Chapter 10: Appendices

Appendix I: Ethics Approvals and Permissions

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

Observational / Interventions Research Ethics Committee

Dr Mohammed Limbada
LSHTM

2 February 2017 Dear Mohammed

Study Title: A Comparison of Different Community Models of ART Delivery Amongst Stable HIV+ Patients in two Urban Settings in Zambia

LSHTM Ethics Ref: 11819

Thank you for responding to the Interventions Committee's request for further information on the above research and submitting revised documentation. The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Approval is dependent on local ethical approval having been received, where relevant.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type	File Name	Date	Version
Local Approval	Community ART approval letter 20160712	23/06/2016	2.3
Investigator CV	CURRICULUM VITAE FOR MOHAMMED LIMBADA	27/07/2016	1
Investigator CV	CURRICULUM VITAE HA	27/07/2016	1
Investigator CV	CURRICULUM VITAE KS	27/07/2016	1
Local Approval	NHRA approval letter Community ART 20160802	02/08/2016	1
Protocol / Proposal	PHD Protocol V2.4. 04aug16	04/08/2016	2.4
Information Sheet	Community ART Quantitative ICF V1 20160915	15/09/2016	1
Information Sheet	Community ART ICF V1 20160915	15/09/2016	1
Sponsor Letter	Letter of sponsorship & Insurance 20161129	29/11/2016	1
Protocol / Proposal	Ethics cover letter	29/11/2016	1
Protocol / Proposal	PHD Protocol V1.0.10Jan17	10/01/2017	1.0
Covering Letter	LSHTM Clarification Cover Letter	24/01/2017	1.0
Information Sheet	Community ART Quantitative ICF V1.0.20170127	27/01/2017	1.0
Information Sheet	Community ART Qualitative ICF V.1.20170127	27/01/2017	1.0

After ethical review

The Chief Investigator (CI) or delegate is responsible for informing the ethics committee of any subsequent changes to the application. These must be submitted to the Committee for review using an Amendment form. Amendments must not be initiated before receipt of written favourable opinion from the committee.

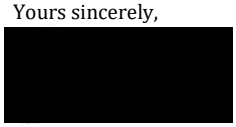
The CI or delegate is also required to notify the ethics committee of any protocol violations and/or Suspected Unexpected Serious Adverse Reactions (SUSARs) which occur during the project by submitting a Serious Adverse Event form.

An annual report should be submitted to the committee using an Annual Report form on the anniversary of the approval of the study during the lifetime of the study.

At the end of the study, the CI or delegate must notify the committee using an End of Study form.

All aforementioned forms are available on the ethics online applications website and can only be submitted to the committee via the website at: http://leo.lshtm.ac.uk Additional information is available at: www.lshtm.ac.uk/ethics

Yours sincerely,



Professor John DH Porter Chair

ethics@lshtm.ac.uk http://www.lshtm.ac.uk/ethics/

London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT
United Kingdom
Switchboard: +44 (0)20 7636 8636

www.lshtm.ac.uk

Research Ethics Committee

Dr. Mohammed Limbada
25 April 2017

Dear Mohammed,

Study Title: A Comparison of Different Community Models of ART Delivery Amongst Stable HIV+ Patients in two Urban Settings in Zambia

LSHTM MSc Ethics ref: 11819 - 1

Thank you for submitting your amendment for the above research project.

Your amendment has been assessed by the Research Governance & Integrity Office and has been approved as a non-substantial change. The amendment does not require further ethical approval from the intervention's ethics committee.

List of documents reviewed:

Document Type	File Name	Date	Version
Other	Community ART ICF V1 20160915 LSTHM	10/01/2017	1
Other	Community ART Quantitative ICF V1 20160915 LSTHM	10/01/2017	1
Other	COMM ART PROTOCOL AMENDMENT 022017	02/02/2017	1
Other	LSTHM Amendment Cover letter 20170424	24/04/2017	1

Any subsequent changes to the application must be submitted to the Committee via an Amendment form on the ethics online applications website: http://leo.lshtm.ac.uk . Best of luck with your project.
Yours sincerely,

[redacted]

Rebecca Carter

Research Governance Coordinator

Ethics@lshtm.ac.uk http://www.lshtm.ac.uk/ethics/

THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

Telephone: 260-1-256067
Telegrams: UNZA, LUSAKA
Telex: UNZALU ZA 44370
Fax: + 260-1-250753
E-mail: unzarec@unza.zm

Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

Assurance No. FWA00000338
IRB00001131 of IORG0000774

12th July, 2016.

Our Ref: 004-05-16.

Dr. Mohammed Limbada,
Zambart Project,
Ridgeway Campus,
P.O Box 50697,
Lusaka.

Dear Dr. Limbada,

RE: RESUBMITTED RESEARCH PROPOSAL: **"A COMPARISON OF DIFFERENT COMMUNITY MODELS OF ART DELIVERY AMONGST STABLE HIV+ PATIENTS IN TWO URBAN SETTINGS IN ZAMBIA" (REF. No. 004-05-16)**

The above-mentioned research proposal was presented to the Biomedical Research Ethics Committee on 6th July, 2016. The proposal is approved.

CONDITIONS:

- This approval is based strictly on your submitted proposal. Should there be need for you to modify or change the study design or methodology, you will need to seek clearance from the Research Ethics Committee.
- If you have need for further clarification please consult this office. Please note that it is mandatory that you submit a detailed progress report of your study to this Committee every six months and a final copy of your report at the end of the study.
- Any serious adverse events must be reported at once to this Committee.
- Please note that when your approval expires you may need to request for renewal. The request should be accompanied by a Progress Report (Progress Report Forms can be obtained from the Secretariat).
- **Ensure that a final copy of the results is submitted to this Committee.**

Yours sincerely,

[redacted]

Dr. S.H Nzala
VICE-CHAIRPERSON

Date of approval: 12th July, 2016. **Date of expiry:** 11th July, 2017.

THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

Telephone: 260-1-256067
Telegrams: UNZA, LUSAKA
Telex: UNZALU ZA 44370
Fax: + 260-1-250753
E-mail: unzarec@unza.zm
Assurance No. FWA00000338
IRB00001131 of IORG0000774

Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

25th August, 2016.

Your Ref: 004-05-16.

Dr. Mohammed Limbada,
ZAMBART PROJECT,
Ridgeway Campus,
P.O Box 50697,
Lusaka.

Dear Dr. Limbada,

RE: **AMENDMENT TO THE PROTOCOL: "COMPARISON OF DIFFERENT COMMUNITY MODELS OF ART DELIVERY AMONGST STABLE HIV+ PATIENTS IN URBAN ZAMBIA" (PROTOCOL VERSION 2.3, DATED 23RD JUNE 2016) (REF. No. 004-05-16)**

We have reviewed the above protocol version 2.4 dated 4th August 2016 and noted and approved the amendments contained in the said protocol and information sheet and consent form for community antiretroviral therapy delivery (Appendix 1).

Yours sincerely,

[redacted]

Dr. S.H Nzala
VICE-CHAIRPERSON

THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

Telephone: 260-1-256067
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E-mail: unzarec@unza.zm
Assurance No. FWA00000338
IRB00001131 of IORG0000774

Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

23th January 2018.

Your Ref: 004-05-16.

Dr. Mohammed Limbada,
ZAMBART PROJECT,
University of Zambia,
Ridgeway Campus,
P.O Box 50697,
Lusaka.

Dear Dr. Limbada,

RE: **RENEWAL FOR THE PROTOCOL: "COMPARISON OF DIFFERENT COMMUNITY MODELS OF ART DELIVERY AMONGST STABLE HIV+ PATIENTS IN URBAN ZAMBIA" (PROTOCOL VERSION 2.4 DATED 4TH AUGUST 2016) (REF. No. 004-05-16)**

We acknowledge receipt of your progress report on the above study. Your request to use Data collected during the period is granted.

Renewal is hereby granted for the period 12th July, 2017 to 11th July, 2018.

Yours sincerely,

[redacted]

Prof. M.C. Maimbolwa PhD
CHAIRPERSON

THE NATIONAL HEALTH RESEARCH AUTHORITY
C/O Ministry of Health
Haile Selaisse Avenue,
Ndeke House
P.O. Box 30205
LUSAKA

MH/101/23/10/1

2nd August, 2016

Dr Mohammed Limbada
Zambart
Ridgeway Campus- University of Zambia
P.O Box 50697
LUSAKA

Re: Request for Authority to Conduct Research

The National Health Research Authority is in receipt of your request for authority to conduct research titled **"A Comparison of Different Community Models of ART Delivery Amongst Stable HIV+ Patients in Two Urban Settings in Zambia"**.

I wish to inform you that following submission of your request to the Authority, our review of the same and in view of the ethical clearance, this study has been approved to carry out the above mentioned exercise on condition that:

1. The relevant Provincial and District Medical Officers where the study is being conducted are fully appraised;
2. Progress updates are provided to NHRA quarterly from the date of commencement of the study;
3. The final study report is cleared by the NHRA before any publication or dissemination within or outside the country;
4. After clearance for publication or dissemination by the NHRA, the final study report is shared with all relevant Provincial and District Directors of Health where the study was being conducted, and all key respondents.

Yours sincerely,

[redacted]

Dr. P. Chanda-Kapata
For/Director
National Health Research Authority

All Correspondence should be addressed to the Permanent Secretary
Telephone: +260 1 253040/5
Fax: +260 1 253344

REPUBLIC OF ZAMBIA
MINISTRY OF HEALTH

In reply please quote:
MH/4/15/1

NDEKE HOUSE
P. O. BOX 30205
LUSAKA

21 February, 2018

Dr. Mohammed Limbada
PI Community ART
Zambart Ridgeway
LUSAKA

RE: SMARTCARE DATA FROM KANYAMA AND CHIPATA HEALTH CENTRES FOR THE "COMPARISON OF DIFFERENT COMMUNITY MODELS OF ART DELIVERY AMONGST STABLE HIV + PATIENTS IN URBAN ZAMBIA" (PROTOCOL VERSION 2.4.DATED 4TH AUGUST 2016)

The Ministry of Health is in receipt of your letter in which you sought permission to extract data from the smartcare database and clinical charts for your study.

Permission is granted on condition that conditions set by the National Health Research Authority are adhered to and Ministry of Health is availed a copy of the study report once completed.

[redacted]

Dr. Jabbin L. Mulwanda
Permanent Secretary – Health Services
MINISTRY OF HEALTH

DAIDS Medical Officer Protocol/SIC Sign-Off Form

The purpose of this form is to provide documentation that FDA submissions of all protocol versions have been reviewed and approved by a DAIDS Clinical Representative (Medical Officer) prior to signature from the Sponsor's Authorized Representative. This form is required in addition to the team sign-off obtained during protocol development by the Clinical Trials Specialist.

Protocol Number/Version/Date: HPTN 071 Community ART, Version 0.8, dated January 6, 2017

Medical Officer: David Burns, M.D., M.P.H.

Date Sent: January 9, 2017.

Protocol/Sample Informed Consent (SIC) Review Outcome (Check One Response):

✓ Approved as written
MO Version will be changed to Final Version and submitted to the Sponsor's Authorized Representative for signature.

_____ Make changes as indicated and return to MO
Required changes will be incorporated by the Clinical Trials Specialist and the protocol will be resubmitted for a second MO sign-off.

_____ Make chan[redacted] MO
Required c[redacted] Clinical Trials Specialist. The protocol does not need to be resubmitte[redacted]

MO Signature: [redacted] Date: 10/JAN/2017

Return completed form and protocol to Jin Chen, **Regulatory Specialist, RSC.**

For RSC Use only: Receipt Date 1/10/2017

The following is only applicable to protocols/SICs requiring a second MO sign-off.

Protocol Number/Version/Date: _____

Medical Officer: _____

Date Sent: _____

This protocol/SIC is approved as written.

MO Signature: _____ Date: _____

Return completed form and protocol to _____, **Regulatory Specialist, RSC.**

For RSC Use only: Receipt Date _____

Appendix II: Participant eligibility and Information and consent sheet

Zambart

COMMUNITY ART DISTRIBUTION MODELS

ELIGIBILITY FORM

COMMUNITY: _____ **DATE:** ___/__/__

NAME: _____ **SEX** ☐ **M/**☐ **F**

ART #: _____ **CHIPS REFERAL** ☐ **Y/**☐ **N**

ADDRESS: _____

A. ELIGIBILITY

1. Is the client above 18 years old? ☐ **YES** ☐ **NO**
2. Is the client on First line treatment > 6months? ☐**YES** ☐ **NO**
   I. Date of starting ART __/__/__
3. Is the client virologically suppressed? ☐ **YES** ☐ **NO**
   I. Date of viral load prior to enrolment: __/__/__
   II. Viral load prior to enrolment: _____copies/mL.
   III. Where was the Lab Test done? ☐ CIDRZ ☐ ZAMBART ☐ GRZ/MOH
   IV. Date of viral load at enrolment: __/__/__
   V. Viral load at enrolment: _____copies/mL
4. Is the client W.H.O stage I & II? ☐ **YES** ☐ **NO**
5. Is the client residing within the intervention catchment area? ☐ **YES** ☐ **NO**

IF **'YES'** TO ALL, CLIENT ELIGIBLE.PROCEED TO CONSENT
IF **'NO'** TO ANY, MAY REASSESS IN 1-3 MONTHS**.**

B. CONSENT

1. Has the client consented to the study? ☐ **YES** ☐ **NO**
2. If **YES** Proceed to Part C.
3. If **NO** end here

C. RESIDENTIAL ZONE **MODEL OF DELIVERY** **KEY**

1. Standard of care

☐ ☐

2. Home Based Delivery
3. Adherence Club.

D. PARTICIPANTS PREFERENCES

1. Did the Participant agree to the model of ART delivery assigned? ☐ **YES** ☐ **NO**
2. Did the participant suggest their own preferred model of delivery? ☐ **YES** ☐ **NO**
   2a. If yes, which Model .....
3. Have the CHiPs contact details been given to the Participant? ☐ **YES** ☐ **NO**

Participant contact numbers: 1. _____
Name & Signature of Nurse: _____Date: _____/_____/___

- ***File this form in the ART Nurse folder***.

A Comparison of Different Community Models of ART Delivery amongst Stable HIV + Patients in Two Urban Settings in Zambia".

INFORMATION SHEET AND INFORMED CONSENT FORM FOR COMMUNITY ANTIRETROVIRAL THERAPY DELIVERY

INFORMATION SHEET

You are being invited to take part in a new type of Anti-Retroviral Therapy (ART) service delivery for HIV stable patients. This is called "Community Models of ART care" and these models include the following:

1. Adherence club
2. Home-Based ART delivery
3. Continue care at the local facility

Adherence Club

The ART adherence club will consist of a group of 20-25 clinically stable HIV patients from this clinic. The members will meet every 3 months at a communal venue in your community where HIV adherence support, a symptom screening and pre-packed drugs will be provided. Community HIV Care Providers (CHiPs) that work in your community will conduct these activities and members will be required to visit the clinic once every 6 months for the next 2 years till the end of the study

Home-Based ART delivery

In this model, the Community HIV Providers (CHiPs) will visit people at home once every 3 months to provide them with adherence support, carry out a symptom screening and dispense pre-packed ART drugs. People who will be part of this model, will only visit the clinic once every 6 months for the next two years till the end of the study.

Continued Access of care at the local clinic

In this model, people will continue to receive care at the local clinic and follow the routine clinic visits that they have been following ever since they started Antiretroviral Therapy (ART).

We are therefore inviting you to participate in this study to see which model works best for the community. Within your community there are several zones and each zone will either have an adherence club, a home based ART delivery or continue receiving care at your local clinic.

Information about the study is supplied in this document. Please make sure that you understand everything described in this document. If you decide to participate, you will be asked to give written consent before you take part. If you sign this form, you will be giving your permission to take part in the study.

This form describes reasons for doing the study, how we will conduct the study and the benefits and risks of the study.

Your participation is voluntary
You do not have to take part in these models of ART service delivery. If you decide today to take part in this study, you may stop at any time without reducing or affecting any care that you receive at this clinic or anywhere else. If we learn any new information during the course of the study that might make you concerned about continuing, we share that information with you.

If you are offered community-based ART, but decide today to continue care at the clinic, you may change your mind later and if you are still living in the same area, you will then begin receiving ART in your community. If you accept community-based ART at any time, you can always decide later to go back to receiving ART at the clinic.

Who is doing the study?
Researchers from the Zambia AIDS Related Tuberculosis (ZAMBART) Project in conjunction with Ministry of Health will be conducting this pilot model in your community.
The study has been approved by the Medical Ethics Committees of the University of Zambia and the London School of Hygiene and Tropical Medicine.

What is the purpose of this study?
The purpose of the study is to compare HIV care and support delivered in your community by two different ways to the care that you would receive normally in the clinic. The two community delivery methods that are being studied are an adherence club where you would be in a group of 20-25 patients receiving care in a club within this community or a program where you would receive care at your home. The other option is that you will continue receiving care in the clinic.

In both the adherence club and home based ART delivery, you will receive adherence support, screening for symptoms and collect your medications rather than travelling to the clinic to collect the drugs.
This is meant to reduce long waiting times at the clinic and also reduce the number of visits you make to the clinic every year to collect your medications.
It will also allow the clinic to attend to patients who clinically unwell to be monitored closely.
The models will be monitored closely by the Zambart research team to determine if it will be successful in retaining HIV patients in care and allow us to roll it out wide in all communities.

What will happen during this study?
For you to be part of this study, we will need to check if you:

- Have been on ART for more than 6 months
- Have an undetectable viral load
- Have no underlying infections such as Tuberculosis (TB) etc
- Have maintained your clinic visits in the last 12 months.

We will review your ART file to see what drug regimens you are and whether you live in this community. If you did not have a viral load done as part of your routine care, we will have the clinic staff collect blood from you to measure your viral load. Once we confirm that you are stable by meeting the above requirements, we will determine which community zone you are living in. if the community zone you are living in has an adherence club, you will be asked to join the club

and if you are not willing to then you are free to continue receiving care at the local clinic. If your zone provides Home based ART service, you will be asked to join this model where HIV care will be provided in your home. If you are not willing to join this model you can continue receiving care at the clinic. If the zone you are living in has no clubs or home based delivery, you will continue coming to the clinic for your care. In all these models we will ask you for your physical address and enter you in either a home ART register or club register which will be kept in this clinic. The research team will also look at your clinic records to determine if you are doing well whilst receiving most of the HIV care in your community and if you did have your 6 monthly laboratory tests as part of your care.

What happens if I am in an Adherence club?

If you belong to an adherence club, you will be asked to meet at a common venue in your community with other members of the club who are also receiving care at this clinic. You will be asked to meet once every 3 months and a trained community HIV provider (CHiP) who works within your community zone will visit your club and do the following:

1. Screen you to determine if you have any symptoms
2. Record your weight
3. Adherence counseling
4. Provide you with 3 monthly supplies of ARVs and Septrin

During these meetings, you will also have an opportunity to discuss any concerns or problems in a private setting with the CHiP.

A Clinic nurse will also accompany the CHiP during one or two meetings to provide support.

The CHiP will also remind when to next go to the clinic for your laboratory tests as well clinical review by the health care worker. You will be required to visit the clinic every 6 months and during this clinical visit, the club meeting will take place in the clinic where we will provide you with adherence support, have the clinician review you and a nurse collects blood for your laboratory tests. We will also give you your 3 months' supply of drugs that should last you until we meet you in 3 months' time at the next club meeting in the community.

When you attend a clinic visit for your laboratory tests and clinical review every 6 months, the results will be entered in your clinic file and the CHiP will also give the results to you.

If you are unwell or the CHiP discovers you have a symptom that requires medical attention, you will be referred to the clinic to be seen by a clinician who will then decide if you are healthy to continue receiving care at the club or should resume care at the clinic.

All the information collected during the club visit will be entered in an electronic tablet. The information collected will then be entered into the clinic register and your care card at the clinic.

The information provided during the meetings will also be used to determine if you will be clinically stable at the end of the study and also if the model works. These results are important to determine if you will be adherent and help us to roll these clubs in other communities in Zambia.

At the end of the study, which is after 2 years, we will then refer you back to the clinic where you will continue your care.

What happens if I am in a Home Based ART delivery model?

If you belong to a zone where home based ART delivery will be provided, we will ask you for your physical address and a CHiP team that works in your community zone will visit you once every 3 months to do the following:

1. Screen you to determine if you have any symptoms
2. Record your weight
3. Adherence counseling
4. Provide you with 3 monthly supplies of ARVs and Septrin

During these home visits, you will also have an opportunity to discuss any concerns or problems in a private setting with the CHiP.
A Clinic nurse will also accompany the CHiP during one or two meetings to provide support.

The CHiP will also remind when to next go to the clinic for your laboratory tests as well clinical review by the health care worker. This will be every 6 months where you will come to the clinic. We will discuss the best date and time for you to go to the clinic so that you can be quickly seen by the clinician and nurse who will collect blood for laboratory tests. During this visit, we will also provide you with adherence counselling and a 3 month supply of drugs that will last you until the next home visit.

When you attend a clinic visit for your laboratory tests and clinical review every 6 months, the results will be entered in your clinic file and the CHiP will also give the results to you.

If you are unwell or the CHiP discovers you have a symptom that requires medical attention, you will be referred to the clinic to be seen by a clinician who will then decide if you are healthy to continue receiving care at home or should resume care at the clinic.

All the information collected during the home visit will be entered in an electronic tablet. The information collected will then be entered into the clinic register and your care card at the clinic.

The information provided during the home visits will also be used to determine if you will be clinically stable at the end of the study and also if this type of model works. These results are important to determine if you will be adherent and help us to roll out this type of service in other communities in Zambia.

At the end of the study that is after 2 years, we will then refer you back to the clinic where you will continue your care.

What if I am not in a club or home based ART model?

If you live in a zone that has no adherence club or home ART delivery services, you will continue receiving care at your local clinic like you have always done. The fact that you will be receiving care at the clinic will help us understand whether continuing receiving care in the clinic is better than the two models we are offering. Even if you continue receiving care at the clinic you will still

be part of the study as we will monitor you at the local clinic and use the clinic data to determine if your care is no different from the other two models.

Regardless of whichever models of care you are in, you may be selected to participate in a set in-depth interviews and a focus group discussion that will be conducted by a group of social scientists from Zambart. The interviews will be held 4 times during the duration of the study while the focus group discussion will be held once. You are free not to participate in these interviews and focus group discussions if you are selected. *If you choose not to participate in the interviews or focus groups, will still be allowed to remain in the study and to remain in the model of care you participate in.*

What are the potential benefits?

There are no direct clinical benefits as a result of participating in the study. However: If you chose to participate in any of the two ART delivery models, it could reduce the amount of time you have to spend at the clinic. When you are referred to the clinic, you will be received and fast tracked through the queues.

Belonging to these types of models will provide a safe venue with whom you can share and get emotional support. When attending the clinic for a clinical review and laboratory tests, you will not need to queue up for drugs as this will be given to you at the club or at home.

What are the possible risks or discomforts?

There are no foreseen risks to being part of the additional study. However, if there were a breach of confidentiality, there is a risk that someone could learn of your status or other personal information. The study team will do everything to ensure confidentiality is maintained and the staffs who will be running these models of care are trained in maintaining confidentiality.

Adherence Clubs - if you are part of an adherence club, it would mean that other members of the club know that you are on ART. The other members in the club will also be from the same clinic that you have been receiving HIV care from. All members of the club should be able and willing to sign a "club charter of rights and responsibilities" in the presence of all club members, which include commitment to maintaining confidentiality. You will need to respect for one another's privacy during and after the club meetings - i.e. don't talk outside the group, ever, about who is in the group and their personal information. Should a member be found to breach this, s/he will be disqualified from the club and returned to mainstream care.

Home-Based Visits - there is a possibility that family, friends and people in your community may find out that you are participating in health related study if they see the CHiPs coming to your home and you may experience stigma but we will do everything we can to protect your privacy. During home-visits, everything discussed between your and the CHiPs will be done in private.

In both of these models you may end up feeling embarrassed or anxious when sensitive questions are being asked. You are free to skip questions you may deem personal or otherwise.

What are my responsibilities?

If you chose to participate in this study, you are agreeing to share the data or information captured with the clinic staff and researchers who will use the results to see if this type of service is ideal for stable patients.

If you choose to participate, you are agreeing to be responsible for visiting the clinic ONCE every 6 months. However, the CHiP will provide you with the date of the clinic visit and also remind you of the appointment.

You are also agreeing to ensure that you receive your drug supply during these home visits and sign off an appropriate form that you have received the drugs.

How will my confidentiality and privacy be protected?
The only people who have access to the information you have provided during these meetings are the clinic staff and Zambart researchers conducting this study.

People who may review the study records include: Biomedical Research Ethics Committee, local regulatory agencies, US National Institutes of Health (NIH), study staff, and study monitors. Institutional Review Boards (IRBs) or Ethics Committees (ECs) are committees that watch over the safety and rights of research participants. Provincial and/or national public health officials may be given community-wide results but not individual results

What are some reasons why I may be withdrawn from this activity without my consent?
You may be withdrawn from the study without your consent if the research study, or part of this study, is stopped or cancelled.

What happens if I am injured by participating in this study?
It is very unlikely that you could be injured as a result of participating in this study. However, if you are injured while participating in this study, you will be given immediate treatment for your injuries. You will not have to pay for this care. There is no program for compensation either through this institution or the United States NIH. You will not be giving up any of your legal rights by signing this Subject Information and Consent Form.

Persons to Contact for Problems or Questions
If you have any questions about your participation in this research study, your rights as a research Participant, or if you feel that you have experienced a research-related injury, contact:

Site Research Staff: DR MOHAMMED LIMBADA

Research Site Address (es): Zambart, School of Medicine, Ridgeway campus,
P.O. Box 50697, Lusaka, Zambia.

Daytime Telephone Number (s): +260 211 254710
Email: Mohammed@zambart.org.zm

If you have any questions or concerns about your rights as a research Participant or want to discuss a problem, get information or offer input, you may contact:

Independent Review Board/Ethics Committee: Biomedical Research Ethics Committee

Address of Independent Review Board: School of Medicine, Ridgeway campus, P.O. Box 50110, Lusaka, Zambia

Daytime Telephone Number: + 260 211-256067

Thank you for reading this information sheet. If you have any questions, please ask them now. If you either have read or have heard the information in this Participant Information and Consent Form, if all of your questions have been answered, and if you agree to take part in the study, please print and sign your name and write the date on the line below.

_____ _____

Participant's Name (print) **Participant's Signature (or fingerprint)**

Date: _____

I certify that the information provided was given in a language that was understandable to the participant.

_____ _____

Name of Study Staff **Study Staff Signature**

Conducting Consent Discussion (print)

Date: _____

_____ _____

Witness' Name (print) **Witness' Signature and Date**
(As appropriate)

Date: _____

Appendix III: Study Documents

A. **Home-Based Delivery (HBD)**

    1. **HBD membership register**
    2. **HBD attendance register**
    3. **HBD study event form**

B. **Adherence Clubs (AC)**

    1. **AC membership register**
    2. **AC attendance register**
    3. **AC study event form**

C. **Clinical Register [for all study participants]**

D. **Study event form [for all study participants]**

E. **Drug Scripts [for HBD and AC participants]**

F. **Drug accountability form [for HBD and AC participants]**

G. **Termination form [for all study participants]**

A1. Home-Based Delivery Membership Register

Zambart

Community Models of ART Delivery
ADHERENCE CLUB MEMBERSHIP REGISTER

PART A : *To be filled in by Community ART Nurse*

COMMUNITY:	**Community ART Nurse**	
ZONE:	**Name:**	
NAME:	**Sign:**	
CLUB No:		
CHiP:1 **Mobile No.1:**	**CHiP:2** **Mobile No.2**	

PART B: ***To be filled in by Community ART Nurse***

ART ID	First Name	Surname	Sex (M/F)	DOB DD/MM/YY	Mobile Numbers	Home Address	Date joined Club (DD/MM/YY)	Scheduled Club visit 1 (DD/MM/YY)	Scheduled Club-Clinic visit 2 (DD/MM/YY)	Scheduled Club visit 3 (DD/MM/YY)	Scheduled Club-Clinic visit 4 (DD/MM/YY)	CD4		Viral load results						Date started ART	Comments	Indicate changes in contact details
														Pre-Enrollment		Post-Enrollment						
												6 months	12months	Date	Value	Date	Value	Date	Value			
				--/--/--			--/--/--	--/--/--	--/--/--	--/--/--	--/--/--			--/--/--		--/--/--		--/--/--		--/--/--		
				--/--/--			--/--/--	--/--/--	--/--/--	--/--/--	--/--/--			--/--/--		--/--/--		--/--/--		--/--/--		
				--/--/--			--/--/--	--/--/--	--/--/--	--/--/--	--/--/--			--/--/--		--/--/--		--/--/--		--/--/--		
				--/--/--			--/--/--	--/--/--	--/--/--	--/--/--	--/--/--			--/--/--		--/--/--		--/--/--		--/--/--		
				--/--/--			--/--/--	--/--/--	--/--/--	--/--/--	--/--/--			--/--/--		--/--/--		--/--/--		--/--/--		
				--/--/--			--/--/--	--/--/--	--/--/--	--/--/--	--/--/--			--/--/--		--/--/--		--/--/--		--/--/--		
				--/--/--			--/--/--	--/--/--	--/--/--	--/--/--	--/--/--			--/--/--		--/--/--		--/--/--		--/--/--		

If patient permanently leaves Club, fill out Event Form
Comment if either the participant has died or left

A2. Home-Based Delivery Attendance Register

Zambart

Community Models of ART Delivery

HOME BASED ART ATTENDANCE REGISTER

Client Name	Community:	Date of Enrollment (V0) :...../...../.....	INSTRUCTIONS FOR THE CHiPS FOR EACH VISIT
ART ID:	ZONE	Date of Home visit (V1) :...../...../.....	1. Was the participant at home YES/NO
D.O.B	CHiPS1:	Date of Home Clinic/Cinic visit (V2) :...../...../.....	2. If YES complete the Register
Sex:	CHiPS2:	Date of Home visit (V3) :...../...../.....	3. If NO Do not complete Register
	CHiPS Mobile No.:		

Visit Number Year 1 (Home/Home Clinic)	DATE	Client Present (Y/N)	Signature of Client (Initials)	Pregnant (Y/N)	Feel ill? (Y/N)	*IF YOU FEEL ILL, have you been experiencing any of the following in the last two weeks?*						Received meds (3 Months) (Y/N)	Referred to clinic (Y/N) (If yes, complete event form)	Signature of CHiPS	Comments
						Fever (Y/N)	Night sweats (Y/N)	Weight loss (Y/N)	Cough (Y/N)	Severe headache (Y/N)	Other (describe)				
Home [1]															
Home / Clinic [2]															
Home [3]															
Home / Clinic [4]															

A3. Home-Based Delivery Event form

Zambart

Community Models of ART Delivery

HOME BASED DELIVERY EVENT FORM

1. Date (DD/MM/YY)	_____/_____/_____
2. Community	
3. Zone	
4. Address	
5. Client ART #	
6. Indicate the EVENT of concern and the ACTION(s) taken below (Only **one** event per form)	

EVENT	***ACTION(s) TAKEN***
1. client was unwell →	▪ ☐Referred to the clinic& HW notified. *Fill in referral form. ▪ ☐ Referred to facility for: ☐TB screening ☐STI screening ☐PMTC ☐VMMC ☐OP ☐ART
2. Participant was not found at home →	▪ Did the CHIP contact Participant Prior to scheduled visit? ☐ Yes ☐ No ▪ If YES, what are the reasons for not attending? ☐Unwell ☐Travelled out. ☐Work commitment ☐No reason ☐want to change model of delivery. ▪ Have medicines been returned to the clinic & Pharmacy notified? ☐Yes ☐No ▪ Was a second attempt to contact participant made? ☐Yes ☐No ▪ If YES,
3. Participant changing Model of delivery →	▪ What is the reason for change? ☐ No longer wants to be in the model of delivery (return to care at clinic) ☐ Transfer to another Community ☐ Defaulting Treatment ☐ Pregnant ☐ Died ☐ Other, specify: _____
4. Participant/CHIP dispute →	▪ How was (or will) the dispute be resolved? ☐ I have/will resolve issue with individual Participant in person. ☐ I have/will arrange a meeting with Other Study staff ☐ Other: _____ ▪ Please specify: _____

Instructions for Filling the HBD Event Form: A separate event form should be filled for *each* event that has occurred

B1. Adherence Club Membership Register

Zambart

Community Models of ART Delivery
ADHERENCE CLUB MEMBERSHIP REGISTER

PART A : ***To be filled in by Community ART Nurse***

COMMUNITY:		**Community ART Nurse**	
ZONE:		**Name:**	
NAME:		**Sign:**	
CLUB No:			
CHiPs:1 **Mobile No.1:**		**CHiPs:2** **Mobile No.2**	

PART B: ***To be filled in by Community ART Nurse***

ART ID	First Name	Surname	Sex (M/F)	DOB DD/MM/YY	Mobile Numbers	Home Address	Date joined Club (DD/MM/YY)	Scheduled Club visit 1 (DD/MM/YY)	Scheduled Club-Clinic visit 2 (DD/MM/YY)	Scheduled Club visit 3 (DD/MM/YY)	Scheduled Club-Clinic visit 4 (DD/MM/YY)	CD4		Viral load results						Date started ART	Comments	Indicate changes In contact details
														Pre-Enrollment		Post-Enrollment						
												6 months	12months	Date	Value	Date	Value	Date	Value			
				--/--/--			--/--/--	--/--/--	--/--/--	--/--/--	--/--/--			--/--/--		--/--/--		--/--/--		--/--/--		
				--/--/--			--/--/--	--/--/--	--/--/--	--/--/--	--/--/--			--/--/--		--/--/--		--/--/--		--/--/--		
				--/--/--			--/--/--	--/--/--	--/--/--	--/--/--	--/--/--			--/--/--		--/--/--		--/--/--		--/--/--		
				--/--/--			--/--/--	--/--/--	--/--/--	--/--/--	--/--/--			--/--/--		--/--/--		--/--/--		--/--/--		
				--/--/--			--/--/--	--/--/--	--/--/--	--/--/--	--/--/--			--/--/--		--/--/--		--/--/--		--/--/--		

If patient permanently leaves Club, fill out Event Form
Comment if either the participant has died or left HCF

B2. Adherence Club Attendance Registers

Zambart

Community Models of ART Delivery

ADHERENCE CLUB ATTENDANCE REGISTER

Community		Adherence Club No.		Date of Meeting (DD/MM/YY):	_ _ / _ _ / _ _
				Club Meeting Place:	

															TO BE COMPLETED BY CHIP
							IF YOU FEEL ILL, have you been experiencing any of the following in the last two weeks?								
ART ID	**First Name**	**Surname**	**Attended (Y/N)**	**Signature (Initials)**	**Pregnant (Y/N)**	**Feel ill? (Y/N)**	**Fever (Y/N)**	**Night sweats (Y/N)**	**Weight loss (Y/N)**	**Cough (Y/N)**	**Severe headache (Y/N)**	**Other (describe)**	**Received meds (Y/N)**	**Signature (Initials)**	**Referred to clinic (Y/N) (If yes, complete event form)**

B3. Adherence Club Study Event Form

Zambart

Community Models of ART Delivery

ADHERENCE CLUB EVENT FORM

1. Date (DD/MM/YY)	_____/_____/ _____
2. Community	
3. Zone	
4. Club Number	
5. Client ART #	
6. Does this event involve only one member of the group?	☐ Yes, Involves only one member. List ART ID: _____ ☐No, Involves more than one member. *Go to "Club Dispute" option below*
7. Indicate the EVENT of concern and the ACTION(s) taken below (Only **one** event per form)	

EVENT	***ACTION(s) TAKEN***
1. Client was unwell →	▪ ☐Referred to the clinic& HW notified. *fill in referral form. ▪ ☐ Referred to facility for: ☐ TB screening ☐ STI screening ☐ PMTC ☐ VMMC ☐ OPD ☐ ART
2. Club member did not attend scheduled adherence club meeting → *Note: If multiple members did not show up to a meeting, fill out an event form for each missing member	▪ Did the CHIP attempt to contact the missing Club member? ☐ Yes ☐ No ▪ If YES, what are the reasons for not attending? ☐Unwell ☐Travelled out. ☐Work commitment ☐No reason ☐want to leave club. ▪ Have the drugs been returned to the clinic & Pharmacy notified? ☐Yes ☐No ▪ Did the participant come to the clinic to collect the Drugs? ☐ Yes ☐ No ▪ Date when participant collected drugs: _/ /_
3.Member leaving club →	▪ What is the reason for departure? ☐ No longer wants to be in the club (return to care at clinic) ☐ Asked to leave Club because not following Club rules. ☐ Transfer to another Community. ☐ Defaulting Treatment ☐ Died ☐ Lost to follow-up (patient cannot be located > 30 days after a missed adherence club meeting or clinic visit) ☐Stigma/social harm ☐Other, specify: _____
4.Death →	Reason: ……
5.Club group dispute →	▪ How was (or will) the dispute be resolved? ☐ I have/will resolve issue with individual Club members(s) in person. ☐ I have/will arrange emergency Club meeting with entire club members. ☐ Other: _____

Instructions for Filling the Adherence club Event Form: A separate event form should be filled for *each* event that has occurred.

C. Clinical Register

ART #	Name	Zone	Enrolment Date	Drug Dispensed		Active TB	WHO stage I, II, III, IV		CD4		Viral Load		Outcome	Date of outcome
				Date	# Days	Date	#	Date	Count	Date	Copies/ml	Date		
1.														
				Date	# Days	Date	#	Date	Count	Date	Copies/ml	Date		
2.														
				Date	# Days	Date	#	Date	Count	Date	Copies/ml	Date		
3.														

MODEL KEY : 1= SoC, 2= HBD, 3= AC

OUTCOMES:

1= Death
2= Participant withdrawal
3= Participant moved out of community
4= Participant moved to another zone
5= Transition to mainstream care by study staff
6= Participants opts out of the intervention model to SoC
7= WHO stage 3 or 4
8= Viral rebound

D. Study Event Form

Zambart

Community Models of ART Delivery
STUDY EVENT FORM

1. Date (DD/MM/YY)	_____/_____/ _____
2. Community	
3. Zone	
4. Address	
5. Client ART #	
6. Date joined the study:_____/_____/_____	

Original zone:	Zone #.....
Original model of ART delivery:	☐Home Based Delivery ☐Adherence club ☐ standard of care
New zone:	Zone #.....
New model of ART delivery:	☐Home Based Delivery ☐Adherence club ☐ standard of care
Reasons for changing	

E. Drug Scripts [for HBD and AC participants]

Zambart

P.O BOX 50697, University of Zambia
Lusaka-Zambia

Community Models of ART Delivery

DRUGSCRIPT

Name:_____ **ART #:_____**

Date:_____/____/_____ **Community:_____ Zone:_____**

Delivery Mode (×)

Home Based Delivery	☐
Adherence Club	☐
Drug Name	**Quantity Issued (×)**
TDF/3TC/EFV	☐30☐ 60☐ 90
TDF/3TC/NVP	☐ 30☐ 60☐ 90
ABC/3TC	☐ 30☐ 60☐ 90
TDF/FTC	☐ 30☐ 60☐ 90
EFV	☐ 30☐ 60☐ 90
NVP	☐ 30☐ 60☐ 90
INH	☐ 30☐ 60☐ 90
CTX	☐ 30☐ 60☐ 90
MVIT	☐ 30☐ 60☐ 90

Dispenser Name/Signature……/…… Date: ……

CHIPs Name/ Signature……/…… Date: ……

Clients Name/Signature (AS CONFIRMATION FOR RECEIPT)……/……

Client's Phone number/Date……/……

F.Drug Accountability Form

Zambart

Community Models of ART Delivery
DRUG ACCOUNTABILITY FORM

1. Date (DD/MM/YY):	__ __ / __ __ / __ __
2. Community:	
3. Zone:	
4. Client ART #:	
5. Model of Delivery	[ ] Home-based [ ] Adherence club

EVENT	***ACTION(s)***
1.Did client receive the 3 months med supply →	☐ Yes ☐ No.
2.If NO, reasons for not receiving medicines→	☐ Not present at home. (Did the CHIP attempt to contact the member? ☐ Yes ☐ No). ☐ Transfer to another zone. ☐ Others.
3. Did the client experience any of the following regarding ARV Refills?	☐Supply < 3months. ☐Seal was broken. ☐Stigma. ☐Wrong medication delivered.
4. If **YES** to any in number **3** above.	☐ Was it self-reported: ☐ Yes ☐ No. Action taken:…… ……

Instructions for Filling the Home Delivery Drug Log Event Form: A separate event form should be filled for *each* event that has occurred

G.Termination form

Zambart

Community Models of ART Delivery

TERMINATION FORM

ART #:_____

Name: _____

Community: _____

Zone: _____ 1. SOC 2. HBD 3. CLUB

Date of enrolment: _____/_____/____
Date of termination: ____/____/____

Reason for termination

☐ Death ☐ Refused further participation.

☐ Relocation / moved out from community.

☐ Unable to Locate.

☐ Incarcerated: ☐ Other: _____

Details:_____
_____
_____
_____

_____ _____

Field staff signature Supervisor signature

Appendix IV.

Additional files of A systematic review of the effectiveness of non- health facility based care delivery of antiretroviral therapy for people living with HIV in sub-Saharan Africa measured by viral suppression, mortality and retention on ART.

1. Search strategy in full for all databases, including Medline, Embase and Global Health

Database: Medline
Search Strategy:

---

1. Antiretroviral Therapy, Highly Active/
2. exp Anti-Retroviral Agents/
3. (Antiretroviral therap* or Anti retroviral therap* or Antiretroviral treat* or Anti retroviral treat* or HAART or ART or Anti Retroviral Agent* or Antiretroviral Agent* or antiretroviral deliver* or anti retroviral deliver*).ab,ti.
4. 1 or 2 or 3
5. exp "Africa South of the Sahara"/
6. (Sub-Saharan Africa or Subsaharan Africa).ab,ti.
7. (Angola or Gambia or Nigeria or Benin or Dahomey or Ghana or Gold Coast or Rwanda or Ruanda or Botswana or Bechuanaland or Kalahari or Guinea or St Helena or Saint Helena or Burkina Fas?o or Upper Volta or Senegal or Burundi or Urundi or Kenya or Seychelles or Cameroon* or Lesotho or Basutoland or Sierra Leone or Cape Verde or Liberia or Somalia or Central African Republic or Ubangi-Shari or Madagascar or Malagasy or South Africa or Chad or Malawi or Nyasaland or Sudan or Comoro* or Iles Comores or Mayotte or Mali or Swaziland or Congo or Kinshasa or Zaire or Katanga or Mauritania or Tanzania or Zanzibar or Tanganyika or Brazzaville or Mauritius or Agalega or Togo or Togolese or Cote dIvoire or Cote d Ivoire or Ivory Coast or Uganda or Eritrea or Mozambique or Portuguese East Africa or Zambia or Rhodesia or Ethiopia or Namibia or Zimbabwe or Gabon or Gabonese Republic or Niger).ab,ti.
8. (Sao Tome and Principe).ab,ti.
9. 5 or 6 or 7 or 8
10. Home Health Aides/
11. Volunteers/
12. Home Nursing/
13. Peer Group/
14. Social Support/
15. Social Welfare/
16. Community Integration/
17. Community Health Workers/
18. Home Care Services/
19. Community Pharmacy Services/
20. (Community adj3 (Health service* or Health Care or Healthcare or ART or antiretroviral therap* or anti retroviral therap*)).ab,ti.
21. (Home base* or Homebase* or Community based).ab,ti.
22. ((Community or Adherence or Peer) adj4 (Program* or support or group* or club* or service* or treatment*)).ab,ti.
23. ((community or village? or peer) adj3 (health worker? or health care worker? or

healthcare worker? or Healthworker? or Health Personnel or Health Care Provider* or Healthcare Provider* or service* or refill or Decentrali#ation or Shift*)).ab,ti.

24. (community adj3 (volunteer? or aide or aides)).ab,ti.

25. (Community adj8 distribution point*).ab,ti.

26. (Treatment partner* or Fieldworker* or Field Worker* or scale up or scaling up).ab,ti.

27. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26

28. 4 and 9 and 27

29. limit 28 to yr="2010 -Current"

Database: Embase
Search Strategy:

---

1. exp highly active antiretroviral therapy/

2. exp antiretrovirus agent/

3. (Antiretroviral therap* or Anti retroviral therap* or Antiretroviral treat* or Anti retroviral treat* or HAART or ART or Anti Retroviral Agent* or Antiretroviral Agent* or antiretroviral deliver* or anti retroviral deliver*).ab,ti.

4. 1 or 2 or 3

5. exp "africa south of the sahara"/ or angola/ or benin/ or botswana/ or burkina faso/ or burundi/ or cameroon/ or cape verde/ or central africa/ or central african republic/ or chad/ or comoros/ or congo/ or cote d'ivoire/ or democratic republic congo/ or djibouti/ or equatorial guinea/ or eritrea/ or ethiopia/ or gabon/ or gambia/ or ghana/ or guinea/ or guinea-bissau/ or kenya/ or lesotho/ or liberia/ or madagascar/ or malawi/ or mali/ or mayotte/ or mozambique/ or namibia/ or niger/ or nigeria/ or rwanda/ or senegal/ or sierra leone/ or somalia/ or south africa/ or sudan/ or swaziland/ or tanzania/ or togo/ or uganda/ or zambia/ or zimbabwe/

6. (Sub-Saharan Africa or Subsaharan Africa).ab,ti.

7. (Angola or Gambia or Nigeria or Benin or Dahomey or Ghana or Gold Coast or Rwanda or Ruanda or Botswana or Bechuanaland or Kalahari or Guinea or St Helena or Saint Helena or Burkina Fas?o or Upper Volta or Senegal or Burundi or Urundi or Kenya or Seychelles or Cameroon* or Lesotho or Basutoland or Sierra Leone or Cape Verde or Liberia or Somalia or Central African Republic or Ubangi-Shari or Madagascar or Malagasy or South Africa or Chad or Malawi or Nyasaland or Sudan or Comoro* or Iles Comores or Mayotte or Mali or Swaziland or Congo or Kinshasa or Zaire or Katanga or Mauritania or Tanzania or Zanzibar or Tanganyika or Brazzaville or Mauritius or Agalega or Togo or Togolese or Cote dIvoire or Cote d Ivoire or Ivory Coast or Uganda or Eritrea or Mozambique or Portuguese East Africa or Zambia or Rhodesia or Ethiopia or Namibia or Zimbabwe or Gabon or Gabonese Republic or Niger).ab,ti.

8. (Sao Tome and Principe).ab,ti.

9. 5 or 6 or 7 or 8

10. exp voluntary worker/

11. exp home care/

12. exp peer group/

13. exp social support/

14. exp social welfare/

15. exp community integration/

16. exp health auxiliary/

17. (Community adj3 (Health service* or Health Care or Healthcare or ART or antiretroviral therap* or anti retroviral therap*)).ab,ti.

18. (Home base* or Homebase* or Community based).ab,ti.

19. ((Community or Adherence or Peer) adj4 (Program* or support or group* or club* or service* or treatment*)).ab,ti.

20. ((community or village? or peer) adj3 (health worker? or health care worker? or healthcare worker? or Healthworker? or Health Personnel or Health Care Provider* or Healthcare Provider* or service* or refill or Decentrali#ation or Shift*)).ab,ti.

21. (community adj3 (volunteer? or aide or aides)).ab,ti.

22. (Community adj8 distribution point*).ab,ti.

23. home health aides.ab,ti.

24. community pharmacy services.ab,ti.

25. (Treatment partner* or Fieldworker* or Field Worker* or scale up or scaling up).ab,ti.

26. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25

27. 4 and 9 and 26

28. limit 27 to yr="2010 -Current"

Database: Global Health

Search strategy

1. exp highly active antiretroviral therapy/

2. exp antiretroviral agents/

3. (Antiretroviral therap* or Anti-retroviral therap* or Antiretroviral treat* or Anti-retroviral treat* or HAART or ART or Anti Retroviral Agent* or Antiretroviral Agent* or antiretroviral deliver* or anti retroviral deliver*).ab,ti.

4. 1 or 2 or 3

5. exp "Africa South of Sahara"/

6. (Sub-Saharan Africa or Subsaharan Africa).ab,ti.

7. (Angola or Gambia or Nigeria or Benin or Dahomey or Ghana or Gold Coast or Rwanda or Ruanda or Botswana or Bechuanaland or Kalahari or Guinea or St Helena or Saint Helena or Burkina Fas?o or Upper Volta or Senegal or Burundi or Urundi or Kenya or Seychelles or Cameroon* or Lesotho or Basutoland or Sierra Leone or Cape Verde or Liberia or Somalia or Central African Republic or Ubangi-Shari or Madagascar or Malagasy or South Africa or Chad or Malawi or Nyasaland or Sudan or Comoro* or Iles Comores or Mayotte or Mali or Swaziland or Congo or Kinshasa or Zaire or Katanga or Mauritania or Tanzania or Zanzibar or Tanganyika or Brazzaville or Mauritius or Agalega or Togo or Togolese or Cote dIvoire or Cote d Ivoire or Ivory Coast or Uganda or Eritrea or Mozambique or Portuguese East Africa or Zambia or Rhodesia or Ethiopia or Namibia or Zimbabwe or Gabon or Gabonese Republic or Niger).ab,ti.

8. (Sao Tome and Principe).ab,ti.

9. 5 or 6 or 7 or 8

10. exp home health aides/

11. exp community health services/

12. exp medical auxiliaries/

13. exp home care/

14. exp peer influence/

15. exp peer relationships/

16. exp support systems/

17. exp social welfare/

18. exp social integration/

19. exp community health services/

20. (Community adj3 (Health service* or Health Care or Healthcare or ART or antiretroviral

therap* or anti-retroviral therap*)).ab,ti.

21. (Home base* or Homebase* or Community based).ab,ti.

22. ((Community or Adherence or Peer) adj4 (Program* or support or group* or club* or service* or treatment*)).ab,ti.

23. ((community or village? or peer) adj3 (health worker? or health care worker? or healthcare worker? or Healthworker? or Health Personnel or Health Care Provider* or Healthcare Provider* or service* or refill or Decentrali#ation or Shift*)).ab,ti.

24. (community adj3 (volunteer? or aide or aides)).ab,ti.

25. (Community adj8 distribution point*).ab,ti.

26. (Treatment partner* or Fieldworker* or Field Worker* or scale up or scaling up).ab,ti.

27. 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26

28. 4 and 9 and 27

29. limit 28 to yr="2010 -Current"

2. Synthesis Without Meta-analysis (SWiM) reporting items

The citation for the Synthesis Without Meta-analysis explanation and elaboration article is Campbell M, McKenzie JE, Sowden A, Katikireddi SV, Brennan SE, Ellis S, Hartmann-Boyce J, Ryan R, Shepperd S, Thomas J, Welch V, Thomson H. Synthesis without meta-analysis (SWiM) in systematic reviews: reporting guideline BMJ 2020;368:l6890.

http://dx.doi.org/10.1136/bmj.l6890

SWiM is intended to complement and be used as an extension to PRISMA			
SWiM reporting item	**Item description**	**Page in manuscript where item is reported**	**Other***
Methods			
1 Grouping studies for synthesis	**1a)** Provide a description of, and rationale for, the groups used in the synthesis (e.g., groupings of populations, interventions, outcomes, study design)	Page 9	
	1b) Detail and provide rationale for any changes made subsequent to the protocol in the groups used in the synthesis	N/A	
2 Describe the standardized metric and transformation methods used	Describe the standardized metric for each outcome. Explain why the metric(s) was chosen, and describe any methods used to transform the intervention effects, as reported in the study, to the standardized metric, citing any methodological guidance consulted	Page 15	
3 Describe the synthesis methods	Describe and justify the methods used to synthesize the effects for each outcome when it was not possible to undertake a meta-analysis of effect estimates.	Page 15	
4 Criteria used to prioritize results for summary and synthesis	Where applicable, provide the criteria used, with supporting justification, to select the particular studies, or a particular study, for the main synthesis or to draw conclusions from the synthesis (e.g., based on study design, risk of bias assessments, directness in relation to the review question)	Page 19	
5 Investigation of heterogeneity in reported effects	State the method(s) used to examine heterogeneity in reported effects when it was not possible to undertake a meta-analysis of effect estimates and its extensions to investigate heterogeneity	Page 15-17 Page 18	
6 Certainty of evidence	Describe the methods used to assess certainty of the synthesis findings.	Page 9-10	
7 Data presentation methods	Describe the graphical and tabular methods used to present the effects (e.g., tables, forest plots, harvest plots). Specify key study characteristics (e.g., study design, risk of bias) used to order the studies, in the text and any tables or graphs, clearly referencing the studies included	Page 15 Page 17 Appendix 6: Table 1	

Results			
8 Reporting results	For each comparison and outcome, provide a description of the synthesized findings, and the certainty of the findings. Describe the result in language that is consistent with the question the synthesis addresses, and indicate which studies contribute to the synthesis	Page 15-18 Appendix 6: Table 1	
Discussion			
9 Limitations of synthesis	Report the limitations of the synthesis methods used and/or the groupings used in the synthesis, and how these affect the conclusions that can be drawn in relation to the original review question	Page 19 Page 21 - 23	

PRISMA=Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

*If the information is not provided in the systematic review, give details of where this information is available (e.g., protocol, other published papers (provide citation details), or website (provide the URL)).