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Project Wellness: A Pilot Feasibility Randomized Controlled Trial

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A. Background

This pilot randomized controlled trial (RCT) serves to replace the original Aim 3 of NIDDK-K01DK105106 to Dr. Samantha Ehrlich, *Physical Activity in Pregnancy for Intergenerational Obesity Prevention*. This modified Aim 3 is well aligned with the award's focus on innovative 'upstream' risk factors and strategies for the prevention of obesity.

In the U.S., the prevalence of overweight or obesity among women of reproductive age is 59%[1]; among children, 17% are classified with class 1 obesity, 6% with class 2 obesity and 2% with class 3 obesity.[2] Once overweight/obese, returning to normal weight is difficult[3-5], hence the appeal of targeting upstream, modifiable factors influencing the in utero environment.[6]

Physical activity (PA) is an important component of weight loss and weight maintenance[7], thereby contributing to the prevention of and reductions in obesity. Some evidence suggests that PA in pregnancy reduces excessive gestational weight gain[8,9] and postpartum weight retention, thereby reducing maternal obesity risk.[10] In regards to the children, PA in pregnancy[11] may protect against fetal overgrowth[12-21] and elevated neonatal adiposity[15,18], both risk factors for childhood obesity[22,23], by mitigating maternal insulin resistance[24] and reducing elevated postprandial glucose[15,16,25-28] that result in fetal over-nutrition.[29] PA in pregnancy may additionally result in epigenetic changes that impact child metabolism[30-34], potentially by countering hyperglycemia-induced changes in DNA methylation.[35-37] As such, PA in pregnancy may be a particularly effective strategy for women with gestational diabetes (GDM).

The children of women with GDM are at increased risk of childhood obesity, across the spectrum of criteria currently used to diagnose GDM.[38,39] Elevated postprandial glucose values in women with GDM are predictive of delivering a large for gestational age (LGA) infant[12-14], a risk factor for childhood obesity[23,40], and PA has been shown to reduce

postprandial glucose levels in women with GDM.[25] A recent study of 162 women with GDM assessed maternal glucose throughout the day (for 7-days) with masked continuous glucose monitors (CGM) and reported that glucose levels were higher in those delivering a LGA infant, particularly overnight glucose levels.[41] The children of women at risk for GDM (i.e., any abnormal value on oral glucose tolerance testing, such as those failing the 50g, 1-hr screening test) are also at increased risk of macrosomia[42] and childhood obesity.[38]

Outside of pregnancy, it is well-established that regular PA improves insulin action, and that glucose uptake may remain elevated for up 48 hours following PA.[43] Increased scientific understanding of these processes in women at risk for or with GDM are desperately needed.

A recent meta-analysis found that prenatal exercise is not statistically significantly associated with childhood obesity (i.e., percent body fat, body weight and BMI), although few studies examined these outcomes.[44] However, to the best of my knowledge, no one has investigated this relationship exclusively among women at risk for or with GDM. It is hypothesized that a PA intervention following a failed screening test will increase PA levels and lower glucose values[15,16,26-28,41], thereby reducing the risks of LGA[12-21] and macrosomia[42] and elevated neonatal adiposity[15,18], and potentially accelerated infant growth[45-48], all precursors to childhood obesity.

The PA intervention is based upon the same theoretical constructs and behavior change strategies previously used by successful weight management interventions targeting pregnancy and the postpartum period[49-52] (and among women with GDM specifically[49,51]); all of these interventions included a PA component. Specifically, the PA intervention is based on Bandura's social cognitive theory[53,54] and the Transtheoretical model.[55] Behavior change techniques[52,56] include self-monitoring of and feedback on behavior (e.g., daily self-monitoring); goal setting; review of behavior goals (e.g., reviewing activity logs and modifying goals accordingly); problem solving; action planning; social support; prompts and cues; self-rewards (e.g., encouraging participants

to give themselves non-food rewards after achieving goals); providing information on health consequences (e.g., information on the benefits of PA during pregnancy); and providing information from a credible source (e.g., lifestyle coach).

Walking is the most common leisure time PA reported by pregnant women[57] and, for most adults, is an easily accessible mode of PA. As such, the PA intervention will specifically focus on walking, or stepping in place when it is not possible to walk (e.g., stormy weather). The primary goal of the PA intervention is for the participant to achieve at least 30 minutes per day of walking/stepping in place. The secondary goal is to use a PA tracker (e.g., the Fitbit Charge 3 provided by the intervention) to log and review their walking/stepping, and to accumulate at least 3,000 steps during their 30 minutes of walking/stepping.

In terms of safety, the frequency, duration and intensity of PA prescribed by the intervention (i.e., the PA goal) is consistent with American College of Sports Medicine's (ACSM) Guidelines for exercise during pregnancy.[58] In terms of frequency, ACSM recommends that pregnant women exercise 'regularly' (no specific number of days per week given). For previously inactive women, ACSM recommends lower intensity and/or duration of exercise rather than a reduced frequency of exercise, and progressively increasing exercise duration from 15 minutes to 30 minutes a day, most days of the week. In addition, as recommended by ACSM, the intervention will prescribe moderate intensity activity. Women will be advised to monitor the intensity with a 'talk test' using the Omni rating of perceived exertion scale[59] (0-10) to tell how hard they are working and to aim for 'Somewhat hard, I can talk with some effort'. The intervention's goal of 3,000 steps during the 30 minutes of walking/stepping is based on previous studies of pregnant[60] and non-pregnant adults[61-63] that identify 100 steps per minute as indicative of moderate intensity walking.

B. Aim

To conduct a pilot feasibility RCT among up to 48 women, either diagnosed with GDM and referred to the High Risk Obstetric Consultants (HiROC) at the University of Tennessee Medical Center Knoxville (UTMC), or at risk for GDM (e.g., failed the 50g, 1-hr screening test) and managed by one of the clinics listed in Section J. The RCT will compare a physical activity (behavior change) intervention (i.e., walking/stepping in place) versus a general wellness intervention (i.e., health education focusing on immunizations, contraceptive options following delivery, etc.) on PA levels, maternal glycemic profile in the third trimester, and infant size and anthropometrics (i.e., weight, length, head, abdominal and upper mid-arm circumference, and skinfolds at the flank, thigh, triceps, bicep and subscapular).

It is hypothesized that the PA intervention will increase PA levels during pregnancy, and improve maternal glycemic profile in the third trimester and infant anthropometric measures at birth. The exploratory hypothesis is that improvements in third trimester glycemic profile mediate the effect of pregnancy PA on the infant anthropometric measures.

C. Study Staff

Student research assistants working on the study (i.e., recruitment, conducting intervention sessions and data assessment visits) will be trained and overseen by Drs. Ehrlich and Maples. All will remain up to date on required IRB trainings and approvals (e.g., CITI trainings and UTMC outside learner approval) for the duration of their work on the study.

D. Usual Care

Usual care at HiROC for women with GDM includes bimonthly to weekly in-person appointments, depending on the patients' needs and adherence to the diabetes

educators' recommendations, to monitor their capillary glucose levels, provide counseling on diet, and prescribe or adjust medications, as needed. PA is usually encouraged at the first GDM appointment, but is not directly prescribed, further discussed or typically tracked in conjunction with usual clinical care. Women at risk for GDM (i.e., who fail the screening but not the diagnostic test), are not seen by HiROC for diabetes education.

E. Data Assessment Overview: The Project Wellness Study Visits

Surveys (e.g., demographic, health behaviors, medical history, dietary intake) will be administered at baseline (initiated < 30 weeks gestation, Study Visit 1) and at follow-up (initiated < 36 weeks gestation, Study Visit 2); see Table 1 for the variables to be assessed and timing of their assessments. PA will be objectively measured at baseline and follow-up with ActiGraph physical activity monitors (PAMs, i.e., the CentrePoint Insight Watch) worn continuously for 7 days on the dominant wrist. Continuous glucose monitors (CGM) will be worn continuously for 7 days on the participants' non-dominant upper arm (posteriorly located) at Study Visits 1 and 2 to assess maternal glycemic profile (i.e., DEXCOM G6 devices, participants will be blinded to their CGM data). Infant outcomes [i.e., weight; length; head, abdominal and upper mid-arm circumferences; and skinfolds at four sites (flank, thigh, triceps, bicep and subscapular skinfolds)][18,64] will be assessed by study staff within 4 days of birth (i.e., the optional delivery visit).

Participants will be randomized to the STEP Up intervention or the Next Steps intervention (described in Section R) once they have successfully completed all of the data assessments for Study Visit 1 (described in Section L). Intervention staff will inform the participants of their program assignment (i.e., STEP Up or Next Steps) and schedule the first intervention session. All intervention sessions will be conducted remotely (i.e., via phone and/or video chat).

Study visits will occur either remotely (i.e., via phone and/or video chat) or take place in private rooms at the UT Medical Center [e.g., a private office or exam room in the High

Risk Obstetrical Consultants (HiROC) clinic or Preston Medical Library; and Labor and Delivery or the Mother/Baby Units on 3 West, 3 East, and 4 West for the delivery visit].

F. Incentives

Participants will receive payments in the amount of: $80 for Study Visit 1, $100 for Study Visit 2, and $100 for the delivery visit (i.e., $280 total). Incentive payments will be Walmart gift cards distributed either in person, by mail, or dropped off at the participants home upon completion of all of the data assessment elements associated with that Visit. If a gift card is sent by mail and not received, a replacement will be dropped off at the participants home.

G. Parking

Participants will receive vouchers to cover the cost of parking at the Medical Center for any in-person Study activities (described in Sections L, N and O; one voucher will be provided at the delivery visit).

Table 1. Variables to be measured at the study visits.

	Medical Chart	Physician Screen/ Study Visit 1 (≤ 30 weeks)	Study Visit 2 (≤ 36 weeks)	Delivery Visit	3-month Infant Follow up Visit	6-month Infant Follow up Visit	9-month Infant Follow up Visit	1-year Infant Follow up Visit
Demographics								
Age		X						
Race-ethnicity		X						
Working status		X	X		X	X	X	X
SES, Marital status, Insurance status		X				X		
Smoking, Alcohol, Illegal drugs		X						
Sleep		X	X					
Biomedical								
Height	X	X						
Weight (pre-pregnancy, during pregnancy and postpartum)	X	X	X		X	X	X	X
Medical history		X			X	X	X	X
Medication use	X	X	X					
Pregnancy history/outcomes	X				X			

Prior use of and intentions for contraceptives		X	X					
Contraception initiation and use following delivery	X				X	X	X	X
Vaccination (flu and Tdap) perceptions and intentions for vaccination	X	X	X		X	X	X	X
Capillary glucose values (i.e., 7 days of values recorded in purple booklets, for women with GDM only)		X	X					
Continuous Glucose Monitor (i.e., 7 days)		X	X					
Infant Anthropometrics				X (optional)	X	X	X	X
Infant feeding and immunizations					X	X	X	X
Actigraph Physical Activity Monitor		X	X		X	X	X	X
Food Frequency Questionnaire (FFQ)		X	X					

Physical activity questionnaires		X	X		X	X	X	X
Stage of change for Physical Activity		X	X					
Diabetes Risk Perception & Family History of Diabetes		X						
Self-efficacy for Physical Activity		X	X		X	X	X	X
Social support for Physical Activity		X	X		X	X	X	X
Symptoms of Depression		X	X					
Adverse events			X					
Acceptance of interventions			X					

H. Advertising the study

The study will be advertised at local clinics affiliated with the University of Tennessee Medical Center [i.e., who refer patients to HiROC upon GDM diagnosis, specifically: University Women's Specialists, UT Ob/Gyn Center (residents' clinic), and University Midwifes]. Posters advertising the study (e.g., women at risk for or with GDM may be eligible, incentive payments will be given for participation, and the study staff's contact information) will be hung in participating the clinics and advertised on their waiting room TV monitors and electronic patient portals, upon receipt of permission from the clinics' leadership. A handout with more details on what participation would entail and the study staff's contact information will also be available at the clinic front desks and in the labs (i.e., where patients are tested for GDM), and will be distributed to potentially eligible patients by clinic staff. Women being referred to HiROC for GDM treatment will be told by the clinic staff that they may be eligible for the study and asked whether they wish to opt out of email, telephone calls and/or text message invitations to learn more about the study. Women who fail the screening test (i.e., 50g, 1-hour OGT) will also be told by clinic staff that they may be eligible for the study and asked if interested or they would like to opt out. Clinic staff will inform study staff of patients opt out/permission to contact status via Message Center (in the EMR) or by email. Those refusing all contact with study staff (i.e., opt outs) will be excluded from the procedures below.

I. Eligibility

Women will be recruited from four clinics associated with the UT Medical Center (listed in Section J); all of these clinics have electronic medical record systems or are soon transitioning to electronic medical record systems that will be used to confirm patient eligibility (i.e., paper charts will be used in the interim, as needed). Study staff will pre-screen the electronic medical records of women diagnosed with GDM who have not refused/opted out of contact with study staff. They will summarize their findings for the physician approvers (e.g., Drs. Fortner and Zite). The physician approvers will review these findings and the medical records before signing off on the physician approval to contact forms confirming the patient meets the primary eligibility criteria; at this point, a

Project Wellness study ID number will be assigned. Study staff will follow up with potentially eligible patients by email, telephone and/or text messages to distribute information about the study and evaluate the secondary eligibility criteria. Staff will arrange by telephone, email, and/or text message to meet eligible and interested women by Zoom or at UTMC.

Primary Eligibility Criteria, Evaluated at the Physician Screening

- Age 18-40 years
- Not previously diagnosed with diabetes (i.e., Type I or Type II diabetes) outside of pregnancy
- Singleton viable pregnancy with low suspicion for clinically significant abnormality or aneuploidy
- Diagnosed with GDM after 24 weeks by:
    - One step diagnostic procedure[65]
- 75-g OGTT after an overnight fast, with plasma glucose measured fasting and at 1 and 2 hrs, and any of the following plasma glucose values are met or exceeded:
        - Fasting: 92 mg/dL (5.1 mmol/L)
        - 1 hr: 180 mg/dL (10.0 mmol/L)
        - 2 hr: 153 mg/dL (8.5 mmol/L)
    - For the Two step diagnostic procedure,[65,66] only Step 1 (i.e., at risk for GDM) is required for eligibility:
- Step 1: 50-g GLT (non-fasting), with plasma glucose measured at 1 hr ≥130 mg/dL
    - Any other abnormal value on oral glucose tolerance testing associated with macrosomia[42]
- No contraindications to exercise (i.e., no absolute contraindications according to published recommendations for exercise during pregnancy[67]), as follows:
        - Hemodynamically significant heart disease
        - Restrictive lung disease
        - Incompetent cervix/cerclage
        - Persistent second or third trimester bleeding
        - Placenta previa or vasa previa after 26 weeks gestation

  - Premature labor during the current pregnancy
  - Confirmed ruptured membranes
  - Preeclampsia/pregnancy-induced hypertension
- Currently non-smoker
- No current illicit drug use
- No current use of daily medications known to alter insulin resistance and metabolic profiles (e.g., metformin, corticosteroids, anti-psychotics)
- Not currently taking medication for polycystic ovarian syndrome (PCOS) (i.e., history of PCOS okay as long as she is not *currently* taking medication for PCOS)
- English speaker and comfortable completing surveys in English (i.e., no translator needed)

Secondary Eligibility Criteria, Evaluated by Study Staff during Recruitment

- Planning/likely to stay in Knoxville through baby's 1st birthday

J. Recruitment Clinics

University Women's Specialists:
https://www.utmedicalcenter.org/medical-care/specialty-practices/university-womens-specialists/
UT Ob/Gyn Center:
https://utimobgyncenter.utmck.edu/portal/ut-obgyn-center/default.aspx
University Midwifes:
https://www.utmedicalcenter.org/medical-care/specialty-practices/university-midwives/

Women's Care Group:
https://www.utmedicalcenter.org/medical-care/medical-services/specialty-practices/womens-care-group-knoxville/

K. Recruitment at HiROC

Study staff will also work with HiROC on study recruitment. HiROC clinic staff (e.g., diabetes educators) will also mention the study to potentially eligible women upon their referral to HiROC for GDM, and those who do not refuse/opt out of receiving more information about the study will be referred to study staff for follow-up. Study staff will pre-screen the medical records and summarize their findings for the physician approvers. Physician approvers will review their findings and the medical records before signing off on the physician approval to contact form; at this point, a Project Wellness study ID number will be assigned. Study staff will follow up with potentially eligible patients by email, telephone and/or text messages to distribute information about the study and evaluate the secondary eligibility criteria. Staff will arrange by telephone, email, and/or text message to connect with eligible and interested women for their Study Visit 1. Study staff will call, email, and/or text the participant to remind her of the scheduled day/time/modality (i.e., remote or in-person at UTMC) of her Study Visit 1.

L. Study Visit 1 (Baseline data assessment, scheduling initiated at after 24 weeks and Study Visit ≤ 30 weeks gestation)

The baseline study visit may occur remotely, via Zoom, or at UTMC. If it is a remote visit, all materials will have been either mailed ahead of time or dropped off at the participants' home. First, study staff will explain what will be asked of study participants, answer any questions they may have, and obtain written informed consent. If it is a remote visit, the consent form will be signed via DocuSign software. Second, the women's weight and height will be measured by study staff, and the 'in-person' survey completed. If it is a remote visit, a scale will be left with at the home with her other study materials, and a weight measurement taken during/soon after the Zoom session. Weight and height will also be obtained from the medical record. Third, study staff will explain the PAM data assessment protocol (e.g., they will be asked to wear the device continuously for 7 days on their dominant wrist, but if that is not possible, they are to record the days/times of device removal in a diary log) and give the women her PAM

and PAM diary log. Fourth, study staff will give the participant a Study Visit 1 at home survey and Food Frequency Questionnaire (FFQ), plus a number 2 pencil for the FFQ.

In addition, the continuous glucose monitor will be applied to the participant. When possible, a telehealth visit with research staff via Zoom or telephone will be scheduled so they may assist the set-up (e.g., walk them through linking the transmitter device to their receiver) and advise on application of the CGM.

Continuous Glucose Monitor (CGM)

A video describing the insertion of the CGM sensor and how to attach the transmitter is available at:
https://provider.dexcom.com/education-research/cgm-education-use/videos/dexcom-g6-how-insert-sensor-attach-transmitter

Information provided by Dexcom indicates that the sensor pod remains adhered to the skin and the sensor probe remains beneath the skin (0.5 inch/1.27 cm) to measure glucose levels. The sensor probe is a platinum/silver wire about the width of 2 human hairs.

Dexcom additionally providers instructions for cleaning and disinfecting the transmitter between users, as the transmitters may be re-used for up 90 days (see 'Dexcom CGM Cleaning (External Studies)' pdf).

Participants may experience skin irritation or redness around the continuous glucose monitor device's adhesive patch, and there is the potential risk of infection. They will be instructed to avoid placing the device near tattoos, scar tissue, and boney areas.

If the participant is conducting the Study Visit in-person, then research staff will apply the CGM transmitter and set up the CGM receiver for them. Applying the CGM transmitter involves using a device-specific applicator to affix an adhesive casing to the back of the upper arm, and then placing the CGM transmitter into this casing so that it

remains continuously on the body. If it is a remote visit, a Zoom or telephone meeting will be scheduled so that research staff may verbally assist the participant and their adult family member/partner who will help them apply the CGM transmitter. For the remote visits, participants and the person helping them apply the CGM transmitter will be instructed to watch the YouTube video (link above) on application. First, an alcohol prep pad will disinfect the upper posterior portion of the participant's non-dominant arm, then research staff or the person helping them at home will apply the adhesive casing (i.e., place the applicator on upper arm, and push the orange button) and then insert the CGM transmitter into the casing. Next, research staff will either set up the CGM receiver, or walk the participant through setting up the receiver by inputting the serial numbers included on the CGM transmitter packaging.

At the end of the CGM assessment, participants, either themselves or with assistance, will peel off and remove the casing/CGM transmitter from their arm. The participants will also disable the CGM receiver once the transmitter has been removed. Only the CGM receiver and charger will be returned to study staff (i.e., the transmitter and its adhesive casing may be discarded).

Participants will be instructed to keep their CGM receivers (i.e., a device the size of a cell phone that records the glucose measurements obtained from the CGM sensor) within 20 feet of themselves as much as possible (e.g., carry it in their purse), to spend no more than 2 hours away from their receivers, and to charge its battery every 3 to 5 days. Participants will also be asked to wear loose fitting clothing for the duration of the CGM assessment. Receivers will be in blind mode, thus the only alerts that may trigger are the signal loss alarm (e.g., when the sensor/transmitter are greater than 20 feet away from then receiver), the sensor fail alarm, and the receiver low battery alarm. No alarms related to CGM readings will trigger in the blind mode.

Participants and their providers will be masked to their CGM data (i.e., receivers set in blind mode) since there is currently insufficient evidence on CGM targets for women with/at risk for GDM and thus no clinical standards to guide the use of CGM for GDM management (i.e., recommended percentages of time spent in range, below range and above range are currently not available for this population).[68] As such, the CGM data will not be monitored by study staff and no feedback will be provided to study participants based on their CGM data. Participants with GDM will use capillary glucose measures as their clinical glucose monitoring metric for the duration of their pregnancy

(i.e., the glucose monitor provided by their health insurance) and receive feedback from HiROC clinic staff based on those metrics. It is anticipated that the investigatory CGM data collected for this study will contribute to increased scientific understanding to inform the adoption of CGM in clinical care of women with GDM in the future (i.e., thereby reducing the burden of finger sticks for capillary glucose readings).

Participants will return their completed Study Visit 1 materials to study staff by leaving them with the HiROC receptionists (e.g., if they have a prenatal care appointment already scheduled) or mailing them (i.e., prepaid FedEx mailers with the study's address will be provided) or arranging for study staff to pick them up from their home. Participants will schedule a date/time for their Study Visit 2 at conclusion of Study Visit 1.

Study staff will make photocopies of the capillary blood glucose values recorded for HiROC clinical care (i.e., between the first new GDM appointment and the follow-up GDM visit one week later, these are recorded in the HiROC purple self-monitoring booklet distributed to all new GDM patients) to supplement the Study Visit 1 data, for women with GDM only. For all participants, all prepregnancy and pregnancy weights, and height, will be abstracted from the medical records, as will the results of all blood glucose testing during pregnancy.

Participants will not be randomized until all elements of Study Visit 1 have been completed (i.e., surveys and FFQ, PAM, PAM diary log, CGM) and received by study staff. These elements must be completed and received by 30 weeks 6 days gestation in order to be randomized.

M. Randomization

Participants will be randomized to one of the two interventions upon completion of the Study Visit 1 data assessment; they will be contacted by text message and/or ultimately by telephone, by their interventionist, to learn the group they are assigned to and

schedule the initial intervention session (described below). We plan to recruit and enroll up to 48 participants so that we may randomize at least up to 36. Randomization will be stratified for at risk for GDM vs. diagnosed with GDM (split evenly between strata). We will utilize block randomization (to ensure equal sample sizes), with a block size of 4. The allocation sequence will be managed by Dr. Cristina Barroso (UTK, Public Health) and concealed from the study intervention staff until it is needed. Intervention staff will contact the participants to inform them of their assigned intervention condition and schedule the initial intervention session (at < 31 weeks 6 days gestation).

N. Study Visit 2 (Follow-up Data Assessment, Study Visit ≤ 36 weeks gestation)

Staff will remind the participant of the scheduled day/time of her Study Visit 2 either during an intervention session or by text message (see Section R for a description of the interventions). Study visit 2 may occur remotely, via Zoom, or at UTMC. If it is a remote visit, all materials will have been either mailed ahead of time or dropped off at the participants' home. First, the women's weight will be measured by study staff and the 'in-person' survey completed (e.g., to collect information on adverse events). If it is a remote visit, a scale will be left with at the home with her other study materials, and a weight measurement taken during/soon after the Zoom session. Weight will also be obtained from the medical record. Second, study staff will review the PAM data assessment protocol (e.g., they will be asked to wear the device continuously for 7 days on their dominant wrist, but if that is not possible, they are to record the days/times of device removal in a diary log) and give the women her PAM and PAM diary log. Third, study staff will give the participant a Study Visit 2 at home survey and Food Frequency Questionnaire (FFQ) to take home, plus a number 2 pencil for the FFQ. Forth, the medical release form for their infants' data will be reviewed.

In addition, the continuous glucose monitor will be applied to the participant.
If the participant has GDM, copies of her purple HiROC capillary glucose record sheets will be obtained. Participants will return their Study Visit 2 materials to study staff by leaving them with the HiROC receptionists (e.g., if they have a prenatal care

appointment already scheduled), mailing them (i.e., prepaid FedEx mailers with the study's address will be provided), or arranging for study staff to pick them up (the later preferred).

O. Newborn Infant Measurements, the Delivery Visit

On the Study Visit 1 in-person survey, participants will be asked if they are interested in participating in the optional delivery visit. If so, they will be asked to provide the names and telephone numbers of 1-2 individuals who plan to be with them at the delivery and to give study staff permission to contact those individuals to help schedule the newborn infant measurements. Participants will be asked to update this information, if it has changed, at Study Visit 2 in-person survey. Study staff will check in with those individuals by text every few days around the woman's estimated delivery date/C-section date to schedule the newborn infant measurements, ideally before she is discharged.

Study staff will also distribute delivery visit reminder cards at Study Visits 1 and 2 that contain the telephone number to call or text once they go into labor; participants will be instructed to keep this reminder card in their hospital bags.

Study staff will also remain in contact with the UTMC staff in labor and delivery so they are aware that the patient is a study participant and will need newborn infant measurements. Study staff will additionally search the Medical Center's electronic admission system and the labor and delivery patient board for study participants as they near delivery. UTMC staff in labor and delivery and the Mother/Baby Units will also help facilitate scheduling the delivery visit to obtain the newborn measurements.

Newborn measurements will not be taken if the baby is admitted to Neonatal Intensive Care and is critically ill. Measurements will take place only at UTMC or the participants' homes.

First, study staff will weigh the baby (using a portable study scale). Second, study staff will measure the length of the infants (i.e., recumbent length with a portable infantometer). Third, study staff will measure the infant's head, abdominal and arm circumferences (i.e., using a tape measure). Forth, study staff will measure flank, thigh, triceps, bicep and subscapular skinfolds with calipers to assess body composition. The mother can hold the infant during the circumference and skin folds measurements. Although there is no risk of harm from these measures, the baby may briefly experience a very mild discomfort resulting from the light pinch of skin with the caliper (this pinching sensation is about as uncomfortable as if one were to lightly take a pinch of skin between the fingers).

Due to COVID-19, the Delivery Visit may potentially be canceled.

P. Interventions

The primary goal of the PA intervention is to achieve at least 30 minutes per day of walking/stepping in place. The secondary goal is to use a physical activity tracker to log and track their walking/stepping in place, and to get at least 3,000 steps during their 30 minutes of walking/stepping. The STEP Up intervention will offer a FitBit Charge 3; the devices will be managed by Fitabase so that both the participant and the interventionists will be able to view her Activity Log (i.e., the Fitbit's record of minutes spent walking/stepping and the number of steps obtained during those minutes), and will thus encourage the use of that device. Women randomized to the PA intervention will have an initial video chat (i.e., Zoom) counseling session to discuss exercising safely and exercising safely during pregnancy, go over the STEP Up program goals, set a walking/stepping goal for the following week, and receive and review use of the Fitbit to track progress towards their goal. They will then participate in 4 telephone/video chat sessions to discuss progress towards their walking/stepping goals and receive behavior change counseling to maintain and increase their walking/stepping (i.e., approximately 1 telephone session per week). They will be offered optional maintenance sessions

through delivery, as requested (i.e., approximately weekly). If the participant does not have internet access, the intervention will be delivered entirely by telephone.

Women randomized to the 'Next Steps' intervention will receive information on mom and baby wellness that is unrelated to physical activity, diet, metabolism, or weight (e.g., her own immunization status during pregnancy and encouragement to immunize her baby on schedule, infant car seats & safety checks, contraceptive options and a contraceptive plan), delivered in 5 telephone/video chat sessions (identical to the STEP Up intervention described above) in order to control for contact time. As such, the trial is called Project Wellness and it will be advertised that all study participants will work with a lifestyle coach on wellness.

For both interventions, study staff will schedule the initial intervention session by phone/email/text message. The first session will be by video chat (i.e., Zoom), if possible, and occur at ≤ 31 weeks 6 days gestation; and the remaining 4 telephone/video chat sessions are to be completed by ≤ 36 weeks 6 days gestation. The first session will last approximately 30-40 minutes. The remaining sessions will be approximately 10-20 minutes in length. Participants in the PA intervention will be given the option to continue their weekly sessions beyond 36 weeks of gestation (i.e., maintenance phase of the intervention, receiving approximately 1 telephone session per week). A subset of intervention sessions will be audio recorded to assess fidelity.

For both interventions, participants will receive an intervention workbook (i.e., specific to Next Steps and STEP up programs), with information organized by session. Intervention staff will offer to send pdfs of the individual sessions' materials via email to those who prefer it.

Given the participants' busy lives, missed intervention sessions are inevitable. For both interventions, after 2 unsuccessful contact attempts to reschedule an intervention session (i.e., participant doesn't call back or send an email/text message with a time to reschedule the session), intervention staff will contact the alternate contact(s) (i.e.,

husband, family member) the participant provided on her baseline Project Wellness survey. Staff will inform the contact person that the participant missed a scheduled phone call/visit and to request she call the staff member back (or send a text) to reschedule the call. These individuals will be contacted only once. After two consecutive weeks of unsuccessful attempts to contact (i.e., with no response by telephone, email or text messaging from the participant or the alternative contact), the participant will be considered a passive drop and will be sent a “passive drop” email (stating she will be dropped from the STEP Up/Next Steps program if she doesn’t reply in 2 days) as a final attempt to reengage her in the intervention.

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