ISRCTN33586883 https://doi.org/10.1186/ISRCTN33586883

Testing a locally adapted approach to identify and care for chronic obstructive pulmonary disease (COPD) earlier in primary care in South America

Submission date
12/11/2026

Recruitment status
Not yet recruiting

Registration date
13/11/2026

Overall study status
Ongoing

Last Edited
13/11/2026

Condition category
Respiratory

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

Plain English summary of protocol
Background and study aims
Chronic obstructive pulmonary disease (COPD) is a long-term lung condition that can make breathing difficult. Many people in South America may not know they have COPD, so they miss out on care and support. This study will develop and test whether a locally adapted approach to finding and caring for people with COPD can be used in primary care in Argentina, Brazil and Peru. It will assess whether the approach is practical to deliver; it is not designed to prove that it improves health.

Who can participate?
Adults aged 50 or over who live near participating primary care centres may be invited for COPD screening. People already diagnosed with COPD may also be invited to take part in the care pathway.

What does the study involve?
Around 3,000 people (in each country) aged 50 or over are expected to be offered screening over six months. Screening may include questions about breathing and risk factors, and a peak-flow breathing test. People with a positive screen will be offered a lung function test called spirometry. People diagnosed with COPD will be offered care and follow-up based on the locally adapted pathway. Participants may complete questionnaires at the start and during follow-up, and some may be invited to an interview. The study plans to collect follow-up information at 6 and 12 months.

What are the possible benefits and risks of participating?
Taking part may help identify COPD that has not previously been diagnosed and connect people with care. However, a direct benefit to each participant is not guaranteed.

Where is the study run from?
The study will take place in selected regions of Argentina, Brazil and Peru.

When is the study starting and how long is it expected to run for?
November 2026 to June 2028

Who is funding the study?
The study is funded by the National Institute for Health and Care Research (NIHR), award NIHR156261.

Who is the main contact?
Dr Onaedo Ilozumba, u.ilozumba@bham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Onaedo Ilozumba

ORCID ID
https://orcid.org/0000-0003-4951-9631

Contact details
Room 212
Murray Learning Building
University of Birmingham
Birmingham
United Kingdom
B15 2FG
+44(0) 7404187819
u.ilozumba@bham.ac.uk

Type(s)
Public

Contact name
Ms Jo Hawley

Contact details
Room 212
Murray Learning Building
University of Birmingham
Birmingham
United Kingdom
B15 2FG
+44 (0) 7967 372585
s.hawley-woodall@bham.ac.uk

Type(s)
Principal investigator

Contact name
Prof Rachel Jordan

ORCID ID
https://orcid.org/0000-0002-0747-6883

Contact details
Room 212
Murray Learning Building
University of Birmingham
Birmingham
United Kingdom
B15 2FG
+44 (0) 7816388432
r.e.jordan@bham.ac.uk

Type(s)
Principal investigator

Contact name
Dr Antonio Bernabe-Ortiz

ORCID ID
https://orcid.org/0000-0002-6834-1376

Contact details
Panamericana Sur Km. 19
Lima
Peru
150142
+51 937 805 894
abernabeo@cientifica.edu.pe

Additional identifiers

Study information

Scientific Title
Feasibility of a locally adapted primary care pathway for the early diagnosis and management of chronic obstructive pulmonary disease in South America: Breathe Well South America

Acronym
Breathe Well South America

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 18/09/2026, Institutional Research Ethics Committee of Universidad Científica del Sur (CIEI-CIENTÍFICA) (Campus Villa 2 - Panamericana Sur Km 19 , Lima, 150142, Peru; +51 9341642912 ; cieicientifica@cientifica.edu.pe), ref: 165-2025-PRO99

2. Approved 27/08/2026, Institutional Review Board for Research Studies (CIREI) (Fundación Médica de Mar del Plata Hospital Privado de Comunidad Córdoba 4545, Mar del Plata, B7602CBM, Argentina; +54 223 499 0000 Int 5435; investigacion@hpc.org.ar), ref: EX-2026-07690429-GDEBA-CCISMSALGP

3. Approved 31/08/2026, THE ETHICS COMMITTEE OF THE PROVINCIAL COUNCIL FOR THE ETHICAL EVALUATION OF HEALTH RESEARCH (CoPEIS) (Av. Ortiz de Ocampo 1700, La Rioja, La Rioja, 5300, Argentina; +54 (261) 423-4425; carloslaino25@gmail.com), ref: 023/2025

4. Approved 14/11/2025, Comitê de Ética em Pesquisa do Hospital Universitário da Universidade de São Paulo (Av. Lauro Gomes, 2000 - Prédio CEPES - 1º andar - sala 30 e 31 - Santo André-SP, CEP, Sao Paulo, 09060-870, Brazil; +55 (11) 3091-9457; cep@hu.usp.br), ref: 79609024.0.1001.0076

5. Approved 11/05/2026, Comitê de Ética em Pesquisa (CEP) da Universidade Federal do Maranhão - UFMA (Avenida dos Portugueses, 1966 CEB Velho Cidade Universitária Dom Delgado, Bacanga, São Luis/MA, CEP, Maranhão, 65080-805, Brazil; + 55 98 3272-8708; atecepufma@ufma.br), ref: 79609024.0.3005.5087

6. Approved 10/02/2026, Comitê de Ética em Pesquisa (CEP) do Centro Universitário FMABC (Av. Lauro Gomes, 2000 - Prédio CEPES - 1º andar - sala 30 e 31 - Santo André-SP,, Santo André, 09060-870, Brazil; +55 (11) 4993-5453; cep@fmabc.br), ref: 9609024.0.3002.0082

7. Approved 31/05/2025, Comitê de Ética em Pesquisa (CEP) UFAM - Hospital Universitário Getúlio Vargas (Rua Tomás de Vila Nova, 300, 5º andar, Torre II, Centro, Manaus/AM, CEP, Manaus, 69020-545, Brazil; +55 92 3305-4707; cep.hugv-ufam@ebserh.gov.br), ref: 79609024.0.2001.9167

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Health services research, Feasibility testing

Study type(s)

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions
In each country, approximately 3,000 adults aged 50 years or older will be recruited from the catchment areas of 6–8 primary healthcare centres over six months. Recruitment may take place through house-to-house visits, primary healthcare centres, condition specific clinics such as tuberculosis clinics, hospitals, or other locally appropriate sources.

The study aims to identify approximately 150–200 new cases of COPD, while also recruiting all known COPD cases residing within the defined catchment areas. Before participation, individuals will receive study information and a participant information sheet. Written informed consent will be obtained, and only individuals able to understand the study and provide consent will be included. People with an active respiratory infection will be rescheduled until recovery.

The screening assessment will be conducted with a standardised Symptom- and exposure-based questionnaire (SBQ) and peak flow measurement. Data will be collected using pre-programmed REDCap forms. A positive screen will be defined as either an SBQ score of 17 or higher or a peak flow of ≤250 L/min for women or ≤350 L/min for men.

Participants with a positive screening result, together with individuals already known to have COPD, will be referred for diagnostic spirometry at an appropriate healthcare facility. Post-bronchodilator spirometry will be offered in all participating countries; prebronchodilator spirometry will additionally be offered in Brazil in accordance with national policy. All participants will complete baseline questionnaires covering sociodemographic characteristics, COPD knowledge and patient activation, symptoms, health behaviours, healthcare utilisation and quality of life. Questionnaires may be self-administered or completed with assistance from a trained interviewer using REDCap.

Participants with confirmed COPD will enter a management and follow-up phase based on the locally developed care pathway.Management may include agreed pharmacological treatment, referral to smoking cessation services, pulmonary rehabilitation or exercise programmes, self-management plans and routine follow-up. A modified version of the baseline questions will be repeated during follow-up. The feasibility study is focused on the evaluation of the delivery of the locally relevant care pathway, and specifically who, how and where the management will take place.

Clinical and implementation outcomes will be assessed at six and twelve months, using information collected through study procedures, participant self-report and review of relevant medical records. The study will therefore combine case-finding, diagnostic assessment, routine-care management and follow-up monitoring within existing primary healthcare pathway.

Intervention Type
Other

Primary outcome(s)
1. Work productivity and activity impairment measured using work productivity and activity impairment (WPAI) questionnaire at baseline, 6-months, 12-months

2. Exercise levels measured using Godin Leisure-Time Exercise questionnaire at baseline, 6-months, 12-months

3. Quality of life measured using EQ-5D-5L/EQ-5D-3L at baseline, 6-months, 12-months

4. Quality of life measured using GAD-7 at baseline, 6-months, 12-months

5. Quality of Life measured using CAT score at baseline, 6-months, 12-months

6. Quality of Life measured using MRC dyspnoea score at baseline, 6-months, 12-months

7. Adherence to medication measured using Test of the Adherence to Inhalers (TAI) questionnaire at baseline, 6-months, 12-months

8. Patient Activation measured using Patient Activation Measure questionnaire at baseline, 6-months, 12-months

9. Health care expenditure measured using Out-of-Pocket Expenditure questionnaire at baseline, 6-months, 12-months

10. Healthcare utilisation measured using Health service utilisation questionnaire at baseline, 6-months, 12-months

11. COPD Exacerbations measured using COPD Exacerbations questionnaire at baseline, 6-months, 12-months

12. Patient uptake measured using percentage invited that attend at each stage of the pathway at baseline, 6-months, 12-months

13. Patient representativeness measured using characteristics of attenders' vs non-attenders at baseline, 6-months, 12-months

14. Delivery of guideline-based care measured using healthcare records at 6-months, 12-months

15. Quality of Indicators measured using conformance, completeness, plausibility of our new COPD indicators recorded within healthcare records at 6-months, 12-months

Key secondary outcome(s)

Completion date
30/06/2028

Eligibility

Key inclusion criteria
1. Aged 50 years or older
2. Residing in the catchment area of selected primary health care facilities
3. Participants able to understand and give consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Patients with active respiratory infections or recent severe acute illness preventing them from participating in a peak flow manoeuvre or spirometry (e.g. heart attack) should be rescheduled for a later time after infection or their health improves

Date of first enrolment
16/11/2026

Date of final enrolment
31/12/2027

Locations

Countries of recruitment
Argentina

Brazil

Peru

Sponsor information

Organisation
Universidad Científica del Sur

ROR
https://ror.org/04xr5we72

Organisation
Instituto de Efectividad Clínica y Sanitaria

ROR
https://ror.org/02nvt4474

Funder(s)

Funder type

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository. In line with the NIHR position on the sharing of research data, when publishing the findings of the research via publications, we will provide a data sharing statement describing how to access the underpinning data. Data relating to publications will be stored in a trusted repository (e.g. https://edata.bham.ac.uk/), in accordance with the NIHR position on the sharing of research data. The correct level of access to the data (open, restricted, closed or upon request) will be determined at the time of publication. If open access is not applicable to the actual data, open access will be given to the metadata.

IPD sharing plan summary
Stored in publicly available repository