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Research Article

The Effect of Information About Gynecological Examination on the Anxiety Level of Women Applying to Gynecology Clinics: A Prospective, Randomized, Controlled Study

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Abstract

Background: Crowded hospital outpatient clinics and endless waiting lines that make patients feel overlooked tend to exaggerate patients' anxiety levels. In addition, fear of pain, shyness, religious and traditional thoughts, women's sexual role in society, and previous information and experience also contribute to people's anxiety levels with regard to gynecologic examination.

Objectives: We aimed to analyze the effect of specific information about gynecologic examination on anxiety levels of women applying to gynecology clinics.

Materials and Methods: In this randomized prospective study, the women applying for a gynecological examination were randomly allocated into control, intervention 1, and intervention 2 groups. Power analysis indicated that in order to achieve a one-point decrease from the previous anxiety score of 43.85 ± 5.41 at one side alpha 0.05 with a power of 80%, at least 79 women were needed in each group. Four medical school students interviewed 75 women (25 in control, 25 in intervention 1, and 25 in intervention 2). The data were collected using the demographic, social, and economic data form, and the Turkish version of the state-trait anxiety inventory (STAI). The women in the intervention 1 and 2 groups were instructed to read a paper that contained brief information about the gynecological examination procedure and the profits obtained from forests, respectively. All participants, including the women in the control group, filled the STAI by themselves. The three groups were compared appropriately.

Results: The demographics pertaining to age, gravidity and parity, miscarriage, induced abortion, ectopic pregnancy, offspring number, place of residence, working status, education level and previous experience of gynecological examination did not differ among the groups (P > 0.05). According to the STAI scores, all groups had mild state (control: 40.20 ± 10.53 , intervention 1: 42.00 ± 11.98 , and intervention 2: 45.30 ± 10.32) and severe continuous (control: 46.78 ± 8.65 , Intervention 1: 47.25 ± 9.57 , and intervention 2: 46.60 ± 9.72) anxiety levels. However, both state and continuous anxiety scores were not significantly different in all groups (P > 0.05).

Conclusions: Providing brief written information about the gynecological examination procedure and the clinic's working discipline is not sufficient to lower the anxiety of women applying for a gynecological examination.

Keywords: Anxiety Disorders, Comparative Study, Gynecological Examination, Hospitals, Obstetrics and Gynecology Department, Outpatients

1. Background

Pelvic examination is a routine part of physical examination in obstetrics and gynecology. It is very important in the diagnostic work-up of gynecologic cancers, gynecologic infections (including sexually transmitted diseases), bleeding disorders, sexual function disorders, infertility, and family planning services. However, many women declare feelings or experiences of fear and anxiety about pelvic examination.

Fear of pain, shyness, religious and traditional thoughts, women's sexual role in society, and previous information and experience contribute to this anxiety (1).

Additionally, during admission to a hospital, the hospital environment and the diagnostic and therapeutic procedures are considered as exhausting and risky (2). Women's anxiety levels are also affected by the unfamiliarity of the hospital environment, working staff, instruments and medical procedures used, unknown medical language, and disregard of individuality and privacy (3). The crowded hospital outpatient clinics and the endless waiting lines that make patients feel overlooked may also exaggerate anxiety levels (4).

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2. Objectives

In this prospective controlled study, we aimed to analyze the effect of specific information on gynecological examination conducted at the pre-examination stage on anxiety levels of women applying to gynecology clinics.

3. Materials and Methods

3.1. Sample

This study was conducted at the obstetrics and gynecology department of Kafkas university, school of medicine in Kars, Turkey. The study population involved women admitted to the obstetrics and gynecology department of Kafkas university school of medicine, and 300 of them were invited to participate.

Before recruitment, we used the state-anxiety scores of a previous study (5) to analyze the power of the study. Power analysis indicated that in order to achieve a one-point decrease from the previous anxiety score of 43.85 \pm 5.41 at one side alpha 0.05 with a power of 80%, at least 79 women were needed in one group. In order to decrease the chance of unpredictable errors, we planned to invite 100 women in each group.

We used a computerized program and sealed cards to assign patients into three groups: control, intervention 1 group, and intervention 2 group. In all groups, the demographic, social, and economic data form was initially obtained by the attending medical student. The control group members, without receiving an intervention, filled the state-trait anxiety inventory (STAI) by themselves. The women in the Intervention 1 and 2 groups were instructed to read a paper containing brief information on the gynecological examination procedure and the profits obtained from forests, respectively. Then, they filled the STAI by themselves.

The information papers consisted of approximately 150 words. The information on gynecological examination consisted of the order of entrance into the doctor's interview room; conversation with the doctor about the duration, localization, severity, and intensity of the complaints; tests; previous results; examinations; medications and medical history; preparation for physical and pelvic examination; and the interventions during the examination. All the participants were interviewed prior to their appointment with the gynecologist.

3.2. Inclusion and Exclusion Criteria

Women with known chronic debilitating or painful diseases including malignancies, infertility, primary or recurrent pelvic inflammatory disease with severe pain, as

well as women with visual, hearing, perception problems and psychological disorders, were excluded. Chronic alcohol consumption, substance and drug use, and smoking also caused exclusion. Additionally, the unwillingness to participate also caused exclusion.

The study comprised women with minor gynecological problems lasting less than a month, and women having appointments for a routine gynecological screening and examination. Minor gynecological disorders included menstrual disorders, foul-smelling vaginal discharge, difficulty in urination, groin pain, discomfort during intercourse, and changes of periods following the insertion of an intrauterine device.

3.3. Data Collection Procedure

After recruitment among voluntary medical students in the last year of undergraduate medical examination, four students received brief information on the details of the study. Each one of them was instructed to conduct interviews with 75 women (25 in control, 25 in Intervention 1, and 25 in Intervention 2 groups) and help the participants to understand and fill in the questionnaires. They were also instructed to provide information on areas where the participants were confused and asked for help. The demographic, social, and economic data form was filled by the students; however, the STAI were filled by the participants.

3.4. Data Collection Tools

3.4.1. Demographic, Social, and Economic Data Form

The demographic, social, and economic data form contained two parts. Part 1 was used to gather information on demographics: age, gravidity and parity, miscarriage, induced abortion, ectopic pregnancy, the number of offspring. Part 2 of the form contained questions seeking information about the standard of living index (SLI) modified from a previous study (6). It included the number of people in the household, monthly income, educational qualification, urban or rural residence, and the economic status of the participant. In order to determine the effect of economic status on daily living standards, information on possession of a house, car, white goods (e.g., refrigerator, dishwasher, etc.), and a heating system in the living quarters was also requested. The SLI also contained questions about the possession of a mobile or local phone, a television set, and the flight experience of the participants in order to gather information about the communication and travelling habits of the participants.

Monthly income was divided by 30 (days) and then divided by the number of household members to calculate the daily household income. The winters are very cold and long in Kars; thus, possession of a heating system in

one room, more than one room, and the whole house was scored 1-3. Having a facility for heating a single room has a score of 1, if the system heats more than one room but not the whole house the score is 2 and finally heating the whole house has a score of 3. Other parameters of the index were coded 1 or 0 for the answers yes or no, respectively. The mean scores per daily household income, heating system, and the other parameters were summed to calculate SLI.

3.4.2. STAI

The STAI was developed by Spielberger (7) in order to determine event-specific and continuous anxiety levels separately. It is a self-evaluation questionnaire that comprises short expressions. In 1983, Oner and Le Compte adapted it into Turkish (8). STAI includes two separate subscales, each having 20 clauses. To obtain data on how someone feels in certain conditions in a certain time period while considering thoughts about current conditions, we administered the state anxiety scale. The state anxiety level may be influenced by the continuous anxiety level; thus, to obtain data on general feelings, we administered the continuous anxiety scale. Each clause has points ranging between 1 and 4 and the total points (for state anxiety, subtract the points of the weighted reverse statements from the points of direct statements and add 50; for continuous anxiety, subtract the points of the weighted reverse statements from the points of direct statements and add 35) reflect the anxiety level as follows: No anxiety below 37, mild anxiety between 37 and 42, and severe anxiety over 42.

3.5. Ethical Considerations

This prospective study was approved by the ethics committee of Kafkas university, School of medicine; the number code was 37 in 2011. All the participants gave informed consent. We kept all participant information confidential.

3.6. Statistical Analysis

The collected data were analyzed statistically using an SPSS program. The data was presented as percentage and mean \pm standard deviation for the categorical and continuous variables, respectively. The groups were compared by using one-way analysis of variance or Kruskal Wallis tests, in cases where the distribution of the variable was normal or non-normal, respectively. Interrelations of variables were tested with Pearson's and Spearman's correlation tests, appropriately. The significance level was defined as 5%.

4. Results

A total of 300 women were invited to participate in the study; however, 29 of them did not participate in the study or complete the study for various reasons: 14 did not want to participate because of lack of time (five, five, and four in Control and Intervention 1 and 2 groups, respectively), nine without a reason (five, three, and one in Control and Intervention 1 and 2 groups, respectively) and six changed their mind about participation after the completion of demographics (two, one, and three in control, Intervention 1 and 2 groups, respectively).

The demographic data on age, gravidity and parity, miscarriage, induced abortion, ectopic pregnancy, off-spring number, place of residence, working status, education level, and previous experience of gynecological examination is summarized in Table 1. The variables did not differ among the control and intervention groups (P > 0.05).

The STAI scores are summarized in Table 2. According to the STAI scores, all groups had mild state (between 37 and 42) and severe continuous (> 42) anxiety levels. However, both state anxiety score and continuous anxiety scores were not significantly different in all groups (P > 0.05). Although the state anxiety score in Intervention 1 group (composed of women who received specific information about gynecological examination) was the highest among the three groups, the difference was not significant (P > 0.05). However, the group's mean state anxiety score was at the border of mild and severe state anxiety. SLI, mostly determined by the daily income per household member of the groups, is summarized in Table 3. The comparison of SLIs scores did not differ significantly among the three groups (P > 0.05).

Correlation analysis of the study variables showed that the state anxiety scores were correlated positively with the variables of gravidity and parity, miscarriages, ectopic pregnancy, offspring number, daily income per household number, SLI, and trait anxiety scores (P < 0.05). However, the state anxiety scores were correlated negatively with working status of the women.

The trait anxiety scores were correlated positively with the variables of age, gravidity and parity, miscarriages, induced abortion, offspring number, daily income per household number, SLI, and state anxiety scores (P < 0.05). However, the trait anxiety scores correlated negatively with working status.

5. Discussion

The anxiety level of women prior to a gynecological examination did not change after being given information

Table 1. The Demographic Findings of the Study Groups^{a,b}

Groups	Control (n = 88)	Intervention 1 (n = 91)	Intervention 2 (n = 92)	P Value ^c
Age	31.93 ± 1.09	33.65 ± 12.29	32.09 ± 11.72	0.632
Gravidity	3	3	2	0.250
Parity	2	2	1	0.342
Miscarriages	0	0	0	0.497
Induced abortion	0	0	0	0.796
Ectopic pregnancy	0	0	0	0.802
Offspring number	2	2	1	0.305
Urban residence rate, %	61.4	52.2	53.8	0.421
Working status, %	18.2	21.7	17.6	0.744
Education year per woman	7.46 ± 4.18	7.65 ± 4.18	7.43 ± 5.52	0.971
Previous experience of gynecological examination, %	69.3	70.3	68.5	0.964

^aValues are expressed as mean \pm SD, median or No. (%).

Table 2. The Anxiety Scores and the Comparison of the Study Groups^{a,b}

Groups	Control (n = 88)	Intervention 1 (n = 91)	Intervention 2 (n = 92)	P Value
State Anxiety	40.20 ± 10.53	42.00 ± 11.98	39.53 ± 10.32	0.470 ^c
Continuous Anxiety	46.78 ± 8.65	47.25 ± 9.57	46.60 ± 9.72	0.888 ^d

 $^{^{\}mathrm{a}}$ Values are expressed as mean \pm SD.

about the examination procedure. The state anxiety levels had a direct relationship with gravidity and parity, miscarriages, ectopic pregnancy, offspring numbers, daily income per household number, SLI, and trait anxiety scores. The trait anxiety levels were directly related to gravidity and parity, miscarriages, induced abortion, offspring numbers, daily income, SLI, and state anxiety scores. Interestingly, having an occupation was inversely related to both the state and trait anxiety levels.

The major complaint of the patients visiting an outpatient clinic was the waiting time before the clinical interview and examination. In one study, patients were found reasonably satisfied if they waited no more than 37 minutes when they were on time, and no more than 63 minutes when they were late for appointments (4). In crowded hospitals, it is hard to reach the goal of organizing the outpatient clinic services, so patients often get lost and dissatisfied with the hospital facilities and waiting times. In our study, it was not practical to judge whether the anxiety

scores were affected by the dissatisfaction and improper outpatient clinic services. In addition, instant hospital conditions changed unavoidably during various instants and days.

The involved groups do not represent the whole population of women living in the Kars province, and the standard of living indices may also be affected by the same problem. Additionally, a self-declaration of living conditions and facilities may be affected by traditional and religious attitudes.

Topics bringing information and instruction about certain medical procedures have attracted many researchers, so quite a lot data have accumulated in the medical literature dealing with the importance of information during various procedures. Further, providing information to caretakers and obtaining their informed consent is an ethical and legal obligation for most interventional procedures (9). However, publications searching for anxiety levels during a routine gynecological examina-

^bThe control group did not receive any intervention before gynecological examination, intervention 1 group received information about a routine pelvic examination in a gynecology clinic, and intervention 2 group received information about the profit obtained from forests.

^cKruskal Wallis Test (because of non-normal distribution determined by Shapiro-Wilk Test).

^bThe control group did not receive any intervention before gynecological examination, intervention 1 group received information about a routine pelvic examination in a gynecology clinic, and Intervention 2 group received information about the profit obtained from forests.

^cKruskal-Wallis test (because of non-normal distribution determined by Shapiro-Wilk Test).

^dAnalysis of variance test (normal distribution).

Table 3. The Summary of Standard of Living Index Based on the Mean and SD of Household Income, and Size and Ownership of Household Goods and Communication Instruments^{a,b}

Groups	Control (n = 88)	Intervention $1 (n = 91)$	Intervention 2 (n = 92)	P Value ^c
Income, TL	2146.00 ± 1102.87	2186.80 ± 1070.46	2119.60 ± 1108.61	0.903
Household number	3	3	3	0.792
Daily income per household ^d , TL	22.98 ± 15.70	23.48 ± 15.24	22.83 ± 11.13	0540
Having a house ^e ,%	53.4	54.9	51.1	0871
Having a car ^e , %	32.9	31.9	34.8	0.915
Having a local phone ^e ,%	81.8	84.6	78.3	0.541
Having a cell phone ^e ,%	85.2	81.3	78.2	0.484
Having a television set ^e , %	96.6	96.7	98.9	0.539
Having a washing-machine ^e ,%	90.9	91.2	94.6	0.593
Having a refrigerator ^e , %	97.7	98.9	98.9	0.753
Having a dish-washer ^e ,%	55.7	56	57.6	0.962
Having a heating system ^f	2.62 ± 0.78	2.49 ± 0.89	2.50 ± 0.87	0.054
Flight experience ^e ,%	42	47.2	45.6	0.775
Standards of living index ^g	31.97 ± 16.42	32.40 ± 15.95	31.71 ± 11.43	0.540

Abbreviation: TL, Turkish Liras.

tion and the strategies to overcome the anxiety resulting from the procedure itself are limited.

In a previous study with 240 Turkish women conducted by Erbil et al. (5), the mean state anxiety scores measured just before the gynecological examination were found to be 43.85 \pm 5.41. Although the Turkish version of the STAI form was used in the study, the researchers used Spielberg's (7) calculation method and ranges to calculate and classify the anxiety levels, respectively. Thus, the score of 43.85 \pm 5.41 was classified as "moderate anxiety."

In the same study, sub-classifications according to age, marital status, level of education, and place of residency did not significantly affect the anxiety levels. However, Erbil et al. stated that women waiting for their first gynecological examination had significantly higher anxiety levels than women with previous experience in gynecological examination.

In our study, we used the Turkish version of the STAI form and assessed the anxiety scores depending on the calculation and ranges defined by Oner and Le Compte (8). Although, we also classified the anxiety levels as "moder-

ate anxiety" in each group, all mean scores were \leq 42, and values higher than 42 represented severe anxiety in our assessment system. However, our study had similar and dissimilar results in comparison with the study conducted by Erbil et al. (5).

In our study, women's age and educational level was not correlated with the STAI scores, concordant with the previous study. However, in contrast with the findings of Erbil et al. in our study, STAI scores were lower among working women.

In a previous study conducted on 104 women by Mete (10), the state and trait anxiety scores prior to gynecological examination were 48.69 \pm 10.28 and 46.13 \pm 9.87, respectively. Although the mean trait score of our control group (46.78 \pm 8.65) was similar to the previous study's scores, the mean state anxiety score of our control group (40.20 \pm 10.53) was significantly lower. This finding may have resulted from the different populations with different characteristics included in the studies. Mete argued that the mean initial state anxiety score decreased with their planned nursery approach. However, the mean anxi-

 $^{^{\}mathrm{a}}$ Values are expressed as mean \pm SD, median or No. (%).

^bThe control group did not receive any intervention before gynecological examination, intervention 1 group received information about a routine pelvic examination in a gynecology clinic, and intervention 2 group received information about the profit obtained from forests.

^cKruskal Wallis Test (because of non-normal distribution determined by the Shapiro-Wilk Test).

^dTo calculate the daily income per household, the (monthly) income was divided by 30 and then by the household number.

eThe categorical variables are represented as percentage and credited 1 or 0 points according to the answers yes or no, respectively.

Because the winters are very cold and long in Kars, heating is important for daily comfort. It was credited point for heating of a single room, 2 points for heating of more than one room, and points for heating of the whole house.

^gCalculation of the standards of living index: the sum of the daily income per household, heating system points, and the categorical points (e.g., if the participant has a cell phone it was credited 1 point, if not 0 point).

ety scores of the control and the intervention groups were not significantly different in our study.

Although providing comprehensive information before gynecological examination has not been studied in detail during the last two decades, the topic has been studied during several medical interventions. Pehlivan et al. in a study conducted on more than 300 patients, provided information before upper gastrointestinal endoscopic examination in order to decrease the anxiety levels, but found that the provided information was ineffective (11). Similarly, Galaal et al. reviewed the results of 1441 women who underwent a colonoscopy; however, they could not demonstrate the beneficial effect of information provided just prior to the procedure (12). The findings of the previous studies might result from improper methods of presentation of the information. In both studies, the information was provided just before the procedure. In contrast, van Zuuren et al. provided the information one day prior to the anticipated gastrointestinal endoscopic examination and showed the beneficial effects of the provided information (13). The presentation of detailed information just prior to the procedure may not be perceived and understood by the subjects, and some subjects may not be interested about the information. Supporting the statement, Pereira et al. noticed that only 54% of their patients had read the provided information paper (14). In our study, although an observer witnessed the participants while they were reading the provided information paper, the information was provided just prior to the anticipated gynecological examination. Thus, the ineffectiveness of the information might have been dependent on the timing of the information presentation.

Levy et al. studied (15) five groups of patients undergoing gastroscopic examination, and they did not give any information, gave minimum information, detailed information, detailed information with pictures or detailed information with video clips. However, they could not demonstrate significantly different anxiety scores. Similarly, other authors could not demonstrate a decrease in their anxiety levels in patients undergoing gastrointestinal endoscopic or colonoscopic examinations by using information brochures or video clips (16, 17). Regarding those studies, we also could not demonstrate beneficial effects of pre-examination information.

On the other hand, Aabakken et al. questioned the quality of the provided information and managed to reduce the anxiety level after preparing a more targeted information paper (18). We could not find a study demonstrating beneficial effects of providing information prior to vaginal examination in order to decrease anxiety levels. However, in some studies, the anxiety levels were decreased after providing information about the procedures

(19-22).

Previous studies have conflicting results about providing information before the anticipated procedures. In our study, we provided a standard information paper informing patients about the stages of an outpatient clinical examination. However, a more detailed information paper or verbal information might be more beneficial. Moreover, providing information oriented by the patient's questions, needs, and interests might better decrease anxiety.

A selective review conducted by Herbig et al. (23) demonstrated an increased rate of psychiatric disorders in unemployed people in comparison with employed ones, with anxiety being one of the most frequent disorders. The authors explained the relation of anxiety and being unemployed learned helplessness. In another study (24), the symptoms of anxiety disorders were not correlated with the residential area, but with the status of being unemployed. Similarly, in our study, having a regular job caused lower anxiety scores, and the anxiety scores did not correlate with the residential area.

In a previous study conducted in the rural areas of India (25), social, economic, and female gender disadvantages were independently related with common psychiatric disorders. In addition, the level of SLI was inversely correlated with the disorders. In contrast to that study, our SLI was directly correlated with anxiety scores. However, the used SLIs and the studied populations were different from each other. Our modified SLI, besides containing income dependent variables, contained variables measuring the capability of the participants to be integrated into a modern lifestyle. These variables included facilities related to communication and travel options. Additionally, basal daily income and the rate of being the owner of a house, car, television set, and durable goods were higher in our study population. Thus, the inverse correlation between SLI and anxiety scores may be attributed to the stress induced by modern life conditions.

This is the first study aiming to reduce the anxiety of women prior to a gynecological examination. Further, beside state anxiety levels, we also measured continuous anxiety levels in order to identify whether the state anxiety levels were affected by continuous anxiety levels. Although our aim was to evaluate the role of specific information on pelvic examination procedure details, we were aware that any information supplementation procedure or any specific interaction with the women prior to the examination would also affect anxiety levels. Thus, we had a second control group (intervention 2) that received information on a general topic unrelated to health and gynecological examination. The part of the questionnaire dealing with the demographics was filled by the medical students; however, the rest of the questionnaire was filled by the partic-

ipants. Additionally, all interviews were performed in the same conditions.

The randomization procedure, involvement of different personnel for data collection and evaluation, and use of a valid and reliable anxiety scale in Turkish are the other strong points of our study.

This study has some limitations. Although we included women with an appointment in the obstetrics and gynecology department, we cannot argue whether all the participants were expecting to have a pelvic examination. The women in the first intervention group might be motivated to think about the details and difficulties of pelvic examination, but at least some of the women in other two groups might not be aware of the possibility of a pelvic examination. Thus, consideration of a direct correlation between the stress of a pelvic examination and the measured anxiety levels may cause bias.

Women having mild/moderate gynecological symptoms have mild state and severe trait anxiety. Being employed decreases anxiety levels, and modern daily life conditions increase anxiety levels. Providing written brief information about the gynecological examination procedure and the clinics' working discipline is not sufficient to lower anxiety. New and targeted strategies are needed to help women to overcome anxiety.

Footnote

Authors' Contribution: Kahraman Ulker: study concept and design, acquisition of data, analysis and interpretation of data, critical revision of the manuscript for important intellectual content, statistical analysis; Yuksel Kivrak: study concept and design, acquisition of data, critical revision of the manuscript for important intellectual content; statistical analysis, drafting of the manuscript, administrative, technical, and material support, study supervision. All authors have read and approved the manuscript.

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