ISRCTN67031403 https://doi.org/10.1186/ISRCTN67031403

Impact of youth lay health workers on HIV service delivery in South Africa

Submission date	**Recruitment status**	[_] Prospectively registered
25/10/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
10/11/2022	Completed	[X] Results
Last Edited	**Condition category**	[X] Individual participant data
05/12/2023	Other	

Plain English summary of protocol

Background and study aims
Youth Health Africa (YHA) places unemployed young adults in one-year internships at health facilities in South Africa. While YHA is primarily designed to foster youth empowerment and improve employment prospects for youth, it also hopes to strengthen the health system. This study was done to assess the impact of YHA interns (specifically those assigned to programmatic roles, like HIV testing) on the delivery of HIV services.

Who can participate?
Health facilities in Ngaka Modiri Molema district of the North West province, South Africa, that partnered with the Aurum Institute for delivery of HIV services

What does the study involve?
This study involved randomising health facilities to receive either administrative interns (e.g., those tasked with data entry) or administrative and programmatic interns (e.g., those tasked with HIV testing or tracing patients who did not return to the clinic for treatment). Once facilities were randomized and interns were placed at the facilities, the YHA program operated as it normally would. Interns were eligible to work for a year and were supervised by health facility staff; in other words, the YHA program in this study was implemented as it was in non-study circumstances. We examined HIV service delivery outcomes, namely HIV testing, linkage to care, and retention in care after interns had been at the facility for eleven months. This study did not involve us collecting study-specific data.

What are the possible benefits and risks of participating?
Benefits for the health facility included the potential to have extra people supporting HIV service delivery at facilities, which could improve patient care. Risks include facility staff being burdened by having extra people to train and support at the health facilities, which could detract from patient care.

Where is the study run from?
The Aurum Institute (South Africa)

When did the study start and how long did it run?
August 2019 to August 2021

Who funded the study?
The Aurum Institute (South Africa)
The Fred Hutchinson Cancer Research Center (USA)

Who is the main contact?
Dr Salome Charalambous (Principal Investigator) (South Africa)
scharalambous@auruminstitute.org

Contact information

Type(s)
Principal Investigator

Contact name
Prof Salome Charalambous

Contact details
The Aurum Institute
29 Queens Rd
Parktown
Johannesburg
South Africa
2194
+27 (0) 82 856 1146
scharalambous@auruminstitute.org

Type(s)
Scientific

Contact name
Dr Deanna Tollefson

ORCID ID
http://orcid.org/0000-0002-6901-1854

Contact details
Fred Hutchinson Cancer Research Center
Seattle
United States of America
98109
+1 6127475573
dtollef@uw.edu

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Impact of youth lay health workers on HIV service delivery in South Africa: a pragmatic cluster randomized trial

Study objectives
The presence of Youth Health Africa program interns at health facilities would strengthen HIV service delivery, as measured by HIV testing, linkage to care, and retention in care

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 01/11/2019, University of Witwatersrand Human Research Ethics Committee (Suite 198, Private Bag x2600, Houghton 2041, Johannesburg, South Africa; +27 11 274 9200; HREC-Medical.ResearchOffice@wits.ac.za), ref: 190907
2. Approved 29/11/2019, North West province Department of Health (3801 First Street, New Office Park, Mahikeng, 2735, South Africa; +27 18 391 4504; NMapogo@nwpg.gov.za), ref: none available

Study design
Pragmatic randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
HIV service delivery, specifically HIV testing, treatment initiation, and retention in care

Interventions

This was a two-arm study, with 1:1 randomization at performed among 20 health facilities to compare the impact of having Youth Health Africa (YHA) program interns on HIV service delivery, as measured by HIV testing, treatment initiation, and retention in care. The health facilities will be randomized to the intervention and the outcome will be assessed using aggregate-level, routinely collected HIV service delivery data from these facilities.

The Aurum Institute held an in-person randomization meeting with the health facility leaders, program leaders, and district health officers to randomize sites. Before the meeting, a computer program was used to generate all possible randomizations (given there were 20 sites and we used 1:1 randomization, there were 184,756 possible ways to allocate 20 facilities to two arms). We then randomly selected 10,000 of the randomisations for convenience and listed these in an Excel spreadsheet. Each randomization option was given a number (0000 to 9999); each randomization option had 10 facility names listed in “Group A” and 10 facility names listed in “Group B”. The randomization process was participatory. Ten golf balls of the same size and color were labelled 0-9 and placed in an opaque bag. Four participants at the event (facility leaders) drew golf balls, with replacement, to determine the randomization option. The first person selected a ball, which would correspond to the first number of the randomization option; the second person pulled a ball that would correspond to the second number of the randomization option, and so on. A fifth person picked a golf ball to determine whether Group A or Group B would be the intervention group (i.e., if the number was ‘even’, Group A would be in the intervention group; if ‘odd’, Group B would be the intervention group.) This process was routinely performed by the Aurum Institute for their clinical trials because host sites find it empowering to be engaged in the randomization process, and thus are more likely to be satisfied with their group allocation.

YHA places young adults as lay health worker interns for one year at health facilities to support non-clinical tasks, including programmatic tasks (e.g., HIV testing and counseling) and administrative tasks (e.g., filing patient records, and data entry). This study tested the impact of this intervention, namely the impact of YHA interns assigned to programmatic tasks (e.g., as HIV testers and counsellors, linkage officers, or tracers). This was a two-arm study, with 1:1 randomization at 20 purposively sampled health facilities. There were 10 facilities in each arm. All 20 facilities received a minimum package: 1-2 interns assigned to administrative roles, such as filing or data capture (henceforth called “admin interns”). This helped to ensure consistent data quality between intervention and control facilities; this was necessary to ensure changes we observed were due to an impact on HIV service delivery and not an artefact of improvements in data quality.

Intervention facilities each received the minimum package plus the intervention package: 1-2 interns assigned to support programmatic roles, like HIV testing and counseling, patient navigating, and tracing (henceforth called “program interns”).

Intervention Type

Other

Primary outcome measure

Aggregate (%) people tested for HIV, measured by the number of people tested for HIV / total number of people who visited the facility (measured by routinely collected variables: received HIV Testing Services (HTS)_ and received test results (TST) / Headcount) assessed in two ways:
1. Cumulative impact (difference-in-difference analysis): January - August 2020 versus January - August 2021

2. Monthly variation (controlled, interrupted time series analysis): October 2019 - Sept 2020 (Pre-intervention) versus October 2020 - August 2021

Data were routinely reported to The Aurum Institute from the facility through TIER.Net, South Africa's national HIV surveillance system

Secondary outcome measures

Testing and Treatment Indicators:
1. % positive for HIV (Number testing positive for HIV / number tested for HIV) (measured by routinely collected variables: HTS_POS/ HTS_TST)
2. % initiated on treatment in 14 days (Number starting treatment within 14 days of HIV diagnosis/total diagnosed with HIV) (Measured by variables: INITIATED_14DAYS / HTS_POS)

Retention Indicators:
3. % early default (Number who did not return for treatment within 28 days of appointment / Number on treatment) (Measured by variables: ART_DEFAULT_EARLY / TX_CURR90)
4. % late default (Number who did not return for treatment within 89 days of appointment / Number on treatment) (Measured by variables: ART_DEFAULT_LATE / TX_CURR90)
5. % loss to follow-up (Number of patients out of care for ≥90 days with no outcome / Number of treatments) (Measured by variables: ART_DEFAULT_ULTF / TX_CURR90)

We assessed these outcomes in two ways:
1. Cumulative impact (difference-in-difference analysis): January - August 2020 versus January - August 2021 (Note: First few months of the trial were designated as a 'run-in' period and thus excluded from this part of the analysis). Note: Testing and treatment outcomes were aggregated across the eight-month baseline and study periods (e.g., % tested for HIV = total tested for HIV over 8 months / total headcount for 8 months).
The denominator used to calculate retention outcomes could not be aggregated by month, so monthly means were calculated for the default and loss to follow-up outcomes for baseline and study periods.
2. Monthly variation (controlled, interrupted time series analysis): Time series containing October 2019 - September 2020 (Pre-intervention) versus October 2020 - August 2021

Tertiary Outcomes:
1. % of HIV testing among young people [aged 10-29 years old] (HIV testing among young people / all tested for HIV)
2. % of HIV testing among males (HIV testing in males / all tested for HIV)
3. % of HIV testing among young males (HIV testing in young males / all tested for HIV)
*Only the 'cumulative impact' was assessed for these indicators, as these were tertiary outcome measures

Data were routinely reported to The Aurum Institute from the facility through TIER.Net, South Africa's national HIV surveillance system

Overall study start date

01/08/2019

Completion date

31/08/2021

Eligibility

Key inclusion criteria
Participant type: Health facilities.
Health facilities were eligible for this study if they were:
1. Located in Ngaka Modiri Molema district
2. Offered HIV services as part of routine clinic programs/operations
3. Had never received interns from YHA
4. Collaborated with Aurum Institute as a PEPFAR implementing partner
5. Had a need for three interns (the minimum number of interns that would be placed in a clinic assigned to the intervention group)
6. Interested in participating in the intervention

Participant type(s)
Other

Age group
Other

Sex
Both

Target number of participants
20

Total final enrolment
20

Key exclusion criteria
1. Not in Ngaka Modiri Molema district, North West province
2. Had previously received interns from YHA
3. Was not a partner of Aurum Institute
4. Was not perceived by healthcare leadership (facility leaders and district/sub-district leaders) to need three interns

Date of first enrolment
01/09/2020

Date of final enrolment
30/09/2020

Locations

Countries of recruitment
South Africa

Study participating centre
Aurum Institute
29 Queens Rd
Parktown

Johannesburg
South Africa
2194

Study participating centre
Gopane Clinic
Ngaka Modiri Molema District
North West Province
South Africa
2882

Study participating centre
Boikhutso Clinic
Ngaka Modiri Molema District
North West Province
South Africa
2740

Study participating centre
Blydeville 2 Clinic
Ngaka Modiri Molema District
North West Province
South Africa
2740

Study participating centre
Driefontien Clinic
Ngaka Modiri Molema District
North West Province
South Africa
2865

Study participating centre
Groot Marico Clinic
Ngaka Modiri Molema District
North West Province
South Africa
2740

Study participating centre
Vrisgewaagte Clinic
Ngaka Modiri Molema District
North West Province
South Africa
2740

Study participating centre
Lehurutshe Hospital
Ngaka Modiri Molema District
North West Province
South Africa
2880

Study participating centre
Thusong Hospital
Ngaka Modiri Molema District
North West Province
South Africa
2740

Study participating centre
Lekubu/Braklaagte Clinic
Ngaka Modiri Molema District
North West Province
South Africa
2740

Study participating centre
Sannieshof CHC
Ngaka Modiri Molema District
North West Province
South Africa
2740

Study participating centre
Atamelang CHC
Ngaka Modiri Molema District
North West Province
South Africa
2740

Study participating centre
Blydeville Clinic
Ngaka Modiri Molema District
North West Province
South Africa
2747

Study participating centre
Delareyville CHC
Ngaka Modiri Molema District
North West Province
South Africa
2740

Study participating centre
Khunotswana Clinic
Ngaka Modiri Molema District
North West Province
South Africa
2740

Study participating centre
Kunana Clinic
Ngaka Modiri Molema District
North West Province
South Africa
2747

Study participating centre
Lichtenburg Municipal Clinic
Ngaka Modiri Molema District
North West Province
South Africa
2740

Study participating centre
General de la ray Hospital
Ngaka Modiri Molema District

North West Province
South Africa
2740

Study participating centre
Itsoseng CHC
Ngaka Modiri Molema District
North West Province
South Africa
2740

Study participating centre
Ottosdal CHC
Ngaka Modiri Molema District
North West Province
South Africa
2740

Study participating centre
Tlhabologang Clinic
1052 Van Der Walt Street
Ngaka Modiri Molema District
North West Province
South Africa
2740

Sponsor information

Organisation
Aurum Institute

Sponsor details
29 Queens Rd
Parktown
Johannesburg
South Africa
2194
+27 (0) 82 856 1146
info@auruminstitute.org

Sponsor type

Research organisation

Website
https://www.auruminstitute.org/

ROR
https://ror.org/01tcy5w98

Funder(s)

Funder type
Research organisation

Funder Name
Aurum Institute

Funder Name
Fred Hutchinson Cancer Research Center

Alternative Name(s)
Hutchinson Center, Fred Hutch, The Hutch, Fred Hutchinson Cancer Research Center, FHCRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United States of America

Results and Publications

Publication and dissemination plan
1. Planned publication in a high-impact peer-reviewed journal
2. Final results were shared with key stakeholders between May-July 2022 in a presentation and manuscript format

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Deanna Tollefson, dtollef@uw.edu. Monthly, aggregate facility-level data for standard HIV prevention and care indicators used in this analysis will be shared. Facility names have been removed (e.g., they will be referred to as Facility 1, Facility 2, etc in datasets shared outside the study team). Data were available at the time of registration. The IRB determined no written consent was necessary as health facilities (not individuals) were participants in this study. Facilities were the subject and unit of analysis in this study. Eligible facilities were invited to participate in the intervention and could decline without consequence. Leaders at the facilities interested in participating verbally agreed to engage in the study. Interns participated in their work program, under normal program circumstances. The study did not collect data on interns, negating the need for consent from these individuals.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			28/04/2023	No	No
Statistical Analysis Plan			28/04/2023	No	No
Dataset	S1 File	30/11/2023	05/12/2023	No	No
Results article		30/11/2023	05/12/2023	Yes	No