Official Title: Cluster Randomized Controlled Trial of Using PrEP, Doing it for Ourselves [UPDOs] Protective Styles: A Salon-based Intervention to Improve PrEP Uptake Among Black Cis-gender Women

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Duke University Health System

Black Women to Participate in a Research Study
ADULT

"Cluster Randomized controlled trial of Using PrEP, Doing it for Ourselves [UPDOs] Protective Styles: A salon-based intervention to improve PrEP uptake among Black cis-gender women."

HIV disproportionately affects Black cisgender women living in the United States south threatening progress toward the Ending the HIV Endemic initiative's 2030 goals. Although Pre-exposure Prophylaxis (PrEP), an oral or injectable medication that if taken is highly effective in preventing HIV, Black cisgender women have not equitably benefited from its use due to multiple complex factors. For example, lack of awareness and knowledge to PrEP, not trusting PrEP, PrEP stigma, providers not knowing about or offering PrEP, accessibility, and cost. These factors all contribute to only 2% of eligible women taking PrEP. Thus, interventions that take into consideration the lived experiences and broad culture for Black cisgender women are urgently needed to take a woman from medication precontemplation to uptake to maintenance. In partnership with Black cisgender women, an established community advisory council (CAC), an online telehealth platform (Q Care Plus), and beauty salon stylists, we have co-developed Using PrEP, Doing it for Ourselves (UPDOs) Protective Styles, an e-Health intervention that strongly considers the unique needs of Black cisgender women, consisting of a training for stylists to become opinion leaders (trusted gatekeepers who share health information in the community) in HIV prevention (i.e., PrEP) and a 6-week web-based, edutainment video series (i.e., six 20-minute episodes), structured debrief blogs, and telehealth service access.

You are being asked to engage in our UPDOs intervention over 6-weeks and provide feedback along the way.

Study participation will include data collection through the use of surveys at baseline with follow-up measures at 1, 12, 24, 32, and 52 weeks.

A secondary purpose of this study is to understand women's decision-making process to take or not to take PrEP. A subsample of women will be asked to participate in semi-structured individual interviews to gain a deeper understanding of their decision-making process. Interviews will be confidential and recorded virtually or face to face and will last no longer than 60-minutes. Post-interviews will be transcribed by approved personnel.

Potential Risks & Benefits

There are no direct benefits to you from participating. The study may lead to information that can be used in the future to help Black women receive health information that is delivered in the salon setting in a way that is more comfortable and accessible. There is also a small risk of loss of confidentiality however, this is minimized by the fact that survey results transmitted to Duke

researchers will be on a secure server and only accessible by the study team. Your contact information will be used only to deliver an electronic gift card and to communicate with you when it is time to take the follow-up surveys. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed. You may stop your participation in this study at any time without penalty or loss of any benefits to which you are entitled. There are surveys to complete in this study. Completing the surveys should take about 15 minutes. You may also be asked to participate in a 90-minute focus group hear your feedback about the implementation of the intervention.

A description of this clinical trial will be available on www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Voluntary and Confidential Nature of Your Answers

Participating in this study is completely voluntary. The choice to do so is up to you. You are free to stop at any time. Your answers will be kept confidential. As a token of our appreciation for your time for completing the survey, you will receive one electronic gift card for $125.00 after completing the study. A $25 Amazon Gift card will be given for the completion of the five surveys completed in year 1 for partial time if participants drop out prior to completion.

Questions

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

If you have any questions about the survey, you may contact the study team at 919-684-3786.

Do you wish to participate based upon the information above?

Please select your choice.

◯ Agree
◯ Disagree

Clicking on the "Agree" button indicates that:

You have read the above information.

You voluntarily agree to participate.

Thank you for considering this study; we understand you do not wish to participate at this time.