iCogCA: An innovative protocol promoting cognitive health through online group interventions for individuals living with a schizophrenia-spectrum disorder

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Table of Contents

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Christy Au-Yeung[1*]; Helen Thai[1*]; Michael Best[2]; Christopher R. Bowie[3]; Synthia Guimond[4]; Katie M. Lavigne[5]; Mahesh Menon[6]; Steffen Moritz[7]; Myra Piat[8]; Geneviève Sauvé[9]; Ana Elisa Sousa[8]; Elisabeth Thibaudeau[5]; Todd S. Woodward[6]; Martin Lepage[6]; Delphine Raucher-Chéné[5*]

[1]Department of Psychology, McGill University, Montréal, QC, Canada Montreal CA
[2]Department of Psychological Clinical Science, University of Toronto, ON, Canada Toronto CA
[3]Queen's University, Kingston, ON, Canada Kingston CA
[4]Department of Psychiatry, The Royal Institute of Mental Health Research, University of Ottawa, ON, Canada Ottawa CA
[5]Department of Psychiatry, McGill University, Montréal, QC, Canada Montreal CA
[6]Department of Psychiatry, University of British Columbia, Vancouver, BC, Canada Vancouver CA
[7]Department of Psychiatry and Psychotherapy, University Medical Centre Hamburg, Germany Hamburg DE
[8]Douglas Research Centre, Montréal QC, Canada Montreal CA
[9]Department of Education and Pedagogy, Université du Quebec à Montreal, Montréal, QC, Canada Montreal CA
[*]these authors contributed equally

Abstract

Background: Cognitive impairments are a key aspect of schizophrenia-spectrum disorders (SSD), significantly affecting clinical and functional outcomes. The COVID-19 pandemic has heightened concerns about mental health services and cognitive stimulation opportunities. Despite evidence-based interventions like action-based cognitive remediation (ABCR) and metacognitive training (MCT), a research-to-practice gap exists in their application across mental health settings.

Objective: The iCogCA study aims to address this gap by implementing virtual ABCR and MCT through a national Canadian collaborative effort using online psychological interventions to enhance cognitive health in SSD.

Methods: The study involves five Canadian sites, with mental healthcare practitioners trained virtually through the E-Cog platform which was developed by our research group. Over 2.5 years, participants with SSD will undergo pre- and post-intervention assessments for clinical symptoms, cognition, and functioning. Each site will run four groups annually for both ABCR and MCT, totaling ~390 participants. A non-randomized concurrent control design will assess effectiveness design in which one intervention (e.g., ABCR) acts as the active control for the other (e.g., MCT) and vice-versa, comparing cognitive and clinical outcomes between the interventions using generalized linear mixed effect modeling. Implementation strategy evaluation will consider the digital platform's efficacy for mental healthcare practitioners training, contextual factors influencing implementation, and sustainability, using descriptive statistics for quantitative data and thematic analysis for qualitative data.

Results: A pilot pragmatic trial has been conducted previously at the Montréal site, evaluating three early implementation outcomes: acceptability, feasibility, and engagement. Patient and therapist acceptability was deemed as high and feasible (75% of recruited service users completed therapy, rated feasible by therapists). Technology did not appear to significantly impede program participation. Therapist-rated levels of engagement were also satisfactory. In the ongoing study, recruitment is underway, and intervention groups have been conducted at all sites, with therapists receiving training via the E-Cog learning platform.

Conclusions: At least three significant innovations will stem from this project. First, this national effort represents a catalyst for the use of digital technologies to increase the adoption of evidence-based interventions and will provide important results on the effectiveness of virtually-delivered ABCR and MCT. Second, the results of the implementation component of this study will generate the expertise needed to inform the implementation of similar initiatives. Third, the proposed study will introduce and validate our platform to train and supervise mental healthcare practitioners to deliver these interventions, which will then be made accessible to the broader mental health community.

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*** = denotes joint first authorship**

§ = denotes joint last authorship

[1] Douglas Research Centre, Montréal QC, Canada
[2] Department of Psychology, McGill University, Montréal, QC, Canada
[3] Department of Psychological Clinical Science, University of Toronto, ON, Canada
[4] Queen's University, Kingston, ON, Canada
[5] Department of psychoeducation and psychology, University of Quebec in Outaouais, QC, Canada
[6] Department of Psychiatry, The Royal Institute of Mental Health Research, University of Ottawa, ON, Canada
[7] Department of Psychiatry, McGill University, Montréal, QC, Canada
[8] Department of Psychiatry, University of British Columbia, Vancouver, BC, Canada
[9] Vancouver Coastal Health, Vancouver, BC, Canada
[10] Department of Psychiatry and Psychotherapy, University Medical Centre Hamburg, Germany
[11] Department of Education and Pedagogy, Université du Quebec à Montreal, Montréal, QC, Canada
[12] BC Mental Health and Addiction Research Institute, Vancouver, BC, Canada

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Methods & Analyses: The study involves five Canadian sites, with mental healthcare practitioners trained virtually through the E-Cog platform which was developed by our research group. Over 2.5 years, participants with SSD will undergo pre- and post-intervention assessments for clinical symptoms, cognition, and functioning. Each site will run four groups annually for both ABCR and MCT, totaling ~390 participants. A non-randomized concurrent control design will assess effectiveness design in which one intervention (e.g., ABCR) acts as the active control for the other (e.g., MCT) and vice-versa, comparing cognitive and clinical outcomes between the interventions using generalized linear mixed effect modeling. Implementation strategy evaluation will consider the digital platform's efficacy for mental healthcare practitioners training, contextual factors influencing implementation, and sustainability, using descriptive statistics for quantitative data and thematic analysis for qualitative data.

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therapists receiving training via the E-Cog learning platform.

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Strengths and limitations of the study

- Utilization of multiple sites across Canada enhances the generalizability of findings within a nationwide context.
- Comprehensive quantitative and qualitative data collection involving service users and mental health practitioners at multiple time points.
- Engagement with diverse stakeholders at different stages of the study, including those with lived experiences, clinicians, researchers, and managers.
- The non-randomized concurrent control design raises concerns about potential group differences; circumvented by statistically controlling for measurable background characteristics.

Introduction

Background

Schizophrenia and related psychoses present debilitating challenges, imposing an enormous burden on individuals, families, and communities[1 2] and are characterized by symptom recurrence, social deterioration, and cognitive impairments.[3-8] Most affected individuals experience persistent positive (e.g. hallucinations, delusions) and negative symptoms (e.g., amotivation, avolition, reduced expressivity), alongside notable cognitive challenges like difficulties in verbal memory, executive functions, and attention. In addition to these impairments are cognitive distortions[9], affecting reasoning and information processing and, collectively, represent a core feature of schizophrenia, impacting clinical and functional recovery.[10-13] Thus, addressing overall cognitive health in schizophrenia is crucial. Over the past 25 years, advancements in psychological interventions, including cognitive remediation and Metacognitive Training (MCT), have shown promise for treatment in schizophrenia spectrum disorders. Both Cognitive Remediation (CR) and MCT have been found to enhance cognitive functioning and decrease cognitive biases.[14 15]

Cognitive Health Interventions in Schizophrenia: State of the Evidence & Delivery Format

Meta-analyses affirm the effectiveness of cognitive remediation in enhancing cognition[14 16 17] and MCT in addressing cognitive biases.[18 19] Notably, various mental health practitioners with an understanding of cognitive processes can be trained to provide these interventions, providing flexibility in service delivery.[20-22] Delivered in a group format, these interventions enable practitioners to reach multiple service users simultaneously.[21] Research indicates the feasibility of using technology for remote cognitive assessment and psychological interventions, as individuals with psychosis express interest and willingness to engage with digital mental health services[23-25] and find this mode of communication more satisfying and less challenging than observed in the general population.[26]

Preliminary Work on Remote Delivery of Cognitive Health Interventions

Our preliminary work investigated the remote delivery of Action-Based Cognitive Remediation (ABCR) and MCT.[27] ABCR is a distinct form of CR, which integrates the traditional cognitive training techniques of CR with simulated workplace scenarios and goal setting.[28] This work involved evaluating three crucial early implementation outcomes: acceptability, appropriateness, and feasibility for both patients and therapists. Across six cohorts (3 ABCR; 3 MCT) conducted within Montreal, patients expressed high acceptability, with overall satisfaction for expectations and perception of progress. The interventions demonstrated feasibility; 75% of the 48 participants completed therapy, attending an average of 80% of sessions.

Using recently developed measures[29], therapists also reported excellent acceptability, appropriateness and feasibility of the interventions.[27] Several facilitators and barriers to delivering these virtual interventions were also identified. Barriers comprised patients' clinical status (e.g., more severe symptomatology, medication side-effects), interaction issues (e.g., lack of involvement, decreased accountability), technological challenges (e.g., access to devices and the internet), program elements (e.g., language options), and scheduling conflicts. On the other hand, facilitators included patients' motivation to learn, therapist characteristics (e.g., warmth and proper training), financial support for internet connectivity, program support (e.g., education on interventions. ice breakers), and logistical adjustments (e.g., offering evening sessions, forming smaller groups).

Objectives

Having established the acceptability, appropriateness and feasibility of our virtual interventions which collectively represent the early stages of implementation, the next step is to examine how the proposed digital strategies promote the uptake of these interventions across mental health care settings. A major challenge with evidence-based psychosocial interventions is that very few are subsequently tested in effectiveness or implementation trials and thus have little impact on population health.[30] The field of Implementation Science has emerged over the last 20 years,

promoting strategies to adopt and integrate evidence-based interventions and change practice patterns within specific settings. Implementation frameworks such as the Consolidated Framework for Implementation Research (www.cfirguide.org), provide the roadmap and tools to achieve this. To test this implementation strategy, we propose a study to spanning five different mental health care sites across Canada. In collaboration with partners and knowledge users, we will conduct a hybrid effectiveness-implementation trial and create a bilingual digital learning platform (English and French) to ensure the long-term use of these online interventions nationwide. The first aim of this study is to investigate the clinical effectiveness of the virtual modality of ABCR and MCT. The second aim of the study is to investigate the implementation strategy involving a) the contextual factors influencing the virtual delivery of cognitive health interventions, b) the effectiveness of a digital learning platform (E-Cog) to train mental health practitioners and c) the sustainability of the maintenance of these interventions within current clinical settings.

Methods

Ethical Considerations

This study was approved by the respective research ethics boards of the five mental health sites and their partner institutions.

Study Design

A hybrid effectiveness-implementation trial[31-33] relying on digital technology will be employed. The effectiveness component involves assessing the outcomes of these interventions, while the implementation component focuses on conducting the research in a way that emulates the naturalistic clinical setting. This design is ideal for transferring evidence-based behavioral interventions into real care environments[31-34] as it confirms clinical effectiveness while targeting necessary procedures to deliver and sustain such interventions in real-world care settings. A non-randomized concurrent control design will be used to assess clinical effectiveness where one

intervention acts as the active control for the other. The non-randomized concurrent control design was selected as it eases access to the preferred intervention by service users, overcoming challenges of randomizing participants in real care settings, and facilitating recruitment.

Sample and Setting

This study takes place across five sites providing care to those with psychotic disorders across Canada. These sites include the CIUSSS de l'Ouest-de l'Ile de Montréal, the Royal's Institute in Ottawa, Kingston Health Sciences Centre, Ontario Shores Centre for Mental Health Sciences in Toronto, and Vancouver Coastal Health. We will recruit 390 service users across the five sites. Inclusion criteria include: 18 years of age or older; diagnosis of affective or non-affective psychosis or related disorder; followed and treated by a clinician at one of the services mentioned above; considered symptomatically stable and capable of using the online platforms and participating in intervention groups, as judged by their primary clinicians; access to a private space to ensure group confidentiality; nomination of an emergency contact and to agree to allow researchers to contact their clinician and/or emergency services in the event of an emergency during study procedures. Most criteria are present for the safety of the group and participants. Exclusion criteria include intellectual disability; hospitalization at the time of recruitment; inability to speak or read English or French; high suicide risk as per evaluation. Service user recruitment will be conducted according to strategies developed based on the needs and expertise of each site. We will recruit 4-6 mental health practitioners per site who will complete training on the E-Cog training platform to deliver the two cognitive health interventions. Practitioners will be eligible if they have a background in psychology, social work, nursing, or any other health-related training.

Measures

To assess the effectiveness of the two virtual cognitive health interventions (objective 1), primary outcomes will encompass quantitative measures of cognitive capacity for ABCR and

cognitive biases for MCT. Secondary outcomes for both interventions will include clinical and functional measures. Propensity score matching will consider background characteristics such as sociodemographic variables, illness duration, medication dosage, length and nature of prior treatment, and subjective reports of cognitive capacity and biases. To evaluate the implementation strategy (objective 2), a combination of quantitative and qualitative data will be gathered. Refer to Table 1 for a breakdown of the data types to be collected, organized by objectives, time points, and stakeholders.

Table 1: Summary of the type of data to be collected as a function of objectives, time points and stakeholders.

Objectives / Data Type	Measures	Measurement Timepoint(s)	Stakeholder Groups
1. Effectiveness (Quantitative)	Subjective Cognition: • Subjective Scale to Investigate Cognition in Schizophrenia (STICSS-Brief) • Cognitive Motivation Scale (CMS) • Davos Assessment of Cognitive Biases Scale (DACOBS)	• Pre-intervention • Post-intervention • 3-month follow-up	Service users

	Cognitive Tests/Tasks: • Brief version of the CANTAB computerized battery (Intra-Extra Dimensional Set Shift, Stocking of Cambridge, Spatial Working Memory) • Weschler Memory Scale (Logical Memory Subscale) • Cognitive Bias Against Disconfirmatory Evidence (BADE story) • Jumping to Conclusion (Beads) Symptoms: • Positive and Negative Syndrome Scale (PANSS-6) • Brief Negative Symptom Scale (BNSS) • Psychotic Symptom Rating Scales (PSYRATS) Psychosocial: • Self-Esteem Rating Scale – Short-form (SERS-SF) • Overall Emotional and Social Loneliness Scale (OES) • Short Warwick-Edinburg Mental Well-Being Scale (SWEMWBS) • Questionnaire about the process of recovery (QPR) • Basic Psychological Need Satisfaction and Frustration Scale (BPNSFS) • Autonomous-Controlled Motivation for Intervention Questionnaire (ACMIQ) • Personal and Social Performance (PSP) Intervention • Health Care Climate Questionnaire (HCCQ) • Autonomous-Controlled Motivation for Intervention Questionnaire (ACMIQ) • MUSIC Cognitive Training Questionnaire • Satisfaction with Therapy (STQ) • Time spent on cognitive drill exercises (ABCR) • Last log in (iCog platform)	• Mid-intervention	Service users
2. Implementation (Quantitative; Qualitative)	2a. Evaluation of E-Cog platform: • Number of practitioners invited to participate in the E-Cog training • Number of practitioners agreeing to participate in E-Cog training • Reasons for non-participation/participation • Number of practitioners not agreeing to participate in E-Cog training • Total number of attendees participating in all of the training modules • Total number of attendees per session or module • Semi-structured interview (health care practitioners) 2b. Evaluation of factors influencing the implementation of the two virtual interventions: • E-Therapy Attitudes and Process Questionnaire – Therapist Version (eTAP-T) • Semi-structured interview (service users and health care practitioners) 2c. Sustainability: • Program Sustainability Assessment Tool (PSAT) • Monitoring of the intervention offer after effectiveness trial at each site	For 2a: • Pre-intervention • During intervention For 2b: • Post-intervention (8-12 months and 24-30 months after the two interventions are implemented) For 2c: • Post-intervention	Healthcare practitioners; service users

Cognitive Health Interventions

Interventions will be delivered through a secure videoconference platform. Network-

connected tablets will be provided as necessary for the trial duration. ABCR[35 36] sessions consist of computer-based cognitive training activities (Brain Training Pro; 60%), teaching of problem-solving strategies (20%), and transfer activities (20%). Transfer activities include discussing and role-playing how cognitive skills are applied in everyday life and teaching potential strategies for overcoming cognitive challenges. ABCR targets include processing speed, attention, memory, executive functions, and social cognition, which are all commonly impaired in psychosis.[37] ABCR will be delivered in 16 sessions lasting 1.5 hours each over an 8-week period. MCT targets cognitive biases and errors in judgment underlying delusions, using the theoretical foundations of CBT.[38] Sessions consist of discussions and activities aimed at increasing participants' awareness of distortions and expanding their current problem-solving strategies. MCT will be delivered in 12 sessions lasting 45–60-minutes each over six weeks.

Training Platform

E-Cog Training Platform (https://e-cog.ca/) is an online platform providing training certifications for ABCR and MCT interventions developed by our group following the ADDIE Model for the design of online learning platforms.[39] Each training certification includes three training modules: 1) impact of cognitive impairments in psychosis and an introduction to remediation strategies (2 hours); 2) technological tools for digital mental health (1 hour); 3) theoretical foundations and practical delivery of ABCR (~9 hours) or MCT (~12 hours). After obtaining the training certification, mental health practitioners participate in weekly supervision by a dedicated experienced trainer using a secure videoconferencing software. In addition, sessions will be audio-recorded and 15% of completed sessions will be randomly selected and reviewed by two experienced psychologists using the treatment integrity assessment tool.

Statistical Analysis

Power

Monte Carlo simulations computed in R were used to estimate the required sample size for our proposed models. Our analyses, based on simulated data, suggest that a total sample size of 300 provides enough statistical power (up to 90%) to detect anticipated effect sizes on primary outcomes of cognitive capacity and cognitive bias based on values from our group and those reported in the literature (CR: d=0.50; MCT: g=0.27).[9 21 28] The attrition rate for our virtual groups has been approximately 20%; we will nonetheless conservatively adjust for an attrition rate of 30%. When considering the propensity score, this results in a requirement of 390 participants. Comparable studies using the same interventions and statistical methods in in-person settings have included similar sample sizes as those proposed at our individual sites.[40 41] Further, this sample size will allow us to detect anticipated effect sizes on secondary outcomes related to symptomatology (CR: *d*=0.28, MCT: *g*=0.38)[42 43] and functioning (CR: d=0.36-0.51, MCT: d=0.37).[43 44] We also anticipate that the proposed sample size will be adequate to explore sex-and-gender-related differences, using subgroup analyses of 2 (male, female) and 4 (men, women, non-binary, other) groups, respectively.

Data analysis

Data related to the analysis of objective 1, focusing on clinical effectiveness, will be compared between both interventions. Primary and secondary outcomes will be compared between the two interventions, using one as the active control for the other. First, propensity score matching will be used to identify a subset of participants who will comprise the active control group that is equivalent to the intervention group on background variables (sociodemographic variables, illness duration, medication dosage, length and nature of prior treatment as well as subjective reports of cognitive capacity and cognitive biases). Then, Z-standardized outcome data will be compared between the groups with generalized linear mixed effect modeling (GLMM) techniques using R software. Factors of interest will include: fixed Time (pre, post, follow-up); fixed Treatment (ABCR, MCT); fixed time and treatment interaction (Time*Treatment); random Site (CIUSSS de l'Ouest-de l'Ile de Montréal, the Royal's Institute in Ottawa, Kingston Health Sciences Centre, Ontario Shores

Centre for Mental Health Sciences in Toronto, and Vancouver Coastal Health); random intercepts (Participants' ID) and random slopes (Participant*Time). Age, illness duration, medication dosage, length and nature of prior psychological treatment will also be included as fixed covariates. This procedure will be done twice, with the active control group subset using propensity score matching. This approach ensures that participants are not counted twice and is an integral part of the propensity score matching procedure. Statistically, performing the procedure twice helps to validate the robustness of the matching process without introducing bias, as each participant is only included once in each comparison. Specifically, the procedure will be as follows: (1) ABCR as the intervention and MCT as the active control, (2) MCT as the intervention and ABCR as the active control. Missing data pattern will be assessed for whether it is missing completely at random, missing at random, or not at random.[45] If data is missing at random multiple imputation will be applied,[46] if data is missing not at random, then the robustness of the primary analyses will be evaluated through sensitivity analyses.

Analyses for all implementation objectives will be executed using descriptive statistics for quantitative data and thematic analysis for qualitative data using Braun and Clarke's interpretive descriptive approach.[47] Emerging themes (e.g., facilitators, barriers) will be identified from the available CFIR semi-structured interview using the Nvivo software.[48] Three raters will independently perform an iterative qualitative analysis and once consensus is reached (≥ 80%) the remaining analyses will be completed by a single rater. A convergent QUAN-QUAL, mixed-methods design[49] will be used to compare the results from the quantitative data analyses for convergence and divergence, with the aim of developing an overall understanding of factors influencing implementation. Side-by-side comparison tables will be used to support our analysis process and to engage our implementation teams in finding interpretation.

Results

A pilot pragmatic trial[27] has been conducted previously at the Montréal site, where six cohorts (3 ABCR, 3 MCT) were run, evaluating three early implementation outcomes: acceptability, feasibility, and engagement. Of the 8 participants attending at least one session, 75% completed more than half of the sessions. All completers reported a positive experience with therapy, 2/3 were not bothered by the remote setting, and 77% trusted the confidentiality of the information shared. Technology did not appear to significantly impede program participation. Therapist-rated levels of engagement were also satisfactory.[27]

The current study was approved by the institutional review board by September 2023. From September 2022 to January 2023 staff training was conducted across all five sites. Intervention materials including intervention manuals and online portals began in June 2022 and continued until November 2023. Therapist training began on the E-Cog learning platform in April 2023 and is ongoing. All sites began recruitment in 2023 and have run cohorts of MCT and/or ABCR in their respective regions. Quantitative data collection occurs prior to and following the intervention group and is ongoing, qualitative data collection for implementation assessment will begin in summer 2024. To date, 56 therapists have completed training on the E-Cog training platform. Seventy-seven service users have been recruited for the study. The updated project timeline can be accessed for those who create free accounts here.

Discussion

Despite the significant impacts of cognitive impairments and cognitive biases in schizophrenia-spectrum disorders, these remain unmet clinical needs in clinical settings across the country. To address this, three significant innovations will emerge from this effectiveness-implementation trial.

First, this proposed national collaborative effort serves as a catalyst for leveraging digital technology to enhance the adoption of evidence-based psychosocial interventions. It will yield

valuable insights into the effectiveness of delivering ABCR and MCT virtually. Additionally, it signifies an adaptive response as the COVID-19 situation which prompted the use of digital platform to deliver services [50]. Providing online services increases the accessibility of services to those with severe mental illnesses, and previous studies have demonstrated that a significant portion of those with severe mental illnesses appear to have the required technological access and ability to join, participate, and benefit from online services.[51 52] If proven effective, these online interventions could be expanded to other service providers offering care for individuals with psychotic disorders and extended to other populations receiving mental health services, where these interventions are equally efficacious (e.g., mood disorders).[53-58]

Second, the implementation component of this study will furnish clinicians, hospital managers, and policymakers with timely and crucial information about leveraging digital health and mobile technologies to enhance access to psychosocial therapies for optimized care. This initiative will develop the essential expertise needed to guide the implementation of similar projects across Canada. Notably, New York State has already fully integrated cognitive remediation into its psychiatric care systems,[59] and parallel efforts are underway in Australia[60] and the UK.[61] Collaborating with a National Steering and Implementation Committee, we will test our set of tools based on the Consolidated Framework for Implementation Research (CFIR) and make them accessible to the mental health community. Site-specific implementation committees, which include patient-partners, will assist with the local implementation of our cognitive health interventions.

Finally, the proposed study will establish the capacity to deliver crucial and engaging online interventions, providing a platform to train and supervise therapists on a national scale. These interventions and training materials will be shared with the entire Canadian community, promoting a learning platform for the dissemination of these interventions.

Limitations

The non-randomized concurrent control design could raise concerns about potential group

differences. However, this is circumvented by statistically controlling for measurable background characteristics. Further, recruitment of therapists could be a limitation as therapists recruited to provide these interventions within this project may not reflect therapists that would provide these interventions in a non-research setting. This is partially mitigated by having therapists in some settings (e.g., BC) being recruited from the regional health authorities and not from research settings. Finally, differences across the five sites could be a limitation due to variability in training experiences and implementation fidelity. To address this concern, the training platforms are standardized to uphold intervention protocols, with fidelity checks conducted randomly across all sites.

Conclusions

In conclusion, this project aims to address pressing clinical needs related to cognitive impairments and biases in schizophrenia-spectrum disorders. It will leverage digital technologies to enhance the adoption of evidence-based interventions in clinical settings, facilitating future implementations of similar initiatives, and validate a platform designed.

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Data Availability

The data are available from the corresponding author upon reasonable request.

Authors' Contributions

CAY and HT: Writing - Original Draft, Investigation, Future Formal analysis; MB, SG, KL, ÉT, GS: Conceptualization, Methodology, Writing - Review & Editing; AES: Visualization, Writing - Review & Editing; CRB, MM, SM, MP, TW: Conceptualization, Methodology, Resources, Writing - Review & Editing; ML: Conceptualization, Methodology, Writing - Original Draft, Writing - Review & Editing, Supervision, Project administration, Funding acquisition; DRC: Conceptualization, Methodology, Writing - Original Draft, Writing - Review & Editing, Supervision.

Conflicts of Interest

CAY, HT, GS, MM, and DRC declare no conflicts of interest. This research was undertaken thanks in part to funding from the Canada First Research Excellence Fund awarded through the Healthy Brains, Healthy Lives initiative at McGill University and by a Canadian Institutes of Health Research Project Grant (#180501). This project is carried out in collaboration with the company SBT which provides licenses for the Happy Neuron platform. ML reports grants from Roche Canada, grants from Otsuka Lundbeck Alliance, personal fees from Boehringer Ingelheim, Janssen, Lundbeck Canada and Otsuka Canada outside the submitted work. SG has received financial compensation for consulting services from Boehringer Ingelheim, outside the submitted work. MB has received consulting fees from Boehringer Ingelheim. KML reports consulting fees from Otsuka Canada, Lundbeck Canada, and Boehringer Ingelheim.

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Supplementary Files

TOC/Feature image for homepages

iCogCA Infographic.