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Sveva: development and evaluation of a supportive care model to reduce breast biopsy pre-operative anxiety: a randomized case-control study

Alessandra Miraglia Raineri ^{1*}, Stefania Pelagotti ², Rosapia Lauro Grotto ¹

Abstract

In order to assess the efficacy of the Supportive Care intervention used to reduce Pre-Operative Anxiety, a randomized case-control study has been performed at the Breast Unit of the Careggi Hospital in Florence, comparing a Supportive Care Group (taking part in a colloquium) to a Control Group receiving standard care. Interventions' efficacy was tested in 2 ANCOVAs and in a 2-ways ANOVA. Women recruited from January 2015 to February 2015 completed: *The Amsterdam Preoperative Anxiety and Information* (Moreman et al., 1996), *State-Trait Anxiety Inventory* (Spielberg, 1983) and the *The Mini -Module Depression* (Sheehan, et al. 1998). In the first ANCOVA, Group produced a significant reduction of APAIS ($p < 0.01$) and its Anxiety subscale ($p < 0.05$), with a significant Trait Anxiety Covariate ($p < 0.01$) ($R^2 = 0.16$). In the second ANCOVA, Group was significant ($p < 0.01$) and the Age Covariate was not ($p > 0.05$) ($R^2 = 0.11$). In the third 2-Ways ANOVA: Group x Depression over Pre-Operative Anxiety, Group was significant ($p < 0.01$), ($R^2 = 0.10$). In our experimental design, a Supportive Care colloquium was found to significantly reduce the level of Pre-Operative Anxiety in women undergoing Breast Biopsy when compared to Standard Care, even when the confounding effect of Trait Anxiety, Age and Depression were included in the models.

¹Department of Health Sciences, Psychology and Psychiatry Unit, University of Florence, Florence, Italy

² University of Florence, Italy

E-mail corresponding author: miraglia83@gmail.com



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1. Introduction

Pre-Operative Anxiety has been recognized as a primary problem for the patients, as it is related not only with other emotional and psychiatric issues, but also with physical problems that affects all stages of the surgical procedure, from anesthesia induction to outcome in the post-operative period (Laufenberg-Felmann & Kappis, 2013; Laufenberg-Felmann et al., 2018). Scientific literature has recently addressed the issue of the assessment and treatment of Pre-Operative Anxiety in many different clinical contexts (Buonanno et al., 2017; Celik & Edipoglu, 2018) among which specific attention has been devoted to the one of Breast Biopsy, due to its

documented impact on the psychological wellbeing of the patients (Lanz et al., 1987; Liao et al., 2007, 2008; Moreman et al., 1996; Pineault, 2007). In fact, Anxiety is a mayor concern for the improvement of the patients' experience of care during the preoperative period in this population (for a systematic review of the studies assessing Pre-Operative Anxiety in women undergoing Breast Biopsy see Miraglia Raineri et al., 2018). It is known that the level of Pre-Operative Anxiety in women undergoing Breast Biopsy depends on several clinical, relational and psycho-social factors (Humprey, 2014; Novy, 2001; Ubhi, 1996). Harding et al. (2014) showed that the levels of State-Anxiety and Depression could be related to Trait-Anxiety levels, the latter known to be a significant predictor of Distress in women undergoing Brest Biopsy; Liao et al. (2008) documented that some Psycho-social factors, such as Age, could be associated with higher levels of perceived uncertainty before diagnosis. Lebel et al. (2003) estimated that about 30% of women undergoing Brest Biopsy report a clinically significant level of Depression while waiting for Biopsy and later, while waiting for the results. However, in addition to these personality or clinical variables, relevant relational and psychosocial aspects shaping the patients' global experience of the pre-operative period were found to be the availability of medical information and perceived quality of the communication with health care providers (Miller, 2013). Based on the systematic review of the literature, Miraglia Raineri et al. (2018) stressed the need of tailored interventions aiming to reduce Pre-Operative Anxiety in women undergoing Breast Biopsy by taking into account the specific factors that were found to influence the patients' experience of the procedure, such as the perceived support from the health care providers, the empathic concern and the quality of communication. Two empirical studies evaluated music therapy interventions aiming to reduce anxiety in women undergoing Breast Biopsy (Bradley Palmer et al., 2015; Huan et al., 2001) point out the positive effect of the intervention on level of anxiety. A different intervention aiming to reduce Pre-Operative Anxiety was recently implemented by Gomez-Urquiza et al. (2016) documenting a significant reduction in Anxiety as measured by STAI-State (Spielberg, 1983) in the two clinical groups conducted a with a photographic display (with music and without music). However no-one of the previous studies considered Pre-Operative Anxiety as clearly operationalized in the specific literature (Miraglia Raineri et al., 2018): in fact the Amsterdam Pre-Operative Anxiety and Information Scale (APAIS) (Moreman et al., 1996) has been validated to specifically assess Pre-Operative Anxiety, and has been used to estimate the level of anxiety in patients waiting to undergo invasive procedure in a very extended range of medical contests (Buonanno et al., 2017 for a recent discussion of the empirical evidences);

APAIS is a short test with two sub-scales named Anxiety and Need-for-Information which were shown to tap the two principal and rather independent sub-dimensions of Pre-operative Anxiety.

According to Byrne and Sebastian (1994), Supportive Care is defined as an attitude or an intervention aiming to reduce the patient's physical or psychological discomfort and to facilitate interpersonal relationships. Palese et al. (2005) showed that emotional support and supplementary information provided by the global case manager were effective in reducing anxiety in women undergoing breast biopsy for cancer diagnosis. Furthermore emotional and informational support have been more recently considered as the crucial elements in devising Supporting Care strategies devoted to women with suspect breast cancer (Liao et al., 2010): the authors proposed a Supportive Care model including three vis-à-vis sessions and two feedback telephone calls with a nurse, and providing health education pamphlets. Liao et al. (2010) stressed the need to perform experimental studies in this domain.

In none of the mentioned studies Pre-Operative Anxiety was explicitly considered as dependent variable: in fact the Amsterdam Pre-Operative Anxiety and Information Scale (APAIS) (Moreman, et al., 1996) is the only psychological scale that has been designed and validated to specifically assess Pre-Operative Anxiety. In particular this is the only measure exploring the two rather independent sub-dimensions of Pre-Operative anxiety, that is, Anxiety and Need-for-Information.

Starting from January 2015, a *Supportive Care Model* was adopted at the Breast Unit of Careggi Teaching Hospital in Florence (Italy) in order to reduce Pre-Operative Anxiety in women undergoing a Breast Biopsy. The intervention is performed by volunteers of the 'Noi per Voi' Social Service Association (Florence), which co-operates with the staff in the Breast Unit. The volunteers are specifically trained and supervised by the psychologist of the Association and by the Head of the Breast Unit to perform the following intervention: women undergoing Breast Biopsy, after being tracked by the nurse, are contacted in the waiting room by the volunteer which introduces him/herself and proposes a 30 minutes supportive colloquium to the patient. The colloquium takes place in a dedicated room that is located next to the waiting room. During the colloquium conversation is oriented to the needs that are expressed by the patient: the volunteer provides emotional support and general information about the procedure; furthermore the patient is free to express her feelings and fears with respect to the procedure or to other aspects of the actual diagnostic process to an empathic listener. The Standard Care practice adopted in the Ward on the contrary required the nurse to provide the patient with a

brochure describing the main medical features of the procedure. In the Supportive Care model, therefore, both emotional support and informative communication are delivered in a face-to-face colloquium with an empathic listener, therefore taking into account both of the sub-dimensions of Pre-Operative Anxiety as operationalized by APAIS. On the contrary in the Standard Care practice of the Breast Unit in Careggi Hospital information is delivered to the patient in a neutral and impersonal medium via an informative brochure, while emotional support is not provided to the patients.

The present study is designed to assess the efficacy of the intervention; in particular, in the research plan we have taken into account the results of the systematic review performed by Miraglia Raineri, et al. (2018) in order to select the clinical and psycho-social variables (Age, presence or absence of Depression, and Trait Anxiety) to be controlled in the experimental design. The research hypothesis of this study is that the Supportive Care intervention is associated with decreased levels of Pre-Operative Anxiety in women undergoing Breast Biopsy, when compared to Standard Care, and that the effect of the Group variable is still significant in reducing Pre-Operative Anxiety when Age, Trait Anxiety and Depression are included in the research design. We are also interested in contrasting the expected reduction of the scores in both the sub-dimensions of APAIS (Anxiety and Need-for-Information). In the present study we performed a randomized case-control study to assess the efficacy of the *Supportive Care Model* adopted at the Breast Unit of Careggi Teaching Hospital in Florence (Italy) in order to reduce Pre-Operative Anxiety, as measured by APAIS (Buonanno et al., 2017) in women undergoing a Breast Biopsy. The main goal of this study was to evaluate the effect of the supportive model for patient undergoing Breast Biopsy by comparing a Clinical (*Supportive Care*) and a Control (*Standard Care*) Group, also controlling for the influence of psychosocial and clinical variables (Age, Trait Anxiety and presence or absence of Depression) on the Pre-Operative Anxiety levels.

2. Methods

2.1 Design

A randomized case-control study was conducted, as suggest Liao et al. (2010). The randomized allocation of the patients produced two groups: the Clinical Group, which received the *Supportive Care* intervention, and the Control Group undergoing Standard Care. We performed a Group comparison with the t statistics in order to evaluate the difference in the Mean levels of Pre-Operative Anxiety, State and Trait Anxiety.

In a preliminary analysis of correlation, we produced an estimate of the Pearson's r coefficient between Pre-Operative Anxiety, State Anxiety, Trait Anxiety and Age.

After checking for the homogeneity of Variances with the Levene test, we therefore performed two different ANCOVAs in order to evaluate the effect of the Group variable over Pre-Operative Anxiety by taking into account Age and Trait Anxiety and as Covariates. We repeated the last analysis by considering the two sub-dimensions of APAIS (Anxiety and Need-for-Information) as dependent variables.

We have checked for a possible interaction between the Group variable and the dichotomous variable Depression (Absent or Present, as screened according to the Module A of the MINI-International Neuropsychiatric Interview of Sheehan D.V. et al. 1998) by performing a Two-Ways ANOVA with Group and MINI-Depression as factors and Pre-Operative Anxiety as dependent variable. Finally we performed a MANCOVA with Group as independent factor and STAI-Trait as a Covariate to compare the centroids of the bivariate distribution of APAIS and STAI-STATE for the Control and the Clinical Groups.

2.2 Participants

Italian-speaking participants were recruited, in January and February 2015, among women undergoing Breast Biopsy at the Breast Unit of the Careggi University Hospital in Florence. The patients were randomly assigned, with the support of a computer algorithm, to a Control Group (N=40), receiving Standard Care, and a Clinical Group (N=40) which was treated according to the Supportive Care Model described above.

Women aged between 18 and 75 and with a minimum of 8 years of education were included in the study. The mean Age in the overall sample was 47.6 years (SD=12.34 years; range=18-73 years; N=80), without any significant difference in the mean of Age between the two groups (t -test= -1.209, $p>0.05$). Participation rate was 96.25%: 3 women refused to take part in the study and non responders rate was 3.75%.

2.3 Ethical Considerations

The study was designed and conducted according to the Standards for Psychological Research of the Italian Association of Psychology (www.aip.org). The approval of the local Ethics Committee of the Careggi Teaching Hospital was obtained on November, the 14th, 2014 with protocol n.2014/0025902 Ref. OSS.14.129 and acronym SVEVA (Studio di Valutazione dell'Efficacia e Validità dell'Accoglienza) [Evaluation of efficacy and validity of Supportive Care]. All participants signed an informed written consensus to take part in the study.

2.4 Measures

A battery of tests and an *ad hoc* socio-demographic grid were administered to the participants. The battery included the following tests:

APAIS -The Amsterdam Preoperative Anxiety and Information, Italian Version

The APAIS, Italian Version, is a six-items 5-points Likert self-report questionnaire for preoperative use, consisting of two scales including a 4-items Anxiety Scale and a 2-items Need-for-Information Scale. All items score from 1 to 5, and therefore the score range is 4-20 for the Anxiety scale and 2-10 for the Need-for-Information scale: the higher the score, the higher the level of Anxiety and Information requirement (Buonanno et al., 2017; Moreman, 1996). Pre-Operative Anxiety is evaluated by the six-items score.

STAI – State-Trait Anxiety Inventory, Italian Version.

The STAI (Spielberg, 1983; Spielberg & Pedrabissi, 1989) is a well-validated and widely used instrument to measure anxiety. The questionnaire consists of two separate, 20-item self-report rating scales which measure Trait and State Anxiety, respectively. The STAI-Trait measures Anxiety as a relatively stable personality disposition and the STAI-State measures situation-related Anxiety.

MINI -The Mini-International Neuropsychiatric Interview, Italian Version. Mini International Neuropsychiatric Interview (MINI), section A (major depressive episode).

The MINI (Rossi et al., 2004; Sheehan et al., 1998) is a structured short diagnostic interview developed and validated in 1990 by a group of psychiatrists and clinicians in the United States and Europe in order to screen for the most common DSM-IV and ICD-10 Psychiatric disorders. It has a mean administration time of approximately 15 minutes, and it was designed to meet the need for a short but accurate structured psychiatric interview for multicenter clinical trials and epidemiology studies.

2.5 Procedures

The research took place twice a week for two months (January and February) in 2015. Participants were contacted by the researcher when they reached the waiting room of the Ward before undergoing Breast Biopsy, according to the schedule of the day. The researcher introduced herself to the patient and obtained a written informed consensus to take part in the study. A copy of the consensus was given to the participant. The researcher therefore allocated the patient to the Clinical (Supportive Care, N=40) or Control Group (Standard Care, N=40) according to a computer generated randomization plan.

Patients belonging to the Control Group received the informative brochure from the nurse and were then asked to complete the socio-demographic questionnaire and the self-report test battery described above. Women belonging to the Clinical Group were introduced by the nurse to the volunteer in line with the Supportive Care Model. They were led into the separate room where the 30 minutes support colloquium took place; the researcher reached back the patient in the waiting room after the colloquium, and asked her to complete the self-report battery. Therefore, for both the Clinical and the Control Group, data were collected by the researcher in waiting room where patients were located before entering the day surgery unit for Breast Biopsy. Compilation time ranged between 20 and 25 minutes for all the patients.

2.6 Data analysis

Data were analyzed using the statistical software Package for Social Science IBM SPSS 25 for Windows. For both groups, we produced the descriptive statistics of all the measured quantitative variables. We performed a Group comparison with the independent sample *t*-test in order to evaluate the difference in the Mean levels of APAIS and its two subscales, Anxiety and Need-for-Information (Buonanno et al., 2017), STAI-State and STAI-Trait (Pedrabissi & Santinello, 1989; Spielberg, 1983) and Age. In a preliminary analysis of correlation we produced an estimate of the Pearson's *r* coefficient between these 5 continuous variables. We also evaluated the normality of the distribution of these variables by inspection and with an estimate of the Skewness (norm(Skewness)<0.5) and kurtosis (<3) indices of the data distribution. After having verified that our data fulfilled the condition of homogeneity of the variances with Levene's Test ($p>0.05$), we performed two different ANCOVAs: in the first one we evaluated the effect of the Group factor over the global APAIS score by taking the STAI-Trait as a Covariate, while in the second one the considered Covariate variable was Age. Finally we considered the categorical Depression variable obtained from the Depression subtest of the MINI (Rossi et al., 2004; Sheehan et al., 1998), which screens the participants according to the presence (Depression YES) or absence (Depression NO) of Depression and derived the (Group x Depression) Contingency Table. We checked for a possible interaction between the Group factor and the Depression categorical factor by performing a Two-Ways ANOVA with Group and MINI-Depression as factors and the global APAIS score as dependent variable.

3. Results

In table 1 we summarize the descriptive statistics for Age and for the continuous measures included in our battery and compare the Mean of the two groups with an independent sample *t*-test.

Table 1. Descriptive Statistics and Mean Group comparison with an independent sample *t-test* for STAI-State and STAI-Trait, APAIS, and its subscales (Need of Information and Anxiety)

	CLINICAL GROUP		CONTROL GROUP				
	N=40		N=40				
	M	DS	M	DS	t	df	p
STAY-STATE	44.4	11.0	47.1	10.8	1.09	78	ns
STAY-TRAIT	38.4	7.70	39.0	8.49	.331	78	ns
APAIS-ANXIETY	6.50	2.12	7.87	2.45	2.84	78	< 0.001
APAIS-NEED-FOR- INFORMATION	3.70	1.34	4.42	1.95	1.93	78	< 0.10
APAIS TOTAL	10.2	2.99	12.3	3.57	2.84	78	< 0.001

The Clinical Group showed a significantly lower level of Pre-Operative Anxiety as measures by APAIS with respect of the Control Group; of the two subscales of the APAIS, the Anxiety scale showed a significant decrement in the Clinical Group, while we detected a strong trend towards significance ($p < 0.06$) in difference of the Means for the Need-for-Information subscale. STAI-State and STAI-Trait, as well as Age, did not differ across conditions.

In Table 2 we analyzed the structure of the correlations between the continuous measures in our sample by estimating Pearson's *r* coefficients.

Table 2. Pearson's *r* correlation coefficients between AGE, APAIS (total score and subscales) AND STAI (STATE and TRAIT)

	AGE	STAI-STATE	STAI-TRAIT	APAIS ANXIETY	APAIS NEED FOR INFORMATION	APAIS TOTAL
AGE	1					
STAI-STATE	,187	1				
STAI-TRAIT	,162	,503**	1			
APAIS-ANXIETY	-,022	,520**	,286*	1		
APAIS-NEED-FOR- INFORMATION	-,114	,281*	,120	,401**	1	
APAIS TOTAL	-,072	,499**	,257*	,891**	,774**	1

The Age variable showed no significant correlation in the data. The two sub-dimensions of the STAI had a different pattern of correlations with the APAIS: STAI-State showed a rather strong correlation with APAIS-total ($r=0.50$, $p<0.05$) and APAIS-Anxiety ($r=0.52$, $p<0.001$), and a weak correlation with APAIS-Need-for-Information ($r=0.28$, $p<0.05$). STAI-Trait instead was found to be weakly correlated with APAIS-total ($r=0.26$, $p<0.05$), and APAIS-Anxiety ($r=0.29$, $p<0.05$), while its correlation with APAIS-Need-for-Information failed to reach significance. In order to test the efficacy of the intervention with the ANCOVAs over APAIS as Dependent Variable, we first verified the homogeneity of the Variances assumption with Levene's Test ($p>0.05$). In the first ANCOVA (Table 3a) we found in the Clinical Group a significant reduction of the level of Preoperative Anxiety as measured by APAIS even when Covariate STAI-Trait is included in the model.

Table 3a. Covariance Analysis with Group as Factor, Trait-Anxiety (STAI-Trait) as Covariate and Pre-Operative Anxiety (APAIS) as Dependent Variable

SOURCE	SUM OF THE SQUARES TYPE III	DF	AVERAGE OF THE SQUARES	F	Sig.
CORRECT MODEL	144,9	2	72,4	7,0	,002
INTERCEPT	168,1	1	168,1	16,3	,000
STAI-TRAIT	56,7	1	56,7	5,5	,021
GROUP	82,8	1	82,8	8,0	,006
ERROR	792,0	77	10,2		
TOTAL	11062,0	80			
TOTALE CORRECT	937,0	79			

$$R^2 = 0.16 \text{ (} R^2_{\text{correct}} = 0.13 \text{)}$$

The ONE WAY ANCOVA shows a significant effect of the Group variable even when the Covariance of APAIS with Trait Anxiety is controlled for.

Overall the model explained around 15% of the Variance in the data ($R^2=0.16$, $R^2_{\text{corrected}}=0.13$). We applied the same statistical model to the two measures obtained from the subscales of APAIS, namely APAIS-Anxiety and APAIS-Need-for-Information.

The Group variable was significant ($p<0.05$, see Table 3b) in the first case, while we detected a trend to significance in the second case ($p<0.10$, see Table 3c).

Table 3b. Covariance Analysis with Group as Factor, Trait-Anxiety (STAI-Trait) as Covariate and Need for Information subscale of Pre-Operative Anxiety (AP AIS) as Dependent Variable

SOURCE	SUM OF THE	DF	AVERAGE OF	F	Sig.
	SQUARES TYPE III		THE SQUARES		
CORRECT MODEL	3,359	2	1,679	2,381	0,099
INTERCEPT	8,044	1	8,044	11,404	0,001
STAI-TRAIT	0,731	1	0,731	1,036	0,312
GROUP	2,522	1	2,522	3,575	0,062
ERROR	54,313	77	0,705		
TOTAL	387,750	80			
TOTALE	57,672				
CORRECT		79			

 $R^2 = 0.06$ ($R^2_{\text{correct}} = 0.03$)
Table 3c. Covariance Analysis with Group as Factor, Trait-Anxiety (STAI-Trait) as Covariate and the Anxiety subscale of APAIS as Dependent Variable

SOURCE	SUM OF THE	DF	AVERAGE	F	Sig.
	SQUARES TYPE III		OF THE SQUARES		
CORRECT MODEL	4,482	2	2,241	7,333	0,001
INTERCEPT	3,327	1	3,327	10,888	0,001
STAI-TRAIT	2,119	1	2,119	6,933	0,010
GROUP	2,195	1	2,195	7,185	0,009
ERROR	23,530	77	0,306		
TOTAL	286,313	80			
TOTAL CORRECT	28,012	79			

 $R^2 = 0.16$ ($R^2_{\text{correct}} = 0.14$)

In the last ANCOVA (Table 4), following the suggestions provided by Liao et al. (2008) we repeated the analysis by considering Age as the Covariate: again the Clinical Group showed a significant reduction in the level of Preoperative Anxiety as measured by APAIS, with no effect of the Covariate. Overall the model explained around 10% of the Variance in the data ($R^2=0.10$, $R^2_{corrected}=0.07$).

Table 4. Covariance Analysis with Group as Factor, Age as Covariate and Pre-Operative Anxiety (APAIS) as Dependent Variable

SOURCE	SUM OF THE SQUARES TYPE III	DF	AVERAGE OF THE SQUARES	F	Sig.
CORRECT MODEL	89,0	2	44,5	7,0	0,02
INTERCEPT	663,6	1	663,6	16,3	,000
AGE	0,87	1	0,87	5,5	0,78
GROUP	84,2	1	84,2	8,0	,007
ERROR	847,9	77	11		
TOTAL	11062,0	80			
TOTAL CORRECT	937,0	79			

$R^2 = 0.10$ ($R^2_{correct} = 0.07$)

The ONE WAY ANCOVA shows a significant effect of the Group variable and no effect of the Age Covariate.

In the last group of planned analyses we considered Depression as a possible confounding variable: Depression was screened with the categorical score (Presence or Absence of Depression) obtained from the MINI-Depression subtest - Module A - of the *The Mini-International Neuropsychiatric Interview* (Sheehan et al., 1998).

In order to evaluate the possible influence of Depression over Pre-Operative Anxiety and in order to evaluate the possible interaction between the Group factor and the Depression factor, we performed a Two-Ways ANOVA with Group and Depression as independent factors and APAIS as the Dependent Variable (See Table 5).

Table 5. TWO WAY ANOVA with Group and Depression (MINI-Depression) as bivariate factors and Pre-Operative Anxiety (APAS) as dependent variable

SOURCE	SUM OF THE	DF	AVERAGE	F	Sig.
	SQUARES TYPE III		OF THE SQUARES		
CORRECT MODEL	100,7	3	33,5	3,0	,034
INTERCEPT	4460,1	1	4460,1	405,3	,000
GROUP	62,2	1	62,2	5,6	,020
MINI-DEPRESSION	12,3	1	12,3	1,1	,292
GROUP * MINI-DEPRESSION	2,0	1	2,0	,190	,665
ERROR	836,2	76	11,0		
TOTAL	11062,0	80			
TOTALE CORRECT	937,0	79			

$$R^2 = 0.11 \text{ (} R^2_{\text{correct}} = 0.07 \text{)}$$

In the model, the interaction between Group and Depression is not significant; there is an effect of Group factor but not of the categorical Depression factor.

The interaction between Group and Depression failed to reach significance and we found an effect of the Group factor, but not of the Depression factor, over the measured Mean of Pre-Operative Anxiety. Again, the model explained around 10% of the Variance in the data ($R^2=0.11$, $R^2_{\text{corrected}}=0.07$).

Overall, our analyses have consistently documented a significant reduction of the Pre-Operative Anxiety level in the Clinical Group, which received the Supportive Care intervention, when contrasted to the Control Group, receiving Standard Care.

The reduction still persisted when Trait Anxiety, Age and Depression were explicitly added as Covariates (Trait Anxiety, Age) or as another independent factor (absence or presence of Depression) in the data analyses.

4. Discussion

In the last two decades a relevant effort has been produced in order to define the theoretical construct of Pre-Operative Anxiety and in order to distinguish it from other related constructs, such as State Anxiety (Buonanno et al., 2017): the construct has been operationalized with the Amsterdam Pre-Operative Anxiety and Information Scale (Moerman et al., 1996), which adds the emotional aspect assessed with the Anxiety sub-scale, a second sub-dimension that has been recognized as Need-for-Information. As recently demonstrated in a systematic review (Miraglia Raineri et al., 2018) Pre-operative Anxiety is a major concern for women undergoing Breast Biopsy, and therefore it is important to design and validate specific interventions aiming to reduce it. In this domain till now some attempts were made to use relaxation with a photographic display with and without music (Gómez-Urquiza et al., 2016), and music therapy (Bradley Palmer et al., 2015; Huan et al., 2001) in order to reduce anxiety in women that were approached while waiting to undergo Breast Biopsy.

Till January 2015, women undergoing Breast Biopsy received from a nurse an informative brochure with details about the procedure while they were sitting in the waiting room. In an attempt to meet the psychological need of the patients, a *Supportive Care Model* was adopted: the patients awaiting Breast Biopsy were offered a supportive colloquium performed with specifically trained volunteers who delivered both informative communication and emotional support. We designed a randomized case-control study to contrast the *Supportive Care Model* to *Standard Care* by taking into account the following points: first, we considered APAIS (Moerman et al., 1996) as dependent measure in order to assess the efficacy of the intervention with respect to the two dimensions of Pre-Operative Anxiety, that is Anxiety and Need-for-Information; second, we included in the comparison some control variables that have been reported to have an influence on Pre-Operative Anxiety, namely Age, Trait Anxiety and Depression (Miraglia Raineri et al., 2018). To our knowledge this is the first study designed to systematically control for these variable in assessing Pre-Operative Anxiety as measured by APAIS (Moerman et al., 1996).

First of all, we observed that a very low percentage of women refused to take part in the study, and in particular all the participants concluded the proposed colloquium; the non respondent percentage is very low: despite the very difficult moment they are facing, they were well motivated in taking part in the research project.

In the univariate group comparison (Supportive Care Group vs Standard Care Group) we detected a significant reduction in Pre-Operative Anxiety as measured by APAIS (Buonanno et al., 2017), while we found that the two groups did not differ neither in the measured level of

Trait Anxiety, nor, quite surprisingly, in the measured levels of State Anxiety as measured by the validated Italian version of the STAI (Pedrabissi & Santinello, 1989). This result supports the specificity of the validated Italian version of APAIS (Buonanno et al., 2017) with respect to STAI-State as a measure of Pre-Operative Anxiety (Miller, 1987; Miller & Mangan, 1983). Nevertheless our correlation analysis confirmed the construct validity of the APAIS, Italian version, when STAI (Pedrabissi & Santinello, 1989) is considered as a criterion, as commonly done in the literature (Buonanno et al., 2017).

In order to control for Age and Trait Anxiety as suggested by a systematic review (Miraglia Raineri et al., 2018), we contrasted the groups with ANCOVAs and we found that in all the analyzed models the Group variable had a significant effect in reducing the APAIS total score and the APAIS Anxiety dependent measures, while in the case of the Need-for-Information measure a strong trend was detected. However, as the Need-for-Information scale is a two-items measure its sensitivity to contextual changes is obviously quite low. It is important to consider that the Standard Care condition of the Careggi Breast Units includes informative support to the patient delivered by a brochure, while in the *Supportive Model* information is delivered within the colloquium with an empathic and supportive volunteer: it is well possible that a larger sample would have allowed to find evidence that providing information in the context of a relational exchange is more effective than providing written information. However the amount of explained variance of the Dependent Variable in our models ranged between 6% (for the Need-for-Information sub-scale of APAIS) to 16% (for the Anxiety subscale of APAIS), leaving for further research efforts to compare the efficacy of *Supportive Care* with respect to other interventions such as music therapy (Gómez-Urquiza et al., 2016), which apparently are quite effective in inducing Pre-Operative relaxation (Montgomery et al., 2007; Shur et al., 2008).

When we performed a 2-Ways ANOVA (Group x Depression) with APAIS as dependent variable, we found that there was no interaction between the two factors; of the two categorical factors (Group and Depression, as screened by MINI-Module A), the Group factor alone was found to influence the dependent variable. The level of explained Variance of the model reached 11% in this case. Our results confirm that the Supportive Care intervention is effective even when Depression is controlled for. However as the MINI-Module A (Sheehan et al., 1998) is a screening test it would be important to replicate the study by considering a quantitative estimate of the Depression level in the future, to be considered in the model as a Covariate.

Our randomized case-control study verified the efficacy of a Supportive Care intervention, including a supportive and informative colloquium with a trained volunteer, in reducing Pre-

Operative Anxiety as measured by APAIS (Moreman et al., 1996), that is, within a two-dimensional theory of this construct. In particular we provided preliminary indications that an informative colloquium could be more suitable than a brochure in meeting the needs of information in women undergoing Breast Biopsy.

The Supportive Care approach was found to be effective even when results were controlled for Trait Anxiety, as measured by STAI-Trait, Age and Depression as screened by MINI-Module A.

Our data confirmed the specificity of APAIS (Moreman et al., 1996) as a measure of Pre-Operative Anxiety (Liao et al., 2010) in the Italian context (Buonanno et al., 2017).

Limits of this study:

- 1) The sample is recruited within a specific Italian Breast Unit, and it is not representative of the general population
- 2) Depression was screened for but not evaluated in the present trial
- 3) This paper utilized a quantitative method, probably a qualitative approach could be proposed to explore the life experience of patients.

5. Conclusions

As Anxiety is a mayor concern for the improvement of the patients' experience of care in women undergoing Breast Biopsy, we devised a randomized case-control study in order to assessed the efficacy of a Supportive Care intervention in reducing the patients' Pre-Operative Anxiety. The study was performed at the Breast Unit of the Careggi Hospital in Florence. The results showed that women belonging to the Supportive Care Group (taking part in a colloquium with a specifically trained volunteer of a Social Service Association while waiting to undergo Biopsy) reported decreased levels of Pre-Operative Anxiety when compared to women belonging to the Control Group, receiving Standard Care. The efficacy of the intervention was confirmed even when the Group comparisons were controlled for Trait-Anxiety, Age and Depression. Further studies should be planned in order to contrast the proposed intervention with other Supportive Care strategies (such as relaxation and music therapy) that have been proposed to improve the patients' experience of care while undergoing Breast Biopsy.

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