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A cluster randomised controlled trial of community-based person-centred enhanced care for people living with HIV/AIDS in Ghana

Submission date
24/09/2024

Recruitment status
Recruiting

Registration date
04/10/2024

Overall study status
Ongoing

Last Edited
27/05/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
This study focuses on people living with HIV/AIDS (PLWHA) who continue to experience distressing symptoms and concerns, so that while taking their HIV medications, they still have physical pain and psychological, social and spiritual concerns that affect their quality of life. These concerns require holistic assessment and management to help improve PLWHA's quality of life. In order to do this, a team of researchers, including healthcare professionals (HCPs), and PLWHA developed and tested a new approach to care assessment and delivery called 'community-based enhanced care intervention' (CECI) in a small study (feasibility trial) in Ghana. In that study, the researchers worked with PLWHA and HCP who work in two different HIV community clinics for which one of these clinics were randomly selected to deliver the CECI intervention and the other clinic delivered standard HIV care.
The HCP in the clinic selected to deliver the CECI were trained to deliver three sessions of the CECI through a holistic assessment of PLWHA's physical, psychological, social and spiritual wellbeing, collaborative care planning with PLWHA contributing to their care decisions and delivery of care based on agreed care plan. The researchers then evaluated the receipt of CECI in a feasibility study, which is done to check whether PLWHA would want to join the study (recruitment) and stay in the study (retention). Some of the PLWHA and HCP were interviewed face to face after receiving and delivering CECI and found that both PLWHA and HCP reported that the study felt safe, comfortable, convenient and useful in discussing their care needs as well as addressing them. The researchers were able to recruit enough PLWHA, and able to keep them in the study until the end (retention), and there was good attendance at the CECI care appointment sessions. There were no issues of PLWHA becoming distressed or more unwell because of taking part in the study. The result from this small study indicated that it is possible to recruit and retain participants in a bigger study of CECI. Also, PLWHA seem to like this new approach to care delivery because it has the potential to improve their quality of life. The researchers therefore aim to conduct a bigger study of CECI (ExtraCECI) to determine how effective and cost-saving this will be in improving the quality of life of PLWHA. The ExtraCECI study builds on the earlier study and asks whether the CECI care approach will improve quality of life and person-centred outcomes for PLWHA compared with those who don't receive it.

Who can participate?
People living with HIV/AIDS (PLWHA) aged 18 years and over

What does the study involve?
Information (data) will be collected about the participants' background and physical, psychological, social and spiritual wellbeing in their respective clinics then the clinics will be randomly allocated either to standard HIV care or ExtraCECI. Random allocation (a bit like tossing a coin heads or tails) means an equal chance for all the participating clinics to receive the ExtraCECI intervention or not. HCPs from the clinics that will be allocated to receive ExtraCECI will be trained on how to deliver ExtraCECI and then they can go on to deliver it to PLWHA in those clinics.
Information will be collected at 1st appointment after randomisation, then 3, 6, 9 and 12 months. PLWHA who are allocated to the ExtraCECI intervention will be compared with those who were not, to see if the ExtraCECI improves their quality of life across their physical, psychological, social and spiritual wellbeing. The researchers will also interview a small group of PLWHA and HCP to find out how they found the study and whether it worked better for some than others and in what circumstances. This will help make decisions about the best ways for ExtraCECI to be included in routine HIV care if it is shown to be successful. The researchers will work with the Ghana AIDS Commission and PLWHA to ensure that person-centred care becomes part of routine HIV care.

What are the possible benefits and risks of participating?
Possible risks of participating include spending time to complete questionnaires; some of the questions may trigger psychological and emotional feelings, or personal harm including disclosure of sensitive information. Participants can ask to take a break or stop the interview at any time when this happens. Possible benefits include the intervention has the potential to improve the quality of life for people living with HIV/AIDS. Study results may also help to know how care for people living with HIV/AIDS can be improved. Participants’ transportation to study sites for study-related activities including data collection would be covered. At the end of the study the researchers will give copies of the final report to participating clinics and participants can have a copy if they want.

Where is the study run from?
Edinburgh Napier University (UK)

When is the study starting and how long is it expected to run for?
May 2024 to April 2028

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Dr Mary Abboah-Offei, m.abboah-offei@napier.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Mary Abboah-Offei

ORCID ID
https://orcid.org/0000-0002-9738-878X

Contact details
School of Health and Social Care
Edinburgh
United Kingdom
EH11 4BN
+44 (0)131 455 2699
m.abboah-offei@napier.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2952376

Study information

Scientific Title
A cluster randomised controlled trial evaluating the effectiveness of a community-based enhanced care intervention compared to standard HIV care to improve the quality of life and person-centred outcomes for people living with HIV/AIDS in Ghana

Acronym
ExtraCECI

Study objectives
Is the extra community-based enhanced care intervention (ExtraCECI) effective and cost-effective in improving quality of life and person-centred outcomes for people living with HIV /AIDS (PLWHA)?

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 11/09/2024, The Ghana Health Service Ethics Review Committee (Research and Development Division, PO Box MB 190, Accra, 00233, Ghana; +233 (0)302 960628; ethics.research@ghs.gov.gh), ref: GHS-ERC 010/07/24

2. approved 21/08/2024, Edinburgh Napier University School of Health and Social Care Research Integrity Committee (School of Health and Social Care, Edinburgh, EH11 4BN, United Kingdom; +44 (0)1314552699; c.hanson@napier.ac.uk), ref: SHSC3681836

Study design
Cluster randomized controlled trial with 1:1 allocation using restricted randomisation and sites grouped into three batches (of 6, 10 and 10), such that sites in batch 1 will begin recruiting first, to be followed in due course by batch 2 sites, and then finally batch 3 sites.

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
HIV/AIDS

Interventions
Current interventions as of 05/02/2025:

The method of randomisation is cluster randomisation with 1:1 allocation.

ExtraCECI, which will be targeted at both cluster and individual participant levels, consists of:
1. A training programme on person-centred communication
2. A holistic assessment of PLWHA's symptoms and concerns in the domains of physical, psychological, social, and spiritual well-being using a structured tool
3. A care plan to capture holistic needs in facilitating collaborative care planning and delivery
4. Empowerment of PLWHA to engage, participate in consultations and contribute to care decisions
5. Working with HCP and Models of Hope to use telehealth to deliver the ExtraCECI
6. Regular support/mentorship for HCP and fidelity monitoring.

Participants allocated to the ExtraCECI arm will attend a scheduled appointment at their respective clinics to be cared for by HCPs who have received training to deliver ExtraCECI. The care will involve a holistic assessment of symptoms and concerns focusing on their physical, psychological, social and spiritual wellbeing. Then HCP together with the participant will plan the possible ways of managing the problems assessed, as well as refer the participant appropriately for further treatment elsewhere. This clinical assessment is part of the ExtraCECI intervention delivery, which will take place at the first intervention appointment and will continue once every three months after the 1st appointment for 12 months. Therefore outcome data will be recorded at first appointment Time 1; then next appointment scheduled at three months at Time 2; sixth month at Time 3; ninth month at Time 4; and final appointment scheduled at twelve month at Time 5.

Standard HIV care:
Clinics randomised to the control arm will continue to deliver SHC as the comparator, which generally consists of PLWHA attending their clinic appointment for either repeat prescription only or for referrals to ART adherence support, nutrition support, CD4 count/viral load testing and for specific problem(s) as described by appointment note. SHC is routinely delivered to PLWHA at their respective clinics, and depending on the stage of illness, this may consist of 6-monthly clinical assessments once ART has been started, with investigations and treatment for any relevant symptoms or problems. Thus, participants in the control arm of the study will continue to receive SHC throughout the study period with similar appointment scheduled as the ExtraCECI intervention arm (first appointment Time 1; then next appointment scheduled at

three months at Time 2; sixth month at Time 3; ninth month at Time 4; and final appointment scheduled at twelve month at Time 5).

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Previous interventions:

The method of randomisation is cluster randomisation with 1:1 allocation.

ExtraCECI, which will be targeted at both cluster and individual participant levels, consists of:
1. A training programme on person-centred communication
2. A holistic assessment of PLWHA's symptoms and concerns in the domains of physical, psychological, social, and spiritual well-being using a structured tool
3. A care plan to capture holistic needs in facilitating collaborative care planning and delivery
4. Sensitisation of PLWHA on how to engage, participate in consultations and contribute to care decisions
5. Regular support/mentorship for HCP and fidelity monitoring.
Participants allocated to the ExtraCECI arm will attend a scheduled appointment at their respective clinics to be cared for by HCPs who have received training to deliver ExtraCECI. The care will involve a holistic assessment of symptoms and concerns focusing on their physical, psychological, social and spiritual wellbeing. Then HCP together with the participant will plan the possible ways of managing the problems assessed, as well as refer the participant appropriately for further treatment elsewhere. This clinical assessment as part of the intervention will continue once every three months over 12 months. Their outcome data will be recorded at Time 1 for month 3, Time 2 for month 6, Time 3 for month 9, and Time 4 for month 12.

Standard HIV care:
Clinics randomised to the control arm will continue to deliver SHC as the comparator, which generally consists of PLWHA attending their clinic appointment for either repeat prescription only or for referrals to ART adherence support, nutrition support, CD4 count/viral load testing and for specific problem(s) as described by appointment note. SHC is routinely delivered to PLWHA at their respective clinics, and depending on the stage of illness, this may consist of 6-monthly clinical assessments once ART has been started, with investigations and treatment for any relevant symptoms or problems. Thus, participants in the control arm of the study will continue to receive SHC throughout the ExtraCECI-cRCT period and will be scheduled to attend the clinic three monthly over 12 months, and their outcome data will be recorded at Time 1 for month 3, Time 2 for month 6, Time 3 for month 9, and Time 4 for month 12.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 05/02/2025:

Quality of life (QoL) measured at the individual level using Medical Outcomes Study–HIV (MOS-HIV) at baseline, 1st appointment after randomisation, then 3, 6, 9 and 12 months.

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Previous primary outcome measure:

Quality of life (QoL) measured at the individual level using Medical Outcomes Study–HIV (MOS-HIV) at baseline, 3, 6, 9 and 12 months

Key secondary outcome(s))
Current secondary outcome measures as of 05/02/2025:

1. Person-centredness and wellbeing of PLWHA measured using the Positive Outcomes HIV PROM at baseline, 1st appointment after randomisation, then 3, 6, 9 and 12 months.
2. Patient-clinician communication, patient involvement in care decisions and patient experience of ExtraCECI/care delivery process, measured using the Picker Patient Experience Questionnaire (PPE-15) at baseline, 1st appointment after randomisation, then 3, 6, 9 and 12 months.
3. The amount of empathy that a patient feels they have received during consultation, measured using the Consultation and Relational Empathy (CARE) Measure at baseline, 1st appointment after randomisation, then 3, 6, 9 and 12 months.

Previous secondary outcome measures:

1. Person-centredness and wellbeing of PLWHA measured using the Positive Outcomes HIV PROM at baseline, 3, 6, 9 and 12 months
2. Patient-clinician communication, patient involvement in care decisions and patient experience of ExtraCECI/care delivery process, measured using the Picker Patient Experience Questionnaire (PPE-15) at baseline, 3, 6, 9 and 12 months
3. The amount of empathy that a patient feels they have received during consultation, measured using the Consultation and Relational Empathy (CARE) Measure at baseline, 3, 6, 9 and 12 months

Completion date
30/04/2028

Eligibility

Key inclusion criteria
Current inclusion criteria as of 05/02/2025:

HIV clinics:
1. Clinics with a minimum travel distance of 3 km apart to minimise treatment ‘contamination’ between the intervention and control arms;
2. The clinic lead must be willing to participate and commit to compliance with ethics requirements
3. At least two HCP per clinic who meet the inclusion criteria must be willing to participate at the time of clinic inclusion.

HCP:
1. HCP who regularly provide hands on care for PLWHA; and
2. HCP providing care for PLWHA in eligible clinics for at least six months.

PLWHA:
1. Adults PLWHA from age 18 years
2. HIV positive diagnosis and in care for at least 6 months, to ensure that PLWHA has the experience of care to reflect on

3. PLWHA who have cognitive ability to consent to participating in the study as guided by the Mental Capacity Act
4. PLWHA who are clinically well to participate (having >200 cells/mm3 CD4 count/ viral load <200 without complications
5. PLWHA attending clinic for ART refill, adherence counselling, psychosocial & spiritual support, including other services targeted at PLWHA who are in care.

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Previous inclusion criteria:

HIV clinics:
1. There must be a minimum distance of 3 km between clinics
2. The clinic lead must be willing to participate and commit to compliance with ethics requirements
3. At least two HCP who meet the inclusion criteria must be willing to participate at the time of clinic inclusion

HCP:
1. HCP including doctors, nurses, pharmacists, counsellors, social workers, and care assistants who regularly provide care to PLWHA;
2. HCP who has been providing care for PLWHA in eligible clinics for at least 6 months

PLWHA:
1. Adults PLWHA from age 18 years
2. A positive diagnosis of HIV/AIDS and in care for at least 6 months, to ensure that PLWHA has the experience of care to reflect on; and
3. PLWHA who have the cognitive ability to consent to participate in the study (the researchers will assume PLWHA have the capacity to consent unless proven otherwise)
4. PLWHA attending the clinic for ART refill, adherence counselling, psychosocial and spiritual support, including other services targeted at PLWHA who are in care

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Current exclusion criteria as of 05/02/2025:

HIV clinics:
1. Clinics that are less than 3 km distance apart with potential for treatment contamination
2. Clinics not willing to participate in the study and or not willing to comply with ethics requirements; and
3. Clinics with less than two HCP who meet the inclusion criteria at the time of clinic inclusion.

HCP:
1. HCP not providing regular hands-on care to PLWHA; and
2. HCP providing care for PLWHA in eligible clinics for less than six months.

PLWHA:
1. PLWHA under age 18 years
2. Diagnosed with HIV and in care for less than 6 months
3. PLWHA not having cognitive ability to consent.
4. PLWHA having <200 cells/mm3 CD4 count or having severe complications/ co-morbidities including cardiovascular diseases, malignancies, pneumonia and requiring specialised treatment at secondary/tertiary health facility).
5. Persons attending clinic for pre-counselling & testing services including prevention of mother-to-child-transmission.

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Previous exclusion criteria:

HIV clinics:
1. Clinics not willing to participate in the study
2. Clinics not willing to commit to comply with ethics requirements
3. Clinics with less than two HCP who meet the inclusion criteria at the time of clinic inclusion

HCP:
HCP who have been working with PLWHA for less than 6 months

PLWHA:
1. PLWHA under age 18 years
2. PLWHA diagnosed less than 6 months
3. PLWHA who do not have the cognitive ability to consent
4. PLWHA who are too ill to participate (having <200 cells/mm3 CD4 count or PLWHA having severe complications/comorbidities including cardiovascular diseases, malignancies, pneumonia and requiring specialised treatment at secondary/tertiary health centres)
5. Patients coming to the clinic for pre-counselling and testing services including prevention of mother-to-child-transmission

Date of first enrolment
07/04/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment

Ghana

Study participating centre
Ghana Health Service clinics in Greater Accra Region, Ghana
Ghana
00233

Sponsor information

Organisation
Edinburgh Napier University

ROR
https://ror.org/03zjvnn91

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Data generated by the project will be made open once appropriate changes have been made to honour assurances of confidentiality and anonymity. Data will be accessible to the research team

including based on the terms that will be agreed in the data-sharing agreement. The Information Commissioner's Office Anonymisation: managing data protection risk code of practice will be adhered to: https://ico.org.uk/media/for-organisations/documents/1061/anonymisation-code.pdf

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/05/2025	27/05/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes