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A randomised controlled trial comparing three methods of teaching home spirometry in adult patients with respiratory symptoms

Submission date
13/04/2023

Recruitment status
No longer recruiting

Registration date
18/05/2023

Overall study status
Completed

Last Edited
15/07/2025

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Spirometry is an important test in the assessment and monitoring of patients with respiratory symptoms. It measures how much air you can get in and out of your lungs and the total volume of air that you can get in and out. Due to the COVID-19 pandemic access to spirometry has become more limited meaning that patients are having to wait longer to have this test.
The aim of this study is to investigate whether patients can perform spirometry measurements at home and which method of teaching patients to perform the test works best.

Who can participate?
Patients aged 18 years or over who require spirometry as part of their standard of care

What does the study involve?
Participants will be allocated to one of three different groups:
Group 1 - Face to Face Teaching
The participant will attend the hospital for their spirometry appointment. At this appointment, they will also be taught how to use the home spirometry equipment and app. The participant will then take the equipment home and perform spirometry measurements.
Group 2 - Virtual Teaching
Participants will be sent the home spirometry equipment and the Spirobank Smart Spirometer Home Spirometry Patient Information Leaflet in the post. They will then have a virtual appointment with a member of the Respiratory Physiology team. At this appointment participants will be taught how to use the home spirometry equipment and app. The participant will then take the equipment home and perform spirometry measurements.
Participants will then attend the hospital for their spirometry appointment.
Group 3 - Self-Directed Learning
Participants will be sent the home spirometry equipment and the Spirobank Smart Spirometer Home Spirometry Patient Information Leaflet in the post. They will also be sent a link to a video demonstrating how to use the equipment. The participant will then take the equipment home and perform spirometry measurements. Participants will then attend the hospital for their spirometry appointment.

After performing home spirometry measurements, participants will email their results to the hospital. Participants will also be asked to complete a questionnaire, which asks questions about how they found using the home spirometry equipment.

What are the possible benefits and risks of participating?
There are no direct benefits to participants in the short term. However in the longer term if successful participants may be able to continue performing spirometry at home which may reduce the number of times that they need to attend appointments at the hospital. They may also gain more information about their respiratory health which might be useful.
Before taking part all participants will be screened to make sure the breathing tests will not pose a risk to them. In some circumstances such as if participants have recently undergone surgery the spirometry test should not be performed and therefore participants would not be able to participate in this study. The breathing tests may cause participants to feel slightly lightheaded or breathless, this is normal and should resolve after a few minutes.

Where is the study run from?
Southmead Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2020 to June 2023

Who is funding the study?
Southmead Hospital Charity (UK)

Who is the main contact?
Dr Caitlin Morgan, caitlin.morgan@nbt.nhs.uk

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)
287426

Study information

Scientific Title
REmote teACHing of home SPIROmetry in patients with respiratory symptoms

Acronym
REACH SPIRO

Study objectives
Remote teaching of home spirometry (using the Spirobank Smart spirometer) produces consistent and acceptable lung function measurements when compared to face-to-face teaching on the same device and when compared to the gold standard (lab-based hospital spirometry).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/05/2021, Office for Research Ethics Committees Northern Ireland (ORECNI), Customer Care & Performance Directorate, Lissue Industrial Estate West, 5 Rathdown Walk, Moira Road, Lisburn, BT28 2RF, UK; +44 (0)28 95361407; RECA@hscni.net), ref: 21/NI/0063

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Respiratory disease

Interventions
Single-centre unblinded randomized controlled trial of remote versus face-to-face teaching of home spirometry on the Spirobank smartmeter in patients presenting with respiratory symptoms. Participants will be randomized in a 1:1:1 ratio. The group allocated indicates which method of teaching that participant receives. Following consent patients were randomised using a secure web-based system (REDCap). It is not practical to conceal which arm a patient was randomised to from the perspective of the participant or the researcher.

Group 1 - Face to Face Teaching
The participant will attend the hospital for their spirometry appointment. At this appointment, they will also be taught how to use the home spirometry equipment and app. The participant will then take the equipment home and perform spirometry measurements.

Group 2 - Virtual Teaching
Participants will be sent the home spirometry equipment and the Spirobank Smart Spirometer Home Spirometry Patient Information Leaflet in the post. They will then have a virtual appointment with a member of the Respiratory Physiology team. At this appointment participants will be taught how to use the home spirometry equipment and app. The participant will then take the equipment home and perform spirometry measurements.
Participants will then attend the hospital for their spirometry appointment.

Group 3 - Self-Directed Learning
Participants will be sent the home spirometry equipment and the Spirobank Smart Spirometer Home Spirometry Patient Information Leaflet in the post. They will also be sent a link to a video demonstrating how to use the equipment. The participant will then take the equipment home and perform spirometry measurements. Participants will then attend the hospital for their spirometry appointment.

After performing home spirometry measurements, participants will email their results to the hospital. Participants will also be asked to complete a questionnaire, which asks questions about how they found using the home spirometry equipment.

Intervention Type
Mixed

Primary outcome(s)
Accuracy and acceptability of measurements produced by remote teaching of home spirometry (MIR Spirobank smartmeter) compared to face-to-face teaching and in-hospital spirometry (the gold standard). One or more home spirometry measurements of Forced Expiratory Volume in 1 second (FEV1), Forced Vital Capacity (FVC), FEV1/FVC and Peak Expiratory Flow Rate (PEFR) and forced expiratory flow (FEF) will be compared between each randomised group and hospital spirometry. Home spirometry recordings are submitted within 6 weeks of hospital spirometry.

Key secondary outcome(s)
1. Feasibility of bronchodilator reversibility performed at home, assessed using home spirometry measurements of FEV1, FVC, PEFR and FEF with subsequent measurements after a short-acting bronchodilator and hospital spirometry. Home spirometry recordings are submitted within 6 weeks of hospital spirometry.
2. Patient acceptability of performing home spirometry, assessed by qualitative analysis of feedback questionnaires following the completion of home and hospital spirometry
3. Factors that affect patient willingness, adherence and quality of home spirometry, assessed by qualitative analysis of feedback questionnaires following completion of home and hospital spirometry
4. Disease-specific effects in ILD and airway disease patients assessed using home and hospital spirometry measurements of FEV1, FVC, PEFR and FEF spirometry. Home spirometry recordings are submitted within 6 weeks of hospital spirometry

Completion date
01/06/2023

Eligibility

Key inclusion criteria

1. Require spirometry as part of their routine clinical care
2. The participant has the required technology (smartphone or tablet and an internet connection) to enable the use of the home spirometry device
3. Able to give informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
106

Key exclusion criteria
1. Age <18 years
2. Spirometry contraindicated

Date of first enrolment
13/07/2021

Date of final enrolment
24/05/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Charity

Funder Name
Southmead Hospital Charity

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No