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Education for HIV prevention for black women who attend college

Submission date
02/07/2020

Recruitment status
No longer recruiting

Registration date
06/07/2020

Overall study status
Completed

Last Edited
31/07/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Study website
https://prepsavvy.emory.edu/

Contact information

Type(s)
Scientific

Contact name
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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 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

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

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 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

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
50

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

Sponsor details
1520 Clifton Rd
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+1 4047278164
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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