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CovPall: Improving palliative care for people affected by the COVID-19 pandemic by sharing learning – the national and international response

Submission date
05/05/2020

Recruitment status
No longer recruiting

Registration date
27/07/2020

Overall study status
Completed

Last Edited
06/08/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The COVID-19 pandemic is placing an unprecedented strain on health services, with an estimated 1-4% of people dying from this new disease. Some of the symptoms, such as breathlessness, fever, agitation and pain, are very distressing. But in this new disease these symptoms are not well understood. Palliative care services are adapting rapidly to this situation, but in different ways, not knowing what is best.
This research aims to rapidly evaluate the palliative care response in COVID-19 to improve care in the future. There are two main components, called work packages, to the research.

Added 11/05/2021:
In December 2020 the researchers received additional funding following a rapid call for COVID-19 data research initiatives by Health Data Research UK, Office for National Statistics and UK Research and Innovation (UKRI) to 'build on existing UKRI and NIHR work to use national data to answer key COVID-19 research questions' (https://www.hdruk.ac.uk/news/projects-to-accelerate-use-of-data-for-vital-covid-19-research/). This project is an extension of CovPall and is called CovPall-Connect.

Who can participate?
WP1. Voluntary hospices, hospital based palliative care teams, home care/community teams and other services that offer palliative and/or end of life care.
WP2. Services participating in WP1 from the UK, able to collect information on ≥10 patients in their care. We aim to recruit ~20 services across settings (hospital, community, voluntary hospice), and areas with different cultural/ethnic and socioeconomic diversities.

What does the study involve?
There are two main components, called work packages, to the research.
WP1 will survey, UK wide, palliative care clinical leads in different services, about their changes in practice, how they use the workforce and volunteers and what symptom management they

are using. Later, we will collect some more detailed information from a small number of services through interviewing them.
WP2 collects data about patients' symptoms, how they change over time, and the effects of treatments.

Added 11/05/2021:
CovPall-Connect will use national data to boost findings from CovPall. The researchers hope to allow the use of CovPall data for other research. They will assess how the response to COVID-19 affects a number of factors, looking at the following:
- Whether the number of people dying during COVID-19 was reported correctly, or if some deaths were missed
- The number of cases of COVID-19 in the UK population
- The number of people admitted to hospital with COVID-19 and the number of people discharged
- Business, financial and social impacts of COVID-19
- How charities have supported health services and how this information can be captured
- How palliative care information should be collected in the future, focusing on patients with more than one illness

What are the possible benefits and risks of participating?
The research team will draw on their considerable experience in conducting research in this area to ensure a design sensitive to this professional and patient group. We have worked with service teams to discuss the acceptability of the research aims, design and local implementation.
WP1: Qualitative case studies: Interviews will be organised at a time and place to suit the participants, and conducted by researchers with experience of discussing sensitive topics. Written consent will be obtained from all participants in the qualitative case studies, and regular checks made that participants are happy to continue. Arrangements will be made to inform participants of support agencies if required. The main anticipated risk is that of becoming unduly distressed whilst discussing issues associated with the extreme challenges of the COVID-19 pandemic. We will work to minimise this risk by conducting the interviews in a sensitive and responsive manner, drawing on our research and clinical experience in this field. We have a clear distress protocol to be followed during the research should any distress be apparent or detected during data collection.
There is also the possibility that participants may disclose information about care which 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 they have a duty to disclose this information to the most relevant person.
WP2: We have designed this data collection to be feasible in the current circumstances by minimising the burden on the direct clinical care team whilst maintaining patient confidentiality. There is no burden
We are collecting individual-level pseudonymised patient data that will be securely transferred to the research team at Kings College London via REDcap. This is done by sending via secure email (e.g. NHS mail) each participating service a unique set of 11 randomly generated codes. They use one code per patient about which they enter information. They keep a local record of the details of which patient has been assigned to which code, but this information is not transferred to the research team. The REDcap database does not include any identifying features, including the name of the service, its region, nor any patient identifiable details.). Obtaining patient consent in the current situation is not feasible therefore we have minimised the dataset to remove any confidential patient information e.g. changed date of birth to age, postcode to LSOA.

These will still be individual-level data, albeit pseudonymised, so we will ensure that these data are transferred securely between research sites and Kings College London. Once on the Kings College London server they will be held securely on password-protected encrypted files. Current infection control policies restrict our ability to display posters at the study sites, but transparency statements will be made available on the Kings College website and all participating study sites so that patients are informed of this study.

Where is the study run from?
1. Cicely Saunders Institute, King's College London (UK) in collaboration with:
2. Wolfson Palliative Care Research Centre at the University of Hull (UK)
3. Martin House Research Centre at the University of York (UK)
4. International Observatory on End of Life Care at Lancaster University (UK)

When is the study starting and how long is it expected to run for?
April 2020 to November 2021

Who is funding the study?
1. Jointly funded by UK Research and Innovation (Medical Research Council) and NIHR (COV0011; MR/V012908/1) (UK)
2. Cicely Saunders International (UK)
3. HDRUK (UK) (HDRUK2020.145)

Who is the main contact?
Mev Hocaoglu or Rachel Cripps (palliativecare@kcl.ac.uk)

Contact information

Type(s)
Public

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Type(s)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
282824

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
LRS-19/20-18541, IRAS 282824

Study information

Scientific Title
Rapid evaluation of the COVID-19 pandemic response in PALLiative and end of life care: national delivery, workforce and symptom management (CovPall)

CovPall-Connect: Evaluation of the COVID-19 pandemic response in palliative and end of life care: connecting to boost impact and data assets

Acronym
CovPall; CovPall-Connect

Study objectives
The aim of this study is to evaluate the UK palliative care and end-of-life care response to COVID-19 in terms of services, workforce and symptom management to provide rapid clinical and policy guidance to optimise the response of palliative care clinicians and services to the COVID-19 pandemic.

Added 11/05/2021:
CovPall-Connect: The aim of the study is to understand the relationship between regional COVID-19 palliative care responses and COVID-19 prevalence, mortality, admissions, discharges, business/social impacts through data linkage with national datasets.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 21/04/2020, King’s College London Research Ethics committee (Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London, SE1 9NH, UK; +44 (0)20 7848 4020; rec@kcl.ac.uk), ref: LRS-19/20-18541

2. Approved 15/05/2020, Health Research Authority (HRA) and NHS Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8010; approvals@hra.nhs.uk), ref: 20/NW/0258

Study design
Observational online survey and qualitative case studies followed by cohort study

Added 11/05/2021: CovPall-Connect: Data linkage

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection), palliative and end of life care

Interventions
WP1: Online survey of palliative care providers, with in-depth qualitative case study of sampled providers. Data will be collected using REDCap.

WP2: Cohort study of people with COVID-19 receiving palliative care input, with data collected at four timepoints, at first assessment (baseline, T0), 24-hour follow-up, ideally twice, but this will depend on survival (T1, T2), and then at death or discharge (D or Di).

WP1 and WP2 are run quickly, (phase I) and analysed. Then both WP1 and WP2 are repeated 6-8 weeks later (phase II), when case studies are added, to gauge key changes.

Intervention Type
Other

Primary outcome(s)
WP1. Innovations in services, workforce and volunteer deployment, and their impacts on care and bereavement services; identification of good practice, and sharing of approaches and knowledge. Change in practice, most effective treatments collected at baseline and 6-8 weeks later
WP2. Symptom and problem assessment measured using IPOS score at first assessment (baseline, T0), 24-hour follow-up, ideally twice, but this will depend on survival (T1, T2), and then at death or discharge (D or Di)

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/11/2021

Eligibility

Key inclusion criteria

WP1: Clinical leads of palliative and hospice care services including: palliative care teams in acute hospitals, in-patient hospices/palliative care wards and palliative care community services providing care in peoples own homes and supporting care homes, usually for adults and children.
WP2: Consecutive patients supported by the participating palliative care services in WP1 (including remote consultation), with clinically diagnosed and/or test confirmed COVID-19 diagnosis. This will include patients with and without pre-existing progressive conditions.

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
1030

Key exclusion criteria
WP1: No lead or delegate available
WP2: Patients who are <18 years old

Date of first enrolment
24/04/2020

Date of final enrolment
21/02/2021

Locations

Countries of recruitment
United Kingdom

England

Argentina

Australia

Brazil

Canada

India

Ireland

Netherlands

Portugal

South Africa

Switzerland

Study participating centre
Cicely Saunders Institute at King’s College London
Bessemer Road
London
United Kingdom
SE5 9PJ

Study participating centre
Wolfson Palliative Care Research Centre at University of Hull
Allam Medical Building, University of Hull
Hull
United Kingdom
HU6 7RX

Study participating centre
Martin House Research Centre at University of York
Area 2 Seebohm Rowntree Building
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United Kingdom
YO10 5DD

Study participating centre
International Observatory on End of Life Care at Lancaster University
Furness College, Hazelrigg Lane
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LA1 4YG

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Organisation
King's College Hospital NHS Foundation Trust

ROR
https://ror.org/01n0k5m85

Funder(s)

Funder type
Government

Funder Name
NIHR ARC South London

Funder Name
Cicely Saunders International

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Health Data Research UK (HDRUK)

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 Prof. Irene Higginson (palliativecare@kcl.ac.uk).
Type of data: CovPall: WS1. A cross-sectional online survey of palliative care services & hospices.
When data will become available and for how long: The researchers welcome data access requests for WP1. Applications for use of the survey data can be made for up to 10 years.
What access criteria data will be shared including with whom, for what types of analyses, and by what mechanism: Data access requests will be considered on a case by case basis on receipt of a methodological sound proposal to achieve aims in line with the original protocol. The study protocol is available on request. All requests for data access should be addressed to the Chief Investigator (Prof. Irene J Higginson; palliativecare@kcl.ac.uk) and will be reviewed by the Study Steering Group.
Whether consent from participants was obtained: Completion of the survey implied consent.
Comments on data anonymisation: An important component is the sharing of data among the collaborators for the benefit of patients and families, for education, research and improving care. Ethical and other agreements with participants included an explicit clause to share anonymised data that was collected as part of CovPall.
Any ethical or legal restrictions: Data access requests will be considered on a case by case basis.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	survey results on challenges	05/02/2021	19/03/2021	Yes	No
Results article		08/02/2022	06/08/2024	Yes	No
Results article		23/03/2021	06/08/2024	Yes	No
Results article	Charitably funded hospices and the challenges associated with the COVID-19 pandemic: a mixed-methods study (CovPall)	10/10/2022	06/08/2024	Yes	No
Results article	Prohibit, Protect, or Adapt? The Changing Role of Volunteers in Palliative and Hospice Care Services During the COVID-19 Pandemic. A Multinational Survey (Covpall)	01/10/2022	06/08/2024	Yes	No
Results article	Symptom management in people dying with COVID-19: multinational observational study	08/09/2022	06/08/2024	Yes	No
Funder report results		01/04/2021	24/11/2021	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint	non-peer-reviewed survey results on service innovation and practice change in preprint	03/11	19/03	No	No

results		/2020	/2021		
Protocol file	version 4.0	28/10 /2020	19/10 /2022	No	No
Study website	CovPall		24/11 /2021	No	No
Study website	CovPall-connect		24/11 /2021	No	No
Study website	Study website	11/11 /2025	11/11 /2025	No	Yes