Study Protocol

Official Title:

Rationale, Design, and Methods for the Sedentary Behavior Reduction in Pregnancy Intervention (SPRING): Protocol for a Pilot and Feasibility Randomized Controlled Trial

ClinicalTrials.gov ID (NCT number):

NCT05093842

Protocol Date:

April 16, 2023

Scientific Background

Cardiovascular disease (CVD) remains the number one health threat in women [1]. Adverse pregnancy outcomes (APOs), such as hypertensive disorders of pregnancy, gestational diabetes, and preterm birth, affect up to 20% of pregnant women and are recognized as major risk factors for latent and future CVD [2,3]. Though research to disentangle the contributions of prepregnancy risk factors from APOs on future CVD risk is ongoing, interventions that prevent APOs as a target for reducing CVD offer immediate and possibly long-term benefits. Effective preventative therapies, however, remain elusive [4]. Moderate to vigorous-intensity physical activity reduces APO risk [5,6], but less than 1 in 4 pregnant women achieve guidelines [7]. This likely reflects that pregnant women report unique exercise barriers such as fatigue, pain, medical restriction, and concern for the baby [8].Therefore, more feasible lifestyle strategies to prevent APOs are needed.

One such strategy could be reducing sedentary behavior (SED), which is defined as low-intensity behavior that occurs in a seated, reclined, or lying posture [9]. Considering barriers to more intensive physical activity during pregnancy, replacing SED across the day with standing and light-intensity physical activities may be more achievable. Excessive SED has been related to an increased risk of CVD and mortality in general populations, even after accounting for moderate- to vigorous-intensity physical activity [10]. Though sparse data on SED during pregnancy exist, our laboratory recently completed a small cohort study among 120 pregnant women that objectively measured SED and physical activity during each trimester [11]. We found that, on average, pregnant women had approximately 9.5 hours per day of SED, which is higher than the general population [12]. Further, using trajectory analysis, women with a pattern of very high SED across pregnancy (approximately 11 hours per day) versus low SED (approximately 8 hours per day) had 6.76 (95% CI 1.20-38.14) higher odds of experiencing an APO [11]. Of interest, women in the low and medium SED groups (approximately 8 and 9 hours per day, respectively) had no excess risk of APO, indicated a possible threshold effect. Similar threshold effects were observed for time spent standing and in the number of steps per day such that only women in the very low trajectory groups had excess risk. Importantly, moderate- to vigorous-intensity activity was not associated with APO outcomes, bolstering support for a strategy of reducing SED by increasing standing and daily steps as a novel intervention target to improve pregnancy health. Yet, few randomized clinical trials (RCTs) testing SED reduction interventions are available, especially in pregnant women.

The Sedentary Behavior Reduction in Pregnancy Intervention (SPRING) pilot and feasibility study, funded by the American Heart Association (20TPA3549099), seeks to address these research gaps. SPRING is an RCT that tests the feasibility, acceptability, and preliminary effects of a novel intervention designed to reduce SED and improve all-day activity patterns among pregnant women at high risk for APOs.

Study Objectives

The SPRING study's specific aims are to (1) evaluate the effect of SPRING versus control on objectively measured SED (*primary outcome, hypothesized to decrease*), standing (*hypothesized*

to increase), and steps per day (*hypothesized to increase*); (2) evaluate the feasibility and acceptability of SPRING, including recruitment, retention, outcome assessment rates, intervention fidelity, and program evaluation; and (3) estimate the preliminary effects of SPRING versus control on maternal-fetal health outcomes including composite APOs (hypertensive disorders of pregnancy, gestational diabetes, and preterm birth), maternal blood pressure and glucose, psychosocial outcomes, gestational age at birth, and infant birth anthropometrics.

Study Design & Methods

Study Design Overview

In the absence of established SED-reduction interventions or guidelines in pregnant women, a pilot and feasibility RCT among pregnant women with higher risk for SED and APOs was chosen as the first logical step to determine if the intervention could successfully reduce SED by increasing standing and steps per day across pregnancy (SPIRIT [Standard Protocol Items: Recommendations for Intervention Trials] checklist [13]. The SPRING pilot and feasibility trial is registered on ClincialTrials.gov (NCT05093842).

Potential participants complete baseline assessments and begin the 1-week baseline activity monitoring protocol between 10 weeks 0 days (100 weeks) and 12 weeks 6 days (126 weeks) of gestation. Upon receipt of valid activity monitoring data with a completed time-use diary and clearance to participate from the participant's prenatal care provider, pregnant women are randomized in a 2:1 ratio to either a multicomponent SED-reduction intervention or a usual care control group. Beginning at approximately 14 weeks of gestation, participants randomized to the intervention group begin the active intervention, which lasts through 38 weeks of gestation or until the participant gives birth, whichever occurs first. Participants randomized to the usual care control arm do not receive the intervention but are mailed a Fitbit Luxe after giving birth.

Participants in both groups complete assessments in each trimester and are remunerated US $40 for completing the first trimester (baseline) assessment between 100 and 126 weeks, US $50 for completing the second-trimester assessment between 200 and 226 weeks of gestation, and US $60 for completing the third-trimester assessment between 320 and 346 weeks of gestation. After participants give birth, maternal-fetal outcomes are abstracted from medical records by trained clinical staff.

All research procedures were approved by the University of Pittsburgh Human Research Protection Office (STUDY20110193).

Recruitment and Screening

Recruitment Methods Participants are recruited from within approximately 50 miles of the University of Pittsburgh's main campus in Pittsburgh, Pennsylvania. A variety of recruitment methods are used, including the University of Pittsburgh Clinical and Translational Science Institute's Pitt+Me research registry and targeted emails sent to the university community. In addition, recruitment messages from the study physician are sent to patients at the University of

Pittsburgh Medical Center's (UPMC) Maternal Fetal Medicine clinic who meet eligibility requirements through the MyUPMC mobile app. Finally, flyers are placed in patient-facing areas of Magee-Womens Hospital of UPMC, the largest birthing hospital in the Pittsburgh region.

Screening, Orientation, and Informed Consent

Interested participants are directed to complete a web-based screening questionnaire using Research Electronic Data Capture (REDCap) [14,15]. The screening questionnaire contains a detailed summary of the study, a request for electronic consent to answer screening questions, and specific questions about the candidate's current pregnancy, risk factors for APO, SED exposure and habits, chronic diseases, medications, and contact information. Trained study staff assess initial eligibility based on the answers to the screening questionnaire and, if a candidate is deemed ineligible, they are informed at that time. Candidates who appear to be eligible during initial screening are invited to a web-based videoconference orientation where the study is described in detail, verbal informed consent is obtained, and then an electronic informed consent document is signed by the participant and study personnel conducting the informed consent. Finally, a detailed medical and reproductive history questionnaire is administered to determine final eligibility.

Randomization

A randomization ratio of 2:1 (2 intervention to 1 control) was chosen to provide more robust data to evaluate the feasibility and acceptability of our intervention and assessment protocols [16]. To help achieve balance over time, blocks of 6 were selected, and 9 blocks of computer-generated, randomly ordered sets were placed sequentially into sealed, numbered envelopes by a blinded study personnel. These envelopes were then provided to the unblinded study personnel (principal investigator and interventionist) and kept in a secure location.

Participant randomization begins with the blinded study coordinator notifying the principal investigator that a participant is eligible and has completed all baseline assessment procedures. The study investigator then opens the next sequential envelope and records the randomization assignment and date in the randomization log. The principal investigator then contacts the participant to inform her regarding her randomization assignment, describe next steps, ensure that the participant comprehends that the intervention and assessment study procedures are separate, and reinforce the importance of continued participation in either group.

Outcome Assessments

Study outcome assessments are conducted by trained, blinded study personnel and occur via web-based videoconference once per trimester of pregnancy. Any necessary assessment materials are mailed to participants prior to study visits.

SED and physical activity are measured in each trimester. Objective assessment of activity patterns is conducted using a thigh-mounted activPAL3 monitor (PAL Technologies, Glasgow) worn for 24 hours over 8 days. This protocol is the best-practice methodology for field monitoring of SED and standing [17], and we have shown it to be a valid measure of moderate-

to vigorous-intensity physical activity in pregnant women [18]. Participants wear the monitor on the anterior upper thigh for 8 days, with removal only for swimming activities. Concurrently, participants are asked to record periods of work, nonwork, sleep, and nonwear in a diary for accurate data processing. Participants are verbally instructed regarding procedures for correct monitor wear at each virtual assessment visit, including visual verification of correct placement. Detailed written instructions on monitor wear and diary completion are also provided. The activPAL3 24-hour event data are downloaded and cleaned by removing periods of sleep and nonwear; remaining valid wear time is used to calculate average daily durations of time spent in SED (total and in prolonged bouts of at least 30 and 60 minutes), standing, and stepping. Daily frequency of steps and sit-stand transitions are also averaged across days. Lastly, to estimate moderate- to vigorous-intensity physical activity, time with a stepping frequency of at least 75 steps per minute and 100 steps per minute are averaged across valid wear days from daily summary data. Averages are calculated overall and during working times (if applicable). Data are considered valid with at least 5 days of at least 10 hours of waking wear time recorded [19].

Self-reported SED and physical activity are assessed using the Pregnancy Physical Activity Questionnaire [20], with questions regarding proportion of time spent in SED during work and nonworking times added to improve the accuracy of self-reported SED assessment [21].

Blood pressure is assessed virtually during study assessment visits in each trimester using a validated oscillometric monitor [22]. Either a UA-611 monitor (A&D Medical) that was provided as part of prenatal care at the University of Pittsburgh Magee-Womens Hospital or a study-provided BP7250 monitor (Omron Healthcare Inc) is used. Participants use the same monitor and cuff for all visits. During the virtual assessment, participants first provide verbal confirmation of abstention from caffeine and nicotine for 1 hour prior. Then, participants place the cuff on the left upper arm and complete a supervised 5-minute quiet rest with their arm supported at chest level, back supported against a chair, and feet flat on the floor or other support with ankles and knees uncrossed. After the rest, the participant initiates the measurement by pressing the start button with the blood pressure monitor facing the video camera and visible only to the assessor (to reduce participant reactivity). The assessor leads the participant through 3 measurements, taken with a 1-minute rest in between, and records blood pressures and heart rates in the database prior to informing the participant of all values. The average of the second and third measurements is used for analysis.

Demographics, medical history, reproductive history, and medication use are collected at baseline using a standardized form. Anthropometry is assessed at baseline via self-reported height and pre-pregnancy weight, which are subsequently verified through medical record abstraction (described later). To capture changes that occurred following randomization, updates to demographics (eg, new employment) are reported in a questionnaire and changes to medical history or medication use (eg, a new diagnosis or starting, stopping, or changing dosage of medications) are assessed during an interval medical history review at each follow-up visit.

Dietary intake is assessed at each visit using the Diet Screening Questionnaire, a semiquantitative questionnaire that measures typical dietary habits [23]. Psychosocial behavioral targets and outcomes are measured at baseline and each follow-up visit via web-based self-report questionnaires. Validated questionnaires assessing behavioral targets of the intervention include

the Sitting during Pregnancy Barriers and Outcome Expectations Questionnaire [24], Expected Outcomes and Barriers for Habitual Physical Activity [25], the Multidimensional Scale of Perceived Social Support [26], and Social Support for Exercise [27]. Validated questionnaires assessing possible psychosocial effects of the intervention include the Profile of Mood States [28], the Centers for Epidemiologic Studies Depression Scale (CES-D) [29], the Perceived Stress Scale [30], Health-Related Quality of Life for Nausea and Vomiting during Pregnancy [31], and the Pittsburgh Sleep Quality Index [32].

Adverse events are collected systematically at follow-up assessment visits by blinded study personnel. Details of new or worsening medical conditions, including pregnancy-related adverse events, are recorded and classified regarding severity and relationship. In addition, ongoing assessment of adverse events in the intervention group is conducted by intervention staff. All adverse events are reviewed by the principal investigator and, if needed, the study physician for accuracy, possible relationship to the intervention, and to make any necessary modifications or terminate participation in the intervention.

Pregnancy health and maternal-fetal outcomes are abstracted from the participant's medical record of prenatal visits and labor and delivery notes. Maternal outcomes extracted include gestational weight gain, clinic-measured blood pressures, pregnancy complications including APOs, glucose screening values, and tolerance tests (if available), and labor and delivery details. Fetal outcomes include gestational age at birth, anthropometrics, and complications. All abstractions are reviewed by a second reviewer and discrepancies are resolved. The study's maternal-fetal medicine physician coinvestigator (AH) confirms all APOs and a random sample of healthy pregnancies for accuracy.

Feasibility and Acceptability

Feasibility and acceptability are also assessed through a variety of methods across the study period. Screening outcomes are recorded prospectively including recruitment sources and yield, eligibility rates and ineligibility reasons, and rates of enrollment. We also administer a study-developed questionnaire at baseline (prior to randomization) to assess participant expectations, motivations, and experiences when enrolling in the SPRING RCT. Rates of valid assessment completion are also prospectively recorded. Intervention fidelity with respect to delivery, receipt, and enactment [33] is assessed at each intervention contact (see Intervention Content and Schedule section). A final web-based program evaluation assesses acceptability and includes 22 short-answer, ranking, and multiple-choice questions. The evaluation is distributed after the last intervention lesson to intervention participants only and aims to evaluate participants' perceptions regarding their health, usefulness of the intervention components, general satisfaction and acceptability of the intervention, and suggestions for improvement.

Intervention

Intervention Content and Schedule

SPRING developed behavioral targets informed by the specific patterns of SED, standing, and daily steps that were associated with lower APO risk in our observation cohort of pregnant

women [11]. Specifically, we observed threshold effects whereby engaging in SED for approximately 9.2 hours per day or less, standing for approximately 3.8 hours per day or more, and accumulating approximately 7801 steps per day or more were the activity patterns associated with a significantly lower risk of an APO [11] along with other maternal and fetal health benefits [46-48]. We also considered additional data from our observational research regarding determinants, barriers, attitudes, and outcome expectations related to SED during pregnancy. Findings from these studies suggested that pregnancy-related physical symptoms such as nausea and fatigue along with work-related sitting were the most commonly reported barriers to reducing SED [24]. Using objectively measured SED data, we also found that desk jobs and fewer children aged 5 years or younger in the home emerged as the factors that are most strongly associated with SED during pregnancy [49]. We then used these data to adapt our existing SED-reduction interventions in nonpregnant adults [50-52] to the new population of pregnant women at high risk for SED and APOs.

Thus, with the overall goal of reducing SED to less than 9 hours per day, we set evidence-based behavioral targets for our intervention as follows: (1) increase standing time by 2-3 hours per day with a daily total target of at least 4 hours per day; (2) increase light-intensity movement across the day, achieving at least 7500 steps per day; and (3) increase steps by at least 250 per hour (up to 8 hours per day). To facilitate behavior change toward these standing and step targets in our intervention group, we developed an evidence- and theory-based, multicomponent intervention strategy across 3 levels of the socioecological model [34,35,37,40].

Safety and fidelity of the intervention are assessed at each contact by measuring contraindications [36], delivery (provision of intervention components), receipt (self-report of intervention components working properly), and enactment (self-report of self-monitoring and goal achievement) [33].

Control Group

Participants assigned to the control group are asked to continue their typical behavior for the duration of their pregnancy and are provided with a general handout regarding recommended physical activity during pregnancy [36] but received no further intervention materials. After delivery, control participants are mailed a report of their objective activity levels that were previously measured during the study assessments and a Fitbit Luxe.

Eligibility Criteria

We recruit participants in their first trimester of pregnancy who are at risk for high levels of SED and who have at least 1 risk factor for APO. These criteria reflect an early gestational age when we can intervene meaningfully across pregnancy and higher SED appropriate for modification (ie, reduction) to reach the levels that we have found to be associated with better pregnancy outcomes [11]. The criteria of having at least 1 risk factor for APO relate to our long-term goal to test whether our intervention can reduce APO risk; therefore, we sought to evaluate feasibility and preliminary effects in this specific population. Lastly, to allow for our exploratory outcome assessment using prenatal records of maternal-fetal outcomes, participants are required to

consent to abstraction either through our affiliation with the University of Pittsburgh Medical Center or through separate medical record release if they are receiving prenatal care elsewhere.

Participants younger than 18 years or older than 45 years are excluded to avoid an inability to provide consent and more complicated pregnancies with advanced age, respectively. Those with preexisting hypertension or diabetes are excluded because existing management of these conditions could affect our study outcomes (eg, prenatal blood pressure and glucose test results). Any other contraindications to exercise during pregnancy or severe mobility limitation are also exclusionary since the intervention asks participants to increase standing and daily steps. We also require participants to receive clearance for participation in the intervention from their prenatal care provider as an additional safety precaution. Lastly, those participating in other interventional research that could confound our study outcomes are excluded to reduce bias or contamination.

Inclusion/Exclusion Criteria

Inclusion criteria

Gestational age:
- Between 10 weeks 0 days and 12 weeks 6 days of gestation

At risk for high sedentary behavior (meets at least one of the following criteria):
- Primarily sitting, full-time desk job (more than 30 hours per week)
- Primarily sitting, part-time desk job (less than 30 hours per week) and reports sitting at least half of the time during nonwork days
- Does not work and reports sitting at least three-fourths of the time
- Reports no more than 6000 steps per day from a wearable activity monitor

Risk factor for adverse pregnancy outcome (APO; meets one of the following criteria):
- Nulliparity
- History of APO
- Pre-pregnancy BMI of 30 kg/m2 or greater
- Age of 35 years or older

Medical record access:
- Plans to deliver at the University of Pittsburgh facility or willing to provide consent for medical record release of prenatal care and birth records

Exclusion criteria

Young or advanced maternal age:
- Younger than 18 years; older than 45 years

Chronic hypertension:
- Resting blood pressure of 140/90 mm Hg or greater or antihypertensive medication use

Pregestational diabetes:
- Type 1 or type 2 diabetes, prior to pregnancy

Contraindication to exercise:

- Serious medical conditions such as underlying cardiac disease, severe anemia, chronic bronchitis, poorly controlled hyperthyroidism, or seizure disorder

Severe mobility limitation:

- Self-report of inability to walk 2 blocks or climb a flight of stairs

No prenatal care provider clearance:

- Unable to obtain a signed permission form from a prenatal care provider to participate in the intervention

Other research intervention:

- Participating in another health-related intervention study that could affect study outcomes

Travel plans restricting participation:

- Plans to travel that limit ability to fully participate in the study protocol

Statistical Considerations

Analytic Strategy for Aim 1 and the Exploratory Aim

We will use Stata (StataCorp) for all analyses with an intention-to-treat philosophy. First, participant flow will be summarized using a Consolidated Standards of Reporting Trials diagram for randomized trials [53]. Second, descriptive statistics will be computed for variables by treatment group and time point. Third, the baseline measures will be compared between the 2 groups using independent samples *t* tests, Wilcoxon rank sum, chi-square, or Fisher exact tests, as appropriate. While significant differences are not expected, any found will be considered in sensitivity analyses. Next, main analyses will fit a series of linear mixed models with follow-up continuous outcomes as the dependent variable (eg, SED); intervention group (intervention or control), follow-up time (eg, second and third trimester), and group × time as fixed effects; baseline value of outcomes as fixed-effect covariates; and a participant random effect to account for multiple observations from the same participant over time. Mean contrasts will estimate the between-group difference at each follow-up time point. Similar methods will be used for the other activity variables (eg, standing and steps). Analysis of the exploratory aim will use similar methods, with logistic regression for dichotomous outcomes (eg, APOs). We will first consider the use of multiple imputation to account for missing data, but we will perform additional sensitivity or exploratory analyses to ensure robustness and extend our findings, for example, complete-data-only or last-value-carried forward strategies for missing data.

Analytic Strategy Aim 2

For the recruitment feasibility outcomes, we will calculate frequencies of recruitment method use and yields; rates of screening contacts, consent, eligibility, and randomization; reasons for ineligibility; and characteristics of enrolled participants. Benchmarks will be 42 (80%) for retention and 40 (95%) of the retained participants for valid outcome assessments. Intervention fidelity will be calculated based on intervention contacts with an overall average benchmark of 30 (85%) of each intervention contact competed. Quantitative or semiquantitative acceptability and program evaluation data will be summarized descriptively. Open-ended questionnaires will be analyzed using a constant comparison method to identify salient categories, themes, and

patterns via open coding, iterative review and codebook generation, code linking into similar categories, and final integration into themes [54].

Sample Size Considerations

The primary outcome of this study is a change in SED. Based on our pilot data that suggest lower SED protects women from APOs [11], we calculated sample size requirements assuming the following: a between-group SED difference of 1 hour (SD 56 minutes) per day, a 2:1 randomization ratio to enhance recruitment and increase program evaluation and feasibility data, 90% power, and α=.05. This yielded a required sample size of 42 (28 intervention and 14 control). A final sample size of up to 53 (35 intervention and 18 control), inflated by 20%, was adopted to account for attrition.

References

1. Heron M. Deaths: leading causes for 2018. Natl Vital Stat Rep 2021;70(4):1-115 [Medline: 34029179]

2. Mosca L, Benjamin EJ, Berra K, Bezanson JL, Dolor RJ, Lloyd-Jones DM, American Heart Association. Effectiveness-based guidelines for the prevention of cardiovascular disease in women—2011 update: a guideline from the American Heart Association. J Am Coll Cardiol 2011;57(12):1404-1423 [FREE Full text] [doi: 10.1016/j.jacc.2011.02.005] [Medline: 21388771]

3. Grandi SM, Filion KB, Yoon S, Ayele HT, Doyle CM, Hutcheon JA, et al. Cardiovascular disease-related morbidity and mortality in women with a history of pregnancy complications. Circulation 2019;139(8):1069-1079 [doi: 10.1161/CIRCULATIONAHA.118.036748] [Medline: 30779636]

4. ACOG. ACOG practice bulletin no. 202: gestational hypertension and preeclampsia. Obstet Gynecol 2019;133(1):1 [doi: 10.1097/AOG.0000000000003018] [Medline: 30575675]

5. Davenport MH, Ruchat S, Poitras VJ, Garcia AJ, Gray CE, Barrowman N, et al. Prenatal exercise for the prevention of gestational diabetes mellitus and hypertensive disorders of pregnancy: a systematic review and meta-analysis. Br J Sports Med 2018;52(21):1367-1375 [doi: 10.1136/bjsports-2018-099355] [Medline: 30337463]

6. Aune D, Saugstad OD, Henriksen T, Tonstad S. Physical activity and the risk of preeclampsia: a systematic review and meta-analysis. Epidemiology 2014;25(3):331-343 [doi: 10.1097/EDE.0000000000000036] [Medline: 24713878]
7. Hesketh KR, Evenson KR. Prevalence of U.S. pregnant women meeting 2015 ACOG physical activity guidelines. Am J Prev Med 2016;51(3):e87-e89 [FREE Full text] [doi: 10.1016/j.amepre.2016.05.023] [Medline: 27544437]

8. Evenson KR, Moos MK, Carrier K, Siega-Riz AM. Perceived barriers to physical activity among pregnant women. Matern Child Health J 2009;13(3):364-375 [FREE Full text] [doi: 10.1007/s10995-008-0359-8] [Medline: 18478322]

9. Tremblay MS, Aubert S, Barnes JD, Saunders TJ, Carson V, Latimer-Cheung AE, et al. Sedentary Behavior Research Network (SBRN)—terminology consensus project process and outcome. Int J Behav Nutr Phys Act 2017;14(1):75 [FREE Full text] [doi: 10.1186/s12966-017-0525-8] [Medline: 28599680]

10. Katzmarzyk PT, Powell KE, Jakicic JM, Troiano RP, Piercy K, Tennant B. Sedentary behavior and health: update from the 2018 Physical Activity Guidelines Advisory Committee. Med Sci Sports Exerc 2019;51(6):1227-1241 [FREE Full text] [doi: 10.1249/MSS.0000000000001935] [Medline: 31095080]

11. Barone Gibbs B, Jones MA, Jakicic JM, Jeyabalan A, Whitaker KM, Catov JM. Objectively measured sedentary behavior and physical activity across 3 trimesters of pregnancy: the monitoring movement and health study. J Phys Act Health 2021;18(3):254-261 [FREE Full text] [doi: 10.1123/jpah.2020-0398] [Medline: 33508775]

12. Matthews CE, Chen KY, Freedson PS, Buchowski MS, Beech BM, Pate RR, et al. Amount of time spent in sedentary behaviors in the United States, 2003-2004. Am J Epidemiol 2008;167(7):875-881 [FREE Full text] [doi: 10.1093/aje/kwm390] [Medline: 18303006]

13. Chan AW, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ 2013;346:e7586-e7586 [FREE Full text] [doi: 10.1136/bmj.e7586] [Medline:23303884]

14. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap) a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42(2):377-381 [FREE Full text] [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]

15. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, et al. The REDCap consortium: building an international community of software platform partners. J Biomed Inform 2019;95:103208 [FREE Full text] [doi: 10.1016/j.jbi.2019.103208] [Medline: 31078660]

16. Orsmond GI, Cohn ES. The distinctive features of a feasibility study: objectives and guiding questions. OTJR (Thorofare N J) 2015;35(3):169-177 [doi: 10.1177/1539449215578649] [Medline: 26594739]

17. Edwardson CL, Winkler EA, Bodicoat DH, Yates T, Davies MJ, Dunstan DW, et al. Considerations when using the activPAL monitor in field-based research with adult populations. J Sport Health Sci 2017;6(2):162-178 [FREE Full text] [doi: 10.1016/j.jshs.2016.02.002] [Medline: 30356601]

18. Jones MA, Diesel SJ, Gibbs BB, Whitaker KM. Concurrent agreement between ActiGraph and activPAL for measuring physical activity in pregnant women and office workers. J Meas

Phys Behav 2022;5(2):69-75 [FREE Full text] [doi: 10.1123/jmpb.2021-0050] [Medline: 36340243]

19. Aguilar-Farias N, Martino-Fuentealba P, Salom-Diaz N, Brown WJ. How many days are enough for measuring weekly activity behaviours with the ActivPAL in adults? J Sci Med Sport 2019;22(6):684-688 [doi: 10.1016/j.jsams.2018.12.004] [Medline: 30579814]

20. Chasan-Taber L, Schmidt MD, Roberts DE, Hosmer D, Markenson G, Freedson PS. Development and validation of a pregnancy physical activity questionnaire. Med Sci Sports Exerc 2004;36(10):1750-1760 [doi: 10.1249/01.mss.0000142303.49306.0d] [Medline: 15595297]

21. Gibbs BB, Paley JL, Jones MA, Whitaker KM, Connolly CP, Catov JM. Validity of self-reported and objectively measured sedentary behavior in pregnancy. BMC Pregnancy Childbirth 2020;20(1):99 [FREE Full text] [doi: 10.1186/s12884-020-2771-z] [Medline: 32046663]

22. Stergiou GS, Asmar R, Myers M, Palatini P, Parati G, Shennan A, et al. Improving the accuracy of blood pressure measurement: the influence of the European Society of Hypertension International Protocol (ESH-IP) for the validation of blood pressure measuring devices and future perspectives. J Hypertens 2018;36(3):479-487 [doi: 10.1097/HJH.0000000000001635] [Medline: 29384984]

23. Thompson FE, Midthune D, Subar AF, McNeel T, Berrigan D, Kipnis V. Dietary intake estimates in the National Health Interview Survey, 2000: methodology, results, and interpretation. J Am Diet Assoc 2005;105(3):352-363 [doi: 10.1016/j.jada.2004.12.032] [Medline: 15746822]

24. Gibbs BB, Jones MA, Whitaker KM, Ross ST, Davis KK. Measurement of barriers, attitudes, and expectations for sitting less in pregnancy. Am J Health Behav 2021;45(6):956-970 [FREE Full text] [doi: 10.5993/AJHB.45.6.1] [Medline: 34969408]

25. Steinhardt MA, Dishman RK. Reliability and validity of expected outcomes and barriers for habitual physical activity. J Occup Med 1989;31(6):536-546 [doi: 10.1097/00043764-198906000-00011] [Medline: 2786559]

26. Zimet GD, Dahlem NW, Zimet SG, Farley GK. The multidimensional scale of perceived social support. J Pers Assess 1988;52(1):30-41 [doi: 10.1207/s15327752jpa5201_2]

27. Sallis JF, Grossman RM, Pinski RB, Patterson TL, Nader PR. The development of scales to measure social support for diet and exercise behaviors. Prev Med 1987;16(6):825-836 [doi: 10.1016/0091-7435(87)90022-3] [Medline: 3432232]

28. Shacham S. A shortened version of the profile of mood states. J Pers Assess 1983;47(3):305-306 [doi: 10.1207/s15327752jpa4703_14] [Medline: 6886962]

29. Radloff LS. The CES-D scale: a self-report depression scale for research in the general population. Appl Psychol Meas 1977;1(3):385-401 [doi: 10.1177/014662167700100306]

30. Cohen S, Kamarck T, Mermelstein R. Measuring Stress: A Guide for Health and Social Scientists, Vol. 10. Oxford: Oxford University Press; 1994:256

31. Munch S, Korst LM, Hernandez GD, Romero R, Goodwin TM. Health-related quality of life in women with nausea and vomiting of pregnancy: the importance of psychosocial context. J Perinatol 2011;31(1):10-20 [FREE Full text] [doi: 10.1038/jp.2010.54] [Medline: 20410906]

32. Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res 1989;28(2):193-213 [doi: 10.1016/0165-1781(89)90047-4] [Medline: 2748771]

33. Gitlin LN, Parisi JM. Twelve: are treatment effects real? The role of fidelity. In: Behavioral Intervention Research: Designing, Evaluating, and Implementing. New York: Springer Publishing; 2016.

34. Hutcheson AK, Piazza AJ, Knowlden AP. Work site-based environmental interventions to reduce sedentary behavior: a systematic review. Am J Health Promot 2018;32(1):32-47 [doi: 10.1177/0890117116674681] [Medline: 27780893]

35. Ferrer DA, Ellis R. A review of physical activity interventions delivered via Facebook. J Phys Act Health 2017;14(10):823-833 [doi: 10.1123/jpah.2016-0534] [Medline: 28556677]

36. Dipietro L, Evenson KR, Bloodgood B, Sprow K, Troiano R, Piercy KL, et al. Benefits of physical activity during pregnancy and postpartum: an umbrella review. Med Sci Sports Exerc 2019;51(6):1292-1302 [FREE Full text] [doi: 10.1249/MSS.0000000000001941] [Medline: 31095086]

37. Compernolle S, DeSmet A, Poppe L, Crombez G, De Bourdeaudhuij I, Cardon G, et al. Effectiveness of interventions using self-monitoring to reduce sedentary behavior in adults: a systematic review and meta-analysis. Int J Behav Nutr Phys Act 2019;16(1):63 [FREE Full text] [doi: 10.1186/s12966-019-0824-3] [Medline: 31409357]

38. Bandura A. The primacy of self-regulation in health promotion. Appl Psychol 2005;54(2):245-254 [doi: 10.1111/j.1464-0597.2005.00208.x]

39. Maes S, Karoly P. Self-regulation assessment and intervention in physical health and illness: a review. Appl Psychol 2005;54(2):267-299 [doi: 10.1111/j.1464-0597.2005.00210.x]

40. Di Loreto C, Fanelli C, Lucidi P, Murdolo G, De Cicco A, Parlanti N, et al. Validation of a counseling strategy to promote the adoption and the maintenance of physical activity by type 2 diabetic subjects. Diabetes Care 2003;26(2):404-408 [doi: 10.2337/diacare.26.2.404] [Medline: 12547870]

41. Sherwood NE, Jeffery RW. The behavioral determinants of exercise: implications for physical activity interventions. Annu Rev Nutr 2000;20(1):21-44 [doi: 0.1146/annurev.nutr.20.1.21] [Medline: 10940325]

42. Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. J Consult Clin Psychol 1983;51(3):390-395 [doi: 10.1037/0022-006X.51.3.390] [Medline: 6863699]

43. Carver CS, Scheier MF. Control theory: a useful conceptual framework for personality–social, clinical, and health psychology. Psychol Bull 1982;92(1):111-135 [doi: 10.1037/0033-2909.92.1.111] [Medline: 7134324]

44. Rodgers WM, Loitz CC. The role of motivation in behavior change: how do we encourage our clients to be active? ACSMs Health Fit J 2009;13(1):7-12 [doi: 10.1249/fit.0b013e3181916d11]

45. Ryan RM, Deci EL. Self-determination theory and the facilitation of intrinsic motivation, social development, and well-being. Am Psychol 2000;55(1):68-78 [doi: 10.1037/0003-066X.55.1.68]

46. Jones MA, Whitaker K, Taverno Ross SE, Davis K, Libertus K, Gibbs BB. Maternal sedentary behavior and physical activity across pregnancy and early childhood growth. Child Obes 2022;18(6):399-408 [doi: 10.1089/chi.2021.0202] [Medline: 35108109]

47. Jones MA, Catov JM, Jeyabalan A, Whitaker KM, Barone Gibbs B. Sedentary behaviour and physical activity across pregnancy and birth outcomes. Paediatr Perinat Epidemiol 2021;35(3):341-349 [FREE Full text] [doi: 10.1111/ppe.12731] [Medline: 33124060]

48. Whitaker KM, Jones MA, Wallace MK, Catov J, Barone Gibbs B. Associations of objectively measured physical activity and sedentary time with pregnancy-specific health-related quality of life. Midwifery 2022;104:103202 [FREE Full text] [doi:10.1016/j.midw.2021.103202] [Medline: 34801955]

49. Jones MA, Whitaker K, Wallace M, Gibbs BB. Demographic, socioeconomic, and health-related predictors of objectively measured sedentary time and physical activity during pregnancy. J Phys Act Health 2021;18(8):957-964 [doi: 10.1123/jpah.2021-0097] [Medline: 34140419]

50. Barone Gibbs B, Hergenroeder AL, Perdomo SJ, Kowalsky RJ, Delitto A, Jakicic JM. Reducing sedentary behaviour to decrease chronic low back pain: the stand back randomised trial. Occup Environ Med 2018;75(5):321-327 [FREE Full text] [doi: 10.1136/oemed-2017-104732] [Medline: 29330230]

51. Gibbs BB, Brach JS, Byard T, Creasy S, Davis KK, McCoy S, et al. Reducing sedentary behavior versus increasing moderate-to-vigorous intensity physical activity in older adults. J Aging Health 2017;29(2):247-267 [doi: 10.1177/0898264316635564] [Medline: 26944808]

52. Gibbs BB, Conroy MB, Huber K, Muldoon MF, Perera S, Jakicic JM. Effect of reducing sedentary behavior on blood pressure (RESET BP): rationale, design, and methods. Contemp Clin Trials 2021;106:106428 [FREE Full text] [doi: 10.1016/j.cct.2021.106428] [Medline: 33971295]

53. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. Lancet 2001;357(9263):1191-1194 [doi: 10.1016/S0140-6736(00)04337-3] [Medline: 11323066]

54. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res 2005;15(9):1277-1288 [doi: 10.1177/1049732305276687] [Medline: 16204405]