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THE INVOLVEMENT OF BREAST CANCER PATIENTS AND FAMILY
MEMBERS DURING ONCOLOGICAL CONSULTATIONS
A STUDY TO EXPLORE THE INFORMATION NEEDS AND TO ASSESS THE
EFFECTS OF A PRE-CONSULTATION INTERVENTION TO INCREASE THE
PATIENTS INVOLVEMENT IN THE INFORMATION EXCHANGE

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ABSTRACT

Background: The interest in communication issues regarding cancer care has steadily increased, in particular concerning the information needs of oncology patients. Studies on patient involvement show that physicians make few attempts to involve their patients who ask few questions if not facilitated. On the other hand, patients who participate in the decision making process show greater treatment adherence and have better health outcomes. Two main intervention techniques have been tested in an attempt to make patients more aware about their needs and to encourage them to make more questions during the consultation. Firstly, they have been encouraged, through a coaching process to generate their own list of questions. Secondly patients have been provided with a structured pre-prepared list of evidence based questions, a Question Prompt Sheet (QPS).

Aims: The aim of this study is to assess the effects of a pre-consultation structured intervention (QPS) compare to a simple intervention (QL) to increase the involvement of breast cancer patients by determining an increase in questioning.

Methods: All patients with breast cancer who attend the Oncology Out-patient Services for the first time are randomly assigned to one of the two intervention groups. The intervention consists of the presentation of a list of relevant illness-related questions (QPS) or a request to generate a list of relevant questions (QL) before the consultation. Standardised questionnaires are administered at baseline (before the randomisation) and immediately after the consultation.

The main outcome measure is the number of questions asked by patients during the consultation

Results: Among all patients (537), 143 were excluded for exclusion criteria. Of the 394 eligible patients, 70 refused to participate in the study, so that the remaining 324 patients, 164 were assigned to the QPS group and 160 to the QL, according to the randomization. 16 audiotapes were lost due to technical reasons so that the final sample comprised 308 patients with complete

data: 158 and 150 respectively in the QPS and QL group.

All Patient asked an average of 14 questions. Patients in the QPS group asked an average of 13 while in the QL group they asked an average of 16 questions. The difference between pooled arms was statistically significant ($t_{(271)} = -1.99, p = .05$). The effect of hierarchical structure of the sample was measured by intra-class correlation (ICC). The results obtained by the mixed linear model, taking into account the hierarchical structure, show that the difference between interventions lost its significance ($b = 1.7; 95\%; CI: -.29; 3.64. p = 9\%$).

Discussion: In our study we compared QPS to an open-ended question (QL) in the other group which can have played an important role as well as the QPS in preparing patients, prior the consultation, to focus better their attention to what they wish to ask their oncologist. Preparing patients for the consultation (using QPS or a QL as well) is a quick and simple way to promote patients asking questions and may improve the overall communication between oncologist and patient.

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1. THEORETICAL OVERVIEW

1.1 Doctor-patient communication

Among inter-personal relationships, the doctor-patient relation is one of the most complex because it involves interaction between individuals who seem to be in non-equal positions, is often non-voluntary, concerns issues of vital importance, is therefore emotionally laden, and requires close cooperation. It is also well known that certain aspects of doctor-patient communication have an influence on patients' behavior and well-being, such as satisfaction with care, adherence to treatment, recall and understanding of medical information, coping with the disease, quality of life, and even state of health (Ong *et al.*, 1995).

Doctor-patient communication becomes even more important in cancer care where there is the need to give information in a sensitive way to patients that are often anxious and worried about their prognosis. Although cancer communication has much in common with communication in other health contexts, several unique elements of cancer care make cancer communication research important: a) few other illness are both life-threatening and potentially curable; b) it involves numerous clinicians and multiple treatment modalities (such as oral and intravenous medications, radiation, and surgery); c) there is often a long period of uncertainty after treatment, and d) the patient's health care team often changes over time (Epstein & Street, 2007).

1.2 Patient involvement

In the last decades something has changed in the doctor-patient relationship due to the fact that patients want more information concerning their illness and its management (Jekins *et al.*, 2001). They want a greater involvement in treatment decisions, so they tend to prefer a more active role in the decision making process regarding their illness, especially in oncology.

Though, cancer patients' preferences for information and decisional involvement vary, meeting these preferences is a complex communication task. It has been observed that what the physician says has an immediate effect on what the patient says and therefore can influence the degree of patient participation in the consultation (Charles *et al.*, 2000; Drew *et al.*, 2001; Zimmermann *et al.*, 2003).

Although patients want to be more involved, they cannot express their treatment preferences and participate in decisions unless they are given sufficient and appropriate information. Therefore, the greatest attention has to be given to their concerns and their information requests and preferences. The discrepancies between physicians and patients' perception of information needs can be an important barrier to providing patients with appropriate information during the medical consultation. In spite of evidence-based requests (Fallowfield *et al.*, 1994; Gattellari *et al.*, 2001; Brown *et al.*, 2012) to routinely involve patients in decision making (Breitsameter, 2010; Charles and Gafni, 2010; Siminoff, 2010), patients are often not involved in decision making (Albrecht *et al.*, 2003a; 2003b; Brown *et al.*, 2004) and their preferences are not being met (Brown *et al.*, 2007; Gattellari *et al.*, 2001; Ford *et al.*, 2003; Bilodeau & Degner, 1996; Sutherland *et al.*, 1989; Brown *et al.*, 2010). Information needs in health is a

concept that is well defined based on theories derived from information science. Information needs emerge because of an underlying dissatisfaction with the existing situation and/or deficiency in a person's knowledge defined and recognized by the individual, motivating the person to seek answers and form questions to find a solution for a particular problem (Ormandy, 2011).

The evidence indicates that patient's preferences for the type and amount of information vary. Moreover the information needs of patients with cancer differ among patients, change over time (Cegala, 2003), vary depending on the type and stage of cancer, and persist throughout the cancer care continuum. This requires physicians to adapt the information giving process to the needs and to the level of comprehension of the single patient. If the expression of such needs is not facilitated or encouraged, these needs tend to remain hidden, with the risk that patient perceives the received information as either too much or too little. Good clinical practice entails the recognition of variations in patient's preferences, and helping patients accomplish these preferences. When physician meets patient's information preferences, patient is better able to handle the information in a way that fits him/her best, which is associated with better quality of care, coping with illness and treatment adherence (Joosten *et al.*, 2008).

1.3 Respective Roles

Historically, the clinician's role was to provide disease-related information and recommendations, and the patient's role was to share symptoms and concerns, but important changes have occurred in the process of information exchange over the past

four decades. The role of patient in the consultation has changed, leaving a paternalistic approach where doctor directs care and makes decisions about treatment while patient remains passive, delivering his or her health into the hands of the doctor. In a more balanced way of view, the patient assumes the role of an expert himself: while physicians know the causes of disease, the diagnostic instruments and the therapeutic interventions, patients know their habits, their own experience of disease and the impact that this one has on their lives and on the social context. So patients' point of view and their preferences are increasingly being considered into their health assessment and treatment.

1.4 Patient-centered approach and share decision-making

The need to take into account these aspects has gradually enhanced the importance of what is called Patient-Centered Approach (Smith, 1997; Mead & Bower, 2000), in which the physician applies an active listening, formulates open questions, provides empathetic responses and encourages patient's requests. Studies showed that patients tend to prefer a patient-centered approach and how this approach is very effective in both the information gathering phase and the final phase of the consultation, increasing the satisfaction and the chance of adherence to treatment (Little *et al.*, 2001; Mead & Bower, 2002). The meeting between two experts who enables a better treatment outcome seems to be the key of success of the patient-centered medicine and the shared approach model, called shared decision-making (Coulter, 2002).

The Shared Decision-Making (SDM) is an approach in which clinicians and patients communicate together using the best available evidence when faced with the task of making decisions. Patients are supported to deliberate about the possible attributes and consequences of options, to arrive at informed preferences in making a determination about the best course of action which respects patient autonomy, as well as ethical and legal norms (Charles *et al.*, 1997).

Patient centered communication has become the gold standard for excellence in clinical communication. It consists of clinicians eliciting and understanding their patients' perspectives and social contexts, reaching a shared understanding and empowering patients by offering meaningful involvement in treatments decisions (Del Piccolo and Goss, 2012).

In a relationship where both, patients and physicians are at the same level, they have equal tasks to achieve patient-centered cancer care. Clinicians often are more informative, accommodative, and supportive with patients who are forthcoming with questions, concerns, opinions, and preferences (Street, 1992; Street, 1991; Brown *et al.*, 2002; Street *et al.* 2005). Similarly, if a patient with cancer is passive, a clinician could use partnering and other facilitative behavior such as asking for the patient's opinion or concerns, or offering encouragement. Such behaviors generally elicit greater patient involvement because the clinician's communication both legitimizes and specifically asks for the patient's views (Street *et al.*, 1995; Street *et al.*, 2003).

However this mutual influence is often below the level of awareness. Clinicians must improve the ability to monitor and consciously adapt communication to meet the patient's needs. A second important issue is discovering the way in which patients want to be involved in decision-making. Clinicians are not particularly good judges of

patients' preferences for involvement in decision-making in the cancer setting (Bruera *et al.*, 2002; Bruera *et al.*, 2001). Thus, it is important to identify these preferences and make appropriate adaptations. An oncologist who routinely solicits and encourages patient involvement in decision-making, may take more responsibility if he or she senses that the patient wants this. This clinician may still actively encourage the patient to talk about his or her concerns, however. Conversely, clinicians who have limited perceptiveness or a fixed communication style will have less adaptability and will find they interact with some patients effectively but have considerable difficulty with others.

In situations characterized by high levels of physical discomfort, anxiety, cognitive complexity, and/or ambiguity, the same patient may become overwhelmed because the cognitive and emotional burden exceeds his or her capacity to adapt to the requirements of the situation. In those cases, clinicians may need to adopt a different communication style than would ordinarily work well for that patient. Similarly, clinicians can become overwhelmed, and as a result, distance themselves from the patient and fail to elicit and respond to the patient's needs. In addition, clinicians must help patients filter and understand clinical information, a *sine qua non* for informed or participatory decision-making (Blanchard *et al.*, 1988; Kim *et al.*, 2001).

On the other hand patients must communicate in a way that reveals their needs, preferences, expectations, concerns, and perspectives. Particularly important are active communication behaviors such as asking questions, expressing concerns, being assertive in stating opinions and preferences, introducing topics for discussion, and telling their "health stories" (Street, 2001). By contrast, a patient who remains passive during the interaction does little to convey his or her needs, fears, expectations, beliefs, and preferences. Health outcomes may be at risk in these situations, and the encounter

will not satisfy the patient's need to feel known, understood, or heard or satisfy the clinician's moral obligation to address the patient's underlying concerns in order to maximize healing.

Regardless of their preferences for the clinician's communication style, patients and their families generally want to be involved in the process of care, be informed of all the treatment options, feel listened to, and feel that their physicians know them as people, not simply diseases (Henman *et al.*, 2002; Thorne *et al.*, 2005). In order to be involved and to feel understood, patients must be able to effectively and actively communicate their needs, concerns, and perspectives.

1.5 Interventions

Effectively the focus of many studies has been recently directed towards the patient activation to be more involved in the consultation and in treatment decision (Clayton *et al.*, 2007). One way to increase activation is by encouraging patients to ask questions. The number of questions asked by patients can be considered a first index of active participation in the discussion and an expression, at the same time, of patient's most immediate information needs (Butow *et al.*, 2002; Eggly *et al.*, 2006; Ellis *et al.*, 1999; Parker *et al.*, 2003; Siminoff *et al.*, 2000). Patients who actively participate in consultations by asking questions are able to change the focus of the consultation and control the duration and the amount of information provided by their physicians (Kaplan *et al.*, 1996). Thus, by enabling patients to ask questions that concern them, doctor-patient communication may be improved (Street, 2001). Interventions to increase

the number of questions by the patient have pointed out that, with the rise of this number, the quality of the information exchange between physician and patient improves in turn (Eggly *et al.*, 2006; Brown *et al.*, 2001; Butow *et al.*, 1994; Clayton *et al.*, 2007).

Two main intervention techniques have been tested in an attempt to make patients more aware about their needs and to encourage them to make more questions during the consultation. Firstly, patients have been encouraged, through a coaching process with an independent assistant to generate their own list of questions (Jones *et al.*, 2002) about their cancer and treatment options (Belkora *et al.*, 2008; Kidd *et al.*, 2004; Sepucha *et al.*, 2000) During coaching, patients have the opportunity to rehearse their questions in preparation for their consultation. A consultation plan is then generated and provide to the patient, family members and the physician to be used as a visual aid during the consultation (Belkora *et al.*, 2006). Secondly patients have been provided with a pre prepared list of evidence based questions, a Question Prompt Sheet (QPS). QPSs are structured lists of prepared questions that prompt patients to consider novel topics before an oncology consultation to stimulate patients to raise these with their physician or to use the QPS as a reminder (Brown *et al.*, 2001; Butow *et al.*, 1994; Clayton *et al.*, 2007; Brown *et al.*, 1999; Bruera *et al.*, 2003). Prior to a consultation, patients are provided with a QPS and asked to circle questions they would like to ask. Patients are then encouraged to take the QPS into the consultation and ask their chosen questions, including other questions as they arise. Formative work in the oncology setting demonstrated that using the QPS, coupled with physician endorsement of question asking, a) encouraged patients to ask questions about sensitive and difficult topics such as prognosis, diagnosis, and issues surrounding end of life care (Brown *et*

al., 2001; Clayton *et al.*, 2007; Brown *et al.*, 1999) and b) improved patient outcomes (Brown *et al.*, 2001; Clayton *et al.*, 2007; Brown *et al.*, 199; Kinnersley *et al.*, 2008, Roter, 1977).

2. OBSERVATIONAL PHASE

2.1 Aims

The experimental phase has been preceded by an observational phase with the aim to assess the sample characteristics and the ongoing hospital setting. It has been described in a paper “in press” on the European Journal of Oncology Nursing.



Information needs of female Italian breast cancer patients during their first oncological consultation

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2.2 Methods

2.2.1 Setting

Patients were recruited during the first six months of 2010 in the outpatient clinic of the Medical Oncology Unit of the “*Ospedale Civile Maggiore*”, Hospital Trust of Verona in

the Veneto region, Italy. This hospital has an outpatient clinic dedicated to patients with breast cancer, with a rotation of 2–5 oncologists and it has been chosen due to its association with the “*Gruppo Senologico Veronese*” (GSV). The GSV members adopt a multi-disciplinary approach to breast cancer in order to offer a personalized care, from prevention through diagnosis, treatment, and post treatment support.

Visits for breast cancer patients were scheduled on fixed weekdays, from four to eight patients a day. Patients have already been diagnosed with cancer, often have undergone the first breast surgery (e.g. lumpectomy) and were referred to the medical oncologist by the surgeon or by the radiologist. Generally, in the first visit with the medical oncologist the aim was to communicate the histological results and to decide further medical treatments (e.g. chemotherapy or hormone therapy). The consultation could vary from 30 to 60 min. Eligible patients were all female patients with an age between 18 and 75 years old, with a recent diagnosis of breast cancer at an early stage. Exclusion criteria were the presence of metastasis or relapse, severe mental deterioration and a difficult comprehension of Italian language.

2.2.2 Data collection procedure

Oncologists informed consent to participate and socio-demographic data were collected at the beginning of the study.

On fixed days the oncology nurses, in accordance with the oncologists, gave to the researcher a list of scheduled patients. At the department waiting room, all consecutive breast cancer patients at their first out-patient visit with the oncologist were asked to

give written informed consent to participate in the study. Consenting patients were then accompanied to a dedicated room where they received an envelope containing five questionnaires to complete before the consultation. Consultations were performed as usual by oncologists according to their clinical practice and were audio-recorded. Just the recording device was present during the consultation and it was managed independently by the oncologists. After the consultation, patients returned to the researcher and completed three other questionnaires. Oncologists reported on a form the cancer stage and type, when the patient had been informed about diagnosis and the therapeutic options appropriate for each patient. The local ethic committee approved the study.

2.2.3 Pre-consultation measures

Socio-demographic and clinical data collected were age, education, family status, employment status, cancer stage and time since diagnosis. Consultation characteristics collected were presence of a relative or companion, type of treatment prescription and consultation length, including the doctor–patient communication attitude of the oncologist, measured with the Doctor-Patient (DP)Scale (De Monchy *et al.*,1988). The instrument has 48 items, with an average score of 1 indicating a “doctor centered-disease oriented ”attitude and an average score of 5 indicating a “patient centered problem oriented” attitude. Other variables likely to be associated with patients' expressed information needs were assessed with the following instruments:

- the State-Trait Anxiety Inventory (STAI-X1) (Spielberger *et al.*, 1983) assessing the level of anxiety;
- the Patient Health Questionnaire depression scale (PHQ-9) (Kroenke *et al.*, 2001) detecting the presence of depression;
- the General Health Questionnaire (GHQ-12) (Politi *et al.*, 1994) indicating psychological distress;
- the Control Preference Scale (CPS) (Giordano *et al.*, 2008) measures patients' preferences in the shared decision making process.
- the Decision Self Efficacy Scale (DSES) (O'Connor, 1995) measuring patients' confidence to make an informed decision.

2.2.4 Post-consultation measures

After the consultation patients complete other three questionnaires:

- the Patient Enablement Instrument (PEI) (Howie *et al.*, 1998) assessing the ability to cope with the illness;
- the Shared Decision Making Questionnaire (SDM-Q) (Simon *et al.*, 2006) measuring the degree that patients felt to be involved in decisions during the consultation
- the Satisfaction With Decision scale (SWD) (Holmes-Rovner *et al.*, 1996) measuring patients' satisfaction with decisions made during the consultation;

Oncologists complete also the Control Preference Scale (CPS).

- the Oncologist version of the CPS evaluates if oncologists guess the role preferred by patients during the consultation. The agreement between patients role preferences and oncologists perception was calculated and used as a new variable.

2.2.5 Audiotapes analysis

The audio-recorded consultations were examined for the conversation length and for the content and number of questions asked by patients. Questions were defined as “utterances in interrogative form that ask for information or clarification” (Street *et al.*, 2007).

Three researchers were involved in the coding process. They identified the five main question categories (symptoms, etiology, prognosis, prevention and illness management) starting from those described in the literature (Jenkins *et al.*, 2001; Brown *et al.*, 2001). A sixth category was added to account for administrative questions.

The illness management category was split then into five other sub-categories: a) treatments specific for breast cancer, including administration, duration, frequency, effectiveness of the therapies (e.g. chemotherapy, hormone therapy, immunotherapy, surgery; b) side effects of treatment; c) check-ups and follow-up visits (e.g. mammography, blood tests); d) other pharmacological treatments related to pathologies in co-morbidity; and e) others not specified elsewhere.

Inter-rater reliability among the three coders was calculated on ten consultations, revealing an average percentage agreement of 62.9% and a Cohen's kappa of 0.49,

which are acceptable according to Landis and Koch (1977). Subsequently, listening to the audiotapes, all direct questions of patients were identified, transcribed *verbatim* and categorized using the categories previously identified.

2.2.6 Statistics

The scores of the scales listed above were tested for their association with patients' information needs (specifically, the number of questions per interview for each category) using Chi-squared test or Pearson's correlation coefficients where appropriate. Kolmogorov-Smirnov, or chi square median test for equality of frequency distribution, were performed when no normality assumptions could be made. The analyses were performed on valid cases, using Stata 11.2 (StataCorp, 2011).

2.3 Observational Results

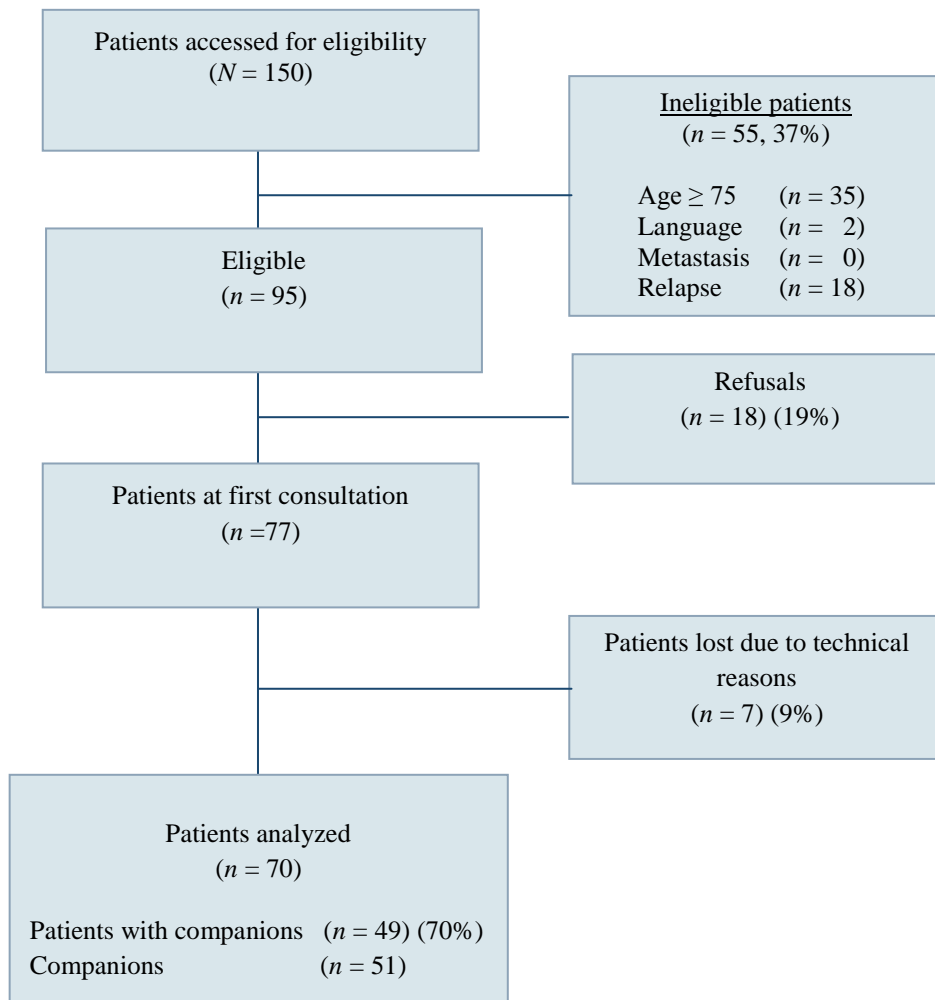
2.3.1 Sample and consultation characteristics

Of the 95 eligible patients, 18 (19%) refused to participate in the study due to several reasons such as high anxiety or hurry to see the physician. Of the remaining 77 audio-recorded consultations, seven consultations (9%) were lost due to technical problems, the final sample therefore consisted of 70 patients (see flow-diagram).

About socio-demographic data, patient's average age was 58 (\pm 9.7, range 31-75). Most patients were married (63%) with children(81%) and had at least 8 years of education (78%). 41% of patients were employed, 34% were retired and 23% were housewives.

Forty-eight patients (69%) attended with a relative who joined the consultation.

Flow diagram



Regarding the clinical data, twenty-two patients (32%) had a carcinoma in situ, 28 (40%) had cancer at stage I, 17 (24%) at stage II and 3 (4%) at stage III. Average time since the communication of diagnosis was two months (average 2.3 ± 1.11 ; range = 0-5). 14% patients did not receive any treatment prescription during the consultation, 22% received one, and 64% two or more prescriptions.

The oncologist prescribed chemotherapy 19 times (27%), radiotherapy 46 times (66%), hormone therapy 47 (67%) and immunotherapy 6 times (8%).

Oncologist 1 and 2 (female) contributed with 52 and 13 consultations respectively, while Oncologist 3 (male) contributed with 4 consultations. Oncologists 1 and 3 reported a doctor-centered attitude on the DP questionnaire (average score of 2.3 for both), while Oncologist 2 reported a balanced attitude (DP average score of 2.9). Oncologists stated that nearly two third of patients (59%) preferred a shared approach, 7% a very or active role and 34% a passive or a very passive role. In half of the cases (55%) the oncologists correctly identified patients' preference regarding their role in making medical decisions (46%, 61% and 25% for Oncologist 1, 2 and 3 respectively). The average consultation length was 34 min (± 12.5 , range 12-72).

2.3.2 Psychological patient characteristics

Before the consultation patients were slightly anxious (STAI-X1), 33% were depressed (PHQ-9) and 64% were emotionally distressed (GHQ-12). More than half of patients reported (on the CPS) to prefer a shared medical decision with the oncologist, a

minority preferred an active role, and about one third preferred a passive or a very passive role.

Before the consultation patients were reasonably confident in treatment decision (DSES), and after the consultation they stated that the oncologist had been good enough, helping them in the decision making process (SDMQ). They reported a high satisfaction with decision (SWD), and said to be somewhat better equipped to cope with their illness than before the consultation (PEI).

2.3.3 Patients' information requests

Patients asked an average of 17.6 questions. Excluding administrative questions, the average dropped to 11.8 questions (± 8.6 , range 0-39). The topics were mostly related to illness management, particularly treatment, and administrative procedures. In contrast, patients asked fewer questions about prognosis, prevention and etiology. Sixty-five patients (93%) asked at least one question about illness management and one question about administrative procedures. Fifty patients (71%) asked at least one question about symptoms. Most patients asked no questions on etiology or prevention (86% and 70% respectively). Half of patients (51%) asked no questions about prognosis. Only one patient asked no questions at all: she was 71 years old, widow, graduate, retired and mildly depressed (PHQ = 8). Her daughter was present at the consultation and asked seven questions. Other four patients (66, 49, 73 and 75 years old) asked no questions about illness management.

2.3.4 Variables affecting question asking

Only significant associations are reported here. Satisfaction With the Decision (SWD) questionnaire was not included among the explorative factors due to its lack of discriminatory power. A greater number of questions were associated with being employed instead of not been employed ($M = 21 \pm 10.5$ and $M = 15 \pm 10.9$ respectively) ($t = .32; p = .04$). A greater number of questions about illness management, particularly about the side effects of radiotherapy, were related to younger age ($r = .28, p = .01$ and $r = .24, p = .05$ respectively). Questions also increased with consultation time ($r = .47, p < .01$), particularly those about illness management ($r = .5, p < .01$) and administrative topics ($r = .27, p = .02$). We explored this finding using cut-off score of 30 min, as it was the scheduled time of the first consultation.

Thirty-three consultations took less than 30 min with an average of 13 questions asked by patients (± 7.4 range 0-32) while 37 consultations took more than 30 min with an average of 21 questions (± 12.4 , range 1-49, $t_{(59.86)} = 3.31, p < .01$).

Patients who were prescribed chemo-therapy asked more questions than those without ($M = 25, \pm 13.5$, range 8-49 vs. $M = 15, \pm 8.4$, range 0-35; $t_{(23.45)} = 3.17, p < .01$), particularly questions on chemotherapy ($M = 8, \pm 4.8$, range 0-16 vs. $M = 3, \pm 2.7$, range 0-12; $t_{(22.14)} = 3.76, p < .01$) and its side effects ($M = 5, \pm 3.6$; range 1-13 vs. $M = 2, \pm 1.9$, range 0-7; $t_{(22.15)} = 3.57, p < .01$).

The longer the time patients knew their diagnosis, the more questions they asked on prevention ($r = .25, p = .05$).

Patients seen by the two oncologists, who favored a doctor-centered approach, asked fewer questions compared to the 14 patients seen by the “balanced” oncologist ($M = 13,$

± 6.3 and $19, \pm 11.9$ respectively; $t_{(56.49)} = 2.81, p < 0.01$). Question asking also increased when the oncologist guessed correctly the patient's preferred role in the decision making process ($19.5, \pm 10.9$ vs. $15.5, \pm 11.1$; chi square median test = $5.47, p = .02$).

A greater patients self-rated ability to cope with illness (PEI) significantly reduced questions about symptoms and illness management ($r = .26, p = .04$ and $r = .28, p = .02$, respectively).

2.4 Considerations

As observational study it has some limitations beside some strengths. One limitation that has to be considered is that these data only permit analysis at the cross-sectional level, which do not allow to make strong causal claims. Furthermore the relatively small sample size reduces the possibility to detect significant relationships and does not allow the assessment of interaction effects on question asking. Moreover, the presence of a recorder in the consultation could be a limit. Patients who did not want to be audio recorded ($n = 3$) were excluded from the sample, so this could introduce a selection bias although the sample representativity seems to be not compromised. The recorder might have had also a bias effect on patient behavior. If so, we think that it could be very slightly for two reasons. Firstly, the device had small dimensions and remained out of sight in a position that did not attract patients' attention. Secondly, analyzing the recorded consultations, no patients expressed a particular bother concerning the device, so we could say that its presence was almost forgotten.

However this study has a homogeneous sample available, which limited the possible confounding factors effect related to settings and service organization. This homogeneity has reduced also the findings variability, due to the oncologists and this has to be considered a strength.

Regarding question asking, patients asked an average of 18 questions, confirming previous findings in literature (Jenkins *et al.*, 2001; Finney Rutten *et al.*, 2005), even though Italian breast cancer patients seem to ask slightly more questions.

As observed before in other countries, the most frequently occurring questions were related to illness management in terms of treatment (Jenkins *et al.*, 2001; Finney Rutten *et al.*, 2005). These findings are not surprising as the primary purpose of the first oncology consultation is to suggest and discuss treatment options. Unexpectedly, the second most frequent topic were related to administrative procedures. Many information requests for administrative procedures addressed to the oncologist take away precious consultation time, and signal the lack of written directives to anticipate and to meet such predictable needs in a more appropriate manner.

Univariate comparisons and Pearson's correlations give some first indications of the variables likely to affect the number and types of questions in this sample. As reported before (Kinnersley *et al.*, 2008), reduced question asking was associated with shorter consultations.

Contrary to previous findings (de Bock *et al.*, 2004), emotional distress, anxiety and depression levels were not associated with information requests, despite in our sample, the presence of psychosocial distress was similar to what was observed in other countries (Kissane *et al.*, 2004; Gallagher *et al.*, 2002).

3. ROLE OF COMPANIONS

Using the same observational data it has been written another article to explore the role of companions in the consultation.



Asking questions during breast cancer consultations: Does being alone or being accompanied make a difference?

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3.1 Introduction

Companions often accompany patients to cancer consultations and participate at the encounter. They provide emotional, informational and logistical support for patients and may also participate at decisions regarding treatment (Laidsaar-Powell *et al.*, 2013; Street and Gordon, 2008). During the consultation companions may contribute significantly in sustaining information needs by helping the patient to ask questions and express concerns (Ishikawa *et al.*, 2005; Clayman *et al.*, 2005). In this way companions can act as a conduit for information, but they may also elicit information from clinicians so that patients may be more informed (Hubbard *et al.*, 2010).

In Italy, the assessment of family members' participation, as well as patients' participation, is a matter of recent interest and exploration that still remains to be further investigated. Recently some surveys on Italian patients' informative needs have been published (Tamburini *et al.*, 2000; De Lorenzo *et al.*, 2004; Travado *et al.*, 2005; Giacalone *et al.*, 2005; Piredda *et al.*, 2008; Annunziata *et al.*, 2009) but very little is known on the characteristics of patients and companions and their contribution to question asking in cancer consultations. No study has been published on data obtained directly from audio recordings.

Regarding the presence of a companion in the consultation, using the observational data the aim was to see if there are differences between Italian patients with, and without, attending companion in terms of socio-demographic and psychological characteristics, shared decision making preferences, decisional confidence, information requests, perception of shared decision making and satisfaction with decisions.

Another aim was to see also if there are differences between patients with, and without, attending companion in terms of frequencies and topics of question asked, perceived shared decision making and satisfaction with decisions. And finally, which is the role played by the companion with question asking during the consultation.

3.2 Methods

Questions asked by companions, after being numbered and defined by their content according to the five categories (symptoms, etiology, prognosis, prevention and

treatment) suggested by Butow *et al.* (1994) and Clayton *et al.* (2003), were then classified also in terms of three possible functions: 1. to *repeat or verify something already said by the oncologist*, 2. to *introduce new information requests (by changing topic)* or 3. to *help completing the collection of information (sharing questions on the same topic or issue already introduced by the patient)*.

After listening to each audio-tape the role of each companion was described adopting the three categories suggested by Street and Gordon (2008): *observer* (contributed to the consultation less actively than the patient and showed a more passive role), *partner* (adopted a shared role), *advocate* (contributed actively to the consultation, stimulating also the patient to ask questions).

3.3 Results

Forty eight out of 70 patients (69%) attended with one or two ($N = 1$) relatives, who joined the consultation. Close family members prevailed (82%). The most frequent relationship was patient-husband/partner (48%), followed by the vertical relationship mother-adult child (23%). About half of the companion sample was gainfully employed and reported high school or University educational level (see Table 1)

Table 1. Characteristics of companions

Relatives(<i>N</i> = 48)	
	<i>N</i> (%)
Male	28 (58.3)
Degree of relationship	
Husband	22 (47.8)
Son	3 (6.2)
Daughter	8 (16.7)
Sister	5 (10.4)
Mother	1 (2.1)
Friend	4 (8.3)
Other	5 (10.4)
Occupation	
Employed	24 (51.1)
Student	1 (2.1)
Housewife	7 (14.9)
Retired	15 (31.9)
Missing	1 (2.1)
Education	
Primary school	7 (14.9)
Junior high school	13 (27.7)
High school	15 (31.9)
University degree	12 (25.5)
Missing	1 (2.1)

There was a trend for triadic consultations to be longer (35.98 ± 13 min) than consultations without attending companion (30.45 ± 10.6 min), resulting in a greater number of total questions per consultation (23.7, SD 15.4 (range 0-70) versus 18, SD 9.4 (range 7-49), but the differences fell short of significance ($t_{(68)} = 1.75$, $p = .09$ and $t_{(62.1)} = -1.9$; $p = .06$ respectively).

Regarding the differences between accompanied and unaccompanied patients, accompanied patients were more often not employed (unemployed, housewife or retired) ($\chi^2_{(1)} = 6.5$, $p = .01$) than unaccompanied patients. No other socio demographic differences emerged. The two patient groups were similar in state anxiety, emotional distress and depression (see Table 2).

Table 2. Comparative characteristics of patients with and without companion during the consultation.

	Patients not accompanied (<i>N</i> = 22)	Patients accompanied (<i>N</i> = 48)	<i>t</i> -test/ <i>x</i> ² , <i>p</i> -value
Marital status	<i>N</i> (%)	<i>N</i> (%)	
Single	5 (22.7)	3 (6.3)	<i>x</i> ² (3) = 6.63 <i>p</i> = .09
Married	13 (59.1)	31 (64.6)	
Widower	1 (4.6)	10 (20.8)	
Divorced	3 (13.6)	4 (8.3)	
Occupation			
Employed	14 (63.6)	15 (31.3)	<i>x</i> ² (3) = 7.01 <i>p</i> = .07
Unemployed	0 (.0)	1 (2.1)	
Housewife	4 (18.2)	12 (25)	
Retired	4 (18.2)	20 (41.7)	
Education			
Primary school	3 (13.6)	12 (26.1)	<i>x</i> ² (3) = 2.65 <i>p</i> = .45
Junior high school	3 (13.6)	10 (37)	
High school	11 (50)	17 (15.2)	
University degree	5 (22.7)	7 (15.2)	
Age	Mean (range) 55.0 (41–68)	Mean (range) 58.0 (31–75)	<i>t</i> ₍₆₈₎ = -1.26 <i>p</i> = .21
STAI-X1 score	42.4 (35–49)	43.8 (32–62)	<i>t</i> ₍₆₈₎ = -1.15 <i>p</i> = .26
GHQ-12 score	4.7 (3.3–6.1)	4.6 (3.7–5.5)	<i>t</i> _(50.4) = .26 <i>p</i> = .80
PHQ-9 score	6.1 (4.1–7.9)	6.0 (4.4–7.5)	<i>t</i> _(49.7) = .04 <i>p</i> = .97
Decision Self Efficacy Scale	33.9 (30.9–36.9)	34.5 (32.4–36.5)	<i>t</i> _(42.4) = -.35 <i>p</i> = .74
Control Preference Scale	<i>N</i> (%)	<i>N</i> (%)	
Active	3 (18.8)	1 (2.6)	<i>x</i> ² (2) = 5.8 <i>p</i> = .06
Shared	10 (62.5)	21 (55.3)	
Passive	3 (18.8)	16 (42.1)	

Patients with a companion showed, from the CPS measure, a tendency to prefer a passive role in the decision making process than those coming alone.

As shown in Table 3, the number of questions was similar in both groups of patients as well as the distribution over the six content categories. Most of the questions focused on illness management (44%) and administrative procedures (37%).

Concerning the frequencies and topics of questions, companions asked significantly less questions per consultation than their kin patient ($t_{(116)} = 6.34$; $p < .01$), but gave priority to the same topics.

Table 3. Frequency of questions asked by patients, accompanied or not, and by companions

Type of question	Unaccompanied patients ($N = 22$)	Accompanied patient ($N = 48$)	Companions ($N = 48$)
	Mean (SD) [range per interview]	Mean (SD) [range per interview]	Mean (SD) [range per interview]
Illness management	8.2 (6.6) [0–33]	7.4 (6.6) [0–27]	2.7 (3.5) [0–19]
Administrative	6.1 (3.9) [0–19]	6.0 (4.2) [0–16]	2.4 (2.8) [0–10]
Symptoms	1.9 (2.2) [0–8]	2.3 (2.4) [0–8]	.6 (1.7) [0–10]
Life style / Prevention	.8 (1.5) [0–5]	.9 (1.5) [0–8]	.2 (.8) [0–5]
Prognosis	.7 (.8) [0–2]	.7 (1.1) [0–6]	.3 (.7) [0–4]
Etiology	.3 (.8) [0–3]	.3 (.7) [0–3]	.1 (.2) [0–1]
Total	18 (9.4) [7–49]	17.5 (11.8) [0–48]	6.2 (6.9) [0–31]

Regarding the role played by the companion on question asking during the consultation, most of the questions asked by the companions introduced requests for new information (53% of times) or helped to complete the obtained information (38%). Checking the information provided by the oncologist was relatively rare (9%). In terms of role, 67% of companions adopted a shared role, only 12% had a passive role and the remaining 21% were active advocates.

3.4 Considerations

Both accompanied and unaccompanied patients showed a high level of psychological distress, suggesting that the emotional condition did not increase the probability of support by a companion.

Accompanied and unaccompanied patients asked on average the same number of questions. A similar finding was reported by Wolff and Roter (2011) who in their review on family presence in routine medical visits showed that “verbal contribution to medical dialogue was comparable when accompanied patients and their family companion were compared with unaccompanied patients”.

Also the topics covered during the consultation were the same, with a preference to illness management issues and administrative procedures. This is not surprising, since the main focus in cancer consultations just after surgery is the discussion of treatment options. The large number of administrative questions burdened the oncologists, with a waste of precious consultation time, which, to our knowledge, has no previous mention in the literature. One possible reason could have been a lack of printed procedural information by which to predict such needs in a more appropriate manner.

Companions asked fewer questions than their kin patient, as observed before for companions of lung cancer patients (Street and Gordon, 2008).

They sought essentially the same type of information from the oncologist as the patients: primarily about treatment options and then about practical aspects of treatment. This finding parallels that of previous studies on information needs of informal caregivers, which showed that caregivers had a similar profile of information needs to those identified by women with breast cancer (Beaver and Witham, 2007; Luker *et al.*,

1995, 1996). The presence of a companion increased, even if not significantly, the total number of questions per consultations, without suppressing question asking of the patients. Indeed companions showed to be active by asking questions on new topics, but at the same time the majority shared the information with the kin patient by helping her to complete the set of information given by the oncologist. This contributed to slightly prolong the consultation by about five minutes. Other studies have shown previously that the doctor spends more time and provides more information when the companion is present (Wolff and Roter, 2011; Eggly *et al.*, 2011; Labrecque *et al.*, 1991).

4. EXPERIMENTAL PHASE

4.1 Aims

The main aim pursued by this study is to assess if a pre-consultation heavily structured intervention, “Question Prompt-Sheet” (QPS) facilitates greater participation of patients (and accompanying key persons when present) in the consultation process, by determining an increase in questioning and/or in the number of different illness related issues (e.g. diagnosis, treatment, prognosis) being discussed with the oncologist; compared to a more simple intervention.

The study pursues other secondary aims as to assess the effect of the QPS on the level of patient involvement by the oncologists, on patient satisfaction and coping, on the oncologist’s perception of patient’s preferred decisional role and to explore the role of key persons accompanying the patient.

In detail the study investigates if the intervention, determines as secondary aim:

- a greater number of personal information needs expressed during the consultation (information needs expressed before the consultation correspond to those expressed during the consultation);
- the perception of a greater capacity to cope with illness and a greater satisfaction with decisions made during the consultation;
- greater patient generated and/or doctor generated involvement of the patient;
- a better understanding of the received information and greater satisfaction;

- a different perception by the oncologist of patient’s preference regarding her participation in therapeutic decisions;
- a different perception by the oncologist and by the patient of the doctor-patient relationship
- a more patient-centered approach during the consultation

4.2 Methods

4.2.1 Design

As a multicenter, randomized controlled trial, patients are attributed randomly to one of the two intervention groups on a 1:1 basis. The randomization sequence is being conducted off-site using the “random allocation of treatments balanced in blocks (ralloc)” package for Stata (Ryan, 2008) and is stratified by center with a 1:1 allocation ratio of treatment. Block randomization (size 4) is used to minimize large imbalances between the intervention groups. The allocation sequences are generated by an independent individual, are stored in computer files and remain unknown to the researchers until the patient is randomized.

Patients in group 1 are given the QPS, a list of 50 specific questions that have been chosen and adapted on the basis of previous studies in the field (Baile *et al.* 2000; Brown *et al.* 1999, 2001; Bruera *et al.* 2003; Clayton *et al.* 2003, 2007; Glynn-Jones *et al.* 2006; Ohlen *et al.* 2006), and are invited to select among the 50 possible questions

those, if any, they would like to ask to the oncologist. On the contrary those in group 2 are given a control sheet on which writing the questions they would like to ask.

Both randomization procedure and treatment allocation have been developed to fully conceal treatment allocation (Moher *et al.* 2010; Altman *et al.* 2001). Patients and oncologists are unaware of the allocation. The raters who analyze the audio-recordings are also blinded to the allocation of patients.

The oncologists perform their consultation as usual, according to the clinical practice of their center. After concluding the consultation, they complete two questionnaires regarding the patient and the consultation.

Standardized questionnaires are administered before the randomization and immediately after the consultation.

4.2.2 Setting

The participants are medical oncologists and patients newly diagnosed with early stage breast cancer who attending an outpatient oncology clinic for the first time. This study was conducted in three outpatient oncology clinics in Northern Italy run by the Hospital Trusts of Verona and Brescia. Visits for breast cancer patients were scheduled on fixed weekdays, from four to eight patients a day. Generally, in the first visit with the oncologist the aim is to communicate the histological results and to decide further medical treatments.

4.2.3 Sample and recruitment

Oncologists

Eligible oncologists include medical oncologists working in one of the three Oncology Departments and who were involved in the treatment of women with early stage breast cancer.

Patients

Patients are included if they are between the ages of 18 to 75 years, are recently diagnosed with early stage breast cancer and have adequate native language skills to complete questionnaires. The exclusion criteria consist in absence of metastasis or relapse and no mental deteriorations.

4.2.4 Procedure

At study commencement oncologists provide demographic data, including their gender, age, and years of oncology experience, and the DP questionnaire to measure their communication style. Consecutive patients at each site were screened for eligibility and informed of the purpose and requirements of the study by the study Research Assistant (RA). Prior to their initial consultation, all willing patients and family members provide written informed consent to participate and for the consultation to be audio recorded.

Immediately Pre-consultation

Once recruited, participants and companions completed a brief questionnaire that collected socio-demographic data and a package containing six questionnaires.

Patients were then randomized in one of the two intervention groups, using a randomization schedule developed by the study statistician. Patients were randomized within each center and recruitment continued until an approximately equal number of patients was recruited at each center to satisfy the sample size calculation.

Group 1 - participants were provided with a Question Prompt Sheet that commenced with a brief introduction explaining the importance of question asking. This was followed with a structured list of 50 evidence-based questions that patients commonly want to ask their oncologist during their first treatment discussion. Participants read through the questions and were asked to circle salient questions, if any, they would like to ask their oncologist.

Group 2 - participants were provided with a blank, lined paper form that commenced with an introduction explaining the importance of asking questions during their consultation. Participants were then asked to self-generate a list of questions they would like to ask their oncologist. Participants were instructed to: "Please indicate the issues which you want to discuss today with your oncologist".

Both forms were collected after they were completed for later analysis. Patients and companions did not take either the QPS or the self-generated list into the consultation. This decision was made in order to keep oncologists blind to which intervention patients had completed. The oncologists performed their visits according to the standard of usual clinical care at their center. All consultations were audio recorded

to allow an analysis of; a) the duration of the consultation and b) patient question asking.

Immediately Post-consultation

Immediately following the consultation, oncologists completed a questionnaire asking for the patient's clinical information.

They also complete a questionnaire measuring the perception of the patient as difficult.

Patients and companions completed then six other questionnaires.

The audio tapes and oncologist' forms are collected and the audio tapes are examined for the content and number of questions asked by patients and companions, and are rated applying the OPTION scale (Elwyn *et al.*, 2005; Goss *et al.*, 2007a, 2007b) and the VR-COPE (Del Piccolo *et al.*, 2008) (Table 4)

Table 4. Study instruments

Scale	Evaluation	Explored area	N items	Time
STAI-X1	Patient and companion	State anxiety level	20	Before the consultation
PHQ-9	Patient and companion	Depression	9	Before
GHQ-12	Patient and companion	Psychological distress	12	Before
DSES*	Patient and companion	Confidence with decision	11	Before
CPS	Patient, companion and oncologists	Role in the decision making process	vignettes	Before
EPQ-R	Patient and companion	Personality traits	24	Before
DP	Oncologists	Oncologists' communication style	48	One time only
PEI	Patient and companion	Ability to cope with illness	6	After the consultation
SDMQ*	Patient and companion	Patient involvement	9	After
SWD*	Patient and companion	Satisfaction with decision	6	After
PDRQ-9*	Patient and companion	Doctor-Patient relationship	9	After
RECALL*	Patient and companion	Recalling and understanding of information	10	After
STAI-X1/R	Patient and companion	State anxiety level	10	After
DDPRQ-10	Oncologists	Difficulties in relationship with the patient	12	After
Audio-recording	Consultation	Interaction between doctor and patient	-	-
OPTION	External rater	Involvement level	12	-
VR-COPE	External rater	Aspects of patient-centered communication	9	-

4.2.5 Study measures

4.2.5.1 Socio demographic and clinical data

Patients' socio demographic data are: age, education, family status and employment status. They were reported by patients and companions during the baseline assessment.

Oncologists' socio demographic data are: age, gender and years of experience. Data for oncology resident (when present during the consultation) was also obtained.

Clinical data are: cancer stage and type, duration of illness, who has informed patient on diagnosis and when, therapeutic options considered appropriate for this patient. All these information were reported on a form by the oncologist.

4.2.5.2 Primary outcome measure

The primary outcome measure is the number of patient's questions during the consultation since question asking is considered an index of the patient's participation during the consultation.

All audio recordings were transcribed. The audiotapes were analyzed for the length of the conversation and for the content and number of questions asked by patients. Questions were defined as "utterances in interrogative form that ask for information or clarification" (Street and Gordon, 2008). Three researchers were involved in the coding process. They identified the five main question categories

(symptoms, etiology, prognosis, prevention and illness management) starting from those described in the literature (Jenkins *et al.*, 2001; Kaplan *et al.*, 1996). A sixth category was added to account for administrative questions.

The illness management category was split then into five other sub-categories: a) treatments specific for breast cancer, including administration, duration, frequency, effectiveness of the therapies (e.g. chemotherapy, hormone therapy, immunotherapy, surgery; b) side effects of treatment; c) check-ups and follow-up visits (e.g. mammography, blood tests); d) other pharmacological treatments related to pathologies in co-morbidity; and e) others not specified elsewhere.

Questions were then coded accordingly to the categories previously identified.

4.2.5.3 Secondary outcome measures

Unmet information needs

The number of unmet information needs that emerge during the consultation will be obtained by comparing the number of questions indicated by patients and their companion before the consultation (i.e., those selected in the QPS by patient) with those actually raised during the consultation (i.e., those identified subsequent to listening to the audio-recordings).

Ability to cope with illness

It was measured with the Patient Enablement Instrument (PEI) (Howie *et al.* 1998). This questionnaire is a self-administered questionnaire of six items on a Likert scale from 0 (same or less) to two (much better, much more).

Patient involvement

It was measured with the Shared Decision Making Questionnaire (SDM-Q) (Simon *et al.*, 2006; Kriston *et al.*, 2010) and the OPTION Scale (Elwyn *et al.*, 2005; Goss *et al.*, 2007a, 2007b). The Shared Decision Making Questionnaire is a self-administered questionnaire of nine items on a Likert scale from 1 (completely disagree) to 6 (agree completely) that assesses patients' perception of the decisional process and their level of involvement during the consultation, the information received on therapeutic options, potential risks and benefits regarding the participation at the decisional process. The OPTION Scale is composed of 12 items of operational definitions of different patient-involving skills, rated on a Likert scale from 0 (behavior absent) to 4 (behavior observed at an excellent skill level).

Satisfaction with decision

It was measured with the Satisfaction with Decision Scale (SWD) (Holmes-Rovner *et al.* 1996). This is a self-report questionnaire of six items on a Likert scale from 0 (completely disagree) to 5 (agree completely). Total score from 6 to 30.

Recall of information

It was measured with the Recall Questionnaire (Brown *et al.*, 2001; Gattellari *et al.*, 2002; Whelan *et al.*, 1999). This questionnaire consists of six items that ask the patient to recall the received information on treatment decisions and pathology (e.g. ‘What was the treatment decision? Which treatment options were discussed?’). The questions have been prepared for the present study with reference to previous studies. The questionnaire enables an evaluation of the accuracy of patient’s recall and understanding of information delivered during the consultation by comparing the patients’ answers with the contents of the actual consultation discussion gathered from the consultation audio recording.

Consultation atmosphere

It was measured with VR-COPE (Del Piccolo *et al.*, 2008). The VR-COPE assesses the content, the process and relational aspects of patient-centered communication during medical consultations on the basis of a multidimensional evaluation and comprises nine items. Each item is defined by operational definitions and rated on a 0 - 10 point scale. The scale is applied by trained raters to the consultation audio recordings. We expect that patients of the intervention group establish a better relationship with their oncologist and show higher scores in patient-centered communication.

Doctor-Patient relationship

It was measured with the Patient–Doctor Relationship Questionnaire (PDRQ-9) (Van der Feltz-Cornelis *et al.*, 2004) and the Difficult Doctor Patient Relationship Questionnaire (DDPRQ-10) (Hahn *et al.*, 1994, 1996). The PDRQ-9 contains nine items on a Likert scale with anchors at 1 (not at all appropriate) to 5 (totally appropriate). The scale measures patient perceptions of their relationship with the doctor. DDPRQ-10 contains 10 items on a Likert scale anchors at 1 (not at all) to 6 (a great deal) and is completed by physicians after the encounter with a patient. The questionnaire identifies the patients experienced as difficult patients.

Perceived patient's preferred role

It was measured with the Control Preference Scale (CPS, Oncologist version) (Degner *et al.*, 1997; Giordano *et al.*, 2008). This scale assesses how the oncologist perceives the role that patient might prefer regarding the decision making process.

4.2.5.4 Process related and potential confounding variables

The measures below have been collected in order to check their possible influence on question asking.

Consultation length and presence of companions

The consultation length was measured in minutes and presence of at least one companion during the consultation was checked.

Anxiety

It was measured with the State Trait Anxiety Inventory (STAI-X1, XR) (Spielberger, 1972; Spielberger *et al.*, 1983; Lazzari, 1980).

The State-Trait Anxiety Inventory X1 is a self-questionnaire completed by patients that measures the state anxiety in the situation contingent and transitory, or when the patient is preparing to visit. It differs from the anxiety trait which is instead a stable trait of the personality and provides a subjective assessment anxiety. The instrument is a validated, widely used measure that consists of 20 items with responses reported on a Likert scale with anchors at 1 (not at all) and 4 (very much) (Italian adaptation of Lazzari and Pancheri, 1980). There are items direct (that directly assess the presence of anxiety: 3, 4, 6, 7, 9, 12, 13, 14, 17, 18) and indirect (that assess the absence of anxiety: 1, 2, 5, 8, 10, 11, 15, 16, 19, 20).

The total raw score is between 20 and 80 The cut-off for the high anxiety (which invalidates the test) is given by a value \geq 95th percentile (raw score = 59-61). A score \geq 90th percentile (raw score = 52-58) is already indicative of a high level of anxiety. For the validity of the instrument is tolerated only one omission in the responses and in this case, the real score is estimated by multiplying by 9.10 the total score calculated on the remaining 9 items. Post Consultation Anxiety was measured using the

Speilberger STAI-X1/R. This is a modified version of the STAI X1 and was developed specifically for the Cognitive Behavioral Assessment Program (CBA) (Sanavio *et al.*, 1986) The CBA is the initiative of a group of Italian Psychologists to produce a viable battery of tools for clinical assessment. The STAI-X1/R is a ten-item version of the STAI-XI with responses reported in an identical manner to the STAI-X1.

Depression

It was measured with the Patient Health Questionnaire depression scale (PHQ-9) (Kroenke *et al.*, 2001, 2009; Thekkumpurath *et al.*, 2011). It 'a self-questionnaire completed by the patient, which assesses the presence of depressive symptoms in the last two weeks. The symptoms reported are taken from the DSM-IV, the first two items relate to depressed mood and anhedonia (the cardinal symptoms of MDD), followed by 7 additional items about alteration in sleep, low energy, appetite, feelings of guilt and failure, difficulty concentrating, hyper / hypokinesia thoughts and self-harm. It consists of 9 items each rated on a Likert scale from 0 (no symptom "never") to 3 (maximum distress caused by the symptom "almost every day"), with total scoring between 0 and 27.

The scoring can be evaluated as a continuous score or with an algorithm. It has become a screening tool for very popular to its brevity and simplicity. A score ≥ 8 and a sensitivity rate of 93% while maintaining adequate specificity of '81%. The standard psychometric screening for depression have not been defined; However, rates of sensitivity '85% and specificity from 70% to 75% are usually considered acceptable

parameters and the PHQ meet these standards when used as a measure of continuity to cut-off ≥ 8 .

Yet the literature does not provide us with suggestions for the statistical treatment of the items are missing, so we decide to handle them as follows: a) with a total score > 8 and only one missing data in the presence of the remaining valid responses, it will calculate the average of the values valid; b) with a total score < 8 and valid questions > 7 will calculate the average of the valid values; c) with a total score < 8 and valid questions < 7 the final score will not be calculated and the questionnaire will be considered lost.

General wellbeing

It was measured with the General Health Questionnaire (GHQ-12) (Politi *et al.*, 1994), a self-questionnaire completed by the patient that allows to evaluate the psychological well-being of the patient and to identify the presence of a possible emotional distress It was developed by Sir D. Goldberg in the seventies and used in various settings. It consists of 12 items each rated on a Likert scale from 1 (no symptom) to 4 (maximum distress caused by the symptom) used to calculate a total score between 0 and 12. The subjects with a score equal to or more than 4 have a probability higher than 80% have psychiatric disorders, such as anxiety and depression. Goldberg argues that with a score > 4 the likelihood of having mental disorders is $> 80\%$. For this study we chose to follow the dichotomous criterion for scores to individual items (0-0-1-1) already adopted previously in an Italian context. For the total score is calculated by adding the scores dichotomous; the cut-off for the presence of an emotional discomfort is given by

a score tot ≥ 3 In the literature there is no suggestion regarding the statistical management of the missing item for which it was decided to handle them in the following way: a) in If the total score ≥ 3 with only one missing data and the remaining valid responses, it will calculate the average of the valid values; b) in the case of total score ≤ 3 and valid questions > 9 , we calculate the mean of valid values; c) in the event of a total score < 3 and valid questions < 9 the final score will not be calculated and the questionnaire will be considered lost.

Personality traits

They were measured with the Eysenck Personality Questionnaire (EPQR-S) (Eysenck *et al.*, 1985). Eysenck initially conceptualized personality as two, biologically-based independent dimensions of temperament measured on a continuum:

Extraversion/Introversion (E): Extraversion is characterized by being outgoing, talkative, high on positive affect (feeling good), and in need of external stimulation. According to Eysenck's arousal theory of extraversion, there is an optimal level of cortical arousal, and performance deteriorates as one becomes more or less aroused than this optimal level. Arousal can be measured by skin conductance, brain waves or sweating. At very low and very high levels of arousal, performance is low, but at a better mid-level of arousal, performance is maximized. Extraverts, according to Eysenck's theory, are chronically under-aroused and bored and are therefore in need of external stimulation to bring them up to an optimal level of performance. About 16 percent of the population tend to fall in this range. Introverts, on the other hand, (also about 16 percent of the population) are chronically over-aroused and jittery and are

therefore in need of peace and quiet to bring them up to an optimal level of performance. Most people (about 68 percent of the population) fall in the midrange of the extraversion/introversion continuum, an area referred to as *ambiversion*.

Neuroticism/Stability (N): Neuroticism or emotionality is characterized by high levels of negative affect such as depression and anxiety. Neuroticism, according to Eysenck's theory, is based on activation thresholds in the sympathetic nervous system or visceral brain. This is the part of the brain that is responsible for the fight-or-flight response in the face of danger. Activation can be measured by heart rate, blood pressure, cold hands, sweating and muscular tension (especially in the forehead). Neurotic people — who have low activation thresholds, and unable to inhibit or control their emotional reactions, experience negative affect (fight-or-flight) in the face of very minor stressors — are easily nervous or upset. Emotionally stable people — who have high activation thresholds and good emotional control, experience negative affect only in the face of very major stressors — are calm and collected under pressure.

For this study we decided to use only these two dimensions excluding the Psychoticism/Socialization (P) and the Lie (L) scales that constitute the full EPQ-R version with 48 items. So we have two axes with a total of 24 items.

Confidence with decision

It was measured with the Decision Self Efficacy Scale (DSES) (O'Connor, 2012). It is a self-questionnaire completed by the patient which allows the assessment of the degree of confidence that the patient has in itself with respect to its ability to make a decision

about their own health. It consists of 11 items, each of which is rated on a Likert scale from 0 (no security) to 4 (very safe), with total scoring between 0 and 44.

Patient's preference role

The role they want to have in the decision making process was measured with the Control Preference Scale (CPS) (Degner *et al.*, 1997; Giordano *et al.*, 2008). The Control Preferences Scale was developed to measure a construct that emerged from a grounded theory of how treatment decisions are made among people with life-threatening illnesses. The control preferences construct is defined as "the degree of control an individual wants to assume when decisions are being made about medical treatment." The CPS consists of five cards that each portrays a different role in treatment decision-making using a statement and a cartoon. These roles range from the individual making the treatment decisions, through the individual making the decisions jointly with the physician, to the physician making the decisions.

Patient-centered communication style

It was measured with the Doctor-Patient (DP) Scale (De Monchy, 1988).

It consists of a self-administered questionnaire where it should be indicated on a five-point Likert scale (1 to 5, the score 3 is neutral), the agreement or disagreement relative to 48 statements regarding medicine general problem, and specifically, the doctor-patient relationship.

The maximum score is 240, the lowest 48.

The reference system is represented by a continuum with two poles regarding two different attitudes:

a) the pole D (score 1) expresses a "centered doctor disease-oriented" position: the physician's role is seen mainly in technical and scientific terms, the focus is more on the disease than on the patient, the doctor-patient aspects appear in the background.

b) the pole P (score 5) expresses a "patient-centered problem-oriented" position: the physician's role is seen primarily in relational terms and the focus is more on the patient than on the disease, promoting a patient individual approach.

4.2.6 *Sample size calculation*

A sample of 300 patients will be recruited. This number has been estimated to account for approximately a 15% of withdrawal rate, so that 250-260 patients will complete the study, with about 130 patients in each arm. The primary outcome measure is the number of patient questions. The international literature reports a mean number of 9 questions (range 0-53) for breast cancer patients. Since such data are not available in the Italian context, an observational phase was conducted. We recruited a sample of 30 patients (10 for each center) with the same characteristics, in order to assess the number and type of questions asked by the patient during the consultation, to understand the ongoing interaction between oncologists and patients in a first encounter and to test the feasibility of procedures and questionnaires. This observational study resulted in a mean number of 18 (SD =13) patient questions asked during a first encounter with the oncologist. An intervention intended to increase the number of questions might be

considered efficacious with an increase of 30%. The sample size required to evidence such difference was calculated using the "sampsi" command of Stata 11 (Stata.Corp., 2011), assuming a power of 80% and a two-sided significant level of 5% on a student *t*-test for differences between independent groups (Pocock, 1983; Sullivan *et al.*, 2003).

4.2.7 Data Analysis

Standard statistical techniques were used to describe characteristics of patients in both groups. The total number of questions asked and the number of questions asked within each arms were calculated.

Comparisons between groups in the socio-demo characteristics were performed to check the randomization balancing, using chi-squared and *t*-test.

In order to explore the presence of confounding effects on the outcome some preliminary analyses were performed using correlation measures. According to literature (Wilson *et al.*, 1991; Wilson & Childs, 2002; Deveugele *et al.*, 2002) we decided to consider mainly the consultation length as a confounding variable along with the presence of a family member.

The primary outcome, number of questions patients asked, was compared between the two intervention groups using simple *t*-tests and also multilevel analyses to take into account the nested structure of data (Skrondal & Rabe-Hesketh, 2004).

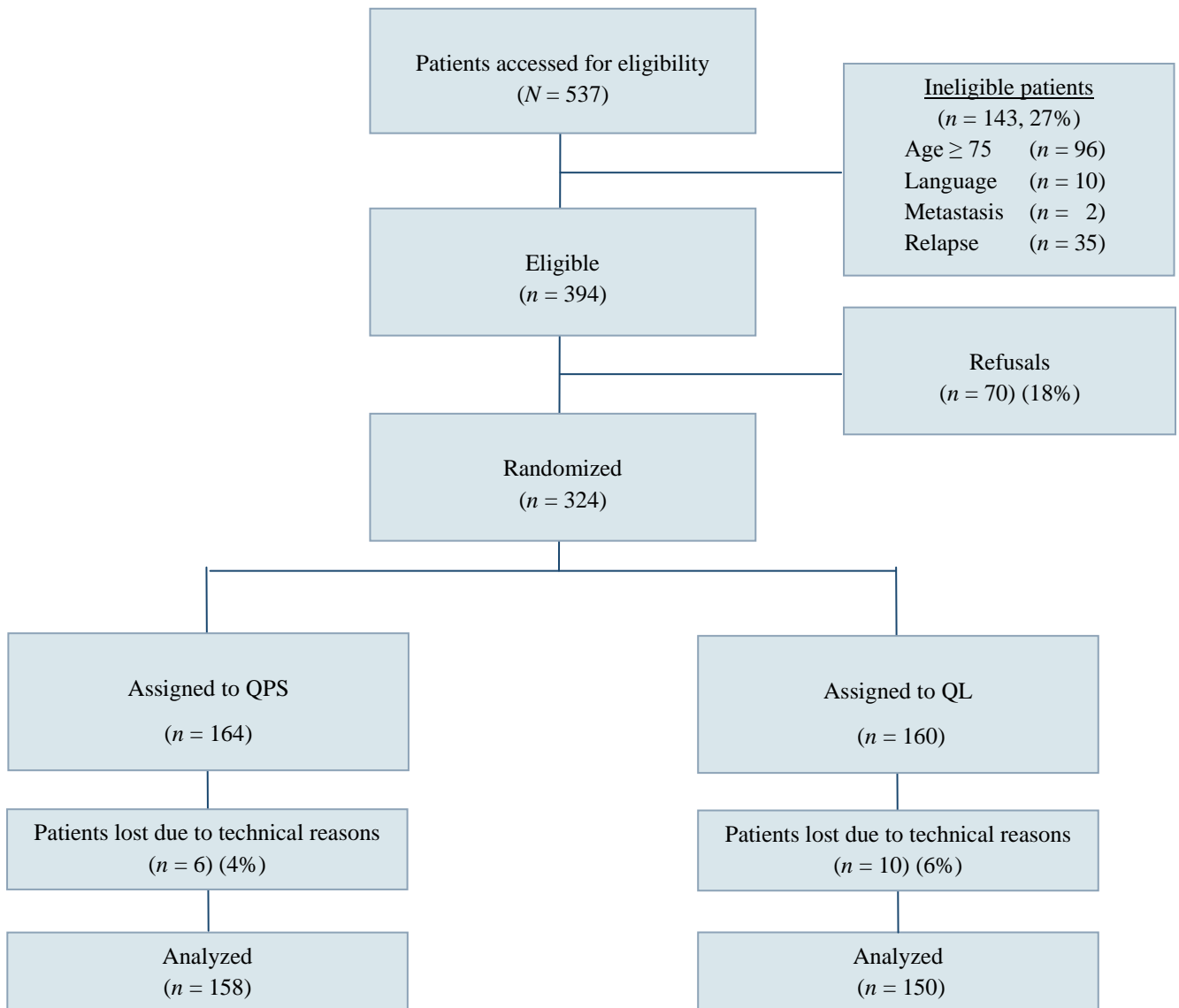
4.3 Results

Among all patients with breast cancer who attend the three oncology divisions during the recruitment phase, a total number of 537 were accessed for eligibility; respectively, 188 in the first center (*Borgo Trento*), 152 in the second (*Brescia*) and 197 in the third (*Borgo Roma*). 143 (26.63%) were excluded according to our exclusion criteria: 96 patients were excluded for age, 10 for language, 2 for the presence of metastases and 35 for the presence of relapse. The exclusion rates are quite homogenous in the three centers: 31.91% ($n = 60$) in center 1, 26.4% ($n = 52$) in center 2 and 20.39% ($n = 31$) in center 3.

Of 394 (73.37%) eligible patients that were recruited, 70 (17.77%) patients refused to participate in the study (also the rejection rates seems to be quite homogeneous: 18.75% ($n = 24$) in center 1, 14.05% ($n = 17$) in center 2 and 20% ($n = 29$) in center 3; so that 324 (82.23%) patients were randomized. 164 patients were assigned to the QPS group while 160 were assigned to the QL group.

We lost 16 (4.94%) audiotapes due to technical reasons: 6 in the QPS group and 10 in the QL group, leaving 308 patients (158 for QPS and 160 for QL) available for the analysis (see flow diagram).

Flow diagram.



4.3.1 Socio-demographic data

Most patients were married (69.8%) with an average age of 55.6 years, had a high school degree (40.5%) and were employed (56%).

Most oncologists were female (85%) with an average age of 38.8 years and an average of 11.3 years as medical oncologists (Table 6).

Table 6. Oncologists' Characteristics

Oncologist Characteristics (<i>N</i> = 20)	Center 1		Center 2		Center 3	
	N	SD	N	SD	N	SD
Average Age	37.2	12.6	41.5	7.9	36.5	9.8
Average Years as Oncologist	10.6	10.9	14.4	6.2	8.3	7.7
Gender (<i>n</i> = female oncologist)	4		7		6	

Comparisons of socio-demo characteristics between the two intervention arms shown no significant differences (see Table 7), so we can say that the randomization generated balanced groups.

Table 7. Patients' characteristics

Patient Characteristics*	Center 1 (n = 100)		Center 2 (n = 101)		Center 3 (n = 107)		Total (n = 308)								
	QPS (n = 53)		QL (n = 47)		QPS (n = 51)		QL (n = 50)		QPS (n = 54)		QL (n = 53)		QPS (n = 158)	QL (n = 150)	Chi ² /t, p-value
	N	%	N	%	N	%	N	%	N	%	N	%	%	%	
Marital Status															
Single	8	15.1	5	10.6	8	16	4	8	4	7.5	5	9.6	12.8	9.4	<i>x</i> ² = 2.42, <i>p</i> = 0.49
Married	34	64.2	36	76.6	33	66	41	82	36	67.9	33	63.5	66	73.8	
Other (Divorced, Widowed)	11	20.7	6	12.8	9	18	5	10	13	24.5	14	26.9	21.2	16.8	
Education															
Primary School	12	22.7	15	31.9	6	12.2	8	16	8	14.8	8	15.1	16.7	20.7	<i>x</i> ² = 1.42, <i>p</i> = 0.70
Secondary School	13	24.5	14	29.8	20	40.8	12	24	14	25.9	13	24.5	30.1	26	
High School	20	37.7	17	36.2	17	34.8	26	52	25	46.4	19	35.8	39.7	41.3	
University	8	15.1	1	2.1	6	12.2	4	8	7	12.9	13	24.6	13.5	72	
Employment															
Employed	30	56.6	30	63.8	26	52	28	56	30	55.5	28	52.8	54.8	57.3	<i>x</i> ² = 0.02, <i>p</i> = 0.88
Unemployed	23	43.4	17	36.2	24	48	22	44	24	44.5	25	47.2	45.2	42.7	
Patient Age M, (SD)	57.2 (13.02)		52.3 (36.8)		57.2 (9.2)		57.1 (9.9)		54.5 (10.4)		55.6 (13.5)		54.9 (27)	57.2 (9.5)	<i>t</i> = 0.99, <i>p</i> = 0.5

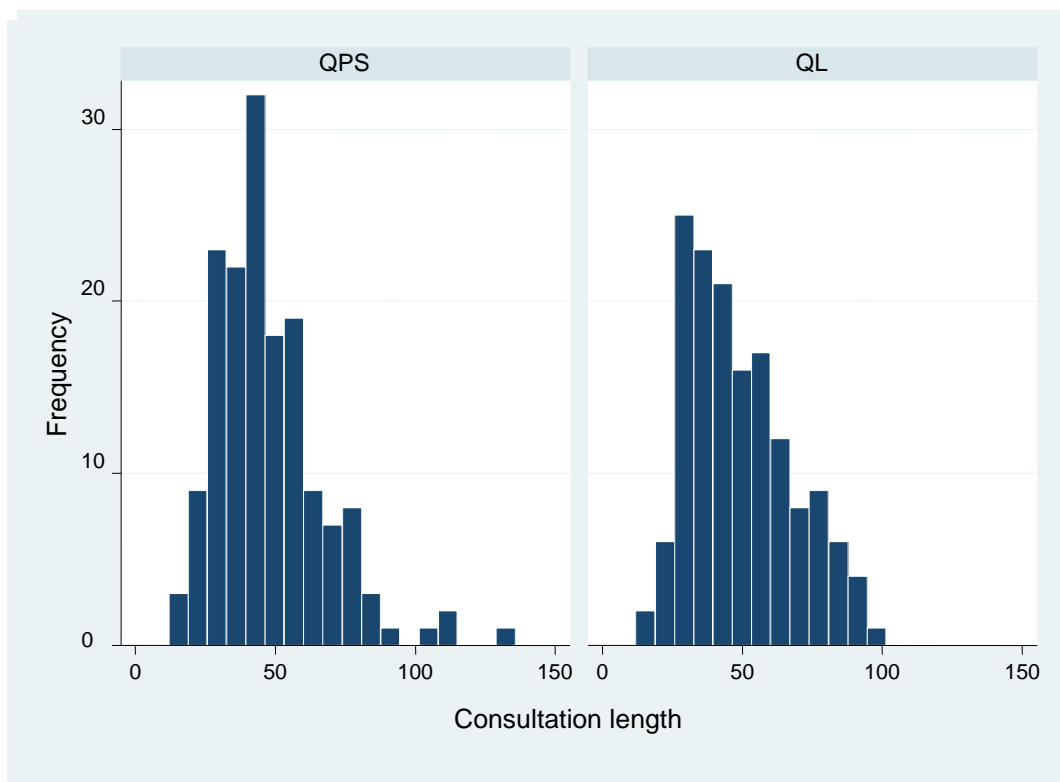
* information is missing in some patients, here the percentage are obtained on valid cases.

4.3.2 Characteristics of the consultation and confounding variables

Consultation length and presence of companions

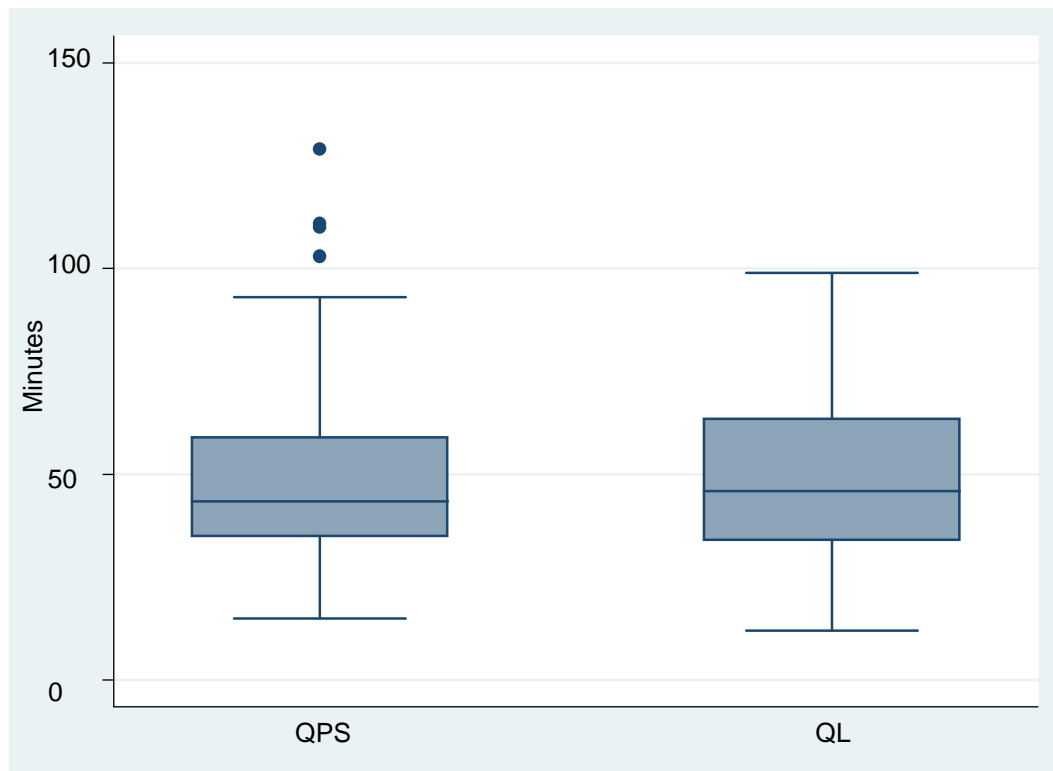
These consultation characteristics represent confounding effects, without interaction with the two intervention arms; therefore they were included into the regression model in order to better evidence the intervention effect.

Graph 1. Consultation length distribution in the two groups.



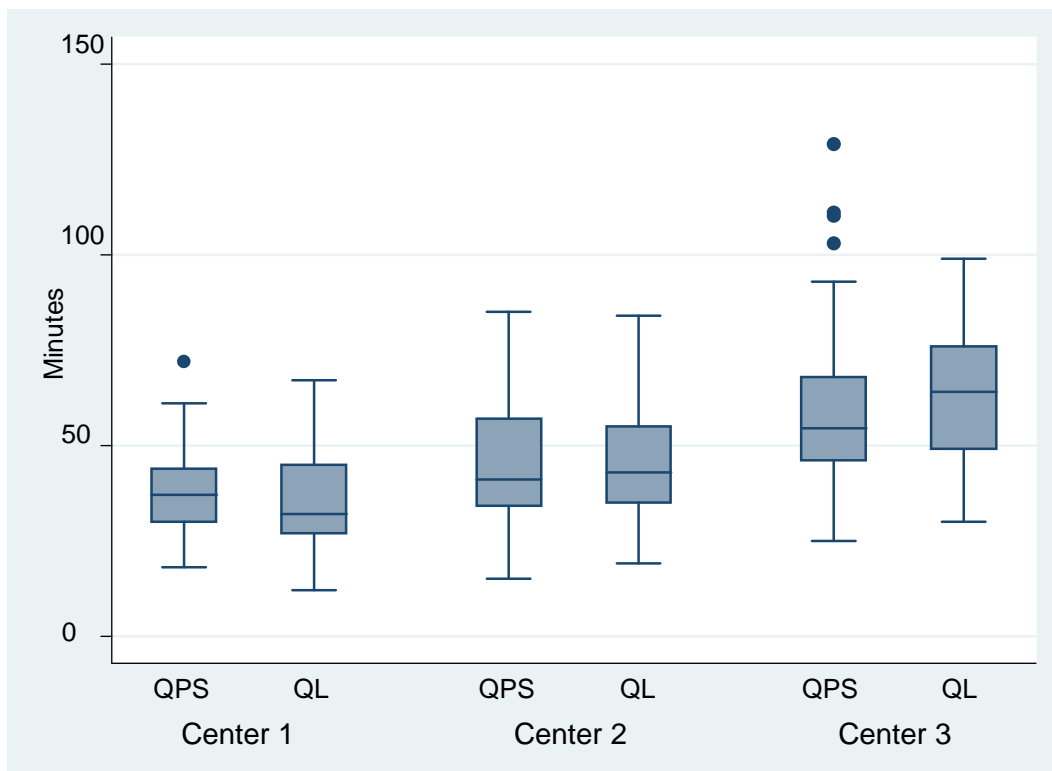
The length of the consultations ranged between 12 and 129 minutes with a mean of 49 minutes (SD = 19) (Graph 2). No statistically significant difference was found between the two groups ($t = -.62$; $p = .53$).

Graph 2. Consultation length comparison in the two intervention groups



If we look inside the three centers (Graph 3) we can notice that in center number 3 the average length was slightly higher.

Graph 3. Comparison of consultation length by groups and by center.



The correlation between the number of questions and the consultation length shows a moderate correlation not statistically significant ($r = .45$; p -value $> .01$), (Graph 4).

Graph 4. Correlation between number of question and consultation length.



A family member was present in 72% of consultations, without any difference in the two groups (Pearson chi-square ($dof 1$) = .17, p -value = .68), (Table 8).

Table 8. Presence of family members

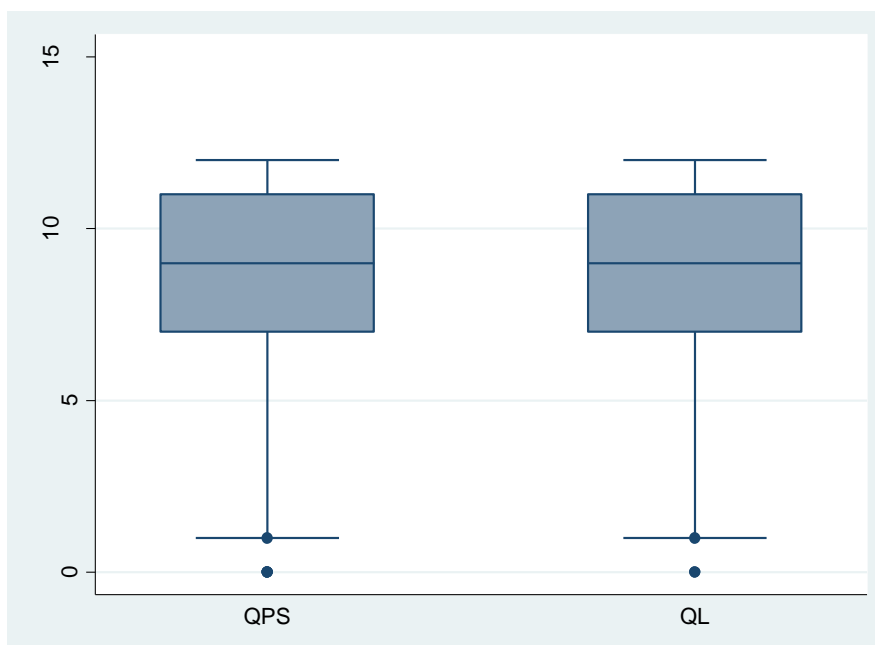
Presence of family member	QPS		QL		Total	
	N	(%)	N	(%)	N	%
Patients with family members	116	73	107	71	223	72
Patients only	42	27	43	29	85	28
Total	158		150		308	

Correlation between the number of questions and the presence of family member was $r = .24$; p -value $>.01$.

Personality traits

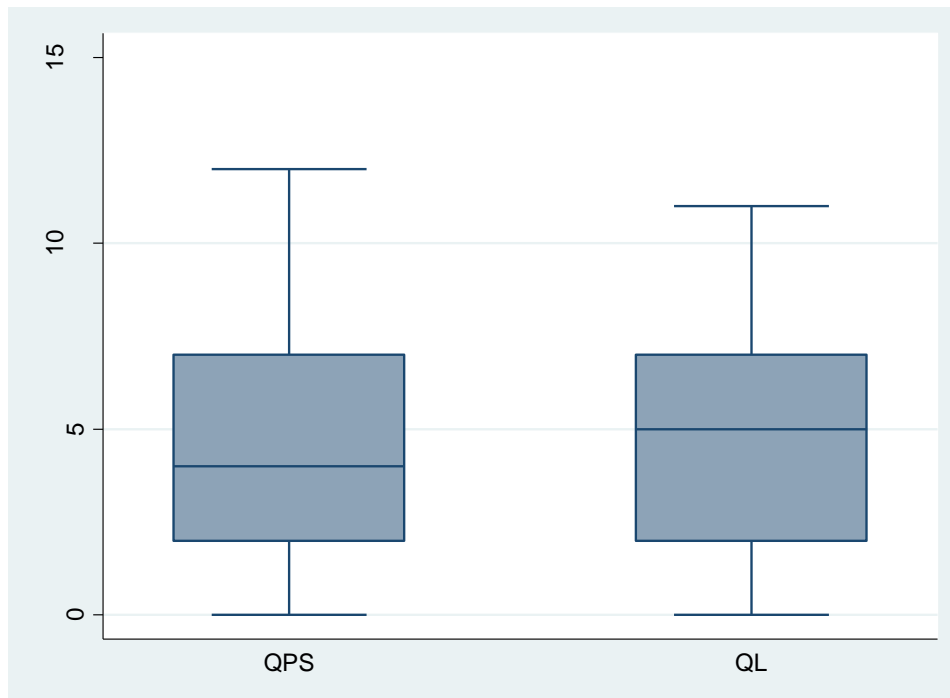
Extroversion scale: the extroversion scale showed equal score between the two groups of intervention (Graph 5). As shown by the Kolmogorov-Smirnov statistic, there are no significant differences between the two groups ($d = .05$; $p = .99$).

Graph 5. Extroversion score.



Neurotism scale: the neurotism scale showed equal score between the two groups of intervention (Graph 6). As shown by the Kolmogorov-Smirnov statistic, there are no significant differences between the two groups ($d = .08$; $p = .06$).

Graph 6. Neurotism score.



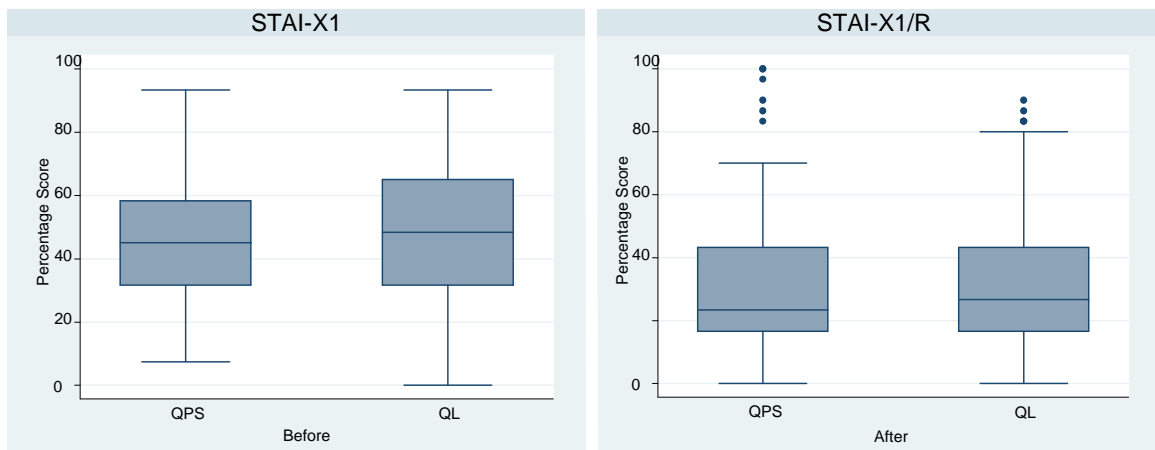
No significant correlation has been found between a high score on the extroversion scale ($r = .08$; $p = .15$) or a low score on the neurotism scale ($r = - .01$; $p = .95$) and the number of questions asked by patients. The correlation was not significant even within the two groups. Respectively the correlation was $r = .02$; $p = .81$ (extroversion); $r = - .03$; $p = .72$ (neurotism) in the QPS group and $r = .13$; $p = .11$ (extroversion); $r = .01$; $p = .87$ (neurotism) in the QL group.

Anxiety

Most of the patients were not anxious (67%) and the anxiety levels were equal between the two groups ($M = 2.39$ and $SD = .57$ in QPS vs. 2.45 and $.62$ in QL; $t_{(302)} = .97$ $p = .33$) prior to the consultation. According to this balanced result we have decided to

consider the anxiety state variation also as a secondary aim, comparing the two states, before (STAI-X1) and after (STAI-X1/R) the consultation. As shown in the two compared box-plots graphs (Graph 7), after the consultations anxiety decrease in similar way in both groups (mean = 1.94 and SD = .64 in QPS vs. 1.93 and .63 in QL $t_{(251)} = .07; p = .94$).

Graph 7. Anxiety comparison before and after the consultation within the two groups of intervention.



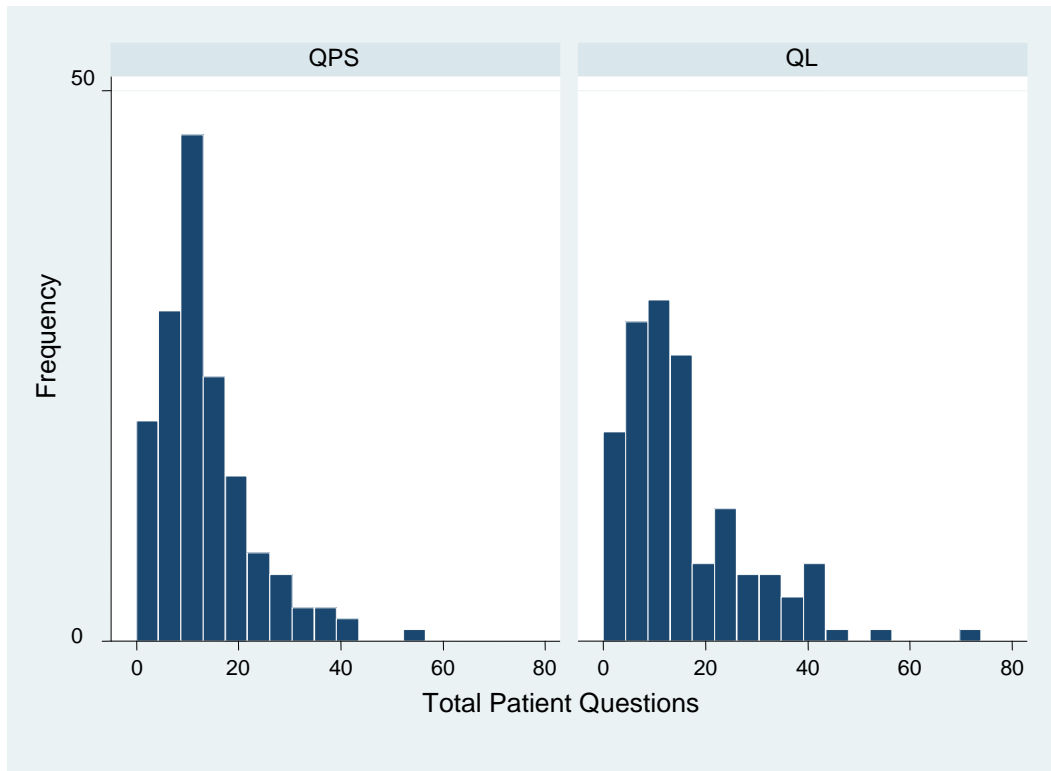
Concerning the depression, most of the patients were not depressed (68%). The difference between the two groups of intervention was not statistically significant even for depression ($\chi^2 = 2.40, p = 0.12$).

4.3.3 Main outcome: impact of the two interventions on question asking

All Patient asked an average of 14 questions (SD = 18.8). Patients in the QPS group asked an average of 13 questions (SD = 9.0), while in the QL group they asked an

average of 16 questions (SD = 12.4). The difference between pooled arms was statistically significant ($t_{(271)} = -1.99, p = .05$).

Graph 8. Question asked distribution



The effect of hierarchical structure of our sample (patients are nested into doctor and doctor nested into centres) was measured by intra-class correlation (ICC, which measures the proportion of the total variability explained by the between-level variance); respectively $ICC(\text{centre}) = .08$ and $ICC(\text{doctor} | \text{centre}) = .12$. The ICC values were moderate (more than 5%) so that the regression model needed to be performed using multilevel techniques.

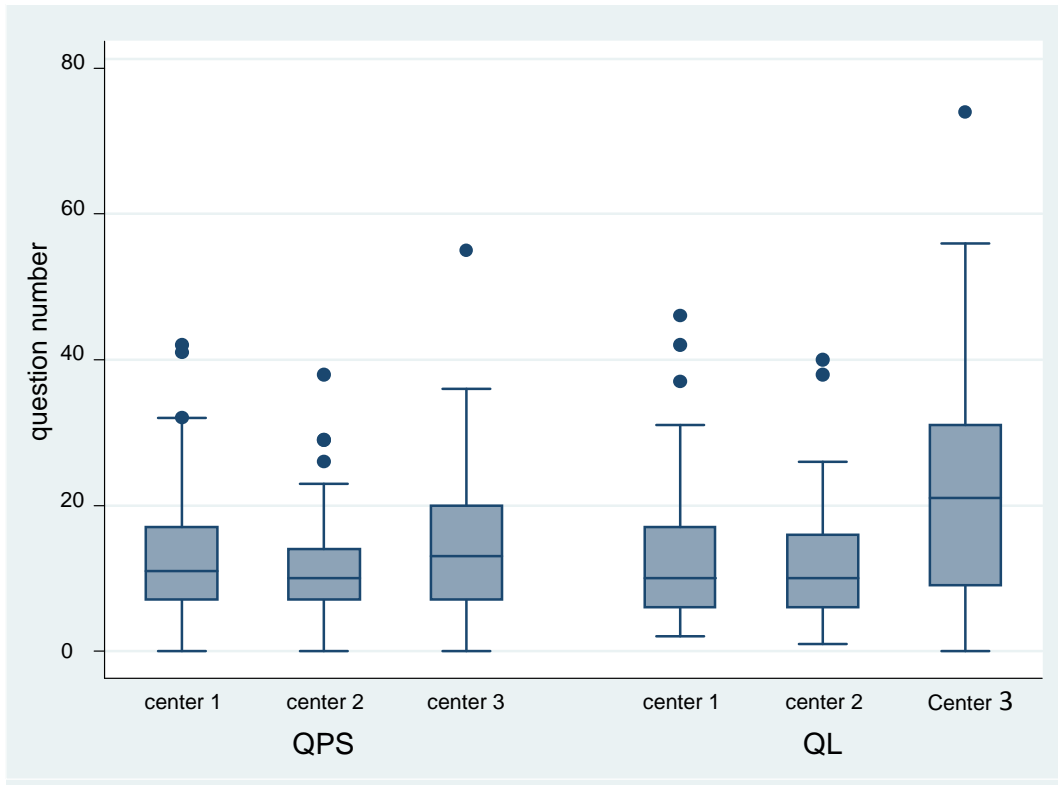
The results obtained by the mixed linear model, taking into account what mentioned above, show that the difference between interventions lost its significance ($b = 1.7$; 95% CI: $-.29 - 3.64$. $p = 9\%$), while the confounding effects, due to consultation length ($b = .29$; 95% CI: $.24 - .33$. $p < 1\%$) and presence of companion ($b = 5.3$; 95% CI: $3.1 - 7.5$ $p < 1\%$) remain already significant (see Table 9).

Table 9. Regression model and Intra-Class Correlation

Variables	β	SE	P-value	95% CI
Groups: QPS vs. QL	1.68	1.00	.09	$-.29 - 3.64$
Presence of companions	5.30	1.12	.00	$3.10 - 7.50$
Length	.29	.024	.00	$.24 - .33$
ICC				
Center	.079	-	-	-
Doctor Center	.117	-	-	-

As illustrated by the Graph 9, there was a slight imbalance in the centers because of a higher average of question asked in center number 3 compared to the other, especially in the QL group.

Graph 9. Question number comparison within centers and groups.



Topics of patient questions

Patient questions were coded by researchers into five main categories describing their contents. They are prevalently addressed to illness management (41.2%) and administrative (32.5%), followed by symptoms (13.9%), prevention (6.9%), prognosis (3.8%) and etiology (1.6%).

Regarding the illness management subcategories, the most frequent questions asked by patients were related to chemotherapy and hormone therapy, in order to better know what they are and how they work. (see Table 10).

Table 10. Mean of question regarding the illness management category in the two groups.

Illness management	QPS		QL		TOTAL	
	Mean	SD	Mean	SD	Mean	SD
Treatment						
Chemotherapy	1.30	2.62	.94	1.73	1.12	2.23
Hormone Therapy	1.09	1.57	1.3	1.85	1.22	1.71
Radiotherapy	.74	1.19	.76	1.30	.75	1.24
Immunotherapy	.14	.73	.08	.54	.11	.64
Surgery*	.54	1.28	.57	1.51	.55	1.40
Other	.16	.49	.14	.47	.15	.48
Side Effects						
Chemotherapy	.75	1.65	.62	1.22	.69	1.45
Hormone Therapy	.54	1.00	.90	1.50	.72	1.28
Radiotherapy	.20	.50	.18	.63	.19	.57
Immunotherapy	.02	.18	.01	.08	.01	.14
Surgery*	.04	.19	.14	.38	.09	.31
Other	.01	.08	.01	.08	.01	.08
Check-Up**	.30	.62	.47	1.05	.38	.86
Other Treatment***	.17	.49	.27	1.19	.22	.90
Other	.01	.08	.01	.12	.01	.10

* Both before and after the consultation

** Mammography, echography, blood test etc.

*** Diseases in co-morbidity

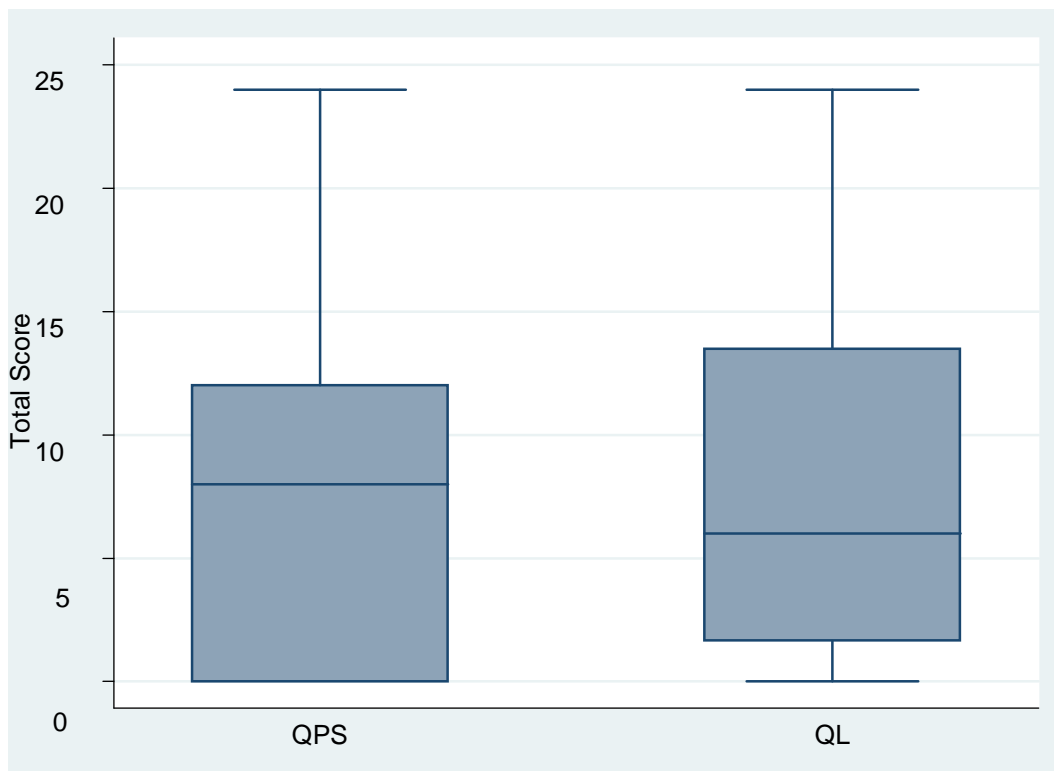
4.3.4 Secondary Outcomes

Concerning the secondary outcomes, it has been adopted the Kolmogorov-Smirnov test for equality of distribution functions to describe the score differences of the questionnaires administered after the consultation in the two groups of interventions.

Shared Decision-Making

The SDMQ showed equal score between the two groups of intervention. As shown by the Kolmogorov-Smirnov there are no significant differences ($d = .08$; $p = .86$), (Graph 10).

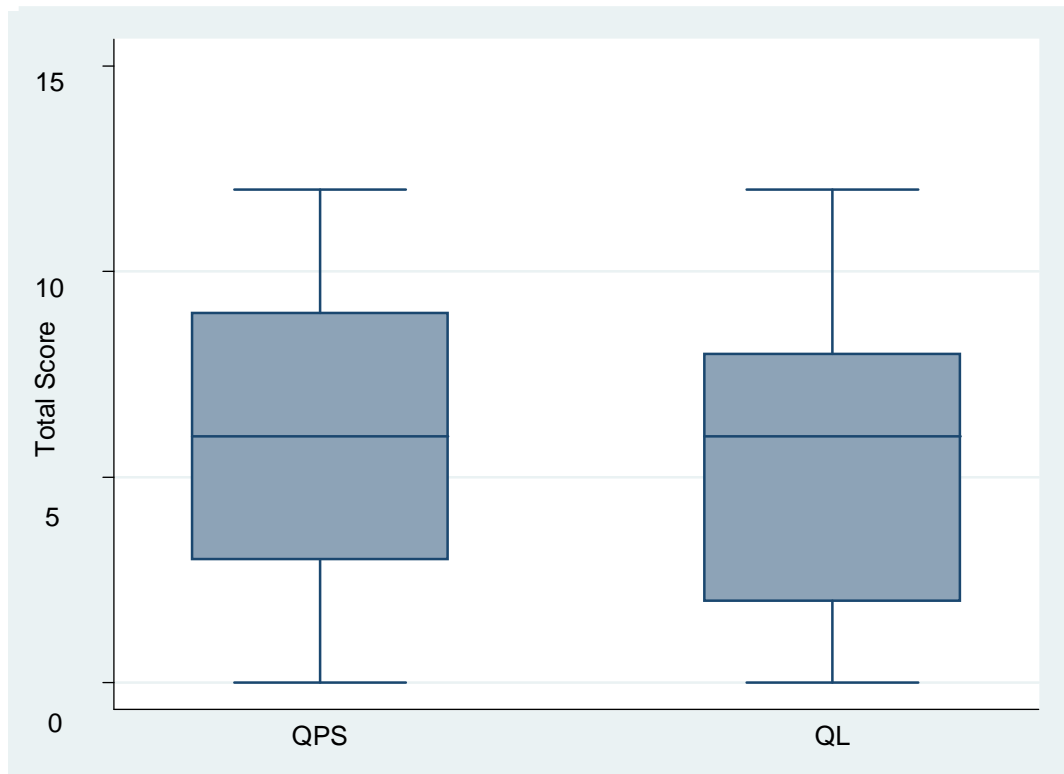
Graph 10. SDMQ score within the two groups.



Patient Enablement

The Patient Enablement Instrument (PEI) showed equal score between the two groups of intervention. As shown by the Kolmogorov-Smirnov test for equality of distribution functions, there are no significant differences ($d = .05$; $p = .99$), (Graph 11).

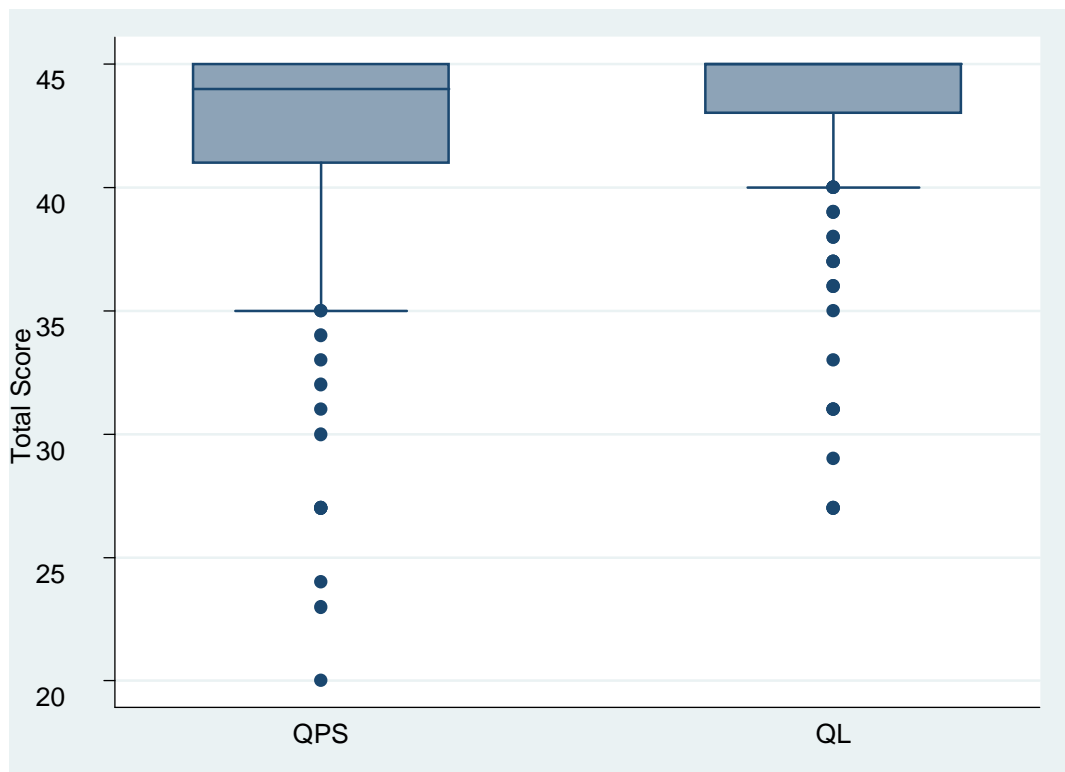
Graph 11. PEI score within the two groups.



Patient-Doctor relationship

The Patient-Doctor Relationship Questionnaire (PDRQ-9) showed equal score between the two groups of intervention. As shown by the Kolmogorov-Smirnov test for equality of distribution functions, there are no significant differences ($d = .16$; $p = .08$) (Graph 12).

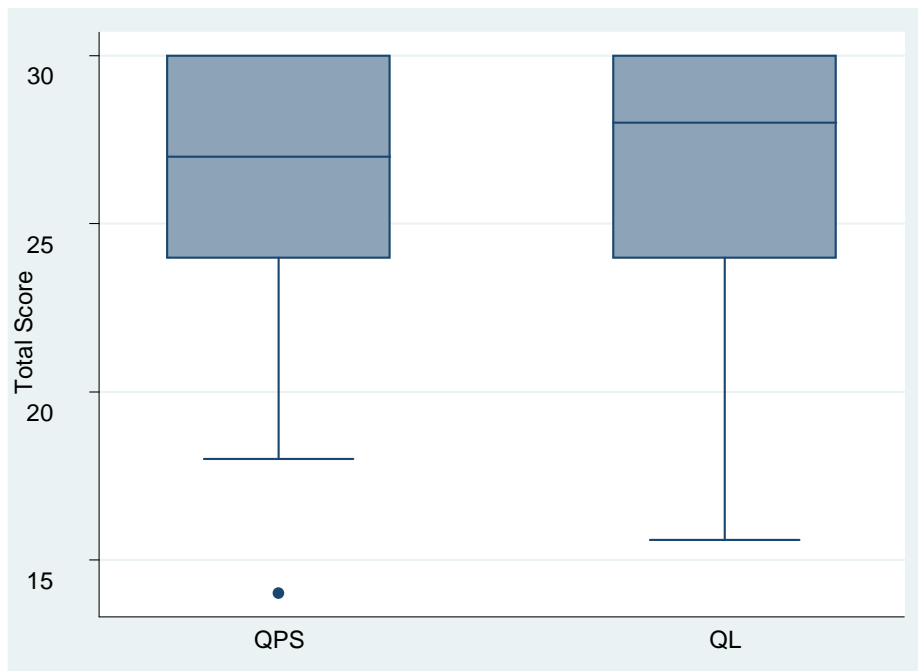
Graph 12. PDRQ-9 score within the two groups.



Satisfaction with decision

Patients showed high levels of satisfaction in both groups (87.5% of patients with a total score higher than 23). As shown by the Kolmogorov-Smirnov test for equality of distribution functions, there are no significant differences ($d = .11$; $p = .38$) (Graph 13).

Graph 13. SWD score within the two groups.



4.4 Discussion

Patients asked a mean of 13 questions in the QPS group and 16 in the QL, confirming previous findings, which showed that cancer patients have many information needs (Jenkins *et al.*, 2001; de Bock *et al.*, 2004). Their information needs were comparable to those reported in the same context in other countries (Siminoff *et al.*, 2000; Butow *et al.*, 2004; Eggle *et al.*, 2011; Clayton *et al.*, 2003; 2007), although Italian patients asked slightly more questions (13-16 in our study vs. 9-13).

We had hypothesized that QPS delivered before the first oncologic consultation would result in patients asking more questions compared to a sample open-ended question (QL) about questions patients wish to ask. No overall increase in question asking was observed in patients receiving a QPS.

We can hypothesize different explanations for our findings.

In our study we compared QPS to an open-ended question (QL) in the other group which can have played an important role as well as the QPS in preparing the patients prior to the consultation to focus better their attention on what they wish to ask their oncologist. Even if we have found that, according to the mixed linear model, the difference between interventions has lost its significance, maybe patients in the QL group ask slightly more questions because of the close and personal nature of those questions. They have the possibility to reflect on their own questions instead of deciding, from a standardized list, those they want to ask. And this can lead to a better recall ability of their questions during the consultation.

We observed no difference between the two groups in the duration of the consultation with a mean duration of 49 minutes (SD = 19.0). These findings are slightly more compared to other studies (Brown *et al.*, 2001; Butow *et al.*, 2002; Clayton *et al.*, 2007). The overall length of the consultation remained unchanged but the time within the consultation might be spent differently. How the oncologist and patient use the time may be as important as the amount of time itself (Wilson *et al.*, 2002). Since the number of questions are quite similar to other studies maybe the Italian oncologists spend more time giving information and explaining carefully all the results.

4.4.1 *Strength, limitations and applicability of findings*

This study explores the effect of QPS delivered before an initial breast cancer consultation in Italy. The sample was large enough to generalise our results to all the patients with the same characteristic (Italian-speaking, female, aged 18-75, breast cancer at an initial stage) referring to the three centres (population in the catching areas about 2.157.305). Results can be extended also to female breast cancer patients in the north of Italy, as services organization and culture are similar; there are doubts about generalizability over all Italy. Results may not be generalizable to other cultural groups, other oncological setting or patients with different stage, therefore replication is recommended.

It has been demonstrated in English speaking countries that a QPS is a useful tool to improve patient's participation during the consultation. However, we contend that consultation communication may vary across cultures and thus there is a need to

explore the efficacy of a QPS in Non English speaking countries to explore cross cultural differences.

To our knowledge there are no published randomized controlled trials in Europe that assess the effects of a pre-consultation QPS on patient and companion communication. Our study has a strong design that incorporates computerised random allocation, blinding of data-collection staff and the use of audio-recordings as an objective measure of consultation communication. The analysis of the consultation recordings is a valuable research method and is a recommended tool for documenting the interaction between patients and oncologists (Tattersall, 2002).

There are some limitations to consider. The QPS in this study was administered before the consultation and collected by the researcher and not available to the patient during the consultation. Thus patients may not remember their questions selected on the QPS and undermine the hypothesis of the greater participation of the QPS intervention group. Moreover some authors (Clyton *et al.*, 2007, Brown *et al.*, 2001) observe that without physician endorsement, the QPS had a limited impact on patient questions. We selected this study method to ensure that participating oncologists were, a) kept blind to the intervention or control status of the patients and b) not forced to change their routine clinical practice.

4.4.2 Clinical implication

The majority of cancer patients in western world now desire full information about their disease, although in all reported studies, there is a small but significant proportion of

patients who prefer minimal information and/or a passive role in decisions about their care (Cassilieth *et al.*, 1980; Degner *et al.*, 1997). Inviting patients to prepare for their consultation (with QPS or just thinking to questions they wish to ask) can be useful to improve patient participation and collaboration and can assist in organising the consultation more efficiently. The opportunity to rehearse their information needs before the consultation can help patients to better focus on them and to use the consultation more efficiently. Preparing for the consultation can modify the process of information exchange, increase patients participation with greater number of satisfied needs, improve satisfaction with the consultation, with potential benefits for treatment adherence and consequently treatment efficacy. Because of the complexity of the interaction between the patient and the oncologist, nevertheless focusing on the patient alone may not produce short and long term benefits for patients. It is plausible that oncologists trained specifically to respond to more active patients can further enhance patient involvement and lead to a more successful consultation. Therefore, changing behaviour of both parties (oncologist and patient) toward the ideal shared decision-making model seems to be the most desirable and the probably most effective intervention. The goal would be to change the overall culture of the consultation, with empowered patients encouraged routinely to identify questions for their oncologists and oncologists effectively trained to identify and adapts to the needs of their patients and to endorse active patients, as part of usual care.

4.4.3 Future directions

Question asking is one indicator of patient involvement in consultations, but what is the desirable number of questions to ask during the usual 20-30 minute consultation? How much information can the patient understand and recall correctly? Moreover, does the great number of patients' questions really represent their information needs, or does it reflect the difficulties of oncologists in providing clear information? We want patients to be more aware of their needs, asking more precise questions to their doctors on one hand, and on the other, to have more skilled doctors to answer those questions. All these are challenging tasks and exploring this aspect would be a worthwhile addition to future research and clinical training.

The impact of an intervention to prepare patients for the consultation used routinely and over time, in terms of cost/effectiveness, needs also to be examined. It is plausible that these preparation interventions may have broad application for facilitating patient and oncologist communication.

Even if we did not find variables associated to question asking, some patients might find the interventions more helpful than others. Further research is needed to identify those patients to whom intervention are likely to be most beneficial.

Finally, increased knowledge of cultural influences on question asking and on doctor-patient communication may contribute to improved mutual understanding between countries. In Europe the advantages of much more mutual understanding may be at medical encounter level with a more fruitful doctor-patient interaction and, at macro-level, with more effective co-operation and integration of European health care policies.

4.5 Conclusion

Patients' involvement and participation in therapeutic programs is of great interest not only to physicians but to all health professionals engaged in improving patients' adherence to treatment regimens or operating in the field of health promotion.

Preparing for the consultation (using QPS or a QL as well) is a quick and simple way of prompting the patients to ask questions and may improve the overall communication between oncologist and patient. Patients can prepare themselves as best they can for the consultation to get the very best out of it. These interventions will be easy to disseminate and to be used in routine clinical practice to increase patient participation. Patients often wait for some time in the waiting room before the visits, and QPS or other preparing sheets, can be used constructively in this time. Adding to this intervention on patient a specific training for oncologist in order to better endorse more active patients in the consultation may allow such interventions to have their full impact on greater patient involvement in decision making processes.

Findings from the present study provided a basis for further research in the field and provide potentially important results for clinicians, patients and policy makers that may lead to a wider use of tools that can help patients to focus on their information need prior the consultation.

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APPENDIX A

LA PARTECIPAZIONE AL PROCESSO INFORMATIVO-DECISIONALE DELLA PAZIENTE AFFETTA DA NEOPLASIA MAMMARIA. UNO STUDIO CLINICO MULTICENTRICO

Informazioni per la paziente

Gentile Signora

Le proponiamo di collaborare ad uno studio sperimentale che ha l'obiettivo di osservare il livello di coinvolgimento della paziente durante la visita medica ed il ruolo dei familiari nel processo informativo-decisionale.

L'obiettivo finale è quello di poter migliorare la qualità delle cure prestate dal nostro Servizio di Oncologia e per dare una risposta sempre più adeguata alle esigenze dei pazienti ed eventualmente dei familiari che li accompagnano.

Le chiediamo di acconsentire:

- a) alla raccolta di alcuni suoi dati personali;
- b) alla audio registrazione del colloquio odierno con l'oncologo;
- c) alla compilazione di 7 questionari prima della visita con l'oncologo (durata complessiva di circa 15 minuti);
- d) alla compilazione di 6 questionari dopo la visita con l'oncologo (durata complessiva circa 15 minuti)

L'audio-registrazione è l'unico modo che ci consente di valutare come avviene lo scambio informativo durante il colloquio.

Verrà garantito il massimo anonimato e il suo nome verrà sostituito con un numero per evitare qualunque possibile identificazione. Avranno accesso ai dati raccolti soltanto le figure professionali coinvolte nella ricerca e che sono comunque tenute a mantenere il segreto professionale.

Tutte le informazioni connesse alla Sua partecipazione saranno trattate in modo strettamente riservato in conformità alle norme sul trattamento dei dati personali (decreto legislativo 196/2003).

La partecipazione a questo studio è completamente volontaria. Lei è libero/a di non partecipare o di ritirarsi in qualsiasi momento (chiedendo di spegnere il registratore in qualsiasi momento del colloquio) senza per questo dover dare alcuna spiegazione; in ogni caso il nostro Servizio di Oncologia continuerà a garantirLe, con la dovuta attenzione, tutta l'assistenza sanitaria di cui ha bisogno.

Firma del paziente per presa visione.....

Nome in stampatello del ricercatore che ha informato la paziente.....

Firma del ricercatore che ha informato la paziente.....

Luogo.....Data.....

[Se la paziente non è in grado di leggere o di firmare, un testimone indipendente dallo staff dello studio deve essere presente durante l'intera discussione relativa al consenso informato. Il testimone deve firmare e datare personalmente la dichiarazione di consenso informato dopo che il modulo stesso e qualsiasi altra informazione scritta siano stati letti e spiegati al soggetto e questi abbia espresso il consenso verbale alla partecipazione allo studio].

In questo caso:

Nome in stampatello del testimone.....

Firma del testimone indipendente.....

LA PARTECIPAZIONE AL PROCESSO INFORMATIVO-DECISIONALE DELLA PAZIENTE AFFETTA DA NEOPLASIA MAMMARIA. UNO STUDIO CLINICO MULTICENTRICO

Informazioni per il familiare

Gentile Signora/Signore

Le proponiamo di collaborare ad uno studio sperimentale che ha l'obiettivo di osservare il livello di coinvolgimento della paziente durante la visita medica ed il ruolo dei familiari nel processo informativo-decisionale.

L'obiettivo finale è quello di poter migliorare la qualità delle cure prestate dal nostro Servizio di Oncologia e per dare una risposta sempre più adeguata alle esigenze dei pazienti ed eventualmente dei familiari che li accompagnano.

Le chiediamo di acconsentire:

- a) alla raccolta di alcuni suoi dati personali;
- b) alla audio registrazione del colloquio odierno con l'oncologo;
- c) alla compilazione di 7 questionari prima della visita con l'oncologo (durata complessiva di circa 15 minuti);
- d) alla compilazione di 6 questionari dopo la visita con l'oncologo (durata complessiva circa 15 minuti)

L'audio-registrazione è l'unico modo che ci consente di valutare come avviene lo scambio informativo durante il colloquio.

Verrà garantito il massimo anonimato e il suo nome verrà sostituito con un numero per evitare qualunque possibile identificazione. Avranno accesso ai dati raccolti soltanto figure professionali che sono tenute a mantenere il segreto professionale.

Tutte le informazioni connesse alla Sua partecipazione saranno trattate in modo strettamente riservato in conformità alle norme sul trattamento dei dati personali (decreto legislativo 196/2003).

La partecipazione a questo studio è completamente volontaria. Lei è libera di non partecipare o di ritirarsi in qualsiasi momento (chiedendo di spegnere il registratore, durante o alla fine del colloquio) senza per questo dover dare alcuna spiegazione; in ogni caso il nostro Servizio di Oncologia continuerà a garantire al Suo familiare, con la dovuta attenzione, tutta l'assistenza sanitaria di cui ha bisogno.

Luogo.....Data.....

Firma del familiare per presa visione.....

Nome in stampatello del ricercatore che ha informato il familiare.....

Firma del ricercatore che ha informato il familiare.....

Luogo.....Data.....

SCHEDA RACCOLTA DATI

Paziente

Data _____

NOME E COGNOME _____ N° Paziente _____

DATA DI NASCITA _____

RECAPITO TELEFONICO _____

STATO CIVILE Nubile

Coniugata/convivente

Vedova

Separata/divorziata

N° FIGLI _____ ETA' DEI FIGLI _____

SCOLARITA':

Analfabeta Alfabeto senza titolo di studio Licenza elementare

Licenza media inferiore

Diploma

Laurea

PROFESSIONE/OCCUPAZIONE:

Occupata/o

Disoccupata/o

Casalinga

Ritirata/o dal lavoro/Pensionata/o

Studente/ssa

Altro (specificare) _____

La paziente rifiuta di partecipare allo studio

Motivo del rifiuto: _____

Familiari presenti e grado di parentela: _____

CRITERI D'ESCLUSIONE

La paziente ha un'età sotto i 18 o sopra i 75 anni

La paziente non comprende bene la lingua italiana

La paziente presenta metastasi (Tx, Nx, M1)

La paziente presenta una recidiva (non è al primo episodio)

**SCHEDA RACCOLTA DATI
Familiare**

Data _____

NOME E COGNOME _____

N° Paziente _____

DATA DI NASCITA _____

Sesso: M F

STATO CIVILE Nubile/Celibe

Coniugato/a/Convivente

Vedovo/a

Separato/a/divorziato/a

N° FIGLI _____ **ETA'** _____

SCOLARITA':

Analfabeta Alfabeto senza titolo di studio Licenza elementare

Licenza media inferiore Diploma Laurea

PROFESSIONE/OCCUPAZIONE:

Occupata/o Disoccupata/o Casalinga

Ritirata/o dal lavoro/Pensionata/o Studente/ssa

Altro (specificare) _____

LEGAME DI PARENTELA CON LA PAZIENTE

Marito Figlio/a Fratello/Sorella Padre/Madre

Cognato/Nuora Cugino/a Zio/a Amico/a

Altro (Specificare) _____

VIVE CON LA PAZIENTE Sì No

Il familiare rifiuta di partecipare allo studio

Motivo del rifiuto: _____

SCHEDA RACCOLTA DATI
Oncologo

Data _____

Iniziali della Paziente _____

N° Paziente _____

INFORMAZIONI RIGUARDANTI IL MEDICO	Iniziali _____	codice _____
Età _____	Anni d'esperienza lavorativa _____	
Sesso: Maschio <input type="checkbox"/>	Femmina <input type="checkbox"/>	

PRESENZA ALTRO MEDICO	Iniziali _____	codice _____
Età _____	Anni d'esperienza lavorativa _____	
Sesso: Maschio <input type="checkbox"/>	Femmina <input type="checkbox"/>	

PRESENZA MEDICO SPECIALIZZANDO	SI <input type="checkbox"/>	NO <input type="checkbox"/>

La paziente chiede di interrompere la registrazione durante la visita

CRITERI D'ESCLUSIONE	
La paziente presenta metastasi (Tx, Nx, M1)	<input type="checkbox"/>
La paziente presenta una recidiva (non è al primo episodio)	<input type="checkbox"/>
La paziente non comprende bene la lingua italiana	<input type="checkbox"/>

La paziente non ha un cancro	<input type="checkbox"/>

INFORMAZIONI RIGUARDANTI LA PAZIENTE

Da quanto tempo la paziente sa della propria malattia (giorni / mesi) _____

Chi ha informato la paziente della diagnosi:

Medico di base Chirurgo Radiologo Oncologo
Altro medico (specificare) _____

Data del I° intervento chirurgico effettuato: _____

Tipo d'intervento:

Conservativo Non conservativo
Ricostruzione sì no
Linfonodo sentinella: sì no
Svuotamento ascellare: sì no
IORT: sì no

Stadio clinico di malattia attuale

Stadiazione: c (clinica) p (patologica)
Carcinoma Lobulare/Duttale in Situ: (LCIS) (DCIS)
T: TX T0 Tis T1 T2 T3 T4
N: NX N0 N1 N2 N3
M: MX M0 M1

Patologie associate:

Diabete Iperensione
Osteoporosi Iper/ipotiroidismo
Ansia/Depressione Altro _____

Terapia farmacologica in atto: _____

Menopausa sì no

Rilevazione peso: kg _____ **Rilevazione altezza:** cm _____

Piano terapeutico concordato con la paziente al termine della visita:

Chemioterapia prevista sì no
Radioterapia prevista sì no
Ormonoterapia prevista sì no
Immunoterapia prevista sì no
Allargamento chirurgico sì no
Da rivalutare dopo ulteriori accertamenti sì no
Svuotamento ascellare sì no
Mastectomia sì no
Altro _____

Eventuale prossima visita no sì data _____

APPENDIX B

QUESTIONARI PRE-COLLOQUIO

N° paziente _____

Data _____

Istruzioni:

Sono di seguito riportate alcune frasi che le persone spesso usano per descriversi. Legga ciascuna frase e poi contrassegni con una crocetta la risposta come Lei si sente ADESSO, cioè in questo momento, mentre sta iniziando a compilare questo test. Non ci sono risposte giuste o sbagliate. Risponda a TUTTE le domande. Non impieghi troppo tempo per rispondere alle domande e scelga la sua risposta tra le seguenti:

PER NULLA UN POCO ABBASTANZA MOLTISSIMO

	PER NULLA	UN POCO	ABBASTANZA	MOLTISSIMO
1. Misentocalmo	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Misentosicuro.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Sonoteso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Hodeirimpianti.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Misentotranquillo.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Misentoturbato.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Sono attualmente preoccupato per possibili disgrazie.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Misento riposato.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Misentoansioso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Mi sento a mio agio.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Mi sento sicuro di me.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Misentonervoso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Son agitato	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Misentomoltoteso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Sonorilassato.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Misentocontento.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Sonopreoccupato.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Mi sento sovraeccitato e scosso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Misento allegro.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Misentobene.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Qui sotto sono elencati alcuni aspetti importanti che riguardano il riuscire a prendere delle decisioni.

Per favore indichi quanta fiducia ha in se stesso nel fare le seguenti cose, scegliendo un numero da 0 (per nulla fiducioso) a 4 (molto fiducioso)

Mi sento fiducioso di:

	Per nullafiduci oso	1	2	3	Molto fiducioso
1. Riuscire ad ottenere le informazioni sulle varie medicine disponibili per me	0	1	2	3	4
2. Riuscire ad ottenere le informazioni rispetto ai benefici delle possibili cure	0	1	2	3	4
3. Riuscire ad ottenere le informazioni rispetto ai rischi e agli effetti collaterali delle cure	0	1	2	3	4
4. Comprendere le informazioni abbastanza per poter prendere una decisione	0	1	2	3	4
5. Porre domande senza sentirmi stupido	0	1	2	3	4
6. Esprimere le mie preoccupazioni rispetto alle possibili cure	0	1	2	3	4
7. Chiedere consigli	0	1	2	3	4
8. Riuscire a trovare le cure che si adattano di più a me	0	1	2	3	4
9. Gestire le eventuali pressioni di altri nella scelta delle cure	0	1	2	3	4
10. Far sapere a coloro che mi hanno in cura qual è la cosa migliore per me	0	1	2	3	4
11. Rimandare la decisione se sento di aver bisogno di più tempo	0	1	2	3	4

Per favore leggete attentamente quanto segue e rispondete a tutte le domande. Rispondete con sincerità. I dati di questo questionario saranno tenuti riservati e saranno utilizzati solo per scopi statistici e scientifici.

Vorremmo sapere se, **durante le ultime settimane**, avete avuto qualche disturbo di tipo medico e in generale come è il Vostro stato di salute. Rispondete, per favore, semplicemente mettendo una X sulla risposta che meglio si adatta a Voi. Ricordate che vorremmo conoscere i disturbi di cui soffrite o di cui avete sofferto recentemente (nelle ultime settimane), non i disturbi di molto tempo fa.

Vi ringraziamo in anticipo per la vostra collaborazione. È importante che Voi tentiate di rispondere a tutte le domande.

RECENTEMENTE:

1. Avete perso molto sonno per delle preoccupazioni?	No	Non più del solito	Un po' più del solito	Molto più del solito
2. Vi siete sentiti costantemente sotto stress (tensione)?	No	Non più del solito	Un po' più del solito	Molto più del solito
3. Siete stato in grado di meno concentrarvi sulle cose che facevate?	Meglio del solito	Come al solito	Meno del solito	Molto del solito
4. Vi siete sentiti utili? meno	Più del solito	Come al solito	Meno utile del solito	Molto del solito
5. Siete stato in grado di affrontare meno i vostri problemi?	Più del solito	Come al solito	Meno del solito	Molto del solito
6. Vi siete sentiti capaci di meno prendere decisioni?	Più del solito	Come al solito	Meno del solito	Molto del solito
7. Avete avuto l'impressione di non essere in grado di superare le difficoltà?	No	Non più del solito	Un po' più del solito	Molto più del solito
8. Vi siete sentiti, tutto sommato, abbastanza contenti?	Più del solito	Circa come al solito	Meno del solito	Molto meno del solito
9. Siete stati in grado di svolgere meno volentieri le vostre attività quotidiane?	Più del solito	Come al solito	Meno	Molto
10. Vi siete sentiti infelici o depressi?	No	Non più del solito	Un po' più del solito	Molto più del solito
11. Avete perso fiducia in voi stessi?	No	Non più del solito	Un po' più del solito	Molto più del solito
12. Avete pensato di essere una persona senza valore?	No	Non più del solito	Un po' più del solito	Molto più del solito

Nelle ultime 2 settimane, con quale frequenza le ha dato fastidio ciascuno dei seguenti problemi?

	Mai	Alcuni giorni	Per più della metà del tempo	Quasi ogni giorno
1. Scarso interesse o piacere nel fare le cose	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Sentirsi giù, triste o disperato/a	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Problemi ad addormentarsi o a dormire tutta la notte senza svegliarsi, o a dormire troppo	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Sentirsi stanco/a o avere poca energia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Scarso appetito o mangiare troppo	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Avere una scarsa opinione di sé, o sentirsi un fallimento o aver deluso se stesso/a o i propri familiari	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Difficoltà a concentrarsi su qualcosa, per esempio leggere il giornale o guardare la televisione	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Muoversi o parlare così lentamente da poter essere notato/a da altre persone. O, al contrario, essere così irrequieto/a da muoversi molto più del solito	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Pensare che sarebbe meglio morire o farsi del male in un modo o nell'altro	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Istruzioni:

Le domande seguenti si riferiscono ad abitudini, comportamenti, tratti del carattere che una persona può avere.

Non vi sono risposte giuste o sbagliate: quello che importa è che risponda a TUTTE le domande pensando effettivamente al suo usuale modo di essere e di comportarsi.

La preghiamo di leggere attentamente una domanda alla volta e di scegliere la sua risposta tra

1. Ho frequenti sbalzi d'umore? SI NO
2. Sono una persona che parla volentieri? SI NO
3. Mi capita mai di sentirmi depresso senza alcuna ragione? SI NO
4. Sono piuttosto allegro di carattere? SI NO
5. Mi irrita facilmente? SI NO
6. Mi piace incontrare gente nuova? SI NO
7. Basta poco per ferire la mia sensibilità? SI NO
8. In una festa animata, riesco in genere a lasciarmi andare, sentirmi a mio agio e divertirmi? SI NO
9. Ho spesso la sensazione di "non poterne proprio più"? SI NO
10. In generale, sono io a prendere l'iniziativa quando si tratta di fare amicizia con qualcuno? SI NO
11. Mi considero una persona nervosa? SI NO
12. Sarei facilmente capace di animare una festa noiosa? SI NO
13. Mi preoccupa facilmente? SI NO
14. Quando sto con la gente, tendo a starmene in disparte? SI NO
15. Mi considero una persona tesa e nervosa? SI NO
16. Mi piace stare in mezzo alla gente? SI NO
17. Mi preoccupa per troppo tempo, dopo un'esperienza imbarazzante? SI NO
18. Mi piace avere tanto movimento e animazione intorno a me? SI NO
19. Soffro di "nervi"? SI NO
20. Me ne sto per lo più in silenzio quando mi trovo con la gente? SI NO
21. Mi sento spesso solo? SI NO
22. La gente mi considera pieno di vitalità? SI NO
23. Ho spesso dei sensi di colpa? SI NO
24. Sono capace di animare una festa? SI NO

Per favore, tra le situazioni sotto rappresentate, indichi segnando con il **numero "1"** quella che, secondo lei meglio la rappresenta. Dopo aver escluso quella vignetta indichi anche una scelta alternativa indicandola con il **numero "2"**.

Voglio avere l'ultima parola sulla mia terapia



Voglio avere l'ultima parola sulla mia terapia, dopo aver valutato attentamente il parere del mio medico



Voglio condividere con il mio medico la decisione sulla terapia più adatta a me



Voglio lasciare al mio medico l'ultima parola sulla terapia che riceverò, dopo una sua attenta valutazione del mio parere



Voglio lasciare al mio medico ogni decisione sulla mia terapia



QUESTIONARI POST-COLLOQUIO

N° paziente _____

Data _____

Per favore indichi quale decisione è stata presa durante l'ultima visita medica:

Di seguito troverà nove frasi che descrivono come si è svolto l'incontro con l'oncologo per quanto riguarda **le decisioni riguardo il trattamento del suo problema di salute**. Per favore barri per ogni affermazione la casella più appropriata per lei.

Faccia sempre riferimento a **quanto le seguenti affermazioni corrispondono a ciò che è realmente accaduto durante la visita che ha appena effettuato** con l'oncologo.

	Sì, esattamente	Sì, più o meno	Più no che sì	No, affatto
1. L'oncologo mi ha comunicato chiaramente che deve essere presa una decisione	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. L'oncologo voleva sapere da me esattamente come volessi partecipare alla decisione	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. L'oncologo mi ha comunicato che esistono diverse possibilità di trattamento per i miei disturbi	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. L'oncologo mi ha spiegato esattamente vantaggi e svantaggi delle diverse possibilità di trattamento	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. L'oncologo mi ha aiutato a capire tutte le informazioni	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. L'oncologo mi ha chiesto quale possibile trattamento preferissi	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. L'oncologo ed io abbiamo valutato accuratamente le diverse possibilità di trattamento	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. L'oncologo ed io abbiamo scelto insieme un trattamento	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. L'oncologo ed io abbiamo trovato un accordo su come procedere in seguito	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Dopo la visita di oggi con il medico mi sento:

	Molto di più	Di più	Uguale o meno	Non applicabile
1. Capace di affrontare la vita				
2. Capace di capire la mia malattia				
3. Capace di affrontare la mia malattia				
4. Capace di mantenermi in buona salute				
5. Fiducioso rispetto alla mia salute				
6. Capace di poter contare su me stesso				

Per favore indichi quanto si sente d'accordo con le seguenti affermazioni riguardanti le decisioni terapeutiche prese durante la visita di oggi.

	Fortemente in disaccordo	Disaccordo	Neutro	D'accordo	Completamente d'accordo
	(1)	(2)	(3)	(4)	(5)
1. Sono stato adeguatamente informato rispetto alle possibili cure disponibili per la mia malattia					
2. La decisione presa secondo me è la migliore per il mio caso					
3. La decisione presa è in linea con i miei valori					
4. Mi aspetto di portare avanti la decisione presa con successo					
5. Ho avuto le informazioni che desideravo per la scelta delle cure					
6. Sono soddisfatto della decisione presa rispetto alle cure					

Leggerà 9 affermazioni che un paziente può fare rispetto all'oncologo che l'ha visitata oggi.

Per favore indichi quanto è appropriata ognuna delle seguenti affermazioni riguardo all'oncologo che l'ha visitata oggi.

	Per nullaappro priato (1)	Pocoapprop riato (2)	Appropriato (3)	Abbastanza appropriato (4)	Completamentea ppropriato (5)
1. L'oncologo mi ha aiutata					
2. L'oncologo mi ha dedicato abbastanza tempo					
3. Ho fiducia nell'oncologo					
4. L'oncologo mi ha capito					
5. L'oncologo si è mostrato disponibile ad aiutarmi					
6. Io e l'oncologo siamo d'accordo sulla natura dei miei sintomi					
7. E' facile parlare con l'oncologo					
8. Sono soddisfatto del trattamento medico ricevuto					
9. Trovo il servizio facilmente accessibile					

	Per nulla	Poco	Abbastanza	Molto	Moltissimo
1. Secondo lei l'oncologo quanto è riuscito a rispondere in maniera chiara e completa alle sue domande?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Quanto sente il bisogno di ricevere altre informazioni oltre a quelle ricevute oggi?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. È stato deciso quali saranno le sue cure?

SI

NO

4. Di **quali terapie** Le ha parlato l'oncologo?

5. Quali informazioni Le ha dato l'oncologo su come si svolgerà la sua terapia, per esempio **durata, frequenza, modalità di somministrazione** (es. farmaci endovena, per bocca, durata, ecc)?

6. Quali informazioni Le ha dato l'oncologo sui possibili **effetti collaterali** indesiderati delle cure?

7. Quali informazioni Le ha dato l'oncologo su cosa si può fare per **controllare e ridurre i possibili effetti collaterali** delle cure?

8. Quali informazioni Le ha dato l'oncologo su quanto sono **efficaci le terapie** nel curare e controllare la sua malattia?

9. L'oncologo le ha consigliato delle **visite di controllo**? Se sì, **di che tipo e con che frequenza**?

Istruzioni:

Legga ciascuna frase e poi contrassegni la risposta che indica come lei si sente ADESSO, cioè in questo momento, ora che ha completato i suoi test. Risponda a TUTTE le domande. Scelga la risposta che le sembra meglio descrivere il suo stato d'animo ATTUALE. Scelga tra le seguenti risposte:

PER NULLA UN POCO ABBASTANZA MOLTISSIMO

	PER NULLA	UN POCO	ABBASTANZA	MOLTISSIMO
1. Misentocalmo.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Sonoteso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Misentotranquillo.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Misentoturbato.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Misento riposato.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Misentoansioso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Misentonervoso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Son agitato	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Sonopreoccupato.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Misentobene.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

APPENDIX C

QUESTIONARI PRE-COLLOQUIO
Familiare F

N° paziente _____

Data _____

Istruzioni:

Sono di seguito riportate alcune frasi che le persone spesso usano per descriversi. Legga ciascuna frase e poi contrassegni con una crocetta la risposta come Lei si sente ADESSO, cioè in questo momento, mentre sta iniziando a compilare questo test. Non ci sono risposte giuste o sbagliate. Risponda a TUTTE le domande. Non impieghi troppo tempo per rispondere alle domande e scelga la sua risposta tra le seguenti:

PER NULLA UN POCO ABBASTANZA MOLTISSIMO

	PER NULLA	UN POCO	ABBASTANZA	MOLTISSIMO
1. Misentocalmo	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Misentosicuro.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Sonoteso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Hodeirimpianti.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Misentotranquillo.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Misentoturbato.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Sono attualmente preoccupato per possibili disgrazie.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Misento riposato.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Misentoansioso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Mi sento a mio agio.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Mi sento sicuro di me.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Misentonervoso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Son agitato	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Misentomoltoteso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Sonorilassato.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Misentocontento.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Sonopreoccupato.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Mi sento sovraeccitato e scosso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Misento allegro.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Misentobene.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Qui sotto sono elencati alcuni aspetti importanti che riguardano il riuscire a prendere delle decisioni.

Per favore indichi quanta fiducia ha in se stesso nel fare le seguenti cose, scegliendo un numero da 0 (per nulla fiducioso) a 4 (molto fiducioso)

Mi sento fiducioso di:

	Per nullafiducioso	1	2	3	Molto fiducioso
1. Riuscire ad ottenere le informazioni sulle varie medicine disponibili per il mio familiare	0	1	2	3	4
2. Riuscire ad ottenere le informazioni rispetto ai benefici delle possibili cure	0	1	2	3	4
3. Riuscire ad ottenere le informazioni rispetto ai rischi e agli effetti collaterali delle cure	0	1	2	3	4
4. Comprendere le informazioni abbastanza per poter prendere una decisione	0	1	2	3	4
5. Porre domande senza sentirmi stupido	0	1	2	3	4
6. Esprimere le mie preoccupazioni rispetto alle possibili cure	0	1	2	3	4
7. Chiedere consigli	0	1	2	3	4
8. Riuscire a trovare le cure che si adattano di più al mio familiare	0	1	2	3	4
9. Gestire le eventuali pressioni di altri nella scelta delle cure	0	1	2	3	4
10. Far sapere a coloro che hanno in cura il mio familiare qual è la cosa migliore per lui	0	1	2	3	4
11. Rimandare la decisione se sentiamo di aver bisogno di più tempo	0	1	2	3	4

Per favore leggete attentamente quanto segue e rispondete a tutte le domande. Rispondete con sincerità. I dati di questo questionario saranno tenuti riservati e saranno utilizzati solo per scopi statistici e scientifici.

Vorremmo sapere se, **durante le ultime settimane**, avete avuto qualche disturbo di tipo medico e in generale come è il Vostro stato di salute. Rispondete, per favore, semplicemente mettendo una X sulla risposta che meglio si adatta a Voi. Ricordate che vorremmo conoscere i disturbi di cui soffrite o di cui avete sofferto recentemente (nelle ultime settimane), non i disturbi di molto tempo fa.

Vi ringraziamo in anticipo per la Vostra collaborazione. È importante che Voi tentiate di rispondere a tutte le domande.

RECENTEMENTE:

1. Avete perso molto sonno per delle preoccupazioni?	No	Non più del solito	Un po' più del solito	Molto più del solito
2. Vi siete sentiti costantemente sotto stress (tensione)?	No	Non più del solito	Un po' più del solito	Molto più del solito
3. Siete stato in grado di meno concentrarvi sulle cose che facevate?	Meglio del solito	Come al solito	Meno del solito	Molto del solito
4. Vi siete sentiti utili? meno	Più del solito	Come al solito	Meno utile del solito	Molto del solito
5. Siete stato in grado di affrontare meno i vostri problemi?	Più del solito	Come al solito	Meno del solito	Molto del solito
6. Vi siete sentiti capaci di meno prendere decisioni?	Più del solito	Come al solito	Meno del solito	Molto del solito
7. Avete avuto l'impressione di non essere in grado di superare le difficoltà?	No	Non più del solito	Un po' più del solito	Molto più del solito
8. Vi siete sentiti, tutto sommato, abbastanza contenti?	Più del solito	Circa come al solito	Meno del solito	Molto meno del solito
9. Siete stati in grado di svolgere meno volentieri le vostre attività quotidiane?	Più del solito	Come al solito	Meno	Molto
10. Vi siete sentiti infelici o depressi?	No	Non più del solito	Un po' più del solito	Molto più del solito
11. Avete perso fiducia in voi stessi?	No	Non più del solito	Un po' più del solito	Molto più del solito
12. Avete pensato di essere una persona senza valore?	No	Non più del solito	Un po' più del solito	Molto più del solito

PHQ – 9 - Familiare

Nelle ultime 2 settimane, con quale frequenza le ha dato fastidio ciascuno dei seguenti problemi?

	Mai	Alcuni giorni	Per più della metà del tempo	Quasi ogni giorno
1. Scarso interesse o piacere nel fare le cose	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Sentirsi giù, triste o disperato/a	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Problemi ad addormentarsi o a dormire tutta la notte senza svegliarsi, o a dormire troppo	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Sentirsi stanco/a o avere poca energia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Scarso appetito o mangiare troppo	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Avere una scarsa opinione di sé, o sentirsi un fallimento o aver deluso se stesso/a o i propri familiari	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Difficoltà a concentrarsi su qualcosa, per esempio leggere il giornale o guardare la televisione	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Muoversi o parlare così lentamente da poter essere notato/a da altre persone. O, al contrario, essere così irrequieto/a da muoversi molto più del solito	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Pensare che sarebbe meglio morire o farsi del male in un modo o nell'altro	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Istruzioni:

Le domande seguenti si riferiscono ad abitudini, comportamenti, tratti del carattere che una persona può avere.

Non vi sono risposte giuste o sbagliate: quello che importa è che risponda a TUTTE le domande pensando effettivamente al suo usuale modo di essere e di comportarsi.

La preghiamo di leggere attentamente una domanda alla volta e di scegliere la sua risposta tra

1. Ho frequenti sbalzi d'umore? SI NO
2. Sono una persona che parla volentieri? SI NO
3. Mi capita mai di sentirmi depresso senza alcuna ragione? SI NO
4. Sono piuttosto allegro di carattere? SI NO
5. Mi irrita facilmente? SI NO
6. Mi piace incontrare gente nuova? SI NO
7. Basta poco per ferire la mia sensibilità? SI NO
8. In una festa animata, riesco in genere a lasciarmi andare, sentirmi a mio agio e divertirmi? SI NO
9. Ho spesso la sensazione di "non poterne proprio più"? SI NO
10. In generale, sono io a prendere l'iniziativa quando si tratta di fare amicizia con qualcuno? SI NO
11. Mi considero una persona nervosa? SI NO
12. Sarei facilmente capace di animare una festa noiosa? SI NO
13. Mi preoccupa facilmente? SI NO
14. Quando sto con la gente, tendo a starmene in disparte? SI NO
15. Mi considero una persona tesa e nervosa? SI NO
16. Mi piace stare in mezzo alla gente? SI NO
17. Mi preoccupa per troppo tempo, dopo un'esperienza imbarazzante? SI NO
18. Mi piace avere tanto movimento e animazione intorno a me? SI NO
19. Soffro di "nervi"? SI NO
20. Me ne sto per lo più in silenzio quando mi trovo con la gente? SI NO
21. Mi sento spesso solo? SI NO
22. La gente mi considera pieno di vitalità? SI NO
23. Ho spesso dei sensi di colpa? SI NO
24. Sono capace di animare una festa? SI NO

Per favore, tra le situazioni sotto rappresentate, indichi segnando con il **numero "1"** quella che, secondo lei meglio la rappresenta. Dopo aver escluso quella vignetta indichi anche una scelta alternativa indicandola con il **numero "2"**.

Voglio avere l'ultima parola sulla mia terapia



Voglio avere l'ultima parola sulla mia terapia, dopo aver valutato attentamente il parere del mio medico



Voglio condividere con il mio medico la decisione sulla terapia più adatta a me



Voglio lasciare al mio medico l'ultima parola sulla terapia che riceverò, dopo una sua attenta valutazione del mio parere



Voglio lasciare al mio medico ogni decisione sulla mia terapia



QUESTIONARI POST-COLLOQUIO
FAMILIARE

N° paziente _____

Data _____

Per favore indichi quale decisione è stata presa durante l'ultima visita medica:

Di seguito troverà nove frasi che descrivono come si è svolto l'incontro con l'oncologo per quanto riguarda **le decisioni riguardo il trattamento del problema di salute del suo familiare**.

Per favore barri per ogni affermazione la casella più appropriata per lei.

Faccia sempre riferimento a **quanto le seguenti affermazioni corrispondono a ciò che è realmente accaduto durante la visita appena effettuata con l'oncologo**.

	Sì, esattamente	Sì, più o meno	Più no che sì	No, affatto
1. L'oncologo ha comunicato chiaramente che deve essere presa una decisione	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. L'oncologo voleva sapere esattamente come il mio familiare volesse partecipare alla decisione	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. L'oncologo ha comunicato che esistono diverse possibilità di trattamento	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. L'oncologo ha spiegato esattamente vantaggi e svantaggi delle diverse possibilità di trattamento	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. L'oncologo ha aiutato a capire tutte le informazioni	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. L'oncologo ha chiesto quale possibile trattamento preferisse il mio familiare	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. L'oncologo ha valutato accuratamente con il mio familiare le diverse possibilità di trattamento	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. L'oncologo ha scelto insieme al mio familiare un trattamento	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. L'oncologo ha trovato un accordo con il mio familiare su come procedere in seguito	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Dopo la visita di oggi con il medico mi sento:

	Molto di più	Di più	Uguale o meno	Non applicabile
1. Capace di affrontare la vita				
2. Capace di capire la malattia del mio familiare				
3. Capace di affrontare la malattia del mio familiare				
4. Capace di mantenermi in buona salute				
5. Fiducioso rispetto alla mia salute e del mio familiare				
6. Capace di poter contare su me stesso				

Per favore indichi quanto si sente d'accordo con le seguenti affermazioni riguardanti le decisioni terapeutiche prese durante la visita di oggi.

	Fortemente in disaccordo	Disaccordo	Neutro	D'accordo	Completamente d'accordo
	(1)	(2)	(3)	(4)	(5)
1. Ritengo che il mio familiare sia stato adeguatamente informato rispetto alle possibili cure disponibili per la sua malattia					
2. La decisione presa, secondo me è la migliore per il suo caso					
3. La decisione presa è in linea con i suoi valori					
4. Mi aspetto che porterà avanti la decisione presa con successo					
5. Ritengo che il mio familiare abbia avuto le informazioni che desiderava per la scelta delle cure					
6. Ritengo che il mio familiare sia soddisfatto della decisione presa rispetto alle cure					

Leggerà 9 affermazioni che un paziente può fare rispetto all'oncologo che ha visitato oggi il suo familiare.

Per favore indichi quanto è appropriata ognuna delle seguenti affermazioni riguardo all'oncologo che ha visitato oggi il suo familiare.

	Per nullaappro priato (1)	Pocoapprop riato (2)	Appropriato (3)	Abbastanza appropriato (4)	Completamentea ppropriato (5)
1. L'oncologo ha aiutato il mio familiare					
2. L'oncologo ha dedicato al mio familiare abbastanza tempo					
3. Ho fiducia nell'oncologo					
4. L'oncologo ha capito il mio familiare					
5. L'oncologo si è mostrato disponibile ad aiutare il mio familiare					
6. L'oncologo ed il mio familiare sono d'accordo sulla natura dei suoi sintomi					
7. E' facile parlare con l'oncologo					
8. Sono soddisfatto del trattamento medico ricevuto dal mio familiare					
9. Trovo il servizio facilmente accessibile					

Recall - Familiare

	Per nulla	Poco	Abbastanza	Molto	Moltissimo
1. Secondo lei l'oncologo quanto è riuscito a rispondere in maniera chiara e completa alle sue domande?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Quanto sente il bisogno di ricevere altre informazioni oltre a quelle ricevute oggi?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. È stato deciso quali saranno le cure del suo familiare?

SI NO

4. Di **quali terapie** ha parlato l'oncologo?

5. Quali informazioni ha dato l'oncologo su come si svolgerà la terapia del suo familiare, per esempio **durata, frequenza, modalità di somministrazione** (es. farmaci endovena, per bocca, durata, etc)?

6. Quali informazioni ha dato l'oncologo sui possibili **effetti collaterali** indesiderati delle cure?

7. Quali informazioni ha dato l'oncologo su cosa si può fare per **controllare e ridurre i possibili effetti collaterali** delle cure?

8. Quali informazioni ha dato l'oncologo su quanto sono **efficaci le terapie** nel curare e controllare la malattia del suo familiare?

9. L'oncologo ha consigliato delle **visite di controllo**? Se sì, **di che tipo e con che frequenza**?

Istruzioni:

Legga ciascuna frase e poi contrassegni la risposta che indica come lei si sente ADESSO, cioè in questo momento, ora che ha completato i suoi test. Risponda a TUTTE le domande. Scegli la risposta che le sembra meglio descrivere il suo stato d'animo ATTUALE. Scegli tra le seguenti risposte:

PER NULLA UN POCO ABBASTANZA MOLTISSIMO

	PER NULLA	UN POCO	ABBASTANZA	MOLTISSIMO
1. Misentocalmo.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Sonoteso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Misentotranquillo.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Misentoturbato.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Misento riposato.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Misentoansioso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Misentonervoso.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Son agitato	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Sonopreoccupato.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Misentobene.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

APPENDIX D

Per favore, tra le situazioni sotto rappresentate, indichi quella che, secondo lei ha scelto la paziente che ha appena visitato.

Voglio avere l'ultima parola sulla mia terapia



Voglio avere l'ultima parola sulla mia terapia, dopo aver valutato attentamente il parere del mio medico



Voglio condividere con il mio medico la decisione sulla terapia più adatta a me



Voglio lasciare al mio medico l'ultima parola sulla terapia che riceverò, dopo una sua attenta valutazione del mio parere



Voglio lasciare al mio medico ogni decisione sulla mia terapia



Per favore risponda ad ognuna delle domande seguenti secondo la scala dove 1 indica per nulla, e 6 moltissimo. Tenga presente che non ci sono risposte giuste o sbagliate.

	Per nulla (1)	(2)	(3)	(4)	(5)	Moltissimo (6)
1. Dopo la visita di oggi, quanto desidera rivedere questa paziente la prossima volta?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Quanto "frustrante" trova questa paziente?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Quanto è manipolativa questa paziente?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. In che misura si sente frustrato dalle vaghe lamentele della paziente?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Quanto le sembra autodistruttiva questa paziente?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Si ritrova a nutrire segretamente la speranza che questa paziente non ritorni?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Quanto si è sentito a suo agio mentre era con questa paziente oggi?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Quanto tempo porta via il prendersi cura di questa paziente?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Quanto è piacevole prendersi cura di questa paziente?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Quanto è difficile la comunicazione con questa paziente?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Quanto impegnativo è stato rispondere alle domande di questa paziente?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Quanto la paziente le è sembrata ansiosa o preoccupata per la propria salute?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Questa paziente le è sembrata depressa?	<input type="radio"/> sì:	<input type="radio"/> lievemente	<input type="radio"/> moderatamente	<input type="radio"/> gravemente		
	<input type="radio"/> no					
14. La paziente ha manifestato un disagio emotivo durante il colloquio?	<input type="radio"/> sì:	<input type="radio"/> lieve	<input type="radio"/> moderato	<input type="radio"/> grave		
	<input type="radio"/> no					