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Understanding data and information needs for palliative cancer care to target a mobile phone-based intervention development in Nigeria, Uganda and Zimbabwe

Submission date
23/01/2019

Recruitment status
No longer recruiting

Registration date
18/02/2019

Overall study status
Completed

Last Edited
23/06/2022

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims

A major challenge to developing palliative cancer care across the African region is the lack of local evidence to ensure practice is evidence-based and replicable and reflects the needs of the population served. It is essential to create channels for gathering patient-level data to inform how feasible, acceptable and sustainable limited services are for patients with cancer. Furthermore, understanding how emerging services are supporting patients with advanced cancer through assessing experiences and outcomes is a priority for palliative care development in the region. This can be achieved through use of validated, context-specific tools for measuring outcomes for palliative care patients and their caregivers in sub-Saharan Africa; tools that the wider research team have over 10 years' success in developing. We now need to explore acceptable, secure and feasible ways to increase their use across palliative care services in the region. This project will focus on supporting technology-based approaches to capturing patient-level data, enabling development and adaptation of palliative care services to ensure they can identify and understand the specific needs of patients with cancer. Such service delivery strengthening is a crucial component of wider efforts to integrate palliative care into national health systems in the region. Previous work by the research team has highlighted the potential of digital health (i.e. the practice of medicine and public health supported by digital technologies , such as mobile devices) to facilitate the collection, sharing and use of patient-level data. We know that mobile phones are frequently used in multiple ways as part of palliative care service provision in the African region and that development of approaches that capitalise on mobile phones is a high priority for providers. In sub-Saharan Africa, more widely, mobile phone services are available to a larger portion of the population than many basic services (such as sanitation and financial services). Approaches using digital health can benefit from the widespread access and low cost to mobile phone devices in the region and have led to improved chronic disease management; patient behaviour change and health systems strengthening; reduced costs of patient monitoring; improved adherence; and better communication. These benefits are greatest in rural areas. Consequently, digital health is viewed as one of the most promising investments for health in developing countries. To date, digital health approaches developed in

palliative care in sub-Saharan Africa have not been guided by or evaluated by research. This project will enable initial engagement with key stakeholders across the health system to define the optimal mechanisms through which patient-level data, captured via digital health approaches, can be integrated into palliative cancer care delivery and improvement. The key aim of the project is to engage with key stakeholders across the health system in Nigeria, Uganda and Zimbabwe to define optimal mechanisms through which patient-level data, captured via digital health approaches, can be used in the development of palliative cancer care in sub-Saharan Africa. We will do this by establishing a consortium of academic researchers (from Nigeria, Uganda, the UK and Zimbabwe) including our research team, non-governmental organisations, palliative care providers, policymakers and digital health development and implementation experts, to catalyse digital health research and generate evidence that can guide palliative cancer care development across sub-Saharan Africa. We will also seek to i) understand the acceptability and optimal implementation of patient-level data collection (e.g. patient-reported outcome measures and patient-reported experience measures) using digita health approaches in Nigeria, Uganda and Zimbabwe through interviews with patients with cancer and caregivers for people with cancer; ii) determine information needs and pathways for leveraging evidence generated from digital health approaches in service development in Nigeria, Uganda and Zimbabwe through health professional and service manager interviews, and; iii) determine information needs and pathways for leveraging evidence generated from digital health approaches in policy-making in Nigeria, Uganda and Zimbabwe through policymaker interviews.

Who can participate?
The study will involve different participant groups. Patients with advanced cancer can participate alongside caregivers of patients with advanced cancer. Health professionals working in palliative care services will also participate. Policymakers working in cancer and non-communicable alongside those with a focus on digital technology will participate. All participants will be over 18 years old.

What does the study involve?
All participants will take part in face-to-face interviews which will last between 30 – 60 minutes.

What are the possible benefits and risks of participating?
It is not considered that there are any risks for the participants by being involved in this study and it is anticipated that no harm will come to participants. For recruitment and consent of patients and caregivers, only clinical staff will access personal information about the potential for their participation as part of routine clinical work prior to discussions about involvement with the study. Clinical staff will conduct initial discussions with the potential patient and caregiver participants. Staff will exercise clinical judgement to determine the adequate physical and mental health of a patient prior to recruiting. Clinical staff undertaking recruitment will be familiar with spheres of consent, ranging from a village elder to extended families or head of household, which may be required to invite an individual to participate. Details of the study will be provided using local language, culturally appropriate idioms, and analogies that prospective participants can understand. For active monitoring of risks and harms to participants, research assistants with previous experience of palliative care research will be involved. Research assistants will work with the primary investigator and academic leads in each country to identify areas of sensitivity in topic guides for patient and caregiver interviews and ensuring secure handling and storage of study documentation and data. A distress protocol has been developed with clinical leads in all three countries for use by research assistants should patients or caregivers become upset during an interview.

Where is the study run from?
The study is led by the University of Leeds in the UK. Participating sites include partners in the UK (Kings College London), Nigeria (University of Lagos, Lagos University Teaching Hospital, Sebeccly Cancer Care and Support Centre), Uganda (African Palliative Care Association, Makerere University, Uganda Cancer Institute, Palliative Care Education and Research Consortium) and Zimbabwe (Island Hospice and Healthcare, University of Zimbabwe).

When is the study starting and how long is it expected to run for?
The study started on the 1st December and is a 12-month study, due to complete on 30th November 2019.

Who is funding the study?
The study is funded by the UK Medical Research Council and Research England QR GCRF.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MRC01 / QRGCRF01

Study information

Scientific Title
Understanding data and information needs for palliative cancer care to target mobile phone-based intervention development in Nigeria, Uganda and Zimbabwe: an observational cross-sectional study

Study objectives

The overall aim of the study is to identify the optimal mechanisms through which patient-level data, captured through digital health approaches, can be used in the development of palliative cancer care in sub-Saharan Africa.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 09/01/2019, Faculty of Medicine and Health Research Ethics Committee, University of Leeds, ref. MREC 18- 032.
2. Approved 28/12/2018, Health Research Ethics Committee, College of Medicine, University of Lagos, ref. HREC/15/04/ 2015.
3. Approved 15/01/2019, Uganda Cancer Institute, Uganda, ref. UCIREC REF: 19-2018.
4. Approved 14/03/2019, Uganda National Council for Science and Technology, ref: HS325ES.
5. Approved 02/04/2019, Research Council of Zimbabwe, ref: 03507.
6. Approved 03/04/2019, Medical Research Council of Zimbabwe, ref: MRCZ/A/2421.

Primary study design
Observational

Study design
Qualitative research design, including qualitative cross-sectional interviews

Study type(s)
Other

Health condition(s) or problem(s) studied
Advanced cancer

Interventions
Patient and caregiver participants will be identified through multiple community-based and hospital-based palliative care services across the three participating countries (Nigeria, Uganda and Zimbabwe). Clinicians working within facilities will oversee the identification and recruitment of patients and caregivers. The sampling of caregivers will include both those where the patient who they care for has also participated in the study, and caregivers where the patient they care for has not been a study participant. When a clinical member of staff identifies an eligible participant, they will discuss the research study and what it would involve of patients and caregivers (i.e. participating in a face-to-face interview). Should the participant express willingness to take part in the study, the clinical staff member will leave an information sheet and consent form for them to review for a minimum of 24 hours. Versions in English and local languages will be available. After this time, if a patient or caregiver agrees to participate, their name and contact details will be shared with the research assistant who will contact them to arrange a convenient time for an interview. The location of the interview will be decided by the patient or caregiver, meeting either at their home, following a clinic appointment at a health facility, on the ward, or at a neutral location, dependent on patient and caregiver preference and the clinical management of a patient at the time of the interview. We plan to conduct interviews with the patient or caregiver participants on their own. For health professionals, the opportunity to participate in interviews will be communicated via the leads for clinical partner organisations. Leads will circulate information sheets about the study with details of what participation will involve and a consent statement. If consent is obtained, interviews will be conducted in a quiet room, where available, in the usual clinical location of the health professional, unless alternative

locations are requested. Potential policymaker participants will be approached by the Research Manager at the African Palliative Care Association by phone or in person. The study and what participation entails will be discussed prior to providing an information sheet and consent form for review. Should a policymaker consent to participate, a research assistant will make contact to arrange a convenient time and location to conduct the interview.

All interviews are planned to last between 30 – 60 minutes. Participation in an interview will be a one-off activity, with no follow-on participation anticipated. All interviews will be audio recorded for transcription and analysis. All participants will be asked if they would like to provide their contact details to receive a summary of the key findings of the study once it is completed.

Intervention Type
Other

Primary outcome(s)
Change mechanisms for digital technology intervention development in palliative cancer care derived from analysis of interview data.

Key secondary outcome(s)
1. Patient and caregiver acceptability and preferences for implementation of patient-level data collection using digital health approaches in Nigeria, Uganda and Zimbabwe.
2. Health professional information needs and pathways for leveraging evidence generated from digital health approaches in palliative care service development in Nigeria, Uganda and Zimbabwe.
3. Policymaker information needs and pathways for leveraging evidence generated from digital health approaches in cancer and digital health policy-making in Nigeria, Uganda and Zimbabwe.

Completion date
30/09/2020

Eligibility

Key inclusion criteria
Patients:
1. Adults with advanced cancer defined as:
1.1. Metastatic cancer
1.1.1. Determined, if possible, through histological, cytological or radiological evidence
1.2. Those receiving anti-cancer therapy with palliative intent
2. Receiving palliative care

Caregivers:
1. Caregivers of patients with advanced cancer

Health professionals:
1. Palliative care doctors, clinical officers and nurses
2. Involvement in palliative care delivery
2.1. Direct patient care
2.2. Service management

Policymakers:
1. Policymakers in Nigeria, Uganda and Zimbabwe

2. Involved in palliative care policy or frameworks for palliative care at the national level and 5 at district levels in each country

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. <18 years old
2. Patients deemed too unwell to participate in the study by clinical staff

Date of first enrolment
01/02/2019

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
United Kingdom

England

Nigeria

Uganda

Zimbabwe

Study participating centre
University of Leeds
Woodhouse Lane
Leeds
United Kingdom
LS2 9JT

Study participating centre

Kings College London
The Strand
London
United Kingdom
WC2R 2LS

Study participating centre
African Palliative Care Association
PO Box 72518, Plot 95, Dr Gibbons Road, Makindye
Kampala
Uganda
PO Box 72518

Study participating centre
Makerere University
PO Box 7062
Kampala
Uganda
PO Box 7062

Study participating centre
Island Hospice and Healthcare
6 Natal Road, Belgravia
Harare
Zimbabwe
Harare

Study participating centre
University of Zimbabwe
15 Phillips Avenue, Belgravia
Harare
Zimbabwe
Harare

Study participating centre
University of Lagos Teaching Hospital
Ishaga Rd, Idi-Araba
Lagos
Nigeria
Lagos

Study participating centre
Uganda Cancer Institute
Plot 6, Lourdel Road, Nakasero, PO Box 7272
Kampala
Uganda
Kampala

Study participating centre
Sebeccly Cancer Care
29 Commercial Ave, Sabo yaba 100001
Lagos
Nigeria
Lagos

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Research England

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available upon request from Dr Matthew Allsop (email: m.j.allsop@leeds.ac.uk). The data will consist of deidentified qualitative transcripts from face-to-face interviews. Requests for access to data will be reviewed by the study team. On request for access to data, an outline of a transparent and accountable access process will be provided.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Role of informal caregivers	23/12/2020	15/03/2021	Yes	No
Results article	Stakeholder perspectives and requirements	01/12/2021	15/03/2021	Yes	No
Results article	Health professional perspectives	01/03/2022	23/06/2022	Yes	No
Protocol article	protocol	31/10/2019	15/01/2021	Yes	No