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INvolvement of breast CAncer patients during oncological consultations: a multicentre randomised controlled trial—the INCA study protocol

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ABSTRACT

Introduction: 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, the patients who participate in the decision-making process show greater treatment adherence and have better health outcomes. Different methods to encourage the active participation during oncological consultation have been described; however, similar studies in Italy are lacking. The aims of the present study are to (1) assess the effects of a preconsultation intervention to increase the involvement of breast cancer patients during the consultation, and (2) explore the role of the attending companions in the information exchange during consultation.

Methods and analysis: All female patients with breast cancer who attend the Oncology Out-patient Services for the first time will provide an informed consent to participate in the study. They are randomly assigned to the intervention or to the control group. The intervention consists of the presentation of a list of relevant illness-related questions, called a question prompt sheet. The primary outcome measure of the efficacy of the intervention is the number of questions asked by patients during the consultation. Secondary outcomes are the involvement of the patient by the oncologist; the patient's perceived achievement of her information needs; the patient's satisfaction and ability to cope; the quality of the doctor–patient relationship in terms of patient-centeredness; and the number of questions asked by the patient's companions and their involvement during the consultation. All outcome measures are supposed to significantly increase in the intervention group.

Ethics and dissemination: The study was approved by the local Ethics Committee of the Hospital Trust of Verona. Study findings will be disseminated through peer-reviewed publications and conference presentations.

Trial registration: ClinicalTrials.gov identifier: NCT01510964

ARTICLE SUMMARY

Article focus

- This article assesses if a preconsultation intervention (QPS) facilitates greater participation of patients in the consultation process, by determining an increase in questioning and/or in the number of different illness related issues (eg, diagnosis, treatment, prognosis) being discussed with the oncologist.
- This article assesses 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 the companion.

Key messages

- The involvement and participation of patients in therapeutic programmes are of great interest to not only physicians but also all health professionals engaged in improving patients' adherence to treatment regimens or operating in the field of health promotion.
- We expect that patients who have the opportunity to rehearse their information needs before the consultation will ask a greater number of questions which in turn will determine their greater involvement by the physician and a greater number of satisfied needs.
- We also expect that the straightforward use of a list of printed questions of potential relevance for cancer patients and their companions at an early stage of illness, by modifying the process of information exchange, will increase their participation and satisfaction with the consultation, with potential benefits for treatment adherence and consequently treatment efficacy.

ARTICLE SUMMARY

Strengths and limitations of this study

- To our knowledge, this is the first randomised controlled trial in Europe which assesses the effects of QPS on cancer patients' involvement during the consultation, on their satisfaction and confidence in coping with illness and which explores the role of the companion during the consultation.
- QPS in this study is 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.

INTRODUCTION

In recent years, the interest in communication issues in cancer care has steadily increased, in particular regarding the information needs of oncology patients, the communication of bad news and the impact of such news on patients, and the development of guidelines on how clinicians can deliver bad news in a sensitive way.[1 2] Research evidence suggests that patients have varying preferences for the amount and type of information they desire.[3] Good clinical practice entails oncologists recognising these variations in patient preferences, and physicians and patients working together to accomplish these preferences. In order to accommodate these varying preferences, the physicians need to elicit patient preferences and to adapt their information giving processes to meet these needs. If the expression of such needs is not facilitated or encouraged, these needs tend to remain hidden; consequently, the patients may perceive that they received too much or too little information. The literature suggests that a better quality of patient care and patient outcomes such as coping with illness and treatment adherence are achieved when preferences are met.[4] How the physician conducts the interview and gives information[5] has a direct effect on the participation of the patient. It has been observed that what the physician says has an immediate effect on what the patients says, and therefore can also influence the degree of patient participation in the consultation.[6 7] One proven method to encourage patients to be more active communicators is to provide question prompt sheets (QPS).[8–16] QPS are structured lists of prepared questions that prompt patients to consider novel topics before a consultation and decide on the question they would like to ask during the consultation. These tools have been shown to increase patient activation during consultation and aid the recall of information after consultation. Although QPS have been shown to be helpful, there is a need to replicate these studies in different cultural contexts in order to test the feasibility of such aids and to support the findings.

In Italy, during the medical consultation, the patients are frequently accompanied and assisted by a companion: a close family member or another key person. In this context, the activation and involvement of the patient interact with that of the companion's and contribute to the communication dynamics of the consultation. Ohlen *et al*[17] explored the importance of significant others in therapeutic decisions and highlighted the notion of 'relational autonomy', which acknowledges that people are defined by their relationships and are dependent on others in making decisions.[18] Future research that analyses patients and their companions as dyadic units would offer further insight into the impact of social relations on the treatment decision-making processes. More evidence on the information needs of the companions regarding the patient and their role in the information and decision-making processes during the consultation is also needed.

To our knowledge, this is the first randomised controlled trial in Europe which assesses the effects of a preconsultation intervention (QPS) on the cancer patients' involvement during the consultation, on their satisfaction and confidence in coping with illness and which explores the role of the companion during the consultation.

METHODS AND ANALYSIS

Study design

This is a multicentre, randomised controlled trial in which the patients are attributed randomly to the intervention or to the control group on a 1:1 basis. The patients in the intervention group are given the QPS, a list of 50 specific questions (see below); those in the control group are given a control sheet on which to write the questions they would like to ask. The oncologists are informed about the study protocol, but are blinded to whether the patient is a participant of the control group or the intervention group. The oncologists perform their consultation as usual according to the clinical practice of their centre. After concluding the consultation, they complete two questionnaires (DPRQ-10 and Control Preference Scale (CPS), see the Measures section for details) regarding the patient and the consultation.

This protocol follows the CONSORT guidelines.[19]

Standardised questionnaires are administered at baseline (before the randomisation) and immediately after the consultation (figure 1, table 1).

The time required to answer the preconsultation questionnaire is approximately 15–20 min, while the post-consultation questionnaire takes between 10 and 15 min to complete.

Intervention

The patients and their companions (if present) of both, intervention and control group, receive a form on which they were asked to write their reply to the following request: 'Please indicate the issues which you want to discuss today with your oncologist'.

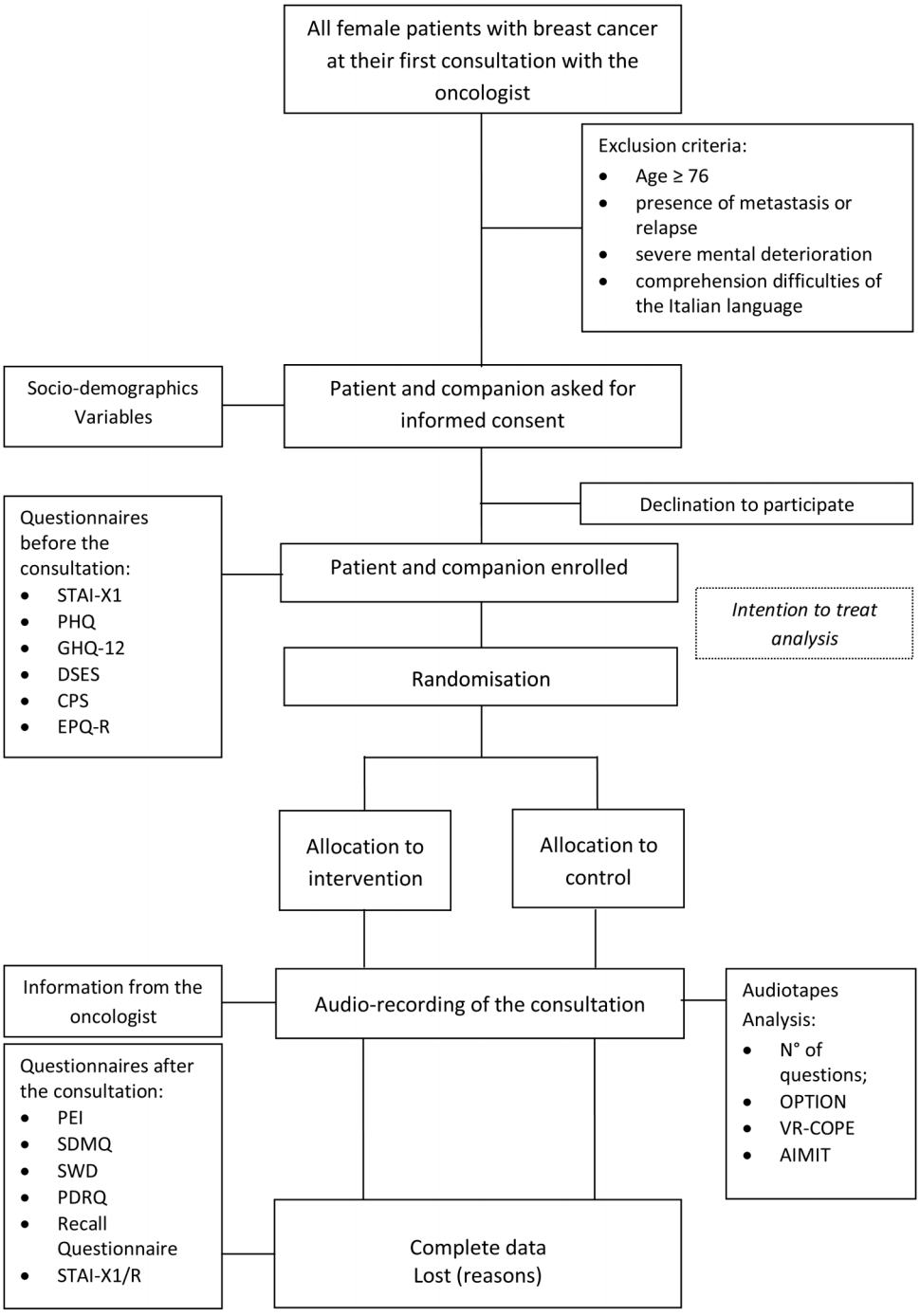

Figure 1 INCA study flow diagram.

The patients and their companions (if present) randomised to the intervention group receive the QPS in addition to the form described above. An introduction explains the importance of asking questions during the consultations. The patients (and their companions) are invited to select and circle the salient questions, if any, from the 50 questions included in the QPS. These questions have been chosen and adapted on the basis of previous studies in the field[8–16] and are divided by topics. The questions were regarding diagnosis (eg, 'Of what type is my cancer?'), treatment (eg, 'What are the advantages and disadvantages of the treatment?'), contribution of the patient and lifestyle ('What can I do to improve the efficacy of treatment?'), prognosis ('What are the chances of relapse?') and other issues (eg, 'Do I need a referral from my GP for the next visit?').

Setting

The patient recruitment phase of this protocol has begun at three oncology departments in Northern Italy:

Table 1 Questionnaires and tools used in the study

Tool	Evaluation	Explored area	Items (n)	Time
State-Trait Anxiety Inventory—X1 (STAI-X1)	Patient and companion	State anxiety level	20	Before the consultation
Patient Health Questionnaire—9 (PHQ-9)	Patient and companion	Depression	9	Before
General Health Questionnaire—12 (GHQ-12)	Patient and companion	Psychological distress	12	Before
Decision Self Efficacy Scale (DSES*)	Patient and companion	Confidence with decision	11	Before
Control Preference Scale (CPS)	Patient and companion	Role in the decision making process	5 vignettes	
Participant chooses the one preferred	Before			
Eysenck Personality Questionnaire—Reduced form (EPQ-R)	Patient and companion	Personality traits	24	Before
Doctor-Patient Scale (DP)	Oncologists	Oncologists' communication style	48	One time only
Patient Enablement Instrument	Patient and companion	Ability to cope with illness	6	After the consultation
Shared Decision Making Questionnaire (SDMQ*)	Patient and companion	Patient involvement	9	After
Satisfaction With Decision scale (SWD*)	Patient and companion	Satisfaction with decision	6	After
Patient–Doctor Relationship Questionnaire—9 (PDRQ-9*)	Patient and companion	Doctor–patient relationship	9	After
Recall questionnaire (RECALL*)	Patient and companion	Recalling and understanding of information	10	After
State-Trait Anxiety Inventory—X1/ Reduced form (STAI-X1/R)	Patient and companion	State anxiety level	10	After
Difficult Doctor-Patient Relationship Questionnaire (DDPRQ-10)	Oncologists	Difficulties in relationship with the patient	12	After
Control Preference Scale (CPS)	Oncologists	Patient's role in the decision making process	5 vignettes	
Oncologist chooses the one supposingly preferred by the patient	After			
AUDIORECORDING	Consultation	Interaction between doctor and patient	–	–
Observing Patient Involvement in Decision Making scale (OPTION)	External rater	Professional behaviours intended to involve patients	12	–
Verona Patient-centred Communication Evaluation scale (VR-COPE)	External rater	Aspects of patient-centred communication	9	–
Assessing Interpersonal Motivations in Transcripts (AIMIT)	External rater	Activity of interpersonal motivational systems	Coding system applied on transcripts	–

*Adapted version for companion.

two run by the Hospital Trust of Verona in the Veneto region (placed in two different part of the city) and one by the Hospital Trust of Brescia in the Lombardia region. The recruitment phase started in June 2011 and will continue for 2 years or until the sample size has been reached.

The population of Verona city and its province in 2010 was about 914 382, and the population of Brescia city and its province about 1 242 923.[20] In the Veneto region, the estimation of the incidence of breast cancer in 2010 was 4424 new cases per year (standardised rate adjusted for age using the European population as standard (std) per 100 000=133). In the Lombardia region, the estimation of the incidence of breast cancer in 2010 was 7456 new cases per year (std=109).[21]

The three oncology departments each have outpatient clinics dedicated to patients with breast cancer with a rotation of 2–5 oncologists. New medical oncology patient appointments are scheduled on fixed days with a number of 4–8 patients per day. Generally, in the first

visit with the oncologist, the histological results are communicated and further medical treatment is decided (eg, chemotherapy, hormone therapy). The length of the visit can vary from 30 to 60 min.

Sample and recruitment

The study sample is composed of consecutive female patients between the age of 18 and 75 years who attend the oncology outpatient clinics at the participating centres and have a recent diagnosis of breast cancer at an early stage (absence of metastasis). Eligible patients have already undergone breast surgery (eg, lumpectomy). Exclusion criteria are the presence of metastasis or relapse, severe mental deterioration and comprehension difficulties of the Italian language. A sample of 300 patients will be recruited, as estimated by the sample size calculation (see below).

Procedure

Before the patient recruitment phase, the oncologists were informed about the study and invited to participate. The willing oncologist provided written informed consent.

Eligible patients attending their first outpatient visit with the oncologist (and their companions if present) are provided with the information about the study by a project member who is available to answer any questions. The willing patients provide written informed consent to participate in the study (figure 1).

Once consented, the patients and their companions receive an envelope containing six questionnaires to answer before the consultation (baseline assessment, table 1). The project staff member (MAM) then randomly allocates consenting patients and their companions to the intervention or control group (see also paragraph 'Randomisation'). Another project staff member (AB, CB, IB or FC) hands out the envelopes with either the intervention QPS or the control sheet and collect the sheets after their completion. In order to keep the oncologists blind to the intervention or control status, patients do not take the QPS into the consultation.

The subsequent consultation is audio-recorded. After the consultation, patients and their companions complete further six questionnaires. In the event that a patient or the companion is distressed after the consultation, a trained project member present (AB, CB, IB or FC) will provide support.

At the completion of the consultation, the oncologists fill the medical details sheet that asks about the cancer stage and type, when and by whom the patient was informed about the diagnosis and the therapeutic options appropriate for this patient. They also complete a questionnaire measuring their perception of the patient as difficult.

The audio tapes and oncologists' forms are collected by the project staff.

The audio tapes are examined for the content and number of questions asked by patients and companions, and are rated applying the OPTION scale,[22–24] which measures the extent to which the oncologist has succeeded to involve the patient in the consultation. The questions that emerge during the consultations are compared with those expressed before the visit. The audio-recorded consultations are also analysed in terms of patient-centredness with the VR-COPE[25] and with the Assessment of Interpersonal Motivation in Transcripts (AIMIT)[26] which evaluates the five different motivational systems that guide the verbal and non-verbal behaviours during interactions.

Randomisation

The randomisation sequence is conducted off-site using the 'random allocation of treatments balanced in blocks (ralloc)' package for Stata[27] and is stratified by centre with a 1:1 allocation ratio of treatment. Block randomisation (size 4) is used to minimise 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 randomised.

The QPS or the control sheet, chosen for the two arms of trial, are placed in opaque envelopes, sealed and numbered in sequence (following the list generated by the randomisation procedure) by a staff member of each centre (MAM and CB), not involved in the data collection phase. Both randomisation procedure and treatment allocation have been developed to fully conceal the treatment allocation.[19 28]

The patients and the oncologists are unaware of the allocation. The raters who analyse the audio recordings are also blinded to the allocation of patients.

Study aims and hypotheses

The main aim is to assess if a preconsultation intervention (QPS) facilitates greater participation of patients in the consultation process, by determining an increase in questioning and/or in the number of different illness related issues (eg, diagnosis, treatment, prognosis) being discussed with the oncologist.

Other aims are 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 (using the CPS, more details see the measures section) and to explore the role of the companion.

In detail, the study investigates if the intervention determines

- A greater number of personal information needs expressed during the consultation (the number and type of the questions asked during the consultation);
- The perception of a greater capacity to cope with illness and a greater satisfaction with decisions made during the consultation (measured with the Patient Enablement Instrument (PEI) and Satisfaction with Decision Scale (SWD); details are described in the Measures section);

- Greater patient-generated and/or doctor-generated involvement of the patient (using the OPTION scale and SDM-Q; details are described in the Measures section);
- A better understanding of the received information and greater satisfaction (measured with the Recall questionnaire and the SWD);
- A more accurate identification by the oncologist of patients' preferred role in the therapeutic decisions (measured with the CPS answered by the oncologist; details are described in the Measures section);
- A more supportive doctor–patient relationship perceived by the oncologist and the patient (using the PDRQ-9 and DDPRQ-10, see Measures section for the details);
- A more patient-centred and sharing approach during the consultation (using the VR-COPE and the AIMIT; see Measures section for the details).

Extending the QPS to the patient's companion (if present) allows us to explore the impact of the QPS on the companions' role and participation during the consultation. The number and type of questions asked by the companion during the consultation are recorded. The companions answer the same questionnaires as the patient—PEI for the evaluation of the ability to cope with the patients' illness, SDM-Q for the evaluation the perceived involvement during the consultation, SWD for the satisfaction with decision, PDRQ-9 for the doctor–patient relationship and Recall Questionnaire for the understanding of the information received. Where necessary, questionnaires were adapted to the companions by substituting the first person (I) used in the patient version, with the third person (she). For example: 'I feel confident that I can get the facts about the medication choices available to her' instead of 'I feel confident that I can get the facts about the medication choices available to me' (item 1 of the DSES Scale).

Study measures

Sociodemographic and clinical data

Sociodemographic data collected from patients are age, education, family status and employment status, type of relationship with the companion (if present), reported both by the patients and their companions during the baseline assessment.

Oncologists' sociodemographic data are age, gender and years of experience. Data for oncology residents (when present during the consultation) are also obtained.

Clinical data are cancer stage and type, duration of illness (who has informed patient on diagnosis and when) and therapeutic options considered appropriate for this patient, all reported on a form by the oncologist.

Primary outcome measure

The primary outcome measure of this study is the number of patient's questions during the consultation regarding diagnosis, prognosis, treatment, lifestyle and other issues. Question asking is considered an index of the patient's participation during the consultation. The QPS aims to increase the number of questions by giving the opportunity to patients to reflect on their informative needs choosing among a wide range of possible questions those which are perceived as most relevant in view of the subsequent consultation. We hypothesise that patients who are randomised to receive the QPS will ask more questions than the patients randomised to the control group.

Secondary outcome measures

The secondary outcome measures are the following:

- The number of unmet information needs obtained by comparing the number of questions indicated by patients and their companion before the consultation (ie, those selected in the QPS by patient) with those actually raised during the consultation (ie, those identified subsequent to listening to the audio recordings).
- Ability to cope with the illness, measured with the PEI. 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).[29] We hypothesise that patients randomised to the intervention group will have higher 'coping with illness' scores compared to patients in the control group.
- Patient involvement, measured with the Shared Decision Making Questionnaire (SDM-Q) and the OPTION Scale. The SDM-Q 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.[30 31] The OPTION Scale is composed of 12 items of operational definitions of different patient-involving skills, rated on a Likert scale from 0 (behaviour absent) to 4 (behaviour observed at an excellent skill level).[22–24] The scale is applied by trained raters to the audio recording of the consultation. In summary, it examines whether problems are well-defined, whether options are formulated, information provided, patient understanding and role preference evaluated, and decisions examined from both the professional and patient perspective. The total score ranges from 0 (0 in all items) to 48 (4 in all items) and is transformed into a 0–100 score. We hypothesise that patients randomised to the intervention group will have higher patient involvement during the consultation compared to patients in the control group.
- Satisfaction with decisions made during the consultation, measured with the SWD. This is a self-report questionnaire of six items on a Likert scale from 0 (completely disagree) to 5 (agree completely).[32] We hypothesise that patients randomised to the

intervention group will have higher patient satisfaction compared to patients in the control group.

- Recalling and understanding of information, measured with the Recall Questionnaire. This questionnaire consists of six items that ask the patient to recall the received information on treatment decisions and pathology (eg, 'What was the treatment decision? Which treatment options were discussed?'). The questions have been prepared for the present study with reference to previous studies.[11 33 34] 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 audiorecording. We hypothesise that patients randomised to the intervention group will recall more precise information compared to patients in the control group.
- Three other questions, rated on a 0 (no at all) to 5 (very much) Likert scale asked whether the patient asked their selected QPS questions, whether the oncologist answered the questions and whether the patient received the information they desired. We hypothesise that patients randomised to the intervention group will feel themselves more successful in question asking. compared to patients in the control group.
- Overall consultation atmosphere, is measured with the Verona Patient-centred Communication Evaluation scale (VR-COPE) and the Assessing Interpersonal Motivations in Transcripts (AIMIT). The VR-COPE[25] assesses the content, the process and relational aspects of patient-centred 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 audiorecordings. We expect that patients of the intervention group establish a better relationship with their oncologist and show higher scores in patient-centred communication. The AIMIT[26] is a coding system applied to transcripts that systematically detects the activity of five interpersonal motivational systems (attachment, caregiving, rank, sexuality and cooperation). We hypothesise that patients randomised to the intervention group will more often evidence a cooperative style during the consultation compared to patients in the control group.
- Perceived Patient–doctor relationship, measured with the Patient–Doctor Relationship Questionnaire (PDRQ-9) and the Difficult Doctor Patient Relationship Questionnaire (DDPRQ-10). 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.[25] The 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.[36 37] The questionnaire identifies the patients experienced as difficult patients. We hypothesise that the doctor–patient relationship in the intervention group is perceived as less difficult compared to the control group.
- Oncologists answered three questions on the potential presence of anxiety, depression or emotional distress in the patient and a fourth on their difficulty experienced in answering the patient's questions. We hypothesise that answering questions of patients in the intervention group will be perceived by oncologists as less difficult.
- Perceived role preference of the patient, measured with the CPS, Oncologist version.[38 39] This scale assesses how the oncologist perceives the role that patient might prefer regarding the decision making process. Oncologists should be better able to identify patients preferred role in the intervention group.
- Duration of the consultation, measured in minutes. We hypothesise a longer duration of the consultation in the intervention group compared to the control group.

Process-related and potential confounding variables

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

- Anxiety, depression and general well-being, measured with the State Anxiety Inventory (STAI-X1, XR),[40–42] the Patient Health Questionnaire depression scale (PHQ-9)[43–45] and the General Health Questionnaire (GHQ-12).[46] STAI-X1 is a self-administered questionnaire of 20 items on a Likert scale from 1 (not at all) to 4 (very much) completed before the consultation. Higher total scores indicate greater state anxiety. The STAI-X1R, administered after the consultation, is a shorter version of 10 out of the 20 items of the STAI-X1, and it is used to evaluate the state anxiety level at the end of the consultation and to compare this level with the one measured at the beginning. PHQ-9 is a self-assessment questionnaire for detecting the presence of depression and consists of nine items with response options of 0 (not at all) to 3 (almost every day), and has a summative score range of 0 to 27. We score it in the standard way, using the sum of the 0–3 scores for each item, and ≥8 as a cut-off score for possible cases of depression.[43–45] GHQ-12 is a self-administrated questionnaire of 12 items and has a summative score range of 0 to 12 and a cut-off score of >3 indicating psychological distress.[46]
- Personality traits, measured with the Eysenck Personality Questionnaire (EPQR-S).[47] The EPQR-S is a self-administered questionnaire of 48 items on yes/no scale. For our study, we use two subscales: the Extroversion/Introversion (12 items) and

Neuroticism/Stability (12 items). The 'Extroversion' is characterised by being outgoing, talkative, high on positive affect (feeling good) and in need of external stimulation. The 'Neuroticism' or emotionality is characterised by high levels of negative effect such as depression and anxiety.

- Confidence with decision, measured with the Decision Self Efficacy Scale (DSES).[48] This self-administered questionnaire for patients consists of 11 items on a Likert scale from 0 (not at all confident) to 4 (very confident).
- Patients' and their companion's preference for the role they want to have in the decision-making process, measured with the CPS.[38 39] This self-administered instrument contains five vignettes with text, depicting different patient roles (from active to passive) from which patients choose the one considered as most appropriate for them.
- Patient-centred communication style and attitude toward the doctor–patient relationship, measured with the Doctor–Patient (DP) Scale.[49] The Scale measures the degree of oncologists' self-reported patient or doctor-centred communication style and attitude. It consists of 48 statements to rate on a Likert scale from 1 (strong agreement) to 5 (strong disagreement). It has a summative score range of 48–240. The scale is completed by all oncologists who join the study.

Sample size calculation

A sample of 300 patients will be recruited. This number has been estimated to account for approximately 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 nine questions (range 0–53) for patients with 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 centre) 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; no significant difference was found between the three centres (median test: χ^2=2.4, p=0.30).

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,[50] assuming a power of 80% and a two-sided significant level of 5% on a Student t test for differences between independent groups.[51 52]

Statistical analysis

The data will be analysed according to intention-to-treat principle.[53] Standard statistical techniques will be used to describe the characteristics of patients in both groups, and CONSORT flow diagram will be shown in order to explain the phases of trial and inform on the findings confidence.[19] The primary outcome, significant increase of patient questions, will be compared in the two arms using t test. If adjustment for possible baseline differences among patients (as well as for oncologists and centres) is needed, an analysis of covariance will be done. Regarding secondary outcome measures, multilevel analyses will be used to taking into account the specific effect of the individual oncologist.[53]

EXPECTED ACHIEVEMENT

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

We expect that patients who have the opportunity to rehearse their information needs before the consultation will ask a greater number of questions and we will observe higher levels of involvement by the physician and a higher number of met information needs. The use of a simple question prompt sheet may improve the overall communication between the oncologist and the patient. This intervention will be easy to disseminate and use in routine clinical practice to increase patient and companion participation.

DISCUSSION

It has been demonstrated in English-speaking countries that a QPS is a useful tool to improve the 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 randomised controlled trials in Europe that assess the effects of a preconsultation QPS on patient and companion communication. The study has a strong design that incorporates computerised random allocation, blinding of data-collection staff and the use of audio recording 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.[55]

There are some limitations to consider. The QPS is not being used prior to the consultation, while, in previous trials reported in literature,[8–16] patients take the QPS into the consultation to serve as a reminder to ask questions. We selected this study method to ensure that participating oncologists are (a) kept blind to the

intervention or control status of the patients and (b) not forced to change their routine clinical practice.

The findings from this study will provide 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 the QPS.

ETHICS AND DISSEMINATION PLANS

The study was approved by the local Ethics Committees of the Hospital Trust of Verona. The study is registered at ClincialTrial.gov (identifier: NCT01510964). This protocol follows the CONSORT guidelines.[19]

Recruitment phase started in June 2011 and will continue till the enrolment will be completed and is expected to be closed in May 2013. Analysis will start after data monitoring and checking is completed. The dissemination of the trial findings will principally be carried out through publications in peer-review journal and presentations at national/international conferences focused on cancer and/or communication, for examples European Association for Communication in Health Care Conferences and International Shared Decision Making Conferences.

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Contribuors CG, LDP, MR and CZ developed the study protocol and together with AG and MGS supervised the all procedures. MAM is the trial statistician and is responsible for generating the randomisation sequences and providing guidance on statistical analysis of trial data. MB is the computer scientist who developed the database to save the data. CG drafted the manuscript in collaboration with RB. CG will oversee enrolment and data collection. GD, AB, FC, CB, IB, AM, EF, RN, CC, SZ, AA, FM, ELS and FR participated in enrolling the patients. All authors saw and approved the final version of the manuscript.

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