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

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|---|---|---|
| **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

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Parktown
Johannesburg
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2194
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scharalambous@auruminstitute.org

### Type(s)
Scientific

### Contact name
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# Additional identifiers

# 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

## Primary study design
Interventional

## Study design
Pragmatic randomized trial

## Study type(s)
Other

## 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(s)
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

## Key secondary outcome(s)
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

### 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

### Healthy volunteers allowed
No

### Age group
Other

### Sex
All

### 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
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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

**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, Fred Hutch Cancer Center, FHCRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
Research institutes and centers

**Location**
United States of America

# Results and Publications

## 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? |
|---|---|---|---|---|---|
| Results article | | 30/11/2023 | 05/12/2023 | Yes | No |
| Dataset | S1 File | 30/11/2023 | 05/12/2023 | No | No |
| Protocol file | | | 28/04/2023 | No | No |
| Statistical Analysis Plan | | | 28/04/2023 | No | No |