

Protocol

Healthy Mom Zone Adaptive Intervention With a Novel Control System and Digital Platform to Manage Gestational Weight Gain in Pregnant Women With Overweight or Obesity: Study Design and Protocol for a Randomized Controlled Trial

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Abstract

Background: Regulating gestational weight gain (GWG) in pregnant women with overweight or obesity is difficult, particularly because of the narrow range of recommended GWG for optimal health outcomes. Given that many pregnant women show excessive GWG and considering the lack of a “gold standard” intervention to manage GWG, there is a timely need for effective and efficient approaches to regulate GWG. We have enhanced the Healthy Mom Zone (HMZ) 2.0 intervention with a novel digital platform, automated dosage changes, and personalized strategies to regulate GWG, and our pilot study demonstrated successful recruitment, compliance, and utility of our new control system and digital platform.

Objective: The goal of this paper is to describe the study protocol for a randomized controlled optimization trial to examine the efficacy of the enhanced HMZ 2.0 intervention with the new automated control system and digital platform to regulate GWG and influence secondary maternal and infant outcomes while collecting implementation data to inform future scalability.

Methods: This is an efficacy study using a randomized controlled trial design. HMZ 2.0 is a multidosage, theoretically based, and individually tailored adaptive intervention that is delivered through a novel digital platform with an automated link of participant data to a new model-based predictive control algorithm to predict GWG. Our new control system computes individual dosage changes and produces personalized physical activity (PA) and energy intake (EI) strategies to deliver just-in-time dosage change recommendations to regulate GWG. Participants are 144 pregnant women with overweight or obesity randomized to an intervention (n=72) or attention control (n=72) group, stratified by prepregnancy BMI (<29.9 vs ≥30 kg/m²), and they will participate from approximately 8 to 36 weeks of gestation. The sample size is based on GWG (primary outcome) and informed

by our feasibility trial showing a 21% reduction in GWG in the intervention group compared to the control group, with 3% dropout. Secondary outcomes include PA, EI, sedentary and sleep behaviors, social cognitive determinants, adverse pregnancy and delivery outcomes, infant birth weight, and implementation outcomes. Analyses will include descriptive statistics, time series and fixed effects meta-analytic approaches, and mixed effects models.

Results: Recruitment started in April 2024, and enrollment will continue through May 2027. The primary (GWG) and secondary (eg, maternal and infant health) outcome results will be analyzed, posted on ClinicalTrials.gov, and published after January 2028.

Conclusions: Examining the efficacy of the novel HMZ 2.0 intervention in terms of GWG and secondary outcomes expands the boundaries of current GWG interventions and has high clinical and public health impact. There is excellent potential to further refine HMZ 2.0 to scale-up use of the novel digital platform by clinicians as an adjunct treatment in prenatal care to regulate GWG in all pregnant women.

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KEYWORDS

pregnancy; gestational weight gain; physical activity; healthy eating; overweight; obesity; intervention

Introduction

Background

High maternal prepregnancy BMI and high gestational weight gain (GWG) elevate the risks for poor pregnancy outcomes (eg, gestational diabetes and hypertension) and fetal outcomes (eg, large for gestational age birth weight) [1-6]. High BMI and GWG may also “program” the child’s metabolism for life [7,8] and increase the future risks for obesity and type 2 diabetes in both mothers and their offspring [1-6]. As such, managing GWG has high clinical and public health significance, and it can improve maternal health and impact the etiology of obesity or diabetes in offspring at a crucial time in the life cycle [1-6,8].

Guidelines from the Institutes of Medicine (IOM) [1] and National Academy of Medicine [2] recommend that the optimal total GWG should be based on a woman’s prepregnancy BMI category (ie, overweight: 6.8-11.3 kg; obese: 5.0-9.1 kg). However, evidence from a meta-analytic review including over 1 million pregnant women found that nearly 50% of women exceeded their recommended goals [9], and this was prevalent among those with normal weight as well as those with overweight or obesity. Furthermore, data from a meta-analysis of almost 200,000 women from 25 international cohort studies in the LifeCycle Project [6] showed the highest risk for adverse outcomes among women with both high BMI and high GWG. Given these concerns as well as the rapidly changing landscape of health care delivery since the COVID-19 pandemic, there is a critical and timely need for scalable approaches to effectively regulate GWG. One such strategy that may reach more pregnant women and reduce the burden on prenatal clinicians who monitor GWG is an automated approach that relies on a digital platform with remote delivery and passive remote data collection to monitor and effectively and efficiently regulate GWG.

Prior Work

Our team’s prior work successfully constructed energy balance models to predict maternal GWG [10] and infant birth weight [11]. Expanding the work of Thomas et al [12], we built a novel dynamic mathematical model of energy balance and behavior to predict GWG [13,14]. It describes how physical activity (PA)

and energy intake (EI) behaviors are influenced by social cognitive determinants (attitude, subjective norm, perceived control, intention, and self-regulation) [15-17] and depicts how components (ie, education, behavior coaching, goal setting, nutrition counseling, and engaging in PA and healthy eating activities) impact PA and EI social cognitive determinants and behaviors to regulate GWG. We also explored how the energy balance model could be extended to explain infant birth weight [11,18].

Prior research has shown that behavioral interventions can impact GWG [19-27] and more specifically that participants who received behavioral intervention components (eg, counseling, guided PA, and prescribed diet) had a lower mean GWG, decreased likelihood of exceeding GWG guidelines, and lower risk for adverse maternal and infant outcomes [20]. There was also evidence for a dose-response relationship whereby intensive interventions with more subject contact were associated with a stronger impact on GWG [20]. Moreover, the findings from qualitative and prospective cohort studies support an intensive approach to managing GWG in pregnant women with overweight or obesity because they may be more likely than women with underweight or normal weight to overestimate the amount of weight they should gain, underreport EI, and have low motivation to engage in PA on their own [28-41]. Taken together, there is ample evidence from the literature for an approach that considers the unique needs of pregnant women with overweight or obesity and personalizes intervention dosages to regulate GWG.

Many GWG interventions use a “one size fits all” approach and are not designed to consider individual variability in how women gain weight over the course of gestation. Our approach adapts personalized dosages for each woman in a way that gives more intensive treatment only to the women who need more assistance to regulate GWG. We piloted a proof-of-concept study [42] and feasibility-initial impact randomized trial [8,10,19,43-45] to examine the impact of the Healthy Mom Zone (HMZ) intervention on GWG. The social cognitive theory-based components [15-17] noted above were designed with the Multiphase Optimization Strategy [46] translational science framework [47-50], and control systems methodology [51-55],

with the long-term goal to scale-up use by clinicians as an adjunct treatment to prenatal care in order to regulate GWG. This multiphase approach [46] builds an intervention in a principled manner whereby key constraints expected to impact scalability (eg, implementation feasibility and subject or staff burden) are considered from the start so that the end goal is an optimized (effective and efficient) and scalable intervention that delivers the best possible outcome [46]. Our translational science framework [47-50] guided by the Quality Implementation Framework [49] and Quality Implementation Tool [50] aligns with the paradigm shift in the literature to prospectively examine implementation markers (eg, subject acceptability, dosage exposure, and staff burden) from the start of an intervention to identify and resolve challenges during delivery that impact efficacy and scalability [49,50].

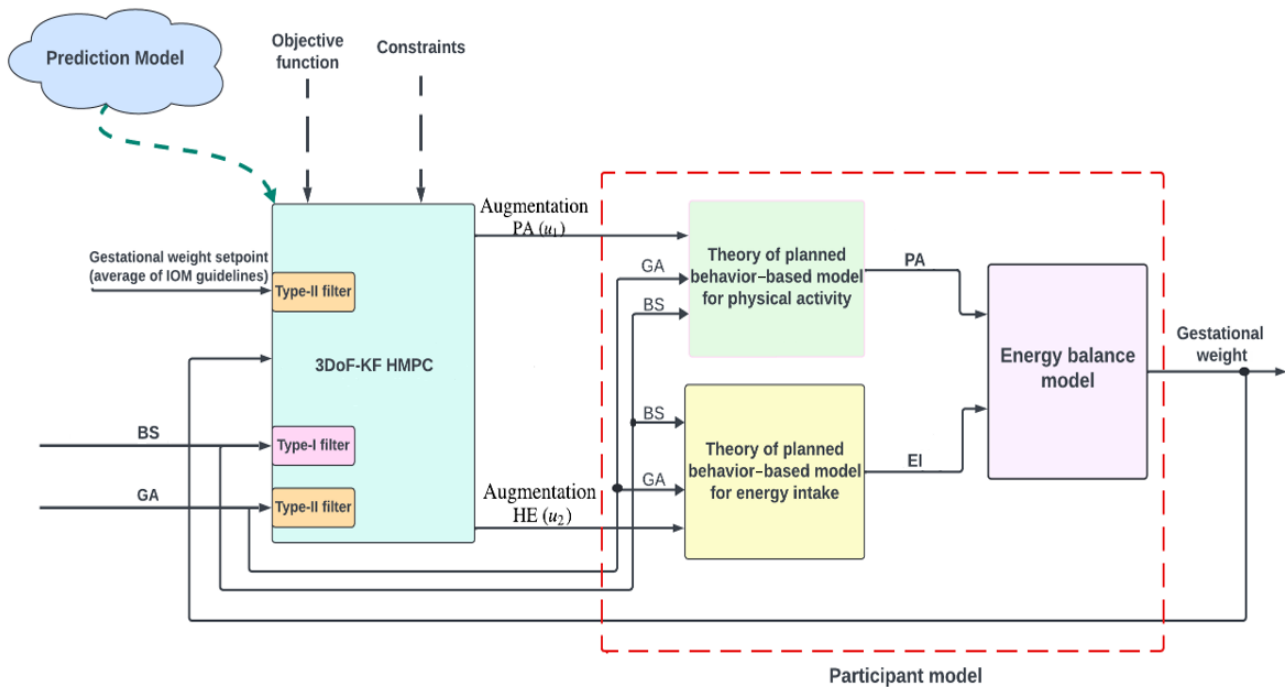
Our feasibility trial that randomized 31 pregnant women with overweight or obesity to the adaptive GWG intervention (delivered in person or remotely) or a control group over the course of pregnancy and used mobile health tools and online surveys to measure study outcomes showed high measurement compliance (85%), low burden (eg, average 1 min per day to complete measures), and low attrition (3%) [19]. The control system driven by decision rules and a woman's observed GWG informed when to adapt dosages (GWG within goals [1,2], maintain dosage; GWG greater than goals, adapt dosage) [19]. Participants in the intervention group had a 21% lower mean GWG and were more likely to have GWG within goals than controls. Exploratory analyses showed promise for the HMZ intervention to impact secondary outcomes, including PA minutes, active kcal, EI kcal, and PA and EI social cognitive determinants. Furthermore, maternal nighttime awakenings were related to higher GWG [45], and maternal eating behaviors (uncontrolled eating or restraint) were related to GWG and infant birth weight [44].

Because our long-term goal is to deliver the best possible impact on GWG and maternal or infant outcomes and develop an

approach that is scalable for future use in the real world, we used these feasibility findings to make refinements to the intervention content (eg, promoting healthy sleep or eating behaviors), delivery (all content available for remote delivery to ensure scalability), and decision process for evaluating and predicting GWG. More specifically, our initial control system was manually operated (ie, plotted each woman's weight in individual participant files) and not particularly scalable. We thus improved this system by designing a new model-based control system with a hybrid model predictive control algorithm and our dynamic model of energy balance and behavior (Figure 1) [10,13,56]. This enables projections of within-person GWG over time (even when data are missing at the current time point) and has been found in past studies to yield robust personalized suggestions and accurate inferential results even with missingness [56-68]. We also built an architecture for a novel digital platform that makes it possible to deliver just-in-time recommendations directly to a subject in ways that target a broader array of outcomes and can reach more women. The platform provides a web-based interface equipped with secure user access control that automates the linkage of subject data collected with mHealth tools to the new model-based predictive control system that implements a Control Optimization Trial approach [10,51] consisting of semiphysical system identification and Hybrid Model Predictive Control. The platform displays graphical or numeric summaries of a woman's past weight, behaviors (eg, PA, EI, and sleep), social cognitive determinants, and other factors; computes optimized dosage changes across multiple maternal variables; and produces a host of personalized PA or EI strategies to regulate GWG. This refined version of the intervention is denoted HMZ 2.0.

In order to activate recruitment, examine participant compliance with the measurement protocol, pilot test the HMZ 2.0 data transfer pipeline, examine intervention session delivery and user acceptability of the digital platform, and conduct simulations for controller-recommended dosage changes, we conducted a 28-day pilot study.

Figure 1. Dynamic model of energy balance and behavior to predict gestational weight gain (GWG). The intervention components are education, counseling, goal-setting, self-monitoring, and physical activity (PA)/healthy eating (HE) active behavior strategies (eg, guided activity sessions and cooking demonstrations). The figure depicts the block diagram of the closed-loop control system framework for managing GWG in pregnant women with overweight or obesity and describes the influence of intervention components, baseline intervention dosage, and gestational age (GA) on GWG. The participant model consists of 2 behavioral models targeting PA and energy intake (EI) behaviors, respectively, and an energy balance model. Outputs from the behavioral models serve as inputs to the energy balance model, which calculates changes in GWG by assessing the difference between EI and energy expenditure. The hybrid model predictive controller (HMPC) uses filtered signals of set point and measured disturbances (baseline intervention dosage and GA). A Type-I filter is used to filter the baseline, represented by a binary signal that indicates the preintervention phase (0) or the intervention phase (1). In contrast, a Type-II filter is used to filter the set point and GA. The HMPC-based optimizer determines a sequence of control actions, referred to as PA and HE dosage augmentations. BS: baseline; IOM: Institutes of Medicine.



HMZ 2.0 Pilot Study Results

We recruited and enrolled 10 pregnant women (mean age: 32.1 years; mean gestational age at enrollment: 14 weeks). Participants completed the HMZ 2.0 preintervention measurement protocol lasting 7 to 9 days (depending on the day of enrollment), completed daily and weekly study measures over a 3-week period while also participating in three 60-minute weekly intervention sessions (content from the first 3 weeks of the HMZ 2.0 baseline intervention) delivered by a trained staff member through the HMZ 2.0 digital platform, and completed the postintervention measurement protocol (7-9 days) and a poststudy brief interview to understand user acceptability. The results of this pilot study are presented below.

We had 59 participant contacts, of which 31 (53%) were assessed for eligibility and 10 (32% of eligible participants) were enrolled in the pilot study. Successful recruitment of participants involved social media (30%), community-based flyers and handouts (eg, campus locations and local events such as farmer's markets; 30%), word of mouth (20%), and clinic referrals (20%).

Participant compliance with the HMZ 2.0 measurement protocol was excellent, with compliance rates of 88% for the daily or weekly online surveys and MyFitnessPal app, 92% for using the Fitbit Aria Wi-Fi scale each day to assess weight, and 98% for wearing the Fitbit Charge 6 monitor each day to assess PA, sedentary behavior, and sleep behaviors. Moreover, the flow of

data through the HMZ 2.0 pipeline was exceptional. Data transfer from devices and Research Electronic Data Capture (REDCap) to the digital platform was smooth, with <2% evidence of technical problems or glitches, and 100% of problems were resolved without issue.

A total of 30 intervention sessions (3 per participant) were delivered, of which 80% (24/30) were delivered with a hybrid approach (in person with the platform) and 20% (6/30) were delivered with a fully remote approach using Zoom and the platform. Attendance and compliance with the sessions were 100%. All the women (10/10, 100%) liked the utility of the HMZ 2.0 digital platform, and 90% (9/10) liked to see their real-time data and set weekly goals with trained study staff. In the poststudy brief interview, 1 woman commented that it was "nice to use [the platform] prior to sessions so I was able to come prepared and ask questions." Another woman said, "The platform was easy to move from page to page." A third woman noted, "We covered different topics during the sessions, so I liked being able to go back to the platform and look at the content again." The participants also provided constructive feedback on the platform and suggested the following refinements: soften the color scheme on the website pages, include a page with session schedule and location information, and include a link to directly email the study staff to reduce the burden of looking through study materials for contact information. The platform was refined to address these concerns.

Simulations to illustrate the estimated model are presented in Figure 2, which shows the Control Optimization Trial framework for the recommended dosages within the system identification phase, adhering to the 2-week and 3-week delay. The first panel displays the participant’s weight in pounds (black solid line) and the setpoint (solid magenta line), which indicates the mean of the IOM guidelines (dashed red line) [1]. Different colors are used to represent the various intervention phases. The preintervention phase lasts for 7 to 9 days (9 days in this case), followed by a 2-week baseline period. During both the preintervention and baseline phases, no augmentations or dosages are administered. The first dosage is recommended after 2 weeks in the dosage 1 phase, starting on gestational day 126. The second dosage follows 2 weeks after dosage 1 in the dosage 2 phase. The second panel contains 2 subpanels: one for the manipulated variable augmentation PA and another for PA kcal. The last panel similarly includes subpanels for augmentation healthy eating and EI kcal. The simulation results show that the hybrid model predictive controller effectively manages the participant’s weight within the IOM bounds once the controller is activated. As illustrated, both in the system

identification and controller phases, recommendations for PA or healthy eating dosages lead to reduced EI (healthy eating dosage recommended) or increased PA (PA dosage recommended), ultimately facilitating weight reduction through decreased EI and increased PA.

After the dosage 2 phase, the controller phase begins, during which the controller recommends further dosages based on predicted participant weight and the logic outlined in Figure 3, which illustrates the conceptual framework for the controller’s augmentation or dosage recommendations, operating similarly to a finite state machine. Each state is represented by 2 digits: the first digit denotes augmentation PA (PA dosage) and the second digit indicates augmentation EI (healthy eating dosage), and either the PA dosage or EI dosage is updated at any given time. The controller recommends dosages with a minimum user-specified delay of 2 weeks between all dosages, except between dosage 2 and dosage 3, where a 3-week delay is specified. Transitions between dosages are governed by an auxiliary signal a_k . If a_k equals 1, the controller can transition from the current dosage state to the next; otherwise, it remains in the current dosage state.

Figure 2. Simulation illustrating the various stages of the control optimization trial implemented in the Healthy Mom Zone (HMZ) 2.0 intervention using an estimated model of an HMZ 1.0 representative participant. EI: energy intake; HE: healthy eating; HMPC: hybrid model predictive controller; IOM: Institutes of Medicine; PA: physical activity; RMSE: root mean square error.

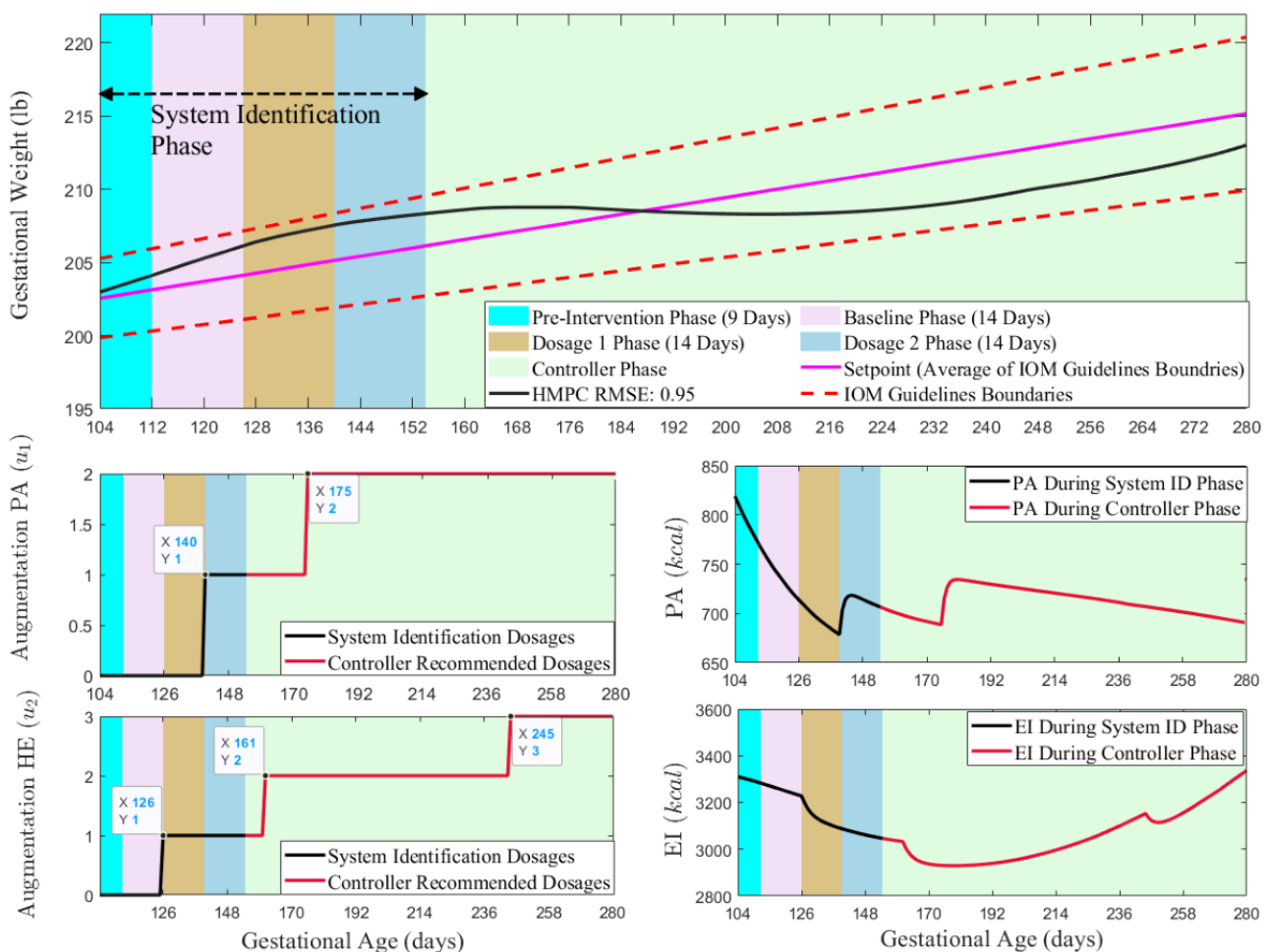
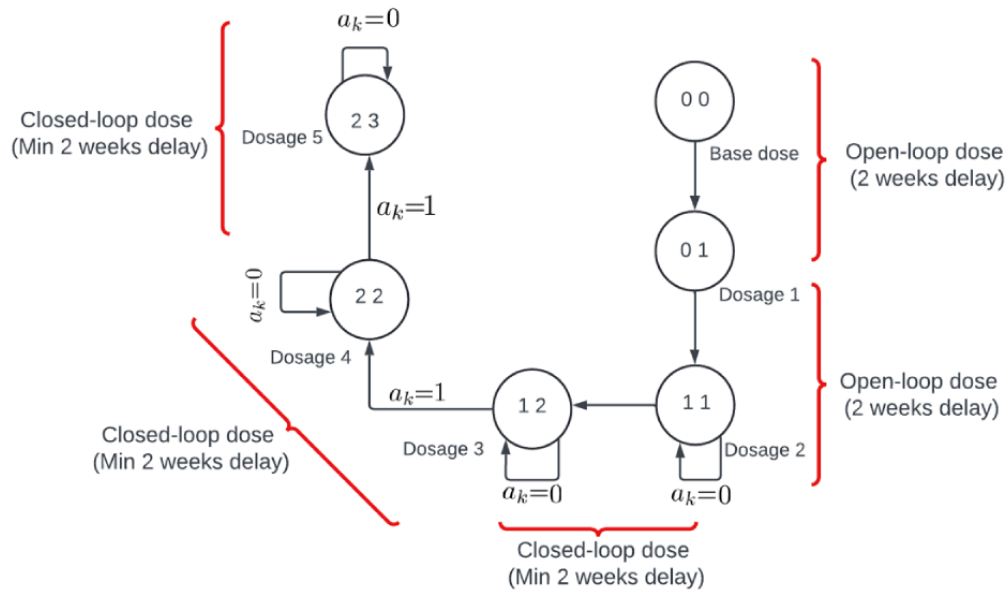


Figure 3. Dosage sequence pattern for the hybrid model predictive controller within the Healthy Mom Zone (HMZ) 2.0 intervention.



Goal of This Study

The goal of this study is to describe the protocol for a randomized controlled optimization trial to examine the efficacy of the enhanced HMZ 2.0 intervention with the new automated control system and digital platform to regulate GWG and influence secondary maternal and infant outcomes while collecting implementation data to inform future scalability. Aim 1 is to examine the efficacy of the intervention in terms of GWG (primary outcome) and maternal PA and EI behaviors and social cognitive determinants on comparing intervention and control groups. It is hypothesized that the intervention group will (1) have lower pre- to postintervention GWG and be more likely than controls to achieve GWG within the guidelines [1,2], and (2) have higher PA kcal (and total kcal) and PA or EI determinants and lower EI kcal than controls. Aim 2a is to measure pre- to postintervention differences in secondary maternal sleep and eating behaviors. It is hypothesized that the intervention group will have fewer nighttime awakenings and less uncontrolled eating than controls. Aim 2b is to examine the impact of the intervention on birth weight and adverse pregnancy, labor, and delivery outcomes. It is hypothesized that the intervention group will show lower birth weight adjusted for gestational age and will have lower occurrences of adverse pregnancy, labor, and delivery outcomes than controls. Aim 3 is to examine the impact of implementation markers on intervention efficacy in terms of GWG and secondary outcomes. It is hypothesized that subject engagement, acceptability, dosage exposure, and staff burden or acceptability will moderate the effect of the intervention on study outcomes. This information will inform how to scale-up the HMZ 2.0 intervention for future use by prenatal clinicians.

Methods

HMZ 2.0 Intervention Description

HMZ 2.0 is a multidosage, individually-tailored, adaptive intervention with social cognitive theory and behavior components [15-17]. The “baseline dosage” is delivered to all

intervention participants, and it consists of up to 24 weekly modules (depending on gestational age at study enrollment) including the following:

- **Education:** Knowledge-based content on meeting guidelines (GWG, PA, EI, sleep behaviors, and good sleep hygiene) [1,2,69-75]; mood (eg, depressive symptoms, stress, and anxiety); safely engaging in prenatal exercise; and awareness of stressful situations that prompt uncontrolled and emotional eating, hunger cues, cravings, and mindful eating choices [76,77]. We also provide knowledge about recently published evidence-based studies on how a mother’s health impacts her baby (eg, sleep, brain development, and food preferences) and developmental milestones (eg, when eyebrows develop), which is shared over the course of the intervention. Our pilot work [42] demonstrated that women specifically asked for education materials that provided this information.
- **Personalized behavior coaching or counseling:** Individually tailored behavior coaching from a prenatal fitness instructor and registered dietitian on GWG, PA, and EI that uses information and feedback from a woman’s prior week to inform the future week’s motivational cues and strategies to increase PA, improve diet quality, and overcome barriers (this can be delivered in person or through a remote synchronous or asynchronous approach for future scalability).
- **Goal setting and action planning:** Guided and self-selected PA and EI goals [69-71,78] using implementation intentions to target when, where, and how each woman will work toward goals and how these PA or EI goals relate to GWG. Example goals include targets for daily steps (eg, 10,000 steps) and activity time (eg, 30 minutes), as well as fruit or vegetable intake for lower energy density [79] and increasing water intake to maintain good hydration [80,81]. HMZ trimester-specific prenatal PA and recipe booklets (developed by our team) provide detailed examples for PA (eg, 150 min/week of moderate-intensity activities; 10,000 steps/day) and EI kcal goals [78].

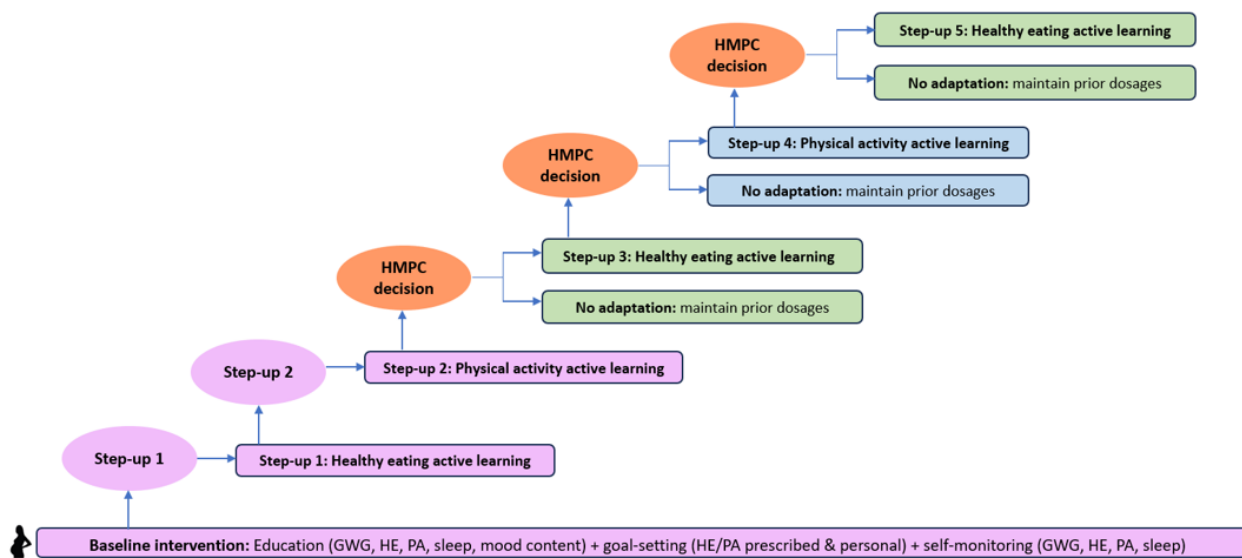
- Self-monitoring: Women use mHealth tools (eg, Wi-Fi weight scale, activity monitor, and dietary intake app) to self-monitor GWG, PA, or EI [82]. The HMZ digital platform visually displays their daily or weekly data. Feedback is given to each woman on how to use the devices and self-monitor their behaviors in relation to their GWG and PA or EI goals [19,43,78,83].

Adaptive Intervention Dosage Changes

The model-based predictive control algorithm in the HMZ 2.0 digital platform continually and automatically evaluates GWG. It relies on a dynamic model and solving a receding horizon online optimization problem that identifies when a woman's forecasted GWG is anticipated to exceed the GWG guidelines [1,2,84-86], and based on a structured sequence of decisions that form part of the model, a dosage change is recommended (Figure 4). Only women who have a forecasted need for added support to regulate GWG will receive adaptive dosages in addition to the baseline intervention. Dosages are additive such that a woman receives more intensive support for eating healthy and engaging in PA with each adaptation up to a maximum of 5 adaptive dosages. The web-based user interface provides an easy and intuitive way to integrate expert-supervised dosage change recommendations to regulate GWG. The HMZ 2.0 prenatal fitness instructor and registered dietitian review the

participant's data and recommend individually tailored behavioral strategies that are delivered through the HMZ 2.0 digital platform. Each woman's unique preferences and past successes with PA or EI strategies are considered when customizing the dosage adaptation to promote engagement, enjoyment, and compliance, which can in turn influence GWG. These active learning strategies include, for example, multiple PA-guided workouts with a variety of prenatal cardiovascular and resistance training exercises (preapproved for safety and with physician consent for participation) [69,70], as well as healthy eating cooking demonstrations, portion size control strategies to substitute high energy density foods with low energy density options such as water-rich fruits or vegetables [43,71], using food scales and portion size containers, customized grocery planning, and meal replacements. There are a host of easy-to-adopt and practical recommendations for integrating PA or EI strategies into daily life (eg, walking in 5- to 10-minute increments throughout the day to increase PA kcal by 200 kcal/day, reduce sitting by 5 min/hour from 9 AM to 5 PM, and replace 8 ounces of whole milk with skim milk to reduce EI kcal by 100 kcal/day) to facilitate behavior change while adhering to safety standards [69,70]. All dosages can be delivered in person or through a remote approach (synchronous and asynchronous for selected sessions), depending on the participant's preference.

Figure 4. Healthy Mom Zone (HMZ) 2.0 adaptive intervention design. Participant weight is measured daily and continuously evaluated against the Institutes of Medicine (IOM) gestational weight gain (GWG) ranges. All intervention women will receive the baseline intervention plus step-up 1 plus step-up 2 during the system identification open-loop experiment. Dosages 3 to 5 are delivered to selected intervention participants based on hybrid model predictive controller (HMPC) decisions in the closed-loop experiment. HE: healthy eating; PA: physical activity.



HMZ 2.0 Automated Data Pipeline and Digital Platform

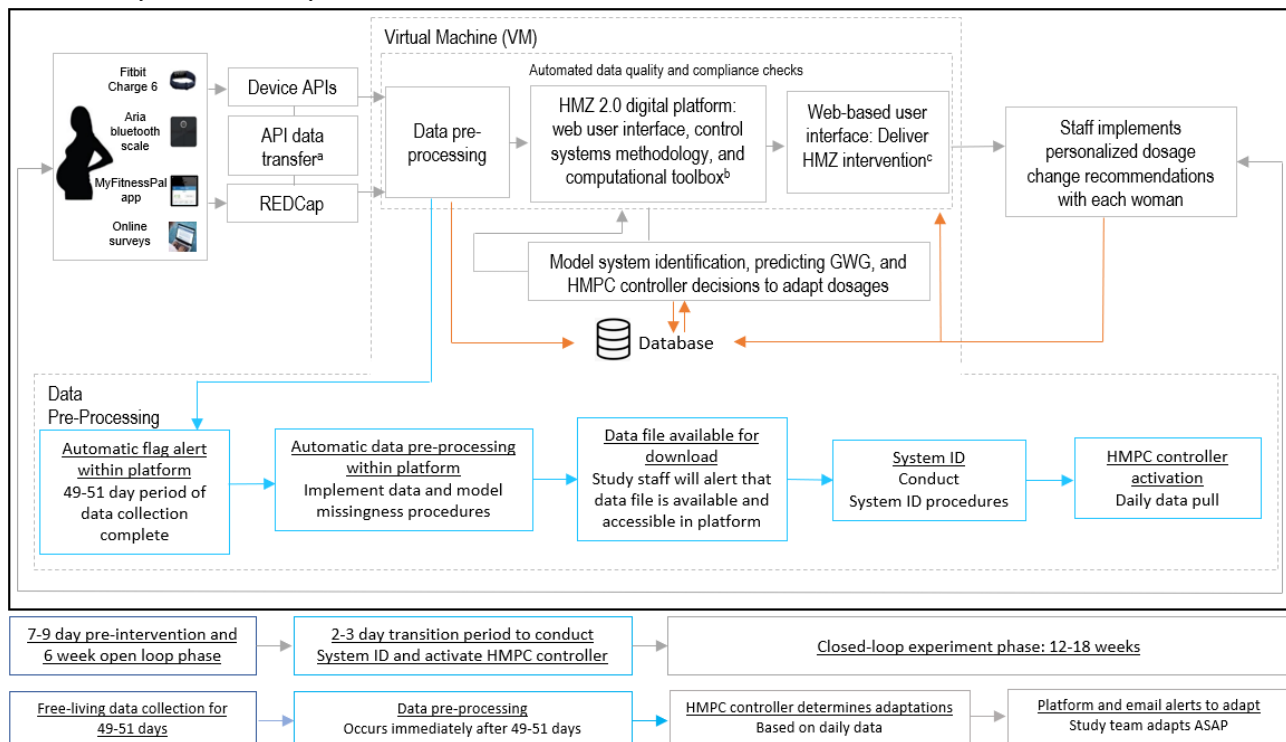
The data pipeline for HMZ 2.0, illustrated in Figure 5, is orchestrated by Apache Airflow [87], a workflow management platform, where daily jobs are scheduled, including (1) retrieving deidentified data from various sources, such as the application programming interface (API) of the REDCap [88] database; (2) preprocessing survey data, including aggregating subscales and back-calculating EI [89,90]; (3) imputing missing data via multiple imputation [91,92] and machine learning-facilitated [93-95] techniques programmed into the platform; (4) feeding

the imputed data into the advanced hybrid model predictive control system to generate the adaptive decision-making process; and (5) continuously monitoring errors and warnings in the Airflow monitoring dashboard during steps 1-4, scanning data quality, and initiating automated alerts that notify different pillars of the study team based on the issue type. As the participants in the study cohort change with time, tasks for each new participant are dynamically created. The scripts are version controlled, and data generated throughout the pipeline are saved in a PostgreSQL relational database to ensure data reproducibility. The HMZ 2.0 web-based platform has been

built with Django, an advanced Python web framework to scale-up future production and access (see Figure 6 for the digital platform architecture and website examples). Heterogeneous user interfaces have been built for study staff (and future clinicians), participants in the intervention group, and participants in the control group. The web-based platform provides an access-controlled admin dashboard where authorized

users can manually update settings, curate data, or export deidentified datasets for further analyses. For example, during intervention sessions, study staff can access participants' general information, data, educational content, goals, and intervention dosages, and participants will have access to selected resources that are tailored to their specific needs.

Figure 5. Healthy Mom Zone (HMZ) 2.0 data transfer pipeline. API: application programming interface; GWG: gestational weight gain; HMPC: hybrid model predictive controller. *Real-time deidentified 24-hour data stream into REDCap, **Access control (user ID) by authorized study staff, ***Access control (user ID) by intervention study staff (and in the future, dissemination to clinicians).



Recruitment

Recruitment began in April 2024 and will continue through May 2027. Pregnant women with overweight or obesity (N=144) are being recruited for this study. Our team has extensive expertise with recruiting pregnant women. Our past studies have yielded over 3100 subject contacts, with recruitment rates of 84%-92% across our studies [19,96-102]. Well-established methods from our past studies are used for recruitment procedures as follows:

- **Clinic:** Nurses identify eligible women at the 1st prenatal visit (eg, appointment schedule and electronic health record) and refer them to the study team for screening. A study flyer with study contact information and a QR code is included in the clinic's prenatal packet and posted in exam rooms.
- **Community:** Study flyers are posted in local areas (eg, daycares and churches) and hospitals, and shared at community events (eg, farmer's markets and celebratory events).
- **Social media:** Study information is shared on Facebook, Instagram, X, YouTube, and study websites.

Using well-established procedures from our past studies [19,96-102], interested participants, regardless of recruitment

method, are screened for eligibility. If interested, participants scan a QR code that directs them to a REDCap survey to complete a screening questionnaire or they send a message by email, text, or voicemail, and a trained study staff member will reply to complete the screening questionnaire over the phone.

The staff member reviews the participant's responses to determine eligibility. The inclusion criteria are as follows: age range 18-45 years; singleton pregnancy with ≥ 8 and < 18 weeks gestation; any parity; any race or ethnicity; BMI of 24-45 kg/m² (> 40 with provider consent); have not gained $> 25\%$ of total GWG (based on BMI and IOM guidelines) from prepregnancy to the date of enrollment [103]; able to read or understand English; access to a computer or phone; able to attend sessions either on-site or remotely; randomization to conditions; no absolute contraindications to PA (and presence of relative contraindications only with health care provider consent to participate); and not a current heavy smoker (> 20 cigarettes per day) [19,69-71]. The exclusion criteria are as follows: outside the age, BMI, gestation, or GWG range; not able to participate (cannot read or understand English, no access to a phone or computer to attend sessions remotely, and cannot use a device or service assistance); absolute contraindications to PA [69-71] or relative contraindications to PA noted by the participant's health care provider as precluding study participation; current

heavy smoker (>20 cigarettes per day) at study entry; and multiple pregnancy. Eligible women are scheduled for the preintervention assessment. Women not meeting the eligibility criteria are thanked for their time and given information on other studies that may be of interest.

Safety Considerations

Prior to enrollment, a study team member informs the participant's health care provider about their potential participation and obtains consent from each provider. The provider completes the consent form (hard copy or REDCap link) confirming eligibility for participation, and the participant is officially enrolled. This process is repeated at mid-study (eg, between the 2nd and 3rd trimesters) to ensure the participant does not have any new medical conditions that may impact study participation.

Because this study includes pregnant women, a vulnerable population as defined by the National Institutes of Health, there is a Data Safety and Monitoring Board with experts in obstetrics and gynecology, prenatal weight gain, PA and nutrition interventions, and fetal growth that will: (1) review the study methodology and procedures, data on recruitment, enrollment and adherence to the inclusion/exclusion criteria, and participant's progress through the study; (2) assure the safety of the study participants; and (3) make recommendations to the research team. Adverse events that the Data Safety and Monitoring Board will be notified of and oversee include: (1) insufficient GWG: indicators of insufficient GWG are weight loss of less than 3% in a week or 0% weight gain in a 4-week cycle [104]; (2) depressive symptomology: all women regardless of initial preintervention assessment scores will be given resources on managing depressive symptoms and a comprehensive list of available resources and supportive services, and depressive symptoms will be monitored monthly [105]; and (3) absolute or relative contraindications to exercise [69-71].

Participants in the intervention group complete verbal assessments of pregnancy symptoms (eg, mild muscle cramping, headaches, and symptoms of labor) and contraindications to exercise (eg, bleeding, severe abdominal cramping, nausea, etc) during activity sessions. The study safety protocol includes steps to understand symptoms, ratings of perceived exertion, and responses if appropriate, including stopping the activity, seeking medical attention, and calling a participant's emergency contact and provider. If a woman experiences a contraindication to PA in pregnancy that precludes her continued participation, she will remain in the study and complete measures as appropriate (intent to treat) but will not engage in PA until provider consent to return to activity is obtained. We also monitor changes in health status and health symptoms. For example, women who develop gestational diabetes during the study will remain in the study and receive the standard of prenatal care by their obstetrician or health care provider, in which an established standard of care plan is provided for the treatment and management of gestational diabetes.

Ethical Considerations

This study has been approved by the Pennsylvania State University Institutional Review Board (IRB; STUDY00019075), and Arizona State University is an IRB-approved participating site (SITE00001437). All members of the study team have appropriate CITI training certifications. Any and all changes made to the protocol will be communicated to participants and other relevant individuals or parties immediately. All study participants provide their informed consent prior to enrollment into the study with the option to decline enrollment or stop participation at any time. Data collected are deidentified, and access is only granted through lock and key as well as secure accounts with passwords. Participants are compensated up to US \$250 in gift cards for either Target or Walmart. Compensation is provided based on the completion of study milestones, such as completing the pre- and postintervention assessments, allowing electronic health record data to be extracted, and attending and completing more than 85% of study sessions and the measurement protocol. Both the intervention and control group participants can receive the same amount of compensation. This study is registered at ClinicalTrials.gov (NCT05807594).

Randomization Procedures

A trained staff member randomizes each participant after the preintervention measures via a randomization module in REDCap [88]. The study's biostatistician has developed the randomization scheme using variable-size random permuted blocks to ensure the number of subjects in each group is balanced after each set of B randomized subjects, where B is block size. The biostatistician programs the REDCap module, and the remaining study staff do not have access to the randomization scheme. Randomization to control ($n=72$) and intervention ($n=72$) groups uses 1:1 allocation; subjects are entered consecutively. Randomization is stratified by prepregnancy BMI status (<29.9 vs ≥ 30 kg/m²). A staff member calls each woman to inform her of study assignment. She is then provided with study information and education materials for her group assignment. The investigator is blinded to intervention assignments.

Treatment Conditions

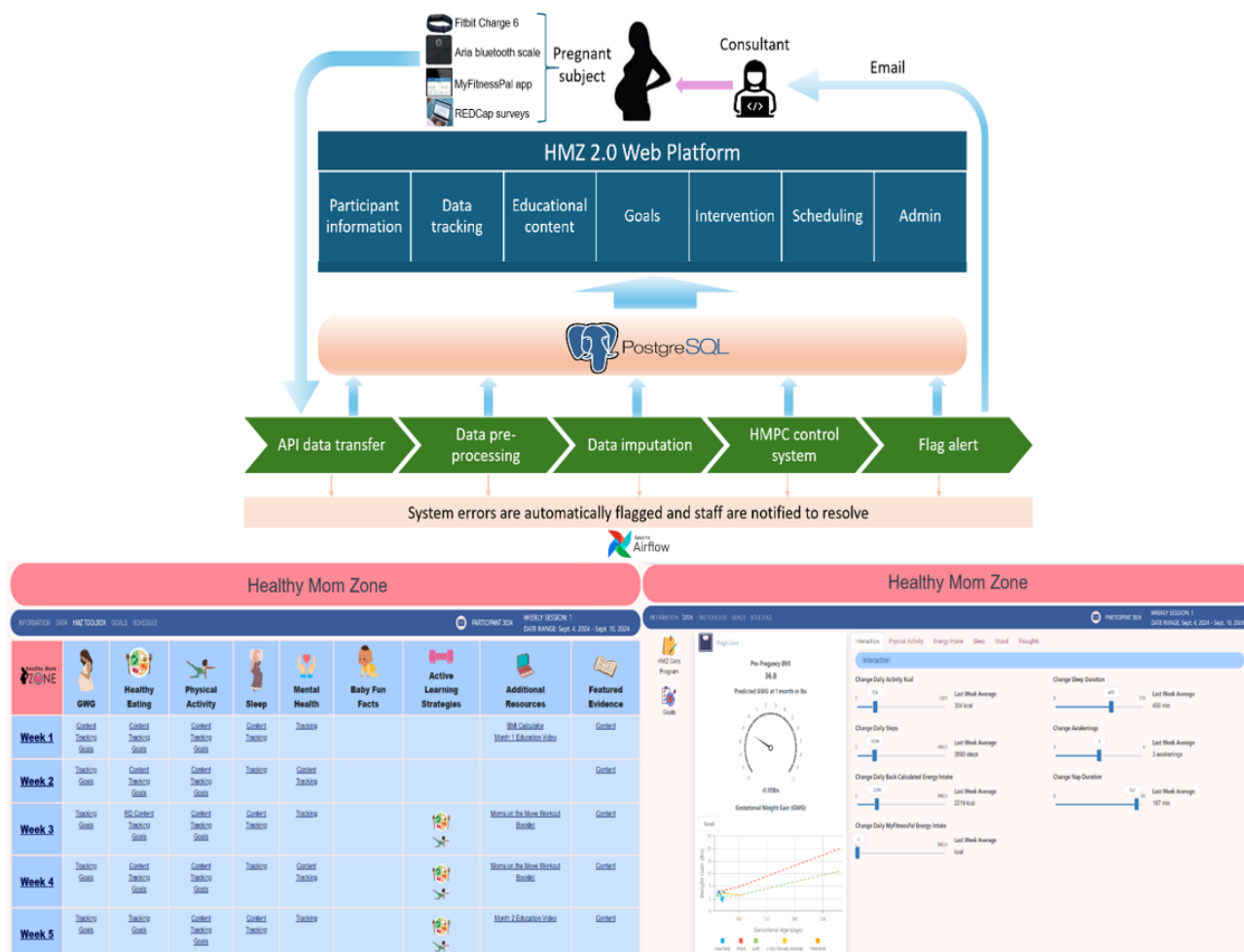
Intervention Condition

Women randomized to the intervention group receive the HMZ 2.0 intervention, described in detail above in the section "HMZ 2.0 Intervention Description," which includes the baseline intervention (education, personalized behavior coaching or counseling, goal setting or action planning, and self-monitoring) and adaptive intervention dosage changes (for the participants who need them). This baseline intervention continues through the duration of the study. Each week over the course of the study, GWG is monitored and evaluated against the recommended upper and lower bounds of the IOM GWG guidelines [1]. Depending on each participant's response to the baseline intervention (eg, GWG within or above guidelines) and her forecasted GWG, the automated control system may recommend a dosage change to adapt the intervention. This adaptive dosage begins after the first 4 weeks of the baseline

intervention (to allow the participants to get used to the intervention and reduce burden) and includes EI and PA active learning interactive components that “step-up” the intensity of the dosage. Dosage change recommendations are automatically delivered through the HMZ 2.0 digital platform (architecture

of the platform is described above); staff implement the recommended dosage change with the participant. As illustrated in Figure 6, there are up to five dosage “step-up” adaptations that can be recommended by the automated control system to regulate GWG.

Figure 6. Healthy Mom Zone (HMZ) 2.0 digital platform architecture and website examples. API: application programming interface; HMPC: hybrid model predictive controller.



Attention Control Condition

Consistent with guidelines for comparator groups [106], all women in the study receive prenatal care offered by recruitment sites with routine provider visits, counseling about prenatal behaviors (eg, no smoking), and clinical oversight of health. To match attention to the intervention group, women in the control group receive (for the first 4 weeks of the study) one-on-one weekly education sessions delivered by trained study staff, and thereafter, they receive monthly education content delivered as asynchronous videos and get check-in support from study staff (eg, phone, text, and email) for the remainder of the study. Content includes topics, such as preparing for labor or delivery; benefits of behavioral pain management strategies (eg, mindfulness-based relaxation, imagery, music, massage, and deep breathing) to regulate pain after childbirth with nonpharmacological approaches [107]; and baby or child safety, health and development, behaviors, and nutrition. Content is drawn from evidence-based guidelines and materials designed by members of the study team for a patient-provider toolbox to

reduce opioid pain management use after childbirth [107], as well as The American Academy of Pediatrics, The March of Dimes, The Centers for Disease Control, and The American College of Obstetrics and Gynecology [108-111]. The matched control group education content is also provided to the intervention group as supplemental material.

Both the intervention and control groups receive the same measurement protocol and frequency of measurement to understand and compare the impact of the intervention on primary and secondary study outcomes. Data are collected from each participant daily (GWG: Aria Wi-Fi scale [112]; PA, sedentary behavior, or sleep: Fitbit Charge 6 monitor [112], logs for device wear time, and PROMIS Sleep Disturbance [113,114] assessment; and self-reported hydration behaviors); weekly (self-reported online in REDCap; social cognitive determinants and EI diet quality: MyFitnessPal app on 2 weekdays and 2 weekend days) [19,115]; and monthly (self-reported online in REDCap; eating behaviors [19,116,117], psychosocial measures, cognition, pain, and temperament measures).

Control Optimization Trial Procedures

Control systems methodology [51-54] in a novel Control Optimization Randomized Controlled Trial (RCT) [51] is used to test the efficacy of the enhanced HMZ 2.0 intervention with a novel digital platform and a new automated control system to regulate GWG and influence secondary outcomes. This idiographic approach uses individual dynamic models (integrating behavioral and energy balance models) informing how each woman responds to HMZ 2.0 to make personalized decisions about intensifying dosages to regulate GWG. We are not aware of any other studies using this unique strategy to regulate GWG. Women start the intervention with an “open-loop” experimentation phase and receive the HMZ 2.0 baseline intervention (dosages are not yet adapted during this time). Semiphysical models estimated using concepts from system identification [85,118-120] allow individual energy balance and behavior models to be built for each subject [51]. Model and dosage personalization is further enhanced by leveraging our team’s expertise in time-varying dynamic systems (systems that show changes in statistical properties over time) and multilevel models that integrate individual- and group-based dynamics and missing data issues [56-68]. Model components are measured with real-time data procedures to predict corresponding deviations from each woman’s target GWG range: overweight, 6.8-11.3 kg total and 0.23-0.32 kg/wk; obese, 5.0-9.1 kg total and 0.18-0.27 kg/wk [1,2]. Model estimation is used to confirm individual models and identify if certain constructs provide maximum impact for the control system. The goal of this open-loop phase is to arrive at a set of personalized dynamic models that capture the effects of dosage augmentations, gestational age, and the baseline intervention. Once the models are identified and the controller commissioned, models will not be updated, but the tuning parameters can be adjusted, if necessary. While there is no set threshold of data compliance for building individual models (models can be built with as little as 50% missing data handled with maximum likelihood estimation) [56-68], we will rely on strategies to achieve high compliance (90%; 10% missing data) similar to that in our feasibility study [19].

These personalized individual energy balance and behavior models are used in the “closed-loop” experimentation phase for the rest of the study period during which a woman’s responsiveness to HMZ 2.0 is considered and dosages are adapted to regulate GWG. Continuous mHealth data are automatically linked to the control system, which considers GWG over a prediction horizon to minimize discrepancies between a woman’s observed GWG and her goal [1,2]. It considers the anticipated rate of GWG change as predicted with the individual model. Currently trained with data from the feasibility trial [19] and pilot data collected on HMZ 2.0 participants, the control system uses the values of each woman’s modifiable factors (eg, PA or EI kcals) in the current week to simulate ways in which these behaviors can be “controlled” or altered to drive GWG closer to the goal in the following week. We are cognizant of potential system identification issues that may arise with limited data available from each subject. If needed, selected parameters from the energy balance models can be constrained to be invariant across subjects to borrow strengths from other subjects and aid model estimation [121,122]. We will identify the optimal balance between control system performance (how well it can produce desired effects as efficiently as possible) and robustness (how well it can produce desired performance under disturbances and uncertainty; eg, poor compliance, change in responsiveness to dosages, and measurement variability) [10,51]. The controller has tuning parameters that allow adjustment of how fast or slow the control system makes recommendations to enable a judicious balance between effectiveness and responsiveness. Computations are performed with toolkits in MATLAB (MathWorks) and IBM ILOG CPLEX Optimizer. Study staff work with subjects to address concerns or technical issues. We will also explore how the individual subject data may inform modifications to the maternal energy balance and behavior model [10,19] and infant birth weight model [11,18].

Primary and Secondary Outcomes

Table 1 summarizes the HMZ 2.0 measurement protocol and timepoints. More details of the primary and secondary outcomes are provided below.

Table 1. Healthy Mom Zone 2.0 measurement protocol and timepoints.

Variable measure	Timepoint
Energy balance model outcomes	
GWG^a /weight (primary outcome)	
High precision adult scale (10 s)	Pre- and postintervention
Aria Wi-Fi Smart Scale (15 s)	Pre- and postintervention and daily
Prenatal records: total GWG	Pre- and postintervention
PA^b and sedentary behavior	
Fitbit Charge 6: activity kcal (passive)	Pre- and postintervention and daily
ActiGraph GT3X: activity min (passive)	Pre- and postintervention and daily
PA log: monitor wear time (1 min)	Pre- and postintervention and daily
Resting metabolic rate	
Predicted equation	Pre- and postintervention and daily
EI^c	
EI kcal: back-calculation method	Pre- and postintervention and daily
EI diet quality: MyFitnessPal app (5 min)	Pre- and postintervention and monthly
PA or EI social cognitive determinants	
Attitude, subjective norm, perceived behavioral control, and intention (3 min)	Pre- and postintervention, daily, and weekly
Behavioral, normative, or control beliefs (2 min)	Pre- and postintervention and monthly
Retrospective self-regulation (1 min)	Pre- and postintervention, daily, and weekly
Secondary outcome measures	
Sleep behaviors	
Pittsburgh sleep quality index (2 min)	Pre- and postintervention and monthly
FitBit Charge 6: sleep behaviors (passive)	Pre- and postintervention and daily
Sleep log: sleep behaviors (30 s)	Pre- and postintervention and daily
PROMIS Sleep Disturbance (30 s)	Pre- and postintervention and daily
Eating behaviors	
3-factor eating inventory: cognitive restraint, disinhibition, and hunger (3 min)	Pre- and postintervention, weekly, and monthly
Maternal-infant labor or delivery and adverse pregnancy outcomes	
Diagnoses of gestational diabetes, insulin use, preeclampsia, and depression	Postintervention only (at delivery)
Labor or delivery issues and other complications	Postintervention only (at delivery)
Infant APGAR score and mode of delivery (vaginal or cesarean)	Postintervention only (at delivery)
Infant birth outcomes	
Birth weight (adjusted for gestational age at delivery), length, sex, gestational age at delivery, and date of birth in the electronic health record	Postintervention only (at delivery)
Clinical and safety protocol measures	
Height	
Stadiometer (5 s)	Preintervention only
Blood pressure	
Screen for preeclampsia (2 min)	Preintervention only
Demographics, medical history, and obstetric history	
Age, race or ethnicity, income, education, medical or pregnancy history, etc (7 min)	Pre- and postintervention
Depressive symptoms and monitoring health	

Variable measure	Timepoint
Center for Epidemiological Studies Depression Scale (3 min)	Pre- and postintervention and monthly

^aGWG: gestational weight gain.

^bPA: physical activity.

^cEI: energy intake.

Primary Outcome

Participant GWG

Weight and GWG are assessed daily at preintervention, during the intervention, and at postintervention at home using the Fitbit Aria Wi-Fi Smart Scale [112] (weights are wirelessly uploaded to an online program). GWG is standardized, and the target weight gain is determined for each woman based on the BMI status (overweight, 14.1-22.7 kg; obese, 11.3-19.1 kg) [1,2]. For the criterion measure to determine when to adapt the intervention, weight gain is calculated to determine if a woman is gaining less than her goal, at the exact amount of her goal, or more than her goal. GWG over the course of the study is calculated as the last measured weight during the study subtracted by the first measured weight during the study. Weight at enrollment is measured, and prepregnancy weight and GWG from the first prenatal visit to the last predelivery weight are abstracted from clinical records.

Energy Balance and Behavior Model Primary Constructs

PA and Sedentary Behavior

PA and sedentary behavior are assessed daily at preintervention, during the intervention, and at postintervention. Participants wear the wrist-worn Fitbit Charge 6 [112] 24 hours per day from the preintervention assessment until the end of the postintervention assessment. The Fitbit Charge 6 allows for continuous passive (low subject burden) PA assessment in the energy balance model [12] to predict GWG. The device measures total kcal, activity kcal, steps, and minutes in sedentary, light, or moderate PA. The waist-mounted ActiGraph GT3X [123] is worn at pre- and postintervention and for the first 2 weeks of the open-loop phase during waking hours to assess PA and sedentary behavior (activity kcal, steps, and minutes in sedentary, light, or moderate PA). Participants track their PA and monitor wear time by completing a self-report PA log and the Leisure Time Exercise Questionnaire [124] daily for cross-validation of the Fitbit data [125].

EI Behavior: Back-Calculation Estimation

EI is estimated daily at preintervention, during the intervention, and at postintervention from measured weight (Aria Wi-Fi scale) [112], PA (Fitbit Charge 6 activity monitor) [112], and resting metabolic rate (RMR), with $k=1, 2, \dots, N$ relating to day 1 to day N . T is the sampling time ($T=1$ day) [8,12,68-71], and RMR is estimated daily as follows:

$$eRMR = 0.1976W^2 - 13.424W + 1457.6 \quad (1)$$

The noise in weight is small relative to the total weight, but the extent of this noise can affect the calculated rate of GWG per day, so a 5-day moving average filter is used to preprocess

(smooth) measured weight before “true” daily EI is estimated [117-119]:

$$EI_{est}(k) = \frac{-W(k+2T)+8W(k+T)-8W(k-T)+W(k-2T)}{12TK_1} - \frac{K_2}{K_1} (PA(k) + RMR(k)) \quad (2)$$

Our team effectively used this back-calculation method for estimating EI in the HMZ proof-of-concept study [42] and feasibility-initial impact randomized trial [8,10,19,43-45].

Secondary Outcomes

Secondary Energy Balance and Behavior Model Constructs

The following aspects are considered:

- Theory of Planned Behavior [15,126]: Involves healthy eating or limiting unhealthy eating, PA attitude, subjective norm, perceived behavioral control, intention, and beliefs. The Theory of Planned Behavior constructs in the dynamic model of energy balance and behavior [13-17] inform individualized model-based interventions for each intervention participant. Participants complete online surveys daily at pre- and postintervention and during the open-loop phase, and daily and weekly during the intervention to assess their attitude, perceived behavioral control, subjective norm, intention to eat healthy and limit unhealthy eating, and participation in PA. Participants complete a one-time online survey at pre- and postintervention and monthly to assess their beliefs about eating healthy, limiting unhealthy eating, and participating in PA.
- Retrospective self-regulation for EI or healthy eating and PA [17]: Retrospective self-regulation in the dynamic model of energy balance and behavior [13-17] informs individualized model-based interventions for each intervention participant. Participants complete two 6-item online surveys daily at pre- and postintervention and during the open-loop phase, and weekly during the intervention to determine how good they are at regulating their EI or healthy eating and PA and how these behaviors impact GWG over the course of pregnancy.

Maternal Health

Participants complete the following measures at preintervention, during the intervention, and at postintervention:

- Diet composition or quality and eating behaviors: Participants use the MyFitnessPal online app on 2 weekdays and 2 weekend days at pre- and postintervention, weekly during the first 2 weeks of the open-loop phase, and once a month during the intervention to assess their diet composition and quality. This information aids in personalized counseling of diet quality for the intervention group [19]. The Three Factor Eating Questionnaire

- [116,117] is completed at pre- and postintervention, weekly during the open-loop phase, and monthly during the closed-loop phase and is used to assess 3 dimensions of eating behaviors: dietary restraint (cognitive control of eating behavior), dietary disinhibition, and susceptibility to hunger.
- Sleep behaviors: The Pittsburgh Sleep Quality Index [127] assesses the quality and patterns of sleep and measures subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. The PROMIS Sleep Disturbance short-form survey [113] assesses difficulties and concerns with getting to sleep and staying asleep; evaluates the perceptions of the adequacy of and satisfaction with sleep; and measures sleep quality, sleep depth, and restoration associated with sleep. Participants also complete a daily self-report sleep log [128] to measure time to sleep and wake, minutes of sleep, nighttime awakenings, time spent awake after sleep onset, daytime naps, and daytime nap duration, and wear the Fitbit Charge 6 Activity Monitor [112] each night to assess time to sleep and wake, minutes of sleep, nighttime awakenings, and light and deep rapid eye movement sleep.

Maternal and Infant Outcomes

Prenatal, labor, and delivery data will be abstracted from the participant's electronic medical record. Maternal and infant outcomes include: mode of delivery (vaginal or cesarean), adverse pregnancy outcomes (eg, diagnosis of gestational diabetes, insulin use, preeclampsia, depression, labor or delivery issues, and other complications), birth weight, length, sex, gestational age, date of birth, APGAR score, and any complications related to the infant during labor and delivery. In the event that labor or delivery data are missing or unavailable from the medical record, the investigators will obtain information from the participant's self-report.

Implementation Marker Procedures

Our team has ample experience with evaluating program implementation [96-98,129-133], including in the HMZ proof-of-concept study [42] and feasibility trial [19]. The Quality Implementation Framework [49] and Quality Implementation Tool [50] will guide examination of the following markers:

- Subject engagement and participation: Fidelity monitoring evaluations are conducted for each subject and staff after each session. A trained staff observer reviews video recordings of 50% of intervention and attention control sessions and follows a review checklist to measure engagement (degree of subject responsiveness with content, discussion, and activities) [134,135].
- Subject acceptability: Subjects and staff complete weekly checklists to assess attendance (0%-100% attendance at pre- and postintervention assessments; 0%-100% attendance at intervention and attention control sessions), compliance (0%-100% compliance with mHealth tools and surveys during free-living pre- and postintervention sessions and over the course of the study for all subjects; 0%-100% compliance with attention control or HMZ 2.0 activities),

and quality and completeness of data (0%-100% of usable data for each subject).

- Dosage exposure is assessed by (1) weekly checklists completed by subjects or staff regarding the amount of program content delivered or received (goal 85%+ coverage) [19]; (2) fidelity monitoring by a trained staff observer who reviews video recordings from the same sample of 50% of video recordings noted above; and (3) tracking of the number of dosage changes determined by the model-based control system, number of days between dosage change recommendation and implementation by staff, and number and type of PA or EI strategies suggested or used.
- Staff engagement: Fidelity monitoring is conducted by a trained staff observer who reviews video recordings from the same sample of 50% of video recordings noted above and follows a checklist to measure engagement (enthusiasm, preparedness, session delivery effectiveness, and responsiveness to the subject).
- Staff burden: Weekly checklists are completed by staff for the amount of time spent preparing for sessions, responding to or following up with subjects, and using the HMZ 2.0 digital platform, and for issues with delivering dosage recommendations to the subjects.
- Study delivery costs: A trained staff member tracks and calculates the time and financial costs of the study. Postintervention semistructured interviews with HMZ 2.0 subjects elicit key facilitators and barriers to study participation. The interview guide has been developed with standard procedures [136,137] from our past studies [10,19,42-45,107,138-140]. Expert feedback will be obtained from key clinician stakeholders (ie, registered dietitians, nurses, obstetrics or gynecology providers, etc) on the strengths and limitations of using the HMZ 2.0 digital platform, potential barriers to scaling-up use in prenatal care (eg, clinician beliefs about technology and connectivity issues), and suggestions for improvements. This valuable feedback will be used to make additional refinements to HMZ 2.0 to scale-up future use by prenatal care clinicians.

Statistical Analysis

For study aims 1 and 2, time series methodology will be used on a subject basis (ie, cubic polynomial spline 3-lag auto-regressive models with maximum likelihood as the estimation method) followed by a fixed effects meta-analytic approach to combine information in order to compare the intervention group to the control group [141-143]. Mixed effects models will be used when the meta-analytic approach does not fit the data [56,62-65]. Potential confounding variables (eg, maternal age, parity, and income; infant sex; and adverse maternal-infant outcomes) [6,144] will be included in the models as covariates when appropriate. We will explore the extent to which prenatal sleep and eating behaviors impact postintervention GWG, PA, or EI and infant birth weight to inform modifications to the maternal energy balance and infant birth weight models. The intent-to-treat principle will be followed. Our statistical approach is robust if data are missing at random (multiple imputation will be considered if missing data are problematic) [145]. Hypothesis tests will invoke a

2-sided significance level of .05. Analyses for the synthesis of mHealth data and the predictive control system are informed by MATLAB toolkits and past experience [51,146,147]. Model personalization will use control-theory models, and requisite computations will be performed for optimal dosage changes [112,113,128,148-150]. For study aim 3, descriptive statistics will be used to examine the percentage and frequency for implementation markers. Formative methods will be used to organize, code, and rank order interview data [136,137]. Study findings will be used to further optimize HMZ 2.0 for effectiveness and scalability. Data will be collected and stored in REDCap [88]. Deidentified data will be exported from REDCap [88] to statistical packages. Subject confidentiality will be maintained with subject IDs. Data security is ensured with Penn State standard procedures.

Power Calculations

The primary outcome is GWG: absolute difference between the intervention and control groups for the mean change in GWG from the start to the end of the trial. From our feasibility study [19], we found that the difference between the intervention and control groups with respect to the absolute mean change in GWG from the start to the end of the trial was 1.9 kg (SD 4.9 kg), with an approximately 21% relative reduction for the intervention group compared to the control group. We compared the mean change in our feasibility trial [19] to that in several other GWG studies comparing intervention and control groups [29,151-154] and found that the intervention group gained on average 1.8 kg less than controls (range: 1.1-3.1 kg). The sample size of 144 randomized to the intervention (n=72) and control (n=72) groups in the proposed research is informed by our feasibility trial showing a mean difference of 1.9 kg (SD 4.9 kg), a 21% relative reduction in GWG in the intervention group compared to the control group, and a 3% dropout. Given our

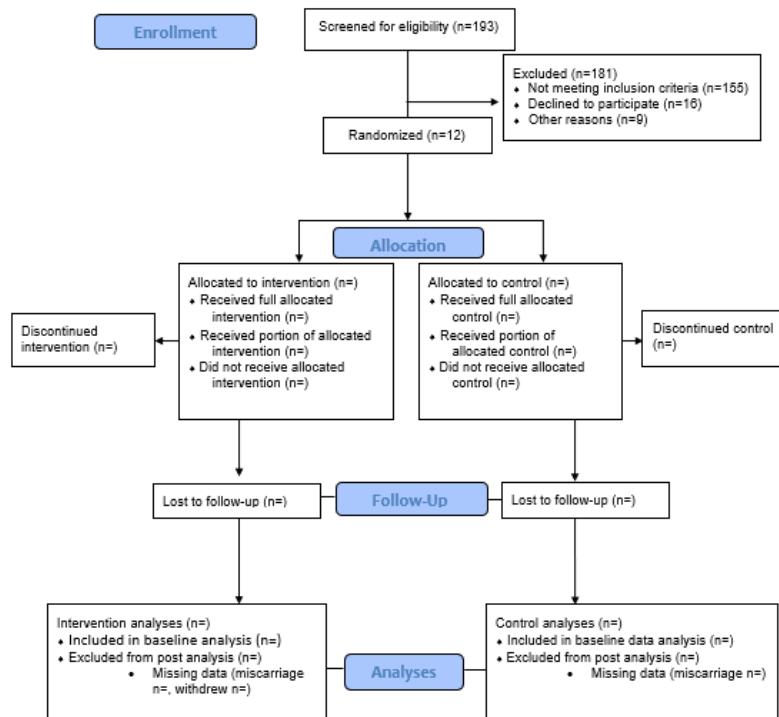
experience with the feasibility trial [19], the series of refinements that we performed following the feasibility trial (eg, adding content on sleep and eating behaviors given their effects on GWG; modifying all content for remote delivery given 100% compliance found for remote sessions in the feasibility trial; replacing the initial control system to make dosage change decisions with the new, automated, dynamic model-based predictive control system that outperformed the initial system for regulating GWG; and adding the novel HMZ 2.0 digital platform to adapt dosages), and the findings from our HMZ 2.0 pilot study (average weekly GWG over the 4-week study period: 0.3 kg, SD 0.4 kg; overall GWG from pre- to postintervention: 1.2 kg, SD 0.8 kg), we expect the HMZ 2.0 intervention to be more effective. We anticipate that our mean difference will be closer to what a recent study [155] found for the mean difference in GWG between the intervention and control groups (mean 3.6 kg, SD 5.7 kg). Conservatively, considering this larger SD of 5.7 kg and anticipating a larger dropout rate of 10%, the sample size of 144 yields 80% statistical power with a 2-sided significance level of .05 to detect an absolute difference of at least 2.9 kg in GWG between groups. Sample sizes for semistructured interviews are adequate to observe data saturation [136,137,141].

Results

HMZ 2.0 Control Optimization Efficacy RCT

Recruitment began in April 2024 and will continue through May 2027. All data are expected to be collected by December 2027. Currently, we have 193 participant contacts, of which 119 (91%) have been assessed for eligibility and 12 (50% of eligible participants) are enrolled in the RCT (Figure 7). Full results will be uploaded on the ClinicalTrials.gov website at the end of the trial, which is anticipated in January 2028.

Figure 7. Healthy Mom Zone (HMZ) 2.0 CONSORT (Consolidated Standards of Reporting Trials) diagram.



Discussion

Overview

To our knowledge, there are no other adaptive behavioral interventions aiming to regulate GWG with a theory-driven, energy balance model-based predictive control system, highlighting the novelty of our approach. We have made every effort to obtain robust and unbiased results in this trial. We have established the proof-of-concept and tested the feasibility of the intervention dosages, safety protocols, and strategies to retain subjects for this trial. The hypotheses to be tested are based on a sound foundation of preliminary data [10,11,13,14,19,42-45,140]. We have also pilot tested several aspects of HMZ 2.0. Findings from the HMZ 2.0 pilot study showed successful recruitment from multiple methods, excellent participant compliance with the measurement protocol and transfer of data from devices and online surveys to the digital platform, user acceptability of intervention sessions delivered through the platform, and utility of the predictive controller for informing dosage change decisions. We will use a randomized study design for the control optimization trial to test the efficacy of the HMZ 2.0 intervention and automated data pipeline and digital web-based platform compared to an attention control group. Data will be collected from all subjects to measure primary and secondary outcomes with valid and reliable measures. We will show the reproducibility of mHealth measures by having all subjects complete the same measures over time. Intervention content, measurement and implementation evaluation protocols, and intervention materials are available for reproducibility. The HMZ 2.0 digital platform and new model-based predictive control system have been built in MATLAB Compiler for reproduction with limited license restrictions. The HMZ 2.0 digital platform is a central hub for the automated data pipeline and web interface for intervention delivery. The data pipeline uses Apache Airflow for robust and dynamic scheduling and implements a multilayer real-time monitoring system. The web interface leverages the Django framework to deliver a rich user experience with role-based access control. The digital platform greatly improves the efficiency of this collaboration study by facilitating information sharing and reducing the turnaround time among researchers,

consultants, and patients. Since both Airflow and Django are readily scalable (eg, through parallelism and caching), this digital platform can easily accommodate scale-up in the future.

Limitations

There are many strengths of this study, including clinical and public health significance, novel methods, introduction of the HMZ 2.0 digital platform and model-based predictive control system with personalized dynamic energy balance models for each subject to automate dosage changes and predict GWG, use of a back-calculation method to estimate EI, pilot data [10,11,13,14,19,42-45,140] to support the rigor and reproducibility of the proposed methods, and strong potential for future scalability. Despite these strengths, participant compliance in RCTs is an ongoing challenge, and thus, we have incorporated strategies (eg, staff support, easy passive data collection, and remote delivery of the intervention) to facilitate compliance. We have also worked through technical aspects of the data pipeline and digital platform to reduce technical challenges. Lastly, there is a risk that the HMZ 2.0 study may be underpowered based on the assumptions used in the sample size estimation, but this is true for any power analysis.

Conclusions

The approach involving the HMZ 2.0 intervention and use of a control optimization trial [46] to examine the efficacy of the intervention in terms of GWG and related maternal-infant outcomes expands the boundaries of GWG interventions, uses novel methods and automated decision making, and has clinical and public health impacts in a high-risk population of pregnant women with overweight or obesity and their offspring. There is excellent potential to further refine HMZ 2.0 in the future to regulate GWG in women of all BMI categories and scale-up HMZ 2.0 for use by clinicians as an adjunct treatment in prenatal care. There may also be a way to optimize the digital platform in the future so that it can be safely and directly used by pregnant women. HMZ 2.0 may also serve as a model for how the control systems methodology and a digital platform can be used to automate dosage change decisions for other behavior interventions such as those involving regulation of diabetes, weight loss, and related health outcomes.

Acknowledgments

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Data Availability

Data cannot be shared publicly because the data collected from human subjects have not been approved for public sharing. Moreover, since the data are of human subjects, a data transfer agreement is needed. Data are available from the principal

investigator DSD (dsd11@psu.edu or 814-863-0456) and the Pennsylvania State University Office for Research Protections (orp@psu.edu or 814-865-1775) for researchers who meet the criteria for access to confidential data.

Authors' Contributions

DSD was responsible for intellectual design, framework, and writing of the manuscript, and organized and led a team for co-writing and providing insights on sections. AMP was responsible for co-writing the methods and results, figures, tables, and references, and provided edits to the manuscript. DER was responsible for assistance with the framework of the manuscript, provided insights on control systems engineering aspects of the paper, and provided edits to the overall manuscript. JSS and AMM were responsible for providing insights on the healthy eating aspects of the Healthy Mom Zone (HMZ) intervention and provided edits to the overall manuscript. SC was responsible for providing insights on intervention personalization, data collection, and analysis descriptions, and provided edits to the overall manuscript. CL and DS were responsible for providing insights on HMZ digital platform description and provided edits to the overall manuscript. JMP was responsible for providing insights on HMZ recruitment and retention descriptions, and provided edits to the overall manuscript. AK was responsible for co-writing of the analysis, power, and sample size descriptions, and provided edits to the overall manuscript. OK was responsible for providing insights on control systems engineering aspects of the paper and developing the figures and figure descriptions, and provided edits to the overall manuscript.

Conflicts of Interest

AK owns stock in Merck, a pharmaceutical company. However, Merck was not involved with this particular manuscript.

References

1. Institute of Medicine and National Research Council. Weight gain during pregnancy: Reexamining the guidelines. Washington, DC. National Academies Press; 2009.
2. National Research Council. Guidelines on weight gain and pregnancy. Washington, DC. National Academies Press; 2013.
3. Walker LO. Predictors of weight gain at 6 and 18 months after childbirth: a pilot study. *J Obstet Gynecol Neonatal Nurs*. Jan 1996;25(1):39-48. [doi: [10.1111/j.1552-6909.1996.tb02511.x](https://doi.org/10.1111/j.1552-6909.1996.tb02511.x)] [Medline: [8627401](https://pubmed.ncbi.nlm.nih.gov/8627401/)]
4. Gunderson EP, Abrams B. Epidemiology of gestational weight gain and body weight changes after pregnancy. *Epidemiol Rev*. Jan 01, 1999;21(2):261-275. [doi: [10.1093/oxfordjournals.epirev.a018001](https://doi.org/10.1093/oxfordjournals.epirev.a018001)] [Medline: [10682262](https://pubmed.ncbi.nlm.nih.gov/10682262/)]
5. Butte NF, Ellis KJ, Wong WW, Hopkinson JM, Smith EO. Composition of gestational weight gain impacts maternal fat retention and infant birth weight. *Am J Obstet Gynecol*. Nov 2003;189(5):1423-1432. [doi: [10.1067/s0002-9378\(03\)00596-9](https://doi.org/10.1067/s0002-9378(03)00596-9)] [Medline: [14634581](https://pubmed.ncbi.nlm.nih.gov/14634581/)]
6. LifeCycle Project-Maternal Obesity and Childhood Outcomes Study Group, Voerman E, Santos S, Inskip H, Amiano P, Barros H, et al. Association of gestational weight gain with adverse maternal and infant outcomes. *JAMA*. May 07, 2019;321(17):1702-1715. [FREE Full text] [doi: [10.1001/jama.2019.3820](https://doi.org/10.1001/jama.2019.3820)] [Medline: [31063572](https://pubmed.ncbi.nlm.nih.gov/31063572/)]
7. Oken E, Taveras EM, Kleinman KP, Rich-Edwards JW, Gillman MW. Gestational weight gain and child adiposity at age 3 years. *Am J Obstet Gynecol*. Apr 2007;196(4):322.e1-322.e8. [FREE Full text] [doi: [10.1016/j.ajog.2006.11.027](https://doi.org/10.1016/j.ajog.2006.11.027)] [Medline: [17403405](https://pubmed.ncbi.nlm.nih.gov/17403405/)]
8. Heerwagen MJR, Miller MR, Barbour LA, Friedman JE. Maternal obesity and fetal metabolic programming: a fertile epigenetic soil. *Am J Physiol Regul Integr Comp Physiol*. Sep 2010;299(3):R711-R722. [doi: [10.1152/ajpregu.00310.2010](https://doi.org/10.1152/ajpregu.00310.2010)] [Medline: [20631295](https://pubmed.ncbi.nlm.nih.gov/20631295/)]
9. Goldstein RF, Abell SK, Ranasinha S, Misso M, Boyle JA, Black MH, et al. Association of gestational weight gain with maternal and infant outcomes: a systematic review and meta-analysis. *JAMA*. Jun 06, 2017;317(21):2207-2225. [doi: [10.1001/jama.2017.3635](https://doi.org/10.1001/jama.2017.3635)] [Medline: [28586887](https://pubmed.ncbi.nlm.nih.gov/28586887/)]
10. Rivera D, Hekler E, Savage J, Downs D. Intensively Adaptive Interventions Using Control Systems Engineering: Two Illustrative Examples. In: Collins L, Kugler K, editors. *Optimization of Behavioral, Biobehavioral, and Biomedical Interventions*. Statistics for Social and Behavioral Sciences. Cham, Switzerland. Springer; 2018:121-173.
11. Savage JS, Downs DS, Dong Y, Rivera DE. Control systems engineering for optimizing a prenatal weight gain intervention to regulate infant birth weight. *Am J Public Health*. Jul 2014;104(7):1247-1254. [doi: [10.2105/AJPH.2014.301959](https://doi.org/10.2105/AJPH.2014.301959)] [Medline: [24832411](https://pubmed.ncbi.nlm.nih.gov/24832411/)]
12. Thomas DM, Navarro-Barrientos JE, Rivera DE, Heymsfield SB, Bredlau C, Redman LM, et al. Dynamic energy-balance model predicting gestational weight gain. *Am J Clin Nutr*. Jan 2012;95(1):115-122. [FREE Full text] [doi: [10.3945/ajcn.111.024307](https://doi.org/10.3945/ajcn.111.024307)] [Medline: [22170365](https://pubmed.ncbi.nlm.nih.gov/22170365/)]
13. Dong Y, Rivera D, Downs D, Savage J, Thomas D, Collins L. Hybrid model predictive control for optimizing gestational weight gain behavioral interventions. *Proc Am Control Conf*. 2013:1970-1975. [FREE Full text] [doi: [10.1109/acc.2013.6580124](https://doi.org/10.1109/acc.2013.6580124)] [Medline: [24336314](https://pubmed.ncbi.nlm.nih.gov/24336314/)]
14. Dong Y. A Novel Control Engineering Approach to Designing and Optimizing Adaptive Sequential Behavioral Interventions. ProQuest. 2014. URL: <https://www.proquest.com/docview/1648655095?pq-origsite=gscholar&fromopenview=true> [accessed 2025-02-18]

15. Ajzen I. The theory of planned behavior. *Organizational Behavior and Human Decision Processes*. Dec 1991;50(2):179-211. [doi: [10.1016/0749-5978\(91\)90020-T](https://doi.org/10.1016/0749-5978(91)90020-T)]
16. Bandura A. *Principles of behavior modification*. New York, NY. Holt, Rinehart & Winston; 1969.
17. Carver CS, Scheier MF. *On the self-regulation of behavior*. Cambridge, UK. Cambridge University Press; 1998.
18. Freigoun MT, Rivera DE, Guo P, Hohman EE, Gernand AD, Downs DS, et al. A dynamical systems model of intrauterine fetal growth. *Math Comput Model Dyn Syst*. 2018;24(6):661-687. [FREE Full text] [doi: [10.1080/13873954.2018.1524387](https://doi.org/10.1080/13873954.2018.1524387)] [Medline: [30498392](https://pubmed.ncbi.nlm.nih.gov/30498392/)]
19. Downs DS, Savage JS, Rivera DE, Pauley AM, Leonard KS, Hohman EE, et al. Adaptive, behavioral intervention impact on weight gain, physical activity, energy intake, and motivational determinants: results of a feasibility trial in pregnant women with overweight/obesity. *J Behav Med*. Oct 2021;44(5):605-621. [FREE Full text] [doi: [10.1007/s10865-021-00227-9](https://doi.org/10.1007/s10865-021-00227-9)] [Medline: [33954853](https://pubmed.ncbi.nlm.nih.gov/33954853/)]
20. Cantor AG, Jungbauer RM, McDonagh M, Blazina I, Marshall NE, Weeks C, et al. Counseling and behavioral interventions for healthy weight and weight gain in pregnancy: evidence report and systematic review for the US preventive services task force. *JAMA*. May 25, 2021;325(20):2094-2109. [doi: [10.1001/jama.2021.4230](https://doi.org/10.1001/jama.2021.4230)] [Medline: [34032824](https://pubmed.ncbi.nlm.nih.gov/34032824/)]
21. Vincze L, Rollo M, Hutchesson M, Hauck Y, MacDonald-Wicks L, Wood L, et al. Interventions including a nutrition component aimed at managing gestational weight gain or postpartum weight retention: a systematic review and meta-analysis. *JBIS Database System Rev Implement Rep*. Mar 2019;17(3):297-364. [doi: [10.11124/JBISRIR-2017-003593](https://doi.org/10.11124/JBISRIR-2017-003593)] [Medline: [30870329](https://pubmed.ncbi.nlm.nih.gov/30870329/)]
22. Lamminpää R, Vehviläinen-Julkunen K, Schwab U. A systematic review of dietary interventions for gestational weight gain and gestational diabetes in overweight and obese pregnant women. *Eur J Nutr*. Aug 2018;57(5):1721-1736. [FREE Full text] [doi: [10.1007/s00394-017-1567-z](https://doi.org/10.1007/s00394-017-1567-z)] [Medline: [29128995](https://pubmed.ncbi.nlm.nih.gov/29128995/)]
23. Dalrymple KV, Flynn AC, Relph SA, O'Keeffe M, Poston L. Lifestyle interventions in overweight and obese pregnant or postpartum women for postpartum weight management: a systematic review of the literature. *Nutrients*. Nov 07, 2018;10(11):1704. [FREE Full text] [doi: [10.3390/nu10111704](https://doi.org/10.3390/nu10111704)] [Medline: [30405088](https://pubmed.ncbi.nlm.nih.gov/30405088/)]
24. Farpour-Lambert NJ, Ells LJ, Martinez de Tejada B, Scott C. Obesity and weight gain in pregnancy and postpartum: an evidence review of lifestyle interventions to inform maternal and child health policies. *Front Endocrinol (Lausanne)*. 2018;9:546. [FREE Full text] [doi: [10.3389/fendo.2018.00546](https://doi.org/10.3389/fendo.2018.00546)] [Medline: [30319539](https://pubmed.ncbi.nlm.nih.gov/30319539/)]
25. Peaceman AM, Clifton RG, Phelan S, Gallagher D, Evans M, Redman LM, et al. LIFE - Moms Research Group. Lifestyle interventions limit gestational weight gain in women with overweight or obesity: LIFE-moms prospective meta-analysis. *Obesity (Silver Spring)*. Sep 2018;26(9):1396-1404. [FREE Full text] [doi: [10.1002/oby.22250](https://doi.org/10.1002/oby.22250)] [Medline: [30230252](https://pubmed.ncbi.nlm.nih.gov/30230252/)]
26. International Weight Management in Pregnancy (i-WIP) Collaborative Group. Effect of diet and physical activity based interventions in pregnancy on gestational weight gain and pregnancy outcomes: meta-analysis of individual participant data from randomised trials. *BMJ*. Jul 19, 2017;358:j3119. [FREE Full text] [doi: [10.1136/bmj.j3119](https://doi.org/10.1136/bmj.j3119)] [Medline: [28724518](https://pubmed.ncbi.nlm.nih.gov/28724518/)]
27. Dodd JM, Turnbull D, McPhee AJ, Deussen AR, Grivell RM, Yelland LN, et al. LIMIT Randomised Trial Group. Antenatal lifestyle advice for women who are overweight or obese: LIMIT randomised trial. *BMJ*. Feb 10, 2014;348(feb10 3):g1285-g1285. [FREE Full text] [doi: [10.1136/bmj.g1285](https://doi.org/10.1136/bmj.g1285)] [Medline: [24513442](https://pubmed.ncbi.nlm.nih.gov/24513442/)]
28. Poston L, Bell R, Croker H, Flynn AC, Godfrey KM, Goff L, et al. UPBEAT Trial Consortium. Effect of a behavioural intervention in obese pregnant women (the UPBEAT study): a multicentre, randomised controlled trial. *Lancet Diabetes Endocrinol*. Oct 2015;3(10):767-777. [FREE Full text] [doi: [10.1016/S2213-8587\(15\)00227-2](https://doi.org/10.1016/S2213-8587(15)00227-2)] [Medline: [26165396](https://pubmed.ncbi.nlm.nih.gov/26165396/)]
29. Vinter C, Jensen D, Ovesen P, Beck-Nielsen H, Jørgensen J. The LiP (Lifestyle in Pregnancy) study: a randomized controlled trial of lifestyle intervention in 360 obese pregnant women. *Diabetes Care*. Dec 2011;34(12):2502-2507. [FREE Full text] [doi: [10.2337/dc11-1150](https://doi.org/10.2337/dc11-1150)] [Medline: [21972411](https://pubmed.ncbi.nlm.nih.gov/21972411/)]
30. Renault KM, Nørgaard K, Nilas L, Carlsen EM, Cortes D, Pryds O, et al. The Treatment of Obese Pregnant Women (TOP) study: a randomized controlled trial of the effect of physical activity intervention assessed by pedometer with or without dietary intervention in obese pregnant women. *Am J Obstet Gynecol*. Feb 2014;210(2):134.e1-134.e9. [doi: [10.1016/j.ajog.2013.09.029](https://doi.org/10.1016/j.ajog.2013.09.029)] [Medline: [24060449](https://pubmed.ncbi.nlm.nih.gov/24060449/)]
31. Phelan S, Phipps MG, Abrams B, Darroch F, Schaffner A, Wing RR. Randomized trial of a behavioral intervention to prevent excessive gestational weight gain: the Fit for Delivery Study. *Am J Clin Nutr*. Apr 2011;93(4):772-779. [FREE Full text] [doi: [10.3945/ajcn.110.005306](https://doi.org/10.3945/ajcn.110.005306)] [Medline: [21310836](https://pubmed.ncbi.nlm.nih.gov/21310836/)]
32. Redman LM, Gilmore LA, Breaux J, Thomas DM, Elkind-Hirsch K, Stewart T, et al. Effectiveness of SmartMoms, a novel eHealth intervention for management of gestational weight gain: randomized controlled pilot trial. *JMIR Mhealth Uhealth*. Sep 13, 2017;5(9):e133. [FREE Full text] [doi: [10.2196/mhealth.8228](https://doi.org/10.2196/mhealth.8228)] [Medline: [28903892](https://pubmed.ncbi.nlm.nih.gov/28903892/)]
33. Petrella E, Malavolti M, Bertarini V, Pignatti L, Neri I, Battistini NC, et al. Gestational weight gain in overweight and obese women enrolled in a healthy lifestyle and eating habits program. *J Matern Fetal Neonatal Med*. Sep 25, 2014;27(13):1348-1352. [FREE Full text] [doi: [10.3109/14767058.2013.858318](https://doi.org/10.3109/14767058.2013.858318)] [Medline: [24175912](https://pubmed.ncbi.nlm.nih.gov/24175912/)]
34. Herring SJ, Cruice JF, Bennett GG, Rose MZ, Davey A, Foster GD. Preventing excessive gestational weight gain among African American women: A randomized clinical trial. *Obesity (Silver Spring)*. Jan 2016;24(1):30-36. [FREE Full text] [doi: [10.1002/oby.21240](https://doi.org/10.1002/oby.21240)] [Medline: [26592857](https://pubmed.ncbi.nlm.nih.gov/26592857/)]

35. Vesco KK, Karanja N, King JC, Gillman MW, Leo MC, Perrin N, et al. Efficacy of a group-based dietary intervention for limiting gestational weight gain among obese women: a randomized trial. *Obesity (Silver Spring)*. Sep 28, 2014;22(9):1989-1996. [[FREE Full text](#)] [doi: [10.1002/oby.20831](https://doi.org/10.1002/oby.20831)] [Medline: [25164259](https://pubmed.ncbi.nlm.nih.gov/25164259/)]
36. Phelan S, Wing RR, Brannen A, McHugh A, Hagobian T, Schaffner A, et al. Does partial meal replacement during pregnancy reduce 12-month postpartum weight retention? *Obesity (Silver Spring)*. Feb 2019;27(2):226-236. [[FREE Full text](#)] [doi: [10.1002/oby.22361](https://doi.org/10.1002/oby.22361)] [Medline: [30421864](https://pubmed.ncbi.nlm.nih.gov/30421864/)]
37. Herring SJ. Pooled findings from the LIFE-moms randomized trials: where do we go from here? *Obesity (Silver Spring)*. Sep 2018;26(9):1391. [[FREE Full text](#)] [doi: [10.1002/oby.22285](https://doi.org/10.1002/oby.22285)] [Medline: [30226006](https://pubmed.ncbi.nlm.nih.gov/30226006/)]
38. Chang M, Brown R, Nitzke S, Smith B, Eghtedary K. Stress, sleep, depression and dietary intakes among low-income overweight and obese pregnant women. *Matern Child Health J*. May 2015;19(5):1047-1059. [doi: [10.1007/s10995-014-1604-y](https://doi.org/10.1007/s10995-014-1604-y)] [Medline: [25102810](https://pubmed.ncbi.nlm.nih.gov/25102810/)]
39. Lindsay KL, Heneghan C, McNulty B, Brennan L, McAuliffe FM. Lifestyle and dietary habits of an obese pregnant cohort. *Matern Child Health J*. Jan 2015;19(1):25-32. [doi: [10.1007/s10995-014-1491-2](https://doi.org/10.1007/s10995-014-1491-2)] [Medline: [24740724](https://pubmed.ncbi.nlm.nih.gov/24740724/)]
40. Nagourney EM, Goodman D, Lam Y, Hurley KM, Henderson J, Surkan PJ. Obese women's perceptions of weight gain during pregnancy: a theory-based analysis. *Public Health Nutr*. Aug 2019;22(12):2228-2236. [[FREE Full text](#)] [doi: [10.1017/S1368980019000703](https://doi.org/10.1017/S1368980019000703)] [Medline: [31134872](https://pubmed.ncbi.nlm.nih.gov/31134872/)]
41. Downs D, Savage J, Rauff E. Falling short of guidelines? nutrition and weight gain knowledge in pregnancy. *J Womens Health Care*. 2014;3(05):1000184. [[FREE Full text](#)] [doi: [10.4172/2167-0420.1000184](https://doi.org/10.4172/2167-0420.1000184)] [Medline: [25599012](https://pubmed.ncbi.nlm.nih.gov/25599012/)]
42. Pauley AM, Hohman E, Savage JS, Rivera DE, Guo P, Leonard KS, et al. Gestational weight gain intervention impacts determinants of healthy eating and exercise in overweight/obese pregnant women. *J Obes*. 2018;2018:6469170. [[FREE Full text](#)] [doi: [10.1155/2018/6469170](https://doi.org/10.1155/2018/6469170)] [Medline: [30364005](https://pubmed.ncbi.nlm.nih.gov/30364005/)]
43. Symons Downs D, Savage JS, Rivera DE, Smyth JM, Rolls BJ, Hohman EE, et al. Individually tailored, adaptive intervention to manage gestational weight gain: protocol for a randomized controlled trial in women with overweight and obesity. *JMIR Res Protoc*. Jun 08, 2018;7(6):e150. [[FREE Full text](#)] [doi: [10.2196/resprot.9220](https://doi.org/10.2196/resprot.9220)] [Medline: [29884603](https://pubmed.ncbi.nlm.nih.gov/29884603/)]
44. Savage JS, Hohman EE, McNitt KM, Pauley AM, Leonard KS, Turner T, et al. Uncontrolled eating during pregnancy predicts fetal growth: the healthy mom zone trial. *Nutrients*. Apr 21, 2019;11(4):899. [[FREE Full text](#)] [doi: [10.3390/nu11040899](https://doi.org/10.3390/nu11040899)] [Medline: [31010102](https://pubmed.ncbi.nlm.nih.gov/31010102/)]
45. Pauley AM, Hohman EE, Leonard KS, Guo P, McNitt KM, Rivera DE, et al. Short nighttime sleep duration and high number of nighttime awakenings explain increases in gestational weight gain and decreases in physical activity but not energy intake among pregnant women with overweight/obesity. *Clocks Sleep*. Nov 14, 2020;2(4):487-501. [[FREE Full text](#)] [doi: [10.3390/clockssleep2040036](https://doi.org/10.3390/clockssleep2040036)] [Medline: [33202691](https://pubmed.ncbi.nlm.nih.gov/33202691/)]
46. Collins L. *Optimization of Behavioral, Biobehavioral, and Biomedical Interventions. The Multiphase Optimization Strategy (MOST)*. New York, NY: Springer; 2018.
47. Czajkowski SM, Powell LH, Adler N, Naar-King S, Reynolds KD, Hunter CM, et al. From ideas to efficacy: The ORBIT model for developing behavioral treatments for chronic diseases. *Health Psychol*. Oct 2015;34(10):971-982. [[FREE Full text](#)] [doi: [10.1037/hea0000161](https://doi.org/10.1037/hea0000161)] [Medline: [25642841](https://pubmed.ncbi.nlm.nih.gov/25642841/)]
48. Onken LS, Carroll KM, Shoham V, Cuthbert BN, Riddle M. Reenvisioning clinical science: unifying the discipline to improve the public health. *Clin Psychol Sci*. Jan 01, 2014;2(1):22-34. [[FREE Full text](#)] [doi: [10.1177/2167702613497932](https://doi.org/10.1177/2167702613497932)] [Medline: [25821658](https://pubmed.ncbi.nlm.nih.gov/25821658/)]
49. Meyers D, Durlak J, Wandersman A. The quality implementation framework: a synthesis of critical steps in the implementation process. *Am J Community Psychol*. Dec 2012;50(3-4):462-480. [doi: [10.1007/s10464-012-9522-x](https://doi.org/10.1007/s10464-012-9522-x)] [Medline: [22644083](https://pubmed.ncbi.nlm.nih.gov/22644083/)]
50. Meyers DC, Katz J, Chien V, Wandersman A, Scaccia JP, Wright A. Practical implementation science: developing and piloting the quality implementation tool. *Am J Community Psychol*. Dec 23, 2012;50(3-4):481-496. [doi: [10.1007/s10464-012-9521-y](https://doi.org/10.1007/s10464-012-9521-y)] [Medline: [22618025](https://pubmed.ncbi.nlm.nih.gov/22618025/)]
51. Hekler EB, Rivera DE, Martin CA, Phatak SS, Freigoun MT, Korinek E, et al. Tutorial for using control systems engineering to optimize adaptive mobile health interventions. *J Med Internet Res*. Jun 28, 2018;20(6):e214. [[FREE Full text](#)] [doi: [10.2196/jmir.8622](https://doi.org/10.2196/jmir.8622)] [Medline: [29954725](https://pubmed.ncbi.nlm.nih.gov/29954725/)]
52. Rivera DE, Pew MD, Collins LM. Using engineering control principles to inform the design of adaptive interventions: a conceptual introduction. *Drug Alcohol Depend*. May 2007;88 Suppl 2(Suppl 2):S31-S40. [[FREE Full text](#)] [doi: [10.1016/j.drugalcdep.2006.10.020](https://doi.org/10.1016/j.drugalcdep.2006.10.020)] [Medline: [17169503](https://pubmed.ncbi.nlm.nih.gov/17169503/)]
53. Nandola NN, Rivera DE. An improved formulation of hybrid model predictive control with application to production-inventory systems. *IEEE Trans Contr Syst Technol*. Jan 2013;21(1):121-135. [doi: [10.1109/tcst.2011.2177525](https://doi.org/10.1109/tcst.2011.2177525)]
54. Lee J, Yu Z. Tuning of model predictive controllers for robust performance. *Computers & Chemical Engineering*. Jan 1994;18(1):15-37. [doi: [10.1016/0098-1354\(94\)85020-8](https://doi.org/10.1016/0098-1354(94)85020-8)]
55. Dong Y, Deshpande S, Rivera D, Downs D, Savage J. Hybrid model predictive control for sequential decision policies in adaptive behavioral interventions. *Proc Am Control Conf*. Jun 2014;2014:4198-4203. [[FREE Full text](#)] [doi: [10.1109/ACC.2014.6859462](https://doi.org/10.1109/ACC.2014.6859462)] [Medline: [25635157](https://pubmed.ncbi.nlm.nih.gov/25635157/)]

56. Chow S, Lee J, Hofman AD, van der Maas HLJ, Pearl DK, Molenaar PCM. Control theory forecasts of optimal training dosage to facilitate children's arithmetic learning in a digital educational application. *Psychometrika*. Jun 01, 2022;87(2):559-592. [doi: [10.1007/s11336-021-09829-3](https://doi.org/10.1007/s11336-021-09829-3)] [Medline: [35290564](https://pubmed.ncbi.nlm.nih.gov/35290564/)]
57. Li Y, Ji L, Oravecz Z, Brick T, Hunter M, Chow S. dynr.mi: An R program for multiple imputation in dynamic modeling. *World Acad Sci Eng Technol*. 2019;13(5):302-311. [FREE Full text] [doi: [10.5281/zenodo.3298841](https://doi.org/10.5281/zenodo.3298841)] [Medline: [31431819](https://pubmed.ncbi.nlm.nih.gov/31431819/)]
58. Ji L, Chen M, Oravecz Z, Cummings EM, Lu Z, Chow S. A Bayesian vector autoregressive model with nonignorable missingness in dependent variables and covariates: development, evaluation, and application to family processes. *Struct Equ Modeling*. Jul 18, 2020;27(3):442-467. [FREE Full text] [doi: [10.1080/10705511.2019.1623681](https://doi.org/10.1080/10705511.2019.1623681)] [Medline: [32601517](https://pubmed.ncbi.nlm.nih.gov/32601517/)]
59. Ji L, Chow S, Schermerhorn AC, Jacobson NC, Cummings EM. Handling missing data in the modeling of intensive longitudinal data. *Struct Equ Modeling*. Feb 08, 2018;25(5):715-736. [FREE Full text] [doi: [10.1080/10705511.2017.1417046](https://doi.org/10.1080/10705511.2017.1417046)] [Medline: [31303745](https://pubmed.ncbi.nlm.nih.gov/31303745/)]
60. Li Y, Wood J, Ji L, Chow S, Oravecz Z. Fitting multilevel vector autoregressive models in Stan, JAGS, and Mplus. *Struct Equ Modeling*. Sep 14, 2022;29(3):452-475. [FREE Full text] [doi: [10.1080/10705511.2021.1911657](https://doi.org/10.1080/10705511.2021.1911657)] [Medline: [35601030](https://pubmed.ncbi.nlm.nih.gov/35601030/)]
61. Jacobson NC, Chow S, Newman MG. The Differential Time-Varying Effect Model (DTVEM): A tool for diagnosing and modeling time lags in intensive longitudinal data. *Behav Res Methods*. Feb 17, 2019;51(1):295-315. [doi: [10.3758/s13428-018-1101-0](https://doi.org/10.3758/s13428-018-1101-0)] [Medline: [30120682](https://pubmed.ncbi.nlm.nih.gov/30120682/)]
62. Chow S, Hamaker EL, Fujita F, Boker SM. Representing time - varying cyclic dynamics using multiple - subject state - space models. *Brit J Math & Statis*. Jan 11, 2011;62(3):683-716. [doi: [10.1348/000711008x384080](https://doi.org/10.1348/000711008x384080)]
63. Chow S, Zu J, Shifren K, Zhang G. Dynamic factor analysis models with time-varying parameters. *Multivariate Behav Res*. Apr 11, 2011;46(2):303-339. [doi: [10.1080/00273171.2011.563697](https://doi.org/10.1080/00273171.2011.563697)] [Medline: [26741330](https://pubmed.ncbi.nlm.nih.gov/26741330/)]
64. Helm JL, Ram N, Cole PM, Chow S. Modeling self-regulation as a process using a multiple time-scale multiphase latent basis growth model. *Struct Equ Modeling*. 2016;23(5):635-648. [FREE Full text] [doi: [10.1080/10705511.2016.1178580](https://doi.org/10.1080/10705511.2016.1178580)] [Medline: [28255223](https://pubmed.ncbi.nlm.nih.gov/28255223/)]
65. Chow S, Ou L, Ciptadi A, Prince EB, You D, Hunter MD, et al. Representing sudden shifts in intensive dyadic interaction data using differential equation models with regime switching. *Psychometrika*. Jun 01, 2018;83(2):476-510. [FREE Full text] [doi: [10.1007/s11336-018-9605-1](https://doi.org/10.1007/s11336-018-9605-1)] [Medline: [29557080](https://pubmed.ncbi.nlm.nih.gov/29557080/)]
66. Chen M, Chow S, Hammal Z, Messinger DS, Cohn JF. A person- and time-varying vector autoregressive model to capture interactive infant-mother head movement dynamics. *Multivariate Behav Res*. Jun 12, 2021;56(5):739-767. [FREE Full text] [doi: [10.1080/00273171.2020.1762065](https://doi.org/10.1080/00273171.2020.1762065)] [Medline: [32530313](https://pubmed.ncbi.nlm.nih.gov/32530313/)]
67. Chow S, Haltigan JD, Messinger DS. Dynamic infant-parent affect coupling during the face-to-face/still-face. *Emotion*. Feb 2010;10(1):101-114. [FREE Full text] [doi: [10.1037/a0017824](https://doi.org/10.1037/a0017824)] [Medline: [20141307](https://pubmed.ncbi.nlm.nih.gov/20141307/)]
68. Li Y, Oravecz Z, Zhou S, Bodovski Y, Barnett IJ, Chi G, et al. Bayesian forecasting with a regime-switching zero-inflated multilevel Poisson regression model: an application to adolescent alcohol use with spatial covariates. *Psychometrika*. Jun 2022;87(2):376-402. [FREE Full text] [doi: [10.1007/s11336-021-09831-9](https://doi.org/10.1007/s11336-021-09831-9)] [Medline: [35076813](https://pubmed.ncbi.nlm.nih.gov/35076813/)]
69. ACOG Committee Obstetric Practice. ACOG Committee opinion. Number 650: Physical activity and exercise during pregnancy and the postpartum period. *Obstet Gynecol*. Dec 2015;126(6):135-142. [doi: [10.1097/AOG.0000000000001214](https://doi.org/10.1097/AOG.0000000000001214)] [Medline: [26595585](https://pubmed.ncbi.nlm.nih.gov/26595585/)]
70. Hayman M, Brown WJ, Brinson A, Budzynski-Seymour E, Bruce T, Evenson KR. Public health guidelines for physical activity during pregnancy from around the world: a scoping review. *Br J Sports Med*. 2023;57:940-947. [doi: [10.1136/bjsports-2022-105777](https://doi.org/10.1136/bjsports-2022-105777)]
71. Evenson KR, Mottola MF, Artal R. Review of recent physical activity guidelines during pregnancy to facilitate advice by health care providers. *Obstet Gynecol Surv*. 2019;74(8):481-489. [doi: [10.1097/OGX.0000000000000693](https://doi.org/10.1097/OGX.0000000000000693)] [Medline: [31418450](https://pubmed.ncbi.nlm.nih.gov/31418450/)]
72. Hirshkowitz M, Whiton K, Albert SM, Alessi C, Bruni O, DonCarlos L, et al. National Sleep Foundation's sleep time duration recommendations: methodology and results summary. *Sleep Health*. Mar 2015;1(1):40-43. [doi: [10.1016/j.sleh.2014.12.010](https://doi.org/10.1016/j.sleh.2014.12.010)] [Medline: [29073412](https://pubmed.ncbi.nlm.nih.gov/29073412/)]
73. Irish LA, Kline CE, Gunn HE, Buysse DJ, Hall MH. The role of sleep hygiene in promoting public health: A review of empirical evidence. *Sleep Med Rev*. Aug 2015;22:23-36. [FREE Full text] [doi: [10.1016/j.smrv.2014.10.001](https://doi.org/10.1016/j.smrv.2014.10.001)] [Medline: [25454674](https://pubmed.ncbi.nlm.nih.gov/25454674/)]
74. American College of Obstetrics and Gynecology (ACOG). ACOG Committee opinion no. 548: weight gain during pregnancy. *Obstet Gynecol*. Jan 2013;121(1):210-212. [doi: [10.1097/01.aog.0000425668.87506.4c](https://doi.org/10.1097/01.aog.0000425668.87506.4c)] [Medline: [23262962](https://pubmed.ncbi.nlm.nih.gov/23262962/)]
75. Luke B. Nutrition during pregnancy: part I, weight gain; part II, nutrient supplements. *JAMA*. Jan 09, 1991;265(2):281. [FREE Full text] [doi: [10.1001/jama.1991.03460020139044](https://doi.org/10.1001/jama.1991.03460020139044)]
76. Dingemans A, Danner U, Parks M. Emotion regulation in binge eating disorder: a review. *Nutrients*. Nov 22, 2017;9(11):1274. [FREE Full text] [doi: [10.3390/nu9111274](https://doi.org/10.3390/nu9111274)] [Medline: [29165348](https://pubmed.ncbi.nlm.nih.gov/29165348/)]
77. Beshara M, Hutchinson AD, Wilson C. Does mindfulness matter? Everyday mindfulness, mindful eating and self-reported serving size of energy dense foods among a sample of South Australian adults. *Appetite*. Aug 2013;67:25-29. [doi: [10.1016/j.appet.2013.03.012](https://doi.org/10.1016/j.appet.2013.03.012)] [Medline: [23548262](https://pubmed.ncbi.nlm.nih.gov/23548262/)]

78. Downs DS, Singer RN. Goal setting and implementation intentions: Preliminary support for increasing exercise behavior. *J Hum Mov Stud.* 2004;45(5):419-432. [FREE Full text]
79. Savage JS, Marini M, Birch LL. Dietary energy density predicts women's weight change over 6 y. *Am J Clin Nutr.* Sep 2008;88(3):677-684. [FREE Full text] [doi: [10.1093/ajcn/88.3.677](https://doi.org/10.1093/ajcn/88.3.677)] [Medline: [18779283](https://pubmed.ncbi.nlm.nih.gov/18779283/)]
80. Rosinger AY, Bethancourt HJ, Pauley AM, Latona C, John J, Kelyman A, et al. Variation in urine osmolality throughout pregnancy: a longitudinal, randomized-control trial among women with overweight and obesity. *Eur J Nutr.* Feb 03, 2022;61(1):127-140. [FREE Full text] [doi: [10.1007/s00394-021-02616-x](https://doi.org/10.1007/s00394-021-02616-x)] [Medline: [34218315](https://pubmed.ncbi.nlm.nih.gov/34218315/)]
81. Pauley AM, Rosinger AY, Savage JS, Conroy DE, Downs DS. Every sip counts: Understanding hydration behaviors and user-acceptability of digital tools to promote adequate intake during early and late pregnancy. *PLOS Digit Health.* May 7, 2024;3(5):e0000499. [FREE Full text] [doi: [10.1371/journal.pdig.0000499](https://doi.org/10.1371/journal.pdig.0000499)] [Medline: [38713720](https://pubmed.ncbi.nlm.nih.gov/38713720/)]
82. Shieh C, Yang Z, Haas DM, Carpenter JS. Feasibility and potential benefits of a self-monitoring enhanced lifestyle intervention to prevent excessive gestational weight gain in women who are overweight or obese. *J Obstet Gynecol Neonatal Nurs.* Mar 2017;46(2):182-196. [FREE Full text] [doi: [10.1016/j.jogn.2016.09.006](https://doi.org/10.1016/j.jogn.2016.09.006)] [Medline: [28063804](https://pubmed.ncbi.nlm.nih.gov/28063804/)]
83. Zielinska AP, Mullins E, Lees C. The feasibility of multimodality remote monitoring of maternal physiology during pregnancy. *Medicine (Baltimore).* Jul 01, 2022;101(26):e29566. [FREE Full text] [doi: [10.1097/MD.00000000000029566](https://doi.org/10.1097/MD.00000000000029566)] [Medline: [35777056](https://pubmed.ncbi.nlm.nih.gov/35777056/)]
84. Khan O, Campregher F, Rivera D, Visioli A, Pauley A, Downs D. An optimized behavioral intervention for managing gestational weight gain using semi-physical modeling and hybrid model predictive control (accepted). 2025. Presented at: 2025 American Control Conference; July 8-10, 2025; Denver, CO, USA. URL: https://css.paperplaza.net/conferences/conferences/ACC25/program/ACC25_ContentListWeb_3.html
85. Guo P. System Identification, State Estimation, And Control Approaches to Gestational Weight Gain Interventions. ASU Library. 2018. URL: <https://keep.lib.asu.edu/items/156977> [accessed 2025-02-20]
86. Guo P, Rivera DE, Dong Y, Deshpande S, Savage JS, Hohman EE, et al. Optimizing behavioral interventions to regulate gestational weight gain with sequential decision policies using hybrid model predictive control. *Comput Chem Eng.* Apr 2022;160:107721. [FREE Full text] [doi: [10.1016/j.compchemeng.2022.107721](https://doi.org/10.1016/j.compchemeng.2022.107721)] [Medline: [35342207](https://pubmed.ncbi.nlm.nih.gov/35342207/)]
87. Apache Airflow. Apache. URL: <https://airflow.apache.org/> [accessed 2025-02-20]
88. 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.* Apr 2009;42(2):377-381. [doi: [10.1016/j.jbi.2008.08.010](https://doi.org/10.1016/j.jbi.2008.08.010)] [Medline: [18929686](https://pubmed.ncbi.nlm.nih.gov/18929686/)]
89. Brown PA, Anderson RA. A methodology for preprocessing structured big data in the behavioral sciences. *Behav Res Methods.* Jun 29, 2023;55(4):1818-1838. [doi: [10.3758/s13428-022-01895-4](https://doi.org/10.3758/s13428-022-01895-4)] [Medline: [35768746](https://pubmed.ncbi.nlm.nih.gov/35768746/)]
90. Ranghetti L, Rivera DE, Guo P, Visioli A, Savage JS, Symons Downs D. A control-based observer approach for estimating energy intake during pregnancy. *Int J Robust Nonlinear Control.* Jun 30, 2023;33(9):5105-5127. [FREE Full text] [doi: [10.1002/rnc.6019](https://doi.org/10.1002/rnc.6019)] [Medline: [37193543](https://pubmed.ncbi.nlm.nih.gov/37193543/)]
91. Buuren SV, Groothuis-Oudshoorn K. mice: multivariate imputation by chained equations in R. *J Stat Soft.* 2011;45(3):1-67. [doi: [10.18637/jss.v045.i03](https://doi.org/10.18637/jss.v045.i03)]
92. Van Buuren S, Brand JP, Groothuis-Oudshoorn CG, Rubin DB. Fully conditional specification in multivariate imputation. *Journal of Statistical Computation and Simulation.* Dec 2006;76(12):1049-1064. [doi: [10.1080/10629360600810434](https://doi.org/10.1080/10629360600810434)]
93. Thomas T, Rajabi E. A systematic review of machine learning-based missing value imputation techniques. *DTA.* Apr 02, 2021;55(4):558-585. [doi: [10.1108/dta-12-2020-0298](https://doi.org/10.1108/dta-12-2020-0298)]
94. Lakshminarayan K, Harp S, Goldman R, Samad T. Imputation of missing data using machine learning techniques. In: *Proceedings of the Second International Conference on Knowledge Discovery and Data Mining.* 1996. Presented at: Second International Conference on Knowledge Discovery and Data Mining; August 2-4, 1996; Portland, OR, USA. URL: <https://aaai.org/papers/kdd96-023-imputation-of-missing-data-using-machine-learning-techniques/>
95. Jerez JM, Molina I, García-Laencina P, Alba E, Ribelles N, Martín M, et al. Missing data imputation using statistical and machine learning methods in a real breast cancer problem. *Artif Intell Med.* Oct 2010;50(2):105-115. [doi: [10.1016/j.artmed.2010.05.002](https://doi.org/10.1016/j.artmed.2010.05.002)] [Medline: [20638252](https://pubmed.ncbi.nlm.nih.gov/20638252/)]
96. Downs DS, Dinallo JM, Birch LL, Paul IM, Ulbrecht JS. Randomized face-to-face vs. home exercise interventions in pregnant women with gestational diabetes. *Psychol Sport Exerc.* May 2017;30:73-81. [FREE Full text] [doi: [10.1016/j.psychsport.2017.02.003](https://doi.org/10.1016/j.psychsport.2017.02.003)] [Medline: [28428728](https://pubmed.ncbi.nlm.nih.gov/28428728/)]
97. Downs DS, Feinberg M, Hillemeier MM, Weisman CS, Chase GA, Chuang CH, et al. Design of the Central Pennsylvania Women's Health Study (CePAWHS) strong healthy women intervention: improving preconceptional health. *Matern Child Health J.* Jan 13, 2009;13(1):18-28. [FREE Full text] [doi: [10.1007/s10995-008-0323-7](https://doi.org/10.1007/s10995-008-0323-7)] [Medline: [18270808](https://pubmed.ncbi.nlm.nih.gov/18270808/)]
98. Hillemeier M, Downs D, Feinberg M, Weisman C, Chuang C, Parrott R, et al. Improving women's preconceptional health: findings from a randomized trial of the Strong Healthy Women intervention in the Central Pennsylvania women's health study. *Womens Health Issues.* Nov 13, 2008;18(6 Suppl):S87-S96. [FREE Full text] [doi: [10.1016/j.whi.2008.07.008](https://doi.org/10.1016/j.whi.2008.07.008)] [Medline: [19059553](https://pubmed.ncbi.nlm.nih.gov/19059553/)]

99. Weisman CS, Hillemeier MM, Downs DS, Feinberg ME, Chuang CH, Botti JJ, et al. Improving women's preconceptional health: long-term effects of the strong healthy women behavior change intervention in the central Pennsylvania women's health study. *Women's Health Issues*. Jul 2011;21(4):265-271. [doi: [10.1016/j.whi.2011.03.007](https://doi.org/10.1016/j.whi.2011.03.007)]
100. Mackeen AD, Young AJ, Lutcher S, Hetherington V, Mowery JW, Savage JS, et al. Encouraging appropriate gestational weight gain in high-risk gravida: A randomized controlled trial. *Obes Sci Pract*. Jun 22, 2022;8(3):261-271. [doi: [10.1002/osp4.565](https://doi.org/10.1002/osp4.565)] [Medline: [35664244](https://pubmed.ncbi.nlm.nih.gov/35664244/)]
101. ONE PATH: Optimizing Nutrition Education for Parents and Teachers for Healthy Growth (ONE PATH). *ClinicalTrials.gov*. URL: <https://clinicaltrials.gov/ct2/show/NCT03817021> [accessed 2025-02-20]
102. Savage J, Kling S, Cook A, Hess L, Lutcher S, Marini M, et al. A patient-centered, coordinated care approach delivered by community and pediatric primary care providers to promote responsive parenting: pragmatic randomized clinical trial rationale and protocol. *BMC Pediatr*. Sep 04, 2018;18(1):293-296. [FREE Full text] [doi: [10.1186/s12887-018-1263-z](https://doi.org/10.1186/s12887-018-1263-z)] [Medline: [30180831](https://pubmed.ncbi.nlm.nih.gov/30180831/)]
103. Clifton RG, Evans M, Cahill AG, Franks PW, Gallagher D, Phelan S, et al. LIFE-Moms Research Group. Design of lifestyle intervention trials to prevent excessive gestational weight gain in women with overweight or obesity. *Obesity (Silver Spring)*. Feb 2016;24(2):305-313. [FREE Full text] [doi: [10.1002/oby.21330](https://doi.org/10.1002/oby.21330)] [Medline: [26708836](https://pubmed.ncbi.nlm.nih.gov/26708836/)]
104. Huang D, Liang M, Xu B, Chen S, Xiao Y, Liu H, et al. The association of insufficient gestational weight gain in women with gestational diabetes mellitus with adverse infant outcomes: A case-control study. *Front Public Health*. 2023;11:1054626. [FREE Full text] [doi: [10.3389/fpubh.2023.1054626](https://doi.org/10.3389/fpubh.2023.1054626)] [Medline: [36908424](https://pubmed.ncbi.nlm.nih.gov/36908424/)]
105. Jahan N, Went TR, Sultan W, Sapkota A, Khurshid H, Qureshi IA, et al. Untreated depression during pregnancy and its effect on pregnancy outcomes: a systematic review. *Cureus*. Aug 2021;13(8):e17251. [doi: [10.7759/cureus.17251](https://doi.org/10.7759/cureus.17251)] [Medline: [34540477](https://pubmed.ncbi.nlm.nih.gov/34540477/)]
106. Freedland KE, King AC, Ambrosius WT, Mayo-Wilson E, Mohr DC, Czajkowski SM, et al. National Institutes of Health Office of Behavioral Social Sciences Research Expert Panel on Comparator Selection in Behavioral Social Science Clinical Trials. The selection of comparators for randomized controlled trials of health-related behavioral interventions: recommendations of an NIH expert panel. *J Clin Epidemiol*. Jun 2019;110:74-81. [FREE Full text] [doi: [10.1016/j.jclinepi.2019.02.011](https://doi.org/10.1016/j.jclinepi.2019.02.011)] [Medline: [30826377](https://pubmed.ncbi.nlm.nih.gov/30826377/)]
107. Downs DS, Pauley AM, Leonard KS, Satti M, Cumbo N, Teti I, et al. Obstetric physicians' beliefs and knowledge on guidelines and screening tools to reduce opioid use after childbirth. *Obstet Gynecol*. Feb 01, 2021;137(2):325-333. [FREE Full text] [doi: [10.1097/AOG.0000000000004232](https://doi.org/10.1097/AOG.0000000000004232)] [Medline: [33416288](https://pubmed.ncbi.nlm.nih.gov/33416288/)]
108. American Academy of Pediatrics. URL: <https://www.aap.org/en> [accessed 2025-02-20]
109. March of Dimes. URL: <https://www.marchofdimes.org/> [accessed 2025-02-20]
110. Centers for Disease Control. URL: <https://www.cdc.gov/> [accessed 2025-02-20]
111. American College of Obstetrics and Gynecology. URL: <https://www.acog.org/> [accessed 2025-02-20]
112. Fitbit. URL: <https://www.fitbit.com/global/us/home> [accessed 2025-02-20]
113. Yu L, Buysse DJ, Germain A, Moul DE, Stover A, Dodds NE, et al. Development of short forms from the PROMIS™ sleep disturbance and Sleep-Related Impairment item banks. *Behav Sleep Med*. Dec 28, 2011;10(1):6-24. [FREE Full text] [doi: [10.1080/15402002.2012.636266](https://doi.org/10.1080/15402002.2012.636266)] [Medline: [22250775](https://pubmed.ncbi.nlm.nih.gov/22250775/)]
114. Marcusson-Clavertz D, West M, Kjell ONE, Somer E. A daily diary study on maladaptive daydreaming, mind wandering, and sleep disturbances: Examining within-person and between-persons relations. *PLoS One*. 2019;14(11):e0225529. [FREE Full text] [doi: [10.1371/journal.pone.0225529](https://doi.org/10.1371/journal.pone.0225529)] [Medline: [31774836](https://pubmed.ncbi.nlm.nih.gov/31774836/)]
115. Gibson A, Sainsbury A. Strategies to improve adherence to dietary weight loss interventions in research and real-world settings. *Behav Sci (Basel)*. Jul 11, 2017;7(3):44. [FREE Full text] [doi: [10.3390/bs7030044](https://doi.org/10.3390/bs7030044)] [Medline: [28696389](https://pubmed.ncbi.nlm.nih.gov/28696389/)]
116. Stunkard AJ, Messick S. The three-factor eating questionnaire to measure dietary restraint, disinhibition and hunger. *J Psychosom Res*. Jan 1985;29(1):71-83. [doi: [10.1016/0022-3999\(85\)90010-8](https://doi.org/10.1016/0022-3999(85)90010-8)] [Medline: [3981480](https://pubmed.ncbi.nlm.nih.gov/3981480/)]
117. Cappelleri JC, Bushmakina AG, Gerber RA, Leidy NK, Sexton CC, Lowe MR, et al. Psychometric analysis of the Three-Factor Eating Questionnaire-R21: results from a large diverse sample of obese and non-obese participants. *Int J Obes (Lond)*. Jun 2009;33(6):611-620. [doi: [10.1038/ijo.2009.74](https://doi.org/10.1038/ijo.2009.74)] [Medline: [19399021](https://pubmed.ncbi.nlm.nih.gov/19399021/)]
118. Guo P, Rivera DE, Downs DS, Savage JS. Semi-physical identification and state estimation of energy intake for interventions to manage gestational weight gain. *Proc Am Control Conf*. Jul 2016;2016:1271-1276. [FREE Full text] [doi: [10.1109/ACC.2016.7525092](https://doi.org/10.1109/ACC.2016.7525092)] [Medline: [27570366](https://pubmed.ncbi.nlm.nih.gov/27570366/)]
119. Guo P, Rivera DE, Savage JS, Hohman EE, Pauley AM, Leonard KS, et al. System identification approaches for energy intake estimation: enhancing interventions for managing gestational weight gain. *IEEE Trans Control Syst Technol*. Jan 2020;28(1):63-78. [FREE Full text] [doi: [10.1109/TCST.2018.2871871](https://doi.org/10.1109/TCST.2018.2871871)] [Medline: [31903018](https://pubmed.ncbi.nlm.nih.gov/31903018/)]
120. Ljung L. *System Identification: Theory for the User*. Hoboken, NJ. Prentice Hall; 1999.
121. Tsow F. Personalized indirect calorimeter for energy expenditure (EE) measurement. *Glob J Obes Diabetes Metab Syndr*. Mar 29, 2015:004-008. [doi: [10.17352/2455-8583.000007](https://doi.org/10.17352/2455-8583.000007)]
122. Molenaar PCM, Nesselroode JR. Merging the idiographic filter with dynamic factor analysis to model process. *Applied Developmental Science*. Oct 2012;16(4):210-219. [doi: [10.1080/10888691.2012.722884](https://doi.org/10.1080/10888691.2012.722884)]
123. Actigraph. URL: <https://theactigraph.com/> [accessed 2025-02-20]

124. Godin G, Shephard RJ. A simple method to assess exercise behavior in the community. *Can J Appl Sport Sci.* Sep 1985;10(3):141-146. [Medline: [4053261](#)]
125. Chevance G, Golaszewski N, Tipton E, Hekler E, Buman M, Welk G, et al. Accuracy and precision of energy expenditure, heart rate, and steps measured by combined-sensing Fitbits against reference measures: systematic review and meta-analysis. *JMIR Mhealth Uhealth.* Apr 13, 2022;10(4):e35626. [FREE Full text] [doi: [10.2196/35626](#)] [Medline: [35416777](#)]
126. Ajzen I. Attitudes, personality, and behavior. Milton Keynes, England. Open University Press; 1988.
127. 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.* May 1989;28(2):193-213. [doi: [10.1016/0165-1781\(89\)90047-4](#)] [Medline: [2748771](#)]
128. Carney C, Buysse D, Ancoli-Israel S, Edinger J, Krystal A, Lichstein K, et al. The consensus sleep diary: standardizing prospective sleep self-monitoring. *Sleep.* Feb 01, 2012;35(2):287-302. [FREE Full text] [doi: [10.5665/sleep.1642](#)] [Medline: [22294820](#)]
129. Beets MW, Glenn Weaver R, Brazendale K, Turner-McGrievy G, Saunders RP, Moore JB, et al. Statewide dissemination and implementation of physical activity standards in afterschool programs: two-year results. *BMC Public Health.* Jul 03, 2018;18(1):819. [FREE Full text] [doi: [10.1186/s12889-018-5737-6](#)] [Medline: [29970046](#)]
130. Beets MW, Glenn Weaver R, Turner-McGrievy G, Saunders RP, Webster CA, Moore JB, et al. Evaluation of a statewide dissemination and implementation of physical activity intervention in afterschool programs: a nonrandomized trial. *Transl Behav Med.* Dec 2017;7(4):690-701. [FREE Full text] [doi: [10.1007/s13142-017-0484-2](#)] [Medline: [28321706](#)]
131. Lau EY, Saunders RP, Beets MW, Cai B, Pate RR. Factors influencing implementation of a preschool-based physical activity intervention. *Health Educ Res.* Feb 01, 2017;32(1):69-80. [FREE Full text] [doi: [10.1093/her/cyw053](#)] [Medline: [28158420](#)]
132. Weaver RG, Moore JB, Huberty J, Freedman D, Turner-McGrievy B, Beighle A, et al. Process evaluation of making HEPA policy practice: a group randomized trial. *Health Promot Pract.* Sep 2016;17(5):631-647. [FREE Full text] [doi: [10.1177/1524839916647331](#)] [Medline: [27216875](#)]
133. Beets MW, Flay BR, Vuchinich S, Acock AC, Li K, Allred C. School climate and teachers' beliefs and attitudes associated with implementation of the positive action program: a diffusion of innovations model. *Prev Sci.* Dec 2008;9(4):264-275. [doi: [10.1007/s11121-008-0100-2](#)] [Medline: [18780182](#)]
134. Weiner BJ, Lewis CC, Stanick C, Powell BJ, Dorsey CN, Clary AS, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implement Sci.* Aug 29, 2017;12(1):108. [FREE Full text] [doi: [10.1186/s13012-017-0635-3](#)] [Medline: [28851459](#)]
135. Borrelli B. The assessment, monitoring, and enhancement of treatment fidelity in public health clinical trials. *J Public Health Dent.* Mar 18, 2011;71(s1):S52-S63. [FREE Full text] [doi: [10.1111/j.1752-7325.2011.00233.x](#)] [Medline: [21499543](#)]
136. Green J, Browne J. Analysing qualitative data. In: Black N, Raine R, Green J, Browne J, editors. *Principles of social research.* New York, NY. McGraw-Hill; 2005:79-80.
137. Guest G, Bunce A, Johnson L. How many interviews are enough? *Field Methods.* Feb 01, 2006;18(1):59-82. [doi: [10.1177/1525822X05279903](#)]
138. Materia FT, Smyth JM, Heron KE, Hillemeier M, Feinberg ME, Fonzi P, et al. Preconceptional health behavior change in women with overweight and obesity: prototype for SMART strong healthy women intervention. *Mhealth.* 2018;4:24. [FREE Full text] [doi: [10.21037/mhealth.2018.06.06](#)] [Medline: [30148139](#)]
139. Downs DS, Smyth JM, Heron KE, Feinberg ME, Hillemeier M, Materia FT. Beliefs about using smartphones for health behavior change: an elicitation study with overweight and obese rural women. *J Technol Behav Sci.* Mar 2019;4(1):33-41. [FREE Full text] [Medline: [31463364](#)]
140. Symons Downs D, Savage JS, Rivera DE, Leonard KS, Pauley AM, Hohman EE, et al. Influence of a feasibility study on the design of an individually-tailored, adaptive intervention to manage weight in overweight and obese pregnant women. *Ann Behav Med.* 2017;51:S1451-S1452. [doi: [10.1007/s12160-017-9903-3](#)]
141. Harrell F. *Regression Modeling Strategies: With Applications to Linear Models, Logistic and Ordinal Regression, and Survival Analysis.* New York, NY. Springer; 2015.
142. Shumway RH, Stoffer DS. *Time Series Analysis and Its Applications: With R Examples.* New York, NY. Springer; 2011.
143. Borenstein M, Hedges L, Higgins J, Rothstein H. *Introduction to meta-analysis.* Chichester, West Sussex, United Kingdom. John Wiley & Sons; 2009.
144. Lederman S, Paxton A. Maternal reporting of prepregnancy weight and birth outcome: consistency and completeness compared with the clinical record. *Matern Child Health J.* Jun 1998;2(2):123-126. [doi: [10.1023/a:1022996924094](#)] [Medline: [10728268](#)]
145. Laird NM, Ware JH. Random-effects models for longitudinal data. *Biometrics.* Dec 1982;38(4):963. [doi: [10.2307/2529876](#)]
146. Navarro-Barrientos J, Rivera DE, Collins LM. A dynamical model for describing behavioural interventions for weight loss and body composition change. *Math Comput Model Dyn Syst.* Jan 12, 2011;17(2):183-203. [FREE Full text] [doi: [10.1080/13873954.2010.520409](#)] [Medline: [21673826](#)]

147. Ranghetti L, Rivera DE, Guo P, Visioli A, Savage JS, Symons Downs D. A control-based observer approach for estimating energy intake during pregnancy. *Int J Robust Nonlinear Control*. Jun 30, 2023;33(9):5105-5127. [FREE Full text] [doi: [10.1002/rnc.6019](https://doi.org/10.1002/rnc.6019)] [Medline: [37193543](https://pubmed.ncbi.nlm.nih.gov/37193543/)]
148. Reid RER, Insogna JA, Carver TE, Comptour AM, Bewski NA, Sciortino C, et al. Validity and reliability of Fitbit activity monitors compared to ActiGraph GT3X+ with female adults in a free-living environment. *J Sci Med Sport*. Jun 2017;20(6):578-582. [doi: [10.1016/j.jsams.2016.10.015](https://doi.org/10.1016/j.jsams.2016.10.015)] [Medline: [27887786](https://pubmed.ncbi.nlm.nih.gov/27887786/)]
149. da Silva SG, Evenson KR, Ekelund U, da Silva ICM, Domingues MR, da Silva BGC, et al. How many days are needed to estimate wrist-worn accelerometry-assessed physical activity during the second trimester in pregnancy? *PLoS One*. 2019;14(6):e0211442. [FREE Full text] [doi: [10.1371/journal.pone.0211442](https://doi.org/10.1371/journal.pone.0211442)] [Medline: [31246953](https://pubmed.ncbi.nlm.nih.gov/31246953/)]
150. Morari M, Zafiriou E. *Robust process control*. Hoboken, NJ. Prentice Hall; 1989.
151. Ronnberg A, Ostlund I, Fadl H, Gottvall T, Nilsson K. Intervention during pregnancy to reduce excessive gestational weight gain—a randomised controlled trial. *BJOG*. Mar 04, 2015;122(4):537-544. [doi: [10.1111/1471-0528.13131](https://doi.org/10.1111/1471-0528.13131)] [Medline: [25367823](https://pubmed.ncbi.nlm.nih.gov/25367823/)]
152. Asbee SM, Jenkins TR, Butler JR, White J, Elliot M, Rutledge A. Preventing excessive weight gain during pregnancy through dietary and lifestyle counseling. *Obstetrics & Gynecology*. 2009;113(2, Part 1):305-312. [doi: [10.1097/aog.0b013e318195baef](https://doi.org/10.1097/aog.0b013e318195baef)]
153. Ferrara A, Hedderson MM, Brown SD, Ehrlich SF, Tsai A, Feng J, et al. A telehealth lifestyle intervention to reduce excess gestational weight gain in pregnant women with overweight or obesity (GLOW): a randomised, parallel-group, controlled trial. *The Lancet Diabetes & Endocrinology*. Jun 2020;8(6):490-500. [doi: [10.1016/s2213-8587\(20\)30107-8](https://doi.org/10.1016/s2213-8587(20)30107-8)]
154. Ruiz JR, Perales M, Pelaez M, Lopez C, Lucia A, Barakat R. Supervised exercise-based intervention to prevent excessive gestational weight gain: a randomized controlled trial. *Mayo Clin Proc*. Dec 2013;88(12):1388-1397. [doi: [10.1016/j.mayocp.2013.07.020](https://doi.org/10.1016/j.mayocp.2013.07.020)] [Medline: [24290112](https://pubmed.ncbi.nlm.nih.gov/24290112/)]
155. Redman LM, Gilmore LA, Breaux J, Thomas DM, Elkind-Hirsch K, Stewart T, et al. Effectiveness of SmartMoms, a novel eHealth intervention for management of gestational weight gain: randomized controlled pilot trial. *JMIR Mhealth Uhealth*. Sep 13, 2017;5(9):e133. [FREE Full text] [doi: [10.2196/mhealth.8228](https://doi.org/10.2196/mhealth.8228)] [Medline: [28903892](https://pubmed.ncbi.nlm.nih.gov/28903892/)]

Abbreviations

- EI:** energy intake
- GWG:** gestational weight gain
- HMZ:** Healthy Mom Zone
- IOM:** Institutes of Medicine
- IRB:** Institutional Review Board
- PA:** physical activity
- RCT:** randomized controlled trial
- REDCap:** Research Electronic Data Capture
- RMR:** resting metabolic rate

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