



The INvolvement of breast CANcer patients during oncological consultations. A multi-centre randomized controlled trial. The INCA study protocol.

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2012-002266
Article Type:	Protocol
Date Submitted by the Author:	25-Oct-2012
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Primary Subject Heading:	Oncology
Secondary Subject Heading:	Patient-centred medicine
Keywords:	patient involvement, breast cancer, docotr-pateint communication

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3 **The INvolvement of breast CANcer patients during oncological consultations. A multi-centre**
4 **randomized controlled trial. The INCA study protocol.**
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58 *Key- word:* patient involvement, breast cancer, doctor-patient communication
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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, patients who participate in the decision making process show greater treatment adherence and have better health outcomes. Different methods to encourage the active participation have been described, however similar studies in Italy are lacking. The aims of the present study are: 1) assess the effects of a pre-consultation intervention to increase involvement of breast cancer patients, and 2) explore the role of the family member in the information exchange during the consultation.

Methods and analysis: All patients with breast cancer who attend the Oncology Out-patient Services for the first time will provide 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 (QPS).

The main outcome measures of the efficacy of the intervention are: 1) the number of questions asked by patients during the consultation, 2) the involvement of the patient by the oncologist, 3) patient's perceived achievement of her information needs, and 4) the quality of the doctor-patient relationship in terms of patient-centeredness.

The hypotheses are: the intervention group will have increases in, the number of questions asked by the patient, his/her involvement in the information exchange and the decisional process, the perception that information needs have been met, and the patient-centeredness of the consultations

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

- Assess if a pre consultation intervention (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.
- 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.

Key messages

- The involvement and participation of patients 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.
- 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.

Strengths and limitations of this study

- To our knowledge this is the first RCT 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 family member during the consultation.

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- QPS in this study is used before the consultation but it could be also brought into the consultation and discussed with the oncologist to further increase patient and companion participation

For peer review only

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 their impact on the patient, and the development of guidelines on how to deliver bad news in a sensitive way.[1, 2]

The evidence indicates that patient's preferences for the type and amount of information vary. 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 the 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 we meet patient's information preferences, the 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.[3]

In the last decade, the focus of many studies has been directed towards activating patients to be more involved in their treatment.[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] To stimulate patients' participation in consultations, patients were encouraged by their doctor to ask questions or advised to prepare a list of questions,[8] or to select their questions from a printed list before the consultation (question prompt sheet-QPS).[4, 9-15] These tools were helpful both for patients and physicians, and improved patient participation during the consultation. Nevertheless 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.

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3 In Italy, patients are frequently accompanied and assisted by a close family member or by another
4 key person during the medical consultation. In this context the activation and involvement of the
5 patient interacts with that of the key person and contributes to the communication dynamics of the
6 consultation. Olhen and colleagues[16] explored the importance of significant others in therapeutic
7 decisions and highlighted the notion of “relational autonomy”, which acknowledges that people
8 are defined by their relationships and are dependent on others in making decisions.[17] Future
9 research that analyses patients and companions as dyadic units would offer further insight into the
10 impact of social relations on treatment decision-making processes. More evidence on the
11 information needs of family members regarding the patient and their role in the information and
12 decision processes during the consultation is also needed.
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25 To our knowledge this is the first RCT in Europe which assesses the effects of a pre-consultation
26 intervention (QPS) on cancer patients’ involvement during the consultation, on their satisfaction
27 and confidence in coping with illness, and which explores the role of the family member during the
28 consultation.
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36 **Study aims and hypotheses**

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38 The study pursues different aims. The main aim is to assess if a pre consultation intervention (QPS)
39 facilitates greater participation of patients (and accompanying key persons when present) in the
40 consultation process, by determining an increase in questioning and/or in the number of different
41 illness related issues (e.g. diagnosis, treatment, prognosis) being discussed with the oncologist.
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47 Other aims are to assess the effect of the QPS on the level of patient involvement by the
48 oncologists, on patient satisfaction and coping, on the oncologist’s perception of patient’s preferred
49 decisional role and to explore the role of key persons accompanying the patient.
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53 In detail the study investigates if the intervention, determines:
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- 55 – a greater number of personal information needs expressed during the consultation (information
56 needs expressed before the consultation correspond to those expressed during the consultation);
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- 3 – the perception of a greater capacity to cope with illness and a greater satisfaction with decisions
- 4 made during the consultation;
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- 7 – greater patient generated and/or doctor generated involvement of the patient;
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- 10 – a better understanding of the received information and greater satisfaction;
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- 12 – a different perception by the oncologist of patient’s preference regarding her participation in
- 13 therapeutic decisions;
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- 16 – a different perception by the oncologist and by the patient of the doctor-patient relationship
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- 19 – a more patient-centred approach during the consultation

20 The potential presence of a companion during the consultation allows us to explore if the “question
21 prompt sheet” intervention (extended to the accompanying key person), changes the key person’s
22 role and participation during the consultation.
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32 **METHODS AND ANALYSIS**

33 **Study design**

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36 This is a multicentre, randomized controlled trial in which patients are attributed randomly to the
37 intervention or to the control group on a 1:1 basis. Patients in the intervention group are given the
38 QPS, a list of 50 specific questions (see below); and those in the control group are given a control
39 sheet on which to write the questions they would like to ask. The oncologists are informed about the
40 study protocol but are blinded to whether the patient is a participant of the control group or the
41 intervention group. The oncologists perform their consultation as usual, according to the clinical
42 practice of their centre. After concluding the consultation, they complete two questionnaires
43 regarding the patient and the consultation.
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55 This protocol follows the CONSORT guidelines.[18]
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Standardized questionnaires are administered at baseline (before the randomization) and immediately after the consultation. (figure 1, table 1)

Figure 1 INCA Study flow diagram

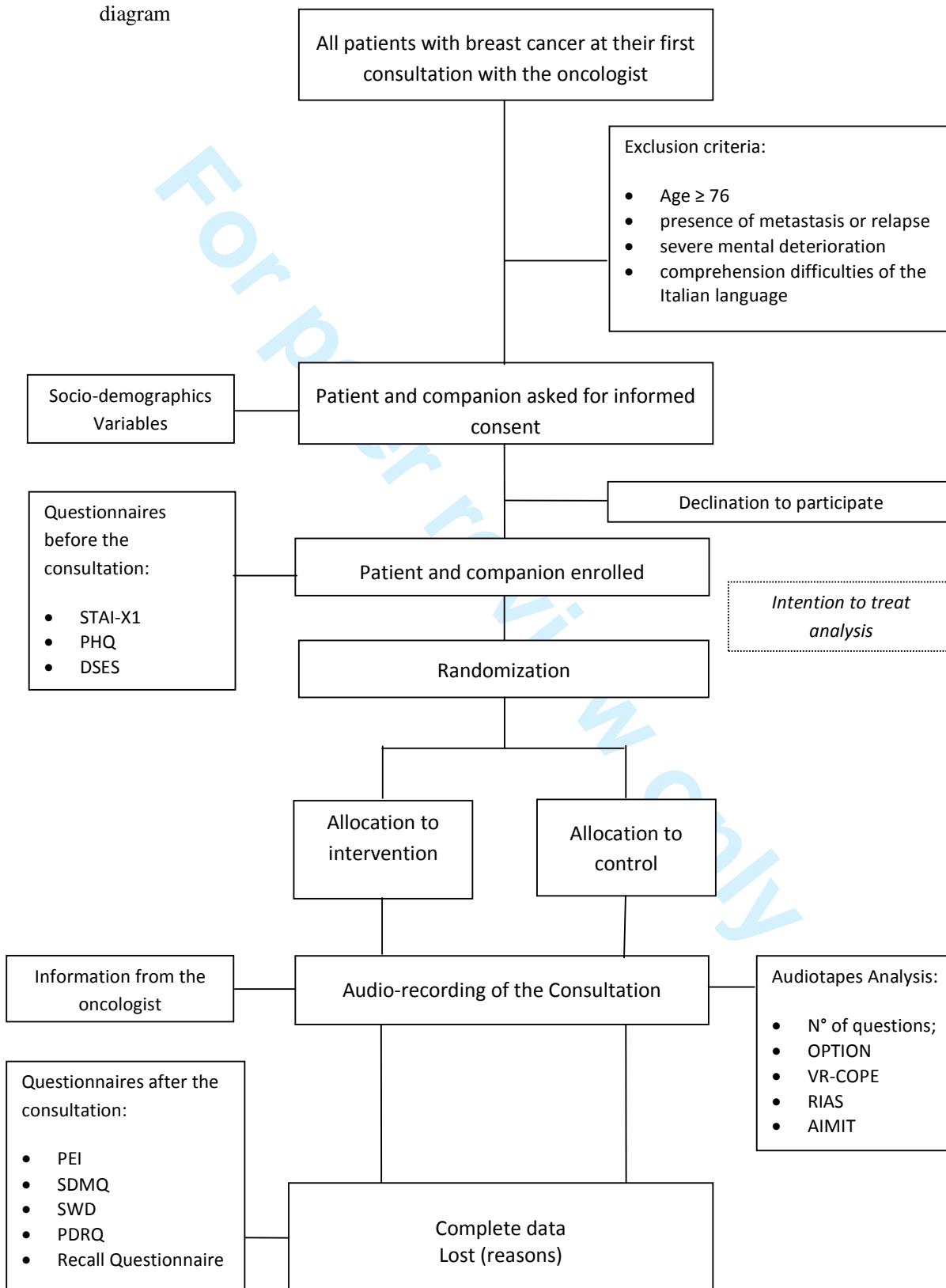


Table 1 Questionnaires and instruments used in the study

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-centred communication	9	-
RIAS	External rater	Verbal communication	40	-
AIMIT	External rater	Activity of interpersonal motivational systems	-	-

*Adapted version for companion

Intervention

Patients and companions (if present) of both, intervention and control group, receive a form on which to write their reply to the following request: "Please indicate the arguments which you want to discuss today with your oncologist".

Patients and companions (if present) of 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 patient (and companion) is invited to select among a written list of about 50 possible questions those, if any, she would like to ask today to the oncologist. These questions have been chosen and adapted on the basis of previous studies in the field[2, 10-15] and are divided by topics. Questions regard diagnosis (e.g. "Of what type is my cancer?"), treatment (e.g. "Which are the pros and cons of the treatment?"), contribution of patient and lifestyle ("What can I do to improve the efficacy of treatment?"), prognosis ("What are the chances of relapse?") and other issues (e.g. "Do I need a referral from my GP for the next visit?").

Setting

Patients are being recruited from three Oncology Departments in Northern Italy: two run by 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 population of Verona city and its province in 2010 is about 914 382, the population of Brescia city and its province about 1 242 923.[19] In the Veneto region the estimation of incidence of breast cancer in 2010 was 4 424 new cases per year (Standardized rate adjusted for age using the European population as standard (std) per 100,000= 133). In the Lombardia region the estimation of incidence of breast cancer in 2010 was 7 456 new cases per year (std = 109).[20]

The three Oncology departments have an out-patient clinic dedicated to breast cancer patients with a rotation of 2-5 oncologists.

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3 Visits are scheduled on fixed day with a number of 4 - 8 patients per day. Patients have already
4 been diagnosed with cancer, have already been visited by the surgeon and undergone the breast
5 operation (e.g. lumpectomy). Generally in the first visit with the oncologist the histological results
6 are communicated and further medical treatment is decided (e.g chemotherapy, hormone therapy).
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12 The length of the visit can vary from 30 to 60 minutes.

16 **Sample and recruitment**

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18 The study sample will be composed of all consecutive patients between the age of 18 to 75 years
19 who attend the Oncology out-patient clinics of the participating centres and who have a recent
20 diagnosis of breast cancer at an early stage. Exclusion criteria are the presence of metastasis or
21 relapse, severe mental deterioration, comprehension difficulties of the Italian language.
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29 **Procedure**

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31 Before the recruitment phase the oncologists were informed about the study and asked to
32 participate, giving a written informed consent.
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36 All breast cancer patients at their first out-patient visit with the oncologist of the Clinical Oncology
37 Department (and their companions if present), are being asked by a project member to give written
38 informed consent to participate in the study (figure 1).
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42 Consenting patients and companions receive an envelope containing six questionnaires to answer
43 before the consultation (baseline assessment) (table 1). The project staff member (MAM) then
44 randomly allocates consenting patients and their companions to the intervention or control group
45 (see also paragraph "Randomization"). Another project staff member (AB, CB, IB or FC) hands out
46 the envelopes with either the intervention prompt sheet or the control sheet and collect the sheets
47 after their completion. The subsequent consultation is audio recorded. After the consultation,
48 patients and their companions complete six other questionnaires, with assistance from the project
49 member (AB, CB, IB or FC).
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3 The oncologists reports on a form, the cancer stage and type, when and by whom the patient was
4 informed about diagnosis, and the therapeutic options appropriate for this patient. They also
5 complete a questionnaire measuring the perception of the patient as difficult.
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9 The audio tapes and oncologist' forms are collected by the project staff. The audio tapes are
10 examined for the content and number of questions asked by patients and companions, and are rated
11 applying the OPTION scale,[21-23] which measures the extent to which the oncologist has
12 succeeded to involve the patient in the consultation. The questions that emerge during the
13 consultations are compared with those expressed before the visit. The audio recorded consultations
14 are also analyzed with the Roter Interaction Analysis System (RIAS),[24, 25] a system for coding
15 doctor-patient communication, with the VR-COPE[26] and with the Assessment of Interpersonal
16 Motivation in Transcripts (AIMIT),[27] for the evaluation of five different motivational systems
17 guiding the verbal and non verbal behaviours during interactions.
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32 **Randomization**

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34 The randomization sequence is being conducted off-site using the “random allocation of treatments
35 balanced in blocks (ralloc)” package for Stata[28] and is stratified by centre with a 1:1 allocation
36 ratio of treatment. Block randomization (size 4) is used to minimize large imbalances between the
37 intervention groups. The allocation sequences are generated by an independent individual, are
38 stored in computer files and remain unknown to the researchers until the patient is randomized.
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45 The QPS or the control sheet, chosen for the two arms of trial, are placed in opaque envelopes,
46 sealed and numbered in sequence (following the list generated by the randomization procedure) by
47 a staff member of each centre (MAM and CB), not involved in the data collection phase. Both
48 randomization procedure and treatment allocation have been developed to fully conceal treatment
49 allocation.[18, 29]
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56 Patients and oncologists are unaware of the allocation. The raters who analyze the audio- recordings
57 are also blinded to the allocation of patients.
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Study measures

Socio demographic and clinical data

Patients' socio demographic data are: age, education, family status and employment status and are 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) is 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 reported on a form by the oncologist.

Primary outcome measure

- The total number of patient's questions during the consultation regarding diagnosis, prognosis, treatment, lifestyle and other issues. Question asking is considered an index of patient's participation during the consultation. The QPS aims to increase the number of question by giving the opportunity to patients and companions to reflect on their informative needs choosing among a wide range of possible questions those ones perceived as most relevant in view of the subsequent consultation.

Secondary outcome measures

- The number of unmet informative needs that emerge during the consultation. This measure is 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).

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- Ability to cope with the illness, measured with the Patient Enablement Instrument (PEI). This questionnaire is a self-administered questionnaire of six items on a Likert scale from 0 (same or less) to 2 (much better, much more).[30]
 - Patient involvement, measured with the Shared Decision Making Questionnaire (SDM-Q) and the OPTION Scale. The SDM-Q is a self administered questionnaire of 9 items on a Likert scale from 1 (completely disagree) to 6 (agree completely) and assesses patients' perception of the decisional process and their level of involvement during the consultation, the information received on therapeutic options, the potential risks and benefits regarding the participation at the decisional process.[31, 32] 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).[21-23] 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.
 - Satisfaction with decisions made during the consultation, measured with the Satisfaction with Decision Scale (SWD).This is a self administered questionnaire of 6 items on a Likert scale from 0 (completely disagree) to 5 (agree completely).[33]
 - Recalling and understanding of information, measured with the Recall Questionnaire. This questionnaire consists of six questions which 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.[11, 34, 35] The questionnaire allows with the help of the audio recorded consultation to evaluate patient's correct recall and understanding by comparing patients' reports with what was actually discussed during the consultation. We added three other

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3 questions, rated on a 0 (no at all) to 5 (very much) likert scale asking whether the patient
4 succeeded in their purpose of question asking, whether the oncologist answered the questions
5 properly and how much more information she would have needed.
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10 – Overall consultation atmosphere, is measured with the Roter Interaction Analysis System
11 (RIAS),[24, 25] and the Assessment of Interpersonal Motivation in Transcripts (AIMIT).[27]
12 VR-COPE,[26] assesses the content, the process and relational aspects of patient-centred
13 communication during medical consultations on the basis of a multidimensional evaluation and
14 comprises nine items. Each item is defined by operational definitions and rated on a 0-10 point
15 scale. The scale is applied by trained raters on the audio-recording of the consultation. RIAS is a
16 coding system of medical consultations, composed by 40 categories describing task-oriented
17 and emotion oriented interactions between doctors and patients. The system will be applied on
18 the consultation audio-recording by trained raters.[24, 25] AIMIT[27] is a coding system to
19 assess in the therapeutic dialogue the activity of interpersonal motivational systems that guide
20 the verbal and non verbal behaviours during interactions (attachment, caring, competition,
21 cooperation, seduction) .
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23 – Perceived Patient-doctor relationship, measured with the Patient – Doctor Relationship
24 Questionnaire (PDRQ-9) and the Difficult Doctor Patient Relationship Questionnaire (DDPRQ-
25 10). PDRQ-9 is a self-administered questionnaire of 9 items on a Likert scale from 1 (not at all
26 appropriate) to 5 (totally appropriate), to measure the relationship between the doctor and the
27 patient, from a patient point of view.[36] The DDPRQ-10 (is a self-report instrument of 10
28 items on a Likert scale from 1 (not at all) to 6 (a great deal), is completed by physicians after the
29 encounter with a patient.[37, 38] The questionnaire identifies the patients experienced as
30 difficult patients. We added four more items for rating anxiety, depression, and psychological
31 distress of the patient and the difficulty experienced by the oncologist in answering the
32 questions asked.
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- Perceived role preference of the patient, measured with the Control Preference Scale (CPS, Oncologist version).[39, 40] This scale assesses how the oncologist perceives the role that patient might prefer regarding the decision making process
- Duration of the consultation, measured in minutes.

Process related and potential confounding variables

- Anxiety, depression and general well being, measured with the State Anxiety Inventory (STAI-X1, XR),[41-43] the Patient Health Questionnaire depression scale (PHQ-9)[44-46] and the General Health Questionnaire (GHQ-12).[47]
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 ten out of the twenty items of the STAI-X1, and it is used to evaluate the state anxiety level at the end of the test and to compare this level with the one measured at the beginning. The score of this scale is used also to compute the difference between the level of state anxiety at the beginning and at the end of the questionnaire (STAI-DIFF), and the level of coherence in the change between the two administrations of the STAI-X1 (STAI-ACC).
- PHQ-9 is a self-assessment questionnaire for detecting the presence of depression and consists of 9 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-score for possible cases of depression.[44-46]
- GHQ-12 is a self administrated questionnaire of 12 items and has a summative score range of 0 to 12 and a cut-score of >3 indicating psychological distress.[47]
- Personality traits, measured with the Eysenck Personality Questionnaire (EPQR-S).[48] The EPQR-S is a self-administered questionnaire of 48 items on yes/no scale. For our study we use two subscales: the Extraversion/Introversion (12 items) and Neuroticism/Stability (12 items).

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3 The “Extroversion” is characterized by being outgoing, talkative, high on positive affect (feeling
4 good) and in need of external stimulation. The “Neuroticism” or emotionality is characterized
5 by high levels of negative affect such as depression and anxiety.
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10 – Confidence with decision, measured with the Decision Self Efficacy Scale (DSES).[49] This
11 self- administered questionnaire for patients consists of 11 items on a Likert scale from 0 (not
12 at all confident) to 4 (very confident).
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16 – Patients’ and their companion’s preference for the role they want to have in the decision making
17 process, measured with the Control Preference Scale (CPS).[39, 40] This self-administered
18 instrument contains 5 vignettes with text, depicting different patient roles (from active to
19 passive) from which patients choose the one considered as most appropriate for them.
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23 – Patient-centred communication style and attitude toward the doctor-patient relationship,
24 measured with the Doctor-Patient (DP) Scale.[50] The Scale measures the degree of
25 oncologists’ self reported patient or doctor-centred communication style and attitude. It consists
26 of 48 statements to rate on a Likert scale from 1 (strong agreement) to 5 (strong disagreement).
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- It has a summative score range of 48 to 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 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 nine 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 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

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2
3 the feasibility of procedures and questionnaires. This observational study resulted in a mean number
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5 of 18 (sd=13) patient questions asked during a first encounter with the oncologist. An intervention
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7 intended to increase the number of questions might be considered efficacious with an increase of
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9 30%. The sample size required to evidence such difference was calculated using the sampsi
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11 command of Stata 11,[51] assuming a power of 80% and a two-sided significant level of 5% on a
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13 student t-test for differences between independent groups.[52, 53]
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16 17 18 **Statistical analysis** 19

20 The data will be analyzed according to intention-to-treat principle.[54] Standard statistical
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22 techniques will be used to describe characteristics of patients in both groups, and CONSORT flow
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24 diagram will be shown in order to explain the phases of trial and inform on the findings
25
26 confidence.[18] The primary outcome, significant increase of patient questions, will be compared in
27
28 the two arms using t-test. If adjustment for possible baseline differences among patients (as well as
29
30 for oncologists and centres) is needed, an analysis of covariance will be done. Regarding secondary
31
32 outcome measures, multilevel analyses will be used to taking into account the specific effect of the
33
34 individual oncologist.[55] Regarding the analyses of the audio-recordings, additional techniques to
35
36 study the doctor patient interaction at a micro level will be used, such as sequence analyses which
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38 study the probabilistic links between subsequent physician and patient turns.[8, 56, 57]
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EXPECTED ACHIEVEMENT

The involvement and participation of patients 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.

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. The use of a question prompt sheet might be a simple and quick device in improving the overall communication between oncologist and patient. It might be routinely used before the consultation and also brought into the consultation and discussed with the oncologist to further increase patient and companion participation. Evidence demonstrates that efficacious communication positively influences the understanding and satisfaction of the patient, treatment adherence and health status. Moreover, the oncologist's knowledge and consideration of the information needs of the family members or other key persons close to the patient who in Italy often accompany the patient may further facilitate patient's participation in the therapeutic program.

ETHICS AND DISSEMINATION PLANS

The study was approved by the local Ethics Committees of the Hospital Trust of Verona. The study is registered at ClinicalTrials.gov (identifier: NCT01510964). This protocol follows the CONSORT guidelines.[18]

Recruitment phase started in June 2011 and will continue till the enrolment will be completed and is expected to be closed in December 2012. Analysis will start after data monitoring and checking is

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2
3 completed. The dissemination of the trial findings will principally be carried out through
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5 publications in peer-review journal and presentations at national/international conferences focused
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7 on cancer and/or communication, for examples European Association for Communication in Health
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9 Care Conferences and International Shared Decision Making Conferences.
10

11 12 13 **FUNDING**

14
15
16 This research received no specific grant from any funding agency in the public, commercial or not-
17
18 for-profit sectors.
19

20 21 22 **COMPETING INTERESTS**

23
24
25 The authors declared that they have no competing interest.
26
27

28 29 30 **AUTHORS' CONTRIBUTIONS**

31
32 CG, LDP, MR, CZ developed the study protocol and together with AG and MGS supervised the all
33
34 procedures. MAM is the trial statistician and is responsible for generating the randomization
35
36 sequences and providing guidance on statistical analysis of trial data. MB is the computer scientist
37
38 that developed the database to save the data. CG drafted the manuscript, will oversee enrolment and
39
40 data collection. GD, AB, FC, CB, IB, AM, EF, RN, CC, SZ, AA, FM, ELS, FR participated in
41
42 enrolling the patients. All authors saw and approved the final version of the manuscript.
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REFERENCES

1. Buckman R. Breaking. Bad news: a guide for healthcare professionals. Baltimore, MD: Jhon Hopkins University Press 1992.
2. Baile WF, Buckman R, Lenzi R, et al. AP. SPIKES - A six-step protocol for delivering bad news: Application to the patient with cancer. *Oncologist* 2000;**5**:302-311.
3. Joosten EAG, DeFuentes-Merilla L, de Weert GH, Sensky T, et al. Systematic review of the effects of shared decision making on patient satisfaction, treatment adherence and health status. *Psychother Psychosom* 2008;**77**:219-226.
4. Clayton JM, Butow PN, Tattersall MH, et al. Randomized controlled trial of a prompt list to help advanced cancer patients and their caregivers to ask questions about prognosis and end-of-life care. *J Clin Oncol* 2007;**25**:715-723.
5. Charles C, Gafni A, Whelan T. How to improve communication between doctors and patients. Learning more about the decision making context is important. *BMJ* 2000;**320**:1220-1221.
6. Drew P, Chatwin J, Collins S. Conversation analysis: a method for research into interactions between patients and health-care professionals. *Health Expectat* 2001;**4**:58-70.
7. Zimmermann C, Del Piccolo L, Mazzi MA. Patient cues and medical interviewing in general practice. Examples of the application of sequential analysis. *Epidemiol Psichiatr Soc* 2003;**12**:115-123.
8. Kidd J, Marteau TM, Robinson S, et al. Promoting patient participation in consultations: a randomized controlled trial to evaluate the effectiveness of three patient-focused interventions. *Patient Educ Couns* 2004;**52**:107-12.
9. Butow PN, Dunn SM, Tattersall MHN, et al. Patient participation in the cancer consultation: evaluation of a question prompt sheet. *Ann Oncol* 1994;**5**:199-204.

10. Brown R, Butow PN, Boyer MJ, et al. Promoting patient participation in the cancer consultation: evaluation of a prompt sheet and coaching in question-asking. *Br J Cancer* 1999;**80**:242-248.
11. Brown RF, Butow PN, Dunn SM, et al. Promoting patient participation and shortening cancer consultations: a randomised trial. *Br J Cancer* 2001;**8**:1273-1279.
12. Bruera E, Sweeney C, Willey J, et al. Breast cancer patient perception of the helpfulness of a prompt sheet versus a general information sheet during outpatient consultation: a randomized controlled trial. *J Pain Symptom Manage* 2003;**5**:412-419.
13. Glynne-Jones R, Ostler P, Lumley-Graybow S, et al. Can I look at my list? An evaluation of a 'prompt sheet' within an oncology outpatient clinic. *Clin Oncol* 2006;**18**:395-400.
14. Clayton J, Butow P, Tattersall M, et al. Asking questions can help: development and preliminary evaluation of a question prompt list for palliative care patients. *Br J Cancer* 2003;**89**:2069-2077.
15. Clayton JM, Butow PN, Tattersall MH, et al. Randomized controlled trial of a prompt list to help advanced cancer patients and their caregivers to ask questions about prognosis and end-of-life care. *J Clin Oncol* 2007;**25**:715-723.
16. Ohlen J, Balneaves L, Bottorff J, et al. The influence of significant others in complementary and alternative medicine decisions by cancer patients. *Soc Sci Med* 2006;**63**:1625-1636.
17. Christman J. Relational autonomy, liberal individualism, and the social constitution of selves. *Philosophical Studies* 2004;**117**:143-164.
18. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomized trials. *BMJ* 2010;**340**:c869. DOI: 10.1136/bmj.c869.
19. Istituto Nazionale di Statistica (ISTAT) Web site.
<http://www.demo.istat.it/pop2010/index.html>. Accessed October 24, 2012.

- 1
- 2
- 3 20. Centro Nazionale di Epidemiologia, Sorveglianza e Promozione della Salute - Istituto
- 4
- 5 Superiore di Sanità (ISS) Web site. http://www.tumori.net/it3/banca_dati/query.php. Accessed
- 6
- 7 October 24, 2012.
- 8
- 9
- 10 21. Elwyn G, Hutchings H, Edwards A, et al. The OPTION scale: measuring the extent that
- 11
- 12 clinicians involve patients in decision-making tasks. *Health Expectat* 2005;**8**:34-42.
- 13
- 14 22. Goss C, Fontanesi S, Mazzi MA, et al. The assessment of patient involvement across
- 15
- 16 consultation. The Italian version of the OPTION scale (in Italian). *Epidemiol Psichiatr Soc*
- 17
- 18 2007;**16**:339-349.
- 19
- 20
- 21 23. Goss C, Fontanesi S, Mazzi MA, et al. Shared decision making: the reliability of the OPTION
- 22
- 23 scale in Italy. *Pat Educ Counsel* 2007;**66**:296-302.
- 24
- 25 24. Roter D, Larson S. The Roter interaction analysis system (RIAS): utility and flexibility for
- 26
- 27 analysis of medical interactions. *Pat Educ Counsel* 2002;**26**:243-251.
- 28
- 29
- 30 25. Roter D. The Roter method of interaction process analysis. RIAS manual. Baltimore, MD:
- 31
- 32 John Hopkins University Press 1991.
- 33
- 34 26. Del Piccolo L, Mazzi MA, Scardoni S, et al. A theory based proposal to evaluate patient-
- 35
- 36 centred communication in medical consultations: the Verona Patient-centred Communication
- 37
- 38 Evaluation scale (VR-COPE). *Health Education* 2008;**108**:355-372.
- 39
- 40
- 41 27. Ardovini C, Cotugno A, Costantini E, et al. Il manuale AIMIT. Analisi degli Indicatori delle
- 42
- 43 Motivazioni Interpersonali nei Trascritti. In: Liotti G, Monticelli F. I sistemi motivazionali nel
- 44
- 45 dialogo clinico. Il manuale AIMIT. Milano, IT: Raffaello Cortina editore 2008.
- 46
- 47
- 48 28. Ryan P. sxd1 4: Random allocation of treatments in blocks. *Stata Journal* 2008;**8**:146.
- 49
- 50 29. Altman DG, Schulz KF, Moher D, et al. The revised CONSORT statement for reporting
- 51
- 52 randomized trials: explanation and elaboration. *Ann Intern Med* 2001;**134**:663-94.
- 53
- 54 30. Howie JG, Heaney DJ, Maxwell M, et al. A comparison of a Patient Enablement Instrument
- 55
- 56 (PEI) against two established satisfaction scales as an outcome measure of primary care
- 57
- 58 consultations. *Fam Pract* 1998;**15**:165-171.
- 59
- 60

- 1
2
3 31. Simon D, Chorr G, Wirtz M, et al. Development and first validation of the shared decision
4 making questionnaire (SDM-Q). *Pat Educ Counsel* 2006;**63**:319-327.
- 5
6
7 32. Kriston L, Scholl I, Hölzel L, et al. The 9-item Shared Decision Making Questionnaire (SDM-
8 Q-9). Development and psychometric properties in a primary care sample. *Patient Educ*
9 *Couns.* 2010;**80**:94-9.
- 10
11
12 33. Holmes-Rovner M, Kroll J, Schmitt N, et al. Patient satisfaction with health care decisions:
13 the Satisfaction with Decision Scale. *Med Decis Making* 1996;**16**:58-64.
- 14
15
16 34. Gattellari M, Voigt KJ, Butow PN, et al. When the treatment goal is not cure: are cancer
17 patients equipped to make informed decisions? *J Clin Oncol* 2002;**20**:503-513.
- 18
19
20 35. Whelan T, Levine M, Gafni A, et al. Mastectomy or lumpectomy? Helping women make
21 informed choices. *J Clin Oncol* 1999;**17**:1727-1735.
- 22
23
24 36. Van der Feltz-Cornelis CM, Van Oppen P, Van Marwijk HWJ, et al. A patient-doctor
25 relationship questionnaire (PDRQ-9) in primary care: development and psychometric
26 evaluation. *Gen Hospit Psychiatry* 2004;**26**:115-120.
- 27
28
29 37. Hahn SR, Thompson KS, Wills TA, et al. The difficult doctor-patient relationship:
30 somatization, personality and psychopathology. *J Clin Epidemiol* 1994;**47**:647-57.
- 31
32
33 38. Hahn SR, Kroenke K, Spitzer RL, et al. The difficult patient: prevalence, psychopathology,
34 and functional impairment. *J Gen Intern Med* 1996;**11**:1-8.
- 35
36
37 39. Degner LF, Sloan JA, Venkatesh P. The Control Preferences Scale. *Can J Nurs Res*
38 1997;**29**:21-43.
- 39
40
41 40. Giordano A, Mattarozzi K, Pucci E, et al. Participation in medical decision-making: attitudes
42 of Italians with multiple sclerosis. *J Neurol Sci* 2008;**275**:86-91.
- 43
44
45 41. Spielberger CD. Anxiety as an emotional state. (Vol. 1). New York: Academic Press 1972.
- 46
47
48 42. Spielberger CD, Gorsuch RL, Lushene R, et al. Manual for the State-Trait Anxiety Inventory.
49 Palo Alto, CA: Consulting Psychologists Press 1983.
- 50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 43. Lazzari R, Pancheri P. S.T.A.I. Questionario di autovalutazione dell'ansia di stato e di tratto.
4
5 Firenze, IT: Organizzazioni Speciali 1980.
6
7 44. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity
8
9 measure. *J Gen Intern Med* 2001;**16**:606-13.
10
11 45. Kroenke K, Streine TW, Spitzer RL, et al. The PHQ-8 as a measure of current depression in
12
13 general population. *J Affect Disord* 2009;**114**:163-173.
14
15 46. Thekkumpurath P, Walker J, Butcher I, et al. Screening for major depression in cancer
16
17 outpatients: the diagnostic accuracy of the 9-item patient health questionnaire. *Cancer*
18
19 2011;**117**:218-227.
20
21 47. Politi PL, Piccinelli M, Wilkinson G. Reliability, validity and factor structure of the 12-item
22
23 General Health Questionnaire among young males in Italy. *Acta Psychiatr Scand*
24
25 1994;**90**:432-437.
26
27 48. Eysenck SBG, Eysenck HJ, Barrett P. A revised version of the psychoticism scale.
28
29 *Personality and Individual Differences* 1985;**6**:21-29.
30
31 49. O'Connor AM. User Manual-Decision Self-Efficacy Scale. Patient Decision Aids, Ottawa
32
33 Hospital Research Institute (OHIR) Web site.
34
35 http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decision_SelfEfficacy.pdf.
36
37 Accessed October 24, 2012.
38
39 50. De Monchy C, Richardson R, Brown RA, et al. Measuring attitudes of doctors: the doctor-
40
41 patient (DP) rating. *Med Educ* 1988;**22**:231-239.
42
43 51. StataCorp. Stata Statistical Software: Release 11.2. College Station, TX: StataCorp LP 2011.
44
45 52. Pocock SJ. Clinical trials: A practical approach. New York: John Wiley & Sons 1983.
46
47 53. Sullivan LM, D'Agostino RB. Robustness and power of analysis of covariance applied to
48
49 ordinal scaled data as arising in randomized controlled trials. *Stat Med* 2003;**22**:1317-1334
50
51 54. Little R, Yau L. Intent-to-treat analysis for longitudinal studies with drop-outs. *Biometrics*
52
53 1996;**52**:1324-1333.
54
55
56
57
58
59
60

- 1
2
3 55. Skrondal A, Rabe-Hesketh S. Generalized latent variable modelling: Multilevel, longitudinal,
4 and structural equation models. New York: Chapman & Hall/CRC 2004.
5
6
7 56. Mazzi MA, Del Piccolo L, Zimmermann C. Event-based categorical sequential analyses of
8 the medical interview: a review. *Epidemiol Psychiatr Soc* 2003;**12**:81-85.
9
10
11 57. Goss C, Mazzi MA, Del Piccolo L, et al. Information-giving sequences in general practice
12 consultations. *J Eval Clin Pract* 2005;**11**:339-349.
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**The INvolvement of breast CANcer patients during
oncological consultations. A multi-centre randomized
controlled trial. The INCA study protocol.**

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2012-002266.R1
Article Type:	Protocol
Date Submitted by the Author:	16-Jan-2013
Complete List of Authors:	Goss, Claudia; University of Verona Ghilardi, Alberto; University of Brescia, Deledda, giuseppe; University of Verona, Buizza, Chiara; University of Brescia, Bottacini, Alessandro; University of Verona, Del Piccolo, Lidia; University of Verona, Rimondini, Michela; University of Verona, Chiodera, Federica; University of Verona, Mazzi, Maria Angela; University of Verona, Ballarin, Mario; University of Verona, Bighelli, Irene; University of Verona, Strepparava, Maria Grazia; University of Milano-Bicocca, Molino, Annamaria; Hospital Trust, Verona, Fiorio, Elena; Hospital Trust, Verona, Nortilli, Rolando; Hospital Trust, Verona, Caliolo, Chiara; Hospital Trust, Verona, Zuliani, Serena; Hospital Trust, Verona, Auriemma, Alessandra; Hospital Trust, Verona, Maspero, Federica; Hospital Trust, Verona, Simoncini, Edda; Spedali Civili, Brescia, Ragni, Fulvio; Spedali Civili, Brescia, Brown, Richard; Vrginia Commonwealth University, Zimmermann, Christa; University of Verona,
Primary Subject Heading:	Oncology
Secondary Subject Heading:	Patient-centred medicine
Keywords:	patient involvement, breast cancer, docotr-pateint communication

SCHOLARONE™
Manuscripts

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3 **The INvolvement of breast CANcer patients during oncological consultations. A multi-centre**
4 **randomized controlled trial. The INCA study protocol.**
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53 *Word count: 4392*
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58 *Key- word:* patient involvement, breast cancer, doctor-patient communication
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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, 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 pre-consultation intervention to increase involvement of breast cancer patients during the consultation, and 2) explore the role of the family member-attending companions in the information exchange during the consultation.

Methods and analysis: All female patients with breast cancer who attend the Oncology Out-patient Services for the first time will provide 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 (QPS).

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 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 pre consultation intervention (QPS) facilitates greater participation of female patients (and attending companions 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.
- 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 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.
- 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.

Strengths and limitations of this study

- To our knowledge this is the first RCT 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

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3 questions selected on the QPS and undermine the hypothesis of the greater participation of the
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5 QPS intervention group.
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For peer review only

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 their impact on the patient, and the development of guidelines on how to deliver bad news in a sensitive way.[1, 2]

The evidence indicates that patient's preferences for the type and amount of information vary. 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 the patient perceives the received information as either too much or too little. Good clinical practice entails the recognition of variations in patients' preferences, and helping patients accomplish these preferences. When we meet patients' information preferences, patients are better able to handle the information in a way that fits them best, which is associated with better quality of care, coping with illness and treatment adherence.[3]

In the last decade, the focus of many studies has been directed towards activating patients to be more involved in their treatment.[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] To stimulate patients' participation in consultations, patients were encouraged by their doctor to ask questions or advised to prepare a list of questions,[8] or to select their questions from a printed list before the consultation (question prompt sheet-QPS).[4, 9-17] These tools were helpful both for patients and physicians. They improved patient participation and the recall of information after the consultation. Nevertheless 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, patients are frequently accompanied and assisted by a companion: a close family member or another key person. In this context the activation and

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3 involvement of the patient interacts with that of the companion and contributes to the
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5 communication dynamics of the consultation. Olhen and colleagues[18] explored the importance of
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7 significant others in therapeutic decisions and highlighted the notion of “relational autonomy”,
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9 which acknowledges that people are defined by their relationships and are dependent on others in
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11 making decisions.[19] Future research that analyses patients and companions as dyadic units would
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13 offer further insight into the impact of social relations on treatment decision-making processes.
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15 More evidence on the information needs of companions regarding the patient and their role in the
16
17 information and decision processes during the consultation is also needed.
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21 To our knowledge this is the first RCT in Europe which assesses the effects of a pre-consultation
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23 intervention (QPS) on cancer patients’ involvement during the consultation, on their satisfaction
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25 and confidence in coping with illness, and which explores the role of the companion during the
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27 consultation.
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30 31 **METHODS AND ANALYSIS**

32 33 **Study design**

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35 This is a multicentre, randomized controlled trial in which patients are attributed randomly to the
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37 intervention or to the control group on a 1:1 basis. Patients in the intervention group are given the
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39 QPS, a list of 50 specific questions (see below), those in the control group are given a control sheet
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41 on which to write the questions they would like to ask. The oncologists are informed about the
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43 study protocol but are blinded to whether the patient is a participant of the control group or the
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45 intervention group. The oncologists perform their consultation as usual, according to the clinical
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47 practice of their centre. After concluding the consultation, they complete two questionnaires
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49 (DPRQ-10 and CPS, see the Measures section for details) regarding the patient and the consultation.
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53 This protocol follows the CONSORT guidelines.[20]

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55 Standardized questionnaires are administered at baseline (before the randomization) and
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57 immediately after the consultation (figure 1, table 1).
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Figure 1 INCA Study flow diagram

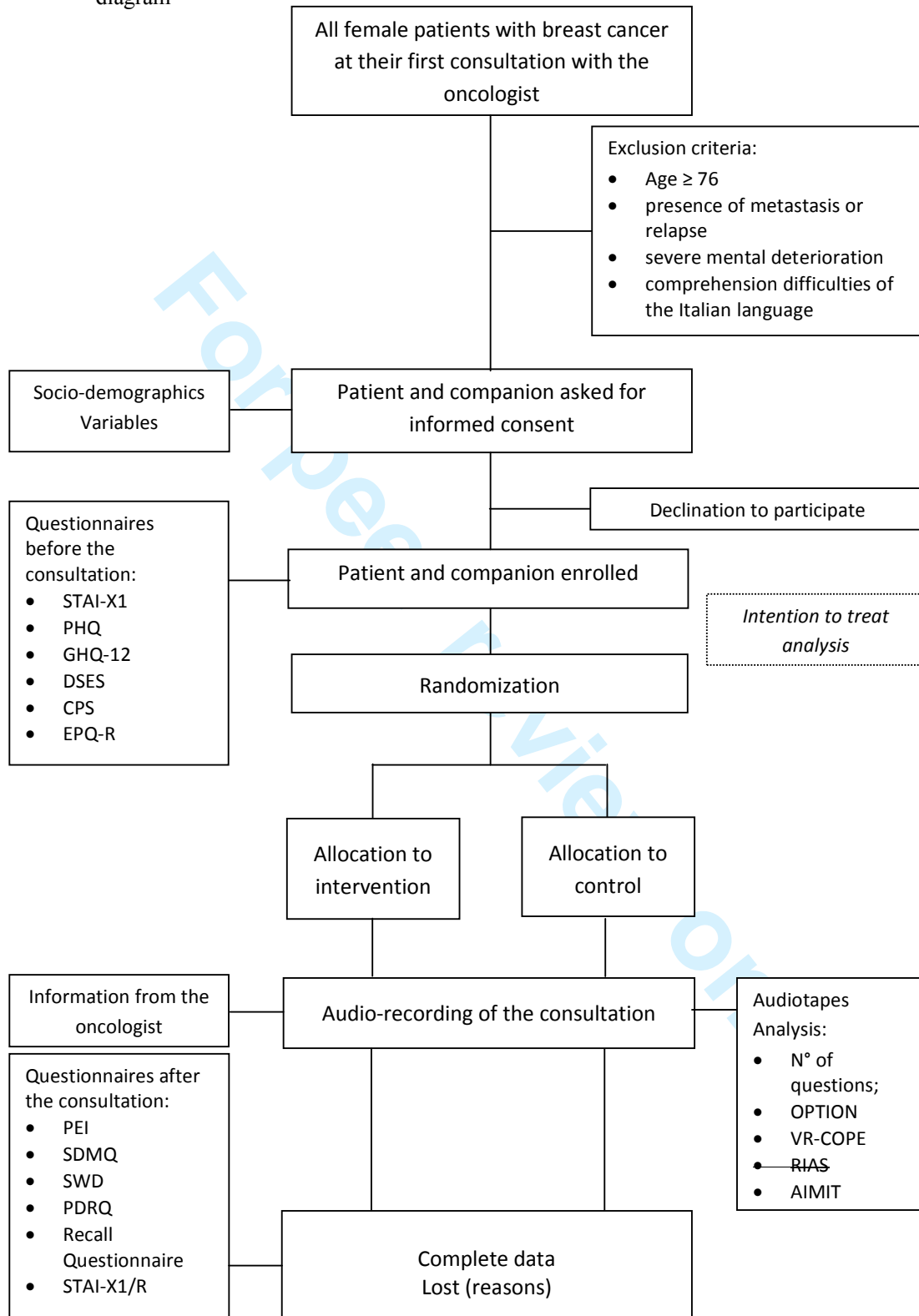


Table 1 Questionnaires and tools used in the study

Tool	Evaluation	Explored area	N° items	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 and oncologists	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 (PEI)	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 supposedly 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	-
RIAS	External rater	Verbal communication	40	-
Assessing Interpersonal Motivations in Transcripts (AIMIT)	External rater	Activity of interpersonal motivational systems	Coding system applied on transcripts.	-

*Adapted version for companion

Time required for answering the questionnaires was approximately 15 – 20 minutes before the consultation and 10 – 15 minutes after.

Intervention

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

Patients and companions (if present) of 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 patient (and companion) is invited to select among a written list of about 50 possible questions those, if any, she would like to ask today to the oncologist. These questions have

1
2
3 been chosen and adapted on the basis of previous studies in the field [4, 9-11] and are divided by
4
5 topics. Questions regard diagnosis (e.g. “Of what type is my cancer?”), treatment (e.g. “Which are
6
7 the pros and cons of the treatment?”), contribution of patient and lifestyle (“What can I do to
8
9 improve the efficacy of treatment?”), prognosis (“What are the chances of relapse?”) and other
10
11 issues (e.g. “Do I need a referral from my GP for the next visit?”).
12
13

16 **Setting**

17
18 Patients are being recruited from three Oncology Departments in Northern Italy: two run by
19
20 Hospital Trust of Verona in the Veneto region (placed in two different part of the city) and one by
21
22 the Hospital Trust of Brescia, in the Lombardia region.
23

24
25 The population of Verona city and its province in 2010 is about 914 382, the population of Brescia
26
27 city and its province about 1 242 923.[21] In the Veneto region the estimation of incidence of breast
28
29 cancer in 2010 was 4 424 new cases per year (Standardized rate adjusted for age using the European
30
31 population as standard (std) per 100,000= 133). In the Lombardia region the estimation of incidence
32
33 of breast cancer in 2010 was 7 456 new cases per year (std = 109).[22]
34

35
36 The three Oncology departments have an out-patient clinic dedicated to breast cancer patients with
37
38 a rotation of 2-5 oncologists.
39

40
41 Visits are scheduled on fixed days with a number of 4 - 8 patients per day. Patients have already
42
43 been diagnosed with cancer, have already been visited by the surgeon and undergone breast
44
45 operation (e.g. lumpectomy). Generally in the first visit with the oncologist the histological results
46
47 are communicated and further medical treatment is decided (e.g chemotherapy, hormone therapy).
48

49
50 The length of the visit can vary from 30 to 60 minutes.
51

54 **Sample and recruitment**

55
56 The study sample will be composed of all consecutive female patients between the age of 18 to 75
57
58 years who attend the Oncology out-patient clinics of the participating centres and who have a recent
59
60

1
2
3 diagnosis of breast cancer at an early stage (absence of metastasis). Exclusion criteria are the
4
5 presence of metastasis or relapse, severe mental deterioration, comprehension difficulties of the
6
7 Italian language. A sample of 300 patients will be recruited, as estimated by the sample size
8
9 calculation (see below). Recruitment phase started in June 2011 and will continue for two years or
10
11 till enrolment will be completed .
12

13 14 15 16 **Procedure**

17
18 Before the recruitment phase the oncologists were informed about the study and asked to
19
20 participate, giving a written informed consent.
21

22
23 All breast cancer female patients at their first out-patient visit with the oncologist of the Clinical
24
25 Oncology Department (and their companions if present), are being asked by a project member to
26
27 give written informed consent to participate in the study (figure 1).
28

29
30 Consenting patients and companions receive an envelope containing six questionnaires to answer
31
32 before the consultation (baseline assessment) (table 1). The project staff member (MAM) then
33
34 randomly allocates consenting patients and their companions to the intervention or control group
35
36 (see also paragraph “Randomization”). Another project staff member (AB, CB, IB or FC) hands out
37
38 the envelopes with either the intervention prompt sheet or the control sheet and collect the sheets
39
40 after their completion. These was done in order to keep the oncologists blind to the intervention or
41
42 control status.
43

44
45 The subsequent consultation is audio recorded. After the consultation, patients and their
46
47 companions complete six other questionnaires.; A project member is present (AB, CB, IB or
48
49 FC)and provides support to the patient or to the companion if they are too much troubled after the
50
51 consultation.
52

53
54 The oncologists reports on a form the cancer stage and type, when and by whom the patient was
55
56 informed about diagnosis, and the therapeutic options appropriate for this patient. They also
57
58 complete a questionnaire measuring their perception of the patient as difficult.
59
60

1
2
3 The audio tapes and oncologists' forms are collected by the project staff.
4

5 The audio tapes are examined for the content and number of questions asked by patients and
6 companions, and are rated applying the OPTION scale,[23-25] which measures the extent to which
7 the oncologist has succeeded to involve the patient in the consultation. The questions that emerge
8 during the consultations are compared with those expressed before the visit. The audio recorded
9 consultations are also analyzed in terms of patient-centredness with the VR-COPE [26] and with the
10 Assessment of Interpersonal Motivation in Transcripts (AIMIT) [27] which evaluates the five
11 different motivational systems that guide the verbal and non verbal behaviours during interactions.
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23 **Randomization**

24
25 The randomization sequence is being conducted off-site using the “random allocation of treatments
26 balanced in blocks (ralloc)” package for Stata[28] and is stratified by centre with a 1:1 allocation
27 ratio of treatment. Block randomization (size 4) is used to minimize large imbalances between the
28 intervention groups. The allocation sequences are generated by an independent individual, are
29 stored in computer files and remain unknown to the researchers until the patient is randomized.
30
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36 The QPS or the control sheet, chosen for the two arms of trial, are placed in opaque envelopes,
37 sealed and numbered in sequence (following the list generated by the randomization procedure) by
38 a staff member of each centre (MAM and CB), not involved in the data collection phase. Both
39 randomization procedure and treatment allocation have been developed to fully conceal treatment
40 allocation.[20, 29]
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47 Patients and oncologists are unaware of the allocation. The raters who analyze the audio- recordings
48 are also blinded to the allocation of patients.
49
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54 **Study aims and hypotheses**

55
56 The main aim is to assess if a pre consultation intervention (QPS) facilitates greater participation of
57 female patients in the consultation process, by determining an increase in questioning and/or in the
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1
2
3 number of different illness related issues (e.g. diagnosis, treatment, prognosis) being discussed with
4
5 the oncologist.

6
7 Other aims are to assess the effect of the QPS on the level of patient involvement by the
8
9 oncologists, on patient satisfaction and coping, on the oncologist's perception of patient's preferred
10
11 decisional role (using the CPS, more details see the measures section) and to explore the role of the
12
13 companion. In detail the study investigates if the intervention determines:

- 14
15 – a greater number of personal information needs expressed during the consultation (the number
16
17 and type of the questions asked during the consultation);
- 18
19 – the perception of a greater capacity to cope with illness and a greater satisfaction with decisions
20
21 made during the consultation (measured with the PEI and SWD; details are described in the
22
23 measures section);
- 24
25 – greater patient generated and/or doctor generated involvement of the patient (using the OPTION
26
27 scale and SDM-Q; details are described in the Measures section);
- 28
29 – a better understanding of the received information and greater satisfaction (measured with the
30
31 Recall questionnaire and the SWD);
- 32
33 – a different perception by the oncologist of patient's preference regarding her participation in
34
35 therapeutic decisions (measured with the CPS answered by the oncologist; details are described
36
37 in the Measures section);
- 38
39 – a different perception by the oncologist and by the patient of the doctor-patient relationship
40
41 (using the DPRQQ 9 and DPRQ-10, see measures section for the details);
- 42
43 – a more patient-centred and sharing approach during the consultation (using the VR-COPE and
44
45 the AIMIT; see Measures section for the details).

46
47 The potential presence of a companion during the consultation allows us to explore if the “question
48
49 prompt sheet” intervention (extended to the companion) changes the companions' role and
50
51 participation during the consultation . Number and type of questions asked by the companion during
52
53 the consultation are also recorded
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2
3 Companions answer the same questionnaires as the patient: PEI for the evaluation of the ability to
4 cope with the patients' illness, SDM-Q for the evaluation the perceived involvement during the
5 consultation, SWD for the satisfaction with decision, PDRQ-9 for the doctor-patient-relationship,
6 and Recall Questionnaire for the understanding of the information received. Where necessary,
7 questionnaires were adapted to the companions by substituting the first person (I) used in the
8 patient version, with the third person (she).For example: "I feel confident that I can get the facts
9 about the medication choices available to her" instead of "I feel confident that I can get the facts
10 about the medication choices available to me" (item 1 of the DSES Scale).
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25 **Study measures**

26 27 28 29 **Socio demographic and clinical data**

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31 Socio demographic data are: age, education, family status and employment status, type of
32 relationship with the companion (if present), reported both by patients and companions during the
33 baseline assessment.
34
35
36

37
38 Oncologists' socio demographic data are: age, gender and years of experience. Data for oncology
39 residents (when present during the consultation) are also obtained.
40
41

42
43 Clinical data are: cancer stage and type, duration of illness (who has informed patient on diagnosis
44 and when), therapeutic options considered appropriate for this patient, all reported on a form by the
45 oncologist.
46
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49 50 51 **Primary outcome measure**

- 52
53
54 – The total number of patient's questions during the consultation regarding diagnosis, prognosis,
55 treatment, lifestyle and other issues. Question asking is considered an index of patient's
56 participation during the consultation. The QPS aims to increase the number of question by
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59
60

1
2
3 giving the opportunity to patients to reflect on their informative needs choosing among a wide
4
5 range of possible questions those ones perceived as most relevant in view of the subsequent
6
7 consultation.
8
9

10 11 **Secondary outcome measures**

- 12
13
14 – The number of unmet information needs that emerge during the consultation. This measure is
15
16 obtained by comparing the number of questions indicated by patients and their companion
17
18 before the consultation (i.e., those selected in the QPS by patient) with those actually raised
19
20 during the consultation (i.e., those identified subsequent to listening to the audio-recordings).
21
22
- 23 – Ability to cope with the illness, measured with the Patient Enablement Instrument (PEI). This
24
25 questionnaire is a self-administered questionnaire of six items on a Likert scale from 0 (same or
26
27 less) to 2 (much better, much more)[30]. We suppose a better ability to cope with the illness in
28
29 the intervention group.
30
31
- 32 – Patient involvement, measured with the Shared Decision Making Questionnaire (SDM-Q) and
33
34 the OPTION Scale. The SDM-Q is a self administered questionnaire of 9 items on a Likert scale
35
36 from 1 (completely disagree) to 6 (agree completely) and assesses patients' perception of the
37
38 decisional process and their level of involvement during the consultation, the information
39
40 received on therapeutic options, the potential risks and benefits regarding the participation at the
41
42 decisional process.[31, 32] The OPTION Scale is composed of 12 items of operational
43
44 definitions of different patient involving skills, rated on a Likert scale from 0 (behaviour absent)
45
46 to 4 (behaviour observed at an excellent skill level)[23-25]. The scale is applied by trained raters
47
48 to the audio recording of the consultation. In summary, it examines whether problems are well
49
50 defined, whether options are formulated, information provided, patient understanding and role
51
52 preference evaluated, and decisions examined from both the professional and patient
53
54 perspective. The total score ranges from 0 (0 in all items) to 48 (4 in all items) and is
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3 transformed into a 0 -100 score. We suppose a higher patient involvement during the
4 consultation in the intervention group.

- 5
6
7 – Satisfaction with decisions made during the consultation, measured with the Satisfaction with
8 Decision Scale (SWD). This is a self administered questionnaire of 6 items on a Likert scale
9 from 0 (completely disagree) to 5 (agree completely) [33]. We suppose a higher patient
10 satisfaction of patients in the intervention group.
- 11
12 – Recalling and understanding of information, measured with the Recall Questionnaire. This
13 questionnaire consists of six questions which ask the patient to recall the received information
14 on treatment decisions and pathology (e.g. “What was the treatment decision? Which treatment
15 options were discussed?”). The questions have been prepared for the present study with
16 reference to previous studies.[11, 34, 35] The questionnaire allows with the help of the audio
17 recorded consultation to evaluate patient’s correct recall and understanding by comparing
18 patients’ reports with what was actually discussed during the consultation. We suppose that
19 patients assigned to the intervention group can recall more precise information.
- 20
21 – Three other questions, rated on a 0 (no at all) to 5 (very much) Likert scale asked whether the
22 patient succeeded in their purpose of question asking, whether the oncologist answered the
23 questions properly and how much more information she would have needed. We suppose that
24 patients assigned to the intervention group felt themselves more successful in question asking.
- 25
26 – Overall consultation atmosphere, is measured with the Verona Patient-centred Communication
27 Evaluation scale (VR-COPE) and the Assessing Interpersonal Motivations in Transcripts
28 (AIMIT).[27] VR-COPE [26] assesses the content, the process and relational aspects of patient-
29 centred communication during medical consultations on the basis of a multidimensional
30 evaluation and comprises nine items. Each item is defined by operational definitions and rated
31 on a 0-10 point scale. The scale is applied by trained raters on the audio-recording of the
32 consultation. We expect that patients of the intervention group establish a better relationship
33 with their oncologist and show higher scores in patient-centred communication. AIMIT[27] is a
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3 coding system applied on transcripts aiming to systematically detect the activity of interpersonal
4 motivational systems. Systems identified are five (attachment, caregiving, rank, sexuality, peer
5 cooperation) and they guide the verbal and non verbal behaviours during interactions. We
6
7 suppose that patients of the intervention group evidence a more cooperative style during the
8 consultation.
9

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14 – Perceived Patient-doctor relationship, measured with the Patient – Doctor Relationship
15 Questionnaire (PDRQ-9) and the Difficult Doctor Patient Relationship Questionnaire (DDPRQ-
16 10). PDRQ-9 is a self-administered questionnaire of 9 items on a Likert scale from 1 (not at all
17 appropriate) to 5 (totally appropriate), to measure the relationship between the doctor and the
18 patient, from a patient point of view.[36] The DDPRQ-10 (is a self-report instrument of 10
19 items on a Likert scale from 1 (not at all) to 6 (a great deal), is completed by physicians after the
20 encounter with a patient.[37, 38] The questionnaire identifies the patients experienced as
21 difficult patients. We suppose that the doctor-patient relationship in the intervention group is
22 perceived as less difficult.
23
24
25 – Oncologists answered three questions on the potential presence of anxiety, depression or
26 emotional distress in the patient and a fourth on their difficulty experienced in answering the
27 patient's questions. Answering questions of patients in the intervention group should be
28 perceived by oncologists as less difficult.
29
30
31 – Perceived role preference of the patient, measured with the Control Preference Scale (CPS,
32 Oncologist version) [39, 40]. This scale assesses how the oncologist perceives the role that
33 patient might prefer regarding the decision making process. Oncologists should be better able to
34 identify patients preferred role in the intervention group.
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36
37 – Duration of the consultation, measured in minutes. We suppose a longer duration of the
38 consultation in the intervention group.
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Process related and potential confounding variables

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3 The measures below have been collected in order to check their possible influence on question
4 asking (primary outcome).
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- 7
8 – Anxiety, depression and general well-being, measured with the State Anxiety Inventory (STAI-
9 X1, XR),[41-43] the Patient Health Questionnaire depression scale (PHQ-9) [44-46] and the
10 General Health Questionnaire (GHQ-12) [47].
11

12
13 STAI-X1 is a self-administered questionnaire of 20 items on a Likert scale from 1 (not at all) to
14 4 (very much) completed before the consultation. Higher total scores indicate greater state
15 anxiety. The STAI-X1R, administered after the consultation, is a shorter version of ten out of
16 the twenty items of the STAI-X1, and it is used to evaluate the state anxiety level at the end of
17 the consultation and to compare this level with the one measured at the beginning. PHQ-9 is a
18 self-assessment questionnaire for detecting the presence of depression and consists of 9 items
19 with response options of 0 (not at all) to 3 (almost every day), and has a summative score range
20 of 0 to 27. We score it in the standard way, using the sum of the 0–3 scores for each item, and
21 ≥ 8 as a cut-score for possible cases of depression [44-46]. GHQ-12 is a self administrated
22 questionnaire of 12 items and has a summative score range of 0 to 12 and a cut-score of >3
23 indicating psychological distress.[47]
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- 38 – Personality traits, measured with the Eysenck Personality Questionnaire (EPQR-S) [48]. The
39 EPQR-S is a self-administered questionnaire of 48 items on yes/no scale. For our study we use
40 two subscales: the Extraversion/Introversion (12 items) and Neuroticism/Stability (12 items).
41 The “Extroversion” is characterized by being outgoing, talkative, high on positive affect (feeling
42 good) and in need of external stimulation. The “Neuroticism” or emotionality is characterized
43 by high levels of negative affect such as depression and anxiety.
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51 – Confidence with decision, measured with the Decision Self Efficacy Scale (DSES).[49] This
52 self- administered questionnaire for patients consists of 11 items on a Likert scale from 0 (not at
53 all confident) to 4 (very confident).
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- 1
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3 – Patients' and their companion's preference for the role they want to have in the decision making
4 process, measured with the Control Preference Scale (CPS) [39, 40]. This self-administered
5 instrument contains 5 vignettes with text, depicting different patient roles (from active to
6 passive) from which patients choose the one considered as most appropriate for them.
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10
11 – Patient-centred communication style and attitude toward the doctor-patient relationship,
12 measured with the Doctor-Patient (DP) Scale [50]. The Scale measures the degree of
13 oncologists' self reported patient or doctor-centred communication style and attitude. It consists
14 of 48 statements to rate on a Likert scale from 1 (strong agreement) to 5 (strong disagreement).
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21 It has a summative score range of 48 to 240. The scale is completed by all oncologists who join
22 the study.
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26

27 **Sample size calculation**

28
29 A sample of 300 patients will be recruited. This number has been estimated to account for
30 approximately a 15% of withdrawal rate, so that 250-260 patients will complete the study, with
31 about 130 patients in each arm. The primary outcome measure is the number of patient questions.
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35
36 The international literature reports a mean number of nine questions (range 0-53) for breast cancer
37 patients. Since such data are not available in the Italian context, an observational phase was
38 conducted. We recruited a sample of 30 patients (10 for each centre) with the same characteristics,
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43 in order to assess the number and type of questions asked by the patient during the consultation, to
44 understand the ongoing interaction between oncologists and patients in a first encounter and to test
45 the feasibility of procedures and questionnaires. This observational study resulted in a mean number
46 of 18 (sd=13) patient questions asked during a first encounter with the oncologist. An intervention
47 intended to increase the number of questions might be considered efficacious with an increase of
48 30%. The sample size required to evidence such difference was calculated using the sampsi
49 command of Stata 11,[51] assuming a power of 80% and a two-sided significant level of 5% on a
50 student t-test for differences between independent groups.[52, 53]
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Statistical analysis

The data will be analyzed according to intention-to-treat principle. [54] Standard statistical techniques will be used to describe 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.[20] 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.[55]

EXPECTED ACHIEVEMENT

The involvement and participation of patients 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.

We expect that female 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. The use of a question prompt sheet might be a simple and quick device in improving the overall communication between oncologist and patient. It might be routinely used before the consultation and also brought into the consultation and discussed with the oncologist to further increase patient and companion participation. Evidence demonstrates that efficacious communication positively influences the understanding and satisfaction of the patient, treatment adherence and health status. Moreover, the oncologist's

1
2
3 knowledge and consideration of the information needs of the companions who in Italy are often
4
5 present may further facilitate patient's participation in the therapeutic program.
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7
8

9 10 **DISCUSSION**

11 It has been demonstrate in English speaking countries that the Question Prompt sheet is an useful
12
13 tool to improve patient's participation during the consultation. There is a need to explore the effect
14
15 of a Question Prompt Sheet during oncological consultation also in other countries. To our
16
17 knowledge there are no published RCTs in Europe which assess the effects of a pre-consultation
18
19 intervention and explore the role and the effect of the companion as well. The study has a strong
20
21 design that incorporates computerised random allocation, blinding of data-collection staff and the
22
23 use of measures on the audio recordings. The analysis of the consultation recordings is a valuable
24
25 research method and is a recommended tool for documenting the interaction between patients and
26
27 oncologists. [56]
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29

30
31 There are some limitations to consider. The QPS was collected prior to the consultation, while in
32
33 previous trials reported in literature [4,10-15], patients were allowed to bring the QPS into the
34
35 consultation to refer to. Patients in our study therefore might not remember all selected questions
36
37 and ask less questions, by this undermining the hypothesis of the greater participation of the QPS
38
39 intervention group. On the other hand, in our study oncologists are kept blind to the intervention or
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41 control status of the patients and are not forced to change their routine clinical
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43 approach to the consultation. Once the study will be completed we will discuss the findings with the
44
45 oncologists and we hope that afterwards the QPS can be used routinely in their practice.
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49 The findings from this study will provide a basis for further research in the field and provide
50
51 potentially important results for clinicians, patients and policy makers that may lead to a wider use
52
53 of QPS also in other context.
54
55

56 57 58 **ETHICS AND DISSEMINATION PLANS**

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3 The study was approved by the local Ethics Committees of the Hospital Trust of Verona. The study
4 is registered at ClinicalTrials.gov (identifier: NCT01510964). This protocol follows the CONSORT
5 guidelines.[20]
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7

8
9 Recruitment phase started in June 2011 and will continue till the enrolment will be completed and is
10 expected to be closed in May 2013. Analysis will start after data monitoring and checking is
11 completed. The dissemination of the trial findings will principally be carried out through
12 publications in peer-review journal and presentations at national/international conferences focused
13 on cancer and/or communication, for examples European Association for Communication in Health
14 Care Conferences and International Shared Decision Making Conferences.
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25 **FUNDING**

26
27 This research received no specific grant from any funding agency in the public, commercial or not-
28 for-profit sectors.
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34 **COMPETING INTERESTS**

35
36 The authors declared that they have no competing interest.
37
38
39

40 **AUTHORS' CONTRIBUTIONS**

41
42 CG, LDP, MR, CZ developed the study protocol and together with AG and MGS supervised the all
43 procedures. MAM is the trial statistician and is responsible for generating the randomization
44 sequences and providing guidance on statistical analysis of trial data. MB is the computer scientist
45 that developed the database to save the data. CG drafted the manuscript, will oversee enrolment and
46 data collection. GD, AB, FC, CB, IB, AM, EF, RN, CC, SZ, AA, FM, ELS, FR participated in
47 enrolling the patients. All authors saw and approved the final version of the manuscript.
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58 **REFERENCES**

- 1
2
3 1. Buckman R. *Breaking bad news: a guide for healthcare professionals*. Baltimore, MD: John
4 Hopkins University Press 1992.
- 5
6
7 2. Baile WF, Buckman R, Lenzi R, et al. AP. SPIKES - A six-step protocol for delivering bad
8 news: Application to the patient with cancer. *Oncologist* 2000;**5**:302-311.
- 9
10
11 3. Joosten EAG, DeFuentes-Merilla L, de Weert GH, Sensky T, et al. Systematic review of the
12 effects of shared decision making on patient satisfaction, treatment adherence and health
13 status. *Psychother Psychosom* 2008;**77**:219-226.
- 14
15
16 4. Clayton JM, Butow PN, Tattersall MH, et al. Randomized controlled trial of a prompt list to
17 help advanced cancer patients and their caregivers to ask questions about prognosis and end-
18 of-life care. *J Clin Oncol* 2007;**25**:715-723.
- 19
20
21 5. Charles C, Gafni A, Whelan T. How to improve communication between doctors and
22 patients. Learning more about the decision making context is important. *BMJ* 2000;**320**:1220-
23 1221.
- 24
25
26 6. Drew P, Chatwin J, Collins S. Conversation analysis: a method for research into interactions
27 between patients and health-care professionals. *Health Expectat* 2001;**4**:58-70.
- 28
29
30 7. Zimmermann C, Del Piccolo L, Mazzi MA. Patient cues and medical interviewing in general
31 practice. Examples of the application of sequential analysis. *Epidemiol Psychiatr Soc*
32 2003;**12**:115-123.
- 33
34
35 8. Kidd J, Marteau TM, Robinson S, et al. Promoting patient participation in consultations: a
36 randomized controlled trial to evaluate the effectiveness of three patient-focused
37 interventions. *Patient Educ Couns* 2004;**52**:107-12.
- 38
39
40 9. Butow PN, Dunn SM, Tattersall MHN, et al. Patient participation in the cancer consultation:
41 evaluation of a question prompt sheet. *Ann Oncol* 1994;**5**:199-204.
- 42
43
44 10. Brown R, Butow PN, Boyer MJ, et al. Promoting patient participation in the cancer
45 consultation: evaluation of a prompt sheet and coaching in question-asking. *Br J Cancer*
46 1999;**80**:242-248.
- 47
48
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 11. Brown RF, Butow PN, Dunn SM, et al. Promoting patient participation and shortening cancer
4 consultations: a randomised trial. *Br J Cancer* 2001;**8**:1273-1279.
- 5
6
7 12. Bruera E, Sweeney C, Willey J, et al. Breast cancer patient perception of the helpfulness of a
8 prompt sheet versus a general information sheet during outpatient consultation: a randomized
9 controlled trial. *J Pain Symptom Manage* 2003;**5**:412-419.
- 10
11
12 13. Glynne-Jones R, Ostler P, Lumley-Graybow S, et al. Can I look at my list? An evaluation of a
13 'prompt sheet' within an oncology outpatient clinic. *Clin Oncol* 2006;**18**:395-400.
- 14
15
16 14. Clayton J, Butow P, Tattersall M, et al. Asking questions can help: development and
17 preliminary evaluation of a question prompt list for palliative care patients. *Br J Cancer*
18 2003;**89**:2069-2077.
- 19
20
21 15. Clayton JM, Butow PN, Tattersall MH, et al. Randomized controlled trial of a prompt list to
22 help advanced cancer patients and their caregivers to ask questions about prognosis and end-
23 of-life care. *J Clin Oncol* 2007;**25**:715-723.
- 24
25
26 16. Van der Meulen N, Jansen J, van Dulmen S, et al. Interventions to improve recall of medical
27 information in cancer patients: a systematic review of the literature. *Psychooncology*
28 2008;**17**:857-68.
- 29
30
31 17. Van Weert JC, Jansen J, Spreeuwenberg PM, et al. Effects of communication skills training
32 and a Question Prompt Sheet to improve communication with older cancer patients: a
33 randomized controlled trial. *Crit Rev Oncol Hematol* 2011;**80**:145-59.
- 34
35
36 18. Ohlen J, Balneaves L, Bottorff J, et al. The influence of significant others in complementary
37 and alternative medicine decisions by cancer patients. *Soc Sci Med* 2006;**63**:1625-1636.
- 38
39
40 19. Christman J. Relational autonomy, liberal individualism, and the social constitution of selves.
41 *Philosophical Studies* 2004;**117**:143-164.
- 42
43
44 20. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration:
45 updated guidelines for reporting parallel group randomized trials. *BMJ* 2010;**340**:c869. DOI:
46 10.1136/bmj.c869.
- 47
48
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 21. Istituto Nazionale di Statistica (ISTAT) Web site.
4
5 <http://www.demo.istat.it/pop2010/index.html>. Accessed October 24, 2012.
6
- 7 22. Centro Nazionale di Epidemiologia, Sorveglianza e Promozione della Salute - Istituto
8
9 Superiore di Sanità (ISS) Web site. http://www.tumori.net/it3/banca_dati/query.php. Accessed
10
11 October 24, 2012.
12
- 13 23. Elwyn G, Hutchings H, Edwards A, et al. The OPTION scale: measuring the extent that
14
15 clinicians involve patients in decision-making tasks. *Health Expectat* 2005;**8**:34-42.
16
- 17 24. Goss C, Fontanesi S, Mazzi MA, et al. The assessment of patient involvement across
18
19 consultation. The Italian version of the OPTION scale (in Italian). *Epidemiol Psichiatr Soc*
20
21 2007;**16**:339-349.
22
- 23 25. Goss C, Fontanesi S, Mazzi MA, et al. Shared decision making: the reliability of the OPTION
24
25 scale in Italy. *Pat Educ Counsel* 2007;**66**:296-302.
26
27
- 28 26. Del Piccolo L, Mazzi MA, Scardoni S, et al. A theory based proposal to evaluate patient-
29
30 centred communication in medical consultations: the Verona Patient-centred Communication
31
32 Evaluation scale (VR-COPE). *Health Education* 2008;**108**:355-372.
33
- 34 27. Fassone G, Valcella F, Pallini S, et al. Assessment of Interpersonal Motivation in Transcripts
35
36 (AIMIT): an inter- and intra-rater reliability study of a new method of detection of
37
38 interpersonal motivational systems in psychotherapy. *Clin Psychol Psychother* 2012;**19**: 224-
39
40 34.
41
42
- 43 28. Ryan P. sxd1 4: Random allocation of treatments in blocks. *Stata Journal* 2008;**8**:146.
44
- 45 29. Altman DG, Schulz KF, Moher D, et al. The revised CONSORT statement for reporting
46
47 randomized trials: explanation and elaboration. *Ann Intern Med* 2001;**134**:663-94.
48
49
- 50 30. Howie JG, Heaney DJ, Maxwell M, et al. A comparison of a Patient Enablement Instrument
51
52 (PEI) against two established satisfaction scales as an outcome measure of primary care
53
54 consultations. *Fam Pract* 1998;**15**:165-171.
55
56
57
58
59
60

- 1
2
3 31. Simon D, Chorr G, Wirtz M, et al. Development and first validation of the shared decision
4 making questionnaire (SDM-Q). *Pat Educ Counsel* 2006;**63**:319-327.
- 5
6
7 32. Kriston L, Scholl I, Hölzel L, et al. The 9-item Shared Decision Making Questionnaire (SDM-
8 Q-9). Development and psychometric properties in a primary care sample. *Patient Educ*
9
10
11
12
13
14 33. Holmes-Rovner M, Kroll J, Schmitt N, et al. Patient satisfaction with health care decisions:
15 the Satisfaction with Decision Scale. *Med Decis Making* 1996;**16**:58-64.
- 16
17
18 34. Gattellari M, Voigt KJ, Butow PN, et al. When the treatment goal is not cure: are cancer
19 patients equipped to make informed decisions? *J Clin Oncol* 2002;**20**:503-513.
- 20
21
22
23 35. Whelan T, Levine M, Gafni A, et al. Mastectomy or lumpectomy? Helping women make
24 informed choices. *J Clin Oncol* 1999;**17**:1727-1735.
- 25
26
27 36. Van der Feltz-Cornelis CM, Van Oppen P, Van Marwijk HWJ, et al. A patient-doctor
28 relationship questionnaire (PDRQ-9) in primary care: development and psychometric
29 evaluation. *Gen Hospit Psychiatry* 2004;**26**:115-120.
- 30
31
32
33 37. Hahn SR, Thompson KS, Wills TA, et al. The difficult doctor-patient relationship:
34 somatization, personality and psychopathology. *J Clin Epidemiol* 1994;**47**:647-57.
- 35
36
37
38 38. Hahn SR, Kroenke K, Spitzer RL, et al. The difficult patient: prevalence, psychopathology,
39 and functional impairment. *J Gen Intern Med* 1996;**11**:1-8.
- 40
41
42
43 39. Degner LF, Sloan JA, Venkatesh P. The Control Preferences Scale. *Can J Nurs Res*
44 1997;**29**:21-43.
- 45
46
47 40. Giordano A, Mattarozzi K, Pucci E, et al. Participation in medical decision-making: attitudes
48 of Italians with multiple sclerosis. *J Neurol Sci* 2008;**275**:86-91.
- 49
50
51
52 41. Spielberger CD. Anxiety as an emotional state. (Vol. 1). New York: Academic Press 1972.
- 53
54 42. Spielberger CD, Gorsuch RL, Lushene R, et al. Manual for the State-Trait Anxiety Inventory.
55 Palo Alto, CA: Consulting Psychologists Press 1983.
- 56
57
58
59
60

- 1
2
3 43. Lazzari R, Pancheri P. S.T.A.I. Questionario di autovalutazione dell'ansia di stato e di tratto.
4
5 Firenze, IT: Organizzazioni Speciali 1980.
6
7 44. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity
8
9 measure. *J Gen Intern Med* 2001;**16**:606-13.
10
11 45. Kroenke K, Streine TW, Spitzer RL, et al. The PHQ-8 as a measure of current depression in
12
13 general population. *J Affect Disord* 2009;**114**:163-173.
14
15 46. Thekkumpurath P, Walker J, Butcher I, et al. Screening for major depression in cancer
16
17 outpatients: the diagnostic accuracy of the 9-item patient health questionnaire. *Cancer*
18
19 2011;**117**:218-227.
20
21 47. Politi PL, Piccinelli M, Wilkinson G. Reliability, validity and factor structure of the 12-item
22
23 General Health Questionnaire among young males in Italy. *Acta Psychiatr Scand*
24
25 1994;**90**:432-437.
26
27 48. Eysenck SBG, Eysenck HJ, Barrett P. A revised version of the psychoticism scale.
28
29 *Personality and Individual Differences* 1985;**6**:21-29.
30
31 49. O'Connor AM. User Manual-Decision Self-Efficacy Scale. Patient Decision Aids, Ottawa
32
33 Hospital Research Institute (OHIR) Web site.
34
35 http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decision_SelfEfficacy.pdf.
36
37 Accessed October 24, 2012.
38
39 40
41
42 50. De Monchy C, Richardson R, Brown RA, et al. Measuring attitudes of doctors: the doctor-
43
44 patient (DP) rating. *Med Educ* 1988;**22**:231-239.
45
46 51. StataCorp. Stata Statistical Software: Release 11.2. College Station, TX: StataCorp LP 2011.
47
48 52. Pocock SJ. Clinical trials: A practical approach. New York: John Wiley & Sons 1983.
49
50 53. Sullivan LM, D'Agostino RB. Robustness and power of analysis of covariance applied to
51
52 ordinal scaled data as arising in randomized controlled trials. *Stat Med* 2003;**22**:1317-1334
53
54 54. Little R, Yau L. Intent-to-treat analysis for longitudinal studies with drop-outs. *Biometrics*
55
56 1996;**52**:1324-1333.
57
58
59
60

- 1
2
3 55. Skrondal A, Rabe-Hesketh S. Generalized latent variable modelling: Multilevel, longitudinal,
4 and structural equation models. New York: Chapman & Hall/CRC 2004.
5
6
7 56. Tattersall MHN, Butow PN. Consultation audio tapes: an underused cancer patient
8 information aid and clinical research tool. *Lancet Oncol* 2002;3:431-437.
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
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3 **The INvolvement of breast CANcer patients during oncological consultations. A multi-centre**
4 **randomized controlled trial. The INCA study protocol.**
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53 **Word count: 4392**
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58 **Key- word:** patient involvement, breast cancer, doctor-patient communication
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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, 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 pre-consultation intervention to increase involvement of breast cancer patients during the consultation, and 2) explore the role of the family member-attending companions in the information exchange during the consultation.

Methods and analysis: All female patients with breast cancer who attend the Oncology Out-patient Services for the first time will provide 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 (QPS).

The primary outcome main 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 companions and their involvement during the consultation. All outcome measures are supposed to significantly increase in the intervention group.

The hypotheses are: the intervention group will have increases in, the number of questions asked by the patient, his/her involvement in the information exchange and the decisional process, the perception that information needs have been met, and the patient-centeredness of the consultations

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 pre consultation intervention (QPS) facilitates greater participation of female patients (and attending companions 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.
- 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 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.
- 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.

Strengths and limitations of this study

- To our knowledge this is the first RCT 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 ~~family member~~ 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 their impact on the patient, and the development of guidelines on how to deliver bad news in a sensitive way.[1, 2]

The evidence indicates that patient's preferences for the type and amount of information vary. 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 the patient perceives the received information as either too much or too little. Good clinical practice entails the recognition of variations in patients' preferences, and helping patients accomplish these preferences. When we meet patients' information preferences, patients are better able to handle the information in a way that fits them best, which is associated with better quality of care, coping with illness and treatment adherence.[3]

In the last decade, the focus of many studies has been directed towards activating patients to be more involved in their treatment.[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] To stimulate patients' participation in consultations, patients were encouraged by their doctor to ask questions or advised to prepare a list of questions,[8] or to select their questions from a printed list before the consultation (question prompt sheet-QPS).[4, 9-15,17] These tools were helpful both for patients and physicians. They improved patient participation and the recall of information after the consultation. Nevertheless 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, patients are frequently accompanied and assisted by a companion: a close family member or another key person. In this context the activation and

1
2
3 involvement of the patient interacts with that of the companion key person and contributes to the
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5 communication dynamics of the consultation. Olhen and colleagues[18] explored the importance of
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7 significant others in therapeutic decisions and highlighted the notion of “relational autonomy”,
8
9 which acknowledges that people are defined by their relationships and are dependent on others in
10
11 making decisions.[19] Future research that analyses patients and companions as dyadic units would
12
13 offer further insight into the impact of social relations on treatment decision-making processes.
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15 More evidence on the information needs of family members companion regarding the patient and
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17 their role in the information and decision processes during the consultation is also needed.
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20 To our knowledge this is the first RCT in Europe which assesses the effects of a pre-consultation
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22 intervention (QPS) on cancer patients’ involvement during the consultation, on their satisfaction
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24 and confidence in coping with illness, and which explores the role of the family member companion
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26 during the consultation.
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32 METHODS AND ANALYSIS

33 Study design

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35 This is a multicentre, randomized controlled trial in which patients are attributed randomly to the
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37 intervention or to the control group on a 1:1 basis. Patients in the intervention group are given the
38
39 QPS, a list of 50 specific questions (see below), those in the control group are given a control sheet
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41 on which to write the questions they would like to ask. The oncologists are informed about the
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43 study protocol but are blinded to whether the patient is a participant of the control group or the
44
45 intervention group. The oncologists perform their consultation as usual, according to the clinical
46
47 practice of their centre. After concluding the consultation, they complete two questionnaires
48
49 (DPRQ-10 and CPS, see the Measures section for details) regarding the patient and the consultation.
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53 This protocol follows the CONSORT guidelines.[20]

54
55 Standardized questionnaires are administered at baseline (before the randomization) and
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57 immediately after the consultation (figure 1, table 1).
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Figure 1 INCA Study flow diagram

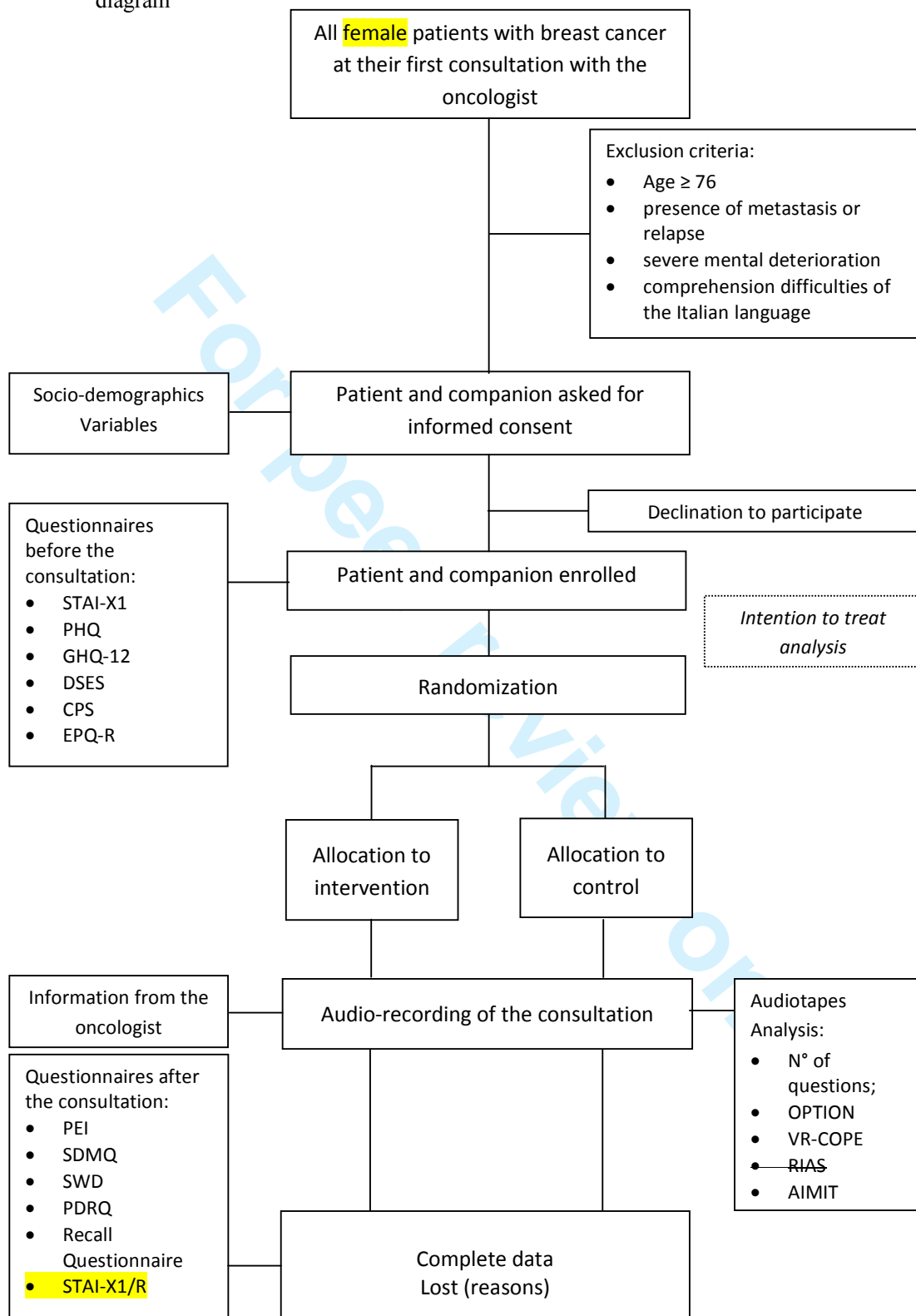


Table 1 Questionnaires and tools used in the study

Tool	Evaluation	Explored area	N° items	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 and oncologists	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 (PEI)	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 supposedly 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	-
RIAS	External rater	Verbal communication	40	-
Assessing Interpersonal Motivations in Transcripts (AIMIT)	External rater	Activity of interpersonal motivational systems	Coding system applied on transcripts.	-

*Adapted version for companion

Time required for answering the questionnaires was approximately 15 – 20 minutes before the consultation and 10 – 15 minutes after.

Intervention

Patients and companions (if present) of both, intervention and control group, receive a form on which to write their reply to the following request: “Please indicate the arguments issues which you want to discuss today with your oncologist”.

Patients and companions (if present) of 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 patient (and companion) is invited to select among a written list of about 50 possible questions those, if any, she would like to ask today to the oncologist. These questions have

1
2
3 been chosen and adapted on the basis of previous studies in the field [4, 9-11] and are divided by
4
5 topics. Questions regard diagnosis (e.g. “Of what type is my cancer?”), treatment (e.g. “Which are
6
7 the pros and cons of the treatment?”), contribution of patient and lifestyle (“What can I do to
8
9 improve the efficacy of treatment?”), prognosis (“What are the chances of relapse?”) and other
10
11 issues (e.g. “Do I need a referral from my GP for the next visit?”).
12
13

14 15 16 **Setting**

17
18 Patients are being recruited from three Oncology Departments in Northern Italy: two run by
19
20 Hospital Trust of Verona in the Veneto region (placed in two different part of the city) and one by
21
22 the Hospital Trust of Brescia, in the Lombardia region.
23

24
25 The population of Verona city and its province in 2010 is about 914 382, the population of Brescia
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27 city and its province about 1 242 923.[21] In the Veneto region the estimation of incidence of breast
28
29 cancer in 2010 was 4 424 new cases per year (Standardized rate adjusted for age using the European
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31 population as standard (std) per 100,000= 133). In the Lombardia region the estimation of incidence
32
33 of breast cancer in 2010 was 7 456 new cases per year (std = 109).[22]
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36
37 The three Oncology departments have an out-patient clinic dedicated to breast cancer patients with
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39 a rotation of 2-5 oncologists.

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41 Visits are scheduled on fixed days with a number of 4 - 8 patients per day. Patients have already
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43 been diagnosed with cancer, have already been visited by the surgeon and undergone breast
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45 operation (e.g. lumpectomy). Generally in the first visit with the oncologist the histological results
46
47 are communicated and further medical treatment is decided (e.g chemotherapy, hormone therapy).
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49
50 The length of the visit can vary from 30 to 60 minutes.
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53 54 **Sample and recruitment**

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56 The study sample will be composed of all consecutive **female** patients between the age of 18 to 75
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58 years who attend the Oncology out-patient clinics of the participating centres and who have a recent
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3 diagnosis of breast cancer at an early stage (absence of metastasis). Exclusion criteria are the
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5 presence of metastasis or relapse, severe mental deterioration, comprehension difficulties of the
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7 Italian language. A sample of 300 patients will be recruited, as estimated by the sample size
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9 calculation (see below). Recruitment phase started in June 2011 and will continue for two years or
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11 till enrolment will be completed .
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13

14 15 16 Procedure

17
18 Before the recruitment phase the oncologists were informed about the study and asked to
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20 participate, giving a written informed consent.
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22
23 All breast cancer female patients at their first out-patient visit with the oncologist of the Clinical
24
25 Oncology Department (and their companions if present), are being asked by a project member to
26
27 give written informed consent to participate in the study (figure 1).
28

29
30 Consenting patients and companions receive an envelope containing six questionnaires to answer
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32 before the consultation (baseline assessment) (table 1). The project staff member (MAM) then
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34 randomly allocates consenting patients and their companions to the intervention or control group
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36 (see also paragraph “Randomization”). Another project staff member (AB, CB, IB or FC) hands out
37
38 the envelopes with either the intervention prompt sheet or the control sheet and collect the sheets
39
40 after their completion. These was done in order to keep the oncologists blind to the intervention or
41
42 control status.
43
44

45
46 The subsequent consultation is audio recorded. After the consultation, patients and their
47
48 companions complete six other questionnaires. with assistance from the project member; A project
49
50 member is present (AB, CB, IB or FC) and provides support to the patient or to the companion if
51
52 they are too much troubled after the consultation.
53

54
55 The oncologists reports on a form the cancer stage and type, when and by whom the patient was
56
57 informed about diagnosis, and the therapeutic options appropriate for this patient. They also
58
59 complete a questionnaire measuring their perception of the patient as difficult.
60

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

4
5 The audio tapes are examined for the content and number of questions asked by patients and
6
7 companions, and are rated applying the OPTION scale,[23-25] which measures the extent to which
8
9 the oncologist has succeeded to involve the patient in the consultation. The questions that emerge
10
11 during the consultations are compared with those expressed before the visit. The audio recorded
12
13 consultations are also analyzed in terms of patient-centredness with the Roter Interaction Analysis
14
15 System (RIAS),[24, 25] a system for coding doctor-patient communication, with the VR-COPE
16
17 [26] and with the Assessment of Interpersonal Motivation in Transcripts (AIMIT) [27] which
18
19 evaluates the five different motivational systems that guide the verbal and non verbal behaviours
20
21 during interactions.
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27 **Randomization**

28
29 The randomization sequence is being conducted off-site using the “random allocation of treatments
30
31 balanced in blocks (ralloc)” package for Stata[28] and is stratified by centre with a 1:1 allocation
32
33 ratio of treatment. Block randomization (size 4) is used to minimize large imbalances between the
34
35 intervention groups. The allocation sequences are generated by an independent individual, are
36
37 stored in computer files and remain unknown to the researchers until the patient is randomized.

38
39 The QPS or the control sheet, chosen for the two arms of trial, are placed in opaque envelopes,
40
41 sealed and numbered in sequence (following the list generated by the randomization procedure) by
42
43 a staff member of each centre (MAM and CB), not involved in the data collection phase. Both
44
45 randomization procedure and treatment allocation have been developed to fully conceal treatment
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47 allocation.[20, 29]
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51 Patients and oncologists are unaware of the allocation. The raters who analyze the audio- recordings
52
53 are also blinded to the allocation of patients.
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58 **Study aims and hypotheses**

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3 The study pursues different aims. The main aim is to assess if a pre consultation intervention (QPS)
4 facilitates greater participation of female patients (and accompanying key persons when present) in
5 the consultation process, by determining an increase in questioning and/or in the number of
6 different illness related issues (e.g. diagnosis, treatment, prognosis) being discussed with the
7 oncologist.
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14 Other aims are to assess the effect of the QPS on the level of patient involvement by the
15 oncologists, on patient satisfaction and coping, on the oncologist's perception of patient's preferred
16 decisional role (using the CPS, more details see the measures section) and to explore the role of the
17 companion. key persons accompanying the patient.
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23 In detail the study investigates if the intervention determines:

- 24 – a greater number of personal information needs expressed during the consultation (the number
25 and type of the questions asked during the consultation);
26
27
- 28 – the perception of a greater capacity to cope with illness and a greater satisfaction with decisions
29 made during the consultation (measured with the PEI and SWD; details are described in the
30 measures section);
31
32
- 33 – greater patient generated and/or doctor generated involvement of the patient (using the OPTION
34 scale and SDM-Q; details are described in the Measures section);
35
36
- 37 – a better understanding of the received information and greater satisfaction (measured with the
38 Recall questionnaire and the SWD);
39
40
- 41 – a different perception by the oncologist of patient's preference regarding her participation in
42 therapeutic decisions (measured with the CPS answered by the oncologist; details are described
43 in the Measures section);
44
45
- 46 – a different perception by the oncologist and by the patient of the doctor-patient relationship
47 (using the DPRQQ 9 and DPRQ-10, see measures section for the details);
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49
- 50 – a more patient-centred and sharing approach during the consultation (using the VR-COPE and
51 the AIMIT; see Measures section for the details).
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3 The potential presence of a companion during the consultation allows us to explore if the “question
4 prompt sheet” intervention (extended to the companion) changes the companions’ role and
5 participation during the consultation . Number and type of questions asked by the companion during
6 the consultation are also recorded

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11 Companions answer the same questionnaires as the patient: PEI for the evaluation of the ability to
12 cope with the patients’ illness, SDM-Q for the evaluation the perceived involvement during the
13 consultation, SWD for the satisfaction with decision, PDRQ-9 for the doctor-patient-relationship,
14 and Recall Questionnaire for the understanding of the information received. Where necessary,
15 questionnaires were adapted to the companions by substituting the first person (I) used in the
16 patient version, with the third person (she). For example: “I feel confident that I can get the facts
17 about the medication choices available to her” instead of “I feel confident that I can get the facts
18 about the medication choices available to me” (item 1 of the DSES Scale).
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34 **Study measures**

35 36 37 38 **Socio demographic and clinical data**

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40 Socio demographic data are: age, education, family status and employment status, type of
41 relationship with the companion (if present), reported both by patients and companions during the
42 baseline assessment.
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46
47 Oncologists’ socio demographic data are: age, gender and years of experience. Data for oncology
48 residents (when present during the consultation) are also obtained.
49

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

- The total number of patient’s questions during the consultation regarding diagnosis, prognosis, treatment, lifestyle and other issues. Question asking is considered an index of patient’s participation during the consultation. The QPS aims to increase the number of question by giving the opportunity to patients to reflect on their informative needs choosing among a wide range of possible questions those ones perceived as most relevant in view of the subsequent consultation.

Secondary outcome measures

- The number of unmet information needs that emerge during the consultation. This measure is 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 the illness, measured with the Patient Enablement Instrument (PEI). This questionnaire is a self-administered questionnaire of six items on a Likert scale from 0 (same or less) to 2 (much better, much more)[30]. We suppose a better ability to cope with the illness in the intervention 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 9 items on a Likert scale from 1 (completely disagree) to 6 (agree completely) and assesses patients’ perception of the decisional process and their level of involvement during the consultation, the information received on therapeutic options, the potential risks and benefits regarding the participation at the decisional process.[31, 32] 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)[23-25]. The scale is applied by trained raters to the audio recording of the consultation. In summary, it examines whether problems are well

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2
3 defined, whether options are formulated, information provided, patient understanding and role
4 preference evaluated, and decisions examined from both the professional and patient
5 perspective. The total score ranges from 0 (0 in all items) to 48 (4 in all items) and is
6 transformed into a 0 -100 score. We suppose a higher patient involvement during the
7 consultation in the intervention group.
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14 – Satisfaction with decisions made during the consultation, measured with the Satisfaction with
15 Decision Scale (SWD). This is a self administered questionnaire of 6 items on a Likert scale
16 from 0 (completely disagree) to 5 (agree completely) [33]. We suppose a higher patient
17 satisfaction of patients in the intervention group.
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23 – Recalling and understanding of information, measured with the Recall Questionnaire. This
24 questionnaire consists of six questions which ask the patient to recall the received information
25 on treatment decisions and pathology (e.g. “What was the treatment decision? Which treatment
26 options were discussed?”). The questions have been prepared for the present study with
27 reference to previous studies.[11, 34, 35] The questionnaire allows with the help of the audio
28 recorded consultation to evaluate patient’s correct recall and understanding by comparing
29 patients’ reports with what was actually discussed during the consultation. We suppose that
30 patients assigned to the intervention group can recall more precise information.
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37 – Three other questions, rated on a 0 (no at all) to 5 (very much) Likert scale asked whether the
38 patient succeeded in their purpose of question asking, whether the oncologist answered the
39 questions properly and how much more information she would have needed. We suppose that
40 patients assigned to the intervention group felt themselves more successful in question asking.
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47 – Overall consultation atmosphere, is measured with the Verona Patient-centred Communication
48 Evaluation scale (VR-COPE) ~~Roter Interaction Analysis System (RIAS)~~, [24, 25] and the
49 Assessing Interpersonal Motivations in Transcripts (AIMIT).[27] VR-COPE [26] assesses the
50 content, the process and relational aspects of patient-centred communication during medical
51 consultations on the basis of a multidimensional evaluation and comprises nine items. Each item
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3 is defined by operational definitions and rated on a 0-10 point scale. The scale is applied by
4
5 trained raters on the audio-recording of the consultation. We expect that patients of the
6
7 intervention group establish a better relationship with their oncologist and show higher scores in
8
9 patient-centred communication. RIAS is a coding system of medical consultations, composed
10
11 by 40 categories describing task-oriented and emotion-oriented interactions between doctors and
12
13 patients. The system will be applied on the consultation audio-recording by trained raters.[24,
14
15 25] AIMIT[27] is a coding system applied on transcripts aiming to systematically detect the
16
17 activity of interpersonal motivational systems. Systems identified are five (attachment,
18
19 caregiving, rank, sexuality, peer cooperation) and they guide the verbal and non verbal
20
21 behaviours during interactions. We suppose that patients of the intervention group evidence a
22
23 more cooperative style during the consultation.
24
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- 27 – Perceived Patient-doctor relationship, measured with the Patient – Doctor Relationship
28
29 Questionnaire (PDRQ-9) and the Difficult Doctor Patient Relationship Questionnaire (DDPRQ-
30
31 10). PDRQ-9 is a self-administered questionnaire of 9 items on a Likert scale from 1 (not at all
32
33 appropriate) to 5 (totally appropriate), to measure the relationship between the doctor and the
34
35 patient, from a patient point of view.[36] The DDPRQ-10 (is a self-report instrument of 10
36
37 items on a Likert scale from 1 (not at all) to 6 (a great deal), is completed by physicians after the
38
39 encounter with a patient.[37, 38] The questionnaire identifies the patients experienced as
40
41 difficult patients. We suppose that the doctor-patient relationship in the intervention group is
42
43 perceived as less difficult.
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- 47 – Oncologists answered three questions on the potential presence of anxiety, depression or
48
49 emotional distress in the patient and a fourth on their difficulty experienced in answering the
50
51 patient's questions. Answering questions of patients in the intervention group should be
52
53 perceived by oncologists as less difficult.
54
55
- 56 – Perceived role preference of the patient, measured with the Control Preference Scale (CPS,
57
58 Oncologist version) [39, 40]. This scale assesses how the oncologist perceives the role that
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3 patient might prefer regarding the decision making process. Oncologists should be better able to
4
5 identify patients preferred role in the intervention group.
6

7 – Duration of the consultation, measured in minutes. We suppose a longer duration of the
8
9 consultation in the intervention group.
10

11 12 13 14 **Process related and potential confounding variables**

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16 The measures below have been collected in order to check their possible influence on question
17
18 asking (primary outcome).
19

20
21 – Anxiety, depression and general well-being, measured with the State Anxiety Inventory (STAI-
22
23 X1, XR),[41-43] the Patient Health Questionnaire depression scale (PHQ-9) [44-46] and the
24
25 General Health Questionnaire (GHQ-12) [47].
26

27 STAI-X1 is a self-administered questionnaire of 20 items on a Likert scale from 1 (not at all) to
28
29 4 (very much) completed before the consultation. Higher total scores indicate greater state
30
31 anxiety. The STAI-X1R, administered after the consultation, is a shorter version of ten out of
32
33 the twenty items of the STAI-X1, and it is used to evaluate the state anxiety level at the end of
34
35 the consultation and to compare this level with the one measured at the beginning. PHQ-9 is a
36
37 self-assessment questionnaire for detecting the presence of depression and consists of 9 items
38
39 with response options of 0 (not at all) to 3 (almost every day), and has a summative score range
40
41 of 0 to 27. We score it in the standard way, using the sum of the 0–3 scores for each item, and
42
43 ≥ 8 as a cut-score for possible cases of depression [44-46]. GHQ-12 is a self administrated
44
45 questionnaire of 12 items and has a summative score range of 0 to 12 and a cut-score of >3
46
47 indicating psychological distress.[47]
48
49

50
51 – Personality traits, measured with the Eysenck Personality Questionnaire (EPQR-S) [48]. The
52
53 EPQR-S is a self-administered questionnaire of 48 items on yes/no scale. For our study we use
54
55 two subscales: the Extraversion/Introversion (12 items) and Neuroticism/Stability (12 items).
56
57 The “Extroversion” is characterized by being outgoing, talkative, high on positive affect (feeling
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3 good) and in need of external stimulation. The “Neuroticism” or emotionality is characterized
4
5 by high levels of negative affect such as depression and anxiety.
6

- 7 – Confidence with decision, measured with the Decision Self Efficacy Scale (DSES).[49] This
8 self- administered questionnaire for patients consists of 11 items on a Likert scale from 0 (not at
9 all confident) to 4 (very confident).
10
- 11 – Patients’ and their companion’s preference for the role they want to have in the decision making
12 process, measured with the Control Preference Scale (CPS) [39, 40]. This self-administered
13 instrument contains 5 vignettes with text, depicting different patient roles (from active to
14 passive) from which patients choose the one considered as most appropriate for them.
15
- 16 – Patient-centred communication style and attitude toward the doctor-patient relationship,
17 measured with the Doctor-Patient (DP) Scale [50]. The Scale measures the degree of
18 oncologists’ self reported patient or doctor-centred communication style and attitude. It consists
19 of 48 statements to rate on a Likert scale from 1 (strong agreement) to 5 (strong disagreement).
20 It has a summative score range of 48 to 240. The scale is completed by all oncologists who join
21 the study.
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38 **Sample size calculation**

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40 A sample of 300 patients will be recruited. This number has been estimated to account for
41 approximately a 15% of withdrawal rate, so that 250-260 patients will complete the study, with
42 about 130 patients in each arm. The primary outcome measure is the number of patient questions.
43
44 The international literature reports a mean number of nine questions (range 0-53) for breast cancer
45 patients. Since such data are not available in the Italian context, an observational phase was
46 conducted. We recruited a sample of 30 patients (10 for each centre) with the same characteristics,
47
48 in order to assess the number and type of questions asked by the patient during the consultation, to
49 understand the ongoing interaction between oncologists and patients in a first encounter and to test
50 the feasibility of procedures and questionnaires. This observational study resulted in a mean number
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3 of 18 (sd=13) patient questions asked during a first encounter with the oncologist. An intervention
4 intended to increase the number of questions might be considered efficacious with an increase of
5 30%. The sample size required to evidence such difference was calculated using the sampsi
6 command of Stata 11,[51] assuming a power of 80% and a two-sided significant level of 5% on a
7 student t-test for differences between independent groups.[52, 53]
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13 14 15 16 **Statistical analysis**

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18 The data will be analyzed according to intention-to-treat principle. [54] Standard statistical
19 techniques will be used to describe characteristics of patients in both groups, and CONSORT flow
20 diagram will be shown in order to explain the phases of trial and inform on the findings
21 confidence.[20] The primary outcome, significant increase of patient questions, will be compared in
22 the two arms using t-test. If adjustment for possible baseline differences among patients (as well as
23 for oncologists and centres) is needed, an analysis of covariance will be done. Regarding secondary
24 outcome measures, multilevel analyses will be used to taking into account the specific effect of the
25 individual oncologist.[55] ~~Regarding the analyses of the audio recordings, additional techniques to
26 study the doctor patient interaction at a micro level will be used, such as sequence analyses which
27 study the probabilistic links between subsequent physician and patient turns.[8, 56, 57]~~
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43 **EXPECTED ACHIEVEMENT**

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45 The involvement and participation of patients in therapeutic programs is of great interest not only to
46 physicians but to all health professionals engaged in improving patients' adherence to treatment
47 regimens or operating in the field of health promotion.
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50
51 We expect that **female** patients who have the opportunity to rehearse their information needs before
52 the consultation will ask a greater number of questions which in turn will determine their greater
53 involvement by the physician and a greater number of satisfied needs. We also expect that the
54 straightforward use of a list of printed questions of potential relevance for cancer patients and their
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3 companions at an early stage of illness, by modifying the process of information exchange, will
4
5 increase their participation and satisfaction with the consultation, with potential benefits for
6
7 treatment adherence and consequently treatment efficacy. The use of a question prompt sheet might
8
9 be a simple and quick device in improving the overall communication between oncologist and
10
11 patient. It might be routinely used before the consultation and also brought into the consultation and
12
13 discussed with the oncologist to further increase patient and companion participation. Evidence
14
15 demonstrates that efficacious communication positively influences the understanding and
16
17 satisfaction of the patient, treatment adherence and health status. Moreover, the oncologist's
18
19 knowledge and consideration of the information needs of the ~~family members or other key persons~~
20
21 ~~close to the patient~~ companions who in Italy are often present may further facilitate patient's
22
23 participation in the therapeutic program.
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29 **DISCUSSION**

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31 It has been demonstrate in English speaking countries that the Question Prompt sheet is an useful
32
33 tool to improve patient's participation during the consultation. There is a need to explore the effect
34
35 of a Question Prompt Sheet during oncological consultation also in other countries. To our
36
37 knowledge there are no published RCTs in Europe which assess the effects of a pre-consultation
38
39 intervention and explore the role and the effect of the companion as well. The study has a strong
40
41 design that incorporates computerised random allocation, blinding of data-collection staff and the
42
43 use of measures on the audio recordings. The analysis of the consultation recordings is a valuable
44
45 research method and is a recommended tool for documenting the interaction between patients and
46
47 oncologists. [56]
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49

50
51 There are some limitations to consider. The QPS was collected prior to the consultation, while in
52
53 previous trials reported in literature [4,10-15], patients were allowed to bring the QPS into the
54
55 consultation to refer to. Patients in our study therefore might not remember all selected questions
56
57 and ask less questions, by this undermining the hypothesis of the greater participation of the QPS
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3 intervention group. On the other hand, in our study oncologists are kept blind to the intervention or
4 control status of the patients and are not forced to change their routine clinical
5 approach to the consultation. Once the study will be completed we will discuss the findings with the
6 oncologists and we hope that afterwards the QPS can be used routinely in their practice.
7
8 The findings from this study will provide a basis for further research in the field and provide
9 potentially important results for clinicians, patients and policy makers that may lead to a wider use
10 of QPS also in other context.
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20 ETHICS AND DISSEMINATION PLANS

21
22 The study was approved by the local Ethics Committees of the Hospital Trust of Verona. The study
23 is registered at ClinicalTrial.gov (identifier: NCT01510964). This protocol follows the CONSORT
24 guidelines.[20]
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29 Recruitment phase started in June 2011 and will continue till the enrolment will be completed and is
30 expected to be closed in May 2013. Analysis will start after data monitoring and checking is
31 completed. The dissemination of the trial findings will principally be carried out through
32 publications in peer-review journal and presentations at national/international conferences focused
33 on cancer and/or communication, for examples European Association for Communication in Health
34 Care Conferences and International Shared Decision Making Conferences.
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45 FUNDING

46 This research received no specific grant from any funding agency in the public, commercial or not-
47 for-profit sectors.
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51 COMPETING INTERESTS

52 The authors declared that they have no competing interest.
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AUTHORS' CONTRIBUTIONS

CG, LDP, MR, 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 randomization sequences and providing guidance on statistical analysis of trial data. MB is the computer scientist that developed the database to save the data. CG drafted the manuscript, will oversee enrolment and data collection. GD, AB, FC, CB, IB, AM, EF, RN, CC, SZ, AA, FM, ELS, FR participated in enrolling the patients. All authors saw and approved the final version of the manuscript.

REFERENCES

1. Buckman R. *Breaking bad news: a guide for healthcare professionals*. Baltimore, MD: John Hopkins University Press 1992.
2. Baile WF, Buckman R, Lenzi R, et al. AP. SPIKES - A six-step protocol for delivering bad news: Application to the patient with cancer. *Oncologist* 2000;**5**:302-311.
3. Joosten EAG, DeFuentes-Merilla L, de Weert GH, Sensky T, et al. Systematic review of the effects of shared decision making on patient satisfaction, treatment adherence and health status. *Psychother Psychosom* 2008;**77**:219-226.
4. Clayton JM, Butow PN, Tattersall MH, et al. Randomized controlled trial of a prompt list to help advanced cancer patients and their caregivers to ask questions about prognosis and end-of-life care. *J Clin Oncol* 2007;**25**:715-723.
5. Charles C, Gafni A, Whelan T. How to improve communication between doctors and patients. Learning more about the decision making context is important. *BMJ* 2000;**320**:1220-1221.
6. Drew P, Chatwin J, Collins S. Conversation analysis: a method for research into interactions between patients and health-care professionals. *Health Expectat* 2001;**4**:58-70.

- 1
2
3 7. Zimmermann C, Del Piccolo L, Mazzi MA. Patient cues and medical interviewing in general
4 practice. Examples of the application of sequential analysis. *Epidemiol Psychiatr Soc*
5 2003;**12**:115-123.
6
7
- 8
9 8. Kidd J, Marteau TM, Robinson S, et al. Promoting patient participation in consultations: a
10 randomized controlled trial to evaluate the effectiveness of three patient-focused
11 interventions. *Patient Educ Couns* 2004;**52**:107-12.
12
13
- 14 9. Butow PN, Dunn SM, Tattersall MHN, et al. Patient participation in the cancer consultation:
15 evaluation of a question prompt sheet. *Ann Oncol* 1994;**5**:199-204.
16
17
- 18 10. Brown R, Butow PN, Boyer MJ, et al. Promoting patient participation in the cancer
19 consultation: evaluation of a prompt sheet and coaching in question-asking. *Br J Cancer*
20 1999;**80**:242-248.
21
22
- 23 11. Brown RF, Butow PN, Dunn SM, et al. Promoting patient participation and shortening cancer
24 consultations: a randomised trial. *Br J Cancer* 2001;**8**:1273-1279.
25
26
- 27 12. Bruera E, Sweeney C, Willey J, et al. Breast cancer patient perception of the helpfulness of a
28 prompt sheet versus a general information sheet during outpatient consultation: a randomized
29 controlled trial. *J Pain Symptom Manage* 2003;**5**:412-419.
30
31
- 32 13. Glynne-Jones R, Ostler P, Lumley-Graybow S, et al. Can I look at my list? An evaluation of a
33 'prompt sheet' within an oncology outpatient clinic. *Clin Oncol* 2006;**18**:395-400.
34
35
- 36 14. Clayton J, Butow P, Tattersall M, et al. Asking questions can help: development and
37 preliminary evaluation of a question prompt list for palliative care patients. *Br J Cancer*
38 2003;**89**:2069-2077.
39
40
- 41 15. Clayton JM, Butow PN, Tattersall MH, et al. Randomized controlled trial of a prompt list to
42 help advanced cancer patients and their caregivers to ask questions about prognosis and end-
43 of-life care. *J Clin Oncol* 2007;**25**:715-723.
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3 16. Van der Meulen N, Jansen J, van Dulmen S, et al. Interventions to improve recall of medical
4
5 information in cancer patients: a systematic review of the literature. *Psychooncology*
6
7 2008;**17**:857-68.
- 8
9
10 17. Van Weert JC, Jansen J, Spreeuwenberg PM, et al. Effects of communication skills training
11
12 and a Question Prompt Sheet to improve communication with older cancer patients: a
13
14 randomized controlled trial. *Crit Rev Oncol Hematol* 2011;**80**:145-59.
- 15
16 18. Ohlen J, Balneaves L, Bottorff J, et al. The influence of significant others in complementary
17
18 and alternative medicine decisions by cancer patients. *Soc Sci Med* 2006;**63**:1625–1636.
- 19
20 19. Christman J. Relational autonomy, liberal individualism, and the social constitution of selves.
21
22 *Philosophical Studies* 2004;**117**:143–164.
- 23
24 20. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration:
25
26 updated guidelines for reporting parallel group randomized trials. *BMJ* 2010;**340**:c869. DOI:
27
28 10.1136/bmj.c869.
- 29
30 21. Istituto Nazionale di Statistica (ISTAT) Web site.
31
32 <http://www.demo.istat.it/pop2010/index.html>. Accessed October 24, 2012.
- 33
34 22. Centro Nazionale di Epidemiologia, Sorveglianza e Promozione della Salute - Istituto
35
36 Superiore di Sanità (ISS) Web site. http://www.tumori.net/it3/banca_dati/query.php. Accessed
37
38 October 24, 2012.
- 39
40 23. Elwyn G, Hutchings H, Edwards A, et al. The OPTION scale: measuring the extent that
41
42 clinicians involve patients in decision-making tasks. *Health Expectat* 2005;**8**:34-42.
- 43
44 24. Goss C, Fontanesi S, Mazzi MA, et al. The assessment of patient involvement across
45
46 consultation. The Italian version of the OPTION scale (in Italian). *Epidemiol Psichiatr Soc*
47
48 2007;**16**:339-349.
- 49
50 25. Goss C, Fontanesi S, Mazzi MA, et al. Shared decision making: the reliability of the OPTION
51
52 scale in Italy. *Pat Educ Counsel* 2007;**66**:296-302.
- 53
54
55
56
57
58
59
60

- 1
2
3 Roter D, Larson S. The Roter interaction analysis system (RIAS): utility and flexibility for
4 analysis of medical interactions. *Pat Educ Counsel* 2002;**26**:243-251.
5
6
7
8 Roter D. The Roter method of interaction process analysis. RIAS manual. Baltimore, MD:
9 John Hopkins University Press 1991.
10
11
12
13
14 26. Del Piccolo L, Mazzi MA, Scardoni S, et al. A theory based proposal to evaluate patient-
15 centred communication in medical consultations: the Verona Patient-centred Communication
16 Evaluation scale (VR-COPE). *Health Education* 2008;**108**:355-372.
17
18
19
20
21 27. Ardevini C, Cotugno A, Costantini E, et al. Il manuale AIMIT. Analisi degli Indicatori delle
22 Motivazioni Interpersonali nei Trascritti. In: Liotti G, Monticelli F. I sistemi motivazionali nel
23 dialogo clinico. Il manuale AIMIT. Milano, IT: Raffaello Cortina editore 2008. Fassone G,
24 Valcella F, Pallini S, et al. Assessment of Interpersonal Motivation in Transcripts (AIMIT):
25 an inter- and intra-rater reliability study of a new method of detection of interpersonal
26 motivational systems in psychotherapy. *Clin Psychol Psychother* 2012;**19**: 224-34.
27
28
29
30
31
32
33
34 28. Ryan P. sxd1 4: Random allocation of treatments in blocks. *Stata Journal* 2008;**8**:146.
35
36
37 29. Altman DG, Schulz KF, Moher D, et al. The revised CONSORT statement for reporting
38 randomized trials: explanation and elaboration. *Ann Intern Med* 2001;**134**:663-94.
39
40
41 30. Howie JG, Heaney DJ, Maxwell M, et al. A comparison of a Patient Enablement Instrument
42 (PEI) against two established satisfaction scales as an outcome measure of primary care
43 consultations. *Fam Pract* 1998;**15**:165-171.
44
45
46
47 31. Simon D, Chorr G, Wirtz M, et al. Development and first validation of the shared decision
48 making questionnaire (SDM-Q). *Pat Educ Counsel* 2006;**63**:319-327.
49
50
51
52 32. Kriston L, Scholl I, Hölzel L, et al. The 9-item Shared Decision Making Questionnaire (SDM-
53 Q-9). Development and psychometric properties in a primary care sample. *Patient Educ*
54 *Couns.* 2010;**80**:94-9.
55
56
57
58
59
60

- 1
- 2
- 3 33. Holmes-Rovner M, Kroll J, Schmitt N, et al. Patient satisfaction with health care decisions:
- 4 the Satisfaction with Decision Scale. *Med Decis Making* 1996;**16**:58-64.
- 5
- 6
- 7 34. Gattellari M, Voigt KJ, Butow PN, et al. When the treatment goal is not cure: are cancer
- 8 patients equipped to make informed decisions? *J Clin Oncol* 2002;**20**:503-513.
- 9
- 10
- 11 35. Whelan T, Levine M, Gafni A, et al. Mastectomy or lumpectomy? Helping women make
- 12 informed choices. *J Clin Oncol* 1999;**17**:1727-1735.
- 13
- 14
- 15 36. Van der Feltz-Cornelis CM, Van Oppen P, Van Marwijk HWJ, et al. A patient-doctor
- 16 relationship questionnaire (PDRQ-9) in primary care: development and psychometric
- 17 evaluation. *Gen Hosp Psychiatry* 2004;**26**:115-120.
- 18
- 19
- 20 37. Hahn SR, Thompson KS, Wills TA, et al. The difficult doctor-patient relationship:
- 21 somatization, personality and psychopathology. *J Clin Epidemiol* 1994;**47**:647-57.
- 22
- 23 38. Hahn SR, Kroenke K, Spitzer RL, et al. The difficult patient: prevalence, psychopathology,
- 24 and functional impairment. *J Gen Intern Med* 1996;**11**:1-8.
- 25
- 26
- 27 39. Degner LF, Sloan JA, Venkatesh P. The Control Preferences Scale. *Can J Nurs Res*
- 28 1997;**29**:21-43.
- 29
- 30
- 31 40. Giordano A, Mattarozzi K, Pucci E, et al. Participation in medical decision-making: attitudes
- 32 of Italians with multiple sclerosis. *J Neurol Sci* 2008;**275**:86-91.
- 33
- 34
- 35 41. Spielberger CD. Anxiety as an emotional state. (Vol. 1). New York: Academic Press 1972.
- 36
- 37 42. Spielberger CD, Gorsuch RL, Lushene R, et al. Manual for the State-Trait Anxiety Inventory.
- 38 Palo Alto, CA: Consulting Psychologists Press 1983.
- 39
- 40 43. Lazzari R, Pancheri P. S.T.A.I. Questionario di autovalutazione dell'ansia di stato e di tratto.
- 41 Firenze, IT: Organizzazioni Speciali 1980.
- 42
- 43 44. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity
- 44 measure. *J Gen Intern Med* 2001;**16**:606-13.
- 45
- 46 45. Kroenke K, Streine TW, Spitzer RL, et al. The PHQ-8 as a measure of current depression in
- 47 general population. *J Affect Disord* 2009;**114**:163-173.
- 48
- 49
- 50
- 51
- 52
- 53
- 54
- 55
- 56
- 57
- 58
- 59
- 60

- 1
2
3 46. Thekkumpurath P, Walker J, Butcher I, et al. Screening for major depression in cancer
4 outpatients: the diagnostic accuracy of the 9-item patient health questionnaire. *Cancer*
5 2011;**117**:218-227.
6
7
8
9
10 47. Politi PL, Piccinelli M, Wilkinson G. Reliability, validity and factor structure of the 12-item
11 General Health Questionnaire among young males in Italy. *Acta Psychiatr Scand*
12 1994;**90**:432-437.
13
14
15
16 48. Eysenck SBG, Eysenck HJ, Barrett P. A revised version of the psychoticism scale.
17 *Personality and Individual Differences* 1985;**6**:21-29.
18
19
20 49. O'Connor AM. User Manual-Decision Self-Efficacy Scale. Patient Decision Aids, Ottawa
21 Hospital Research Institute (OHIR) Web site.
22 http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decision_SelfEfficacy.pdf.
23
24
25
26
27 Accessed October 24, 2012.
28
29
30 50. De Monchy C, Richardson R, Brown RA, et al. Measuring attitudes of doctors: the doctor-
31 patient (DP) rating. *Med Educ* 1988;**22**:231-239.
32
33
34 51. StataCorp. Stata Statistical Software: Release 11.2. College Station, TX: StataCorp LP 2011.
35
36
37 52. Pocock SJ. Clinical trials: A practical approach. New York: John Wiley & Sons 1983.
38
39 53. Sullivan LM, D'Agostino RB. Robustness and power of analysis of covariance applied to
40 ordinal scaled data as arising in randomized controlled trials. *Stat Med* 2003;**22**:1317-1334
41
42
43 54. Little R, Yau L. Intent-to-treat analysis for longitudinal studies with drop-outs. *Biometrics*
44 1996;**52**:1324-1333.
45
46
47 55. Skrondal A, Rabe-Hesketh S. Generalized latent variable modelling: Multilevel, longitudinal,
48 and structural equation models. New York: Chapman & Hall/CRC 2004.
49
50
51 ~~Mazzi MA, Del Piccolo L, Zimmermann C. Event based categorical sequential analyses of the~~
52 ~~medical interview: a review. *Epidemiol Psychiatr Soc* 2003;**12**:81-85.~~
53
54 ~~Goss C, Mazzi MA, Del Piccolo L, et al. Information giving sequences in general practice~~
55 ~~consultations. *J Eval Clin Pract* 2005;**11**:339-349.~~
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55
56
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56. Tattersall MHN, Butow PN. Consultation audio tapes: an underused cancer patient information aid and clinical research tool. *Lancet Oncol* 2002;3:431-437.

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**The INvolvement of breast CANcer patients during
oncological consultations. A multi-centre randomized
controlled trial. The INCA study protocol.**

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2012-002266.R2
Article Type:	Protocol
Date Submitted by the Author:	11-Feb-2013
Complete List of Authors:	Goss, Claudia; University of Verona Ghilardi, Alberto; University of Brescia, Deledda, giuseppe; University of Verona, Buizza, Chiara; University of Brescia, Bottacini, Alessandro; University of Verona, Del Piccolo, Lidia; University of Verona, Rimondini, Michela; University of Verona, Chiodera, Federica; University of Verona, Mazzi, Maria Angela; University of Verona, Ballarin, Mario; University of Verona, Bighelli, Irene; University of Verona, Strepparava, Maria Grazia; University of Milano-Bicocca, Molino, Annamaria; Hospital Trust, Verona, Fiorio, Elena; Hospital Trust, Verona, Nortilli, Rolando; Hospital Trust, Verona, Caliolo, Chiara; Hospital Trust, Verona, Zuliani, Serena; Hospital Trust, Verona, Auriemma, Alessandra; Hospital Trust, Verona, Maspero, Federica; Hospital Trust, Verona, Simoncini, Edda; Spedali Civili, Brescia, Ragni, Fulvio; Spedali Civili, Brescia, Brown, Richard; Vrginia Commonwealth University, Zimmermann, Christa; University of Verona,
Primary Subject Heading:	Oncology
Secondary Subject Heading:	Patient-centred medicine
Keywords:	patient involvement, breast cancer, docotr-pateint communication

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Manuscripts

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3 **The INvolvement of breast CANcer patients during oncological consultations. A multi-centre**
4 **randomized controlled trial. The INCA study protocol.**
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58 *Key- word:* patient involvement, breast cancer, doctor-patient communication
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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, 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 pre-consultation intervention to increase involvement of breast cancer patients during the consultation, and 2) explore the role of attending-companions in the information exchange during the consultation.

Methods and analysis: All female patients with breast cancer who attend the Oncology Out-patient Services for the first time will provide 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 (QPS).

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 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 pre consultation intervention (QPS) facilitates greater participation of patients (and attending companions 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.
- 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 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.
- 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.

Strengths and limitations of this study

- To our knowledge this is the first RCT 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

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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 recognizing these variations in patient preferences, and physicians and patients working together to accomplish these preferences.

In order to accommodate these varying preferences physicians need elicit patient preferences and to adapt their information giving process to meet these needs. If the expression of such needs is not facilitated or encouraged, these needs tend to remain hidden, consequently patients may perceive that they received too much or too little information. The literature suggests that better quality of patient care and patient outcomes such as coping with illness and treatment adherence are achieved when preferences being 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 a Question Prompt Sheets (QPS). [8- 16] QPS are structures lists of prepared questions that prompt patients to consider novel topics before a consultation and decide on question they would like to ask during the consultation. These tools have been shown to increase patient activation during the consultation and aid recall of information after the 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, patients are frequently accompanied and assisted by a companion: a close family member or another key person. In this context the activation and

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3 involvement of the patient interacts with that of the companion and contributes to the
4 communication dynamics of the consultation. Olhen and colleagues [18] explored the importance of
5 significant others in therapeutic decisions and highlighted the notion of “relational autonomy”,
6 which acknowledges that people are defined by their relationships and are dependent on others in
7 making decisions. [19] Future research that analyses patients and companions as dyadic units would
8 offer further insight into the impact of social relations on treatment decision-making processes.
9 More evidence on the information needs of companions regarding the patient and their role in the
10 information and decision processes during the consultation is also needed.

11
12 To our knowledge this is the first RCT in Europe which assesses the effects of a pre-consultation
13 intervention (QPS) on cancer patients’ involvement during the consultation, on their satisfaction
14 and confidence in coping with illness, and which explores the role of the companion during the
15 consultation.

16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 **METHODS AND ANALYSIS**

32 **Study design**

33
34 This is a multicentre, randomized controlled trial in which patients are attributed randomly to the
35 intervention or to the control group on a 1:1 basis. Patients in the intervention group are given the
36 QPS, a list of 50 specific questions (see below); those in the control group are given a control sheet
37 on which to write the questions they would like to ask. The oncologists are informed about the
38 study protocol but are blinded to whether the patient is a participant of the control group or the
39 intervention group. The oncologists perform their consultation as usual, according to the clinical
40 practice of their centre. After concluding the consultation, they complete two questionnaires
41 (DPRQ-10 and CPS, see the Measures section for details) regarding the patient and the consultation.

42
43 This protocol follows the CONSORT guidelines. [20]

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45 Standardized questionnaires are administered at baseline (before the randomization) and
46 immediately after the consultation (figure 1, table 1).
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Figure 1 INCA Study flow diagram

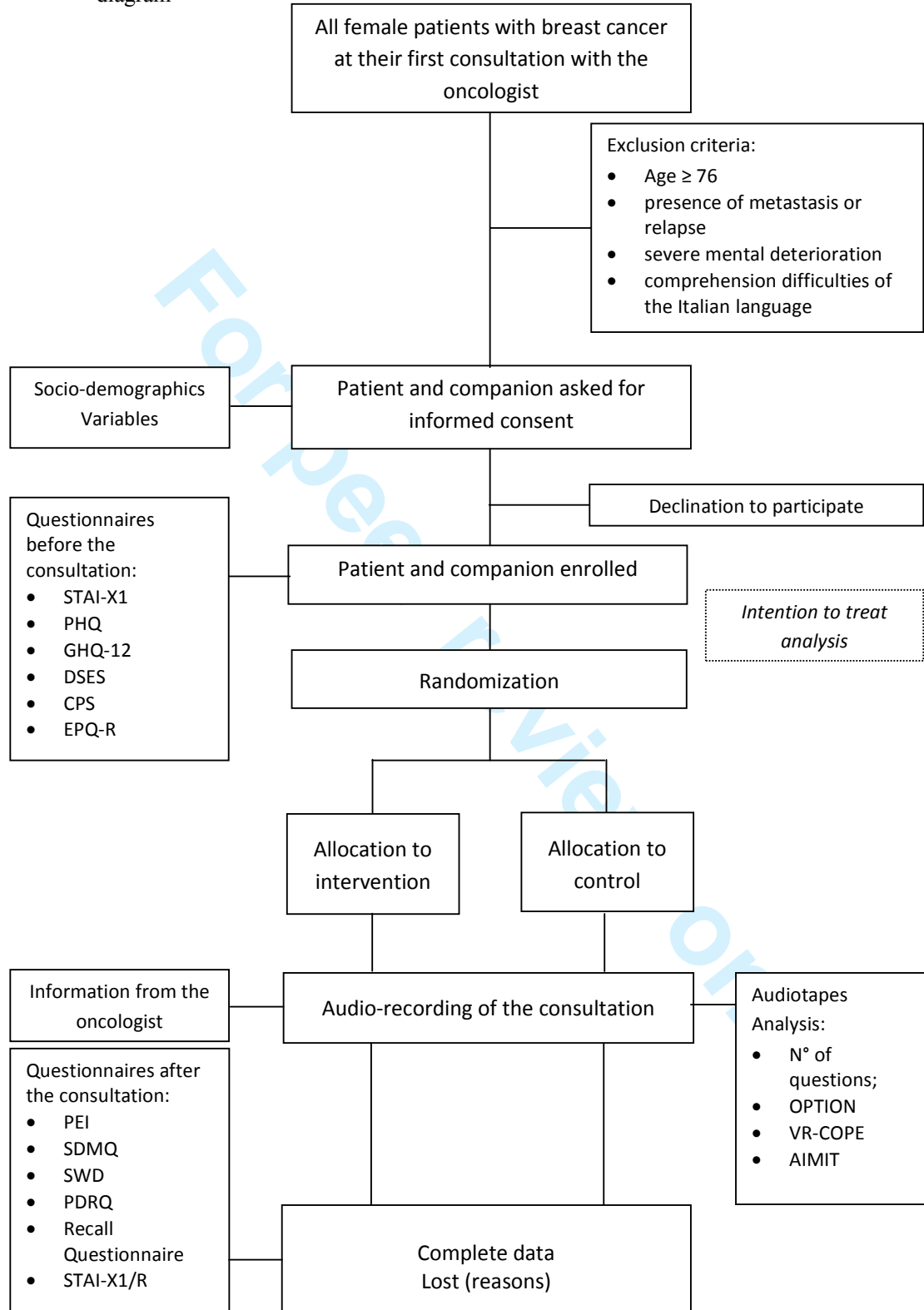


Table 1 Questionnaires and tools used in the study

Tool	Evaluation	Explored area	N° items	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 (PEI)	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 supposedly 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

Time required to answer the pre consultation questionnaire is approximately 15 – 20 minutes while the post consultation questionnaire takes between 10 – 15 minutes to complete.

Intervention

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

Patients and companions (if present) randomized 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 patient (and companion) are invited to select and circle 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. Questions regard diagnosis (e.g. "Of what type is my cancer?"), treatment (e.g. "Which are the pros and cons

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3 of the treatment?), contribution of patient and lifestyle (“What can I do to improve the efficacy of
4 treatment?”), prognosis (“What are the chances of relapse?”) and other issues (e.g. “Do I need a
5 referral from my GP for the next visit?”).
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10 11 **Setting**

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14 The patient recruitment phase of this protocol has begun at three Oncology Departments in
15 Northern Italy: two run by Hospital Trust of Verona in the Veneto region (placed in two different
16 part of the city) and one by the Hospital Trust of Brescia, in the Lombardia region. The recruitment
17 phase started in June 2011 and will continue for two years or until the sample size has been reached.
18
19
20 The population of Verona city and its province in 2010 is about 914 382, the population of Brescia
21 city and its province about 1 242 923. [21] In the Veneto region the estimation of incidence of
22 breast cancer in 2010 was 4 424 new cases per year (Standardized rate adjusted for age using the
23 European population as standard (std) per 100,000= 133). In the Lombardia region the estimation of
24 incidence of breast cancer in 2010 was 7 456 new cases per year (std = 109). [22]
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34 The three Oncology departments each have out-patient clinics dedicated to breast cancer patients
35 with a rotation of 2-5 oncologists. New medical oncology patient appointment are scheduled on
36 fixed days with a number of 4 - 8 patients per day. Generally in the first visit with the oncologist the
37 histological results are communicated and further medical treatment is decided (e.g chemotherapy,
38 hormone therapy). The length of the visit can vary from 30 to 60 minutes.
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47 **Sample and recruitment**

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49 The study sample is composed of consecutive female patients between the age of 18 to 75 years
50 who attend the Oncology out-patient clinics of the participating centres and who have a recent
51 diagnosis of breast cancer at an early stage (absence of metastasis). Eligible patients have already
52 undergone breast surgery (e.g. lumpectomy). Exclusion criteria are the presence of metastasis or
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3 relapse, severe mental deterioration, comprehension difficulties of the Italian language. A sample of
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5 300 patients will be recruited, as estimated by the sample size calculation (see below).
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8 9 **Procedure**

10 Before the patient recruitment phase the oncologists were informed about the study and invited to
11
12 participate. Willing oncologist provided written informed consent.
13

14
15 Eligible patients attending their first out-patient visit with the oncologist (and their companions if
16
17 present), are provided with information about the study by a project member who are available to
18
19 answer any questions. Willing patients provide written informed consent to participate in the study
20
21 (figure 1).
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24
25 Once consented patients and companions receive an envelope containing six questionnaires to
26
27 answer before the consultation (baseline assessment) (table 1). The project staff member (MAM)
28
29 then randomly allocates consenting patients and their companions to the intervention or control
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31 group (see also paragraph “Randomization”). Another project staff member (AB, CB, IB or FC)
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33 hands out the envelopes with either the intervention QPS or the control sheet and collect the sheets
34
35 after their completion. In order to keep the oncologists blind to the intervention or control status
36
37 patients do not take the QPS into the consultation.
38
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40
41 The subsequent consultation is audio recorded. After the consultation, patients and their
42
43 companions complete a further six questionnaires. In the event that a patient or companion is
44
45 distressed after the consultation trained project member is present (AB, CB, IB or FC) and provides
46
47 support.
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49
50 At the completion of the consultation the oncologists completes a medical details sheet that asks
51
52 about the cancer stage and type, when and by whom the patient was informed about diagnosis, and
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54 the therapeutic options appropriate for this patient. They also complete a questionnaire measuring
55
56 their perception of the patient as difficult.
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59 The audio tapes and oncologists’ forms are collected by the project staff.
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3 The audio tapes are examined for the content and number of questions asked by patients and
4 companions, and are rated applying the OPTION scale, [23-25] which measures the extent to which
5 the oncologist has succeeded to involve the patient in the consultation. The questions that emerge
6 during the consultations are compared with those expressed before the visit. The audio recorded
7 consultations are also analyzed in terms of patient-centredness with the VR-COPE [26] and with the
8 Assessment of Interpersonal Motivation in Transcripts (AIMIT) [27] which evaluates the five
9 different motivational systems that guide the verbal and non verbal behaviours during interactions.
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20 **Randomization**

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22 The randomization sequence is conducted off-site using the “random allocation of treatments
23 balanced in blocks (ralloc)” package for Stata [28] and is stratified by centre with a 1:1 allocation
24 ratio of treatment. Block randomization (size 4) is used to minimize large imbalances between the
25 intervention groups. The allocation sequences are generated by an independent individual, are
26 stored in computer files and remain unknown to the researchers until the patient is randomized.
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34 The QPS or the control sheet, chosen for the two arms of trial, are placed in opaque envelopes,
35 sealed and numbered in sequence (following the list generated by the randomization procedure) by
36 a staff member of each centre (MAM and CB), not involved in the data collection phase. Both
37 randomization procedure and treatment allocation have been developed to fully conceal treatment
38 allocation. [20, 29]
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45 Patients and oncologists are unaware of the allocation. The raters who analyze the audio- recordings
46 are also blinded to the allocation of patients.
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50 **Study aims and hypotheses**

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

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7 Other aims are to assess the effect of the QPS on the level of patient involvement by the
8
9 oncologists, on patient satisfaction and coping, on the oncologist's perception of patient's preferred
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11 decisional role (using the CPS, more details see the measures section) and to explore the role of the
12
13 companion.
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16 In detail the study investigates if the intervention determines:

- 17
18 – a greater number of personal information needs expressed during the consultation (the number
19
20 and type of the questions asked during the consultation);
- 21
22 – the perception of a greater capacity to cope with illness and a greater satisfaction with decisions
23
24 made during the consultation (measured with the PEI and SWD; details are described in the
25
26 measures section);
- 27
28 – greater patient generated and/or doctor generated involvement of the patient (using the OPTION
29
30 scale and SDM-Q; details are described in the Measures section);
- 31
32 – a better understanding of the received information and greater satisfaction (measured with the
33
34 Recall questionnaire and the SWD);
- 35
36 – a more accurate identification by the oncologist of patients' preferred role in the therapeutic
37
38 decisions (measured with the CPS answered by the oncologist; details are described in the
39
40 Measures section);
- 41
42 – a more supportive doctor-patient relationship perceived by the oncologist's and patient's (using
43
44 the PDRQ -9 and DDPQR-10, see measures section for the details);
- 45
46 – a more patient-centred and sharing approach during the consultation (using the VR-COPE and
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48 the AIMIT; see Measures section for the details).
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54 Extending the QPS to the patient's companion (if present) allows us to explore the impact of the
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56 QPS on the companions' role and participation during the consultation. The number and type of
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58 questions asked by the companion during the consultation are recorded
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3 Companions answer the same questionnaires as the patient: PEI for the evaluation of the ability to
4 cope with the patients' illness, SDM-Q for the evaluation the perceived involvement during the
5 consultation, SWD for the satisfaction with decision, PDRQ-9 for the doctor-patient-relationship,
6 and Recall Questionnaire for the understanding of the information received. Where necessary,
7 questionnaires were adapted to the companions by substituting the first person (I) used in the patient
8 version, with the third person (she).For example: "I feel confident that I can get the facts about the
9 medication choices available to her" instead of "I feel confident that I can get the facts about the
10 medication choices available to me" (item 1 of the DSES Scale).
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23 **Study measures**

24 25 26 27 **Socio demographic and clinical data**

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29 Socio demographic data collected from patients are: age, education, family status and employment
30 status, type of relationship with the companion (if present), reported both by patients and
31 companions during the baseline assessment.
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36 Oncologists' socio demographic data are: age, gender and years of experience. Data for oncology
37 residents (when present during the consultation) are also obtained.
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41 Clinical data are: cancer stage and type, duration of illness (who has informed patient on diagnosis
42 and when), therapeutic options considered appropriate for this patient, all reported on a form by the
43 oncologist.
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49 **Primary outcome measure**

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51 The total number of patient's questions during the consultation regarding diagnosis, prognosis,
52 treatment, lifestyle and other issues. Question asking is considered an index of patient's
53 participation during the consultation. The QPS aims to increase the number of question by giving
54 the opportunity to patients to reflect on their informative needs choosing among a wide range of
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possible questions those ones perceived as most relevant in view of the subsequent consultation. We hypothesize that patients who are randomized to receive the QPS will ask more questions than patients randomized to the control group.

Secondary outcome measures

- The number of unmet information needs that emerge during the consultation. This measure is 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 the illness, measured with the Patient Enablement Instrument (PEI). This questionnaire is a self-administered questionnaire of six items on a Likert scale from 0 (same or less) to 2 (much better, much more) [30]. We hypothesize that patients randomized 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 9 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, the potential risks and benefits regarding the participation at the decisional process.[31, 32] 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) [23-25]. 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

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3 transformed into a 0 -100 score. We hypothesize that patients randomized to the intervention
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5 group will have higher patient involvement during the consultation compared to patients in the
6
7 control group.

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10 – Satisfaction with decisions made during the consultation, measured with the Satisfaction with
11
12 Decision Scale (SWD). This is a self-report questionnaire of 6 items on a Likert scale from 0
13
14 (completely disagree) to 5 (agree completely) [33]. We hypothesize that patients randomized to
15
16 the intervention group will have higher patient satisfaction compared to patients in the control
17
18 group.
- 19
20 – Recalling and understanding of information, measured with the Recall Questionnaire. This
21
22 questionnaire consists of six items that ask the patient to recall the received information on
23
24 treatment decisions and pathology (e.g. “What was the treatment decision? Which treatment
25
26 options were discussed?”). The questions have been prepared for the present study with
27
28 reference to previous studies.[11, 34, 35] The questionnaire enables an evaluation of the
29
30 accuracy of patient’s recall and understanding of information delivered during the consultation
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32 by comparing the patients’ answers with the contents of the actual consultation discussion
33
34 gathered from the consultation audiorecording. We hypothesize that patients randomized to the
35
36 intervention group will recall more precise information compared to patients in the control
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38 group.
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40 – Three other questions, rated on a 0 (no at all) to 5 (very much) Likert scale asked whether the
41
42 patient asked their selected QPS questions, whether the oncologist answered the questions and
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44 whether the patient received the information they desired. We hypothesize that patients
45
46 randomized to the intervention group will feel themselves more successful in question asking.
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48 compared to patients in the control group.
- 49
50 – Overall consultation atmosphere, is measured with the Verona Patient-centred Communication
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52 Evaluation scale (VR-COPE) and the Assessing Interpersonal Motivations in Transcripts
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54 (AIMIT). [27] The VR-COPE [26] assesses the content, the process and relational aspects of
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3 patient-centred communication during medical consultations on the basis of a multidimensional
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5 evaluation and comprises nine items. Each item is defined by operational definitions and rated
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7 on a 0-10 point scale. The scale is applied by trained raters to the consultation audio-recordings
8
9 We expect that patients of the intervention group establish a better relationship with their
10
11 oncologist and show higher scores in patient-centred communication.
12

13
14 The AIMIT [27] is a coding system applied to transcripts that systematically detects the activity
15
16 of five interpersonal motivational systems (attachment, caregiving, rank, sexuality,
17
18 cooperation). We hypothesize that patients randomized to the intervention group will more
19
20 often evidence a cooperative style during the consultation compared to patients in the control
21
22 group.
23

- 24
25 – Perceived Patient-doctor relationship, measured with the Patient – Doctor Relationship
26
27 Questionnaire (PDRQ-9) and the Difficult Doctor Patient Relationship Questionnaire (DDPRQ-
28
29 10). The PDRQ-9 contains 9 items on a Likert scale with anchors at 1 (not at all appropriate) to
30
31 5 (totally appropriate). The scale measures patient perceptions of their relationship with the
32
33 doctor.[36] The DDPRQ-10 contains 10 items on a Likert scale anchors at 1 (not at all) to 6 (a
34
35 great deal) and is completed by physicians after the encounter with a patient.[37, 38] The
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37 questionnaire identifies the patients experienced as difficult patients. We hypothesize that the
38
39 doctor-patient relationship in the intervention group is perceived as less difficult compared to
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41 the control group.
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45 – Oncologists answered three questions on the potential presence of anxiety, depression or
46
47 emotional distress in the patient and a fourth on their difficulty experienced in answering the
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49 patient's questions. We hypothesize that answering questions of patients in the intervention
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51 group will be perceived by oncologists as less difficult.
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- 54
55 – Perceived role preference of the patient, measured with the Control Preference Scale (CPS,
56
57 Oncologist version) [39, 40]. This scale assesses how the oncologist perceives the role that
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3 patient might prefer regarding the decision making process. Oncologists should be better able to
4 identify patients preferred role in the intervention group.
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- 6
7 – Duration of the consultation, measured in minutes. We hypothesize a longer duration of the
8 consultation in the intervention group compared to the control group.
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11 12 13 14 15 16 **Process related and potential confounding variables**

17 The measures below have been collected in order to check their possible influence on question
18 asking (primary outcome).
19

- 20
21 – Anxiety, depression and general well-being, measured with the State Anxiety Inventory (STAI-
22 X1, XR), [41-43] the Patient Health Questionnaire depression scale (PHQ-9) [44-46] and the
23 General Health Questionnaire (GHQ-12) [47].
24
25

26 STAI-X1 is a self-administered questionnaire of 20 items on a Likert scale from 1 (not at all) to
27 4 (very much) completed before the consultation. Higher total scores indicate greater state
28 anxiety. The STAI-X1R, administered after the consultation, is a shorter version of ten out of
29 the twenty items of the STAI-X1, and it is used to evaluate the state anxiety level at the end of
30 the consultation and to compare this level with the one measured at the beginning. PHQ-9 is a
31 self-assessment questionnaire for detecting the presence of depression and consists of 9 items
32 with response options of 0 (not at all) to 3 (almost every day), and has a summative score range
33 of 0 to 27. We score it in the standard way, using the sum of the 0–3 scores for each item, and
34 ≥ 8 as a cut-score for possible cases of depression [44-46]. GHQ-12 is a self administrated
35 questionnaire of 12 items and has a summative score range of 0 to 12 and a cut-score of >3
36 indicating psychological distress. [47]
37
38

- 39 – Personality traits, measured with the Eysenck Personality Questionnaire (EPQR-S) [48]. The
40 EPQR-S is a self-administered questionnaire of 48 items on yes/no scale. For our study we use
41 two subscales: the Extraversion/Introversion (12 items) and Neuroticism/Stability (12 items).
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3 The “Extroversion” is characterized by being outgoing, talkative, high on positive affect (feeling
4 good) and in need of external stimulation. The “Neuroticism” or emotionality is characterized
5 by high levels of negative affect such as depression and anxiety.
6
7

- 8
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10 – Confidence with decision, measured with the Decision Self Efficacy Scale (DSES). [49] This
11 self- administered questionnaire for patients consists of 11 items on a Likert scale from 0 (not at
12 all confident) to 4 (very confident).
13
14
15 – Patients’ and their companion’s preference for the role they want to have in the decision making
16 process, measured with the Control Preference Scale (CPS) [39, 40]. This self-administered
17 instrument contains 5 vignettes with text, depicting different patient roles (from active to
18 passive) from which patients choose the one considered as most appropriate for them.
19
20
21 – Patient-centred communication style and attitude toward the doctor-patient relationship,
22 measured with the Doctor-Patient (DP) Scale [50]. The Scale measures the degree of
23 oncologists’ self reported patient or doctor-centred communication style and attitude. It consists
24 of 48 statements to rate on a Likert scale from 1 (strong agreement) to 5 (strong disagreement).
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26 It has a summative score range of 48 to 240. The scale is completed by all oncologists who join
27 the study.
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40 **Sample size calculation**

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42 A sample of 300 patients will be recruited. This number has been estimated to account for
43 approximately a 15% of withdrawal rate, so that 250-260 patients will complete the study, with
44 about 130 patients in each arm. The primary outcome measure is the number of patient questions.
45
46 The international literature reports a mean number of nine questions (range 0-53) for breast cancer
47 patients. Since such data are not available in the Italian context, an observational phase was
48 conducted. We recruited a sample of 30 patients (10 for each centre) with the same characteristics,
49
50 in order to assess the number and type of questions asked by the patient during the consultation, to
51 understand the ongoing interaction between oncologists and patients in a first encounter and to test
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3 the feasibility of procedures and questionnaires. This observational study resulted in a mean number
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5 of 18 (sd=13) patient questions asked during a first encounter with the oncologist; no significant
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7 difference was found between the three centres (median test: $\chi^2=2.4$, $p=0.30$).
8

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10 An intervention intended to increase the number of questions might be considered efficacious with
11
12 an increase of 30%. The sample size required to evidence such difference was calculated using the
13
14 `sampsi` command of Stata 11, [51] assuming a power of 80% and a two-sided significant level of
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16 5% on a student t-test for differences between independent groups. [52, 53]
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20 21 **Statistical analysis**

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23 The data will be analyzed according to intention-to-treat principle. [54] Standard statistical
24
25 techniques will be used to describe characteristics of patients in both groups, and CONSORT flow
26
27 diagram will be shown in order to explain the phases of trial and inform on the findings confidence.
28
29 [20] The primary outcome, significant increase of patient questions, will be compared in the two
30
31 arms using t-test. If adjustment for possible baseline differences among patients (as well as for
32
33 oncologists and centres) is needed, an analysis of covariance will be done. Regarding secondary
34
35 outcome measures, multilevel analyses will be used to taking into account the specific effect of the
36
37 individual oncologist. [55]
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43 **EXPECTED ACHIEVEMENT**

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45 The involvement and participation of patients in therapeutic programs is of great interest not only to
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47 physicians but to all health professionals engaged in improving patients' adherence to treatment
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49 regimens or operating in the field of health promotion.
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52 We expect that patients who have the opportunity to rehearse their information needs before the
53
54 consultation will ask a greater number of questions and we will observe higher levels of
55
56 involvement by the physician and a higher number of met information needs. The use of a simple
57
58 question prompt sheet may improve the overall communication between oncologist and patient.
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3 This intervention will be easy to disseminate and use in routine clinical practice to increase patient
4 and companion participation.
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9 10 **DISCUSSION**

11 It has been demonstrated in English speaking countries that a QPS is a useful tool to improve
12 patient's participation during the consultation. However, we contend that consultation
13 communication may vary across cultures and thus there is a need to explore the efficacy of a QPS in
14 Non English speaking countries to explore cross cultural differences. To our knowledge there are
15 no published randomized controlled trials in Europe that assess the effects of a pre-consultation
16 QPS on patient and companion communication. The study has a strong design that incorporates
17 computerised random allocation, blinding of data-collection staff and the use of audiorecordings as
18 an objective measure of consultation communication. The analysis of the consultation recordings is
19 a valuable research method and is a recommended tool for documenting the interaction between
20 patients and oncologists. [56]
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34 There are some limitations to consider. The QPS is not being used prior to the consultation, while,
35 in previous trials reported in literature, [8-16] patients take the QPS into the consultation to serve as
36 a reminder to ask questions. We selected this study method to ensure that participating oncologists
37 are, a) kept blind to the intervention or control status of the patients and b) not forced to change
38 their routine clinical practice.
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45 The findings from this study will provide a basis for further research in the field and provide
46 potentially important results for clinicians, patients and policy makers that may lead to a wider use
47 of the QPS .
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53 54 **ETHICS AND DISSEMINATION PLANS**

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3 The study was approved by the local Ethics Committees of the Hospital Trust of Verona. The study
4 is registered at ClinicalTrials.gov (identifier: NCT01510964). This protocol follows the CONSORT
5 guidelines. [20]
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9 Recruitment phase started in June 2011 and will continue till the enrolment will be completed and is
10 expected to be closed in May 2013. Analysis will start after data monitoring and checking is
11 completed. The dissemination of the trial findings will principally be carried out through
12 publications in peer-review journal and presentations at national/international conferences focused
13 on cancer and/or communication, for examples European Association for Communication in Health
14 Care Conferences and International Shared Decision Making Conferences.
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25 **FUNDING**

26
27 This research received no specific grant from any funding agency in the public, commercial or not-
28 for-profit sectors.
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34 **COMPETING INTERESTS**

35
36 The authors declared that they have no competing interest.
37
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39

40 **AUTHORS' CONTRIBUTIONS**

41
42 CG, LDP, MR, CZ developed the study protocol and together with AG and MGS supervised the all
43 procedures. MAM is the trial statistician and is responsible for generating the randomization
44 sequences and providing guidance on statistical analysis of trial data. MB is the computer scientist
45 that developed the database to save the data. CG drafted the manuscript in collaboration with RB.
46
47
48 CG will oversee enrolment and data collection. GD, AB, FC, CB, IB, AM, EF, RN, CC, SZ, AA,
49 FM, ELS, FR participated in enrolling the patients. All authors saw and approved the final version
50 of the manuscript.
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REFERENCES

1. Buckman R. Breaking bad news: a guide for healthcare professionals. Baltimore, MD: John Hopkins University Press 1992.
2. Baile WF, Buckman R, Lenzi R, et al. AP. SPIKES - A six-step protocol for delivering bad news: Application to the patient with cancer. *Oncologist* 2000;**5**:302-311.
3. Jefford M. & Tattersall M.H. (2002). Informing and involving cancer patients in their own care. *Lancet Oncology* 3(10), 629-637.
4. Joosten EAG, DeFuentes-Merilla L, de Weert GH, Sensky T, et al. Systematic review of the effects of shared decision making on patient satisfaction, treatment adherence and health status. *Psychother Psychosom* 2008;**77**:219-226.
5. Charles C, Gafni A, Whelan T. How to improve communication between doctors and patients. Learning more about the decision making context is important. *BMJ* 2000;**320**:1220-1221.
6. Drew P, Chatwin J, Collins S. Conversation analysis: a method for research into interactions between patients and health-care professionals. *Health Expectat* 2001;**4**:58-70.
7. Zimmermann C, Del Piccolo L, Mazzi MA. Patient cues and medical interviewing in general practice. Examples of the application of sequential analysis. *Epidemiol Psychiatr Soc* 2003;**12**:115-123.
8. Clayton JM, Butow PN, Tattersall MH, et al. Randomized controlled trial of a prompt list to help advanced cancer patients and their caregivers to ask questions about prognosis and end-of-life care. *J Clin Oncol* 2007;**25**:715-723.
9. Butow PN, Dunn SM, Tattersall MHN, et al. Patient participation in the cancer consultation: evaluation of a question prompt sheet. *Ann Oncol* 1994;**5**:199-204.
10. Brown R, Butow PN, Boyer MJ, et al. Promoting patient participation in the cancer consultation: evaluation of a prompt sheet and coaching in question-asking. *Br J Cancer* 1999;**80**:242-248.

- 1
2
3 11. Brown RF, Butow PN, Dunn SM, et al. Promoting patient participation and shortening cancer
4 consultations: a randomised trial. *Br J Cancer* 2001;**8**:1273-1279.
- 5
6
7 12. Bruera E, Sweeney C, Willey J, et al. Breast cancer patient perception of the helpfulness of a
8 prompt sheet versus a general information sheet during outpatient consultation: a randomized
9 controlled trial. *J Pain Symptom Manage* 2003;**5**:412-419.
- 10
11
12 13. Glynne-Jones R, Ostler P, Lumley-Graybow S, et al. Can I look at my list? An evaluation of a
13 'prompt sheet' within an oncology outpatient clinic. *Clin Oncol* 2006;**18**:395-400.
- 14
15
16 14. Clayton J, Butow P, Tattersall M, et al. Asking questions can help: development and
17 preliminary evaluation of a question prompt list for palliative care patients. *Br J Cancer*
18 2003;**89**:2069-2077.
- 19
20
21 15. Clayton JM, Butow PN, Tattersall MH, et al. Randomized controlled trial of a prompt list to
22 help advanced cancer patients and their caregivers to ask questions about prognosis and end-
23 of-life care. *J Clin Oncol* 2007;**25**:715-723.
- 24
25
26 16. Van der Meulen N, Jansen J, van Dulmen S, et al. Interventions to improve recall of medical
27 information in cancer patients: a systematic review of the literature. *Psychooncology*
28 2008;**17**:857-68.
- 29
30
31 17. Van Weert JC, Jansen J, Spreeuwenberg PM, et al. Effects of communication skills training
32 and a Question Prompt Sheet to improve communication with older cancer patients: a
33 randomized controlled trial. *Crit Rev Oncol Hematol* 2011;**80**:145-59.
- 34
35
36 18. Ohlen J, Balneaves L, Bottorff J, et al. The influence of significant others in complementary
37 and alternative medicine decisions by cancer patients. *Soc Sci Med* 2006;**63**:1625-1636.
- 38
39
40 19. Christman J. Relational autonomy, liberal individualism, and the social constitution of selves.
41 *Philosophical Studies* 2004;**117**:143-164.
- 42
43
44 20. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration:
45 updated guidelines for reporting parallel group randomized trials. *BMJ* 2010;**340**:c869. DOI:
46 10.1136/bmj.c869.
- 47
48
49
50
51
52
53
54
55
56
57
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59
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- 1
2
3 21. Istituto Nazionale di Statistica (ISTAT) Web site.
4
5 <http://www.demo.istat.it/pop2010/index.html>. Accessed October 24, 2012.
6
- 7 22. Centro Nazionale di Epidemiologia, Sorveglianza e Promozione della Salute - Istituto
8
9 Superiore di Sanità (ISS) Web site. http://www.tumori.net/it3/banca_dati/query.php. Accessed
10
11 October 24, 2012.
12
- 13 23. Elwyn G, Hutchings H, Edwards A, et al. The OPTION scale: measuring the extent that
14
15 clinicians involve patients in decision-making tasks. *Health Expectat* 2005;**8**:34-42.
16
- 17 24. Goss C, Fontanesi S, Mazzi MA, et al. The assessment of patient involvement across
18
19 consultation. The Italian version of the OPTION scale (in Italian). *Epidemiol Psichiatr Soc*
20
21 2007;**16**:339-349.
22
- 23 25. Goss C, Fontanesi S, Mazzi MA, et al. Shared decision making: the reliability of the OPTION
24
25 scale in Italy. *Pat Educ Counsel* 2007;**66**:296-302.
26
27
- 28 26. Del Piccolo L, Mazzi MA, Scardoni S, et al. A theory based proposal to evaluate patient-
29
30 centred communication in medical consultations: the Verona Patient-centred Communication
31
32 Evaluation scale (VR-COPE). *Health Education* 2008;**108**:355-372.
33
34
- 35 27. Fassone G, Valcella F, Pallini S, et al. Assessment of Interpersonal Motivation in Transcripts
36
37 (AIMIT): an inter- and intra-rater reliability study of a new method of detection of
38
39 interpersonal motivational systems in psychotherapy. *Clin Psychol Psychother* 2012;**19**: 224-
40
41 34.
42
43
- 44 28. Ryan P. sxd1 4: Random allocation of treatments in blocks. *Stata Journal* 2008;**8**:146.
45
46
- 47 29. Altman DG, Schulz KF, Moher D, et al. The revised CONSORT statement for reporting
48
49 randomized trials: explanation and elaboration. *Ann Intern Med* 2001;**134**:663-94.
50
51
- 52 30. Howie JG, Heaney DJ, Maxwell M, et al. A comparison of a Patient Enablement Instrument
53
54 (PEI) against two established satisfaction scales as an outcome measure of primary care
55
56 consultations. *Fam Pract* 1998;**15**:165-171.
57
58
59
60

- 1
2
3 31. Simon D, Chorr G, Wirtz M, et al. Development and first validation of the shared decision
4 making questionnaire (SDM-Q). *Pat Educ Counsel* 2006;**63**:319-327.
- 5
6
7 32. Kriston L, Scholl I, Hölzel L, et al. The 9-item Shared Decision Making Questionnaire (SDM-
8 Q-9). Development and psychometric properties in a primary care sample. *Patient Educ*
9 *Couns.* 2010;**80**:94-9.
- 10
11
12 33. Holmes-Rovner M, Kroll J, Schmitt N, et al. Patient satisfaction with health care decisions:
13 the Satisfaction with Decision Scale. *Med Decis Making* 1996;**16**:58-64.
- 14
15
16 34. Gattellari M, Voigt KJ, Butow PN, et al. When the treatment goal is not cure: are cancer
17 patients equipped to make informed decisions? *J Clin Oncol* 2002;**20**:503-513.
- 18
19
20 35. Whelan T, Levine M, Gafni A, et al. Mastectomy or lumpectomy? Helping women make
21 informed choices. *J Clin Oncol* 1999;**17**:1727-1735.
- 22
23
24 36. Van der Feltz-Cornelis CM, Van Oppen P, Van Marwijk HWJ, et al. A patient-doctor
25 relationship questionnaire (PDRQ-9) in primary care: development and psychometric
26 evaluation. *Gen Hospit Psychiatry* 2004;**26**:115-120.
- 27
28
29 37. Hahn SR, Thompson KS, Wills TA, et al. The difficult doctor-patient relationship:
30 somatization, personality and psychopathology. *J Clin Epidemiol* 1994;**47**:647-57.
- 31
32
33 38. Hahn SR, Kroenke K, Spitzer RL, et al. The difficult patient: prevalence, psychopathology,
34 and functional impairment. *J Gen Intern Med* 1996;**11**:1-8.
- 35
36
37 39. Degner LF, Sloan JA, Venkatesh P. The Control Preferences Scale. *Can J Nurs Res*
38 1997;**29**:21-43.
- 39
40
41 40. Giordano A, Mattarozzi K, Pucci E, et al. Participation in medical decision-making: attitudes
42 of Italians with multiple sclerosis. *J Neurol Sci* 2008;**275**:86-91.
- 43
44
45 41. Spielberger CD. Anxiety as an emotional state. (Vol. 1). New York: Academic Press 1972.
- 46
47
48 42. Spielberger CD, Gorsuch RL, Lushene R, et al. Manual for the State-Trait Anxiety Inventory.
49 Palo Alto, CA: Consulting Psychologists Press 1983.
- 50
51
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53
54
55
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- 1
2
3 43. Lazzari R, Pancheri P. S.T.A.I. Questionario di autovalutazione dell'ansia di stato e di tratto.
4
5 Firenze, IT: Organizzazioni Speciali 1980.
6
7 44. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity
8
9 measure. *J Gen Intern Med* 2001;**16**:606-13.
10
11 45. Kroenke K, Streine TW, Spitzer RL, et al. The PHQ-8 as a measure of current depression in
12
13 general population. *J Affect Disord* 2009;**114**:163-173.
14
15 46. Thekkumpurath P, Walker J, Butcher I, et al. Screening for major depression in cancer
16
17 outpatients: the diagnostic accuracy of the 9-item patient health questionnaire. *Cancer*
18
19 2011;**117**:218-227.
20
21 47. Politi PL, Piccinelli M, Wilkinson G. Reliability, validity and factor structure of the 12-item
22
23 General Health Questionnaire among young males in Italy. *Acta Psychiatr Scand*
24
25 1994;**90**:432-437.
26
27 48. Eysenck SBG, Eysenck HJ, Barrett P. A revised version of the psychoticism scale.
28
29 *Personality and Individual Differences* 1985;**6**:21-29.
30
31 49. O'Connor AM. User Manual-Decision Self-Efficacy Scale. Patient Decision Aids, Ottawa
32
33 Hospital Research Institute (OHIR) Web site.
34
35 http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decision_SelfEfficacy.pdf.
36
37 Accessed October 24, 2012.
38
39
40
41
42 50. De Monchy C, Richardson R, Brown RA, et al. Measuring attitudes of doctors: the doctor-
43
44 patient (DP) rating. *Med Educ* 1988;**22**:231-239.
45
46
47 51. StataCorp. Stata Statistical Software: Release 11.2. College Station, TX: StataCorp LP 2011.
48
49 52. Pocock SJ. Clinical trials: A practical approach. New York: John Wiley & Sons 1983.
50
51 53. Sullivan LM, D'Agostino RB. Robustness and power of analysis of covariance applied to
52
53 ordinal scaled data as arising in randomized controlled trials. *Stat Med* 2003;**22**:1317-1334
54
55 54. Little R, Yau L. Intent-to-treat analysis for longitudinal studies with drop-outs. *Biometrics*
56
57 1996;**52**:1324-1333.
58
59
60

- 1
2
3 55. Skrondal A, Rabe-Hesketh S. Generalized latent variable modelling: Multilevel, longitudinal,
4 and structural equation models. New York: Chapman & Hall/CRC 2004.
5
6
7 56. Tattersall MHN, Butow PN. Consultation audio tapes: an underused cancer patient
8 information aid and clinical research tool. *Lancet Oncol* 2002;3:431-437.
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3 **The INvolvement of breast CANcer patients during oncological consultations. A multi-centre**
4 **randomized controlled trial. The INCA study protocol.**
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53 **Word count: 4549**
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58 **Key- word:** patient involvement, breast cancer, doctor-patient communication
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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, 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 pre-consultation intervention to increase involvement of breast cancer patients during the consultation, and 2) explore the role of attending-companions in the information exchange during the consultation.

Methods and analysis: All female patients with breast cancer who attend the Oncology Out-patient Services for the first time will provide 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 (QPS).

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 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 pre consultation intervention (QPS) facilitates greater participation of patients (and attending companions 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.
- 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 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.
- 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.

Strengths and limitations of this study

- To our knowledge this is the first RCT 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

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3 selected on the QPS and undermine the hypothesis of the greater participation of the QPS
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5 intervention group.
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For peer review only

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 recognizing these variations in patient preferences, and physicians and patients working together to accomplish these preferences. In order to accommodate these varying preferences physicians need elicit patient preferences and to adapt their information giving process to meet these needs. If the expression of such needs is not facilitated or encouraged, these needs tend to remain hidden, consequently patients may perceive that they received too much or too little information. The literature suggests that better quality of patient care and patient outcomes such as coping with illness and treatment adherence are achieved when preferences being 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 a Question Prompt Sheets (QPS). [8- 16] QPS are structures lists of prepared questions that prompt patients to consider novel topics before a consultation and decide on question they would like to ask during the consultation. These tools have been shown to increase patient activation during the consultation and aid recall of information after the 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, patients are frequently accompanied and assisted by a companion: a close family member or another key person. In this context the activation and

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3 involvement of the patient interacts with that of the companion and contributes to the
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5 communication dynamics of the consultation. Olhen and colleagues [18] explored the importance of
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7 significant others in therapeutic decisions and highlighted the notion of “relational autonomy”,
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9 which acknowledges that people are defined by their relationships and are dependent on others in
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11 making decisions. [19] Future research that analyses patients and companions as dyadic units would
12
13 offer further insight into the impact of social relations on treatment decision-making processes.
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15 More evidence on the information needs of companions regarding the patient and their role in the
16
17 information and decision processes during the consultation is also needed.
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21 To our knowledge this is the first RCT in Europe which assesses the effects of a pre-consultation
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23 intervention (QPS) on cancer patients’ involvement during the consultation, on their satisfaction
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25 and confidence in coping with illness, and which explores the role of the companion during the
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27 consultation.
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30 31 **METHODS AND ANALYSIS**

32 33 **Study design**

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35 This is a multicentre, randomized controlled trial in which patients are attributed randomly to the
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37 intervention or to the control group on a 1:1 basis. Patients in the intervention group are given the
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39 QPS, a list of 50 specific questions (see below); those in the control group are given a control sheet
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41 on which to write the questions they would like to ask. The oncologists are informed about the
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43 study protocol but are blinded to whether the patient is a participant of the control group or the
44
45 intervention group. The oncologists perform their consultation as usual, according to the clinical
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47 practice of their centre. After concluding the consultation, they complete two questionnaires
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49 (DPRQ-10 and CPS, see the Measures section for details) regarding the patient and the consultation.
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53 This protocol follows the CONSORT guidelines. [20]

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55 Standardized questionnaires are administered at baseline (before the randomization) and
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57 immediately after the consultation (figure 1, table 1).
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Figure 1 INCA Study flow diagram

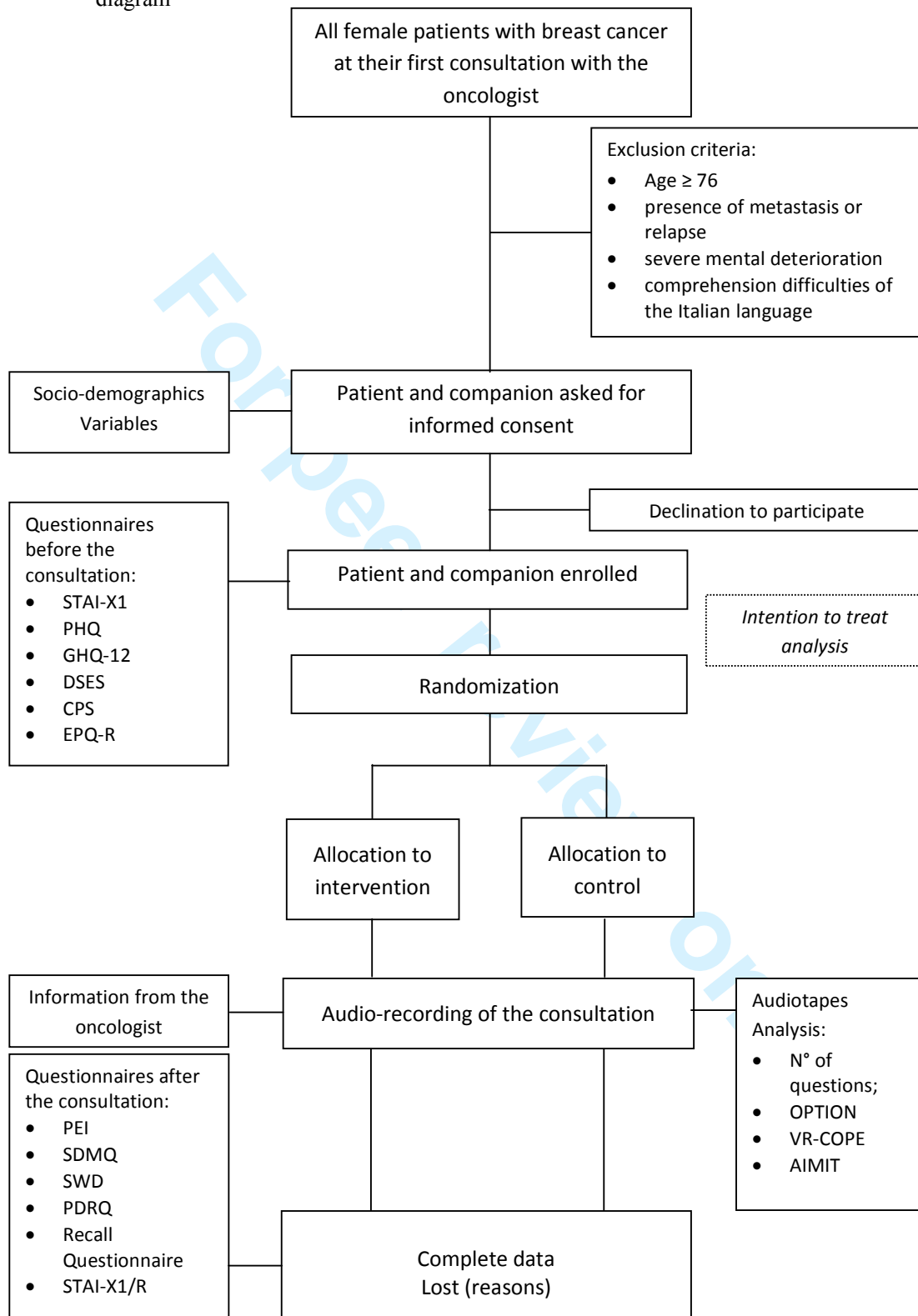


Table 1 Questionnaires and tools used in the study

Tool	Evaluation	Explored area	N° items	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 (PEI)	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 supposedly 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

Time required to answer the pre consultation questionnaire is approximately 15 – 20 minutes while the post consultation questionnaire takes between 10 – 15 minutes to complete.

Intervention

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

Patients and companions (if present) randomized 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 patient (and companion) are invited to select and circle 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. Questions regard diagnosis (e.g. “Of what type is my cancer?”), treatment (e.g. “Which are the pros and cons

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3 of the treatment?), contribution of patient and lifestyle (“What can I do to improve the efficacy of
4 treatment?”), prognosis (“What are the chances of relapse?”) and other issues (e.g. “Do I need a
5 referral from my GP for the next visit?”).
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10 11 **Setting**

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14 The patient recruitment phase of this protocol has begun at three Oncology Departments in
15 Northern Italy: two run by Hospital Trust of Verona in the Veneto region (placed in two different
16 part of the city) and one by the Hospital Trust of Brescia, in the Lombardia region. The recruitment
17 phase started in June 2011 and will continue for two years or until the sample size has been reached.
18
19
20 The population of Verona city and its province in 2010 is about 914 382, the population of Brescia
21 city and its province about 1 242 923. [21] In the Veneto region the estimation of incidence of
22 breast cancer in 2010 was 4 424 new cases per year (Standardized rate adjusted for age using the
23 European population as standard (std) per 100,000= 133). In the Lombardia region the estimation of
24 incidence of breast cancer in 2010 was 7 456 new cases per year (std = 109). [22]
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34 The three Oncology departments each have out-patient clinics dedicated to breast cancer patients
35 with a rotation of 2-5 oncologists. New medical oncology patient appointment are scheduled on
36 fixed days with a number of 4 - 8 patients per day. Generally in the first visit with the oncologist the
37 histological results are communicated and further medical treatment is decided (e.g chemotherapy,
38 hormone therapy). The length of the visit can vary from 30 to 60 minutes.
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47 **Sample and recruitment**

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49 The study sample is composed of consecutive female patients between the age of 18 to 75 years
50 who attend the Oncology out-patient clinics of the participating centres and who have a recent
51 diagnosis of breast cancer at an early stage (absence of metastasis). Eligible patients have already
52 undergone breast surgery (e.g. lumpectomy). Exclusion criteria are the presence of metastasis or
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3 relapse, severe mental deterioration, comprehension difficulties of the Italian language. A sample of
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5 300 patients will be recruited, as estimated by the sample size calculation (see below).
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8 9 **Procedure**

10 Before the patient recruitment phase the oncologists were informed about the study and invited to
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12 participate. Willing oncologist provided written informed consent.
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15 Eligible patients attending their first out-patient visit with the oncologist (and their companions if
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17 present), are provided with information about the study by a project member who are available to
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19 answer any questions. Willing patients provide written informed consent to participate in the study
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21 (figure 1).
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24
25 Once consented patients and companions receive an envelope containing six questionnaires to
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27 answer before the consultation (baseline assessment) (table 1). The project staff member (MAM)
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29 then randomly allocates consenting patients and their companions to the intervention or control
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31 group (see also paragraph “Randomization”). Another project staff member (AB, CB, IB or FC)
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33 hands out the envelopes with either the intervention QPS or the control sheet and collect the sheets
34
35 after their completion. In order to keep the oncologists blind to the intervention or control status
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37 patients do not take the QPS into the consultation.
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41 The subsequent consultation is audio recorded. After the consultation, patients and their
42
43 companions complete a further six questionnaires. In the event that a patient or companion is
44
45 distressed after the consultation trained project member is present (AB, CB, IB or FC) and provides
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47 support.
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50 At the completion of the consultation the oncologists completes a medical details sheet that asks
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52 about the cancer stage and type, when and by whom the patient was informed about diagnosis, and
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54 the therapeutic options appropriate for this patient. They also complete a questionnaire measuring
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56 their perception of the patient as difficult.
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59 The audio tapes and oncologists’ forms are collected by the project staff.
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3 The audio tapes are examined for the content and number of questions asked by patients and
4 companions, and are rated applying the OPTION scale, [23-25] which measures the extent to which
5 the oncologist has succeeded to involve the patient in the consultation. The questions that emerge
6 during the consultations are compared with those expressed before the visit. The audio recorded
7 consultations are also analyzed in terms of patient-centredness with the VR-COPE [26] and with the
8 Assessment of Interpersonal Motivation in Transcripts (AIMIT) [27] which evaluates the five
9 different motivational systems that guide the verbal and non verbal behaviours during interactions.
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20 21 **Randomization**

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23 The randomization sequence is conducted off-site using the “random allocation of treatments
24 balanced in blocks (ralloc)” package for Stata [28] and is stratified by centre with a 1:1 allocation
25 ratio of treatment. Block randomization (size 4) is used to minimize large imbalances between the
26 intervention groups. The allocation sequences are generated by an independent individual, are
27 stored in computer files and remain unknown to the researchers until the patient is randomized.
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34 The QPS or the control sheet, chosen for the two arms of trial, are placed in opaque envelopes,
35 sealed and numbered in sequence (following the list generated by the randomization procedure) by
36 a staff member of each centre (MAM and CB), not involved in the data collection phase. Both
37 randomization procedure and treatment allocation have been developed to fully conceal treatment
38 allocation. [20, 29]
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45 Patients and oncologists are unaware of the allocation. The raters who analyze the audio- recordings
46 are also blinded to the allocation of patients.
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50 51 52 **Study aims and hypotheses**

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

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7 Other aims are to assess the effect of the QPS on the level of patient involvement by the
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9 oncologists, on patient satisfaction and coping, on the oncologist's perception of patient's preferred
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11 decisional role (using the CPS, more details see the measures section) and to explore the role of the
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13 companion.

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16 In detail the study investigates if the intervention determines:

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18 – a greater number of personal information needs expressed during the consultation (the number
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20 and type of the questions asked during the consultation);
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22 – the perception of a greater capacity to cope with illness and a greater satisfaction with decisions
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24 made during the consultation (measured with the PEI and SWD; details are described in the
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26 measures section);
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28 – greater patient generated and/or doctor generated involvement of the patient (using the OPTION
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30 scale and SDM-Q; details are described in the Measures section);
- 31
32 – a better understanding of the received information and greater satisfaction (measured with the
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34 Recall questionnaire and the SWD);
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36 – a more accurate identification by the oncologist of patients' preferred role in the therapeutic
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38 decisions (measured with the CPS answered by the oncologist; details are described in the
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40 Measures section);
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42 – a more supportive doctor-patient relationship perceived by the oncologist's and patient's (using
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44 the PDRQ -9 and DDPRQ-10, see measures section for the details);
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46 – a more patient-centred and sharing approach during the consultation (using the VR-COPE and
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48 the AIMIT; see Measures section for the details).

49
50 Extending the QPS to the patient's companion (if present) allows us to explore the impact of the
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52 QPS on the companions' role and participation during the consultation. The number and type of
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54 questions asked by the companion during the consultation are recorded
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3 Companions answer the same questionnaires as the patient: PEI for the evaluation of the ability to
4 cope with the patients' illness, SDM-Q for the evaluation the perceived involvement during the
5 consultation, SWD for the satisfaction with decision, PDRQ-9 for the doctor-patient-relationship,
6 and Recall Questionnaire for the understanding of the information received. Where necessary,
7 questionnaires were adapted to the companions by substituting the first person (I) used in the patient
8 version, with the third person (she).For example: "I feel confident that I can get the facts about the
9 medication choices available to her" instead of "I feel confident that I can get the facts about the
10 medication choices available to me" (item 1 of the DSES Scale).
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23 **Study measures**

24 25 26 27 **Socio demographic and clinical data**

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29 Socio demographic data collected from patients are: age, education, family status and employment
30 status, type of relationship with the companion (if present), reported both by patients and
31 companions during the baseline assessment.
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36 Oncologists' socio demographic data are: age, gender and years of experience. Data for oncology
37 residents (when present during the consultation) are also obtained.
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41 Clinical data are: cancer stage and type, duration of illness (who has informed patient on diagnosis
42 and when), therapeutic options considered appropriate for this patient, all reported on a form by the
43 oncologist.
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49 **Primary outcome measure**

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51 The total number of patient's questions during the consultation regarding diagnosis, prognosis,
52 treatment, lifestyle and other issues. Question asking is considered an index of patient's
53 participation during the consultation. The QPS aims to increase the number of question by giving
54 the opportunity to patients to reflect on their informative needs choosing among a wide range of
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possible questions those ones perceived as most relevant in view of the subsequent consultation. We hypothesize that patients who are randomized to receive the QPS will ask more questions than patients randomized to the control group.

Secondary outcome measures

- The number of unmet information needs that emerge during the consultation. This measure is 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 the illness, measured with the Patient Enablement Instrument (PEI). This questionnaire is a self-administered questionnaire of six items on a Likert scale from 0 (same or less) to 2 (much better, much more) [30]. We hypothesize that patients randomized 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 9 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, the potential risks and benefits regarding the participation at the decisional process.[31, 32] 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) [23-25]. 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 hypothesize that patients randomized 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 Satisfaction with Decision Scale (SWD). This is a self-report questionnaire of 6 items on a Likert scale from 0 (completely disagree) to 5 (agree completely) [33]. We hypothesize that patients randomized 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 (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.[11, 34, 35] 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 hypothesize that patients randomized 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 hypothesize that patients randomized 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). [27] The VR-COPE [26] assesses the content, the process and relational aspects of

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2
3 patient-centred communication during medical consultations on the basis of a multidimensional
4
5 evaluation and comprises nine items. Each item is defined by operational definitions and rated
6
7 on a 0-10 point scale. The scale is applied by trained raters to the consultation audio-recordings
8
9 We expect that patients of the intervention group establish a better relationship with their
10
11 oncologist and show higher scores in patient-centred communication.
12

13
14 The AIMIT [27] is a coding system applied to transcripts that systematically detects the activity
15
16 of five interpersonal motivational systems (attachment, caregiving, rank, sexuality,
17
18 cooperation). We hypothesize that patients randomized to the intervention group will more
19
20 often evidence a cooperative style during the consultation compared to patients in the control
21
22 group.
23

24
25 – Perceived Patient-doctor relationship, measured with the Patient – Doctor Relationship
26
27 Questionnaire (PDRQ-9) and the Difficult Doctor Patient Relationship Questionnaire (DDPRQ-
28
29 10). The PDRQ-9 contains 9 items on a Likert scale with anchors at 1 (not at all appropriate) to
30
31 5 (totally appropriate). The scale measures patient perceptions of their relationship with the
32
33 doctor.[36] The DDPRQ-10 contains 10 items on a Likert scale anchors at 1 (not at all) to 6 (a
34
35 great deal) and is completed by physicians after the encounter with a patient.[37, 38] The
36
37 questionnaire identifies the patients experienced as difficult patients. We hypothesize that the
38
39 doctor-patient relationship in the intervention group is perceived as less difficult compared to
40
41 the control group.
42

43
44 – Oncologists answered three questions on the potential presence of anxiety, depression or
45
46 emotional distress in the patient and a fourth on their difficulty experienced in answering the
47
48 patient's questions. We hypothesize that answering questions of patients in the intervention
49
50 group will be perceived by oncologists as less difficult.
51
52

53
54 – Perceived role preference of the patient, measured with the Control Preference Scale (CPS,
55
56 Oncologist version) [39, 40]. This scale assesses how the oncologist perceives the role that
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2
3 patient might prefer regarding the decision making process. Oncologists should be better able to
4
5 identify patients preferred role in the intervention group.
6

- 7
8 – Duration of the consultation, measured in minutes. **We hypothesize a longer duration of the**
9
10 **consultation in the intervention group compared to the control group.**
11

12 –

13 14 15 16 **Process related and potential confounding variables**

17
18 The measures below have been collected in order to check their possible influence on question
19
20 asking (primary outcome).
21

- 22
23 – Anxiety, depression and general well-being, measured with the State Anxiety Inventory (STAI-
24
25 X1, XR), [41-43] the Patient Health Questionnaire depression scale (PHQ-9) [44-46] and the
26
27 General Health Questionnaire (GHQ-12) [47].
28

29
30 STAI-X1 is a self-administered questionnaire of 20 items on a Likert scale from 1 (not at all) to
31
32 4 (very much) completed before the consultation. Higher total scores indicate greater state
33
34 anxiety. The STAI-X1R, administered after the consultation, is a shorter version of ten out of
35
36 the twenty items of the STAI-X1, and it is used to evaluate the state anxiety level at the end of
37
38 the consultation and to compare this level with the one measured at the beginning. PHQ-9 is a
39
40 self-assessment questionnaire for detecting the presence of depression and consists of 9 items
41
42 with response options of 0 (not at all) to 3 (almost every day), and has a summative score range
43
44 of 0 to 27. We score it in the standard way, using the sum of the 0–3 scores for each item, and
45
46 ≥ 8 as a cut-score for possible cases of depression [44-46]. GHQ-12 is a self administrated
47
48 questionnaire of 12 items and has a summative score range of 0 to 12 and a cut-score of >3
49
50 indicating psychological distress. [47]
51
52

- 53
54 – Personality traits, measured with the Eysenck Personality Questionnaire (EPQR-S) [48]. The
55
56 EPQR-S is a self-administered questionnaire of 48 items on yes/no scale. For our study we use
57
58 two subscales: the Extraversion/Introversion (12 items) and Neuroticism/Stability (12 items).
59
60

1
2
3 The “Extroversion” is characterized by being outgoing, talkative, high on positive affect (feeling
4 good) and in need of external stimulation. The “Neuroticism” or emotionality is characterized
5 by high levels of negative affect such as depression and anxiety.
6
7

- 8
9
10 – Confidence with decision, measured with the Decision Self Efficacy Scale (DSES). [49] This
11 self- administered questionnaire for patients consists of 11 items on a Likert scale from 0 (not at
12 all confident) to 4 (very confident).
13
14
15
16 – Patients’ and their companion’s preference for the role they want to have in the decision making
17 process, measured with the Control Preference Scale (CPS) [39, 40]. This self-administered
18 instrument contains 5 vignettes with text, depicting different patient roles (from active to
19 passive) from which patients choose the one considered as most appropriate for them.
20
21
22
23 – Patient-centred communication style and attitude toward the doctor-patient relationship,
24 measured with the Doctor-Patient (DP) Scale [50]. The Scale measures the degree of
25 oncologists’ self reported patient or doctor-centred communication style and attitude. It consists
26 of 48 statements to rate on a Likert scale from 1 (strong agreement) to 5 (strong disagreement).
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It has a summative score range of 48 to 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 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 nine 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 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

1
2
3 the feasibility of procedures and questionnaires. This observational study resulted in a mean number
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5 of 18 (sd=13) patient questions asked during a first encounter with the oncologist; no significant
6
7 difference was found between the three centres (median test: $\chi^2=2.4$, $p=0.30$).
8

9
10 An intervention intended to increase the number of questions might be considered efficacious with
11
12 an increase of 30%. The sample size required to evidence such difference was calculated using the
13
14 sampsi command of Stata 11, [51] assuming a power of 80% and a two-sided significant level of
15
16 5% on a student t-test for differences between independent groups. [52, 53]
17
18
19

20 21 **Statistical analysis**

22
23 The data will be analyzed according to intention-to-treat principle. [54] Standard statistical
24
25 techniques will be used to describe characteristics of patients in both groups, and CONSORT flow
26
27 diagram will be shown in order to explain the phases of trial and inform on the findings confidence.
28
29 [20] The primary outcome, significant increase of patient questions, will be compared in the two
30
31 arms using t-test. If adjustment for possible baseline differences among patients (as well as for
32
33 oncologists and centres) is needed, an analysis of covariance will be done. Regarding secondary
34
35 outcome measures, multilevel analyses will be used to taking into account the specific effect of the
36
37 individual oncologist. [55]
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43 **EXPECTED ACHIEVEMENT**

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45 The involvement and participation of patients in therapeutic programs is of great interest not only to
46
47 physicians but to all health professionals engaged in improving patients' adherence to treatment
48
49 regimens or operating in the field of health promotion.
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51
52 We expect that patients who have the opportunity to rehearse their information needs before the
53
54 consultation will ask a greater number of questions and we will observe higher levels of
55
56 involvement by the physician and a higher number of met information needs. The use of a simple
57
58 question prompt sheet may improve the overall communication between oncologist and patient.
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3 This intervention will be easy to disseminate and use in routine clinical practice to increase patient
4
5 and companion participation.
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7

8 9 **DISCUSSION**

10
11 It has been demonstrated in English speaking countries that a QPS is a useful tool to improve
12
13 patient's participation during the consultation. However, we contend that consultation
14
15 communication may vary across cultures and thus there is a need to explore the efficacy of a QPS in
16
17 Non English speaking countries to explore cross cultural differences. To our knowledge there are
18
19 no published randomized controlled trials in Europe that assess the effects of a pre-consultation
20
21 QPS on patient and companion communication. The study has a strong design that incorporates
22
23 computerised random allocation, blinding of data-collection staff and the use of audiorecordings as
24
25 an objective measure of consultation communication. The analysis of the consultation recordings is
26
27 a valuable research method and is a recommended tool for documenting the interaction between
28
29 patients and oncologists. [56]
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33
34 There are some limitations to consider. The QPS is not being used prior to the consultation, while,
35
36 in previous trials reported in literature, [8-16] patients take the QPS into the consultation to serve as
37
38 a reminder to ask questions. We selected this study method to ensure that participating oncologists
39
40 are, a) kept blind to the intervention or control status of the patients and b) not forced to change
41
42 their routine clinical practice.
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45
46 The findings from this study will provide a basis for further research in the field and provide
47
48 potentially important results for clinicians, patients and policy makers that may lead to a wider use
49
50 of the QPS .
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52 53 **ETHICS AND DISSEMINATION PLANS**

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3 The study was approved by the local Ethics Committees of the Hospital Trust of Verona. The study
4 is registered at ClinicalTrials.gov (identifier: NCT01510964). This protocol follows the CONSORT
5
6
7 guidelines. [20]

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9
10 Recruitment phase started in June 2011 and will continue till the enrolment will be completed and is
11
12 expected to be closed in May 2013. Analysis will start after data monitoring and checking is
13
14 completed. The dissemination of the trial findings will principally be carried out through
15
16 publications in peer-review journal and presentations at national/international conferences focused
17
18 on cancer and/or communication, for examples European Association for Communication in Health
19
20 Care Conferences and International Shared Decision Making Conferences.
21

22 23 24 25 **FUNDING**

26
27 This research received no specific grant from any funding agency in the public, commercial or not-
28
29 for-profit sectors.
30

31 32 33 34 **COMPETING INTERESTS**

35
36 The authors declared that they have no competing interest.
37
38
39

40 41 42 43 **AUTHORS' CONTRIBUTIONS**

44
45 CG, LDP, MR, CZ developed the study protocol and together with AG and MGS supervised the all
46
47 procedures. MAM is the trial statistician and is responsible for generating the randomization
48
49 sequences and providing guidance on statistical analysis of trial data. MB is the computer scientist
50
51 that developed the database to save the data. CG drafted the manuscript in collaboration with RB.
52
53 CG will oversee enrolment and data collection. GD, AB, FC, CB, IB, AM, EF, RN, CC, SZ, AA,
54
55 FM, ELS, FR participated in enrolling the patients. All authors saw and approved the final version
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57 of the manuscript.
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REFERENCES

1. Buckman R. Breaking bad news: a guide for healthcare professionals. Baltimore, MD: John Hopkins University Press 1992.
2. Baile WF, Buckman R, Lenzi R, et al. AP. SPIKES - A six-step protocol for delivering bad news: Application to the patient with cancer. *Oncologist* 2000;**5**:302-311.
3. Jefford M. & Tattersall M.H. (2002). Informing and involving cancer patients in their own care. *Lancet Oncology* 3(10), 629-637.
4. Joosten EAG, DeFuentes-Merilla L, de Weert GH, Sensky T, et al. Systematic review of the effects of shared decision making on patient satisfaction, treatment adherence and health status. *Psychother Psychosom* 2008;**77**:219-226.
5. Charles C, Gafni A, Whelan T. How to improve communication between doctors and patients. Learning more about the decision making context is important. *BMJ* 2000;**320**:1220-1221.
6. Drew P, Chatwin J, Collins S. Conversation analysis: a method for research into interactions between patients and health-care professionals. *Health Expectat* 2001;**4**:58-70.
7. Zimmermann C, Del Piccolo L, Mazzi MA. Patient cues and medical interviewing in general practice. Examples of the application of sequential analysis. *Epidemiol Psychiatr Soc* 2003;**12**:115-123.
8. Clayton JM, Butow PN, Tattersall MH, et al. Randomized controlled trial of a prompt list to help advanced cancer patients and their caregivers to ask questions about prognosis and end-of-life care. *J Clin Oncol* 2007;**25**:715-723.
9. Butow PN, Dunn SM, Tattersall MHN, et al. Patient participation in the cancer consultation: evaluation of a question prompt sheet. *Ann Oncol* 1994;**5**:199-204.
10. Brown R, Butow PN, Boyer MJ, et al. Promoting patient participation in the cancer consultation: evaluation of a prompt sheet and coaching in question-asking. *Br J Cancer* 1999;**80**:242-248.

- 1
2
3 11. Brown RF, Butow PN, Dunn SM, et al. Promoting patient participation and shortening cancer
4 consultations: a randomised trial. *Br J Cancer* 2001;**8**:1273-1279.
- 5
6
7 12. Bruera E, Sweeney C, Willey J, et al. Breast cancer patient perception of the helpfulness of a
8 prompt sheet versus a general information sheet during outpatient consultation: a randomized
9 controlled trial. *J Pain Symptom Manage* 2003;**5**:412-419.
- 10
11
12 13. Glynne-Jones R, Ostler P, Lumley-Graybow S, et al. Can I look at my list? An evaluation of a
13 'prompt sheet' within an oncology outpatient clinic. *Clin Oncol* 2006;**18**:395-400.
- 14
15
16 14. Clayton J, Butow P, Tattersall M, et al. Asking questions can help: development and
17 preliminary evaluation of a question prompt list for palliative care patients. *Br J Cancer*
18 2003;**89**:2069-2077.
- 19
20
21 15. Clayton JM, Butow PN, Tattersall MH, et al. Randomized controlled trial of a prompt list to
22 help advanced cancer patients and their caregivers to ask questions about prognosis and end-
23 of-life care. *J Clin Oncol* 2007;**25**:715-723.
- 24
25
26 16. Van der Meulen N, Jansen J, van Dulmen S, et al. Interventions to improve recall of medical
27 information in cancer patients: a systematic review of the literature. *Psychooncology*
28 2008;**17**:857-68.
- 29
30
31 17. Van Weert JC, Jansen J, Spreeuwenberg PM, et al. Effects of communication skills training
32 and a Question Prompt Sheet to improve communication with older cancer patients: a
33 randomized controlled trial. *Crit Rev Oncol Hematol* 2011;**80**:145-59.
- 34
35
36 18. Ohlen J, Balneaves L, Bottorff J, et al. The influence of significant others in complementary
37 and alternative medicine decisions by cancer patients. *Soc Sci Med* 2006;**63**:1625-1636.
- 38
39
40 19. Christman J. Relational autonomy, liberal individualism, and the social constitution of selves.
41 *Philosophical Studies* 2004;**117**:143-164.
- 42
43
44 20. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration:
45 updated guidelines for reporting parallel group randomized trials. *BMJ* 2010;**340**:c869. DOI:
46 10.1136/bmj.c869.
- 47
48
49
50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 21. Istituto Nazionale di Statistica (ISTAT) Web site.
4
5 <http://www.demo.istat.it/pop2010/index.html>. Accessed October 24, 2012.
6
- 7 22. Centro Nazionale di Epidemiologia, Sorveglianza e Promozione della Salute - Istituto
8
9 Superiore di Sanità (ISS) Web site. http://www.tumori.net/it3/banca_dati/query.php. Accessed
10
11 October 24, 2012.
12
- 13 23. Elwyn G, Hutchings H, Edwards A, et al. The OPTION scale: measuring the extent that
14
15 clinicians involve patients in decision-making tasks. *Health Expectat* 2005;**8**:34-42.
16
- 17 24. Goss C, Fontanesi S, Mazzi MA, et al. The assessment of patient involvement across
18
19 consultation. The Italian version of the OPTION scale (in Italian). *Epidemiol Psichiatr Soc*
20
21 2007;**16**:339-349.
22
- 23 25. Goss C, Fontanesi S, Mazzi MA, et al. Shared decision making: the reliability of the OPTION
24
25 scale in Italy. *Pat Educ Counsel* 2007;**66**:296-302.
26
27
- 28 26. Del Piccolo L, Mazzi MA, Scardoni S, et al. A theory based proposal to evaluate patient-
29
30 centred communication in medical consultations: the Verona Patient-centred Communication
31
32 Evaluation scale (VR-COPE). *Health Education* 2008;**108**:355-372.
33
34
- 35 27. Fassone G, Valcella F, Pallini S, et al. Assessment of Interpersonal Motivation in Transcripts
36
37 (AIMIT): an inter- and intra-rater reliability study of a new method of detection of
38
39 interpersonal motivational systems in psychotherapy. *Clin Psychol Psychother* 2012;**19**: 224-
40
41 34.
42
43
- 44 28. Ryan P. sxd1 4: Random allocation of treatments in blocks. *Stata Journal* 2008;**8**:146.
45
46
- 47 29. Altman DG, Schulz KF, Moher D, et al. The revised CONSORT statement for reporting
48
49 randomized trials: explanation and elaboration. *Ann Intern Med* 2001;**134**:663-94.
50
51
- 52 30. Howie JG, Heaney DJ, Maxwell M, et al. A comparison of a Patient Enablement Instrument
53
54 (PEI) against two established satisfaction scales as an outcome measure of primary care
55
56 consultations. *Fam Pract* 1998;**15**:165-171.
57
58
59
60

- 1
2
3 31. Simon D, Chorr G, Wirtz M, et al. Development and first validation of the shared decision
4 making questionnaire (SDM-Q). *Pat Educ Counsel* 2006;**63**:319-327.
- 5
6
7 32. Kriston L, Scholl I, Hölzel L, et al. The 9-item Shared Decision Making Questionnaire (SDM-
8 Q-9). Development and psychometric properties in a primary care sample. *Patient Educ*
9 *Couns.* 2010;**80**:94-9.
- 10
11
12 33. Holmes-Rovner M, Kroll J, Schmitt N, et al. Patient satisfaction with health care decisions:
13 the Satisfaction with Decision Scale. *Med Decis Making* 1996;**16**:58-64.
- 14
15
16 34. Gattellari M, Voigt KJ, Butow PN, et al. When the treatment goal is not cure: are cancer
17 patients equipped to make informed decisions? *J Clin Oncol* 2002;**20**:503-513.
- 18
19
20 35. Whelan T, Levine M, Gafni A, et al. Mastectomy or lumpectomy? Helping women make
21 informed choices. *J Clin Oncol* 1999;**17**:1727-1735.
- 22
23
24 36. Van der Feltz-Cornelis CM, Van Oppen P, Van Marwijk HWJ, et al. A patient-doctor
25 relationship questionnaire (PDRQ-9) in primary care: development and psychometric
26 evaluation. *Gen Hospit Psychiatry* 2004;**26**:115-120.
- 27
28
29 37. Hahn SR, Thompson KS, Wills TA, et al. The difficult doctor-patient relationship:
30 somatization, personality and psychopathology. *J Clin Epidemiol* 1994;**47**:647-57.
- 31
32
33 38. Hahn SR, Kroenke K, Spitzer RL, et al. The difficult patient: prevalence, psychopathology,
34 and functional impairment. *J Gen Intern Med* 1996;**11**:1-8.
- 35
36
37 39. Degner LF, Sloan JA, Venkatesh P. The Control Preferences Scale. *Can J Nurs Res*
38 1997;**29**:21-43.
- 39
40
41 40. Giordano A, Mattarozzi K, Pucci E, et al. Participation in medical decision-making: attitudes
42 of Italians with multiple sclerosis. *J Neurol Sci* 2008;**275**:86-91.
- 43
44
45 41. Spielberger CD. Anxiety as an emotional state. (Vol. 1). New York: Academic Press 1972.
- 46
47
48 42. Spielberger CD, Gorsuch RL, Lushene R, et al. Manual for the State-Trait Anxiety Inventory.
49 Palo Alto, CA: Consulting Psychologists Press 1983.
- 50
51
52
53
54
55
56
57
58
59
60

- 1
2
3 43. Lazzari R, Pancheri P. S.T.A.I. Questionario di autovalutazione dell'ansia di stato e di tratto.
4
5 Firenze, IT: Organizzazioni Speciali 1980.
6
7 44. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: validity of a brief depression severity
8
9 measure. *J Gen Intern Med* 2001;**16**:606-13.
10
11 45. Kroenke K, Streine TW, Spitzer RL, et al. The PHQ-8 as a measure of current depression in
12
13 general population. *J Affect Disord* 2009;**114**:163-173.
14
15 46. Thekkumpurath P, Walker J, Butcher I, et al. Screening for major depression in cancer
16
17 outpatients: the diagnostic accuracy of the 9-item patient health questionnaire. *Cancer*
18
19 2011;**117**:218-227.
20
21 47. Politi PL, Piccinelli M, Wilkinson G. Reliability, validity and factor structure of the 12-item
22
23 General Health Questionnaire among young males in Italy. *Acta Psychiatr Scand*
24
25 1994;**90**:432-437.
26
27 48. Eysenck SBG, Eysenck HJ, Barrett P. A revised version of the psychoticism scale.
28
29 *Personality and Individual Differences* 1985;**6**:21-29.
30
31 49. O'Connor AM. User Manual-Decision Self-Efficacy Scale. Patient Decision Aids, Ottawa
32
33 Hospital Research Institute (OHIR) Web site.
34
35 http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decision_SelfEfficacy.pdf.
36
37 Accessed October 24, 2012.
38
39
40
41
42 50. De Monchy C, Richardson R, Brown RA, et al. Measuring attitudes of doctors: the doctor-
43
44 patient (DP) rating. *Med Educ* 1988;**22**:231-239.
45
46
47 51. StataCorp. Stata Statistical Software: Release 11.2. College Station, TX: StataCorp LP 2011.
48
49 52. Pocock SJ. Clinical trials: A practical approach. New York: John Wiley & Sons 1983.
50
51 53. Sullivan LM, D'Agostino RB. Robustness and power of analysis of covariance applied to
52
53 ordinal scaled data as arising in randomized controlled trials. *Stat Med* 2003;**22**:1317-1334
54
55
56 54. Little R, Yau L. Intent-to-treat analysis for longitudinal studies with drop-outs. *Biometrics*
57
58 1996;**52**:1324-1333.
59
60

- 1
2
3 55. Skrondal A, Rabe-Hesketh S. Generalized latent variable modelling: Multilevel, longitudinal,
4 and structural equation models. New York: Chapman & Hall/CRC 2004.
5
6
7 56. Tattersall MHN, Butow PN. Consultation audio tapes: an underused cancer patient
8 information aid and clinical research tool. *Lancet Oncol* 2002;3:431-437.
9
10
11
12
13
14
15
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18
19
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21
22
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