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Effects of personalized exercise training on physical activity, health-related fitness, sleep quality, and quality of life among middle-aged and older adults with multiple health problems

Submission date
29/10/2020

Recruitment status
No longer recruiting

Registration date
29/10/2020

Overall study status
Completed

Last Edited
15/03/2022

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The presence of multimorbidity in middle-aged and older adults, which reduces their physical activity and quality of life, is a global health challenge. We designed a 12-week personalized aerobic exercise training program for middle-aged and older adults with Multimorbidity.

Who can participate?
Adults, over 40 years old, with multimorbidity.

What does the study involve?
Participants were randomized by a research assistant to one of three groups:
1. The intervention group, which received 12 weeks of multidiscipline (including a physician, nurse, and physiotherapist) personalized aerobic exercise training in the rehabilitation department and personalized exercise and medication recommendations at home
2. The comparison group, which received 12 weeks of personalized exercise and medication recommendations at home
3. The control group, which received 12 weeks of usual care. The outcomes were measured at baseline and after 12 weeks in all participants

What are the possible benefits and risks of participating?
Participants may have benefits to increase physical activity and improve fitness, sleep quality and quality of life.
Participants may have risks of some aerobic exercise side effects like excessive sweating, muscle fatigue and soreness etc.

Where is the study run from?
Tri-Service General Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
November 2016 to June 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Yi Pang Lo (winfly1017@hotmail.com)

Contact information

Type(s)
Scientific

Contact name
Prof LiChi Chiang

ORCID ID
https://orcid.org/0000-0002-6383-7495

Contact details
School of Nursing
National Defense Medical Center
161 Sec. 6 Mingchuan E. Rd.
Taipei
Taiwan
114
+886-02-87923100 ex 18765
lichichiang@gmail.com

Type(s)
Public

Contact name
Mr YiPang Lo

ORCID ID
https://orcid.org/0000-0001-8079-4215

Contact details
School of Nursing
National Defense Medical Center
161 Sec. 6 Mingchuan E. Rd.
Taipei
Taiwan
114
+886-0988-082940
808010023@mail.ndmctsgh.edu.tw

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effect of aerobic exercise training on physical activity, health-related fitness, sleep quality, and quality of life among middle-aged and older adults with multimorbidity

Study objectives
A 12-week personalized aerobic exercise training program in a rehabilitation center can increase physical activity and improve health-related fitness, sleep quality, and quality of life in middle-aged and older adults with multimorbidity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/11/2016, Institutional Review Board, Tri-Service General Hospital (No.325, Sec.2, Cheng-Kung Rd. Neihu 11490, Taipei, Taiwan, R.O.C;), ref:

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multimorbidity (more than two of the following: hypertension, hyperlipidemia, diabetes, stroke, cancer, heart disease, kidney disease, asthma, chronic obstructive pulmonary disease, osteoporosis, degenerative arthritis, gout, depression, schizophrenia, and bipolar disorder)

Interventions
A randomized controlled trial with three groups was created. All eligible middle-aged and older adults with multimorbidity were randomized by a research assistant to one of three groups:
1. The intervention group, which received 12 weeks of multidiscipline (including a physician, nurse, and physiotherapist) personalized aerobic exercise training in the rehabilitation department and personalized ExRx recommendations at home
2. The comparison group, which received 12 weeks of personalized ExRx recommendations at home
3. The control group, which received 12 weeks of usual care

The randomization sequence was generated using the random number function in Microsoft Excel. Block randomization was designed and stratified by age (<65 years old, ≥65 years old) and gender (male, female). The researchers involved in the data collection were blinded to the group allocation.

Intervention Type
Behavioural

Primary outcome(s)
Measured at baseline and after 12 weeks:
1. Demographic data measured by self report
2. Self-perceived health status measured using the Self-perceived health status scale (Chinese version)
3. Activity measured using the International Physical Activity Questionnaire (IPAQ)-Chinese version short form
4. Objective measurements of health-related physical fitness parameters were performed by a well-trained research assistant:
4.1. Resting heart rate and blood pressure
4.2. Body mass index (BMI) (kg/m²)
4.3. Upper limb grip strength
4.4. Muscular endurance measured using the 30-second chair stand test
4.5. Flexibility measured using the chair sit-and-reach test
4.6. Pulmonary function tests
4.7. Cycle ergometer-based graded exercise test (GXT) using a ramp protocol supervised by a rehabilitation/sports medicine physician to collect data on maximal oxygen uptake (VO2 max), anaerobic threshold (AT), and work, etc., to assess cardiorespiratory fitness

Key secondary outcome(s))
1. Sleep quality measured using PSQI scale Chinese version at baseline and after 12 weeks
2. Quality of life measured using SF-36 Chinese version at baseline and after 12 weeks

Completion date
30/06/2017

Eligibility

Key inclusion criteria
1. Over 40 years old with multimorbidity
2. No cognitive impairment (MMSE > 24)
3. Able to communicate in Mandarin
4. Provided informed consent
5. Current physical activity amount does not meet the WHO recommendations (<150 minutes of moderate-intensity physical activity/week or <75 minutes of vigorous-intensity physical activity /week).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
43

Key exclusion criteria
1. Aerobic exercise training contraindications according to the updated ACSM recommendations for exercise preparticipation health screening as demonstrated by a rehabilitation/sports medicine physician
2. Unable to tolerate moderate to vigorous aerobic exercise training due to impaired neurogenic /musculoskeletal conditions
3. Unable to cooperate with aerobic exercise training
4. Unable to walk without assistance
5. Have been judged to be unsuitable for participation in this study by a rehabilitation/sports medicine physician for other reasons

Date of first enrolment
09/11/2016

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
Algeria

American Samoa

Andorra

Angola

Anguilla

Antarctica

Antigua and Barbuda

Argentina

Armenia

Aruba

Taiwan

Study participating centre
Tri-Service General Hospital
No.325, Sec.2
Cheng-Kung Rd.
Neihu
Taipei
Taiwan
11490

Sponsor information

Organisation
National Defense Medical Center

ROR
https://ror.org/02bn97g32

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/12/2020	15/03/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes