PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	Ambulatory Cancer Care Electronic Symptom Self-Reporting (ACCESS) for Surgical Patients – A Randomized Controlled Trial Protocol
AUTHORS	Stabile, Cara; Temple, Larissa; Ancker, Jessica S.; Basch, E; Carter, Jeanne; Miranda, Magen; Stein, Daniel; Stetson, Peter; Vickers, Andrew; Simon, Brett; Pusic, Andrea

VERSION 1 – REVIEW

REVIEWER	Christine Miaskowski School of Nursing University of California, San Francisco USA
REVIEW RETURNED	28-Apr-2019

GENERAL COMMENTS	This extremely well written paper describes a study protocol for a randomized clinical trial of an ambulatory cancer care electronic symptom self-reporting application to improve patient outcomes following a number of ambulatory surgery procedures. The only comment I would make is for the authors to consider revising the title of the paper, so that it is clear to a reader that this paper describes a study protocol.

REVIEWER	Enrique Soto Pérez de Celis Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Mexico.
REVIEW RETURNED	18-May-2019

GENERAL COMMENTS	Dear Editors of BMJ Open Thank you very much for allowing me to review the manuscript by Stabile et al regarding a randomized controlled trial of patient reported outcomes after ambulatory surgery. This is a very interesting and well-written study protocol, which looks into the use of electronic symptom reporting and monitoring as a strategy to reduce unnecessary emergency department visits among patients who underwent ambulatory surgery. The study's methods are very clear, as well as the main objectives and measures that will be utilized. The statistical section, sample size calculations, and planned analyses are appropriate for the outcomes. The authors have followed available guidelines for the reporting of study protocols appropriately. I have some comments and suggestions regarding the manuscript: 1. The limitations of the study are nicely stated. However, I think that one of the most important limitations, beyond the characteristics of the patients, is that the "control" arm of the study is not standard for most patients undergoing postoperative care

	worldwide, which limits the generalizability of the results. More should be said regarding the study limitations. 2. It is not clear if the study is already recruiting participants or if it has not yet begun. Please add the date of study start or the planned date for starting recruitment. 3. The primary outcome seems to be emergency department visits without admissions in the first 30 days, although in the outcomes section this is not clear and other endpoints are included. Please clarify the primary outcome. 4. More information should be provided regarding the secondary outcomes such as the number of calls. 5. One of the study's hypotheses is that the Enhanced Feedback will diminish visits to the Emergency Department by improving patient engagement. However, this enhancement in information might also lead to more calls to the care team. More information is needed regarding how these calls will be handled, what kind of interventions or recommendations will be made over the phone, and in which cases the patients will be prompted to go to the emergency department. 6. The study details registered in clinicaltrials.gov (NCT03178045) state that the estimated enrollment is of 4125 participants. However, the current submission mentions a sample size of 2750 participants. Why is this different? 7. More data regarding how the emergency department visits will be captured is needed. For instance, some patients in the Enhanced Feedback cohort might be prompted to go to the Emergency Department due to the alerts generated by the ACCESS system, just as the Team Monitoring Cohort. Therefore, it would be relevant to see exactly what component of the follow-up monitoring is triggering visits or interventions. 8. Please replace "cancer patients" with "patients with cancer" throughout the manuscript. Thank you very much for allowing me to review this very exciting protocol. Best regards

VERSION 1 – AUTHOR RESPONSE

Reviewer 1:
Christine Miaskowski
School of Nursing, University of California, San Francisco, USA

Comment: This extremely well written paper describes a study protocol for a randomized clinical trial of an ambulatory cancer care electronic symptom self-reporting application to improve patient outcomes following a number of ambulatory surgery procedures. The only comment I would make is for the authors to consider revising the title of the paper, so that it is clear to a reader that this paper describes a study protocol.
Response: Thank you. We revised the title of the paper to clarify that it describes a study protocol. The paper is now entitled, "Ambulatory Cancer Care Electronic Symptom Self-Reporting (ACCESS) for Surgical Patients – A Randomized Controlled Trial Protocol".

Reviewer 2:
Enrique Soto Pérez de Celis
Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Mexico

Comment 1: The limitations of the study are nicely stated. However, I think that one of the most important limitations, beyond the characteristics of the patients, is that the "control" arm of the study is not standard for most patients undergoing postoperative care worldwide, which limits the generalizability of the results. More should be said regarding the study limitations.
Response 1: We replaced the last entry in the "Strengths and Limitation of this Study" section with the following: "While the use of electronic patient-reported symptom monitoring, the control arm of this study, is not standard for most patients undergoing postoperative care worldwide and may limit the immediate generalizability of the results, this study may provide important guidance for the development of such systems in the future."

Comment 2: It is not clear if the study is already recruiting participants or if it has not yet begun. Please add the date of study start or the planned date for starting recruitment.

Response 2: Enrollment began in August 2017 and is projected to end in September 2019. This was added to the "Participants, Setting, and Recruitment" section.

Comment 3: The primary outcome seems to be emergency department visits without admissions in the first 30 days, although in the outcomes section this is not clear and other endpoints are included. Please clarify the primary outcome.
Response 3: The primary study outcome is to determine if providing enhanced reporting to patients regarding their symptoms will impact potentially avoidable urgent care and emergency department visits (i.e., those that do not result in hospital admission) up to 30 days after ambulatory cancer surgery. In addition, we will examine readmissions and symptom-triggered interventions (pain management referrals, nursing calls). Secondary outcomes include patient engagement, patient anxiety, and caregiver burden using validated PRO measures and qualitative interviews. This was clarified in the "Objectives and Scientific Aims" section.

Comment 4: More information should be provided regarding the secondary outcomes such as the number of calls.
Response 4: We have clarified in the "Emergency Department Visits and Adverse Events" section that these data exist as structured fields in our data warehouse and will be further verified through selected chart review.

Comment 5: One of the study's hypotheses is that the Enhanced Feedback will diminish visits to the Emergency Department by improving patient engagement. However, this enhancement in information might also lead to more calls to the care team. More information is needed regarding how these calls will be handled, what kind of interventions or recommendations will be made over the phone, and in which cases the patients will be prompted to go to the emergency department.
Response 5: All calls, both incoming from patients and outgoing to patients in response to alerts, are handled by standard Memorial Sloan Kettering Cancer Center (MSK) clinical nursing practice by each surgeon's office and documented in formatted notes, with structured data identifying the reason for the call, who initiated it, action taken, etc. As stated in the manuscript, we will evaluate the frequency and type of nursing calls and actions. These results will be shared in subsequent manuscripts in detail.

Comment 6: The study details registered in clinicaltrials.gov (NCT03178045) state that the estimated enrollment is of 4125 participants. However, the current submission mentions a sample size of 2750 participants. Why is this different?
Response 6: The study details in clinicaltrials.gov provides the overall total number of participants we plan to enroll on the trial (n=4,125). This, unfortunately, does not separate the number of patients (n=2,750) versus caregivers (n=1,375) that we plan to recruit. In the “Participants, Setting, and Recruitment” section, we state, “A total of 2,750 patients and 1,375 caregivers will be recruited for this study over a period of three years.”

Comment 7: More data regarding how the emergency department visits will be captured is needed. For instance, some patients in the Enhanced Feedback cohort might be prompted to go to the Emergency Department due to the alerts generated by the ACCESS system, just as the Team Monitoring Cohort. Therefore, it would be relevant to see exactly what component of the follow-up monitoring is triggering visits or interventions.
Response 7: Emergency department visits and readmissions at MSK and patient self-reported outside visits and admissions are captured from our institutional database system in the same way for both study arms. It may or may not be possible to determine what component of the follow-up monitoring is triggering visits or interventions, but we will know whether the rates are different between the two groups. During our analysis, we will certainly look to explore factors that might have contributed to these visits or other interventions through our qualitative interviews and analysis of the nursing call notes data.

Comment 8: Please replace “cancer patients” with “patients with cancer" throughout the manuscript.
Response 8: As one of the largest dedicated cancer centers in the world, we routinely use both phrases in our literature and patient-targeted communications. However, we have replaced “cancer patients” with “patients with cancer” in several locations in the manuscript for variety.