Developing palliative and end-of-life care research partnerships and capacity in the North West Coast of England

The overarching aim is to build a broad palliative care research partnership across the North West Coast region between Universities, palliative care providers, patients, family carers and the public, and existing regional infrastructure such as the CRN and ARC. This will be underpinned by an exploration of local barriers to such research, how they can be overcome, and implementation of a range of capacity building activities. This will enable the delivery of high quality, practice-relevant, fundable research grant applications that focus on needs, especially those of underserved populations, in North West Coast and beyond.

Background and Scientific Rationale

The need for a focus on the North West Coast region: The North West Coast region of England has high palliative care need (third highest prevalence in England) and historically low recorded NIHR research activity (second lowest research recruitment rate in England). People with palliative care needs, and their family carers, deserve care that is informed by the highest quality evidence, enabled by research active and informed health and social care professionals, within research imbued organisations and services: it is known that care within research active organisations is superior[1]. There is a clear need for more palliative and end-of-life care research integrated across this region.

There is a high incidence of life-limiting disease within the region[2 3], compounded by high levels of socioeconomic deprivation[4]. Regionally, this is characterised by clusters of multidimensional disadvantage, including populations known to be underserved, such as areas with ageing or ethnic minority populations, and the deprivation associated with coastal and rural communities[5]. For example, Blackpool, a coastal town in this region, is the most deprived local authority area in England, and has the lowest life expectancy in England[5]. The number of people who will require palliative care is predicted to increase because of the ageing population, as is the number of people living and dying with chronic and complex conditions[6 7]. In the majority of North West CCGs, a higher proportion of patients are admitted within the last 90 days of life with a greater than UK average number of patients dying in hospital in the North West[8]. Patients in the North West are known to be referred to specialist palliative care services later than in other regions (35 days vs 55 days in the South of England)[9]. Late referrals will also affect the window of opportunity for people to participate in research across the region.

The challenges of conducting research in palliative and end-of-life care: There are personal, cultural and organisational reasons for patients and their family carers not accessing services nor engaging in research[10]. Patients are viewed as vulnerable and can have complex needs[11-13]. Gatekeeping access to research studies can be a particularly challenging issue with concerns about patient and carer burden, despite evidence suggesting patients and family are willing to engage in research at the end of life[14-19]. Palliative care research itself can be challenging because of a lack of funding, difficulties in identifying suitable study participants and lack of research infrastructure in non-NHS settings such as nursing homes or hospices, issues the applicant team have experienced[20-29].

Addressing barriers to research in palliative and end-of-life care: Our previous work in the North West Coast region, particularly in hospices, identified a number of barriers to research including the lack of a strong research culture, poor or absent research infrastructure, lack of research expertise and capacity, and concerns about adequate governance arrangements[30]. Strategies to address some of these barriers may include reducing and managing the demands on clinicians of being involved in research, having research staff on site[15 31], training on how to recruit to palliative care studies[32 33], and improving communication with patients and their families to promote research participation,

and within staff teams to address gatekeeping. We want to build and expand on this work through this partnership to develop a more active and confident palliative care regional research network helping to nurture good research practice and combat barriers to recruitment.

Objectives of the proposed palliative care research partnership

Our vision is to build a sustainable palliative and end-of-life care research partnership and infrastructure within, and across, key organisations in the North West Coast region. We aim to increase the opportunities for patients and family carers to access high quality, clinically relevant research that improves their experiences and outcomes of care.

Objectives:

i) To develop a sustainable palliative care partnership infrastructure across NWC, embedded within existing organisations such as the CRN and ARC, involving strong PPI, as a focus for palliative and end-of-life care research in the region.
ii) To work with palliative care providers, patients and the public, and research staff to further understand local barriers and facilitators to palliative and end-of-life care research, and develop and implement solutions to these barriers.
iii) To build clinical capacity in palliative and end-of-life care research through the mentorship of emerging research leaders and share academic expertise across organisations.
iv) To facilitate the development of high-quality research grant applications that address important clinical research questions that meet the needs of the NWC population (and beyond) focused on the NIHR palliative and end-of-life care calls (NIHR PHR, EME, HS&DR and HTA) in 2022.

Partnership Plan

DEVELOP AND EMBED AN ACTIVE PALLIATIVE CARE PARTNERSHIP NETWORK ACROSS NORTH WEST COAST (to meet objective i) Activities to embed this will be actioned throughout the phased activities below. Building on the wide engagement for preparing this bid, we will further develop an 'umbrella' partnership across academics, clinical care providers, and our PPI network, embedded in current structures (e.g. the Clinical Research Network, End of Life Care Network, North West Hospice Group, ARC, and academic centres of excellence) to enable sustained work on facilitating palliative and end-of-life care research. This will include one of the partners hosting a webpage for people to understand and engage with the partnership, with regular virtual meetings (including grant planning, research seminars etc.) to develop the partnership across all stakeholders, separate to the management of this grant.

PHASE ONE (0-6 months): RAPID IDENTIFICATION OF CURRENT LOCAL BARRIERS TO RESEARCH AND THEIR SUSTAINABLE SOLUTIONS (to meet objective ii)

We will identify current local barriers to palliative care research, building on and extending past work with hospices, and our more general work on research barriers[29-31 34]. This will ensure that our activities are focused on identifying and implementing appropriate solutions to contemporary local issues, and which can be embedded into existing infra-structure.

i. ***Online survey*** across NWC to identify current local research barriers and suggestions for sustainable solutions. This will be circulated online (using Qualtrics™) via stakeholders engaged in this partnership including academic centres, hospices, generalist and specialist palliative care clinicians and provider organisations, CRN, ARC, End of Life Care Network etc. We will endeavour to include those groups that are part of the NHS workforce transformation strategy where research is a role descriptor, but where research

participation is historically low (e.g. Clinical Nurse Specialists and Advanced Clinical Practitioners).

ii. ***Working groups, using a nominal group technique***[35] to explore barriers and facilitators in more depth, running in parallel with the survey but drawing from any initial survey analysis. Groups (n=4) will be convened for a single meeting (virtual via Teams or in-person depending on prevailing circumstances) of 2-3 hours. Each working group meeting will have 2-3 facilitators from this partnership team, and involve up to 15-20 participants from single key stakeholder groups. Proposed stakeholder groups include research nurses (and other key CRN staff); hospices (with nominated key decision makers which may include Chief Executives, clinical or research leads); clinicians (across all provider settings including primary and secondary care); and public, patient and community representatives (to ideally include known under-served populations including those from minority ethnic populations, particular disease groups e.g. head/neck cancer). We will work with our PPI lead, PPI group and draw from the public advisor network in the ARC to facilitate reaching these groups. Brief 10-minute presentations on the current 'state of the science' will orient attendees to existing knowledge. Nominal group techniques will then include the silent, written, generation of ideas, sharing and grouping these thematically, and group discussion. This will result in a prioritised list within each group of perceived barriers and proposed solutions, which will be further aggregated and analysed by this partnership team.

The REC approved protocol for the survey and working groups is appended (Appendix 1).

PHASE TWO (7-12 months). PERSONAL MENTORSHIP AND SUPPORT TO CO-DESIGN AND PREPARE RESEARCH GRANT APPLICATIONS (to meet objective iii and iv)

First, we will focus on individual and group support including interactive workshops, action learning sets, peer support and mentorship to build research capabilities and capacity to support high quality research grant applications.

i. ***Peer support and/or action learning sets***: We will facilitate the development of emerging research leaders in palliative care research across NWC through facilitated action learning sets to provide structured sessions which enable peers to meet regularly, identify areas of shared learning to address current research challenges, and be supported through the partnership in learning to address issues. Nominations to attend can be made by any individual or stakeholder organisation within NWC against clear criteria, and will include emerging leaders that are part of this application. Areas of interest may include support from senior academics, research support offices, the CRN etc. in understanding financial aspects of bid development, building a team, writing a clear narrative etc. We will run a maximum of 3 individual sets, each with no more than 5-6 members, mentored by a senior applicant.
ii. ***Mentorship***: Providing expert 1:1 mentorship to up to 6 emerging research leaders, especially clinicians, including research and advanced practice nurses, so that they can be co-principal investigator on bids and/or contribute effectively to their development.
iii. ***Time:*** We will buy time for clinically focused staff named in this bid to have concentrated time to contribute to grant development, and ensuring bids are clinically relevant. We propose one-two blocks of time for staff to be released at key junctures in the grant development process, timing dependent on release of grant calls.

PHASE TWO (7-18 months). IMPLEMENT IDENTIFIED SOLUTIONS TO ENABLING BETTER PALLIATIVE AND END-OF-LIFE CARE RESEARCH ACROSS NORTH WEST COAST (to meet objectives ii and iv)

Second, we will focus on infrastructure developments to facilitate palliative and end-of-life care research across NWC. This work will continue to 18 months recognising the complexity of embedding and sustaining solutions, but also ensuring that these are in place prior to the commencement of any successful funding applications. These activities cannot be fully finalised until the results from phase one are known, but we indicate some proposed activities and solutions based on existing evidence and local knowledge:

i. ***Recruitment training***. Recruitment to palliative care studies has particular challenges and complexities, and the emotional labour of this work has been recognised[29]. Training to acknowledge this, creating and maintaining a community of practice amongst research nurses and others, and identifying appropriate approaches and communication patterns should facilitate recruitment to these studies. Training will be co-facilitated with our PPI group to enable a more powerful shift of perceptions about the acceptability of participation in such studies, this has already been piloted in a previous study[36].
ii. ***Research governance***. As (mostly) independent, charitable organisations, hospices and care-homes generally do not have an established research governance infrastructure. We will form a network of North West Coast 'research ready' hospices learning from the CRN ENRICH care home model, including facilitating sharing of templates for research approval and governance processes, learning from research active hospices, and integrating this network within existing infrastructure such as the CRN and existing groupings of North West Hospices.
iii. ***Public and Patient Involvement***. The nature of disease progression and individual deterioration means that sustaining an active PPI network in palliative care can be challenging. We plan to create a network – facilitated by our PPI lead and PPI group, ARC and their public advisor network, drawing from learning from existing PPI groups (e.g. Lancaster Partners/CECo[37]).

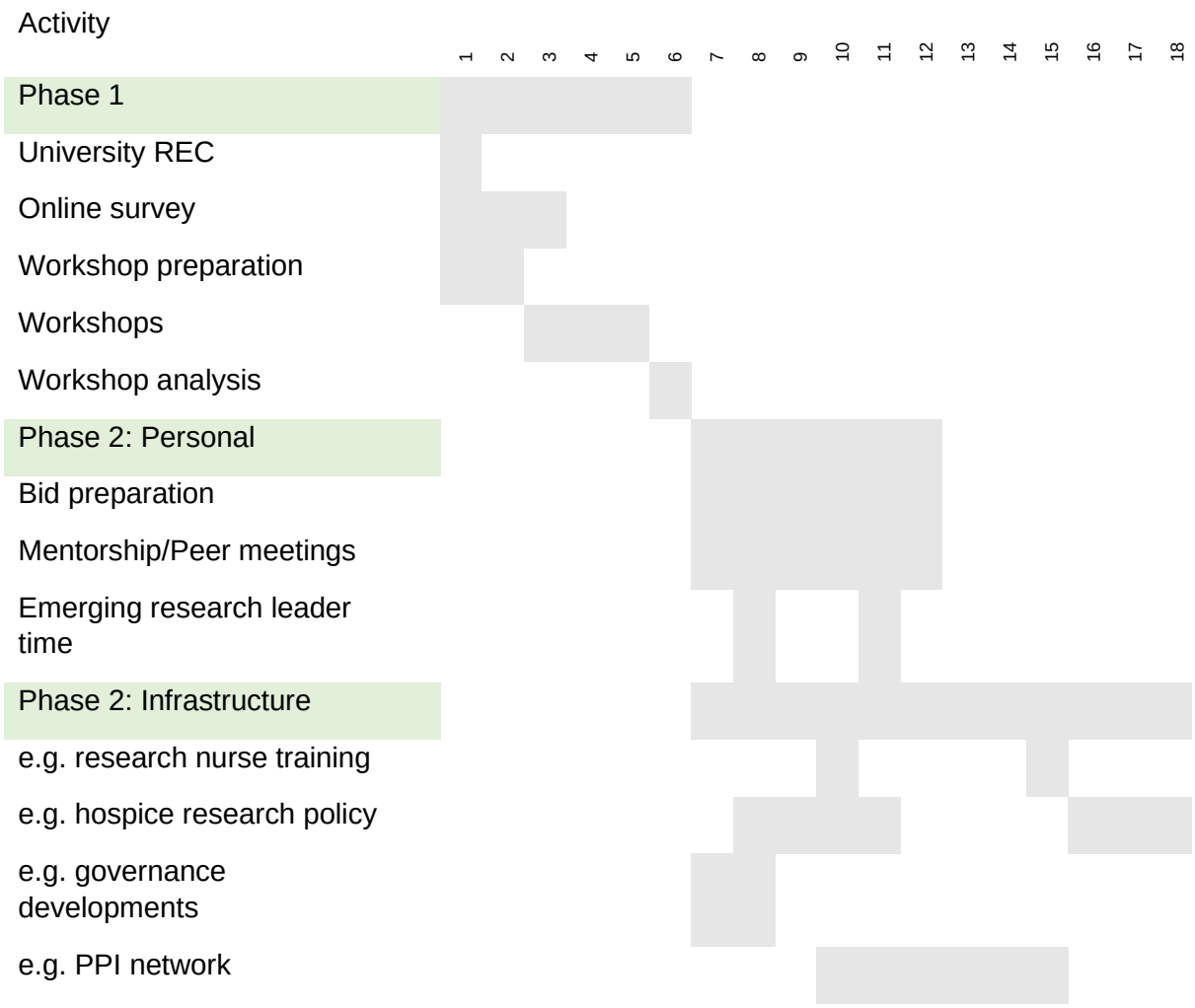
PHASE THREE (7-12 months) DEVELOPING AND SUBMITTING HIGH QUALITY CLINICALLY RELEVANT RESEARCH PROPOSALS (to meet objective iv)

We have identified indicative contender research ideas that map onto gaps identified in the commissioning call, addressing palliative care needs identified above, including reducing inequalities in access to services, care integration, and planning and managing end-of-life care, although we are very open to supporting new research areas identified in phases one and two. These indicative ideas all address research priorities identified as part of the James Lind Alliance Priority Setting Partnership[38], and build on existing academic expertise to enhance competitiveness. These involve emerging research leaders, and will benefit from the infrastructure developments in earlier phases. We will make links to other relevant funded partnerships from this call to enhance these or other supported ideas where relevant. We hope that this partnership will support at least 3 submitted bids to the calls in 2022, but we will continue to support those developing all bids to future submission and beyond.

Dissemination, Outputs and anticipated Impact: We expect to support submission of high quality, clinically relevant, applications to the forthcoming palliative and end-of-life care calls. These will be underpinned by a sustainable infrastructure to facilitate and enable high quality research. This will include a visible, virtual, network embedded in existing infrastructure with a web-presence so that people within and outside North West Coast are aware of research capacity and interest in this field. There will be greater capacity to engage in palliative and end-of-life care research at all levels from the development of research leaders, research active clinicians, through all levels of the research process.

Project / research timetable: The 18 months of this study (from January 2022) is carefully chosen to overlap with the anticipated research calls to facilitate both partnership project work specifically focused on high quality bids, but also the development of underpinning

sustainable infrastructure that will be in place whenever a project may start. There are no key-interdependencies in terms of continuance of employment for any partnership members.



Project management and governance: The project will be led and managed by Professor Catherine Walshe, with Lancaster University as the lead institution, and with a partnership co-ordinator co-applicant (Dunleavy). A partnership steering committee will be set up for the duration of the project involving all named co-applicants, including PPI co-applicant. This committee will meet virtually monthly for the first six months of the project, and 6-8 weekly after this, recognising the time-commitment of steering committee members to developing individuals and research bids integral to this partnership. The steering committee will co-opt partners as determined by stage two of the project, but this is likely to include representation from the group of North West Coast Hospices, the North West Coast Palliative and End-of-Life Care Clinical Network, and other relevant charities (e.g. Marie Curie, Macmillan).

Ethics / Regulatory Approvals: Not required for capacity development work, but NHS REC approval will be sought for the survey and workshops.

Success criteria

i. Submission of at least 3 full applications on palliative and end-of-life care topics to NIHR funding streams in 2022.

ii. Formal capacity development programme for clinicians and emerging research leaders to build capacity as co-leads or co-applicants to NIHR bids.
iii. 70% of CRN research nurses attend additional training on recruitment to palliative care studies, (training course now embedded in CRN programme in NW)
iv. Research ethics and governance for hospices template agreed by CEOs of most hospices in NWC
v. New NWC regional PPI network in palliative care linked to ARC

Risks and mitigation

i. Future waves of COVID-19 may impact upon clinician's time and therefore opportunities for capacity building. However, we have excellent online mentorship skills and have costed some 'buy-out' funding for promising research-active clinicians.
ii. Lack of engagement from key stakeholders such as hospice CEOs. We are aware of competing pressures on many of our stakeholders and will endeavour to work flexibly through existing networks to ensure 'buy-in', but their initial high engagement in these ideas should mitigate this risk.

Appendix One. Protocol.

Protocol

Developing palliative and end-of-life care research partnerships and capacity in the North West Coast of England

This protocol has regard for the HRA guidance and order of content

Research Team:
Professor Catherine Walshe
Professor Nancy Preston
Professor Sheila Payne
Professor John Ellershaw
Professor Vanessa Taylor
Professor Nick Hulbert-Williams
Dr Lesley Dunleavy
Dr Stephen Mason
Dr Amara Nwosu
Dr Amy Gadoud
Dr Ruth Board
Dr Brooke Swash
Dr Seamus Coyle
Dr Andrew Dickman
Ms Andrea Partridge
Mr Jaime Halvorsen

Research lead:
Professor Catherine Walshe
Director of the International Observatory on End of Life Care
International Observatory on End of Life Care
Division of Health Research
Lancaster University
Lancaster
LA1 4AT

Tel: 01524 510124
c.walshe@lancaster.ac.uk

Contents

Glossary

Specialist palliative care: Services/practitioners who provide specialist palliative care to adults/and or children in hospices. They may also provide specialist advice and support in the hospital and/or in the community setting.

Generalist palliative care: Generalist palliative care is provided to adults/and or children by the patient's usual care team in hospital, primary care and nursing/care homes (e.g. district nurse, GP, physio).

Research staff: Research focused staff (e.g. research nurses, researchers, R&D staff).

NIHR: National Institute for Health Research

CRN: Clinical Research Network

ARC: Applied Research Collaborative

PPI: Patient and public involvement

1.0 Key Study Contacts

Chief Investigator	Professor Catherine Walshe Professor of Palliative Care Director of the International Observatory on End of Life Care International Observatory on End of Life Care Division of Health Research Health Innovation One Sir John Fisher Drive Lancaster University Lancaster LA1 4AT 01524 510124 c.walshe@lancaster.ac.uk
Sponsor	Ms Claire O'Donnell, Acting Head of Research Quality and Policy, Lancaster University, LA1 4YT Tel: +44 (0)1524 592981, email **sponsorship@lancaster.ac.uk**
Study Funder	This study has been funded by the NIHR (Ref: NIHR135334).
Key Protocol Contributors	Professor Catherine Walshe Professor Nancy Preston Professor Sheila Payne Professor John Ellershaw Professor Vanessa Taylor Professor Nick Hulbert-Williams Dr Lesley Dunleavy Dr Stephen Mason Dr Amara Nwosu Dr Amy Gadoud Dr Ruth Board

Dr Brooke Swash

Dr Seamus Coyle

Dr Andrew Dickman

Ms Andrea Partridge

Mr Jaime Halvorsen

2.0 Study summary

Study Title	Developing palliative and end-of-life care research partnerships and capacity in the North West Coast of England
Short title	Palliative care research capacity and partnership building in the North West
Study Design	Online survey and working groups, using nominal group techniques
Study Participants	Stakeholders (palliative care providers and research staff) and patient, family carer/members and community representatives across North West Coast.
Planned Size of Sample	Each of the working groups will involve around 10-15 participants if online or 15-20 participants if in person (total sample n=40-80) purposively sampled from single key stakeholder groups. For the survey we plan to recruit as many participants as possible of those working in palliative and end of life care and research across North West Coast. We do not have a definitive population count, but estimate a response rate of around 30-40% of those to whom it is circulated.
Follow up duration	No follow up
Planned Study Period	March 2022-September 2022 Survey: March 2022- May 2022 Working groups, using nominal group techniques: April 2022- July 2022
Research Question/Aim(s)	To explore local barriers to palliative and end-of-life care research within North West Coast and to identify how they can be overcome.

3.0 Background

The need for a focus on the North West Coast region

The North West Coast region of England has high palliative care need (third highest prevalence in England) and historically low recorded NIHR research activity (second lowest research recruitment rate in England). People with palliative care needs, and their family carers, deserve care that is informed by the highest quality evidence, enabled by research active and informed health and social care professionals, within research imbued organisations and services: it is known that care within research active organisations is superior(1). There is a clear need for more palliative and end-of-life care research integrated across this region.

There is a high incidence of life-limiting disease within the region(2, 3), compounded by high levels of socioeconomic deprivation(4). Regionally, this is characterised by clusters of multidimensional disadvantage, including populations known to be underserved, such as areas with ageing or ethnic minority populations, and the deprivation associated with coastal and rural communities(5). For example, Blackpool, a coastal town in this region, is the most deprived local authority area in England, and has the lowest life expectancy in England(5). The number of people who will require palliative care is predicted to increase because of the ageing population, as is the number of people living and dying with chronic and complex conditions (6, 7). In the majority of North West CCGs, a higher proportion of patients are admitted within the last 90 days of life with a greater than UK average number of patients dying in hospital in the North West(8). Patients in the North West are known to be referred to specialist palliative care services later than in other regions (35 days vs 55 days in the South of England)(9). Late referrals will also affect the window of opportunity for people to participate in research across the region.

The challenges of conducting research in palliative and end-of-life care

There are personal, cultural and organisational reasons for patients and their family carers not accessing services nor engaging in research(10). Patients are viewed as vulnerable and can have complex needs (11-13). Gatekeeping access to research studies can be a particularly challenging issue with concerns about patient and carer burden, despite evidence suggesting patients and family are willing to engage in research at the end of life (14-19). Palliative care research itself can be challenging because of a lack of funding, difficulties in identifying suitable study participants and lack of research infrastructure in non-NHS settings such as nursing homes or hospices, issues the applicant team have experienced(20-29).

Addressing barriers to research in palliative and end-of-life care

Our previous work in the North West Coast region, particularly in hospices, identified a number of barriers to research including the lack of a strong research culture, poor or absent research infrastructure, lack of research expertise and capacity, and concerns about adequate governance arrangements(30). Strategies to address some of these barriers may include reducing and managing the demands on clinicians of being involved in research, having research staff on site(15, 31), training on how to recruit to palliative care studies(32, 33), and improving communication with patients and their families to promote research participation, and within staff teams to address gatekeeping. We want to build and expand on this work through this partnership to develop a more active and confident palliative care regional research network helping to nurture good research practice and combat barriers to recruitment.

4.0 Project plan

4.1 Aims:

The overarching aim of this project is to build a broad palliative care research partnership across the North West Coast region between Universities, palliative care providers, patients, family carers and the public, and existing regional infrastructure such as the Clinical Research Network (CRN) and Applied Research Collaborative (ARC). This will be underpinned by an exploration of local barriers to such research, how they can be overcome, and implementation of a range of capacity building activities. This will enable the delivery of high quality, practice-relevant, fundable research grant applications that focus on needs, especially those of underserved populations, in North West Coast and beyond.

The research outlined in this protocol aims to explore local barriers to palliative and end-of-life care research within North West Coast and to identify how they can be overcome.

4.2 Objectives:

The project has a number of objectives ***but this protocol specifically outlines how objective ii) will be met:***

Objectives:

v) To develop a sustainable palliative care partnership infrastructure across North West Coast, embedded within existing organisations such as the CRN and ARC, involving strong PPI, as a focus for palliative and end-of-life care research in the region.

vi) To work with palliative care providers, patients and the public, and research staff to further understand local barriers and facilitators to palliative and end-of-life care research, *and develop and implement solutions to these barriers.*

vii) To build clinical capacity in palliative and end-of-life care research through the mentorship of emerging research leaders and share academic expertise across organisations.

viii) To facilitate the development of high-quality research grant applications that address important clinical research questions that meet the needs of the North West Coast population (and beyond) focused on the NIHR palliative and end-of-life care calls (NIHR PHR, EME, HS&DR and HTA) in 2022.

4.3 Research design

Two approaches to data collection are proposed. First, an online survey and second, working groups**,** using nominal group technique (34). Both will be used to rapidly identify current local barriers to research and their sustainable solutions. This activity builds on and extends previous work with hospices, and our more general work on research barriers (29-31, 35). This will ensure that our activities are focused on identifying and implementing appropriate solutions to contemporary local issues, and which can be embedded into existing infra-structure.

4.3.1 Online survey

An online cross-sectional survey will be circulated to stakeholders (palliative care providers and research staff) across North West Coast to identify “research readiness” amongst staff and current local research barriers and suggestions for sustainable solutions.

4.3.2 Working groups, using a nominal group technique

Working groups, using nominal group technique (n=4-8 approximately, depending on whether online or in person) will be held with stakeholders (palliative care providers and research staff) and patient, family carer/member and community representatives to explore barriers and facilitators in more depth. These will run in parallel with the survey but draw from any initial survey analysis.

4.4 Setting

Data will be collected from academic centres, hospices, tertiary, secondary and primary care, nursing homes/care homes, Clinical Research Network, Applied Research Collaborative and End of Life Care Network.

4.5 Participants

Participants in both the survey and working groups will be stakeholders (palliative care providers and research staff). Additionally, patient, family carer/members and community representatives will be invited to participate in working groups.

Stakeholders' (palliative care providers and research staff) inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Provide health and/or social care for patients and carers with palliative/end of life care needs.	
and/or	
Involved or would wish to be involved in palliative/end of life care research	
Aged 18+, no maximum age	Under 18 years of age
Working within the North West Coast geography	Working outside the North West Coast geography

Patient, family carer/member, and community representatives' inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Any patient, family carer/member or community representative who self identifies as a person who has relevant experience related to the provision of general or specialist palliative care services.	Lack capacity to consent to participate in the research.
Aged ≥16 years, no maximum age	Unable to participate in a working group using English.

and the primary service user is accessing care within the North West Coast geography

4.6 Sample

4.6.1 Online survey

We aim to recruit stakeholders (health and social care providers and research staff) from multiple settings across North West Coast. This will include those groups that are part of the NHS workforce transformation strategy where research forms part of a role descriptor, but where research participation is historically low (e.g. Clinical Nurse Specialists and Advanced Clinical Practitioners). For the survey we plan to recruit a diverse sample as possible of those working in palliative and end of life care and research across North West Coast. We do not have a definitive population count, but estimate a response rate of around 30-40% of those to whom it is circulated. There are 37 NHS Trusts/Hospices, and one private care provider, providing palliative care within the North West Coast region and of whom 32 indicated they would be happy to circulate the survey to eligible participants. North West Coast Clinical Research Network have agreed to circulate the survey to their primary care contacts. We do not have a population count within each NHS Trust/hospice organisation/primary care provider.

4.6.2 Working groups, using nominal group techniques

We plan a number of working groups, the size of which may vary depending on whether they are run in-person or online, as experience shows that online working groups are easier to manage when there are fewer participants than the equivalent in person groups. Working groups will be constituted with similar participants which may include; research nurses (and other key CRN staff); hospices (with nominated key decision makers which may include Chief Executives, clinical or research leads); practitioners (across all provider settings including primary and secondary care); and patient, family carer/members and community representatives (to ideally include known under-served populations including those from minority ethnic populations, particular disease groups e.g. head/neck cancer, stroke). Each of the working groups will involve around 10-15 participants if online or 15-20 participants if in person (total sample n=40-80) purposively sampled from single key stakeholder groups. We are not striving for a representative sample but aim to be inclusive by ensuring particularly hard to reach to groups are targeted for recruitment.

4.7 Recruitment

4.7.1 Recruitment to the online survey

An email with a link to an electronic survey will be sent, via a local collaborator in participating organisations (e.g. R&D staff, clinical lead), to eligible stakeholders. The survey may also be advertised in participating organisations via additional communication channels (e.g. newsletter, poster in staff areas, institutional website). A recruitment flyer/poster for this purpose is included in this application for ethical approval. We will also disseminate information on the survey through our institutional websites, social media and personal networks. An online recruitment flyer for this purpose is included in this application for ethical approval.

4.7.2 Recruitment to working groups, using nominal group techniques

4.7.2.1 Recruitment of stakeholders

Stakeholders will be provided with invitation packs by the research team to enable them to consider participation in the working groups. A local collaborator (e.g. clinical lead, head of department, R&D staff) will be asked to suggest eligible stakeholders in their locality to whom packs could be sent. Invitations will be sent out by a local collaborator to their known contacts, not by the research team. The packs will be sent with an email invitation, and will include a copy of the consent form, and a participant information sheet. Participants can indicate their interest in participating by responding by email or telephone directly to the researchers responsible for conducting the working groups. Participants who express an interest but have not confirmed participation one week after contacting the research team will be sent a reminder.

Additional recruitment methods

Stakeholders who took part in the survey and who expressed an interest in taking part in further research will be contacted by a member of the research team and sent information (invitation letter, participant information sheet and consent form) about the working group. Participants can respond to the invitation by email if they are interested in taking part. If no response is made within one week, then a reminder will be sent. Additionally, we may advertise for stakeholders to participate via social media channels (potentially Twitter, Facebook and Instagram). An online recruitment flyer for this purpose is included in this application for ethical approval. People volunteering to participate via this channel will be asked to contact the research team to indicate an interest in participating and request a study information pack. The packs will be sent with an email invitation, and will include a copy of the consent form, and a participant information sheet. Participants can respond to the invitation by email. If no response is made within one week, then a reminder will be sent.

4.7.2.1 Recruitment of patient, family carer/member and community representatives

We will work with our PPI lead, PPI group and draw from the public advisor network in the ARC to facilitate reaching these groups, including using their existing social media channels. We will attempt to recruit people that represent the population served across North West Coast paying attention to reaching underserved communities. People will be asked to contact the research team to indicate an interest in the project, and to request an information pack about the project. The packs will be sent with an email invitation, and will include a copy of the consent form, and a participant information sheet. Participants can indicate their interest in participating by responding by email or telephone directly to the researchers responsible for conducting the

working groups. Participants who express an interest but have not confirmed participation one week after contacting the research team will be sent a reminder.

4.8 Informed consent

Informed consent will be sought from participants prior to taking part in the study. We will take written consent wherever possible, but if this is not possible because of COVID restrictions we will take and document verbal consent (see section 4.8.2 for further details). Returning consent forms in a stamped addressed envelope is not a feasible option currently because of unpredictable infection control measures necessary due to the COVID-19 pandemic.

4.8.1 Online survey

Interested participants will be instructed to follow the link to the online survey where they will be able to read the study information and consent statement. Participants will be informed that participation in the survey is voluntary. Participants will be asked to 'click' on to the next page after the home page to indicate and confirm that they consent to take part in the survey.

4.8.2 Working groups, using nominal group techniques

All potential working group participants (who have expressed an interest in taking part) will be sent an invitation letter, participant information sheet and copy of the consent form in advance of the scheduled working group. They can therefore read about the study and understand what their participation involves. Informed consent will then be taken in either of three different ways, depending on the prevailing COVID situation, manner in which the working group is being run, and preferences of the participants. All potential participants will be given the opportunity to discuss the study, and any concerns, beforehand.

i) Written consent taken in person prior to the commencement of the working group.
ii) Electronic consent taken prior to the commencement of the working groups indicated by the return of an electronically completed consent form or photograph/scan of a completed form returned via email or post.
iii) Verbal consent taken via Teams/telephone prior to the commencement of the working group. In this instance the elements of the consent form will be discussed with the participant and documented by the research team on the consent form.

4.9 Data collection

Data collection will be via an online survey (using Qualtrics™) and working groups**,** using a nominal group technique(34).

4.9.1 Online Survey

The online survey will be circulated to stakeholders (palliative care providers and research staff) across North West Coast (using Qualtrics™). The survey will identify current and desired levels of palliative care research involvement, current local research barriers, suggestions for sustainable solutions and research training needs. The survey was developed from the IPOS survey (a survey of the research barriers and training needs within the International Psycho-Oncology Society)(35) and literature on barriers and facilitators to palliative care research (15). Survey development followed an iterative approach, with members of the project steering committee reviewing survey questions to ensure the survey was appropriate.

The survey includes sections covering; basic demographic information (e.g. role, palliative care experience), current and desired level of palliative care research involvement, barriers to participating in palliative care research within North West Coast, activities that would facilitate participation in palliative care research within North West Coast and research training needs. Open-ended questions are also included to allow participants to express needs and preferences that are not covered in the set survey options.

4.9.2 Working groups, using a nominal group technique

Groups (n=4-8 approximately) will be convened for a single meeting (virtual via Teams or in-person depending on prevailing circumstances) of 2 hours. The number of groups will be dependent on whether they take place online or in person. Each working group meeting will have 2-3 facilitators from this partnership team, and involve around 10-15 participants if online or 15-20 participants if in person (total sample n=40-80) from single key stakeholder groups. The nominal group technique meeting starts by welcoming the participants and setting the ground rules that acknowledge that all ideas are important. Participant's questions are answered and their informed consent will be obtained (see section 4.8.2 for further information). The participants will introduce themselves and the 'facilitators' of the meeting will present the overall research question to orientate people to the topic. A brief 10-minute presentation on the current 'state of the science' will orient attendees to existing knowledge. Next, during 5-10 minutes of silence each participant will individually think about the research question and his/her ideas. Afterwards each participant in turn will list their ideas, with no evaluative comments among participants. The ideas will be listed on a board or flip chart (or in the Chat function/secure online documentation if online). Following this, there will be a discussion of the listed ideas to fully understand them and add more ideas as necessary (20-30 minutes). This is done with the intention of paying each idea full attention and not to discard ideas prematurely. The more quantitative part of the process will start by asking participants to rank their top ten ideas. This will be done using a personal priority sheet; each participant selects and ranks the top ten ideas from the list. These are shared in the group and a collective ranking of ideas is achieved. Participants will vote on the top ten ideas. They will be asked to rank with a weighing of ten for most preferred and one for least preferred. This open discussion of voting on the top ten ideas may involve several revisions, re-ranking and voting until reaching an acceptable conclusion. The meeting will end by thanking participants for their contribution and reminding them of the confidentiality requirements. The meeting will take not more than 2 hours. The working group will be recorded using secure digital video conferencing software (Microsoft Teams) if it takes place on line. If the working group takes place in person it will be digitally audio recorded. All participants will be asked to fill in a brief sociodemographic questionnaire in which no name will be included prior to the start of the meeting.

In preparation for the meeting, it will be suggested participants pre-test the microphone and cameras on their electronic devices, and Wi-Fi/Internet connection where they will participate. Instruction guides/brief videos will be circulated regarding the use of the online interactive elements (e.g. chat function, shared secure online documentation method such as teams or one drive) before the meeting to prepare participants. Time will

also be built within the meeting to practice using the online interactive elements. It will be suggested that participants use a tablet/laptop/personal computer, and avoid using mobile phones if possible (36).

In case of connectivity issues

Data collected using online methods described above rely on stable internet connections. Any participants whose participation in working groups is hindered by poor connectivity will be offered options to improve their connectivity, such as turning off their video or participating to the discussion by writing contributions using the chat function/ shared secure online documentation method. Any data contributed via the chat function/shared secure online documentation method will be stored following the procedure for saving audio and video recordings. Those whose connectivity means they cannot contribute to the discussion online will be followed up with afterwards and asked if they would like to participate in a separate session, if feasible.

4.10 Data analysis activities

4.10.1 Online survey

Descriptive analysis of basic demographic information (e.g. role, palliative care experience), current and desired level of palliative care research involvement, barriers to participating in palliative care research within North West Coast, activities that would facilitate participation in palliative care research within North West Coast and research training needs. Responses to open-ended questions will be analysed using open coding, in which similar responses are grouped together into meaningful categories. Categories will then be grouped into clusters to identify broader themes. Consensus of themes will be achieved through discussion among the research team.

4.10.2 Working groups, using a nominal group technique

Content analysis of the recorded data will be conducted. The recordings/transcript of the recordings will be listened to/read and the key issues will be coded. The units of significance will be coded to describe all aspects of the content. The list of codes will be reviewed and grouped together under similar categories, removing repetitious or very similar headings. The results will be both qualitative content categories and themes, and ranking of priorities for perceived barriers and proposed solutions, and compared across groups. This process will lead to a further understanding of local barriers and facilitators to palliative and end-of-life care research, and what solutions need to be developed and implemented to address these identified barriers.

4.11 Risks and Benefits

4.11.1 Participants

Participants taking part in the online survey or working groups are likely to experience few risks. For the survey, participants are asked to contact the research team if they wish to withdraw their responses, up to 2

weeks following completion. In the working groups, they may potentially feel uncomfortable discussing their experiences and thoughts in the presence of others. This will be mitigated by full information being available to potential participants, with no coercion to participate. The option is available to withdraw from the group or take breaks. Ground rules will be agreed within the groups ahead of discussions beginning (e.g. what happens in the group, stays in the group, issues of respect, no right or wrong answers, the importance of capturing a range of views). We have a robust distress protocol to be followed which is included in this application for ethical review.

There is also the possibility that participants may disclose information about care that reveals risk or poor practice. If they do, this situation will be discussed with the participant and their views on sharing this information with a senior member of staff sought. Where possible their views will be respected, but if a situation is revealed which severely compromises their own or others health or wellbeing, the researcher will inform the participant that the researchers have a duty to disclose this information to the most relevant person.

5.0 Regulatory requirements

5.1 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from NHSREC for the study protocol, and other relevant documents. Substantial amendments that require review by NHSREC will not be implemented until that review is in place and other mechanisms are in place to implement at site. All correspondence with the REC will be retained.

5.2 Regulatory Review & Compliance

Before any site can inform potential participants about the study, the Chief Investigator/Principal Investigator or designee will ensure that appropriate approvals from participating organisations are in place.

5.3 Amendments

If a substantial amendment is required to the REC application or the supporting documents, we will submit a valid notice of amendment to the REC for consideration. Amended documentation or the protocol will be sequentially numbered and dated. The requirements for amendments may be identified by the research team, or participating sites.

5.4 Protocol compliance

Accidental protocol deviations can happen at any time. They will be adequately documented and reported to the Chief Investigator immediately. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

6.0 Data protection and patient confidentiality

All investigators and study site staff will comply with the requirements of GDPR and the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. Further information about how Lancaster University processes personal data for research purposes and addresses data rights is on our webpage: www.lancaster.ac.uk/research/data-protection.

6.1 Confidentiality, data handling and security

6.1.1 Data handling

Data storage and handling will comply with Lancaster University policies, with files stored on university approved secure encrypted cloud storage under password protection. Data at Lancaster University will be stored in study specific files on university approved secure cloud servers, accessible only by authorised members of the research team. Data collected by all members of the research team, including those external to Lancaster, will be saved in study specific files on university approved secure cloud servers. Paper data will be stored in locked filing cabinets within a locked room. The study CI Professor Catherine Walshe has overall responsibility for the collection and management of data generated by this research. External members of the research team involved in data collection and analysis will be provided access to the project specific files stored on university approved secure encrypted cloud storage under password protection. All study investigators will be responsible for completing relevant data and information security training.

Online survey

Qualtrics, a Lancaster University approved online tool for distributing and managing electronic surveys will be used for the practitioner survey. Survey data will be downloaded from Qualtrics for analysis purposes and saved in the research study's specific files on university approved secure cloud servers, accessible only by authorised members of the research team. The survey will be deleted from the Qualtrics main server on publication of findings.

Working groups, using nominal group technique

Working groups will be digitally recorded (video and audio) on Microsoft Teams, with recordings automatically saved to an area of an encrypted secure server accessible only to the member of the research team who initiated the working group meeting. Any data contributed via the chat function/shared secure online documentation method during the recording will be saved in the same way. All recordings will be labelled only with the working group alphanumeric code. Recordings will be moved immediately to the study specific files on university approved secure cloud servers, accessible only by authorised members of

the research team. Combined video and audio recordings (where video and audio are recorded at the same time) will be converted for the purposes of analysis to audio recording only (eg mp4 to mp3) using approved conversion software supported by Lancaster University (e.g. VLC). If the working group takes place in person, the digital recordings will be transferred as soon as possible online to the to the study specific files on university approved secure cloud servers, accessible only by authorised members of the research team. Audio files will be uploaded to the study specific files on university approved secure cloud servers accessible only to authorised member of the research team. Once this has been done, the audio recording of participants' voices on the portable recording device will be deleted. In the meantime, the digital recorder will be handled and stored securely. All participants will be named using alphanumeric codes and if direct quotations from respondents are used, they will only be used in such a way as to ensure individual and organisational anonymity.

6.1.2 Confidentiality and anonymity

The names of files of recordings and survey responses will be alphanumeric codes and participants and identifiable organisations mentioned will be provided pseudonyms; direct quotations from respondents used in publications will only be used in such a way as to ensure anonymity. The key to pseudonymisation will be kept in a separate location in a password-protected study file in university approved secure encrypted cloud storage under password protection. There is a limit to confidentiality when participating in working groups as the nature of participation means that other participants will hear what has been said. However, participants will be told that all discussions taking place in the working group should not be discussed outside that working group. Participants will be told that any contributions made in the working groups will treated confidentially as far as possible, and told about the steps taken to protect their anonymity and how data they provide including quotes may be used in published materials. Participants will also be told before taking part that, while participating in an online video working group using Microsoft Teams is secure, the internet cannot be completely guaranteed as a secure means of communication (participants will subsequently be given the opportunity to withdraw from the study before recording begins).

6.1.3 Data archiving, preservation and destruction

Working group data and survey data will be archived for 10 years following the end of the project. Audio and video recordings will be kept until findings from the research project have been published. Any personal contact data will be destroyed at the end of the study period, once any requirement to contact participants (e.g. to disseminate findings) has passed. At the end of the default retention period (10 years) all working group data and survey data will be confidentially destroyed by a secure method, along with anything relating to the identification of participants.

6.2 Indemnity

The study is indemnified by Lancaster University.

6.3 Data sharing

The full data set will be held by Lancaster University. Anonymised data will be shared with external members of the research team involved in data collection and analysis via study specific files stored on university approved secure cloud servers under password protection. These data will be destroyed after 10 years. All publications will include a data access statement that will clarify which data was used and provide details about the availability of data.

7 Dissemination policy

Dissemination is planned at professional and academic conferences and in peer-reviewed journals, as well as in applications for further funding. Dissemination may also occur in the form of online content, including via websites, blogs, media, and social media. We will also share findings with the organisations who participated or have shown an interest in the study. A results summary written for a lay audience will be made available to research participants and the communities and sites from which they are drawn. Oral presentation of the results to the relevant local professional and health and social care communities will be offered. Any lay participant requesting results of the research will be included in the circulation of the summary.

References

1. Boaz A, Hanney S, Jones T, Soper B. Does the engagement of clinicians and organisations in research improve healthcare performance: a three-stage review. BMJ Open. 2015;5(12):e009415.
2. Bhatnagar P, Wickramasinghe K, Williams J, Rayner M, Townsend N. The epidemiology of cardiovascular disease in the UK 2014. Heart (British Cardiac Society). 2015;101(15):1182-9.
3. Arık A, Dodd E, Streftaris G. Cancer morbidity trends and regional differences in England-A Bayesian analysis. PloS one. 2020;15(5):e0232844.
4. Giebel C, McIntyre JC, Alfirevic A, Corcoran R, Daras K, Downing J, et al. The longitudinal NIHR ARC North West Coast Household Health Survey: exploring health inequalities in disadvantaged communities. BMC public health. 2020;20(1):1257.
5. Department of Health and Social Care. Chief Medical Officer's Annual Report 2021 Health in Coastal Communities. London; 2021.
6. Etkind SN, Bone AE, Gomes B, Lovell N, Evans CJ, Higginson IJ, et al. How many people will need palliative care in 2040? Past trends, future projections and implications for services. BMC Medicine. 2017;15(1):102.
7. Bone AE, Gomes B, Etkind SN, Verne J, Murtagh FE, Evans CJ, et al. What is the impact of population ageing on the future provision of end-of-life care? Population-based projections of place of death. Palliative medicine. 2018;32(2):329-36.
8. Public Health England. Atlas of Variation for Palliative and End-of-Life Care in England 2021 [Available from: http://tools.england.nhs.uk/images/EOLCatlas/atlas.html.
9. Allsop MJ, Ziegler LE, Mulvey MR, Russell S, Taylor R, Bennett MI. Duration and determinants of hospice-based specialist palliative care: A national retrospective cohort study. Palliative medicine. 2018;32(8):1322-33.
10. Mondor L, Wodchis WP, Tanuseputro P. Persistent socioeconomic inequalities in location of death and receipt of palliative care: A population-based cohort study. Palliative Medicine. 2020;34(10):1393-401.
11. LeBlanc TW, Lodato JE, Currow DC, Abernethy AP. Overcoming recruitment challenges in palliative care clinical trials. Journal of Oncology Practice. 2013;9(6):277-82.
12. Kaiser KS, McGuire DB, Keay TJ, Haisfield-Wolfe ME. Methodological challenges in conducting instrumentation research in non-communicative palliative care patients. Applied Nursing Research. 2020;51:151199.
13. Pereira SM, Hernández-Marrero P. Research ethics in palliative care: A hallmark in Palliative Medicine. Palliative medicine. 2019:1-2.
14. Kars MC, van Thiel GJ, van der Graaf R, Moors M, de Graeff A, van Delden JJ. A systematic review of reasons for gatekeeping in palliative care research. Palliative medicine. 2016;30(6):533-48.
15. Dunleavy L, Walshe C, Oriani A, Preston N. Using the 'Social Marketing Mix Framework' to explore recruitment barriers and facilitators in palliative care randomised controlled trials? A narrative synthesis review. Palliative medicine. 2018;32(5):990-1009.
16. Bloomer MJ, Hutchinson AM, Brooks L, Botti M. Dying persons' perspectives on, or experiences of, participating in research: An integrative review. Palliative medicine. 2018;32(4):851-60.
17. White C, Noble S, Watson M, Swan F, Nelson A, Johnson MJ. Optimised clinical study recruitment in palliative care: success strategies and lessons learned. BMJ Supportive & Palliative Care. 2019:bmjspcare-2019-001820.
18. Aoun S, Slatyer S, Deas K, Nekolaichuk C. Family Caregiver Participation in Palliative Care Research: Challenging the Myth. Journal of pain and symptom management. 2017;53(5):851-61.
19. Coyle S, Scott A, Nwosu AC, Latten R, Wilson J, Mayland CR, et al. Collecting biological material from palliative care patients in the last weeks of life: a feasibility study. BMJ open. 2016;6(11):e011763.
20. Higginson IJ. Research challenges in palliative and end of life care. BMJ Supportive & Palliative Care 2016;6:2-4.
21. Vinches M, Neven A, Fenwarth L, Terada M, Rossi G, Kelly S, et al. Clinical research in cancer palliative care: a metaresearch analysis. BMJ Supportive & Palliative Care. 2020.

22. Dunleavy L, Griggs A, Wiley G, Hughes M. Overcoming the hurdles: setting up clinical trials in three UK hospices. International journal of palliative nursing. 2011;17(3):131-4.
23. Moore DC, Payne S, Van den Block L, ten Koppel M, Szczerbińska K, Froggatt K. Research, recruitment and observational data collection in care homes: lessons from the PACE study. BMC research notes. 2019;12(1):1-6.
24. Stone PC, Gwilliam B, Keeley V, Todd C, Kelly LC, Barclay S. Factors affecting recruitment to an observational multicentre palliative care study. BMJ Supportive & Palliative Care. 2013;3(3):318-23.
25. Edwards Z, Bennett MI, Petty D, Blenkinsopp A. Evaluating recruitment methods of patients with advanced cancer: a pragmatic opportunistic comparison. International Journal of Pharmacy Practice. 2019;27(6):536-44.
26. Bouça-Machado R, Rosário M, Alarcão J, Correia-Guedes L, Abreu D, Ferreira JJ. Clinical trials in palliative care: a systematic review of their methodological characteristics and of the quality of their reporting. BMC Palliative Care. 2017;16(1):10.
27. Visser C, Hadley G, Wee B. Reality of evidence-based practice in palliative care. Cancer biology & medicine. 2015;12(3):193-200.
28. Eule C, Bhulani N, Paulk E, Rhodes R, Beg MS. Characteristics and impact of the most-cited palliative oncology studies from 1995 to 2016. BMC cancer. 2018;18(1):1281.
29. Dunleavy L. Health care professional recruitment of patients and family carers to palliative care randomised controlled trials: A qualitative multiple case study.: Lancaster University; 2021.
30. Payne S, Preston N, Turner M, Rolls L. Research in palliative care: can hospices afford not to be involved. International Observatory on End of Life Care, University of Lancaster. 2013.
31. Preston NJ, Farquhar MC, Walshe CE, Stevinson C, Ewing G, Calman LA, et al. Strategies to increase participant recruitment to research studies by healthcare professionals. Cochrane Database of Systematic Reviews. 2012;2012(9).
32. Evans C, Yorganci E, Lewis P, Koffman J, Stone K, Tunnard I, et al. Processes of consent in research for adults with impaired mental capacity nearing the end of life: systematic review and transparent expert consultation (MORECare_Capacity statement). BMC medicine. 2020;18(1):1-55.
33. Higginson I, Evans C, Grande G, Preston N, Morgan M, McCrone P, et al. Evaluating complex interventions in End of Life Care: the MORECare Statement on good practice generated by a synthesis of transparent expert consultations and systematic reviews. BMC Medicine. 2014;11(111):doi:10.1186/741-7015-11-111.
34. Jünger S, Payne S. The crossover artist: consensus methods in health research. Handbook of Theory and Methods in Applied Health Research: Edward Elgar Publishing; 2020.
35. Lambert SD, Coumoundouros C, Hulbert-Williams NJ, Shaw J, Schaffler J. Building the capacity for psycho-Oncology research: a survey of the research barriers and training needs within the International Psycho-Oncology Society. Journal of Psychosocial Oncology Research and Practice. 2020;2(3):e023.
36. Mason S, Ling J, Mosoiu D, Arantzamendi M, Tserkezoglou AJ, Predoiu O, et al. Undertaking Research Using Online Nominal Group Technique: Lessons from an International Study (RESPACC). Journal of palliative medicine. 2021;24(12):1867-71.