PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Study Protocol for a Randomized Controlled Feasibility Trial of a Virtual Intervention (STRIDE) for Symptom Management, Distress, and Adherence to Adjuvant Endocrine Therapy after Breast Cancer
AUTHORS	Jacobs, Jamie; Rapoport, Chelsea; Horenstein, Arielle; Clay, Madison; Walsh, Emily; Peppercorn, Jeffrey; Temel, Jennifer; Greer, Joseph

VERSION 1 – REVIEW

REVIEWER	Kay Sundberg Karolinska Institutet Sweden
REVIEW RETURNED	20-Jul-2020

GENERAL COMMENTS	The Study Protocol for a Randomized Controlled Feasibility Trial of a Virtual Intervention (STRIDE) for Symptom Management, Distress, and Adherence to Adjuvant Endocrine Therapy after Breast Cancer" describes an interesting work of a patient-centered intervention, relevant for the group in target. The protocol is in general well written. There are a few things the authors could clarify that may benefit the protocol. The background literature mirrors the problem of research well, however the reference by Lebovits et al. (1990) describing areas associated with non-adherence to AET is rather old and should be replaced by a more recent one. The method section is comprehensive and well described but could be more structured. For instance, the power calculation for the study sample would be better placed in the paragraph regarding “Participants selection”. Further, the paragraph “Study procedure” could be divided into different parts, whereas the actual intervention could be one part. Moreover, it would be logical that the paragraph about “Patient and Public involvement” was placed where the intervention is described. Regarding the outcomes, it is not really motivated why there are so many self-reported questionnaires. Considering this is a feasibility study and has not enough power to determine any group differences. Limitations of the study is thereby not just the fact that the patients are from one medical center but rather that the study is underpowered.

REVIEWER	Joseph Sparano Montefiore Medical Center United States
REVIEW RETURNED	14-Sep-2020

GENERAL COMMENTS	No comments.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Kay Sundberg
Institution and Country: Karolinska Institutet, Sweden
Please state any competing interests or state ‘None declared’: none declared

The Study Protocol for a Randomized Controlled Feasibility Trial of a Virtual Intervention (STRIDE) for Symptom Management, Distress, and Adherence to Adjuvant Endocrine Therapy after Breast Cancer" describes an interesting work of a patient-centered intervention, relevant for the group in target.
The protocol is in general well written. There are a few things the authors could clarify that may benefit the protocol.

Response to Reviewer: Thank you for these helpful comments and we appreciate your acknowledgment of this work.

The background literature mirrors the problem of research well, however the reference by Lebovits et al. (1990) describing areas associated with non-adherence to AET is rather old and should be replaced by a more recent one.

Response to Reviewer: Thank you for pointing this out. We agree that a more recent reference is appropriate, and have replaced this article with more recent ones in two areas.

The method section is comprehensive and well described but could be more structured. For instance, the power calculation for the study sample would be better placed in the paragraph regarding “Participants selection”. Further, the paragraph “Study procedure” could be divided into different parts, whereas the actual intervention could be one part. Moreover, it would be logical that the paragraph about “Patient and Public involvement” was placed where the intervention is described.

Response to Reviewer: Thank you for these suggestions to better structure the manuscript. We have moved these sections per the reviewer’s suggestions and believe they are now better placed. With regard to the methods section, specifically, we divided the study procedures section into multiple parts with headers, of which the intervention is one of, per the reviewer’s suggestion. We also moved patient and public involvement to this intervention section, following the description of the actual intervention.

Regarding the outcomes, it is not really motivated why there are so many self-reported questionnaires. Considering this is a feasibility study and has not enough power to determine any group differences. Limitations of the study is thereby not just the fact that the patients are from one medical center but rather that the study is underpowered.

Response to Reviewer: Thank you for your comment. We agree that the study is underpowered to examine secondary outcomes and have included this in the limitations section now. We also comment about the fact that the inclusion of all study questionnaires is necessary as it is part of the process of assessing study feasibility and acceptability in this pilot study with the goal of informing a future full-scale efficacy trial.

Reviewer: 2
Reviewer Name: Joseph Sparano
Institution and Country: Montefiore Medical Center, United States
Please state any competing interests or state ‘None declared’: None declared

No comments.

Thank you for your review of this article.