

Effectiveness of Evidence-Based Measures on Nausea and Vomiting during First Trimester of Pregnancy

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ABSTRACT

Context: Nausea and vomiting are the most common pregnancy symptoms that negatively affect many pregnant women. Severity varies from mild distaste for certain foods to more severe vomiting.

Aim: The present study aimed to examine the effectiveness of applying evidence-based measures on nausea and vomiting during the first trimester of pregnancy.

Methods: A quasi-experimental (pre/post-test) design was used. The study was conducted at the antenatal clinics at Ain Shams University Maternity Hospital. A purposive sample of forty-seven pregnant women was included in this study. All women received the evidence-based intervention. Data were collected using three tools. A structured interviewing questionnaire, pregnancy symptoms inventory (PSI), and weekly follow-up record. In addition to Arabic Evidence-based guide for alleviating nausea and vomiting during the first trimester of pregnancy. All pregnant women that suffered from nausea and vomiting followed the evidence-based guidelines designed by the researcher that involved instructions related to lifestyle modification. Besides, one of the following: herbal therapy, acupuncture, and aromatherapy to relieve nausea and vomiting.

Results: The study sample mean age was 28.1 ± 6.42 , with a mean gestational age of 9.43 ± 3.88 . 72% of them used nothing to overcome nausea and vomiting, while 18% used medication, and only 10% used a lifestyle modification before intervention. All women adopt lifestyle modification; 72.3% use herbal therapy after the intervention. The present study demonstrates a highly significant difference between responses before and after the intervention related to nausea and vomiting ($p < 0.004$). There is a significant association between the evidence-based measure used and the relief of nausea and vomiting at $p < 0.01$.

Conclusion: The current study concluded that evidence-based measures positively alleviated nausea and vomiting during the first trimester of pregnancy. A leaflet or booklet about evidence-based measures for alleviating minor discomforts during pregnancy as a hospital protocol for guiding nurses in the application is strongly recommended.

Keywords: Evidence-based measures, nausea, vomiting, the first trimester of pregnancy

1. Introduction

Pregnancy is a long and very special journey for a woman. It is a wonderful experience, yet it is associated with minor discomfort like nausea, vomiting, heartburn, and constipation that appear normal for any pregnant woman. However, late diagnosis and management can develop these minor discomforts into major problems (Gebbe *et al.*, 2017).

According to WHO (2016), symptoms of nausea and vomiting are most common during the first trimester of pregnancy and are experienced by approximately 70% of pregnant women. Nausea and vomiting of pregnancy (NVP) are the most common symptoms that happen early in pregnancy, in response to increasing levels of Human Chorionic Gonadotrophin (HCG), progesterone, and the resulting relaxation of the smooth muscle of the stomach and altered carbohydrate metabolism. It begins between 4-8 weeks of pregnancy and usually subsides by the third month (first trimester).

Severity varies from mild distaste for certain foods to more severe vomiting. The condition may be triggered by the sight or odor of various foods (Stables & Rankin, 2017).

Inquiring about NVP when interviewing pregnant women during their first visits to health care providers is an essential part of history. Many women do not volunteer this information because others might have minimized their symptoms, or they have been informed that it is a normal part of pregnancy and something they must tolerate, but they did not realize that problem may lead to hospitalization if not managed well (Cleveland Clinic, 2018).

Severe nausea and vomiting lead to vitamin deficiency (especially thiamin), resulting in conditions as Wernicke syndrome, as well as severe dehydration of the body, electrolyte imbalance (hypokalemia), acid-base imbalance, impressive maternal weight loss. NVP also has undesirable impacts on pregnant women's quality of life and daily activities, causing sleep disturbances, fatigue, anxiety, malnutrition, irritability, decreased social activity, and disorders in social function, marital relationship, and mother-child interaction (Kroumpouzou & Cohen, 2001).

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Hence health care providers should be aware of the evidence-based information regarding various treatment modalities and offer them to pregnant women when appropriate. Evidence-based management is guided by symptom severity, the impact on the woman's life, maternal-fetal safety profile, and patient preference.

Evidence-based measures include dietary modifications, dehydration prevention, and avoidance of triggers that have helped deal with nausea and vomiting of pregnancy (NVP) along with complementary therapies (herbal remedies, aromatherapy, acupuncture, and acupressure), which tend to be the first choice for most women (*Department of Health, Australian Register of Therapeutic Goods, 2016*).

Many women turn to nonpharmacologic therapies for NVP because of concerns about the adverse effects of drugs during embryonic and early fetal development. In one survey report, 61% of callers to the Motherisk NVP HelpLine reported using complementary and alternative medicine (CAM) (*Jewell & Young, 2003*). Herbal remedies were commonly mentioned as treatments for NVP and hyperemesis gravidarum (HG) in a recent survey of midwives in Texas (*Bayles, 2007*).

2. Significance of the study

Nausea and vomiting are associated with pregnancy due to either hormonal or physical changes that happen during this period. They are not dangerous but may threaten the women's life if not managed well. So, it is better to spot symptoms of these discomforts quickly to manage them as early as possible and avoid the negative consequences on women and their fetuses if neglected (*Tharpe et al., 2017*).

According to *Ahmed (2017)*, symptoms of nausea and vomiting are most common during the first trimester of pregnancy and are experienced by approximately 88% of pregnant women. Fortunately, they can be managed safely and effectively at home after differential diagnosis to exclude other pathological causes as H. pylori, Cholecystitis, Gastroenteritis, and Gastroesophageal reflux. In general, lifestyle modification and complementary therapies (herbal therapy, acupressure, and aromatherapy) are required to get rid of morning sickness, heartburn, and constipation. These therapies mainly prevent adverse effects on the fetus and pregnant women (*Climent, 2018*).

It was mandatory to evaluate the effectiveness of applying evidence-based measures on alleviating nausea and vomiting during the first trimester of pregnancy to enable new mothers to enjoy their pregnancy and prevent serious complications which may develop for mother and fetus.

3. Aim of the study

The study aims to examine the effectiveness of applying evidence-based measures on nausea and vomiting during the first trimester of pregnancy through:

- Assess each woman for the presence of nausea and vomiting associated with pregnancy in the first trimester and how to deal with it.

- Using the developed evidence-based guide for alleviating nausea and vomiting during the first trimester of pregnancy.
- Evaluating the effectiveness of the application of evidence-based measures on nausea and vomiting during the first trimester of pregnancy.

3.1. Research Hypothesis

The evidence-based guide will have a positive effect on nausea and vomiting during the first trimester of pregnancy.

4. Subjects & Methods

4.1. Research Design

An intervention design was used in carrying out the study. A quasi-experimental research (pre/post-test) design was utilized to achieve the aim of this study. A quasi-experimental design aims to establish a cause-and-effect relationship between an independent and dependent variable. The quasi-independent variable (the variable that is manipulated in order to affect a dependent variable) as lifestyle modification along with one of the complementary therapies are the independent variables that relieve nausea and vomiting of pregnancy (dependent variables) (*Leedy & Ormrod, 2019*).

4.2. Study setting

The study was conducted at the antenatal clinics at Ain Shams University Maternity Hospital and was completed through antenatal visits and between visits through telephone calls. The antenatal clinics are present on the second floor of the clinics building and consist of three rooms and a waiting area. The setting is prepared with facilities needed to examine pregnant women.

4.3. Subjects

A purposive sample technique was used. The sample size was calculated according to the following statistics formula $n = Z^2 \cdot p(1-p) / d^2$. The current study included forty-seven pregnant women admitted to the previously mentioned setting for one year, fulfilled the criteria, and received the intervention (evidence-based measures for alleviating nausea and vomiting during the first trimester of pregnancy).

Inclusion criteria

Women with gravida one and two; have single intrauterine pregnancy; during the first trimester of pregnancy; suffer from nausea and vomiting; without present or previous pregnancy complication; free from medical and gynecological disease; just read and write and not exceed 12 weeks of pregnancy.

Exclusion criteria

Medical and paramedical professionals are excluded.

4.4. Tools of data collection

Three tools were used for data collection:

4.4.1. A Structured Interviewing Questionnaire

The researcher designed it based on the literature review of *Annamma (2019)*. It was divided into two parts: Part 1 was used to assess women's socio-demographic data (age, occupation, educational level, and marital status). Part 2 was used to assess present obstetric history as gravidity, parity, gestational age by weeks, and how to deal with it.

4.4.2. Pregnancy symptoms inventory (PSI)

It was adapted from *Foxcroft et al. (2013)*. The original tool assessed the presence of all minor discomforts during three trimesters of pregnancy and its frequency during the last month. The current tool was modified to assess the frequency of nausea and vomiting during the first trimester of pregnancy. It was used twice (before and after the intervention).

Scoring system

Scoring of the pregnancy symptoms inventory subscale is based on the presence of the symptoms and their bother ratings. Specifically, women first indicate whether they had the symptom in the last week. If they did have the symptom, they then report the frequency of these symptoms on a 3-point scale (one for rarely, two for sometimes, three for often). These points were measured according to the following:

- One to two times/day was considered that it does not interrupt the daily activities.
- Three to six times/day was considered to have a minimal interruption for daily activities.
- Seven times/day was completely interrupting the daily activities (*Dilorio & VanLier, 1989*).

4.4.3. Weekly Follow-Up Record

The researcher designed it to identify evidence-based measures used during, after the intervention, and in follow-up. It was divided into two parts:

Part 1 was used to assess response to measures used before intervention

Part 2 was used to identify evidence-based measures and women's responses after usage.

In addition to Arabic evidence-based guide that contains all necessary information, pictures, and figures about stages of pregnancy, physiological changes during the first trimester of pregnancy, the most common minor discomfort during the first trimester of pregnancy (nausea, vomiting), how to deal with it depending on evidence-based measures for alleviating nausea and vomiting (lifestyle modification, herbal medicine, aromatherapy, and acupressure) (*Committee on Practice Bulletins-Obstetrics, 2018; Judith, & Jerrie, 2018; Downe et al., 2016; Hinkle et al., 2016*).

4.5. Procedures

Tools were reviewed for the appropriateness of items through an expert panel to assure content and face validity. The evidence-based measure (herbal therapy, acupressure, and aromatherapy) was validated by a specialist regarding

the safe doses, frequencies, and techniques. Internal consistency reliability was assessed in the present study's tools via Cronbach's Alpha reliability analysis to indicate how well the items in the instrument fit together conceptually. It was 0.781 for the structured interviewing questionnaire, 0.87 for pregnancy symptoms inventory, and 0.642 for a weekly follow-up record.

Ethical considerations: The approval was obtained from the Scientific Research Ethical Committee in the Faculty of Nursing at Ain Shams University before starting the study. The researcher clarified the aim of the study to pregnant women included in the study. The researcher assured maintaining anonymity and confidentiality of the subject data. There is no harmful intervention that occurs to pregnant women. Pregnant women had the right to withdraw from the study at any time.

The preparatory phase included reviewing the current local and international related literature using books, articles, scientific journals, and periodicals to develop tools for data collection. Official approval was obtained from the Dean of faculty of nursing, Ain Shams University, and the director of Ain Shams University Maternity Hospital as approval for data collection through a written letter containing the title and aim of the study.

A pilot study was conducted on the cases attended to the hospital (10% of total) on six pregnant women from 1/9/2018 to 30/9/2018. It was conducted to evaluate the feasibility of the research process and the validity of the tools to find the possible obstacles and problems faced during data collection. Accordingly, the necessary modification of the data collection plan and tools was done. Pregnant women included in the pilot study were excluded from the sample size.

Fieldwork: After obtaining the official approval for data collection, data was collected 3 days/week from 9 am to 1 pm during one year from 1/10/2018 to 30/9/2019 as the period planned for the study was six months and extended for one year to reach presentable sample at antenatal outpatient clinics at Ain Shams Maternity University Hospital.

Assessment phase: At first, the researcher introduced herself to each pregnant woman and explained the aim of the study to gain their confidence and trust, and finally, verbal consent was obtained from the participant.

Cases were interviewed individually in the sitting area of the antenatal outpatient clinics using a structured interviewing questionnaire to collect personal data. Pregnancy symptom inventory was used to identify the frequency of nausea and vomiting within a time ranging from 15-20 minutes, taking into consideration the use of simple Arabic language that suits the level of each woman.

Implementation phase: After the diagnosis of nausea and vomiting, the researcher conducted an orientation session plus two instruction sessions with pregnant women according to detected discomfort in the waiting area of antenatal outpatient clinics as the following:

The researcher started the orientation session by providing women knowledge about stages of pregnancy, physiological changes during the first trimester of

pregnancy, the most common minor discomfort during the first trimester of pregnancy (nausea and vomiting), and briefly how to deal with it depending on evidence-based measures for alleviating minor discomforts (lifestyle modification along with one of the complementary therapies).

The first instruction session included lifestyle modification as a part of evidence-based measures used to alleviate nausea and vomiting for each pregnant woman. This teaching session ranged from 10-15 minutes. Instructions related to lifestyle modification included dietary modification, dehydration prevention, and avoidance of triggers, were explained in a simple and detailed manner using visual aids (pictures) and group discussion.

The second instruction session was related to complementary therapies as another part of evidence-based measures used for alleviating nausea and vomiting for each pregnant woman. This teaching session ranged from 15-20 minutes. Complementary therapies included herbal therapy, aromatherapy, and acupressure. Each one was explained in a detailed manner as the following:

Each measure with different methods of use, dose, precautions, frequency of usage, using Arabic illustrated guidelines to facilitate understanding the effect of evidence-based measures on alleviating nausea and vomiting of pregnancy. This Arabic guide contains all the necessary information and figures about these measures. The previous session was done after consulting specialists in this field by the researcher to detect suitable dose of herbs, frequency and detect acupressure points and proper technique. Demonstration and re-demonstration were done for each woman).

After teaching sessions had been completed, the woman was allowed to choose the most preferred and applicable method (considering that each woman should follow all instructions related to lifestyle modification and one of the complementary therapies chosen by women). In addition, the researcher told the woman that if she felt any undesirable symptom or side effect, report the symptom she felt to the researcher as early as possible through a telephone call. At the end of the session, each woman received an Arabic booklet containing the needed information and figures to facilitate learning and applying these measures at home.

Evaluation phase: The researcher followed each woman weekly for a month to take a verbal report about her self-assessment and motivate her to use the evidence-based measures she chose through antenatal visits and between visits through telephone calls.

4.6. Limitations of the study

Five cases were omitted from the study due to the inability to reach them during follow-up. Cases that attended the setting and fulfilled the criteria were tiny, and the researcher extended the period from 6 months to 1 year to obtain a presentable sample.

4.7. Data analysis

The collected data were coded, organized, revised, and analyzed by the researcher through Pentium 4 personal computer using Excel version 2000 and statistical package of social science (SPSS) version 22. The result was presented in tables and figures. Data were presented using descriptive statistics in the form of frequencies and percentages. Test of significance was used to determine the association between the variables using the Friedman test and Chi-square test (X^2). The significance of the results was considered as follows:

- No significant difference was obtained at $p > 0.05$.
- The significant difference was obtained at $p < 0.05$.
- The highly significant difference was obtained at $p < 0.01$.

5. Results

Table 1 demonstrates that 42.6% of the pregnant women's age ranged from 27 to 32 years with a mean of 28.1 ± 6.42 years. Regarding occupation, 59.6% of the pregnant women were not working. Regarding educational level, 40.4% of them had secondary education. Also, it demonstrates that 97.9% of pregnant women were married.

Table 2 shows that 63.8% of the pregnant women are gravida one, and 63.8% were para 0. Regarding gestational age, 78.8% of the pregnant women's gestational age ranged from 8-11 weeks, with a mean of 9.43 ± 3.88 .

Figure 1 shows that 72% of pregnant women who suffer from nausea and vomiting used nothing for dealing with them before the intervention, while 18% used medications and 10% used lifestyle measures.

Figure 2 shows that all pregnant women that suffer from nausea and vomiting follow instructions related to lifestyle modification; besides, 72.3% of them used herbal therapy, 21.3% used acupressure, and 6.4% used aromatherapy.

Table 3 shows a highly statistically significant difference between the mean score of nausea and vomiting before and after intervention (p -value 0.000).

Table 4 demonstrates a highly statistically significant difference between women's responses before and after intervention related to nausea and vomiting (p -value 0.004).

Table 5 demonstrates a highly statistically significant association between measures used and the relief of nausea and vomiting at the fourth week of intervention at a p -value < 0.01 . The lifestyle modification was the best in relieving nausea and vomiting among 100% of the participants.

Table (1): Frequency and percentage distribution of the pregnant women’s socio-demographic characteristics (n=47).

Socio-demographic characteristics	No	%
Age (year)		
17-21 Year	8	17
22-26 Year	19	40.4
27-32 Year	20	42.6
Mean±SD	28.1±6.42	
Occupation		
Work	19	40.4
Not work	28	59.6
Educational level		
Primary education	1	2.1
Preparatory education	14	29.8
Secondary education	19	40.4
High education	13	27.7
Marital status		
Married	46	97.9
Divorced	1	2.1

Table (2): Frequency and percentage distribution of the pregnant women's obstetrical history (n=47).

Obstetrical history	No	%
Gravidity		
Primigravida	30	63.8
Gravida Two	17	36.2
Parity		
Zero	30	63.8
1	17	36.2
Gestational age (weeks)		
5-<8 Week	10	21.2
8- 11 Week	37	78.8
Mean±SD	9.43±3.88	

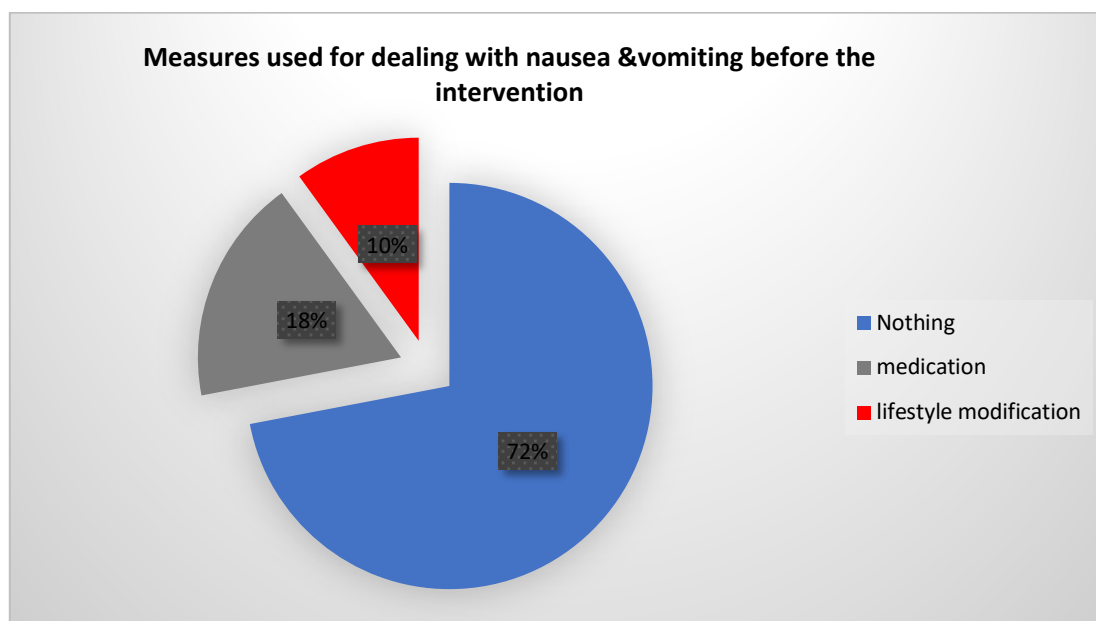


Figure (1): Percentage distribution of pregnant women’s measures used for dealing with minor discomforts before the intervention (n=47).

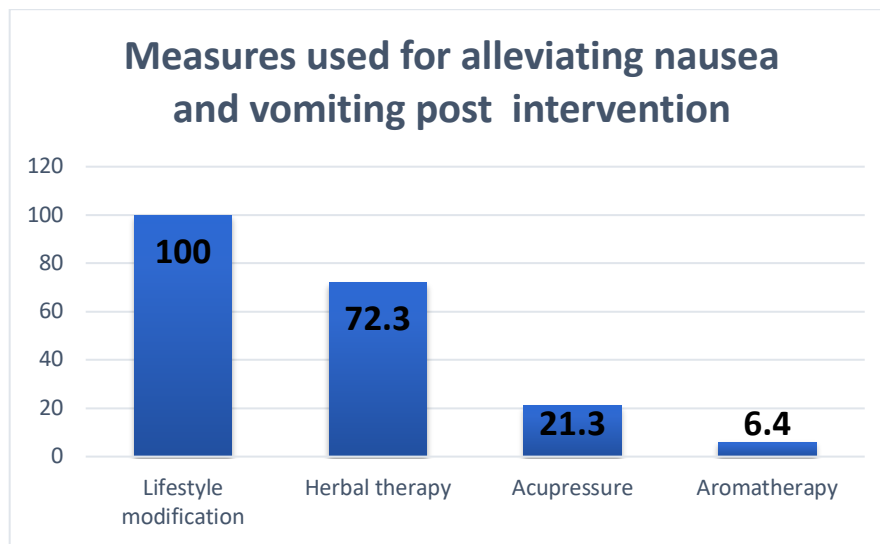


Figure (2): Percentage distribution of pregnant women’s measures to alleviate nausea and vomiting postintervention (N=47).

Table (3): Comparison of the pregnant women mean scores of nausea and vomiting before and after the intervention.

Minor discomforts	Before intervention		After Intervention				F-test	P-value
	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD		
Nausea & Vomiting	2.63±0.57	2.11±0.63	1.85±0.49	1.36±0.62	0.84±0.18	19.761	0.000	

Table (4): Comparison of the pregnant women's response to intervention before and after intervention.

Women response	Before intervention		After Intervention								Friedman test	p-value
	N	%	1 st week		2 nd week		3 rd week		4 th week			
			N	%	N	%	N	%	N	%		
Nausea & vomiting												
Relieved	0	0	37	78.7	43	91.5	46	97.9	47	100	12.379	0.004
Not relieved	47	100	10	21.3	4	8.5	1	2.1	0	0		

Table (5): Relation between measures used during the intervention and the relief of nausea and vomiting at the fourth week of intervention(n=47).

Evidence-based measures	Number of cases relived		Chi-square	p-value
	N	%		
Lifestyle modification	47	100	14.058	<0.01
Herbal therapy	34	72.3		
Acupressure	10	21.3		
Aromatherapy	3	6.4		

6. Discussion

Nausea and vomiting are the most common pregnancy symptoms that affect many pregnant women with serious consequences. It cannot be ignored because dehydration and its consequences on women and fetuses (Einarson et al., 2007).

Minor discomfort can be managed by proper explanation, simple remedies, and lifestyle pattern modification. Based on this important issue, the present study was conducted to evaluate the effect of evidence-based measures on alleviating nausea and vomiting during the first trimester of pregnancy.

Regarding socio-demographic characteristics of the studied women, their mean ages were 28.1±6.42 years,

more than half of them were not working, and most of them were married near half of them had secondary education.

Concerning measures used for dealing with nausea and vomiting during the intervention, the current study shows that all pregnant women followed instructions related to lifestyle modification after intervention besides one of the following complimentary therapies (herbal as (ginger, peppermint), acupressure pericardium 6 (P6 point), aromatherapy). This finding can be justified as pregnant women usually prefer methods that are safe on pregnancy outcomes and easy to use.

The present study findings were inconsistent with Adane et al. (2020), who conducted eight studies in Ethiopia to assess the use of herbal medicine and its predictors among pregnant women attending antenatal care. The study showed that half of the women attending

antenatal care preferred herbal medicine, which was relatively high. The most consumed herbal medicine during pregnancy was ginger.

Regarding pregnant women's response to intervention, the present study demonstrates a highly statistically significant difference between women's responses before and after the intervention related to nausea and vomiting (p-value 0.004). This significant improvement reflects the positive effect of evidence-based measures in decreasing the frequency of nausea and vomiting after the intervention compared to their frequency pre-intervention (p-value 0.000). These findings support the current research hypothesis.

The present study findings were in the same line of *Ozgoli, and GhareNaz (2018)*, who conducted multiple studies (twenty-one clinical trials) on pregnant women in Iran to assess the effects of complementary medicine on nausea and vomiting in pregnancy and illustrated that most studies have demonstrated a positive effect on reducing NVP; however, no adverse effect was reported.

The present study findings agree with *El-Sharkawy et al. (2020)*, who conducted a study to assess the effectiveness of self-instructional module on knowledge and remedial practices regarding selected minor ailments among primigravida and demonstrates a statistically significant difference between the occurrence of minor ailments at the post-intervention phase compared to the pre-intervention phase in favor of post-intervention regarding (morning sickness, heartburn, constipation, gingivitis, leg cramps, backache, and dyspnea) with $p \leq 0.05$. In addition to another study done by *Alageswari and Dash (2019)* agreed with the present study and concluded that teaching about minor ailments of pregnancy and its management helped the women to manage these discomforts at home by themselves effectively.

The present study findings were also supported by *AbdElhaliem et al. (2018)*, who conducted a study at antenatal clinic at Benha University Hospital on two hundred and eighty primipara women to evaluate the effect of a self-care practice guideline on relieving minor discomfort among pregnant women and revealed that self-care practice guidelines improved knowledge and self-care reported practice regarding relieving minor discomfort. These similarities with previous studies and present findings are due to the effectiveness of evidence-based measures that were designed to suit the need of pregnant minor discomforts of nausea and vomiting.

Regarding the relation between measures used during intervention and women's response, the present study's result demonstrates a highly significant relationship between measures used and the relief of nausea and vomiting at the fourth week at a p-value < 0.01 . This result can be justified as measures used had a positive effect on relieving NVP.

The present study findings were in the same line of *Dehghanmehr et al. (2017)*, who conducted a study in Iran on pregnant women to investigate the impact of acupressure on pregnancy nausea and vomiting and revealed that P6, KID21 and K-K9 acupressure points are shown to have a

positive impact in the reduction of nausea and vomiting in pregnancy.

The present study findings also agree with *Thomson et al. (2016)*, who conducted a meta-analysis of clinical trials studies on five hundred and eight pregnant women and illustrated a significant improvement of pregnancy-related nausea and vomiting in the ginger group and reported that that ginger is an effective non-pharmacological treatment for NVP.

The present study findings were also in the same line of *Matthews et al. (2015)*, who conducted a study on five thousand and four hundred forty-nine women to assess the effectiveness and safety of all interventions for nausea, vomiting, and retching in early pregnancy, up to twenty weeks gestation and concluded that complementary therapy as ginger products was helpful to women in alleviating NVP.

7. Conclusion

In the light of the previous study findings, it was concluded that there was a highly significant difference between women's responses before and after the intervention related to nausea and vomiting. This significance in women's response reflects the positive effect of evidence-based measures in decreasing the frequency of nausea and vomiting, which supports the current research hypothesis. Besides, a statistically significant association between the evidence-based measures used and the relief of nausea and vomiting.

8. Recommendations

In the light of the findings of this study, the following recommendations are suggested:

- Illustrative educational programs should be developed to increase the awareness of pregnant women and their husbands about evidence-based measures for alleviating minor discomforts during the first trimester of pregnancy.
- Inclusion of leaflet or booklet about evidence-based measures for alleviating minor discomforts during pregnancy as a hospital protocol for guiding the nurses in the application.

Further research is suggested:

- Study the effect of an evidence-based guide on alleviating minor discomforts during all trimesters of pregnancy on a large number of pregnant women and involve women who cannot read and write.
- Apply a comparative study between primigravida and multigravida women about the effectiveness of evidence-based guidelines on alleviating minor pregnancy discomforts.

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