Examining the Impact of a Co-Developed Multicomponent e-Health Lifestyle Intervention on Physical Activity and its Association with Gestational Weight Gain in Underserved Women: A State-Wide Randomized Controlled Trial

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Abstract

Background: Over two-thirds of women experience inappropriate gestational weight gain (GWG) during pregnancy which can detrimentally impact the long-term health of both mother and child. Physical activity can assist with appropriate GWG attainment. However, pregnant women facing economic disadvantages are particularly at risk for inappropriate GWG and often lack resources that would allow for adoption of healthy lifestyle behaviors.

Objective: This report describes the effects of a state-wide randomized controlled trial testing the effectiveness of a multicomponent e-Health lifestyle intervention on change in physical activity and sedentary time across pregnancy and its association with GWG in underserved women.

Methods: Pregnant women enrolled in the Louisiana Special Supplemental Nutrition program for Women, Infants, and Children (WIC) were randomly assigned to a multicomponent e-Health intervention for GWG management or Usual Care (standard WIC care) prior to 16 weeks gestation. Physical activity, including movement duration and context, and sedentary time were assessed at baseline (early pregnancy) and at the end of the intervention (late pregnancy) using accelerometry (N=294) and the pregnancy physical activity questionnaire (PPAQ) (N=315). GWG was determined based on weight collected at study visits in early and late pregnancy. Linear mixed models were used to assess intervention effects within and between groups and to assess associations between changes in physical activity and GWG.

Results: A decrease in physical activity duration was observed in both groups across pregnancy. The Intervention Group reported an increase in sports participation across pregnancy compared to the Usual Care Group (adjusted effect estimate [95% confidence interval]: +4 MET-hours/week [2; 7], p=0.002). There were no associations between physical activity or sedentary time measures and GWG.

Conclusions: An e-Health multicomponent behavioral lifestyle intervention that included guidance to increase physical activity towards national guidelines did not meaningfully impact physical activity outcomes or GWG in pregnant women who were enrolled in Louisiana WIC. Clinical Trial: ClinicalTrials.gov NCT04028843

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Abstract

Objective: Over two-thirds of women experience inappropriate gestational weight gain (GWG) during pregnancy which can detrimentally impact the long-term health of both mother and child. Physical activity can assist with appropriate GWG attainment. However, pregnant women facing economic disadvantages are particularly at risk for inappropriate GWG and often lack resources that would allow for adoption of healthy lifestyle behaviors. This report describes the effects of a state-wide randomized controlled trial testing the effectiveness of a multicomponent e-Health lifestyle intervention on change in physical activity and sedentary time across pregnancy and its association with GWG in underserved women. **Study Design:** Pregnant women enrolled in the Louisiana Special Supplemental Nutrition program for Women, Infants, and Children (WIC) were randomly assigned to a multicomponent e-Health intervention for GWG management or Usual Care (standard WIC care) prior to 16 weeks gestation. Physical activity, including movement duration and context, and sedentary time were assessed at baseline (early pregnancy) and at the end of the intervention (late pregnancy) using accelerometry (N=294) and the pregnancy physical activity questionnaire (PPAQ) (N=315). GWG was determined based on weight collected at study visits in early and late pregnancy. Linear mixed models were used to assess intervention effects within and between groups

and to assess associations between changes in physical activity and GWG. **Results:** A decrease in physical activity duration was observed in both groups across pregnancy. The Intervention Group reported an increase in sports participation across pregnancy compared to the Usual Care Group (adjusted effect estimate [95% confidence interval]: +4 MET-hours/week [2; 7], p=0.002). There were no associations between physical activity or sedentary time measures and GWG. **Conclusions**: An e-Health multicomponent behavioral lifestyle intervention that included guidance to increase physical activity towards national guidelines did not meaningfully impact physical activity outcomes or GWG in pregnant women who were enrolled in Louisiana WIC. **Trial Registration**: ClinicalTrials.gov NCT04028843

Keywords: Gestation; Maternal Health; Obesity; Overweight; Pregnancy; Movement Behaviors

Introduction

Physical activity is an important aspect of a healthy lifestyle, particularly during pregnancy. Regular physical activity during pregnancy is associated with lower gestational weight gain (GWG) and a lower risk of adverse perinatal outcomes.[1,2] Despite the benefits of physical activity, only 32% of pregnant women achieve the recommended amount of at least 150 minutes of moderate physical activity per week throughout pregnancy.[3] As such, pregnant women spend more than 50% of their time being sedentary,[4] which is linked to higher GWG, gestational hypertension, and infant macrosomia.[4] This imbalance of physical activity and sedentary behaviors may contribute to inappropriate GWG. As only one third of pregnant women gain an appropriate amount of weight,[5] pregnancy is a critical period for changes to physical activity with known benefits on body weight.

Prenatal lifestyle interventions have been shown to attenuate GWG in pregnant women,[6-8] but the extent to which GWG benefits attributable to changes in diet and/or physical activity remains unclear. In a meta-analysis of 23 randomized controlled trials including 4,462 pregnant women, GWG was decreased (−1.02 kg [95% CI: −1.35 to −0.70]) with exercise performed at least three times a week for a minimum of 30 minutes.[9] However, a secondary analysis of 1,150 pregnant women in the LIFE-Moms consortium using a multicomponent behavioral intervention with dietary and physical activity components found no change in moderate-to-vigorous physical activity (MVPA) from early to late pregnancy across a diverse United States population, despite lower total GWG (-1.59 kg) in the intervention group.[8]

Pregnant women who face economic disadvantages have an increased risk for adverse perinatal outcomes coupled with reduced access to nutritious foods and less opportunities for safe physical activity.[10-12] These disparities are notably prevalent in Louisiana, where one in five adults (18.5%) experiences poverty.[13] The federally funded Special Supplemental Nutrition Program for Women, Infants and Children (WIC) aims to reduce nutrition-related health inequalities through the provision of food vouchers and nutrition education to pregnant women and their families. In its 50 years of existence, the WIC program has contributed to reductions in the prevalence of infant mortality, preterm birth, and childhood anemia in addition to improvements in birth weight, and maternal diet quality.[14,15] WIC therefore provides a unique setting for the delivery of a multicomponent lifestyle intervention with the goal of implementing health behavior change in a population that is traditionally hard to reach.

Leveraging the reach of WIC to underserved communities, we co-developed an eHealth lifestyle intervention with community stakeholders and conducted a parallel randomized controlled trial aimed at promoting appropriate GWG among underserved women.[16] The co-developed multicomponent intervention consisted of daily weighing, self-monitoring of steps with an activity monitor, physical activity counseling (e.g., in the form of videos suggesting an exercise of the week using study-provided exercise equipment), behavioral counseling on diet quality, interaction with health coaches, and social support through a private Facebook group.[17] Participants in the Intervention Group gained less total and weekly weight across gestation compared to the Usual Care Group.[16] Given the known health benefits of engaging in regular physical activity and decreasing sedentary time, the objective of this pre-specified secondary analysis was to 1) examine the impact of this pragmatic, multicomponent lifestyle intervention on physical activity and sedentary time, and 2) explore associations between changes in physical activity and sedentary time and GWG.

Methods

Study Design

This is a secondary analysis of a randomized controlled trial in pregnant women enrolled in Louisiana WIC that was designed to test the effectiveness of a remotely delivered behavior modification program to promote appropriate weight gain during pregnancy as recommended by the 2009 National Academy of Medicine (NAM) GWG per week guidelines (NCT04028843).[18] A detailed report of the study design[17] and CONSORT diagram have previously been described.[16] Briefly, the parallel-arm trial randomized individuals either to the Healthy Beginnings intervention in addition to WIC services (Intervention Group) or usual WIC Nutrition only (Usual Care Group), with randomization stratified by body mass index (BMI: normal weight, overweight, obesity) and Louisiana Department of Health (LDH) region. The intervention spanned approximately 24 weeks with participants being randomized between the 10-16th week of pregnancy and participating until delivery. Outcomes were assessed at three study visits which occurred early (10,0 to 16,6 weeks gestation), mid (24,0 to 27,6 weeks), and late (35,0 to 36,6 weeks gestation) pregnancy. The primary outcome of GWG has been published;[16] the present analysis evaluates the pre-specified secondary outcome of changes in physical activity from study visits conducted in early and late pregnancy. At these visits, participants completed the Pregnancy Physical Activity Questionnaire (PPAQ)[19] and were administered an accelerometer to wear over three to seven days to assess habitual physical activity and sedentary time. The study was monitored by the Institutional Review Boards at Pennington Biomedical Research Center and LDH, and participants provided informed consent prior to study procedures.

Participants

Eligible individuals were pregnant with a singleton viable pregnancy, BMI between 18.5 to 40 kg/m^2 from study-measured weight and height, gestational age ≥ 10,0 weeks but ≤ 16,6 weeks at enrollment, and certified to receive WIC services during the current pregnancy. Detailed exclusion criteria have been previously reported.[16,17] Inclusion in this secondary analysis also required that, participants had at least three days of valid accelerometry data (≥10 hour of awake wear time per day) at either the early and/or late pregnancy time point.[20]

Treatment Groups

In brief, the Intervention Group received an intensive behavior modification program that targeted healthy GWG through daily self-monitoring of weight and physical activity data, as well as several resources including weekly one-on-one virtual coaching, a cellular network connected scale, an activity tracker (Fitbit), exercise equipment (yoga mats, dumbbells, resistance bands), personalized feedback from counselors, social interactions in a closed Facebook group, and tailored videos promoting evidence-based behavioral habits. The physical activity component of the intervention promoted moderate-intensity physical activity of 150 minutes per week, as recommended during pregnancy. The focus of the physical activity component was to reduce sedentary time through increasing lifestyle activities (e.g., reaching 5,000-10,000 steps per day), such as taking the stairs instead of the elevator, actively commuting (e.g., walking or cycling) whenever possible, and replacing sedentary activities with more active options. Counselor feedback was individually tailored to each participants' environment. Participants received a weekly 'exercise of the week' clip within the closed Facebook group, and access to eight live exercise sessions that featured pregnant women with likeness to the participant population. Physical activity data derived from Fitbit were monitored ~weekly by the participants' health coaches.

The Usual Care Group received the exercise equipment (yoga mats, dumbbells, resistance bands) as the Intervention Group, and they received the same general health information that not related to weight management. Participants were included in a separate closed Facebook group and were

contacted monthly by a health coach for retention.

Procedures

Movement Behaviors

Movement Duration. Physical activity was assessed for up to seven days in early and late pregnancy using the Actigraph GT3X+ accelerometer (Actigraph, LLC Actigraph, LLC, Pensacola, FL, USA). Participants were asked to wear the accelerometer on their non-dominant wrist [21,22] for 24 hours per day including overnight and while bathing. The monitors were initialized to record at a 50 hz sampling rate, the highest sampling rate possible for an up to seven day monitoring period.

The data were downloaded using the ActiLife software (version 6.5.2 and GENEActiv personal computer software version 2.2) and then processed with the GGIR algorithm in R.[23] The GGIR Lite algorithm was used to detect non-wear time. GGIR was used to determine physical activity and sedentary time duration. The Euclidian Norm Minus One (ENMO) value calculated by GGIR as a proxy for energy expenditure was used to classify level of activity (inactive [< 44.8 mg], light [44.8 mg to ≤ ENMO < 100.6 mg], moderate [100.6 mg to ≤ ENMO < 428.8 mg], vigorous [> 428.8 mg]) and the time spent in each activity.[24-28] To avoid capturing random wrist movements, only activity bouts of ≥ 1 minute where 80% of the activity was classified as MVPA were included to capture physical activity.[28,29]

Variables were summarized for each participant across valid days and each timepoint as counts or non-weighted averages. Data collected from the accelerometer relevant for this analysis included inactive time (minutes/day), light activity (minutes/day), moderate activity (minutes/day), vigorous activity (minutes/day), MVPA (minutes/day), and number of 1-to-5-minute MVPA bouts per day. Inactive time was renamed sedentary time to align with consensus for reporting sedentary measures.[30]

Movement Context. Participant-reported physical activity and sedentary time was collected with the PPAQ; a validated questionnaire that evaluates time spent on 33 activities categorized into household/caregiving (16 activities), occupational activities (5 activities), sports/exercise (9 activities), and transportation (3 activities).[19] Participants recalled the time spent on each activity during the current trimester. Response options varied by activity, which included activities performed while not at work or going places (0-3+ hours/day), activities completed for fun or exercise (0-3+ hours/week), and activities performed at work (0-6+ hours/day). Two open-ended questions allowed participants to provide any additional activities they participated in for fun or for exercise during the week. The time spent in each activity was multiplied by its intensity (sedentary, light, moderate, or vigorous) to arrive at a measure of average weekly energy expenditure (MET-hours/week where 1 MET is the metabolic equivalent of the energy expended at rest) attributable to each activity. These values were then summed to derive the weekly total activity sum. The energy expended was also calculated according to each activity domain and each intensity level (sedentary [< 2.0 METs], light [2.0 ≤ activity < 3.0 METs], moderate [3.0 ≤ activity ≤ 6.0 METs] or vigorous [> 6.0 METs]).[31]

Gestational Weight Gain

Weight was measured in light clothing and without shoes using a digital scale at study visits. Study-observed GWG (kg) was calculated as the difference between the early and late pregnancy

visit weights. GWG per week (kg/week) was calculated as study-observed GWG divided by the number of weeks between visits. For participants that missed their late pregnancy visit (e.g., due to an early delivery) but had an intermediary mid-pregnancy weight data point, weekly GWG was calculated analogously based on weight assessed at that time point. GWG guideline attainment was based on weekly GWG and defined as meeting the 2009 NAM weight gain recommendations in the second and third trimesters for pregnant women with normal weight (0.35 – 0.50 kg/week), overweight (0.23 – 0.33 kg/week), or obesity (0.17 – 0.27 kg/week).[16,32]

Statistical Analysis

Data are presented as mean ± standard deviation or percentages for continuous or categorical variables, respectively. For all outcomes, p-values of < 0.05 were considered to indicate statistical significance. Analyses were performed using R (version 4.3.2).

Physical activity data were analyzed using a linear mixed model including fixed effects for time (early and late pregnancy) and group (Intervention Group, Usual Care) as well as the interaction, and a random effect for participant. The model was adjusted for BMI category (normal weight, overweight, obesity) at randomization. Model-derived estimated marginal means alongside corresponding 95% confidence intervals as well as within- and between-group effect estimates with associated confidence intervals and p-values are reported. The main effect of interest is the between-group effect estimate. Furthermore, the treatment heterogeneity across the different BMI categories was explored via a three-way interaction including time, group, and BMI category, with custom comparisons exploring intervention effects on physical activity within and between BMI categories (**Supplemental Table 1**).

To examine the effect of changes in physical activity on GWG outcomes (study-observed GWG, weekly GWG, and GWG guideline attainment), we used data from all participants collapsed across intervention groups (i.e., independent of randomization assignment). These analyses used a linear model including a fixed effect for the change across the intervention period in both MVPA and inactivity (adjusting for each other in the same model) as measured via Actigraph and adjustments for BMI category at randomization, parity (categorically defined as nulliparous vs non-nulliparous), and gestational age at enrolment. Effects are presented as regression coefficients (study-observed GWG, weekly GWG) or odds ratios (GWG guideline attainment) for each predictor with 95% confidence intervals and corresponding p-values.

Results

Participants:

Participants (**Table 1)** mostly identified as non-Hispanic Black (57%) and were 27.0 ± 6.0 years old with pregnancy weight at enrollment (xxx weeks) of 75.1 ± 16.9 kg and corresponding BMI of 28.5 ± 5.8 kg/m^2. Of the 351 enrolled participants, 7% (N = 25) participants were excluded from this analysis due to missing accelerometry data at both time points (i.e., neither early nor late pregnancy accelerometry was available), and an additional 4% (n = 13) were excluded due to an inadequate number (i.e., **<** 3) of valid days at either time point. Overall, 89% (n = 313) of participants had ≥ 3 valid days for at least one time point, with 84% (n = 294) and 48% (n = 168) having at least three valid days at the early and late pregnancy time points, respectively.

Intervention Engagement:

Participants in the Intervention Group demonstrated engagement with the physical activity component of the intervention. Fitbit data were available from 149 (83%) participants in the Intervention Group. Of the 149 participants, more than half (56%) recorded their steps at least 3

days per week, with over 40% recording their step count on more than 5 days per week on average. On average, participants achieved their step goal of 5,000 and 10,000 steps per day on 39 ± 26% and 8 ± 13%, respectively, of the days that they recorded steps. Participants took an average of 4560 ± 2168 steps per day across the intervention period, which was consistent between the second (4785 ± 2293) and third (4602 ± 2231) trimesters.

Table 1. Baseline characteristics for participants by randomization assignment.

Demographic Characteristics	**Overall** (N = 351)	**Intervention** (N = 179)	**Usual Care** (N = 172)
Maternal Age (years)	27.0 ± 6.0	27.0 ± 6.0	28.0 ± 6.0
Body Weight (kg)	75.1 ± 16.9	74.8 ± 17.5	75.4 ± 16.4
BMI (kg/m^2)	28.5 ± 5.8	28.6 ± 5.9	28.5 ± 5.7
Normal Weight, %	33%	32%	33%
Overweight Weight, %	28%	29%	28%
Obesity, %	39%	39%	39%
Race/Ethnicity, %			
Hispanic	7%	6%	8%
Non-Hispanic White	31%	31%	31%
Non-Hispanic Black	57%	59%	55%
Multiracial/Other	5%	4%	6%
Education Level, %			
College Education	63%	61%	65%
No College Education	37%	39%	35%
Marital Status, %			
Married or Living with Significant Other	57%	58%	56%
Not married	43%	42%	44%
Nulliparous, %	43%	48%	38%
Actigraph Accelerometer Wear	**N = 249**†	**N = 145**†	**N = 149**†
Total Valid Days	5.5 ± 1.2	5.5 ± 1.4	5.5 ± 1.0
Weekdays	3.6 ± 1.0	3.7 ± 1.1	3.5 ± 0.9
Weekends	1.9 ± 0.5	1.8 ± 0.6	1.9 ± 0.3
≥3 Valid Days	84%	81%	87%

Data are presented as mean ± standard deviation or %. †**,** data presented for participants with ≥ 3 days of at least 10 hours of wear time in early pregnancy.

Accelerometer Movement Duration:

Baseline: Participants across both groups spent over 10 hours per day of their waking time in sedentary activities, with an additional ~3 hours and 1.25 hours per day spent doing light and moderate activity, respectively (**Table 2**). The proportion of time spent in each movement behavior was similar across BMI categories (**Supplemental Table 1**). Almost all participants met the physical activity guideline recommendations of at least 150 minutes per week of MVPA per week in early (~22.5 min/day; 142/145 in the Intervention Group, 146/149 in the Usual Care Group) and late (79/86 in the Intervention Group, 80/82 in the Usual Care Group) pregnancy (**Supplemental Figure 1**).

Change Within Groups: Participants in the Intervention Group significantly increased sedentary

time (adjusted effect estimate [95% CI]: 62 min/day [42; 83], p<0.001) and significantly decreased moderate activity (-13 min/day [-20; -6], p<0.001), total MVPA (-14 min/day [-21; -7], p<0.001), and MVPA in 1-5-min bouts (-4 bouts/day [-7; -2], p<0.001) from early to late pregnancy (**Table 2, Figure 1**). Similarly, the Usual Care Group significantly increased inactivity time (52 min/day [31; 72], p<0.001) and significantly decreased moderate activity (-10 min/day [-17; -3], p=0.005), total MVPA (-10 min/day [-18; -3], p=0.006), and 1-5-min MVPA bouts (-4 bouts/day [-7; -2], p<0.001) (**Table 2, Figure 1**).

Table 2. Actigraph accelerometry-measured physical activity levels during early and late pregnancy per randomization assignment.

	Intervention			Usual Care			
	Early Pregnancy (N=145)	Late Pregnancy (N=86)	Within-Group Change	Early Pregnancy (N=149)	Late Pregnancy (N=82)	Within-Group Change	Between-Group p-value
Sedentary time, minutes/day	698 [682; 715]	761 [741; 781]	62 [42; 83]*	686 [670; 702]	738 [716; 758]	52 [31; 72]*	0.47
Light activity, minutes/day	182 [174; 190]	184 [174; 194]	2 [-8; 13]	189 [182; 197]	183 [173; 193]	-7 [-17; 3]	0.21
Moderate activity, minutes/day	74 [69; 80]	61 [54; 69]	-13 [-20; -6]*	81 [76; 87]	72 [64; 79]	-10 [-17; -3]*	0.57
Vigorous activity, minutes/day	2 [1; 3]	1 [0; 2]	-1 [-2; 0]	2 [1; 3]	2 [1; 3]	0 [-1; 1]	0.35
MVPA, minutes/day	77 [71; 83]	62 [55; 70]	-14 [-21; -7]*	83 [77; 89]	73 [66; 80]	-10 [-18; -3]*	0.45
MVPA 1-5 minute bouts/day	15 [13; 17]	11 [8; 13]	-4 [-7; -2]*	18 [16; 20]	13 [11; 16]	-4 [-7; -2]	0.91

Data presented as estimated marginal means alongside corresponding 95% confidence intervals with within- and between-group effect estimates and p-value derived from a linear mixed model including fixed effects for time and group as well as the interaction, and a random effect for participant. Model adjusted fo body mass index category at enrollment. *, within-group change p<0.05. MVPA = moderate-to-vigorous physical activity

Change Between Groups: From early to late pregnancy, there were no significant differences between the Intervention and Usual Care Groups for the change in any physical activity measure (**Table 2**). When examining between-group changes separately by BMI categories, there was an intervention effect within obesity for sedentary time (48 [1; 95], p=0.04), suggesting a greater increase in sedentary time in the Intervention Group in individuals with obesity. There were no between-group differences within or between BMI categories in physical activity measures (**Supplemental Table 1**).

*Participant Self-Reported Movement Context***:**

Baseline: At baseline (i.e., in early pregnancy), participants in both groups reported ~300 MET-hours per week of total activity which was mainly comprised of 120-130 MET-hours per week of both light and moderate activity with very little vigorous activity, and ~45 MET-hour per week of sedentary activity (**Table 3**). Most of the activity was reported to result from within household and occupational contexts, with limited activity arising from transportation (< 30 MET-hours per week) or sports (~15 MET-hours per week).

Change Within Groups: From early to late pregnancy, the Intervention Group reported a significant decrease in total activity (-32 MET-hours/wk [-57; -6], p=0.01), moderate activity (-25 MET-hours/wk [-43; -7], p=0.006), occupational activity (-19 MET-hours/wk [-38; 0], p=0.04), and sedentary time (-4 MET-hours/wk [-9; 0], p=0.05). Similarly, within the Usual Care Group, participants reported significantly decreased total activity (-39 MET-hours/wk [-65; -12], p=0.01), moderate activity (-34 MET-hours/wk [-53; -15], p<0.001), and occupational activity (-29 MET-hours/wk [-48; -9], p=0.004) from early to late pregnancy (**Table 3**).

Change Between Groups: From early to late pregnancy, the Intervention Group reported an increase in sports participation (2 MET-hours/wk [0; 4], p=0.02) whereas the Usual Care Group reported a decrease in sports participation (-2 MET-hours/wk [-4; 0], p=0.04), resulting in a statistically significant between-group difference (4 MET-hours/week [2; 7], p=0.002) (**Table 3**).

There were no other statistically significant differences between groups over time in self-reported physical activity or sedentary activities.

Table 3. Self-reported physical activity during early and late pregnancy per randomization assignment.

	Intervention			Usual Care			
	Early Pregnancy (N=179)	**Late Pregnancy (N=140)**	**Within-Group Change**	**Early Pregnancy (N=172)**	**Late Pregnancy (N=125)**	**Within-Group Change**	**Between p-va**
Movement Behaviors (MET-hr/wk)							
Total Activity	301 [277; 324]	269 [243; 295]	-32 [-57; -6]*	307 [283; 332]	269 [241; 296]	-39 [-65; -12]*	0.7
Sedentary Time	48 [44; 52]	44 [40; 48]	-4 [-9; 0]*	43 [38; 47]	43 [39; 48]	1 [-4; 5]	0.1
Light Activity	123 [113; 134]	120 [109; 131]	-3 [-14; 8]	129 [119; 140]	124 [113; 136]	-5 [-16; 7]	0.8
Moderate Activity	126 [110; 141]	101 [84; 118]	-25 [-43; -7]*	132 [117; 148]	99 [81; 116]	-34 [-53; -15]*	0.4
Vigorous Activity	3 [3; 4]	3 [3; 4]	0 [-1; 1]	3 [3; 4]	3 [2; 4]	-1 [-1; 0]	0.2
Contextual Behaviors (MET-hr/wk)							
Household Activity	108 [96; 120]	98 [85; 112]	-10 [-21; 2]	112 [100; 125]	103 [89; 117]	-9 [-22; 3]	0.9
Occupation Activity	96 [80; 112]	77 [59; 94]	-19 [-38; 0]*	105 [89; 121]	76 [58; 95]	-29 [-48; -9]*	0.4
Sports Activity	14 [12; 16]	16 [15; 18]	2 [0; 4]*	15 [13; 16]	13 [11; 14]	-2 [-4; 0]*	**0.0**
Transportation Activity	28 [23; 32]	27 [22; 32]	-1 [-7; 5]	26 [21; 31]	26 [21; 31]	0 [-6; 6]	0.8
Sedentary Time	55 [51; 60]	51 [46; 56]	-4 [-9; 1]	49 [45; 54]	51 [45; 56]	1 [-4; 7]	0.1

Data presented as estimated marginal means alongside corresponding 95% confidence intervals with within- and between-group effect estimates and p-values derived from mixed model including fixed effects for time and group as well as the interaction thereof, and a random effect for participant. Model adjusted for body mass index cate enrollment. *, within-group change p<0.05. MET = metabolic equivalent of the energy expended at rest

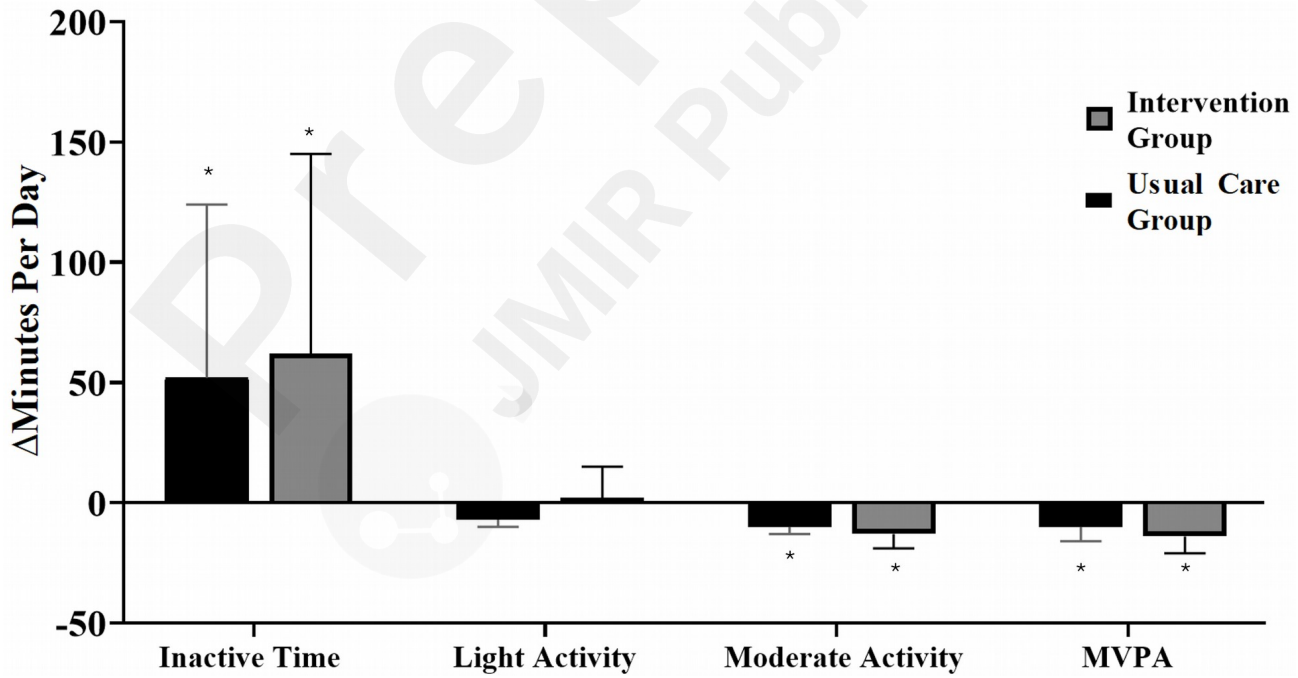

Figure 1. A comparison of physical activity changes from early to late pregnancy assessed via accelerometry between the Intervention and Usual Care groups. *denotes significant within-group change from early to late pregnancy (p<0.05). There were no significant differences between groups for these outcomes. MVPA = moderate to vigorous physical activity.

Movement Duration and Gestational Weight Gain

As there were no statistically significant or clinically meaningful differences in physical activity changes between the Intervention and Usual Care Groups, we combined the groups to evaluate

the effect of movement duration on GWG. Changes in sedentary time (adjusted β [95% CI]: 4 g [-4; 12], p=0.31) or MVPA (-7 g [-32; 18], p=0.57) were not related to study-observed GWG. Similarly, inactivity time (0 g/wk [0; 1], p=0.30) or MVPA (0 g/wk [-1; 1], p=0.49) did not predict weekly GWG. Furthermore, there was no relationship between the change in MVPA and GWG guideline attainment (adjusted odds ratio [95% CI]: 0.99 [0.97; 1.01], p=0.58) or between the change in inactivity and GWG guideline attainment (1.00 [0.99; 1.01], p=0.91).

Discussion

Principal Results

This study assessed the impact of an e-health behavior modification program adapted for pregnant individuals in Louisiana WIC on movement behaviors measured by accelerometry and participant self-report, and its impact on GWG. Almost all participants met the physical activity guideline recommendations of at least 150 minutes per week of MVPA at baseline in early pregnancy (142/145 in the Intervention Group, 146/149 in the Usual Care Group). There were no significant between-group differences in accelerometry-derived physical activity over time, but within both groups, physical activity outcomes measured by accelerometry decreased from early to late pregnancy. In agreement, sedentary time significantly increased similarly across gestation within both groups. In contrast, the Intervention Group reported an increase in sport participation and a significant decrease in sedentary time from early to late pregnancy. Opportunities to sustain an adequate movement behavior across gestation in pregnant women facing economic disadvantages are needed.

Comparison with Prior Work

In this study, both the Intervention and Usual Care Groups demonstrated a decrease in moderate physical activity and total MVPA from early to late pregnancy (range: -14 to -10 minutes/day) and self-reported decreased moderate physical activity and total activity (-25 to -39 MET-hours/ week). These within-group trends were consistent within each BMI category. Our findings are consistent with another study that assessed how a lifestyle intervention based on a brochure (passive) or on in-person education sessions (active) compared to a control group affected physical activity. The study demonstrated a decrease in physical activity from early to late pregnancy within each group (passive, active, or control), but lacked differences between groups showing physical activity decreased for all study participants across pregnancy.[33] Additionally, we found that sedentary time measured objectively with accelerometry increased across pregnancy and in both groups (+52 minutes/day for the Usual Care Group and +62 minutes/day for the Intervention Group), while self-reported sedentary time did not change across pregnancy (-4 MET-hour/week for Intervention Group and 1 MET-hour/week for the Usual Care Group). Our values of sedentary time align with previous investigations in pregnant women (range: 420-760 min/day) and suggest pregnant women increase their sedentary time during pregnancy.[1,4,34]

We used a consultative research approach to inform the physical activity component of the intervention. With the goal of better meeting the needs of underserved women facing economic disadvantages,[17] the feedback from the community stakeholders resulted in the provision of a Fitbit, development of exercise aids (photographs and videos) featuring pregnant women, and the provision of exercise equipment that could be used at home.[17] Even so, the provision of self-

monitoring tools and a passive prescription of physical activity did not increase physical activity across pregnancy. However, the Intervention Group self-reported an increase in sport participation whereas the Usual Care Group reported a decrease. Previous trials have evaluated the effects of MVPA interventions lasting 8 to 30 weeks, varying in intensity from high-intensity, supervised in-person sessions (active interventions) to low-intensity approaches, such as encouraging 10,000 steps per day with self-monitoring (passive interventions).[1,35] These studies demonstrate that the relationship between the intensity of the intervention and the effects on physical activity are closely related. The generally null results of the current trial suggest that interventions promoting physical activity guidelines and providing resources without supervised exercise sessions, may reduce total GWG but are unlikely to significantly impact physical activity levels during pregnancy in underserved, hard-to-reach populations often excluded from biomedical research, even when that intervention was co-developed with stakeholders in the community. Together, this study and others suggest that more intensive interventions are needed to maintain physical activity across pregnancy.[36]

The present trial did not observe a relationship between changes in movement duration and GWG. While our e-Health intervention included a physical activity component, the change in physical activity was not the primary outcome of the intervention. A systematic evaluation of the existing evidence across 18 studies including a total of 1,934 pregnant women found that physical activity interventions in pregnant women result in a decrease of ~0.69 kg (95% CI: -1.30 to -0.08, p=0.03) in total GWG compared to comparator groups.[37] Possible reasons we did not see an effect of change in MVPA or movement behaviors on GWG in the present study may be due to greater physical demands from home chores, family responsibilities, and physically intensive jobs, rather than structured exercise, in this population.[38] Additionally, other lifestyle interventions in socioeconomically disadvantaged individuals have cited barriers to success such as unsafe neighborhoods limiting the ability to exercise, time demands of occupation, and lack of access to exercise equipment.[38] Our intervention provided items to assist utilization of their existing physical environment (e.g., equipment, home-based exercise videos) and social environment (e.g., Facebook group). However, larger policy, systems, and large-scale environmental factors may be needed to maintain or increase physical activity in economically disadvantaged populations.[39] Despite the uncertain impact of physical activity changes on GWG in the present trial, previous trials have demonstrated that physical activity in the perinatal period provides many maternal health benefits, including improved glucose control, reduced systemic inflammation and reduced risks for preeclampsia and gestational hypertension, even without changing GWG. [1,40,41] These measures were beyond the scope of the present trial.

Strengths and Limitations

Strengths of this prespecified secondary outcome analysis of changes in movement behaviors in the context of an innovative e-Health multicomponent lifestyle intervention included multiple methods for assessing movement behaviors across the state of Louisiana in an economically disadvantaged population. We obtained multiple days of objective data in a population that is often hard to reach. Our rigorous randomized controlled trial included masked clinical staff for primary outcomes, thereby minimizing bias outcome assessment. Furthermore, the intervention was developed with input from stakeholders in the community to directly address the needs of pregnant women in WIC and provide targeted assistance tailored to this unique population. Yet,

our study has limitations related to study conduct, movement behavior assessment, and varying interaction levels with the intervention. First, our study was conducted during the COVID-19 pandemic, which may have negatively influenced physical activity habits in our population. Second, the self-report physical activity method may be biased based on participant perception of their daily activities and their health literacy. However, the use of the Actigraph as a device measure of physical activity strengthens the current methodology, and using self-report and device-based measures is considered the best practice for holistic evaluation of physical activity. Even so, there is no consensus on processing data from wrist-worn devices, definition of valid days, or use of cut-points/threshold considerations, though we used methods and analysis software aligning with previous research.[42]

Conclusions

In summary, this secondary analysis of an e-Health multicomponent behavioral lifestyle intervention including guidance to increase physical activity towards national guidelines did not meaningfully impact physical activity outcomes in pregnant women who were enrolled in Louisiana WIC. While the intervention was effective at reducing GWG, our results demonstrate that physical activity decreased from early to late pregnancy across both intervention groups and without effect on GWG. Interestingly, self-reported participation in sports slightly increased in the Intervention Group, suggesting that participants may have perceived themselves to participate in more activities outside of homecare, work, and transportation. Our study provides empirical data in a population of pregnant women who face economic disadvantages and thereby provides a foundation for understanding the importance of multi-level interventions to improve movement behaviors in pregnancy. While our physical activity component was co-developed with our target population, it did not appear intensive enough to support positive physical activity changes in the Intervention Group compared to Usual Care.

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Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations:

GWG: Gestational Weight Gain
MVPA: Moderate to Vigorous Physical Activity
WIC: Women, Infants, and Children

Data Availability: The datasets used and/or analyzed during the current study are available from

the corresponding author on reasonable request.

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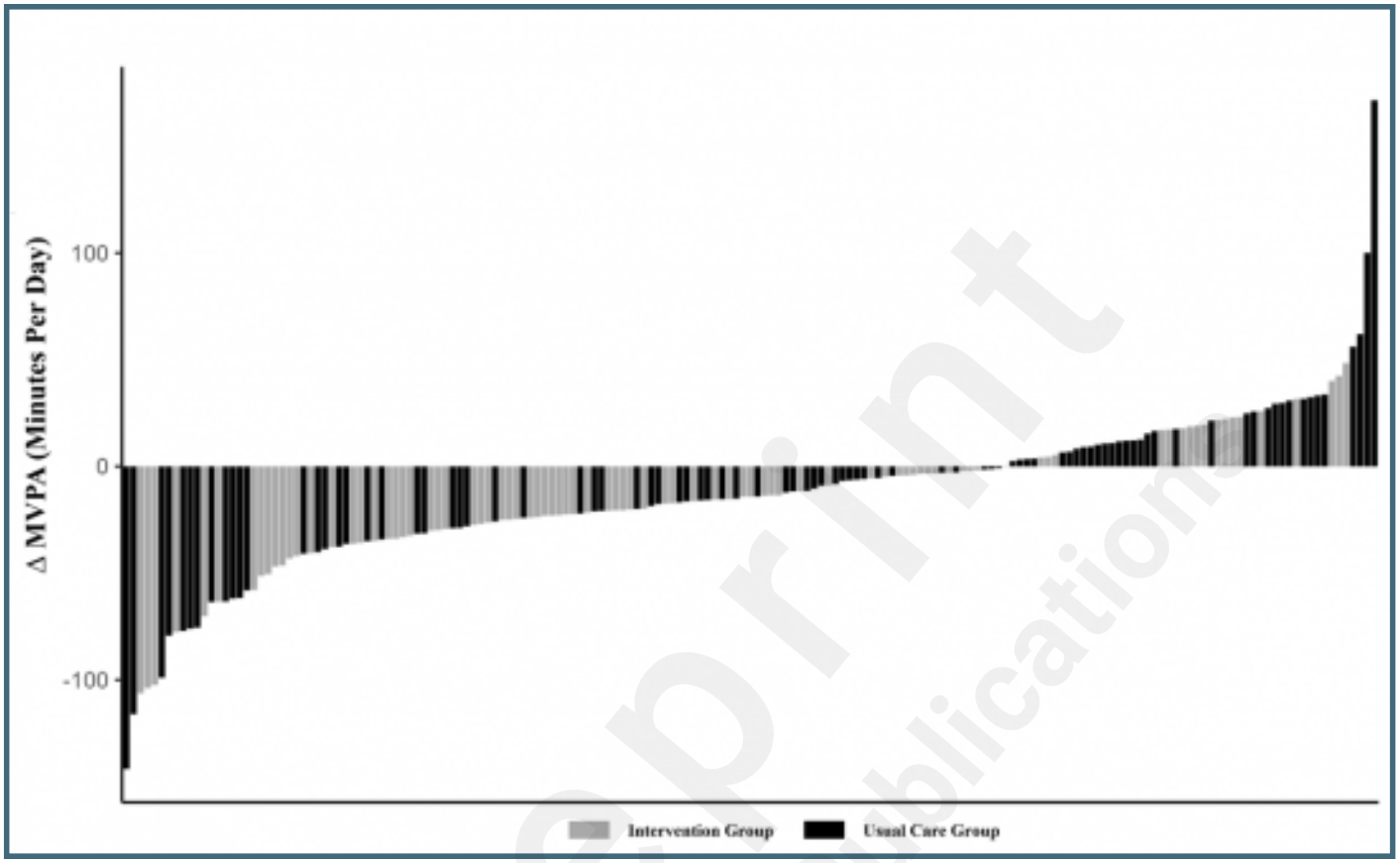
Supplementary Files

Figures

Supplemental figure 1. A waterfall plot demonstrating the change in moderate to vigorous physical activity (minutes per day) from baseline to the end of pregnancy in the intervention group (grey) and usual care group (black).



Multimedia Appendixes

Supplementary table 1. Device-measured physical activity levels during early and late pregnancy per randomization assignment and BMI category.
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