ISRCTN15207611 https://doi.org/10.1186/ISRCTN15207611

# Implication of gender and sex on the combined effects of physical activity and air pollution exposure in patients with and without chronic respiratory disease

| | | |
|---|---|---|
| **Submission date**<br>13/01/2026 | **Recruitment status**<br>Recruiting | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>14/01/2026 | **Overall study status**<br>Ongoing | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>14/01/2026 | **Condition category**<br>Respiratory | [_] Individual participant data<br>[X] Record updated in last year |

## Plain English summary of protocol

Background and study aims

Air pollution and climate change are major threats to health, especially for older adults. People aged 60 years and over are more vulnerable to the effects of air pollution because of age-related changes in the heart and lungs. Physical activity, such as walking, is known to improve health and wellbeing, including for people with long-term lung conditions like asthma and chronic obstructive pulmonary disease (COPD). However, being physically active can also increase exposure to air pollution because people breathe faster and deeper when they move. Living in cities can make this problem worse, as pollution levels are often higher and there may be less access to green spaces. Women may be particularly affected because they tend to live longer and may have different daily activities and exposures than men.

The aim of the INCLUDE study is to understand how sex (biological differences) and gender (social and behavioural factors) influence how older adults respond to physical activity and air pollution. The study looks at breathing symptoms, lung function, and wellbeing in older adults with and without chronic lung disease. The results will help inform future advice on physical activity and support healthier urban environments for ageing populations.

Who can participate?

Adults without chronic respiratory disease, and patients with asthma or chronic obstructive pulmonary disease (COPD), aged 60 years and older.

What does the study involve?

Participants will take part in a study lasting about three weeks.

Each participant will complete a baseline visit and four supervised outdoor walks on two additional visits. The walks will differ by:

• Air pollution level (less polluted areas and more polluted areas), and

• Walking speed (slow walking and brisk walking)

The order of the walks will be different for each participant.

Before and after each walk, participants will be asked about breathlessness (shortness of

breath) and will have simple lung function tests. During the walks, participants will wear portable equipment to measure physical activity, breathing, location, and personal air pollution exposure.
Between the walking visits, participants will also take part in a one-week monitoring period in their normal daily life. During this time, they will wear sensors to record everyday physical activity and air pollution exposure and will complete a short daily diary about breathing symptoms.
Participants will also be invited to take part in an optional interview to talk about their experiences of physical activity, air pollution, ageing, and daily life. Taking part in the interview is voluntary.

What are the possible benefits and risks of participating?
Participants may benefit from learning more about their breathing, physical activity, and how their body responds to different environments. The study may also help improve future advice on physical activity and urban planning for older adults.
The risks are low. Walking may cause temporary breathlessness or tiredness, especially in people with lung disease. The walking routes and speeds are chosen to be safe, and participants are monitored during the walks. Wearing sensors may cause minor discomfort but does not involve radiation or invasive procedures.

Where is the study run from?
The study is run by an academic research team based at the University of Basel, the University of Zurich, and the Barcelona Institute of Global Health.

When is the study starting and how long is it expected to run for?
The study is expected to begin recruitment in January 2026 and finish recruitment by March 2028. Each participant will take part for approximately three weeks.

Who is funding the study?
1. National Agency for Health, Food and Occupational Safety, Switzerland.
2. Swiss National Science Foundation, Switzerland.
3. Catalan Society of Pulmonology, Spain.

Who is the main contact?
Prof. Sarah Koch, PhD, sarah.koch@unibas.ch

# Contact information

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


### Contact name
Prof Sarah Koch

### ORCID ID
https://orcid.org/0000-0001-9461-8407

### Contact details
Grosse Allee 6
Basel
Switzerland

4052
+41 61 207 47 49
sarah.koch@unibas.ch

# Additional identifiers

### SNF NRP 83 Gender Medicine and Health grant no.
408340_227244

# Study information

### Scientific Title
Implication of gender and sex on the combined effects of physical activity and air pollution exposure in patients with and without chronic respiratory disease (INCLUDE)

### Acronym
INCLUDE

### Study objectives
The objectives of the INCLUDE study are to:

(1) quantitatively determine how gender and sex-differences affect the cardiorespiratory and mental health responses to physical activity and air pollution; Null-Hypothesis: Sex and gender do not modify the cardiorespiratory and mental health responses to physical activity and air pollution.

(2) qualitatively identify how gender and sex affect physical, emotional and social physical activity experiences, in the current context of climate change, rapid urbanization and population aging; Null-Hypothesis: Sex and gender do not modify the qualitatively-assessed cardiorespiratory and mental health responses to physical, emotional and social physical activity experiences.

(3) and integrate identified gender and sex dimensions in the development of urban planning policies and physical activity guidelines in aging populations; Null-Hypothesis: Not applicable.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
1. approved 17/12/2025, Ethics Committee North-Western Switzerland (Tellplatz 11, Basel, 4053, Switzerland; +41 061 268 13 50; eknz@bs.ch), ref: 2025-01662

2. approved 17/12/2025, Ethics Committee Zurich (Stampfenbachstrasse 121, Zurich, 8090, Switzerland; +41432597970; info.kek@kek.zh.ch), ref: 2025-01662

3. approved 30/06/2025, Comité de Ética de la Investigación con medicamentos del Hospital Clínic de Barcelona (Casanova 150, 2nd Floor, Barcelona, 08036, Spain; +34 932275766; sectec.recerca@clinic.cat), ref: HCB/2025/0024

### Study design

INCLUDE is designed as a national, multi-center, randomized, repeated measures, cross-over study conducted at the Department of Sport, Exercise and Health of the University of Basel, Switzerland (main center) and the Epidemiology, Biostatistics and Prevention Institute (EBPI) of the University of Zurich. Briefly, each participant will perform four walking circuits (two at study visit II and two at study visit III) in a randomized order and separated at least by one and a maximum of four weeks. Pre, within-, and post-walking circuit measurements will be taken.

## Primary study design
Observational

## Study type(s)
Prevention, Other

## Health condition(s) or problem(s) studied
The study investigates older adults with and without chronic respiratory diseases (CRD), specifically chronic obstructive pulmonary disease (COPD) and asthma, to assess the combined effects of physical activity and air pollution exposure.

## Interventions
Participants will complete a series of four supervised outdoor walking circuits under differing environmental exposure and physical activity intensity conditions. Each participant will act as their own control in a randomised cross-over design.

The walking circuits will vary by:
- Ambient air pollution exposure:
Two circuits conducted in relatively less polluted environments. Two circuits conducted in relatively more polluted urban environments.

- Walking intensity:
One slow walking circuit and one brisk walking circuit in each pollution condition. The order of walking circuits will be randomised for each participant. Circuits will be completed over approximately two weeks, with adequate recovery time between visits.

During each walking circuit, participants will be equipped with:
- Wearable sensors to measure physical activity and physiological responses
- Portable equipment to assess respiratory gases
- Personal air pollution monitoring devices
- GPS

Respiratory outcomes, including dyspnoea severity and lung function, will be assessed before and after each walking circuit.

Ambulatory free-living monitoring:
Between the supervised walking circuit visits, participants will undergo an ambulatory monitoring period of approximately one week in their usual living environment. During this period, participants will:
- Wear sensors to continuously record free-living physical activity and personal air pollution exposure
- Complete a daily dyspnoea diary to capture symptom severity in real-life conditions

These data will be used to characterise habitual activity, exposure patterns, and symptom variability between structured experimental conditions.

Optional qualitative component:
Participants will be invited to take part in an optional semi-structured interview to explore gender- and sex-related physical, emotional, and social experiences of physical activity in the context of air pollution, climate change, and ageing.

### Intervention Type
Behavioural

### Primary outcome(s)
1. Dyspnoea severity measured using data collected from a daily dyspnoea diary at daily for one week

### Key secondary outcome(s))
1. Lung function measured using oscillometry at before and after each walking circuit

### Completion date
01/03/2028

## Eligibility

### Key inclusion criteria
60 years and older

### Participant type(s)
Healthy volunteer, Patient

### Healthy volunteers allowed
Yes

### Age group
Mixed

### Lower age limit
60 years

### Upper age limit
100 years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
1. Presence of any alteration that may limit mobility or physical performance.
2. Inability to follow the study procedures (e.g. due to language barriers, psychological disorders,

dementia, etc.)
3. Inability to provide informed consent

Participants without chronic respiratory disease:
1. Diagnosis or pharmacological treatment for any chronic respiratory disease and/or presence of respiratory symptoms (chronic cough, wheezing, breathlessness at rest or at low intensity exercise, etc).
2. Exercise-induced asthma

Participants with COPD:
1. Having undergone major lung surgery (e.g. lung transplant) or lung volume reduction within 6 months before inclusion
2. Primary respiratory diseases other than COPD
3. Substantial limitations in mobility due to factors other than COPD
4. Lung volume reduction within 6 months before inclusion
5. Diagnosis of asthma

Participants with asthma
1. Primary respiratory diseases other than asthma
2. Overlap asthma and COPD
3. Presence of any condition that may limit mobility or physical performance due to factors other than asthma

### Date of first enrolment
31/01/2026

### Date of final enrolment
01/10/2027

## Locations

### Countries of recruitment
Spain

Switzerland

### Study participating centre
**Department of Sport, Exercise and Health, University of Basel**
Grosse Allee 6
4052 Basel
Basel
Switzerland
4052

### Study participating centre
**Epidemiology, Biostatistics and Prevention Institute (EBPI), University of Zurich**
Hirschengraben 84

Zürich
Switzerland
8001

**Study participating centre**
**Barcelona Institute for Global Health**
Doctor Aiguader, 88
Barcelona
Spain
08003

# Sponsor information

**Organisation**
Swiss National Science Foundation

**ROR**
https://ror.org/00yjd3n13

**Organisation**
Agence Nationale de Sécurité Sanitaire de l’Alimentation, de l’Environnement et du Travail

**ROR**
https://ror.org/0471kz689

**Organisation**
Societat Catalana de Pneumologia (SOCAP)

# Funder(s)

**Funder type**
Not defined

**Funder Name**
Agence Nationale de Sécurité Sanitaire de l’Alimentation, de l’Environnement et du Travail

**Alternative Name(s)**

French Agency for Food, Environmental and Occupational Health & Safety, Anses - Agence nationale de sécurité sanitaire de l'alimentation, L'Agence nationale de sécurité sanitaire de l'alimentation, ANSES

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
France

**Funder Name**
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

**Alternative Name(s)**
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

**Funding Body Type**
Private sector organisation

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

**Location**
Switzerland

**Funder Name**
Societat Catalana de Pneumologia

**Alternative Name(s)**
Catalan Society of Pneumology, socapnet, Societat Catalana de Pneumologia Fundació Acadèmia de Ciències Mèdiques i de la Salut de Catalunya i de Balears, SOCAP

**Funding Body Type**
Private sector organisation

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

**Location**
Spain

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and /or analyzed during the current study will be available upon request from Sarah Koch (sarah.koch@unibas.ch)

### IPD sharing plan summary
Available on request