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Adaptation of an exercise intervention for pregnant women to community-based delivery: a study protocol

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ABSTRACT

Introduction Despite well-established guidelines and benefits to exercise, the majority of pregnant women in the USA fail to meet recommended activity levels. Studies need to determine feasible ways to translate clinical interventions to community settings by engaging pregnant women in widely accessible locations to ensure benefits to more women. The aim of this study is to adapt and determine feasibility, acceptability and fidelity of the research clinic-based *Expecting* intervention (NCT02125149) with pregnant women with obesity in community settings.

Methods and analysis We will use the Replicating Effective Programs (REP) to guide the adaptation and implementation of the research clinic-based intervention into the community. REP provides a four-phase process for implementing evidence-based interventions including collection of feedback from community stakeholders, iterative piloting of the intervention in the community and a process for standardising the intervention across community settings. Following adaptation, the updated intervention will be piloted. The pilot study will include 60 expecting women. We will randomise half to receive the community-adapted *Expecting* intervention (intervention, N=30) and half to receive standard of care (control, N=30). Feasibility and Acceptability of Intervention Measures are primary outcomes as key indicators of feasibility. Secondary outcomes will include the number of intervention sessions completed, the change in the number of minutes of physical activity as measured by accelerometer, as well as change in health indicators from enrolment to time of delivery and 6 months post-delivery (ie, body mass index, blood pressure and total cholesterol).

Ethics and dissemination This study has been approved by the Institutional Review Board (#260132). Findings will be shared with study participants and stakeholder advisors through written summaries and in-person presentations; results will also be shared through presentations at scientific conferences and publications in peer-reviewed journals.

Trial registration number NCT04298125; Pre-results.

Strengths and limitations of this study

- This study will provide comparative data to the clinic-based intervention to determine if similar physical activity levels are being achieved in the community-adapted programme.
- We will collect ratings of feasibility and acceptability from participants to assess if our stakeholder-informed adaptation meets the needs of our target audience.
- The study will be conducted in one state of the southern USA which may limit wider generalisability.
- The study includes an intentionally designed and robust process of adaptation that will maximise the likelihood of an externally valid pilot study to inform a subsequent full-scale implementation trial.
- This study will rely on a combination of objective outcome assessments and self-report measures rather than self-report measures alone.

BACKGROUND

Exercise during pregnancy is safe and has shown promising maternal-fetal benefits (table 1), which has led to its endorsement for all women with uncomplicated pregnancies by a number of prominent organisations like the American College of Obstetricians and Gynecologists (ACOG).[1–3] The Physical Activity Guidelines for Americans recommend that pregnant women do at least 150 min of moderate-intensity aerobic activity throughout the week,[4] which is consistent with guidelines from other countries.[5] There are a limited number of studies on strength training during pregnancy[6 7] with few international guidelines (not including the USA) conservatively recommending strengthening exercises.[5] The ACOG provides more specific guidance on contraindications to exercise in pregnancy, such as significant heart or lung disease, cervix incompetence and persistent bleeding.[3] The ACOG also lists activities to avoid, such as contact sports, horseback riding and scuba diving.[3]

Despite well-established guidelines and benefits to exercise, the majority of pregnant women in the USA fail to meet recommended activity levels.[8–12] Women often decrease their physical activity throughout pregnancy and are less active than their non-pregnant counterparts because of reported barriers such as: feeling tired, lacking time

Table 1 Impacts of exercise during pregnancy

Maternal	Infant
► ↑Physical fitness levels[61] ► ↑Body image[62] ► ↑Appropriate gestational weight gain[3 61–66] ► ↓Postpartum weight retention[66] ► ↓Lumbopelvic pain[62 67] ► ↓Risk of pre-eclampsia,[8 68] gestational hypertension,[8 68] urinary incontinence,[69] postpartum depression[4 70 71] and gestational diabetes mellitus (GDM)[3 8 68 72] ► ↓Blood glucose levels most effectively among women with GDM without inducing hypoglycaemia[73] ► ↓Quantity of insulin required by women with GDM[73] ► ↓Odds of caesarean section[1 74] ► Does not induce maternal hyperthermia[75] ► Does not affect the odds of preterm rupture of membranes[74]	► ↓Odds of macrosomia at birth without affecting the odds of growth-restricted, preterm or low birthweight babies[61 76 77] ► ↓Excessive fat accumulation[61] ► Does not induce congenital anomalies[75] ► Not associated with infant mortality[4 78]

or childcare or having physical limitations due to pregnancy.[8 13–20] Beliefs about the safety of exercise during pregnancy have also been shown to significantly impact activity levels.[14 21] Mudd *et al* found that pregnant women (65%) who either believed exercise to be unsafe during pregnancy or were unsure of its safety were two times less likely to have done moderate exercise and almost three times less likely to have done vigorous exercise in the past month while pregnant.[21] Another obstacle is the lack of social norms encouraging exercise, which may deprive women of role models and emotional support from friends and family.[14–16 19 20] Pregnancy is characterised by complex changes that offer unique challenges to physical activity; interventions tailored to the needs of pregnancy may help women meet established exercise recommendations and experience its benefits.[14]

Facilitators to exercise during pregnancy have been documented in predominately white, affluent women[15 22] while fewer studies have documented results in nationally representative samples, and a only a handful of studies have targeted specific at-risk subgroups such as women with obesity.[14 16 19 20] Women report being motivated to exercise during pregnancy because they enjoy physical activity, feel more self-confident and perceive that it improves their energy levels and mood, promotes weight control and facilitates labour.[14 15 17 19 22 23] The most common exercise that pregnant women engage in is walking as a form of active transport.[8 9 13 16 24–26] Walking may be salient among this population because it is easily integrated into daily activities, can be done as a family and is socially acceptable.[16 19] More research is needed on the feasibility and efficacy of interventions during pregnancy that leverage these identified facilitators, and that reach socioeconomically diverse populations with a higher risk of inactivity.[14 16]

To date, research on the effects of exercise during pregnancy has largely focused on internal validity by conducting experiments in clinical settings with highly qualified professionals using face-to-face contacts and effective behaviour change techniques.[27–29] Although these types of interventions often demonstrate positive effects, they reach a limited number of women and are intensive, expensive and demanding.[27] Further, there is opportunity to more comprehensively use behaviour change theory in the development of interventions and in measuring the intervention's effect on targeted theoretical constructs.[14 16 28 29] Other limitations to evaluation of interventions include the regular use of self-reported physical activity measures that are prone to desirability bias and a paucity of reporting on implementation, adoption and maintenance measures of the intervention.[14 17 27–30] Future studies need to determine feasible ways to translate clinical interventions to community settings by engaging pregnant women in widely accessible locations to ensure benefits to more women.[16] Using Implementation Science approaches is a way to achieve this end.

We have engaged an existing randomised trial of exercise for pregnant women, the *Expecting* intervention, which has shown strong compliance and promising preliminary results in a clinical setting, to adapt its delivery and test its implementation in community settings using an Implementation Science approach.

METHODS

Aim

The aim of this study is to adapt and determine feasibility, acceptability and fidelity of the research clinic-based *Expecting* intervention (NCT02125149) with pregnant women with obesity in community settings. Specifically, we will show effective application of the Replicating Effective Programs (REP) framework[31] (eg, feasibility, acceptability, fidelity) to translate the *research clinic-based intervention* to community settings. REP provides a four-phase process for implementing evidence-based interventions and has demonstrated effective application to translate clinical interventions to community settings.[31–35]

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 standardising the intervention across community settings. Following adaptation, the updated intervention will be piloted. The pilot study will include 60 expecting women. We will randomise half to receive the community-adapted *Expecting* intervention (intervention, N=30) and half to receive standard of care (control, N=30). Standard of care is the comparator of choice given the lack of standardised community-based programmes for exercise in pregnancy in community settings. This is a pilot-and-feasibility study of a community-adapted exercise intervention to determine feasibility in improving physical activity among obese expecting mothers. Thus, a formal power calculation is not warranted. However, our targeted sample size is consistent with those in similar feasibility studies.[36–38]

Ethics and dissemination

The Institutional Review Board (IRB) at the University of Arkansas for Medical Sciences has been informed of the aim of our study and has approved the first phase (# 260132); we will guarantee approval on the specifics of the further phases of our work based on the results of phase 1 and stakeholder feedback. All important study modifications will be reported to the IRB as well as the clinical trial registry. Findings of our study will be shared with study participants and stakeholder advisors through written summaries and in-person presentations; stakeholders will contribute to a community dissemination plan. Results will also be shared through presentations at scientific conferences and publications in peer-reviewed journals.

Patient and public involvement

The focus of this study is to reduce participant barriers to engaging in the intervention and to provide an accessible intervention for community settings. The study will be supported by a stakeholder advisory group (detailed below), which will provide input for each phase of the research. This advisory group will meet on a regular basis for the duration of the study. Specifically, stakeholders will advise on the adaptation of the intervention, the design of the study, recruitment for the study, appropriate burden for participants and the informational material to support the intervention. At the end of the study, the stakeholder advisory group will comment on the findings and contribute to the dissemination plan to ensure return of findings to participants and other relevant community stakeholders.

Setting and participants

This study has three sets of participants: (1) past and current participants of the *research clinic-based intervention* providing feedback based on their experience, (2) community stakeholders advising on the adaptation of the intervention through Evidence-Based Quality Improvement (EBQI)[39] methods and (3) participants in the pilot of the adapted intervention.

1. Past participants will be recruited based on their compliance to the *research clinic-based intervention* protocol, if they agreed to be contacted for future research studies. Both participants with high compliance in attending physical activity sessions and participants that demonstrated lower compliance will be engaged to provide feedback. To identify possible participants, the *research clinic-based intervention* Principal Investigator (PI) will provide a list of the top and bottom 10% of participants in regard to compliance with the exercise intervention. We will randomly select and recruit participants until a target of 24 participants is reached to participate in one of three focus groups: one consisting of participants from the high compliance group, one with participants from the low compliance group and one mixed. This will maximise the diversity of interactions solicited. Participants will be recruited from the pool of past and current participants taking part in the *research clinic-based intervention* study at the Arkansas Children's Nutrition Center (ACNC). The PI will consult with study team to identify and approach eligible participants.
2. Community stakeholders for EBQI panels will be recruited based on their unique perspectives for assessment of opportunities and challenges to translation of the *research clinic-based intervention* into a community setting. We have existing partnerships with the targeted sectors (eg, state public health, fitness, faith communities, early Head Start, Women, Infants and Children (WIC)), and we will request nomination of a delegate from each sector for attendance at EBQI sessions.
3. Participants for the pilot community-based study will be pregnant women with obesity recruited from local Head Start sites, WIC clinics, and obstetrics and gynaecology clinics. Head Start is a federally-funded programme in the USA designed to promote health and school readiness for children in families with income below the poverty guidelines. Head Start serves pregnant women, infants and toddlers, as well as children aged 3–4 years and their families. WIC also serves pregnant women, infants, toddlers and children up to age 5. WIC provides nutrition education, breastfeeding support, healthcare referrals and access to nutrition foods for children and families. Families served by WIC have an income at or below 185% of federal poverty guidelines. The EBQI stakeholders will partner with the research team to co-develop recruitment materials and referral processes (eg, sample scripts for clinicians) before pre-testing and refinement to ensure reach to the targeted audience.

Women will be required to get a release note from their physician to participate and engage in physical activity (PA). Enrolment will occur within the first trimester and prior to the 15th week of pregnancy. Exclusion criteria include (1) contraindications for exercise (pre-eclampsia–eclampsia, premature rupture of the

membranes, antepartum haemorrhage, placenta previa, multiple gestation and other defined conditions)[29] and (2) illicit drug use. Inclusion criteria are: (a) body mass index >30, (b) singleton pregnancy, (c) between 11 and 15 weeks of pregnancy (at enrolment), (d) sedentary (defined as those expending less than 10% of their daily energy in the performance of moderate-intensity and high-intensity activities)[40] and (e) cleared by physicians.

Criteria for inclusion and exclusion in the pilot are intended to be less stringent than those from the clinic-based intervention. Compared with the clinic-based study, the pilot for community translation has a later enrolment cut-off (gestation week 15 vs 13), will allow participants who conceive through fertility treatments and will not exclude mothers with pre-existing conditions (eg, diabetes, hypertension, thyroid disorders, heart disease) or taking medications when exercise is deemed safe by their physician. Consistent with the aim of translational research,[41–43] the goal of this pilot study is to begin the translation of the promising *Expecting* intervention from a rigorous randomised controlled trial (ie, efficacy trial) to real-world settings (ie, effectiveness trial). A distinguishing feature of effectiveness trials are their less stringent inclusion and exclusion criteria: 'For effectiveness trials, eligibility criteria must allow the source population to reflect the heterogeneity of external populations: the full spectrum of the human population, their comorbidities, variable compliance rates and use of other medications (or other therapies).'[42] To comply with the National Institutes of Health recommendations, we will widen the inclusion and exclusion criteria for this study compared with the efficacy trial in order to collect useful preliminary data for the future large-scale effectiveness trial.

Intervention

Women participating in the *Expecting* study are recruited by gestation week 12 and randomised to a standard of care group or an exercise intervention consisting of aerobic and strength training exercises three times per week at the research facility under the supervision of a trainer. Interim analyses of this ongoing *Expecting* trial support that the exercise training intervention is effective in maintaining cardiorespiratory fitness in pregnant women compared with the decrease in cardiorespiratory fitness experienced in sedentary pregnant women over the course of pregnancy. A submaximal fitness test administered at gestation week 12 and 24 revealed no differences between groups pre-intervention, but at gestation week 24, the intervention group walked on a steeper incline on the treadmill (n=25: 9.6%±0.4% and n=27: 7.7%±0.5%, respectively, p=0.008) and had a higher O_2 uptake than the standard of care group (17.8±0.4 and 15.9±0.4 mL·kg-1·min-1, respectively, p=0.0007).

The *Expecting* intervention at the ACNC includes three 30–45 min, in-person exercise sessions per week. The sessions are gradually increased in length over the first weeks of participation and are comprised of 15–30 min of moderate aerobic activity (recumbent bike, walking on a treadmill or on an elliptical machine) as well as 5–10 min of resistance training using hydraulic exercise equipment. The sessions conclude with stretching exercises. Throughout the session, a personal trainer assesses the rating of perceived exertion using the 6–20 point Borg Scale.[44] Between sessions, participants are asked to monitor their daily step count with a target of 10 000 steps per day using a pedometer provided to the participant. This number is recorded or downloaded by the personal trainer at each in-person session. These elements will be adapted to provide a similar exercise experience that is accessible to women in their local community. The communities of interest for this study will be in an urban area of a southern state in the USA.

Design

See table 2 for a timeline of the REP phases. While parts of the *research clinic-based* intervention will be adapted based on stakeholder input, core components that drive the intervention effect (e.g., type (cardio vs strength), frequency and amount of exercise) will remain consistent with weekly goals in the research clinic-based intervention. 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,[45] monitoring fidelity and adoption of the clinic-based protocol to the community settings, as well as collecting qualitative data on aspects of the intervention that are contributing to or hindering participants' perceptions of acceptability and feasibility.

Pre-conditions development

To complete phase 1 of REP shown in table 2, we will complete up to three focus groups with the clinic-study participants and 10 qualitative interviews with the clinic-study participants. Participants will be asked to discuss their barriers and facilitators to participation in the study protocol. We will include both past and current participants in the focus groups and interviews. Participants will provide suggestions for how they would change or adapt the programme to be delivered in their local community setting. The combination of interviews and focus groups will allow for us to capture both in-depth detail about individual experiences as well as observe conversations between participants and the building of ideas as a collaborative process. Both sets of interview guides will be informed by the Consolidated Framework for Implementation[46 47] to guide the constructs targeted for interviews. Trained team members will also use spontaneous probing questions to clarify or further elicit information on critical feedback provided. In addition, focus groups will include open-ended brainstorming activities on key topics (eg, incentives, delivery mode) informed

Table 2 Replicating Effective Programs phases timeline

Pre-conditions development	Pre-implementation development	Pilot implementation	Evolution
► Assess potential barriers	► Collect input from stakeholders (eg, review package, advise on training, plan implementation logistics, refine core elements and menu options)	► Train target sites/trainers	► Present pilot outcome data and collect stakeholders' feedback to inform future revisions
► Adapt intervention to fit community setting	► Pre-test and further refine package	► Begin recruitment	► Prepare refined package for large-scale trial (intervention, training, materials and assessments)
► Package intervention for community setting (eg, core elements vs menu options)	(5–8 participants)	► Continue stakeholder meetings	
► Package training, promotional materials and assessment forms	► Interview participants and trainers on feasibility, acceptance and barriers	► Collect pilot outcome data: intervention fidelity, participant outcomes, costs	
	► Orientation meetings and champion trainings at targeted sites		

*Adapted from Kilbourne *et al*.[31]

by Liberating Structures[48] and the Nominal Group Technique.[49] Participants in both focus groups and interviews will be provided a snack in addition to a US$25 compensation. The consent process will include an overview of the study, rights as a study participant, reminder of the voluntary and anonymous nature of participation, and contact information for the IRB. All participants will provide verbal consent for participation in the interviews and focus groups as well their recording. This process will be led by a research assistant certified in human subjects protection. We expect each focus group and interview to last 60–90 min and to be conducted in person or virtually (ie, telephone, video conference). Language for the consent process is found in online supplemental file 1.

Pre-implementation development

We will form an advisory stakeholder panel comprised of community leaders and relevant stakeholders to the future phases of the project (eg, WIC staff, early Head Start director, faith leaders, community centre staff, gym partners). These panels will be conducted consistent with principles of EBQI approaches.[39 50] 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 three and six EBQI meetings . 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 clinical-based study protocol for the community. Second, we will present potential adaptations and implementation strategies informed by the Expert Recommendations for Implementing Change.[51] To reach a consensus on the implementation strategies, we will use techniques outlined by Powell *et al*, including concept mapping.[52] This method provides quantifiable information and promotes efficient collection of input in real time. Third, we will present the draft strategies/tools, training, promotional materials and assessment forms to 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 community-based pilot study to inform iterations and improvements to the approach. Stakeholders will be paid out-of-county travel costs and a US$50 compensation for each session; snacks will be provided.

In addition, we will pre-test the community-adapted intervention with five to eight participants during this phase. This will provide an opportunity to refine processes for data collection and fidelity monitoring as well as to see how the adapted intervention operates on a very small scale. Participants and trainers involved in the pre-test will be interviewed for their perceptions of feasibility and acceptability as well as remaining barriers to engagement. These data will inform any final iterations before the pilot. Consistent with REP, we will also finalise our community partner sites for the pilot during this phase, conduct orientation meetings at those sites and train local champions at those sites to add in recruitment, programme promoting and ongoing site engagement.

Table 3 Study assessments for mothers

Measures	Community evaluation			
	Trimester			Post partum
	1	2	3	6 months
Feasibility of Intervention Measure[53]			X	
Acceptability of Intervention Measure[53]			X	
Number of intervention sessions complete		X	X	
Fidelity of session delivery	X	X	X	
Number of minutes of physical activity measured through accelerometer (ie, fidelity to study protocol)		X	X	X
Mother's body mass index *	X		X	X
Mother's blood pressure *	X		X	X
Mother's total cholesterol*	X		X	X

*Will collect baseline at enrolment, which will occur at or before 15 weeks.

Pilot implementation

Participants will be randomised to two groups using computer-generated random numbers by a blinded statistician: an intervention group (N=30) and a standard of care group (N=30), balanced on baseline body mass index (BMI). We expect the pilot to begin in the Spring of 2022 and last until the Spring of 2024. Participants will be required to seek medical care at enrolment if they have not yet done so, to ensure they are provided with adequate prenatal care and to receive a doctor's release for participation. Standard of care group participants will receive usual care from their medical team. Women in the intervention group will be compensated for every week of compliance with the exercise intervention. We will decide appropriate compensation in collaboration with stakeholders after the adaptations and delivery model are decided. We expect to offer women options to exercise at a gym of their choice, at a community centre or at home with minimal equipment to reach the exercise target. All participants will receive a FitBit arm bracelet to self-monitor their activity levels and for the research team to monitor their physical activity levels. Participants will begin the intervention in their first trimester (prior to 15 weeks) and continue throughout their pregnancy; participants will discontinue if directed by their physician.

Participants in this study will complete the community evaluation plan (table 3), which includes valid and reliable measures of PA (eg, accelerometers, ActiGraph, Pensacola, Florida, USA). To obtain health outcome information, a medical record release will be obtained from each participant to gather specific data pertaining to their prenatal care. The following information will be extracted from the medical records: parity, live births, date of last menstrual period, medical diagnoses, medications taken during pregnancy, metabolic and lipid panels, anthropometrics and vital signs (eg, blood pressure). Engagement in physical activity (ie, fidelity to the study protocol) will be monitored through continuously collected data from the FitBit device. At the end of the intervention, participants will rate the feasibility and acceptability of the adapted intervention and its implementation using pragmatic measures from Weiner and colleagues.[53] Mothers will have a 6-month follow-up visit to assess physical activity after pregnancy. We will seek to complete follow-up visits with mothers regardless of adherence rate and intervention retention. Feasibility and Acceptability of Intervention Measures are primary outcomes as key indicators of feasibility.[53] Secondary outcomes will include the number of intervention sessions completed, the change in the number of minutes of PA as measured by accelerometer, as well as change in health indicators from enrolment to time of delivery and 6 months post-delivery (ie, BMI, blood pressure and total cholesterol). We will monitor fidelity to session delivery in an ongoing fashion and ensure corrections as needed.

We will report adverse events to the IRB immediately and share relevant information with the participants' healthcare team. Participants will provide informed consent consistent with a process that the IRB approves. We will code participant's records in our datasets and save them in secure locations that are password and/or key protected; we will never share the participants' identity before, during or after the trial.

Evolution. In the last phase, we will present pilot outcome data to our EBQI panel and collect stakeholders' feedback to inform future revisions. Information from the stakeholders will inform the final iteration of intervention materials, training or approach to data collection assessments. That is, we will prepare the intervention for testing in a large-scale trial in this final phase.

Results from each phase of our process will be disseminated to both scientific and local communities. We will publish our findings and share results at professional meetings. We will also prepare summaries of our findings to share with study participants and project stakeholders. We will present our findings to partnering agencies as requested.

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 clinic-based 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.[54 55] Details on data management procedures are available in our protocol submitted to the clinical trial registry.

Statistical analyses of pilot data will focus on feasibility and acceptability of the intervention and study procedures as well as a preliminary evaluation of the community-adapted intervention, in accordance with recommendations for feasibility studies.[56] Descriptive statistics on implementation outcomes (ie, feasibility, acceptability) will provide valuable data to understand women's perceptions of the intervention and adherence. We will also compare item and summary scores across participant characteristics to examine for potential patterns. For health outcomes (ie, BMI, blood pressure, cholesterol), we will not conduct inferential statistics or effect sizes from the feasibility study due to concerns about inflation of type I and type II errors in small samples sizes.[37 57] We will focus on the following recommended alternatives: (a) examining variance in outcomes (b) examination and presentation of CIs[38] and (c) examination of clinically meaningful effects. We will identify characteristics that predict missing data when missing data are greater than 5% and use these characteristics to inform analyses using Full Informational Maximum Likelihood to account for missing data. The statistician will be blinded when examining health outcomes.

DISCUSSION

This study will produce data on the feasibility, acceptability and fidelity of a community-based PA intervention for pregnant women through the application of the REP framework to translate a *research clinic-based intervention* to community settings. We anticipate the pre-conditions development (interviews and focus groups) to identify barriers similar to those reported in the literature (eg, lacking time, childcare or social support)[8 13–18] and to illuminate barriers unique to our high-risk group of women with obesity in a southern US state. Our work will also help to understand the facilitators to engagement in exercise, given the high rate of compliance to date in the clinic-based study. Women in the clinic-based study may experience feelings of safety during exercise since their sessions are monitored by a personal trainer; whether this is a determinant in the community studies will be of interest. We will be able to consider the barriers unique to our local population and leverage identified facilitators to inform our adaptation of the intervention.

Implementation Science principles hold that intervention implementation is more likely to achieve quality delivery, intended reach and maintenance over time with stakeholder input.[58] Our stakeholder engagement activities of the pre-implementation phase will increase this possibility. Stakeholders will guide key decisions about where the intervention will be delivered, the mode of intervention delivery, and the recruitment and incentive structures for the community-based approach. Prior work to engage stakeholders in intervention efforts to improve the health of pregnant women and their children has been limited to work outside the USA and not targeted to exercise.[59 60] We expect that stakeholder input will promote launching an intervention that is valued and supported by community members and existing structures.[18 23]

Strengths and limitations

Engaging prior participants in the developmental stages of our project will help to ensure our adaptation and translation efforts are grounded in real-world considerations. We will mitigate potential problems in engaging with prior participants across the spectrum of compliance by (a) oversampling from the pool of lower compliance participants until target numbers are reached and (b) offering a virtual option for attendance at focus groups and interviews. Piloting the community-adapted intervention will provide critical information to determine if participants will begin and continue a community-based exercise programme for the duration of their pregnancy. This study will also provide comparative data to the clinic-based intervention to determine if similar PA levels are being achieved in the community-adapted programme. In comparing to the clinical study, we will also be able to assess for differences in enrolment and engagement/fidelity by sociodemographic characteristics that have been shown to predict exercise during pregnancy in prior studies (eg, income, education, race/ethnicity, number of children in the home, prior activity).[10 13 14 18] Specifically, our recruiting partners were selected, in part, because they serve diverse populations who are impacted by limited income. By recruiting from these two locations in addition to doctor's offices, we believe we will optimise our potential to reach families in need of the intervention and assess our ability to recruit across sociodemographic characteristics. We will also be able to establish processes for obtaining and extracting data from the mother's medical record, a step that will be crucial for testing the intervention on a larger scale. Finally, we will obtain ratings of feasibility and acceptability from participants to assess if our stakeholder-informed adaptation meets the needs of our target audience.

Translation of clinical interventions to community settings can be challenging. Combining the expertise of the current clinic-based research team with the experience and knowledge of the Implementation science team with strong community partnerships will ensure a successful translation. We have intentionally designed a robust

process of adaptation that will maximise the likelihood of a successful, full-scale implementation trial. This study has also been designed to address some of the limitations highlighted in previous research on community-based exercise interventions during pregnancy. Specifically, we will intentionally seek to serve a racially diverse sample. In addition, our design will be informed by theory and consider the identified barriers to exercise for our target group. Finally, we will include objective outcome assessments rather than self-report measures alone. Taken together, we believe these strengths will contribute to a meaningful pilot study that will provide the preliminary data needed to pursue the appropriate next steps with the community-adapted intervention.

To our knowledge, this will be the first effort to translate a standardised pregnancy-based exercise protocol that has been tested in a research clinic setting into a community-based programme. This is possible through the application of Implementation Science models and methods. Study results are expected to contribute to a limited, but growing body of evidence on the acceptability, feasibility and fidelity of community-based exercise interventions for pregnant women. This study addresses a significant scientific question on how to effectively engage a community of women in prenatal exercise because of the important public health implications (table 1). Our goal is a comprehensively adapted, community-based exercise intervention for testing in a future large scale trial.

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Contributors TS led the design of this study and writing of this manuscript; AM contributed to the writing of this manuscript; AA and EB contributed to the study design and writing of this manuscript as well as the original clinical study on which this one builds.

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