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Activity in old age - Evaluation of a 12-week multidimensional home-based exercise program for the elderly, integrated in the primary health care setting [Aktivität im Alter - Evaluation eines 12-wöchigen multidimensionalen Heimübungsprogramms für das hohe Lebensalter, eingebunden in das hausärztliche Umfeld]

Submission date
23/03/2009

Registration date
30/03/2009

Last Edited
18/09/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Other

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.priscus.net

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01ET0720 (German Federal Ministry of Education and Research)

Study information

Scientific Title
Feasibility of a multidimensional home-based exercise program for the elderly with structured support given by primary care practices: a single arm trial preparing a randomised controlled trial

Study objectives
Introduction: physical inactivity and multimorbidity -
Little data exists for the multimorbid elderly concerning their physical activity habits and how to change them. Despite the known benefits of physical activity for health, functioning and quality of life, most of the older adults seem to fail existing physical activity guidelines. On the other hand, physical inactivity is one of the primary contributors to functional decline in the elderly. Chronic medical conditions also have been shown to be one of the most potent contributors to functional decline.

Background: physical activity programs -
A multidimensional activity program that includes endurance, strength, balance, and flexibility training is generally considered to be optimal for older adults. Activities should be tailored to the individual to ensure maximal enjoyment with the goal of optimising adherence (American College of Sports Medicine [ACSM]/American Heart Association [AHA] 2007). In addition, participants receiving high-intensity counselling increase physical activity over a longer period than other groups. The authors concluded that partnering primary care providers with specialised exercise counsellors for age- and health-appropriate physical activity counselling is effective.

Aim of the study:
On the individual level: to develop a physical activity program according to the ACSM guidelines
On the institutional level: to initiate a cooperation between primary care physician and exercise specialists, recruiting and supporting participants
On the methodological level: to analyse the feasibility and functional effects of the programme, and the adherence of the participants, thus gaining preliminary data for the preparation of a randomised controlled study

This trial belongs to subproject 4 of PRISCUS, a joint research programme on prerequisites for a new health care model for elderly people with multimorbidity. Using a previous framework, the present study belongs to phase II and is to prepare a phase III study.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ruhr-University of Bochum (Germany) Ethics Committee approved on the 10th February 2009 (ref: 3054-07)

Study design
Interventional single arm phase II feasibility study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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
Physical inactivity and multimorbidity

Interventions
The intervention program lasts 12 weeks. It consists of physical activity counselling and a home-based multidimensional activity program that has been developed according to current recommendations on physical activity in older adults (ACSM/AHA 2007). Every participant is instructed and supervised by his/her personal exercise therapist. Every exercise therapist holds a bachelor of sports science or a higher sports science degree. The exercise therapist provides an initial introduction (theoretically and practically) into the program (week 1), a given number of additional personal consultations within the practice of the participant's primary care physician (week 2, 4 and 6) and a given number of consultations on the telephone (week 3, 5, 7, 9 and 11).

Physical activity counselling:
Every participant receives standardised counselling by the exercise therapist pertaining to the benefits of physical activity. The counselling is aiming to improve knowledge and understanding of the preventive and therapeutic effects of physical activity on particular chronic conditions. The counselling also contains a systematic assessment of the actual physical activity status, a discussion of potential barriers, problem solving to overcome barriers (e.g. by creating an activity timetable), and the creation of individual physical activity goals. Every participant receives the German Olympic Sports Federation workbook 'Bewegungsangebote 70 plus' (Deutscher Olympischer Sport Bund, 2009) that contains information about physical activity programs for seniors.

Activity program:
The program consists of two main components that should be performed in alternating order:
1. A combination of home-exercises to improve strength, flexibility and balance (3 days per week)
2. Walking for exercise to improve aerobic capacity (4 days per week)

Based on the assessment of the actual physical activity habits of the participant, the exercise therapist adapts the activity program to the participant's abilities and needs and to his readiness to exercise. The activity program usually starts with a selection of a few simple exercises and with short walks. Additional exercises are taught by and by with the progression of the intervention. The duration of the walks is also increased in a stepwise manner. Every participant is taught (theoretically and practically) by his/her exercise therapist to correctly perform the home-exercises. A pictorial guidebook (including contact information for the exercise therapist and a statement of the physical activity goal) is provided to each participant to assist them in correct exercise performance. Days of rest are accepted according to the patient's needs. Patients are instructed to record their daily activity (activity log).

1. Home-exercises:
1.1. Strengthening exercises (10):
In order to train all major muscle groups, strengthening exercises comprise a combination of three lower body exercises, one core exercise and six upper body exercises.

Every exercise can be performed in two different variations: less intensive ('basic') or more intensive ('intensive'). Some exercises are to be performed using an elastic resistance band (Thera-Band® GmbH, Dornburg-Frickhofen, Germany). Depending on the performance and the progress, participants can be instructed to increase intensity by resistance advancing to the next color of elastic band (yellow band = lower resistance; red band = higher resistance). The level of effort should be moderate (5 or 6 on a 10-point scale, where no movement is 0, and maximal effort of a muscle group is 10). Participants should perform 3 sets of 15 repetitions of every exercise. They are instructed to not hold their breath during the exercises in order to prevent exercise induced blood pressure elevations.

1.2. Flexibility exercises (4):
Flexibility exercises (stretching) comprise two upper body and two lower body exercises. Participants are instructed to perform the exercises slowly, holding each position for approximately 15 seconds. They are instructed to stretch to a point of moderate tension without pain in the joints or muscles, gradually increasing the range of motion.

1.3. Balance exercises (2):
The program comprises two balance exercises that can be performed in two different variations ('basic' or 'intensive') depending on the participant's abilities.

2. Walking:
To improve aerobic capacity, participants are instructed to walk for exercise (around their homes) four times a week for 30 minutes. The level of effort should be moderate (5 or 6 on a 10-point scale, where sitting is 0 and all-out effort is 10). Depending on the physical activity habits and the abilities of the participant, it can be necessary to start with shorter walks of lower intensity. With the progress of the intervention, duration of the walks and intensity level can be increased in a stepwise manner after talking to the personal exercise therapist. Participants are instructed in the use of a pedometer and asked to begin recording daily pedometer counts.

Consultations with the exercise therapist in the primary care practice:
Within the consultations with the exercise therapist, patients get the opportunity to discuss problems with the exercise program. Exercises are controlled for correctness. New exercises are taught. Choice and intensity of exercises is adapted to performance level. The activity log is discussed. The consultations aim to improve knowledge and self-efficacy of the participants so that they are able to perform their activity program independently. Support is reduced in a stepwise manner and personal consultations are replaced by telephone consultations.

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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Appraisal by partaking primary care physicians (structured interview: would you participate again? Why/why not? Ideas for programme improvements?), measured after the last patient finished the study
2. Documentation of any undesirable event during the intervention (standardised report protocol: medical/non-medical; caused/not caused by exercise; subject may/may not continue exercises), measured continously during the training phase
3. Adherence and drop-out measures (drop-out conditions: medical reason, change or misjudgement of inclusion criteria, subject's own decision), measured at every contact with the patient (phone call, personal visit to the surgery, etc.)

Secondary outcome measures
1. Effect measures, measured before and after the individual training phase:
1.1. Motor tests: Timed Up and Go Test, Chair Rising Test, Tandem Stand, Tandem Walk, grip strength, Sit-and-Reach Test
1.2. Phone interview: 8-item Short Form Health Survey (SF-8), three month recall of frequency of falls, Falls Efficacy Scale (FES-I), PRISCUS-Physical activity questionnaire
2. Evaluation by participant, measured after the individual training phase:
2.1. Utility rating scale for programme actions and devices: instruction, personal and phone consultation, exercise booklet and diary, pedometer and elastic resistance band
2.2. Structured interview on programme features: duration, frequency of phone and personal consultation, recommendation for extent and intensity of exercise
2.3. Open question: concrete proposals for program improvements
3. Evaluation of exercise execution by the exercise therapist (three point scale rating: execution is correct, is not correct but without/and possibly with harmful consequences), measured after the individual training phase
4. Focus group discussion with stakeholder representatives (investigator, exercise therapists, primary care physicians, surgery personnel, participants, drop outs), measured after the last patient finished the study

Overall study start date
01/04/2009

Completion date
31/07/2009

Eligibility

Key inclusion criteria
All participants are recruited consecutively by primary care physicians within prespecified time periods. All patients aged greater than or equal to 70 years who are seen by the physician within his consultation hours within that time period are screened for eligibility for the study. Inclusion criteria include:
1. Aged greater than or equal to 70 years, either sex
2. Medical clearance from the primary care physician to participate in the study
3. Walking ability (with or without walking aid) and ability to get to repeated consultations in the primary care physician's practice
4. Patient being able to cooperate appropriately and to follow the instructions of the home-based activity program (primary care physician's judgement)
5. Patient providing written informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
90

Total final enrolment
91

Key exclusion criteria
1. Intervention doesn't fit into the patient's schedule
2. Untreated arterial hypertension or arterial hypertension despite antihypertensive medication (primary care physician's judgement)
3. Deterioration of an insufficiently controlled diabetes mellitus within the past 3 months (primary care physician's judgement) or HbA1c greater than 10% (if available)
4. Chronic heart failure New York Heart Association (NYHA) grade III - IV
5. Clinically relevant cardiovascular event within the past 3 months (e.g. unstable angina pectoris, myocardial infarction, coronary angiography/angioplasty, cardiac surgery)
6. Clinically relevant cerebrovascular event within the past 3 months (e.g. stroke, recurrent transient ischaemic attack [TIA])
7. Acute psychiatric disorder (e.g. depression)

8. Severe consuming illness
9. Any inpatient surgical procedure within the past 3 months
10. Concurrent participation in another clinical trial

Date of first enrolment
01/04/2009

Date of final enrolment
31/07/2009

Locations

Countries of recruitment
Germany

Study participating centre
Ruhr-University Bochum
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Sponsor type
University/education

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ROR
https://ror.org/04tsk2644

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany) - conducted within the research cooperation PRISCUS ('Prerequisites for a new health care model for elderly people with multimorbidity') (ref: 01ET0720)

Funder Name
Ruhr-University Bochum (Germany) - funding received from:

Funder Name
1. Department of Sports Medicine and Sports Nutrition

Funder Name
2. Department of Medical Informatics, Biometry and Epidemiology

Funder Name
University Münster (Germany) - Institute of Sport Science

Funder Name
University Witten/Herdecke (Germany) - Department of General Practice

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	17/08/2009		Yes	No
Results article	results	01/01/2013	18/09/2019	Yes	No