PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	The eTRIO trial: Study protocol of a randomised controlled trial of online education modules to facilitate effective family caregiver involvement in oncology
AUTHORS	Juraskova, Ilona; Laidsaar-Powell, R; Keast, Rachael; Schofield, Penelope; Costa, Daniel; Kay, Judy; Turner, Sandra; Koczwara, Bogda; Saunders, Christobel; Jefford, Michael; Yates, Patsy; Boyle, Frances; White, Kate; Miller, Annie; Morton, Rachael; Butt, Zoe; Butow, Phyllis

VERSION 1 – REVIEW

REVIEWER	Sun, Virginia Division of Nursing Research and Education, Department of Population Sciences, City of Hope
REVIEW RETURNED	29-Jan-2021

GENERAL COMMENTS	This paper describes the study protocol for an RCT of online educational modules to support family caregiver involvement in cancer care. The paper is relatively short and is missing several important and underreported items from the SPIRIT guidelines. These include: 1. Expected recruitment rate and duration of recruitment over the study period. 2. Individual who will assign participants; authors stated that envelopes will be opened but unclear by whom. 3. No information on addressing data collection methods: duplicate measurements, training related to data collection. 4. Strategies to promote retention particularly for clinicians. 5. Lack of clear indication on who will be included in main analysis. 6. How missing data will be handled.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1
The reviewer commented that the paper is relatively short and is missing several important and underreported items from the SPIRIT guidelines. These include:

1. Expected recruitment rate and duration of recruitment over the study period.

Recruitment and data collection is expected to take 15 months. Recruitment of clinicians is expected to span a six-month period. We expect to recruit 5 clinicians per month over the course of this six months. Once recruited, clinicians will begin recruiting patient-carer dyads.

We expect to recruit 31 patient-carer dyads per month over the course of nine months, which equates to approximately 5-6 patient-carer dyads per site per month over a nine-month period.

We have updated the manuscript to describe expected recruitment rate and duration. See bold text below, which can be found on page 12 of the manuscript. The SPIRIT checklist also reflects this addition.

“Clinician champions will be eligible to participate in the trial if they are not existing members of the study team and have not been involved in development of the eTRIO or eTRIO-pc modules. We expect to recruit five clinicians per month over the course of six months.”

“Recruitment must take place prior to the third consultation with a participating clinician. We expect to recruit approximately 31 patient-carer dyads per month over the course of nine months.”

2. Individual who will assign participants; authors stated that envelopes will be opened but unclear by whom.

We thank the reviewer for their comment and apologise for this omission.

A research assistant who is not involved in the enrolment of clinicians will open the envelopes containing the allocation. This has been updated on page 13 of the manuscript and can be seen in bold text below:

“Allocation will be concealed in sequentially numbered, opaque, sealed envelopes which will be opened by a research assistant not involved in the enrolment of clinicians, during the randomisation process.”

3. No information on addressing data collection methods: duplicate measurements, training related to data collection.

The accuracy of all questionnaires has been ensured through an internal quality control process including four researchers who have checked each questionnaire against the original source/protocol. Several trial runs of questionnaire completion, data retrieval, and data exporting have been conducted.
We have added the following text on page 18 of the manuscript:

“Data Collection
Quantitative data will be collected through REDCap, a secure online survey platform which will allow close adherence to the study protocol. All primary outcome measures have been designed within the questionnaires to require a response, thereby minimizing issues of missing data.

Research personnel have completed training in Good Clinical Practice Guidelines (internationally accepted standards for conducting clinical trials). They also completed training in REDCap questionnaire formation, data collection, storage, and retrieval.”

4. Strategies to promote retention particularly for clinicians.

We thank the reviewer for their suggestion and have provided additional details on retention strategies, which can be seen on page 14 of the manuscript and below in bold:

“Once enrolled and randomised, every reasonable effort will be made by study staff to follow all participants for the entire study period. Clinicians will be sent encouraging emails throughout the study. Participating clinicians will also be offered a $50 gift card for participating in the study; to, in a small way, compensate them for time given to the study. In addition, clinicians could use the intervention to count towards continuing professional development points.

Patients and carers will be followed up three times at different times of the day by phone or email if questionnaires are not completed.”

5. Lack of clear indication on who will be included in main analysis.

We have now more explicitly stated who will be included in the main analysis on page 19 of the manuscript. See the additional text in bold:

“Analyses will consist of a random effects linear regression model (i.e. mixed effects model), with caregivers as the unit of analysis and intervention vs. control as a clinician-level predictor.”

6. How will missing data be handled?

We have now more explicitly stated how missing data will be handled on page 18 of the manuscript. See additional text below in bold:

“All caregivers who provide data at any time point will be included in the analysis. At the item level, missing data will be mean-imputed if at least half of the data are not missing. For aggregated variables (i.e., those included in analysis), we will examine patterns of missingness, and the random effects model handles missing data by using all available information, i.e., no explicit imputation.”