CTN STUDY REPORTING TEMPLATE	
STUDY INFORMATION	
CTN or CTNPT Study #: **318**	Date: May 24, 2024
Study Title/Name: **Integrating cognitive-behavioural therapy for social anxiety disorder with HIV risk reduction counselling for HIV negative gay and bisexual men who are at high risk for HIV: A randomized controlled trial**	
Principal Investigator(s): **Trevor Hart**	
Phone: **416 979 5000 ext. 552179**	E-mail: **susan.chow@torontomu.ca**

STUDY PROGRESS

1. Please describe study progress during the period of 01 April 2023 to 31 March 2024 (for example, have you met your enrolment targets, have there been any SAEs?):

Since April 1, 2023, we have enrolled 18 participants in the trial. Data collection is ongoing and we continue to recruit participants across social media platforms and dating apps.

We have not had any SAEs since the start of this project, however we have had three adverse events (AE) which have been reported to REB. Documents related to these events have been attached to this submission.

CTN FUNDING

2. Is the CTN providing funding? ☒ Yes ☐ No (if no, proceed to Question 3)

2a. Are the study financial statements attached? ☐ Yes ☒ No (if no, describe why)

Financial statement to be submitted separately by Marina Tseng-Yip.

2b. Please describe how the funds provided by the CTN have been used to date and justify why the release of the next instalment is required:

To date, CTN funding has been used to compensate our nursing staff, as part of our essential research activities in collecting participant health data. The release of the next instalment is necessary to help our study continue to conduct specimen collection and testing to measure change in participants' sexual behaviour.

CTN STUDY REPORTING TEMPLATE

KNOWLEDGE TRANSLATION ACTIVITIES

3. Please provide a list of publications, presentations, and conference submission details over the past year (may be provided in a separate attachment). If available, please include the Digital Object Identifiers (DOIs) for publications.

N/A. There currently are no publications for the past year and there have been no abstract submissions.

3a. Has the CTN been acknowledged in all publications connected to this study? ☐ Yes ☐ No (if no, describe why)

Study is still in data collection phase; KT activities have not yet commenced. No publications have been published or submitted to conferences.

4. Please provide details of any publications, presentations, and abstract submissions that are planned for the upcoming year:

Plans for upcoming year: As we are in the middle of data collection, we do not have any data-based papers to present as of yet.

5. Please provide details on other knowledge translation activities, such as media interviews, webinars, articles in newsletters, community presentations, etc. over the last year:

N/A

CTN STUDY REPORTING TEMPLATE

COLLABORATIONS

6. Please describe activities conducted with partners and collaborators over the last year:

N/A

6a. Have there been any new collaborators, partners, or external funders (not listed in the original submission documents) over the past year? ☐ Yes ☒ No

If yes, please name them here:

N/A

STUDY ACTIVITIES FOR UPCOMING YEAR

7. Please describe the study plans over the next year(s) (include the end date of the study, both last participant, last visit date, and estimated date of completing the final manuscript):

Our plan is to continue to collect data. As of April 1st, 2024, we have enrolled 73 participants out of the 176 target sample. Of those 73 participants, 32 participants have completed the intervention and 16 participants have completed every phase of the trial.

The projected end of enrolment date is April 30th, 2025. We expect the last patient visit date to be March 31st, 2026. We also expect the manuscripts to be completed by 2027.

CTN STUDY REPORTING TEMPLATE

STUDY IMPACT

8. Please describe the anticipated impact and significance of this study:

MSM continue to have high rates of HIV infection, and new HIV preventions interventions that address MSM's mental health needs as well as their sexual health are desperately needed. Similarly, diagnoses of other STBBI's such as syphilis, chlamydia, gonorrhea, and hepatitis C virus (HCV), remain common among MSM. The STBBI epidemic among MSM has failed to decline despite biomedically-driven efforts to reduce infectiousness through the proliferation of antiretroviral Treatment as Prevention, and the emergence of HIV Pre-Exposure Prophylaxis (PrEP) to reduce HIV susceptibility. There is mounting evidence that the presence of co-existing psychosocial health problems increases HIV risk behaviours and rates of HIV infection in this group. It has been strongly recommended that HIV prevention interventions in MSM focus on addressing the psychosocial factors that predict increased sexual risk for HIV. Moreover, researchers have noted that those same psychosocial factors may reduce the effectiveness of traditional HIV prevention interventions. The study objectives are consistent with these recommendations, with the additional goal of developing the intervention at an ASO in order to sustain the intervention in the community beyond completion of the research program.

CBT has good efficacy data to support its use in treating social anxiety and substance use. CBT has been successfully adapted in the past to treat other complex presenting problems and as such, represents a flexible treatment to augment current sexual risk reduction interventions in MSM. By successfully treating the distress and substance use behaviours associated with social anxiety, in the context of a HIV prevention intervention administered at an ASO, we anticipate 1) effecting reductions in sexual risk behaviour among MSM and 2) increasing the capacity of STBBI prevention workers to conduct effective STBBI preventions that incorporate the mental health needs of MSM.

The present study supports the efforts outlined in the Federal government of Canada's *Accelerating our response: Government of Canada five-year action plan on sexually transmitted and blood-borne infections* and addresses the need for combination prevention efforts among MSM who are at increased risk of STBBIs. In response to the rise in rates of other sexual transmitted and blood-borne infections (STBBI; e.g., syphilis, chlamydia) among MSM in Canada, the present study also supports the reduction of STBBI rates more broadly, beyond an HIV-only approach. If we wish to meet the STBBI prevention needs of MSM, we need to augment STBBI prevention interventions by addressing the mental health problems that contribute to increased risk in this group and that impede the efficacy of traditional STBBI prevention efforts as well as take into account evolving trends of STBBI incidence and prevalence over time. This study investigates a novel integrated STBBI prevention intervention that combines empirically supported treatments for social anxiety with STBBI risk reduction counseling to reduce sexual risk behaviour.

CTN Study Reporting Template

Please use this space to provide any further details you need to report:

We are adding a second experimental stratum to the existing trial that will allow HIV-negative gbMSM engaging in condomless anal sex with the use of PrEP and/or with a man of any HIV status to participate in the trial. The proposed extension trial has been reviewed and approved by the Toronto Metropolitan University's Research Ethics Board. The decision to expand the study's inclusion criteria was due to recruitment challenges we faced as well as the changing landscape in HIV risk-reduction strategies and attitudes towards STBBIs more broadly (e.g., increase in PrEP uptake, U = U). Given the large increase in bacterial STI incidence, and the focus of our trial on sexual empowerment, the additional stratum will allow us to test an extension of our original HIV prevention-specific focus to a broader lens on STBBI risk reduction.

The arms of the intervention (CBT and Applied Relaxation) and procedures of both parts of this overall umbrella study are almost identical. The primary outcome for the original stratum is any serodiscordant CAS within the past 6 months (CAS with partners of unknown or HIV-positive status), without participant use of PrEP, based on response at 6 months (yes/no). The primary outcome for the second stratum will be any CAS, regardless of PrEP use and HIV status. The goal of the new stratum is not to pool results across strata but instead to see what a potential signal of difference for the intervention will be with a broader focus on STBBI prevention. The second stratum will not add to our statistical power but instead will add to our ability to test the effect of the Sexual Confidence treatment on a more modern and updated definition of STBBI risk reduction.