is assessed using the Fear of Falling Avoidance-Behavior Questionnaire (FFABQ)
2.3. Quality of life is measured using the EuroQol health status questionnaire (EQ-5D)
2.4. Apathy is measured using the Apathy Evaluation Scale (AES)
2.5. Social support is assessed using the German questionnaire "Soziale Situation" developed by Nikolaus et al.
3. Cognitive performance (i.e., working memory) is measured using a sub-scale of the Wechsler Adult Intelligence Scale [WAIS] at at baseline, 3 months and 6 months
4. Costs of the intervention are measured using the Questionnaire for Health-Related Resource Use in an Elderly Population (FIMA) at baseline, 3 months and 6 months

Overall study start date
01/03/2015

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Geriatric patients following ward-based rehabilitation
2. Cognitive impairment defined as a Mini-Mental State Examination (MMSE) score of 17-26
3. Aged 65 years or over
4. Ability to independently walk 4 meters
5. Residence ≤ 30 kilometers away from study center
6. No simultaneous participation in other studies
7. Telephone contact possible
8. Capacity to give written informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
101

Total final enrolment
118

Key exclusion criteria
1. Delirium (positive Confusion Assessment Method; CAM)
2. Severe somatic or psychiatric diseases, which doesn’t allow participation
3. Insufficient hearing ability to conduct phone calls
4. Patient is not able to understand and speak German
5. Progressive, terminal status

Date of first enrolment
01/11/2015

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
Germany

Study participating centre
Agaplesion Bethanien Krankenhaus Heidelberg gGmbH
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Sponsor information

Organisation
AGAPLESION Bethanien Krankenhaus Heidelberg gGmbH

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/040z4nv21

Funder(s)

Funder type
Government

Funder Name
Ministry of Labour and Social Affairs, Families, Women and Senior Citizens

Funder Name
Municipal Association for Youth and Social Affairs Baden-Wuerttemberg

Results and Publications

Publication and dissemination plan
Publication of a study protocol, results and subgroup analyses are planned.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/09/2017	10/12/2020	Yes	No
Other publications	Embedded feasibility study	13/02/2020	17/01/2024	Yes	No
Results article		29/12/2022	17/01/2024	Yes	No