

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	CURATE.AI COR-Tx platform as a digital therapy and digital diagnostic for cognitive function in brain tumour patients post-radiotherapy treatment: Protocol for a prospective mixed-methods feasibility clinical trial
AUTHORS	Remus, Alexandria; Tadeo, Xavier; Kai, Grady Ng Shi; Blasiak, Agata; Kee, Theodore; Vijayakumar, Smrithi; Nguyen, Le; Raczowska, Marlena; Chai, Qian Yee; Aliyah, Fatin; Rusalovski, Yaromir; Jia, Teo Ke; Yeo, Tseng Tsai; WONG, Andrea Li Ann; Chia, David; Asplund, Christopher L.; Ho, Dean; Vellayappan, Balamurugan A.

VERSION 1 – REVIEW

REVIEWER	Gameiro-Santos, Rita Centro Hospitalar Barreiro Montijo EPE, Medical Oncology
REVIEW RETURNED	31-Aug-2023

GENERAL COMMENTS	Very clear protocol. Very interesting. Software already validated in other themes. Relevant area lacking therapeutic options. Small study but it is good to start and to structure future trials.
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REVIEWER	Shiba, Satoshi National Cancer Center Hospital, Outpatient Treatment Center
REVIEW RETURNED	18-Sep-2023

GENERAL COMMENTS	<p>This study protocol is well-designed and investigated appropriately to proceed next study phase. So I hope that the present research will go well and look forward to the result in the future.</p> <p>However, there is only one concern about eligibility criteria, namely patient participants.</p> <p>Although the authors regulate study participants using inclusion and exclusion criteria, it is assumed that characteristics and backgrounds of participants will be exceedingly various, which depend on pathologic diagnosis, tumor grading, surgical methods and the brain part of surgical resection. As a result, it may be difficult to decide eligibility criteria when the authors consider participants in the next step, multi-centered RCT study. Its concern is ineluctable because of the nature of a feasibility study. The authors mentioned the limitations including unexpected issues and they could cope with those problems adequately in designing a next RCT study.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Rita Gameiro-Santos, Centro Hospitalar Barreiro Montijo EPE

Comments to the Author:

Very clear protocol. Very interesting. Software already validated in other themes. Relevant area lacking therapeutic options. Small study but it is good to start and to structure future trials.

Thank you for your comments. We appreciate your understanding in the appropriateness of the small study to inform future trials.

Reviewer: 2

Dr. Satoshi Shiba, National Cancer Center Hospital

Comments to the Author:

This study protocol is well-designed and investigated appropriately to proceed next study phase. So I hope that the present research will go well and look forward to the result in the future.

However, there is only one concern about eligibility criteria, namely patient participants.

Although the authors regulate study participants using inclusion and exclusion criteria, it is assumed that characteristics and backgrounds of participants will be exceedingly various, which depend on pathologic diagnosis, tumor grading, surgical methods and the brain part of surgical resection. As a result, it may be difficult to decide eligibility criteria when the authors consider participants in the next step, multi-centered RCT study. Its concern is ineluctable because of the nature of a feasibility study. The authors mentioned the limitations including unexpected issues and they could cope with those problems adequately in designing a next RCT study.

Thank you for your comments. We agree with your comment and have included reference to the concerns about future trial eligibility criteria into the limitations bullet point. This now reads “The non-randomised single-arm feasibility trial does not simulate a randomised control trial as closely as a randomised pilot and is limited in informing on issues that may arise from the logistical process on a larger scale, including future decisions on determining eligibility criteria from a diverse patient population.”