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Sarcoma patient willingness to participate in cancer surveillance research: a cross-sectional patient survey

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ABSTRACT

Objectives: To determine the proportion of extremity soft-tissue sarcoma patients who would be willing to participate in a clinical trial in which they would be randomized to one of four different post-operative sarcoma surveillance regimens. Additionally, we assessed patients' perspectives on the burden of cancer care, factors that influence comfort with randomization, and the importance of cancer research.

Design: Prospective, cross-sectional patient survey.

Setting: Outpatient sarcoma clinics in Canada, the United States and Spain between May 2017 – April 2020. Survey data was entered into a study-specific database.

Participants: Extremity soft-tissue sarcoma patients who had completed definitive treatment from seven clinics across Canada, the United States and Spain.

Main Outcome Measures: The proportion of extremity soft-tissue sarcoma patients who would be willing to participate in a randomized controlled trial (RCT) that evaluates varying post-operative cancer surveillance regimens.

Results: One hundred and thirty complete surveys were obtained. Respondents reported a wide range of burdens related to clinical care and surveillance. The majority of patients (85.5%) responded that they would agree to participate in a cancer surveillance RCT if eligible. The most common reason to participate was that they wanted to help future patients. Those that would decline to participate most commonly reported that participating in research would be too much of a burden for them at a time when they are already feeling overwhelmed. However, most patients agreed that cancer research will help doctors better understand and treat cancer.

Conclusions: These results demonstrate that most participants would be willing to participate in an RCT that evaluates varying post-operative cancer surveillance regimens. Participants' motivation for trial participation included altruistic reasons to help future patients and deterrents to trial participation included the overwhelming burden of a cancer diagnosis. These results will help inform the development of patient-centered RCT protocols in sarcoma surveillance research.

Level of Evidence: V

ARTICLE SUMMARY

Strengths and limitations of this study

- The primary objective of this study was to investigate the proportion of extremity sarcoma patients who would be willing to participate in a clinical trial in which they would be randomized to one of four different post-operative cancer surveillance regimens.
- The results of this study have been used to directly inform the definitive phase of the Surveillance AFter Extremity Tumor SurgerY (SAFETY) trial.
- Patient engagement in the preliminary trial development is expected to improve the trial's relevance, increase transparency and, ultimately, accelerate the adoption of findings into practice.



Sarcomas are a rare and heterogenous group of cancers with distinct biology that represent less than one percent of all malignancies¹⁻⁶. Following treatment for a sarcoma, patients remain at risk for the development of local and systemic disease recurrence, which necessitates careful post-operative surveillance. Almost 50% of all sarcoma patients will develop a local or distant recurrence; however, the risk of recurrence is greatest in the first few years, with 68% occurring by two years and 90% by five years⁷⁻⁹. Metastasis to the lung is the most frequent single location of disease recurrence in sarcoma patients, occurring in approximately one half of all patients⁹⁻¹². Earlier detection of less advanced and resectable disease relapse may prolong patient survival; however, once advanced metastases are detected, the median length of survival is 12 to 15 months⁹.

As such, routine follow-up following the completion of sarcoma treatment is standard practice, and generally entails regular visits to sarcoma outpatient clinics in the first five to ten years after surgery. These visits typically include a clinical history, a physical examination and imaging of the lungs. Regular, intensive surveillance is more likely to identify recurrent disease earlier than would less intensive surveillance. This may provide reassurance to patients and clinicians as if the interval screening is negative, the patient is considered at that time to be disease-free.

However, the adverse effects of intensive surveillance practices on patients are also noteworthy. Intensive surveillance can threaten the financial security of patients, due in part to the direct costs, including travel, accommodation, personal care and homemaking, and indirect costs, including lost wages for patients and their caregivers, incurred as a result of follow-up appointments¹³. As a result, patients' health and quality of life can be dramatically impacted should they decide to forego further treatment or alter their lifestyles in order to alleviate financial difficulties^{13–15}. Furthermore, intensive surveillance investigations can also induce anxiety, and earlier knowledge of disease recurrence may adversely impact patients' psychosocial wellbeing for those whose mortality risk cannot be significantly reduced by further medical interventions¹⁶. In fact, the first recommendation put forward by *Choosing Wisely Canada* for oncology is not to "order tests to detect recurrent cancer in asymptomatic patients if there is not a realistic expectation that early detection of recurrence can improve survival or quality of life" 17.

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A randomized controlled trial (RCT) would be the ideal approach to determine the optimal post-operative surveillance strategy that balances potential gains in survival, costs and quality of life. Due to the rarity of sarcoma, this RCT will require extensive international collaboration and patient willingness to be randomly allocated to varying surveillance regimens. In this study, we conducted a patient survey to investigate the proportion of extremity soft-tissue sarcoma patients that would be willing to participate in a clinical trial in which they would be randomized to one of four different post-operative sarcoma surveillance regimens. We also assessed the burden of cancer care on patients, the factors that influence patient comfort with being randomized to different surveillance protocols, and we explored patient views on the importance of cancer research.

METHODS

We conducted a cross-sectional multi-centre survey between May 2017 and April 2020 at seven sarcoma outpatient clinics in Canada (three sites), the United States (three sites) and Spain (one site). The Methods Centre received approval from the Hamilton Integrated Research Ethics Board (HiREB) (Protocol No. 2954). Approval from each of the local ethics committees was obtained in writing prior to the local commencement of the study.

Participants

In order to be eligible for participation, patients must have: 1) been at least 18 years of age; 2) been able to read, understand and write in English, French or Spanish; 3) have recently completed treatment of an extremity soft-tissue sarcoma; and 4) provided consent to participate.

Questionnaire Objectives

Given that patient willingness to participate in cancer surveillance research is the ultimate determinant of overall study feasibility, the primary objective of this questionnaire was to determine whether extremity sarcoma patients would be willing to participate in the Surveillance AFter Extremity Tumor surgerY (SAFETY) trial¹⁸. The SAFETY trial, initiated in early 2020, is a 2X2 factorial design RCT in which sarcoma patients are randomized to one of four different surveillance regiments. The primary objective of the SAFETY trial is to determine the effect of surveillance intensity on long-term survival in the soft-tissue sarcoma population. The current cross-sectional survey served as background work for the trial's development.

Secondary objectives of this cross-sectional patient survey included: 1) assessment of the burden of cancer care on patients; 2) assessment of factors that influence patient comfort with being randomized to different surveillance protocols; and 3) the exploration of patient views on the importance of cancer research.

Questionnaire Development

Item Generation

We developed a unique patient questionnaire for the purposes of this study. The development of this questionnaire was informed by a review of the current literature on patient surveillance and in consultation with experts in orthopaedic oncology, research methodology and patient recruitment. We utilized a 'sampling-to-redundancy' approach in which we solicited feedback from new orthopaedic oncologists and research methodologists until no new items for the questionnaire emerged.

Pretesting and Validity Assessments

The questionnaire was reviewed by nine additional experts, who were either orthopaedic oncologists or health research methodologists. These experts evaluated whether the questionnaire as a whole appeared to adequately address the question of whether extremity soft-tissue sarcoma patients would participate in cancer surveillance research (face validity) and whether the individual questions adequately addressed the objectives of the current study (content validity). These nine experts also assessed the questionnaire's comprehensiveness and flow, as well as identified any redundant, irrelevant or poorly worded questions.

Survey Description

The final survey was comprised of 58 questions using Likert scales, multiple choice, and brief open-ended questions. The following sections were included: (A) **Demographics**, including medical history and income, (B) **Cancer History**, including the number of treatment visits thus far required, (C) **Perceptions of Cancer Research**, (D) **Financial Burden of Cancer Care**, (E) **Logistical Burden of Cancer Care**, and (F) **The SAFETY Trial**, including perceptions of cancer surveillance, the trial design and willingness to participate in such a trial, and reasons for accepting or declining to participate. The survey is provided as **Appendix 1**.

All questions were straightforward and utilized clear and layman terminology to enhance the validity of the results. The survey length was kept to a minimum in an effort to maximize the

response rate and to limit barriers that could have affected its proper completion. The survey included questions regarding the participants' demographics, cancer history, the financial and logistical burden of cancer care and views on the importance of cancer research.

Survey Administration and Data Collection

We approached all new post-operative extremity soft-tissue sarcoma patients for participation in this patient survey. After obtaining informed consent, the site Study Coordinator provided each participant with a paper copy of the questionnaire to complete in a private location. Participants were allowed to leave a question blank if they found it uncomfortable to answer. Upon completion, the participant returned the questionnaire to the site Study Coordinator who verified that all questions had been answered. Completed questionnaires were then entered into a study-specific database using the REDCapTM electronic data capture software system.

Statistical Analysis

Descriptive analyses, including frequency counts and percentages, were calculated for all collected data. Continuous data are presented as means and standard deviations.

Role of the Funding Source

The funding source had no role in the design or conduct of the study; the collection, management, analysis or interpretation of the data; or the preparation, review or approval of the manuscript. None of the authors have been paid to write this article. The study team had full access to all of the study data and takes responsibility for the integrity of the data and the accuracy of the data.

Patient and public involvement

Although this study evaluates the patient perspectives on participating in clinical trials and cancer research, patients were not involved in the design, conduct or reporting or dissemination of this research. However, the results of this study will help inform the development of patient-centered clinical trial protocols in sarcoma surveillance research.

RESULTS

Characteristics of Respondents

A total of 142 patients were approached to complete the survey and 130 agreed (response rate 92%). Patient demographic and cancer history data are shown in **Table 1**. The mean patient age

was 56.4 years (SD 16.9 years) and 60.8% of patients were male. The majority of patient respondents were white (82.3%) and country of residence was reported as Canada in 40.8%, the United States in 52.3% and Spain in 6.9%. Most respondents were married or in a common law relationship (70.5%). There was a broad range of educational levels reported with a high school diploma as the most common response (31.3%), and a wide range of household incomes were reported. The most common anatomic location for the sarcoma was the lower extremity (66.7%), and patients reported receiving multidisciplinary treatment including chemotherapy (21.9%) and radiotherapy (68.4%). Travel times to the clinic ranged evenly across the spectrum from less than 30 minutes, to over 2 hours. Most patients reported travelling to medical appointments by personal vehicle (75%) by themselves (46.9%) or with a spouse (41.4%). Seventy-five percent of patient respondents reported not having previously been involved in a clinical research study.

Burden of Cancer Care

Respondent details for Burden of Cancer Care are shown in **Table 2**. The majority of patients reported at least some form of financial burden related to their cancer care and surveillance. These included transportation and travel expenses (87.7%), accommodation and meal expenses (76.6%), family and living expenses (78.9%), caregiving expenses (56.3%) and personal loss of wages (38%). Logistical burdens are also very significant for some patients. These included coordination of medical visits (46.5%), arrangement of time off work (31.5%) and arrangement of childcare when applicable.

The SAFETY Trial: Reasons to Participate and Views on Cancer Research

A summary of patient perceptions on cancer research and the SAFETY trial specifically are outlined in **Tables 3** and **4**. The most common reasons for agreeing to participate in cancer research represented trust in the healthcare team and altruism: "I want to contribute to scientific research" (79%), "I trust the doctor treating me" (75%), "I believe the results from the study could benefit other patients in the future" (78.1%), and "I believe that the study offers the best treatment available" (61.9%). With respect to overall views and perceptions of cancer research, approximately 2/3 of patients (68.7%) feel that they have a good understanding of clinical research. Notably, only about half (53.5%) are generally comfortable with the process of randomization, in which their treatment or surveillance arm could be determined by chance. However, an

overwhelming majority of patients (128/130, 98.5%) strongly agree or agree that cancer research will help doctors better understand and treat cancer. In addition, 93.9% of respondents strongly agree or agree that the primary reason cancer research is done is to improve the treatment of future cancer patients. Interestingly, over half of respondents (68/130, 52.3%) strongly agree or agree that they would not benefit directly from participating from cancer research.

A total of 106 of 124 respondents that answered the question "Would you participate in the SAFETY trial if eligible?" reported that they would agree to participate (85.5%). Those that believed they would not agree to participate reported that they would decline for the following reasons: (1) "I do not believe that I can currently cope with the additional requirements of a research study" (8, respondents, 44.4%), (2) "I have concerns about possibly being followed less intensively in this study" (4 respondents, 22.2%), (3) "I have concerns about additional radiation exposures from CT scans" (4 respondents, 22.2%), and (4) "I believe that the quality of care I receive would be inferior to what I would receive if I did not participate" (3 respondents, 16.7%). Other less common reasons to decline the study included "I do not believe that the study offers the best treatment available", "My family is not keen for me to participate", as well as travel and religious reasons. One respondent reported a negative experience with a previous trial.

DISCUSSION

Summary of Findings

This study explored the perceptions of international extremity soft-tissue sarcoma patients on cancer surveillance. We found that patients endure significant financial and logistical burdens associated with sarcoma care and follow-up. In general, patients are very interested in participating in clinical research, and specifically in cancer surveillance research. The reasons for participating in research include the desire to help future patients and the perception that their care would be improved in the context of a clinical trial. However, some participants expressed a lingering concern with leaving their care and/or surveillance to chance (randomization) and several indicated that they believe that they would not participate in research due to feeling overwhelmed with their

cancer diagnosis and treatment. Overall, the results of this study will help inform the SAFETY trial and guide approaches to eligible patients when obtaining consent.

Strengths and Limitations

This study has several strengths. First, we used a rigorous process for the development of the patient questionnaire and extensive piloting of the survey. This stepwise process created a questionnaire that was acceptable for patients and sufficiently clear and comprehensive to provide a robust dataset. Second, we surveyed patients across Canada, the United States and Spain. Although this required translation of English documents into French and Spanish, it provided a more global picture of patient perceptions. The SAFETY trial is an international endeavor, and therefore international participation in the background survey was critical. Finally, this survey study represents an important step in engaging patients in randomized controlled trial development and inception, thus improving the patient-centered nature of cancer research.

Our study also had some limitations to consider. First, there may have been selection bias in that those who agreed to participate in the survey study are also more likely to participate in research in general. This would overestimate the acceptance rate of the SAFETY study and interest in clinical research. However, our response rate was 92%, somewhat mitigating these concerns. Second, the survey was not a validated survey; however, it allowed us to determine the proportion of participants who would theoretically consent to participating specifically in the SAFETY trial, as well as investigate patients' views on the burden of cancer care and on cancer research in greater detail than would have been possible with standardized questionnaires. Third, the demographics of the respondents were not diverse with respect to race (82.3% white) and continent (93.1% from North America). This somewhat limits the external validity of the findings with respect to Europe and other international sites. Finally, the survey did not evaluate the optimal timing and method to approach patients to participate in the SAFETY trial.

Relevance to previous research

The exploration of patient perceptions of sarcoma surveillance in the context of a randomized surveillance trial has not, to our knowledge, previously been reported. However, as far back as 1979, researchers interviewed sarcoma patients to determine reasons for acceptance of randomization in treatment related trial clinical trials¹⁹. The authors of this study concluded that patient acceptance of participation in treatment related clinical trials was associated with treatment factors such as burden of care and drug toxicities. Within the field of orthopaedic surgery, Creel et al surveyed patients with meniscal tears and determined willingness to participate in a trial in which they would be randomized to operative vs. non-operative treatment²⁰. The authors found that lack of strong treatment preferences and male gender were significantly associated with willingness to participate in such a trial. Only 46% of patients reported that they would be definitely willing or probably willing to participate.

A large survey study of 1,227 Swiss patients in which 4 different clinical trial vignettes were described found that all studies were not equally acceptable to patients. A higher willingness to participate was found when a new drug was considered safe, no extra logistical burden of care was required, results were openly available to the public, and the project was approved by a research ethics committee. In contrast, use of placebo controls, and random allocation to study arms were associated with a lower likelihood of participation²¹. Similarly, Halpern et al found that in hypertensive patients, inconvenience, fear of known side effects, and the possibility of receiving placebo were the most common concerns for patients in clinical trials²². Similar to the orthopaedic trial outlined above, only 47% of patients would be willing to participate in a placebo controlled trial.

Implications

In this study we found that a high percentage of soft-tissue sarcoma patients would be willing to participate in surveillance research. In comparison to other published patient survey studies of treatment related RCTs, the willingness to participate identified in this study is significantly greater. This has positive implications for sarcoma surveillance research in general, and specifically for the SAFETY trial. However, survey responses do not necessarily align with actual participation. Moreover, the sense of being overwhelmed with the diagnosis of sarcoma and the need for intensive treatment, can deter patients from accepting an additional dimension to their

care in the form of a trial. Nevertheless, the patient engagement strategy used in this study is likely to increase enrollment in the SAFETY trial and help guide study implementation²³.

Conclusions

The results of this patient survey demonstrate that the majority of participants would be willing to participate in a randomized controlled trial that evaluates different post-operative sarcoma surveillance regimens. Participants' motivations for trial participation included trust in the healthcare system and altruistic reasons to help future patients. Those that would decline the study for the most part would do so because of the overwhelming burden of a cancer diagnosis. These results will help inform the development of patient-centered clinical trial protocols in cancer surveillance research and specifically the implementation of the SAFETY trial.

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Contributors

PS and MG designed this study and are the principal authors of this manuscript. VG and DG contributed significantly to data collection and data analysis. DW, RT, MI, BM, JH, RLR, KJ, and RV contributed to the conception of the study and acquisition of data. All authors reviewed and approved the manuscript.

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Competing Interests

Each author certifies that he or she, or a member of his or her immediate family, has no funding or commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

Ethics Approval

Each author certifies that his or her institution approved or waived approval for the human protocol for this investigation and that all investigations were conducted with ethical principles of research.

Data availability statement

The data sets generate during this study are not publicly available, but are available from the corresponding author on reasonable request.

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Table 1. Participant Demographics

| Characteristic | N = 130 |
|---|-------------|
| Age [years], mean (SD) | 56.4 (16.9) |
| Gender, n (%) | |
| Male | 79 (60.8) |
| Female | 51 (39.2) |
| Ethnicity, n (%) | - (-,-) |
| White / Caucasian | 107 (82.3) |
| Black | 3 (2.3) |
| Native | 1 (0.8) |
| Asian | 4 (3.1) |
| | 9 (6.9) |
| Hispanic Other (Specific) | 5 (3.8) |
| Other (Specify) | 2 (2.0) |
| Country, n (%) | 52 (40.0) |
| Canada | 53 (40.8) |
| United States | 68 (52.3) |
| Spain | 9 (6.9) |
| Marital Status, n (%) | |
| Single | 20 (15.5) |
| Separated | 0 (0) |
| Divorced | 11 (8.5) |
| Common Law | 8 (6.2) |
| Married | 83 (64.3) |
| Widowed | 7 (5.4) |
| Highest Level of Education, n (%) | |
| Did Not Complete High School | 11 (8.6) |
| High School Diploma | 40 (31.3) |
| College / Trade Diploma | 31 (24.2) |
| Undergraduate Degree | 18 (14.1) |
| Masters Degree | 11 (8.6) |
| Doctorate Degree | 3 (2.3) |
| Professional Degree | 7 (5.5) |
| Annual Household Income, n (%) ¹ | |
| Less than \$20,000 | 12 (9.8) |
| \$20,000 to \$39,999 | 25 (20.3) |
| \$40,000 to \$59,999 | 21 (17.1) |
| \$60,000 to \$79,999 | 13 (10.6) |
| \$80,000 to \$99,999 | 15 (12.2) |
| \$100,000 + | 37 (30.1) |
| Cancer Type, n (%) | |
| Chondrosarcoma | 5 (3.9) |
| Ewing's Sarcoma | 1 (0.8) |
| Fibrosarcoma | 8 (6.3) |
| | 2(1.6) |
| Fibrous Histiocytoma | 4 (3.1) |
| Leiomyosarcoma | 16 (12.6) |
| Liposarcoma | 8 (6.3) |
| Osteosarcoma | 4 (3.1) |
| Rhabdomyosarcoma | 11 (8.7) |
| Synovial Sarcoma | 49 (38.6) |
| Other | ., (50.0) |
| Location of Tumor, n (%) | |
| Upper Extremity | 29 (22.5) |
| Lower Extremity | 95 (73.6) |
| Other | 5 (3.9) |
| Pelvis | 2 (1.6) |
| Trunk | 3 (2.3) |
| Cancer Treatment Modalities, n (%) | |
| Chemotherapy | 25 (21.9) |
| Radiation therapy | 78 (68.4) |
| | |

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| Physiotherapy | 4 (3.5) |
|--|------------------------------------|
| Other | 46 (40.4) |
| Travel Time to Sarcoma Clinic, n (%) | |
| Less Than 30 Minutes | 24 (18.6) |
| 30 – 59 Minutes | 38 (29.5) |
| 60 – 89 Minutes | 19 (14.7) |
| 90 – 119 Minutes | 23 (17.8) |
| 120 Minutes + | 25 (19.4) |
| Primary Mode of Transportation to Sarcoma Clinic, n (%) | |
| Public Transit | 8 (6.5) |
| Personal Vehicle | 93 (75.0) |
| Taxi | 3 (2.4) |
| Bicycle | 0 (0) |
| Foot | 1 (0.8) |
| Hospital Transportation | 2(1.6) |
| Relative's / Friend's Vehicle | 13 (10.5) |
| | 4 (3.2) |
| Other (Specify) | |
| Primary Caregiver, n (%) Self | 60 (46.9) |
| ~ | 53 (41.4) |
| Spouse / Partner | . , |
| Parent | 8 (6.3) |
| Sibling | 1 (0.8) |
| Child | 5 (3.9) 0 (0) |
| Grandchild | |
| Friend | 1 (0.8) 0 (0) |
| Other (Specify) | 0 (0) |
| Previous Participation in Research Study, n (%) | |
| No | 98 (75.4) |
| Yes | 32 (24.6) |
| 1 | 22 (71.0) |
| 2 | 8 (25.8) |
| 3 | 1 (3.2) |
| Over 3 | 0 (0) |
| orting household income in Furos (€) were converted to CAD | and placed in the respective group |

¹Participants reporting household income in Euros (€) were converted to CAD and placed in the respective group at the time of manuscript preparation. Reported household income values include both CAD and USD as currency was not collected from participants when responding to this question.

Table 2. Burden of Cancer Care

| Burden | N = 130 |
|--|------------|
| Financial Burdens | |
| Transportation & Travel Expenses, n (%) | |
| No | 16 (12.3) |
| Yes | 114 (87.7) |
| Accommodation & Meal Expenses, n (%) | |
| No | 30 (23.4) |
| Yes | 98 (76.6) |
| Family & Living Expenses, n (%) | |
| No | 27 (21.1) |
| Yes | 101 (78.9) |
| Caregiving Expenses, n (%) | |
| No | 56 (43.8) |
| Yes | 72 (56.3) |
| Personal Loss of Wages, n (%) | |
| Not Applicable | 40 (31.0) |
| No | 40 (31.0) |
| Yes | 49 (38.0) |
| Caregiver Loss of Wages, n (%) | |
| Not Applicable | 38 (29.9) |
| No | 62 (48.8) |
| Yes | 27 (21.3) |
| Logistical Burdens | · |
| Coordination of Frequent Medical Appointments, n (%) | |
| No | 69 (53.5) |
| Yes | 60 (46.5) |
| Completion and Submission of Paperwork, n (%) | |
| Not Applicable | 20 (15.4) |
| No | 76 (58.5) |
| Yes | 34 (26.2) |
| Submission of Medical Bills, n (%) | |
| Not Applicable | 28 (21.5) |
| No | 61 (46.9) |
| Yes | 41 (31.5) |
| Arrangement of Time Off Work, n (%) | |
| Not Applicable | 53 (40.8) |
| No | 36 (27.7) |
| Yes | 41 (31.5) |
| Arrangement of Childcare, n (%) | |
| Not Applicable | 88 (67.7) |
| No | 27 (20.8) |
| Yes | 15 (11.5) |

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Table 3. Reasons for Trial Participation

| Reason | N = 130 N (%) |
|---|------------------|
| I believe that the study offers the best treatment available. | 65 (61.9) |
| I want to contribute to scientific research. | 83 (79.0) |
| I believe that the quality of care I receive would be better as part of this study. | 42 (40.0) |
| I trust the doctor treating me. | 79 (75.2) |
| I believe the benefits of participating would outweigh any negative side-effects. | 53 (50.5) |
| I believe the results from the study could benefit other patients in the future. | 82 (78.1) |
| I believe that I would be monitored more closely as part of this study. | 42 (40.0) |
| I think my cancer will get worse unless I participate in this study. | 1 (1.0) |
| I had a positive experience in a previous research study. | 6 (5.7) |
| Other (Specify) | 0 (0) |

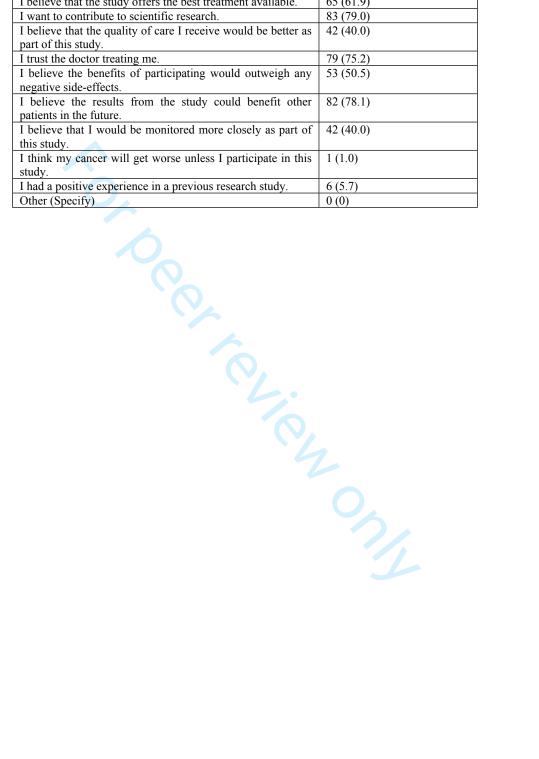


Table 4. Views on Cancer Research

| View | N = 130 N (%) |
|---|------------------|
| I am interested in participating in clinical research related to my | . (, °) |
| cancer. | |
| Strongly Agree | 63 (49.2) |
| Agree | 51 (39.8) |
| Neither Agree nor Disagree | 11 (8.6) |
| Disagree | 2 (1.6) |
| Strongly Disagree | 1 (0.8) |
| I have a good understanding of clinical research. | |
| Strongly Agree | 31 (24.2) |
| Agree | 57 (44.5) |
| Neither Agree nor Disagree | 31 (24.2) |
| Disagree | 3 (2.3) |
| Strongly Disagree | 6 (4.7) |
| Some clinical research determines by chance what treatment a | |
| patient receives (randomization). I am comfortable with being | |
| randomly assigned (randomized) to receive a treatment. | |
| Strongly Agree | 24 (18.6) |
| Agree | 45 (34.9) |
| Neither Agree nor Disagree | 35 (27.1) |
| Disagree | 15 (11.6) |
| Strongly Disagree | 10 (7.8) |
| Cancer research will help doctors better understand and treat | |
| cancer. | |
| Strongly Agree | 102 (78.5) |
| Agree | 26 (20.0) |
| Neither Agree nor Disagree | 2 (1.5) |
| Disagree | 0 (0) |
| Strongly Disagree | 0 (0) |
| The primary reason cancer research is done is to improve the | |
| treatment of future cancer patients. | |
| Strongly Agree | 86 (66.2) |
| Agree | 36 (27.7) |
| Neither Agree nor Disagree | 3 (2.3) |
| Disagree | 3 (2.3) |
| Strongly Disagree | 2 (1.5) |
| I will not directly benefit from participating in cancer research. | |
| Strongly Agree | |
| Agree | 26 (20.0) |
| Neither Agree nor Disagree | 42 (32.3) |
| Disagree | 31 (23.8) |
| Strongly Disagree | 28 (21.5) |
| | 3 (2.3) |
| Patients who participate in research studies should be told the | |
| results when the study is compete. | |
| Strongly Agree | 46 (35.4) |
| Agree | 62 (47.7) |
| Neither Agree nor Disagree | 20 (15.4) |
| Disagree | 1 (0.8) |
| Strongly Disagree | 1 (0.8) |
| I would agree to participate in the SAFETY trial | |
| if eligible (N=124) | |
| Yes | 106 (85.5) |
| No | 18 (14.5) |

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| | Complet | tion Da | ate | | |
|----|---------|---------|-----|----|--|
| | | 2 | 0 | | |
| DD | MM | | | ~~ | |

Surveillance AFter Extremity Tumor SurgerY (SAFETY) Protocol Study

Participant ID

PATIENT QUESTIONNAIRE

Thank you for agreeing to complete this questionnaire. Your responses will help orthopaedic oncology researchers better understand whether sarcoma patients are willing to participate in research evaluating different post-operative follow-up schedules. This questionnaire should take you approximately 15 minutes to complete. A participant ID number will be assigned to track completion of the questionnaires. A master list linking the ID number will be maintained during the data collection phase. Once all guestionnaires from each round have been received, the list will be destroyed and your responses will be anonymized.

<u>copyright, i</u>ncluding for uses related to text and data mining, Al training, and similar technologies Some of the questions may be uncomfortable for you to answer. However, we ask that you try your best in answering all of the questions. Your participation is important to us and those whom may benefit from this research.

Part A: DEMOGRAPHICS

Participant Initials

This section asks a few basic questions to let us know a little bit more about you.

| 1. V | Vhat is your age? | | | | |
|------|---------------------------|------|---------|-------------------|------------------|
| | years | | | | |
| 2. V | Vhat is your gender? | | | | |
| | Male | | | Female | |
| | Other (specify): | | | | |
| 3. V | Vhat is your race/ethnic | ity? | | | |
| | Caucasian | | | Native/Aboriginal | |
| | African/Caribbean | | | East Asian | |
| | Hispanic/Latino | | | South Asian | |
| | Middle Eastern | | | Other (specify): | |
| | Mixed (specify): | | | | |
| | | | | | |
| 4. V | Vhere do you live? | | | | |
| | Canada | | | Spain | |
| | Netherlands | | | USA | |
| | Other (specify): | | | | |
| 5. V | Vhat is your first langua | ge? | | | |
| | Arabic | | French | Korean | Spanish |
| | Cantonese | | German | Mandarin | Urdu |
| | Dutch | | Hindi | Portuguese | Vietnamese |
| | English | | Italian | Russian | Other (specify): |

| | Participant Init | ials | Participant ID | | | | |
|--------|--------------------------------|---------------------------------------|--------------------------------------|-----|--|------------|---|
| 6. V | Vhat is your m | arital status? | | | | | |
| | ∟ Single | Separated | ∟ I Divorced | Col | ∟ nmon Law | ∟ rried | ∐ Widowed |
| | Siligle | Separated | Divorced | COI | IIIIOII Law Wa | irrieu | widowed |
| 7. V | Vhat is your hi | • | | _ | | | |
| | | nplete High S | chool | | High School Diplor | | - - 9 |
| | College/Trac | - | | | Undergraduate Deg | gree | (a) |
| | Masters Deg Professiona | | | | Doctorate Degree Other (specify): | | 5 |
| Ш | i iolessiona | Degree | | Ш | other (specify). | | |
| 8. A | Are you curren | | | | | | e e |
| | - | | current occupation? | | | | |
| | II <i>no</i> , | please specify Retired | wny: | | Homemaker | | ğ |
| | | Student | | | Unemployed | | <u>.</u> |
| | | Doctor's Adv | ice/Disability | | Other (specify): | | 2 |
| | Please select A None Addiction | • | Diabetes (Type I) Diabetes (Type II) | | Inflammatory Bowel Disease Kidney Transplant | | Peripheral Vascular Disease Psychoses Pulmonary |
| | AIDS/HIV | | Heart Disease | | Liver Failure Neurological | | Circulation Disorder |
| Ш | Anemia | | Hepatitis | Ш | Disorders | | Renal Failure Rheumatoid |
| | Cardiac Arrhy | <u>—</u> | Hypertension | | Obesity | | Arthritis |
| | Chronic Pulm Disease | nonary | Hyperthyroidism | | Osteoarthritis | | Systemic Lupus Erythematosus Other (specify): |
| | Depression | | Hypothyroidism | | Osteoporosis | | Other (specify): |
| 10. Do | o you smoke? | ☐ Former | ☐ Current | | | | |
| | Never | Smoker | Smoker | | | | |
| 11. Do | o you routinely | | | | | | |
| | Never | Former Use | er Current User | | | | |
| 12. Ho | | nol do you drir Drinks/Week | nk on a weekly basis? | | | | |

If you live in **Canada** or the **USA**, please proceed to **Page 3**. If you live in the **Netherlands** or **Spain**, please proceed to **Page 4**.

| Pl | Participa LEASE | | | THIS | Participant ID PAGE IF | YOU | LIVE IN CANADA O | R THE USA. | BMJ Open: first published |
|------------|-------------------------------------|-------------------------|---|---|--|----------------------------------|---|--------------------|---|
| | Less th | an \$2 | 20,000 | | before taxes ^a | | \$60,000 to \$79,999 \$80,000 to \$99,999 \$100,000+ 14B if you live in the USA. | | تة |
| (A) F h | or Cana ealth ins No Yes → | dian urand If yes | patients, do ce plan? s, please indic Employer-F Personally | you have cate what ty Provided In Purchased | any <i>additiona</i> pe of additiona surance Insurance | I medi | \$100,000 to \$99,999 \$100,000+ 14B if you live in the USA. ical insurance coverage outside al insurance coverage: Military/Veteran Other (specify): coverage? | de of your provinc | 10.1136/bmjopen-2020-042742 on 26 F Protected by copyright, including for |
| (B) F | | | | cate what ty Provided In Purchased | pe of additiona surance | I medi | cal insurance coverage: Medicaid Military/Veteran Other (specify): | | 2021. Downloaded from http prement Superieur (ABES) . lated to text and data mining |
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| ersion 1 | .0 | | For peer i | eview only - | http://bmjopen | 3 of 12 .bmj.co | om/site/about/guidelines.xhtml | 16 March 2 | 2017 |

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| | Participant Initials Participant ID | |
|-------|--|--|
| PL | LEASE COMPLETE THIS PAGE IF YOU SPAIN. | |
| 13. W | Vhat is your yearly household income before taxes? Less than €14,500 □ €14,500 to €28,999 □ €29,000 to €43,499 □ | €43,500 to €57,999 €58,000 to €71,999 €72,000+ |
| 14. D | No Yes If yes, please indicate what type of additional med | |
| | ☐ Employer-Provided Insurance ☐ | Military/Veteran |
| | Personally-Purchased Insurance Please proceed to Part | Other (specify): B on Page 5. |
| | | |

| | Participant Initi | als | Participant ID | | | | |
|--------|-----------------------------------|-----------------------------|--------------------|---------|------------------|---|----------|
| This s | | | | | | been diagnosed with more n clinic for today. | than one |
| 15. W | hat type of car | ncer do you have? | • | | | | |
| | Chondrosard | coma | | | Ewing's sarce | oma | |
| | Fibrosarcom | ıa | | | Fibrous histic | ocytoma | ; |
| | Giant cell tur | mor of bone | | | Leiomyosarc | oma | |
| | Liposarcoma | a | | | Non-osteoge | nic sarcoma of bone | |
| | Osteosarcon | na | | | Rhabdomyos | arcoma | |
| | Synovial sar | coma | | | Other (specify | y): | _ |
| | Not Sure | | | | | | |
| 16 \\ | boro io vour o | nnor located? | | | | | |
| 16. vv | here is your ca | ancer localed? | | | Leg | | |
| | Not Sure | | | | Other (specify | v)· | |
| | itot Guio | | | | Canon (opcon) | ,, | |
| 17. W | hen were you | diagnosed with ca | ancer? | | YYYY | | |
| 18. Ho | ow long have y | ou been a cancer | patient at the cer | nter w | here you are for | your current treatment? | |
| | ess Than 2 Weeks | 2 - 4 Weeks | 1 - 6 Months | | Over Months | | |
| | ow has your ca lease select Al | ancer been treated | d so far? | | | | g |
| \Box | Chemothera | • • • | | | Radiation the | rapy | |
| | Physiothera | ру | | | Other (specify | | <u> </u> |
| 20. Ho | ow many times | s have you seen y | our orthopaedic o | ncolo | gist (cancer sur | geon)? | |
| F | irst Visit | Once Before | 2 - 3 Times | Ov | er 3 Times | | |
| 04 LL | ow long doos : | t tunioally tales was | , got from home to | s tha ! | popital for a se | noor appointment? | |
| ∠1. ⊞(| ow long does it | г <i>турісан</i> у таке уог | ı germom nome to | ıne i | | ncer appointment? | |
| Le | ess Than | 30 - 59 | 1 - 1.5 | | 1.5 - 2 | Over 2 | |
| |) Minutes | Minutes | Hours | | Hours | Hours | |
| | | | | | | | |

| Participant Initials | | Participant ID — | | |
|--|--|---|----------------------------------|--|
| 22. How do you typical | ly travel to the | hospital for a cancer | _ ` ` | |
| ☐ Public Transit | | L | ☐ Personal Veh | icle |
| ∐ Taxi | | L | ☐ Bicycle | |
| ☐ Foot ☐ Relative/Friend | 'a Vahiala | L | ☐ Hospital Tran ☐ Other (cnecify | |
| Relative/Frieliu | 5 Verlicie | L | Other (specify | /)· |
| 23. Who is your primary A primary caregiver is | y caregiver? s the person wh | o assumes the most re | sponsibility in caring | for your health and wellbeing. |
| Myself | | | Spouse/Partn | er ඉ |
| Parent | | | Sibling | оруг |
| ☐ Child | | L | Grandchild | ig ht |
| | | | Other (specify | /): <u>s</u> i |
| Part C: IMPORTANCE This section asks question opinion question, please | E OF CANCER ons about your p rate your level a | RESEARCH previous participation in greement with each sta | research and your o | Protected by copyright, including for your health and wellbeing. er ppinion on cancer research. For each opinion on cancer research. |
| 24. I am interested in p | articipating in o | clinical research relat | ed to my cancer. | es relai |
| Strongly Agree | Agree | Neither Agree Nor Disagree | Disagree | Strongly Bisagree |
| 25. Have you previousl | y participated i | in any other research | studies? | ext and da |
| Yes → If yes, ho | ow many other re | esearch studies have yo | ou previously particip | pated in? |
| [| | | | |
| | 1 | 2 | 3 | Over 3 |
| 26. How many different treatment? | nt research st | udies have been di | scussed with you | over the course of your cancer |
| | | | | |
| 0 | 1 | 2 | 3 | Over 3 |
| 27. I have a good unde | erstanding of cl | inical research. | | Over 3 Strongly Disagree |
| □ • | | Neither Agree | □ D : | Strongly |
| Strongly Agree | Agree | Nor Disagree | Disagree | Disagree g |
| | | es by chance what the assigned (randomized | | t receives (randomization). I am |
| Strongly Agree | Agree | Neither Agree Nor Disagree | Disagree | Strongly Disagree |

| Participa | | Participant II | | | | BMJ Open: first published as |
|---|---|---|--|-----------------------------|--------------------------------|--|
| 29. Cancer rese | earch will help doctor | 's better understai | nd and treat cance | r. | | rst p |
| Strongly Agre | ee Agree | Neither Agree Nor Disagree | | Strongly Disagree | | ublishec |
| 30. The primary | reason cancer rese | arch is done is to | improve the treatm | ent of <i>future</i> cancer | patients. | l as 1 |
| | | | | | • | 0.11: Prot |
| Strongly Agr | ee Agree | Neither Agree Nor Disagree | Illeanrad | Strongly Disagree | | 36/bmjo ected b |
| 31. I will not dire | ectly benefit from par | rticipating in cance | er research. | | | pen-202 v copyri |
| Strongly Agr | ee Agree | Neither Agree Nor Disagree | Illeanrad | Strongly Disagree | | 10.1136/bmjopen-2020-042742 Protected by copyright, inclu |
| 32. Patients wh | o participate in resea | arch studies shoul | d be told the result | s when the study is | complete. | 0.1136/bmjopen-2020-042742 on 26 Fe Protected by copyright, including for |
| Strongly Agr | ee Agree | Neither Agree Nor Disagree | Illeanrad | Strongly Disagree | | ebruar; Ense r uses r |
| This section asks they are a finance | CIAL BURDEN OF (equestions about some ial burden to you. A fine tration and travel explose of transportation in fares. | of the costs you manancial burden is an | ue to your cancer of | care naid by you/you | ır family? | ownlo Supe text a |
| ☐ No | | | | | | ABE a mi |
| ☐ Yes → I | f yes, please indicate I | now much of a finar | cial burden these co | sts are to you: | , | ning |
| | | | | | | Alt |
| | Unmanageable Burden | Significant Burden | Somewhat of a Burden | Slight Burden | No Burden | j <mark>open</mark> rainin |
| | nodation and meal e | | | | our family? at restaurants. | //bmjopen.bmj.com/ on June 10, 2025 Al training, and similar technologies |
| _ | f yes, please indicate I | now much of a finar | icial burden these co | sts are to you: | | on J ilar t |
| | | | | | | une ' |
| | Unmanageable Burden | Significant Burden | Somewhat of a Burden | Slight Burden | No Burden | 10, 2025 ologies. |
| Version 1.0 | | Pai | ge 7 ,of 12 | | 16 March 2017 | June 10, 2025 at Agence Bibliographique de l technologies. |
| | For peer reviev | v only - nttp://bmjop | ge 7, of 12 en.bmj.com/site/abou | t/guideiines.xhtml | | é |

| 35. Are family and living expenses incurred due to your cancer paid by you/your family? Some examples of family and living expenses include costs related to running your household, childca housekeeping. No Yes → If yes, please indicate how much of a financial burden these costs are to you: Unmanageable Significant Somewhat of a Burden Slight Burden No Burden 36. Are caregiving expenses incurred due to your cancer care paid by you/your family? Some examples of caregiving expenses include costs from hiring a person to prepare meals or drive appointments, extended nursing care, homecare, and personal support workers. No | |
|--|--|
| Unmanageable Burden Significant Burden Slight Burden No Burden 36. Are caregiving expenses incurred due to your cancer care paid by you/your family? Some examples of caregiving expenses include costs from hiring a person to prepare meals or drive appointments, extended nursing care, homecare, and personal support workers. No | cted by |
| Burden Burden Burden Burden 36. Are caregiving expenses incurred due to your cancer care paid by you/your family? Some examples of caregiving expenses include costs from hiring a person to prepare meals or drive appointments, extended nursing care, homecare, and personal support workers. No No | en Protected by cop |
| Burden Burden Burden Burden 36. Are caregiving expenses incurred due to your cancer care paid by you/your family? Some examples of caregiving expenses include costs from hiring a person to prepare meals or drive appointments, extended nursing care, homecare, and personal support workers. No No | en otected by cop |
| Some examples of caregiving expenses include costs from hiring a person to prepare meals or drive appointments, extended nursing care, homecare, and personal support workers. No | you toop |
| West Notes to the second of th | yright |
| Yes If yes, please indicate how much of a financial burden these costs are to you: | t, inc |
| | ludi |
| Unmanageable Significant Somewhat of a Burden Burden Burden No Burd | en ng for a |
| 37. Have you experienced a loss of your own wages due to your cancer care? Not Applicable → I was not employed prior to my cancer diagnosis. No Yes → If yes, please indicate how much of a financial burden this loss of income is to you: | nseignement S es related to te |
| | supe extai |
| Unmanageable Significant Somewhat of a Slight Burden No Burd Burden Burden Burden | rieur (A nd data en |
| | ⊸ m |
| 38. Has your primary caregiver experienced a loss of wages due to your cancer care? ■ Not Applicable → My primary caregiver was not employed prior to my cancer diagnosis. | nining, |
| | ≥ |
| Not Applicable → My primary caregiver was not employed prior to my cancer diagnosis. | ≥ |
| Not Applicable → My primary caregiver was not employed prior to my cancer diagnosis. No | ≥ |
| Not Applicable → My primary caregiver was not employed prior to my cancer diagnosis. No | ≥ |
| Not Applicable → My primary caregiver was not employed prior to my cancer diagnosis. No Yes → If yes, please indicate how much of a financial burden this loss of income is to your primary caregiver. Unmanageable Significant Somewhat of a Burden Slight Burden No Burden Part E: LOGISTICAL BURDEN OF CANCER CARE This section asks questions about some of the tasks you may have to manage as a result of your cancer treatment. | Al training, and similar tec |
| Not Applicable → My primary caregiver was not employed prior to my cancer diagnosis. No Yes → If yes, please indicate how much of a financial burden this loss of income is to your primary caregiver. Unmanageable Significant Somewhat of a Burden Slight Burden No Burden No Burden Surden Somewhat of a Burden Slight Burden No Burden Somewhat Slight Burden No Burden Slight Burden No Burden Somewhat Slight Burden No Burden Slight Sl | Al training, and similar tec |
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Sarcoma patient willingness to participate in cancer surveillance research: a cross-sectional patient survey

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ABSTRACT

Objectives: To determine the proportion of extremity sarcoma patients who would be willing to participate in a clinical trial in which they would be randomized to one of four different post-operative sarcoma surveillance regimens. Additionally, we assessed patients' perspectives on the burden of cancer care, factors that influence comfort with randomization, and the importance of cancer research.

Design: Prospective, cross-sectional patient survey.

Setting: Outpatient sarcoma clinics in Canada, the United States and Spain between May 2017 – April 2020. Survey data was entered into a study-specific database.

Participants: Extremity sarcoma patients who had completed definitive treatment from seven clinics across Canada, the United States and Spain.

Main Outcome Measures: The proportion of extremity sarcoma patients who would be willing to participate in a randomized controlled trial (RCT) that evaluates varying post-operative cancer surveillance regimens.

Results: One hundred and thirty complete surveys were obtained. Respondents reported a wide range of burdens related to clinical care and surveillance. The majority of patients (85.5%) responded that they would agree to participate in a cancer surveillance RCT if eligible. The most common reason to participate was that they wanted to help future patients. Those that would decline to participate most commonly reported that participating in research would be too much of a burden for them at a time when they are already feeling overwhelmed. However, most patients agreed that cancer research will help doctors better understand and treat cancer.

Conclusions: These results demonstrate that most participants would be willing to participate in an RCT that evaluates varying post-operative cancer surveillance regimens. Participants' motivation for trial participation included altruistic reasons to help future patients and deterrents to trial participation included the overwhelming burden of a cancer diagnosis. These results will help inform the development of patient-centered RCT protocols in sarcoma surveillance research.

Level of Evidence: V

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Strengths and limitations of this study

- The primary objective of this study was to investigate the proportion of extremity sarcoma patients who would be willing to participate in a clinical trial in which they would be randomized to one of four different post-operative cancer surveillance regimens.
- The results of this study have been used to directly inform the definitive phase of the Surveillance AFter Extremity Tumor SurgerY (SAFETY) trial.
- Patient engagement in the preliminary trial development is expected to improve the trial's relevance, increase transparency and, ultimately, accelerate the adoption of findings into practice.
- Patients who agreed to participate in the survey study may be more likely to participate in research in general, thus possibly introducing selection bias. This may have resulted in an overestimation of the acceptance rate of the SAFETY study and interest in clinical research. However, our response rate of 92% may have somewhat mitigated these concerns.



Sarcomas are a rare and heterogenous group of cancers with distinct biology that represent less than one percent of all malignancies^{1–6}. Following treatment for a sarcoma, patients remain at risk for the development of local and systemic disease recurrence, which necessitates careful post-operative surveillance. Almost 50% of all sarcoma patients will develop a local or distant recurrence; however, the risk of recurrence is greatest in the first few years, with 68% occurring by two years and 90% by five years^{7–9}. Metastasis to the lung is the most frequent single location of disease recurrence in sarcoma patients, occurring in approximately one half of all patients^{9–12}. Earlier detection of less advanced and resectable disease relapse may prolong patient survival; however, once advanced metastases are detected, the median length of survival is 12 to 15 months⁹.

As such, routine follow-up following the completion of sarcoma treatment is standard practice, and generally entails regular visits to sarcoma outpatient clinics in the first five to ten years after surgery. These visits typically include a clinical history, a physical examination and imaging of the lungs. Regular, intensive surveillance is more likely to identify recurrent disease earlier than would less intensive surveillance. This may provide reassurance to patients and clinicians as if the interval screening is negative, the patient is considered at that time to be disease-free.

However, the adverse effects of intensive surveillance practices on patients are also noteworthy. Intensive surveillance can threaten the financial security of patients, due in part to the direct costs, including travel, accommodation, personal care and homemaking, and indirect costs, including lost wages for patients and their caregivers, incurred as a result of follow-up appointments¹³. As a result, patients' health and quality of life can be dramatically impacted should they decide to forego further treatment or alter their lifestyles in order to alleviate financial difficulties^{13–15}. Furthermore, intensive surveillance investigations can also induce anxiety, and earlier knowledge of disease recurrence may adversely impact patients' psychosocial wellbeing for those whose mortality risk cannot be significantly reduced by further medical interventions¹⁶. In fact, the first recommendation put forward by *Choosing Wisely Canada* for oncology is not to "order tests to detect recurrent cancer in asymptomatic patients if there is not a realistic expectation that early detection of recurrence can improve survival or quality of life".

A randomized controlled trial (RCT) would be the ideal approach to determine the optimal postoperative surveillance strategy that balances potential gains in survival, costs and quality of life.

Given the rarity of sarcoma, possible patient anxiety related to both less- and more-intensive
sarcoma surveillance and the fact that clinical trial recruitment is often slower than anticipated,
such a RCT will require extensive international collaboration and patient willingness to be
randomly allocated to varying surveillance regimens. Patient perceptions of surveillance and of
participation in a surveillance RCT are required in order to develop a study protocol that is patientcentered, compelling and feasible, and is capable of answering this high priority clinical question
in a reasonable timeframe^{18,19}. In this study, we conducted a patient survey to investigate the
proportion of extremity sarcoma patients that would be willing to participate in a clinical trial in
which they would be randomized to one of four different post-operative sarcoma surveillance
regimens. We also assessed the burden of cancer care on patients, the factors that influence patient
comfort with being randomized to different surveillance protocols, and we explored patient views
on the importance of cancer research.

METHODS

We conducted a cross-sectional multi-centre survey between May 2017 and April 2020 at seven sarcoma outpatient clinics in Canada (three sites), the United States (three sites) and Spain (one site). The Methods Centre received approval from the Hamilton Integrated Research Ethics Board (HiREB) (Protocol No. 2954). Approval from each of the local ethics committees was obtained in writing prior to the local commencement of the study.

Participants

Clinical Sites

Clinical sites within our international orthopaedic oncology research network were carefully screened for the following criteria: 1) sufficiently high sarcoma volume defined as greater than or equal to 20 participants per year; 2) adequate research personnel and infrastructure to manage the study; and 3) an interest in participating in the Surveillance AFter Extremity Tumor surgerY (SAFETY) trial. Clinical sites that met the eligibility criteria were invited to participate in this cross-sectional study.

Patients

In order to be eligible for participation, patients must have: 1) been at least 18 years of age; 2) been able to read, understand and write in English, French or Spanish; 3) have recently completed treatment of an extremity sarcoma; and 4) provided consent to participate.

Questionnaire Objectives

Given that patient willingness to participate in cancer surveillance research is the ultimate determinant of overall study feasibility, the primary objective of this questionnaire was to determine whether extremity sarcoma patients would be willing to participate in the SAFETY trial. The SAFETY trial, initiated in early 2020, is a 2X2 factorial design RCT in which sarcoma patients are randomized to one of four different surveillance regiments. The primary objective of the SAFETY trial is to determine the effect of surveillance intensity on long-term survival in the soft-tissue sarcoma population. The current cross-sectional survey served as background work for the trial's development.

Secondary objectives of this cross-sectional patient survey included: 1) assessment of the burden of cancer care on patients; 2) assessment of factors that influence patient comfort with being randomized to different surveillance protocols; and 3) the exploration of patient views on the importance of cancer research.

Questionnaire Development

Item Generation

We developed a unique patient questionnaire for the purposes of this study. The development of this questionnaire was informed by a review of the current literature on patient surveillance and in consultation with experts in orthopaedic oncology, research methodology and patient recruitment. We utilized a 'sampling-to-redundancy' approach in which we solicited feedback from new orthopaedic oncologists and research methodologists until no new items for the questionnaire emerged.

Pretesting and Validity Assessments

The questionnaire was reviewed by nine additional experts, who were either orthopaedic oncologists or health research methodologists. These experts evaluated whether the questionnaire as a whole appeared to adequately address the question of whether extremity sarcoma patients would participate in cancer surveillance research (face validity) and whether the individual questions adequately addressed the objectives of the current study (content validity). These nine

experts also assessed the questionnaire's comprehensiveness and flow, as well as identified any redundant, irrelevant or poorly worded questions.

Survey Description

The final survey was comprised of 58 questions using Likert scales, multiple choice, and brief open-ended questions. The following sections were included: (A) **Demographics**, including medical history and income, (B) **Cancer History**, including the number of treatment visits thus far required, (C) **Perceptions of Cancer Research**, (D) **Financial Burden of Cancer Care**, (E) **Logistical Burden of Cancer Care**, and (F) **The SAFETY Trial**, including perceptions of cancer surveillance, the trial design and willingness to participate in such a trial, and reasons for accepting or declining to participate. The survey is provided as **Appendix 1**.

All questions were straightforward and utilized clear and layman terminology to enhance the validity of the results. The survey length was kept to a minimum in an effort to maximize the response rate and to limit barriers that could have affected its proper completion.

Sample Size

Convenience sampling of consecutive patients was utilized at the seven participating sites. One hundred thirty patients completed the patient survey, which represents a robust sample in the study of rare diseases²¹.

Survey Administration and Data Collection

Initially, we approached all extremity sarcoma patients in person that had consented for sarcoma surgery. However, after consulting with the SAFETY trial's Steering Committee members on the study's protocol in May 2018, we determined that patients would be approached, consented, and randomized into the SAFETY trial after definitive treatment for their extremity sarcoma, as it was deemed a less stressful time for patients to make an informed decision, as well as a time point closer to the initiation of surveillance. After this decision was made, we began approaching all recent post-operative extremity sarcoma patients for participation in this survey study, either at a post-operative clinical appointment or via telephone. After obtaining informed consent, the site Study Coordinator provided each participant with a paper copy of the questionnaire to complete in a private location. Participants were allowed to leave a question blank if they found it uncomfortable to answer. Upon completion, the participant returned the questionnaire to the site Study Coordinator who verified that all questions had been answered. Completed questionnaires

were then entered into a study-specific database using the REDCapTM electronic data capture software system.

Statistical Analysis

Descriptive analyses, including frequency counts and percentages, were calculated for all collected data. Continuous data are presented as means and standard deviations.

Role of the Funding Source

The funding source had no role in the design or conduct of the study; the collection, management, analysis or interpretation of the data; or the preparation, review or approval of the manuscript. None of the authors have been paid to write this article. The study team had full access to all of the study data and takes responsibility for the integrity of the data and the accuracy of the data.

Patient and Public Involvement

Although this study evaluates the patient perspectives on participating in clinical trials and cancer research, patients were not involved in the design, conduct or reporting or dissemination of this research. However, the results of this study will help inform the development of patient-centered clinical trial protocols in sarcoma surveillance research.

RESULTS

Characteristics of Respondents

A total of 142 patients were approached to complete the survey and 130 agreed (response rate 92%). To the best of our knowledge, no patients were missed during the recruitment period. Participant demographic and cancer history data are shown in **Table 1**. The mean participant age was 56.4 years (SD 16.9 years) and 60.8% of participants were male. The majority of patient respondents were white (82.3%) and country of residence was reported as Canada in 40.8%, the United States in 52.3% and Spain in 6.9%. Most respondents were married or in a common law relationship (70.5%). There was a broad range of educational levels reported with a high school diploma as the most common response (31.3%), and a wide range of household incomes were reported. The most common anatomic location for the sarcoma was the lower extremity (66.7%), and participants reported receiving multidisciplinary treatment including chemotherapy (21.9%) and radiotherapy (68.4%). Travel times to the clinic ranged evenly across the spectrum from less than 30 minutes, to over 2 hours. Most participants reported travelling to medical appointments by

believed they would not agree to participate reported that they would decline for the following reasons: (1) "I do not believe that I can currently cope with the additional requirements of a research study" (8, respondents, 44.4%), (2) "I have concerns about possibly being followed less intensively in this study" (4 respondents, 22.2%), (3) "I have concerns about additional radiation exposures from CT scans" (4 respondents, 22.2%), and (4) "I believe that the quality of care I receive would be inferior to what I would receive if I did not participate" (3 respondents, 16.7%). Other less common reasons to decline the study included "I do not believe that the study offers the best treatment available", "My family is not keen for me to participate", as well as travel and religious reasons. One respondent reported a negative experience with a previous trial.

DISCUSSION

Summary of Findings

This study explored the perceptions of international extremity sarcoma patients on cancer surveillance. We found that patients endure significant financial and logistical burdens associated with sarcoma care and follow-up. In general, patients are very interested in participating in clinical research, and specifically in cancer surveillance research. The reasons for participating in research include the desire to help future patients and the perception that their care would be improved in the context of a clinical trial. However, some participants expressed a lingering concern with leaving their care and/or surveillance to chance (randomization) and several indicated that they believe that they would not participate in research due to feeling overwhelmed with their cancer diagnosis and treatment. Overall, the results of this study will help inform the SAFETY trial and guide approaches to eligible patients when obtaining consent.

Strengths and Limitations

This study has several strengths. First, we used a rigorous process for the development of the patient questionnaire and extensive piloting of the survey. This stepwise process created a questionnaire that was acceptable for patients and sufficiently clear and comprehensive to provide a robust dataset. Second, we surveyed patients across Canada, the United States and Spain.

Although this required translation of English documents into French and Spanish, it provided a more global picture of patient perceptions. The SAFETY trial is an international endeavor, and therefore international participation in the background survey was critical. Finally, this survey study represents an important step in engaging patients in randomized controlled trial development and inception, thus improving the patient-centered nature of cancer research.

Our study also had some limitations to consider. First, there may have been selection bias in that those who agreed to participate in the survey study are also more likely to participate in research in general. This would overestimate the acceptance rate of the SAFETY study and interest in clinical research. However, our response rate was 92%, somewhat mitigating these concerns. Second, the survey was not a validated survey; however, it allowed us to determine the proportion of participants who would theoretically consent to participating specifically in the SAFETY trial, as well as investigate patients' views on the burden of cancer care and on cancer research in greater detail than would have been possible with standardized questionnaires. Third, the demographics of the respondents were not diverse with respect to race (82.3% white) and continent of residence (93.1% from North America). The incidence data collected in the Surveillance, Epidemiology and End Results (SEER) database of the National Cancer Institute as the SEER database demonstrates similar rates of sarcomas between white and black populations^{22–25}. This is also inconsistent with the overall North American demographic data, as black individuals comprise approximately 13% of the North American population^{26,27}. These demographic discrepancies somewhat limit the external validity of the findings with respect to Europe and other international sites. And while it is not uncommon for non-white racial/ethnic groups to be underrepresented in cancer clinical trials, the race demographics of this survey have highlighted an important gap to address in our recruitment strategy for the SAFETY trial^{28–30}. Fourth, while the survey addressed indirect costs of sarcoma surveillance (such as the cost of travel or missed work to attend a clinic visit) it did not address the direct costs of surveillance (such as the cost to patients of different thoracic imaging techniques or additional imaging and clinic visits). However, post-operative sarcoma surveillance is considered standard of care despite being highly varied among orthopaedic oncologists with respect to thoracic imaging and frequency^{31–33}. Therefore, direct costs should not apply to most patients as a wide spectrum of surveillance care regimens are within the range of standard practice

and should be covered by the patients' federal, provincial/state, or private health insurance³⁴. Nevertheless, this cost data would likely prove valuable when considering trial participation of patients without private health insurance in countries without socialized health care such as the USA. Finally, the survey did not evaluate the optimal timing and method to approach patients to participate in the SAFETY trial.

Relevance to previous research

The exploration of patient perceptions of sarcoma surveillance in the context of a randomized surveillance trial has not, to our knowledge, previously been reported. However, as far back as 1979, researchers interviewed sarcoma patients to determine reasons for acceptance of randomization in treatment related trial clinical trials³⁵. The authors of this study concluded that patient acceptance of participation in treatment related clinical trials was associated with treatment factors such as burden of care and drug toxicities. Within the field of orthopaedic surgery, Creel et al surveyed patients with meniscal tears and determined willingness to participate in a trial in which they would be randomized to operative vs. non-operative treatment³⁶. The authors found that lack of strong treatment preferences and male gender were significantly associated with willingness to participate in such a trial. Only 46% of patients reported that they would be definitely willing or probably willing to participate.

A large survey study of 1,227 Swiss patients in which 4 different clinical trial vignettes were described found that all studies were not equally acceptable to patients. A higher willingness to participate was found when a new drug was considered safe, no extra logistical burden of care was required, results were openly available to the public, and the project was approved by a research ethics committee. In contrast, use of placebo controls, and random allocation to study arms were associated with a lower likelihood of participation³⁷. Similarly, Halpern et al found that in hypertensive patients, inconvenience, fear of known side effects, and the possibility of receiving placebo were the most common concerns for patients in clinical trials³⁸. Similar to the orthopaedic trial outlined above, only 47% of patients would be willing to participate in a placebo-controlled trial.

Implications

Conclusions

The results of this patient survey demonstrate that the majority of participants would be willing to participate in a randomized controlled trial that evaluates different post-operative sarcoma surveillance regimens. Participants' motivations for trial participation included trust in the healthcare system and altruistic reasons to help future patients. Those that would decline the study for the most part would do so because of the overwhelming burden of a cancer diagnosis. These results will help inform the development of patient-centered clinical trial protocols in cancer surveillance research and specifically the implementation of the SAFETY trial.

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Contributors

PS and MG designed this study and are the principal authors of this manuscript. VG and DG contributed significantly to data collection and data analysis. DW, RT, MI, SM, BM, JH, YCD,

KG, RLR, KJ, and RV contributed to the conception of the study and acquisition of data. All authors reviewed and approved the manuscript.

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Competing Interests

Each author certifies that he or she, or a member of his or her immediate family, has no funding or commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

Ethics Approval

Each author certifies that his or her institution approved or waived approval (McGill University Health Centre Research Ethics Board) for the human protocol for this investigation and that all investigations were conducted with ethical principles of research.

Data Availability Statement

The datasets generated during this study are not publicly available, but are available from the corresponding author on reasonable request.

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Table 1. Participant Demographics

| ticipant Demographics | |
|---|-----------------------|
| Characteristic | N = 130 |
| Age [years], mean (SD) | 56.4 (16.9) |
| Gender, n (%) | |
| Male | 79 (60.8) |
| Female | 51 (39.2) |
| Ethnicity, n (%) | |
| White / Caucasian | 107 (82.3) |
| Black | 3 (2.3) |
| Native | 1 (0.8) |
| Asian | 4 (3.1) |
| Hispanic | 9 (6.9) |
| Other (Specify) | 5 (3.8) |
| Country, n (%) | |
| Canada | 53 (40.8) |
| United States | 68 (52.3) |
| | 9 (6.9) |
| Spain Marital Status n (9/) | 7 (0.5) |
| Marital Status, n (%) Single | 20 (15.5) |
| | 0 (0) |
| Separated | 11 (8.5) |
| Divorced | 8 (6.2) |
| Common Law | 83 (64.3) |
| Married | 7 (5.4) |
| Widowed | 7 (3.4) |
| Highest Level of Education, n (%) | 11 (0.0) |
| Did Not Complete High School | 11 (8.6) |
| High School Diploma | 40 (31.3) |
| College / Trade Diploma | 31 (24.2) |
| Undergraduate Degree | 18 (14.1) 11 (8.6) |
| Masters Degree | 3 (2.3) |
| Doctorate Degree | 7 (5.5) |
| Professional Degree | 7 (3.3) |
| Annual Household Income, n (%) ¹ | 12 (0.0) |
| Less than \$20,000 | 12 (9.8) |
| \$20,000 to \$39,999 | 25 (20.3) |
| \$40,000 to \$59,999 | 21 (17.1) |
| \$60,000 to \$79,999 | 13 (10.6) |
| \$80,000 to \$99,999 | 15 (12.2) |
| \$100,000 + | 37 (30.1) |
| Cancer Type, n (%) | 5 (2.0) |
| Chondrosarcoma | 5 (3.9) |
| Ewing's Sarcoma | 1 (0.8) |
| Fibrosarcoma | 8 (6.3) |
| Fibrous Histiocytoma | 2 (1.6) |
| Leiomyosarcoma | 4 (3.1) |
| Liposarcoma | 16 (12.6) |
| Osteosarcoma | 8 (6.3) |
| Rhabdomyosarcoma | 4 (3.1) 11 (8.7) |
| Synovial Sarcoma | 49 (38.6) |
| Other | 7/ (30.0) |
| Location of Tumor, n (%) | |
| Upper Extremity | 29 (22.5) |
| Lower Extremity | 95 (73.6) |
| Other | 5 (3.9) |
| Pelvis | 2 (1.6) |
| Trunk | 3 (2.3) |
| Cancer Treatment Modalities, n (%) | |
| Chemotherapy | 25 (21.9) |
| Radiation therapy | 78 (68.4) |
| | |

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| Physiotherapy | 4 (3.5) |
|---|-----------------------------------|
| Other | 46 (40.4) |
| Travel Time to Sarcoma Clinic, n (%) | |
| Less Than 30 Minutes | 24 (18.6) |
| 30 – 59 Minutes | 38 (29.5) |
| 60 – 89 Minutes | 19 (14.7) |
| 90 – 119 Minutes | 23 (17.8) |
| 120 Minutes + | 25 (19.4) |
| Primary Mode of Transportation to Sarcoma Clinic, n (%) | |
| Public Transit | 8 (6.5) |
| Personal Vehicle | 93 (75.0) |
| Taxi | 3 (2.4) |
| Bicycle | 0 (0) |
| Foot | 1 (0.8) |
| Hospital Transportation | 2 (1.6) |
| Relative's / Friend's Vehicle | 13 (10.5) |
| Other (Specify) | 4 (3.2) |
| Primary Caregiver, n (%) | |
| Self | 60 (46.9) |
| Spouse / Partner | 53 (41.4) |
| Parent | 8 (6.3) |
| Sibling | 1 (0.8) |
| Child | 5 (3.9) |
| Grandchild | 0 (0) |
| Friend | 1 (0.8) |
| Other (Specify) | 0 (0) |
| Previous Participation in Research Study, n (%) | |
| No | 98 (75.4) |
| Yes | 32 (24.6) |
| | 22 (71.0) |
| 2 | 8 (25.8) |
| 3 | 1 (3.2) |
| Over 3 | 0 (0) |
| porting household income in Euros (€) were converted to CAD | and placed in the respective grou |

¹Participants reporting household income in Euros (€) were converted to CAD and placed in the respective group at the time of manuscript preparation. Reported household income values include both CAD and USD as currency was not collected from participants when responding to this question.

Table 2. Burden of Cancer Care

| Burden | N = 130 |
|--|------------|
| Financial Burdens | |
| Transportation & Travel Expenses, n (%) | |
| No | 16 (12.3) |
| Yes | 114 (87.7) |
| Accommodation & Meal Expenses, n (%) | |
| No | 30 (23.4) |
| Yes | 98 (76.6) |
| Family & Living Expenses, n (%) | |
| No | 27 (21.1) |
| Yes | 101 (78.9) |
| Caregiving Expenses, n (%) | |
| No No | 56 (43.8) |
| Yes | 72 (56.3) |
| Personal Loss of Wages, n (%) | ` ' |
| Not Applicable | 40 (31.0) |
| No | 40 (31.0) |
| Yes | 49 (38.0) |
| Caregiver Loss of Wages, n (%) | , |
| Not Applicable | 38 (29.9) |
| No | 62 (48.8) |
| Yes | 27 (21.3) |
| Logistical Burdens | |
| Coordination of Frequent Medical Appointments, n (%) | |
| No | 69 (53.5) |
| Yes | 60 (46.5) |
| Completion and Submission of Paperwork, n (%) | |
| Not Applicable | 20 (15.4) |
| No | 76 (58.5) |
| Yes | 34 (26.2) |
| Submission of Medical Bills, n (%) | |
| Not Applicable | 28 (21.5) |
| No | 61 (46.9) |
| Yes | 41 (31.5) |
| Arrangement of Time Off Work, n (%) | (4.12) |
| Not Applicable | 53 (40.8) |
| No | 36 (27.7) |
| Yes | 41 (31.5) |
| Arrangement of Childcare, n (%) | |
| Not Applicable | 88 (67.7) |
| No | 27 (20.8) |
| Yes | 15 (11.5) |
| 1 03 | 15 (11.5) |

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 Table 3. Reasons for Trial Participation

| Reason | N = 130 N (%) |
|---|------------------|
| I believe that the study offers the best treatment available. | 65 (61.9) |
| I want to contribute to scientific research. | 83 (79.0) |
| I believe that the quality of care I receive would be better as part of this study. | 42 (40.0) |
| I trust the doctor treating me. | 79 (75.2) |
| I believe the benefits of participating would outweigh any negative side-effects. | 53 (50.5) |
| I believe the results from the study could benefit other patients in the future. | 82 (78.1) |
| I believe that I would be monitored more closely as part of this study. | 42 (40.0) |
| I think my cancer will get worse unless I participate in this study. | 1 (1.0) |
| I had a positive experience in a previous research study. | 6 (5.7) |
| Other (Specify) | 0 (0) |

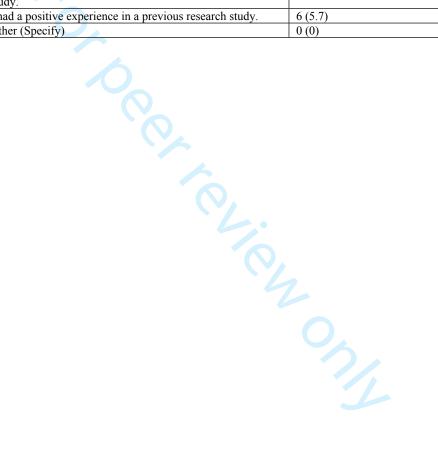


Table 4. Views on Cancer Research

| View | N = 130 N (%) |
|---|------------------|
| I am interested in participating in clinical research related to my | |
| cancer. | |
| Strongly Agree | 63 (49.2) |
| Agree | 51 (39.8) |
| Neither Agree nor Disagree | 11 (8.6) |
| Disagree | 2 (1.6) |
| Strongly Disagree | 1 (0.8) |
| I have a good understanding of clinical research. | |
| Strongly Agree | 31 (24.2) |
| Agree | 57 (44.5) |
| Neither Agree nor Disagree | 31 (24.2) |
| Disagree | 3 (2.3) |
| Strongly Disagree | 6 (4.7) |
| Some clinical research determines by chance what treatment a | |
| patient receives (randomization). I am comfortable with being | |
| randomly assigned (randomized) to receive a treatment. | |
| Strongly Agree | 24 (18.6) |
| Agree | 45 (34.9) |
| Neither Agree nor Disagree | 35 (27.1) |
| Disagree | 15 (11.6) |
| Strongly Disagree | 10 (7.8) |
| Cancer research will help doctors better understand and treat | |
| cancer. | |
| Strongly Agree | 102 (78.5) |
| Agree | 26 (20.0) |
| Neither Agree nor Disagree | 2 (1.5) |
| Disagree | 0 (0) |
| Strongly Disagree | 0 (0) |
| The primary reason cancer research is done is to improve the | |
| treatment of future cancer patients. | |
| Strongly Agree | 86 (66.2) |
| Agree | 36 (27.7) |
| Neither Agree nor Disagree | 3 (2.3) |
| Disagree | 3 (2.3) |
| Strongly Disagree | 2 (1.5) |
| I will not directly benefit from participating in cancer research. | |
| Strongly Agree | |
| Agree | 26 (20.0) |
| Neither Agree nor Disagree | 42 (32.3) |
| Disagree | 31 (23.8) |
| Strongly Disagree | 28 (21.5) |
| 21-0-18-7 = 10-18-00 | 3 (2.3) |
| Patients who participate in research studies should be told the | |
| results when the study is compete. | |
| Strongly Agree | 46 (35.4) |
| Agree | 62 (47.7) |
| Neither Agree nor Disagree | 20 (15.4) |
| Disagree | 1 (0.8) |
| Strongly Disagree | 1 (0.8) |
| I would agree to participate in the SAFETY trial | |
| if eligible (N=124) | |
| Yes | 106 (85.5) |
| No | 18 (14.5) |

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|--|---|--|---------------------------------|---|
|--|---|--|---------------------------------|---|

Participant Initials Participant ID Completion Date DD MM YYYY

Surveillance AFter Extremity Tumor SurgerY (SAFETY) Protocol Study

PATIENT QUESTIONNAIRE

Thank you for agreeing to complete this questionnaire. Your responses will help orthopaedic oncology researchers better understand whether sarcoma patients are willing to participate in research evaluating different post-operative follow-up schedules. This questionnaire should take you approximately 15 minutes to complete. A participant ID number will be assigned to track completion of the questionnaires. A master list linking the ID number will be maintained during the data collection phase. Once all questionnaires from each round have been received, the list will be destroyed and your responses will be anonymized.

Some of the questions may be uncomfortable for you to answer. However, we ask that you try your best in answering all of the questions. Your participation is important to us and those whom may benefit from this research.

Part A: DEMOGRAPHICS

This section asks a few basic questions to let us know a little bit more about you.

| 1. V | Vhat is your age? years | ; | | | |
|------|---------------------------|----------|---------|-------------------|------------------|
| 2. V | What is your gender? | | | | |
| | Male | | | Female | |
| | Other (specify): | | | | |
| 3. V | What is your race/ethnic | city? | | | |
| | Caucasian | | | Native/Aboriginal | |
| | African/Caribbean | | | East Asian | |
| | Hispanic/Latino | | | South Asian | |
| | Middle Eastern | | | Other (specify): | |
| | Mixed (specify): | | | | |
| | | | | | |
| 4. V | Where do you live? | | | | |
| Ш | Canada | | | Spain | |
| | Netherlands | | | USA | |
| | Other (specify): | | | | |
| 5. V | What is your first langua | age? | | | |
| | Arabic | | French | Korean | Spanish |
| | Cantonese | | German | Mandarin | Urdu |
| | Dutch | | Hindi | Portuguese | Vietnamese |
| | English | | Italian | Russian | Other (specify): |

| | Participant Init | ials | Participant ID | | | | | | |
|-------|---|------------------|---------------------|------------------------|---------------------------------------|------------|-----------------------------------|--|--|
| 6. | What is your ma | arital status? | | | | | | | |
| | ⊔ Single | ∟ Separated | ⊔ d Divorced | Co | ───────────────────────────────────── | ∟ rried | ⊔ Widowed | | |
| _ | _ | • | | | | | | | |
| 7. | What is your hig Did Not Com | • | | | High School Diplor | na | | | |
| | College/Trad | - | | ☐ Undergraduate Degree | | | | | |
| | Masters Deg | ree | | | ☐ Doctorate Degree | | | | |
| | ☐ Professional Degree | | | | Other (specify): | | | | |
| 8. | Are you current Yes → If yes | | current occupation? | | | | | | |
| | No \rightarrow If no, | | why: | | | | | | |
| | Retired Student | | | | Homemaker Unemployed | | Ú | | |
| | Doctor's Advice/Disability | | | | Other (specify): | | | | |
| | | | | | | | | | |
| | Please select A | | | y uise | | | | | |
| | None | | Diabetes (Type I) | | Inflammatory Bowel Disease | | Peripheral Vascular Disease | | |
| | Addiction | | Diabetes (Type II) | | Kidney Transplant | | Psychoses | | |
| | AIDS/HIV | | Heart Disease | | Liver Failure | | Pulmonary Circulation Disorder | | |
| | Anemia | | Hepatitis | | Neurological Disorders | | Renal Failure | | |
| | Cardiac Arrhy | rthmia 🗌 | Hypertension | | Obesity | | Rheumatoid g Arthritis | | |
| | Chronic Pulm Disease | onary | Hyperthyroidism | | Osteoarthritis | | Systemic Lupus Erythematosus | | |
| | Depression | | Hypothyroidism | | Osteoporosis | | Other (specify): | | |
| 10. [| Do you smoke? | | | | | | | | |
| | Never | Former Smoker | Current Smoker | | | | | | |
| 11. [| Oo you routinely | use recreation | onal drugs? | | | | u S | | |
| | Never | Former Us | er Current User | | | | | | |
| 12. F | 12. How much alcohol do you drink on a weekly basis?Drinks/Week | | | | | | | | |

If you live in **Canada** or the **USA**, please proceed to **Page 3**. If you live in the **Netherlands** or **Spain**, please proceed to **Page 4**.

| P | Particip LEASE | | | ETE TH | | GE IF Y | OU | LIVE IN CANADA | OR THE | USA. | BMJ Open: first published |
|----------------------|---------------------------------------|---------|---|-------------|----------------------|------------------------------------|------------------------|--|----------------|---------------|---|
| | Less th | nan \$2 | 20,000 | | | ore taxes? | | \$60,000 to \$79,999 \$80,000 to \$99,999 \$100,000+ | | | 01 |
| (A) F | For Cana nealth ins No Yes → | If yes | patients be plan? s, please Employ | indicate w | hat type o ed Insura | additional f additional nce urance | medic | \$80,000 to \$99,999 \$100,000+ 14B if you live in the USA. Ical insurance coverage out cal insurance coverage: Military/Veteran Other (specify): coverage? cal insurance coverage: Medicaid | ıtside of your | provincial | 10.1136/bmjopen-2020-042742 on 26 F Protected by copyright, including for |
| (B) F | For Amer No Yes → | If yes | | ally-Purch | ased Ins | urance | | coverage? cal insurance coverage: Medicaid Military/Veteran Other (specify): 3 on Page 5. | | | ownloaded from http Superieur (ABES) . Sext and data mining |
| | | | | | | | | | | | ://bmjopen.bmj.com/ on June 10, 2025 at Agence Bibliographique de l , Al training, and similar technologies. |
| Version ² | 1.0 | | Forp | peer review | only - http: | .//bmjopen.l | of 12 bmj.co | m/site/about/guidelines.xhtml | I | 16 March 2017 | ນgraphique de l ັ |

| | Participant Initials Participant ID Participant ID |
|-------|---|
| PL | LEASE COMPLETE THIS PAGE IF YOU LIVE IN THE NETHERLANDS OR SPAIN. |
| 13. W | Vhat is your yearly household income before taxes? Less than €14,500 □ €43,500 to €57,999 €14,500 to €28,999 □ €58,000 to €71,999 €29,000 to €43,499 □ €72,000+ |
| 14. D | No Yes If yes, please indicate what type of additional medical insurance coverage: Employer-Provided Insurance Military/Veteran Personally-Purchased Insurance Other (specify): |
| | Please proceed to Part B on Page 5. |

| | Participant Initi | als | Participant ID | | | | |
|---------|--------------------|-------------------------------------|--------------------|---------|------------------|---------------------|----------------------|
| This se | | | | | | | d with more than one |
| 15. Wł | nat type of car | ncer do you have? | | | | | |
| | Chondrosard | - | | | Ewing's sar | rcoma | |
| | Fibrosarcom | a | | | Fibrous his | tiocytoma | |
| | Giant cell tur | nor of bone | | | Leiomyosa | rcoma | |
| | Liposarcoma | 1 | | | Non-osteog | genic sarcoma o | f bone |
| | Osteosarcon | na | | | Rhabdomy | osarcoma | |
| | Synovial sare | coma | | | Other (spec | ;ify): | |
| | Not Sure | | | | | | |
| 16. Wł | nere is your ca | ncer located? | | | | | |
| | Arm | | | | Leg | | C |
| | Not Sure | | | | Other (spec | ;ify): | |
| 17. Wł | nen were you | diagnosed with ca | ncer? | | YYYY |] | |
| 18. Ho | w long have v | ou been a cancer | patient at the cer | nter w | here vou are | for vour current tr | eatment? |
| | | | | | | , | |
| | ss Than Weeks | 2 - 4 Weeks | 1 - 6 Months | | Over 6 Months | | |
| | w has your ca | incer been treated L that apply. | I so far? | | | | ę |
| | Chemothera | оу | | | Radiation tl | herapy | |
| | Physiotherap | ру | | | Other (spec | cify): | |
| 20. Ho | w many times | have you seen yo | our orthopaedic o | ncolo | gist (cancer s | urgeon)? | |
| Fi | rst Visit | Once Before | 2 - 3 Times | Ov | er 3 Times | | |
| 11 | i St ViSit | Clice Deloie | Z - J IIIICS | OV | ei a i iiiiea | | |
| 21. Ho | w long does it | typically take you | get from home to | o the I | nospital for a | cancer appointme | ent? |
| _ | | | | | | | C |
| | ss Than Minutes | 30 - 59 Minutes | 1 - 1.5 Hours | | 1.5 - 2 Hours | Over 2 Hours | |

| Participant Initials | | Participant ID — | | | |
|--|--|--|-------------------------------|---|------------------------------|
| 22. How do you typical | lly travel to the | hospital for a cancer | | | |
| ☐ Public Transit | | L | ☐ Personal Veh | icle | |
| ∐ Taxi | | L | ☐ Bicycle | | |
| ☐ Foot ☐ Relative/Friend | l'a Vahiala | L | ☐ Hospital Tran | - | |
| Relative/Friend | s venicie | L | Other (specif | у) | Pro |
| 23. Who is your primar A primary caregiver is | y caregiver? s the person wh | o assumes the most re | sponsibility in caring | ı for your health and wellbeing. | tected |
| ☐ Myself | | | Spouse/Partr | ner · | by c |
| Parent | | | Sibling | : | opyr |
| ☐ Child | | L | ☐ Grandchild | | ight |
| | | <u></u> | 」 Other (specif | y): | incl |
| Part C: IMPORTANCE This section asks question opinion question, please | E OF CANCER ons about your p rate your level a | RESEARCH previous participation in agreement with each sta | research and your atement. | y): for your health and wellbeing. ner y): opinion on cancer research. For each | Ens uding for uses |
| 24. I am interested in p | earticipating in | clinical research relat | ed to my cancer. | | nseignoses relat |
| Strongly Agree | Agree | Neither Agree Nor Disagree | Disagree | Strongly Disagree | ed to te |
| 25. Have you previousl | ly participated | in any other research | studies? | | ext and da |
| Yes → If yes, ho | ow many other r | esearch studies have ye | ou previously partici | pated in? | ta mi |
| [| | | | | ning: |
| | 1 | 2 | 3 | Over 3 | <u>,</u> ≥ |
| 26. How many different treatment? | nt research st | tudies have been di | scussed with you | over the course of your cancer | training |
| | | | | | , anc |
| 0 | 1 | 2 | 3 | Over 3 | sim |
| 27. I have a good unde | erstanding of cl | linical research. | | | ng, and similar technologies |
| □ • | | Neither Agree | D' | Strongly | nolc |
| Strongly Agree | Agree | Nor Disagree | Disagree | Disagree | gies |
| | | es by chance what assigned (randomized | | nt receives (randomization). I am | • |
| Strongly Agree | Agree | Neither Agree Nor Disagree | Disagree | Strongly Disagree | |

| Cancer rese | arch will help docto | ors better understan | nd and treat cancer. | | |
|---|---|--|--|--|---|
| | | | | | |
| rongly Agre | e Agree | Neither Agree Nor Disagree | INGANIDA | Strongly Disagree | |
| The primary | reason cancer rese | earch is done is to i | mprove the treatme | ent of <i>future</i> cancer | |
| | | | | | |
| rongly Agre | e Agree | Neither Agree Nor Disagree | INGANIDA | Strongly Disagree | |
| I will not dire | ctly benefit from pa | articipating in cance | r research. | _ | |
| | | | | | , |
| ongly Agre | e Agree | Neither Agree Nor Disagree | | Strongly Disagree | J |
| Patients who | participate in rese | earch studies should | d be told the results | when the study is | complete. |
| ー rongly Agre | Agree | Neither Agree | Disagree | Strongly | |
| oligiy Agre | e Agree | Nor Disagree | Disagree | Disagree | |
| section asks are a financia | ar burden to you. A n | e of the costs you may inancial burden is any | y cost or fee triat is di | ппсин ю рау. | eatment and whether |
| section asks are a financio Are transpor Some examp transportation | questions about som al burden to you. A f tation and travel ex les of transportation | e of the costs you may inancial burden is any openses incurred du | ue to your cancer c | are paid by you/you | |
| section asks are a financia Are transpor Some examp transportation | questions about some al burden to you. A f tation and travel ex bles of transportation fares. | e of the costs you may inancial burden is any xpenses incurred du n and travel expens | ue to your cancer cases include costs fro | are paid by you/you om gas, tolls, parkin | ır family? |
| section asks are a financia Are transpor Some examp transportation | questions about some al burden to you. A f tation and travel ex bles of transportation fares. | e of the costs you may inancial burden is any openses incurred du | ue to your cancer cases include costs fro | are paid by you/you om gas, tolls, parkin | ır family? ng, taxis, and public |
| section asks are a financia Are transpor Some examp ransportation No Yes → If | questions about some al burden to you. A f tation and travel ex bles of transportation fares. | e of the costs you may inancial burden is any xpenses incurred du n and travel expens | ue to your cancer cases include costs fro | are paid by you/you om gas, tolls, parkin | ır family? ng, taxis, and public |
| section asks are a financia Are transport Some example ransportation No Yes Are accomm | questions about some al burden to you. A fatation and travel exples of transportation fares. yes, please indicate Unmanageable Burden odation and meal expenses. | e of the costs you may inancial burden is any expenses incurred dunt and travel expenses how much of a financial Significant | ue to your cancer cases include costs from the costs include costs from the costs include costs from the costs include to your cancer cancer include to your cancer | are paid by you/you om gas, tolls, parking sts are to you: Slight Burden care paid by you/you | ır family? ng, taxis, and public |
| section asks are a financia Are transport Some example ransportation No Yes → If Are accomm Some example No No | questions about some al burden to you. A fatation and travel exples of transportation fares. yes, please indicate Unmanageable Burden addation and meal eles of accommodation | e of the costs you may inancial burden is any openses incurred du n and travel expens how much of a finance Significant Burden expenses incurred of | cial burden these cos Somewhat of a Burden due to your cancer s include costs from h | are paid by you/you om gas, tolls, parking sts are to you: Slight Burden care paid by you/you otel stays and meals | ır family? ng, taxis, and public |
| section asks are a financia Are transport Some example transportation No Yes → If Are accomm Some example No | questions about some al burden to you. A fatation and travel exples of transportation fares. yes, please indicate Unmanageable Burden addation and meal eles of accommodation | e of the costs you may inancial burden is any openses incurred dun and travel expenses how much of a financial significant Burden expenses incurred on and meal expenses in and meal expenses | cial burden these cos Somewhat of a Burden due to your cancer s include costs from h | are paid by you/you om gas, tolls, parking sts are to you: Slight Burden care paid by you/you otel stays and meals | ır family? ng, taxis, and public |
| S section asks vare a financial Are transportation No Are accommanded Are accommanded Some example No No No No No No No No No | questions about some al burden to you. A fatation and travel exples of transportation fares. yes, please indicate Unmanageable Burden addation and meal eles of accommodation | e of the costs you may inancial burden is any openses incurred dun and travel expenses how much of a financial significant Burden expenses incurred on and meal expenses in and meal expenses | cial burden these cos Somewhat of a Burden due to your cancer s include costs from h | are paid by you/you om gas, tolls, parking sts are to you: Slight Burden care paid by you/you otel stays and meals | ır family? ng, taxis, and publio |
| section asks are a financia Are transport Some exampt transportation No Yes → If Are accomm Some exampt No Yes → If | questions about some al burden to you. A fatation and travel exples of transportation fares. yes, please indicate Unmanageable Burden codation and meal eles of accommodation yes, please indicate yes, please indicate Unmanageable | e of the costs you may inancial burden is any openses incurred du n and travel expense how much of a finance Significant Burden expenses incurred of n and meal expenses how much of a finance Significant | see to your cancer cases include costs from the cos | are paid by you/you om gas, tolls, parking sts are to you: Slight Burden care paid by you/you otel stays and meals sts are to you: | Ir family? Ing, taxis, and public No Burden Our family? at restaurants. |

| | Таппора | ant Initials | Participant — | | | | 1 |
|--|---|---|---|--|--|--|---|
| So | | nples of family and | | our cancer paid by y clude costs related to | rou/your family? o running your house | hold, childcare, and | d - |
| | Yes → | If yes, please indicat | e how much of a fina | ancial burden these co | sts are to you: | | ! |
| | | | | | | | |
| | | Unmanageable Burden | Significant Burden | Somewhat of a Burden | Slight Burden | No Burden | otected |
| So | ome exam | nples of caregiving | expenses include d | nncer care paid by yo costs from hiring a p d personal support wor | erson to prepare me | als or drive you to | Ensei Protected by copyright, including for uses r |
| | | If was please indicat | e how much of a fine | ancial burden these co | ests are to vou: | | ht, i |
| ш | 163 | | | | | | Clu |
| | | Unmanageable Burden | Significant Burden | Somewhat of a Burden | Slight Burden | No Burden | ding for |
| 37. Ha | Not App No | olicable → I was n | ot employed prior to | due to your cancer my cancer diagnosis. | | | Enseignement uses related to |
| Ш | res | if yes, please indicat | e now much of a fina | ancial burden this loss | of income is to you: | | text |
| | | ∐ Unmanageable | ∟ Significant | Somewhat of a | | | superieur (ext and dat |
| | | Burden | Burden | Burden | Slight Burden | No Burden | ur (A data |
| | Not App | olicable → My prin | nary caregiver was n | of wages due to your not employed prior to m | ny cancer diagnosis. | | BES) . mining, / |
| | | | | | | | 7 |
| ш | Yes → | If yes, please indicat | e how much of a fina | ancial burden this loss | of income is to your pr | imary caregiver: | rainin |
| | Yes → | If yes, please indicat | e how much of a fina | ancial burden this loss | of income is to your pr | rimary caregiver: | raining, aı |
| | Yes→ | If <i>ye</i> s, please indicated Unmanageable Burden | e how much of a fina Significant Burden | ancial burden this loss Somewhat of a Burden | of income is to your pr | rimary caregiver: | raining, and simi |
| Part E This so whether people | Yes → E: LOGIS ection ask er they are e that is dif | Unmanageable Burden STICAL BURDEN C as questions about so a logistical burden to fficult to manage. | Significant Burden CANCER CARI Tome of the tasks you o you. A logistical but | Somewhat of a Burden may have to manage urden is any task that it | of income is to your property of income is to your property of the state of your continuous the coordination of the state of your property of the your property of th | rimary caregiver: No Burden ancer treatment and on of many details o | raining, and similar technologi |
| Part E This so whethe people 39. I fi | Yes → E: LOGIS ection ask er they are e that is dif | If yes, please indicate Unmanageable Burden STICAL BURDEN Cases a questions about see a logistical burden to fficult to manage. STICAL BURDEN Cases a logistical burden to manage. | Significant Burden PF CANCER CARI Ome of the tasks you o you. A logistical but | Somewhat of a Burden may have to manage urden is any task that i | of income is to your process. Slight Burden e as a result of your continuous the coordination care is a logistical be | rimary caregiver: No Burden ancer treatment and on of many details of urden. | raining, and similar technologies. |
| Part E This so whether people 39. I fi | No | | | | of income is to your property of income is to your property of Slight Burden e as a result of your coinvolves the coordination of the care is a logistical burden medical appointment. | | raining, and similar technologies. |
| Part E This so whethe people 39. I fi | No | | | | | | raining, and similar technologies. |

| 40. l f | | ompleting and subm | • | lated to my cancer | care is a logistical b | | BMJ Open: first published as 10.1136/bmjopen-2020-042742 |
|--|---|--|--|--|--|--|--|
| | No | | | | e related to my cancer | | publishe |
| | Yes → | If <i>ye</i> s, please indicate | how much of a logist | tical burden completi | ing additional paperwo | rk is to you: | d as |
| | | Unmanageable Burden | Significant Burden | Somewhat of a Burden | Slight Burden | No Burden | 10.1136/k |
| 41. I f | Not App | rocessing medical b | • | • | | No Burden No Burden No Burden No Burden | mjopen-20 |
| | No Yes → | If yes, please indicate | how much of a logist | tical burden process | ing additional medical | bills is to you: |)20-04 |
| | | | | | | | 2742 |
| | | Unmanageable Burden | Significant Burden | Somewhat of a Burden | Slight Burden | No Burden | on 26 |
| 42. I f | ind that ar Not App No | ranging for time off volicable → I am not | work to attend medi currently employed. | cal appointments f | or my cancer care is | a logistical burden.ធ្ល ខ ខ្លួ | February 202 Enseignen |
| | Yes→ | If yes, please indicate | how much of a logist | tical burden arrangin | g for time off work is to | you: | nen 1 |
| | | | | | | | |
| | | | O:: (f1 | | | | ownic t Supe |
| | | Unmanageable Burden | Significant Burden | Somewhat of a Burden | Slight Burden | No Burden | |
| | Not App | Burden rranging childcare to | Burden attend medical ap have children OR I do | Burden pointments for my o not have children th | cancer care is a logi | istical burden. | from http: (ABES) |
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| Part I Pleas asking 44. TI For the where three | Not App No Yes → F: THE SA e review the g your opinate the post-op the first two e you had you years. At fi | rranging childcare to licable I do not lead to licable I do not lead to lead t | Burden Di attend medical apphave children OR I do have children OR I do how much of a logist Significant Burden Sheet for the SAFET devel of agreement with chedule described between the same of th | Burden pointments for my not have children the dical burden arranging Somewhat of a Burden Y Trial before answer the each statement. Delow is standard of see you every three our doctor will see you are you once a year. | cancer care is a logi | istical burden. iidcare. No Burden stions. For questions technology ancer. fumor will grow back every six months for | from http: (ABES) |
| Part I Pleas asking 44. TI For the where three | Not App No Yes → F: THE SA e review the g your opinate the post-op ne first two e you had ye years. At fi | Burden rranging childcare to blicable → I do not lead to lea | Burden Di attend medical apphave children OR I do have children OR I do how much of a logist Significant Burden Sheet for the SAFET devel of agreement with chedule described between the same of th | Burden pointments for my not have children the dical burden arranging Somewhat of a Burden Y Trial before answer the each statement. Delow is standard of see you every three our doctor will see you are you once a year. | cancer care is a logical currently require chart currently require chart currently require chart currently require chart chart is to you: Slight Burden Find the following questions to see if the target for the same reasons | istical burden. iidcare. No Burden stions. For questions technology ancer. fumor will grow back every six months for | from http: (ABES) |
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| Participant Initial | s | Participant ID | | | |
|----------------------|-------------------|-------------------------------|--------------------|---|-----------------------|
| The past operative | الموروب بيوالوارو | | | antifically proven to be the | haat far may |
| type of cancer. | e follow-up sch | ledule described abo | ve nas been scie | entifically proven to be the | best for my |
| | | | | | |
| Strongly Agree | Agree | Neither Agree Nor Disagree | Disagree | Strongly Disagree | |
| 6. Compared with th | ne standard fol | llow-up schedule, no | one of the other | study follow-up schedules Strongly Disagree ss frequently. Strongly Disagree ans or x-rays. | s carry any |
| additional risks or | discomforts. | | | П | Gecte |
| Strongly Agree | Δαree | Neither Agree | Disagree | Strongly | d by |
| on ongry Agree | Agree | Nor Disagree | Disagree | Disagree | сору |
| . I have concerns a | bout being follo | owed by my orthopae | edic oncologist le | ss frequently. | right |
| | | Noither Agree | | Strongly | , inc |
| Strongly Agree | Agree | Nor Disagree | Disagree | Disagree | |
| I have concerns a | hout my expos | ure to radiation from | additional CT sc | ans or x-rays | g tor |
| | | | | | uses |
| Strongly Agree | Agree | Neither Agree | Disagree | Strongly | rea |
| | • | Nor Disagree | • | Disagree | ited t |
| . I have concerns th | nat CT scans w | rill miss any cancer n | odules that were | n't detected on a chest x-r | ay. Ö |
| | | Neither Agree | | ∟ Strongly | t and |
| Strongly Agree | Agree | Nor Disagree | Disagree | Disagree | d dat |
| . Compared with the | ne standard fol | llow-up schedule, fe | wer follow-up ap | pointments would ease the | he financial |
| burden of my can | cer care. | | | | ing, |
| | | └ │ Neither Agree | | □ Strongly | <u> </u> |
| Strongly Agree | Agree | Nor Disagree | Disagree | Disagree | training. |
| . Compared with th | ne standard fol | low-up schedule, fev | wer follow-up ap | pointments would ease th | |
| burden of my can | cer care. | | | | |
| | | L. Noither Agree | | Strongly | niiar |
| Strongly Agree | Agree | Neither Agree Nor Disagree | Disagree | Disagree | tecn |
| 2. Would you discus | s this research | study with anyone b | efore deciding to | / not to participate in this | similar technologies. |
| Yes → If yes, p | olease specify w | ho: | | | |
| □ s | pouse/Partner | | Parent | | |
| | Sibling | | Child | | |
| ☐ F | riend | | Grandchild | | |
| _ F | amily Physicia | n | Other (spec | ify): | |
| | | | (40 | | 4014 + 554= |
| rsion 1.0 | For peer review | only - http://bmjopen.b | mj.com/site/about/ | guidelines.xhtml | 16 March 2017 |

| Participant Initials Participant ID Participant ID Participant ID No No No Yes → If yes, please specify where: Internet Hospital Resources Other Organization (specify): | Literature (books/journals)Patient Support Group(s) |
|--|---|
| 54. Would you participate in the SAFETY trial? | Other (specify): Other (specify): opyright, includy was easy. |
| 55. My decision to / not to participate in this research student of the state of th | Other (specify): Udy was easy. Disagree Strongly Disagree Disagree Other (specify): Strongly Disagree Disagree |
| 56. Please answer 56A if you would participate in the participate in the SAFETY Trial.(A) Why would you agree to participate in this research Please select ALL that apply. | SAFETY trial. Please answer 56B if you would not related to to the study? |
| A. I believe that the study offers the best treatment available. B. I want to contribute to scientific research. C. I believe that the quality of care I receive would | F. I believe the results from the study could benefit other patients in the future. G. I believe that I would be monitored more closely as part of this study. |
| be better as part of this study. D. I trust the doctor treating me. E. I believe that the benefits of participating | L. I think my cancer will get worse unless I participate in this study. J. I had a positive experience in a previous |
| would outweigh any negative side-effects. | participate in this study. J. I had a positive experience in a previous research study. K. Other (specify): earch study? |
| (B) Why would you choose not to participate in this res Please select ALL that apply. A. I do not believe that the study offers the best treatment available. | F. I have concerns about the additional radiation exposure from CT scans. G. My family is not keen for me to participate. |
| B. I do not want to contribute to scientific research. | G. My family is not keen for me to participate. |
| C. I believe that the quality of care I receive would be inferior to what I would receive if I did not participate. | H. I believe that this study would cause issues with my insurance coverage. I. I do not believe that I can currently cope with the additional requirements of a research study. J. I had a negative experience in a previous research study. K. Other (specify): |
| D. I do not trust the doctor treating me. | I. I do not believe that I can currently cope with the additional requirements of a research study. |
| E. I have concerns about possibly being followed less intensively in this study. | J. I had a negative experience in a previous research study. |
| | K. Other (specify): |
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|-------|---|
| 57. | Participant Initials Participant ID Participant ID Which of the reasons above was the most important reason for you deciding to / not to participate in the |
| 07. | SAFETY trial? |
| 58. | Additional Comments: |
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| | Thank you for completing this questionnaire! |
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lated to text and data mining, Al training, and similar technologies