ISRCTN17727272 https://doi.org/10.1186/ISRCTN17727272

Activity in old age [Aktivität im Alter]

Submission date
19/08/2011

Recruitment status
No longer recruiting

Registration date
19/09/2011

Overall study status
Completed

Last Edited
28/09/2016

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Exercise programmes are used to treat patients with a number of chronic diseases and help to improve mobility and physical functioning in older adults. Until now, such programmes targeted either healthy community-dwelling seniors or elderly people living in special residences or care institutions. Chronically ill or mobility restricted people, however, are difficult to reach when they live in their own homes. We have evaluated a new home-based exercise programme, delivered to the participant by an exercise therapist in counselling sessions in the GP's practice and on the telephone. The aim of this study is to evaluate the effects of the exercise programme on patients' physical function, physical activity and quality of life.

Who can participate?
Community-dwelling, chronically ill and mobility restricted patients, aged 70 or over, who visit their GP's practice.

What does the study involve?
Eligible patients will be invited for an assessment in the GP's practice and randomly allocated to one of two groups. One group will undergo the new home-based exercise programme, delivered by an exercise therapist in counselling sessions in the GP's practice and on the telephone. The other group will attend counselling sessions promoting physical activities such as light intensity walking.

What are the possible benefits and risks of participating?
Increasing physical activity may initially increase the risk of injuries compared to a sedentary lifestyle. However, in the long term, an increase in physical activity is considered to lead to an improvement in gait and mobility and a reduction of fall and injury risk. For the patients who are eligible for the study, the expected cardiovascular benefit of the programme exceeds the risk for adverse cardiovascular events. To reduce the risk of adverse events, the exercise programme is tailored to the patient's abilities by an exercise therapist (in cooperation with the GP).

Where is the study run from?
Study management and overall coordination are performed by the Department of Sports Medicine and Sports Nutrition, Ruhr-University Bochum, Germany. The study will take place at about 15 GP practices around the city of Bochum, Germany.

When is the study starting and how long is it expected to run for?
Patients will be enrolled in the study between December 2011 and March 2013, so that the last participant is expected to finish the intervention in June 2013.

Who is funding the study?
The study is funded by the German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung [BMBF]).

Who is the main contact?
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Study website
http://www.ruhr-uni-bochum.de/homefit/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01ET1005A

Study information

Scientific Title
Effects of an exercise programme for chronically ill and mobility restricted elderly with structured support given by the general practitioner's practice (HOMEfit) - a randomized controlled trial

[Effekte eines Bewegungsprogramms für chronisch kranke und mobilitätseingeschränkte Ältere mit strukturierter Unterstützung durch die hausärztliche Praxis (HOMEfit) - ene randomisierte kontrollierte Studie]

Acronym
HOMEfit

Study objectives
The objective of this trial is to evaluate the effects of a new multidimensional home-based exercise programme for chronically ill and mobility restricted elderly with structured support given by the general practitioner's (GP) practice on physical function, physical activity, health-related quality of life, fall-related self-efficacy, and exercise self-efficacy.

Main hypothesis:
The new programme (experimental intervention) is more effective in increasing functional lower body strength (measured by a timed test of 5 sit-to-stand cycles [chair rising test]) than the control intervention after 12 weeks.

Follow up study to http://www.isrctn.com/ISRCTN58562962

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Witten/Herdecke Ethics Committee, 15/08/2011, ref: 77/2011

Study design
Randomized controlled multi-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Aged, physical inactivity, chronic disease, mobility restriction

Interventions

The duration of the intervention is 12 weeks.
The experimental intervention has been designed according to state-of-the-art physical activity recommendations for older adults (ACSM/AHA 2007). It consists of:
1. Multidimensional (strength, endurance, balance, flexibility) home-based exercise integrating preventive and therapeutic recommendations
2. Consultations provided by an exercise therapist (in the GP's practice and via telephone) including attention, instruction, and methods fostering behavioural change.

The control intervention promotes baseline physical activities, and thus consists of:
1. Baseline activities of daily life, e.g. light-intensity walking
2. Consultations provided by an exercise therapist (in the GP's practice and via telephone) including attention and instruction.

Details of the experimental intervention have already been published in the study protocol of the feasibility study (see Publications). Some modifications have been performed to the programme as a result of quantitative and qualitative analyses.

For all participants, additional medical treatment is permitted before and during the trial except ongoing rehabilitation measures following an inpatient surgical procedure (see exclusion criteria).

Intervention Type
Behavioural

Primary outcome measure
Primary efficacy endpoint (after 12 weeks of intervention):
Functional lower body strength measured by the chair rising test (timed test of 5 sit-to-stand cycles)

Secondary outcome measures
Secondary efficacy endpoints (after 12 weeks of intervention):
1. Physical functioning (battery of motor tests: timed up and go, 2-minute step-in-place, tandem stand, tandem walk, grip strength, chair sit-and-reach)
2. Physical activity (step count)
3. Health-related quality of life (Short Form-8 Health Survey)
4. Fall related self-efficacy (Falls Efficacy Scale-International Version)
5. Exercise self-efficacy (SSA-Scale)

Further measures:
1. Patient compliance
2. Appraisal by participants
3. Appraisal by GPs
4. Appraisal by exercise therapists
5. (Serious) adverse events
6. Reasons for discontinued intervention

Overall study start date
01/12/2011

Completion date
30/06/2013

Eligibility

Key inclusion criteria
1. Community-dwelling (not institutionalized) primary care patient
2. Age 70 years or above, either gender
3. Diagnosed with at least one of the following diseases:
3.1. Arterial hypertension
3.2. Diabetes mellitus type 2
3.3. Coronary heart disease
3.4. Chronic heart failure
3.5. Peripheral arterial disease
3.6. Chronic obstructive lung disease
3.7. Renal insufficiency
3.8. Degenerative spine disease
3.9. Hip or knee osteoarthritis
3.10. Osteoporosis with or without pathologic fracture
4. Mobility limitation defined by self-report of at least some difficulties in either walking 2 km or climbing one flight of stairs
5. Ability to at least walk short distances within rooms with or without a walking aid; but without the help of another person
6. Ability to visit the GP's practice for repeated consultations
7. Medical clearance from the GP to participate in the study
8. Ability to cooperate appropriately and to follow the instructions of the home-based exercise programme
9. Written informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
210 (recruited in about 15 general practices)

Key exclusion criteria
1. Inability to attend or complete the proposed course of intervention and follow-up (including not having a telephone or being unable to have telephone conversations)
2. Spouses of participants, persons living in the same household and former participants of the feasibility trial
3. Inability to perform the 'chair rising test' (primary outcome)
4. Regular performance of exercises, sporting activities or leisure activities that cause sweating and/or harder breathing for 2 hours or more per week; or walking outdoors for 4 hours or more per week
5. Untreated arterial hypertension or significantly elevated blood pressure despite antihypertensive medication (GP's judgement)
6. Higher grade chronic heart failure (NYHA grade IIIIV)

7. Higher grade chronic obstructive pulmonary disease (GOLD grade IV)
8. Acute psychiatric disorder (e.g. severe depression)
9. Severe consuming illness
10. Clinically relevant cardiovascular event within past 3 months
11. Clinically relevant cerebrovascular event within past 3 months
12. Deterioration of insufficiently controlled diabetes mellitus (according to GP's judgement) within past 3 months, or HbA1c exceeding 10% (if available)
13. Ongoing rehabilitation measures following an inpatient surgical procedure
14. Concurrent participation in another clinical trial

Date of first enrolment
01/12/2011

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
Germany

Study participating centre
Ruhr-University Bochum
Bochum
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44801

Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/04tsk2644

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Funder Name
Department of Sports Medicine and Sports Nutrition, Ruhr-University Bochum, Germany

Funder Name
Department of Medical Informatics, Biometry and Epidemiology, Ruhr-University Bochum, Germany

Funder Name
Institute of General Practice and Family Medicine, University Witten/Herdecke, Germany

Funder Name
Institute of Sport and Exercise Science, University of Muenster, Germany

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 summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	21/12/2011		Yes	No
Results article	results	02/12/2013		Yes	No
Results article	results	01/02/2015		Yes	No
Results article	results	01/11/2016		Yes	No