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Determining the best airflow rate from a handheld fan for recovery from exertional breathlessness in people with chronic breathlessness

Submission date 30/06/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/07/2021	**Overall study status** Completed	
Last Edited 16/07/2024	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Many people with long-term lung and heart conditions suffer from persistent and disabling breathlessness despite taking the best medication for their disease. Cool airflow from a handheld fan can help patients manage persistent breathlessness, including giving a faster recovery from shortness of breath after activity. Confidence in managing exertion-induced breathlessness is an important part of encouraging people to maintain or even increase physical activity – important in maintaining function and quality of life.
However, we do not know the most effective airflow rate for relief of breathlessness and as there are different types of fans available there is no guarantee that a person's chosen fan will deliver the right airflow for maximal recovery from exertion-induced breathlessness. Some patients also do not use the fan, even though it helps, due to embarrassment because of its appearance. The aim of this study is to find out the fan airflow rate which best speeds up recovery from exertion-induced breathlessness in people with chronic breathlessness, and which fan appearance and airflow speed is preferred.

Who can participate?
Adults living with chronic breathlessness

What does the study involve?
Participants will perform fiveshort bouts of exercise each for a maximum of 1 minute (1 minute sit to stand test). Participants can stop the exercise before 1 minute if they need to for any reason before then. Following each exercise test participants will be asked to sit in a chair while they recover. During, the first 10 minutes of each recovery period, participants will have airflow from a fan directed towards their nose and mouth held approximately 10 to 15 cm from their face for four of the tests and no fan airflow for a control test. The researchers will use a fan with four airflow settings. The airflow speeds and the control will be administered in a random order for each participant.
The researchers will measure the following for each test: i) how breathless the participant feels

at the start and at every minute during recovery for a maximum of 10 minutes, and ii) heart rate, oxygen levels at baseline and every 30 seconds during recovery for 10 minutes, and iii) a skin temperature “photo-map” of the participant’s face at baseline, at the end of the exercise test and after 3 and 5 minutes of recovery. Once all tests are complete, the researchers will ask participants to tell us about their fan and flow-rate preferences. We will use the results from this study to help design a fan with the best airflow speed for recovery from breathlessness after exercise, and the appearance of the fan which patients would feel most comfortable using in everyday life.

What are the benefits and risks of participating?
There is not likely to be any direct benefit for any participant, although any participant who has not previously used a fan may find benefit from trying a fan in this study and as a result may wish to continue using a fan for relief of breathlessness in the future.
It is also possible that some may feel benefit due to the altruism involved in taking part in a study and knowing they are helping with the design of the fan which might benefit patients with breathlessness in the future.
This is a low-risk trial, and it is not anticipated that taking part in a fan research study will involve any potential risk or burden for the participants. In previous studies of the battery-operated hand-held fans, there have been no serious adverse reactions related to the use of the fan. This is in keeping with a device that is in widespread community use, available for unmonitored purchase by the lay population including many elderly people with serious medical conditions. The safety of the adapted commercial fans (battery replacement with a motor and a dial to change the flow rates) has been assessed and the fans PAT tested by the Department of Engineering, University of Hull. The external motor is covered to minimise potential risk. All participants will be taught the correct use of the fan and closely supervised by the researcher during fan use.

Where is the study run from?
Castle Hill Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2021 to August 2022

Who is funding the study?
University of Hull (UK)

Who is the main contact?
Dr Flavia Swan
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
300915

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 300915

Study information

Scientific Title
FAN Facial Airflow Recovery from Exercise Patient (FanFARE-P) trial

Acronym
FanFARE-P

Study objectives
Does cool facial airflow improve recovery from exertion-induced breathlessness in patients with chronic breathlessness due to medical conditions, and what is the optimal airflow rate?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/10/2021, West of Scotland REC 4 (Research Ethics, Clinical Research and Development, Dykebar Hospital, Grahamston Road, Paisley PA2 7DE United Kingdom; +44 (0)141 314 0214; WoSREC4@ggc.scot.nhs.uk), ref: 21/WS/0102

Study design
Single-centre prospective experimental two-factorial within-subjects cross-over trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic breathlessness

Interventions
Current intervention as of 18/03/2022:
The intervention is a handheld fan (fan) with four airflow speeds and the control condition is no airflow. The four airflow speeds and the control (no airflow) will be administered in a random order for each participant during the first 10 minutes of recovery from each exercise test.

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Previous intervention:
The intervention is the handheld fan (fan). Two different fan types (blades enclosed and blades open), with five airflow settings between them as well as a control condition (no airflow) will be used. The fans/airflow speeds/control will be administered in a random order for each participant during the first 10 minutes of recovery from each exercise test.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Handheld fan

Primary outcome(s)
Breathlessness measured using the 0 to 10 Numerical Rating scale (NRS) at baseline, at maximal breathlessness after the sit to stand test and every 1 minute during the first 10 minutes of recovery from maximal breathlessness or until return to baseline breathlessness level, whichever occurs first

Key secondary outcome(s))
Current secondary outcome measures as of 18/03/2022:
1. Heart rate measured using a pulse-oximeter at baseline, at maximal breathlessness after the sit to stand test and every 30 seconds during the first 10 minutes of recovery from maximal breathlessness
2. Oxygen saturation measured using a pulse-oximeter at baseline, at maximal breathlessness after the sit to stand test and every 30 seconds during the first 10 minutes of recovery from maximal breathlessness
3. A thermal image of the temperature of the participant's cheek trigeminal nerve area, recorded with a thermal camera at baseline, at maximal exertion and after 3 and 5 minutes recovery time from the sit to stand test
[These measures are recorded during recovery after each of the five sit to stand tests (four with different airflow rates and one with no airflow - control)]
4. The pleasantness of the airflow speeds from the fan measured using the 0 to 10 Numerical Rating scale (NRS) after completion of all the tests
5. The number of sit to stands completed in 1 minute recorded for each of the five sit to stand

tests
6. The participant preferred airflow rate from the fan on completion of all the tests
7. The participant's preferred fan from 3 different models recorded on completion of all the tests

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Previous secondary outcome measures:
1. Heart rate measured using a pulse-oximeter at baseline, at maximal breathlessness after the sit to stand test and every 30 seconds during the first 10 minutes of recovery from maximal breathlessness
2. Oxygen saturation measured using a pulse-oximeter at baseline, at maximal breathlessness after the sit to stand test and every 30 seconds during the first 10 minutes of recovery from maximal breathlessness
3. A thermal image of the temperature of the participant's cheek trigeminal nerve area, recorded with a thermal camera at baseline, at maximal exertion and after 3 and 5 minutes recovery time from the sit to stand test
These measures are recorded during recovery after each of the six sit to stand tests (five with different airflow rates and one with no airflow - control)
4. The pleasantness of airflow from the fan measured using the 0 to 10 Numerical Rating scale (NRS) after completion of each of the five different airflow rate tests
5. The number of sit to stands completed in 1 minute recorded for each of the six sit to stand tests
6. The participant preferred flow rate (high, medium or low) recorded on completion of all the tests
7. The participants preferred type of fan (blades enclosed or blades open) recorded on completion of all the tests
8. The participant personal preferred flow rate is recorded for the fans by "free-hand" adjusting the dial to vary the flow rate and the perceived pleasantness of the preferred airflow rate is measured with a 0 to 10 NRS score

Completion date
30/08/2022

Eligibility

Key inclusion criteria
1. Chronic breathlessness; due to chronic non-malignant lung disease such as Chronic Obstructive Pulmonary Disease,(COPD), any Interstitial Lung Disease (ILD), or other respiratory diseases
2. Modified Medical Research Council (mMRC) breathlessness 3 or 4
3. Able to provide informed written – or witnessed verbal - consent, complete study exercise tests and outcome measures
4. Patients may have current or prior, or no, fan use experience
5. Adults, no upper age limit

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
10

Key exclusion criteria
1. Unable to provide informed consent
2. Unable to complete study measures
3. Unable to perform the sit to stands tests due to musculoskeletal problems, or currently advised by a usual care clinician to avoid such physical activity for any other reason
4. Unable to tolerate fan or trigeminal nerve damage
5. Patients using ambulatory oxygen for confirmed exercise-related oxygen desaturation, or long-term oxygen therapy

Date of first enrolment
01/11/2021

Date of final enrolment
12/08/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Castle Hill Hospital
Respiratory Clinical Trials Unit
Cottingham Road
Hull
United Kingdom
HU16 5JQ

Sponsor information

Organisation
University of Hull

ROR

https://ror.org/04nkhwh30

Funder(s)

Funder type
University/education

Funder Name
University of Hull

Alternative Name(s)
HU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Chief Investigator Dr Flavia Swan (Flavia.swan@hyms.ac.uk). The researchers will share anonymized data with other authorized researchers where relevant for secondary analyses studies – but only with explicit consent from participants. This is requested on the participant consent form. Those declining consent for data sharing will have their data omitted from a “to share” dataset. The “to share” dataset is available after completion of the primary study, for 5 years before it is destroyed.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			17/07/2023	No	Yes
Protocol file		25/06/2021	04/08/2021	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes