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Women of worth (WOW) project

Submission date
17/02/2020

Recruitment status
No longer recruiting

Registration date
20/04/2020

Overall study status
Completed

Last Edited
18/01/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The African continent is currently undergoing a youth bulge. It is estimated that by 2030, 1 in every 4 individuals will be African, the vast majority of them under the age of 35 years. However, over 40% of all new HIV infections occur among youth and 85% of young people living with HIV live in Sub-Saharan Africa. Adolescents and young adults are at increased risk of HIV infection due to the many developmental, psychological, social, and structural transitions that take place in this period of the life course, yet engaging and retaining adolescents actively in health care promotion and provision is challenging in every setting worldwide.

Adolescent girls and young women (AGYW) are particularly affected and bear the brunt of the African HIV epidemic. In South Africa, young women are 4-6 fold more likely to be HIV infected than their male counterparts and in 2014 South African girls alone contributed 10% to global new HIV infections among 15-19-year-old girls. The HIV epidemic in South Africa is generalised and dominated by heterosexual HIV transmission. Drivers of HIV risk among young South African women include early age of sexual debut (<15 yrs), multiple and often older sexual partners, inconsistent/ poor condom use (<50%), coercion and violence (10%), trans-generational sex (25%), transactional sex (25%), and sex with strangers (12%). This correlates with the high prevalence of HIV and other STI's, as well as the high incidence of teenage pregnancy (94 000 SA school girls fell pregnant in 2011) in South African young women and girls.

The WOW study aim is to enhance participants' sexual and reproductive health and well-being through preventive and promotive health and psychosocial interventions, whilst enhancing their meaningful transition to adulthood.

Who can participate?
Both HIV-infected and un-infected young women aged 19-24 years

What does the study involve?
The first 5,000 participants will be randomised to receive either a care "empowerment" initiative alone, or to an empowerment programme attached to R300 cash incentive conditional on attendance. The next 5,000 participants will all receive care plus cash incentive based on the success of the initiative in the first 5,000 participants. Each participant will receive up to 12 months' active empowerment intervention and up to 36 months' passive clinic service, including uptake monitoring and evaluation.

What are the possible benefits and risks of participating?
Possible benefits include:
1. A reduction in the measured outcomes, including HIV incidence and unintended pregnancy prevalence in young women
2. The incentive + care package will encourage more women to attend the empowerment sessions and directly or indirectly lead to an improvement in measurement outcomes, greater than that seen with the care alone package (as has been in seen in similar intervention studies)
3. This project will supplement a broader Global Fund project run by the DTHF under the auspices of the Western Cape Provincial Government and will support achievement of the project's overall goals.
This project does not pose any threat to participant physical or emotional wellbeing; but it is possible that they could suffer loss of privacy or be stigmatized in some way due to participation

Where is the study run from?
Desmond Tutu HIV Foundation (South Africa)

When is the study starting and how long is it expected to run for?
May 2017 to December 2020

Who is funding the study?
1. The Global Fund for AIDS, Tuberculosis, and Malaria
2. Health Department, Provincial government of the Western Cape (PAWC) (South Africa)

Who is the main contact?
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Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
WOW Protocol

Study information

Scientific Title
A social protection plus empowerment programme for young women (19-24 years)

Acronym
WOW

Study objectives
1. Both incentive + care and care only packages will result in a reduction in the measured outcomes, including HIV incidence and unintended pregnancy prevalence in young women
2. The incentive + care package will encourage more women to attend the empowerment sessions and directly or indirectly lead to an improvement in measurement outcomes, greater

than that seen with the care alone package (as has been in seen in similar intervention studies)
3. This project will supplement a broader Global Fund project run by the DTHF under the auspices of the Western Cape Provincial Government and will support the achievement of the project's overall goals

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/04/2017, University of Cape Town Faculty of Health Sciences Human Research Ethics Committee (Room E53-46 Old Main Building, Groote Schuur Hospital, Observatory, 7925, Cape Town, South Africa; +27 (0) 21 406 6492; sumayah.ariefdien@uct.ac.za), ref: 033/2017

Study design
Interventional randomized controlled trial with follow up non-randomised study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
None

Interventions
The first 5,000 participants enrolled will be randomly assigned to either a care "empowerment" initiative alone, or to an empowerment programme attached to R300 cash incentive conditional on attendance.
The next 5,000 participants will all receive care plus cash incentive (this group of participants has been added after the initial recruitment started)
Each participant will receive up to 12 months' active empowerment intervention and up to 36 months' passive clinic service, including uptake monitoring and evaluation.

After registration into the biometric data capturing system and being assigned a unique participant identification number (PID) also referred to as a 'client code', participants officially enrol once they complete attendance of the first empowerment session by checking in and then out using fingerprints captured in said system.

The PIDs are then randomised into one of the two study arms by the following randomization process:

• A list of non-randomized participants that have attended the session is extracted
• A randomization seed is generated from a concatenation of PIDs
• This seed is uploaded to a randomization service (https://random.org) for randomization
• A list of participants for each study arm is generated and then saved to a randomization table together with the randomization seed and the date of randomization
• The randomisation is documented in a Payment Randomisation Note (PRN)

Intervention Type
Behavioural

Primary outcome measure
At baseline, programme exit and at follow up intervals from 12 months after enrolment:
HIV incidence measured using self-report questionnaires and participant health records as and where available from Western Cape Department of Health records.

Secondary outcome measures
At baseline, programme exit and at follow up intervals from 12 months after enrolment, self-report responses will be cross referenced with participant health records as and where available from Western Cape Department of Health (WCDOH) records.

1. Pregnancy prevalence measured using self-report questionnaires and WCDOH health records.
2. Unwanted pregnancies measured using self-report questionnaires.
3. Terminations measured using self-report questionnaires
4. STIs measured using self-report questionnaires and WCDOH health records
5. Contraception adherence measured using self-report questionnaires and WCDOH health records
6. ANC attendance measured using self-report questionnaires
7. HIV testing uptake measured using self-report questionnaires and WCDOH health records
8. PrEP uptake measured using self-report questionnaires
9. Condom use measured using self-report questionnaires
10. PMTCT measured using WCDOH health records
11. QOL measured using self-report questionnaires I do not see that we asked this in the questionnaire
12. Substance use measured using self-report questionnaires
13. Alcohol use measured using self-report questionnaires
14. Mental Health – Depression measured using self-report questionnaires and Center for Epidemiologic Studies Depression Scale (CES-D)
15. Education level measured using self-report questionnaires
16. Employment history measured using self-report questionnaires
17. Volunteerism, work experience measured using self-report questionnaires
18. Linkage to care measured using self-report questionnaires and WCDOH health records
19. ART uptake measured using self-report questionnaires and WCDOH health records
20. Viral load suppression measured using self-report questionnaires and WCDOH health records
21. Partner number measured using self-report questionnaires
22. Partner status measured using self-report questionnaires
23. Partner age measured using self-report questionnaires
24. GBV measured using self-report questionnaires
25. Transactional sexual activities measured using self-report questionnaires
26. Condomless sex measured using self-report questionnaires
27. Impact of cash on livelihoods measured using self-report questionnaires and in-depth qualitative interviews

Overall study start date
04/04/2017

Completion date
30/12/2020

Eligibility

Key inclusion criteria
Both HIV-infected and un-infected young women aged 19-24 years

Participant type(s)
Mixed

Age group
Other

Sex
Female

Target number of participants
10,000 young women: approx. 2500 women for care alone; approx. 7500 women for incentive + care

Total final enrolment
11494

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/05/2017

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
South Africa

Study participating centre
Desmond Tutu HIV Foundation
Klipfontein/ Mitchell's Plain Health Sub-district facilities
Cape Town
South Africa
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Sponsor information

Organisation
Desmond Tutu HIV Foundation

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Sponsor type
Charity

Website
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Funder(s)

Funder type
Charity

Funder Name
The Global Fund for AIDS, Tuberculosis, and Malaria

Funder Name
Health Department, Provincial government of the Western Cape (PAWC)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/06/2022	18/01/2023	Yes	No