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A Nordic-walking intervention program to improve physical fitness in middle-age and older adult Serbian women

Submission date	Recruitment status	[_] Prospectively registered
08/01/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/01/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/02/2024	Other	

Plain English summary of protocol

Background and study aims:
Aging and lack of physical exercise are related to a decrease in fitness of the heart, lungs, and muscles, and is also linked to worsened metabolism.

The main aim of this study was to examine the effect of recreational walking, Nordic walking, or no change in physical activity, over 12 weeks on body composition and heart rate in middle-aged and older adult women.

Who can participate?
Healthy middle-aged and older adult women aged 50 to 69 years

What does the study involve?
Participants in this study will be assessed at the start of the study and after 12 weeks using the Urho Kaleva Kekkonen walking test. They will be divided into three groups: a control group who do not make any changes to their physical activity; a Nordic walking group who will have 12 weeks of nordic walking training, 3 sessions a week; and a recreational walking group who will have 12 weeks of walking training, 3 sessions a week. The training program will be supervised by physical exercise specialists and will be adapted individually, for each of the participants. Heart rate will be monitored during the recreational walking and nordic walking training to ensure the intensity of training is suitable. Over the 12 weeks, the duration and intensity of this training will increase. The training sessions will last between 35 and 45 minutes.

What are the possible benefits and risks of participating?:
Participants in the recreational walking and Nordic walking groups may observe improvements in their physical fitness.

The risks of participating in the recreational walking and Nordic walking training are minimal because the eligible participants are healthy and the physical activity will be observed and controlled by specialists.

Where is the study run from?
University of Novi Sad (Serbia)

When is the study starting and how long is it expected to run for?
From August 2019 to October 2021

Who is funding the study?:
Investigate initiated and funded

Who is the main contact?:
1. Dr. Nebojsa Cokorilo (Serbia)
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2. Dr. Pedro J. Ruiz-Montero (Spain)
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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
12-weeks Nordic-walking intervention program: cardiorespiratory capacity and physical fitness in middle-age and older adult Serbian women

Acronym
12NW

Study objectives
To examine the effect of an intervention of 12-week in three groups (control, Recreational walking and Nordic walking) on body composition and heart rate variables, and maximal oxygen consumption in middle-age and older adult women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/06/2020, University of Novi Sad Faculty of Sport and Physical Education Ethics Committee - Commission (Novi Sad 21000, Serbia;+381 21 450 188; fsfv@uns.ac.rs), ref: 46-06-03 /2020-1

Study design
Interventional open non-randomized controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cardiorespiratory health and physical fitness

Interventions
Participants will be divided into one of 3 groups: the recreational walking (RW) training group, the Nordic walking (NW) training, and the control group.

Data will be collected on two occasions. The participants will visit the measuring area in the University of Novi Sad, and their body composition characteristics will be measured in a session of approximately 20 min, 48 hs before starting the interventional program for the baseline assessment, and 48 h after the 12-week training process is complete. On both occasions, participants will be evaluated in the morning and with environmental conditions controlled.

The recreational walking (RW) and Nordic walking (NW) training will last for a duration of 12 weeks, with sessions occurring three times a week, in the morning, with a duration between 35 and 45 min. During the intervention of RW and NW programs, the participants of this study took part in no other physical activity.

The participants from the NW group will use specific poles for three months. NW is convenient for intensifying training and what is especially important is the fact that joints are protected. The use of walking poles unburdens the passive walking apparatus, such as tendons and connective tissue, back, and joints (especially knees). That is why NW is ideal as a rehabilitation sport for people with orthopedic injuries and other health problems as obesity.

Participants from the RW group will use no poles. Walking without sticks could be considered as RW. RW is one of few activities which suits the majority of people: it is pleasant, people spend time outside in the fresh air, it is good for socializing, it does not put such an effort on the body as other activities, injuries are rare and there are no special preconditions for its implementation. Therefore, RW alone is not enough to reach an intensity necessary to produce a training modification in healthy middle-aged and older adults.

The complete program will take place in trim track (park “Sremska Kamenica”, Novi Sad, Serbia) which offers good conditions for this activity. The training program will be supervised by physical exercise specialists and will be adapted individually, for each of the participants, complying with the principles of sports training and the age of the participants. Moreover, the individual physical characteristics of each of the participants will be considered and controlled the correctness, range, and intensity of exercising during the whole treatment.

Prior to each activity, the participants will know what the necessary heart rate (HR) during the training was. The program of walking was conceptualized in such a way that the participants will always be in the aerobic zone of performance. During the walking exercise, HR will be monitored by use of a pulse meter and used to determine load intensity.

Both training programs were divided into three parts different by volume and intensity (calculated as a percentage of maximum heart rate). Participants will receive three weekly training sessions of 35 min of continuous aerobic work during the first four weeks (first month of the training program) at an intensity (percentage of maximum heart frequency) of 60%-65%

of the total. From the fifth to eighth training week (second month of the training program), the duration of training sessions will be 40 min of continuous aerobic work three times per week at 65%-70% intensity. Finally, in the final 4 weeks, sessions will last 45 min of continuous aerobic work, three times per week, with an intensity of 75%-80%.

During the intervention of the RW group and NW group, participants will do a warm-up for ten minutes in a limited space of the trim track. Specifically, the participants will perform movement exercises such as lateral steps, knee elevation, tiptoe walk, fast arms movement, etc. After the warm-up, the main block of the session will be followed by 20 minutes (in weeks 1 to 4), 25 minutes (in weeks 5 to 8), and 30 minutes (in weeks 9 to 12) of continuous aerobic work by walk, RW or NW depending on the experimental group. There will also be a cool-down involving stretching activities lasting 5 minutes after each session.

The control group will not have any supervised training sessions and were recommended not to modify daily activities.

Cardiorespiratory fitness and body composition will be assessed at baseline (pre-intervention) and after 12 weeks (post-intervention) for all participants. To measure the cardiorespiratory capacity the Urho Kaleva Kekkonen walk test for adults aged between 18-69 will be used. The UKK walk test lies in walking 2 km on a flat surface at as brisk a pace as possible. The results of this test indicate a fitness index, taking into consideration the age, gender, body height, body weight, and time taken to complete the 2 km walking, and heart rate (HR) at the end of the test.

Age and gender were asked by two ad hoc questions. Body height was measured to +/- 0.1 kg using a stadiometer (SECA 213, Hamburg, Germany) whereas the body weight (kg) was measured with an electronic scale (SECA, Hamburg, Germany) with participants wearing light indoor clothing and no shoes. BMI (kg/m^2) will be calculated. The HR at the end of the UKK walk test and the walking HR during the UKK walk test were measured by a pulse watch and chest belt (Polar FT2, Kempele, Finland).

Before the body composition measurement, participants were requested to fast for 4 h prior, to not drink alcohol the 8 h prior, and to not perform any physical exercise 8 h prior. The participants visited the measuring area in the University of Novi Sad, and their body composition characteristics were measured in a session of approximately 20 min, 48 h before starting the interventional program and 48 h after. They were evaluated in the morning and environmental conditions were controlled.

All tests were repeated at the same space and time in post-test with the same condition humidity (30-40%).

Intervention Type
Other

Primary outcome measure
1. Cardiorespiratory fitness measured using the time taken to complete the Urho Kaleva Kekkonen (UKK) walk test, a pulse meter, stadiometer, and electronic scales to calculate the UKK fitness index at baseline and 12 weeks

Secondary outcome measures
1. Maximal oxygen consumption (VO2max) during the Urho Kaleva Kekkonen walk test measured using a pulse meter, stadiometer, and electronic scales and calculated using an

equation (116.2-[2.98 x time {min/sec}]-[0.11x heart rate {bpm}]-[0.14 x age {years}]-[0.30 x BMI {kg/m²}]) at baseline and 12 weeks

Overall study start date
01/08/2019

Completion date
30/10/2021

Eligibility

Key inclusion criteria
1. Aged between 50 and 69 years
2. Able to complete the walking test of 2 km without assistance
3. Able to communicate by spoken or written communication

Participant type(s)
Healthy volunteer

Age group
Senior

Sex
Female

Target number of participants
166

Total final enrolment
166

Key exclusion criteria
1. Declined to participate
2. Severe somatic or psychiatric disorders

Date of first enrolment
01/05/2019

Date of final enrolment
30/07/2021

Locations

Countries of recruitment
Serbia

Study participating centre

Faculty of Sport and Physical Education, University of Novi Sad
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Sponsor information

Organisation
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Sponsor type
University/education

Website
http://www.uns.ac.rs/sr/

ROR
https://ror.org/00xa57a59

Funder(s)

Funder type
Other

Funder Name
Investigators initiated and funded

Results and Publications

Publication and dissemination plan
We plan to publish this study in a high-impact peer-reviewed journal as BMC Geriatrics.

Intention to publish date
20/01/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request via email from Dr. Pedro Jesús Ruiz-Montero (pedrorumo@ugr.es). The anonymised raw data will be available between 01/03/2021 and 30/07/2021 for quantitative analysis by one-way variance (ANOVA) in the pre-intervention and post-intervention tests.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/05/2022	28/02/2024	Yes	No