

Randomised evaluation of the One Community programme in Malawi

Submission date 13/02/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/03/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/03/2017	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The human immunodeficiency virus (HIV) is a type of virus known as a retrovirus. HIV attacks and weakens the immune system, making it more difficult for a sufferer to fight infections. It is a highly contagious disease and can be spread through blood, semen and vaginal fluids. There is currently no cure for HIV, but there are a range of drug treatments that can allow people who are HIV positive to control the virus and even decrease the likelihood of spreading it. However, many people are unaware of their HIV status, due to a lack of education, health resources and knowledge about the virus. This is especially prevalent in vulnerable populations. Areas with high rates of HIV in Malawi have implemented programmes that aim to educate about HIV prevention, sexual behaviours, and gender based violence. The One Community (OC) programme aims to improve the wellbeing and decrease the risk of HIV in three priority populations: orphans and vulnerable children (OVC), out of school adolescent girls and young women (AGYW) and other vulnerable populations (OVP). The aim of this study is to assess the One Community program in order to see how effective it is in improving the health of these three vulnerable populations.

Who can participate?

Caregivers of orphans and vulnerable children, adolescent girls and young women (aged 15-24) and other vulnerable populations (over the age of 18).

What does the study involve?

Participants of the OC programme are randomly allocated to participate in interview surveys. The OC programme addresses the needs of people living with HIV. Participants are surveyed about their age, level of education, household wealth, HIV testing, HIV status, sexual behaviours, use of health services, attitudes towards violence, gender and social norms and their exposure to the OC programme. The interviews are conducted before the intervention and three additional interviews are conducted in 10 to 12 months intervals. Participants are randomly selected as to when they are interviewed, and it is not likely that they will be interviewed more than once throughout the evaluation process.

What are the possible benefits and risks of participating?

There are no direct benefits to participants, but the program can help improve health over the

long-term. The main risks of participation are possible breaches of participant confidentiality, as well as exposure to sensitive questions about sex, and HIV during the study interviews. As a result, some of the participants may become uncomfortable or upset.

Where is the study run from?

This study is being run from the University of Malawi College of Medicine (Malawi) and is taking place in five districts in the Southern region of Malawi.

When is the study starting and how long is it expected to run for?

October 2015 to June 2020

Who is funding the study?

United States Agency for International Development (USA)

Who is the main contact?

Dr Paul C. Hewett

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Study website

<http://www.popcouncil.org/research/supporting-operational-aids-research-project-soar>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PC785

Study information

Scientific Title

Stepped-wedge cluster randomised evaluation of the impact of the One Community programme on the wellbeing and HIV prevention behaviours of orphans and vulnerable children, adolescent girls and young women and other vulnerable populations in Southern Malawi

Study objectives

1. For orphans and vulnerable children and their caretakers, the One Community (OC) programme will improve their wellbeing, increase their awareness of their current HIV status, reduce their sexual risk behaviours and will increase their holding of more positive and gender equitable norms
2. For adolescent girls and young women, the OC programme will increase their awareness of their current HIV status, reduce their sexual risk behaviours and will increase their holding of more positive and gender equitable norms
3. For other vulnerable populations, the OC programme will increase their awareness of their current HIV status, reduce their sexual risk behaviours and will increase their holding of more positive and gender equitable norms

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Population Council Institutional Review Board, 09/11/2016, ref: p785
2. University of Malawi, College of Medicine, Ethical Review Committee, 31/01/2017, P.11/16/2067

Study design

Multi-centre cluster stepped-wedge randomised evaluation repeat cross-sectional observational study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

HIV/AIDS

Interventions

The Population Council, in collaboration with the University of Malawi College of Medicine, is conducting an evaluation of a USAID supported programme entitled “One Communalities” that is being implemented in communities in the Southern region of Malawi. Residents living in areas where the One Community (OC) programme is being implemented are eligible to participate in the OC evaluation. The evaluation seeks to assess the extent of which the OC programme is effective in improving the wellbeing and decreasing the risk of HIV acquisition among three priority populations:

1. Orphans and vulnerable children (OVC)
2. Out-of-school adolescent girls and young women (AGYW)
3. Other vulnerable populations (OVP) this includes fisherfolk, estate workers, vendors etc.

To evaluate the OC programme, communities are randomly assigned to initiate the OC programme at different times over approximately three years. Some communities initiate the program immediately, some mid-way and some toward the end of the evaluation. A total of 24 communities are participating in the evaluation. Residents in the communities who are OVC, AGYW and OVP are eligible to participate in the OC programme and therefore are able to participate in this study, the evaluation. Interviews of OVC, AGYW and OVC are conducted by study trained enumerators and take place at their households at four times, once prior to the start of the OC programme and three additional times, approximately every 10 to 12 months. Interviews with eligible residents are conducted whether they participate in the OC programme or not, although it is expected a significant proportion do participate. Interviews take place immediately prior to each step where the OC programmes initiates in a new set of communities. Only a small number of eligible OVC, AGYW and OVP in any one community, at any one time, are randomly selected for interviews, thus, eligible participants are not likely to be interviewed more than once throughout the evaluation.

The interviews include a range of questions about participants and their experiences, including questions about age, level of education, household wealth, HIV testing and current HIV status (self-reported); sexual behaviours (e.g. condom use, number of sexual partners), use of HIV prevention services (e.g., HTC, VMMC), attitudes toward violence; gender and social norms, communication with partners and exposure to OC programme activities. Most of the questions asked each eligible population (OVC, AGYW, OVP) are the same, but some questions are asked only to certain eligible populations, particularly OVC.

The evaluation of the effectiveness of the OC programme is based on determining whether conditions and behaviour improve significantly in communities after the programme has been implemented in them. The measures used to assess effectiveness includes: use of HIV prevention, health and other social services, adoption of HIV risk reduction sexual behaviours, measures of social and economic assets, indicators of well-being and nutrition, and support for harmful gender norms.

Intervention Type

Behavioural

Primary outcome measure

1. Percent of school-aged children regularly attending school is measured using a survey interview at baseline and three follow up rounds, with 10-12 months between each round
2. Percent of caregivers who agree that harsh physical punishment is an appropriate means of discipline or control in the home is measured using a survey interview at baseline and three follow up rounds, with 10-12 months between each round
3. Percent of children too sick to participate in daily activities is measured using a survey

interview at baseline and three follow up rounds, with 10-12 months between each round

4. Percent of caregivers who know their child's status is measured using a survey interview at baseline and three follow up rounds, with 10-12 months between each round
5. Percent of HIV-negative participants who have obtained the results of an HIV test within the previous six months is measured using a survey interview at baseline and three follow up rounds, with 10-12 months between each round
6. Percent of participants reporting using a condom at last sex is measured using a survey interview at baseline and three follow up rounds, with 10-12 months between each round
7. Percent of participants reporting sexual behaviour with 2 or more partners in the previous 30 days is measured using a survey interview at baseline and three follow up rounds, with 10-12 months between each round
8. Percent of participants who hold positive norms regarding gender-based violence is measured using a survey interview at baseline and three follow up rounds, with 10-12 months between each round
9. Percent of participants who hold equitable norms regarding the roles of women and men is measured using a survey interview at baseline and three follow up rounds, with 10-12 months between each round

Secondary outcome measures

No secondary outcomes.

Overall study start date

01/10/2015

Completion date

30/06/2020

Eligibility

Key inclusion criteria

Orphans and vulnerable children (OVC) caregivers:

1. Be identified as a household with one or more OVC children from the household screening
2. Serving as a main caregiver or guardian for an OVC child in their household
3. Must be 18 years of age or older
4. Willing and able to provide informed consent to participate

Adolescent girls and young women (AGYW) :

1. Be identified as a household with one or more out-of-school AGYW from the household screening
2. Must be 15–24 years of age and not currently attending school
3. Randomly selected if there is more than one out-of-school AGYW in the household
4. If aged 15-17, have a guardian willing and able to provide informed consent to participate
5. If aged 15-17, be willing and able to provide informed assent to participate
6. If aged 18-24, be willing and able to provided informed consent to participate

Other vulnerable populations (OVP):

1. Be identified as a household with one or more OVP from the household screening
2. Must be 18 years of age or older
3. Randomly selected if there is more than one OVP in the household
4. Willing and able to provide informed consent to participate

Participant type(s)

Mixed

Age group

Mixed

Lower age limit

15 Years

Sex

Both

Target number of participants

2070 participants (643 OVC, 657 AGYW, 770 OVP), 24 clusters

Key exclusion criteria

1. Not identified as being among eligible groups
2. Outside of age range
3. Incapable of providing informed consent/assent

Date of first enrolment

06/03/2017

Date of final enrolment

31/12/2019

Locations**Countries of recruitment**

Malawi

Study participating centre

University of Malawi, College of Medicine

Department of Public Health

School of Public Health & Family Medicine

University of Malawi College of Medicine

Private Bag 360

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Blantyre

Malawi

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Sponsor information**Organisation**

Population Council

Sponsor details

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Sponsor type

Research organisation

Website

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ROR

<https://ror.org/03zjj0p70>

Funder(s)

Funder type

Government

Funder Name

United States Agency for International Development

Results and Publications

Publication and dissemination plan

The key audiences for this study are governmental decision-makers, HIV service and programme providers, donors, and the communities themselves. We will promote research utilization through active outreach at the start of the study, and periodically throughout. We will plan to enlist an advisory group of relevant stakeholders and disseminate final results locally and internationally.

We will produce both a full technical report and manuscripts for peer-reviewed publication. Information generated from the study will be shared with the research communities through well established relationships with University of Malawi, College of Medicine and other academic institutions in Malawi and internationally. We also will disseminate study findings to key stakeholders in evaluation districts, including the Ministry of Health, as well as nationally. Results will also feed into regional and inter-regional dissemination efforts.

Intention to publish date

30/06/2021

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date