Official Title: Protecting Against Lenacapavir Misinformation With Young Women in Gauteng, South Africa

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Pre-registration for PROTECT-L trial

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This trial will test the effect of psychological inoculation messages on intentions to receive Lenacapavir following exposure to misleading information and misinformation about Lenacapavir.

The intervention consists of one 4 minute 7 seconds TikTok style video that delivers inoculation-based messages. The attention control condition consists of one 3 minute 41 seconds TikTok style video that delivers information and education about diabetes. The two videos have the same look and feel and the same characters and actors, but the attention control video does not incorporate psychological inoculation.

The sample will include ±1,500 women aged 18-29 years who are enrolled from various study sites within Gauteng Province, South Africa, including health clinics providing services to young women, and institutions of higher education.

Participants complete a Quatrics-based baseline survey after providing informed consent. The baseline survey procedures include: a self-administered survey (sociodemographic, attitudinal and behavioral questions); pre-intervention measurement of LEN intentions; randomisation to either the intervention or control group; participants being asked to watch either the intervention or control video (depending on group assignment); exposure to misinformation or misleading claims about Lenacapavir; and then additional survey questions, including repeat questions to measure post-intervention LEN intentions (primary outcome) and secondary outcomes. The baseline survey ends with a debrief explaining what information viewed is false or misleading. A follow-up survey sent to participants at 2-4 weeks after the baseline includes: repeat exposure to the primary misinformation claim for the study and exposure to new claims; repeat questions to measure the primary and secondary outcomes.

We will examine the following study outcomes:

Primary outcome:
Lenacapavir intention post-intervention and post exposure to the main misinformation claim measured in the baseline survey. Measured with the question: “Now on a scale from 1 to 10, where 1 is extremely unlikely and 10 is extremely likely, please answer the following question about LEN: “If LEN was offered to you, how likely would you be to take it?”

Secondary outcomes:
Lenacapavir intention, baseline survey: Intention to get Lenacapavir, measured using the same question as for the primary outcome, at the end of the survey following additional misinformation exposure.

Lenacapavir intention, follow-up survey: Intention to get Lenacapavir, measured using the same question as for the primary outcome and following additional exposure to misinformation claims.

Recommend to friends, baseline survey: Intention to recommend Lenacapavir to friends, measured at baseline survey post intervention and misinformation exposure. Measured with the question: “On a scale from 1 to 10, where 1 is extremely unlikely and 10 is extremely likely,

please answer the following question about LEN: How likely are you to recommend LEN to your friends?"

Recommend to friends, follow-up survey: Intention to recommend Lenacapavir to friends, measured at follow-up survey following additional misinformation exposure. Measured with the question: "On a scale from 1 to 10, where 1 is extremely unlikely, 10 is extremely likely, please indicate how you feel about the following statement: How likely are you to recommend LEN to your friends?"

Request for additional information about LEN made (yes vs no) assessed by whether or not the participant completed a request for information form that was sent to all participants who responded in the baseline survey that they were interested in receiving additional information about LEN. The form was sent to participants by the study team after completion of the baseline survey.

Credibility, emotional response to, and shareability of misinformation claims (claim #1-#6), baseline survey. For all claims: 1) the extent to which the claim is credible, 2) the extent to which the claim makes you anxious or nervous about Lenacapavir, and 3) the likelihood of you sharing the claim. The exact questions asked to participants were:

- Credibility: "How much do you believe this post is true?" (1–7 scale)
- Anxiousness: "How much does this post make you anxious or worried about the LEN?" (1–7 scale)
- Shareability: "If you saw this post on social media, how likely would you be to share it?" (1–7 scale)

For the baseline survey, there are 18 separate outcomes for credibility, emotional response to, and shareability of misinformation claims. In addition, 3 composite measures will be created using the the five claims considered as misleading/misinformation claims (claims #1, 2, 3, 4, 5). Claim #6 is considered an accurate or true claim. One composite measure will be created for credibility as the sum of the scores for the credibility questions for claims #1, 2, 3, 4, and 5 (score of 5-35). One composite measure will be created for anxiousness as the sum of the scores for the anxiousness questions for claims #1, 2, 3, 4, and 5 (score of 5-35). One composite measure will be created for sharability as the sum of the scores for the sharability questions for claims #1, 2, 3, 4, and 5 (score of 5-35).

Credibility, emotional response to, and shareability of the main study claim (claim #1, inoculated claim) at follow-up: 1) the extent to which the claim is credible, 2) the extent to which the claim makes you anxious or nervous about Lenacapavir, and 3) the likelihood of you sharing the claim.

The exact questions asked to participants were:

- Credibility: "How much do you believe this post is true?" (1–7 scale)
- Anxiousness: "How much does this post make you anxious or worried about the LEN?" (1–7 scale)
- Shareability: "If you saw this post on social media, how likely would you be to share it?" (1–7 scale)

For the follow-up survey, there are 3 separate outcomes for the main study claim (claim #1) for credibility, emotional response to, and shareability of misinformation claims.

Credibility, anxiousness, and shareability of new claims claims #7-9 at follow-up. : For all claims: 1) the extent to which the claim is credible, 2) the extent to which the claim makes you anxious or nervous about Lenacapavir, and 3) the likelihood of you sharing the claim. The exact questions asked to participants were:

- Credibility: “How much do you believe this post is true?” (1–7 scale)
- Anxiousness: “How much does this post make you anxious or worried about the LEN?” (1–7 scale)
- Shareability: “If you saw this post on social media, how likely would you be to share it?” (1–7 scale)

For the follow-up survey, there are 9 separate outcomes for credibility, emotional response to, and shareability of the three new claims (#7, #8, #9).

In addition, 3 composite measures will be created using the the three claims considered as misleading/misinformation claims (claims #1, #7, #8). Claim #9 is considered an accurate or true claim. One composite measure will be created for credibility as the sum of the scores for the credibility questions for claims #1, #7, #8 (score of 3-21). One composite measure will be created for anxiousness as the sum of the scores for the anxiousness questions for claims #1, #7, #8 (score of 3-21). One composite measure will be created for sharability as the sum of the scores for the sharability questions for claims #1, #7, #8 (score of 3-21).

Statistical analysis

We will test the hypothesis that inoculation messages protect participants’ intentions to initiate LEN following exposure to misinformation. The primary analysis will use an analysis of covariance (ANCOVA) approach, implemented as linear regression of LEN intention (post-intervention and post main misinformation (claim #1) exposure) on treatment assignment, adjusting for baseline intention; demographic, socioeconomic and individual characteristics; and recruitment setting. We will estimate marginal differences and corresponding 95% confidence intervals.

For outcomes measured on scales, and composite measures based on these scales, we will use ANCOVA models (linear regression with baseline adjustment where possible) as the main analysis. For binary secondary outcomes, we will use logistic regression models with the same covariate adjustment.

Subgroup analyses:
We will conduct subgroup analysis for 10 participant subgroups: Age group (18-24 vs. 25-29), prior PrEP experience (ever vs. never), HIV risk score (dichotomized), COVID-19 vaccine history (ever vs. never), location of enrollment (youth focused programmes vs higher learning institutions), information avoidance scale (dichotomized), education level (dichotomized), type of location of residence (dichotomized into less vs more formal housing), food insecurity (yes vs no) and high HIV risk behaviour (whether they had multiple partners, had condomless sex, or age-disparate sexual partners). For each subgroup we will assess subgroup differences in the following outcomes:

- Lenacapavir intention, baseline post-intervention and post exposure to the main misinformation claim
- Lenacapavir intention, baseline at the end of the survey following additional misinformation exposure.

- Lenacapavir intention, follow-up
- Interest in receiving additional information about lenacapavir
- Request made for additional information about lenacapavir
- Recommend to friends, baseline post-intervention
- Recommend to friends, follow-up
- Credibility of inoculated claim #1 and new claims #2-#5 at baseline
- Anxiousness of inoculated claim #1 and new claims #2-#5 at baseline
  Shareability of inoculated claim #1 and new claims #2-#5 at baseline

Mediation analyses:
We will assess the potential mediated effect of motivational threat on the relationship between intervention and outcome for:

- Lenacapavir intention, baseline post-intervention and post exposure to the main misinformation claim
- Lenacapavir intention, baseline at the end of the survey following additional misinformation exposure.
- Lenacapavir intention, follow-up
- Contact information provided for request made for additional information about lenacapavir
- Recommend to friends, baseline post-intervention
- Recommend to friends, follow-up