

## Evaluation of the Effects of an Educational Intervention Based on the Ottawa Nutritional Guideline on Health-Related Quality of Life in Pregnant Women with Nausea and Vomiting

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ARTICLE INFO	ABSTRACT
<p><b>Article type:</b> Original article</p>	<p><b>Background &amp; aim:</b> Nausea and vomiting during pregnancy (NVP) is among the most common problems in pregnant women. As explained in guidelines, combination of non-drug treatments, including nutritional modifications, lifestyle changes, and use of alternative medicine for the treatment of NVP has been less highlighted. The present study was performed with the aim of determining the effect of an educational intervention (based on the Ottawa nutritional guideline) on health-related quality of life in pregnant women with NVP.</p> <p><b>Methods:</b> This single-blind clinical trial was performed on 60 pregnant women, referred to Daneshamouz and Ahmadi health centers in Mashhad, Iran in 2015. The intervention group received two 60-min training sessions based on the Ottawa nutritional guideline, while the control group received routine care. The data collection tools included the subject selection form, demographic and midwifery information form, health-related quality of life for nausea and vomiting during pregnancy (NVPQOL) questionnaire, and the Ottawa guideline checklist. For data analysis, Chi-square, Fisher's exact test, Mann-Whitney test, independent t-test, paired t-test, and ANOVA were performed, using SPSS version 16. P-value less than 0.05 were considered statistically significant.</p> <p><b>Results:</b> The demographic characteristics of the subjects such as education, occupational status, age, gestational age, and body mass index were homogenous in the two groups. The mean NVPQOL score was significantly different between the intervention and control groups after the study (<math>P &lt; 0.001</math>). Also, the difference between the pre- and post-intervention scores was significant in the intervention group (<math>P &lt; 0.001</math>).</p> <p><b>Conclusion:</b> Based on the findings, training based on the Ottawa nutritional guideline could improve health-related quality of life in women with NVP; therefore, this type of training is recommended as an effective method.</p>
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### Introduction

Nausea and vomiting during pregnancy (NVP) is among the most common problems in pregnant women. Although the cause of this condition remains unknown, more than one mechanism seems to be involved in its occurrence. NVP begins between the first and

second cycles of absent menstruation and continues until the fourth cycle. In cases where the human chorionic gonadotropin is more produced (e.g., multiple or molar pregnancy), increased incidence of NVP can be observed (1).

NVP is reported in 80% of all pregnancies,

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and 4-7% of hospitalized cases before the second month of pregnancy are attributed to this condition. Previous research suggests that 50-90% of women experience nausea, while 30-50% experience vomiting during pregnancy (2). Severe and prolonged NVP can lead to the development of hyperemesis gravidarum, thus giving rise to reduced maternal weight, severe dehydration of the body, electrolyte imbalance, and disposal of ketones in urine (in 1-2% of pregnancies) (3).

NVP has undesirable impacts on quality of life and daily activities of pregnant women, causing sleep disturbances, fatigue, anxiety, malnutrition, irritability, decreased social activity, and disorders in social function, marital relationship, and mother-child interactions (4). According to a study by Chou et al. (2007), NVP causes disturbance in physical activity, mental health, quality of life, relationship with family members, and professional, occupational, and social activities of pregnant women; in addition, it can lead to negative fetal outcomes such as low birth weight (5).

In a study by Jouybari et al. (2013), NVP was reported to be severe, moderate, and mild in 21.7%, 59.2%, and 32.5% of women, respectively. Quality of life was reported to be low in 40% of women with NVP, while it was more desirable in women with less severe NVP (2). Health-related quality of life emphasizes on the physical, psychological, and social aspects of health. Overall, the aim of published studies on quality of life is to increase women's satisfaction and help them lead a more meaningful life (6). Also, health-related quality of life is considered as a new indicator of the quality of healthcare services in different populations (7).

Considering the unknown cause of NVP, there are few treatment strategies available (8). Treatment and management of NVP depend on its severity and symptoms. Time of treatment is of great significance, as early treatment can reduce the severity and intensity of NVP symptoms, decrease the need for hospitalization, reduce time waste for working pregnant women, and diminish psychological disorders and psychiatric problems (9).

Treatment of NVP includes pharmaceutical (e.g., vitamin B6, antihistamine, phenothiazine, and metoclopramide) and non-pharmaceutical

methods (9, 10). Pharmaceutical techniques should be applied for women with continuous NVP, besides dietary and lifestyle modifications (11). Concerns about the traumatic effects of prescribed drugs during the embryonic period, especially due to the adverse effects of thalidomide use in 1960's, have majorly limited drug treatments for NVP. As a result, pregnant women with NVP seek non-pharmacological and complementary treatments to relieve their symptoms during pregnancy (12).

Non-pharmacological remedies include dietary modifications, dehydration prevention, rest, exercise, fresh air breathing, herbal remedies (such as ginger and peppermint), aromatherapy, sleep pattern adjustments, psychotherapy, hypnosis, homeopathy, music therapy, and acupuncture (e.g., electro-acupuncture, electrical nerve stimulation through the skin, and acupressure) (13, 14).

Nutritional care and lifestyle changes are important parts of treatment for NVP. Nutritional modifications, such as use of carbohydrates and carbonated drinks, as well as relaxation techniques are effective in this area (15). Previous research on women with NVP shows that dietary changes lead to a moderate decline in the symptoms (16). Also, a recent study showed that women on a high-protein diet experience less severe NVP (17).

Other recommendations for women with NVP include minimizing the time for preparing food, lying down after digestion, eating food in quiet and comfortable places, avoiding warm places with thick odors, drinking liquid half an hour before and after a meal, drinking a cup of herbal tea with honey (such as mint and chamomile), and wearing comfortable clothes (18). Brushing the teeth after a meal, drinking mint tea, or sucking on peppermint candy after meals can also improve postprandial nausea (18).

Based on a systematic review by Jewel et al. (2003) and a meta-analysis by Badell et al. (2006), it seems that the first step in the non-pharmacological treatment of NVP is lifestyle and dietary changes, although there is insufficient empirical evidence in this area (19). Another complementary treatment for NVP is acupressure, which is one of the branches of acupuncture with the exception that it does not employ needles to stimulate the pressure points.

Generally, Neiguan point is the most frequently stimulated site in acupressure for the treatment of NVP (20).

In a study by Salehian et al. (2005), acupressure was found to be effective in improving NVP by using a C-band on the Neiguan point (21). A large number of clinical studies have evaluated the effect of acupressure on the management of NVP. Nevertheless, although some promising findings have been reported, especially for acupressure, the results are limited and inconsistent to date (22).

Matthews et al. (2010) in a systematic review showed that although complementary therapies could effectively relieve NVP, empirical evidence in this area is insufficient and contradictory (23). Considering the inconsistent results regarding the effects of pharmaceutical and non-pharmaceutical treatments, including those reported by Jewel (2003), Badell (2006), and Matthews (2010), in this study, we aimed to assess the effects of the Ottawa nutritional guideline on quality of life in pregnant women with NVP.

The Ottawa nutritional guideline has been developed for managing NVP and raising pregnant women's awareness of self-care in order to improve their quality of life. In this guideline, recommendations about lifestyle modifications, nutritional therapies, complementary medicine, and acupressure have been included (24). This guideline aims to provide evidence-based instructions for the early treatment of NVP and suggests strategies for the early diagnosis and treatment of this condition in order to prevent hyperemesis gravidarum, need for injection therapy, and increased cost of hospitalization (24).

The Ottawa nutritional guideline is a booklet, designed at Ottawa Hospital, Canada for the management of NVP. In this guideline, management of NVP is multilateral and aims to restore optimal nutrition and quality of life during pregnancy (24). With this background in mind, the present study was performed with the aim of evaluating the effects of an educational intervention based on the Ottawa nutritional guideline on health-related quality of life in women with NVP, referring to Mashhad healthcare centers in 2015.

## **Materials and Methods**

This single-blind, two-group clinical trial was performed from May 5 to August 27, 2015 on 60 eligible pregnant women, referred to the midwifery units of Daneshamouz and Ahmadi health centers in Mashhad, Iran. The sample size was calculated based on a pilot study and the mean comparison formula; finally, 30 cases were assigned to each group.

The inclusion criteria were as follows: 1) being an Iranian resident of Mashhad; 2) having a phone number; 3) gestational age of 6-11 weeks; 4) singleton pregnancy; 5) age range of 18-35 years; 6) high school level education (minimum); 7) lack of physical or mental disorders; 8) avoidance of medications reducing NVP, except for vitamin B6; 9) score of 3-16 on the Rhodes index of nausea, vomiting, and retching; 10) body mass index (BMI)  $\leq$  30 kg/m<sup>2</sup>; 10) wanted pregnancy; 11) no use of assisted reproductive techniques; 12) lack of oral/speech impairments or mental retardation; 13) lack of two consecutive miscarriages before the current pregnancy; 14) no narcotic use or alcohol drinking; 15) lack of stressful events over the past six months; and 16) scores below 10, 14, and 17 in domains of depression, anxiety, and stress on the depression, anxiety, and stress scale (DASS-21), respectively.

On the other hand, the exclusion criteria were as follows: subject's unwillingness to continue the study, occurrence of obstetric complications during the study, and hyperemesis gravidarum. The data collection tools in this study were as follows: subject selection form, demographic and midwifery data form, Rhodes index of nausea, vomiting, and retching, health-related quality of life for nausea and vomiting during pregnancy (NVPQOL) questionnaire, DASS-21, and checklist of Ottawa guideline implementation.

The Rhodes index of nausea, vomiting, and retching is a tool for the assessment of nausea, vomiting, and retching over the past 12 hours. This tool contains eight questions and is scored on a five-point Likert scale. The score of each question ranges from 0 (absence of nausea, vomiting, or retching) to 4 (maximum intensity). In this scale, three questions are related to the frequency, severity, and duration of nausea (score range: 0-12), three questions are concerned with the frequency, intensity,

and amount of vomiting (score range: 0-12), and two questions are related to the frequency and severity of retching (score range: 0-8). The total score of Rhodes index ranges between 0 and 32 (25).

NVPQOL questionnaire is specifically used to assess the quality of life among women with NVP over the past week. The questions are about the symptoms of NVP and how these symptoms can affect a person's mood and activities. This tool consists of 30 questions (rated on a 7-point Likert scale), covering four domains of physical symptoms and aggravating factors (9 questions), fatigue (4 questions), emotions (7 questions), and limitations (10 questions); the scores range from 1 (never) to 7 (always). Scores of physical symptoms and aggravating factors, fatigue, emotions, and limitations range from 9 to 63, 4 to 28, 7 to 49, and 10 to 70, respectively; the total score is within the range of 30-210.

The emotional domain of NVPQOL questionnaire includes questions about depression, sexual desire, frustration, feeling sick, joy of pregnancy, reassurance about the normality of the symptoms during pregnancy, and the impact of pregnancy on the individual's feelings. The limitation dimension contains questions about women's difficulty in accomplishing tasks (taking longer than usual), maintaining social relationships and family responsibilities, grocery shopping, and preparing food; lower scores indicate higher quality of life (26).

Another applied scale in this study was DASS-21, containing 21 questions and three major parts, i.e., depression, anxiety, and stress, scored on a 4-point Likert scale, ranging from normal to very severe (score: 0 to 3). Scores of 6-8, 4-5, and 5-6 show mild depression, anxiety, and stress, respectively, while scores above 10, 14, and 17 indicate very severe depression, anxiety, and stress, respectively (27).

The content validity method was used to determine the validity of the subject selection form, demographic and midwifery questionnaire, and checklist of Ottawa guideline implementation. The Rhodes index of nausea, vomiting, and retching has been validated in several studies including those by Liu et al. (2013) (19), Shishehgar (2008), and Modares (2012) in Iran (1, 28). This index is a standard tool for the measurement of NVP. In a study by

Nourani et al. (2012), the reliability of this tool was calculated and confirmed, using Cronbach's alpha coefficient ( $\alpha=0.89$ ) (25). Also, in the present study, the reliability of this scale was confirmed via Cronbach's alpha coefficient ( $\alpha=0.87$ ) by evaluating 10 subjects.

In addition, NVPQOL questionnaire is an international standard tool, validated in multiple studies. In a study by Liu et al., the internal validity of this questionnaire was 92.29% (19). Also, its validity was confirmed in a study by Shishehgar et al. in 2008 (1). This questionnaire is a standard tool for the assessment of quality of life in women with NVP. Also, in a study by Liu et al., its reliability was confirmed via Cronbach's alpha coefficient ( $\alpha=0.84$ ) (19). Similarly, in the present study, reliability of the questionnaire was confirmed via Cronbach's alpha coefficient by evaluating 10 subjects ( $\alpha=0.82$ ).

The subjects were selected via simple sampling and were randomly divided into control and intervention groups. For this purpose, first, we determined the intervention and control groups by flipping a coin. Then, the subjects were selected from each center through simple accessible sampling, based on the inclusion criteria. The intervention group was selected from Daneshamouz center by drawing lots, while the control group was selected from Ahmadi health center. The reason for selecting these centers was the frequent referral of qualified people to these centers and their convenient location for training. Considering the information leakage between the groups, we could not randomly allocate the subjects.

The objectives, advantages, and disadvantages of the Ottawa nutritional guideline and the possibility of random assignment to the intervention and control groups were explained to all research units. Informed consent forms were obtained from the participants, and they were assured about the confidentiality of the information and the results in general. The subjects were allowed to withdraw from the study due to physical injury, financial loss, or interference of the intervention with health or treatment measures.

Pregnant women were enrolled in the study if their scores were below 10, 14, and 17 in the

domains of depression, anxiety, and stress in DASS-21, respectively. After obtaining the written consent forms, the participants completed the Rhodes index every night according to their status from 8 a.m. to 8 p.m. for three days. The participants delivered the questionnaires to the researcher in the following morning. If the mean score of Rhodes index was 3-16, the demographic and NVPQOL questionnaires were completed in the presence of the researcher.

The days of training sessions were scheduled and the intervention group was informed about the time of the sessions on the day before via phone calls. Then, the Ottawa educational guideline was presented in two 60-min sessions (3-5 cases) in form of lecture, questions and answers, and group discussions (a 40-min lecture with a slide presentation, 20 min of questions and answers, and group discussion). The time interval between the sessions was three days.

The content of the training sessions was as follows: first session, Ottawa general guidelines for nausea and vomiting; second session, other Ottawa guideline tips including lifestyle changes, use of alternative medicine and acupressure (how to apply pressure on the Neiguan point of the wrist for 1 to 2 min in case of nausea), and suggestions about rest positions. After the end of the second session, booklets were given to the intervention group to study at home. During the first two weeks of the study, all the participants were given the Rhodes index, and the intervention group was asked to complete the checklist of Ottawa guidelines every night before sleep. After the end of two weeks, the subjects delivered the checklist (which was completed every night) to the researcher.

Afterwards, over two weeks, the checklist of Ottawa guideline implementation was given to the intervention group, while the Rhodes index was handed out to both intervention and control groups (three days before delivery); during this period, the intervention group received phone calls twice a week within a three-day interval. Overall, during these four weeks, the control group received routine care.

By the end of the fourth week, the Rhodes index (completed three days before delivery)

and health-related quality of life were again completed by the intervention and control groups. The indicators were assessed by an assistant researcher who was unaware of scoring at baseline. Both groups received routine prenatal care by a midwife at the healthcare centers. If the subjects experienced hyperemesis gravidarum or dehydration, they were excluded from the study and referred to medical centers for necessary measures.

In total, 33 women were enrolled in the intervention group. However, two cases due to absence from a training session and one case due to complicated hyperemesis gravidarum were excluded from the study. On the other hand, 31 subjects were enrolled in the control group. Nevertheless, one case was eliminated due to non-referral for completing the final questionnaire. The final sample size in each group was determined as 30. This study was registered in the IRCT (IRCT 2015011920716 N1).

Statistical analysis was performed, using SPSS version 16. Chi-square and Fisher's exact test were used to compare the nominal qualitative variables, while Mann-Whitney test was applied for the quantitative variables. Independent t-test was used to compare the mean values of normally-distributed quantitative variables, while Mann-Whitney test was employed for those which were not normally distributed. Also, analysis of covariance and paired t-test were applied for the intergroup comparison of the total score of NVPQOL before and after the study. In addition, independent t-test was used for intragroup comparison before and after the study. P-value less than 0.05 was considered statistically significant.

## **Results**

A total of 60 women (30 subjects in the intervention group and 30 subjects in the control group) were evaluated in the present study. The participants were not significantly different in terms of demographic characteristics, such as education, occupational status, spouse's educational level, spouse's occupational status, housing status, family income, or duration of marriage. Also, the subjects were matched regarding age, gestational age, and BMI (Table 1).

In terms of health-related quality of life, independent t-test results showed that the two

groups were not significantly different in terms of physical symptom scores before the study

**Table 1.** Comparison of the mean ( $\pm$ SD) age, gestational age, and body mass index (BMI) at baseline in the groups

Variables	Intervention group		Control group		Total		Independent t-test and Mann-Whitney test results	P-value
	Mean $\pm$ SD	Median	Mean $\pm$ SD	Median	Mean $\pm$ SD	Median		
Age (years)	27.0 $\pm$ 5.02	27.00	27.33 $\pm$ 4.59	27.00	27.20 $\pm$ 4.77	27.00	t=-0.215 df=58	0.831
Gestational age (weeks)	8.43 $\pm$ 1.64	8.21	9.21 $\pm$ 1.56	9.57	8.82 $\pm$ 1.63	9.00	t=-1.880 df=58	0.065
BMI	24.71 $\pm$ 3.64	24.65	25.09 $\pm$ 3.51	25.60	24.90 $\pm$ 3.55	25.00	t=-0.324 df=58	0.543

( $P=0.402$ ), whereas following the intervention, a significant difference was found between the two groups (based on the analysis of covariance by controlling the baseline) ( $P<0.001$ ).

Before the study, the two groups were not significantly different in terms of aggravating factors of NVP ( $P=0.830$ ), while after the intervention, a significant difference was found between the two groups (based on the analysis of covariance by controlling the baseline) ( $P=0.003$ ). In addition, before the study, the two groups were not significantly different in terms of fatigue ( $P=0.288$ ), whereas following the intervention, there was a statistically significant difference ( $P=0.001$ ).

As the findings revealed, the two groups were not significantly different in terms of the emotional domain prior to the study ( $P=0.665$ ), whereas the difference was significant after the

intervention ( $P=0.005$ ). In addition, there was no statistically significant difference between the two groups in terms of limitations associated with NVP before the study ( $P=0.657$ ); however, after the study, a statistically significant difference was found between the two groups ( $P=0.001$ ) (Table 2).

Based on the results, the two groups were not significantly different in terms of the total score of NVPQOL before the study ( $P=0.370$ ), while after the intervention, a statistically significant difference was observed between the groups ( $P<0.001$ ). The results of inter-group analysis via paired t-test showed a statistically significant difference between the results before and after the study in the intervention group ( $P<0.001$ ), whereas no statistically significant difference was found in the control group ( $P=0.874$ ) (Table 3).

**Table 2.** Mean and standard deviation of the domains of health-related quality of life in women with nausea and vomiting during pregnancy (NVPQOL) in the intervention and control groups

Domains of NVPQOL	Groups		The results of independent t-test and analysis of covariance by controlling the baseline before the intervention
	Intervention Mean $\pm$ SD	Control Mean $\pm$ SD	
Physical symptoms			
Before the study	26.4 $\pm$ 7.0	24.8 $\pm$ 7.7	$P=0.402$
After the study	16.7 $\pm$ 4.7	23.9 $\pm$ 5.9	$P<0.001$
Aggravating factors of NVP			
Before the study	8.7 $\pm$ 3.2	8.5 $\pm$ 2.8	$P=0.830$
After the study	6.0 $\pm$ 2.2	8.3 $\pm$ 3.0	$P=0.003$
Fatigue			
Before the study	14.0 $\pm$ 4.9	12.0 $\pm$ 5.5	$P=0.288$
After the study	9.5 $\pm$ 3.9	13.6 $\pm$ 5.3	$P=0.001$
Emotions caused by NVP			
Before the study	24.2 $\pm$ 6.7	23.4 $\pm$ 7.5	$P=0.665$
After the study	18.1 $\pm$ 5.3	22.7 $\pm$ 6.9	$P=0.005$
Limitations associated with NVP			
Before the study	32.9 $\pm$ 14.0	31.2 $\pm$ 15.5	$P=0.657$

After the study	22.5±8.7	31.2±10.5	P=0.001
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**Table 3.** Mean and standard deviation of the total score of health-related quality of life in pregnant women with nausea and vomiting during pregnancy (NVPQOL) in the intervention and control groups

Health-related quality of life in pregnant women with nausea and vomiting during pregnancy (NVPQOL)	Groups		Total	Independent t-test and analysis of covariance results (by controlling the baseline before the intervention)
	Intervention	Control		
	Mean±SD	Mean±SD	Mean±SD	
Before the study	106.1±30.5	98.7±32.6	102.4±31.5	P=0.370
After the study	72.8±21.0	99.5±24.0	86.2±26.1	P<0.001
Difference between the two periods	33.27±26.82	0.80±27.47	16.23±31.93	P<0.001
Results of paired t-test	P<0.001	P=0.874	P<0.001	

## Discussion

The present findings revealed the effects of the applied educational intervention based on the Ottawa nutritional guideline on health-related quality of life in women with NVP. As the results indicated, health-related quality of life improved in the intervention group. These results were consistent with the findings reported in a study by Liu et al. (2013), which was performed with the aim of determining the impact of professional support on quality of life in women with nausea and vomiting in early pregnancy (19). In their study, professional support, comprised of training with a booklet and telephone support, could reduce NVP and improve health-related quality of life in the intervention group.

The results of the present study were consistent with the findings of a study by Abbaszadeh (2014) on the effects of telephone support on health-related quality of life in 60 women with NVP; based on the findings, telephone support was effective in improving health-related quality of life in pregnant women (26). In the present study, the intervention was carried out over four weeks, followed by two weeks of training. Phone calls were made twice a week and the emphasis was on accurate performance. The cause of consistency between the mentioned studies and the present research might be the analysis of similar populations and the analogous design of these studies.

In a study by Hasani et al. (2015), which was performed to compare the effects of relaxation and vitamin B6 on physical and psychological symptoms of premenstrual syndrome in 150 students (living in dormitory), Vitamin B6 was more effective than relaxation in reducing the

symptoms (29). Also, in a study by Pakgozar et al. (2004), entitled as "Comparison of hypericum perforatum and placebo in treatment of physical symptoms of premenstrual syndrome", the results showed a decline in the severity of physical symptoms in the hypericum group, compared to the placebo group (P=0.00) (30). One of the reasons for the increase in the mean score of physical symptoms after the intervention in these studies can be randomization. Similarly, vitamin B6 was used in the present study, which can be the cause of consistency between the present results and the findings reported by Hasani and colleagues.

Furthermore, in a study by Basiri Moghadam et al. (2013), which aimed to determine the effect of progressive muscle relaxation technique on fatigue in patients undergoing hemodialysis, the results showed no significant difference between the two groups in terms of fatigue before the intervention (P=1.000), while the difference was statistically significant after the intervention (P<0.001) (31). The present results were in line with previous research possibly due to the use of training classes, checklist of muscle relaxation technique (by the intervention group), and contact with the participants (through phone calls). Additionally, according to a study in Canada, which evaluated the quality of life in pregnant women with NVP, the efficacy of 50% of working women reduced in the workplace and 25% needed to leave their job (7). In the present study, the multifactorial nature of the intervention can explain its effects on various aspects of health-related quality of life in women with NVP.

This study had several limitations. First, individual and genetic differences of the subjects were effective on the incidence and severity of

NVP and quality of life; however, the researcher obviously had no control over these factors. Also, NVP improved as the gestational age increased; therefore, the internal validity of the study might be questionable. This problem was controlled through random allocation of the subjects to the intervention and control groups. Finally, comparison between the effects of the present educational intervention (based on the Ottawa nutritional guideline) and the national guideline of obstetric and midwifery services on health-related quality of life in women with NVP is highly recommended.

## Conclusion

In this study, the educational intervention based on the Ottawa nutritional guideline could improve health-related quality of life in pregnant women. Therefore, it is recommended to teach the proposed guidelines to pregnant women in order to improve their quality of life.

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## Conflicts of interest

The authors declare no conflicts of interest.

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