Adapting Cognitive Remediation Group Therapy as an Online or Hybrid Intervention for People Aging With HIV and Cognitive Concerns: Focus Group Protocol

Andrew D. Eaton¹,², Jenny Hui¹,³, Marvelous Muchenje¹,², Kate Murzin⁴, Soo Chan Carusone⁵, Francisco Ibáñez-Carrasco⁶, Nuelle Novik¹, John W. McCullagh⁷, Susanne Nicolay⁸, and Sharon L. Walmsley⁹

Abstract
Cognitive impairment is a significant health issue for people aging with HIV/AIDS. Cognitive challenges can include forgetfulness, trouble concentrating, and increasing struggles to learn new skills, all of which contribute to poorer mental health and decreased quality of life. Although there is no specific drug therapy that can reverse the brain impairment, group therapies may help people aging with HIV and cognitive challenges to better cope with their symptoms when combined with their usual medical treatment and follow-up. This community-based study will involve peer-led focus groups to discuss cognitive remediation group therapy – a combination of mindfulness-based stress reduction and brain training activities tested in a pilot randomized, controlled trial – as an in-person intervention for people aging with HIV in 2019. Via a brief demographic survey and technology-mediated focus groups (n = 40) in Ontario and Saskatchewan, we will determine how the intervention could be adapted in an online or hybrid format considering the ongoing COVID-19 pandemic. Content analysis will be employed whereby a team of independent coders will code the focus group transcripts in line with the co-design framework and “Double Diamond” model of developing interventions, including intervention structure, content, and mode of delivery. Given the aging of the HIV population in Canada, increasing support will be required in addition to medical care to improve quality of life, and proactively address concerns about cognition. This protocol provides a roadmap for adapting in-person psychosocial interventions using community-based and technology-mediated methods.

Keywords
focus groups, community-based research, methods in qualitative inquiry, virtual environments, action research

¹Faculty of Social Work, University of Regina, SK, Canada
²Factor-Inwentash Faculty of Social Work, University of Toronto, ON, Canada
³Ontario Institute for Studies in Education, University of Toronto, ON, Canada
⁴Realize, Toronto, ON, Canada
⁵Collaborative for Health and Aging, McMaster University, Hamilton, ON, Canada
⁶Dalla Lana School of Public Health, University of Toronto, ON, Canada
⁷HQ Toronto, ON, Canada
⁸Wellness Wheel Medical Clinic, First Nations and Métis Health Services, Saskatchewan Health Authority, Regina, Canada
⁹Toronto General Research Institute, University Health Network, Toronto, ON, Canada

Corresponding Author:
Andrew D. Eaton, Faculty of Social Work - Saskatoon Campus, University of Regina, 111-116 Research Dr, Saskatoon, SK S7N 3R3, Canada.
Email: andrew.eaton@uregina.ca

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Background

HIV and Aging

As the HIV/AIDS epidemic enters its fifth decade, aging with the virus has become a priority area of focus due to new HIV diagnoses among older adults and increased life expectancy for people living with HIV. In Canada, approximately half of the population living with HIV is now over fifty (Bourgeois et al., 2017), with 24.6% of new HIV diagnoses in 2017 occurring in this age group (McMillan et al., 2020; Public Health Agency of Canada, 2021). The Canadian provinces of Ontario and Saskatchewan are the setting of this study. In Ontario, the number of people over the age of 45 diagnosed with HIV increased from 2551 to 10,063 between 2000 and 2015 (Ontario HIV Epidemiology and Surveillance Initiative, 2018), and figures have continued to rise. Saskatchewan has the highest rate of new HIV infections in Canada, with the 40+ age group exhibiting the highest proportion of new infections (36.8/100,000) in the latest epidemiological report (Saskatchewan Ministry of Health, 2018). Life expectancy for people living with HIV who initiate treatment early, consistently adhere to combination antiretroviral therapy (cART), and are retained in HIV care may now be comparable to that of the general population (Wandel et al., 2016). However, aging-related comorbidities may present at an earlier age and in greater frequency among people living with HIV than among their seronegative peers (Ahn et al., 2019; Allavena et al., 2018; Wandel et al., 2016). HIV-related cognitive impairment is among the most common of these challenges (Allavena et al., 2018; Greene et al., 2015; Alford & Vera, 2018).

Psychosocial Support for Cognitive Impairment

Cognitive impairment is a significant comorbidity for people aging with HIV, yet biomedical interventions to improve cognition have largely been unsuccessful (Watkins & Treisman, 2015). Psychosocial support is needed to reduce the impacts, such as stress, anxiety, and poor coping, associated with irreversible health conditions (Gao et al., 2020). However, there is a paucity of cognition-focused psychosocial therapies tailored for people aging with HIV (Tedaldi et al., 2015). Those individuals have identified group interventions as their preferred approach to address cognitive challenges accompanying living with HIV (Illa et al., 2014; Liboro et al., 2019). Groups can foster social connection and reduce isolation, which is prevalent for people facing cognitive challenges (Eaton, 2021; Illa et al., 2014). Further, combination psychosocial interventions that blend strategies and discussion to ameliorate HIV-related health concerns may have better outcomes than single technique approaches (Evans et al., 2019). Our team has developed cognitive remediation group therapy (CRGT), a combination psychosocial intervention that was piloted in person amongst people aging with HIV and cognitive concerns in Canada in 2019 (Eaton et al., 2019, 2021). However, psychosocial interventions are increasingly being adapted as online or hybrid models due to the ongoing COVID-19 pandemic, and shifts in healthcare delivery towards online and hybrid formats appear to be lasting changes (Kasparian et al., 2022; Ye et al., 2022).

Summary of Preparatory and Pilot Research

This protocol is grounded in the needs of people aging with HIV in the context of community-based and clinical HIV organizations in Ontario and Saskatchewan. Our team has interviewed Ontario-based HIV service providers to learn about how they address cognitive challenges faced by people aging with HIV. The predominant response was that they implement educational sessions (Liboro et al., 2018). We have also interviewed people aging with HIV and cognitive concerns in Ontario. They identified a need for models of support that extend beyond these educational sessions (Illa et al., 2014; Liboro et al., 2019).

In response to these requests from people aging with HIV, our community-based team conducted a pilot RCT in 2019 to evaluate the novel CRGT model—combining MBSR and BTA in group therapy—against an active control of mutual aid group therapy for people diagnosed with mild-to-moderate HIV-Associated Neurocognitive Disorder (HAND) (Eaton et al., 2019, 2021). In this pilot, CRGT demonstrated better or equal results to mutual aid on outcomes of feasibility, acceptability, fidelity, stress, anxiety, coping, and use of mindfulness and BTA (Eaton et al., 2019, 2021). However, the small sample size (n = 12) limited the conclusions we could draw from the pilot. It was predominantly due to participants being required to have a formal HAND diagnosis, which is difficult to conclude (Eaton et al., in press; Ramirez-Garcia et al., 2019). That, by itself, limited our sampling frame to 40 individuals. Additionally, the onset of the COVID-19 pandemic at the time paused all in-person group therapy initiatives. The pandemic’s continuation suggests that group therapies may have to be delivered exclusively online, or using a hybrid model, for the foreseeable future. This proposal will determine how to adapt this promising intervention for an online or hybrid mode of delivery.

The in-person version of CRGT consists of nine three-hour sessions delivered once per week (Eaton et al., 2019; 2021). An initial three-hour group orientation session involves intervention goal setting, participant and facilitator introductions, establishing group norms and guidelines, principles of mindfulness-based stress reduction (MBSR) and brain training activities (BTA)—including how they will be combined—and setting participants up with BTA software. Eight weekly intervention sessions then occur, each comprised of: (a) 2 hours of MBSR to teach meditation, body scans, deep breathing, and other exercises to relieve stress; and (b) 1 hour of BTA, consisting of discussion on training progress and
challenges, alongside time for individual practice (Eaton et al., 2019, 2021).

MBSR follows a published curriculum of mindfulness and meditation activities both in session and via weekly homework assignments (Kabat-Zinn et al., 2017), that can reduce cognition-related stress (Chouinard et al., 2018) and anxiety (Berk et al., 2017). BTA are games or activities that can be completed on paper or available as software (e.g., PositScience by BrainHQ), that when practiced for >2 hours per week for >8 weeks can improve cognition-related coping (Vance et al., 2018). The pilot RCT of CRGT was the first known instance of BTA offered in a group setting, and the peer facilitators used a participatory approach to structure sessions as a mix of individual practice and group discussion on training progress and challenges (Eaton et al., 2019, 2021). This approach will be manualized with adaptations emerging from this study, as part of this study.

**Methods**

This study will utilize a co-design framework for adapting psychosocial interventions for online delivery (Banbury et al., 2021; Bevan Jones et al., 2020; Yeates et al., 2022). Co-design is one method of community-based participatory research that actively involves and centres the input of participants at each stage of intervention development, from defining key issues and developing solutions to delivering and evaluating services (Elbers et al., 2021; Thabrew et al., 2018). Importantly, this approach extends beyond simply soliciting participants’ feedback about an intervention or gauging participants’ responses to an intervention, because it “involves jointly exploring and articulating needs and jointly exploring and making solutions” (Thabrew et al., 2018, p. 1). In recent years, researchers have increasingly implemented co-design studies to develop psychosocial and health care interventions (Boyd et al., 2012; Elbers et al., 2021), particularly interventions delivered through digital or mobile platforms (Bevan Jones et al., 2020; Thabrew et al., 2018; Verbiest et al., 2019; Yeates et al., 2022).

To guide to our co-design approach, the proposed study will adopt a “Double Diamond” model of design (Figure 1) (Banbury et al., 2021; Design Council, 2019). This model consists of four phases: (1) Discover, (2) Define, (3) Develop, and (4) Deliver. Each phase may be categorized as diverging (exploring ideas and brainstorming options) or converging (taking focused action to implement ideas and prototypes) (Design Council, 2019; Elbers et al., 2021).

The first phase of the model, Discover (diverging), involves exploring problems and generating ideas by spending time with participants to understand their needs and perspectives (Banbury et al., 2021; Elbers et al., 2021). In this protocol, the initial phase will consist of two different forms of data collection: (a) a 15-minute survey questionnaire administered online via Qualtrics (Supplementary file 1); and (b) a 2-hour, semi-structured, peer-led focus group that will take place over Zoom (Supplementary file 2). The aim will be to gain a deeper understanding of participants’ needs regarding an online or hybrid adaptation of cognitive remediation group therapy (CRGT). For example, participants will be asked for their overall thoughts on how CRGT could support their cognitive health, including their opinions on the content and length of each session.

The second phase, Define (converging), typically involves defining and refining problems, as well as creating a framework for understanding the problems that emerged in phase one (Banbury et al., 2021). In this study, the second phase will occur through the transcription and analysis of data that was collected in the first phase. A team comprised of people aging with HIV, service providers, and researchers will take a participatory approach to content analysis in order to identify recurrent themes in the data.

The third phase, Develop (diverging), consists of creating, exploring, and testing solutions (Banbury et al., 2021). In our study, the third phase will employ: (a) member-checking with participants, with the aim of gathering feedback about the results of the study; and (b) partnership development, whereby sites (such as community-based HIV organizations) will be asked to host and co-host the intervention in a clinical trial. During this stage, participants will have the option of reviewing our draft findings (qualitative themes and adaptation plan) — either through web conference or e-mail (depending on the participants’ choice) — and sites will have the opportunity to provide input on the intervention plan.

The fourth and final phase, Deliver (converging), involves implementing and evaluating the intervention that was refined in the Develop phase. Implementation of the intervention could include discarding parts that do not work and improving on parts that are effective (Banbury et al., 2021). Within the proposed study, the last phase will deliver a trial of the adapted CRGT intervention to people aging with HIV and cognitive concerns in Ontario and Saskatchewan.

**Recruitment**

Individuals will be eligible to participate if they self-identify as HIV-positive, are over age 40, have concerns about their cognitive health, and reside in Ontario or Saskatchewan. Forty participants – ideally 20 from each province – will attend one of 5–6 online focus groups (each comprising 4–6 participants); this sample size has been used in extant research to co-design intervention adaptations (Yeates et al., 2022). Participants will be recruited using purposive sampling, as this method optimizes the recruitment of “respondents that are most likely to yield appropriate and useful information” in qualitative studies (Kelly, 2010, p. 317). Purposive sampling therefore strives to increase the depth—as opposed to the breadth—of understanding about a given topic, and operates from the assumption that specific individuals should be included in the sample because they hold differing and important views about the issue at hand (Campbell et al., 2020). Members of the research team will recruit via their
professional networks and within their organizations. Peer researchers will conduct community outreach at relevant community meetings and events. We will also promote the study via our partners’ websites and social media, and conduct additional outreach to other gerontological and HIV organizations in Ontario and Saskatchewan.

**Data Collection**

Data collection will consist of focus groups—preceded by a brief survey questionnaire—conducted with people aging with HIV in Ontario and Saskatchewan. The groups will have discussions regarding CRGT, how it could be adapted to an online or hybrid format, and related topics regarding HIV, aging, and cognition. The proposed study employs a community-based participatory research (CBPR) framework: peer researchers (i.e., people aging with HIV and with concerns about cognition) will be hired and trained using our team’s curriculum for peer researchers engaged in community-based participatory HIV research, which involves synchronous and asynchronous activities to prepare for research engagement (Eaton et al., 2018; Santorelli et al., 2017). Peers will subsequently assist with recruitment, co-facilitate the focus groups, contribute to analysis, co-author knowledge mobilization outputs, and join the team to prepare the proposal for an efficacy RCT. Peer researchers thus play a central role in our study, underscoring CBPR’s commitment to (1) collaborative, equitable partnerships and (2) co-learning and building capacity among all partners (Wallerstein et al., 2005).

Data collection will involve two primary methods: (1) a 15-minute survey questionnaire administered online via Qualtrics (Supplementary file 1), and (2) a 2-hour, semi-structured focus group that will take place over Zoom (Supplementary file 2). The survey questionnaire will be presented at an initial Zoom meeting with the first author, in which the participants may ask questions about the study, review the consent form, provide oral consent, and complete the online survey questionnaire. During this meeting, participants may also schedule their participation in a focus group. This survey is designed to gather information about participant demographics and cognitive health. Note that surveys have been designed to use wording that is accessible to individuals of Grade 4–5 reading

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**Figure 1.** Double diamond adaptation model.
level, as assessed using byreadable.com (an online readability evaluation software).

The focus group guide will begin with a description of the present study and a presentation on cognitive remediation group therapy (CRGT), including the results of the 2019 in-person pilot RCT. We decided to utilize a focus group guide because this qualitative methodology enables “favorable environmental conditions for spontaneous expression and interaction between the participants, encouraging people to share ideas, beliefs, experiences, or opinions during guided discussions” (Irazoki et al., 2021, p. 3), and it has been widely used to elicit feedback, opinions, and user experience among participants with cognitive impairment (e.g., Contreras-Somoza et al., 2022; Irazoki et al., 2021; Stephan et al., 2018; Vance et al., 2017). When the focus group commences, the facilitators will make a presentation of CRGT and its in-person RCT in 2019. The first section of questions will seek participant input on CRGT’s current components—an 8-session weekly 3-hour intervention consisting of 2 hours of mindfulness-based stress reduction and 1 hour of brain training activities (Eaton et al., 2019, 2021)—and query how these components could be modified for an online or hybrid intervention, and which components may be preferably synchronous or asynchronous. Participants will also be asked for their preferred sites to access CRGT (in the case of a hybrid model) and where they would most likely find recruitment information for CRGT. The second section will address participants’ cognitive health, including their current concerns, any medical or community support sought, compensatory strategies they have already attempted, and their interpersonal experiences discussing brain health (including possible instances of stigma). Following a break where focus group facilitators will check in on participants’ well-being, a third section will address cognitive screening considerations for an efficacy trial of CRGT. Based on our team’s experience piloting the in-person CRGT RCT and our combined years of research and practice, we have identified that a clinical diagnosis of HIV-associated neurocognitive disorder (HAND) may be a barrier to participation in CRGT. As such, a brief screen of cognition may be a more suitable entry condition with the option of referral to HAND testing upon completion of the intervention (Eaton et al., in press). Exploring the receptivity of this proposed process by people aging with HIV and cognitive concerns in focus groups will be important to determining a suitable, community-driven study design for the efficacy RCT.

Data Analysis

Each focus group will be audio-recorded and transcribed verbatim. The analysis team (people aging with HIV, service providers, and researchers) will then employ a participatory approach to content analysis (Bengtsson, 2016). Each team member will carefully read and review the transcripts to extract and organize quotes into a spreadsheet; quotes reflecting similar concepts or themes will be grouped together. Independent coding of the data will permit individual conceptualizations of participants’ preferences for an adapted CRGT and an efficacy RCT, while team meetings will subsequently take place to discuss convergence and divergence of identified themes, with the goal of achieving consensus regarding concepts and themes to include in an adapted intervention plan and RCT proposal (Grubin et al., 2022). All coding will be informed by the Consolidated Standards of Reporting Trials (CONSORT) checklist for reporting necessary components of an RCT, as we intend to define, develop, and deliver a clinical trial of the adapted CRGT intervention (Schulz et al., 2010). Prior to disseminating the results, we will conduct member-checking to discuss findings with participants via web conference or e-mail.

Ethics

This study poses minimal risks to participants, that the research team will strive to mitigate. Cognitive impairment and HIV/AIDS can be sensitive topics that together present a unique form of dual stigma and there is a possibility that participants may experience distress as a result (Eaton et al., 2021). The initial survey meeting is designed as an opportunity to thoroughly discuss the study’s consent form and upcoming focus group with each participant individually. Further, if participants indicate feeling distressed after any study meeting, the research team will provide local resources for additional support (Valdez & Gubrium, 2020).

Other ethical issues may emerge from the use of online platforms (e.g., Zoom, Qualtrics) for data collection and storage, thus this study will implement measures to ensure participants’ confidentiality and data security. When using Zoom for focus groups, recordings will be saved locally to the principal investigator’s computer—not to the cloud. Only the principal investigator will have access to the Zoom recordings; they will be deleted once the focus groups have been transcribed in a de-identified manner. When using Qualtrics online survey software for the brief questionnaire, participants will be assigned a unique identifier so that they do not have to provide identifiable information such as their names. Further, the online database of survey responses will be deleted once the survey is closed and responses have been downloaded to the principal investigator’s computer.

Co-design models strive for equity in research, yet a power dynamic inherent in conducting research with and for a marginalized population—in this case, people aging with HIV and cognitive concerns—remains (Eaton, 2021). The research team is comprised of members who possess extensive experience living as, researching with, and/or caring for people aging with HIV and related cognitive challenges. As such, the proposed study takes steps to centre the well-being, input, and lived experiences of people aging with HIV. They will be collaboratively involved throughout the entire research process, from recruiting participants to member-checking the final results and manuscript.
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Rigor

To establish and maintain qualitative rigor, the proposed study draws from Guba and Lincoln’s seminal model for “trustworthiness” in qualitative research, which identifies four evaluative criteria: (1) credibility, or internal validity; (2) transferability, or generalizability; (3) dependability, or reliability; and (4) confirmability, or objectivity (Guba & Lincoln, 1985).

Additionally, this study will use member-checking to ascertain credibility (Thomas & Magilvy, 2011). Participants will have the option of reviewing our draft findings (qualitative themes and adaptation plan) before dissemination and providing feedback, either through web conference or e-mail (according to the participants’ choice). Transferability will be established by providing detailed information about the sample being studied, for example, by elucidating the demographic and geographic boundaries of the study (Thomas & Magilvy, 2011). In writing thick descriptions of the study sample and context, this protocol lays essential groundwork for future researchers to transfer our findings to a different sample or context (Morse, 2015). Purposive sampling further enhances this study’s transferability, as such detailed inclusion criteria enables a full, contextual picture of the sample (Campbell et al., 2020). Meanwhile, dependability will be achieved through an “audit trail,” which involves detailed description of the purpose, methods, and findings of the study; this includes the present protocol (Thomas & Magilvy, 2011). The audit trail will also serve to establish confirmability, as an “audit trail offers visible evidence—from process and product—that the researcher did not simply find what [they] set out to find” (Bowen, 2009, p. 307).

Conclusion

This study protocol describes the use of the “Double Diamond” co-design framework to adapt a psychosocial Cognitive Remediation Group Therapy (CRGT) intervention for people aging with HIV and cognitive concerns to an online or hybrid format. Aspects of this protocol may be pertinent to other community-academic teams involved in developing, adapting, scaling, and implementing therapeutic strategies for comorbid, complex health conditions.

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ORCID iD

Andrew D. Eaton https://orcid.org/0000-0003-1331-1222

Supplemental Material

Supplemental material for this article is available online.

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