

Education for HIV prevention for black women who attend college

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

Plain English Summary

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

Study website

<https://prepsavvy.emory.edu/>

Contact information

Type(s)

Scientific

Contact name

Dr Rasheeta Chandler

ORCID ID

<http://orcid.org/0000-0003-2021-6346>

Contact details

6876 Spreadlong Oaks Dr

Stone Mountain

United States of America

30087

+1 6788342024

r.d.chandler@emory.edu

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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 hypothesis

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

Secondary study design

Randomised parallel trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

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

Condition

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 measure

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

Secondary outcome measures

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])

Overall study start date

05/10/2016

Overall study end date

30/12/2019

Eligibility

Participant 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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

50

Total final enrolment

43

Participant exclusion criteria

1. Biologically born male

Recruitment start date

02/02/2017

Recruitment end date

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

Sponsor details
1520 Clifton Rd
Atlanta
United States of America
30322
+1 4047278164
urcappl@emory.edu

Sponsor type
University/education

Website
<http://www.emory.edu/home/index.html>

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

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

03/01/2021

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?
Results article	results	28/07/2020	31/07/2020	Yes	No