ISRCTN21220201 https://doi.org/10.1186/ISRCTN21220201

Long-term effects of group exercise on leg muscle strength in female primary care patients with cardio-metabolic risk factors

Submission date
16/09/2019

Recruitment status
No longer recruiting

Registration date
18/09/2019

Overall study status
Completed

Last Edited
23/11/2020

Condition category
Other

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

Plain English summary of protocol

Background and study aims
To optimize prevention and treatment according to guidelines of common diseases and disorders with physical activity, aerobic and resistance training, knowledge about the patient's psychological symptoms, physical function - for example, reduced leg-muscle strength - and eating behaviors, is important. Therefore, simple tests of the patient's leg strength and leg function in everyday clinical practice could be useful. A standardized method for testing leg-muscle strength and leg function in each leg to assess an individual's maximal step-up height (MSH) for comparison - i.e. the mean step-up height of left and right leg - has already been developed. The researchers have also investigated the short-term effects of a 3-month lifestyle intervention with a group exercise program on MSH and correlations between cardio-metabolic risk factors and MSH. Maximal step-up height has been suggested to be a health indicator. The main aim of this study is to investigate the long-term effects (mean 22 months) of the 3-month group exercise programme on leg-muscle strength and leg function in female patients with common diseases, elevated cardio-metabolic risk, musculoskeletal pain and reduced capacity for work. Furthermore, the researchers studied factors associated with long-term effects on MSH in the whole study population, in subgroups of patients of different ages, as well as in subgroups with high, medium or low maintenance of leg muscle strength assessed as maximal step-up height (MSH).

Who can participate?
Women aged over 19 with various symptoms and diseases related to the musculoskeletal system, obesity, cardiovascular diseases, diabetes, and psychological ill health (depression, stress and psychosocial problems), for whom physicians found that increased physical activity would potentially have a favourable effect as treatment

What does the study involve?
All participants receive the same kind of intervention in this study. They are interviewed by the project nurse about medical problems, medication, psychosocial functioning and lifestyle, earlier experience of physical activity, and finally patient barriers to regular exercise. The nurse gives medical guidance to the patient's choice of supervised group exercise according to the medical

diseases and disorders. Measurements of bodyweight, height, waist circumference, maximal step-up test, and cycle ergometer test are carried out at the start of the study, directly after the 3-month training period and after 22 months at long-term follow-up. At every test session the results are discussed with the patient and the individual initial plan for group training could be adjusted. Training sessions take place three times per week. The patient could choose from around 15 different types of group exercise. The exercises are classified as most aerobic fitness or strength or both, and training of balance and coordination. All sessions are supervised by medically educated and experienced trainers. The training takes place outside the health care provider’s premises, in gyms, school buildings, in the hospital and the community indoor swimming facilities and on forest tracks, to enhance capacity and make it possible to include patients consecutively. The patients are asked at the beginning of group training to choose the training they want to continue with. At the 3-month follow-up immediately after the group training period, the patient is told that the timing of the long-time follow-up could not be specified. The patients are told that a notice would come later within a few years for the long-term follow-up. No contact with the research team is planned in the meantime. The usual care is given for the patient's illnesses and complaints in the meantime until the invitation comes.

What are the possible benefits and risks of participating?
Assessment of maximal step-up height (MSH) could allow the trainer to detect low muscle strength and abnormalities in the locomotor system not observed with the patient in a resting position. The routines at every training session in the study will educate the patient on how to plan the individual training based on the patients MSH and cycle ergometer test. It helps the patient together with the trainer to choose the right intensity level at the start. This will reduce the risk of any side effects. Acute injuries and overload injuries will be prevented as far as possible based on the design of the study with individualized training and supervised training of medically educated trainers. Musculoskeletal complaints could be explained and followed by lower MSH. No adverse effects of the MSH assessments or cycle ergometer tests, and no serious adverse effects in connection with the training sessions, were reported in previous study. Muscle stiffness was the most common reported at the beginning of the training period.

Where is the study run from?
Karolina Primary Health Care Centre (Sweden)

When is the study starting and how long is it expected to run for?
February 2002 to August 2015

Who is funding the study?
1. Karolina Primary Health Care Centre (Sweden)
2. Karolinska Institutet (Sweden)

Who is the main contact?
Dr Lillemor A. Nyberg
lillemor.nyberg@oru.se

Contact information

Type(s)
Scientific

Contact name
Dr Lillemor A. Nyberg

ORCID ID
https://orcid.org/0000-0003-3086-7548

Contact details
School of Medical Sciences, Research and Education
Faculty of Medicine and Health
Örebro University
Örebro
Sweden
SE-701 82
+46 (0)19 303 000
lillemor.nyberg@oru.se

Additional identifiers

Study information

Scientific Title
Long-term effects of group exercise intervention on maximal step-up height in female primary care patients with cardio-metabolic risk factors

Acronym
MABRA

Study objectives
Low physical performance is a predictor of morbidity and mortality. This study looks at long-term effects of an exercise intervention, the MABRA project in primary health care, on leg muscle strength and function assessed with the standardised maximal step-up test (MST) as maximal step-up height (MSH) in female patients with low physical function. Furthermore, the researchers studied correlates to changes in MSH with common changes in cardio-metabolic risk factors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/01/2002 and 05/05/2003, Regional Scientific Ethics Committée at Region Örebro County, Örebro, Sweden (from 01/01/2019 this ethics committee is included in the Swedish Ethical Review Authority, Box 2110, SE-750 02 Uppsala, Sweden, Tel: +46 (0)10 475 08 00; Email: registrator@etikprovning.se), refs: Dnr 500:16, 1180/01, Dnr 500:16, 161/03

Primary study design
Interventional

Study design
Single-centre interventional non-randomised study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic diseases and common illnesses treatable with physical activity/aerobic fitness and strength training according to clinical guidelines both physical and psychiatric

Interventions
After a personal visit and examination, three weekly training sessions were agreed with each patient when they began the program in the MABRA project. Every training session was supervised by medically trained and experienced coaches. Local gyms, the municipal swimming pool, outdoor tracks and school facilities were used. At each training session, coaches met the patients before training and explained the intensity of the exercise in order to individualise the training for each patient at every session due to patient's self-reported health status. The patients were trained to use the 6-20 Borg RPE Scale to record perceived intensity at every session. Start level was low at Borg 7-8. The highest level was Borg 14-15. Group exercise included 3 sessions/week of mixed aerobic fitness - predefined with ordinary, light or light-light intensity according to Borg scale - and strength training.

Intervention Type
Behavioural

Primary outcome(s)
Maximal step-up height (MSH) assessed, at preset levels 3 cm apart, with MST in a step-up device, the step-up box, built by the first author. The MST assesses the individual’s current highest step-up height on each leg. The MST method, which includes information to the examiner on how to instruct and encourage the patient during the MST, is thoroughly described elsewhere. Measured at baseline (T0), after 3 months (T1) and after mean 22 months (T2)

Key secondary outcome(s)
Measured at baseline (T0), after 3 months (T1) and after mean 22 months (T2):
1. Age (years) extracted from the official patient records at baseline
2. Height measured without shoes to the nearest 0.5 cm using a scale fixed to the wall at baseline
3. Bodyweight measured in light clothing without shoes to the nearest 0.1 kg using an electronic balance (Seca Delta model 707)
4. BMI calculated according to standard practice (kg·m-2), both measurements at baseline, 3 and 22 months
5. Waist circumference (cm) assessed at the level of the umbilicus according to standard practice at baseline, 3 and 22 months
6. VO2-max estimated as described by Åstrand from each participant’s individual heart rate response to a given submaximal workload (i.e. 50–150 W, depending on the participant’s weight and self-reported physical activity) using a bicycle ergometer (Monark, Varberg, Sweden) and recorded at steady-state with a heart rate 120-150 beats·min-1, and quantified as peak absolute oxygen consumption per kg body weight per minute (mL·kg-1·min-1)
7. Self-reported exercise and physical activity (PA) levels assessed using a validated questionnaire common in occupational health care in Sweden at baseline and at the third assessment at long-term follow-up (mean 22 months). The PA question included a definition of exercise, i.e. allocates time for exercise in order to maintain or improve fitness, health and wellness, and one of five levels were registered. Leisure-time PA or sedentary behaviour was not registered during the 3-month group exercise intervention. Patients filled in their own exercise diary at each group training session during the study and coaches checked and signed the diary.
8. The Swedish version of a generic health-related quality of life scale, the SF-36 scores, was administered and the subscale of physical function was extracted for further analyses:
8.1. Physical function score (PF, 0-100)

8.2. Any limitations score reported in the PF's item 3b, 3d, 3f and 3g, respectively (1=severely limited, 2=somewhat limited, 3=no limitation, item score range 1-3)
8.3. The summary of any limitations score in item 3b, 3d, 3f and 3g ranging from 4-12 (from 4=severely limited in all items to 12=no limitation in any of the four items)

Completion date
31/08/2015

Eligibility

Key inclusion criteria
Out of 214 female patients consecutively referred from primary health care, 178 attended a first test (T0) and 156 participated in a 3-month group exercise intervention program and took part in a second assessment (T1). Out of these 156 patients, 114 were randomly invited for a third assessment (T2) out of whom 101 agreed to participate and were included in this study on long-term effects. No significant difference in baseline measurements between the 101 participating patients and remaining were found regarding anthropometry, education, sick leave, self-reported pain and/or reduced physical function.

The inclusion criteria were:
1. Women who presented themselves for primary care with various symptoms and diseases related to the musculoskeletal system, obesity, cardiovascular diseases, diabetes, and psychological ill health (depression, stress and psychosocial problems)
2. For whom physicians found that increased physical activity would potentially have a favourable effect as treatment
3. Was over 19 years old
4. Were sufficiently motivated and could accept group training three times per week for three months
5. Was able to take part in group training without personal assistance and able to transport themselves independently to and from the exercise activities
6. Could understand Swedish

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
101

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
10/05/2003

Date of final enrolment
30/09/2004

Locations

Countries of recruitment
Sweden

Study participating centre
Karolina Primary Health Care Centre, Karlskoga, Region Örebro County
Urbrinken 4
Karlskoga
Sweden
SE-691 81

Sponsor information

Organisation
Örebro University

ROR
https://ror.org/05kytsw45

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Karolina Primary Health Care Centre

Funder Name
Karolinska Institutet

Alternative Name(s)
Karolinska Institute, KI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analyzed during the current study are not publicly available as it is a clinical study on patients, but are available from the investigator/corresponding author Dr Lillemor Nyberg (lillemor.nyberg@oru.se) on reasonable request for research. The dataset in Excel contains a description of patients, baseline measurements and at 3 and 22 months follow-up of primary and secondary variables. This data will be available after publication for one year. Data anonymization, no other restrictions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/03/2020	23/11/2020	Yes	No