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Feasibility testing of a new community-based enhanced care intervention to improve person-centred outcomes for people living with HIV /AIDS

Submission date
01/03/2019

Recruitment status
No longer recruiting

Registration date
05/03/2019

Overall study status
Completed

Last Edited
04/12/2020

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims

People living with HIV/AIDS can have distressing symptoms and concerns, so that even while taking their HIV medications, they still experience physical pain and psychological, social and spiritual concerns that affect their quality of life. These symptoms and concerns of people living with HIV/AIDS require holistic (looking at the whole issue from different angles) assessment and management to help improve their lives. In order to improve wellbeing, retention in care and quality of life for people living with HIV/AIDS, this research group has developed a new approach to care delivery called enhanced care. They want to test how likely it is that people living with HIV/AIDS will want to participate in order to prepare for running a bigger study in the future. The researchers also want to know how this enhanced care will be different from the usual care that people living with HIV/AIDS receive when they attend the clinic. They want to determine the potential effectiveness of this enhanced care, and also to determine whether the tools they used to assess the outcome of care are good enough to use in a future study when we want to determine the actual effectiveness of this new approach to care. This study aims to recruit a total of 60 people living with HIV/AIDS from 2 clinics (30 people from clinic 1 and another 30 people from clinic 2) in Ghana.

Who can participate?

Adults (both male and female) over the age of 19 who have been living with HIV for at least 6 months, whose doctors do not think that they are too sick or have any confusion in their mind so that they cannot understand things properly and so, cannot participate in this study.

What does the study involve?

The researchers will compare the new enhanced care with the usual care that people normally receive. Participants will be randomly allocated to receive either the new enhanced care or usual care. Participants are asked to join this study while they are at the HIV clinic. Participants must pass the screening questions about their age and how long they have been diagnosed with HIV before participating. Participants who pass the screening questions will be asked to answer

questions about themselves, their home and their general living conditions and wellbeing using tools in the form of questionnaires before the clinic is randomly allocated to either the new enhanced care or usual care. It will take 45 to 60 minutes to complete all the questionnaires. The two clinics are randomly allocated to either provide the new enhanced care or continue to provide usual care. The clinic allocated to provide the new enhanced care will have their healthcare professionals trained on how to assess and manage the physical, psychological, social and spiritual symptoms and concerns of people living with HIV/AIDS before they provide care for the participants in that clinic. The clinic randomised to provide usual care will continue to provide usual care for the participants without any training of their healthcare professionals in that clinic. Participants will be asked to complete the questionnaires before randomisation and 1 month, 2 months and 3 months after the start of the intervention. The study lasts 6 to 7 months in total. Ten participants each from the two clinics are asked to be interviewed to share their experience with the new enhanced care and of their participating in the study. Six to seven healthcare professionals who were trained to deliver the new enhanced care will also be interviewed about the training and delivery of care with this new approach.

What are the possible benefits and risks of participating?
There may be immediate direct benefit or long-term benefits to those taking part as a result of seeing healthcare professionals on a monthly basis before going to see the researcher to complete the outcome assessment tools. Participants' transportation fees will also be reimbursed and when the researchers finish the study, they will give copies of the final report to the clinic and arrange to discuss the results with participants, or participants can have a copy of this report on request. There should also be future benefits in terms of HIV care delivery because the results of the study are likely to improve care outcomes, retention, wellbeing and quality of life for people living with HIV/AIDS. While taking part in this study, participants might be exposed to potential risks such as psychological, emotional or personal harm including disclosure of sensitive information. There is a distress protocol in place to manage any form of distress that they may experience. Participants will also receive 12.50 Ghanaian cedis (equivalent to £2) to pay for transport to the clinic

Where is the study run from?
There are two clinics taking part in this study: The Public Health Unit of the University of Ghana Legon Hospital and the West African AIDS Foundation, both in Accra, Ghana. The study will be managed from Kings College London.

When is the study starting and how long is it expected to run for?
May 2018 to January 2019.

Who is funding the study?
Ghana Education Trust Fund.

Who is the main contact?
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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
N/A

IRAS number

ClinicalTrials.gov number
N/A

Secondary identifying numbers
HR-17/18-7216

Study information

Scientific Title
Phase II mixed methods feasibility cluster randomised controlled trial of a novel community-based enhanced care intervention to improve person-centred outcomes for people living with HIV/AIDS in Ghana

Acronym
N/A

Study objectives
To test the feasibility of a cluster randomised controlled trial of the community-based enhanced care intervention in terms of participant recruitment and retention, intervention delivery, estimate of potential effect, fidelity and to appraise measures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 02/07/2018, King's College London PNM Research Ethics Committee (Research Ethics Office, Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London, SE1 9NH; +44 (0)207 848 4020/4070/4077; rec@kcl.ac.uk), ref: HR-17/18-7216.
2. Approved 18/07/2018, Ghana Health Service Ethics Review Committee (Ghana Health Service Ethics Review Committee, Research & Development Division, Ghana Health Service, P. O. Box MB 290, Accra; 233-302-681109; ghserc@gmail.com), ref: GHS-ERC008/06/18.
3. Approved 04/07/2018, Noguchi Memorial Institute for Medical Research Institutional Review Board (Noguchi Memorial Institute for Medical Research, University of Ghana, P. O. Box LG 581, Legon, Accra; 00233-302-916438; nirb@noguchi.ug.edu.gh), ref: NMIMR-IRB CPN 004/17-18 (amended 2018).

Study design
Cluster-randomised study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See additional files

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

Interventions
This is a feasibility cluster trial. In this study conducted at two clinics in Ghana, one clinic will deliver a novel intervention and the second clinic will provide usual care.

The unit of randomization is the cluster (clinic), thus a cluster of people living with HIV/AIDS in one community clinic will be allocated to either the intervention or usual care using a computer system of randomization by an independent statistician.

The two clinics will be randomised after baseline data collection and before implementation of training on the intervention at the clinic randomised to deliver the intervention.

Intervention
This is a person-centered approach to care delivery where healthcare professionals will assess patients' symptoms and concerns in the domains of physical, psychological, social and spiritual wellbeing using a holistic assessment tool. Healthcare professionals will then involve patients in

collaborative care planning on how to manage their symptoms and concerns. This process will be repeated at monthly intervals for 3 months, and outcome data will be collected at each visit after receiving the intervention.

Intervention components:
This intervention has three components: a) training for healthcare professionals on person-centered care practice and assessment of physical, psychological, social and spiritual concerns using a manual developed for the training; b) use of holistic assessment tool to assess patient symptoms and concerns, and c) 2-weekly support and mentorship meetings for healthcare professionals to discuss the intervention delivery, the use of the holistic assessment tool and other challenges that may arise as the intervention is being delivered. This is to ensure that healthcare professionals deliver the intervention based on the training manual and fully complete the holistic assessment tool.

Intervention training:
This intervention care package will be delivered by healthcare professionals at the clinic that will be randomised to deliver the intervention. The healthcare professionals will receive 3 days of training on person-centred communication and holistic needs assessment in the domains of physical, psychological, social and spiritual wellbeing, followed by 2-weekly mentorship and support. This training is intended to equip healthcare professionals to be able to use the holistic assessment tool to assess patients and collaboratively plan and manage their symptoms and concerns, and be able to refer complex cases for further management.
The training method includes discussion, PowerPoint presentation and a role-play exercise to demonstrate what was taught.
The minimum package of this intervention consists of one visit per month following recruitment, baseline data collection, randomisation and training of healthcare professionals; one further visit in the second month, and then one last visit in the third month.

Usual care:
The clinic randomised to deliver usual care (control arm) will continue to deliver usual care. This means that healthcare professionals in this clinic will not receive any training and will not perform any holistic assessment of patients' symptoms and concerns. Patients attending this clinic will be scheduled to come to the clinic on a monthly basis to see healthcare professionals for their medication refill and any required laboratory investigation that is due. After seeing the healthcare professionals, patients will complete outcome measures at month 1, month 2 and month 3.

Outcome measurement tools:

1. Demographic Health Survey: The participant's demographic record will be administered once only at baseline. This brief record will be used to record age, gender, relationship status, sexual orientation, ART status, year of diagnosis, CD4 count, family support and employment status among other things.
2. The APCA African Palliative Outcome Scale (APCA African POS): The APCA African POS consists of 10 items which measures the physical and psychological symptoms, spiritual, practical and emotional concerns and psychosocial needs of the patient and family with progressive disease using a scoring method appropriate for a range of literacy skills. Each item is scored on a scale of 0–5, and can be scored verbally or using the 'hand' method commonly used in Africa. Using this method, a closed fist represents '0', moving up to an open hand scoring '5'. These methods have been validated among 300 patents under palliative care in Africa. For those with no family carer, family items are scored as '0', i.e. no problem. The APCA African POS has sound psychometric properties and a median time of 7 min to complete.

3. The Medical Outcomes Study-HIV (MOS-HIV): The MOS- HIV was originally developed as a general health questionnaire in the USA. A modified HIV-specific version was developed and widely used. It has been culturally adapted to the Ugandan HIV setting and has been used in Rwandan, Zimbabwean and Ugandan populations. The 35 items address the domains of role function, pain, physical functioning, cognitive functioning, social functioning, general health perception, mental health, health distress and vitality.
4. The Positive Outcomes HIV PROM: Recently developed at the Cicely Saunders Institute (2018), this 23-item tool is a brief patient-centred PROM that reflects the range of outcomes relevant for PLWHA to drive and evaluate care (validation in progress).
5. CARE Measure: The CARE Measure is a 10-item person-centred process measure that measures the amount of empathy that a patient feels they have received during a consultation. The CARE Measure has been rigorously developed, tested and validated for use by most health professionals in adult out-patients; and it is free to use. Patients complete the measure after the consultation in their own time and takes up to 10 minutes to complete.
6. Patient Experience Questionnaire (PEQ): The PEQ is an 18-item self-reported measure which measures patient experience along the domains of communication; emotions; short-term outcomes; barriers; and relations with staff. The PEQ can be used to gain feedback on the practitioner-patient relationship across these domains. This PEQ is a reliable, and validated measure for use only in one-on-one consultation with outpatients. Although the PEQ was developed for use by doctors, the questions are generic and could be easily adapted to be used by other health professionals. It is free to use and takes up to 10 minutes to complete.

Data collection and time points:
Data collection will be scheduled to coincide with clinic appointments where possible in order to reduce the burden of participants having to travel to the clinic at different times. Data collection will be done at 3 time points after baseline assessment to correspond with follow ups: T1 (1 month follow-up), T2 (2 months follow-up) and T3 (3 months follow-up). A local research assistant has been recruited and trained in quantitative and qualitative data collection methods, using all the tools that is being used in this study, to assist with the data collection at the control arm.

Semi-structured Interview Schedule: This will be administered to 10 patients at both the intervention and control arms, and 6-8 healthcare professionals in the intervention arm only, after the trials. The semi-structured interviews have been developed to explore the views of patients and healthcare professionals about their participation in the intervention and the in the trial.

Intervention Type
Behavioural

Primary outcome measure
1. Physical and psychological symptoms, spiritual, practical and emotional concerns and psychosocial needs assessed using APCA African POS questionnaire at baseline and 1 month, 2 months, 3 months after the start of the intervention.
2. Health Related Quality of Life assessed using MOS-HIV questionnaire at baseline and 1 month, 2 months, 3 months after the start of the intervention.
3. Health and wellbeing assessed using Positive Outcomes HIV PROM questionnaire at baseline and 1 month, 2 months, 3 months after the start of the intervention.
4. The amount of empathy that a patient feels they have received during consultation assessed using Care Measure questionnaire at baseline and 1 month, 2 months and 3 months after the start of the intervention.

5. Patient experience along the domains of communication, emotions, short-term outcomes, barriers and relations with staff assessed using Patient Experience questionnaire at baseline and 1 month, 2 months and 3 months after the start of the intervention

Secondary outcome measures
N/A

Overall study start date
01/05/2018

Completion date
15/01/2019

Eligibility

Key inclusion criteria
1. Adults from age 20 years (using the WHO definition of an adult as a person older than 19 years)
2. A positive diagnosis of HIV/AIDS, known to the patient for at least 6 months or more, to ensure that the person living with HIV/AIDS (PLWHA) has the experience of care to reflect on

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 (30 from each clinic)

Total final enrolment
60

Key exclusion criteria
1. PLWHA who have health problem such as HIV-associated dementia which will hinder cognition and communication
2. PLWHA who have been assessed by a clinician to be too ill to participate;
3. People coming to the clinic for pre-counselling and testing services including prevention of mother-to-child-transmission

Date of first enrolment
18/07/2018

Date of final enrolment
22/08/2018

Locations

Countries of recruitment
Ghana

Study participating centre
West Africa AIDS Foundation/ International Health Care Center
Plot 650
Haatso Ecomog Ave
Haatso
Accra
Ghana
00233

Study participating centre
University of Ghana Hospital Public Health Unit
P.O. Box LG 25
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Sponsor information

Organisation
Ghana Education Trust Fund

Sponsor details
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Sponsor type
Government

ROR
https://ror.org/03fhdst60

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned to disseminate the results of this trial including the feasibility and acceptability of this intervention in:
1. Internal report (my thesis)
2. Journals
3. Conferences
4. Discussion with the clinics involved
5. Policy makers at the Ghana Health service

Intention to publish date
30/06/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			02/04/2019	No	Yes
Basic results		09/01/2020	10/01/2020	No	No
Results article	results	01/05/2020	04/12/2020	Yes	No