Title: Monitoring Movement and Health Study

ClinicalTrials.gov ID: NCT03084302

Document Date: May 4, 2020

Monitoring Movement and (MoM) Health Protocol - FINAL

Aim 1: Objectively measure sedentary behavior across pregnancy trimesters
Aim 2: Relate objectively-measured sedentary behavior to blood pressure and gestational weight gain across pregnancy
Aim 3: Characterize correlates and determinants of sedentary behavior during pregnancy

1) Informed consent
- potential participants will be provided with an informed consent and will be asked to read over the consent in full. After they have read the consent, a designated and trained research assistant or investigator will explain the procedures, risks/benefits, and participant rights for participating in the study. The participant will be given an opportunity to ask questions. If the trained research assistant is conducting the informed consent process, the participant will be informed that they can talk to a study investigator before joining the study if they wish. After all questions are answered, eligible subjects interested in joining the study will sign the informed consent. Informed consent will happen either in the Magee ACRC (on floor 0 of Magee Womens Hospital) or at the Physical Activity and Weight Management Research Center (PAWMRC) in Oak Hill, adjacent to the Pitt campus.

2) Visit 1 will be conducted by an investigator or research assistant and will occur in the Magee ACRC, the PAWMRC, or the Mt. Oliver Magee Outpatient Clinic. This visit will take approximately 90 minutes.
a. Height and weight will be measured using the Magee CRC resources with shoes removed and in light clothing. All measured will be taken in duplicate and will be repeated if measures differ by >0.5 cm (height) and >0.1 lb (weight).
b. Blood pressure will be measured using an Omron HEM-705 oscillometric blood pressure monitor on the left arm. Participants will sit quietly with arm at chest level and feet flat on the floor for 10 minutes. Two blood pressures will be taken with a 1-minute rest between measurements. If SBP differs by more than 10 mmHg or DBP differs by more than 6 mmHg, a third measure will be taken after a 1-min rest.
c. An interview and questionnaires will be completed in a private location. These will include:
- Demographics, Smoking, and Medical and Reproductive History
- Pregnancy Physical Activity Questionnaire (note this will be repeated once for PRIOR to pregnancy and once for CURRENT level of activity)
- Sedentary Behavior (Current and prior to pregnancy)
- Depressive Symptoms (Center for Epidemiological Studies Short Form)
- Reasons for Sitting during Pregnancy Questionnaire
- Pregnancy Symptoms (NVPQoL) Questionnaire
- Quality of Life (SF-12)
- Feelings (POMS Questionnaire)
- Abbreviated Neighborhood Environment and Walkability Scale (NEWS-A)
- Sleep (Pittsburgh Sleep Quality Index)
- Diet (Dietary Screening Questionnaire)
d. Participants will receive activity monitors (ActivPAL and Actigraph) and a diary. Participants will be provided with detailed instructions on wearing the monitors and these will be reviewed. Participants will also be provided with an envelope to return the device after the 7 day wear period. Participants will also be asked how they would like to be contacted (phone or email) during the wear period. Research staff will contact participants on day 2 and 7 during the monitor wear time to troubleshoot, answer questions, and improve adherence to wear and mailing back instructions.

3) Visits 2 and 3 procedures
A reminder text/phone call/email/letter will be sent 1 week prior to the visit. Participants will visit the Magee ACRC, the Oak Hill PAWMRC, or the Mt. Oliver Magee Outpatient Clinic and repeat some procedures from visit 1. These will include:
a. blood pressure as in Visit 1
b. weight as in Visit 1
c. questionnaires

- Smoking, updates to Medical history and demographics
- Pregnancy Physical Activity Questionnaire
- Sedentary Behavior (Current and prior to pregnancy)
- Depressive Symptoms (Edinburgh Post natal Depression Scale)
- Reasons for Sitting during Pregnancy Questionnaire
- Pregnancy Symptoms (NVPQoL) Questionnaire
- Quality of Life (SF-36)
- Feelings (POMS Questionnaire)
- Sleep (Pittsburgh Sleep Quality Index)
- Diet (Dietary Screening Questionnaire)
- Only if the participant has moved: Neighborhood Environment and Walkability Scale
- At the 3rd visit only: Participants will be asked to complete a Kick-count Questionnaire (uploaded as attachment)
- At the 3rd visit only: Physical Activity Provider Interactions and Self Efficacy Quesitonnaire (NOTE: this questionnaire will be completed AFTER activity monitoring so that it does not influence behavior. The questionnaire can be completed on paper, and returned with the monitors, or can be completed online via Qualtrics)

d. activity monitoring as in Visit 1

Medical records will be abstracted after the participant has finished participation in the study to abstract birth outcomes and eventual pregnancy weight gain. Medical records will be accessed through EPIC. The following outcomes will be abstracted:

a. Results of glucose tolerance testing, gestational diabetes status
b. All clinic blood pressure and weights from prenatal visits
c. Pregnancy outcomes and complications

Statistical Considerations.

We calculated sample size requirements using Stata v14.0 and G*Power v3.1.9.2. For aim 1, n=100 subjects would be required to detect a 30-min increase in sedentary time between any two trimesters with 80% power and two-sided $\alpha = 0.05$. The 30-min difference was observed in the only relevant published study where sedentary time increased from 12.4 ± 1.7 hr/day to 12.9 ± 2.2 hr/day (d= 30 min, SD = 97, p=0.07) from the 2nd to 3rd trimester in pregnant women.(Di Fabio DR, Blomme CK, Smith KM, Welk GJ, Campbell CG. Adherence to physical activity guidelines in mid-pregnancy does not reduce sedentary time: an observational study. Int J Behav Nutr Phys Act. 2015;12:27.) A difference of 30-min is also considered clinically meaningful and has been related to health benefits. Though we will do our best to obtain complete data on all enrolled subjects, a 20-30% increase in sample size will be applied to preserve adequate statistical power in the case of missing data (lost pregnancy, loss to follow-up, invalid activity data). Thus, we will plan to recruit n=130 subjects or until we have complete data on 100 subjects. For Aim 2, if we identify three sedentary behavior trajectory groups of roughly equal sample size, and have 5-8 additional covariates in the model (e.g., wear time, MVPA, age, race, prepregnancy BMI), 100 subjects would afford 80% power to detect significant associations if sedentary behavior trajectory group explains 8% (small effect) of the variance in outcomes (i.e., BP, GWG).