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Original Article

Comparison the effect of trained and untrained family presence on their anxiety during invasive procedures in an emergency department: A randomized controlled trial

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ABSTRACT

Objective: The present study was aimed to compare the effect of the trained and untrained family presence on their anxiety during invasive procedures in an emergency department.

Methods: In this randomized controlled clinical trial, 90 patients who were candidates for receiving invasive nursing procedures were selected in an emergency department based on the inclusion criteria, and then were equally assigned into 3 groups by the random minimization method: A ("presence of the trained family member group"), B ("presence of the untrained family member group"), and C ("absence and untrained family member group"). The anxiety level was measured before and after implementation of the procedure using the *Spielberger State-Trait Anxiety Inventory (STAI)*. The data were analyzed by SPSS software using the Kolmogorov-Smirnov test, Chi-Square test, Kruskal Wallis Independent-Samples test, Paired Samples T-test, and ANOVA at the significance level of 0.05.

Results: The three groups were similar in terms of demographic variables. In all three groups, the SATI score significantly decreased after intervention phase ($p = 0.001$). The mean changes of the SATI score were not statistically different between the groups. However, The STAI score decreased significantly after intervention in the group B compared to the group A ($p = 0.011$) and C ($p = 0.042$). However, there was no significant difference between the SATI score in the group A and C ($p = 0.867$).

Conclusion: The results of the study revealed that, the "presence of the untrained" family members caused them to experience significantly less anxiety than the other two groups. However, changes in the anxiety score were not significant between the groups.

1. Introduction

Undergoing emergency care often causes fear and anxiety for both the patients and their family members. On the other hand, the focus of attention of healthcare providers on patients and their needs has caused the family members' needs to be neglected.¹ Meanwhile, today the concept of family-centered care as a philosophy of care emphasizes the collaborative participation of patients, families, and care providers, considering the plans to promote this involvement.²

Although the presence of families with their loved ones is not permitted in most Iranian healthcare centers, but following the growth of family-centered care programs and involvement of families in the healthcare decision-making, rigorous policies on visiting the patient have become weaker, such that the presence of families is allowed even during invasive procedures.^{3,4} The previous studies also indicated that, most patients and their family members tend to be present during the emergency and invasive procedures.^{5–8}

Today, the family members' presence bedside the patient during the

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invasive procedures is considered as a challenging problem in health-care systems. Some believe that the presence of family members may be led to the loss of emotional control and disruption of the medical team performance. It can also increase the risk of medico-legal litigation,⁹ invading the patients' privacy.^{10,11} In some researches, positive aspects of the family's presence have been reported including the increased quality of care¹² satisfaction,⁹ reduced severity of stress, anxiety, and depression of family members¹³ and length of hospitalization.¹⁴ The presence of the family is also believed to help in understanding the severity of life-threatening events, facilitating the relationship between the family and treatment team, as well as reducing the family grief.¹⁰

Some researchers have emphasized on the evaluation of the psychosocial needs of patients and family members and their desire for presence during invasive procedures, and have suggested their training before the presence.¹⁵ However, there is no sufficient evidence comparing the effect of the presence and training before presence on anxiety of family members of adult patients. Study in this area has been reported to be in its early phases, and its various aspects should be scrutinized carefully.^{16,17} Some reports have also suggested no positive results in this regard.¹⁸ Therefore, this study was designed to compare the effect of the trained and untrained family presence on their anxiety during invasive procedures in an emergency department.

2. Methods

2.1. Study design

This randomized clinical trial was conducted from March to June 2018.

2.2. Study population

According to the rules of the Shahid Ranamoun Hospital in Yazd, Iran, family members are not allowed to stay with the patients during implementation of invasive procedures. But by coordinating with the management of the hospital, during the implementation of the study, the strategy of the hospital was changed to provide the presence of some members of the family with the staff nurse permission, who was one of the researchers.

The study population was the family members and patients who were in acute and emergency conditions, and were candidate for receiving the nursing invasive procedures. Samples were preliminary selected based on some of the inclusion criteria and then, the eligible patients and family members were asked to sign the written informed consent. The inclusion criteria for patients included: having informed consent to participate in the study, having 18–75 years of age, being alert and having the proper level of cognitive ability to answer the questions, willingness of family members for presence, candidates for unplanned invasive nursing procedures (doing sutures, wound dressing, serum attachment, injections, blood sampling, as well as bladder and stomach catheterization), no history of undergoing nursing invasive procedures. On the other hand, the inclusion criteria for the family members included: being a first-degree family member (father, mother, child, sister or brother, spouse, and grandparents), being selected by the patient for presence, having the desire to be beside the patient, having 18–75 years of age, no history of being beside the patient under invasive procedures, no history of known mental diseases and having the proper level of cognitive ability to answer the questions. In contrast, the exclusion criteria for patients included worsening of the patient's condition, and reluctance to continue the participation. The exclusion criteria for family members included intolerance to attend up to the end of the invasive procedure, and quitting the research.

2.3. Outcomes

The family member's anxiety score was the main outcome of this study. Data collection tools consisted of a demographic questionnaire for patients and family (including information on age, gender, marital status, occupation, level of education, and type of invasive procedure), and *Spielberger State-Trait Anxiety Inventory* (STAI). The STAI contains 40 questions on a self-report basis. This questionnaire comprises of two parts: obvious and hidden anxiety. The obvious anxiety scale consists of 20 questions capturing individual emotions at the moment of answering, and the hidden anxiety scale, which includes 20 questions measuring the general emotions of individuals. In this study, the 20-question obvious anxiety scale was used.

2.4. Randomization

90 family members were equally assigned in three groups through the random minimization method: A (presence of the trained family member group), B (presence of the untrained family member group), and C (absence and untrained family member group).¹⁹ Using this randomization method in order to control the effect of confounding factors, the samples in the three groups were matched in terms of sex (in male and female classes), and type of invasive procedure (in three classes: 1. injections, 2. suture and dressing, and 3. catheterization of the bladder and stomach). The first and second patients entered into each classes of each group in a simple random way, and the rest were included based on the total number of samples per class until the total number of the classes in each group became equal. Sampling continued until the intended sample size of the study was obtained.

2.5. Intervention

To perform a pre-test for family members across all three groups, anxiety inventory was completed through the face-to-face interview by the researcher co-worker. Then, in the group A, one of the family members was selected by the patient and, according to their satisfaction with presence, before attending the patient's bedside, he or she was instructed for 3–5 min about the process, procedure, and conditions that should be observed during the presence, including the positioning, patients' privacy, making eye contact, touching, and speaking with the patient for palliation. The family members were asked to stay beside the patient in a position not interfering with the treatment measures, trying to constantly support the patient and making the patient calm by touching and talking. In the group B, the intervention was performed only at the presence of the family members alongside the patient, so that they could have visual or physical contact with the patient based on their desire and respect to the patients' privacy, but they did not receive any training. The family members in the third group (group C) did not receive any training, and despite their desire to be alongside the patient, they stayed in the waiting room behind the procedure room. Finally, the family members' anxiety was measured again in each of the three groups using the *Spielberger State-Trait Anxiety Inventory* immediately after implementation of the procedure.

2.6. Blinding

To date, none of personnel involved in invasive procedures were aware of the study objectives. They were told that, the presence of families with their loved ones is implemented as a family-centered care program. Also, to diminish the effect of confounding factors, the patients and their family members were not completely informed about the goals of the study, although, the informed written consent was obtained from each of them by completing a request form for attending the family member at the patients' bedside during while performing the invasive procedures as a family-centered caring method, as well as filling the questionnaire. Also, the person who collected the data did not

know about the allocation of samples in the study groups.

2.7. Ethical aspect

This trial was approved and registered in the Iranian Registry of Clinical Trials with the code of IRCT20180109038287N1. After approving the project at the research council of Rafsanjan University of Medical Sciences, the ethics code was obtained from the research committee of the university (code of ethics: IR.RUMS.REC.1396.166), and then one of the researchers who was the staff nurse in emergency ward, attended in the hospital.

2.8. Statistical analysis

The data were analyzed using the SPSS software version 22, at the significance level of 0.05. Kolmogorov-Smirnov test was used for determining the normal distribution of the quantitative variables; Chi-Square test was used for comparison of ratios, and the Paired Samples T-test was used for comparison of anxiety score within groups. Also, Kruskal-Wallis Independent-Samples test was used for comparison of median and interquartile range of non-normal distributed variables, and then the ANOVA test was used for comparison of anxiety score between the three groups.

2.9. Power analysis

Power of the study was calculated as 0.996 by considering the type I error of 5%, the mean STAI score of 40.56, and standard deviation of 7.30 for group A, and the mean STAI score of 35, and standard deviation of 6.30 for group B.

3. Results

In the current study, a total of 110 patients and their family members were assessed in terms of the inclusion criteria. 90 patients and their family members were randomly allocated in three study groups. About 20 individuals were excluded from the study, including 18 individuals who were excluded because of the exclusion criteria, and 2 individuals were excluded as they declined to participate. All of patients and family members were followed up, and there was no attrition in the study process (Fig. 1).

The results of Kolmogorov-Smirnov test showed that, all of the quantitative variables had normal distribution except of the family member's age.

The results of data analysis revealed that, the median and interquartile range of the family member's age were equal to 34 ± 15.25 with a minimum and maximum of 18 and 66 years old, respectively. No significant difference was found between the three groups in terms of age, level of education, gender, marital status, occupation, and type of aggressive procedure. In other words, no significant difference was observed between the three groups regarding the demographic characteristics (Table 1).

Results of the intra-group comparison of STAI score before and after intervention in the group A showed that, the mean changes \pm SD of STAI score was equal to 12.53 ± 11.28 . Results of the Paired Samples T-test showed that, this change in STAI score was statistically significant ($p = 0.001$ 95% CI: 8.32, 16.74). For group B, the results of the Paired Samples T-test showed that, the mean changes \pm SD of STAI score was equal to 14.13 ± 9.16 , and this change in STAI score was statistically significant ($p = 0.001$ 95% CI: 10.71, 17.55). Also, in group C the mean changes \pm SD of STAI score was equal to 16.06 ± 9.14 , and the results of the Paired Samples T-test showed a statistically significant difference in this regard ($p = 0.001$ 95% CI: 12.65, 19.48) (Table 2).

Results of the inter-group comparison showed that, the mean \pm SD of STAI score was equal to 53.10 ± 11.34 (95% CI: 48.86, 57.33)

before intervention in group A, in groups B and C, it was equal to 49.66 ± 10.51 (95% CI: 45.74, 53.59) and 55.76 ± 11.93 (95% CI: 51.30, 60.22), respectively. Although, the mean STAI score in group A was higher before intervention than two other groups, but there were no statistically significant differences between three groups in the base line ($P = 0.116$). However, the mean and standard deviation of STAI score for group A was equal to 40.56 ± 7.30 (95% CI: 37.83, 43.29) after intervention, in groups B and C, it was equal to 35.53 ± 6.31 (95% CI: 33.17, 37.89) and 39.70 ± 6.05 (95% CI: 37.44, 41.96), respectively. Results of the One-Way ANOVA showed a statistically significant difference in the STAI score between three groups after intervention ($p = 0.009$). But, no statistically difference was observed in comparing mean changes of the STAI score between the study groups (Table 3).

Results of the Post-hoc Tukey HSD test indicated that, the mean difference was statistically significant between the STAI scores after intervention for groups A and B, where the group A experienced a higher mean STAI score than the group B ($p = 0.011$ 95% CI: 0.98, 9.08). Further, the mean difference of STAI scores was lower in group B after intervention than that of the group C, and the mean difference was statistically significant ($p = 0.042$ 95% CI: 8.21, -0.11). However, no statistically significant difference was observed in the mean difference of the STAI score for the group C compared to group A ($p = 0.867$ 95% CI: 3.18, 4.91) (Table 4).

4. Discussion

The results of the study showed that, although the family members who attended without receiving any training reported less anxiety than the two other groups, but the SATI score changes were the same between the three groups.

Few studies are available on the effect of family presence and their training on their anxiety levels. Most studies have focused on the presence of parents during the implementation of CPR and patients' anxiety. Also the related studies have reported contradictory results in this regard. Compared to our results, the results of the study by Meyers et al. showed that, the family member's needs were fulfilled after being present during implementation of Cardiopulmonary Resuscitation (CPR) and invasive procedures, and they did not report any adverse psychological effects.²⁰ It is noteworthy that, this satisfaction can be occurred despite the high stress in parents. In our study, family members who were trained before presence reported higher anxiety than the two other groups. In a study by Mangurten et al. the parents who were supported before being present during CPR and invasive procedures were satisfied with their presence, and did not report any traumatic memory three months after their presence.²¹ In another study, parents also found their presence useful to provide emotional support for their children, and health information to the treatment team.²² Contrary to the parents' satisfaction with presence beside their children, the researchers reported that the presence of adult patients' family members did not have any significant effect on family member's distress level.¹⁸ Also, according to another study, though the anxiety level of parents who were not present, was lower than those who were just present, and those who were present while being involved in the implementation of the procedure, but the anxiety was not significantly different between the three groups.²³ Although, sudden and unexpected situations such as admissions to emergency departments in hospitals can be a stressful event for family members, the difference between the presence of parents alongside the children and, the presence of family members beside the adult patients should not be ignored due to the nature of emotional relationships between them. Therefore, some researchers believed that, justifying the need for the presence of family members beside the adult patients does not seem logical due to the lack of documented evidence.²⁴ So, the appropriate evaluation cannot be considered in relation to the presence or absence of family members. They suggested that, the policymakers of each hospital are required to

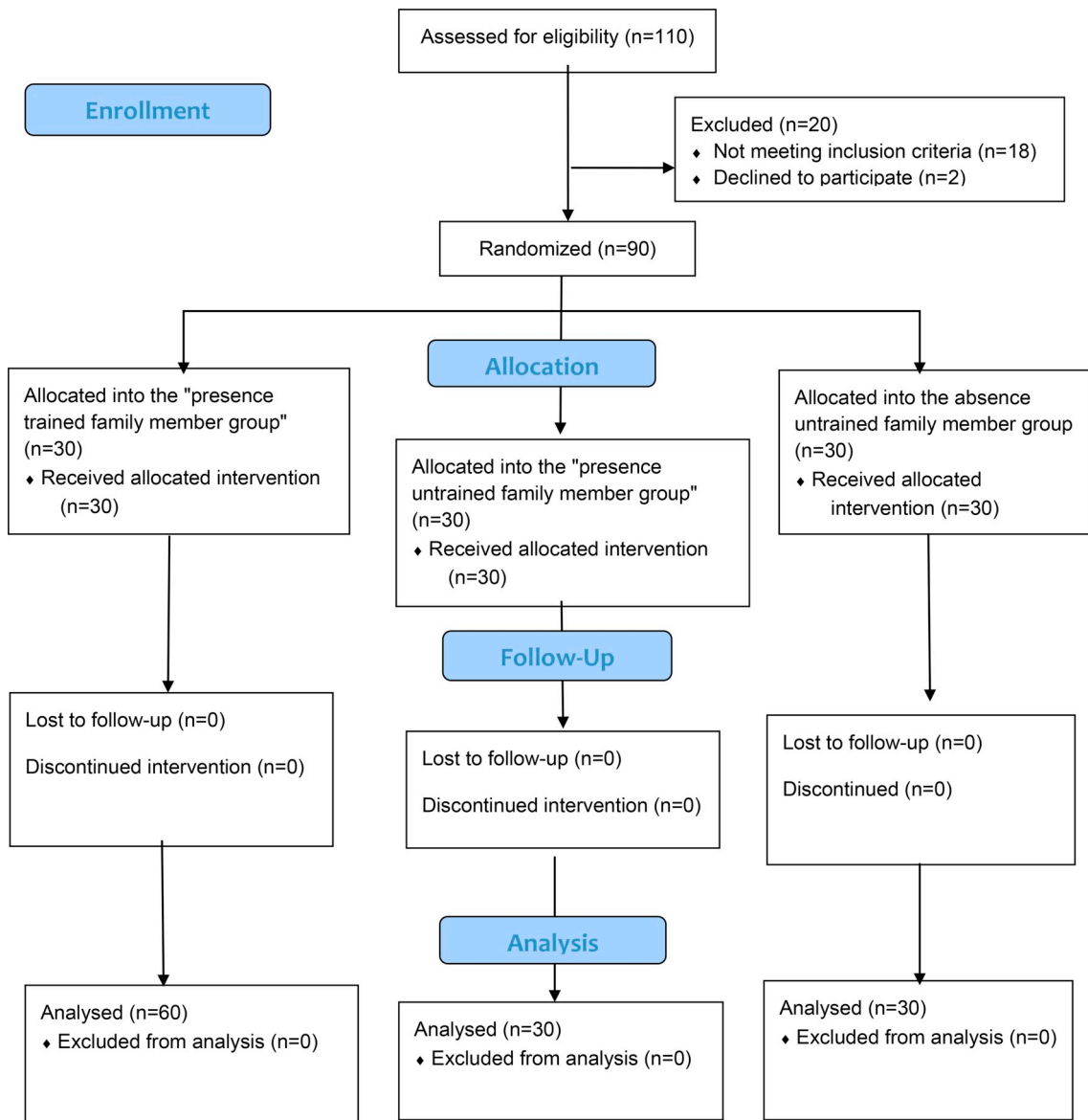


Fig. 1. CONSORT 2010 flow diagram.

Table 1
Comparison of demographic characteristics of the study groups.

		Presence trained group Number (%)	Presence untrained group Number (%)	Absence untrained group Number (%)	P-Value
Education Status	Illiterate	1 (3.3)	2 (6.7)	0(0)	0.458 ^a
	Uder diploma	6(20)	6(20)	11(36.7)	
	Diploma university	11(36.7)	13(43.3)	12(40)	
Sex	Male	19(63.3)	15(50)	14(46.7)	0.392 ^a
	Female	11(36.7)	15(50)	16(53.3)	
Marital Status	Single	6(20)	9(30)	6(20)	0.572 ^a
	Married	24(80)	21(70)	24(80)	
Job	Self-employed	8(26.7)	6(20)	6(20)	0.828 ^a
	Employee	12(40)	10(33.3)	10(33.3)	
	Unemployed	10(33.3)	14(46.7)	14(46.7)	
Invasive Procedures	Injections	11(36.7)	11(36.7)	11(36.7)	0.997 ^a
	Suture & Dressing	13(43.3)	13(43.3)	12(40)	
	Catheterization	6(20)	6(20)	7(23.3)	
Age		Median ± IQR%25-%75 34.5 ± (27.75–43)	Median ± IQR%25-%75 33 ± (27.75–44)	Median ± IQR%25-%75 34.5 ± (24.5–45.25)	0.873 ^b

^a Chi-square test.

^b Independed-sample Kruskal Wallis.

Table 2Results of paired sample *t*-test in comparison of STAI score before and after intervention inside each group.

	Before intervention Mean \pm SD	After intervention Mean \pm SD	Mean changes \pm SD	%95 CI		P-value
				Lower	Upper	
Presence trained group	11.34 \pm 53.10	7.30 \pm 40.56	12.53 \pm 11.28	8.32	16.74	0.001
Presence untrained group	10.15 \pm 49.66	6.31 \pm 35.53	14.13 \pm 9.16	10.71	17.55	0.001
Absence Untrained group	11.93 \pm 55.76	6.05 \pm 39.70	16.06 \pm 9.14	12.65	19.48	0.001

Table 3

Results of One-Way ANOVA test in comparison of STAI score before and after intervention and its changes between groups.

	Presence trained group	Presence untrained group	Absence Untrained group	P-Value
	Mean \pm SD	Mean \pm SD	Mean \pm SD	
Before intervention	11.34 \pm 53.10	10.15 \pm 49.66	11.93 \pm 55.76	0.116
After intervention	7.30 \pm 40.56	6.31 \pm 35.53	6.31 \pm 39.70	0.009
Mean changes \pm SE	12.53 \pm 11.28	14.13 \pm 9.16	16.06 \pm 9.14	0.389

weigh the advantages and disadvantages of this matter carefully.²⁵

The results of our study showed that, the family members who had received information about the presence conditions and the procedure of intervention before attending experienced significantly more anxiety than those who were present without receiving any training and, those who were absent. Indeed, receiving training on the process of implementation of the procedure and requirements of the presence could increase the anxiety of these individuals, even more than the absent group, though the anxiety changes were not statistically different between the groups. In a similar study by Bauchner et al. the researchers found no significant difference in terms of anxiety or satisfaction level between the trained and untrained parents that were present alongside of their children, though they experienced less anxiety than the absent group.²⁶ In contrast to the results of the present study, in a study by Nanette et al. again the parents of children who had to undergo the resuscitation due to a trauma were trained by a social worker prior to attending, and were supported during the presence. Finally, they reported that along with other positive outcomes, parents felt that their presence was helpful to both their children and themselves²⁷ but in this study, parents' anxiety was not considered by the researchers.

Current evidence suggests that the presence of family members, if necessary, regarding providing the support during implementation of invasive procedures can have positive outcomes for the family, patient, and the health staff.³ Nevertheless, it should be acknowledged that the need for the presence of family members during invasive procedures should be decided based on the patient and family preferences and access to staff who can provide the necessary support for the family.²⁸ Also, in addition to the cognitive and emotional state of the family members, the ability of family members in controlling their emotions, needs, and supportive role of the treatment team during an invasive procedure should not be ignored.

Finally, it can be stated that, the role of the family members

presence can be considered as two sides of a coin, i.e. this intervention can be both harmful and supportive. Therefore, various aspects of the family's presence during implementation of invasive procedures in adult patients should be considered in future studies. The aspects include information related to who, when, where, why, how and under what conditions they should be present, and how the family member should be protected to experience less anxiety.

5. Limitations

In this study, a group was not considered to evaluate the anxiety level of family members who were not trained and not present, and this could be considered as a limitation. The anxiety level in the case of presence or training could be attributed better, if there was a non-present, but trained group. The selection of samples based on their willingness to presence (due to ethical issues) was another limitation. This can influence the generalizability of the results. Also, the family member satisfaction with their presence was not measured in this study.

6. Conclusion

The results of the present study revealed that, the family members who were present and received no training experienced significantly less anxiety than the other two groups. There was no significant difference in the anxiety score of the family members who were present and received training with those who were absent. However, changes in the anxiety score were not significant between the groups.

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Table 4

Results of Tukey HSD test in paired comparison of mean differences of STAI score between groups in after intervention phase.

		Mean diff \pm SE	%95 CI		P-value
			Lower	Upper	
Presence trained group	presence untrained group	5.03 \pm 1.69	0.98	9.08	0.011
	absence untrained group	0.86 \pm 1.69	-3.18	4.91	0.867
presence untrained group	presence trained group	5.03 \pm 1.69	-9.08	-0.98	0.011
	absence untrained group	4.16 \pm 1.69	-8.21	-0.11	0.042

Author contribution

All authors contributed to this study. All authors read and approved the final version of manuscript.

Alireza Zaeri fathabadi; Study design, data acquisition.

Ali Ansari Jaber; Study design, supervisor, critical revising.

Tayebeh Negahban Bonabi; Study design, data analysis, interpretation of data, article drafting.

Conflicts of interest

There is no conflict of interest to be declared.

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