

# Early interventions for palliative care

<b>Submission date</b> 22/10/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 17/12/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/09/2023	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Background and study aims

End-of-life care (palliative care ) is support for people who are in the last months or years of their life.

One of the reasons why palliative care does not completely fulfil population needs is that most of the palliative care programmes and units are more focused and addressed to patients with cancer.

The aim of the project and the clinical trial is to find out whether early intervention of palliative care services for non-cancer patients (respiratory (COPD / multi-morbid)) can help improve their quality of life during the later stages of their disease.

Who can participate?

Patients over the age of 55 with respiratory disease/severe state multi-morbidity and a small number of their carers/healthcare professionals can take part if they meet the inclusion and exclusion criteria.

What does the study involve?

The study involves a randomised controlled trial of Care as Usual versus an intervention of a Palliative Care Needs Assessment (400 participants across the 4 sites). There is an additional Service Evaluation stage where four different site-based pilot interventions are evaluated. These interventions are largely focused on the remote delivery of supportive/quality-of-life interventions).

What are the possible benefits and risks of participating?

Possible benefits of taking part are (if engaging with the interventions) receiving improved focus on patient needs.

Where is the study run from?

1. NHS Highland (UK)
2. Santa Casa Da Misericordia Da Amadora (Portugal)
3. Aristotle University of Thessaloniki (Greece)
4. Hospital Universitario y Politécnico La Fe (Spain)

When is the study starting and how long is it expected to run for?

June 2019 to September 2023

Who is funding the study?  
European Union Horizon 2020 Programme.

Who is the main contact?  
Frances Hines, frances.hines@nhs.scot

## Contact information

**Type(s)**  
Public

**Contact name**  
Ms Frances Hines

**Contact details**  
NHS Highland RDI Division Centre for Health Science  
Old Perth Road  
Inverness  
United Kingdom  
IV2 3JH  
+44 (0)1463255822  
frances.hines@nhs.scot

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
270472

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
IRAS 270472

## Study information

**Scientific Title**  
Clinical trial of outcomes from early interventions for palliative care patients - a stratified approach for severe respiratory illness and multimorbidities using a pilot randomised controlled trial (InAdvance)

**Acronym**  
InAdvance

**Study objectives**

Are clinical and quality of life benefits obtainable from early interventions of palliative care for patients with severe respiratory disease and/or multimorbidities from the perspective of patients, carers and health care professionals?

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 06/01/2021, South Central - Oxford B Research Ethics Committee (Whitefriars Level 3, Block B Lewin's Mead, Bristol , BS1 2NT, United Kingdom; +44 (0)2071048058; oxfordb.rec@hra.nhs.uk), ref: 20/SC/0415

## **Study design**

Multicentre interventional randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Diagnostic, Quality of life, Treatment, Efficacy

## **Health condition(s) or problem(s) studied**

Later-stage respiratory disease and multi-morbidity late stages (COPD/multimorbidity) patients (and their carers and healthcare professionals (HCP))

## **Interventions**

Current interventions as of 13/09/2023:

The Stage One intervention is a Palliative Care Needs Assessment; this will take place at one visit, either face-to-face or remotely, by trained personnel, with a follow-up of 12 months (T1, T2, T3, T4). These occur at each of the 4 European sites - NHS Highland (UK), Amadora (Portugal), Valencia Hospital (Spain), and Thessaloniki Hospital (Greece).

The Stage Two interventions are done as Service Evaluations and are not part of the research of the Clinical Trial. The aim is to vary per European site and will start after 12-month assessments

- NHS Highland will run a Remotely Delivered Living Well Course - hour-long weekly sessions lasting 8 weeks using video-conferencing techniques.
- Hospital Universitari i Politècnic la Fe, Valencia, Spain will randomise to usual care or a Multi-dimensional 9 Step Programme of intervention activities including physical therapy, psychological support and caregiver support – duration 6 months
- Santa Casa da Misericórdia da Amadora, Portugal will randomise Care as Usual or to a Multi-Stage Programme of Palliative Care including early referral to a national Palliative Care network, multi-disciplinary support team, Health Promotion Programme, Carers support and Loss & Grief support – duration 6 months.
- Hippokrateio General Hospital of Thessaloniki, Greece, will use randomise to usual care or an electronic platform containing patient-centred tools for self-support combined with e-forums for peer support along with live empathy sessions for care professionals, as well as using a monitoring system for pressure ulcers, and an AI-based behavioural intervention to improve self-management - duration 6 months.

The randomisation process is a sequential, two-stage, unstratified 50/50 process to Standard care vs Needs Assessment (Stage one Intervention).

Previous interventions:

The Stage One intervention is a Needs Assessment; this will take place at one visit, either face-to-face or remotely, by trained personnel, with a follow-up of 12 months

The Stage Two interventions vary per site and will start after 12 month assessments –

- NHSH and Leeds will randomise to usual care or a Remotely Delivered Living Well Course - hour-long weekly sessions lasting 8 weeks using video-conferencing techniques.
- Hospital Universitari i Politècnic la Fe, Valencia, Spain will randomise to usual care or a Multi-dimensional 9 Step Programme of intervention activities including physical therapy, psychological support and caregiver support – duration 6 months
- Santa Casa da Misericórdia da Amadora, Portugal will randomise to Care as Usual or to a Multi-Stage Programme of Palliative Care including early referral to national Palliative Care network, multi-disciplinary support team, Health Promotion Programme, Carers support and Loss & Grief support – duration 6 months.
- Hippokrateio General Hospital of Thessaloniki, Greece, will use randomise to usual care or an electronic platform containing patient-centred tools for self-support combined with e-forums for peer support along with live empathy sessions for care professionals, as well as using a monitoring system for pressure ulcers, and an AI-based behavioural intervention to improve self-management - duration 6 months.

The randomisation process is a sequential, two stage, unstratified 50/50 process - first to Standard care vs Needs Assessment (Stage one Intervention), then to standard care vs Stage two intervention by means of the CASTOR web-based randomisation allocation system

## **Intervention Type**

Mixed

## **Primary outcome(s)**

Current primary outcome measures as of 13/09/2023:

Stage One

Measured at baseline, 6 weeks, 6 months, 12 months and 18 months

1. Quality of life (EQ-5D-5L)
2. Intensity of symptoms (POS1/POS2)
3. Functional status (PPSv2)

Previous primary outcome measures:

Stage One

Measured at baseline, 6 weeks, 6 months, 12 months and 18 months

1. Quality of life (EQ-5D-5L)
2. Intensity of symptoms (POS1/POS2)
3. Functional status (PPSv2)

Stage 2

Measured at baseline, 6 weeks, 6 months, 12 months and 18 months

1. Quality of life (EQ-5D-5L)
2. Intensity of symptoms (POS1/POS2)
3. Functional status (PPSv2)

## **Key secondary outcome(s))**

Measured at baseline, 6 weeks, 6 months, 12 months and 18 months (unless otherwise noted):

1. Emotional distress (HADS)
2. Within-trial cost analysis of participants' service use and out of pocket expenses measured using patient interview
3. For carers: caregiving burden (brief ZBI)
4. Perceived quality of care is assessed among patients and carers using a 5-point Likert scale
5. Treatment adherence measured using the Treatment Acceptability/Adherence Scale and the Medical Outcomes Study tool
6. Treatment adherence, acceptability, appropriateness and feasibility will be assessed by qualitative interview with staff using data collection tools based on the Consolidated Framework for Implementation Research (CFIR) at baseline and 18 months
7. Cost categories measured for cost-consequence analysis and cost-effectiveness to be calculated at 18 months:
  - 7.1. The intervention costs: Resource units consumed and their unit costs will be collected using uniform reporting templates. Depending on the intervention, resource units may concern the minutes spent by health and social care professionals (e.g. medical specialists, nurses, social workers, other therapists), diagnostic procedures (e.g. medical imaging, laboratory services), consumables (e.g. drugs, fluids and disposables) and overheads.
  - 7.2. Other healthcare costs will be measured with the Medical Consumption Questionnaire (MCQ), which will be completed by patients. The MCQ includes questions related to frequently occurring contacts with health care providers.
  - 7.3. Informal care costs will be determined by multiplying the number of hours taking care of the patient with corresponding hourly productivity costs. The number of hours taking care of the patient will be collected using items from the Valuation of Informal Care Questionnaire (VICQ).

## **Completion date**

30/09/2023

## **Eligibility**

### **Key inclusion criteria**

Current participant inclusion criteria as of 13/09/2023:

Patient:

1. Severe respiratory illness related to COPD or has respiratory disease as part of multimorbid state or has multi-morbid severe condition (Heart Failure etc)
2. Over the age of 55
3. Identified using the stratification model as being appropriate for receiving support / palliative care
4. Able to give written informed consent
5. Carer/HCP related to the patient participating also included as long as able to give written informed consent/adult

Previous participant inclusion criteria:

Patient:

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**Participant type(s)**

Patient, Health professional, Carer

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

55 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

370

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/01/2021

**Date of final enrolment**

30/11/2022

**Locations**

**Countries of recruitment**

United Kingdom

Scotland

Greece

Portugal

Spain

**Study participating centre**

**NHS Highland RDI Division Centre for Health Science**  
Old Perth Road  
Inverness  
United Kingdom  
IV2 3JH

**Study participating centre**  
**Hospital Universitario y Politécnico La Fe**  
Avinguda de Fernando Abril Martorell, 106  
València  
Spain  
46026

**Study participating centre**  
**Aristotle University of Thessaloniki**  
School of Medicine  
University Campus  
Thessaloniki  
Greece  
54124

**Study participating centre**  
**Santa Casa Da Misericordia Da Amadora**  
Estrada da Portela  
Quinta das Torres  
Portugal  
2610-143

## **Sponsor information**

**Organisation**  
NHS Highland

**ROR**  
<https://ror.org/010ypq317>

## **Funder(s)**

**Funder type**

Government

## Funder Name

Horizon 2020 Framework Programme

## Alternative Name(s)

EU Framework Programme for Research and Innovation H2020, Horizon 2020, Horizon 2020 Framework Programme (H2020), Rahmenprogramm Horizont 2020, Horizont 2020, Programa Marco Horizonte 2020, Horizonte 2020, Programme-cadre Horizon 2020, Orizzonte 2020, Programma quadro Orizzonte 2020, H2020

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

# 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 Frances Hines, frances.hines@nhs.scot.

The final goal is to make data openly accessible for as long as possible and for as long as the information they contain are relevant for further research purposes. The decision about the long-term provision of data collected and processed under the InAdvance project will be taken as the data are stored. After completing the trials, data collected during the InAdvance project will be openly accessible if the following requirements are met: i) data collection and processing are completed.; ii) data checking – in terms of quality control – is performed; and iii) after the completion of consortium partners' exploitation plan both in terms of scientific publications and commercial purposes. A possible period to make InAdvance data openly accessible may be 2 years after data collection. However, this time frame will be discussed and agreed by the project General Assembly. Also, discussions about licenses and terms of re-use will be also done by the project General Assembly, with the support and/or supervision of the Data Protection Officer and the Ethics Advisory Board, if necessary.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		21/10/2022	24/10/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other unpublished results</a>	Executive summary		13/09/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes

[Study website](#)

Study website

11/11/2025 11/11/2025 No

Yes