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# Measured and supervised physical exercise for older Individuals (MIOLI). Effects of exercise interventions on physical activity, functional capacity, quality of life and health service usage

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| **Submission date**<br>21/05/2024 | **Recruitment status**<br>Recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>07/06/2024 | **Overall study status**<br>Ongoing | |
| **Last Edited**<br>11/06/2026 | **Condition category**<br>Respiratory | |

## Plain English summary of protocol

Background and study aims
The measured and supervised physical exercise for older individuals (MIOLI) intervention study targets older adults with respiratory and circulatory diseases in the North Savo region. The MIOLI study focuses on physical activity, functional capacity, quality of life and use of health services. The aim of the study is to improve long-term physical and daily activity, functional capacity and quality of life in older adults, with respiratory and circulatory diseases. The study consists of two parts, including a physical activity mini-intervention in phase 1, and a randomised controlled physical activity intervention in phase 2. The physical activity interventions in the MIOLI study are accessible to all, easy to implement at different times of the year and affordable.

Who can participate?
Adults aged 55 - 80 years with well-controlled asthma and/or chronic obstructive pulmonary disease (COPD) and/or sleep apnea

What does the study involve?
Phase 1 of the study. Physical activity mini-interventions is a cross-sectional study with follow-up. The aim is to increase physical activity and daily activity through short (2-4 hours) physical activity trials and counselling. The mini-intervention physical activity events are also recruitment events for the RCT study.

Phase 2 of the study: a randomised controlled physical activity intervention. The aim is to improve physical fitness, functional capacity, respiratory health, regular physical activity and quality of life through a 3-month long, group-based, supervised physical activity intervention. The target group is people aged 55-80 years, living in North Savo, with asthma and/or chronic obstructive pulmonary disease (COPD) and/or sleep apnea, who have reported being sedentary. The assumption is that correctly measured, individual guidance and physical activity training will improve physical fitness, functional capacity and respiratory health, and increase self-motivated physical activity. The effects of the intervention will be assessed using objective and subjective

measures of physical fitness and activity before the intervention, immediately after the intervention and 6 months after the intervention. Measurements will also include assessments of health status, functional capacity, quality of life and service use. A total of 100 subjects will participate in the Physical Activity Intervention Study, of whom 50 will be allocated to the intervention group and 50 to the control group. Physical activity training for the intervention group will include the development of an individualised physical activity plan, Nordic walking, balance and muscle strength training. Those, in the control group, will be encouraged to continue their daily activities and physical activity as they have been doing independently in the past. Control group participants will receive physical activity counselling and advice after the end of the physical activity intervention for intervention group participants. Subjects in both groups will undergo a medical examination, laboratory tests, respiratory and circulatory function tests and measures of functional capacity and quality of life.

What are the possible benefits and risks of participating?
All participants benefit from receiving information, guidance and advice about their daily physical activity, functional capacity and health, and quality of life. Participants who receive the personalized Nordic Walking program may benefit from improved daily physical activity, functional capacity, quality of life and respiratory health. There is a small risk that participants may fall or become injured during Nordic Walking training.

Where is the study run from?
Savonia University of Applied Sciences (Finland)

When is the study starting and how long is it expected to run for?
February 2023 to December 2027

Who is funding the study?
Kuopion Seudun Hengityssäätiö (Finland)
OLVI-Säätiö (Finland)

Who is the main contact?
Marja marja.aijo@savonia.fi

# Contact information

### Type(s)
Public, Scientific, Principal investigator

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# Additional identifiers

# Study information

### Scientific Title
Measured and supervised physical exercise for older Individuals (MIOLI). Effects of exercise interventions on physical activity, functional capacity, quality of life and health service usage

### Acronym
MIOLI

### Study objectives
A randomized controlled physical activity intervention. The aim is to improve physical fitness, functional capacity and respiratory health and increase regular physical activity and quality of life through three months of group-based, supervised physical activity intervention.
Hypothesis 1: It is assumed that physical activity training with individualized guidance will improve physical fitness, functional capacity and respiratory health.
Hypothesis 2: It is assumed that physical activity training with individualized guidance will increase self-motivated physical activity and quality of life.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 19/03/2024, changes approved 17/06/2025, Regional Medical Research Ethics Committee of Wellbeing Services County of North Savo (Pohjois-Savon hyvinvointialue, Puijonlaaksontie 2, PL 1711, Kuopio, 70211, Finland; +358 (0)17 173 311; tutkimuseettinentoimikunta@pshyvinvointialue.fi), ref: 892/13.00/2023

### Primary study design
Interventional

### Study design
Randomized controlled trial

### Study type(s)
Prevention, Quality of life

### Health condition(s) or problem(s) studied
Asthma, chronic obstructive pulmonary diseases, cardio-vascular diseases

### Interventions
Participants randomized to the physical activity intervention group will engage in a three months individualized training program. The exercise programme includes three times per week guided group-based exercise in which included in twice a week Nordic walking exercise and once a week muscle strength, balance, and flexibility exercise. In addition to supporting independent practice, participants will be guided through individual self-practice. The training time increases progressively from 30 minutes to an hour during the intervention. The Nordic-walking training is designed to be progressive, monitoring the workload of the training with a heart rate monitor.

The exercise programme will be given to the subjects in written form and its implementation will be monitored and supported by supervised exercise sessions, giving the subjects the opportunity to discuss with the physiotherapist the exercise.

The physical activity training during the intervention will be monitored by means of a physical activity diary. In addition, daily physical activity in both groups will be monitored using ActiGraph GT3X accelerometers (ActiGraphTM wGT3X-B; Pensacola, FL, USA) and an exercise diary (exercise card) throughout the three months. The ECG of the intervention group will be monitored using a Beat2Phone (Vital-Signum, Helsinki, Finland) during exercise and recovery.

People in the control group are encouraged to continue their daily activities and physical activity as they have done independently in the past. Control group participants will receive physical activity guidance and advice at 3 months from the start of the physical activity intervention to support independent physical activity during the follow-up period.

Randomization
Randomization is stratified for asthma and COPD participants. After the baseline measurements, the patients will be randomized by permuted block randomization based on computer-generated random numbers and these blocks are created to asthma and COPD participants separately. The block size is fixed to contain 4 participants: 2 to control, 2 to intervention group. After the randomization, study subjects will be advised not to discuss issues related to group allocation during the assessments. The participants will be re-informed of the study design and procedures at the time of randomization. Study participants will be told that the goal of the study is to explore whether 12-week exercise intervention will have an effect on cardiorespiratory fitness. All baseline data are collected prior to the randomization to prevent participants and study personnel from being biased due to group assignment. At follow-up measurements, the investigators who will perform or evaluate the outcome measures will be blinded to the study groups.

### Intervention Type
Behavioural

### Primary outcome(s)
Cardiorespiratory endurance: 6 minutes walking test: baseline, 3 and 9 months

### Key secondary outcome(s)
1. Functional capacity: Short Physical Performance Battery (SPPB) the total score of the test sections, baseline, three and nine months: baseline, 3 and 9 months
2. Physical activity, Survey, International Physical Activity Questionnaire (IPAQ), baseline, 3 and 9 months
3. Spirometry: forced expiratory volume in one second (FEV1): baseline, 3 and 9 months
4. Quality of life, The RAND 36-Item Health Survey 1.0: baseline, 3 and 9 months

### Completion date
31/12/2027

## Eligibility

### Key inclusion criteria
Current inclusion criteria as of 02/09/2025:
1. Place of residence: North Savo region

2. Age 55-80 years
3. To have well-controlled asthma or chronic obstructive pulmonary disease (COPD) or sleep apnea
4. No recurrent exacerbations or daily symptoms
5. Symptoms score in COPD Assessment Test™ (CAT) < 10 points
6. Forced expiratory volume in one second FEV1, measurement Z-score ≥ -2.5
7. No need for regular symptom-relieving medication
8. The health status (physician assessment) is adequate for participation in physical exercise.
9. New York Heart Association classification (NYHA) 1-2
10. Self-reported low physical activity: Does not engage in physical activity independently or in guided groups on a weekly basis. Engages in physical activity an average of 1–3 times or less per week.
11. Normal or mildly elevated blood pressure

Previous inclusion criteria as of 07/11/2024:
1. Place of residence: Kuopio and Siilinjärvi, North Savo region
2. Age 55-80 years
3. To have well-controlled asthma or chronic obstructive pulmonary disease (COPD)
4. No recurrent exacerbations or daily symptoms
5. Symptoms score in COPD Assessment Test™ (CAT) < 10 points
6. Forced expiratory volume in one second FEV1, measurement Z-score ≥ -2.5
7. No need for regular symptom-relieving medication
8. The health status (physician assessment) is adequate for participation in physical exercise.
9. New York Heart Association classification (NYHA) 1-2
10. Self-reported low physical activity: Does not engage in physical activity independently or in guided groups on a weekly basis. Engages in physical activity an average of 1–3 times or less per week.
11. Normal or mildly elevated blood pressure

Previous inclusion criteria:
1. Place of residence: Kuopio, North Savo region
2. Age 55-75 years
3. To have well-controlled asthma or chronic obstructive pulmonary disease (COPD)
4. No recurrent exacerbations or daily symptoms
5. Symptoms score in COPD Assessment Test™ (CAT) < 10 points
6. Forced expiratory volume in one second FEV1, measurement Z-score ≥ -2.5
7. No need for regular symptom-relieving medication
8. The health status (physician assessment) is adequate for participation in physical exercise.
9. New York Heart Association classification (NYHA) 1-2
10. Self-reported low physical activity: Does not engage in physical activity independently or in guided groups on a weekly basis. Engages in physical activity an average of 1–2 times or less per week.
11. Normal or mildly elevated blood pressure

## Participant type(s)
Other

## Healthy volunteers allowed
No

## Age group

Mixed

## Lower age limit
55 Years

## Upper age limit
80 Years

## Sex
All

## Total final enrolment
0

## Key exclusion criteria
Current exclusion criteria as of 02/09/2025:
1. Place of residence: Other than North Savo region
2. Age under 55 years or over 80 years
3. Suffers from uncontrolled asthma or chronic obstructive pulmonary disease (COPD)
4. Experiences recurrent exacerbations or daily symptoms
5. Symptoms score in COPD Assessment Test™ (CAT ) >10 points
6. Forced expiratory volume in one second FEV1,FEV1 measurement Z-score < -2.5
7. Requires regular symptom-relieving medication
8. Physician-identified health barrier to participate in the intervention
9. Severe/unstable heart disease, not well controlled
10. Symptoms during exertion/exercise in daily life
11. New York Heart Association classification (NYHA) 3-4
12. Engages in moderate or vigorous physical activity actively more than 3 times a week
13. Blood pressure 160/100 mmHg (discretionary)

Previous exclusion criteria as of 07/11/2024:
1. Place of residence: Other than Kuopio or Siilinjärvi, North Savo region
2. Age under 55 years or over 80 years
3. Suffers from uncontrolled asthma or chronic obstructive pulmonary disease (COPD)
4. Experiences recurrent exacerbations or daily symptoms
5. Symptoms score in COPD Assessment Test™ (CAT ) >10 points
6. Forced expiratory volume in one second FEV1,FEV1 measurement Z-score < -2.5
7. Requires regular symptom-relieving medication
8. Physician-identified health barrier to participate in the intervention
9. Severe/unstable heart disease, not well controlled
10. Symptoms during exertion/exercise in daily life
11. New York Heart Association classification (NYHA) 3-4
12. Engages in moderate or vigorous physical activity actively more than 3 times a week
13. Blood pressure 160/100 mmHg (discretionary)

Previous exclusion criteria:
1. Place of residence: Other than Kuopio, North Savo region
2. Age under 55 years or over 75 years
3. Suffers from uncontrolled asthma or chronic obstructive pulmonary disease (COPD)
4. Experiences recurrent exacerbations or daily symptoms
5. Symptoms score in COPD Assessment Test™ (CAT ) >10 points

6. Forced expiratory volume in one second FEV1,FEV1 measurement Z-score < -2.5
7. Requires regular symptom-relieving medication
8. Physician-identified health barrier to participate in the intervention
9. Severe/unstable heart disease, not well controlled
10. Symptoms during exertion/exercise in daily life
11. New York Heart Association classification (NYHA) 3-4
12. Engages in moderate or vigorous physical activity actively more than 3 times a week
13. Blood pressure 160/100 mmHg (discretionary)

### Date of first enrolment
30/01/2025

### Date of final enrolment
31/12/2027

## Locations

### Countries of recruitment
Finland

### Study participating centre
**Savonia University of Applied Sciences**
PO Box 6 (Microkatu 1)
Kuopio
Finland
70210

### Study participating centre
**University of Eastern Finland**
Institute of Biomedicine, Sports and Exercise Medicine
PO Box 1627
Kuopio
Finland
70211

### Study participating centre
**Kuopio Research Institute of Exercise Medicine**
Yliopistonrinne 3
Kuopio
Finland
70210

### Study participating centre

**University of Jyväsylä**
PO Box 35
Jyväskylä
Finland
40014

**Study participating centre**
**Kuopion Seudun hengitysyhdistys**
Viestikatu 3
Kuopio
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70600

# Sponsor information

**Organisation**
Savonia University of Applied Sciences

**ROR**
https://ror.org/0238fqd79

# Funder(s)

**Funder type**
Charity

**Funder Name**
Kuopion Seudun Hengityssäätiö

**Alternative Name(s)**
Kuopio Region Respiratory Foundation

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
Finland

**Funder Name**
OLVI-Säätiö

**Alternative Name(s)**
Olvi Foundation

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
Finland

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Data sharing statement to be made available at a later date

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 10/06/2026 | 11/06/2026 | Yes | No |