HYPERTENSION IN PREGNANCY

Hypertension in Pregnancy

ISSN: (Print) (Online) Journal homepage: www.tandfonline.com/journals/ihip20

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To cite this article: Wilson Koike, Maria Laura Costa, José Paulo Guida, James M Roberts, Ana Paula Martins, Larissa Martinez Soldá, Vitor Lira Vilela dos Reis, Tábata Regina Zumpano dos Santos, Richard J McManus & Leandro De Oliveira (2025) LifeAPP: self-monitoring of blood pressure after preterm preeclampsia: a randomized controlled feasibility trial, Hypertension in Pregnancy, 44:1, 2439312, DOI: 10.1080/10641955.2024.2439312

To link to this article: https://doi.org/10.1080/10641955.2024.2439312

Published online: 27 Feb 2025.

HYPERTENSION IN PREGNANCY
2025, VOL. 44, NO. 1, 2439312
https://doi.org/10.1080/10641955.2024.2439312

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LifeAPP: self-monitoring of blood pressure after preterm preeclampsia: a randomized controlled feasibility trial

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ABSTRACT

Objective: This was a pilot study to investigate the feasibility of developing a low-cost mobile technology-based intervention to encourage blood pressure (BP) monitoring and adoption of healthy lifestyle habits.

Methods: This was a prospective, controlled, randomized, non-blinding feasibility study that involved the use of electronic BP monitor and smartphone. Eligible participants in the intervention group were instructed to send the BP measurements to members of the LifeAPP team digitally from an application for smartphones linked to the BP device by Bluetooth and also via WhatsApp. The LifeAPP team sent feedback containing information as follows: a) safety of the BP levels; b) motivational messages aiming at maintaining self-monitoring; c) motivational messages aiming at the importance of developing healthy lifestyle habits. The primary outcome was feasibility: recruitment capacity, retention, and compliance with follow-up rates.

Results: Between 1 June 2020 and 24 January 2021, 48 participants were randomized to the intervention group, and 48 participants were randomized to the control group. The recruitment capacity of the participating centers proved to be adequate. Among the participants recruited for intervention group, 21 (43.7%) attended predefined visits at 3 months and only 12 (25%) attended predefined visits at 6 months. Similar loss to follow-up was observed in the control group.

Conclusion: Despite successful recruitment of a cohort of women following preterm preeclampsia, there was no sufficient retention of participants. Therefore, new strategies for long-term follow-up of women who developed preeclampsia are needed before a further study in this group of patients can be contemplated.

ARTICLE HISTORY
Received 10 September 2024
Accepted 2 December 2024

KEYWORDS
Preeclampsia; gestational hypertension; cardiovascular disease; self-monitoring of blood pressure; healthy lifestyle

Introduction

Cardiovascular diseases (CVD) are important causes of morbidity and mortality among women worldwide (1). Several risk factors are involved in the increased prevalence of CVD, including gestational hypertension and preeclampsia (2). Preeclampsia (PE) is a multisystemic disease responsible for high rates of maternal and perinatal morbidity and mortality, mainly in low- and middle-income countries (3,4). The pathophysiology of PE has similarities with some mechanisms of CVD, such as oxidative stress, endothelial dysfunction, and metabolic diseases (5). Meta-analysis of 25 studies (3,488,160 women, 198,252 with a history of PE) demonstrated that women with a history of PE had higher risks of developing chronic hypertension [Relative Risk (RR) = 3.7], coronary heart disease (RR = 2.16), stroke (RR = 1.81), and thromboembolism (RR = 1.79) than women with pregnancies without PE (6). Similarly, another systematic review demonstrated that women with a history of PE or eclampsia were at significantly increased odds of fatal or CVD [odds ratio (OR) = 2.28], cerebrovascular disease (OR = 1.76), and hypertension (RR = 3.13) (7).

Despite the impact of PE on CVD risks, few evidence-based interventions have been evaluated to reduce these risks in high-income countries. But none of these interventions have been investigated in low- and middle-income countries. Regarding chronic hypertension, self-monitoring of BP in conjunction with co-interventions (including systematic medication titration by doctors, pharmacists, or patients; education; or lifestyle counseling) leads to BP reduction which persists for at least 12 months and therefore has the potential to reduce the risks of CVD in general population (8).

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The literature on self-monitoring of BP in the postpartum period is scarce, mainly after PE. One of the authors of this study (Dr. McManus) has been conducting new studies on the subject. A feasibility study conducted in the United Kingdom (SNAP-HT) demonstrated that self-monitoring and self-management of BP was feasible among women who had gestational hypertension or PE and were discharged from hospital after delivery on antihypertensive medications, potentially leading to lower BP even years after the intervention (9). Participants from the SNAP-HT were invited to participate in a Clinical Trial to investigate whether postpartum self-monitoring would lead to better long-term BP control (10). Authors demonstrated that reductions in diastolic BP at 6 months, following self-management of BP postpartum, are maintained 3.6 years later as measured by lower 24-hour diastolic BP.

The SNAP-HT study presented good results regarding retention of patients and possible effect of the self-monitoring on BP control among postpartum women in the United Kingdom. Additionally, the clinical trial developed after the SNAP-TH study demonstrated that this sort of monitoring may have any impact on the risks of CVD after a pregnancy with PE. However, these hypotheses have not been tested in large clinical trials elsewhere. Therefore, the main objective of the LifeAPP (Life After a Pregnancy with Preeclampsia) was to investigate the feasibility of developing a low-cost mobile technology-based intervention to encourage BP monitoring and adoption of healthy lifestyle habits during the first year postpartum among women who had preterm preeclampsia.

Methods

Study design

This was a prospective, controlled, randomized, non-blinding feasibility study involving electronic devices: an electronic BP monitor and smartphone.

Eligible participants were women aged 18 years or older who received the diagnosis of preterm preeclampsia and gave birth at one of the two participating centers (Botucatu Medical School – Botucatu São Paulo State University, the coordinator center, and the University of Campinas – CAISM/UNICAMP). Preeclampsia definition followed the International Society for Study of Hypertension in Pregnancy criteria (11). Preterm preeclampsia was defined as the disease presenting after 20 gestational weeks, but before 37 weeks. Participants also needed to have internet/smartphone access. Predefined exclusion criteria were the presence of other comorbidities that could require individualized monitoring (kidney disease, diabetes requiring insulin treatment and the beginning of a new pregnancy).

All eligible participants were approached between day 1 and day 3 postpartum, always before hospital discharge. Participants randomized to the intervention group received instructions on how to perform self-monitoring of BP using a device (Incoterm Mp100 – Brazilian Regulatory Agency registration number: 10343209009) provided by the investigators. All participants in this group were instructed to send the measurements achieved to members of the LifeAPP team (Dr. Wilson Koike and Dr. Ana Paula Martins) digitally from an application for smartphones linked to the BP device by Bluetooth and also via WhatsApp. Blood pressure monitoring should be performed at least 3 times a week during one year after childbirth, regardless of the use of antihypertensive medications. Upon receiving the results, the LifeAPP team was trained to send feedback containing information as follows: a) safety of the reported BP levels (<140 × 90 mmHg and asymptomatic), as well as guidance on whether the levels were considered high (≥140 × 90 mmHg and < 150 × 100 mmHg), very high (≥150 × 100 mmHg) or low (diastolic BP <60 mmHg), and necessity of medical assistance; b) motivational messages aiming at maintaining self-monitoring; c) motivational messages aiming at the importance of developing healthy lifestyle habits were sent weekly to participants in the intervention group.

Participants randomized to the intervention group were instructed to attend visits with nurses and clinicians of the participating centers at 3, 6, and 12 months postpartum. Participants randomized to the control group were instructed to perform BP monitoring according to local health system guidelines and schedule regular visits with nurses and clinicians of the participating centers at 3, 6, and 12 months postpartum. Free public transport was provided to all patients (control an intervention group), and the longest distance from residences to health units was 20 miles.

Local guidelines advise patients to seek medical assistance if they experience any symptoms such as headache or visual disturbances. Patients are also advised to visit local health units to assess their BP periodically. Therefore, for this project, patients recruited for control group did not receive BP monitors.

The objective of the study was not to evaluate the impact of the intervention on treatment of hypertension or adoption of healthy lifestyle habits. But rather the possibility of having adequate patient recruitment and retention to develop a large clinical trial to evaluate the impact of the intervention based on self-monitoring of BP on risk reduction for CVD. Therefore, the primary outcome was feasibility: recruitment capacity, retention, and compliance with follow-up rates. The

predefined success criteria were attrition rate <20%, compliance with follow-up visits rate >90%, and no site should contribute with <5% of participants.

Secondary outcomes included differences in BP levels during self-monitoring (systolic BP and diastolic BP) and adherence to healthy lifestyle habits (self-reported).

Phone calls (predefined in ethics application) were planned to talk to participants and identify reasons for possible loss to follow-up or incomplete submission of information.

The SNAP-HT Trial randomized 91 women: 45 to self-monitoring group and 46 to usual care group. Based on the SNAP-HT study, with a sample of 96 women, the full study would have 80% power to demonstrate the feasibility of conducting a larger clinical trial to compare self-monitoring of BP using a smartphone app versus usual monitoring among Brazilian women who had a pregnancy with preterm PE. This number was considered sufficient for a feasibility study (12).

Women were randomized in a 1:1 ratio to intervention or usual postnatal care. The randomization sequence was computer-generated, and a secure web-based randomization software was used to ensure allocation concealment. Neither participants nor investigators were masked. Outcome measurement was not blinded but used automated BP monitors to minimize investigator bias.

Standard methods were used for the descriptive tables. Continuous variables were summarized as means with SD or median with IQR and categorical variables as counts and percentages. As our main outcomes were recruitment and retention rates, with predefined success criteria, these results are presented as descriptive data. A formal statistical comparison (p values) was not given to the results because any differences between groups at this point must arise by chance (if randomized properly).

The trial was registered at The Brazilian Registry of Clinical Trials (REBEC): RBR-6hwx3k

Results are presented in accordance with the Consort 2010 Statement: extension to randomized pilot and feasibility trials (13).

Results

Between 1 June 2020, and 24 January 2021, 120 eligible women were approached for the study. Of these, 24 women refused to participate, and 96 women agreed to participate and gave informed consent: 48 were randomized to the intervention group, and 48 were randomized to the control group (usual care). The flow of participants is shown in Figure 1. Regarding predefined visits, of the 48 participants randomized to the intervention group, 1

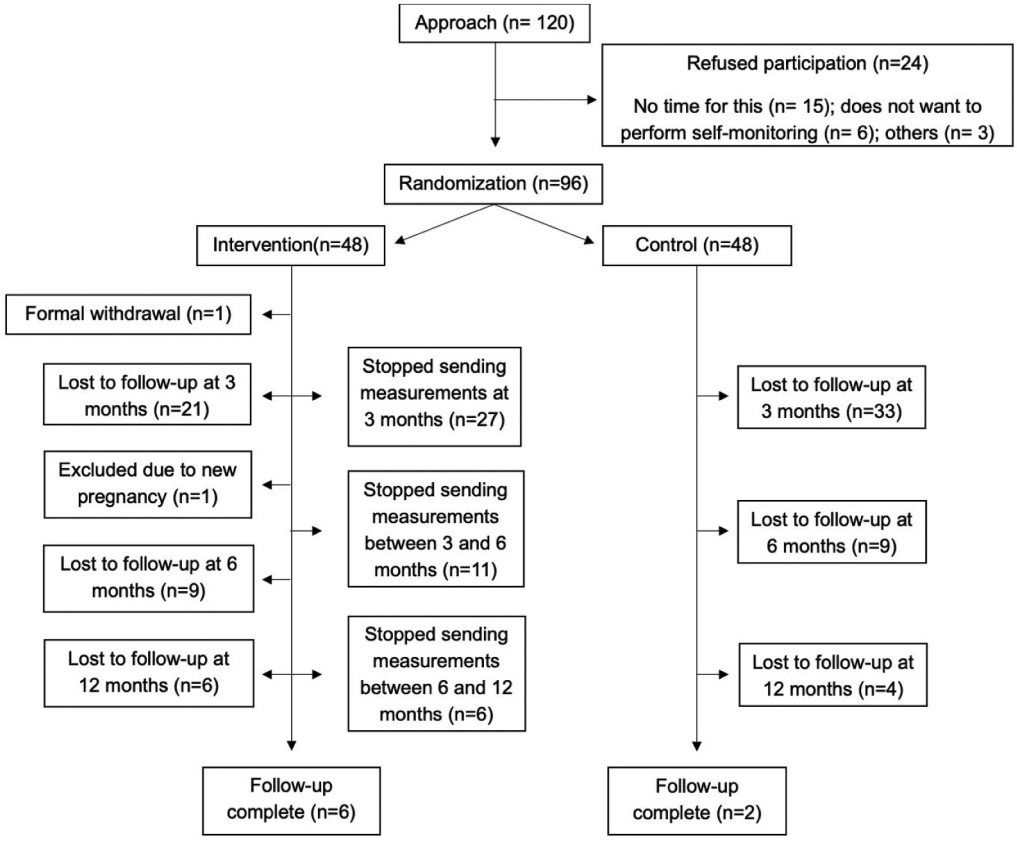

Figure 1. Flow through the trial.

withdrew consent, 1 was excluded between 1 and 3 months due to a new pregnancy, 24 were lost to follow-up at 3 months, 9 were lost to follow-up at 6 months, and 6 were lost to follow-up at 12 months. Of the 48 participants randomized to the control group, 33 were lost to follow-up at 3 months, 9 were lost to follow-up at 6 months, and 4 were lost to follow-up at 12 months. Six participants (12.5%) completed one-year follow-up in the intervention group and 2 (4.2%) completed one-year follow-up in the control group.

Characteristics at enrollment are shown in Table 1. Severe features including eclampsia, imminent eclampsia, and HELLP syndrome were more frequent in the intervention group.

Table 2 shows data regarding feasibility measures. The recruitment capacity of the participating centers proved to be adequate, with 80% of the approached women accepting to participate. The randomization rate was 12 participants per month. The retention rate was not adequate. Among the participants recruited for intervention group, 21 (43.7%) attended predefined visits at 3 months and only 12 (25%) attended predefined visits at 6 months. Similar loss to follow-up was observed in the control group. The small number of participants that completed the follow-up and provided information on BP control and the adoption of healthy lifestyle did not allow statistical analyses.

Table 3 shows mean blood pressure at predefined visits. The high rates of loss to follow-up did not allow the characterization of BP levels in order to compare the groups. A phone call (predefined in ethics application) was made to ask participants the reasons for the loss to follow-up. Regarding this investigation, 28 participants from the intervention group and 24 participants from the control group reported specific reasons. These results are demonstrated in Table 4 of which a lack of time and social isolation due to the COVID-19 pandemic were the most commonly reported reasons. Interestingly, 6 patients from each group reported controlled BP as the reason for no adherence. Two patients (7.2%) from the intervention group and 7 (29.2%) patients from the control group reported distance from home to health unit as the reason for no adherence.

Twenty-six participants (54.2%) in the intervention group reported checking the messages of encouragement to adopt a healthy lifestyle. However, the extent of loss to follow-up did not allow the characterization of such adherence.

Table 1. Demographic characteristics.

	Control (48)	Intervention (48)
Variable		
Age (Mean, SD)	28.8 (7.3)	28.4 (7.5)
BMI at the beginning of prenatal care (Mean, SD)	30.2 (5.6)	29.9 (5.9)
Ethnicity		
White	40 (83.7%)	38 (80%)
Black	5 (10.8%)	1 (2.5%)
Brown	3 (5.4%)	9 (17.5%)
Other	0	0
Education		
Total years of fulltime education Median (IQR)	11.0 (9.0,12.0)	11.0 (9.0,11.5)
Parity		
0	20 (41.6%)	28 (58.3%)
1	10 (20.8%)	5 (10.4%)
≥2	18 (37.5%)	15 (31.2%)
Obstetrics history		
Previous pre-eclampsia (n/women with 1 or more deliveries)	9 (18.9%)	3 (6,5%)
Chronic hypertension	18 (37.8%)	4 (9%)
Gestational or type 2 diabetes	3 (6.2%)	2 (5%)
Days of hospitalization before delivery	3 (3.3)	3.4 (3.6)
Days of postpartum hospitalization	4 (1.9)	4.2 (2.8)
Gestational age at birth (Mean, SD)	34.3 (3.1)	35.3 (2.5)
Indications for delivery		
Reached 37 gestational weeks	14 (29.1%)	19 (39.5%)
Uncontrolled blood pressure	13 (27.0%)	18 (37.5%)
Fetal distress	6 (12.5%)	5 (10.4%)
Eclampsia	2 (4.1%)	0
Imminent eclampsia	2 (4.1%)	0
HELLP syndrome	5 (10,4%)	1 (2.0%)
*Others	6 (12.5%)	5 (10.4%)
Mode of delivery		
Vaginal	7 (15%)	8 (16.6%)
Cesarean	41 (85%)	40 (83.4%)

*Others = Spontaneous labor, premature rupture of membranes, fetal growth restriction.

Table 2. Feasibility measures – LifeAPP.

Recruitment			
Recruitment rate	80% (96 randomized, 120 approached)		
Consent rate	80% (96 randomized, 120 approached)		
Retention rate (Primary outcome)	Whole population ($n = 96$)	Intervention ($n = 48$)	Control ($n = 48$)
3 months	40 (41.6%)	21 (43.7%)	15 (31.3%)
6 months	18 (18.7%)	12 (25%)	6 (12.5%)
12 months	8 (8.3%)	6 (12.5%)	2 (4.2%)
Participants who reported to check messages of encouragement along the study (only intervention group)	-	26 (54.2%)	-

Table 3. Mean blood pressure at follow-up.

	Day 1–3	Day 10	1 Month	3 Months	6 Months	12 Months
Nº of participants in the intervention group	48	38	25	21	12	6
I, SBP, mmHg (mean [SD])	135.5 (3.7)	120.8 (14.3)	116.7 (17.3)	118.8 (21.8)	111.4 (16)	114.5 (5.6)
I, DBP, mmHg (mean [SD])	86.7 (2.5)	81.2 (12.6)	77 (14)	74.4 (13.8)	74.3 (12)	79.7 (4.8)
Nº of participants in the control group	48	35	28	15	6	2
C, SBP, mmHg (mean [SD])	135.5 (3.6)	115.0 (7.9)	116.2 (10.5)	116.9 (12)	121 (14.3)	115 (5)
C, DBP, mmHg (mean [SD])	86.5 (3.6)	74.9 (6.8)	78.4 (8.0)	79 (8.2)	84 (9.3)	80 (0)

I: Intervention; C: Control; SBP: Systolic blood pressure; Diastolic blood pressure; SD: Standard deviation.

Table 4. Reported reasons to stop predefined visits to health units.

Reason	InterventionN = 28	ControlN = 24
Social isolation due to pandemic	10 (35,7%)	5 (20,8%)
No time to spend with herself due the newborn	10 (35,7%)	6 (25,0%)
Blood pressure was already controlled	6 (21,4%)	6 (25,0%)
Distance to health unit	2 (7,2%)	7 (29,2%)

Discussion

This preparatory study, which tested a novel self-monitoring-based intervention for women following a pregnancy complicated by preterm preeclampsia, has found that while women were prepared to be recruited and randomized at participating centers, their attendances at follow-up visits were insufficient for a full-scale clinical trial to be feasible at the moment.

Given the long-term impact of preeclampsia on the development of CVD, novel interventions such as this need to be tested for which establishing a follow-up strategy is a prerequisite. This will likely require clinical infrastructure as well as an educational program to present the importance of having a medical follow-up to identify risk factors for CVD among patients who had preeclampsia (14). Unfortunately, the lack of such a strategy following hypertensive pregnancy in Brazil proved unsurmountable in this current study.

Strengths and limitations

This was the first study in Brazil to attempt to implement a self-monitoring-based intervention following hypertensive pregnancy. While recruitment was sufficient, particularly in the context of the pandemic, the lack of retention revealed several limitations.

The lack of community information to clarify the importance of the follow-up for patients who had complications such as preeclampsia certainly impacted this study. Initially, the study did not include the dissemination of this knowledge transfer as it could represent a possible bias toward the control group. Currently, the generally adopted protocol recommends outpatient clinic visits only 40 days postpartum and do not include earlier visits if patients did not have major organ dysfunctions. A recent Brazilian study reported that missing appointments scheduled 40 days postpartum among patients with chronic hypertension reached 52% (15). Therefore, we realized that a program to implement a routine follow-up to detect persistent postpartum hypertension and ongoing hypertension 6–12 months postnatally to the same population could have improved the results of the study. This problem regarding missing appointment has also been reported in the United States. Suresh et al. (2021) published their results of an initiative consisted of a bundle of clinical interventions including health care professional and

patient education, a dedicated nurse educator, and protocols for postpartum hypertensive disorders of pregnancy care in the inpatient, outpatient, and readmission setting (14). A total of 926 patients who delivered between September 2018 and November 2019 were included in the study. The initiative started in January 2019 at the University of Chicago and proved to be important to improve postpartum hypertension visit adherence from the preintervention period (33.5%) compared with the full implementation period (59.4%) ($p < 0.001$).

Another limitation was the impact of the COVID-19 pandemic. We realize that this was not the main responsible for the failure of our study. But while we advised patients on the importance of attending routine visits, several other sources of information advised the opposite. The general media continuously advised that all people should avoid going to health care services due to the risk of contagion by COVID-19 unless absolutely necessary. This bias certainly negatively impacted the results. Not only there was the concern reported by patients but also the institutional consequences of the pandemic, with several months of decreased number of available outpatient clinic visits (making it difficult to schedule visits, especially for the control group) and forced closure of research facilities/activities. Therefore, visits for 3, 6 and 12 months were delayed, reschedules and this most likely impacted the findings.

Generalization

A recent cohort study demonstrated the importance of having 1-year follow-up to identify patients who will develop chronic hypertension after a pregnancy with hypertensive disorders (HDP) (16). The authors reported that patients who had HDP had 4-fold increased odds of new diagnosis of chronic hypertension. Forty-six participants (42.2%) had a new diagnosis of chronic hypertension at the 6-to 12-month postpartum medical assessment. These results endorse our concerns about defining strategies for postnatal follow-up after pregnancy hypertension.

The results achieved in this study proved that establishing easy follow-up strategies is crucial for the success of future studies. The health care network in Brazil is mainly composed of primary care units, generally connected to distant secondary and tertiary centers. In the study, patients were instructed to attend visits in tertiary centers for follow-up due to the possible necessity of complex exams and immediate clinical evaluation, difficult to obtain from primary care units. The P4 study (Post-Partum Physiology, Psychology and Pediatric), a study developed to determine the upper limit of normal blood pressure (BP) 6 months postpartum and the frequency of women with prior preeclampsia who had BP above these limits demonstrated that patients who had preeclampsia were more likely to have diastolic dysfunction 6 months after delivery, identified by echocardiograph examination (17). This result endorses our initial idea of needing complex exams in future trials.

The SNAP-HT feasibility study demonstrated that self-management of hypertension after birth seems to be feasible and safe (9). Actually, the recruitment rate for the study was not high as 91/154 (59%) of those eligible participants who agreed to participate. However, the adherence to follow-up was really good. Among the 82 (90.1%) participants who finished follow-up, 403/410 (98%) of follow-up visits were completed. Two components of the SNAP-HT methodology may have contributed to the success of the study: 1) BP levels sent to the monitoring center were important to define titration of antihypertensive medications. This may have increased adherence to follow-up; 2) The study included home visits by health professionals. None of these components were included in our study. Additionally, routine home visits by general practitioners are not a practice well established in Brazil. Therefore, our results have provided interesting information to encourage the development of this practice in obstetrics, commencing at least with communities close to central areas. Importantly, researchers should consider this approach in future studies. Additionally, the involvement of general practitioners and family physicians in the follow-up seems to be essential.

Another strategy that may be of great interest to test in the context of postpartum follow-up is the applicability of telemedicine. Colbert GB et al. (2020) discussed the usefulness of telemedicine in the era of COVID-19 (18). Authors suggested that the telemedicine approach could work as an important triage method. This interpretation may also work for postpartum BP monitoring. Interestingly, telemedicine has been initially developed for primary care needs, but this innovative approach has been helpful in the context of specialized and urgent situations too (19). With the COVID-19 crisis in 2020 telemedicine and smartphone approaches quickly became important methods to identify patients with symptoms of the disease, keeping them safe through social distancing and quarantine (20). Sanghavi M et al. (2022) evaluated the potential of telemedicine to implement an effective postpartum follow-up (21). Authors had 236 unique new patient visits scheduled and analyzed. Interestingly, the completion rate was 32% for in-person clinic visits and 70% for telemedicine visits. Although telemedicine visits were more effective to

maintain a consistent follow-up, a high number of patients also did not attend online appointments. These results endorse the difficulties related to implementing a program for postpartum monitoring.

The use of telemedicine is just commencing in Brazil, mainly in supplementary health assistance covered by health insurance companies. Even smartphones and apps use still represents a challenge in many under-resourced settings. While the use of devices is very prevalent, patients frequently change phone numbers and lose contact or do not have consistent access to the internet.

Two interesting trials on follow-up of women with hypertensive disorders in pregnancy were recently published. Hirsh et al. (2023) conducted a sub-study of the prospective Blood Pressure Postpartum (BP2) study, a three-arm randomized controlled trial conducted at six hospitals in metropolitan Sydney, Australia (22). The authors aimed to evaluate the adoption of healthy lifestyle by the participants. A total of 2310 eligible participants were contacted 5 months postpartum to provide the required information. Of these, 915 women declined to participate or declined to receive further information about the trial, and 840 were not contactable, representing 75% of loss to follow-up, similar to the LifeAPP trial.

Additional results of the P4 study evaluated either clinical conditions or adoption of healthy lifestyle at 6 months and 2 years postpartum. A total of 392 women were initially enrolled, being 302 normotensive patients (NP) and 90 preeclamptic patients (PP) (23). At 2 years, 129 NP participants, and 52 PP had a postpartum visit, representing 43% and 58% of the 6-month cohort, respectively. These results were really considerable, as most of the women usually do not return for any additional evaluation. In contrast to our feasibility study, the Australian trial did not propose frequent contact with patients, raising even more importance to the P4 results. Additionally, like in our study, the authors faced difficulties in maintaining the proposed protocol during the COVID-19 pandemic, also demonstrating the necessity of creating different strategies for postpartum monitoring in adverse conditions.

Interpretation

The early weeks following a pregnancy complicated by preeclampsia bring new challenges for women and their families. The time needed to care for the newborn, who are often premature in preeclampsia, can prevent mothers from devoting time to themselves (15). The transfer of care between secondary and primary care, particularly when geographically distant, adds further complications. In our study, the greatest distance between the residence and the tertiary center where visits were scheduled was 20 miles. However, free public transport was available to all patients. Despite of such facilities, patients did not attend predefined visits. Current results achieved have suggested that efficient strategies for reducing CVD need to reach the patient. Therefore, a future successful clinical trial needs to include not only self-monitoring accompanied by technologies such as smartphones but also better training for women and additional support-like home visits and telemedicine. Additionally, considering the difficulties imposed by the COVID-19 pandemic is important, and it is necessary to establish strategies of follow-up that may not be affected by events like this.

Conclusion

Feasibility studies are important in shaping the design of larger trials, and this has been demonstrated here. In the LifeAPP study, we observed that despite successful recruitment of a cohort of women following preterm preeclampsia, there was insufficient retention of participants to understand if the intervention had any effect. Therefore, new strategies for long-term follow-up of such women are needed before a further study in this group can be contemplated.

Article highlights

- There are no evidence-based interventions to reduce cardiovascular risks after preeclampsia in low- and middle-income countries
- Feasibility studies are important to design larger trials
- Attendances at postpartum visits are insufficient for a full-scale clinical trial
- Efficient strategies to reduce cardiovascular risks after preeclampsia must reach the patient
- Educational programs must be part of strategies to reduce cardiovascular risks after preeclampsia

Acknowledgments

We thank all collaborators at the participant centers and their obstetricians, nurses, and midwives involved in trial enrollment and management of patients. This study was financed by the São Paulo Research Foundation (FAPESP), Brasil. Process Number 2018/22705-0.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

This work was supported by the Fundação de Amparo à Pesquisa do Estado de São Paulo [2018/22705-0].

Details of ethical approval

This study was approved by each local ethical committee of the participating centers (CAAE: 15781919.3.1001.5411).

Contribution to authorship

WK, MLC, RJM, and LDO were involved in design. LDO coordinated the trial. APM, LMS, VLVR, TRZS were involved in data collection at CAISM/UNICAMP. WK was involved in data collection, data cleaning, and preparation of results. JPG coordinated data collection at CAISM/UNICAMP. WK and LDO wrote the first version of the manuscript. RJM, JMR, and LDO edited the later version of the manuscript. All authors contributed read and commented the final version before submission.

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