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Patient-centred peer support intervention to promote the detection, reporting and management of adverse drug reactions among people living with HIV in Uganda

Submission date
26/04/2021

Recruitment status
No longer recruiting

Registration date
02/06/2021

Overall study status
Completed

Last Edited
03/01/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Patient-centred peer support has shown promise in the management of chronic illnesses such as diabetes and mental health, and in improving retention in HIV care and adherence to HIV medicines. Peer support could be used to promote the detection, reporting and management of side effects related to HIV medicines in people living with HIV in Uganda. This study aims to develop and pilot-test a patient-centred peer support intervention to strengthen the detection, reporting and management of side effects to HIV medicines among people living with HIV receiving dolutegravir-containing regimens and/or isoniazid preventive therapy in Uganda.

Who can participate?
People aged 15 years and older who are living with HIV and receiving dolutegravir-based regimens and isoniazid preventive therapy, as well as community health workers and expert clients.

What does the study involve?
The study plans to implement a peer support intervention to help people living with HIV to report side effects of their HIV medicines. Mobile technologies will be used such as the unstructured supplementary service data (USSD) protocol which is compatible with both basic phones and high-tech smartphones; and the Med Safety® mobile application for high-tech smartphones.
People living with HIV will be assigned to peers to support their antiretroviral therapy for 4-6 months. The peer supporters will constitute a mixed group of community health workers and expert clients. The peer supporter will be a layperson who a person living with HIV can identify with and rely on to improve his/her healthcare-seeking behaviour. This layperson will be a person living with HIV with more experience in the use of antiretroviral therapy than the targeted person living with HIV; or a recognized community health worker.

People living with HIV at 12 intervention sites will receive peer support and training on how to use the USSD code and Med Safety® and 12 control sites will receive only training on the USSD code and Med Safety®.

What are the possible benefits and risks of participating?
The data collected will ultimately improve medication safety for people living with HIV. Also, the improved management of drug-related side effects as a result of increased linkage to care will promote good health outcomes.

Where is the study run from?
Makerere University (Uganda)

When is the study starting and how long is it expected to run for?
November 2020 to June 2022

Who is funding the study?
World Health Organization (Switzerland)

Who is the main contact?
Dr Ronald Kiguba
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MAKSHSREC-2020-64

Study information

Scientific Title
Development and implementation of a patient-centred peer support intervention to promote the detection, reporting and management of adverse drug reactions among people living with HIV in Uganda

Study objectives
1. The peer support intervention for promoting the detection, reporting and management of adverse drug reactions among people living with HIV (PLHIV) is feasible and acceptable
2. The peer support intervention will increase the number of adverse drug reaction reports submitted to the National Pharmacovigilance Centre by PLHIV during 4-months of follow-up

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/01/2021, Makerere University School of Health Sciences Research & Ethics Committee (PO Box 7072, Kampala, Uganda; +256 (0)200903786; healthsciences.irb@gmail.com, deanshs@chs.mak.ac.ug), ref: MAKSHSREC-2020-64

Study design
Quasi-experimental design with pre-post and there-there comparisons

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Pharmacovigilance among people living with HIV

Interventions
PLHIV in the intervention group will be assigned to peers to support their antiretroviral therapy (ART) for 4-6 months. Peer supporters will constitute a mixed group of community health workers (CHWs) and expert clients. The peer supporter will be a layperson whom a PLHIV can identify with and rely on to improve his/her healthcare-seeking behaviour. This layperson will be a PLHIV with more experience in the use of ART than the targeted PLHIV; or a recognized CHW.

The assignment of PLHIV to peer supporters will not be random; it will depend on the available number and calibre of peer supporters. Each peer supporter will be assigned five (5) PLHIVs from his/her community with the target of having weekly (minimum fortnightly) face-to-face and phone call interactions between the peer -supporter and each assigned PLHIV. Thus, a peer - supporter will be expected to interact with one PLHIV per day and five PLHIV in 5 days each week. Peer supporters will use one-on-one in-person support blended with mobile phone-based interaction to encourage each assigned PLHIV to recognize and report suspected adverse drug reactions (ADRs) to the peer supporter, health care professional (HCP) or National Pharmacovigilance Centre (NPC). The peer supporter will also administer a short weekly questionnaire to each assigned PLHIV regarding ADR experience in the past 1 week.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 04/04/2022:

1. Attrition rate measured by number of study participants who remain in the study until the end of follow-up at 4 months
2. Number of ADR reports submitted to NPC by PLHIV as measured by questionnaire and data abstraction from the national pharmacovigilance database at baseline and 4 months

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Previous primary outcome measure:

Attrition rate recorded as the number of study participants who remain in the study until the end of follow-up at 4 months

Secondary outcome measures
Current secondary outcome measures as of 12/04/2022:

1. Acceptability of the peer support intervention measured using a questionnaire and qualitative interviews at 4 months post-intervention
2. Barriers/facilitators of the peer support intervention measured using a questionnaire during

the intervention and qualitative interviews at 4 months post-intervention
3. Fidelity to the peer support intervention measured using a questionnaire and qualitative interviews at 4 months post-intervention
4. Rate of ADR-reporting to NPC by PLHIV as measured by questionnaire and data abstraction from the national pharmacovigilance database at baseline and 4 months
5. Quality of ADR-reports by PLHIV measured by questionnaire and data abstraction from the national pharmacovigilance database at baseline and 4 months
6. Time to ADR-reporting to NPC by PLHIV since enrolment measured by questionnaire and data abstraction from the national pharmacovigilance database during the 4 months
7. Time from ADR onset to registration in the national pharmacovigilance database measured by questionnaire and data abstraction from the database during 4 months
8. Health-related quality of life measured by questionnaire at baseline and 4 months
9. Management of ADRs recorded using a questionnaire during the 4 months
10. Number of PLHIV linked to health facilities by peer supporters for ADR management as measured by questionnaire during the 4-month intervention period
11. Health-seeking behaviour measured using a questionnaire at baseline and 4 months
12. Self-efficacy to report ADRs measured by questionnaire at baseline and 4 months
13. Self-reported ART adherence measured by questionnaire at baseline and 4 months
14. Mood (positive/ negative affect) measured by questionnaire at baseline and 4 months

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Previous secondary outcome measures as of 04/04/2022:

1. Acceptability of the peer support intervention measured using questionnaires and qualitative interviews at 4 months post-intervention
2. Barriers/facilitators of the peer support intervention measured using a questionnaire during the intervention and qualitative interviews at 4 months post-intervention
3. Rate of ADR-reporting by PLHIV measured using a questionnaire at baseline and 4 months
4. Time to ADR-reporting by PLHIV measured using a questionnaire from baseline
5. Health-related quality of life measured using a questionnaire at baseline and 4 months
6. Management of ADRs recorded using a questionnaire during the 4 months
7. Health seeking behaviour measured using a questionnaire at baseline and 4 months
8. Positive and negative affect measured using a questionnaire at baseline and 4 months

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Previous secondary outcome measures:

1. Acceptability of the peer support intervention measured using questionnaires and qualitative interviews at 4 months post-intervention
2. Barriers/facilitators of the peer support intervention measured using a questionnaire during the intervention and qualitative interviews at 4 months post-intervention
3. Number of ADRs reported by PLHIV using a questionnaire at baseline and 4 months
4. Rate of ADR-reporting by PLHIV measured using a questionnaire at baseline and 4 months
5. Time to ADR-reporting by PLHIV measured using a questionnaire from baseline
6. Health-related quality of life measured using a questionnaire at baseline and 4 months
7. Management of ADRs recorded using a questionnaire during the 4 months
8. Health seeking behaviour measured using a questionnaire at baseline and 4 months
9. Positive and negative affect measured using a questionnaire at baseline and 4 months

Overall study start date

01/11/2020

Completion date
30/06/2022

Eligibility

Key inclusion criteria
PLHIV:
1. Accessible PLHIV aged 15 years and older
2. Receiving antiretroviral therapy at the study sites
3. Own a mobile phone (smartphone or basic feature phone)
4. Provide written/thumb-printed informed consent

Community health workers and expert clients recognized and seconded by the study sites or patient safety groups, who own mobile phones

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
600 PLHIV, 60 peer supporters

Key exclusion criteria
1. PLHIV who will have received antiretroviral therapy for less than 6 months
2. Community health workers and expert clients who are unable to commit at least 4 months to the study

Date of first enrolment
15/05/2021

Date of final enrolment
15/06/2021

Locations

Countries of recruitment
Uganda

Study participating centre
Makerere University
Department of Pharmacology & Therapeutics

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Sponsor information

Organisation
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Sponsor type
University/education

Website
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ROR
https://ror.org/03dmz0111

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organization

Alternative Name(s)
, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Switzerland

Results and Publications

Publication and dissemination plan
1. The study protocol will be peer-reviewed and published
2. The mobile app and unstructured supplementary service data (USSD) users will immediately benefit from two-way communication as they will receive medication-safety alerts from NPC in addition to their submission to NPC of ADR reports.
3. The researchers plan to present the project's research findings at local stakeholders' workshops organized to ensure the balanced representation of HCPs, administrators, policymakers, patient safety groups, the public and other local and international partners. At least one policy brief will be prepared from this work. The researchers shall also disseminate the results at three or more local and international conferences, engage the public through local and international television channels, and through social media (Facebook, Twitter, WhatsApp, blogging etc). They shall publish at least two manuscripts from this work in internationally recognized peer-reviewed journals.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
Current individual participant data (IPD) sharing statement as of 30/11/2021:
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

Previous individual participant data (IPD) sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Ronald Kiguba (kiguba@gmail.com). The raw data will become available as soon as possible after data curation and indefinitely.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		19/05/2022	23/05/2022	Yes	No