Long-Term Care in Motion - promoting physical activity in nursing home residents

Submission date	Recruitment status	Prospectively registered
10/07/2014	No longer recruiting	[X] Protocol
Registration date	Overall study status	Statistical analysis plan
31/07/2014	Completed	[X] Results
Last Edited	Condition category	Individual participant data
22/01/2019	Other	

Plain English summary of protocol

Background and study aims

Older people living in nursing homes are likely to not be very physically active. This can be due to a number of somatic (e.g. presence of a number of chronic medical conditions, physical disabilities and cognitive problems) and psycho-social (e.g. depression, fear of falling, apathy, isolation) factors. However, physical activity has been shown to prevent some of these problems, which is why low levels of physical activity may make them worse. The quantity (amount) and quality of physical activity observed in nursing homes have, to date, not been documented with high technology devices or analysed. The documentation of the amount of physical activity in nursing homes, as well as its promotion, is important for future research and for improving the quality of life for nursing home residents. In this study, we are aiming to promote the physical activity of nursing home residents over a 12 week period.

Who can participate?

Nursing home residents who are able to stand or step with or without close supervision and support. Nursing home staff are invited to take part in communication training.

What does the study involve?

The study involves participants of two nursing homes in Germany. One nursing home serves as the intervention facility, the other as the waiting control facility. Residents of the intervention facility receive exercise training and dancing video game training (the intervention) for 12 weeks. Staff members in the same nursing home attend 12 weekly sessions of communication training. Data for the study is assessed at the start of the trial, at the end of the trial and then 3 months afterwards. The other nursing home undergoes a run-in period (period where no intervention is offered). Data is collected for this nursing home as well and comparisons between nursing home residents that have, or have not received the intervention are made.

What are the possible benefits and risks of participating?

Benefits for nursing home residents taking part in the study include the prevention of the somatic and psycho-social factors that can happen due to physical inactivity. They may also benefit from the social interaction involved and enjoy the experience, leading to a better quality

of life. Staff members taking part gain an awareness of how important physical activity is for their elderly residents. Any risk from doing the exercises are minimised as much as possible due to a high level of supervision and support.

Where is the study run from?
Heidelberg University, Department of Psychological Aging Research (Germany)

When is the study starting and how long is it expected to run for? July 2014 to November 2015

Who is funding the study? The European Commission 'INNOVAGE - Social Innovations Promoting Active and Healthy Ageing' project (UK)

Who is the main contact? Professor Klaus Hauer

Study website

http://www.innovage.group.shef.ac.uk/project-partners/2013/04/24/uhei/

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Long-term care in motion - promoting physical activity in nursing home residents: A quasi experimental pre-post-assessment study

Acronym

LTCMo

Study objectives

LTCMo aims to document and increase physical activity (PA) of frail nursing home residents. An innovative approach was chosen for assessment strategies using high tech body worn sensors and novel research perspectives ('life space' assessment). Interventional strategies address residents including supervised group exercise and a serious games approach as well as a setting specific staff training. Study hypotheses include:

- 1. Primary hypotheses
- 1.1. The intervention will increase physical activity and extend the area of activity ('life space')
- 1.2. Effects of training will be sustainable after end of intervention period
- 2. Secondary hypotheses
- 2.1. Exercise training will improve motor performance
- 2.2. Residents' PA will be related to outcomes of well-being, depression and control strategies (e. q. self-efficacy, locus of control).
- 2.3. Participating staff members will have higher awareness of the importance of PA in nursing home (NH) residents, less negative age stereotypes as well as a changed way to interact with residents

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethic Board Review of the Faculty of Behavioral and Cultural Studies of Heidelberg University, 19 /12/2012

Study design

Quasi-experimental pre-post-assessment study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

A guidebook on the intervention is currently under preparation and will soon be available in web based format.

Health condition(s) or problem(s) studied

Activity promotion in nursing homes

Interventions

1. Physical exercise training for nursing home residents

The overall goal of the program is to enhance physical activity in nursing home residents. The physical exercise intervention is based on multiple exercise approaches: supervised group sessions, a serious games approach and specific training in severely impaired persons. Supervised group sessions will include functional and strength exercises to improve key motor qualifications mandatory for mobility, autonomy and motion security, i.e. standing, walking, sitting down and standing up. Improvement of motor status may increase physical activity. Each session will consist of a warm-up, a core of several exercises and a cool-down and will last 45 minutes. Training intensity will be increased according to individual progress. The sessions will be offered twice a week over a 12-week period in small groups up to a maximum of 8 residents. To ensure homogeneity, group composition will be determined according to residents' motor and cognitive status, i.e. based on impressions and results derived from performance based tests and cognitive screening. The exercise sessions will be supervised by trained sport scientists to support motivation/adherence and prevent adverse events such as falls. Trainers are instructed to use communicational strategies developed for use in patients with cognitive impairment. Residents with distinct behavioral problems resulting in disturbance of exercise activities or residents with advances postural deficits will not be included in exercise group sessions. However, they will still be eligible for an individual training which is based on exercises used in the group training and adapted to the individual abilities of the participants.

2. Serious Games component for nursing home residents

A 'Serious Games' component, i.e. a stepping video game, will be installed in the institutions. It is constituted as both a cognitive and motor training in which the exercise character is substituted by a game character. It will be conducted in small groups of 3-4 residents with only one person playing at a time. To play the game, the participant has to stand on a dance plate which is connected to a computer via USB. The dance video game screen is projected on a TV screen. A scrolling display of squares moving up, down, right or left across the screen cues each move and participants have to execute the indicated steps (forward, backward, right or left) when the squares reach corresponding squares at the top, bottom, right or left side of the screen. For each training session, participants will have to perform 10 levels of 90 seconds duration each, with a break of about 2 minutes after each level (waiting until a second player is finished). Progression of performance will be controlled by modification of the difficulty level (higher movement speed of the squares) and will be individually adjusted.

3. Competence training for staff members

The competence training will be offered to nursing staff and will be integrated into their regular in-house training schedule. The training will comprise twelve sessions: eight 1-hour-sessions including theoretical as well as practical contents and four 30-minutes-sessions serving as case discussions. Each session will be offered twice a week to facilitate staff attendance. Major aim of the training is to enable staff members to interact with residents in a way that encourages their PA. The training is based on generally accepted models of person-environment relations in long-term care institutions as well as on psychological models of motivation/self-regulation (e.g. social cognitive theory, theory of planned behavior). Staff members will get education about the role of PA in later life, about the role of aging stereotype in this regard, about barriers and facilitators of being physically active and about ways to overcome related obstacles. They will learn about how to use communication and interaction techniques to encourage residents to be more active (e.g. positivity, motivational interviewing). In role plays staff members will get extensive practice opportunities. The aim of the subsequent four case discussions is to jointly discuss the practical application of communication strategies in caring routines, to develop strategies for upcoming challenges and to monitor the achievement via feedback-loops.

The study design does not follow an RCT design, nor is it cluster randomised, so some of the features to be recorded, deviate from this established RCT study protocols. The nursing home chosen to start intervention or serve as control was randomly selected. The setting approach in

this study did not allow an individual randomisation of participants. The first nursing home is reported as an intervention home, although the intervention will also be replicated in the second home after a usual care period without any intervention to document the natural course within the intervention period (waiting control design). The study design thus allows a pre-post comparison for effects of intervention and a matched pair comparison between Intervention and control setting. The two nursing homes are run by the same care provider, are situated in the same part of the city (400 meters apart), and are built within a period of 3 years both following modern concepts of nursing home architecture. The residents do not differ with respect to descriptive characteristics such as age, gender, income, available space /per resident, or social class/income. As the care provider is identical in both settings, staff resources, care concept and activities are standardised and highly comparable. Both facilities are also comparable with respect to number of residents. The high congruity of both facilities represented a mandatory selection criteria for their selection. The intervention period/ facility differs with respect to intervention strategies, as recorded for the study, only.

Intervention Type

Behavioural

Primary outcome measure

Apart from the descriptive measures which will only be recorded at baseline to describe the study sample, all primary and secondary measures will be recorded at baseline (T1), end of intervention (T2) and end of follow up (T3).

Residents:

- 1. Physical activity: The duration, intensity, and frequency of residents' physical activity (lying, sitting, standing, walking) will be recorded using triaxial accelerometers ('uSense') for 48 consecutive hours.
- 2. Life space: Residents' life space will be measured objectively using a wireless tracking method ('s-net') recording residents' position continuously. Data concerning residents' covered distance, the amount of time spent at defined locations and the duration and frequency of changes of locations will be assessed.

Secondary outcome measures

Residents:

- 1. Physical and functional performance (Short Physical Performance Battery; Timed Up & Go; Gait speed, inherent motor-cognitive assessment of stepping game)
- 2. Various assessments of psycho-social variables (Fear of falling [short FES-I], Depression [Geriatric Depression Scale, GDS; Montgomery-Åsberg Depression Rating Scale, MÅDRS], general self-efficacy [Allgemeine Selbstwirksamkeit Kurzskala, ASKU], Social integration [De Jong Gierveld loneliness scale])

Descriptive characteristics of residents (age, gender etc.) will be assessed at baseline.

Staff:

- 1. Work-related consequences of strain (e.g., difficulty relaxing after work) (Irritation Scale)
- 2. Satisfaction with work (single item)
- 3. Age stereotypes (Expectations Regarding Aging Survey [ERA-12]; domain-specific age stereotypes questionnaire)
- 4. Subjective nursing competency (Fragebogen zur pflegerischen Handlungskompetenz, in German)
- 5. Contact with residents: Staff motivation when interacting with residents (e.g., preference for

dependence- or independence-supportive behavior) in interaction with residents (self-developed items)

Overall study start date

14/07/2014

Completion date

30/11/2015

Eligibility

Key inclusion criteria

Residents:

- 1. Permanent resident in included nursing homes
- 2. Written informed consent (resident/legal representative)
- 3. For participation in exercise sessions: Ability to stand (supervised group training) or ability to walk (stepping video game)

Staff level:

- 1. Permanent staff member of included nursing homes
- 2. Informed consent

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Approximately 120 residents living in 2 nursing homes and 30 staff members of the same facilities.

Key exclusion criteria

Residents:

- 1. Short-term resident in one of the two nursing homes
- 2. Behavioral problems resulting in disturbance of exercise activities (with respect to participation in group sessions)

Date of first enrolment

14/07/2014

Date of final enrolment

30/11/2015

Locations

Countries of recruitment

Study participating centre Rohrbacher Str. 149 Heidelberg Germany 69126

Sponsor information

Organisation

Heidelberg University, Department of Psychological Aging Research (Germany)

Sponsor details

Bergheimer Str. 20 Heidelberg Germany 69115

Sponsor type

University/education

ROR

https://ror.org/038t36y30

Funder(s)

Funder type

Government

Funder Name

The European Commission 'INNOVAGE - Social Innovations Promoting Active and Healthy Ageing' project (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Protocol article	protocol	18/11 /2014		Yes	No
Results article	results	01/01 /2017	22/01 /2019	Yes	No
Results article	results of does a physical activity program in the nursing home impact on depressive symptoms?	01/06 /2018	22/01 /2019	Yes	No
Results article	results of life-space and movement behavior in nursing home residents.	28/01 /2017	22/01 /2019	Yes	No
Results article	results of physical activity intervention in nursing home residents.	14/09 /2018	22/01 /2019	Yes	No
Results article	results of the effects of interventions on physical activity in nursing home residents,	01/09 /2015	22/01 /2019	Yes	No
Results article	results of understanding depressive symptoms in nursing home residents.	08/02 /2018	22/01 /2019	Yes	No