

# Effect of comfort theory-based nursing care on pain and comfort in women undergoing hysterosalpingography: a randomized controlled trial

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## SUMMARY

**OBJECTIVE:** This study aims to examine the effect of comfort theory-based nursing care on pain and comfort in women undergoing hysterosalpingography.

**METHODS:** This randomized control trial was conducted on 126 women (42 in each intervention and control group). Virtual reality glasses group (n=42), mobile-assisted education group (n=42), and control group (n=42). The control group received only routine care. Comfort levels were evaluated at the beginning and end of the study using the General Comfort Scale and pain levels evaluated at the beginning and end of the study using the Visual Analog Scale.

**RESULTS:** The comfort theory-based nursing care (virtual reality glasses and mobile-assisted education group) was effective in increasing women's comfort with painful invasive procedures such as hysterosalpingography and reducing pain.

**CONCLUSION:** It is recommended that a nurse be present in the hysterosalpingography process, providing nursing care services continuously and introducing this program to working nurses.

Clinical Trial Registration Number: NCT04676932.

**KEYWORDS:** Comfort. Hysterosalpingography. Nursing care. Pain. Virtual reality.

## INTRODUCTION

Hysterosalpingography (HSG), a minimally invasive treatment, is one of the diagnostic methods for infertility<sup>1-4</sup>. HSG is often uncomfortable and leads to discomfort<sup>5</sup>. In addition to pain and discomfort, women may experience other symptoms during HSG, such as nausea, vomiting, fainting, and increase in body temperature. HSG is usually performed in outpatient treatment units, and it is extremely important to apply physical and emotional nursing care that covers the perioperative processes and maintains patient comfort<sup>5-7</sup>.

In this study, the authors focus on the effect of comfort theory-based nursing care (CT<sub>b</sub>NC) on pain and comfort in women undergoing HSG. Important aspects of this theory are that comfort is holistic and should not be confused with pain as it involves more than physical discomfort or suffering. Valid measures of the effectiveness of holistic interventions are needed to improve nursing practice. With the increased interest in holistic interventions that target responses in the context of human experience (i.e., physical, psychospiritual, social, and environmental), holistic measures that are multidimensional

and entail many interrelated parts are essential for understanding effects on an indivisible whole<sup>8</sup> (Table 1). The goal of interventions (e.g., guided imagery, massage therapy, and therapeutic touch) is that many desirable changes will be experienced simultaneously by recipients. These changes might include increased relaxation, positive thinking, well-being, and contentment. Virtual reality glasses (VRG) is one of the imaginary methods used to reduce pain. The reason for using mobile-assisted education (MAEC) is to raise awareness among individuals and clarify the issues they do not understand.

The literature appears that a focal point in studies was additional interventions (video, training and counseling, virtual reality glasses (VRG), listening to music, etc.) during the HSG procedure have a reducing effect on pain or anxiety<sup>2,9-11</sup>. However, pain, privacy concerns, not having information about the procedure, having to face a problem such as infertility, environmental conditions such as sound, smell, and images, and relational dimensions such as not being with a partner or a supportive person during HSG are also characterized by deterioration in comfort<sup>11,12</sup>.

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Conflicts of interest: the authors declare there is no conflicts of interest. Funding: The research reported in this publication is supported by the Ondokuz Mayıs University and funded by the Scientific Research Projects Coordination Unit under number 1904.21.002.

Received on August 09, 2023. Accepted on August 15, 2023.

This study was accepted as an oral presentation at the 2nd International Nursing Care and Research Congress held between November 17 and 19, 2022, in Ankara, Türkiye.

**Table 1.** Comfort theory-based nursing care.

Comfort	Levels		
Dimensions	Relief	Ease	Transcendence
Physical	<ul style="list-style-type: none"> <li>-Women stating that the pain that may occur in the perineum area and abdomen due to hysterosalpingography is low on the Visual Analogue Scale</li> <li>-Vital signs being within the normal range</li> <li>-Ensuring effective breathing</li> <li>-Fasting before the procedure</li> <li>-Ensuring elimination before the procedure</li> <li>-Placing the patient in a comfortable position during the procedure</li> <li>-Coping with post-procedure risks (bleeding, nausea, vomiting risk, infection risk, tissue integrity deterioration, etc.)</li> <li>-Ensuring adequate rest</li> </ul>	<ul style="list-style-type: none"> <li>-Less pain due to hysterosalpingography, ensuring that the patient can stay calm and peaceful during the procedure</li> <li>-Providing counseling to the mobile-assisted education group on hysterosalpingography</li> <li>-Allowing the virtual reality glasses group to experience less pain by diverting attention</li> </ul>	<ul style="list-style-type: none"> <li>-Increasing comfort level with nursing care based on comfort theory</li> </ul>
Psychospiritual	<ul style="list-style-type: none"> <li>-Ensuring that women can easily express their pain and fear,</li> <li>-Supporting participation in decisions</li> <li>-Informing patients</li> <li>-Helping women to prepare for the procedure</li> <li>-Showing women proper places to put their clothes</li> <li>-Helping women sit in the proper place where the procedure will be performed</li> <li>-Supporting the woman to sit down</li> <li>-Respecting patient decisions before and during the procedure</li> <li>-Treating the patients diligently before and during the procedure</li> <li>-Allowing patients to worship in accordance with their beliefs during the procedure</li> <li>-Supporting the sense of achievement after the procedure</li> </ul>	<ul style="list-style-type: none"> <li>-Providing counseling on the results of treatment for the mobile-assisted education group and providing relief during the hysterosalpingography procedure</li> </ul>	<ul style="list-style-type: none"> <li>-Increasing comfort level with nursing care based on comfort theory</li> </ul>
Environmental	<ul style="list-style-type: none"> <li>-Ensuring that the ambient temperature does not fall below 20 degrees and does not rise above 27 degrees</li> <li>-Ensuring that noise in the environment is kept to a minimum</li> <li>-Ensuring privacy</li> <li>-Showing nature videos to patients</li> </ul>	<ul style="list-style-type: none"> <li>-Delivery of the training booklet for the mobile-assisted education group and ensuring relief during the hysterosalpingography procedure</li> <li>-Ensuring virtual reality glasses group to watch nature videos and to provide relaxation by diverting their attention from the procedure</li> </ul>	<ul style="list-style-type: none"> <li>-Increasing comfort level with nursing care based on comfort theory</li> </ul>
Sociocultural	<ul style="list-style-type: none"> <li>-Informing patients</li> <li>-Ensuring effective communication</li> </ul>	<ul style="list-style-type: none"> <li>-Delivery of the training booklet for the mobile-assisted education group and ensuring relaxation during the procedure</li> <li>-Providing the necessary information to the virtual reality glasses group before and during the procedure</li> </ul>	<ul style="list-style-type: none"> <li>-Increasing comfort level with nursing care based on comfort theory</li> </ul>

There are studies where training and counseling services are provided to women undergoing HSG<sup>2,5,13,14</sup> or VRG are used<sup>9,15</sup>. However, to the best of our knowledge, there are no studies in which CT<sub>b</sub>NC or a similar theory is applied during HSG and its effectiveness is evaluated and compared with the use of VRG. Therefore, this is the first randomized controlled trial to use VRG or MAEC intervention with CT<sub>b</sub>NC in HSG and to compare the efficacy of these methods.

## METHODS

### Study design and location

This research was designed as a randomized controlled trial with a parallel group pre-test-post-test design. The study was

conducted in accordance with the CONSORT guidelines. The study was registered on clinicaltrials.gov (ClinicalTrials.gov Identifier: NCT04676932). The study was conducted between September 2020 and April 2021 in the obstetric outpatient clinics of a public hospital in northern Turkey.

### Sample size and characteristics

Sample size was determined based on a similar study in the literature<sup>16</sup>. Power analysis was performed with an effect size of  $d=0.79$ , a confidence interval of 0.95 ( $1-\beta$ ), an alpha error rate of 0.05, and a power of 0.95. Accordingly, the minimum sample size was calculated as 108 participants (36 women in each group). Considering possible data loss, a total of 126 women, 42 in each group, were included in the study. Healthy women aged >18 years who had not been diagnosed with any psychiatric disease, had no

mental and communication problems, not having drug sensitivity or allergies, not having an active genital infection, and having a mobile phone were included in the study. Those who did not meet the inclusion criteria were excluded from the study. Considering possible losses (nausea, vomiting, fainting, and increased body temperature), a total of 126 women (42 in VRG, 42 in MAEC, and 42 in control groups) were included in the study, and the research was completed with the participation of 122 women.

### Data collection tools

The introductory information form developed by the researchers in line with the relevant literature consists of 11 items<sup>2,17,18</sup>. The form contains questions related to the sociodemographic characteristics and obstetric histories of women.

### Visual Analog Scale

The pain was monitored with a VAS, a 10-cm, one-dimensional measuring tool commonly used to measure the severity of pain. The scale begins with “no pain” (0) and ends with “unbearable pain.” A score of 0–4 refers to “no pain,” 5–6 refers to “moderate pain,” and 7–10 refers to “severe pain”<sup>13</sup>.

### General Comfort Scale

Kolcaba developed Glasgow Coma Scale (GCS) in 1992 to determine individuals' comfort requirements and evaluate nursing interventions providing and improving patient comfort<sup>19</sup>. It is a 4-point Likert-type scale consisting of 48 items. The questions evaluate the taxonomic structure of comfort with three levels and four dimensions<sup>20</sup>. The score that can be obtained from the scale ranges between 48 and 192.

The total score obtained is the number of scale items. The average value is determined by dividing the total score obtained by the number of scale items and the result is indicated in the 1–4 distribution. Low comfort is expressed with one point, and high comfort with four points. The Cronbach's alpha coefficient of the scale is 0.85. Permission to use the scale has been obtained.

### Randomization

Randomization into one of the three study groups was performed with the use of the Excel software (Microsoft, Redmond, Washington) to generate random numbers.

### Collection of data

After the consent of all women was obtained and randomization was performed, the sociodemographic and obstetric characteristics and comfort levels were determined via the pre-tests. Routine care in intervention and control groups continued without any interference during the study period.

### Intervention groups

In the MAEC intervention group, the day after the pre-test, participants were contacted telephonically. Notably, 48 h before the HSG procedure, the training booklet based on CT, which was created for the HSG procedure, was delivered to the patients via their mobile application, and two participants were provided via e-mail, and kept open for training and counseling. MAEC intervention was continued with women in need through phone calls and text messaging until the day of the process. In total, 180 interviews were conducted with 42 women. The average time for phone calls was 10 min.

The VRG intervention involved the use of VRG during the HSG procedure. Before the process, VRG were introduced to the women and told how to use them. During HSG, each woman was shown the same video with 360° virtual reality, including scenes from nature and a feeling of comfort and peace while making the viewer feel like they were there.

### Control group

This group only received routine care in the hospital. This group (n=42) filled out the introductory information form and GCS.

### Evaluation of data

Variables were presented as mean, standard deviation, number, and percentage. Shapiro-Wilk test was performed to check whether the data conformed to normal distribution. It was found that the data did not show the normal distribution and non-parametric tests were performed in statistical analysis. Mann-Whitney U test was used for binary categorical variables, and the Kruskal-Wallis H test was used for categorical variables with three or more categories. The signed rank test was performed to compare the pre-test and post-test scores between the groups. Tukey's post-hoc test was performed to find the group causing the difference.

### Ethics

Ethical permission (approval number: 41, approval date: 13/02/2019) was obtained from a University Clinical Research Ethics Committee. All participants provided voluntary, informed, written consent prior to being enrolled in the study and could withdraw their consent at any time.

## RESULTS

Table 2 shows that the groups are similar, and there is no significant difference between the groups. Participants' age, age during marriage, educational status, employment status, level

Table 2. Descriptive characteristics of women.

Characteristics	Virtual reality glasses (n=42)		Mobile-assisted education (n=40)		Control (n=40)		Statistical analysis
	Number	%	Number	%	Number	%	
Age							
$\bar{x}\pm SD$ (min-max)	27.4 $\pm$ 3.14 (22-36)		27.8 $\pm$ 4.59 (19-37)		28.33 $\pm$ 4.55 (21-40)		H=0.618 p=0.734
Duration of marriage							
1-2 years	27	64.3	30	75.0	27	67.5	x <sup>2</sup> =1.554 p=0.817
3-4 years	8	19.0	6	15.0	6	15.0	
4 years and above	7	16.7	4	10.0	7	17.5	
Education level							
Secondary school	13	30.9	14	35.0	12	30.0	x <sup>2</sup> =9.983 p=0.266
High school	7	16.7	8	10.0	10	25.0	
University and above	22	52.4	18	45.0	18	45.0	
Employment in an income-generating job							
Working	23	54.7	18	45.0	22	55.0	x <sup>2</sup> =1.051 p=0.591
Non-working	19	45.2	22	55.0	18	45.0	
Receiving hysterosalpingography information							
Yes	32	76.2	22	55.0	29	72.5	x <sup>2</sup> =4.776 p=0.092
No	10	23.8	18	45.0	11	27.5	
Body mass index							
Normal	27	64.3	18	45.0	20	50.00	x <sup>2</sup> =4.381 p=0.357
Overweight	10	23.8	11	27.5	12	30.0	
Obese	5	11.9	11	27.5	8	20.0	
Menarche age							
$\bar{x}\pm SD$ (min-max)	13.07 $\pm$ 1.26 (11-16)		13.38 $\pm$ 1.46 (11-16)		13.17 $\pm$ 1.41 (11-16)		H=0.7995 p=0.670
Menstruation pattern							
Regular	39	92.8	33	82.5	34	85.0	x <sup>2</sup> =2.114 p=0.288
Irregular	3	7.2	7	17.5	6	15.0	
Dysmenorrhea							
Yes	22	52.4	24	60.0	25	62.5	x <sup>2</sup> =0.942 p=0.624
No	20	47.6	16	40.0	15	37.5	
Frequency of menstruation							
$\bar{x}\pm SD$ (min-max)	28.3 $\pm$ 3.43 (24-45)		27.6 $\pm$ 3.6 (22-40)		28.4 $\pm$ 4.55 (21-40)		H=1.3615 p=0.506
Duration of menstruation							
$\bar{x}\pm SD$ (min-max)	5.79 $\pm$ 0.92 (4-9)		5.62 $\pm$ 1.46 (3-9)		5.66 $\pm$ 0.99 (4-7)		H=0.5603 p=0.755

H: Kruskal-Wallis H test; p: significance;  $\bar{x}$ : mean, SD: standard deviation; min: minimum; max: maximum.

of income, health insurance and family type, and smoking use are similar ( $p>0.05$ ).

Table 3 shows the comparison of the GCS and VAS scores between and within groups. In the GCS pre-test and post-test measurements, the difference between all three groups and both intervention and control groups was significant ( $p<0.05$ ). This increase in the GCS scores of the intervention groups was statistically significant ( $p=0.000$ , Table 3). The mean GCS score of the control group decreased, and the difference between the intervention and control groups was significant ( $p=0.000$ ). In the post-test, the statistically significant difference between the MAEC and VRG intervention groups and the MAEC and control groups continued, and there was a statistically significant difference between the VRG and control groups ( $p=0.000$ , Table 3).

While no significant difference was found in the mean pain scores during the HSG procedure between the intervention and control groups ( $p=0.240$ ), it was found that the VAS scores of the women decreased after the procedure regardless of their group and a significant difference was found in VAS scores within all groups ( $p=0.00$ , Table 3). After the process, women in the control group defined higher pain levels than women in both intervention groups. The MAEC group had the lowest VAS score during HSG and was also the group with the highest reduction in pain level after HSG. The mean scores of the MAEC group were significantly different from both VRG and control groups. On the contrary, as shown in Table 3, there was

a statistically significant difference between VRG and control groups in favor of VRG ( $H=21.15$ ,  $p=0.000$ , Table 3).

## DISCUSSION

Researchers of this study suggest that CT<sub>b</sub>NC positively affects care outcomes. HSG procedure is characterized by anxiety, pain, and deterioration in comfort for women<sup>2</sup>. In the literature, women rated how uncomfortable the HSG procedure was, and the mean score was found to be  $6.36\pm 2.19$ <sup>21</sup>. With proper nursing care, it is possible and more humane for women to experience less pain and anxiety and have higher comfort during HSG.

Comfort theory-based nursing care has been applied in various research studies<sup>8,16,22-24</sup>, and it has been found that comfort has increased in intervention groups receiving theory-based care. According to the results of this study, it was found that both MAEC and VRG caused a significant increase in overall comfort levels in women. In contrast, the comfort level in the control group decreased after the HSG procedure. The highest comfort levels after the procedure were observed in the MAEC group. In Guvenc's study, a 30-min training was given to women before the HSG procedure by the nurse, and the anxiety level of the women decreased in the intervention group<sup>2</sup>. With MAEC, women were allowed to ask questions about the issues they were concerned about regarding HSG, which increased their comfort levels. Some studies emphasize

**Table 3.** Comfort levels and pain levels of participants according to groups and measurement times (n=122).

Glasgow Coma Scale	Virtual reality glasses (n=42)	Mobile-assisted education (n=40)	Control (n=40)	Test statistic
	$\bar{x}\pm SD$ (min-max)	$\bar{x}\pm SD$ (min-max)	$\bar{x}\pm SD$ (min-max)	
Pre-test	2.55±0.50 (1.5-3.63) <sup>b</sup>	2.99±0.42 (1.73-3.65) <sup>a</sup>	2.65±0.47 (1.25-3.63) <sup>b</sup>	H=22.82 <b>p=0.000</b>
Post-test	3.10±0.57 (1.54-3.75) <sup>b</sup>	3.16±0.42 (1.79-3.75) <sup>a</sup>	2.44±0.69 (1.25-3.5) <sup>c</sup>	H=26.80 <b>p=0.000</b>
Intra-group statistical analysis				
S / p	-304 / <b>0.000</b>	-252 / <b>0.000</b>	146 / 0.057	
Pain levels (Visual Analog Scale)	$\bar{x}\pm SD$ (min-max)	$\bar{x}\pm SD$ (min-max)	$\bar{x}\pm SD$ (min-max)	Test statistic
During hysterosalpingography	8.24±1.65 (5-10)	7.76±2.10 (4-10)	8.50±1.81 (4-10)	H=2.85 p=0.240
15 min after the procedure	3.00±2.22 (0-8) <sup>b</sup>	2.76±2.50 (0-10) <sup>c</sup>	5.14±2.70 (2-10) <sup>a</sup>	H=21.15 <b>p=0.000</b>
Intra-group statistical analysis				
S / p	430.5 / <b>0.000</b>	410 / <b>0.000</b>	410 / <b>0.000</b>	

S: signed rank test; H: Kruskal-Wallis H test; p: significance;  $\bar{x}$ : mean, SD: standard deviation; min: minimum; max: maximum; a, b, c: There is no difference between data indicated by the same letter. Statistically significant values are indicated in bold.

that it is essential to provide counseling to reduce anxiety before applying assisted reproductive techniques<sup>2</sup>. The result of this study supports the role of counseling in reducing stress.

Mobile-assisted education aimed to increase comfort and control the pain experienced by providing safety and information. In this study, women identified pain during the procedure that was not significantly different between the intervention and control groups and was higher than the level of pain<sup>21</sup>. In other words, neither MAEC nor VRG affects the pain experienced during the procedure. On the contrary, women in the MAEC group had the lowest level of pain indicated during and after the process. Although the difference between the groups is not significant, this decrease in the level of pain indicated in the MAEC group is most likely due to supporting external well-being-seeking behaviors (education and counseling) according to Kolcaba and the simultaneous control of the environmental factors (light, noise, color, temperature, etc.) that form the external background of the human experience during the procedure. The fact that the post-test pain level indicated in the MAEC group was significantly lower than the VRG and control groups supports this view.

Pain management is a growing healthcare issue all over the world. Swiftly addressing women's need for painkillers after painful procedures will increase patient satisfaction and reduce healthcare costs<sup>25</sup>. VRG reduces pain by distracting individuals from processing signals from pain receptors<sup>26</sup>. It is a non-invasive and low-cost intervention that can be used to cope with pain during outpatient surgical procedures. An increasing body of evidence points to the positive effect of VRG use in acute pain management<sup>14</sup>, during various medical procedures such as chemotherapy<sup>27,28</sup>, and in wound care<sup>29,30</sup>.

In contrast, it has been found that VRG as a distraction method does not affect pain during cystoscopy<sup>31</sup>. In this study, CT<sub>b</sub>NC-VRG did not significantly impact the level of pain during HSG but led to a substantial reduction in pain level 15 min after the procedure compared to the control group. Similar to our result, in the Yılmaz Sezer et al.'s study, women in the VR group had lower pain levels during and 15 min after HSG than in the control group<sup>15</sup>. According to this result, companionship (social context of comfort) during the process, regulating the environment, and ensuring and maintaining comfort (environmental

context of comfort) via CT<sub>b</sub>NC-VRG effectively reduce women's pain levels after HSG.

## CONCLUSION

This study showed a significant statistical and clinical improvement in pain and comfort in women undergoing HSG. With CT<sub>b</sub>NC, the post-procedural comfort level of women increased and their pain level decreased.

The study's results are also crucial, as they show the positive impact of virtual care technologies on health outcomes and training and counseling. In situations where continuous counseling cannot be provided for HSG, VRG can be used in conjunction with comfort-enhancing measures.

## Limitation

Owing to its single-centered nature, the results cannot be generalized to all healthy women.

## ETHICS

Permissions were obtained from Ondokuz Mayıs University Clinical Research Ethics Committee (approval number: 41, approval date: 13/02/2019).

## ACKNOWLEDGMENTS

The authors would like to thank all the experts who gave their opinions and suggestions about the training booklet, all the participants, and the medical staff who helped during the HSG procedure. The authors would like to express their gratitude to Prof. Dr. Mehmet Ziya Firat, an expert statistician, for his contribution to data analysis.

## AUTHORS' CONTRIBUTIONS

**SB:** Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Validation, Visualization, Writing – original draft, Writing – review & editing. **ÖK:** Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Software, Validation, Writing – review & editing.

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