Study Title: Community Translation of the Expecting Study

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Abstract

The proposed research is a sub-objective of a larger research study lead by Dr. Aline Andres. This protocol has one primary aim:

Adapt and determine acceptability, feasibility and fidelity of the *Expecting* intervention with pregnant obese women in community settings.

The *Expecting* intervention as delivered in prior studies in a clinical setting is described in a previous approved IRB submission (Protocol 202954). The current project will seek to engage community stakeholders to translate *Expecting* to a community-delivered intervention and to test its acceptability, feasibility, and fidelity in a proof of principle study with 60 expecting mothers. **At the time of this submission, we are seeking approval for the first year of activities of the project only.** This is because community stakeholder input will direct the future stages of the project including recruitment, assessment, and delivery of the intervention. We will seek approval for additional years of the project prior to their activities, and we describe them in general terms in this submission.

Background and Rationale

Expecting is a study of exercise training in sedentary pregnant women with obesity. Training visits are led by a coach 3 times per week with components of both aerobic and resistance exercise. The *Expecting* intervention has shown strong compliance and promising results in a clinical setting. The preliminary results of the *Expecting* intervention suggest a need for preparation for large-scale tests in community settings. One question is whether or not such a program is feasible in a “real-world” environment. We will use an implementation science approach, a specific field of translational science, to translate the *Expecting* intervention to community settings. Implementation science emphasizes monitoring fidelity to the protocol, reaching the target population with the right intervention dosage, and maintaining the intervention across time.[1] Intervention implementation is more likely to achieve these outcomes with stakeholder input.[2] The Replicating Effective Programs (REP) strategy provides a four-phase process for implementing evidence-based interventions and has demonstrated effective application to translate clinical interventions to community settings.[3–7] Built into the REP framework is the collection of feedback from community stakeholders, iterative piloting of the intervention in the community, and a process for standardizing the intervention across community settings. Application of the REP framework will provide a strong approach to adapt and pilot test the feasibility of a pregnancy exercise intervention in a

community setting. We expect that REP will provide an adequate implementation strategy to ensure desired levels of fidelity and adoption for three key reasons. First, REP has a strong evidence base as a proven implementation strategy. Second, REP includes a rigorous and structured process of stakeholder engagement, which will ensure that perspectives of those targeted by the intervention are represented in the adaptation. Third, throughout the pilot study, we will conduct a rigorous process evaluation[8] monitoring fidelity and adoption of the *Expecting* protocol.

Hypothesis

Our hypothesis is that a community-adapted *Expecting* intervention will demonstrate acceptability, feasibility and fidelity among participating pregnant women. Specifically, we will show effective application of the REP framework (e.g., fidelity, feasibility, acceptability) to translate the *Expecting* intervention to community settings.

Study Design and Procedures

Design

REP will provide the structure and process for translating and piloting the *Expecting* intervention in a community setting. The first year will focus on Phase one of REP. The activities of this phase are detailed in Table 1.

Table 1. REP Phase 1
Pre-Conditions development 2019 - 2020
-Assess potential barriers. -Adapt intervention to fit community setting. -Package intervention for community setting (e.g., core elements versus menu options). -Package training, promotional materials, & assessment forms.

To complete the steps of the REP shown in Table 1, we will complete up to 3 focus groups with past participants in the fitness center based *Expecting* study at ACNC, and 10 qualitative interviews (outlined in the interview guide document) with current study participants. Past participants will be asked to discuss their barriers and facilitators to participation in the study protocol. Importantly, we will further solicit suggestions for how they would change or adapt the program to be deliverable in their local community setting. Current participants will provide similar information; however, their perspective will have the benefit of drawing on recent and ongoing participation in the *Expecting* Study protocol. Both sets of interviews will be informed by the Consolidated Framework for Implementation Research [9,10] to guide the constructs targeted for interviews. (See Community Expecting Interview Guide).

Trained researchers in qualitative research will also use spontaneous probing questions to clarify or further elicit information on important points. In addition, focus groups will apply by Liberating Structures[11] and the Nominal Group Technique[12] to solicit participant input. That is, both the qualitative interviews and focus groups will cover the same content (See Expecting Community Interview Guide). However, we are requesting to format some questions with interactive techniques as designated with an asterisk on the guide. For example, we might use a "1-2-4 All" Liberating Structure to ask participants to write their barriers (Q11) on their own (1) and then to discuss and combine with a partner (2) and then small group (4). This encourages representation and capturing of all perspectives without an individual having to speak up in front of the whole group. As another example, we could employ the Nominal Group Technique to facilitate brainstorming on how the Expecting protocol could be translated to the community (Q7). These techniques can serve to redistribute power in the group if a couple participants begin dominating the conversation or if some participants do not seem engaged in participation. We are requesting the flexibility to use these techniques as the dynamics of the group unfold and as time allows. The PI and Research Assistant will co-lead interviews and are experienced with facilitating focus groups and use of these techniques. We would not cover any additional topics than what is included in the interview guide. Participants in both focus groups and interviews will be provided a snack in addition to a $25 incentive. We expect the focus groups and interviews to last 60-90 minutes.

We will also form an advisory stakeholder panel comprised of community leaders and relevant stakeholders to the future phases of the project (e.g., WIC staff, Early Head Start director, faith leaders, community center staff, gym partners). These panels will be conducted consistent with principles of Evidence Based Quality Improvement (EBQI) approaches.[13–15] EBQI is a flexible process conducted across a series of meetings with topic-driven agendas; each session will last 2 hours. We expect to hold between 3 and 6 EBQI meetings over the coming year. ***First,*** the research team will present a summary of interview findings, conduct a "member checking" exercise with participants to check the validity of findings, and reach consensus on key barriers and facilitators that will drive the adaptation of the *Expecting* study protocol for the community. ***Next,*** we will present potential adaptations and implementation strategies informed by the Expert Recommendations for Implementing Change (ERIC),[16] taxonomy of implementation strategies with consideration of the theoretical domains of behavior change.[17] To reach a consensus on the implementation strategies, we will use techniques outlined by Powell et al,[79] including concept mapping. This method provides quantifiable information

and promotes efficient collection of input in real time. *Then*, we will present the draft strategies/tools, training, promotional materials, & assessment forms. We will collect feedback for revisions, and receive final approval to pilot test them. *In later sessions* (after the pilot is initiated), we will present data from the pilot study to inform iterations and improvements to the approach. Stakeholders will be paid out-of-county travel costs and a $50 incentive for each session; snacks will be provided.

Study Population

For this phase of the study, there are two primary target populations: (1) prior and current participants in the *Expecting* Study and (2) community stakeholders with relevant perspectives to inform recruitment and conduct of our pilot study.

Recruitment

Past participants will be recruited based on their compliance to the *Expecting* Study protocol if they agreed to be contacted for future research studies. That is, we will target those with both high compliance in attending physical activity sessions and those that demonstrated lower compliance. To identify possible participants, the *Expecting* PI will provide a list of the top and bottom 10% of participants in regard to compliance. We will randomly select and recruit participants until we reach our target of 24 participants to participate in one of three focus groups. Focus groups will include one consisting of participants from the high compliance group, one with participants from the low compliance group, and one mixed. This will maximize the diversity of interactions we will solicit.

Current participants will be recruited from the pool of participants currently taking part in the *Expecting* Study at the ACNC. The PI will consult with ACNC study staff to identify and approach eligible participants.

Stakeholders for EBQI panels will be recruited based on their unique perspective to assess opportunities and challenges to translation of the *Expecting* Study to a community setting. We have existing partnerships with the targeted sectors, and we will request nomination of a delegate from each sector for attendance at EBQI sessions.

Risks and Benefits

As in all research, there exists the potential risk to study participants of loss of confidentiality. Measures to protect the confidentiality of study participants will be implemented, including secure storage of all study data on encrypted servers or locked file cabinets on ACNC campus. No physical risks related to participation in this study

are foreseen. Some women may experience discomfort as a result of answering questions that they consider personal in nature. This risk will be minimized by their ability to withdraw from the study or to refuse to answer any question which makes them uncomfortable.

There may be some indirect benefit to participants taking part in this study. As we learn about the adaptations needed to translate physical activity interventions for expecting women in the community, we can contribute to the health of women in the community through offering programs in collaboration with our community partners. It is also possible that participants will experience no direct benefit as a result of participation.

Data Handling and Recordkeeping

The PI will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study. All study subject information obtained will be summarized without identification. Participants will have no identifying information linked with their responses. Study documentation will be kept in a locked file in the principal investigator's office, if hardcopy, or on a password-protected server. The interview tapes and transcriptions will be de-identified. We will retain the audio tapes until 7 years from the final reporting of the study at which point they will be destroyed. De-identified transcripts will be retained by the study team indefinitely to inform future projects. Identifiers necessary to execute the project (for the purpose of contact, scheduling, and payment) will be stored on secure ACNC severs. Any related physical copies of information will be locked in UAMS file cabinets in badge-access buildings while in use for the project (e.g., until analysis is complete). All files will ultimately be stored at the ACNC. We will destroy identifiers and contact of study participants after final data collection and analysis are complete and results of the project shared with participants. We expect this to take up to 7 years.

Data Analysis

Formative phases (pre-conditions and pre-implementation development) will produce valuable qualitative information on the process of engaging stakeholders in the adaptation of a clinical intervention for community sessions. All activities in these phases will be captured with audio recording to facilitate transcription and coding. We will apply best practices in qualitative analysis for implementation science and employ a hybrid of deductive and inductive thematic analyses techniques.[18,19]

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board (IRB) to conduct the study.

A waiver of documentation of consent is requested for the project as this research involves no more than minimal risk to the subjects, and waivers of documentation of consent will not adversely affect the rights and welfare of the subjects. For these aims, the only record linking the subject and the study would be the consent document making the principal risk a breach of confidentiality. Therefore, we are requesting verbal consent consistent with the language in the interview guide.

Dissemination of Data

We will employ a multi-pronged strategy to ensure that findings from this research are disseminated to scientists and community stakeholders. These efforts will not contain any identifiable information that could be linked to a participant.

Scientists. We will disseminate these findings to scientists with interests in physical activity and maternal and child health. We plan to present our findings at premier conferences such as the *International Society for Behavioral Nutrition and Physical Activity* and the *Science of Dissemination and Implementation*. Additionally, we will submit findings for publication to appropriate journals in the field such as *Pilot and Feasibility Studies*. We will also share abstracts and publications with academic listservs and professional social networking sites on which we are members.

Community Stakeholders. Expecting mothers and those providing services to this population (e.g., WIC, Head Start, and healthcare providers) are primary stakeholders in the findings of this research. We will share back findings of all stages of the project to participants and partnering agencies. We will also send a thank you letter to participants involved this project, which will summarize our findings and next steps.

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