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Early interventions for palliative care

Submission date 22/10/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol
Registration date 17/12/2020	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 13/09/2023	**Condition category** Respiratory	[_] 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 feasibilty will 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

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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?
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
Study website	Study website	11/11/2025	11/11/2025	No	Yes