ISRCTN77379187 https://doi.org/10.1186/ISRCTN77379187

Nurse-led palliative care intervention for heart failure patients in Uganda

Submission date
13/06/2025

Recruitment status
Recruiting

Registration date
27/06/2025

Overall study status
Ongoing

Last Edited
16/06/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Patients with heart failure have significant symptom burden, care needs, and often a progressive course to end-stage disease. During the course of heart failure, patients typically experience a high burden of physical and psychological symptoms, they become highly dependent, and have a poor quality of life. They also experience pain which remains under-recognized and undertreated. Palliative care approach helps to improve quality of life and alleviates suffering for those living with serious illness, regardless of prognosis.
Studies conducted in high-income countries have shown that palliative care interventions improve quality of life, reduce symptom burden, and health service costs. The benefits of palliative care interventions in Africa have been demonstrated only in HIV/AIDS and multidrug-resistant tuberculosis, no study has been conducted in the heart failure population in Africa. This study aims to assess the effects of a nurse-led palliative care intervention for adult heart failure patients in Uganda.

Who can participate?
1. Adults (aged at least 18 years) of age receiving care with diagnosed heart failure
2. Advanced heart failure at Stages III or IV as confirmed by the doctor
3. Able to communicate in English, Luganda or Swahili (common languages spoken in Uganda)
4. Able to give informed consent after a careful clinical examination by the doctor
5. Willing to be randomised to the intervention or control group
6. Live within a 30 km radius of Kampala (through self-report)

What does the study involve?
Patients who decide to take part will meet a study researcher and will be asked to describe their health-related needs and concerns, and the services which they use. The researcher will then extract clinical records: diagnosis, date of diagnosis, other illnesses, clinical stage of your illness, current medication, hospitalisation history, etc. The researcher will record patients' answers about their health-related needs and clinical records. Patients will then be assigned at random to the control group or intervention group. The allocation will be done by a computer. Patients have a 50% chance of being allocated to either of the two groups. Those who have been allocated to the control group will receive care as usual from doctors, nurses, and all other healthcare professionals at Uganda Heart Institute. Those allocated to the intervention group

will receive care as usual from doctors, nurses, and all other healthcare professionals at Uganda Heart Institute. They will also be referred to Hospice Africa Uganda to receive additional care from nurses working at that facility. Nurses will conduct a comprehensive assessment to identify problems and concerns and provide physical, psychological, social and spiritual care. Patients will meet the nurses every month. Nurses will also call patients every 2 weeks after each clinic appointment to check how they are doing and answer any questions they may have or discuss any issues which require attention.

What are the possible benefits and risks of participating?
There are no direct benefits to study participants, though it may benefit future patients.
The questions which the researcher will ask may upset participants. If participants become upset or distressed, we will offer them a chance 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 participants at no cost should they need these services.
This study will provide novel evidence on nurse-led palliative care intervention for heart failure patients in the African context. This work will generate evidence on the mechanism of action and context of how palliative care interventions work. Findings from this trial will inform the management of problems and concerns experienced by heart failure patients.

Where is the study run from?
Uganda Heart Institute

When is the study starting and how long is it expected to run for?
May 2024 to July 2026

Who is funding the study?
King's College London (UK)

Who is the main Contact?
UK: Dr Kennedy Nkhoma, kennedy.nkhoma@kcl.ac.uk
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Contact information

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Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A randomised controlled trial to evaluate the effectiveness of a nurse-led outpatient palliative care intervention for people with heart failure in Uganda in terms of patient-reported outcomes

Acronym
ULTRASONIC

Study objectives
Aim:
To evaluate the effectiveness of a nurse-led palliative care intervention for adult heart failure patients in Uganda on patient-reported outcomes, compared to usual care.

Objectives:
1. To test the effectiveness of the nurse-led palliative care intervention among heart failure patients compared to existing care in an RCT design in terms of patient-reported outcomes.
2. To determine patients' and healthcare professionals' views regarding the processes, mechanisms and outcomes of the intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 18/11/2024, Uganda Heart Institute (Mulago Hospital Complex, PO Box 7051, Kampala, Box 7051, Uganda; +256 (0)417720350; info@uhi.go.ug), ref: UHIREC-2024-18

2. Approved 28/05/2024, King's College London Health Faculties Research Ethics Committee (5-11 Lavingstone Street, London, SE1 0NZ, United Kingdom; +44 (0)207848 4070/4077/3871; rec@kcl.ac.uk), ref: HR/DP-23/24-40916

Study design
Single-site randomized parallel group-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Heart failure

Interventions
Randomisation will be a 1:1 allocation ratio, such that each participant has a 50% chance of receiving the intervention or usual care. We will use block randomisation and vary block sizes of 4, 6, 8, and 10. We therefore anticipate that characteristics will be evenly distributed between groups. However, by chance there may be some differences which randomisation will not manage to achieve because we are not using stratification.
For data analysis we have planned to conduct statistical adjustments for baseline scores to determine if demographic and clinical characteristics will predict any outcomes between the two groups. We will not match and stratify in the analysis.

Control group:
Heart failure patients allocated to the control arm of the trial will receive usual care delivered by the designated cardiac full team at Uganda Heart Institute (UHI). This consists of clinical

assessment and management from the cardiologists (depending on the heart condition, this may include surgery, clinical management, provision of general nursing such as drug administration for pain and infection, health education on nutrition.

Typically, at UHI, the inpatient admission ranges from one to four weeks. Within the first week, preliminary laboratory investigations are conducted to ascertain the clinical stage and determine which ward to allocate the patient. Some patients are subsequently seen at the outpatient clinic and depending on their clinical symptoms, they are treated as outpatients or admitted (mainly stage III and IV are admitted). However, some patients with stages III and IV may decline admission due to costs.

Intervention group:
In addition to usual care, participants randomly allocated to the intervention group will receive care from palliative care nurses. This will consist of clinic appointments/contacts between the patient and a Hospice Africa Uganda (HAU) nurse. Nurses will conduct person-centred assessment, guide patients to set goals of care, provide symptom management based on the problems and concerns and self-management. The components of the intervention are summarised below:
1. Person-centered assessment
2. Action plan, goal setting, ACP (goals of care, symptom management)
3. Symptom control and management
4. Self-management, education, and counselling
5. Individualised care
Study participants allocated to the intervention group will receive an initial face-to-face assessment using an integrated assessment form used at HAU. For each review appointment, the standard care will be provided in addition to the integrated palliative care package based on the Hospice Africa Uganda Model. This model is in line with the African Palliative Care Association's standards for providing palliative care, which focuses on holistic assessment of the patient and management of psychological, spiritual, physical and social problems.
The intervention will consist of four palliative care appointments. Patients will also receive a phone call between each appointment (two weeks after each appointment) to follow up on issues during the appointment or any problems that may have arisen after the appointment and plan for the next appointment. The intervention will be provided at Uganda Heart Institute or Hospice Africa Uganda or patient homes, wherever convenient for the patient.
There is no plan to provide the intervention routinely to control group participants. If found to be beneficial, the impact of the project might be to raise awareness, access and use of hospice services in the target population, but provision of this is not in the remit of this work. We will encourage discussion and recommendations to the clinical sites.

Intervention Type
Other

Primary outcome measure
Palliative care outcome measured using the African Palliative Care Association (APCA) Integrated African Palliative Care Outcome Scale (IAPOS) at baseline (time 0), month 2 (time 1), and month 4 (time 2)

Secondary outcome measures
1. Physical performance status measured using the Australia-modified Karnofsky Performance Scale (AKPS) at baseline (time 0), and month 4 (time 1)
2. Depression measured using the Center for Epidemiologic Studies Depression Scale (CES-D) at

baseline (time 0) and month 4 (time 1)
3. Quality of life measured using the WHO-QoL BREF at baseline (time 0), and month 4 (time 1)
4. Client Service Receipt assessed using the Client Service Receipt Inventory (CSRI) at baseline (time 0), and month 4 (time 1)
5. Number of admissions/readmissions will be recorded at baseline (time 0) and month 4 (time 1)
6. Medication adherence/pill count: at baseline (time 0) the researchers will record the tablets patients take for heart failure and at month 4 (time 1) they will ask about any missed doses for the prescribed heart failure medication

Overall study start date
28/05/2024

Completion date
31/07/2026

Eligibility

Key inclusion criteria
1. Adults (aged at least 18 years) of age receiving tertiary care with a confirmed heart failure diagnosis by a cardiologist.
2. Stage III and IV using the NYHA (based on clinical judgement by cardiologist. Cardiologists will identify patients who meet criteria if staging is not documented in the patient records
3. Able to communicate in English, Luganda or Swahili (common languages spoken in Uganda)
4. Able to give informed consent after a careful assessment by the cardiologists
5. Have the cognitive ability to make a decision by self to participate in the study.
6. Willing to be randomised as stated in the information sheet and consent form
7. Within a 30 km catchment area or radius for follow-up and logistics (through self-report)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
99 Years

Sex
Both

Target number of participants
154

Key exclusion criteria
1. Unable to give informed consent due to cognitive problems
2. Outside 30 km catchment area (through self-report)

Date of first enrolment
01/04/2025

Date of final enrolment
30/10/2025

Locations

Countries of recruitment
Uganda

Study participating centre
Uganda Heart Institute
Mulago Hospital Complex
Kampala
Uganda
PO Box 7051

Sponsor information

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Funder(s)

Funder type
University/education

Funder Name
King's College London

Alternative Name(s)
King's College, King's College London UK, KCL, King's

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We will disseminate findings to study participants, healthcare professionals, and members of the public through local and national conferences. We will prepare policy beliefs, hold dissemination workshops locally.
All co-investigators, research team and clinicians involved in the study will be invited for authorship. They will have to contribute actively, or they will be acknowledged in the acknowledgements section of the publication. We will not use any professional writers because we have experienced writers and researchers within the team who have published widely and have vast experience in writing.
We will not grant full protocol, patient-level data and statistical code to the public. We did not seek ethics approval for this. Our priority journal is Lancet Global Health.

Intention to publish date
01/08/2026

Individual participant data (IPD) sharing plan
Data not available for sharing. The data will be held at the African Palliative Care Association and will be shared electronically with King’s College London through a data sharing agreement policy. The researchers do not have ethics approval for data sharing with third parties.

IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available