PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Efficacy and cost-effectiveness of an online mindfulness program (MindOnLine) to reduce fear of recurrence among people with cancer: study protocol for a randomized controlled trial
AUTHORS	Livingston, Patricia; Russell, Lahiru; Orellana, Liliana; Winter, Natalie; Jefford, Michael; Girgis, Afaf; Austin, David; O, Eric; Mihalopoulos, Cathrine; Ugalde, Anna; Chambers, Richard; Phipps-Nelson, Jo; Herath, Dishan; Botti, Mari; Rasmussen, Bodil; Whitfield, Kathryn; Ftanou, Maria; Smith, Allan; Pilatti, Kirsten; Sara, Sally; Wootten, Addie; Gillan, Kate; Singh, Madhu; Campbell, David; Pillay, Brindha; White, Victoria

VERSION 1 – REVIEW

REVIEWER	Simone Cheli Guglielmo Marconi University
REVIEW RETURNED	05-Nov-2021

GENERAL COMMENTS	The authors present an interesting and needed research protocol to test the effectiveness of an online mindfulness intervention for patients diagnosed with cancer. The primary objective and focus of the intervention is a pivotal theme of modern psycho-oncology research: fear of recurrence. The study has considerable merits, but I believe it could benefit from the following reviews: - Competeting and/or ongoing studies: It is important to clearly report if and how authors reviewed existing studies on the topic. They generally refer to this issue, I would suggest to better explain what they did and outcomes. Please refer to existing studies led for example by Linda Carlson's group in Canada. - Inclusion/exclusion criteria: It may be not clear to the reader if recruited patients are (or not) NED (non evidence of disease). It is a very important counfounding variable including only NED patients or including also (as it seems by reading exclusion critteria) people with low stage metastatic cancer. There are two very different types of experience, and many studies support that. Please clarify this point. Please also specify why you excluded patients undergoing specific treatments. Personally speaking, I would consider reducing the biases rather than maximizing the sample: it's maybe better having a preliminary study on just a specific sample. - Control group: I find the way the control group is presented a bit confusing. Initially it is described as a waiting-list, then it is described as a TAU but we do not know what happens. All guidelines suggest that a TAU is to be preferred for both ethical and methodological reasons. I would consider the possibility of talking about TAU and

	redefining the project in these terms. - Active group: mindfulness intervention can mean many things. I would suggest that the authors be clearer on this point. The reader must be able to quickly understand: (i) whether the protocol is "new" / "original" or a repetition or adaptation of an existing one; (ii) which general model they refer to (eg MBSR, MBCT, MBCR, etc.) in terms of the structure of the intervention; (iii) to which theoretical and clinical rationale they refer considering the many models (eg the "more traditional" model of Carlson and Speca, the model of detached mindfulness of Butow, etc.) and the different target mechanisms of the intervention; (iv) the practices they describe in the protocol which "scripts" do they refer to? - Sample size: The choice of criteria for defining the sample size is not clear to me. The authors present preliminary data from a study, but then seem to refer to the data from Butow's studies in the calculation. Such a choice must be well justified. I hope the comments will be of help in developing the protocol. An online mindfulness intervention for fear of cancer recurrence is definitely needed. I hope the comments will be of help in developing the protocol. An online mindfulness intervention for fear of cancer recurrence is definitely needed.

REVIEWER	Sheeja Pathrose Western Sydney University, School of Nursing and Midwifery
REVIEW RETURNED	08-Nov-2021

GENERAL COMMENTS	This mindfulness based digitalised self-directed intervention is timely and will be of interest to the readers of the journal. The protocol is very well written, and the writing flow logically. The methodology of the protocol is thorough and given an adequate explanation. Please find attached the minor comments and all the best for the trial. The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1 comments	
Competing and/or ongoing studies: It is important to clearly report if and how authors reviewed existing studies on the topic. They generally refer to this issue, I would suggest to better explain what they did and outcomes. Please refer to existing	Lines 105-117 We thank the reviewer for this comment and agree that this is an influential and important body of work that should be adequately recognised. We have outlined this body of work across several references including: Toivonen (2017), Carlson

studies led for example by Linda Carlson's group in Canada.	2016, Compen 2018, Zernicke 2016. We have also referred to key systematic reviews that summarise the literature (e.g. Toivonen et al 2017, Keng et al 2011, Russell et al 2018).
Inclusion/exclusion criteria: It may be not clear to the reader if recruited patients are (or not) NED (non evidence of disease). It is a very important confounding variable including only NED patients or including also (as it seems by reading exclusion criteria) people with low stage metastatic cancer. There are two very different types of experience, and many studies support that. Please clarify this point. Please also specify why you excluded patients undergoing specific treatments. Personally speaking, I would consider reducing the biases rather than maximizing the sample: it's maybe better having a preliminary study on just a specific sample.	Lines' 225. We agree that different populations will have different experiences and possibly different responses to the intervention. Given our primary outcome was fear of recurrence, patients with a Stage 4 prognosis are less likely to have a fear of recurrence as it would have been identified that the prognosis was less than 12 months. We also needed to ensure that participants were more likely to have a 12+ month prognosis to complete the study. Line 231. We have clarified the exclusion criteria by removing ' ~~*or metastatic'*~~ disease, and included *with less than a 12 month prognosis of survival)*.
- Control group: I find the way the control group is presented a bit confusing. Initially it is described as a waiting-list, then it is described as a TAU but we do not know what happens. All guidelines suggest that a TAU is to be preferred for both ethical and	Line292-6. We have clarified the control group with the following: Participants allocated to the waitlist group will receive usual care. Following randomisation, they will receive an email with a list of services they may contact for information and support. They

methodological reasons. I would consider the possibility of talking about TAU and redefining the project in these terms.	will be informed that they will be granted access to MindOnLine intervention in 9-month's time *when intervention participants have completed the final survey.*
- Active group: mindfulness intervention can mean many things. I would suggest that the authors be clearer on this point. The reader must be able to quickly understand: (i) whether the protocol is "new" / "original" or a repetition or adaptation of an existing one; (ii) which general model they refer to (eg MBSR, MBCT, MBCR, etc.) in terms of the structure of the intervention; (iii) to which theoretical and clinical rationale they refer considering the many models (eg the "more traditional" model of Carlson and Speca, the model of detached mindfulness of Butow, etc.) and the different target mechanisms of the intervention; (iv) the practices they describe in the protocol which "scripts" do they refer to?	Lines 138-148. We have added additional information as part of the Background. *MindOnline was initially developed as a 6-week online mindfulness-base intervention and follows the Framework for mindfulness-based program described by Crane and colleagues[10]. The program promoted awareness and acceptance of thoughts and emotions, and empowered participants to address their distressing thoughts and emotions in more adaptive ways. Through this action, participants learn to manage anxious and depressive moods. These moods are triggered by unhelpful and intrusive thoughts, which are strongly associated with moderate to high levels of fear of cancer recurrence[17]. A pilot study was conducted to assess the potential impact of a 6-week mindfulness program and explore whether the intervention impacted on FCR, worry, and perceived stress compared to usual care. Details of the intervention are published elsewhere[6].*
	Lines 159-164. *The structure of MindOnline reflects the*

	Mindfulness Based Stress Reduction (MBSR) approach by incorporating characteristics typical of mindfulness-based programs, namely educational component, and formal and informal mindfulness practices. Keeping in line with Crane et al's (2017) Framework for adaptation of mindfulness-based programs, MindOnline adapted the delivery of the program to an online version to facilitate access and convenience of use. *Line 312. We have corrected the word 'script'* to *'transcripts'.*
Reviewer 2 comments	
Page 3 Article summary "Involvement of consumer advocacy groups to support recruitment.": consider consumer advocacy groups for development of intervention.	Lines 78-9 We have now included the following: • *Involvement of consumer advocacy groups to support recruitment, interpretation of results, dissemination and translation*
Page 5 Introduction Survivors of breast, prostate and colorectal cancer: You may detail the rational for choosing this population specifically	Line 124 We have included a statement about why we included breast, prostate and colorectal cancer. The aim of this study is to conduct a randomised controlled trial of MindOnLine, an online 9 session mindfulness-based intervention, for survivors of breast, prostate and colorectal cancer, *the most common solid tumours among men and women in Australia*,[1] to determine the effectiveness and cost-effectiveness of the program.

Page 6 Aim 3: You are comparing the effect between groups in AIM 1 &2. Lacks clarity here	Lines 179-181 We have modified the wording of Aim 3. To assess if the ~~intervention effects~~ effect of the intervention on the primary and secondary outcomes, relative to usual care, are sustained at the nine-month follow-up.
Page 11 Consent and screening: is it implied consent?	Lines' 54 & 525 We have included the following: *All participants will be required to provide written informed consent has been included in the Abstract and main text.*
Page 14 Data collection: How long will take to complete the survey?	Line 418 We have included the following sentence: *The surveys will take approximately 20 minutes to complete.*

VERSION 2 – REVIEW

REVIEWER	Simone Cheli Guglielmo Marconi University
REVIEW RETURNED	05-Dec-2021

GENERAL COMMENTS	The authors significantly improved the paper. However, they did not respond to the following comment which perhaps needs clarification: - Sample size: The choice of criteria for defining the sample size is not clear to me. The authors present preliminary data from a study, but then seem to refer to the data from Butow's studies in the calculation. Such a choice must be well justified. I hope the comments will be of help in developing the protocol. An online mindfulness intervention for fear of cancer recurrence is definitely needed.