

# Education for HIV prevention for black women who attend college

<b>Submission date</b> 02/07/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 06/07/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/07/2020	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Background and study aims

Consistent use of Pre-Exposure Prophylaxis (PrEP) for HIV negative persons, can lower their chances of getting HIV. Black women are a group to consider PrEP use as their chances of getting HIV is much higher than all other women groups.

Who can participate?

Black women aged 18 - 24 years who attend college

What does the study involve?

Participating in either an online or in-person HIV prevention education module that promotes PrEP education and future PrEP use.

What are the possible benefits and risks of participating?:

Benefits: Increased PrEP knowledge; Risks: No risks identified

Where is the study run from?

Emory University (USA)

When is the study starting and how long is it expected to run for?

February 2017 to December 2019

Who is funding the Study?

Emory University (USA)

Who is the main contact?

Rasheeta Chandler, r.d.chandler@emory.edu

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Rasheeta Chandler

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

IRB00091765

**Study information****Scientific Title**

Comparing an online and in-person HIV prevention educational intervention (Pre-Exposure Prophylaxis; PrEP) for black college women

**Acronym**

PrEPSavvy

**Study objectives**

Post participating in the PrEP education module, regardless of delivery modality, participants will have increased PrEP knowledge and will be more likely to initiate PrEP in the future

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 02/02/2017, Emory University Institutional Research Board (1599 Clifton Rd, Atlanta, GA 30322, USA; +1 (404) 712-0720; urcappl@emory.edu), ref: IRB00091765

**Study design**

Pilot single-centre randomized parallel trial

**Primary study design**

Interventional

**Study type(s)**

Prevention

**Health condition(s) or problem(s) studied**

Prevention of HIV

**Interventions**

The intervention consists of a PrEP Education Intervention that lasts one-hour and is formatted for two delivery platforms - traditional in-person small groups and an online modular session. Participants are randomized (1:1) to either the traditional in-person small group delivery platform or the online delivery platform. Once randomized, all participants complete a pre-test at baseline evaluating their PrEP knowledge prior to the intervention and after completing the pre-test they are given a follow-up post-test appointment scheduled for 2 weeks after completing the intervention.

**Intervention Type**

Behavioural

**Primary outcome(s)**

Feasibility and acceptability of the in-person and online PrEP curriculum assessed through quantitative and qualitative methods:

1. Quantitative measurement includes survey questions administered two-weeks after the intervention using the following questions: "How helpful was the program for understanding PrEP?" "How helpful was the program for learning about PrEP?" "Quality of the information provided" "Usefulness of the information provided"
2. Qualitative measurement obtained one-week after the intervention via two 90-minute focus groups

**Key secondary outcome(s)**

1. PrEP Knowledge measured at baseline and at two-weeks after the intervention using two questions: a) Before this study, had you ever heard of PrEP; and b) What is your knowledge of PrEP? (range: where 0 is no knowledge and 10 is expert knowledge).
2. PrEP intentions assessed at baseline and two-weeks after the intervention using the following question: How likely are you to use PrEP in the future? (Responses ranged from—Very unlikely [0] to Very likely [5])

**Completion date**

30/12/2019

**Eligibility****Key inclusion criteria**

1. Self-identified as black
2. Cis-gender female
3. Enrolled part-time or full-time at the designated university
4. Between the ages of 18 - 24 years

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Total final enrolment**

43

**Key exclusion criteria**

1. Biologically born male

**Date of first enrolment**

02/02/2017

**Date of final enrolment**

30/12/2018

## **Locations**

**Countries of recruitment**

United States of America

**Study participating centre**

**Emory University**

1520 Clifton Rd

Atlanta

United States of America

30322

## **Sponsor information**

**Organisation**

Emory University

**ROR**

<https://ror.org/03czfpz43>

# Funder(s)

## Funder type

University/education

## Funder Name

Emory University

## Alternative Name(s)

Emory, The Emory University, Emory College, EU

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Universities (academic only)

## 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 will be available upon request from (Rasheeta Chandler, PhD; r.d.chandler@emory.edu; descriptive data will be available after initial peer reviewed article [estimated to be by January 3, 2021] for at least 3 years; Access criteria: 1. Provide study proposal/protocol; and 2. IRB approval to complete secondary data analysis submitted to Rasheeta Chandler, PhD r.d.chandler@emory.edu by e-mail; 3. Any results generated and disseminated will require acknowledgement of data source and reference to any parent study publications. Agreement to adhere to any additional institutional legal requirements will be required before release of data.)

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	28/07/2020	31/07/2020	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes