

Positive experiences of patient-centred care are associated with intentions to comply with fertility treatment: findings from the validation of the Portuguese version of the PCQ-Infertility tool

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STUDY QUESTION: Are positive experiences of different aspects of patient-centred care (PCC) associated with higher intentions to comply with fertility treatment?

SUMMARY ANSWER: Positive experiences regarding information received, respect from staff about values and preferences, continuity in treatment and competence of staff are directly associated with higher compliance intentions, while positive experiences regarding accessibility to and involvement in the treatment and communication with staff are indirectly associated, via associations with less concerns about treatment.

WHAT IS KNOWN ALREADY: The quality of infertility services can influence patients' intentions to comply with treatment. Patients cite negative care experiences as one of the main reasons why they discontinue treatment prematurely. Delivering PCC in routine infertility care is associated with higher quality of life and lower distress during treatment.

STUDY DESIGN, SIZE, DURATION: In this cross-sectional study of 265 women and 83 men, we investigated first, the psychometric properties of the Portuguese version of the Patient-Centredness Questionnaire (PCQ)-Infertility tool, which assesses infertility PCC, and secondly, the associations between PCC and intentions to comply with treatment.

PARTICIPANTS/MATERIALS, SETTING, METHODS: Men and women undergoing fertility diagnostic investigation or treatment at Portuguese fertility clinics were recruited online and in clinical setting. Participants filled out a socio-demographic and fertility data file and other questionnaires to assess PCC (PCQ-Infertility), intentions to comply with treatment (FertiQoL Persistence Scale), wellbeing (Anxiety and Depression subscales of the BSI and FertiQoL), concerns about treatment (CART Scale) and treatment tolerability (FertiQoL Tolerability Domain).

MAIN RESULTS AND THE ROLE OF CHANCE: There were 265 women and 83 men who completed the questionnaires. The confirmatory factor analysis for the PCQ-Infertility indicated a good fit [$\chi^2 = 479.097$; $P < 0.001$; comparative fit index = 0.929; root mean square error of approximation = 0.058 (0.051–0.065)]. All PCQ-Infertility dimensions showed good internal consistency ($\alpha \geq 0.70$, excepting for organization: $\alpha = 0.57$). Information provision, respect for patients' values, continuity of care and competence of the team were directly associated with higher intentions to comply with treatment (r from 0.13 to 0.23). Greater accessibility, patient involvement and good communication were negatively associated with concerns about treatment (r from -0.14 to -0.16) and less concerns were associated with higher intentions to comply with treatment (r from -0.14 to -0.15).

LIMITATIONS, REASONS FOR CAUTION: Of the sample, 49% were recruited online. Patients recruited online had higher education and were more likely to be undergoing assisted reproduction treatment and this could have influenced the ratings of PCC reported. We did not account for treatment prognosis factors and/or doctor censoring and this may have resulted in underestimation of the strength of associations

reported involving compliance intentions. The cross-sectional design of the study does not allow for cause and effect analysis between the study variables.

WIDER IMPLICATIONS OF THE FINDINGS: To promote treatment compliance, clinics should allow patients to establish stable relationships with a reference doctor who is competent and respectful of their interests and values and who provides them with the information they need. Clinics can also alleviate their patients' concerns regarding medical procedures by ensuring that these professionals are easily accessible, have good communication skills, and involve patients in the treatment process and associated decision-making. The Portuguese version of the PCQ-Infertility tool is valid and reliable.

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Key words: infertility / patient-centred care / PCQ-Infertility / psychometric properties / compliance

Introduction

Patient-centred care (PCC) is a practice that respects and responds to each patient's individual needs and preferences to ensure that clinical decisions are based on the patient's values (Corrigan *et al.*, 2001). Delivering PCC in routine infertility care may be an efficient way to promote patients' compliance during treatment, as it is known that PCC is associated with higher quality of life and lower distress during treatment (Aarts *et al.*, 2012). The main goal of this study was to investigate if and how PCC is associated with patients' intentions to comply with treatment. A secondary goal was to validate the Portuguese version of the Patient-Centredness Questionnaire-Infertility (PCQ-Infertility; van Empel *et al.*, 2010a,b), a tool specifically developed to assess patients' views on the PCC they receive at fertility clinics.

Recent studies have shown that the quality of infertility services can influence patients' intentions to comply with treatment (Boivin *et al.*, 2011; van Empel *et al.*, 2011). Compliance refers to the uptake of all fertility treatment recommended by the doctor until pregnancy is achieved (Gameiro *et al.*, 2013). Although compliance is associated with a higher likelihood of treatment success (Gameiro *et al.*, in press), a prospective study that followed patients through their entire treatment pathway showed that 23.5 and 17.9% of patients discontinue treatments prematurely when undergoing first-order and assisted reproductive technologies (ART) treatment, respectively (Brandes *et al.*, 2009). A recent systematic review showed that some of the main reasons cited by patients for discontinuing treatment were related to the quality of care, such as the lack of empathy by the medical team and lack of continuity of care (Gameiro *et al.*, 2012). Discontinuity as a result of the lack of quality of care appears to happen across the entire treatment process, as it was observed during pre-ART treatments, while on the waiting list for ART and after the first unsuccessful cycle of ART (Gameiro *et al.*, 2012). Thus, researchers and clinical staff have been aiming to reach a better understanding of how to better organize their services to promote treatment compliance (Boivin *et al.*, 2012). Research suggests that PCC could be directly and indirectly associated with compliance. Figure 1 illustrates these associations. Direct associations hypothesize that patients who receive PCC will have stronger intentions to comply with treatment (see Fig. 1, solid line). There is empirical support for this hypothesis as issues such as a lack of empathy from staff or a lack of attention to psychological aspects of treatment (Meynol *et al.*, 1997; Van den Broeck *et al.*, 2009) have been cited by patients as reasons to abandon treatment.

Indirect associations (see Fig. 1, dashed lines) hypothesize that patients who receive PCC will experience the treatment as more tolerable and will have lower concerns about treatment-related issues. Patients with higher tolerability to treatment and lower concerns will in turn have stronger intentions to comply with treatment. For example, an organized diagnosis and treatment plan may reduce the number of patients' visits to the clinic and waiting period between treatment cycles (Dancet *et al.*, 2010), thus making treatment more tolerable. In turn, a greater tolerability to treatment is known to be associated with stronger intentions to continue treatment (Boivin *et al.*, 2011; Melo *et al.*, 2012). Similarly, providing information concerning the medical procedures should address patients' fears and concerns about treatment, which should translate into stronger patients' intentions to comply with treatments (Boivin *et al.*, 2012).

The PCQ-Infertility (van Empel *et al.*, 2010a,b) is a tool specifically developed to measure PCC in infertility care. Its design was based on a model of PCC that took into account the specificities of infertility care. This model was developed by Dancet and colleagues, based on the Picker Institute's theoretical model of PCC (Corrigan *et al.*, 2001) and on a systemic review of the infertility literature (Dancet *et al.*, 2010) and several focus groups (Dancet *et al.*, 2011). The PCQ-Infertility assesses the 53 aspects of PCC that patients considered most important (regardless of perceived quality), for instance, having a contact number for emergencies, having a physician who listens carefully and gives patients the opportunity to ask questions and involves the partner in the treatment process. The validation study of the pilot version of the PCQ-Infertility included a sample of 888 patients from 30 fertility clinics in The Netherlands (van Empel *et al.*, 2010a,b). The questionnaire includes 46 items organized in eight distinct dimensions: accessibility, information, communication, involvement of the patient, respect, continuity and transition of the treatment, competence and organization (van Empel *et al.*, 2010a,b). All dimensions except organization showed good internal consistency (Cronbach's alpha >0.70). The PCQ-Infertility revealed good construct validity, as it showed that patients who had better quality treatments (e.g. access to their medical record, had a regular doctor, received written information and planning for their treatment) reported more positive experiences of PCC than patients without these quality indicators. In general, the validation study of the PCQ-Infertility demonstrated that it is a valid tool for evaluating PCC and can provide clinics and health care professionals with useful information to improve care (van Empel *et al.*, 2010a,b). The high

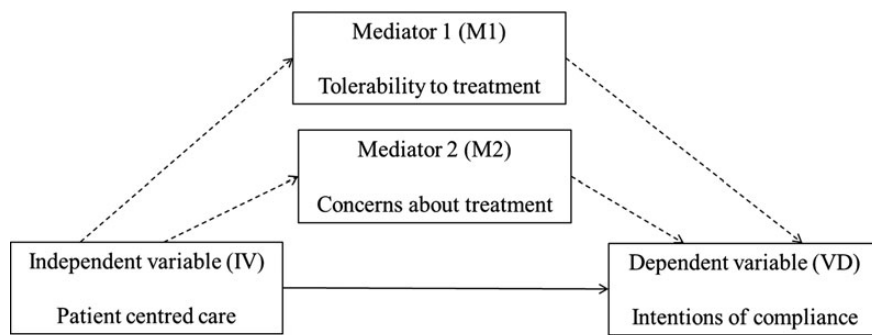


Figure 1 Hypothesized associations between PCC and patients' intentions to comply with treatment. Full line indicates direct associations between PCC and intention whereas dashed line indicates indirect associations operating through tolerability to treatment or concerns about treatment. PCC, patient-centred care.

rate of successfully completed questionnaires (80%) obtained in that study suggests that the use of the PCQ-Infertility in the clinical context is viable. However, the multidimensional structure of the instrument has not yet been investigated and therefore there is currently no quantitative data about the validity of the theoretical model of PCC that is proposed to underlie the tool. To confirm this model, it is necessary to perform a confirmatory factor analysis (CFA) of the instrument to confirm that the items group into the eight proposed dimensions and that all dimensions prove to be reliable. In addition, the CFA should also show that this structure remains invariant for all patients (men and women) undergoing different types of treatment (non-ART and ART). Similarly, it is important to determine whether the PCQ-Infertility can be used as an indicator of the quality of the fertility treatments by investigating if it associates positively with other tools that assess quality of care (i.e. FertiQoL Treatment Module) and quality of life (i.e. QoL: FertiQoL Core Module) and negatively with other tools that measure distress (i.e. Brief Symptom Inventory).

The present study had two main goals. The main goal was to investigate the relationship between PCC and the patients' intentions about treatment compliance. It was investigated whether this relationship was direct, or indirect via higher treatment tolerability and/or lower treatment concern. A secondary goal was to investigate the psychometric characteristics of the Portuguese version of the PCQ-Infertility (i.e. construct validity and internal consistency) in a group of patients undergoing diagnostic investigation or fertility treatments in Portugal. Although secondary, this goal was conducted first so that we could ascertain the validity of results concerning PCC, as it was evaluated with the PCQ-Infertility tool.

Materials and Methods

Study design and procedures

Ethical approval was obtained from the Ethics and Research Committee of the University Hospital of Coimbra. The data were collected in two recruitment drives. One from January 2011–June 2011 and another from September 2011–February 2012. Women and men were recruited online and in clinical setting (Human Reproduction Services of the University Hospital of Coimbra). Online recruitment was done through an online questionnaire that was posted on the site of APFertilidade, which is the main infertility

patient advocacy group in Portugal. A 'cause' was also created on Facebook and shared among all 'friends' of APFertilidade. In the clinic recruitment, patients were consecutively invited to participate. The inclusion criteria for online and clinic recruitment were a minimum age of 18 years and undergoing fertility diagnostic investigation and/or treatments in a Portuguese fertility clinic. It was assumed that all participants were either married or lived with their partners in a heterosexual relationship for a period of at least 2 years, as defined by the Portuguese law (Law 32/2006, of July 26) for access to fertility treatments.

Materials

Socio-demographic information included gender, age, relationship duration and education (years of education and university education). Fertility information (self-reported) included parity, duration of infertility, number of previous fertility treatments and current treatment [diagnostic examination, medication/injections, intrauterine insemination (IUI), waiting list for ART, ART].

PCC was evaluated using the Portuguese version of the PCQ-Infertility tool (Gameiro and Canavarro, 2010, original version by van Empel et al., 2010a,b). To develop the Portuguese version of PCQ-Infertility, we followed the recommendations by Hambleton (2005). More specifically, the questionnaire items were translated to Portuguese by two English fluent independent researchers. Both translations were compared in order to detect discrepancies in the translation. An English native-speaker who was also a Portuguese fluent speaker back translated the Portuguese version to English. Similarity in item formulation across the initial and back translated versions confirmed the equivalence of the original English and Portuguese versions and changes were made in items where differences were found. The instrument includes the following eight subscales: Accessibility (2 items; e.g. 'How often have you been able to speak to someone when you called the Fertility Department?'); Information and explanations (11 items; e.g. 'Was the information about the investigations you would undergo comprehensive?'); Communication skills of the medical team (7 items; e.g. 'Were caregivers honest and clear about what to expect from the fertility care service?'); Involvement in the treatment (3 items; e.g. 'Was the decision-making shared with you, if you preferred?'); Respect towards the patients' values and needs (7 items; e.g. 'How often did your physician have empathy of your emotions and your current situation?'); Continuity and transition during treatment (7 items; e.g. 'Did you have one lead physician (a physician for moments of evaluation and decision-making)?'); Competence of the team (6 items; e.g. 'Did the physician(s) seem competent to you?'); and Service organization (3 items; e.g. 'How often did you have to wait more than 3 weeks if you wanted to make an

appointment with the physician?'). Items scoring system varied across items but scores always ranged between 0 and 3. Individual items scores were averaged into their respective subscales, with higher values indicating better care.

Quality of life was assessed with the Fertility Quality of Life (FertiQoL) tool (Boivin et al., 2011), which consists of 26 items organized into the following four domains of quality of life: Emotional (6 items; e.g. 'Do your fertility problems make you angry?'); Mind/Body (6 items; e.g. 'Are you bothered by fatigue because of fertility problems?'); Relational (6 items; e.g. 'Are you and your partner affectionate with each other even though you have fertility problems?'); and Social (6 items; e.g. 'Do you feel your family understand what you are going through?'). The questions are answered based on a five-point Likert Scale. Scores range from 0 to 100, with higher values indicating a better quality of life. The FertiQoL tool demonstrated good psychometric properties in the Portuguese population (Melo et al., 2012). In the current sample, the Cronbach's alpha of the domains ranged between 0.72 and 0.89.

Distress symptoms were assessed with the Somatization (e.g. 'Fainting or dizziness'), Depression (e.g. 'Feeling sad') and Anxiety (e.g. 'Nervousness or shakiness inside') scales of the Portuguese version of the Brief Symptom Inventory—BSI (Derogatis, 1993, Derogatis (1993, Portuguese version by Canavarro, 2007). The answers were based on a five-point Likert scale ranging from 'Never' (0) to 'Very often' (4). The total of each scale is the sum of the item scores with higher values indicating more psychopathological symptoms. The BSI demonstrated good psychometric characteristics in the Portuguese population (Canavarro, 2007). In the current sample, Cronbach's alpha ranged between 0.86 and 0.88.

The patients' perception of the quality of care was evaluated using the Treatment Module of the FertiQoL tool (Boivin et al., 2011). This module is composed of 10 items that assess the following two domains: Environment (6 items; e.g. 'Are you satisfied with your interactions with fertility medical staff?'); and Treatment tolerability (4 items; e.g. 'Are you bothered by the

effect of the treatment on your daily or work-related activities?'). The scores of these two domains varied between 0 and 100, with higher values indicating better quality of life during treatment. In the current sample, the Cronbach's alpha was 0.81 for the environment domain and 0.75 for the tolerability domain.

Treatment concerns regarding the medical procedure were assessed based on the Concerns During Assisted Reproductive Technologies (CART) scale (Klonoff-Cohen et al., 2007). This scale is composed of six items that evaluate concerns with secondary effects, surgery, insufficient information and others. The response scale is based on a three-point Likert scale ('not concerned', 'moderately concerned' and 'very concerned'). The total score ranges from 1 to 3, with higher values indicating greater concerns regarding medical procedures. The Cronbach's alpha was 0.78 for the instrument validation study and 0.74 for the current sample.

Intentions to comply with treatment were assessed using the Persistence Scale of the FertiQoL project (Boivin et al., 2011). This scale is composed of six items (e.g. 'If this treatment fails, how likely are you to try another treatment?') rated using a five-point Likert scale (1–5) that were summed to compose a total score that varied from 6 to 30, with higher scores indicating stronger intentions to persist with treatment. In the current sample, the Cronbach's alpha was 0.76.

Data analysis

First the psychometric characteristics of the PCQ-Infertility were investigated. These were construct validity (CFA of its structure, correlation analysis between the different subscales of PCQ-Infertility and between these and the FertiQoL and BSI) and internal consistency. The CFA of the PCQ-Infertility was performed using Amos v19.0 and it tests the theoretical model proposed by van Empel et al. (2010a,b) that includes the eight dimensions of PCC

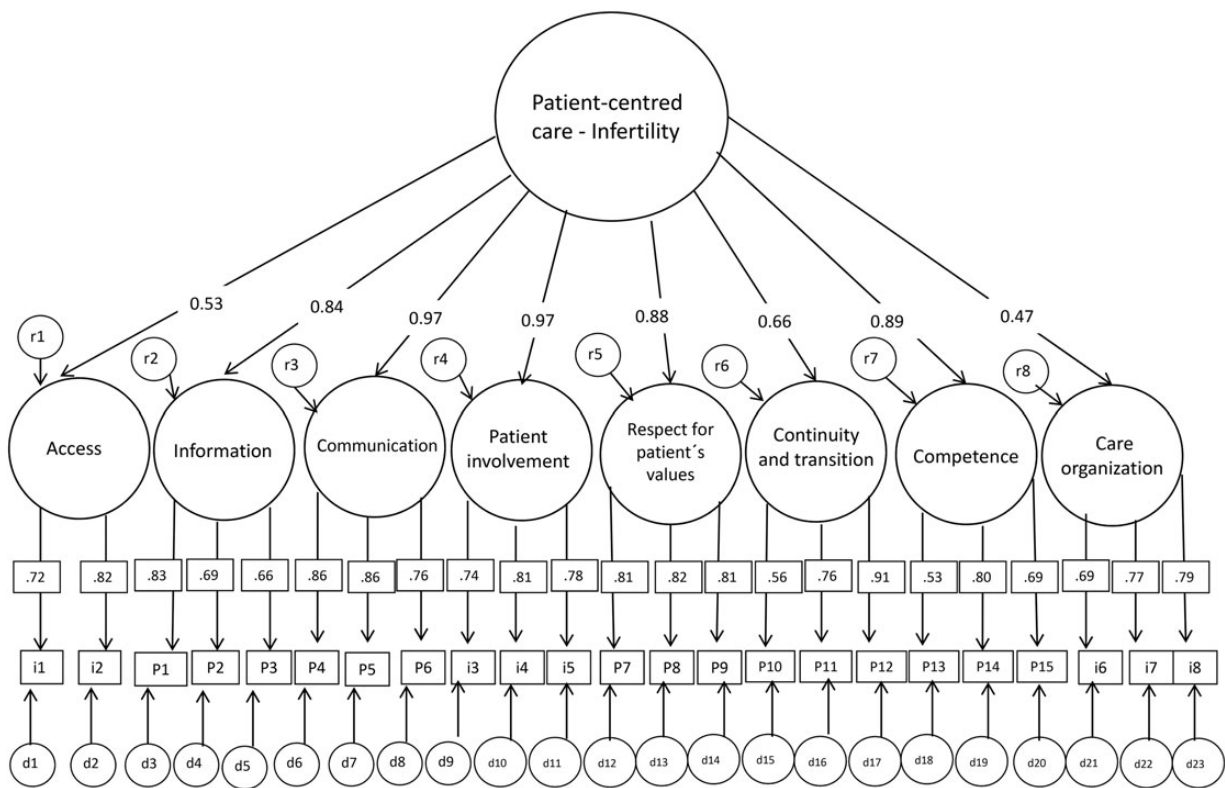


Figure 2 Standardized regression weights of factor loadings in Model I (model with eight subscales). Note: d, error; r, residual; P, Parcel; i, item.

(Model 1, see Fig. 2). An alternative measurement model (Model 2, see Supplementary data, Fig. S2) was also tested. This model corresponds to the validated PCQ-Infertility tool and only includes seven subscales of PCC, with the items that comprise the Organizational subscale being considered individually (as they showed low internal consistency, $\alpha = 0.46$). Parcelling was used to decrease the complexity of the model (Matsunaga, 2008). Model fitness was assessed with the χ^2 statistics, Comparative Fit Index (CFI) and Root Mean Square Error of Approximation (RMSEA) (Byrne, 2010). Model fitness is considered good when the χ^2 is not significant, the CFI is ≥ 0.90 , and the RMSEA is below 0.10 (Kline, 2005). To test whether PCQ-Infertility may be used with different groups of patients, the invariance of the measurement and model structure were tested in terms of the type of treatment (non-ART and ART) and gender. A model is considered invariant if the χ^2 difference is not significant (Byrne, 2010). Internal consistency was evaluated using Cronbach's alpha coefficient and item-total correlations.

After, direct and indirect associations between PCC and intentions to comply with treatment were investigated. In Portugal, the state subsidizes all non-ART treatment cycles and three cycles of ART and the expectation is that people would undergo all three cycles (if required) to achieve pregnancy. Therefore, to exclude the hypothesis of lack of compliance due to financial issues, only individuals undergoing treatment at a public clinic who had not yet undergone three ART cycles were included. We used the INDIRECT macro developed for SPSS by Hayes and Preacher (available at <http://www.afhayes.com/spss-sas-and-mplus-macros-and-code.html>) using bootstrap with 5000 samples. Two mediators were investigated: FertiQoL tolerability to treatment (mediator 1, or M1) and CART concerns about treatment (mediator 2, or M2). If a significant indirect effect was found (dashed arrows in Fig. 1) it would indicate that PCC (IV) is associated with intentions to comply with treatment (DV) through its associations with the mediator(s) variable(s) (M1 or M2) (Preacher and Hayes, 2008). If a significant direct effect was found (solid arrow in Fig. 1) it would mean that PCC (IV) is associated with intentions (DV) controlling for all mediators (and/or other covariate) variables investigated. Eight models corresponding to the eight PCQ-Infertility subscales were tested. All continuous variables were converted into z-scores to facilitate the interpretation of results. Years of education was a covariate as previous findings suggest that PCC experiences vary as a function of education (van Empel et al., 2010a,b).

Results

Sample

The final sample consisted of 265 women and 83 men with an infertility diagnosis who were undergoing diagnostic investigation or fertility treatment in Portugal. They were recruited online ($n = 171$, 49.1%) and in a clinic setting ($n = 177$, 50.9%). Supplementary data, Fig. S1 shows the sample recruitment flowchart. Of a total of 446 questionnaires filled out online and at the clinic, 348 (78%) were usable for the present study. There were 98 questionnaires (22%) excluded because $< 80\%$ of the PCQ was filled ($n = 88$) or were identified as outliers ($>$ or $<$ mean ± 3.29 SD) based on age, duration of relationship and time trying to conceive ($n = 10$).

Table I shows the socio-demographic and clinical characteristics of the sample. Women and men were in their early thirties, married/cohabitating for ~ 8 years with close to 14 years of education. Participants from the clinic group were significantly older ($t_{(346)} = -2.19$, $P = 0.029$) and had fewer years of education ($t_{(279)} = 8.78$, $P < 0.001$) than the online group. The majority of the participants did not have children and had been attempting to conceive for ~ 5 years. Participants from the online group were in a more advanced treatment phase

Table I Sample socio-demographic and fertility characteristics (N = 348).

Socio-demographic	
Gender, n (%) women	265 (76.1)
Women's age (years), mean (SD)	33.12 (3.62)
Men's age (years), mean (SD)	34.78 (4.15)
Relationship duration (years), mean (SD)	7.63 (3.40)
Education	
Years of education, mean (SD)	13.47 (3.87)
College or University Education, n (%) yes	168 (48.7)
Fertility	
Parity, n (%) 1 or more children	40 (11.6)
Infertility duration (years), mean (SD)	4.68 (2.5)
Number of previous treatments, mean (SD)	
IUI	0.52 (1.15)
IVF	1.03 (1.38)
Current treatment, n (%)	
Diagnostic investigation	70 (20.5)
Medication/injections	64 (18.7)
IUI	26 (7.6)
Waiting list to start IVF/ICSI	54 (15.8)
IVF/ICSI	128 (37.4)

SD, standard deviation; IUI, intrauterine insemination; IVF, *in vitro* fertilization; ICSI, intra cytoplasmic sperm injection.

($\chi^2_{(4)} = 10.68$, $P = 0.03$) and had undergone a higher number of IVF treatments ($t_{(261.3)} = 5.71$, $P < 0.001$) than individuals from the clinic group.

Participants' experiences of the PCC they receive in their fertility clinics

Table II shows Cronbach's alphas and descriptive statistics (mean and standard deviation) for the study variables and correlations between the subscales of the PCQ-Infertility and between these and the remaining study variables. A multivariate repeated measures analysis of variance that took into account all of the PCQ-Infertility subscales showed that patients rated their experiences regarding the several subscales of PCC differently (Wilks' Lambda = 0.358, $F_{(7)} = 77.22$, $P < 0.001$, $\eta^2 = 0.642$). Patients rated more positively their experiences regarding continuity [$M = 2.22$, $SE = 0.03$, 95% confidence interval (CI) 2.162–2.279], competence ($M = 2.19$, $SE = 0.03$, 95% CI 2.150–2.250), communication ($M = 2.18$, $SE = 0.04$, 95% CI 2.108–2.270), and accessibility ($M = 2.18$, $SE = 0.05$, 95% CI 2.074–2.259) and more negatively their experiences regarding organization ($M = 1.27$, $SE = 0.06$, 95% CI 1.167–1.389), information ($M = 1.89$, $SE = 0.04$, 95% CI 1.789–1.955) and respect ($M = 1.84$, $SE = 0.04$, 95% CI 1.836–1.983).

Psychometric characteristics of the Portuguese version of the PCQ-Infertility

Construct validity

The CFA of the original theoretical structure of the PCQ-Infertility (Model 1, see Fig. 2) showed a significant χ^2 value

($\chi^2_{222} = 479.097$; $P < 0.001$). The other fit indices were CFI = 0.929 and RMSEA = 0.058 (90% CI 0.051–0.065). The CFA of the alternative validation model of the PCQ-Infertility (Model 2, see [Supplementary data, Fig. S2](#) of the supplemental material) also showed a significant χ^2 value ($\chi^2_{223} = 666.488$; $P < 0.001$), with CFI = 0.878 and RMSEA = 0.076 (90% CI 0.069–0.082).

Given that fit indexes indicated a better fit of Model 1 than Model 2, only the invariance of Model 1 was investigated. Results are shown in [Supplementary data, Table SI](#). None of the χ^2 differences concerning the multigroup analysis for gender and type of treatment were significant. These results attest the measurement and structural invariance of Model 1.

Table II shows the correlations between the subscales of the PCQ-Infertility and between these and the FertiQoL and BSI. Correlational analysis indicated that all the subscales of the PCQ-Infertility were significantly associated with each other ($P < 0.05$). In general, the subscales of the PCQ-Infertility were positively associated with the two dimensions of the Treatment Module of the FertiQoL, especially the Environment domain. Significant associations were found between some subscales of the PCQ-Infertility and the Core Module of the FertiQoL. These correlations varied from weak (e.g. continuity and social domain) to moderate (e.g. communication and relational domain). The subscales of the PCQ-Infertility revealed small negative associations with all subscales of the BSI (somatization, depression and anxiety).

Internal consistency

Table II also shows the Cronbach's alpha for the eight subscales of the PCQ-Infertility. All revealed good internal consistency, except for the subscale of continuity and transition. [Supplementary data, Table SII](#) shows descriptive statistics of the items of the PCQ-Infertility, correlations between each item and its subscale and Cronbach's alpha of the subscales if the item is deleted. Item-subscale correlations varied between 0.29 and 0.79 with the exception of the continuity and transition subscale, in which items 1 and 2 showed low correlation scores (0.09 and 0.20, respectively).

Direct and indirect associations between PCC and intentions to comply with treatment

Table III shows the results of analyses to investigate the direct and indirect associations between the various PCC dimensions and patients' intentions to comply with treatment, as hypothesized and represented in Fig. 1. Figure 3 presents a schematic representation of the significant direct and indirect associations found. The results demonstrated significant direct associations (see column: Effect of IV on DV, controlling for M) regarding information, respect, continuity and competence. Significant indirect associations (see column: Effect of IV on DV, through M) were identified for the subscales of accessibility, communication and patient involvement. Greater accessibility, communication and patient involvement were associated with fewer treatment concerns (see column: Effect of IV on M) and, in turn, treatment concerns was inversely associated with compliance intentions (see column: Effect of M on DV). The models explained between 5 and 9% of the variance related to the intentions of patients to comply with treatment.

Discussion

The results of the present study validate the original theoretical model proposed by [van Empel et al. \(2010a,b\)](#) for infertility PCC, which includes eight distinct dimensions of PCC. In general, the Portuguese version of the PCQ-Infertility tool proved to be valid and reliable for evaluating PCC and can be administered to both men and women participating in any type of fertility treatment. Patients with more positive PCC experiences had stronger intentions to comply with fertility treatment. Together the results indicate that the PCQ-Infertility can be a useful tool for clinics to assess and implement better PCC services, which are expected to promote their patients' wellbeing during treatment and their intentions to comply with the treatment they are recommended to undertake in order to conceive.

The present study validated the multidimensional construct of PCC, as assessed by the PCQ-Infertility, in a sample of women and men undergoing infertility diagnosis or treatment in Portugal. The CFA confirmed that the PCQ-Infertility tool assesses patients' experiences of eight distinct aspects of PCC: accessibility, information, communication, respect, patient involvement, competence, continuity and service organization. The moderate to strong correlations found between these dimensions further support the measurement structure of the model by suggesting that the dimensions measure different aspects of the same underlying construct. These results provide initial support to the validity of the PCC model for infertility care developed by [Dancet et al. \(Dancet et al., 2010, van Empel et al., 2010a,b\)](#). Although no other CFAs were performed with samples from other countries (including the Dutch population where the instrument was first developed and validated), the infertility PCC model was also validated in an international sample of 48 patients from other four European countries using focus groups ([Dancet et al., 2012](#)). However, it should be noted that two dimensions of the PCC model (emotional support and physical comfort) were not included in the PCQ-Infertility (due to low reliability of items and lower importance attributed by patients) and therefore we could not test them as part of the model. Thus, further testing of the full infertility PCC model is still warranted.

Results from this study also indicate that the PCQ-Infertility tool can be used as an indicator of the quality of the fertility care provided. It was already known that general PCC ratings are positively associated with higher quality of life and lower distress ([Aarts et al., 2012](#)). Consistent with this finding, this study showed that many of the PCC dimensions are associated with higher quality of life and lower distress. More importantly, it showed that all PCC dimensions are moderately to strongly associated with more positive evaluations of the clinics' environment (FertiQoL Environment domain) and that some PCC dimensions are also associated with higher treatment tolerability. In addition, this study also showed that the PCQ-Infertility tool can be used with all infertility patients, regardless of their gender and the type of treatment they are undergoing. The tool was originally designed to be filled out by couples but it is important to take into consideration that the man and the woman of the same couple may undergo different medical procedures and have different care expectations that may result in different PCC evaluations. A recent study examining differences in PCC experiences within couples revealed that women's partners were more satisfied than were women concerning respect for patients' values and involvement in treatment. In addition, they showed that gender differences in evaluation were moderated by other factors such as ethnicity,

Table II Chronbach's alpha and descriptive statistics for the study variables and correlations between the subscales of the PCQ-Infertility and the remaining study variables, i.e. wellbeing, quality of care, concerns about treatment and intentions to comply with treatment (n = 348).

	Reliability	Descriptive statistics		PCC (PCQ-Infertility)							
				Correlations							
	Cronbach's alphas	Mean	SD	Access	Info	Com	Involv	Resp	Cont	Comp	Org
PCC (PCQ-Infertility)											
Accessibility (Access)	0.73	2.18	0.83	1	–	–	–	–	–	–	–
Information (Info)	0.78	1.89	0.67	0.42**	1	–	–	–	–	–	–
Communication (Com)	0.85	2.18	0.72	0.38**	0.64**	1	–	–	–	–	–
Involvement (Involv)	0.82	2.07	0.79	0.37**	0.62**	0.79**	1	–	–	–	–
Respect (Resp)	0.84	1.84	0.74	0.34**	0.60**	0.71**	0.72**	1	–	–	–
Continuity (Cont)	0.57	2.22	0.53	0.32**	0.49**	0.51**	0.50**	0.47**	1	–	–
Competence (Comp)	0.70	2.19	0.46	0.39**	0.58**	0.70**	0.61**	0.58**	0.56**	1	–
Organization (Org)	0.80	1.27	1.01	0.16**	0.21**	0.31**	0.26**	0.22**	0.32**	0.49**	1
Well being											
Quality of life (FertiQoL Core Module)											
Emotional	0.88	61.85	21.29	0.05	0.13*	0.22**	0.20**	0.17**	0.04	0.11	–0.04
Mind/body	0.89	65.31	23.37	0.10	0.12*	0.24**	0.19**	0.16**	0.09	0.16**	–0.08
Relational	0.72	77.71	15.84	0.10	0.22**	0.25**	0.23**	0.24**	0.09	0.19**	–0.05
Social	0.78	67.93	20.22	0.07	0.09	0.19**	0.15**	0.17**	0.02	0.15**	–0.07
Distress symptoms (Brief Symptom Inventory)											
Somatization	0.86	3.36	4.47	–0.12*	–0.15**	–0.12*	–0.14*	–0.11*	–0.12*	–0.12*	–0.00
Depression	0.88	4.55	4.86	–0.04	–0.14*	–0.22**	–0.17**	–0.18**	–0.10	–0.17**	0.02
Anxiety	0.88	5.46	4.80	–0.13*	–0.14*	–0.19**	–0.12*	–0.13*	–0.11	–0.16*	0.01
Quality of care (FertiQoL Treatment Module)											
Environment	0.81	63.11	17.60	0.32**	0.55**	0.61**	0.54**	0.55**	0.36**	0.55**	0.23**
Treatment tolerability	0.75	67.97	19.50	0.17**	0.07	0.16**	0.11	0.09	0.11*	0.14*	–0.02
Concerns about treatment (CART scale)	0.74	1.91	0.43	–0.13*	–0.13*	–0.16**	–0.14*	–0.13*	–0.12*	–0.15**	–0.02
Intentions of compliance (FertiQoL Persistence scale)	0.76	24.07	4.15	0.10	0.17**	0.16**	0.15**	0.17**	0.20**	0.26**	0.11*

SD, standard deviation; PCC, patient-centred care; PCQ, patient-centred questionnaire.

duration of the relationship and type of treatment (Huppelschoten et al., 2013).

The tool demonstrated construct validity, supported by the results obtained from the CFA and the significant correlations between the PCC dimensions and between these and other measures of quality of life, distress and quality of care. In general, the Cronbach's alphas of the subscales indicate that the PCQ-Infertility is reliable. However, the Continuity dimension showed an alpha value of 0.57, which is slightly below moderate. This value is a result of item 1 ('Was one staff member assigned to you to contact any time you had any questions or problems (e.g. a nurse)?'), which showed an item-dimension correlation of 0.09. In the absence of this item, the subscale Cronbach's alpha was 0.66 (see Supplementary data, Table SII). In the original version of the instrument, this item presented an item-dimension correlation of 0.32 and the alpha value for Continuity was acceptable ($\alpha = 0.64$). It seems that this item may not be a good indicator of continuity of care in Portugal, but

further investigation is necessary to determine whether the item should be eliminated from the Portuguese version of the PCQ-Infertility.

Individuals varied on their evaluations of the different dimensions of PCC and the PCQ-Infertility was able to detect this variation. These indicates that the tool is sensitive to variations across different aspects of care provided and can thus be used to pinpoint the more problematic aspect of care in each infertility clinic or country. The more negatively rated dimensions by patients of Portuguese infertility clinics were organization, respect and information. There are indications that these problems are not specific to the Portuguese reality, as they were also identified as problematic in other countries. For instance, in a study performed by Dancet et al. (2011), patients considered that information deliverance, team-patient relation and respect for the patients' values were important but problematic aspects of infertility care. In other studies, patients also reported being unsatisfied with organization of care (Haagen et al., 2008, van Empel et al., 2010a,b). Nevertheless, the point is that clinics

Table III Direct and indirect associations between PCC and intentions of compliance with fertility treatment, via tolerability to treatment or concerns about treatment.

PCC (IV)	Mediators (M)	Effect of IV on M	Effect of M on DV	Effect of IV on DV, controlling for M: Direct effect	Effect of IV on DV, through M: Indirect effect	Total effect of IV on DV	R ²
		B (SE)	B (SE)	B (SE)	B (SE) [BC 95% CI]	B (SE)	
Accessibility	Tolerability	0.22 (0.06)***	0.08 (0.07)	0.09 (0.06)	0.02 (0.02) [−0.013, 0.058]	− 0.13 (0.06)*	0.05*
	Concerns	− 0.16 (0.07)*	− 0.14 (0.07)*		0.02 (0.02) [0.001, 0.069]		
Information	Tolerability	0.04 (0.07)	0.12 (0.07)	0.13 (0.07)*	0.01 (0.01) [−0.009, 0.038]	0.16 (0.07)*	0.07**
	Concerns	− 0.14 (0.07)*	−0.13 (0.07)		0.02 (0.02) [−0.001, 0.063]		
Communication	Tolerability	0.16 (0.07)*	0.11 (0.07)	0.12 (0.06)	0.02 (0.02) [−0.004, 0.059]	0.16 (0.06)*	0.07*
	Concerns	− 0.16 (0.07)*	− 0.14 (0.07)*		0.02 (0.02) [0.001, 0.066]		
Involvement	Tolerability	0.13 (0.06)*	0.08 (0.07)	0.11 (0.06)	0.01 (0.01) [−0.005, 0.045]	0.14 (0.06)*	0.06**
	Concerns	− 0.14 (0.07)*	− 0.15 (0.07)*		0.02 (0.02) [0.001, 0.066]		
Respect	Tolerability	0.07 (0.07)	0.12 (0.07)	0.14 (0.07)*	0.01 (0.01) [−0.004, 0.047]	0.16 (0.07)*	0.07**
	Concerns	− 0.15 (0.07)*	−0.13 (0.07)		0.02 (0.02) [−0.001, 0.066]		
Continuity	Tolerability	0.14 (0.07)	0.11 (0.07)	0.15 (0.07)*	0.02 (0.02) [−0.002, 0.065]	0.18 (0.07)**	0.07**
	Concerns	− 0.15 (0.07)*	− 0.13 (0.07)*		0.02 (0.02) [−0.001, 0.068]		
Competence	Tolerability	0.22 (0.07)**	0.09 (0.07)	0.23 (0.07)**	0.02 (0.02) [−0.009, 0.073]	0.27 (0.07)***	0.09***
	Concerns	− 0.19 (0.07)*	−0.12 (0.07)		0.02 (0.02) [−0.001, 0.073]		
Organization	Tolerability	−0.00 (0.08)	0.10 (0.07)	0.10 (0.08)	0.00 (0.01) [−0.021, 0.021]	0.09 (0.08)	0.05*
	Concerns	0.08 (0.08)	− 0.14 (0.07)*		−0.01 (0.02) [−0.060, 0.009]		

All analyses were conducted controlling for years of education. Effects were considered significant when the bias-corrected CI did not contain the 0 value.

IV, independent variable; M, mediator; DV, dependent variable; SE, standard error; BC, bias-corrected and accelerated; CI, confidence interval; PCC, patient-centred care.

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$, bold indicates significant associations ($P < 0.05$) or effects.

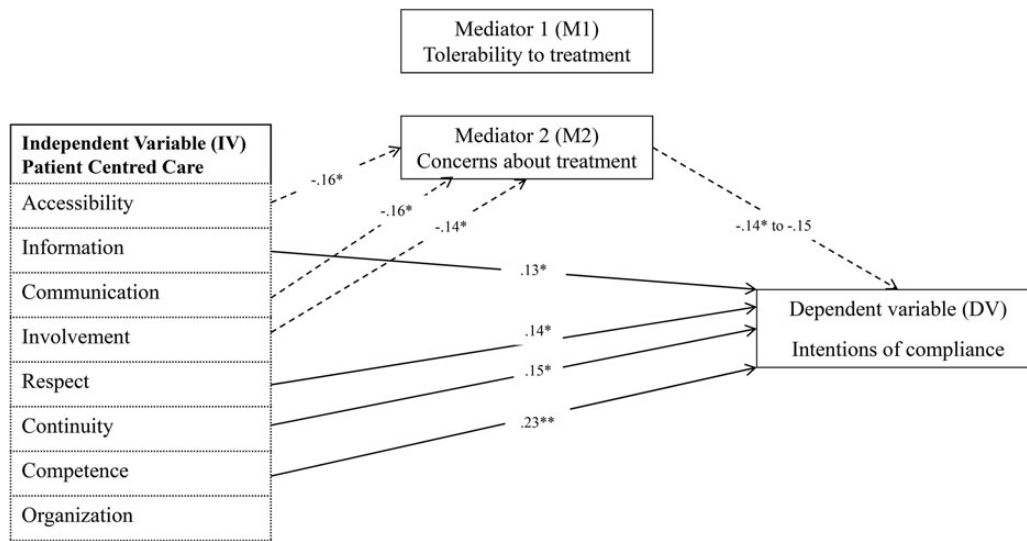


Figure 3 Significant direct (full lines) and indirect (dashed lines) associations found between patient-centred care dimensions and intentions of compliance with fertility treatment, via tolerability to treatment or concerns about treatment. * $P < 0.05$, ** $P < 0.01$.

can use the PCQ-Infertility as a diagnosing tool to delineate effective strategies to improve the quality of care delivered. One hypothesis is to identify those dimensions that patients identify as most problematic and, from these, tackle the ones that are more dependent on internal clinic policies and less affected by external issues (e.g. respect) or the ones that are more strongly associated with better treatment (e.g. pregnancy rates) and patient outcomes (e.g. wellbeing).

This study showed that better PCC experiences across all dimensions except Organization are directly or indirectly associated with higher intentions to comply with recommended treatment. This is important as compliance translates in increased treatment success rates (Gameiro et al., 2013). The existence of significant direct and indirect associations that explain between 5 and 9% of intentions to comply with treatment is consistent with the idea that clinic, patient and medical factors have reciprocal influences and interact to influence compliance (Boivin et al., 2012). Although prospective research has not clarified what are the important predictors within each domain (Gameiro et al., 2012), it is clear that the clinic staff needs to take this into consideration by adopting an integrated approach in the provision of infertility care that gives equal attention to these three sources of treatment burden (Boivin et al., 2012). In particular, it should be noted that the lack of direct associations between care provided and treatment outcomes does not mean that the first do not affect the later.

Direct associations found show that individuals may be more willing to comply with treatment if they are able to establish stable relationships with a reference doctor who is competent and respectful of their interests and values and who provides them with the information they need. In addition, the indirect associations show that individuals may also be more willing to comply with treatment if their concerns about the medical procedures are addressed in routine care. The best way to do this seems to be by ensuring that patients have easy and fast access to professionals who have good communication skills and involve them in the treatment and decision-making processes. Indeed, these aspects are highly valued by patients (Dancet et al.,

2010, Dancet et al., 2011) who are willing to forgo a degree of convenience in the treatment administration process in exchange for effective communication and shared decision-making with their doctors (Palumbo et al., 2011).

Tolerability to treatment did not emerge as an important factor in this context. Patients may be willing to bear the distress of undergoing treatments if they are aware of their safety and efficacy. In fact, a study showed that patients are willing to sacrifice convenience, for example, the travel time to the clinic, in exchange for a higher success rate (van Empel et al., 2011). However, it is important to note that we evaluated compliance intentions, which are related to the anticipation of future events and not actual behaviour. Only 37% of the patients were undergoing ART and on average they had done only one attempt. It is possible that as patients undergo repeated cycles of treatment, tolerability becomes more relevant.

This study involved a large sample of women and men undergoing any type of treatment at public and private clinics. The sample size and advanced statistical procedures used assure the reliability of the results presented and their generalization to the majority of patients who use infertility care. The CFA allowed for the study and validation of the first PCC model developed specifically for the infertility context. Despite these strengths, some limitations must be taken into account. First, 49.1% of the sample was recruited online. The higher percentage of patients with university education and undergoing ART in this group could have influenced the overall ratings of PCC reported, as observed in previous studies (van Empel et al., 2010a,b). Secondly, the non-consideration of treatment prognosis factors and the possibility of doctor censoring is known to result in the underestimation of compliance behaviour (Gameiro et al., 2013) and the same can be expected for intentions. This fact may have resulted in the underestimation of the strength of associations reported involving compliance intentions. Finally, the cross-sectional design of the study does not allow for cause and effect analysis between the study variables. Definitive conclusion about the effect of PCC on compliance require a longitudinal study

assessing actual compliance behaviour, as recommended by Gameiro *et al.* (2013).

In conclusion, the PCQ-Infertility is a valid and reliable tool, developed based on a specific model of PCC for infertility care, that is validated across different European countries. The tool can be used with any patient, regardless of gender and type of treatment being undertaken. It is able to detect variations across different aspects of care provided and can be used as an indicator of quality of care. Clinics can use the PCQ-Infertility to assess, monitor and improve the provision of PCC. The Portuguese version of the PCQ-Infertility is sound. Clinics interested in fostering their patients' intentions to pursue recommended treatment should allow them to establish stable relationships with a reference doctor who is competent and respectful of their interests and values and who provides them with the information they need. They can also alleviate their patients' concerns regarding medical procedures by ensuring that these professionals are easily accessible, have good communication skills, and involve the patients in the treatment process and associated decision-making.

Supplementary data

Supplementary data are available at <http://humrep.oxfordjournals.org/>.

Authors' roles

S.G., M.C.C. and J.B. designed the study. J.P. and S.G. performed data collection, analysis and interpretation. J.P. and S.G. drafted the manuscript and all authors made significant contributions to its improvement and approved the final version for submission.

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Conflict of interest

None declared.

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