

Early interventions for palliative care

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

Study website
<http://www.inadvanceproject.eu/>

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

EudraCT/CTIS number
Nil known

IRAS number
270472

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospice, Hospital

Study type(s)

Diagnostic, Quality of life, Treatment, Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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)

Secondary outcome measures

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).

Overall study start date

01/06/2019

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:

1. Severe respiratory illness related to COPD or has respiratory disease as part of multimorbid state

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Participant type(s)

Patient, Health professional, Carer

Age group

Mixed

Lower age limit

55 Years

Upper age limit

100 Years

Sex

Both

Target number of participants

Stage 1 400 across 4 sites

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

Greece

Portugal

Scotland

Spain

United Kingdom

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

Sponsor details

NHS Highland RDI Division Centre for Health Science
Old Perth Road
Inverness
Scotland
United Kingdom
IV2 3JH
+44 (0)1463 255822
nhsh.randd@nhs.scot

Sponsor type

Hospital/treatment centre

Website

<https://www.nhshighland.scot.nhs.uk/Pages/welcome.aspx>

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, Rahmenprogramm Horizont 2020, Programa Marco Horizonte 2020, Programme-cadre Horizon 2020, Programma quadro Orizzonte 2020, Program ramowy Horyzont 2020, Horizont 2020, Horizonte 2020, Orizzonte 2020, Horyzont 2020, Horizon 2020 Framework Programme (H2020), H2020

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Results and Publications

Publication and dissemination plan

As part of a large scale EU funded project with a total of 14 organisations as partners, it is expected there will be a large number of academic and clinical publications in a wide range of peer reviewed journals. Contributions to conferences and other events has already taken place and will continue to occur.

Intention to publish date

30/11/2023

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?
Protocol article		21/10/2022	24/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other unpublished results	Executive summary		13/09/2023	No	No