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Randomized Trial to Reduce Cardiovascular Risk in Women with Recent Preeclampsia

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Abstract

Background: To reduce cardiovascular disease (CVD) risk, we tested an online intervention to improve healthy lifestyle for women with recent preeclampsia.
Methods: We conducted a randomized controlled 9-month clinical trial, Heart Health 4 Moms (HH4M), among 151 U.S. women with preeclampsia within 5 years. Sample size was planned to detect differences of 0.5 standard deviation units in primary outcomes between study arms. Preeclampsia history was validated by medical records; women with chronic hypertension were excluded. The intervention included online educational modules, a community forum, and communication with a lifestyle coach. The control group received internet links to CVD risk reduction information. Primary outcomes were self-efficacy to eat a healthy diet and increase physical activity; change in physical in/activity; adherence to the Dietary Approaches to Stop Hypertension (DASH) diet; and knowledge of and personal control over CVD risk. Secondary outcomes were weight and blood pressure.
Results: In the intervention arm, 84% of participants accessed at least one online educational module; 89% completed at least three scheduled calls with the coach. At 9 months, intervention participants reported significantly greater knowledge of CVD risk factors (corrected $p = 0.01$), increased self-efficacy for healthy eating ($p = 0.03$), and less physical inactivity than controls ($p = 0.0006$). The groups did not differ in sense of personal control of CVD risk factors, adherence to the DASH diet, self-efficacy for physical activity, or reported physical activity. There were no differences in secondary outcomes between groups.
Conclusions: The HH4M program improved CVD risk knowledge, self-efficacy to achieve a healthy diet, and reduced physical inactivity among women with recent preeclampsia.

Keywords: preeclampsia, women's health, cardiovascular health, randomized controlled trial, intervention, pregnancy, hypertension

Introduction

In their lifetime, 4%–8% of American mothers will have at least one pregnancy complicated by preeclampsia, a hypertensive disorder defined by new-onset hypertension in pregnancy with proteinuria or systemic manifestations.[1–4] Women with prior preeclampsia have four times the risk of developing chronic hypertension, and have double the risk for coronary heart disease, stroke, and venous thromboembolic events in the decades after pregnancy.[5] Since 2011, the American Heart Association (AHA) has recommended that clinicians consider history of preeclampsia as a risk factor for cardiovascular disease (CVD), and that obstetricians refer women with a history of preeclampsia to primary care

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physicians or cardiologists for monitoring and control of CVD risk factors.[6] Women with a history of preeclampsia have greater body mass index (BMI), blood pressure, and higher levels of glucose, insulin, diabetes, and C-reactive protein, and they tend to develop these risk factors earlier than women with normotensive pregnancies.[7,8] However, many clinicians remain unaware of the implications of preeclampsia for chronic disease, and do not counsel lifestyle modifications that are proven to reduce CVD risk–diet, physical activity, weight management–to women with prior preeclampsia.[9]

To understand the patient experience with primary care providers (including internists, obstetricians, and midwives) and their preferences for programs to reduce cardiovascular risk, we previously conducted focus groups with women from across the United States who had preeclampsia within the past 5 years. Patients said that they were motivated to improve their diet during pregnancy and wanted to continue a healthy lifestyle after pregnancy. Many women experienced preeclampsia as a ''wake up call,'' their first major health event. These findings support the notion that the postpartum period may be a ''window of opportunity'' for behavior change.[10] However, for women with young families, the lack of time to travel and cost of childcare required to participate in face-to-face programs provide major barriers to participation.[11,12]

Internet-based health programs offer the potential to reach patients at home. Previous studies have demonstrated the potential for web-based technology to improve care of chronic diseases, including diabetes, elevated blood pressure, and hypertension,[13] in the general population and for women with a history of gestational diabetes.[14]

Based on the patient-provided recommendations from our focus groups and the potential for the internet to reach the population of women with recent preeclampsia, we conducted a randomized controlled trial of an internet-based lifestyle intervention, Heart Health 4 Moms (HH4M). Our primary aims were to test the extent to which the 9-month intervention would improve self-efficacy (confidence in one's ability to make behavior change)[15] to reduce cardiovascular risk through healthy eating and physical activity; increase adherence to the Dietary Approaches to Stop Hypertension (DASH) diet; increase physical activity; reduce physical inactivity; and improve patient knowledge of CVD risk after preeclampsia as well as sense of personal control over that risk. Secondary aims were to test the extent to which the program would lower weight and blood pressure.

Materials and Methods

Study recruitment

From July 2015 to May 2016, we recruited women living in the United States with recent preeclampsia through the websites and social media (including Facebook and Twitter) of the Preeclampsia Foundation, the March of Dimes Foundation, BabyCenter.com, and Craigslist. Recruitment materials were in English and Spanish.

Participant eligibility

Women were eligible if they had preeclampsia in the past 5 years (this criterion was expanded from 6 months to 5 years to meet recruitment deadlines); were ≥18 and <45 years of age; had systolic blood pressure (SBP) <140 and diastolic blood pressure (DBP) <90 mm Hg; weighed <350 lbs with a BMI between 18.5 and 40 kg/m^2; had access to the internet *via* computer or mobile device using iOS or Android operating systems; and could communicate in English or Spanish at an eighth grade level or above. Women were excluded if they were currently pregnant or had: diabetes, history of cardiovascular or kidney disease, gastric bypass or bowel surgery resulting in malabsorption, active medical problems affecting diet or blood pressure (including eating disorders, drug or alcohol addiction), or medications affecting weight or blood pressure. Women whose baby from the preeclamptic pregnancy had died or was not living at home at the time of enrollment were not included, as the intervention focused on lifestyle change incorporating infants and young children in the home. Inclusion criteria were evaluated through an online recruitment questionnaire, phone screen with a research assistant, medical record abstraction, and review of wirelessly transmitted weight and blood pressure readings. Women who became pregnant during follow-up were asked to discontinue the intervention and complete their final assessment at that point.

Participants signed a medical record release form that allowed study staff to obtain prenatal records, labor and delivery records, delivery discharge summary, and postpartum notes. Two investigators (E.W.S., G.S.) independently reviewed medical records to confirm the diagnosis of preeclampsia, using criteria from the International Society for the Study of Hypertension in Pregnancy: new-onset hypertension after 20 weeks' gestation (SBP >140 mm Hg and/or DBP >90 mm Hg, measured at least twice, 4 hours apart) with positive proteinuria (>300mg by 24-hour urine collection, urine protein:creatinine ratio >0.3, or positive urine dipstick ≥1+).[16] Elevated blood pressures during labor were not counted. Women with proteinuria and only one elevated blood pressure who had a clinician diagnosis of preeclampsia documented in the record were considered to have had preeclampsia. This definition was used to provide consistency in inclusion criteria throughout the years in which participants' preeclampsia was diagnosed.

Women who were eligible following medical record review were mailed an electronic scale (iHealth® Lite Wireless Scale, model HS4; iHealth Lab Inc., Mountain View, CA) and a blood pressure monitor (iHealth® Wireless Blood Pressure Monitor BP5) to verify weight and blood pressure eligibility. Eligible women reviewed the consent form with a research assistant before signing and returning the form to the study team. Participants were then emailed a link to a questionnaire regarding demographics and baseline study measures. Once the questionnaire and measures were completed, participants were randomized to either the control or intervention group using a random number generator in blocks of six. Research assistants interacting with prospective participants during recruitment were unaware to which arm a participant would be randomized.

Control group intervention

The control group received access to the HH4M control website, which included information publicly available on the internet regarding cardiovascular risks associated with

preeclampsia and lifestyle recommendations to prevent CVD. This included links to the Preeclampsia Foundation website regarding cardiovascular risk after preeclampsia (www.preeclampsia.org/health-information/heart-disease-stroke), the AHA's diet and lifestyle recommendations website (https://www.heart.org/en/healthy-living/healthy-eating/eat-smart/nutrition-basics/aha-diet-and-lifestyle-recommendations), the National Institutes of Health's Dietary Approaches to Stop Hypertension website (www.nhlbi.nih.gov/health/health-topics/topics/dash), the National Cancer Institute's smoking cessation website (http://smokefree.gov/), and the American College of Obstetricians and Gynecologists' statement about preeclampsia and future health.[6]

Active intervention

Participants randomized to the intervention group received access to the HH4M lifestyle program website which included: audiovisual modules on topics, including healthy eating, using the balanced plate and modeled on the DASH diet,[17] increasing physical activity, and identifying promoters and barriers to adopting a healthy lifestyle (Appendix Table A1). Since a key to increasing self-efficacy is the actual experience of mastery of skills, lifestyle change was broken down into small changes (one to two per module) to provide the patient with the experience of success.[18] Participants received online badges for completing modules and setting action plans. Participants also received personalized lifestyle coaching from a registered dietitian trained in patient-centered counseling to help them set and meet positive lifestyle goals. Coaching was provided through six scheduled calls and three scheduled emails, with interim *ad hoc* communication as initiated by participants. Participants also had access to an online community forum where they could communicate with each other and the lifestyle coach, as well as a ''toolbox'' of additional resources, including meal plans, recipes, and videos demonstrating exercises that could be done with an infant. The program was designed to deliver the 12 ''core'' modules (Appendix Table A1) and lifestyle coach counseling (four phone calls) in the first 3 months, with continued access to the website materials and two follow-up calls and three emails with the lifestyle coach after 3 months.

Follow-up and assessment of outcomes

Women in both groups received monthly emails thanking them for their participation. All participants underwent three assessments: baseline (prerandomization), 3 months, and 9 months. At each assessment, participants completed online questionnaires that assessed study outcomes and provided measured weight and blood pressure values that were automatically transmitted from the iHealth devices to the secure HH4M website. For these measurements, participants were asked to weigh themselves twice in the morning wearing light clothes and to sit at rest for 5 minutes before taking four blood pressure readings, each 2 minutes apart. The average of the measurements was used in analysis.

Self-efficacy. To assess the primary aim of improving patients' self-efficacy toward achieving and maintaining a healthy diet and level of physical activity, we adapted the validated Sallis Eating Habits Confidence Survey and Exercise Confidence Survey scales.[19]

Dietary change. To measure adherence to the DASH diet, we used the validated DASH Online Questionnaire,[20] a food frequency questionnaire, and adapted it by incorporating items from the validated Arizona Food Frequency Questionnaire[21] to include more foods consumed by Hispanic populations. The questionnaire prompts recall of daily servings of foods and beverages consumed in the past 30 days. We adapted a measure of DASH diet adherence[22] to calculate a DASH score based on daily intake of eight components (fruits, vegetables, nuts and legumes, whole grains, low-fat dairy, sodium, lean meats and poultry, and sweets). Quintile rankings were summed across components to obtain a summary DASH score for each participant that ranged from 8 to 40.

Physical activity and inactivity. To measure physical activity and inactivity, we adapted the Pregnancy Physical Activity Questionnaire,[23] a validated questionnaire for women that includes activities relevant to caring for young children. Our measure ascertained type, duration, and frequency of recreational activity and childcare activity. It also measured inactivity (sedentary behavior), such as reading, using a computer, and watching TV. The time spent in each activity is multiplied by its intensity (metabolic equivalent of task value) to yield the average weekly energy expenditure related to that activity.

Knowledge of and control over CVD risk. We assessed participants' sense that they felt informed about CVD risk based on the question, ''How informed are you about hypertension and heart disease in women who have had preeclampsia?'' (not at all; moderately; well; very well informed). This is modeled on a CVD knowledge question used in an AHA survey.[24] To assess women's sense of personal control over their health, we adapted Kim and Walker's survey on perception of chronic diabetes risk among women with a history of gestational diabetes,[25] using factor analysis (with varimax rotation) to reduce seven items from the Kim scales to a single factor we named ''Personal Control over Cardiovascular Disease Risk.'' The resulting measure had a Cronbach's alpha of 0.73.

Statistical analysis

Overview. We followed the intention-to-treat principle and included all randomized participants. Primary outcomes were analyzed using a mixed effects model for repeated measures (MMRMs), a special form of the general mixed effects regression model for longitudinal data. Specifically, treatment-by-time interaction contrasts provide direct estimates and statistical tests of the difference between intervention groups in mean change from baseline to 3- and 9-month endpoints. An unstructured covariance matrix was used to model the within-subject errors or correlation among the repeated measures on the same subject without making assumptions about within-subject variability. A p-value <0.05 was considered statistically significant. To account for multiplicity due to the analysis of seven primary outcomes, the p-values for the difference in change between the study groups were adjusted using Hochberg's step-up testing procedure for these outcomes at 9 months.[26] For comparison with the literature, we also calculated effect size (ES) of the

intervention as Cohen's *d*. The *p*-values derived from mixed effects model account for baseline values of the outcome, while effect size estimates do not; for this reason, we present only *p*-values from the mixed effects model to assess the role of chance.

Missing data. Missing data ranged from 0% to 9% for primary outcomes, with the exception of the 9-month DASH Food Frequency Questionnaire for which 19% were missing. The MMRM models incorporate partially observed data on subjects; based on a ''missing at random'' assumption, the likelihood-based MMRMs provide valid inferences on intervention effects with incomplete data.

Sample size. Based on previous literature, we calculated that a sample size of 150, evenly split between arms, would yield at least 80% statistical power for two-sided hypothesis tests at $\alpha = 0.05$ to detect ± 0.5 standard deviation (SD) unit differences between study arms in the continuously measured outcomes, such as the self-efficacy scales. One woman was censored shortly after randomization when she moved outside the United States and consequently lost internet connection necessary to complete the outcome assessments. Because we were still recruiting patients at the time she dropped out, we enrolled an additional patient to the intervention arm to compensate for the loss of statistical power.

Patient-centered approach. A patient-centered approach was employed throughout the study.[27] Preeclampsia survivors affiliated with the Preeclampsia Foundation were involved in the design of all intervention content, website layouts, review and interpretation of results, and writing of the article (E.T.).

Institutional approval

The protocol was approved by the Institutional Review Board of Partners Healthcare and all participants provided written informed consent. Study data were collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools hosted at Brigham and Women's Hospital. All analyses were conducted in SAS (version 9.4; SAS Institute, Inc., Cary, NC). There were no significant adverse events reported by participants.

Results

During 11 months, 1,493 women entered the recruitment process by completing an online survey (Fig. 1). We excluded 1,342 women: the majority ($n = 871$; 65%) did not meet study inclusion criteria, while others either declined to participate ($n = 43$, 3%), were lost to follow-up during the recruitment process ($n = 167$, 12%), had unattainable medical records ($n = 1$), or were still in the recruitment process when it closed because we reached our target enrollment ($n = 260$, 19%).

Baseline characteristics of the 151 HH4M study participants are summarized in Table 1. On average, participants were 31.1 years of age, predominantly white non-Hispanic ($n = 124$, 82%) with a college degree ($n = 106$, 70%), overweight or obese ($n = 95$, 63%), and 1.3 years removed from their index preeclamptic pregnancy. Participants were most commonly recruited through the Preeclampsia Foundation ($n = 69$, 46%) or Facebook ($n = 61$, 40%) and lived in 41 states (Fig. 2). Average blood pressures were largely normal; only three women had SBP ≥120 mm Hg or DBP ≥80 mm Hg. Baseline characteristics were well balanced across the control and intervention arms.

During the study, 69% of controls accessed the control website and all but one intervention participant (99%) accessed the intervention website ($p < 0.00001$ for difference between arms). Eighty-four percent of intervention group participants accessed at least one educational module on the website. Eighty-nine percent of intervention group participants completed at least three of the six scheduled calls with the lifestyle coach.

Ten women became pregnant during the study and discontinued the intervention (three before the 3-month assessment; seven between the 3- and 9-month assessments). Another nine women did not complete the final assessment (one lost internet access before the 3-month assessment and eight were lost to follow-up between 3 and 9 months). Retention rates at the end of the 9-month intervention were 93% in the control group and 91% in the intervention group.

At baseline, none of the outcome measures differed significantly between groups. Table 2 presents the primary study results, comparing the difference in change in primary endpoints between control and intervention arms from baseline to 9 months.

At 9 months, the difference between control and intervention arm participants' change in their self-efficacy to eat a healthy diet was statistically significant ($p = 0.005$, Effect Size = 0.5, Hochberg corrected $p = 0.03$). Intervention arm participants had an average healthy eating self-efficacy score of 4.5 (0.6 SD) compared with a score of 4.2 (0.7) in control arm participants; the longitudinally adjusted difference in change over time was 0.2 units higher in the intervention participants than in control participants. There was no difference in change in physical activity self-efficacy between study arms at 9 months ($p = 0.20$, ES = 0.4, corrected $p = 0.60$).

Change in physical activity levels did not differ between study arms. However, physical inactivity (time spent watching television, reading, or on the computer) decreased more in the intervention group than in the control group over time ($p < 0.0001$, ES = −0.5, corrected $p = 0.0006$). At 9 months of follow-up, intervention arm participants decreased their physical inactivity by an average of 7.8 hours per week more than had control arm participants. DASH diet scores remained relatively unchanged in both arms at 9 months.

The degree to which participants felt informed about the risk of hypertension and CVD in women with a history of preeclampsia increased in both groups over follow-up: from 2.0 (0.9) at baseline to 2.5 (0.9) at 9 months in the control participants and from 1.9 (0.8) to 2.7 (0.8) among intervention participants. The increase in knowledge was significantly higher among intervention arm participants ($p = 0.002$, ES = 0.2, corrected $p = 0.01$). Sense of personal control over CVD risk did not differ between arms once corrected for multiple testing ($p = 0.03$, ES = 0.0, corrected $p = 0.12$).

Secondary outcomes were not impacted by the 9-month intervention. Average weight decreased by 0.7 kg in the control and 0.8 kg in the intervention arm, with no significant difference between arms ($p = 0.80$). Mean SBP increased by 2.4 in controls and 0.2 mm Hg in the intervention arm; mean DBP increased by 1.2 in the control arm and 0.6 mm Hg in the intervention arm. These differences were not statistically significant ($p = 0.89$ for SBP and 0.16 for DBP).

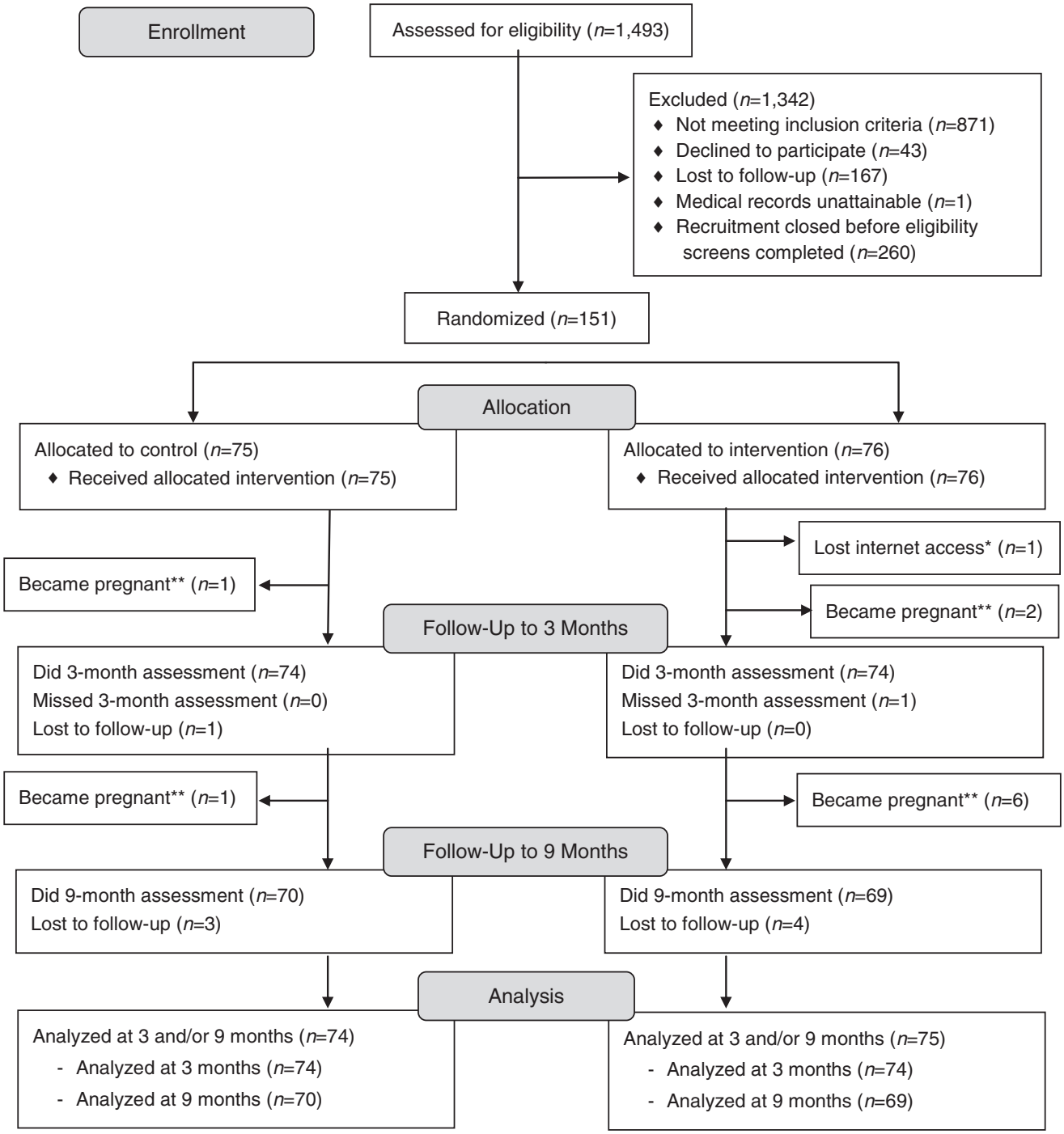

FIG. 1. HH4M participant flow diagram. *One participant moved out of the country and lost internet access; she could not complete 3- or 9-month assessments. **Participants who became pregnant during follow-up discontinued the intervention and completed their final assessments (*i.e.*, final questionnaire and final weight and blood pressure measurements) while pregnant. Women were asked to complete the final questionnaire relating back to the time just before they became pregnant. Women who became pregnant before the 3 or between the 3- and 9-month assessment contribute to the 3- and 9-month assessment totals, respectively, presented here. After completing those assessments, pregnant participants were censored from further follow-up. Among the intervention arm participants, given the 1 woman who lost internet access, the 2 pregnancies before 3 months of follow-up and the 4 participants lost to follow-up between 3 and 9 months, 69 women completed the 9-month assessment. HH4M, Heart Health 4 Moms.

Table 1. Baseline Characteristics of Heart Health 4 Moms Trial Participants by Study Arm

Characteristic	*Control* (n = *75*)	*Intervention* (n = *76*)	p-*Value*
Age, years	31.7 (4.5)	30.5 (4.8)	0.11
Parity, *n* (%)			0.11
One birth	39 (55)	50 (71)	
Two births	26 (37)	15 (21)	
Three or more births	6 (9)	5 (7)	
Time since index pregnancy, years	1.3 (1.2)	1.2 (1.0)	0.44
≤1 year postpartum, *n* (%)	45 (60)	43 (57)	0.67
Recruitment source, *n* (%)			0.14
Preeclampsia Foundation (website, Facebook, or Twitter)	39 (52)	30 (40)	
Facebook	26 (35)	35 (47)	
BabyCenter website	3 (4)	1 (1)	
Craigslist	—	1 (1)	
Doctor referral/clinic flyer	—	4 (5)	
Family/friend	4 (5)	2 (3)	
Other	3 (4)	3 (4)	
Race/ethnicity, *n* (%)			0.87
Non-Hispanic White	63 (84)	61 (80)	
Non-Hispanic African American	2 (3)	2 (3)	
Non-Hispanic Asian	1 (1)	2 (3)	
Non-Hispanic multirace	2 (3)	1 (1)	
Hispanic/Latina	7 (9)	10 (13)	
Level of education, *n* (%)			0.46
Grades 1–8	1 (1)	0 (0)	
High school graduate	5 (7)	2 (3)	
Some college, technical education, or associate's degree	16 (22)	19 (25)	
College degree or higher	52 (70)	54 (72)	
Annual household income, *n* (%)			0.44
Less than $20,000	6 (8)	4 (5)	
$20,000–$24,999	2 (3)	2 (3)	
$25,000–$34,999	6 (8)	3 (4)	
$35,000–$49,999	10 (13)	9 (12)	
$50,000–$74,999	16 (21)	9 (12)	
$75,000+	27 (36)	43 (57)	
Prefer not to answer	8 (11)	6 (8)	
BMI, kg/m^2	27.6 (4.9)	27.3 (5.2)	0.66
BMI categories, *n* (%)			0.87
Normal weight (18.5–24.9)	28 (37)	27 (36)	
Overweight (25.0–29.9)	24 (32)	27 (36)	
Obese (30.0–39.9)	23 (31)	21 (28)	
SBP, mm Hg	112 (10)	112 (8)	0.83
DBP, mm Hg	75 (7)	74 (7)	0.74
Elevated blood pressure,[a] *n* (%)	1 (1)	0 (0)	0.31
High blood pressure: stage 1,[b] *n* (%)	2 (3)	0 (0)	0.15

Values are mean and SD unless otherwise noted. Counts may not sum to $n = 75$ in each arm due to missing data. Percentages may not sum to 100% due to rounding.

[a]SBP: 120–129 mm Hg and DBP <80 mm Hg.

[b]SBP: 130–139 mm Hg or DBP 80–89 mm Hg.

BMI, body mass index; DBP, diastolic blood pressure; SBP, systolic blood pressure; SD, standard deviations.

Interim results at the 3-month assessment (Appendix Table A2) paralleled those at the 9-month endpoint. The exception was greater increase in physical activity self-efficacy in the intervention arm ($p = 0.02$, ES = 0.2), which was no longer evident at 9 months.

Sensitivity analyses

Neither adjustment for income nor parity made any material difference to results. Excluding the 10 participants who became pregnant during the trial had no material effect on estimates.

The per protocol analysis was restricted to the 69% of control arm participants who accessed the control website and the 69% of intervention arm participants who completed at least three contacts with the lifestyle coach and opened at least three modules. Findings were largely similar in the per protocol and intention-to-treat analyses, although the latter had more statistical power (Appendix Table A3).

Discussion

The HH4M web-based intervention, designed with input from patients and the Preeclampsia Foundation, was effective

FIG. 2. Geographic distribution of HH4M participants across the United States. The above map of HH4M participants was created through http://batchgeo.com (BatchGeo LLC).

in improving the knowledge of women with recent preeclampsia regarding their future risk of CVD and their self-efficacy for healthy eating. Women in the intervention group reported large decreases in physical inactivity compared with the control group. There were no differences observed in other primary outcomes: self-efficacy for physical activity, adherence to the DASH diet, personal control over CVD risk, or self-reported physical activity.

The AHA recommended in 2011 that clinicians consider a history of preeclampsia as a CVD risk factor, and physicians implement Class I Lifestyle Recommendations for women with a history of preeclampsia, including: (1) smoking cessation; (2) DASH-like diet; (3) regular physical activity; and (4) weight management.[6] While websites can be found regarding these lifestyle recommendations, no integrated programs have been designed specifically for the needs of women with a history of preeclampsia with an infant or young child at home. Our work has shown that this population faces specific barriers,[11,12] some of which may be overcome with a web-based program that eliminates travel and provides a community of women with similar experiences. Web-based programs may be particularly effective in postpartum populations.[14]

A primary aim of HH4M was to improve self-efficacy of participants to improve their diet and physical activity. Self-efficacy is defined by Bandura as an individual's judgment of his/her capabilities to perform skills to attain a certain outcome.[15] Self-efficacy for new behaviors has been shown repeatedly to predict the attainment and maintenance of new behaviors as well as reattainment if relapse occurs.[18] An increase in self-efficacy positively impacts management of a wide spectrum of chronic diseases.[28]

The changes in self-efficacy achieved in the present study are comparable or greater than those reported for health behavior change in other populations. The effect size (Cohen's *d*) of the change in self-efficacy for healthy eating that we achieved (0.5) was twice that achieved in an online intervention to increase healthy eating in college students (0.2).[29] Similarly, the effect size of the change in self-efficacy for physical activity at 9 months (0.4), while not statistically significant, was large relative to the effect size (0.16) reported by a meta-analysis of 27 interventions aimed at improving self-efficacy for physical activity, which included studies conducted *via* face-to-face and phone counseling sessions; email feedback; and behavior change classes and discussion groups.[30] As we observed a statistically significant increase in self-efficacy for physical activity at 3 months (effect size = 0.2), more work needs to be done to determine what factors led to this loss of self-efficacy for physical activity by 9 months.

In 2004, the AHA surveyed American women including the question, ''How informed are you about heart disease in women?''[24] Responses ranged from 1 (not at all) to 4 (very well) and the mean score was 3.1. When we asked participants ''How informed are you about hypertension and heart disease in women who have had preeclampsia?'' at baseline, scores were 2.0 (control) and 1.9 (intervention) (Table 2). This suggests that women may feel less informed about CVD risk after preeclampsia than about CVD risk in general. By the end of the study, these scores had risen to 2.5 (control) and 2.7 (intervention), with intervention participants reporting a statistically significantly greater increase in knowledge about CVD risk than the control group.

Women in the intervention arm had significantly lower physical inactivity at both 3 and 9 months. Over 9 months, the

Table 2. Difference in Primary Outcomes at Baseline and 9 Months Between Intervention and Control Arms

	Missing	*Within-arm mean (SD)*		*Between-arm difference in change*[a]	p-*Value*[b]	*Corrected* p-*value*[c]	*Effect size*[d]
		Control	*Intervention*				
Self-efficacy[e]							
Eating habits							
Baseline	0	4.3 (0.6)	4.4 (0.6)				
9 Months	13	4.2 (0.7)	4.5 (0.6)	0.2	0.005	0.03	0.5
Physical activity							
Baseline	0	3.9 (0.8)	3.9 (0.7)				
9 Months	13	3.7 (1.0)	4.0 (0.7)	0.1	0.20	0.60	0.4
Behavior							
Physical activity, METs/week							
Baseline	0	26.3 (20.1)	23.5 (16.8)				
9 Months	10	25.8 (18.2)	26.6 (19.5)	–0.5	0.87	0.87	0
Physical inactivity, hours/week							
Baseline	0	24.4 (14.9)	22.7 (15.3)				
9 Months	10	22.7 (16.5)	16.5 (10.7)	–7.8	<0.0001	0.0006	–0.5
DASH diet score[f]							
Baseline	0	23.1 (4.8)	24.4 (4.9)				
9 Months	26	23.6 (4.8)	24.5 (4.7)	0.2	0.81	0.87	0.2
Cardiovascular disease risk knowledge and sense of control[g]							
Feel informed about cardiovascular disease risk							
Baseline	0	2.0 (0.9)	1.9 (0.8)				
9 Months	13	2.5 (0.9)	2.7 (0.8)	0.4	0.002	0.01	0.2
Feel personal control over cardiovascular disease risk[h]							
Baseline	0	3.2 (0.4)	3.2 (0.4)				
9 Months	13	3.2 (0.4)	3.2 (0.4)	0.1	0.03	0.12	0.0

[a]Intervention minus control difference in the change in the outcome from baseline to 3 and baseline to 9 months, respectively.
[b]*p*-Values obtained for the contrast between baseline and each follow-up time point.
[c]*p*-Values for primary outcomes are corrected for multiple comparison testing by the Hochberg method.
[d]Standardized mean difference (Cohen's *d*).
[e]Range of possible values: 1 (low self-efficacy)–5 (high self-efficacy).
[f]Range of possible values: 8 (low DASH diet compliance)–40 (high DASH diet compliance).
[g]Range of possible values: 1 (low knowledge/control)–4 (high knowledge/control).
[h]Score was built by averaging seven items identified through factor analysis.
DASH, Dietary Approaches to Stop Hypertension.

intervention group's physical inactivity fell by 27%, compared with 7% in the control group. The effect size (–0.5) is slightly higher than the effect size (–0.4) from a meta-analysis of six controlled trials of combined physical activity and sedentary behavior interventions,[31] suggesting that new mothers are able to reduce inactivity at least as much as other population groups.

We did not see concomitant increases in physical activity in the intervention arm. Self-report questionnaires, such as the one we used, can be insensitive to change in light-intensity physical activities, which may explain the discrepancy between the large drop in inactivity and the lack of a corresponding increase in activity.[32] An objective measure of physical activity, such as accelerometer, may improve measurement in future studies.

We saw no improvement in the DASH diet score despite improvements in self-efficacy for healthy eating. Some of our dietary counseling departed from the original DASH diet, to reflect updated standards of healthy eating. For example, the Lifestyle Coach counseled against excessive fruit juice consumption, and advised patients to switch healthy fats for unhealthy fats (*e.g.*, replace trans fats or saturated fats with monounsaturated and polyunsaturated fats). The online food frequency questionnaire we utilized may not have been as sensitive to diet change as food records or 24-hour recall, which have more participant burden.

The HH4M intervention did not have an impact on the secondary outcomes of weight loss or fall in blood pressure. The main emphasis of the intervention was healthy eating rather that weight reduction. However, as 60% of the population had a BMI $\geq 25\,kg/m^2$, future iterations may benefit from an emphasis on weight loss for women with overweight or obesity. All study participants except three had baseline normal blood pressure (<120 mm Hg SBP and <80 mm Hg DBP). As per protocol, we excluded women who developed chronic hypertension between pregnancy and study recruitment. As a result, women who progressed from elevated blood pressures to chronic hypertension within 5 years of pregnancy (our recruitment window) may have been missed by our study. However, as 58% of participants were less than a year since pregnancy, this is unlikely to be a large reason we observed, on average, normal blood pressures. Given the normal blood pressure profile of the cohort, no fall in blood pressure would be expected from the DASH diet.[33] However, the DASH diet may be effective in lowering blood pressure in women with a history of preeclampsia with higher blood pressures.

In the HH4M intervention arm, 84% of participants accessed at least one online educational module and 89% completed at least three scheduled calls with the coach. Two successful lifestyle intervention programs used remote education and counseling to reduce postpartum weight retention in women with recent gestational diabetes. The Balance after Baby intervention[14] recruited women from the Boston area and provided web-based educational modules and lifestyle counseling delivered *via* telephone and/or email; 50% of participants self-reported completion of 9 per 12 modules and 50% completed 7 per 12 lifestyle coach contacts. The Gestational Diabetes' Effects on Moms program recruited women from an integrated health care delivery system (Kaiser Permanente Northern California Perinatal Center) to offer a printed lifestyle guidebook and telephone-based lifestyle counseling; 50% of participants completed one or more telephone sessions with the coach.[34] Although not directly comparable—HH4M participants were recruited *via* the internet and received neither in-person clinic or study contact—the degree of HH4M participant engagement with HH4M's resources falls within the range of these studies. In the future, engagement with HH4M may be increased by the use of an application (app) for easy access or by integrating HH4M within a clinical care system.

One of the study's strengths was that it recruited women from 41 states. A limitation of the study is that participants were predominantly white and educated beyond high school. Most women found out about HH4M because they were proactive enough to seek out information about preeclampsia from the Preeclampsia Foundation website or Facebook. As a result, it is likely that the women in our study had greater self-efficacy and a healthier lifestyle at baseline than might be expected in a population that did not self-refer; this may explain why our participants had lower weight and blood pressure than suggested by studies following women after preeclampsia.[35,36] A more diverse population of women, such as those referred to HH4M by a clinician, might benefit even more from HH4M's health empowerment, information, and coaching. It is important to also note that the control group received more information than most women receive as ''usual care,'' in which many clinicians are unaware of, or do not communicate, the increased risk of CVD to mothers with a history of preeclampsia, nor provide counseling to reduce that risk.[9,11,12] The enhancement of the control arm might lead to an underestimation of the potential impact of implementing HH4M in actual care settings.

The HH4M is, to our knowledge, the first trial of an intervention to reduce CVD risk in women with a history of preeclampsia. With patient input, we created an educational resource that is easy for new mothers to access, designed specifically to address their history of preeclampsia and its future health implications, and tailored to their changing lifestyle as new mothers. Taking into account feedback from participants, the next iteration of HH4M will include a mobile app that will enhance or add features that participants found especially valuable. Targeted health apps may be an effective way to reach groups that identify with shared health history and concerns.

Conclusions

This trial demonstrates that women with recent preeclampsia will actively engage for many months with a web-based program to improve their long-term cardiovascular health. After 9 months, the primary goals of the HH4M lifestyle intervention to increase self-efficacy for healthy eating, to increase CVD risk knowledge, and decrease physical inactivity were achieved. The other primary goals of increasing physical activity, increasing adoption of a modified DASH diet, and enhancing a sense of personal control over CVD risk were not achieved. The HH4M provides a model for an online, easily accessible lifestyle program to improve CVD risk factors in women with recent preeclampsia.

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(Appendix follows →)

Appendix Table A1. Heart Health 4 Moms Online Educational Module Topics

Twelve core modules
Module 1: Welcome to HH4M!
Module 2: Eating the DASH Way
Module 3: Part 1: Getting Support: Who's on My Team? Part 2: Giving Support: How Can I Help?
Module 4: Balancing My Plate with DASH
Module 5: Less Salt, More DASH!
Module 6: My Healthy Weight
Module 7: Let's Get Active!
Module 8: What Makes Up Our Food?
Module 9: Nutrition Labels: What? Where? Why?
Module 10: Staying on Track
Module 11: Getting the Most Out of Your Health Care
Module 12: What's Next?
Seven bonus modules
Eating Out: Take DASH with You
Healthy Choices for Holidays and Special Events
Identifying Triggers and Managing Cravings
Healthy Snacking on the Go
Breastfeeding Maintenance and Nutrition
Breastfeeding and Nutrition (Part 2)
Living a Smoke-Free Lifestyle

DASH, Dietary Approaches to Stop Hypertension; HH4M, Heart Health 4 Moms.

Appendix Table A2. Difference in Primary Outcomes at Baseline and 3 Months Between Intervention and Control Arms

		Within-arm mean (SD)				
	Missing	*Control*	*Intervention*	*Between-arm difference in change*[a]	p-*Value*[b]	*Effect size*[c]
Self-efficacy[d]						
Eating habits						
Baseline	0	4.3 (0.6)	4.4 (0.6)			
3 Months	4	4.3 (0.6)	4.5 (0.4)	0.3	0.01	0.4
Physical activity						
Baseline	0	3.9 (0.8)	3.9 (0.7)			
3 Months	3	3.7 (0.9)	3.9 (0.8)	0.3	0.02	0.2
Behavior						
Physical activity, METs/week						
Baseline	0	26.3 (20.1)	23.5 (16.8)			
3 Months	8	30.4 (22.0)	28.8 (19.7)	2.2	0.46	–0.1
Physical inactivity, hours/week						
Baseline	0	24.4 (14.9)	22.7 (15.3)			
3 Months	8	25.0 (17.6)	16.1 (9.3)	–4.9	0.01	–0.6
DASH diet score[e]						
Baseline	0	23.1 (4.8)	24.4 (4.9)			
3 Months	2	22.4 (5.0)	23.2 (5.9)	–0.04	0.73	0.2
Cardiovascular disease risk knowledge and sense of control[f]						
Feel informed about cardiovascular disease risk						
Baseline	0	2.0 (0.9)	1.9 (0.8)			
3 Months	4	2.4 (1.0)	2.7 (0.8)	0.3	0.04	0.3
Feel personal control over cardiovascular disease risk[g]						
Baseline	0	3.2 (0.4)	3.2 (0.4)			
3 Months	4	3.2 (0.4)	3.3 (0.3)	0.0	0.99	0.3

[a]Intervention minus control difference in the change in the outcome from baseline to 3 and baseline to 9 months, respectively.
[b]*p*-Values obtained for the contrast between baseline and each follow-up time point.
[c]Standardized mean difference (Cohen's *d*).
[d]Range of possible values: 1 (low self-efficacy)–5 (high self-efficacy).
[e]Range of possible values: 8 (low DASH diet compliance)–40 (high DASH diet compliance).
[f]Range of possible values: 1 (low knowledge/control)–4 (high knowledge/control).
[g]Score was built by averaging seven items identified through factor analysis.
METs, metabolic equivalent of tasks.

Appendix Table A3. Per Protocol Analysis of Difference in Outcomes of Interest at 3 and 9 Months Between Intervention and Control Arms, Among Participants Defined as Adherent (the 69% of Control Participants Who Logged on to the Control Website and the 69% of Intervention Participants Who Completed at Least Three Lifestyle Coach Contacts and Accessed at Least Three Core Learning Modules)

		Within-arm mean (SD)		*Between-arm difference in change*[a]	p-*Value*[b]	*Effect size*[c]
	Missing	*Control*	*Intervention*			
Self-efficacy[d]						
Eating habits						
Baseline	0	4.3 (0.5)	4.4 (0.6)			
3 Months	1	4.2 (0.6)	4.6 (0.4)	0.3	0.001	0.8
9 Months	3	4.2 (0.7)	4.6 (0.4)	0.3	0.002	0.7
Physical activity						
Baseline	0	3.9 (0.7)	3.8 (0.7)			
3 Months	1	3.6 (0.9)	3.9 (0.7)	0.5	0.002	0.4
9 Months	3	3.6 (1.0)	4.1 (0.6)	0.3	0.03	0.6
Behavior						
Physical activity, METs/week						
Baseline	0	25.1 (20.9)	24.2 (16.3)			
3 Months	2	28.9 (20.8)	28.4 (16.3)	2.9	0.37	0
9 Months	2	24.4 (17.0)	27.2 (18.9)	–0.8	0.80	0.2
Physical inactivity, hours/week						
Baseline	0	24.5 (14.7)	22.2 (15.0)			
3 Months	2	26.3 (17.3)	16.6 (10.0)	–4.9	0.01	–0.7
9 Months	2	22.2 (16.8)	17.2 (11.5)	–7.8	<0.0001	–0.4
DASH diet score[e]						
Baseline	0	22.8 (4.9)	25.0 (4.8)			
3 Months	0	22.1 (5.4)	23.6 (6.0)	0	0.95	0.3
9 Months	4	23.3 (5.1)	24.8 (4.4)	0.5	0.66	0.3
Cardiovascular disease risk knowledge and sense of control[f]						
Feel informed about risk						
Baseline	0	2.1 (1.0)	2.0 (0.7)			
3 Months	1	2.5 (1.0)	2.8 (0.8)	0.2	0.32	0.3
9 Months	3	2.6 (1.0)	2.8 (0.7)	0.3	0.07	0.2
Personal control over cardiovascular disease risk[g]						
Baseline	0	3.3 (0.4)	3.2 (0.4)			
3 Months	1	3.2 (0.4)	3.2 (0.4)	0.0	0.78	0
9 Months	3	3.3 (0.4)	3.2 (0.4)	0.1	0.08	–0.3

[a]Intervention minus control difference in the change in the outcome from baseline to 3 and baseline to 9 months, respectively.
[b]*p*-Values obtained for the contrast between baseline and each follow-up time point.
[c]Standardized mean difference (Cohen's *d*).
[d]Range of possible values: 1 (low self-efficacy)–5 (high self-efficacy).
[e]Range of possible values: 8 (low DASH diet compliance)–40 (high DASH diet compliance).
[f]Range of possible values: 1 (low knowledge/control)–4 (high knowledge/control).
[g]Score was built by averaging seven items identified through factor analysis.