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Protecting women from economic shocks to fight HIV in Africa

Submission date
19/05/2021

Recruitment status
No longer recruiting

Registration date
27/05/2021

Overall study status
Completed

Last Edited
25/10/2024

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
HIV/AIDS is one of the leading cause of mortality globally and the leading cause among women aged 15 – 44 years. African women aged 15 – 24 are twice as likely to be infected with HIV than their male counterparts. In Cameroon, one of the countries with the highest gender disparity in HIV globally, adolescent girls are five times as likely to be infected with HIV than boys of the same age. Sexually transmitted infections (STIs) and HIV not only affect women and their sexual partners, they are also a special concern during pregnancy and pose serious health risks to unborn children. Reducing STI and HIV acquisition in high-risk women can translate into much wider societal benefits, and targeted interventions may provide excellent value for money. There is a growing number of studies showing that risks taken during transactional sex and commercial sex – in addition to biological susceptibility – are responsible for gender inequalities in HIV/AIDS. However, there is a superficial understanding of the main causes driving risky sexual behaviours of women who engage in those practices in Africa. Recent studies have shown that women mainly adopt risky sexual behaviours in order to cope with negative income shocks (e.g., agricultural and climatic shocks, illness or death of family members) and suggest that economic shocks are a substantial piece of the HIV puzzle in Africa. If women adopt risky sexual behaviours to cope with negative economic shocks, providing women with formal risk-coping strategies could be a very promising approach to prevent HIV. However, there are still important gaps in knowledge, mainly because no previous study has been designed to specifically answer this research question. The aim of this study is to estimate the effectiveness of health insurance as a strategy to protect women from economic shocks in order to prevent STIs and HIV.

Who can participate?
Adolescent girls and young women aged between 15 and 24 years old, who engage in commercial or transactional sex in Yaounde, Cameroon, and who have at least one economic dependent living in that area.

What does the study involve?
Participants are randomly allocated into two different groups, a treatment group and a control group. The treatment group will receive free health insurance for the participant and up to six of their economic dependents and the control group will not. Over a 12-month period participants will be asked to answer weekly SMS survey diaries (10 questions each week) and participate in

three surveys which last 1 hour 30 minutes on average. The researchers will also test for STIs and HIV through the collection of vaginal swabs and blood. Some of the participants will also be asked to participate in interviews and focus groups to supplement information collected in the surveys.

What are the possible benefits and risks of participating?
Participants in the treatment group will benefit from a free health insurance product for 12 months. Participants will receive XAF 2,000 after each survey in order to compensate for the time lost and to reimburse any transport cost incurred. Participants will also be given free SMS to reply to weekly SMS diary surveys. A compensation of XAF 1,000 will also be given every month to participants with a diary completion rate of over 90% over the last 30 days in order to compensate you for the time spent replying to the SMS. Participants will have four free STI tests at the beginning, middle and end of the study period, free counselling services will be provided to all participants. STI treatment and HIV testing and treatment will be provided to those who test positive. Some of the topics discussed are difficult to discuss and can cause participants stress, but participants will be able to speak to a health professional/counsellor at any time.

Where is the study run from?
Johns Hopkins Cameroon Program (Cameroon)

When is the study starting and how long is it expected to run for?
August 2018 to September 2022

Who is funding the study?
UK Research and Innovation (UK)

Who is the main contact?
Dr Aurelia Lepine
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Study website
https://www.ucl.ac.uk/global-health/research/z-research/power-project

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
17341/001

Study information

Scientific Title
Protecting women from economic shocks to fight HIV in Africa (POWER): a randomised controlled trial

Acronym
POWER

Study objectives
Current study hypothesis as of 26/11/2021:
Women at high risk of HIV in Africa use risky sexual behaviours as a way to cope with economic shocks. Providing health insurance to their economic dependents is effective to reduce risky sexual behaviours, and prevent sexually transmitted infections (STIs) and HIV infection among adolescent girls and young women who are at risk of HIV.

Previous study hypothesis:
Women who engage in transactional and commercial sex in Africa use risky sexual behaviours as a way to cope with economic shocks. Providing health insurance to their economic dependents is effective to reduce risky sexual behaviours, and prevent sexually transmitted infections (STIs) and HIV infection among adolescent girls and young women who engage in commercial and transactional sex.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 22/05/2020, UCL Research Ethics Committee (Office of the Vice Provost Research, 2 Taviton Street, University College London, UK; +44 (0)20 7679 8717; ethics@ucl.ac.uk), ref: 17341/001
2. Approved 03/12/2020, the national ethics committee in Cameroon (CNERSH, Yaoundé Cameroun, Hygiène Mobile, Messa; +237 (0)222 23 45 79; minsanterecherche@yahoo.fr), ref: 2020/12/1313

Study design
Multicenter interventional non-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Prevention of HIV and other STIs

Interventions
Participants will be recruited using respondent-driven sampling (RDS), a chain-referral sampling model. Sampling begins with the selection of seeds, and each seed is asked to recruit up to three members of their social network who satisfied the study's eligibility criteria.

The main aim of the project is to determine whether having health insurance reduces risky sexual behaviours, STIs and HIV transmission. To do this, the research team will implement a two-armed, blinded randomised controlled trial which compares the outcomes of those who are given a free health insurance product to the participant and their economic dependents over a period of 12 months with that of the control group. The health insurance product covers illness and accident up to a value of FCFA 500,000 for the participant and up to six of their economic dependents. Economic dependents can include family members, friends and sex work intermediaries (e.g. pimp). The product excludes chronic disease. The health insurance product is provided by GMC assurances and medical care is provided by Hospital Cite Verte in Yaounde.

Randomisation will be participative, participants will draw a ball from a sealed bag individually in a private environment. The choice of randomisation was informed by formative research that has indicated that this method would be acceptable while avoiding most adverse effects (e.g. jealousy, risk of violence).

The treatment and control group will participate in three quantitative surveys and complete biological tests (blood test and vaginal swabs to test for STIs and HIV) at month 1 (baseline), month 6 and month 12 of the study. The surveys take place at the two partner community-based organisations sites. Both groups will complete weekly SMS diaries which require that they answer questions on their economic shocks and sexual behaviours for the week. The SMS survey is conducted by DINA surveys.

Some of the participants will also engage in in-depth interviews and focus groups to understand further their experiences.

Participants are recruited onto the study participants initially. They are made aware that they may later have to re-consent onto the study as “treatment group” or "control group"

participants once recruitment and baseline have taken place. At the initial stage of recruitment, participants are not given full information about the treatment in order to minimise the incentives of taking part in the study. Once recruitment onto the study is complete, all participants will be randomly allocated to either the treatment or control group. Participants will then be informed of the group they have been allocated to and will receive insurance contract for themselves and their economics dependents.

Intervention Type
Behavioural

Primary outcome measure
Measured using questionnaires developed by the study team where not otherwise stated at 1, 6 and 12 months:
1. STI acquisition measured using % test positive for syphilis, % test positive for chlamydia, % test positive for gonorrhoea. STI symptoms prevalence measured using % who had any symptoms of STI in the last 30 days: vaginal discharge, lower abdominal pain outside of diarrhoea or menstrual period, wound or ulcer on genitals, burns during urination, swelling in the groin, itching in the genital area, pain during the sexual act, bleeding outside of period
2. HIV status measured using % testing HIV positive

Secondary outcome measures
Measured using questionnaires developed by the study team where not otherwise stated at 1, 6 and 12 months:
1. Physical health of participants measured using % of participants with good health, % of participants with chronic illness other than Hepatitis B, average number of chronic illnesses, % participants who were sick in the last 30 days, % who sought treatment from a qualified health worker if sick in the last 30 days
2. Physical health of economic dependents measured using % of economic dependents with good health, % of economic dependents with a chronic illness, average number of chronic illnesses per economic dependent, % economic dependents who were sick in the last 30 days, % economic dependent who were sick during sex act with last client, % economic dependent who were sick during sex act with the penultimate client, % of children with good health
3. Beliefs regarding control over own health measured using % who believe that nothing can be done to prevent illness, % who believe that being in good health is a matter of luck
4. Poverty measured using total expenditures, asset index, income from sex work, amount of savings, % who have Informal shock-coping strategies, average amount of transfers received and sent, % who have a debt, amount of the debt, food insecurity
5. Education/training measured using % school dropout, new enrolment in schools, % who are undertaking professional training
6. Other occupation measured using transitions out of sex work, % who have other occupation, share of sex work income in total income
7. Risky sexual behaviours measured using % of condom use with last and penultimate client using a double list experiment and the colourbox method, a newly indirect elicitation method developed by the team members, number of clients per week, type of sex acts performed with last client, self-reported risk preferences with sex (out of 10 scale), % of were pregnant the last 6 months, % who performed both transactional sex and sex work
8. Violence measured using % who experienced violence (threats, physical, sexual, emotional /psychological) the last time they had sex with a client, % who experienced violence the penultimate time they had sex with a client, % who experienced violence by current partner in the last 6 months, % who experienced violence by a sugar daddy in the last 6 months, % who experienced violence by another sex worker in the last 6 months, % who experienced violence

by occasional client in the last 6 months, % who experienced violence by a regular client in the last 6 months, % who experienced violence by police in the last 6 months, % who experienced violence by their pimp in the last 6 months, % who experienced violence by hostel owners in the last 12 months
9. Stress measured using perceived stress scale 4 (PSS-4)
10. Self-efficacy measured by participants ability to deal with issues in different domains of their life
11. Loneliness measured using UCLA 3 Item Loneliness scale
12. Discrimination measured using Everyday Discrimination Scale (Short Version)
13. Stigma measured using % who have at least one of their family or friends aware that the participant has having paid sex, % who expect discrimination by family if HIV positive, % who consider themselves as a sex worker
14. HIV and STI knowledge measured using knowledge of participants regarding ways HIV can be transmitted, average knowledge of STI symptoms
15. Social network measured using the number of friends in sex work, the number of peers who provide financial support
16. Mental health measured using % that are depressed using PHQ-9 scale, % who are happy, % satisfied with life, % with good self-esteem

Overall study start date
01/08/2018

Completion date
01/09/2022

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 26/11/2021:
1. Engaging in risky sexual practices in Yaounde region, Cameroon
2. Aged between 15 and 24 years old
3. Not married
4. Woman
5. Have at least one economic dependent living in Yaounde
6. Be able to respond to text messages on phone
7. Have a password-protected cell phone
8. Be HIV negative at enrolment

Previous participant inclusion criteria:
1. Be engaged in commercial or transactional sex in Yaounde region, Cameroon
2. Aged between 15 and 24 years old
3. Not married
4. Identify as a woman
5. Have at least one economic dependent living in Yaounde
6. Be able to respond to text messages on phone
7. Have a password-protected cell phone
8. Be HIV negative at enrolment

Participant type(s)
Other

Age group
Mixed

Sex
Female

Target number of participants
1500

Key exclusion criteria
1. HIV positive
2. Not have the consent of a parent or guardian for those under 21

Date of first enrolment
02/06/2021

Date of final enrolment
02/07/2021

Locations

Countries of recruitment
Cameroon

Study participating centre
RENATA
Yaounde
Cameroon
BP 14606

Study participating centre
Horizons Femmes
938, Rue Elig Effa Mini Ferme-Melen, en face de Fokou Melen
Yaounde
Cameroon
8480

Sponsor information

Organisation
UK Research and Innovation

Sponsor details

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Swindon
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+44 (0)1793 444 164
JeSHelp@je-s.ukri.org

Sponsor type
Government

Website
https://www.ukri.org/

ROR
https://ror.org/001aqnf71

Funder(s)

Funder type
Government

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
At the end of this study, the researchers plan to organise a national workshop bringing together 70 national stakeholders and including researchers, health professionals, senior advisors, all relevant national and international non-governmental organizations (NGOs)/community-based organizations (CBOs), government officials and study participants to feedback, reflect on the

study results together, as well as discuss policy implications. Results will be presented at conferences in economics and public health. Results will be published in high-impact peer-reviewed journals.

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
Data will be made openly available through the University College London (UCL) data repository, subject to the ability to remove personally identifiable information. Data will be deposited with the UCL research data repository (https://www.ucl.ac.uk/library/research-support/research-data-management/ucl-research-data-repository), where it will be given a Digital Object Identifier (DOI). The DOI will be cited in project reports and journal publications through a Data Access Statement or citation list. Metadata will also be made available to 3rd party research catalogues, such as https://datamed.org/.
Anonymised data will be made openly available using a permissive licence, such as Creative Commons Attribution (CC-BY). If complete anonymity cannot be provided, it will be made available through a controlled access system. If data must be made available via controlled access, interested parties will be asked to provide information on their research (purpose, institutional affiliation, ethics approval) and sign a data-sharing agreement indicating they will comply with the consent form and will not attempt to re-identify individuals. Access requests will be evaluated by the project team in the first instance. In cases where an access request is denied and the requester wishes to appeal, the request will be escalated to the UCL Research Governance Committee for consideration. Informed consent from all participants (and their guardian/parent if needed) will be sought at all stages of the study.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/10/2024	25/10/2024	Yes	No