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Testing whether air filters can prevent winter respiratory infections (including COVID-19) in care homes

Submission date
26/11/2021

Recruitment status
No longer recruiting

Registration date
10/12/2021

Overall study status
Completed

Last Edited
09/01/2025

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Respiratory infections such as COVID-19, coughs, colds and flu are more serious in older people. In care homes, infections can spread easily in shared spaces when people breathe in or swallow airborne droplets containing germs when others cough or sneeze. This study aims to find out whether air filtration using portable high-efficiency particulate air (HEPA) filters can reduce symptoms of respiratory infections in residents of older people's care homes during the winter period. Although we know they trap airborne particles, no one has tested if they can improve human health.

Who can participate?
Care homes that predominantly focus on care for older people (residential home/nursing home)

What does the study involve?
Care homes will be divided into two groups at random, with one continuing with usual care AND receiving air filters, and the other continuing with usual care only. The researchers are interested to see whether filters placed in communal and private rooms reduce infection symptoms, antibiotic use and the number of falls as well as the cost-effectiveness of the filters. They are also interested in the effect of the filters on staff sickness days away from work. Care home staff will collect data about residents' symptoms and will recruit 10 residents per care home. These residents in the air filter group will consent to receive an air filter in their bedroom and access to their medical records. For the usual care group, they will consent for their medical records to be accessed. The aim is to include 740 residents who will be in the trial for up to 8 months each. The results of this trial will help understand whether or not filters can reduce the spread of infections.

What are the possible benefits and risks of participating?
The main benefit of this study would be to answer the question about whether using HEPA air filters in care homes reduces the chance of getting a respiratory infection (cough, cold, flu or COVID-19). This information would help care homes and residents whether it is worth purchasing air filters. It is not known whether taking part in the study will reduce the risk of

infection symptoms in care home residents or staff. It is possible that more frequent completion of study questionnaires and collection of information about symptoms may mean that symptoms of respiratory infections are managed more promptly than usual. Taking part in the study may also provide a better understanding of infection prevention and control strategies for residents and/or their families/carers. There is a risk (in care homes allocated to the air filter group) that if the air filter is not positioned carefully, residents, staff or visitors could trip over the unit or cables. The researchers will reduce this risk to a minimum by working with care home staff to carefully position the filters away from the main walkways in rooms and ensure that all electrical cables are behind the units.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
July 2021 to December 2024

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
298022

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 50819, IRAS 298022

Study information

Scientific Title
Air Filtration to prevent symptomatic winter Respiratory Infections (including COVID-19) in care homes: the AFRI-c cluster randomised controlled trial with a nested internal pilot, process and economic evaluations (AFRI-c)

Acronym
AFRI-c v1.0

Study objectives
Using HEPA air filters will reduce overall winter respiratory infection rates in care homes.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/11/2021, London - Harrow Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, United Kingdom; +44 (0)207 104 8098, +44 (0)207 104 8246; harrow.rec@hra.nhs.uk), ref: 21/HRA/4318

Study design
Randomized; Both; Design type: Prevention, Physical, Qualitative

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Respiratory infections, including COVID-19 (SARS-CoV-2 infection)

Interventions
1. Study design
This is a two-arm, cluster randomisation trial of portable HEPA air filters versus no air filters for reducing symptomatic winter respiratory infections (including COVID-19) in care home residents with a mixed-method process and economic evaluation. The RCT design is the most scientifically rigorous method of hypothesis testing available and is regarded as the gold standard trial for evaluating the effectiveness of interventions.

Care homes are allocated to the two treatment arms by stratifying whether they provide nursing care yes/no; and socioeconomic tertile (high/medium/low) using a randomisation list pre-generated by a CTU statistician with no other involvement in recruitment activities. Participants in each care home will be randomly approached for consent either to have an air filter in their private room and access to their medical records (intervention arm) or access to their medical records only (control arm). Care homes in both arms will follow usual care in terms of infection prevention and control strategies such as hand washing. Care homes have a 50/50 chance of being allocated to either arm. The null hypothesis is that there is no difference between the number of symptomatic days at the end of the winter period with or without air filters in care home residents.

2. Blinding
The central research team, clinicians, other researchers, care home staff and participants will be not remain blinded to the allocation of the intervention group. The Trial Management Group (TMG) will not review unblinded data until all follow-up and data queries have been resolved at the end of the trial. Two statisticians based at the University of Bristol (UoB) will support this trial. The lead statistician will be blinded throughout the trial. Two health economists based at UoB will be blinded when cleaning data and preparing the analysis plan, but the junior health economist will be unblinded when conducting the analysis.

3. Sample size
The aim is to recruit up to 74 care homes who will then aim to consent up to 834 adults who reside in a care home. Recruitment will be over three winter periods (September to April).
The primary objective is to investigate the effect of portable HEPA air filters in private residential, communal and staff only rooms on the “ten” residents’ symptomatic winter respiratory infection episodes (including COVID-19) in care homes with air filters compared with residents in care homes without air filters. Previous research suggests ~30% of residents will wish to take part and ~40% will leave the care home or die during the study, reflecting the frailty and vulnerability of the study population. To maintain study power, the researchers will continually recruit new residents, resulting in an expected overall study data attrition of ~20%. They consider the advantages in power outweighs the potential disadvantage arising from the unblinded recruitment of a proportion of study participants.
New residents joining the care home will be informed of the study and will be added to the anonymised resident registry. Data collection will commence on new residents unless they opt out of study involvement, or they become a resident in the care home after the 1 March (since they will not be able to contribute at least 2 months of data collection).

4. Identification
Care home recruitment
Care homes belonging to organisations such as the NIHR ENRICH Research Ready Care Home Network and other networks known to the co-applicants will be approached via the CRN/directly by the study team using a study Research Information Sheet for Care Homes (RISCH) or provided access to other study promotional materials.

Resident identification
Once the care home has agreed to take part in the study, each care home will have trained staff (managers and study champions) who will be asked to provide a register for all residents at the care home. The study champions will then confirm which residents meet the eligibility criteria, this will form the screening log. To ensure residents are easily identifiable to care home staff, resident names will be recorded on the database which will only be visible to the care home staff. Their name will be recorded next to a corresponding study ID, both of which are visible to the care home staff. When the data is passed to the study team, only anonymised data will be visible (only the study ID will be visible). The register will be maintained throughout the care home data collection period.

The anonymised study register will be sent to the study team to create a random order of eligible residents for the care home managers/study champions to approach and invite residents to receive an air filter in their private bedrooms and/or provide access to their medical records. If the study champions approach the first 10 on the list and some decline, the study team will request they work their way down the random list until they have consented approximately 10 residents.
Residents will have the option to opt out of any data being collected about them. This will be recorded on the register.

5. Trial assessment overview
The care home data collection period will be the winter months (defined as 1 September to 30 April) during which the air filters will be switched on and anonymised infection data collected daily from all eligible residents that do not opt-out of study involvement.
To summarise, the following research activity will take place:
1. Care homes will be identified and screened
2. Care homes will sign up to take part in the trial and be randomised
3. Eligible residents will contribute baseline and follow-up data on a daily basis over the winter period
4. Care home staff will be invited to complete baseline and follow up questionnaires on an optional basis
5. Some care home staff, residents/consultees and residents' relatives will be invited to take part in a qualitative interview

A subgroup of residents (approximately 10 per care home) will be selected at random to be consented to provide permission to access medical records. In intervention care homes, these 10 residents will also be invited to receive air filters in their private bedroom.

6. Care home set-up
Interested care homes will be asked to complete an expression of interest form (EoI), containing information required for the study team to carry out an eligibility assessment. Eligibility will be determined using the EoI form and checked against the relevant criteria. Any care homes found to be ineligible will be informed of why they are not eligible to take part in the study. For those that are eligible, care home managers will be asked to provide written confirmation from the care home-owner for the study to be conducted. At this point all inclusion and exclusion criteria

will have been assessed with the exception of care home willingness to take part. Eligible care homes will be invited to hold a care home study meeting.

Once the study meeting has been completed and everyone is on board and willing, they will progress through the set-up process, provide details of study champions and complete care home baseline data collection.

7. Care home baseline
Baseline data collection will include data captured on the EoI form and the information detailed below. The care home manager will complete this using an online care home baseline data collection form. The researchers understand some data will vary with time, and that this is essentially a baseline cross-sectional survey.

Data collected will be: Staff roles and numbers (FTE, permanent and agency); CQC rating; number and type of rooms in care home; care home ventilation policy (windows open/closed); IPC policy; care home manager and additional study champion contact details; funding (private /public); use of additional air filters in communal, staff and private bedrooms (acquired outside of the study).

On an individual basis residents' frailty will also be assessed using the clinical frailty scale (a judgement-based frailty tool that evaluates specific domains including comorbidity, function, and cognition to generate a frailty score ranging from 1 (very fit) to 9 (terminally ill)).

Staff will be asked to complete the infection prevention and control & care home satisfaction questionnaires.

Care homes will then be randomised and if allocated to the intervention arm will receive additional training regarding the use of the air filters.

8. All resident baseline
For all eligible residents, regardless of consent status the following anonymised aggregate baseline data will be collected by trained staff: age; sex; ethnicity; receiving nursing care.

9. Consented resident baseline
For eligible and consented residents, the following baseline data will be collected on an individual level: name; date of birth; sex; ethnicity; NHS number; receiving nursing care, infection symptoms.
Study champions will ask eligible and consented residents to complete the resident infection prevention and control & care home satisfaction questionnaires. Consented residents in the intervention arm will receive an air filter for the winter period.

10. All resident data collection
Data will be collected on all eligible residents in the winter months, during which time the air filters will be switched on in the intervention care homes. Data may be collected on a paper CRF, on a daily basis and entered into the study database (bespoke made by Xeropoint) at the end of each week or entered directly into the database on a daily basis. Where possible, data will be collected by the same staff member/study champion.

In control care homes, data collection will begin once sufficient residents (approx. 10) have been approached and consented. In intervention care homes, data collection will begin once sufficient residents (approx. 10) have been approached and consented and the air filters have been switched on. In both circumstances, data collection should start no earlier than 1 September.

The following data will be collected on a daily basis on each eligible resident in an anonymised format unless they opt out of the study: Resident register to be kept up to date, infection symptoms, antibiotic consumption and frequency of adverse events.

11. Consented resident data collection
In addition to the above, consented residents will also be asked to complete the following:
• Infection prevention control strategies questionnaire (frequency: end of March)
• Care home satisfaction questionnaire (frequency: end of March)
• End of follow-up medical notes review. The central study team will contact the relevant GP practice for those residents and ask them to provide data between baseline and end of follow-up. Data will include: medically diagnosed infections (respiratory, urinary, gastrointestinal and skin/soft tissue infections); number and names of antibiotic prescriptions, hospital admissions, adverse events and GP consultations.

Intervention consented residents will also be asked to complete an Air filter Satisfaction questionnaire (frequency: end of March).

Control care homes will also indicate if their consented residents have had an installation and use of new air filters in their private rooms (frequency: daily): Care home managers/study champions will record whether any new air filters are installed in residents' private rooms. Once a new filter is installed, the number of days it is switched on for will be captured.

12. Care home data collection
Care home staff will also have data collected on the following: Infection prevention control strategies questionnaire (frequency: end of March; care home satisfaction questionnaire (frequency: end of March); staff absenteeism (frequency: daily/weekly) - managers will anonymously report absenteeism, number of days absent and reason for absence e.g. whether it was related to an infection and staff roles and numbers.
Intervention care homes will also complete a questionnaire on air filter satisfaction at the end of March.

13. Public Health England data (collected retrospectively)
Public health data regarding outbreaks within the care home will be collected in an anonymised format for all residents and staff (this will include residents who opt out due to the anonymous format). This data will include:
• SARS-CoV-2 PCR testing and results
• Other respiratory virus testing
• Other infections testing

14. Adverse events
In this study population (S)AEs are expected due to the participants being older residents in a care home setting. Care home staff are responsible for recording AEs for their residents, in the care home records as per standard practice. It is anticipated that most AEs related to infection and falls will be captured as part of the study CRF, but other AEs will not be recorded in the study documentation unless required for outcome measures.
The researchers do not expect there to be any SAEs related to a research procedure, with the exception of an SAE possibly related to the intervention. The only expected SAE related to the intervention (use of an air filter) is a trip, fall or injury due to the air filtration unit being placed in a resident's bedroom or in a communal area. SAEs that are related and expected will be recorded on the SAE log.

15. End of trial
Participant: The participant ends their involvement with the trial when their last assessment (including medical notes review for consented residents) are completed (or they have changed their participation status/opted-out from the study).
Trial: The end of trial for AFRI-c will be when the last resident has completed their follow-up, which includes completion of the medical notes review, all data queries have been resolved and the database has been locked, with subsequent data analysis completed.

16. Integrated qualitative research/process evaluation
Information regarding the qualitative research will be included in the main information sheets as required but the qualitative researcher will have their own information sheets prior to consenting to take part in an interview. Semi-structured interviews with care home staff, residents and their relatives/friends will explore perceptions and experiences of using the air filters including perceived/experiences benefits and harms, intervention acceptability and intervention implementation process including context- intervention interactions and dependencies with reference to the core Normalisation Process Theory (NPT) constructs. Within the pilot phase the researchers will also explore the feasibility and acceptability of trial processes including consent pathways. Interviews will be conducted by the study qualitative researcher. Qualitative data will be collected in parallel throughout the duration of the study.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 25/10/2024:
Number of symptomatic winter respiratory infection episodes measured using case report forms (CRFs) completed by staff and/or the resident per winter, defined as the period starting on 1 September and ending on 31 May

Previous primary outcome measure:
Number of symptomatic winter respiratory infection episodes measured using case report forms (CRFs) completed by staff and/or the resident per winter, defined as the period starting on 1 September and ending on 30 April

Key secondary outcome(s))
Current secondary outcome measures as of 25/10/2024:
1. Number of days with respiratory infection symptoms measured using the AFRI-c data collection form completed by staff daily throughout the study period
2. Presence of fever and/or delirium and/or acute deterioration in physical ability measured using the AFRI-c data collection form completed by staff daily throughout the study period
3. Number of gastro-intestinal infection episodes and number of symptomatic days of gastro-intestinal infection symptoms measured using the AFRI-c data collection form completed by staff daily throughout the study period
4. Number of days antibiotics are consumed and prescribed (number and name) measured using the AFRI-c data collection form completed by staff daily throughout the study period
5. Number of falls/near falls measured using the AFRI-c data collection form completed by staff daily throughout the study period
6. Number of possible SARS-CoV-2 infection episodes and possible Influenza-like illness episodes measured using the AFRI-c data collection form completed by staff daily throughout the study period
7. Number of PCR confirmed SARS-CoV-2 infections measured through linkage with UKHSA per

winter
8. Number of PCR (or other test) confirmed Influenza A&B infections measured through linkage with UKHSA per winter
9. Number of other microbiologically confirmed infections as investigated by PHE during care home outbreaks, including Streptococcal, Meningococcal, Respiratory Syncytial Virus, Norovirus, and Human Metapneumovirus infections measured through linkage with UKHSA per winter
10. Number of diagnosed respiratory (including COVID), gastrointestinal, skin, and urinary infections measured using medical records check per winter
11. Perception of care home environment measured using staff and resident questionnaires per winter
12. Number of staff sickness days away from work measured using the AFRI-c data collection form completed by staff per winter
13. Number of staff sickness days away from work due to respiratory infections
14. Number of staff sickness days away from work due to any other infection
15. Change over time in staff confidence in, and use of, infection prevention and control strategies measured using staff questionnaires per winter
17. Staff perception of care home environment measured using staff questionnaires per winter
18. Care Homes' number of days experiencing PCR or other microbiologically confirmed infection outbreaks measured through linkage with UKHSA per winter
19. Overall healthcare resource use (costs) measured using the AFRI-c data collection form completed by staff over the study period
20. Views of care homes, local authority, and CCG commissioners on intervention maintenance, sustainability, and possible dissemination measured through meeting with relevant stakeholders over the study period
21. Staff, resident and residents’ relatives/friends’ attitudes to and perceptions and experiences of air filters and determine factors influencing their use including acceptability, satisfaction, and potential benefits and harms measured using study questionnaires over the study period
22. Fidelity to intervention measured using trial monitoring processes and AFRI-c data collection forms weekly and over the trial period

Previous secondary outcome measures:
1. Number of days with respiratory infection symptoms measured using the AFRI-c data collection form completed by staff daily throughout the study period
2. Presence of fever and/or delirium and/or acute deterioration in physical ability measured using the AFRI-c data collection form completed by staff daily throughout the study period
3. Number of gastro-intestinal infection episodes and number of symptomatic days of gastro-intestinal infection symptoms measured using the AFRI-c data collection form completed by staff daily throughout the study period
4. Number of days antibiotics are consumed and prescribed (number and name) measured using the AFRI-c data collection form completed by staff daily throughout the study period
5. Number of falls/near falls measured using the AFRI-c data collection form completed by staff daily throughout the study period
6. Number of possible SARS-CoV-2 infection episodes and possible Influenza-like illness episodes measured using the AFRI-c data collection form completed by staff daily throughout the study period
7. Number of PCR confirmed SARS-CoV-2 infections measured through linkage with UKHSA per winter
8. Number of PCR (or other test) confirmed Influenza A&B infections measured through linkage with UKHSA per winter
9. Number of other microbiologically confirmed infections as investigated by PHE during care home outbreaks, including Streptococcal, Meningococcal, Respiratory Syncytial Virus, Norovirus, and Human Metapneumovirus infections measured through linkage with UKHSA per winter

10. Number of diagnosed respiratory (including COVID), gastrointestinal, skin, and urinary infections measured using medical records check per winter
11. Perception of care home environment measured using staff and resident questionnaires per winter
12. Number of staff sickness days away from work measured using the AFRI-c data collection form completed by staff per winter
13. Change over time in staff confidence in, and use of, infection prevention and control strategies measured using staff questionnaires per winter
14. Number of staff PCR confirmed SARS-CoV-2 infections measured through linkage with UKHSA per winter
15. Number of staff PCR (or other tests) confirmed Influenza A & B infections measured through linkage with UKHSA per winter
16. Number of other staff microbiologically confirmed infections as investigated by UKHSA during care home outbreaks, including Streptococcal, Meningococcal, Respiratory Syncytial Virus, Norovirus, and Human Metapneumovirus infections measured through linkage with UKHSA per winter
17. Staff perception of care home environment measured using staff questionnaires per winter
18. Overall healthcare resource use (costs) measured using the AFRI-c data collection form completed by staff over the study period
19. Views of care homes, local authority, and CCG commissioners on intervention maintenance, sustainability, and possible dissemination measured through meeting with relevant stakeholders over the study period
20. Staff, resident and residents' relatives/friends' attitudes to and perceptions and experiences of air filters and determine factors influencing their use including acceptability, satisfaction, and potential benefits and harms measured using study questionnaires over the study period
21. Fidelity to intervention measured using trial monitoring processes and AFRI-c data collection forms weekly and over the trial period

Completion date
31/03/2025

Eligibility

Key inclusion criteria
Care homes:
1. ≥30 residents residing in single bedrooms*
2. Care homes that predominantly focus on care for older people (residential home/nursing home)
3. Willing to maintain a register of all residents, to be updated weekly until the end of February (after which new residents will not be invited)
4. Willing to invite residents to receive air filters and/or accept medical notes review until ten agree ("the ten") per care home
5. Willing to provide anonymised resident infection data, administer brief resident and staff questionnaires, and respond to data queries
6. Care home owner permission to take part in the study
7. Willing to commit to installing air filters in the care home if allocated to the intervention group
8. Willing to commit to not installing air filters if allocated to control group

*Single bedrooms: residents residing in a room of single occupancy will be referred to as residents in a private and/or single bedroom. Residents may share bathroom facilities.

All residents:
1. Expected to reside in the care home for at least 2 months of the care home data collection period

Consented residents – 'the ten':
The following eligibility criteria are for "the ten" residents invited to receive an air filter and/or permit medical notes review only:
1. In a single-occupancy bedroom
2. Expected to reside in the care home for at least 2 months of the care home data collection period
3. Able to give informed consent (or if lacks capacity, a consultee is willing to complete a consultee declaration form)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
1168

Key exclusion criteria
Care homes:
1. CQC website rates as 'inadequate' or 'requiring improvements'
2. ≥10% private bedroom use of portable HEPA filtration devices
3. Participating in a competing care home level study

All residents:
1. Terminal illness (death expected within 7 days)

Consented residents – 'the ten':
1. Participating in any interventional* study
2. Terminal illness (death expected within 7 days)

*Interventional study: Interventional studies are those which involve an 'intervention'. In medical terms this could be a drug treatment, surgical procedure, diagnostic test or psychological therapy. Examples of public health interventions could include action to help someone to be physically active or to eat a more healthy diet. Examples of social care interventions could include safeguarding or support for carers. If a site becomes aware that a participant has enrolled in an interventional study whilst taking part in AFRI-c, they should inform the central research team (UoB). The research team will evaluate whether it is appropriate for the resident to continue participating in AFRI-c.

Date of first enrolment

10/01/2022

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Not provided at time of registration
United Kingdom
-

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR129783

Results and Publications

Individual participant data (IPD) sharing plan
The final anonymised trial data set will be stored as restricted data on the data.bris research data repository for at least 5 years after the end of the study (i.e. until at least 31/12/2029). Data

will be made available, after the end of the study, to approved bona fide researchers only, after their host institution has signed a data access agreement. Details of how to request access are available at the University of Bristol's data repository website.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/07/2024	16/10/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version 12.0	11/11/2025	11/11/2025	No	Yes
Protocol file		05/09/2024	16/10/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes