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Are patients at risk for emotional maladjustment to fertility treatment less willing to comply with treatment? Results from the validation of the Portuguese version of the SCREENIVF

Vanessa Gaudêncio Borges Lopes (e-mail: vanessagbl@hotmail.com)

Are patients at risk for emotional maladjustment to fertility treatment less willing to comply with treatment? Results from the validation of the Portuguese version of the SCREENIVF

Background: Many couples do not comply with fertility treatment because of its psychological burden. The SCREENIVF can be used to screen patients at risk for emotional maladjustment during treatment by assessing risk factors for maladjustment (distress, infertility cognitions and social support). The psychometric properties of the Portuguese version of the SCREENIVF were examined. This study also investigated if patients at risk for emotional maladjustment during fertility treatment reported lower intentions to comply with treatment than patients not at risk and which risk factors were associated with lower compliance intentions.

Methods: Sample was composed of 383 infertile women and men undergoing any stage of fertility treatment in Portugal. They completed the Portuguese version of the SCREENIVF and other self-report questionnaires assessing wellbeing, partner support, child wish and intentions to comply with treatment.

Results: Confirmatory factor analysis showed good fit of the SCREENIVF structural model. SCREENIVF presented good reliability and was significantly associated with other measures of distress, partner support and child wish. Patients at risk and not at risk for maladjustment reported similar compliance intentions. Negative associations found between distress and compliance intentions were moderated by patients' cognitions regarding control perceived over fertility and its treatment and capacity to accept a future without biological children.

Conclusion: The Portuguese version of the SCREENIVF is valid and reliable. Patients are overconfident about their ability to comply with treatment. Patients need to have information and feel control over treatment in order to make informed and satisfactory decisions about treatment uptake.

Key Words: infertility treatment, compliance, screening, risk factors, psychological adjustment

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Contents

Table and figure index

I – Conceptual framework

Infertility affects 9% of couples worldwide (Boivin, Bunting, Collins, & Nygren, 2007) and 8.9% in Portugal (Silva- Carvalho & Santos, 2009). Chances of conceiving are high if infertile couples are willing to undergo repeated fertility treatment cycles (Pinborg, Hougaard, Andersen, Molbo, & Schmidt, 2009). However, a significant proportion of couples, ranging from 34% (Rajkhowa, Mcconnell, & Thomas, 2006) to 60% (Malcom & Cumming, 2004) do not comply with recommended treatment, despite having good medical prognosis (Rajkhowa et al., 2006) and ability to cover treatment cost (Olivius, Friden, Borg, & Bergh, 2004; Verberg et al., 2008). Patients refer the psychological burden of fertility treatment as one of the main reasons to discontinue treatment (Brandes et al., 2009; Domar, Smith, Conboy, Iannonne, & Alper, 2010; Gameiro, Boivin, Peronace, & Verhaak, 2012, in press; Olivius et al., 2004; Rajkhowa et al., 2006). Factors that increase patients' psychological vulnerability to the burden of treatment may thus also affect patients' willingness to comply with treatment. The main goal of the present study was to investigate if patients at risk for emotional maladjustment during fertility treatment reported lower intentions to comply with recommended treatment and which risk factors were associated to lower compliance intentions.

The World Health Organization defines treatment adherence or compliance as "… the extent to which a person's behaviour follows medical advice or corresponds with recommendations from the health care provider…" (WHO, 2003, p.3). In fertility care compliance refers to the uptake of all fertility treatments recommended by the medical team, ranging from first order treatments to Assisted Reproductive Technologies (ART), as long as there is ability to cover treatment costs (Boivin et al., 2012). Non-compliance should be considered a negative outcome for patients and clinics alike. From the patients' point of view, it represents giving up the goal of biological parenthood. For clinics non-compliance translates in lower pregnancy rates (Verhagen, Dumoulin, Evers, & Land, 2008), that is less effectiveness.

Different studies show that patients identify the psychological distress of undergoing treatment as one of the main reasons for noncompliance. In the only prospective study that followed patients across their complete treatment pathway, 22% of patients reported that they did not comply with treatment because of the emotional distress treatment implied (Brandes et al., 2009; Verberg et al., 2008). Patients cite psychological distress as a reason for not complying with treatment more often than other reasons such as financial issues (36% versus 23%) (Rajkhowa et al., 2006), physical burden (26% versus 6%) or marital problems/divorce (26% versus 15%) (Olivius et al., 2004). A recent systematic review of patients' stated reasons for noncompliance showed that most reasons vary across stages (e.g., "Physical burden of treatments" during ART) but that psychological burden of treatment is cited at all stages (Gameiro et al., 2012). Taken together these data suggest that patients showing greater psychological vulnerability to

treatment may also present lower intentions to comply with it.

Although patients cite the psychological burden of treatment as one of the most important reasons for noncompliance, empirical research in the field has not yet been able to identify which are the psychological risk factors behind noncompliance decisions (Gameiro et al., 2012). Fertility treatments can be highly demanding for couples. They involve complex medical procedures and the uncertainty about the success of each treatment attempt is high (Dunkel-Schetter & Lobel, 1991). These challenges can lead to states of high anxiety (Verhaak et al., 2007). Patients are also confronted with a long process of repeated decision-making (Cousineau & Domar, 2007) and they state that the necessity to decide about uptake of further treatment can in itself be distressful (Peddie, van Teijlingen, & Bhattacharya, 2005). Highly anxious patients may cope with stress by avoiding treatment even when there is a good prognosis, which would reflect in lower intentions to comply with recommended treatment.

The inability to conceive a child originates a sense of loss that can result in increased depressive symptoms (Dunkel-Schetter & Lobel, 1991), which can be accentuated by the experience of treatment failure (Verhaak, Smeenk, Evers, van Minnen, & Kraaimaat, 2005a). It is in this emotional context of loss and grief due to treatment failure, usually associated with less optimistic visions of the future (Beck, Rush, Shaw, & Emery, 1979) that patients need to decide about uptake of further treatment. In this context, more depressed patients may be less willing to comply with treatment.

Patients' cognitions about treatment and parenthood may also influence their compliance decision-making. Helplessness cognitions reflect a sense of lack of control over infertility and its treatment and are associated with higher distress after a failed treatment (Verhaak et al., 2005a), avoidance behaviours (Seligman, 1975) and limited capacity to make decisions (Rauprich, Berns, & Vollmann, 2011), possibly resulting in lower compliance. On the other hand, acceptance of a childless lifestyle can promote the pursue of other relevant life goals (e.g. profession, adoption) (van Balen, Verdurmen, & Ketting, 2006) and thus facilitate noncompliance. However, it is more likely that cognitions relate with compliance by conditioning the choices of more distressed patients. Highly distressed patients that feel helpless in relation to infertility and its treatment and who are more able to accept a childless lifestyle may be less willing to comply than those who are also highly distressed but still feel some control over treatment or cannot accept life without children.

Social support is an important resource to cope with a low control stressor such as infertility (Jordan & Revenson, 1999) and the literature has shown that it is associated with a more adaptive response to failure in fertility treatment (Verhaak et al., 2005a). In the context of infertility, the spouse, family and friends are the most frequent sources of social support (Boivin, Scanlan, & Walker, 1999). Likewise, support groups may help couples because they offer the opportunity to experience communality (Lentner & Glazer, 1991 as cited in Lemmens et al., 2004) and share relevant information (Aarts et al., 2012) about infertility and its treatments,

which should increase confidence and willingness to pursuit recommended treatment.

Women show more intense emotional reactions to *in vitro* fertilization (IVF) treatments than men. They are subjected to more medical procedures and show higher physical fatigue during treatment (Boivin et al., 1998). At the same time, they seem less able to accept a childless lifestyle and to stop treatment than men (Wright, Bissonnette, & Duchesne, 1991). They are also more prone to seek social support to deal with their fertility problems (Boivin et al., 1998; Jordan & Revenson, 1999). It is thus expected that the associations between risk factors for psychological maladjustment and compliance will be different for women and men.

In summary, patients' emotional adjustment to treatment (i.e., anxiety and depression), their cognitions about infertility treatment and parenthood and the social support available may be associated with patients' intentions to comply with treatment. These five factors were already identified as risk factors for a negative emotional response to the first (Verhaak et al., 2005a) and subsequent ART treatment cycles (Verhaak, Smeenk, van Minnen, Kremer, & Kraaimaat, 2005b). Based on these five risk factors, Verhaak and colleagues (Verhaak, Lintsen, Evers, & Braat, 2010) developed the SCREENIVF, the first screening tool specific for fertility care that aims to identify women at risk for maladjustment during ART. Cut-off scores that indicate clinical relevant problems were established for each risk factor. The tool classifies women as at risk for emotional problems when their scores indicate that they are at risk for at least one of the five risk factors. The SCREENIVF was tested on a sample of 279 women and proved to be an effective tool to differentiate women entering IVF treatment who later presented or not clinical relevant psychological problems during treatment. In addition, a study conducted in The Netherlands showed that the use of the SCREENIVF tool in the clinic context is feasible. More specifically, it showed that 78% of patients who were requested to fill the SCREENIVF actually did it and that this allowed identifying patients at risk for emotional problems (approximately 30%). Patients found the SCREENIVF instructions easy to understand and stated that the length of the questionnaire was acceptable (Van Dongen, Kremer, Van Sluisveld, Verhaak, & Nelen, 2011). Taken together, these data suggest that the SCREENIVF may constitute an important and useful tool for patients and clinics alike. However, only its Dutch version has been validated (Verhaak et al., 2010) and its reliability and validity have not been investigated in men or patients undergoing less advanced treatment stages than ART.

II - Goals

The main purpose of the present study was to investigate if patients identified as at risk for emotional maladjustment during fertility treatment were also at higher risk for not complying with treatment. Specific goals were to: (1) investigate the psychometric properties of the Portuguese version of the SCREENIVF tool (i.e., construct validity, reliability and discriminant validity) in a sample of infertile women and men undergoing

any stage of fertility diagnosis or treatment in Portugal; (2) investigate if patients identified by the SCREENIVF as at risk for emotional maladjustment reported lower intentions to comply with treatment; (3) investigate associations between the SCREENIVF risk factors and patients' intentions to comply with treatment; (4) investigate if cognitions about treatment and parenthood (i.e. helplessness and acceptance) moderated associations between anxiety and depression and patients' intentions to comply with treatment and (5) investigate if such relationships were moderated by gender.

III – Methods
1. Procedures

The study was approved by the Ethics Committee of the Coimbra University Hospitals.

Participants were recruited online and at the clinical setting between January 2011 and February 2012. Inclusion criteria were being adult and undergoing fertility diagnosis or treatment at a fertility clinic in Portugal. Online recruitment was done through a web based survey that was divulged in the APFertilidade website, the main patient advocacy group in Portugal. A *Facebook cause* was also created and divulged among all APFertilidade *Facebook* friends. The clinic setting consisted of a large university based hospital where individuals were systematically invited to participate in the study. Individuals could choose between four ways to participate: (1) fill the questionnaire at the hospital and return it to the research team; (2) take the questionnaire home and return it during the following consultation at the hospital; (3) take the questionnaire home and return it to the research team by post mail in a pre-addressed envelope; (4) complete the questionnaire on-line. In the three later cases, if patients did not return or filled online the questionnaires, a reminder text message was sent two and four weeks after. All participants signed an informed consent and confidentiality was guaranteed. Figure 1 of supplemental material presents the sample collection flowchart. At the clinical setting, 478 patients were invited to participate and 233 delivered the questionnaire. Two hundred and twenty two questionnaires were submitted online. Of these, nine were excluded because were duplicates. In total 446 questionnaires were delivered. From these, only those where 80% of the SCREENIVF was filled were retained and 12 were excluded because they were identified as outliers

2. Materials

Socio-demographic (e.g., age, educational level) and clinical (e.g., duration of infertility, stage of treatment) background characteristics were assessed with a self-report questionnaire.

Risk for emotional maladjustment was assessed with the SCREENIVF tool (Original Version: Verhaak, Lintsen, Evers, &Braat, 2010; Portuguese Version: Gameiro, &Canavarro, 2011). The SCREENIVF is composed of 34 items organized in five dimensions that assess risk for maladjustment. The Anxiety dimension (10 items, e.g., "I get very nervous and worried when

thinking about my current troubles") was based on a short version of the Spielberger State and Trait Anxiety Inventory (Spielberger, 1983). The Depression dimension (7 items, e.g., "I feel sad") was based on the Beck Depression Inventory, version for patients of general practitioners (Beck, Guth, Steer, & Ball, 1997). Helplessness (6 items, e.g., "My fertility problems control my life") and Acceptance cognitions (6 items, e.g., "I can accept my fertility problems") were assessed with items from the Illness Cognition Questionnaire for IVF patients (Evers, Kraaimaat, Lankveld, Jongen, & Biijlsma, 2001; Verhaak et al., 2005b). The Social Support dimension (5 items, e.g., "When I feel sad there is always someone I can talk to") was composed by items derived from the Inventory of Social Involvement (van Dam-Baggen & Kraaimaat, 1992). The original version of the SCREENIVF exhibited excellent reliability in all scales (Cronbach's alphas between .82 and .92). Based on patients' scores on the five risk factors, the tool classifies patients as "at risk" or "not at risk" for emotional maladjustment. The SCREENIVF correctly identified 69% of the total of patients who presented clinical significant emotional difficulties and 77% of those who did not (Verhaak et al., 2010). To develop the Portuguese version of the SCREENIVF, we followed Humbleton, Merenda, & Spielberg (2005) recommendations' for adapting tests. To classify individuals as at risk, we followed the procedures described by Verhaak et al. (2010). The cut-off score for depression was four or higher, which is in line with previous studies (Beck et al., 1997; Verhaak et al., 2010). For anxiety, helplessness and acceptance cognitions and social support, scores were based on one standard deviation above or below the sample mean scores. Thus, cut-off score for anxiety was 27 or above; for helplessness cognitions was 15 or above; for acceptance cognitions was 11 or below; and for social support was 13 or below. In each of the five risk factors, if patients scored above/below the cut-off point, it was assigned to them a score of 1 (at risk); otherwise, it was 0 (not at risk). Patients are classified as "at risk" if they are at risk in at least one of the five risk factors.

Anxiety and depression were assessed with the anxiety (6 items, e.g., "I feel tense or nervous") and depression (6 items, e.g., "I'm not too pessimistic or feel discouraged about the future") scales of the Brief Symptom Inventory (Original Version: Derogatis, 1982; Portuguese Version: Canavarro, 1995) which have a 5-point Likert scale ranging from 0 (*Never*) to 4 (*Very often*). Total scores correspond to the sum of the scale items and range from 0 to 24, with higher scores indicating more symptoms. The Portuguese version of the BSI is sound (Canavarro, 1995). Cronbach's alpha values in the present sample were of .89 for both dimensions.

Quality of life was assessed with the Fertility Quality of Life tool (FertiQol; Original Version: Boivin, Takefman, &Braverman, 2011; Portuguese Version Gameiro, & Canavarro, 2010). FertiQol is composed of 24 items organized in four quality of life domains: emotional (6 items, e.g., "Do your fertility problems cause feelings of jealousy and resentment?"), mind-body (6 items, e.g., "Are your attention and concentration impaired by thoughts of infertility?"), relational (6 items, e.g., "Have fertility problems

strengthened your commitment to your partner?") and social (6 items, e.g., "Do you feel social pressure on you to have (or have more) children?"). Total scores range from 0 to 100, with higher scores indicating higher quality of life. The Portuguese version of the FertiQoL has good psychometric characteristics (Melo, Gameiro, & Canavarro, in press). In the present sample Cronbach's alpha values varied from .71 to .90.

Relational adjustment was assessed with the Revised Dyadic Adjustment Scale (RDAS; Original Version: Busby, Christensen, Crane, & Larson, 1995; Portuguese Version: Pereira, Canavarro, & Davide, 2009). This scale is composed of 14 items (e.g., "How often do you discuss or have you considered divorce, separation, or terminating your relationship?") that assess satisfaction with an intimate relationship. The total score ranges from 0 to 69. Higher scores reflect higher relational adjustment. Cronbach's alpha value for the total scale was .82.

Partner support was assessed with one single item constructed by the researchers. Individuals had to rate on a 5-point Likert scale ranging from 1 (*Never*) to 5 (*Always*) the degree to which the sentence "Do you feel support and understanding from your partner in relation to your fertility problems and fertility treatments?" described their experience.

Child wish was assessed by a unique question, assessing the extent to which the participant wanted to have a child, with a response scale ranging from 0 (*No desire*) to 10 (*Very strong desire*).

Compliance intentions were assessed with the FertiQoL persistence scale (Boivin, Takefman, & Braverman, 2011). This scale is composed of six item (e.g., "How often do you consider withdrawal from treatment?"), with a 5-point Likert answering scale ranging from 1 (*Never*) to 5 (*Always*), assessing patient's motivation to persist in treatment. Scores vary from 6 to 30, with higher scores indicating stronger intentions to do more treatments. In the present sample Cronbach's alpha value was .77.

3. Data analysis

The psychometric properties of the SCREENIVF investigated were construct validity, reliability and discriminant validity.

Construct validity was examined through Confirmatory Factor Analysis (CFA) and by testing the criterion validity of the five risk factors. The CFA was performed using AMOS, version 17.0, to test the structure of the SCREENIVF tool. The model was a first-order model with five latent variables that correspond to the five risk factors for emotional maladjustment. For each of the dimensions of the SCREENIVF, three parcels were generated by randomly combining the items of that dimension (Little, Cunningham, Shahar, & Widaman, 2002), a statistical procedure that is known to ameliorate model fit and to produce less bias in the estimation of structural parameters (Bandalos, 2002). To assess model fit different parameters commonly used were analysed: X^2, the comparative fit index (CFI) and the root-mean-square error of approximation (RMSEA) (Byrne, 2010). A model is considered to have very good fit if the X^2 value is non-significant (p > .05), the CFI is greater than .95 and the RMSEA is less than

.06 (Hu & Bentler, 1998).To investigate if the SCREENIVF can be used with different groups of patients its measurement (associations of observed scores to the latent variables) and structural (associations of latent variables with each other) invariance was tested across gender and treatment stage (first order treatments versus ART). Invariance in the model occurs when the X^2 difference between the tested models is non-significant (Byrne, 2010) or the CFI difference is smaller than <.01 (Cheung & Rensvold, 2002). Criterion validity of the SCREENIVF was tested through the investigation of the correlations between the different SCREENIVF risk factors and between these and other measures of anxiety and depression, relational adjustment, partner support and child whish.

The reliability (internal consistency) of the SCREENIVF was investigated using Cronbach's alpha and by analysing the correlations between each item and its specific dimension. Finally, discriminant validity was examined using multivariate analysis of variance (Manova) to investigate if patients classified as at risk for maladjustment reported worse wellbeing (i.e., higher anxiety and depression and lower quality of life and relational adjustment) than patients not at risk.

To investigate if patients identified by the SCREENIVF as at risk for emotional maladjustment reported lower intentions to comply with treatment than patients not at risk we used univariate analysis of variance (Anova).

Finally, to investigate how the five risk factors were associated with intentions to comply with treatment, one hierarchical linear regression was performed. Firstly, any socio-demographic or clinic characteristics that were associated with patients' compliance intentions were entered in the first step of the model along with the five SCREENIVF dimensions and gender. In step two the interaction products between the five risk factors and gender were entered. In step three the four interaction terms between cognitions (helplessness and acceptance) and emotional adjustment (anxiety and depression) were entered. Finally, in the fourth step, three-way interactions of gender, cognitions and emotional adjustment were entered. Continuous variables were transformed into z-scores to avoid multicolinearity problems in the interaction products (Baron & Kenny, 1986).

In all analyses where compliance intentions was the dependent variable we only considered a subgroup of 295 patients who were undergoing treatment at a public clinic and had done less than three IVF/ICSI (Intracytoplasmic Sperm Injection) cycles, thus assuring that patients met the legal criteria to access governmental funding for treatment in Portugal.

IV - Results
1. Participants

The final sample was composed of 291 women and 92 men. Sample demographic and clinical characteristics are presented in Table 1. Both women and men were in their early thirties. Individuals were with their partners for an average of seven years. Women and men recruited at the clinical setting were significantly older than women and men recruited

online. Individuals recruited at the clinic context were less likely to attend college or university than individuals recruited online. The majority of participants did not have children (89.7%) and they were trying to get pregnant for an average of four years, having done on average 0.43 intrauterine insemination (IUI) and 0.90 IVF treatment cycles. Participants recruited at the clinical context were more likely to be at less advanced stages of treatment and had done significantly less IVF treatments than individuals recruited online.

Table 1. Mean (SD) or frequencies for sample socio-demographic and clinic characteristics (N = 383)

Characteristics	Total N= 383	Online n = 182	Clinic n = 201	t/X^2
Socio-demographic				
Gender, n (%)				37.94 [1]***
Female	291 (76.00)	164 (90.10)	127 (63.20)	
Male	92 (24.00)	18 (9.90)	74 (36.80)	
Age (years), mean (SD)	33.50 (3.78)	33.01 (3.60)	33.95 (3.89)	-2.46[1]*
Female	33.06 (3.57)	32.92 (3.54)	33.24 (3.62)	
Male	34.90 (4.09)	33.78 (4.15)	35.18 (4.05)	
Relationship duration (years), mean (SD)	7.07 (3.33)	6.91 (3.38)	7.21 (3.29)	-0.89[1]
Education				
Years of education, mean (SD)	13.39 (3.92)	15.01 (3.53)	11.50 (3.48)	8 .78[1]***
College or University				39.59 [1]***
Education, n (%)				
No	197 (52.00)	63 (35.00)	134 (67.30)	
Yes	182 (48.00)	117 (65.00)	65 (32.70)	
Socioeconomic status, n (%)				0.28[2]***
Low	141 (37.40)	43 (23.80)	98 (50.00)	
Medium	203 (53.80)	115 (63.50)	88 (44.9)	
High	33 (8.80)	23 (12.7)	10 (5.10)	
Religion, n (%)				8.76 [1]**
Catholic	311 (85.67)	132 (80.98)	179 (89.50)	
Other	10 (2.75)	3 (1.84)	7 (3.50)	
None	42 (11.58)	28 (17.18)	14 (7.00)	
Residence zone, n (%)				77.70 [1]***
Urban	244 (64.20)	156 (87.20)	88 (43.80)	
Rural	136 (35.80)	23 (12.80)	113 (56.20)	
Clinic				
Infertility duration (years), mean (SD)	4.30 (2.51)	4.21 (2.60)	4.37 (2.44)	-0.59[1]
Number of previous treatments, mean (SD)				
IUI	0.43 (1.03)	0.49 (1.20)	0.37 (0.84)	1.07[1]
IVF/ICSI	0.90 (1.38)	1.26 (1.61)	0.56 (0.90)	5.11[1]***
Children, n (%)				0.30[1]
No	341 (89.70)	159 (88.80)	182 (90.50)	
Yes	39 (10.30)	20 (11.20)	19 (9.50)	
Current treatment stage, n (%)				0.22[2]**
	101 (26.90)	42 (23.10)	59 (30.60)	
Taking medication / injections	68 (18.10)	23 (12.60)	45 (23.30)	
IUI	24 (6.40)	13 (7.10)	11 (5.70)	

| Waiting to start IVF | 56 (14.90) | 38 (20.90) | 18 (9.30) |
| IVF/ICSI | 126 (33.60) | 66 (36.30) | 60 (31.10) |

Note: * $p < .05$. ** $p < .01$. *** $p < .001$.IUI = Intrauterine insemination; IVF = In vitro fertilization; ICSI = Intracytoplasmic sperm injection (1) Studen*t's t-test*. . (2) *Cramer's V*.

2. Psychometric properties of the SCREENIVF
2.1. Construct validity

Figure 2 of supplemental material presents standardized estimates for measurement and structural paths of the tested model. The X^2 value of the model was significant ($X^2_{(80)} = 188.50$; p<.001). The indexes values were very good and good, respectively: CFI = 0.97; RMSEA = 0.06 [confidence interval (CI) 90% 0.05-0.07]; (Hu & Bentler, 1998). All the standardized factor loadings of the item parcels into their correspondent latent construct were statically significant (p < .001) and higher than .75.Table 2 presents results of the test of the measurement and structural invariance of the SCREENIVF. Results indicate that the SCREENIVF was invariant across treatment stages. Significant structural variance was observed for gender.

Table 2. Results of multigroup analysis testing the measurement and structural invariance of SCREENIVF

	X^2	Df	RMSEA	CIF	ΔX^2	Δdf	ΔCFI
Gender							
Unconstrained	296.02	160	.05 (.04 .06)	.965			
Measurement invariance	326.81	170	.05 (.04 .06)	.960	30.79***	10	.005
Structural invariance	382.845	185	.05 (.05 .06)	.949	86.83***	25	.016
Treatment stage							
Unconstrained	277.078	160	.04 (.04 .05)	.970			
Measurement invariance	287.246	170	.04 (.03 .05)	.970	10.17	10	.000
Structural invariance	306.297	185	.0 (.03 .05)	.969	29.22	25	.001

Note: * p< .05, ** p< .01, ***p < .001; Df = degrees of freedom, RMSEA = root-mean-square error of approximation, CIF = comparative fit index, $\Delta X^2 = X^2$ change, Δdf = degrees of freedom change, ΔCFI =comparative fit index change

Table 3 presents associations between the different SCREENIVF dimensions and between these and other measures of anxiety and depression, relational adjustment, partner support and child wish. Anxiety and depression were positively associated with helplessness cognitions and negatively associated with acceptance cognitions and social support. Social support was negatively associated with helplessness cognitions and positively associated with acceptance cognitions. Finally, helplessness cognitions were negatively associated with acceptance cognitions. Associations between the different dimensions of the SCREENIVF and measures of anxiety and depression, relational adjustment, partner support and child wish were as expected. Anxiety and depression, as measured with the SCREENIVF, were more strongly related with the BSI subscales of anxiety and depression. Social support was more strongly related with anxiety and depression and partner support. Helplessness and acceptance cognitions were more strongly related with child wish.

Table 3. Correlations between the SCREENIVF risk factors and anxiety and depression, relational adjustment, partner support and child wish

	Mean (SD)	n (%) At risk	SCREENIVF				
			Anxiety	Depression	Helplessness cognitions	Acceptance cognitions	Social support
SCREENIVF							
Anxiety	20.87 (6.28)	70 (18.40)	1				
Depression	2.51 (3.09)	106 (28.10)	.70**	1			
Helplessness cognitions	11.10 (4.29)	83 (21.70)	.62**	.65**	1		
Acceptance cognitions	15.68 (4.68)	70 (18.30)	-.58**	-.51**	-.55**	1	
Social support	16.48 (3.70)	70 (18.30)	-.37**	-.39**	-.27**	.32**	1
TOTAL	---	180 (47.00)					
Total women		152 (52.20)					
Total men		28 (30.40)					
Anxiety BSI	5.73 (5.07)		.63**	.61**	.58**	-.46**	-.28**
Depression BSI	4.76 (5.11)		.65**	.72**	.59**	-.52**	-.27**
Relational adjustment	54.41 (7.42)		-.34**	-.32**	-.17**	.26**	.41**
Partner support	4.50 (.94)		-.31**	-.25**	-.21**	.15**	.24**
Child wish	9.52 (.97)		.16**	.13**	.19**	-.20**	-.04**

Note: ** p <.01; * p< .05; SD = standard deviation.

2.2. Reliability

Table 1 of supplemental material shows mean and standard-deviation values for each item, item-subscales correlations, Cronbach's alpha values if the item was deleted and Cronbach's alpha values for each subscale (for women and men).The correlations item-subscale values varied from .45 (" I worry too much about not really important things", anxiety subscale) to .92 ("When I am sad there is someone to talk about", social support subscale), indicating that all items adequately represent the concept that each subscale measures (Cohen, 1992). Cronbach's alpha varied from .85 (Depression) to .93 (Acceptance cognitions) for women and between .66 (Depression) and .91 (Social support) for men. This means that all dimensions had good internal consistency, excepting Depression for men, that is not considered appropriate (Kline, 1999; as cited in Field, 2006).

2.3. Discriminant validity

The SCREENIVF did not present structural invariance across gender and so its discriminant validity was tested separately for women and men. Table 4 shows differences between women and men classified as at risk and not at risk in terms of wellbeing. Results showed that women and men identified by the SCREENIVF as at risk for maladjustment reported worse wellbeing than women ($F_{7, 237}$ = 28.68, η^2 = .46, $p<$ .001Pillai's trace = .46) and men ($F_{7, 73}$ = 3.32, η^2 = .24, p = .004; Pillai's trace =.24) not at risk.

Table 4. Differences between women and men classified as at risk and not at risk regarding wellbeing and intentions to comply with treatment

	Women						Men					
	At risk n=124		Not at risk n= 121				At risk n = 22		Not at risk n = 59			
	Mean	SD	Mean	SD	F	η_p^2	Mean	SD	Mean	SD	F	η_p^2
Wellbeing												
Anxiety	8.66	5.57	3.68	3.02	75.16***	.24	5.50	4.43	3.08	3.83	5.84*	.07
Depression	7.99	5.45	2.06	2.41	120.25***	.33	5.20	3.98	2.69	4.49	5.32*	.06
Quality of Life												
Emotional	45.13	18.75	71.80	15.08	150.11***	.38	65.72	14.02	80.22	15.57	16.20***	.17
Mind-Body	49.03	21.99	75.70	16.96	112.62***	.32	70.19	20.87	82.85	15.08	9.09**	.10
Relational	70.45	17.24	85.52	11.31	65.14***	.21	75.95	15.74	84.46	11.73	6.96*	.08
Social	54.45	20.47	76.52	14.99	92.32***	.28	73.07	15.87	80.44	12.51	4.79*	.06
Relational Adjustment	51.68	7.94	57.06	6.33	34.30***	.12	51.82	6.89	56.10	6.39	6.90*	.08
	At risk n=104		Not at risk n= 101				At risk n = 25		Not at risk n = 50			
	Mean	SD	Mean	SD	F	η_p^2	Mean	SD	Mean	SD	F	η_p^2
Intentions to comply with treatment	23.98	4.16	24.84	4.32	2.11	.01	23.47	3.81	24.46	3.96	1.07	.01

Note. *p<.05, **p<.01 *** p < .001, SD = Standard deviation, η_p^2= partial eta squared

Women and men classified as at risk for emotional maladjustment reported higher levels of anxiety and depression, worse quality of life across all domains (emotional, mind-body, relational and social) and worse relational adjustment.

3. Differences between patients classified as at risk and not at risk for maladjustment regarding intentions to comply with treatment

The SCREENIVF did not present structural invariance across gender and so these analyses were run separately for women and men. Table 4 shows results for patients at risk and not at risk regarding their intentions to comply with treatment. Women and men at risk for maladjustment presented similar intentions to comply that women and men not at risk, respectively.

4. Associations between risk factors for emotional maladjustment and intentions to comply with treatment

Table 5 presents results from the hierarchic regression investigating predictors of patients' intentions to comply with treatment. Age was negatively associated with patients' intentions to comply with treatment. Significant effects were found for the interactions between helplessness cognitions and anxiety and helplessness cognitions and depression. Post hoc analysis for these interactions showed that for patients with low helplessness

cognitions, higher anxiety was associated with lower intentions to comply with treatment (β = -.45, p = .01). However, for patients with high helplessness cognitions, no significant association was found between anxiety and intentions to comply with treatment (β = .25, p = .13). Moreover, results showed that for patients with high cognitions of helplessness, higher depression was associated with lower intentions to comply with recommended treatment (β = -.33, p = .02). No association was not observed for patients with low helplessness cognitions (β = .19, p = .30).

A significant effect for the three-way interaction between gender, acceptance cognitions and anxiety was also found. Post hoc analysis showed that for men the interaction between acceptance cognitions and anxiety was significant (β =-.53; p = .02), but for women it was not (β =.10; p = .46). For men with high levels of acceptance cognitions, higher anxiety was associated with lower intentions to comply with treatment (β = -.60; p = .03). On the other hand, for men with low levels of acceptance cognitions anxiety was not associated with their intentions to comply with treatment (β =.38; p = .21).

Table 5. Hierarchic regression for intentions to comply with treatment (N = 274)

Predictors	B	SE	β	ΔF	AdjR^2	Δ R^2	P
Step 1				**2.97**	**.05**	**.07**	**.005**
Age	**-.24**	**.07**	**-.22**				**.001**
Gender	-.03	.74	-.00				.963
Anxiety	-.42	.45	-.10				.350
Depression	-.30	.50	-.07				.547
Helplessness Cognitions	.43	.45	.10				.343
Acceptance Cognitions	.13	.37	.03				.720
Social support	.06	.31	.01				.851
Step 2				.41	.04	.01	.840
Gender x Anxiety	-.05	.94	-.01				.960
Gender x Depression	-.55	1.13	-.05				.628
Gender x Helplessness cognitions	.29	.84	.03				.735
Gender x Acceptance cognitions	-.62	.90	-.07				.491
Gender x Social support	.48	.66	.06				.464
Step 3				1.22	.04	.02	.303
Helplessness cognitions x Anxiety	**1.47**	**.54**	**.44**				**.007**
Helplessness cognitions x Depression	**-1.09**	**.46**	**-.44**				**.019**
Acceptance cognitions x Anxiety	.41	.54	.10				.456
Acceptance cognitions x Depression	-.51	.56	-.16				.361
Step 4				**2.64**	**.07**	**.04**	**.035**
Gender x Helplessness cognitions x Anxiety	-1.82	1.05	-.19				.082
Gender x Helplessness cognitions x Depression	1.40	.94	.14				.138
Gender x Acceptance cognitions x Anxiety	**-2.47**	**1.04**	**-.30**				**.018**
Gender x Acceptance cognitions x Depression	2.90	1.51	.26				.056

Note: B = b-values, SE = Standard Error, β = beta values, ΔF = F change, AdjR^2= Adjusted R squared, ΔR^2=R squared change. Bold indicates p < .05

V - Discussion

The Portuguese version of the SCREENIVF proved valid and reliable to assess risk factors for emotional maladjustment. Women and men at risk for emotional maladjustment were equally willing to comply with treatment as those not at risk. Associations between patients' distress (anxiety and depression) and their willingness to comply with it are conditioned by the degree of control patients perceive in relation to fertility and its treatments and their capacity to accept a future without biological children.

Results from this study validated the measurement model of the SCREENIVF. The CFA showed that the five risk factors assessed by this instrument are independent but structurally related. In general, the subscales that assess the five risk factors presented good reliability and were related with other measures that assess similar constructs. Measurement invariance was ascertained across gender and treatment stage, indicating that the SCREENIVF items contribute equally to the assessment of each risk factor for all patients. This supports the use of one single cut-off score for classifying patients as at risk or not for emotional maladjustment, regardless of gender and treatment stage. These results show that the SCREENIVF is a valid and reliable tool to assess risk for emotional maladjustment to infertility treatment.

Since the validity and the reliability of the Portuguese version of the SCREENIVF were good, we can expect its screening capacity to be similar to that of the original Dutch version (Verhaak et al., 2010). Although the SCREENIVF was firstly developed to screen women entering ART, the fact that it is invariant across treatment stages suggests that it can be applied to all women, regardless of the treatment stage they are undergoing (i.e., from diagnosis to ART). However, results of the CFA showed structural variance across gender, suggesting that the way in which the five risk factors associate is different for women and men. Implications for screening men are not clear and therefore need further investigation. Comparing with the original study of the SCREENIVF (Verhaak et al., 2010), our results show that more patients scored above the cut-off scores (i.e., classified as at risk) in terms of anxiety and depression (10% and 11% versus 18 and 28%, respectively). In the original study all participants were recruited in clinical context and therefore contacted personally with the research team. In our study, 48% of our sample was recruited online. Filling the questionnaire online may diminish social desirability bias because patients are anonymous, which may have resulted in more patients scoring above the cut-off scores. Another possibility is that online recruitment attracts patients who are highly involved in their treatment process and, consequently, more emotionally activated. Although the literature indicates that infertile patients recruited online are representative of their subpopulation (Schmidt 1997), further research is advisable to investigate if different cut off scores should be defined for clinical samples.

Women and men identified by the SCREENIVF as at risk for emotional maladjustment presented lower individual and relational wellbeing than individuals classified as not at risk. This classification

identifies which individuals are at risk to develop clinically relevant mental health problems. However, results show that at the time they are classified as at risk they already present worse health status (e.g., lower quality of life). This fact supports the idea that patients at risk should receive additional psychosocial support (Verhaak et al., 2010). Such support has been regarded as preventive only, but our results suggest that it should already include strategies to increase wellbeing.

Women and men at risk were equally willing to comply with treatment as those not at risk. On average patients reported high intentions to comply with treatment (24 on a scale from 0 to 30). Additionally, only 10% of patients referred that they never or rarely though about continuing treatment, but research shows that noncompliance is a real phenomenon (Rajkhowa et al., 2006).These data suggest that patients may be overconfident about their ability to comply with treatment, as has already been observed in patients with other medical conditions that require demanding treatment such as breast cancer (Güth, Myrick, Kilic, Eppenberger-Castori, & Schmid, 2012). These data suggests that patients should be informed from the start that fertility treatment is demanding and that some patients are not able to fully comply with recommendation. Such information may allow patients to prepare in advance to the challenges of treatment, for instance, by activating support from their social networks or seeking professional aid.

Anxiety and depression were related with patients' willingness to comply with treatment, but these relationships were conditioned by the degree of control patients perceive in relation to fertility and its treatments and their capacity to accept a future without biological children. While anxiety is an emotional reaction associated to the experience of treatment and uncertainty about its success, depression tends to result from the experience of treatment failure (Dunkel-Schetter & Lobel, 1991). These two situations present patients with different proactive decision-making: during treatment the proactive decision would be to stop treatment, while after a failed cycle the proactive decision would be to start another cycle. Results showed that only patients in control (i.e., low helplessness) were more willing to stop a treatment that was making them anxious and that only patients who had no control (i.e., high helplessness) were less willing to start another cycle when depressed. In summary, these results suggest that only patients in control are able to make proactive decisions. In this context, empowerment-oriented intervention can be helpful to reduce helplessness. The clinical staff can have an important role in promoting patients' personal efficacy, competence and mastery regarding treatment related issues. Helplessness can also be avoided by involving patients in the treatment process and all associated decision-making (Israel, Checkoway, Schulz, & Zimmerman, 1994; Perkins & Zimmerman, 1995). Having control and information will allow patients to make more satisfying compliance decisions because they probably will better understand the implications and consequences of their decisions.

Anxious men who accepted their infertility were less willing to

comply with treatment. No association between anxiety and compliance was found for men with low acceptance and for women. Indeed, as already stated, it is easier for men to accept their infertility, to stop treatment after repeated failure (Ulbrich, Tremagliocoyle, &Llabre, 1990; as cited in Webb & Daniluk, 1999) and to focus on other activities (Wright et al., 1991). This means that women and men cope differently with stress and this reflects in their compliance intentions, possibly triggering intra-couple strain. In this context, decisional-aid about treatment uptake should be directed at both members of the couple and integrate life and relationship values clarification techniques (Gameiro et al, 2012). Such an approach may help both members of the couple to reconcile their individual perspectives and lead to a final compliance decision that is satisfactory for both.

This study presented methodological limitations that must be considered. First, the sample included a small number of men. While the overall and women only sample size ensured enough power to detect small to medium effect sizes in multivariate analysis (p< .05, power = .80, effect size from .05 to .09), for men only medium to large effect sizes could be detected (p< .05, power = .80, effect size = .33) (Faul, Erdfelder, Lang, & Buchner, 2007), which means that some associations might have not been detected. Therefore, more research should be conducted to investigate if and how the SCREENIVF should be used with men. Second, 48% of participants were recruited online and differences between participants recruited online and in clinical setting were observed. Although the literature indicates that data collected through online recruitment is valid (Lieberman, 2008) one would need to determine whether the differences observed may have implications as, for instance, in the definition of cut-off scores for classifying individuals as at risk for maladjustment. Third, we did not test the screening properties of the Portuguese version of the SCREENIVF. Thus, and although we can expect its screening capacity to be similar to that of the original Dutch version (Verhaak et al., 2010), longitudinal research for this purpose is still required. Finally, although we investigated risk factors for women and men, we did not investigate how the psychopathological vulnerability of one couple's member may affect the other member and the couples' compliance behavior, which should also be the subject of future research.

VI - Conclusion

The Portuguese version of the SCREENIVF proved to be valid and reliable, meaning that it can be used with women undergoing any stage of fertility treatment. Further investigation is needed to attest its usefulness with men. The use of the SCREENIVF will allow professionals to identify which patients need and benefit more from psychosocial support to increase wellbeing and prevent future emotional difficulties. Clinics need to ensure that couples have the necessary conditions to make satisfactory and informed decisions about treatment uptake. For the effect, patients need to have control over their treatment and may benefit from a moderated environment to discuss treatment alternatives with their partners.

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Supplemental material
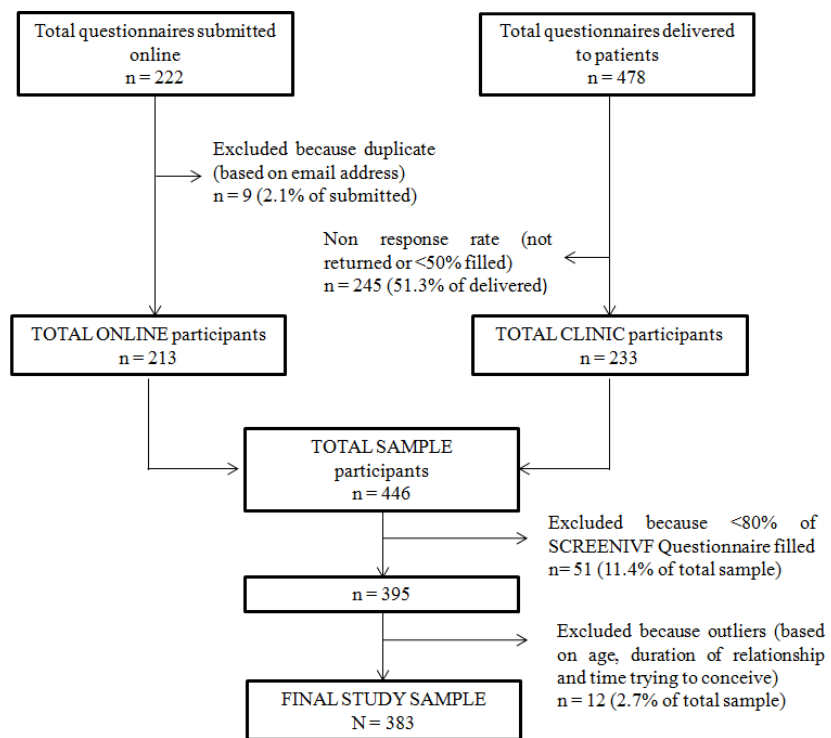
Figure 1. Sample collection procedures

Are patients at risk for emotional maladjustment to fertility treatment less willing to comply with
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Vanessa Gaudêncio Borges Lopes (e-mail: vanessagbl@hotmail.com) 2012
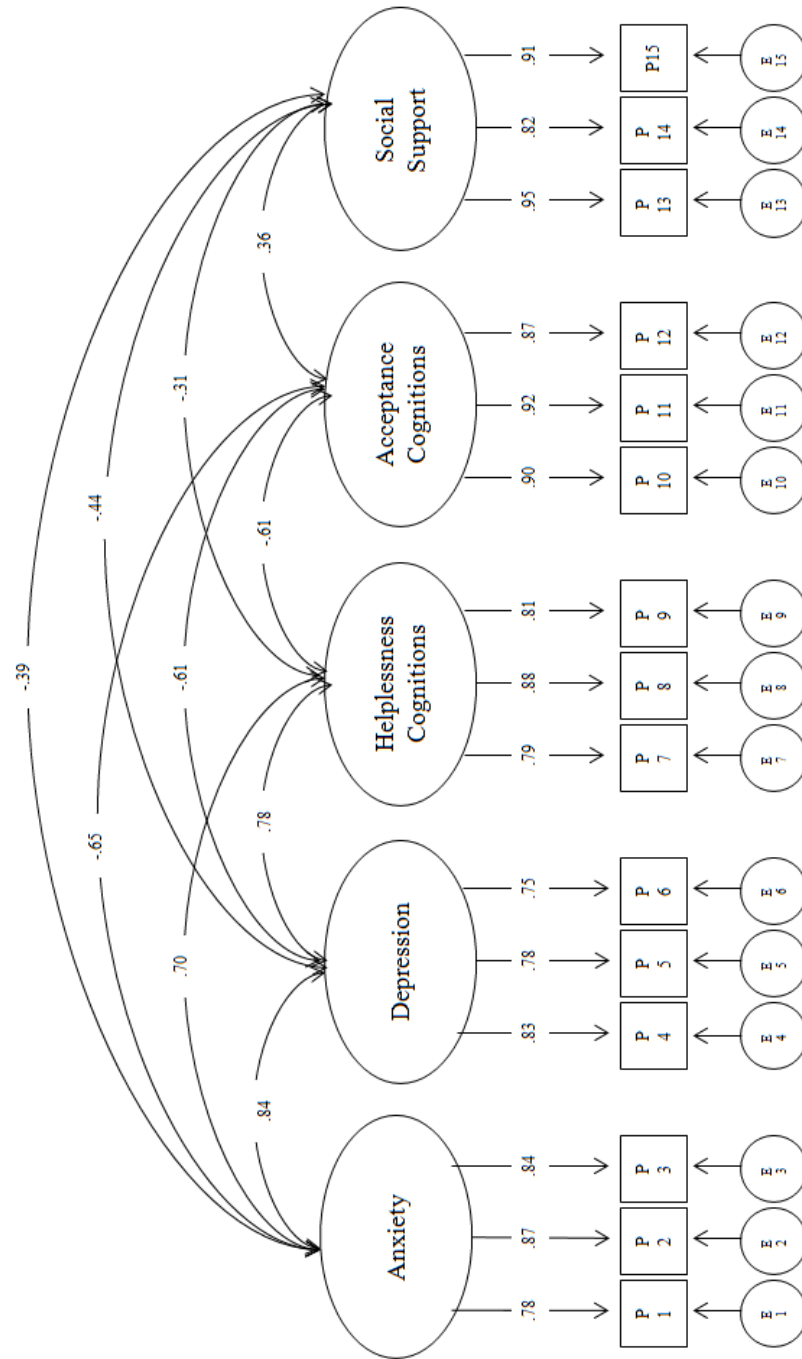
Figure 2. Standardized regression weights of factor loadings. Note: E, error, P, parcel

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Table 1. Correlations between each subscale and its items

	Mean	SD	Correlation item-subscale	Cronbach's alpha if item deleted	Cronbach's Alpha Women	Cronbach's Alpha Men
Anxiety	20.87	6.28			.90	.87
I feel fine	1.96	0.85	.78[**]	.88		
I feel satisfied	2.21	0.87	.77[**]	.88		
I worry too much about not really important things	2.26	0.87	.45[**]	.91		
I am happy	1.99	0.87	.74[**]	.88		
I am troubled by disturbing thoughts	1.97	0.89	.73[**]	.89		
I feel safe	2.19	0.90	.70[**]	.89		
I am pleased	2.04	0.80	.77[**]	.88		
There are thoughts that keep hauting me	2.04	0.88	.73[**]	.89		
I take my disappointments so seriously that I cannot get them out of my mind	1.95	0.92	.78[**]	.88		
I get very nervous and worried when thinking about my current problems	2.30	0.90	.75[**]	.89		
Depression	2.51	3.09			.85	.66
I feel sad	0.49	0.71	.79[**]	.81		
I'm not too pessimistic or feel discouraged about the future	0.46	0.64	.66[**]	.83		
I do not have the feeling of having failed	0.46	0.75	.80[**]	.81		
I'm not unhappy with anything in particular	0.40	0.63	.77[**]	.81		
I am not displeased with me	0.21	0.48	.77[**]	.81		
I do not feel any worse than anyone else	0.37	0.65	.67[**]	.83		
I have no thoughts of harming myself	0.06	0.32	.49[**]	.85		
Social Support	16.48	3.70			.92	.91
When I feel tense or nervous, there is someone to help me	3.20	0.90	.87[**]	.90		
When I experience some nice things, there is someone to talk about	3.49	0.73	.85[**]	.90		
When I am in pain there is someone to comfort me	3.31	0.87	.91[**]	.88		
When I am sad there is someone to talk about	3.28	0.86	.92[**]	.88		
When I need help with a job I cannot carry out alone there is someone to help me	3.19	0.89	.79[**]	.93		
Acceptance cognitions	15.68	4.68			.93	.88
I deal with the consequences of me fertility problems	2.72	0.87	.81[**]	.92		
I have learned to live with my fertility problems	2.75	0.90	.88[**]	.90		
I have learned to accept my fertility problems	2.59	0.95	.85[**]	.91		
I can accept my fertility problems	2.61	0.95	.87[**]	.90		
I think I can cope with my fertility problems even if they are not solved	2.47	0.91	.80[**]	.92		
I can cope with well with my fertility problems	2.53	0.95	.86[**]	.91		
Helplessness cognitions	11.10	4.29			.87	.80
Because of my fertility problems , I miss	1.70	0.85	.71[**]	.86		

the things that are most important for me				
My fertility problems control my life	1.79	0.94	.81**	.84
My fertility problems sometimes give me the feeling of being useless	1.78	0.98	.80**	.84
My fertility problems make my life incomplete	2.48	1.02	.79**	.85
My fertility problems affect everything that is important for me	1.74	0.89	.84**	.83
I often feel helpless because of my fertility problems	1.60	0.83	.72**	.86

Note: ** $p < .01$