# HOME | ECRHS A blue and white logo Description automatically generated

# European Community Respiratory Health Survey (ECRHS)

# Pilot OVERNIGHT study: A nOVEl approach to impRoviNg symptoms for people with pre-COPD usInG Hepa fiLTers (Ethics ID: XX)

Allergy and Lung Health Unit

Melbourne School of Population and Global Health

The University of Melbourne

|  |  |
| --- | --- |
| **Principle Investigator** | Dr. Daisy Dai |
| **Associate Investigators** | A/Prof Caroline Lodge, Prof. Shyamali Dharmage, Dr. Rachel Tham, Dr. Dinh Bui, Dr. Anurika DeSilva |

**PARTICIPANT INFORMATION SHEET**

We would like to invite you to take part in a small sub-study of the European Community Respiratory Health Survey (ECRHS). Before you decide you need to understand why the research is being done and what it would involve for you. This participant information sheet tells you about this research project. It explains what is involved and knowing this will help you decide if you want to take part in the research. Please read this information carefully. Ask questions if anything you read is not clear or would like more information.

**What is the purpose of this project?**

Chronic obstructive pulmonary disease (COPD) is progressive lung disease that causes millions of deaths annually worldwide. Pre-COPD is a term describing the period before a diagnosis of COPD, when lung damage has already begun. This period is likely to span years or decades, and only some people with early indications of lung damage will go on to get COPD. The Pre-COPD phase has been recognized as a critical time during which interventions may prevent progression to COPD. People are identified as potentially having pre-COPD by comparing the rate of decline of their lung function with others of similar age. All adults experience a normal decline in lung function with age, however people who potentially have pre-COPD have a greater decline compared to their peers. Pre-COPD is a new research area in which there has been limited progress. Household air pollution (HAP) is associated with COPD. However, there have been no studies investigating the effect of reducing HAP in people with pre-COPD.

We aim to test the feasibility of using High Efficiency Particulate Air (HEPA) filters at home for people with pre-COPD. We aim to do this through a randomized clinical trial of the use of HEPA filters. A standard HEPA filter can remove particles > 0.3 microns in diameter with 99.97% efficiency. This means that for every 10,000 particles in your household air, only 3 particles will be missed by HEPA filter. These tiny particles enter our lungs through breathing, and they may remain there causing inflammation and damage. HEPA filters can also trap dust mites, mould spores, pet allergens and pollens which are far larger than 0.3 microns. It is important for us to understand whether it is acceptable for people to sleep with HEPA filters running in their bedrooms and whether use of these filters helps with respiratory symptoms.

Before starting a full trial, we planned this pilot trial to find out if people want to take part in a study like this. We need your feedback on whether the HEPA filters are acceptable and easy to use or if changes need to be made. The information from this pilot trial will help us to modify our procedures to make the planned larger trial a success.

**Why have I been asked to take part?**

You have been asked to take part as we noticed that your had lower lung function than others at ECRHS IV and you are experiencing some respiratory symptoms.

**Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, and your relationship with researchers at the University of Melbourne.

**What will happen if I take part?**

1. Consent

If you decide to take part, you will be asked to sign a consent form. Your participation is voluntary and you are free to withdraw from the study at any time.

1. Inclusion

Our research nurse will send you a link for a health survey to confirm your current respiratory symptoms. The research nurse can also conduct telephone interviews if you prefer.

1. Randomisation

You will be allocated either to the intervention arm or the control arm. The allocation will be random and hence there is a chance that you may be in either the intervention arm or the control arm. The intervention arm will receive a true HEPA filter air purifier, the control arm will receive an air purifier without HEPA filter and carbon filter. The filters will look exactly the same. It is important, in the larger planned trial, that the filters look and perform identically. Trials of interventions, where it is not certain that the intervention will be effective, always need to have a placebo arm to make sure that we are not seeing improvements because of a placebo effect.

1. All participants – what is expected of me?

HEPA filters will be placed in your bedroom for three months. The HEPA filters will be automatically turned on and off from 8pm to 8am every day. An SMS will be sent at 3 days, 7 days and 14 days after starting using HEPA filters to get your feedback. At the end of month 1, month 2, and month 3, SMSs with online survey links will be sent to measure respiratory symptoms and sleep quality. The online surveys are very short and simple, you can complete them within 5-10 minutes. You will not know if your filter is a real filter or a placebo.

An air quality sensor will be placed along with the HEPA filter which will assist use to monitor the indoor air quality. The sensors will provide a continuous output of real time air quality to our secured research platform using a pre-installed sim card. You will not be able to see the air quality readout during the trial.

1. Follow up

During the study, if there is no response from our SMS, our research nurse will contact you by telephone. Occasionally if you have difficulties filling the surveys online or by telephone, we can post paper surveys to you, that you can mail back to us using pre-paid envelopes.

1. Control arm only

After all participants have completed the study, you will be notified of your randomisation. If you find that you were enrolled in the control arm, you may decide that you want to try the active filter for another three months. We will provide a HEPA filter for you without cost if you would like to try using it for 3 months.

1. Recycle of HEPA filters

Our research nurse will contact you about returning HEPA filters to the University of Melbourne after completion of the study.

1. Recompense of inconvenience

At the end of your participation in this study, you will be given a $100 gift card as recompense for your time, energy usage at home and inconvenience.

1. Information to GP

If you require, a letter explaining the trial and how we identified your pre-disease status will be sent to your GP.

**What are the possible benefits of taking part?**

This is a pilot trial. You may or may not get a direct benefit from this trial. However, the knowledge gained from the study will contribute to further research aimed at reducing COPD burden in the community.

**What are the possible risks of taking part?**

It is not thought that there are many risks, all surveys can be answered online and there is no clinical testing in this study. However, it is possible that you may be inconvenienced by using HEPA filters at night (due to noise) and by answering multiple surveys over 3 months.

Also, there may be a risk of distress from being identified as possibly having pre-COPD. Please read the following information on this newly identified condition:

* There is an increased risk of developing COPD in the future if you are identified as having pre-COPD, but we believe that most people that we identify with symptoms and lower lung function will never develop COPD.
* Unlike COPD, people with Pre-COPD have normal lung function.
* The transition from pre-COPD to COPD occurs over a long period of time.

If you are experiencing distress, you can call our participants’ free hotline 1800 779 558 to discuss. You may also look for medical advice from your GP, or contact one of the following support services:

Lifeline 13 11 14 (24 hours), [www.lifeline.org.au](http://www.lifeline.org.au)

Beyond Blue, 1300 22 4636, [www.beyondblue](http://www.beyondblue).org.au

**What if there is a problem?**

It is extremely unlikely that you will suffer harm related to this study. However, if you have concerns about any aspect of this study, please contact the study manager Dr. Daisy Dai (email: [ecrhs-4@unimelb.edu.au](mailto:ecrhs-4@unimelb.edu.au), ECRHS 4 free participants hotline: 1800 779 558).

**What will happen to information about me?**

All data obtained during this study will be stored on a firewall protected local network sever maintained by the University of Melbourne. Identifying data will be kept in a folder with access restricted to the research team. At the end of the research, we will analyse the data and publish the results. No identifying information will be published as a result of this study. We will also send you a summary of the results via the ECRHS Newsletter.

**Who is organising the research?**

This pilot study has been organised by Dr. Daisy Dai who is a research fellow at the University of Melbourne and a registered nurse. The study is funded by the Faculty of Medicine, Dentistry and health Sciences, the University of Melbourne.

**Who can I contact if I have any concerns about the project?**

This research project has been approved by the Human Research Ethics Committee of the University of Melbourne. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research E3thics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email to Human ethicscomplaints@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence, please provide the name of the research team or the name or ethics ID number of the research project.