Impact of a mobile application for tracking nausea and vomiting during pregnancy (NVP) on NVP symptoms, quality of life, and decisional conflicts regarding NVP treatments: the MinSafeStart randomized controlled trial

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ABSTRACT

Background

Pregnant women are active users of mobile applications (app) for health purposes. These apps may improve self-management of health-related conditions. Up to 70% of pregnant women experience nausea and vomiting (NVP). Even mild NVP can significantly reduce the quality of life (QoL), and it can become an economic burden for both the woman and society. NVP often occurs before the first maternal care visit; therefore, apps can potentially play an important role in empowering pregnant women to recognize, manage, and seek appropriate treatment for NVP, when required.

Objective

This study investigated whether the MinSafeStart mobile application (MSS app) could impact NVP-related symptoms, QoL, and decisional conflicts regarding NVP treatment.

Methods

This randomized controlled trial enrolled 222 pregnant women with NVP in Norway from 2019-2020. The intervention group had access to the MSS app, which could be used to track NVP symptoms and access tailored advice. NVP severity was rated with the Pregnancy Unique Quantification of Emesis (PUQE) score. The control group followed standard maternal care. We collected data on maternal baseline characteristics, NVP severity, QoL, and decisional conflicts with two sets of online questionnaires. One set of questionnaires was completed at enrollment, and the other was completed after two weeks. We performed linear regression analyses to explore whether the use of the MSS app was associated with NVP severity, QoL, or decisional conflicts.

Results

Among the 222 women enrolled in the study, 192 (86.5%) completed the baseline questionnaires and were randomized to either the intervention (n=89) or the control group (n=103). In the intervention group, 88 women downloaded the app, and 468 logs were recorded. In both groups, women were enrolled at a median of 8 gestational weeks. At baseline, the average PUQE scores were 4.9 and 4.7; the average QoL scores were 146 and 149; and the average decisional conflict scores were 40 and 43, in the intervention and control groups, respectively. The app had no impact on NVP severity (aβ: 0.6, 95% CI: -0.1, 1.2), QoL (aβ: -5.3; 95% CI: -12.5, 1.9), or decisional conflicts regarding NVP treatment (aβ: -1.1, 95% CI -6.2, 4.2), compared to standard care.

Conclusion

Tracking NVP symptoms with the MSS app was not associated with improvements in NVP symptoms, QoL, or decisional conflicts after two weeks, compared to standard care. Future studies should include a process evaluation to improve our understanding of how pregnant women use the app and how to optimize its utility within maternity care. Specifically, studies should focus on how digital tools might facilitate counseling and communication between pregnant women and health care providers, regarding NVP management during pregnancy.

Keywords: eHealth, mHealth, decision support tool, nausea and vomiting, pregnancy, RCT

INTRODUCTION

Background

Pregnant women and women of reproductive age are active users of mobile applications (apps) for health purposes [1]. The available apps are designed for promoting self-management of chronic diseases, such as migraine and diabetes; tracking gestational weeks, weight, belly measurements during pregnancy; and keeping track of pregnancy development, in general [1, 2]. These apps are often used to supplement routine care, because women tend to search for health-related information early in pregnancy, before and after health consultations, and when making decisions [1, 3-5]. Often, the primary motivation for using the apps is the need for easily accessible health information [6]. Our recent systematic review on decision support tools in pregnancy revealed that few studies had investigated the effect of digital tools on the course of pregnancy and pregnancy-related ailments. However, the available studies showed that the apps could have a positive impact on the knowledge level of pregnant women, when integrated as part of patient care. Pregnant women also seemed to appreciate and were satisfied with digital tools [7].

Nausea and vomiting in pregnancy (NVP) is one of the most common pregnancy-related conditions. NVP affects up to 70% of pregnant women worldwide [8, 9]. NVP symptoms often occur during the first few weeks of pregnancy, on average, at around gestational week four [10]. The etiology of NVP is not clearly understood, but it is thought to be multifactorial and complex [10]. The severity of NVP can range from mildly uncomfortable to hyperemesis gravidarum (HG), which is the most severe form of NVP. HG affects up to 1-3% of all pregnant women, and it is the most common reason for hospitalization in early pregnancy [8]. Although HG is a relatively rare

condition, it is essential to recognize the burden of NVP, in general. Previous studies have shown that even mild NVP symptoms significantly reduced the quality of life (QoL) of pregnant women and their willingness to become pregnant again [11, 12]. The increasing severity of NVP has been associated with increased costs for society, due to increased hospital and emergency room admissions, health care visits, prescribed medications, and income loss for both the woman and her partner [13].

NVP treatment guidelines recommend early recognition and treatment to prevent/reduce more severe symptoms. The first-line management of mild symptoms consists of non-pharmacologic measures, including lifestyle and dietary changes (Multimedia appendix 1). Pharmacological treatment is indicated when NVP symptoms are moderate to severe or when symptoms significantly impact the women's daily activities [14, 15]. The first NVP symptoms typically occur early in pregnancy, and often, before the first maternal care visit. Therefore, it is important to empower pregnant women to ensure that they can optimally manage NVP symptoms [15, 16].

Digitalization, eHealth initiatives, and the wide use of the internet have opened up new possibilities for using digital tools in maternal care [17]. Mobile apps can enable pregnant women to take a more active role in self-care and disease management during pregnancy. Moreover, these apps can provide large amounts of patient-generated data during pregnancy for research purposes [17, 18]. The Pregnancy Unique Quantification of Emesis (PUQE) score is an internationally validated tool for categorizing the severity of NVP, based on three questions regarding vomiting, nausea, and retching symptoms [19, 20]. In the latest (2009) version of the PUQE score, women are asked to rate the severity of symptoms that occurred in the last 24

hours [19]. A translated and validated Norwegian version of the PUQE score became available in 2015 [21]. Incorporating the PUQE score into an app could potentially empower women by improving their management of NVP. The app could allow women to track symptoms over time and record responses to interventions. Because 99-100% of women of reproductive age use smartphones [22], and most women use health-related apps [23, 24], digital tools should be particularly suitable for maternal care.

A recent review pointed out that, although there is a growing number of apps available for monitoring and managing health-related issues, the majority are never tested or clinically validated [25]. That finding implied that it remains largely unknown whether the available apps are beneficial or whether they even have an effect on clinical outcomes. A prior study showed that integrating apps into professional clinical services could potentially improve the effectiveness of health care [26]. Our previous review concluded that the innovative use of eHealth initiatives and digitalization could potentially empower pregnant patients and improve maternal care [7]. However, at the same time, a more scientific approach is needed for testing and evaluating these apps and other digital tools. Indeed, health care providers should encourage patients to use only tools that are beneficial and effective as a supplement to routine maternity care.

Objective

The primary aim of this study was to investigate whether the MinSafeStart mobile application (MSS app) could impact NVP severity in pregnant women. The secondary aims were to assess whether the MSS app could affect the QoL of pregnant women and improve their ability to make decisions regarding NVP treatment.

Specifically, the primary research question was:

Do women that used the MSS app for two weeks have different NVP symptoms, based on the Pregnancy Unique Quantification of Emesis (PUQE) scores, compared to women that followed standard maternal care without the MSS app?

The specific secondary research questions were:

1. Do women that used the MSS app for two weeks have different QoL, based on Health-related Quality of Life for Nausea and Vomiting during Pregnancy (NVPQOL) scores, compared to women that followed standard maternal care without the MSS app?
2. Do women that used the MSS app for two weeks have different decisional conflict scores regarding NVP treatment, compared to women that followed standard maternal care without the MSS app?
3. Does the use of the MSS app modify the association between the PUQE score and the NVPQOL score (ie, is the MSS app an effect modifier)?

METHODS

Study Design, Study Population, and Sample Size

This MinSafeStart study was a randomized controlled trial. We recruited pregnant Norwegian women with NVP, between September 2019 and June 2020. All pregnant women were eligible for inclusion when they were over 18 years old, owned a smartphone (iOS or Android), and could speak and understand Norwegian.

Results from a power analysis suggested that we would need a total of 250 pregnant women (n=125 in each group, two-tailed hypothesis) to detect a mean difference of 3

points in the PUQE score between the groups, with a power of 80% (Cohen`s d=0.5). This total sample size included a 25% dropout rate.

Recruitment

Participants were primarily recruited through social media ads. Invitations to participate in the study were available on the study Facebook page, the Norwegian Hyperemesis Gravidarum Patient Organization's Facebook page, and other pregnancy-related webpages/forums, such as "altformamma.no" and "tryggmammamedisin.no". Invitations were additionally accessible through the Helseoversikt app. Helseoversikt is a digital platform used by health care centers all over Norway, which provides relevant health information to pregnant women and parents.

Randomization

An automated software program was specifically developed for the project. The software automatically managed participant enrollment, randomization to study groups, and email distributions of electronic information and online questionnaires to the study participants. This software was developed for the project by the University Center for Information Technology (USIT) at the University of Oslo (www.usit.uio.no/english)

Development of the MinSafeStart Mobile Application

The MSS app was a patient-centered app for women with NVP. Our research group developed the MSS app in collaboration with interaction designers, programmers, and researchers from USIT. The app was user-tested and launched for iOS and Android smartphones in July 2018. The app utilized the daily PUQE score to categorize NVP

severity (eg, mild, moderate, or severe) and it displayed the fluctuations over time in a graph (Figures 1 and 2).

Data Collection

In this MinSafeStart study, we collected data from the MSS app and from four sets of questionnaires (Q1-Q4) that were completed electronically. The Q1 was administered to participants at enrollment (baseline), and the Q2 was administered two weeks later. Q3 and Q4 were additional follow-up questionnaires administered at 4 and 6 weeks after baseline, respectively. All questionnaires were sent to participants by email with the automated software developed for the study. This study only analyzed data from the Q1 and Q2 sets of questionnaires (appendix 1). We selected a two-week follow-up for this study, because we considered that two weeks was sufficient time to become familiar with the app.

The Intervention Group

All women in the intervention group were free to log their NVP symptoms into the app whenever convenient. The app recommended logging symptoms every 24 h, because the PUQE score was calculated based on NVP symptoms over the past 24 h. Users could also compare their symptoms to the expected population average NVP score. Thus, women received individual treatment advice based on their PUQE scores (Multimedia appendix 1). Women also received general dietary and lifestyle advice (eg, rest, stay hydrated, eat small meals frequently, and avoid fatty and spicy food [27]), independent of their PUQE score. Women with moderate or severe symptoms received additional advice about antiemetic medications. When a woman scored ≥13

points (ie, severe NVP) for more than three consecutive days, they would see a pop-up message that encouraged them to see their doctor.

The Control Group

The control group received standard maternal care, without the MSS app.

Outcome Measures

NVP Severity

The PUQE score was an internationally validated tool for rating the severity of NVP symptoms over the past 24 h [19, 21]. The scale consisted of three questions. Each question was rated from 1 to 5. The total score ranged from 3 to 15 points, where ≤6 points indicated mild NVP, 7–12 points indicated moderate NVP, and 13 or higher indicated severe NVP. This study utilized the translated and validated Norwegian version of the PUQE score [21]. We evaluated the change in PUQE scores from Q1 to Q2 (ie, after 2 weeks).

Quality of Life

The NVPQOL was used to rate the QoL [28] experienced in the past week. The score included 30 items, covering four general domains: physical symptoms and aggravating factors; fatigue; emotions; and limitations. Each item was rated on a Likert scale that ranged from 1 (never) to 7 (all the time). The total score ranged from 30 to 210 points, and lower scores indicated a better quality of life. The NVPQOL score was significantly associated with the SF-12 health-related quality-of-life questionnaire [28]. We evaluated the change in NVPQOL scores from Q1 to Q2.

Decisional Conflict

Decisional conflict was measured with the Decisional conflict score (DCS). The DCS measured the individual`s perception of uncertainty in choosing options, changeable factors that contributed to uncertainty, and decision-making effectiveness [29, 30]. The DCS has been widely used in previous studies among pregnant women to evaluate their decision-making abilities regarding the use of antidepressants and the choice between vaginal birth or cesarean section [31, 32]. The DCS consisted of 16 items and five response categories (strongly agree, agree, neither agree nor disagree, disagree, and strongly disagree). The total score ranged from 0 to 100 points. Scores below 25 points indicated low decisional conflict, scores of 25 to 37.5 points indicated moderate decisional conflict, and scores above 37.5 points indicated high decisional conflict. We evaluated the change in DCS scores from Q1 to Q2.

Statistical Analyses

Descriptive Analysis

Categorical variables (ie, relationship status, education level, work situation, parity, and prior NVP symptoms) are presented as percentages in each group (intervention and control group). Continuous variables are presented as the median and range (ie, gestational week) or the mean and standard derivation (SD; ie, maternal age). We performed the Pearson`s Chi-squared test to compare categorical variables, except when the expected cell count was less than five; in those cases, we performed Fisher`s exact test. We performed the Student’s t-test to compare continuous variables. All analyses were performed with Stata/MP v.16.1. *P*-values <.05 were considered statistically significant.

Primary and Secondary Analyses

We performed univariate and multivariable linear regressions to estimate associations between the use of the MSS app and (1) NVP severity, (2) QoL, and (3) decisional conflict. All results are presented as the crude and adjusted beta-coefficients (β) with 95% confidence intervals (CI). We adjusted the multivariable linear regression model with predefined covariates (ie, baseline PUQE score, baseline NVPQOL score, and baseline decisional conflict score) [33].

Subanalyses

We performed a pre-specified stratified analysis to assess whether employment in the health sector modified the association between the use of the MSS app and the PUQE score. We reasoned that women employed in the health sector might have better access to information and advice regarding NVP management, and thus, they may have less need of an app for tracking their NVP symptoms than women employed in other settings. Alternatively, they may have received more support or information from co-workers in the field that allowed them to capitalize on the information provided by the app, compared to women employed in other settings.

Ethical Approval

This study was approved by the Regional Committees for Medical and Health Research Ethics in Norway (Ref: 2018/2298). Informed consent to participate in the study was obtained from all participants.

Trial Registration

This trial was registered at ClinicalTrails.gov (identifier: NCT04719286, registration date: January 22, 2021).

RESULTS

Study Population

Overall, 222 women consented to participate in the study (Figure 3). Of these, 192 (86.5%) responded to the baseline questionnaires (Q1) and were randomized to either the intervention group (n=89) or the control group (n=103). In total, 137 women responded to the follow-up questionnaires, two weeks later (Q2). The dropout rates were 34% (n=30) for the intervention group and 24% (n=25) for the control group. The main reason for dropout was “lack of response”.

At enrollment, the median stage of pregnancy was the same in both groups: 8 (range: 4-36) gestational weeks in the intervention group, and 8 (range: 4-39) gestational weeks in the control group. These groups had the same mean age at enrollment: 32 years (SD=4.6) and 32 years (SD=3.9), respectively. Most women had been pregnant previously (73.0 and 73.8%, respectively). In both groups, 80% had experienced NVP in at least one previous pregnancy. None of the women reported severe NVP (ie, PUQE score ≥13) at baseline. A comparison of baseline characteristics indicated no statistical difference (all $P<.05$) between the two study groups (Table 1).

Table 1: Baseline characteristics of the study population (n=192), stratified by whether they used the MSS app (intervention) or received standard maternity care (control)

	Intervention group (n=89)		Control group (n=103)	
CHARACTERISTICS	**n**	**Value**	**n**	**Value**
Gestational week at enrollment	89	8 (4-36)	103	8 (4-39)
Age, years	89	32 (4.6)	103	32 (3.9)
Relationship status				
Married/co-habitation	85	95.5	100	97.1
Other[a]	4	4.5	3	2.9
Higher education				
Yes	69	77.5	85	22.5
No	20	82.5	18	17.5
Working situation				
Employed	55	61.8	60	58.2
Employed in the health sector	19	21.4	31	30.1
Other[b]	15	16.8	12	11.7
Primigravida				
Yes	24	27.0	27	26.2
No	65	73.0	76	73.8
NVP during previous pregnancy/pregnancies				
Yes	52	80.0	61	80.3
No	13	20.0	15	19.7

SD = standard deviation, **NVP** = nausea and vomiting during pregnancy
Values are expressed as the percentage, as the mean (SD), or as the median (range), as indicated
[a]*Other* includes single/unmarried and divorced/separated women
[b]*Other* includes students and unemployed women
Statistics: Baseline characteristics were compared between the two study groups with the students t-test (gestational week and age), chi-squared test (higher education, working situation, primigravida, and NVP during previous pregnancy/pregnancies)m or Fisher-exact test (relationship status). No differences between groups were statistically significant (all $P \geq .05$)

The Intervention

Of the 89 women randomized to the intervention group, 88 downloaded the MSS app. These women performed a total of 468 logs. Two women dropped out of the study, because they were not satisfied with the app. They reported no benefit in using the MSS app.

Impact on NVP Severity

The groups showed no differences in the change in PUQE scores between Q1 and Q2 (adjusted β: 0.6, 95% CI: -0.1,1.2). Among women employed in the health sector, those that used the MSS app had a significantly higher PUQE score (adjusted β: 2.1, 95% CI: 0.9,3.2) after two weeks, than those that did not use the app. However, among women employed in other sectors, the PUQE scores were not significantly different between the intervention and control groups (Table 2).

Table 2: Associations between the use of the MSS app and the PUQE score

	Q1		Q2		Change in PUQE (Q2-Q1)		
	n	**PUQE** Mean (SD)	**n**	**PUQE** Mean (SD)	Mean change (SD)	Crude difference in mean changes (β) (95% CI)	Adjusted difference in mean changes[a] (β) (95% CI)
Primary analysis							
Intervention group	89	4.9 (2.0)	59	5.6 (1.8)	0.8 (2.0)	0.4 (−0.3,1.2)	0.6 (−0.1,1.2)
Control group	103	4.7 (1.9)	78	4.9 (1.8)	0.4 (2.3)	*Reference*	*Reference*
Sub-analyses by employment							
Women employed in the health sector							
Intervention group	19	4.6 (1.9)	14	6.6 (1.7)	1.8 (2.5)	2.1 (0.3,3.9)	2.1 (0.9,3.2)
Control group	31	4.5 (1.9)	23	4.6 (1.6)	−0.3 (2.7)	*Reference*	*Reference*
Women employed in other sectors							
Intervention group	55	4.9 (2.1)	38	5.2 (1.7)	0.4 (1.7)	−0.1 (−0.8,0.7)	0.0 (−0.7,0.7)
Control group	60	4.7 (1.9)	45	5.1 (1.8)	0.5 (1.9)	*Reference*	*Reference*

PUQE = Pregnancy Unique Quantification of Emesis score; this score ranges from 3 to 15 points, and symptoms are rated as follows: mild: ≤6 points; moderate: 7–12 points; severe ≥13 points. **Q1** = Baseline questionnaire, **Q2** = Follow-up questionnaire, **SD** = standard deviation, **CI** = confidence interval

[a]Adjusted for the baseline PUQE score

Impact on Quality of Life

The adjusted primary analysis showed that the changes in NVPQOL scores from baseline to Q2 were not significantly different between the intervention and control groups (adjusted β: −5.3; 95% CI: −12.5, 1.9) (Table 3).

Table 3: Association between the use of the MSS app and quality of life

	Q1		Q2		Change in NVPQOL (Q2-Q1)		
	n	**NVPQOL** Mean (SD)	**n**	**NVPQOL** Mean (SD)	Mean change (SD)	Crude difference in mean changes (β) (95% CI)	Adjusted difference in mean changes[a] (β) (95% CI)
Intervention group	89	145.7 (34.0)	59	143.8 (29.7)	−4.5 (22.4)	−4.2 (−11.9,3.5)	−5.3 (−12.5,1.9)
Control group	103	148.5 (28.8)	78	151.6 (28.9)	−0.3 (22.9)	*Reference*	*Reference*

NVPQOL = Health-Related Quality of Life for Nausea and Vomiting during Pregnancy scale; this score ranges from 30 to 210 points, and lower scores indicate better quality of life. **Q1** = Baseline questionnaire, **Q2** = Follow-up questionnaire, **SD** = standard deviation, **CI** = confidence interval

[a]Adjusted for baseline NVPQOL score

Impact on Decisional Conflict Score

The mean changes in the DCS between Q1 and Q2 were −5.9 (SD=16.4) for the intervention group and −5.3 (SD=15.5) for the control group (Table 4). The changes in DCS were not significantly different between the women in the intervention group and the women in the control group (adjusted β: −1.1, 95% CI: −6.2, 4.2).

Table 4: Association between the use of the MSS app and the decisional conflict score

	Q1		Q2		Change in DCS (Q2-Q1)		
	n	**DCS** Mean (SD)	**n**	**DCS** Mean (SD)	Mean change (SD)	Crude difference in mean changes (β) (95% CI)	Adjusted difference in mean changes[a] (β) (95% CI)
Intervention group	89	40.3 (17.9)	59	36.2 (21.6)	−5.9 (16.4)	−0.7 (−6.1,4.7)	−1.1 (−6.2,4.2)
Control group	103	42.5 (20.9)	78	38.1 (20.3)	−5.3 (15.5)	*Reference*	*Reference*

DCS = Decisional conflict scale; this score ranges from 0 points (no decisional conflict) to 100 points (extremely high decisional conflict). **Q1** = Baseline questionnaire, **Q2** = Follow-up questionnaire, **SD** = standard deviation, **CI** = confidence interval.

[a]Adjusted for baseline decisional conflict score

Association Between NVP Severity and Quality of Life

Women with more severe NVP (higher PUQE scores) had lower NVPQOL scores than women with lower PUQE scores (Figure 4).

DISCUSSION

Main Findings

The MinSafeStart trial was the first to investigate the effectiveness of a patient-centered mobile app that was designed to empower pregnant women in managing their NVP symptoms optimally. We found no significant associations between the use of the MSS app and the severity of NVP symptoms, the QoL, or decisional conflicts, compared to standard maternal care. These results should be interpreted with caution, because the study was slightly underpowered, due to a higher drop-out rate than expected.

Our results showed no associations between the use of the MSS app and NVP symptoms at two weeks after baseline. This may be explained by several factors, but the main factors were most likely the characteristics of the study population and the study design. First, we included women at any gestational stage in pregnancy. In fact, 15% of the women included were beyond the first trimester, which is the most relevant time window for NVP. On average, NVP occurs during gestational week 4 [10] and peaks during gestational weeks 10-16 [34, 35]. However, our intervention group had completed a median of 8 gestational weeks at enrollment, with a range of 4-36 weeks. Therefore, in many cases, it may have been too late for women to benefit from the app. Second, a 2-week follow-up may not have been optimal for evaluating the effect of the intervention. We could not exclude the possibilities that natural fluctuations in NVP severity could have affected the results or that a shorter follow-up time before the app assessment might have been a better choice. Moreover, there might not be a particular time that is optimal for measuring the effects of the app. Indeed, NVP severity varies from morning to evening and from day to day. Therefore, selecting a specific time point for follow-up and reporting the PUQE score in Q2 may not have fully captured the changes in NVP severity over time. Future studies should consider these elements when designing a trial to evaluate the effect of using a digital tool during pregnancy.

Another factor that may have affected the results was that the study included a high proportion of parous women with a prior NVP history. First-time pregnant women are more likely to need health information and to search for information online, compared to multiparous women [36]. In the first pregnancy, women often search for information about concerns and symptoms related to the first period of pregnancy [6, 36-39]. However, most of our sample had been pregnant previously, and more than half had

also experienced NVP in previous pregnancies. Therefore, these women may have already been informed about optimal NVP management and treatment, and consequently, they may not have needed more information with an NVP tool.

Strengths and Limitations

The main strength of this study was that very few studies have been conducted to assess the effectiveness of mobile apps on disease management among pregnant women. This study provided new insights in this regard. An important strength of this study was the use of the randomized controlled trial study design, which is considered the gold standard in evidence-based medicine [40]. Another strength of this study included our use of the internet for recruitment and electronic data collection. This approach facilitated the participation of pregnant women all over Norway, which may have increased the representativeness of the study sample, and thus, the generalizability of the results. In addition, the NVPQOL may have provided an advantage over other quality-of-life scales, because the NVPQOL is more specific [40].

The major limitation of this study was that we did not reach our targeted number of participants, which was 250 women, including a 25% dropout rate. Furthermore, the use of the internet might have introduced a self-selection bias of parous women with higher sociodemographic status. This bias may have resulted in a more resourceful and motivated study population that differed from the general birthing population.

Future Research

Digitalization and eHealth have provided opportunities to develop innovative apps that support pregnant women. These mobile applications must be tested in clinical studies

before they can be included in the health care system or recommended by healthcare personnel. Our review from 2020 demonstrated that decision support tools could potentially benefit pregnant women. However, the tools were mainly useful when relevant information was assembled into one digital tool, and when the woman could share her recordings with her health care provider [7]. Based on the results of this study, future research should focus on how to design trials to determine the effect of digital tools on pregnancy outcomes that are most important to pregnant patients. Future studies should also investigate whether digital tools and apps might be more effective when developed as part of a more extensive health intervention. Specific focus should be placed on how digital tools might facilitate counseling and communication between pregnant women and health care providers regarding NVP management in pregnancy.

Conclusion

This study showed that tracking NVP symptoms with a mobile application was not associated with reduced NVP symptoms, less decisional conflicts, or improved QoL after two weeks of use. These findings may have been influenced by study design-related factors, such as the gestational week of enrollment, the women's parity, the time to follow-up, and the sample size. Future studies should include a process evaluation to improve our understanding of how pregnant women use the app and how to optimize its utility within maternity care.

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DISCLOSURE OF INTEREST

The authors declare no conflicts of interest.

CONTRIBUTION TO AUTHORSHIP

EN, MT, and HN designed the study. EN conducted the main analysis. EN drafted the first version of the manuscript. EN, MT, DW, and HN contributed to the interpretation of the results and the critical appraisal of the manuscript. All authors approved the final manuscript.

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MULTIMEDIA APPENDIX

Multimedia appendix 1: NVP treatment guideline

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604

ABBREVIATIONS

app: Mobile application

DCS: Decisional conflict scale

HG: Hyperemesis gravidarum

MSS app: MinSafeStart mobile application

NVP: Nausea and vomiting in pregnancy

NVPQOL: Health-Related Quality of Life for Nausea and Vomiting during Pregnancy scale

PUQE: Pregnancy Unique Quantification of Emesis score

Q1: Questionnaire 1

Q2: Questionnaire 2

Q3: Questionnaire 3

Q4: Questionnaire 4

QoL: Quality of life

USIT: University Center for Information Technology