PROTOCOL TITLE: Scale it up: Effectiveness-implementation research to enhance HIV-related self-management among adolescents and young adults: Tailored Motivational Interviewing Implementation Intervention (TMI)

PRINCIPAL INVESTIGATOR:

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	8/9/19	Adding 2 key personnel, a release of information form, and clarifying protocol on coding lab	No
2	12/8/21	Updating language related to data for future use (section 7.0 – Data and specimen banking) to comply with NIH data sharing policies	No

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1.0 Study Summary

Study Title	Scale it up: Effectiveness-implementation research to enhance HIV-related self-management among adolescents and young adults: Tailored Motivational Interviewing Implementation Intervention (TMI)
Study Design	Multi-site clinical intervention targeting health care providers
Primary Objective	Test a multi-faceted Tailored Motivational Interviewing Implementation intervention (TMI), based on the DAP to scale up an EBP in multidisciplinary adolescent HIV care settings while balancing flexibility and fidelity
Secondary Objective(s)	Sustainment through communities of practice (CoP)
Research Intervention(s)	multi-faceted Tailored Motivational Interviewing Implementation intervention
Study Population	10 Adolescent HIV sites in the US
Sample Size	Average of 15 providers per site (current N=139)
Study Duration for individual participants	3 years
Study Specific Abbreviations/ Definitions	Tailored Motivational Interviewing Implementation intervention (TMI); Dynamic Adaptation Process (DAP); implementation science (IS); youth living with HIV (YLH); Motivational Interviewing (MI); evidence-based practice (EBPs); exploration, preparation, implementation, and sustainment phases (EPIS); Communities of Practice (CoP); Implementation team (iTeam)

2.0 Objectives*

The goal of this proposal is to test a multi-faceted Tailored Motivational Interviewing Implementation intervention (TMI), based on the Dynamic Adaptation Process (DAP) to scale up an EBP in multidisciplinary adolescent HIV care settings, while balancing flexibility and fidelity.

To address this goal, we are using a dynamic wait-listed design to determine the impact of TMI on the integration of MI with fidelity in 10 adolescent HIV sites in the United States with an average of 15 providers and 100 patients each. At the start of TMI, clinics were randomly assigned in 5 blocks of (2 sites each) sites 3 months apart. Role play completion is considered consent to participate. Provider competence ratings (primary outcome) are collected quarterly during pre-implementation, implementation, and sustainment. Across sites, providers preceding the implementation intervention form a control or comparison group, and the providers following the start of the implementation intervention form the intervention group. As each block completes a year of implementation, those sites are re-randomized to internal facilitation (a person from each site will be chosen to be an MI supervisor to be available for ongoing coaching) plus Communities of Practice (CoP), or CoP only. For the CoP, the site will decide how to meet as a group to continue MI practice.

3.0 Background*

The NIH Office of AIDS Research called for implementation science (IS) to address the behavioral research-practice gap. Motivational Interviewing (MI) is the only behavioral intervention to date shown to be effective to improve self-management for youth living with HIV (YLH). MI was also the only intervention to demonstrate success across the youth HIV care cascade. MI interventions can target multiple behaviors and be delivered by multiple provider-types as is common in adolescent HIV care settings. Finally, MI is already embedded in the clinical guidelines for HIV care and HIV risk reduction. Implementation Science is the scientific study of methods to promote the uptake of research findings and evidence-based practice (EBPs) to improve the quality of behavior change approaches in health care settings. A primary challenge of scaling up EBPs is the balance of flexibility (adaptation to context) and fidelity (provider adherence and competence). The Dynamic Adaptation Process (DAP) guides tailoring of MI implementation at the exploration, preparation, implementation, and sustainment phases (EPIS) of scale up. The goal of this project is to test a multi-faceted Tailored Motivational Interviewing Implementation intervention (TMI), based on the DAP to scale up an EBP in multidisciplinary adolescent HIV care settings while balancing flexibility and fidelity.

4.0 Study Endpoints*

One of the primary goals of this study is to help participants hone and develop new MI skills to increase medication and treatment adherence among the youth that they serve in HIV clinics. Thus, the primary outcome is improving MI skills among the health care provider participants in the study, with secondary goals of improving health outcomes for youth living with HIV and risk reduction among youth at risk for contracting HIV.

5.0 Study Intervention

TMI Implementation Intervention Strategies:
Pre-Implementation: Key stakeholders were identified for the Implementation team (iTeam). The iTeam have conference calls during the baseline period to discuss barriers and facilitators and iteratively draft locally-customized implementation strategies until iTeam members and experts "approve" the strategies. The first iTeam call is initiated 6 months prior to the start of the Implementation phase at each site and monthly iTeam calls start 3 months prior to the start of the Implementation phase at each site. In addition, the iTeams have the option of implementing an anonymous consumer satisfaction of clinic environment survey, which will be provided via a Qualtrics survey link and anonymous data is shared with the study team. This survey is administered 1-month prior to the workshop, 1 month after the workshop, and 1 year after the workshop.

Implementation. Adapted training begins in this phase. The iTeam continues to meet monthly to review adherence to program requirements and external MINT facilitator reports and recommends further adaptations as necessary while maintaining fidelity to minimum requirements detailed below.

Initial Workshop. Ten hours of group workshop training were delivered by members of MINT (Todd, Hartlieb, Cockern), adapted from findings of sequential analysis in our pilot work and interactions with the local iTeams. MI training relies on experiential activities developed by the network while minimizing didactic presentations. Cooperative learning methods allow staff members to coach each other in small groups to promote experiential learning and group cohesion. Group MI methods are included to increase intrinsic motivation for implementation strategies. Non-TMI participants to attend the workshop if desired. Attendance was capped at 25 so that sufficient individualized attention could be given to attendees, and TMI participants were prioritized for attendance. TMI participants were only eligible to continue beyond baseline participation if they attended at least 50% of the workshop.

Fidelity Monitoring. Provider MI competency will be measured with the MI Coach Rating Scale (see Measures below) during the baseline, implementation, and sustainment periods. Individual coaching following each quarterly assessment will be triggered by a provider falling below the competency threshold on the standardized patient interaction for the quarterly assessments during the implementation period only. To define this threshold, during the project start-up phase, Dr. Chapman will lead an IRT-based standard setting process. To accomplish this, there are several steps: (1) Enlist a sample of approximately 8 - 10 MI experts. (2) Obtain each expert's (independently rated) pool of "essential" MI items. This will be achieved using a survey format that is similar to traditional "bookmark" standard setting procedures, with the expert indicating whether or not each item is essential for acceptable TMI competence. (3) Compute the average "difficulty" of the selected items for each expert based on the item difficulty calibrations from the NHLBI-funded center grant, and compute the average difficulty across experts. (4) Compute confidence bounds for the mastery level using the standard error of the Rasch measure. (5) Construct the competence threshold score (i.e., the standard) as the criterion score + mastery level ± confidence level. (6) Apply the competence standard to data from the previous projects with scale (NHLBI-funded center grant and ATN 128), and, as a source of validity evidence, test whether key outcomes differ for providers above and below the competency threshold.

Coaching Feedback. Providers receive written feedback regarding their competency scores based on the RA coding of recordings of standard patient interactions. All participants will receive two, 1-hour coaching sessions by a MINT trainer following the workshop, but before the next quarterly assessment. Participants may receive a 45-minute coaching session by a MINT trainer following each quarterly assessment during the implementation period only. This coaching is required if scores fall below competency and optional if scores are above competency. The standardized coaching includes a brief interaction to elicit change talk around MI implementation, feedback on two highest and two lowest ratings, review of the role play audio recording and interactive coaching activities (e.g., role plays) targeting the lowest ratings.

Organizational Supports. While many aspects of this implementation strategy are adaptable, organizational leadership will review data on completion of the role play and coaching sessions and will determine corrective action for suboptimal adherence. Each site will receive the same incentive budget (equivalent of $50 per staff member) and will determine whether incentives will be provided episodically or after program completion. The iTeam will decide how to deliver incentives (i.e., directly to individuals for completion of program requirements, utilize a lottery system, or provide a group reward when all site participants adhere to program requirements); however, beginning in cycle 8, participants must be provided at least a $10 incentive for completing role plays.

Sustainment. The iTeam will guide the site(s) to develop a community of practice (CoP). CoPs are based on a view of learning as an individual and social phenomenon rather than a one-way transfer of formal knowledge between groups or individuals. By having providers participate in the implementation phase, a CoP is already beginning to develop at the sites. The iTeam will guide the continued development of the CoP as needed by assisting with scheduling and setting meeting agendas to encourage MI practice, peer coaching and potentially fidelity monitoring, and prevent drift. In addition to CoP, half the sites will be randomized to receive 0.1 FTE of funding during the sustainment period for an internal facilitator who will be trained to continue quarterly fidelity monitoring and coaching feedback when scores fall below competency. The funding may be split among two facilitators to account for staff turnover. The iTeam will choose the facilitator(s) based on participant competency, provider interest and motivation, and the participant's role within the organization. The chosen internal facilitator will be given the option of declining this position for any reason. If they choose to accept the appointment, they will be asked to sign a release of information to help the study team and site ensure their ability to act in the role of internal facilitator. The internal facilitator will be able to choose how much information is shared and with whom the information will be shared.

6.0 Procedures Involved*

Participants will be part of a multi-phase motivational interviewing (MI) implementation program through the sites where they are employed. MI training will be conducted at sites as part of ongoing professional development.

Participation in the study includes:

(1) Fidelity Assessments: Quarterly for three years, participants will complete audio recorded standardized patient interactions (a total of 13) over the phone (approximately 30 minutes each) with a study staff member. The study staff member will role play as a patient with HIV and record the session, which will be rated using the MI Coach Rating Scale. This is being done to conduct assessments of their MI skills.

(2) MI training. An MI training workshop will be conducted as part of professional development at the sites. The timing of the training will depend on randomization (two sites are randomized to receive MI training every three months for up to 15 months). Prior to a participant's site's MI training, they will complete standard patient interactions quarterly. While the total number of interactions does not change, the number of interactions they do prior to training depends on their sites randomization and will vary from 2 to a maximum of 6. In the period following initial training, but before the next fidelity assessment, participants will complete two 1-hour coaching sessions over the phone. Following this period, participants may receive additional coaching quarterly for one year following the fidelity assessments described above.

After one year, sites will be randomized to internal facilitation (a person from each site will be chosen to be an MI supervisor to be available for ongoing fidelity monitoring and coaching) plus CoP (the site will decide how to meet as a group to continue MI practice), or to CoP only.

Implementation Teams (iTeams): There will also be an opportunity for some participants to be part of the iTeam at each site. The iTeam will meet monthly to review study progress and make recommendations for how best to implement and sustain MI at each Tailored Motivational Interviewing (TMI) Implementation Intervention site.

Data is formative, longitudinal, qualitative, and quantitative in nature.

7.0 Data and Specimen Banking*

The database will be password protected and stored on a password protected computer and cloud server.

At the end of the study data collected will be made available, in accordance with the NIH Data Sharing Policy (http://grants.nih.gov/grants/policy/data_sharing). These data will be saved for future use and may be shared with other researchers. The data stored and shared cannot be linked to participants (i.e., deidentified data will not link information to PHI, site, date, and city).

8.0 Sharing of Results with Subjects*

Participant providers are part of the Adolescent treatment network (ATN) and may access the findings of the study once published through this network.

9.0 Study Timelines*

At this time all participants are enrolled and all sites have either begun or completed the implementation phase. All sites are projected to complete participation by November 2020.

10.0 Subject Population*

The table below provides a breakdown of the current participant pool and participation in the beginning of cycle 8. Participants are affiliated with clinical sites within the ATN.

PROGRESS BY SITE	
Site 1	
17	Total Consented
6	Discontinued TMI participation
11	Active (current participants)
0	Completed this cycle
11	Not completed
Site 2	
19	Total Consented
6	Discontinued TMI participation
13	Active (current participants)
2	Completed this cycle
11	Not completed
Site 3	
18	Total Consented
8	Discontinued TMI participation
10	Active (current participants)
0	Completed this cycle
10	Not completed
Site 6	
29	Total Consented
9	Discontinued TMI participation
20	Active (current participants)
3	Completed this cycle
17	Not completed
Site 7	
18	Total Consented
3	Discontinued TMI participation
15	Active (current participants)
1	Completed this cycle
14	Not completed
Site 8	
16	Total Consented
4	Discontinued TMI participation
12	Active (current participants)
0	Completed this cycle
12	Not completed
Site 10	
11	Total Consented
1	Discontinued TMI participation
10	Active (current participants)
0	Completed this cycle
10	Not completed
Site 11	
15	Total Consented
4	Discontinued TMI participation
11	Active (current participants)
0	Completed this cycle
11	Not completed
Site 12	
24	Total Consented
5	Discontinued TMI participation
19	Active (current participants)

0	Completed this cycle
0	Not completed
Site 13	
23	Total Consented
5	Discontinued TMI participation
18	Active (current participants)
2	Completed this cycle
16	Not completed
TOTAL	
190	Total Consented
51	Discontinued TMI Participation
139	Active (current participants)
8	Completed this cycle
112	Not completed this cycle

11.0 Vulnerable Populations*

N/A

12.0 Local Number of Subjects

N/A – all participants are at external sites.

13.0 Recruitment Methods

N/A – the study is no longer recruiting participants. Participants were recruited using the following protocol: "The site Co-PI or his/her designated research staff will complete the TMI Potential Participants form (attached) to refer potential staff to the TMI research staff for potential participation in TMI. The site Co-PI's and site designated research staff will have to option to provide referred staff at their site with an initial introduction to TMI. This introduction will include a review of the TMI information sheet, along with a description the basic procedure and time commitment for the training and implementation of the study. Staff will be informed that participation is voluntary and they will be provided with an opportunity to ask questions. TMI research staff will be available to attend the introductory meeting by telephone or Skype if the site Co-PI so desires. Alternatively, TMI research staff will conduct the introductory meeting by telephone or Skype with referred staff as a group or individually. Referred staff will be encouraged to follow up with TMI research staff individually with additional questions or to decline participation. Referred staff may also decline participation at any time through their site Co-PI or designated representative if they so desire. Once the Co-PI or designated representative has confirmed that the referred staff have received an initial introduction to the TMI study, TMI research staff will contact each referred staff member by email to invite them to participate in TMI by completing a TMI role play. The procedures for scheduling a role play will be described and staff will be reminded that their completion of a TMI role play is their consent to participate in the study (this is described in the information sheet as well). The information sheet will be included in this recruitment contact and staff will be encouraged to review it if they have not already done so and to contact the TMI research staff by phone or email with questions or concerns (recruitment email content is included in the Email Templates document). Interested staff members will initiate scheduling an appointment for a TMI role play. At the time of the TMI role play appointment, the study staff member conducting the role play will verbally confirm with the staff member that s/he understands that completion of the role play is his/her consent to participate in the TMI study. If the staff member confirms, then the TMI role play is completed. If the staff member does not confirm, or has additional questions, the actor will

refer him/her to the TMI project coordinator or TMI senior project assistant for follow-up. The staff member can choose to complete the role play at that time (enrolling in the TMI study), delay a completion decision until after s/he has contacted the TMI project coordinator or senior project assistant, or decline participation in TMI."

14.0 Withdrawal of Subjects*

Participants may choose to leave the study at any point. Participants may be removed from the study based on changes in their clinical role and if they have less than 4 hours of client contact per week on average. Participant data will be included, unless a participant requests that their data is removed. In such cases, the participant's data will be deleted.

15.0 Risks to Subjects*

This study carries no known risks to participants, because it is a study of motivational interviewing (MI) training for staff and implementation of MI in HIV ATN network clinical sites.

16.0 Potential Benefits to Subjects*

Participants will hone new skills expected to be beneficial to increasing the adherence of the youth they serve in their HIV clinics. Motivational interviewing (MI) is a set of skills to expand the capacity of people working with youth living with HIV to provide culturally competent care services and increase successful care outcomes. Participants in this study will receive intensive training and support in MI to improve communication with youth living with HIV during HIV care visits, to improve outreach, as well as prevention programs.

17.0 Data Management* and Confidentiality

Data will be analyzed using formative, longitudinal, qualitative, and quantitative methods. Participants are identified in the research records only by a codename or number. Site staff do not have access to individual participant competency scores, but the iTeam is aware of the extent of participation and aggregated competency. Percentages of site participants above or below competency are shared with the iTeam only after the end of each cycle to avoid inadvertently compromising participant privacy. All staff involved on the project have completed the necessary CITI human subjects training.

In regard to data management, the TMI coding lab functions as a forum to train coders in use of the Motivational Interviewing Coach Rating Scale (MI-CRS), to improve the utility of the MI-CRS, and to coordinate and monitor the ongoing inter-rater reliability (IRR) of coders. Coders use recorded roleplays as practice for coding to maintain the reliability of the data.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

N/A

19.0 Provisions to Protect the Privacy Interests of Subjects

Participants are identified in the research records only by a codename or number. Site staff do not have access to individual participant competency scores, but the iTeam is

aware of the extent of participation and aggregated competency. Percentages of site participants above or below competency are shared with the iTeam only after the end of each cycle to avoid inadvertently compromising participant privacy. Participants complete some group trainings (i.e., MI workshop), but may choose to end participation or withdraw from the study at any time. Participants may choose not to answer questions that cause them discomfort. Only approved staff will have access to participant data.

20.0 Compensation for Research-Related Injury

N/A

21.0 Economic Burden to Subjects

N/A

22.0 Consent Process

A waiver of documentation of consent was previously approved for the current study; however, the TMI information sheet was provided to all participants at the time of the initial introduction to TMI or emailed to them ahead of time. It was provided by email again when the recruitment email was sent. Consent was discussed verbally immediately prior to completion of the first TMI role play. Documentation of consent was not obtained as completion of a role play is considered consent to participate.

23.0 Process to Document Consent in Writing

N/A – a waiver of documentation of consent was previously approved for this study.

24.0 Setting

This is a sub-study associated with the larger SIU study, in which we use the same sites for other associated studies. These sites are a part of the Adolescent Medicine Trials Network for HIV/AIDS Intervention (ATN); please reference protocol number 2017.21748. Research has been ongoing at these sites since 2017.

25.0 Resources Available

Participants have already been recruited and are involved in ongoing research at the sites listed above and below. The CTBScience and FSU College of Medicine are providing other resources not described in site reliance agreements. Multiple study personnel are clinical psychologists and health professionals in the case of an unexpected adverse event.

26.0 Multi-Site Research* (Delete this section if this is not a Multi-Site Research Study.)

Below, presented in the table, are the number of participants active in the study by clinical site for the beginning of cycle 8. All recruitment is complete at this phase of the study. All sites have

existing reliance agreements with the FSU IRB. See attached for the communications worksheet between sites. Communication is open and ongoing between the study team, Site co-PIs, and Study Coordinators. Our team has a designated communication liaison who completes a majority of communication between the team and sites in order to reduce possible confusion.

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14	Not completed
Site 8	
16	Total Consented
4	Discontinued TMI participation
12	Active (current participants)
0	Completed this cycle
12	Not completed
Site 10	
11	Total Consented
1	Discontinued TMI participation
10	Active (current participants)
0	Completed this cycle
10	Not completed
Site 11	
15	Total Consented
4	Discontinued TMI participation
11	Active (current participants)
0	Completed this cycle
11	Not completed
Site 12	
24	Total Consented
5	Discontinued TMI participation

19	Active (current participants)
0	Completed this cycle
0	Not completed
Site 13	
23	Total Consented
5	Discontinued TMI participation
18	Active (current participants)
2	Completed this cycle
16	Not completed
TOTAL	
190	Total Consented
51	Discontinued TMI Participation
139	Active (current participants)
8	Completed this cycle
112	Not completed this cycle