ISRCTN45800298 https://doi.org/10.1186/ISRCTN45800298

The ICLEAR service model to integrate palliative care and respiratory medicine for chronic obstructive pulmonary disease patients

Submission date
22/10/2024

Recruitment status
Recruiting

Registration date
28/10/2024

Overall study status
Ongoing

Last Edited
09/11/2026

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[X] 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 lung condition that prevents airflow to the lungs, causing difficulty breathing, discomfort, fatigue, and other symptoms that contribute to poor quality of life. People with COPD often have unmet needs across physical, emotional, social, and care domains. Palliative care can help address these unmet needs for people with COPD, but the referral and access to palliative care for this population is not optimal. A proactive approach which integrates palliative care into routine care for COPD can help reduce the impact of the illness and help patients have timely discussions about their preferences for care.
Through the EU PAL-COPD project, the aim is to achieve better quality of life and improved well-being for people with advanced COPD, by integrating palliative care into routine respiratory care. For this, we propose an intervention called ICLEAR-EU, which focuses on identifying palliative care needs; integration between palliative, respiratory, and community care; shared decision-making about care goals and advance care planning; and regular review of these decisions. Originally developed in the UK, ICLEAR-EU has been adapted to fit the healthcare context of six countries where the trial will be carried out: Belgium, the Netherlands, the United Kingdom, Denmark, Hungary, and Portugal.
With this trial study, which will last 27 months in total, we will test the effectiveness of ICLEAR-EU for people with advanced COPD who are admitted to the hospital for an exacerbation, or sudden worsening, of their symptoms. With three hospitals per country participating, we aim to evaluate the effects on outcomes for patients and their family caregivers, explore differences in outcomes across countries and subgroups, evaluate the intervention's cost-effectiveness, and assess the intervention's implementation process.

Who can participate?
Patients with advanced COPD, admitted to the hospital for an exacerbation, can participate if they meet the eligibility criteria. The patient's family caregiver can also participate.

What does the study involve?
In each country, participating hospitals begin the study in the control group, providing patients

with usual care. In a randomly allocated order, the hospitals will begin the ICLEAR-EU intervention after 6, 12, or 18 months of following the control condition. During the month before starting the intervention, the healthcare professionals delivering the intervention will receive training about the intervention and the study procedures. Patients and family caregivers will be recruited throughout a 24-month period, starting from the beginning of the study. The researchers will collect data through questionnaires, with a 90-day follow-up period for patients and caregivers. There will also be a process evaluation to understand how the intervention was implemented, for which we will use data collection methods such as attendance lists, questionnaires, and interviews.

What are the possible benefits and risks of participating?
Taking part in the study helps the EU PAL-COPD research team evaluate an international intervention, which aims to improve patient-centred care and quality of life for people with advanced COPD. For participants in the control condition, there are no immediate benefits to taking part in the study. However, completing questionnaires may facilitate thinking about care needs, which can be shared with a healthcare professional. For participants in the intervention, participating in conversations with healthcare professionals about future care goals may help identify and meet care needs and preferences.
There are minimal to no risks anticipated in participating. For some participants, thinking and talking about their health and (palliative) care, or answering questions about palliative care and the end of life, may be distressing. The research team will have procedures in place to respond to distress and can provide information about support services.

Where is the study run from?
The study is conducted in six countries: Belgium, the Netherlands, the United Kingdom, Denmark, Hungary, and Portugal.

When is the study starting and how long is it expected to run for?
January 2024 to November 2027

Who is funding the study?
EU PAL-COPD is funded by the European Union under the Horizon Europe Programme (HORIZON-HLTH-2023-DISEASE-03). The project is also supported by Innovate UK, and the Ministry of Culture and Innovation of Hungary from the National Research, Development, and Innovation Fund.

Who is the main contact?
1. Prof. Koen Pardon (Vrije Universiteit Brussel): koen.pardon@vub.be
2. Prof. Luc Deliens (Vrije Universiteit Brussel): luc.deliens@vub.be

Contact information

Type(s)
Principal investigator

Contact name
Prof Koen Pardon

ORCID ID
https://orcid.org/0000-0002-0571-709X

Contact details
End of Life Care Research Group
Laarbeeklaan 103
Jette
Belgium
1090
(+32 0)2 477 47 57
koen.pardon@vub.be

Type(s)
Principal investigator

Contact name
Prof Luc Deliens

ORCID ID
https://orcid.org/0000-0002-8158-2422

Contact details
End of Life Care Research Group
Laarbeeklaan 103
Jette
Belgium
1090
(+32 0)2 477 47 57
luc.deliens@vub.be

Type(s)
Public, Scientific

Contact name
Dr Julie Stevens

ORCID ID
https://orcid.org/0000-0002-1417-0436

Contact details
End of Life Care Research Group
Laarbeeklaan 103
Jette
Belgium
1090
(+32 0)2 477 47 54
julie.joseph.stevens@vub.be

Additional identifiers

Protocol serial number
101136621

Study information

Scientific Title
Evaluation of the ICLEAR-EU intervention to integrate palliative care in the treatment of people with advanced chronic obstructive pulmonary disease and their family caregivers: an international stepped wedge cluster randomised controlled trial in six European countries

Acronym
EU PAL-COPD

Study objectives
Current study objectives as of 12/09/2025:
The aim is to compare the ICLEAR-EU intervention to current usual care (treatment as usual) with regard to its:

1. Effectiveness in healthcare systems, as indicated by:

Primary Outcome Measure:
The percentage of patients who have respiratory-related hospital readmissions within 90 days from baseline (or until death if before 90 days from baseline); it is hypothesized that fewer patients in the intervention phase will require readmissions

Secondary Outcome Measures:
1. Patient outcomes: illness perception, quality of life, mental wellbeing, existential wellbeing, presence of advance decisions to refuse treatment and documentation of advance care planning, preferred place of death
2. Caregiver outcomes: quality of life, mental wellbeing, existential wellbeing, family carer burden, bereaved caregiver views of quality of care and death
3. Healthcare utilisation outcomes: Place of death, concordance between preferred and actual place of death, all-cause mortality, number of readmissions, length of hospital stays on readmission, referrals to specialist palliative care, ICU and emergency department admissions
4. Cost-effectiveness: cost per quality-adjusted life year (QALY)
5. Process and implementation evaluation: feasibility of integration into standard care, barriers and facilitators to implementation, and mechanisms involved in achieving outcomes in each participating country.

2. Effects on subgroups, including subgroups defined by characteristics known to affect health equity and equitable access:
2.1. Comparison of trials across participating countries
2.2. Effects on subgroups according to age, gender, socioeconomic status, cohabitation status, and location (rural vs urban)

Previous study objectives:
The aim is to compare the ICLEAR-EU intervention to current usual care (treatment as usual) with regard to its:

1. Effectiveness in healthcare systems, as indicated by:

Primary Outcome Measure:
The percentage of patients who have respiratory-related hospital readmissions within 90 days from baseline (or until death if before 90 days from baseline); it is hypothesized that fewer patients in the intervention phase will require readmissions

Secondary Outcome Measures:
1. Patient outcomes: illness perception, quality of life, mental wellbeing, presence of advance decisions to refuse treatment and documentation of advance care planning, preferred place of death
2. Caregiver outcomes: quality of life, mental wellbeing, family carer burden, bereaved caregiver views of quality of care and death,
3. Healthcare utilisation outcomes: Place of death, concordance between preferred and actual place of death, all-cause mortality, number of readmissions, length of hospital stays on readmission, referrals to specialist palliative care, ICU and emergency department admissions
4. Cost-effectiveness: cost per quality-adjusted life year (QALY)
5. Process and implementation evaluation: feasibility of integration into standard care, barriers and facilitators to implementation, and mechanisms involved in achieving outcomes in each participating country.

2. Effects on subgroups, including subgroups defined by characteristics known to affect health equity and equitable access:
2.1. Comparison of trials across participating countries
2.2. Effects on subgroups according to age, gender, socioeconomic status, cohabitation status, and location (rural vs urban)

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 26/05/2025, medical ethics committee (MEC) of Ghent University (UGent) and Ghent University Hospital (UZ Gent)/Commissie voor Medische Ethiek U(Z) Gent, ref: ONZ-2025-0050
2. The Medical Ethics Evaluation Commission (METC Oost-Nederland) reviewed whether the study falls under the Dutch Medical Research Involving Human Subjects Act (WMO). METC Oost-Nederland determined that the study does not fall under WMO. It does not require positive evaluation by METC nor by other medical ethics committees. The study was also presented to the RUMC commission for human research (CMO Radboudumc), which reviews non-WMO research in certain cases. The CMO Radboudumc deemed that since the study did not meet the criteria for evaluation, no advice from them is necessary for the conduct of the study. Date: 11 /03/2025; ref: 2025-17958.
3. Approved 11/07/2025, HRA and Health and Care Research Wales (HCRW), ref: 25/SC/0194
4. 02/07/2024, Regional Health Research Ethics Committees in the Capital Region in Denmark waived the need for ethical approval of the project, ref: F-24036330
5. Approved 04/07/2025, ETT TUKEB – Scientific and Research Ethics Committee of the Medical Research Council, Hungary, ref: BM/16149-1/2025
6. Approved 03/10/2025, Comissão de Ética para a Saúde (CES) do HDES, followed 24/10/2025 by the Conselho de Administração (BA) (Av. D. Manuel I, 9500-370 Ponta Delgada, +351 (0)296 203 000; helio.tm.oliveira@azores.gov.pt), ref: S-HDES/2025/625
7. Approved 03/09/2025, Comissão de Ética para a Saúde (CES) do HSEIT, followed 11/09/2025 by the Conselho de Administração (BA) (Canada do Breado 9700 049, 9700-049 Angra do Heroísmo, Portugal; +351 (0)295 403 200 ext 11008;

Sandra.MS.Lobao@azores.gov.pt), ref: Nº 10/2025; SAI-HSEIT/2025/1259
8. Approved 08/09/2025, Comissão de Ética para a Saúde (CES) do HH, followed 12/09/2025 by the Conselho de Administração (BA) (Estr. Príncipe Alberto do Mónaco, 9900-038 Faial, Portugal; +351 (0)292 201 205; Maria.FT.Pereira@azores.gov.pt), ref: Nota Interna Nº DOC.: 68; Sai-HH /2025/976

Primary study design
Interventional

Study design
Multicenter study with a stepped wedge cluster-randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Advanced chronic obstructive pulmonary disease

Interventions
Control:
Hospitals will provide patients with treatment as usual. Care will be provided according to the routine practice of each hospital, and in accordance with the practice of the healthcare system in each country.

Intervention:
The ICLEAR-EU intervention is a novel, staged, multi-faceted approach to care for those with advanced COPD, to identify and respond to palliative care needs. The intervention consists of five core components:

1. Identification of unmet palliative care needs using the Edmonton Symptom Assessment System (ESAS).
2. Communication about goals of care and sharing with patient, family, and care team.
3. Shared decision-making regarding Levels of Escalation as part of the communication with the patient, family, and care team, contributing to a patient management plan for future care.
4. Initiating advance care planning conversations with the patient and their family carer, led by a member of the care team in hospital or in the community.
5. Ongoing Review and management of palliative care needs during follow-up visits with healthcare professionals, and revision of the patient management plan when necessary.

Clinicians delivering the intervention will be provided with an intervention manual detailing each of the five intervention components and will be trained to use the intervention.

Each hospital will go through four wedges, each wedge with a duration of 6 months, for a total of 24 months. All sites start as control sites for 6 months. The timing of cross-over from control to intervention will be randomly assigned at study onset and unblinded to the country research teams at 4, 10, and 16 months to allow preparation of the transition. Hospitals will cross over to the intervention at 6-monthly intervals (cross-over at 6, 12, and 18 months). After the final 6 months, there will be an additional 90 days follow-up so that data can be collected up to the last patient included.

Intervention Type

Behavioural

Primary outcome(s)
Percentage of patients who have a respiratory-related readmission to hospital within 90 days of baseline (or until death if within these 90 days), assessed via health record review.

Key secondary outcome(s)
Current secondary outcome measures as of 12/09/2025:
For patients:
1. Perception of illness measured using the Brief Illness Perception Questionnaire at baseline, 30 days, and 90 days
2. Quality of life measured using the Short Form Chronic Respiratory Questionnaire (SF-CRQ), EQ-5D-5L, and ICECAP Supportive Care Measure (ICECAP-SCM) at baseline, 30 days, and 90 days
3. Mental wellbeing measured using the Patient Health Questionnaire-4 (PHQ-4) at baseline, 30 days, and 90 days
4. Existential wellbeing measured using the McGill Quality of Life Questionnaire-Revised (MQOL-R) existential subscale
5. Preferred place of death + whether this has been discussed with health care professionals measured using a questionnaire item at baseline, 30 days, and 90 days
6. Presence of advance decisions to refuse treatment (ADRTs) and advance care plans (ACPs) assessed through ICLEAR-EU form and medical notes at 90 days
For (bereaved) caregivers:
1. Quality of life measured using the EQ-5D-5L at baseline, 30 days, and 90 days
2. Mental wellbeing measured using the PHQ-4 at baseline, 30 days, and 90 days
3. Existential wellbeing measured using the McGill Quality of Life Questionnaire-Revised (MQOL-R) existential subscale
4. Family caregiver burden measured using the Zarit Burden Interview (ZBI-12) at baseline, 30 days, and 90 days
5. Bereaved caregiver views of quality of care and death assessed via VOICES-SF at 3 months post-bereavement

Process evaluation:
1. Reach assessed through training attendance list after each ICLEAR-EU training; ICLEAR-EU meeting attendance list after each ICLEAR-EU meeting; Screening log of patients
2. Effectiveness assessed using Self-Efficacy regarding End-Of-Life Communication (S-EOLC) and palliative and end-of-life care-specific education needs (End-of-life Professional Caregiver Survey [EPCS]) at 1-4 weeks before training, 1-4 weeks after start of first intervention wedge; interview with patients and relatives approx. 4 weeks after hospital discharge; Interview with relatives 3 months after bereavement; interview with clinicians during the follow-up period after the last wedge
3. Adoption assessed using addendum to the ICLEAR-EU meeting form after each ICLEAR-EU meeting
4. Implementation assessed according to:
4.1. Adherence, measured using the inclusion log and a fidelity checklist
4.2. Ease of use, measured using interval scale after every wedge
4.3. Satisfaction with ICLEAR-EU training/trainer, measured using evaluation questionnaire immediately after training
4.4. Satisfaction with the ICLEAR-EU intervention measured using interval scale after every wedge
4.5. Fidelity to core components ICLEAR measured using check based on ICLEAR form or patient medical record after every wedge

4.6. Barriers and facilitators to implementation assessed using short questionnaire with text box after every intervention wedge, regular check-in with the local research team by phone
5. Maintenance assessed according to
5.1. Intention for using ICLEAR in the future measured using interval scale after the last wedge
5.2. Organizational intention for long-term implementation measured using interval scale after the last wedge
5.3. Recommendations for improving the usability of the intervention program assessed via interview with two clinicians from the ICLEAR-EU team after the last wedge

Previous secondary outcome measures:
For patients:
1. Perception of illness measured using the Brief Illness Perception Questionnaire at baseline, 30 days, and 90 days
2. Quality of life measured using the Short Form Chronic Respiratory Questionnaire (SF-CRQ), EQ-5D-5L, and ICECAP Supportive Care Measure (ICECAP-SCM) at baseline, 30 days, and 90 days
3. Mental wellbeing measured using the Patient Health Questionnaire-4 (PHQ-4) at baseline, 30 days, and 90 days
4. Preferred place of death + whether this has been discussed with health care professionals measured using a questionnaire item at baseline, 30 days, and 90 days
5. Presence of advance decisions to refuse treatment (ADRTs) and advance care plans (ACPs) assessed through ICLEAR-EU form and medical notes at 90 days

For (bereaved) caregivers:
1. Quality of life measured using the EQ-5D-5L at baseline, 30 days, and 90 days
2. Mental wellbeing measured using the PHQ-4 at baseline, 30 days, and 90 days
3. Family caregiver burden measured using the Zarit Burden Interview (ZBI-12) at baseline, 30 days, and 90 days
4. Bereaved caregiver views of quality of care and death assessed via VOICES-SF at 3 months post-bereavement

Healthcare utilisation outcomes:
1. Place of death assessed through medical notes or contacting GP as appropriate
2. Concordance between preferred place of death and actual place of death, assessed through questionnaire item regarding preferred place of death and medical notes or contacting GP to assess the actual place of death, as appropriate
3. All-cause mortality assessed via medical notes as appropriate
4. Number of readmissions to hospital assessed through medical notes at 90 days
5. Median length of hospital stays on readmission assessed through medical notes at 90 days
6. Number of referrals to specialist palliative care assessed through medical notes at 90 days
7. Intensive Care Unit (ICU) admissions assessed through medical notes at 90 days
8. Emergency Department admissions assessed through medical notes at 90 days

Health economic evaluation:
1. Formal healthcare utilisation and unpaid family care measured through Client Service Receipt Inventory (CSRI) at baseline, 30 days, and 90 days

Process evaluation:
1. Reach assessed through training attendance list after each ICLEAR-EU training; ICLEAR-EU meeting attendance list after each ICLEAR-EU meeting
2. Effectiveness assessed using Self-Efficacy regarding End-Of-Life Communication (S-EOLC) and palliative and end-of-life care-specific education needs (End-of-life Professional Caregiver Survey [EPCS]) at 1-4 weeks before training, 1-4 weeks after first wedge; interview with patients and

relatives approx. 4 weeks after hospital discharge; Interview with relatives 3 months after bereavement; interview with clinicians during the follow-up period after the last wedge
3. Adoption assessed using addendum to the ICLEAR-EU meeting form after each ICLEAR-EU meeting
4. Implementation assessed according to:
4.1. Adherence, measured by the number of patients ICLEAR vs usual care after every wedge
4.2. Ease of use, measured using interval scale after every wedge
4.3. Satisfaction with ICLEAR-EU training/trainer, measured using interval scale immediately after training
4.4. Satisfaction with the ICLEAR-EU intervention measured using interval scale after every wedge
4.5. Fidelity to core components ICLEAR measured using check based on ICLEAR form after every wedge
4.6. Barriers and facilitators to implementation assessed using short questionnaire with text box after the last wedge, regular check-in with the local research team by phone
5. Maintenance assessed according to
5.1. Intention for using ICLEAR in the future measured using interval scale after the last wedge
5.2. Organizational intention for long-term implementation measured using interval scale after the last wedge
5.3. Recommendations for improving the usability of the intervention program assessed via interview with two clinicians from the ICLEAR-EU team after the last wedge

Completion date
30/11/2027

Eligibility

Key inclusion criteria
Participant inclusion criteria:
Patients:
1. Have a diagnosis of advanced COPD:
1. Spirometry (FEV1):
1.1. Severe COPD: 30% ≤FEV1 <50% predicted OR
1.2. Very severe COPD: FEV1 <30% predicted
OR
2. High symptom burden:
2.1. Modified Medical Research Council (mMRC) >2 OR
2.2. COPD Assessment Test (CAT) >20
OR
3. High-risk exacerbation history:
3.1. ≥ 1 exacerbation leading to previous hospitalisation in the past year OR
3.2. ≥ 1 exacerbation leading to previous ICU admission in the past year

2. Admission to the respiratory ward of the hospital that lasts ≥48 hours (or likely to be admitted for ≥48 hours) for an acute exacerbation
3. Live at home

Family caregivers:
1. Identified by the patient as the person who gives him or her the most help and support at home on a regular basis
2. Aged 18 years or over

Participant type(s)
Carer, Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Patient exclusion criteria:
1. Currently receiving care from a formally recognised specialised palliative care team
2. Cognitive impairment preventing informed consent
3. Not able to speak or understand the language in which measurements are conducted, these being:
3.1. English (United Kingdom)
3.2. Dutch (Belgium, the Netherlands)
3.3. Danish (Denmark)
3.4. Portuguese (Portugal)
3.5. Hungarian (Hungary)
4. Patients can be included in the study only once and cannot be re-enrolled during the overall duration study, even if at a different wedge.

Family caregiver exclusion criteria:
1. Cognitive impairment preventing informed consent
2. Not able to speak or understand the language in which measurements are conducted

Date of first enrolment
01/09/2025

Date of final enrolment
31/08/2027

Locations

Countries of recruitment
United Kingdom

England

Belgium

Denmark

Hungary

Netherlands

Portugal

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
England
M23 9LT

Study participating centre
Blackpool Victoria Hospital
Whinney Heys Road
Blackpool
England
FY3 8NR

Study participating centre
Royal Lancaster Infirmary
Ashton Road
Lancaster
England
LA1 4RP

Study participating centre
Universitair Ziekenhuis Gent (UZ Gent, Ghent University Hospital)
Corneel Heymanslaan 10
Ghent
Belgium
9000

Study participating centre

Herlev/Gentofte Hospital
Borgmester Ib Juuls Vej 1
Herlev
Denmark
2730

Study participating centre
OLVG Amsterdam
Amsterdam
Netherlands
1061 AE

Study participating centre
Isala Zwolle
Zwolle
Netherlands
8025 AB

Study participating centre
Radboud UMC Nijmegen
Nijmegen
Netherlands
6525 GA

Study participating centre
Ziekenhuis aan de Stroom (ZAS)
Lindendreef 1
Antwerpen
Belgium
2020

Study participating centre
Vitaz Ziekenhuis
Moerlandstraat 1
Sint-Niklaas
Belgium
9100

Study participating centre

Sygehus Lillebælt, Vejle
Beriderbakken 4
Vejle
Denmark
7100

Study participating centre
Sjællands Universitetshospital, Roskilde og Næstved
Ringstedgade 61
Næstved
Denmark
4700

Study participating centre
University of Pecs Medical School,
First Department of Medicine
Division of Pulmonology
Pecs
Hungary
H-7623

Study participating centre
University of Pecs Medical School
Hospital of Komlo
Department of Pulmonology and Respiratory Rehabilitation
Komlo
Hungary
H-7300

Study participating centre
National Koranyi Institute for Pulmonology
Budapest
Hungary
H-1121

Study participating centre
Hospital do Divino Espírito Santo de Ponta Delgada (HDES)
São Miguel Island, Azores
Av. D. Manuel I

Ponta Delgada
Portugal
9500-370

Study participating centre
Hospital do Santo Espírito da Ilha Terceira (HSEIT)
Terceira Island, Azores
Canada do Breado
Angra do Heroísmo
Portugal
9700-049

Study participating centre
Hospital da Horta (HH)
Horta, Faial Island, Azores
Estrada Príncipe Alberto do Mónaco
Faial
Portugal
9900-038

Sponsor information

Organisation
Vrije Universiteit Brussel

ROR
https://ror.org/006e5kg04

Funder(s)

Funder type
Government

Funder Name
European Commission under the Horizon Europe Programme (HORIZON-HLTH-2023-DISEASE-03)

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
Innovate UK

Alternative Name(s)
Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Ministry of Culture and Innovation Hungary from the National Research, Development, and Innovation Fund

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 non-publicly available repository. EU PAL-COPD data are first stored and organized at the institution level, such as within a designated secure, encrypted area of each institution's storage environment. For the aggregated dataset of pseudonymised participant data containing personal information, in consultation with the Vrije Universiteit Brussel Research Data Management team, we will deposit these in the VUB institutional repository. Data will be retained for a minimum of 10 years, and a maximum of 20 years after the completion of the study. Use of restricted data by third parties will be subject to evaluation by the coordinators of the project and the principal investigators of each participating institution, together with the relevant persons such as legal and ethics officers, and data protection officers. These data will only be shared with third parties upon reasonable request and upon signing a unilateral data sharing agreement.

Personal data of participants will be collected (through informed consent sheets; and through data collection which includes demographic data, health data, and questionnaire data). Participants will provide written informed consent before data is collected. Data will be pseudonymised using alphanumeric codes.

Prior to start of data collection, each institution or organization in the six participating countries will obtain the necessary ethical approvals from (research) ethics committees at their institution and/or within each trial site, according to the procedures and regulations applicable for each.

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		02/11/2026	09/11/2026	Yes	No
Statistical Analysis Plan	version 2.0	02/12/2025	09/01/2026	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes