STUDY PROTOCOL

A TECHNOLOGY-DELIVERED PEER-TO-PEER SUPPORT ART ADHERENCE INTERVENTION FOR SUBSTANCE-USING HIV+ ADULTS

NCT02704208
APRIL 2, 2018

INSTRUCTIONS:

- *Use "SOCIAL TEMPLATE PROTOCOL (HRP-580)" to prepare a document with the information from following sections.*
- *If your research involves physical or invasive interventions, e.g., physical examinations, blood draws or specimen collection, or exercise activities, then you must use "MEDICAL TEMPLATE PROTOCOL (HRP-590)" instead.*
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PROTOCOL TITLE:

A Technology-Delivered Peer-to-Peer Support ART Adherence Intervention for Substance-using HIV+ Adults

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?

Table of Contents

After completing your protocol, right click on the Table of Contents below and select "Update Field." If prompted, select "Update entire table." This will automatically update the protocol sections and page numbers for you. Do this also each time you modify your protocol after initial approval.

ABBREVIATIONS/DEFINITIONS

Include any abbreviations or definitions for key or technical terms you use in your protocol.

- AIDS — Acquired Immunodeficiency Syndrome
- ART — Antiretroviral Therapy
- AUDIT — Alcohol Use Disorders Identification Test
- BSSS-4 — Brief Sensation Seeking Scale
- CASI — Computer Assisted Self-Interview
- CES-D — Center for Epidemiologic Studies Depression Scale
- CFR — Code of Federal Regulations
- CHEST — Center for HIV Educational Studies & Training
- HIPAA — Health Insurance Portability and Accountability Act
- HIV — Human Immunodeficiency Virus
- IMB — Information-Motivation-Behavioral Skills
- IMB-AAQ — IMB ART Adherence Questionnaire
- IRB — Institutional Review Board
- MASRI — Medication Adherence Self-report Inventory
- MSM — Men who have Sex with Men
- NICHD — National Institute of Child Health and Development
- NIDA — National Institute on Drug Abuse
- NIH — National Institutes of Health
- NYC — New York City
- PI — Principal Investigator
- PLWH — People Living With HIV
- OHRP — Office for Human Research Protections
- RCG — Radiant Creative Group
- RCT — Randomized Controlled Trial
- SMS — Short Message Service
- SSL — Secure Sockets Layer
- TWM — Thrive With Me
- UMN — University of Minnesota
- VL — Viral Load
- YO — Years Old

STUDY SUMMARY

Study Title	A Technology-Delivered Peer-to-Peer Support ART Adherence Intervention for Substance-using HIV+ Adults
Study Design	Randomized Controlled Trial
Primary Objective	Primary aims (Aims 1 and 2) are to examine the efficacy of the online and mobile-enabled TWM intervention in a full-scale randomized controlled trial.
Secondary Objective(s)	Aim 3 (a secondary aim) is to examine the effects of the intervention on theory-based change processes (i.e., IMB factors and social support) for improving VL, ART adherence, and substance use outcomes.
Primary Study Intervention or Interaction	The "Thrive with Me" (TWM) intervention is a technology-delivered peer-to-peer social support intervention grounded in the Information, Motivation, and Behavioral Skills (IMB) model for HIV-positive men who have sex with men (MSM). In addition to asynchronous peer-to-peer support capabilities, the TWM intervention provides participants with Antiretroviral Therapy (ART) adherence self-monitoring tools, medication dose reminders, and HIV-related informational content.
Study Population	HIV-positive men who have sex with men
Sample Size (number of participants)	400
Study Duration for Individual Participants	12 months

1.0 Objectives

1.1 Purpose:

The "Thrive with Me" (TWM) intervention is a technology-delivered peer-to-peer social support intervention grounded in the Information, Motivation, and Behavioral Skills (IMB) model for HIV-positive men who have sex with men (MSM). In addition to asynchronous peer-to-peer support capabilities, the TWM intervention provides participants with Antiretroviral Therapy (ART) adherence self-monitoring tools, medication dose reminders, and HIV-related informational content. The study will be based on the encouraging findings of the TWM pilot study (completed in 2011) and the need for novel, evidence-based effective ART adherence interventions.

2.0 Background

2.1 Significance of Research Question/Purpose:

Fifty thousand persons are estimated to be infected with HIV in the US each year [1]. In 2011, men who have sex with men (MSM) accounted for 65% of all new infections and were the only transmission group for which HIV infections did not show a year-over-year decline [1]. Current US Guidelines for the Use of Antiretroviral Agents [2] state that undetectable viral load (VL) "is the most important indicator of initial and sustained response to ART" (p. C-5), which requires that people living with HIV (PLWH) demonstrate sufficient and sustained adherence to antiretroviral therapy (ART). Optimal ART adherence reduces excess morbidity and mortality among PLWH [3] and lowers the probability of forward transmission to sexual partners [4]. However, it is estimated that only between 19-25% of all PLWH and 27% of MSM with HIV are virally suppressed [5, 6]. Despite the disproportionate burden of HIV in MSM communities, only 2 of 10 medication adherence interventions included in CDC's Compendium of Evidence-based Behavioral Interventions are tailored to MSM; one is a provider implemented approach evaluated over a decade ago and the other is an intensive one-on-one counseling approach. Clearly, advancing targeted and innovative ART adherence interventions for HIV-positive MSM remains a high priority [7].

Technology-based ART adherence approaches have proliferated in recent years [8, 9] due to the widespread adoption of technology across sociodemographic groups [10], their ability to reach a broad audience, and their low implementation costs [11]. However, recent computerized ART adherence interventions [12, 13] are individually delivered and fail to leverage peer-to-peer interactivity that has come to symbolize Web 2.0 [14]. Peer-to-peer support is a recommended strategy to improve ART adherence [7], is widely used by PLWH

[15], and has enormous immediate appeal as a generalizable intervention approach. Furthermore, peer support interventions provide unique social incentives to maintain high engagement in ART adherence interventions.

2.2 Preliminary Data:

To address the lack of generalizable interventions for MSM and leverage innovations in Internet and peer-to-peer social media, our team developed and piloted the "Thrive with Me" (or TWM) technology-delivered and theoretically-grounded peer-to-peer social support intervention [16] to improve ART adherence among HIV-positive MSM. In addition to direct peer-to-peer communication features, participants were given options for self-monitoring ART adherence, receiving ART dose reminders, and viewing relevant online HIV informational content. Among the 123 MSM in the pilot, 90% were retained at 1month follow-up, and participants rated the intervention high in perceived information and system quality, usefulness, and overall satisfaction (Means>5.0 on a 1-7 scale). Men randomized to receive the TWM intervention showed improvement across all ART adherence outcomes compared to control participants, with greatest benefits for current drug-using MSM.

2.3 Existing Literature:

See sections 2.1 and 26.0.

3.0 Study Endpoints/Events/Outcomes

3.1 Primary Endpoint/Event/Outcome:

Primary Aim 1: Determine the efficacy of the *TWM* intervention to increase the proportion of virally suppressed HIV-positive MSM at post-intervention time points.
H1: A higher proportion of participants in the TWM intervention than control participants will have undetectable VL at post-intervention time points.

Primary Aim 2: Assess whether the *TWM* intervention is most beneficial for HIV-positive MSM who report recent drug use at baseline compared to HIV-positive MSM who do not.
H2: Recent drug-using participants in the TWM intervention will demonstrate greatest improvements in VL and self-reported ART adherence at post-intervention time points compared to non-drug-using participants.

3.2 Secondary Endpoint(s)/Event(s)/Outcome(s):

Secondary Aim 3: Examine the effects of the *TWM* intervention on theory-based change process (i.e., IMB factors and social support) for improving VL, ART adherence, and drug use outcomes.

H3: Tailored adherence information, motivation for adherence, adherence behavioral skills, and peer social support will be associated with VL suppression and improved ART adherence and drug use outcomes.

3.3. Additional information about study design and endpoints

Primary aims (Aims 1 and 2) are to examine the efficacy of the online and mobile-enabled TWM intervention in a full-scale randomized controlled trial. HIV-positive adults (all men who have sex with men [MSM]) with detectable HIV viral load (VL) residing in New York City will be randomized to receive the TWM intervention or an information-only HIV/ART intervention for a 6-month period. Recruitment will be stratified by recent drug use, such that half will report recent illicit drug use. HIV VL, validated self-reported ART adherence, and intervention utilization measures will be collected at baseline, post-intervention, and 6-, and 12-month follow up. We hypothesize that participants in the TWM intervention will demonstrate significant improvements in self-reported ART adherence and VL at each follow-up time point compared to control participants, with greatest improvements among recent drug users.

We will use an experimental research design to assess the effects of the TWM intervention on HIV VL and self-reported ART adherence among the total sample, drug-using participants, and non-drug-using participants. Data collected from participants will only be used for the purposes of this study. Data will be collected in the form of biologic specimens (blood AND urine) and computerized surveys to assess socio-demographic variables, psychological measures, and behavioral measures (e.g., drug use, ART adherence). Biological specimens and computerized surveys will be collected on-site at the Center for HIV Educational Studies and Training (CHEST) at Hunter College in New York City (NYC).

The primary outcome measure is biological viral load (VL) at each assessment period. Specifically, blood draws will be taken at baseline, immediate post-intervention, 6- and 12-month post-intervention follow-up assessment points to assess the effects of the TWM intervention on VL, the most important biological marker for adherence. Blood will be drawn by a certified phlebotomist at the CHEST in NYC and analyzed by Quest Diagnostics. Plasma VL is considered undetectable at <20 copies/mm3 and we will provide test results to participants after each visit.
Men will take urine screens at each assessment time point to assess for the following illicit substances: cocaine, methamphetamines, marijuana, opiates, and PCP, using the Integrated E-Z Split Key Cup II-5 panel (Innovacon Laboratories). This test is capable of detecting drugs from one to four days after use, except for chronic marijuana use, which can be detected for up to

30 days. Although the urine toxicology procedures will not permit objective verification of self-report for the entire follow-up interval, it will provide some means of verifying abstinence versus non-abstinence from drugs. Research staff at CHEST have extensive experience in collecting and processing urine samples.

A full list of survey items are attached with this application (Measures). The primary biological measure (VL) will be examined against self-reported ART adherence items (collected via computerized surveys). Items adapted from the Medication Adherence Self-report Inventory (MASRI) (see attached survey items) will be used to assess dimensions of ART adherence in the past 30 days, including the percentage (0-100%) of overall ART correctly taken and the percentage of ART taken within 2 hours of the correct dose time.

Secondary outcome measures will include a) self-reported adherence information, motivation, and behavioral skills by completing the IMB-AAQ which is a 33-items measure that assess adherence-related information and b) a modified version of two social support questionnaires to assess social support.

Other Self-Report Measures: The following self-report measures will also be collected as part of the TWM trial:

- Demographic and Medical Variables. Common demographic (e.g., gender, age, race/ethnicity, income, educational attainment, employment status) and medical (years since HIV/AIDS diagnosis, time on ART, and medication side-effects) variables will be adapted from prior online studies by this study group.
- Substance Use. Items will be adapted from those used in the TWM pilot study to assess recent (past 5 months) and lifetime illicit drug use and patterns of illicit drug use (i.e., frequency, location, and circumstances of use). The AUDIT (10-item alcohol abuse scale) will be used assess problematic alcohol use.
- Empirically-derived Psychosocial Risk Factors for Poor Adherence. We will assess a broad range of mental health factors with widely-used and validated standardized scales, including the CES-D (10-item depression scale) [14], HIV Symptom Index scale, Perceived Stress Scale (14-items), the Brief Sensation Seeking Scale (BSSS-4) and a 6-item Life Chaos scale, and HIV Stigma scale.
- Technology Use and Internet Knowledge. Participants will indicate how often they access the Internet and for what purposes. Internet knowledge will be assessed with the iKnow measure. Smart phone use will be assessed by asking participants what data plan they have (e.g., unlimited vs. limited vs. no data plan), what mobile phone

carrier they use (e.g., Verizon, AT&T, Sprint), and the frequency of use of smartphone features (e.g., SMS messaging, accessing the Internet on their smartphone).

- Intervention Acceptability. Intervention acceptability items will be drawn from prior research by this research team and from the System Usability Scale. Users will be asked to rate the intervention on system quality, information quality, their overall satisfaction with the application and their beliefs about whether the application improved their health behaviors.
- Finally, user engagement in the TWM intervention will be assessed by: a) frequency of log-ins; b) among log-ins, whether the log-in was via computer, smartphone, or tablet (to assess whether use or outcomes differ by modality by which the intervention is accessed); b) frequency of message posting and responding to other participants' posts; c) frequency of updating medication adherence, drug use, and mood self-monitoring graphs; c) frequency of viewing articles, videos, and links; d) frequency of SMS medication reminders. Among control participants, the number of weekly informational webpages opened and time spent on each weekly webpage will be tracked during the trial period.

The combination of using an experimental design to compare the TWM intervention to control arm participants, and collecting biological, computerized self-report survey data, and user engagement data will allow us to examine the full range of potential effects of the TWM intervention on participant's physical and mental health.

4.0 Study Intervention(s)/Interaction(s)

4.1 Description:

The TWM intervention has two major components: an individualized self-monitoring component and a social support component. For the self monitoring component, users can enter their daily ART medications into a private profile page. Many men will only take one dose of medication per day, while others may take multiple doses. Men can then customize how they would like to set up SMS medication reminders. Based on the participant's preferred time, a daily text message will be sent 5 minutes after the participant is supposed to take their medication. Participants can choose from standardized language from our website for this text message or they can customize the language for further discretion. The standard language will ask: "Have you taken your dose today? Respond "1" yes, respond "2" no skipping today, respond "3" remind me again in an hour." Participants will then be asked how they feel at the moment and will be given a choice of

5-6 common emotions (happy, sad, anxious/worried, angry, tired). Responses collected via text message will be synched directly to participants' private profile page and they will be able to view their adherence and mood tracking throughout the course of the intervention. Once a week we will ask participants to log-in to the website directly to report substance abuse for the week. Participants will be asked to check which days they used alcohol; which days they used marijuana; and which days they used other drugs. Participants will be able to view their medication adherence, mood, and substance use for the entire week on the same screen.

The social support component of the website is a social network page similar to Facebook, but with targeted content being placed in the feed. TWM intervention staff will create approximately 300 "Thrive Tips" based on addressing barriers identified in the IMB-AAQ survey (all participants take the IMB-AAQ at baseline and this survey is included in the attached appendices under Measures) . Participants will see 4 unique Thrive Tips per day posted to their daily feed. If a participant has identified specific barriers to medication adherence (e.g. fear of someone seeing them take their medications), the Thrive Tips associated with their identified barriers will be highlighted differently in their personal feed to draw more attention to them. Participants can comment on the Thrive Tips to start discussions with other members, or they can start their own topics of discussion. Research staff may also pose questions to the group to spur discussion among members. Research staff will monitor the page daily for hostile interactions or misinformation. Hostile interactions can be flagged by users or admins and removed. In the pilot trial of TWM, admins found that other users would often correct misinformation in a prompt manner and research staff rarely had to step in. Our intention is for users to create community throughout these interactions and also to demonstrate leadership in the group by either starting topics, sharing information, and/or correcting misinformation with minimal guidance from research staff. Participants will be able to privately message with research staff through the TWM website. Participants will not be able to privately message each other through the website. All 300 Thrive Tips will be made available over the course of the first 75 days of the intervention. After the first 75 days, the intervention group will take another IMB-AAQ through the TWM website to see if their medication adherence barriers have changed. The 300 Thrive Tips will be re-ordered and released 4 per day for the remaining 75 days of the intervention.

5.0 Procedures Involved

5.1 Study Design:

Based in the results of the TWM pilot study, we will evaluate the TWM intervention in a randomized controlled efficacy trial (RCT). Recruitment

will be stratified by drug use, such that half of participants will report illicit drug use in the prior 5 months at baseline (see inclusion criteria in Section 9.1). MSM will be recruited in New York City metropolitan area, screened, and randomized to receive either the TWM intervention or HIV-information only control condition. VL, validated self-report ART adherence, and drug use will be collected at baseline, immediate post-intervention, and 6- and 11-month post intervention to test the study hypotheses.

5.2 Study Procedures:

Partners:

Key partners for the study and their roles are as follows:

- CHEST, Subcontractor – CHEST will manage recruitment, screening, training, and retention of participants. They have received IRB approval through the City University of New York.
- Rivet Amico, Co-Investigator and Subcontractor – Rivet will only have contact with participants in extenuating circumstances (if multiple people from the UMN study team are not available, which has not occurred thus far in the study) and will otherwise only have access to de-identified data. She has received IRB approval through the University of Michigan.
- Christina Sun, Collaborator – Christina will conduct qualitative data analysis and will only have access to de-identified data. She will receive IRB approval through Portland State University.

Usability Testing:

Before the full RCT begins, we will conduct pilot/usability testing with 10 HIV positive men recruited by CHEST staff in New York City. Participants recruited for usability testing will be scheduled for an in-person appointment at CHEST. At this visit they will sign the consent form and take the baseline survey using Qualtrics. CHEST staff will then give the participant a unique username and password for the TWM website and ensure they can log-in. The participants will then be given a task list of actions they need to perform on the website (i.e. start a discussion topic, share and comment on a Thrive Tip, create a profile, etc.) over the course of 1-2 weeks. After that period is over, they will return to CHEST to complete a 45 minute interview with the PI, project coordinator, and a CHEST staff member. While a CHEST staff member will be present to facilitate, an in-person telephone interview between the project coordinator and the participant will be held. Both the task list and interview questions are attached to this application (Website Tasks and Usability Interview Questions). The interview is intended to illicit feedback on programmatic components, not to draw out personal information regarding medication adherence, sexual behaviors or substance

use. Responses from usability testing will be used to complete development of the TWM website and make any final changes before launch.

Randomized Clinical Trial:

Persons interested in the study will be scheduled for an in-person appointment at CHEST to complete the screener items, baseline VL blood draw, and urine samples for drug use. Participant-identifying information, including informed consent forms, locator forms, or any file linking ID numbers to names are kept in locked cabinets at all times at CHEST. Secure (i.e., using SSL encryption and online survey software supported by the University of Minnesota) online survey software will be used to collect baseline and follow-up self-reported data, and will be managed by research staff at the University of Minnesota. Participants may be asked to sign a HIPPA Authorization/Release form, that (if signed) will grant permission for research staff to obtain the participant's medical record. As stated in the consent form, HIPPA authorization will only be sought in the rare event that viral load is unable to be evaluated or requires confirmation. Participants will be contacted and informed that their healthcare provider is going to be contacted before such contact is made. Participants are not required to sign the HIPPA Authorization/Release form.

Biological Data Acquisition and Transmission. Blood draws will be collected at CHEST during the baseline, immediate post-intervention, 6-, and 12-month post-intervention visit to assess the effects of the TWM intervention on viral load, the most important biological marker for adherence. Blood will be drawn by a certified phlebotomist at CHEST and analyzed by Quest Diagnostics. Plasma VL is considered undetectable at <20 copies/mm3 and we will provide test results to participants after each visit. We have successfully used this procedure with MSM in prior studies. The urine sample will be tested for metabolites of methamphetamines, cocaine, ecstasy, marijuana, and opiates using the Integrated E-Z Split Key Cup II- 5 Panel (Innovacon Laboratories). Though studies have consistently supported the validity of self-reported drug use assessment instruments, research has shown that when individuals are informed that their self-reported behavior will be validated through biological measurement, they are more likely to accurately report their behaviors. All biological specimen samples collected will be destroyed as soon as they are tested. Results from the blood and urine screens will be entered into Qualtrics and tied to the participant's study ID and will never be included in the person's medical record. Attached to this application is a screenshot from CHEST regarding how they enter HIV outcomes into Qualtrics (Sample HIV Outcomes Measures); please note that the University of Minnesota logo will appear on all TWM survey screens.

Men who meet eligibility criteria will be guided through the consent process. Trained research staff at CHEST will meet in an assessment room with participants and will be available to answer any questions on the consent form. Signed paper consent forms will be stored in a separate, locked file cabinet at our research center, CHEST. Next, they will complete a computer-assisted baseline survey (using Qualtrics, which is online survey software supported by the University of Minnesota) which is anticipated to take 30-45 minutes. The baseline survey will include questions about medication adherence, engagement in care, demographic characteristics, social support, mental health, and intervention content and features. Following well-established security protocols by this research team, data will be stored electronically, with identifying information (e.g., name, e-mail address, contact information) stored separately on a secure server from other responses. Identifying information and other data will be linked by a unique computer-generated number that will be kept in a third table and stored separately from the other two tables. The PI, the project statistician, the project coordinator, and key CHEST staff involved in enrollment and retention will have access to identified data. Other team members will have access only to the de-identified dataset.

Next, men will be randomized to the TWM intervention or control group using a blinded randomization process. The sample will be stratified by recent drug use and non-recent drug use. Those assigned to the TWM intervention will be shown example webpages of the intervention, given basic training on how to navigate the intervention, and given the opportunity to ask questions they have about the website. Control condition assigned participants will be shown example webpages they will receive during the intervention period.

After the baseline visit, participants will have access to the TWM or control intervention components. Those in the control arm will receive weekly emails with links to web pages containing information on living with HIV and tips for improving quality of life. These web pages will not be specifically focused on improving medication adherence. Control participants will receive approximately 25 emails of unique content over the course of five months.

Upon entering the TWM intervention, men will be guided through a series of pages in which they will create a unique username (not containing identifying information) and password to use throughout the study. Men will be able to choose from pre-designed icons for a profile image that will accompany their username when they post on the TWM website. Participants in the treatment arm will have access to the full intervention for 5 months. After 5 months, participants will no longer have access to the social support component of the website and they will no longer receive SMS reminders. They will still have access to the Thrive Tips and their self-monitoring personal profile page while the website is online. The TWM

intervention website is currently being developed. Screenshots from the pilot trial of TWM (NIH R34 MH083549) are attached to this application (Appendix E: Screenshots from TWM Feasibility Trial). The intervention for the full-scale RCT is modeled after the pilot screen shots.

5.3 Follow-Up:

After the intervention period, men will contacted by CHEST study staff to schedule an in-person appointment to complete the immediate post-intervention survey (also using Qualtrics), VL blood draw, and drug urine screen. The same procedure will be used to schedule men for their 6- and 12-month post-intervention visits. If a participant moves out of the area served by CHEST, they will be offered the option to consent to take any remaining follow-up surveys remotely, and to complete any remaining viral load tests with their healthcare provider or at a central lab and have the results sent to CHEST.

6.0 Data Banking

The following identifiers are collected and maintained during the duration of the study: names, telephone number, birthdate, and email address. It is necessary to record identifiers since payment to subjects will be through Amazon that will be sent to their e-mail accounts. In addition, such information will be collected to successfully enact the retention protocols described in the grant proposal.

Participants demographic and survey data will be identified by a unique number. The identification number will not be linked to the participant's identity or contact information in any way. The contact information will be stored in a separate electronic file from the participant's demographic and survey data, with the two files being linked by a separate "linking file" stored in a separate location.

Identifiable study data will be destroyed 1 year after the completion of the study. We established this timeframe in the event participants have follow-up questions regarding their participation in the study. De-identified study data will be kept for 7 years after the completion of the study, which is in accordance with NIH policy. Three copies of the de-identified dataset will be maintained (a working one and two archived at different sites).

7.0 Sharing of Results with Participants

Results will be shared with participants in several ways. First, we will publish the results of studies resulting from this study. We will attempt to publish them in Open Access journals (as we did with the results from Aim 1) so that anyone may access those articles. In addition, we will make available a summary of study results to participants who request it.

Upon request, results of viral load tests will be shared with participants by CHEST staff.

8.0 Study Duration

Individuals in the intervention arm will have access to the site for 5 months, and will complete follow up after 12 months. The total anticipated duration of the study, including analysis is from 7/1/15-5/31/20.

9.0 Study Population

9.1 Inclusion Criteria:

1) 18+ years of age;
2) Male gender;
3) Sex with 1+ men in the prior year;
4) Diagnosis of HIV and currently prescribed ART;
5) Self-reported detectable VL in past 12 months OR self-reported problems with HIV medication adherence;
6) Residing in the New York City metropolitan area and availability meet with project staff at each assessment time point; and
7) English-speaking (since the intervention will be in English).
8) Self-reported recent drug use (the sample will be stratified by recent drug use and non-recent drug use)

9.2 Exclusion Criteria:

1) 17 years of age or younger;
2) Not male gender;
3) 0 male sex partners in the prior year;
4) No diagnosis of HIV and/or not currently prescribed ART;
5) No self-reported detectable VL in past 12 months OR self- reported very good/excellent HIV medication adherence;
6) Residing outside of the New York City metropolitan area and/or no availability meet with project staff at each assessment time point; and
7) Non-English-speaking (since the intervention will be in English).

9.3 Screening:

Persons interested in the study will be scheduled for an in-person appointment at CHEST to complete the screener items, baseline VL blood draw, and urine samples for drug use. Those that meet the inclusion criteria and do not meet the exclusion criteria will be guided through the consent process and randomized.

10.0 Vulnerable Populations

10.1 Vulnerable Populations: *Identify which of the following populations will be involved in this study. (You may not include members of the populations*

below as participants in your research unless you indicate this in your inclusion criteria above.)

☐ Children
☐ Pregnant women/Fetuses/Neonates
☐ Prisoners
☐ Adults lacking capacity to consent and/or adults with diminished capacity to consent, including, but not limited to, those with acute medical conditions, psychiatric disorders, neurologic disorders, developmental disorders, and behavioral disorders
☐ Non-English speakers
☐ Those unable to read (illiterate)
☐ Employees of the researcher
☐ Students of the researcher
☒ None of the above

10.2 *Adults lacking capacity to consent and/or adults with diminished capacity to consent:*

N/A

10.3 Additional Safeguards:

N/A

11.0 Number of Participants

11.1 Number of Participants to be Consented:

410

12.0 Recruitment Methods

12.1 Recruitment Process:

In order to recruit at least 20 eligible men per month during the full randomized controlled trial, research staff at CHEST will use multiple approaches, all coordinated by the Director of Recruitment who has several years of experience recruiting MSM for RCTs at CHEST. First, two recruiters will be utilized for active field-based recruitment efforts. They will target venues such as gay bars, community events, and HIV clinic settings. Potential participants will be given project related materials, and can call later for an appointment, provide contact information for a CHEST staff member to call them to schedule the in-person baseline visit, or schedule the appointment at the time of recruitment, depending on the venue and interests of the participant. Rigorous efforts will be undertaken to ensure that recruitment staff maintain adherence to the study protocols, and recruiters receive extensive training in how to approach potential participants and follow strict written guidelines regarding ethics and

professional conduct. All recruitment images and text for flyers, palm cards, and online banner ads are attached (Recruitment Materials).

Recruiters work in pairs to ensure their safety and adherence to protocol. Recruiters utilize palm cards with information about the study, and conduct on-site preliminary screening via iPads. After each recruitment shift, recruiters complete a report to facilitate the overall monitoring of the recruitment process. Second, a passive recruitment strategy through advertising will be developed by our consultant, who has been leading marketing efforts for intervention trials at CHEST for over ten years. Advertisements will be run in publications targeting MSM in NYC, brochures will be developed for distribution at HIV clinics and AIDS service organizations, and online recruitment will be conducted via Facebook postings.

Men recruited for usability testing will be recruited using similar methods as described above.

12.2 Source of Participants:

Participants will be recruited through a combination of the active and passive recruitment strategies described above, both from the community and from CHEST's network.

12.3 Identification of Potential Participants:

Participants will self-identify in response to banner ads, flyers, or targeted outreach by CHEST recruiters.

12.4 Recruitment Materials:

Recruitment materials will include palm cards, flyers, and web ads, samples of which are attached.

12.5 Payment:

Participants will be offered $50 in cash for every study visit at baseline, 6-month, and 12-month follow-up. In addition, we will offer a $25 Amazon gift card raffle each week for participants who engage with the TWM intervention in a weekly basis. Thus, participants could possibly earn up to $750 if they won the raffle each time (which is highly unlikely). However, realistically, participants will earn $200 for completing the assessments and possibly a $25 Amazon raffle if they are chosen in a given week. Raffle winners will receive their gift card code via email.

Participants in the usability testing group will be given $50 cash at each study visit, baseline and follow-up interview. Payment to subjects will be made during each visit (baseline, 6-month, and 12-month follow-up) and will be administered by CHEST staff. Each study visit will provide the opportunity to earn $50 and therefore the payment will not be prorated.

Subjects will be paid during each assessment period and therefore participants will be paid only for those assessments they present for. If a participant has elected to continue to participate in the study after moving out of the study area, payment for follow-up visits will be sent by electronic Amazon gift card.

13.0 Withdrawal of Participants

13.1 Withdrawal Circumstances:

Due to its social nature the intervention website will be monitored regularly by study staff. If a participant is found to be behaving in an inappropriate or abusive manner, or is not acting in accordance with the community guidelines established on the site, the study coordinator will reach out to the individual about modifying their behavior. If an individual continues to disrupt the experiences of other participants they may be withdrawn from the site. Participants may also choose to withdraw themselves from study participation at any time.

13.2 Withdrawal Procedures:

When a participant is withdrawn for any reason, data collection will cease and no further follow-up will occur. For control participants, CHEST staff will record the reason for their withdrawal and remove them from the email list for the control emails and cease follow-up. For intervention participants, CHEST will record the reason for their withdrawal and cease follow-up, and UMN staff will terminate the participant's access to the TWM site. Data that has been already collected will be deleted at the request of the participant.

13.3 N/A

14.0 Risks to Participants

14.1 Foreseeable Risks:

We identified the following 6 items as possible risks to subjects:

1) By misspelling a web address or "surfing" the net, some individuals may unintentionally go to the study website. We deem this unlikely as we will use the prefix "https:" to prohibit persons from coincidentally viewing the site, and we intend to recruit from a website that is explicitly for HIV-related information. Nonetheless, if someone were to mistakenly view the study website home page, we anticipate that the information contained on the homepage will be benign to viewers.
2) Potential participants or participants enrolled in the study may have concerns about others finding out about their HIV status or other personal behavior (e.g., sexual behavior). We anticipate that the likelihood of this occurring is high given that a major feature of the intervention is for participants to network with one another and that eligibility for enrollment in the study requires participants to identify as

a HIV+. Subjects will be informed during the consent process of the basic features of the intervention and those who are not comfortable interacting with other HIV+ persons will be encouraged to not participate in the study. Those who do enroll will be given the option of utilizing intervention features with which they feel comfortable, although utilization of all features will be encouraged.

3) Participants may feel discomfort in answering personal questions during the assessments and/or revealing aspects of themselves during the intervention period with other participants. Similar to #2 above, the nature of the assessment and intervention is such that participants will be encouraged to provide personal information about themselves and therefore the likelihood of this occurring is high. During the assessments, participants will given the option to choose a "refuse to answer" response, and, during the intervention, participants can divulge as little or much about their personal history as they choose. We anticipate that these steps will ensure that risk to the participant is minimized to his comfort level.
4) Participants may receive hostile communications or incorrect information from other participants during the course of the intervention. It is possible that some participants may respond aggressively or with hostility to other participants. Likewise, although well-intended, participants may provide inaccurate information about adherence or its risk factors to other participants by interactions through the website message boards/social networking wall.
5) Participants may be concerned about the security of their data, particularly since it is collected and stored electronically. Our study team has significant experience developing security protocols for Internet-based studies, and we will take a variety of steps to ensure participant security, including using a dedicated server behind a firewall, encryption of data, separation of identifiers from responses, and password-protected access to data. Therefore, we believe that this risk will be minimal.
6) Discomfort or infection due to phlebotomy.

14.2 Reproduction Risks:

N/A

14.3 Risks to Others:

N/A

15.0 Incomplete Disclosure or Deception

15.1 Incomplete Disclosure or Deception:

N/A

16.0 Potential Benefits to Participants

16.1 Potential Benefits:

Potential Benefits. Participation in the TWM arm may provide participants with information and exercises that help them build peer social support, monitor their medication adherence and HIV-related care appointments, and develop skills. Participants in the control group may gain basic knowledge about medication adherence and links to outside resources. In either the experimental or control condition, the primary benefit is access to health information that may assist participants to improve adherence and quality of life. Secondary benefits include positive feelings related to having assisted in the development and testing of a novel Internet-based adherence intervention, and if proven effective, the future availability of this intervention to others.

17.0 Data Management

17.1 Data Analysis Plan:

Analyses will be performed using Stata/SE v13 or later. The study design is a 2 (Condition: Intervention vs Control) X 4 (Time: baseline, immediate post-intervention, 6-, and 12-month post-intervention) randomized trial, with Condition a between-subjects effect and Time a within-subjects effect. The two primary outcomes are dichotomous: undetectable VL (undetectable=VL<20 copies/mm3 vs. detectable=VL>20 copies/mm3) and adherence to ART (high adherence>=90% adherence vs. low adherence<90% adherence). Mixed-effect logistic regression models will be used to test hypotheses. These models will include main effects for Condition and Time and the Condition*Time interaction (a 3 degree-of-freedom comparison; the overall test of the hypothesis) and model-based rate-ratios and risk differences will be estimated. We will also estimate a series of single degree-of-freedom comparisons (using planned contrasts) to estimate the effect of the intervention on adherence at immediate post-intervention, and at 11- and 17-month follow-ups points relative to baseline.

The multilevel model will accommodate missing values in the outcome over time without dropping participants. Multiple imputation will be implemented, as necessary, to deal with missing covariate data. We will investigate confounder imbalance address any imbalances by modeling covariates or, if necessary, propensity score matching. We will primarily estimate effects as ITT, but will also examine as treated estimates, always being clear what we report and why. Efficacy of the TWM intervention will be indicated by a statistically discernable improvement in ART adherence and viral load at 10-month post intervention assessment. We will graph observed and predicted values for easy interpretation.

We will investigate whether there is greater benefit from the TWM intervention for drug-using participants compared to non-drug-using participants. We will use the approach describe above with the two additional factors, self-reported current (past 5 months) drug use and the interaction with intervention (and time). In a similar manner, we will conduct exploratory analyses to identify other baseline participant risk groups for which the intervention is most beneficial. In addition, for participants in the TWM intervention, we will examine the effect of type and amount of intervention exposure (i.e., which component usage are related to outcomes) on improvement in ART adherence. All models will be altered and examined for robustness to specification.

17.2 Power Analysis:

With N=400 (200 I, 200 C) and baseline undetectability of approximately 60%, at any single time point are powered to detect an approximately 14% difference in detectability. If both groups have approximately 60% undetectability at baseline, and we assume that the Intervention group will sustain that going forward, we could detect a difference of 14% undetectability at 5 months. Specifically, 60% undetectability in the Intervention group and 46% undetectability in the Control group at 5 months.

17.3 Data Integrity: *N/A*

18.0 Confidentiality

18.1 Data Security:

In this study, all paper consent forms will be stored at CHEST in a locked file cabinet in Dr. Jeffrey Parsons' office. All other paper documents will be stored in a filing cabinet used by the study team, and thus accessible to all the investigators. Original documents about subjects that could identify a subject will be kept in a separate locked filing cabinet in the PI's office. Nearly all of the data will be collected electronically by either entering it in Qualtrics or collected through the TWM intervention website. That data will be stored on a secure password protected UMN server.

Data are collected and stored on University of Minnesota servers. Identifying information are separated from their data into distinct tables. Participant information is stored at the time of enrollment and identification numbers are generated by computer. Only the PI, project statistician and project coordinator have access to this identifying information, protected in a password-protected database. All data stored within computer files will be password protected behind a firewall to ensure that access is available only to those directly involved in the study analysis. Only data that has been stripped of all personal identifying information is made available to study investigators. At study completion, the link between the identifying

information and their data is destroyed, as is contact information. Two sets of the cleaned data set will be maintained—one working copy at the University of Minnesota computer system and one on a password protected drive stored in a locked filing cabinet. This approach ensures that the data survives in the event of failure of the computer system. Finally, all study investigators and staff will have completed the CITI Course in the Protection of Human Research Subjects online training in research ethics to ensure that all staff are compliant with confidentiality training.

Data collected from surveys, blood draws for VL, and urine screens will be entered into Qualtrics. Qualtrics is the preferred survey and screening tool for the University of Minnesota because it "meets stringent information security requirements" including a password protected log-in based on our institution's x500 system. Participants will be assigned a user ID upon enrollment. Enrollment data with identifying information will be de-coupled from survey responses and records of VL and substance use. The TWM website will use an https URL and entry into the website is also password protected.

19.0 Provisions to Monitor the Data to Ensure the Safety of Participants

The PI is responsible for monitoring adverse events occurring during the study. In the event the PI is unavailable, Dr. Erickson has overall responsibility during his absence. The role of the person responsible is to: 1) to identify the concern, 2) activate an appropriate response (consulting where ever possible) to minimize the adverse event, and 3) ensure the adverse event is reported to the responsible authority in a timely manner.

Anticipated adverse events: In this behavioral research, the risks as a result of participation are considered minimal and primarily involve a) emotional discomfort due to the sensitive nature of the questions asked in the surveys and the information presented, as well as the features available in the intervention, b) the potential for hostile interactions with other participants, c) obtaining inaccurate information about adherence from other participants, and d) the risk of loss of confidentiality. Because this study includes individuals living with HIV/AIDS, there is also the potential for a participant to become physically ill during participation at the study site.

Emotional discomfort: Emotional discomfort may be identified in two ways. First, participants may directly correspond with project staff and report emotional discomfort. Second, emotional distress may be identified through daily monitoring of user-generated content during the intervention. To address the risk of participant distress, all

participants are given information on how to contact the PI, the project coordinator, and the human subjects protection program. Situations in which emotional distress is noted through daily monitoring, study staff will contact the participant directly via e-mail and/or telephone. If such contact is made, the PI or project coordinator will assess the degree of emotional discomfort and either reassure the participant or provide resource information to locate a mental health provider for counseling. The PI and project coordinator will be available at any point to assist with locating an appropriate mental health provider. When indicated, the investigator will ask for permission to phone the participant at an appropriate follow-up time (e.g., the next day) to ensure any potential adverse event is followed-up adequately. If the project coordinator is handling the matter, he is responsible for informing the PI as soon as logistically possible that an adverse event may have occurred. All reasonable steps will be taken to ensure that the participant's confidentiality is protected while attempting to facilitate the appropriate level of care.

Hostile interactions: We will use the daily monitoring as an opportunity to flag hostile interactions between participants. Hostile interactions between participants will be handled by, first, reminding the participants in the interaction of the "group rules" regarding appropriate interactions. If the hostility continues, the offending participants will be given a warning that the continued hostility will result in withdrawal from the study if it continues. On the third offense, the offending participant will be withdrawn from the study. Text containing hostile exchanges will be removed from the study website and unavailable to view.

Inaccurate adherence information: We have established a daily monitoring protocol to review user-created content for inaccurate adherence information (in addition to emotional discomfort arising from hostile interactions or intervention activities). In cases in which inaccurate information is found in the forums, project staff will post a comment on the forum that provides accurate information on the topic.

Risk of loss of confidentiality: The protections against loss of confidentiality have been summarized in the protection against risks section above. The PI is the person primarily responsible for ensuring that no loss of confidentiality occurs. Any loss of confidentiality that occurs despite these protections will be dealt with on a case-by-case basis. We would expect to hear about any loss of confidentiality in one of the following ways:

- Loss of confidentiality secondary to attempt to subpoena. Should someone attempt to subpoena our data, the PI will immediately activate our emergency response protocol. This protocol includes informing the university attorneys, our IRB office, and the project officer at NIH, that a legal attempt is being made to subpoena a person's data. In the first instance, the PI is responsible for seeking legal advice on how to respond to the request. Where a specific participant is named, the PI shall ask the NIH project officer, our IRB, and our legal advisor whether or not to inform the subject that an attempt to subpoena his data has been made.
- Loss of confidentiality secondary to theft, hacking or other illegal activity. During the course of the study, if we discover that despite security precautions our computer system has been hacked, or if someone has illegally gained access to any data, then the PI will try to determine to what extent the hacking has been successful. The investigator is responsible for informing the President's office, the University of Minnesota attorneys, our IRB, the NIH project officer, and, if deemed appropriate, our police department. The PI, in consultation with the above persons, is responsible for determining what action, if any, is appropriate. It is anticipated that in the unlikely event such an action occurred, we would first attempt to contact every subject to inform them that their data may have been hacked, and second, where a person or agency is suspected of having illegally gained access to confidential materials, to seek legal recourse to prevent further use or distribution of the data. Upon reasonable suspicion that our database has been hacked, all data collection shall be suspended until such time that the incident has been reviewed and a secure mechanism of continuing to obtain and store data has been re-established.
- Death occurring during the study. AIDS, by definition is a life-threatening condition. We may anticipate some loss to follow-up due to death. We expect notification of death to come primarily when all attempts to contact the participant have failed, and we call their contact person. In such cases, we will identify ourselves as "calling from the Hunter College, trying to locate <<person's name>> in regard to a study we are conducting." Requests for information about the study will be politely declined since they could constitute a threat to confidentiality. Where contacts report a participant has died, it will be our practice to express our sympathies to the person, thank them for providing the information, and to terminate the call, as soon as propriety allows. While IRB requirements for clinical studies include to report all deaths during a study, such requirement do not pertain to the evaluation of behaviorally-based Internet-based interventions.

Hence, we will seek permission from our IRB not to report deaths occurring during the follow-up phase of the study, but instead to log these as natural events to be reported at the end of the study.

20.0 Provisions to Protect the Privacy Interests of Participants

20.1 Protecting Privacy:

During assessments with CHEST NYC, participants will be given the option to choose a "refuse to answer" response, and, during the intervention, participants can divulge as little or much about their personal history as they choose. We anticipate that these steps will ensure that risk to the participant is minimized to his comfort level. In online interactions with the site, users will post and comment under anonymous usernames and site guidelines will prohibit the posting of personal information or identifiable photographs.

20.2 Access to Participants:

In-person access to participants will be limited to trained staff at CHEST who interact with them in-person at CHEST offices or by telephone. Online access to participants will be limited to trained staff at CHEST and UMN who will interact with them virtually through the password protected TWM interface and through occasional general e-mails (i.e., when we need to reach participants about the prize drawing) that do not reveal the nature of the study and protect the privacy of the participants.

21.0 Compensation for Research-Related Injury

21.1 Compensation for Research-Related Injury:

N/A

21.2 Contract Language:

N/A

22.0 Consent Process

22.1 Consent Process (when consent will be obtained):

Men who meet eligibility criteria will be guided through the consent process by trained research staff at CHEST. All study staff will undergo a thorough training and certification procedures prior to protocol implementation, including mandatory Protection of Human Subjects training in research ethics. The initial training will be conducted in-person by Dr. Horvath and will include an overview of the study, detailed explanation of the study protocol, and discussion of specific protocol components. Study staff will be observed at least twice a year to determine whether appropriate protocols are being followed. If protocols are not followed, retraining will be done as needed.

- Persons will be asked to do the following to assess understanding of the study:
- Please describe this study in your own words.
- Please describe what you will be asked to do during the study.
- Please describe your rights as a research participant.
- Please describe what will happen to you should you choose to withdraw from this research study.

Participants will be told during the consent process that his participation in this study is purely voluntary and that he has the right to withdraw from the study at any time. Participants will also be informed that their relationship with CHEST or the University of Minnesota will not be affected in any way should they choose to withdraw or not participate in the study. Finally, participants will be assessed as to their understanding of the voluntary nature of this study.

22.2 Waiver or Alteration of Consent Process (when consent will not be obtained, required information will not be disclosed, or the research involves deception):

N/A

22.3 Non-English Speaking Participants:

N/A

22.4 Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age):

N/A

22.5 Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent:

N/A

22.6 Adults Unable to Consent:

N/A

23.0 Setting

23.1 International Research:

N/A

23.2 Community Based Participatory Research:

N/A

23.3 Research Sites:

The partner site for this study will be Hunter College Center for HIV Educational Studies and Training (CHEST; Director: Dr. Jeffrey Parsons). CHEST is a behavioral research center in New York City with a 17-year

history of recruitment, enrollment, and retention of MSM and PLWH into behavioral intervention trials. CHEST is well prepared to carry out the proposed study activities, has expertise in optimizing retention for follow-up assessments, and has capacity to conduct on-site VL testing and urine drug screening, having done this for numerous NIH funded RCTs. After gaining approval from UMN IRB, CHEST will also submit an IRB application to their IRB (City University of New York). CHEST will be responsible for recruitment, on-site VL testing and urine drug screening, and training of participants when they begin using the site.

24.0 Multi-Site Research

24.1 Study-Wide Number of Participants:

410

24.2 Study-Wide Recruitment Methods:

Participants will be recruited through banner ads on a number of social networking sites including those that are specifically for MSM (sample ads attached), and by CHEST. CHEST will utilize both active (e.g., direct outreach) and passive (e.g., advertising in clinic settings, internet-based) recruitment approaches to effectively recruit HIV+ MSM into the trial.

24.3 Study-Wide Recruitment Materials:

Sample flyers, banner ads, and palm cards are attached.

24.4 Communication Among Sites:

N/A

24.5 Communication to Sites:

The study coordinator and CHEST will hold weekly phone calls to discuss general updates, and any issues will be promptly communicated between the University of Minnesota research team and CHEST by email. Interim and final results will be shared electronically as appropriate.

25.0 Resources Available

25.1 Resources Available:

Recruitment Feasibility: Men residing in the New York City metropolitan area will be recruited by CHEST staff to participate in this study. New York City was chosen as an ideal location to conduct the study because of the high numbers of HIV-infected MSM residents and since only 38% of residents with HIV are estimated to be virally suppressed. CHEST utilizes both active (e.g., direct outreach) and passive (e.g., advertising in clinic settings, internet-based) recruitment approaches to effectively recruit HIV+ MSM into intervention trials; and their field-based recruitment efforts are successful in enrolling substance users. In addition, they have had success with field-based recruitment in AIDS service organizations (ASOs) in

enrolling HIV+ MSM men of color who are not engaged in clinic-based care, but rely on services offered by ASOs. In previous intervention trials with substance using HIV+ MSM, more than 50% of enrolled participants were men of color.

In order to recruit and enroll 20 eligible men per month, CHEST will use multiple approaches, all coordinated by our Director of Recruitment who has several years experience recruiting MSM for RCTs at CHEST. First, two recruiters will be utilized for active field-based recruitment efforts. They will target venues such as gay bars, community events, and HIV clinic settings. Potential participants will be given project related materials, and can call later for an appointment, provide contact information for a CHEST staff member to call them to schedule the in-person baseline visit, or schedule the appointment at the time of recruitment, depending on the venue and interests of the participant. Rigorous efforts will be undertaken to ensure that recruitment staff maintain adherence to the study protocols, and recruiters receive extensive training in how to approach potential participants and follow strict written guidelines regarding ethics and professional conduct. The first several recruitment shifts are monitored by the Director of Recruitment, and random spot-checks will be made on subsequent trips. Recruiters work in pairs to ensure their safety and adherence to protocol. Recruiters utilize palm cards with information about the study, and conduct on-site preliminary screening via iPads. After each recruitment shift, recruiters complete a report to facilitate the overall monitoring of the recruitment process. Second, a passive recruitment strategy through advertising will be developed by our consultant, who has been leading our marketing efforts for intervention trials at CHEST for over ten years. Advertisements will be run in publications targeting MSM in NYC, brochures will be developed for distribution at HIV clinics and AIDS service organizations, and online recruitment will be conducted via banner ads, pop-ups on social apps, craigslist postings, and through listserv and e-blast advertising.

CHEST Facilities:

Adequate office space will be provided for study staff at CHEST's research space in midtown Manhattan. CHEST is within close proximity (walking distance) to a variety of health and community service providers including the NYC Department of Health. Further, because CHEST is located in central Manhattan, there is minimal travel time between community and health service providers who may be further away (e.g., in Queens, the Bronx, Brooklyn, Jersey City, Staten Island). This proximity has resulted in established linkage agreements between CHEST and community providers (i.e., referring participants, linking them to care), a vast array of resources for CHEST to recruit potential participants and spread the word about

research opportunities at CHEST, and in rapidly disseminating our findings to our community partners (i.e., in disseminating our findings and identifying community-based needs, our team regularly meets with community providers across NYC). CHEST has maintained NYC-based office space for over 15 years, moving to a newly renovated space in 2012. In addition to the space at CHEST, facilities are also available at Hunter College, and the CUNY Graduate Center located three blocks away.

At CHEST, staff members are provided with a desk, computer (equipped with password encryption), telephone, high-speed internet access, and printer. CHEST maintains all necessary office equipment including copy-machine, fax, teleconference capabilities, LCD overhead projector (necessary for project meetings and staff training/supervision), and dynamic network computer server (where electronic files are securely backed up). CHEST maintains full capacity to operate as a research space in tandem to an office environment (e.g., full conference room for project-related meetings and trainings, office space for staff, private waiting area for participants, and private interview rooms). The private interview rooms vary in size and are all equipped with a computer, video camera and digital voice recorder. Each project maintains a secure-locked storage and filing cabinet to house physical copies of participant information (e.g., consent forms).

Important for both project administration and individual career and skills development, CHEST has established protocols in place for training, supervision, and monitoring of data collection and analysis, for the ethical conduct of research, and for mentorship. In addition, extensive protocols have been established with regard to recruitment of research participants and intervention fidelity monitoring.

Resources for Participants:

Names, descriptions, and contact information for crisis hotlines and local assistance programs are provided on the TWM website for users who may need them, and users are directed to them as needed.

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