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Effect of pre-exposure prophylaxis (PrEP) on risky sexual behaviours of female sex workers in Dakar, Senegal

Submission date
11/03/2021

Recruitment status
No longer recruiting

Registration date
11/03/2021

Overall study status
Completed

Last Edited
19/08/2025

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
PrEP (pre-exposure prophylaxis) is medicine people at risk for HIV take to prevent them from getting HIV. Senegal is in the process of rolling out PrEP gradually nationally. Female sex workers are one of the target groups for PrEP due to their high risk of contracting HIV. However, there is also a policy concern that taking PrEP might reduce their incentives for using a condom, especially when unprotected sex has higher renumeration. This may have public health consequences as condom use also curbs the transmission of other sexually-transmitted infections (STIs). Therefore, this study aims to study whether the drop in condom use is large enough to be of concern, and if possible, among which groups this drop is concentrated in.

Who can participate?
Female sex workers aged 18 and over who took part in the July 2020 wave of a panel survey held in Dakar, Senegal who are still working in sex work at the point of that survey

What does the study involve?
Survey respondents are randomly allocated into the treatment group and the control group. The contact details of survey respondents allocated to the treatment group are given to the partner organisation rolling out PrEP. This gives them a potential pool of female sex workers whom they can contact to explain what PrEP is, and how they can receive PrEP. If a respondent is interested in PrEP, she is required to visit one of the associated clinics where PrEP is offered in order to check her eligibility. Part of this process involves a HIV test and a kidney function test as seronegativity and sufficient kidney function are necessary for PrEP usage. If a respondent is found to be eligible, it will be possible for her to take PrEP. The contact details of the survey respondents allocated to the control group are not given to the partner organisation. To better reach female sex workers, the partner organisation rolling out PrEP will be adopting mobile clinics as their key strategy for dispensing PrEP. The outcomes of the study will be collected with a survey after PrEP has been offered to the treatment group. Condom use with each of the last two clients and the last five clients will be measured with a combination of these methods: direct questioning, a list experiment, as well as via a new instrument aiming to elicit individual condom use without compromising the confidentiality of the respondent. Subjective

perceptions of the necessity of condom use will also be collected. The survey will also measure the number of clients, perceived risk of clients, price of last two clients, type of sex acts with the last two clients, whether the respondent stayed overnight with the last two clients, earnings from sex work, household expenditure, food insecurity, self-reported STI symptoms with the last two clients, and mental health.

What are the possible benefits and risks of participating?
PrEP is an established treatment with proven high effectiveness against HIV. Taking up PrEP treatment typically involves short-term side-effects, such as nausea, tiredness, vomiting, dizziness, and headaches, that tend to be relatively mild and lessen over time. Longer-term side effects may involve kidney function and reduction in bone mineral density. A test for sufficient kidney function as a prerequisite for eligibility for PrEP. Regular follow-up visits provide the opportunity for monitoring the health of those on PrEP.

Where is the study run from?
1. Alliance Nationale des Communautés pour la Santé (ANCS) (Senegal)
2. Ministry of Health and Social Action (Senegal)
3. University College London (UCL) (UK)
4. Erasmus University Rotterdam (Netherlands)

When is the study starting and how long is it expected to run for?
July 2019 to March 2022

Who is funding the study?
1. MRC Public Health Intervention Development Scheme (UK)
2. D.P. Hoijer Fonds, Erasmus Trustfonds, Erasmus University Rotterdam (Netherlands)

Who is the main contact?
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Scientific

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Additional identifiers

Protocol serial number
17341/001

Study information

Scientific Title
Randomized controlled trial of the effect of pre-exposure prophylaxis on risky sexual behaviours of female sex workers in Dakar, Senegal

Study objectives
1. Pre-exposure prophylaxis (PrEP) reduces the use of condoms among female sex workers.
2. PrEP reduces the perceived necessity of the use of condoms among female sex workers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/05/2020, UCL Research Ethics Committee (Office of the Vice Provost Research; 2 Taviton Street University College London; +44 (0)20 7679 8717; ethics@ucl.ac.uk), ref: 17341/001

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Prevention

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

Interventions

The study randomises respondents into a treatment arm and a control arm. This randomisation is stratified according to two criteria: 1) prior use of PrEP and 2) self-reported risk preferences in sex. A respondent is deemed to have prior use of PrEP if she answered in any of the previous survey waves in 2017 and 2020 that she took part in the 2015-2016 PrEP demonstration project in Senegal. Respondents are asked to self-report their risk preferences in sex on a Likert-like scale in the July 2020 survey waves. This forms the basis to categorise respondents into a high risk and a low-risk group. After the control and the treatment lists were generated, to account for the possibility of recruitment caps by the partner organisation rolling out PrEP, the participants the treatment list were ordered such that the proportion of each strata was as close to that of the control group as possible. This ensures that if participants were called in order, and recruitment stops at some point in the list, the balance of stratified characteristics of those who were contacted and the control group remains similar. If there were to be no limitations on recruitment, following this order will not be necessary.

The contact details of survey respondents allocated to the treatment group are given to the partner organisation rolling out PrEP. This gives them a potential pool of female sex workers whom they can contact to explain what PrEP is, and how they can receive PrEP. PrEP will be distributed via multiple avenues, primarily through mobile clinics.

The contact details of the survey respondents allocated to the control group are not given to the partner organisation.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome(s)
Measured with a survey expected to be held 3 months after the roll-out of PrEP:
1. Condom use with each of the last two clients and the last five clients measured via a combination of these methods:
1.1. Via direct questioning
1.2. Via list experiment
1.3. Via a newly-designed instrument aimed at eliciting individual condom use without compromising respondent confidentiality
2. Subjective perceptions of the necessity of condom use measured using a Likert-like scale

Key secondary outcome(s)
Measured with a survey expected to be held 3 months after the roll-out of PrEP:
1. Number of occasional and regular clients seen in a fixed time frame, e.g. 7 days
2. Perceived HIV risk of clients
3. Price of each of the last two clients
4. Type of sex acts with last two clients/stayed overnight with last two clients
5. Earnings from sex work in a fixed time frame, e.g. 30 days
6. Household expenditure in a fixed time frame, e.g. 30 days

7. Food insecurity
8. Self-reported STI symptoms with last two clients
9. Mental health measured using the PHQ-9 questionnaire

Completion date
13/05/2022

Eligibility

Key inclusion criteria
1. Female sex workers who participated in the July 2020 survey wave of a female sex worker panel survey
2. Female sex workers who in the July 2020 survey wave responded that they are still doing sex work

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
500

Key exclusion criteria
If it was recorded in any of the past three survey waves held in 2015, 2017 and 2020 that the female sex workers has a medical record that indicates seropositive status

Date of first enrolment
01/07/2021

Date of final enrolment
31/10/2021

Locations

Countries of recruitment
Senegal

Study participating centre
Mobile clinic for PrEP and Survey location - Rufisque
Dakar

Senegal
25000

Study participating centre
Mobile clinic for PrEP and Survey location - Pikine
Dakar
Senegal
17000

Study participating centre
Mobile clinic for PrEP and Survey location - Mbao
Dakar
Senegal
17000

Study participating centre
Survey location - Sebikotane
Dakar
Senegal
20200

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Organisation
Erasmus University Rotterdam

ROR
https://ror.org/057w15z03

Organisation
Alliance Nationale des Communautés pour la Santé

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
D.P. Hoijer Fonds, Erasmus Trustfonds

Results and Publications

Individual participant data (IPD) sharing plan
Deanonymised data will be publicly available via the UCL research data repository (https://rdr.ucl.ac.uk) after the publication of the paper. Consent from participants will be obtained during the survey.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/08/2025	19/08/2025	Yes	No