Effectiveness of a trainingsprogram on the metabolic syndrome, heart failure and cognition in institutionalysed elderly.

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The objective of the study is to investigate effects of training on insulin resistance (IR), chronic heart failure (CHF) and cognition of resthome residents.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON35216

Source
ToetsingOnline

Brief title
MetS study

Condition

- Heart failures
- Glucose metabolism disorders (incl diabetes mellitus)
- Cognitive and attention disorders and disturbances

Synonym
insulin resistance

Research involving
Human

Sponsors and support

Primary sponsor: Stichting de Hoven
Source(s) of monetary or material Support: UMCG;Stichting de Hoven

Intervention

Keyword: chronic heart failure, insulin resistance, resthome residents

Outcome measures

Primary outcome

Metabolic syndrome (Insulin resistance)

Secondary outcome

chronic heartfailure .

Cognition

Study description

Background summary

Background of the MetS study:
Western lifestyle leads to increase of the metabolic syndrome (MetS) and cardiovascular diseases (CVD), containing chronic heart failure (CHF). The MetS and CHF are associated and characterised by atherosclerosis and similar risk factors. The MetS prevales in 40% of aged of 70 plus in the USA. Insulin resistance (IR) is the most important indicator of the MetS. The CHF prevalence is nearly a quarter of the institutionalised elder people of the Netherlands. There is much evidence that exercise will decrease MetS, CHF and cognitive impairment in elder people, associated with quolity of life. Training seems important as means to improve quality of life of institutionalised elder people (RH-residents).
However, RH-residents are restricted in their possibilities to exercise because of multimorbidity, no exercise culture in resthomes, no companion to exercise with and financial shortage of the rest home. The question is whether RH-residents are able to exercise long and intensively enough to reach the depicted improvements on MetS, CHF and cognition, is still unanswered. The hypothesis is that RH-resdents can reach these improvements on MetS, CHF and cognition and this pilot is to test this hypothesis. The aim of this pilot study is to assess the number of participants needed to be able to test the

hypothesis in a definit study.

Study objective

The objective of the study is to investigate effects of training on insulin resistance (IR), chronic heart failure (CHF) and cognition of resthome residents.

Study design

Design: Randomised controlled intervention pilot study, unblinded, multicentre. The participants will be allocated at random at experimental and control group. Randomisation will be performed in any participating rest home. Measurements at base line and after intervention will be performed.

Intervention

Experimental intervention
A trainingsprogram is developed based on results of a literature review and on the ACSM/ AHA guidelines 27. The training is specifically composed for frail elder people and suitable to perform in rest homes. The intervention consists of training of diverse body functions. No specific equipment is required.
The program is a groupsintervention, with a group size of 8 till 10 persons .
The programma consists of :
1. Power training
2. Flexibility training
3. Balance training
4. Functional training, in which components of training sorts 1.-3. will be combined and which attributes movements used in activities of daily living.
The training last 1 hour and is to be performed twice a week during 16 weeks.
The ratio of training intensity, frequency and duration is as follows: The intensity depends on individual fitness level of the participants. These levels will be established during the first training session. The participants wil be enhanced to exert more than in normal life. The exertion level will be measured with the *Rating of Perceived Exertion Scale* during this training session on all 4 parts of the training program.
The training frequency is twice a week. Although more training effects are to be expected of a training frequency of trice a week, literature shows that frail institutionalised elderly drop off largely at training frequencies of trice a week with loss of study results confidence as a consequence.
The total training duration is based on literature. Moderate till strong effects of a functional mixed training are gained by training durations of at least 4 months.

Description of 1 hour training is as follows:
1. Warming up: low-intensity all round mobility exercises adressing major

muscle group of the upper and lower extremities. Durance10 min.
2. Power training: moderate to intensive progressive resistance training of the major muscle groups of upper and lower extrimities and trunc. Muscle groups: m. biceps brachii, m. triceps brachii, m. deltiodeus, m. pectoralis, m. latissimus dorsi, mw quadriceps femoris, mm. glutei, mm. adductores, mm. adductors, m.gastrocnemius, m. tibialis ant., ankle mm. Durance 15 min.
3. Balance training: moderate to intensive balance training. The intensity increases by decreasing the supporting body surface area and the manual support. The intensity of the exercises is at individual level. Durance 15 min.
4. Functional training: exercises simulating activities of daily life, just as walking, turning, get up and go, stair climbing. Durance 10 min.
5. Flexibility training: exercises from the cooling-down. Mobility will be improved by stretching. Durance 10 min.

Intervention of the control group
The interventions of the control group are similar to those of the experimental group concerning numbers, frequencies and duration of the sessions and group numbers. The control group sessions consists of social and informative activities. Activities are : video watching, music listening, social talks, games adressing relaxation but not cognitive or physical activities. Activities adressing cognotive or physical arousal are not desirable because of the risk of side-effects of the control group on the exeprimental group.

Study burden and risks

Rest home residents are asked to follow a twice a week trainingprogram or an informative/social program during 16 weeks. That applies to commitment and sustainability. Motives to keep on are plaisure in social contacts, feelings of fitness after training.
Also, participants will be subjected to questions, questionnaires, physical examination concerning their health. Most times, resthome residents will experience this positively as a serious form of attention to their problems.
And, one is subjected to blood sample taking before and after the study. Bloodsample taking has less risks.
Participants are exposed to a higher risk on falls during the training hours twice a week. At the other hand, risks on falls decrease after balance training and at increase of fitness. The risks might cancel each other out.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

resthome resident
has signed informed consent
willingness concerning this study
competence to walk > 10 m

Exclusion criteria

laser foto coagulation of retinopathia within the last 6 months
serious Parkinson Disease
serious multiple sclerosis
MMSE <21

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	05-01-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL25710.042.10