**Human Research Ethics**

**Placement of air purifiers in rooms of residents in Australian Aged Care Facilities**

**INFORMATION FOR PARTICIPANTS**

**Introduction**

We invite you to take part in a research study. The study will explore if air purifiers can reduce respiratory infections in aged care homes. Respiratory infections are sometimes thought of as the common cold or influenza. Coughing, laughing, and talking causes tiny germ particles to hang in the air we breathe for a long period of time. People then breathe these germ particles into their lungs, and this causes respiratory infections. Air purifiers work by cleaning the air we breathe.

**What is the research about?**

This study will test if air purifiers can prevent respiratory infections by cleaning the air within a person's bedroom in an aged care home.

The study will divide participants into two groups. Each person in each group will have an air purifier put into their room. Deciding which group you are in at the beginning of the study will be like tossing a coin. You will have a 50% of chance of being in the group that receives active air filtration and 50% chance of being in the group without air filtration.

The study includes two parts. Half of the people will have air purifiers with an active air filter, and the other group will have air purifiers with no filter. The groups will then swap. By the end of the study, each person will receive air purification in their room with and without an air filter. Neither the participant nor the person collecting data will be aware of which group a person is in. This is important to ensure the accuracy of results in the study.

**Where is the research being done?**

This study is being conducted within the aged care facility where you live. It is part of a research study (PhD in Nursing) by Mrs Bismi Khadar who is supervised by:

* Associate Professor Jenny Sim (Principal Investigator and supervisor of the project)
* Professor Brett Mitchell (Co-researcher and supervisor of the project)
* Dr Julee McDonagh (Co-researcher and supervisor of the project)

The University of Newcastle has sponsored the project. Funding is from an Australian Government Research Training Program grant. The air purifiers used in this study have been donated by GAMA Healthcare. GAMA Healthcare plays no role at all in the study design, data collection, or analysis.

**Who can take part in the research?**

People who are living in aged care homes are able to take part in the study. To be included in the study you must live in a single room. If you have a terminal illness and are receiving end-of-life care or, if you are under the care of the Public Guardian, you are not able to take part.

Information about the study has been given to you because you live in an aged care home that is part of this study.

**What choice do you have?**

You do not have to take part in this study. If you do, you can stop at any time without having to give a reason. Also, any data collected about you will be withdrawn. No matter what you decide, it will not affect your care. Only the nursing staff and the researchers in the study will be aware of your choice to take part in the study.

During research, new information becomes available about the concepts being studied. While you are involved in this study, you will be told of any new findings which may affect your decision to continue in the study.

**What would you be asked to do if you agree to take part?**

If you agree to take part in this study, you will be asked to sign the Participant Consent Form. You will then have an air purifier installed in your room. The researchers will visit you and access your care records. They will record information about your medical history, mobility, medications, and vaccination status. They will record if you have had any signs and symptoms of any respiratory infections. They will also record the results from tests or treatments you may have had (including any visits to hospital).

The air purifier you use within the study will be available for your ongoing use at the end of the project. There are no conditions associated with the use of the air purifier. But the cost of changing air filters after the study is finished will be at your own expense. If you do not wish to keep the air purifier, it will be removed by the research team.

**What are the risks and benefits of participating?**

**Risks**

All medical procedures and equipment involve some risk of injury. Some of these risks are not currently known and are unable to be predicted. It is possible that you may develop complications from participating in this study.

Although there are very few risks involved in this study, the use of an air purifier in your room may lead to:

* Dryer than normal room air (Uncommon)
* Some extra noise in your room due to the air purifier (Uncommon)

**Benefits**

This research aims to improve what we know about preventing respiratory infections. It is possible that taking part in this study may not benefit you. But it may reduce your risk of getting a respiratory infection. There are no monetary benefits to members of the research team or to participants in the study.

If you are injured while taking part in this study, you should contact the researcher or the Registered Nurse on duty to arrange medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

You have a right to take legal action to get compensation for any injuries or adverse effects resulting from the study. Compensation may be available if your injury or complication is serious and caused by unsafe equipment, or by the negligence of a person involved in the study. You do not give up any legal rights to compensation by participating in this study.

**Will the study cost you anything?**

Participation in this study will not cost you anything, nor will you receive payment.

**How will your privacy be protected?**

All information collected from you will be safely stored and protected. Only the researchers will have access to study materials. The study results will be shared in a thesis, in conference presentations and/or in scientific publications. No participant will be identified in any of these materials.

All data will be accessed, used and stored under Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002.

If you decide to stop participating in the study, all the information collected from and about you will be removed. Once data has been documented in the study database, it will be de-identified, and it may not be possible to withdraw any de-identified data. If this occurs, you will be notified that your de-identified data will be included in the final analysis. This data will remain confidential and be destroyed under Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002.

**Further Information**

When you have read this information, Bismi will discuss it with you and answer any questions you may have. If you would like to know more at any stage, please feel free to contact her on the mobile at 0405087353.

Since this is a clinical trial that may need further study, the data will need to be kept for 15 years. Data will be stored in a locked filing cabinet, or on a password protected University database at the University of Newcastle and will be destroyed in compliance with the data management policy. You will be contacted if there is a request to be involved in future research or similar studies.

This information statement is for you to keep.

Thank you for considering this invitation.

**Ethics:** This research has been **approved** by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 2022/ETH02470.

**Complaints about this research:** Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, please contact the **HNE Research Office,** Hunter New England Local Health District, Level 3, POD, HMRI, Lot 1 Kookaburra Circuit, New Lambton Heights NSW 2305. Telephone: 02 4921 4140. Email: HNELHD-ResearchOffice@health.nsw.gov.au and quote the reference number: 2022/ETH02470.