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TPS1615 **Poster Session**

Mixed-methods clinical trial to evaluate the feasibility of the CURATE.AI optimised digital cognitive rehabilitation therapeutic (COR-Tx) in patients post brain radiotherapy.

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Background: Cognitive decline may be exacerbated, in brain tumour patients, by prior radiotherapy (RT). Traditional interventions to mitigate this typically involve fixed dose or intensity pharmacological and/or cognitive rehabilitation therapies that often elicit sub-optimal or no response, due to the dynamically evolving patient state and low adherence. Personalised digital therapeutics (DTx) may be more effective for this population. Further, gamification has previously shown to induce positive health behavioural change and improve intervention adherence. To this end, we have developed the CURATE.AI COR-Tx platform, a gamified DTx, that combines a previously validated, small-data artificial intelligence-derived dose optimisation technology with digital multitasking cognitive training. This novel DTx dynamically personalises treatment by using the patient's own longitudinal performance data to generate an evolving digital avatar that guides training intensity throughout the intervention. Herein, we aim to evaluate feasibility, user experience and usability of the DTx platform in brain tumour patients post-RT. **Methods:** This is a prospective, mixed-methods, interventional, single-arm, decentralised feasibility clinical trial. The primary objective is to evaluate feasibility of the CURATE.AI COR-Tx platform as both a digital intervention (DI) and digital diagnostic (DD) for cognitive function in 15 patients with brain tumour post-RT. The personalised and home-based DI involves completing three 12-min sessions per week for 10 weeks, starting 1 month post-RT. Cognitive function will be assessed via a combined non-digital cognitive evaluation and a DD session at five time points: prior to RT, pre- & post-DI and 16- and 32-weeks post-DI. Feasibility outcomes relating to acceptability, demand, implementation, practicality and limited efficacy testing and additional secondary and exploratory outcomes relating to usability and user experience will be collected by the clinical team and through semi-structured patient interviews and a study team focus group discussion at study completion. We will adopt a mixed-methods approach for data analysis. Feasibility of the CURATE.AI COR-Tx platform will be evaluated through thematic analysis for qualitative outcomes (acceptability and practicality), and descriptive and correlational analysis for quantitative outcomes (demand and implementation). We will adopt the CONSORT traffic light system to decide on future expansion into a large-scale randomised control trial. This trial began in April 2021 and has enrolled 14 of planned 15 patients at the time of submission. Clinical trial information: NCT04848935. Research Sponsor: Singapore Cancer Society; National Research Foundation Singapore.

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