ISRCTN98225483 https://doi.org/10.1186/ISRCTN98225483

Is it possible to run a trial of early palliative care to improve person-centred outcomes of prostate and cervical cancer patients in Zimbabwe?

Submission date
02/11/2024

Recruitment status
No longer recruiting

Registration date
19/12/2024

Overall study status
Ongoing

Last Edited
15/10/2025

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
People living with prostate and cervical cancer experience pain, shortness of breath and other physical problems and concerns and may require support with physical, psychosocial or spiritual care. This study is designed to understand the care of patients and families living with cervical or prostate cancer to see if additional care (focussing on physical e.g. pain, psychological e.g. worry, social e.g. costs and spiritual e.g. your religious beliefs) will improve patient and caregiver experience of living with cervical or prostate cancer.

Who can participate?
1. Adult (at least 18 years old) patients with a confirmed diagnosis of cervical or prostate cancer attending care at Parirenyatwa or Mpilo hospitals in Zimbabwe
2. Adult family caregivers (at least 18 years old) of patients living with cervical or prostate cancer
3. Cervical or prostate cancer patients who are receiving any form of cancer treatment either chemotherapy, radiotherapy, surgery, immunotherapy
4. Patients who are able to communicate in English, Shona or Ndebele and able to give informed consent

What does the study involve?
The following will happen if patients and caregivers decide to part:
1. They will be asked to meet a study researcher to describe their health-related needs and concerns, and the services that they use
2. The researcher will extract the patient's health records held at the health facility where the patient receives medical care. The records to be extracted include the date of diagnosis, other illnesses, clinical stage of the illness, current treatment, hospitalisation history, etc.
3. The researcher will read aloud questions to study participants, and participants will provide responses/answers, the researcher will then record the responses/answers. This interview will be conducted at the health care facility or patient's home initially as they enrol in the study and every month for 12 months. Follow-up interviews may be conducted by phone.

4. After all patients and caregivers enrol in the study, the two sites (Parirenyatwa and Mpilo Hospital) will be randomly allocated to intervention and control. Either Parirenyatwa or Mpilo Hospital will become the intervention or control site.
5. Healthcare professionals at the intervention facility will be trained to provide person-centred care (cancer care alongside supportive care). Healthcare professionals at the control facility will not receive any training. They will provide care as usual (cancer care only).
6. Patients and caregivers at the intervention site receive care from healthcare professionals who have received training.
7. Patients and caregivers at the control site will receive care from health professionals with no exposure to training.

What are the possible benefits and risks of participating?
There are no known direct benefits to the participants at the moment, though it may benefit future patients.
The risks expected with participation in this study are related to the questions that the researchers are going to ask participants about cancer illness. Some of the questions might cause distress. If patients or caregivers become upset or distressed, the researchers will offer a chance for them to take some time out of the interview and then either carry on or stop the interview completely. In addition, the services of a counsellor will be made available to all participants at no cost should they need these services.

Where is the study run from?
Parirenyatwa Hospital in Harare and Mpilo Hospital in Bulawayo (Zimbabwe)

When is the study starting and how long is it expected to run for?
We are starting recruitment on 15th October 2025, and we expect to finalise recruitment on 31st October 2026.

Who is funding the study?
The National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
UK: Prof. Richard Harding, richard.harding@kcl.ac.uk
Zimbabwe: Dr Dickson Chifamba

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Prof Richard Harding

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Type(s)
Public, Scientific

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ORCID ID
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Additional identifiers

National Institute for Health and Care Research (NIHR)
134440

Protocol serial number
GHRUG

Study information

Scientific Title
Integrated Palliative Oncology Care Intervention (IPOC): a hybrid parallel cluster feasibility trial

Acronym
IPOC

Study objectives
Aim:
To determine the feasibility of evaluating an integrated cancer/oncology palliative care using a randomized controlled trial (RCT) design.

Objectives:
1. Determine trial recruitment rates to an RCT for prostate and cervical cancer patients and family members
2. Measure completion of potential patient and family outcome and staff cost data, intervention

implementation
3. Determine staff, patient and family views of the intervention and its processes
4. Confirm primary outcome measure and potential effect size, identify contamination, and develop full trial protocol if full trial is warranted
5. Develop methodological guidance for palliative care trials in Low- and Middle-Income Countries (LMICs) and intervention manual adaptation to partner countries

Research questions:
1. What is a feasible and acceptable model of integrated palliative care to improve self-reported outcomes for cancer patients and their families, and can it be implemented?
2. Is an RCT feasible in terms of delivery of the intervention and recruitment/retention to the trial?
3. What are stakeholder views of the intervention and evaluation processes?
4. Is a full trial warranted and what is the optimum trial design?

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 17/10/2024, King's College London Research Ethics Committee (Research Ethics Office, 5-11 Lavington St, London, SE1 0NZ, United Kingdom; +44 (0)207 848 5554; rec@kcl.ac.uk), ref: HR/DP-23/24-45379

2. Approved 08/11/2024, Medical Research Council of Zimbabwe (20 Cambridge Road, Avondale, Harare, -, Zimbabwe; +263 (0)8644073772; mrcz@mrcz.org.zw), ref: MRCZ/A/3029

3. Approved 20/03/2024, Joint Research Ethics Committee (The University of Zimbabwe, Faculty of Medicine and Health Sciences (FMHS) & Parirenyatwa Group of Hospitals (PGH) JREC Office No.4, 5h Floor, Faculty of Medicine and Health Sciences Building, Harare, -, Zimbabwe; +263 242 708140/791631Extns 2241/2242 ; jrec.office@gmail.com), ref: JREC 180/23

Primary study design
Interventional

Study design
Hybrid parallel cluster feasibility randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Prostate and cervical cancer

Interventions
Current interventions as of 15/10/2025:

The IPOC intervention consists of three parts:

1. IPOC training:
The training component of the IPOC intervention will consist of the following:
1. Training of healthcare professionals/oncologists and palliative care on:

2. The principles of Palliative care
3. The principles of Oncology care
4. Palliative care and oncology integration
5. Person-centered care
6. Pain and symptom assessment and management
7. Psychosocial care and decision-making support
8. Spiritual care and support
9. Person-centred communication, including handling difficult communication and prognosis, breaking bad news
10. Documentation
11. Goal setting
12. Developing action plans
13. End-of-life care discussions and bereavement support
14. Joint clinical appointments/ward rounds
15. Referral mechanism and signposting
16. For patients and caregivers
17. Goal setting and developing action plans
18. Information provision
19. Patient education

2. Process Logic Model
The current processes of care delivery within the healthcare facilities will be taken into consideration, to ensure the IPOC intervention fits with the current structure and can be adapted easily to the current structure. The researchers conducted a theory of change workshop and developed a process logic model to guide all stakeholders involved in the delivery of the intervention. The logic model clarifies the care pathway for prostate and cervical cancer patients and their families as they access the IPOC intervention, and the other preliminary activities needed for the scaling of the intervention into healthcare facilities.

3. Mentorship and support
The other component of the IPOC intervention is mentorship and support. This will consist of weekly sessions between trained healthcare professionals and mentees from Island Hospices and the University of Zimbabwe. The mentor and mentee will develop mentorship goals, plans and strategies to implement the goals, including identification of resources.

The researchers will recruit 39 cervical cancer and 39 prostate cancer patients at Parirenyatwa Hospital in Harare-Zimbabwe. They will also recruit 39 cervical cancer and 39 prostate cancer patients at Mpilo in Bulawayo-Zimbabwe. Patients will be recruited with their family caregivers. They aim to recruit these patients within one month. The patients will be invited to complete self-reported measures which capture their demographic and clinical characteristics, symptoms and concerns, and their experiences receiving care at the two facilities.
Using a computer, the researchers will allocate one of the two sites to receive the intervention, which is palliative care and cancer care provided together. The site that has been chosen to receive the intervention will deliver new methods of care to cancer patients and their families. All healthcare professionals working at the site will undergo weekly training for 1 month (four sessions in total). Duration of each session is approximately 2 hours.

Training will consist of:
1. Provision of cancer care and palliative care
2. Person-centred care

3. Person-centred communication
4. Pain and symptom management
5. End of life care

Trained healthcare professionals will also be mentored, supported and supervised by experienced palliative care and cancer professionals. Mentorship sessions will be held every two weeks until the study is completed. All patients will continue to receive care from healthcare professionals at both sites. All patients and their families from both study sites will complete self-reported outcomes monthly for 12 months.

Hospitals sites will be randomised. One site will be the intervention site. At the intervention site healthcare professionals will receive the intervention. Patients will therefore receive care from healthcare professionals who have been trained in palliative and oncology care. At the control site, patients will receive care from healthcare professionals with no exposure to the intervention.

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Previous interventions:

The IPOC intervention consists of three parts:

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Using a computer, the researchers will allocate one of the two sites to receive the intervention, which is palliative care and cancer care provided together.
The site that has been chosen to receive the intervention will deliver new methods of care to cancer patients and their families. All healthcare professionals working at the site will undergo weekly training for 1 month consisting of:
1. Provision of cancer care and palliative care
2. Person-centred care
3. Person-centred communication
4. Pain and symptom management
5. End of life care

After the training healthcare professionals will then use the new knowledge and skills to provide palliative and cancer care to patients and their families.

Trained healthcare professionals will also be mentored, supported and supervised by experienced palliative care and cancer professionals.
Mentorship sessions will be held every two weeks for 10 months. All patients will continue to receive care from healthcare professionals at both sites. All patients and their families from both study sites will complete self-reported outcomes monthly for 12 months.

Hospitals sites will be randomised. One site will be the intervention site. At the intervention site healthcare professionals will receive the intervention. Patients will therefore receive care from healthcare professionals who have been trained in palliative and oncology care. At the control site, patients will receive care from healthcare professionals with no exposure to the intervention.

Intervention Type
Behavioural

Primary outcome(s)
1. Trial recruitment at each site:
1.1. Number of eligible prostate and cervical cancer participants who consent to participate in the study within 6 weeks
1.2. Number of eligible family caregivers of prostate and cervical cancer participants who consent to participate in the study within 6 weeks

2. Trial retention at each site:
2.1. Number of prostate and cervical cancer participants who consented to participate and remain in the study each month for 12 months
2.2. Number of family caregivers of prostate and cervical cancer participants who consented to participate and remain in the study each month for 12 months

Key secondary outcome(s)

Current secondary outcome measures as of 15/10/2025:

1. Number of prostate and cervical cancer patients, approached, meet inclusion criteria; have a family member who consents to participate in the study within 4 weeks at each site
2. Number of cervical and prostate cancer patients able to complete each timepoint; die within follow-up period; and place of death
3. Time to complete person-reported outcome measures (researcher read aloud and record response)
4. Intervention exposure, intervention fidelity: number of contacts with the intervention staff
5. Contamination/control group contacts with the intervention (% of intended contacts and activity, control exposure)

Patient self-reported outcomes:
1. Symptoms and concerns measured using the African Palliative Care Association, Integrated Palliative care Outcome Scale (APCA IPOS).
2. Psychological morbidity measured using General Health Questionnaire (GHQ-12)
3. Physical function measured using the Palliative Performance Scale
4. Quality of life measured using the functional assessment of chronic illness therapy-palliative care (FACIT-Pal-14)
5. Patient experience (communication; emotions; short-term outcomes; barriers; and relations with staff) measured using the Patient Experience Questionnaire (PEQ)
6. Empathy that a patient feels they have received during a consultation, measured using Consultation And Rational Empathy (CARE)

Family caregiver self-reported outcomes:
1. Symptoms and concerns measured using the African Palliative Care Association, Integrated Palliative care Outcome Scale (APCA IPOS).
2. Family burden measured using the Zarit Burden Inventory (ZBI-12)

All patient and caregiver self-reported outcomes will be administered at baseline and monthly for 12 months.

For all outcomes, the researchers will collect data at baseline then monthly.

Previous secondary outcome measures:

1. Number of prostate and cervical cancer patients, approached, meet inclusion criteria; have a family member who consents to participate in the study within 6 weeks at each site.
2. Number of cervical and prostate cancer patients able to complete each timepoint; die within follow-up period; and place of death
3. Time to complete person-reported outcome measures (researcher read aloud and record response)
4. Intervention exposure, intervention fidelity: number of contacts with the intervention staff

5. Contamination/control group contacts with the intervention (% of intended contacts and activity, control exposure)

Patient self-reported outcomes:
1. Symptoms and concerns measured using the African Palliative Outcome Scale
2. Psychological morbidity measured using General Health Questionnaire (GHQ-12)
3. Physical function measured using the Palliative Performance Scale
4. Quality of life measured using the functional assessment of chronic illness therapy-palliative care (FACIT-Pal)
5. Patient experience (communication; emotions; short-term outcomes; barriers; and relations with staff) measured using the Patient Experience Questionnaire
6. Empathy that a patient feels they have received during a consultation, measured using Consultation And Rational Empathy
7. Informal and formal service use, chemotherapy and surgery, admissions and length of stay, treatment access, measured using Patient and Carer Cancer Cost (PaCCCt)

Family caregiver self-reported outcomes:
1. Symptoms and concerns measured using the African Palliative Outcome Scale
2. Family burden measured using the Zarit Burden Inventory

All patient and caregiver self-reported outcomes will be administered at baseline and monthly for 12 months.

For all outcomes, the researchers will collect data at baseline then monthly.

Completion date
31/10/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 15/10/2025:

Cancer patients:
1. Adults (aged at least 18 years)
2. Diagnosis of cervical or prostate cancer (histological diagnosis is confirmed for each cancer)
3. Life expectancy of at least 6 months
4. Able to communicate in English, Shona or Ndebele
5. Able to give informed consent

Caregivers:
1. Primary caregiver to be identified by the patient, in line with the definition of caregiver “unpaid, informal providers of one or more physical, social, practical and emotional tasks. In terms of their relationship to the patient, they may be a friend, partner, ex-partner, sibling, parent, child or other blood or non-blood relative"
2. Adult at least 18 years of age
3. Able to communicate in English, Shona or Ndebele
4. Able to give informed consent

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Previous inclusion criteria:

Cancer patients:
1. Adults (aged at least 18 years) attending tertiary care at Parirenyatwa or Mpilo hospitals
2. Diagnosis of cervical or prostate cancer (histological diagnosis is confirmed for each cancer)
3. Clinical criteria: Any clinical stage of cancer. Receiving cancer treatment either chemotherapy, radiotherapy, surgery, immunotherapy or any cancer treatment
4. Able to communicate in English, Shona or Ndebele
5. Able to give informed consent

Caregivers:
1. Primary caregiver to be identified by the patient, in line with the definition of caregiver "unpaid, informal providers of one or more physical, social, practical and emotional tasks. In terms of their relationship to the patient, they may be a friend, partner, ex-partner, sibling, parent, child or other blood or non-blood relative"
2. Adult at least 18 years of age
3. Able to communicate in English, Shona or Ndebele
4. Able to give informed consent

Participant type(s)
Patient, Carer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 15/10/2025:

Cancer patients:
1. Housebound and unable to attend tertiary care
2. Patients without a confirmed diagnosis of cancer through histology

Caregivers:
1. Paid caregivers such as nurses, social workers

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Previous exclusion criteria:

Cancer patients:
1. Housebound and unable to attend tertiary care
2. Unable to give informed consent due to loss of capacity

3. Those who cannot communicate in English, Shona, Ndebele
4. Any other type of cancer other than cancer of the cervix or prostate
5. Without a confirmed diagnosis of cancer through histology

Caregivers:
1. Paid caregivers such as nurses, social workers
2. Those below 18 years of age
3. Those not involved in day-to-day care for the cancer patient
4. Those involved in day-to-day care for other cancer type

Date of first enrolment
15/10/2025

Date of final enrolment
31/10/2026

Locations

Countries of recruitment
Zimbabwe

Study participating centre
Parirenyatwa Hospital
Mazowe Street
Harare
Zimbabwe
PO Box CY 198

Study participating centre
Mpilo Hospital
Mpilo Central Hospital
Bulawayo
Bulawayo
Zimbabwe
PO Box 2096

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The researchers do not have ethics approval for data to be made available. They will store their data securely on King's SharePoint and King's OneDrive, their institutional platforms.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes