FULL TITLE:	IN HAND - Cognitive remediation group therapy to improve older adults' ability to cope with HIV-Associated Neurocognitive Disorder (HAND): A pilot randomized, controlled trial
Protocol No.	CTNPT 029
Sponsor:	University Health Network
Principal Investigator(s):	Mr. Andrew Eaton, AIDS Committee of Toronto (ACT), Factor-Inwentash Faculty of Social Work at the University of Toronto
Sub-Investigators / Collaborators:	Dr. Sharon L. Walmsley, Toronto General Research Institute (TGRI), University, Health Network (UHN) Dr. Shelley L. Craig and Dr. Barbara A. Fallon, Factor-Inwentash Faculty of Social Work at the University of Toronto Dr. Sean B. Rourke, St. Michael's Hospital, University of Toronto, Ontario HIV Treatment Network (OHTN)
Study Support/ Funding:	CIHR Canadian HIV Trials Network (CTN)
ClinicalTrials.gov Identifier:	<Type here>
Version No.	1.0
Date:	[31-October-2017]

Compliance Statement

This clinical study will be conducted in accordance with International Conference on Harmonisation (ICH) guidelines on current Good Clinical Practice (GCP), the Tri-Council Policy Statement Version 2 (TCPS2) and the Declaration of Helsinki.

Confidentiality Statement

This clinical study protocol contains information which is of a confidential, trade-secret or proprietary nature. The protocol is for the use of Andrew Eaton and his designated representatives participating in the investigational trial. It is not to be disclosed to any other person or party without the prior written approval of Andrew Eaton.

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INVESTIGATOR AGREEMENT

Protocol Title:	IN HAND - Cognitive remediation group therapy to improve older adults' ability to cope with HIV-Associated Neurocognitive Disorder (HAND): A pilot randomized, controlled trial
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This clinical study will be conducted in accordance with ICH guidelines on current GCP, the Tri-Council Policy Statement Version 2 (TCPS2) and the Declaration of Helsinki.

I confirm that I have read and understand this protocol and I agree to conduct this clinical study in accordance with the design and specific provisions of the protocol, with the exception of a change intended to eliminate an immediate hazard to participants. Any deviation from the study protocol will be documented in the case report form.

I agree to promptly report to the applicable ethics boards any changes in the research activity and all unanticipated problems involving risks to human participants or others. Additionally, I will not make any changes in the research without prior ethics and sponsor approval, except where necessary to ensure the safety of study participants.

Andrew Eaton		31-Oct-2017
Name	Signature	Date (dd-mmm-yyyy)

STUDY CONTACT DETAILS

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Sponsor	University Health Network (UHN)

ABBREVIATIONS AND DEFINITONS

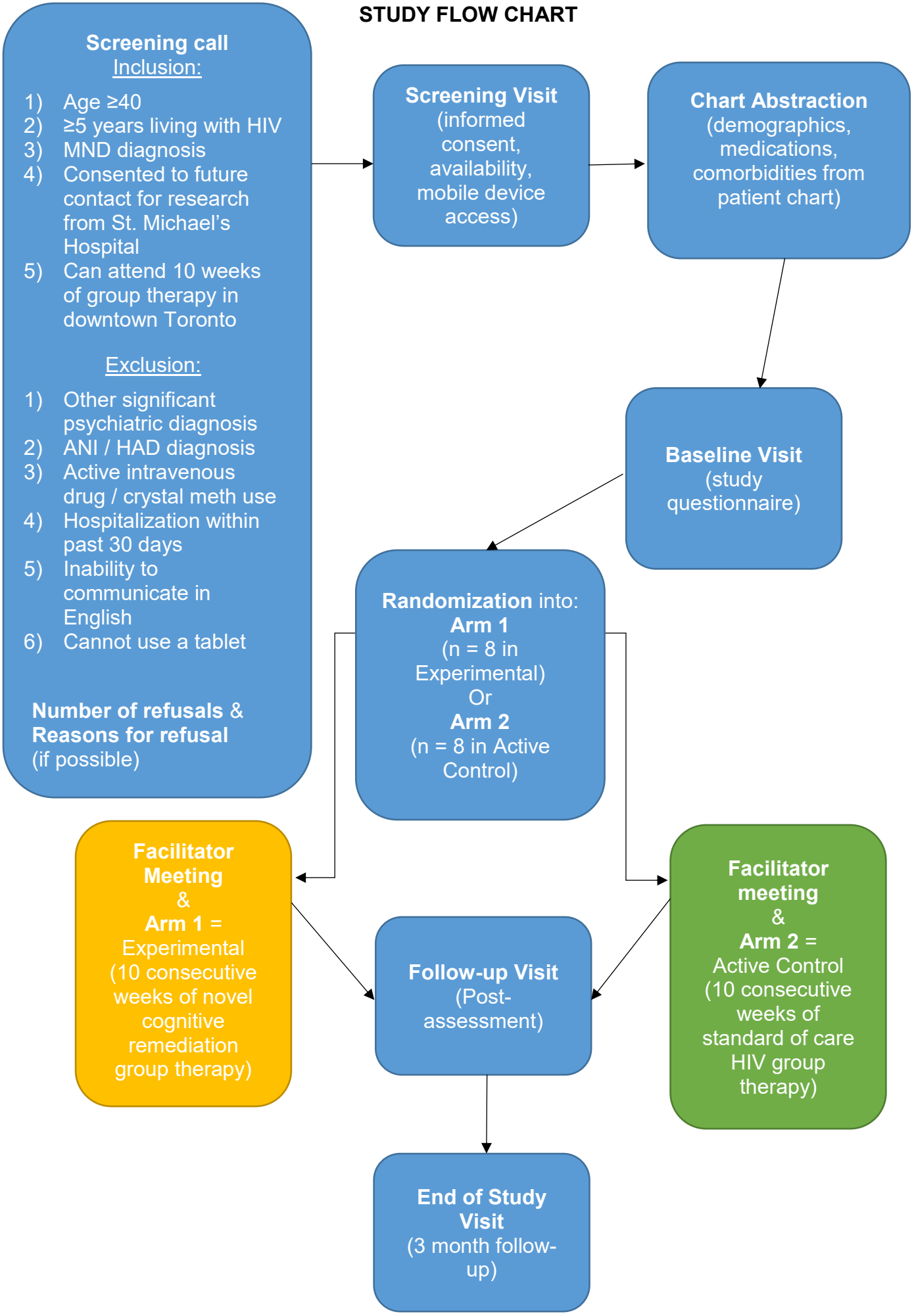
Acronym / Abbreviation	Definition
AIDS	Acquired immune deficiency syndrome
ANI	Asymptomatic neurocognitive impairment
ART	Anti-retroviral therapy
cART	Combination anti-retroviral therapy
CBR	Community-based research
CRGT	Cognitive remediation group therapy
DBT	Dialectical behavioural therapy
HAD	HIV-associated dementia
HAND	HIV-associated neurocognitive disorder
HIV	Human immunodeficiency virus
MBCT	Mindfulness-based cognitive therapy
MBSR	Mindfulness-based stress reduction
MND	Mild neurocognitive disorder
PLWH	People living with HIV

PROTOCOL SYNOPSIS

Full Title	IN HAND - Cognitive remediation group therapy to improve older adults' ability to cope with HIV-Associated Neurocognitive Disorder (HAND): A pilot randomized, controlled trial
Short Title	IN HAND
Protocol No.	CTNPT 029
Study Duration	Enrollment period: Three months
	Study period: Six months
Sponsor	University Health Network
Number of Centres	3
Study Design	Pilot; Parallel design randomized, controlled trial
Primary Objective	To compare the feasibility and acceptability of cognitive remediation group therapy (CRGT) against an active control as psychosocial treatment for older HIV-positive adults who have been diagnosed with mild-to-moderate HAND
Secondary Objectives	To determine the fidelity of the cognitive remediation group therapy (CRGT) model.
Exploratory Objectives	1. Change in stress, anxiety, and coping from pretest to posttest (between groups) 2. Sustained use of brain training activities 3. Change in use of mindfulness strategies (between groups)
Sample Size	N = 16
Randomization	1:1 8 in the treatment group and 8 in the active control group
Study Population	HIV-positive people ≥ 40 years of age who have been living with HIV for more than 5 years and who have completed neuropsychological testing, received a diagnosis of Mild Neurocognitive Disorder (MND)
Experimental Therapy Description	**Cognitive remediation group therapy:** 10 weekly 3-hour sessions; each session is comprised of 45 minutes of tablet-based cognitive training using PositScience, a 15-minute break, and 1.75 hours of Mindfulness-Based Stress Reduction (MBSR) with a 15-minute break halfway through the MBSR component.
Active Control	10 weekly 3-hour sessions with a 15-minute break at the end of each hour; each session is comprised of process-oriented facilitation using a mutual aid model (i.e., encouraging peer discussion of effects of HIV, aging, and cognitive impairment to identify and initiate coping strategies).
Duration of Study	Ten weeks
Outcome Measures	**Primary:** **Feasibility:** The sampling frame is approximately 100 people. The following targets (all based on a denominator of 100) would need to be met for a larger study to be considered feasible: $\geq$30% of those contacted agree to participate, $\geq$25% complete the pre-test, $\geq$20% attend the first session, $\geq$16% complete the full series and complete the post-test. Each participant must attend 80% (8/10) of the group sessions to be considered as completing the series.

	Acceptability: The sampling frame will be described (i.e., age, gender, ethnicity, length of time living with HIV, length of HAND diagnosis, length of time since last HAND follow-up at St. Michael's Hospital) in terms of those who agree and decline to participate. For those who cancel participation in the study, the research coordinator will follow-up by phone to ascertain the reason for attrition and this will be described, if the participant agrees. Participants will complete a standardized satisfaction scale (i.e., the Helping Characteristics of Self-Help and Support Groups Measure) that will be complemented by questions about session length, number of sessions, activities used, and evaluation of facilitators.
	Secondary: **Intervention fidelity:** Facilitators of both study arms will submit weekly session reports. These reports will include checklists of the therapy components; use of an average 80% of components listed will be considered as good fidelity. These reports will also include open-ended questions about the sessions, including questions on group dynamics, challenges faced, and detail on activities used.
	Exploratory: • Change in stress, anxiety, and coping. • Sustained use of brain training activities • Change in use of mindfulness strategies **Scales/Questionnaires:** • Anxiety in Cognitive Impairment and Dementia Scale • Coping Self-Efficacy Scale of Health Problems • HIV/AIDS Stress Scale • Five Facet Mindfulness Questionnaire—Short Form (FFMQ-SF)
Statistical Analysis	Depending on the nature of the exploratory results and the true sample size, non-parametric tests or a power analysis on the exploratory outcomes may be appropriate.

STUDY FLOW CHART



1. INTRODUCTION, BACKGROUND, AND STUDY RATIONALE

1.1 Background

Cognitive impairment is a significant co-morbidity for people aging with Human Immunodeficiency Virus (HIV). It is estimated that approximately 50% of the aging HIV-positive population will be affected by HIV-Associated Neurocognitive Disorder (HAND) (Greene et al., 2015; Grant et al., 2014). HAND is diagnosed in three forms based on Frascati criteria: (a) ***Asymptomatic Neurocognitive Impairment (ANI)*** – evidence of neuropsychological impairment in at least two cognitive domains but no evidence of functional impairment or difficulty with daily functioning; (b) ***Mild Neurocognitive Disorder (MND)*** – evidence of impairment in at least two cognitive domains and evidence of subtle but significant functional daily impairments or difficulty with daily functioning (e.g., with work or in social situations); and (c) ***HIV-Associated Dementia (HAD)*** – evidence of marked impairment in several of all cognitive domains and evidence of significant functional daily impairments or difficulty with everyday functioning and activities of daily living (Antinori et al., 2007). If untreated, HIV-infected persons may progress through these stages in rapid succession as shown by high rates of HAD prior to the introduction of successful Combination Anti-retroviral therapy (cART) (Monforte et al., 2004). With the development and widespread use of modern cART, and the trend towards earlier treatment initiation, HAND is now less common and less severe, although still exists (Grant et al., 2014). It is of particular concern in the Acquired Immune Deficiency Syndrome (AIDS) survivors – those who are currently aging with HIV, and who frequently were treated with incompletely suppressive antiretroviral regimens, medications that had higher rates of mitochondrial toxicity, and often after an AIDS defining illness or when the immune system was very weak (Antinori et al., 2013; Hopcroft et al., 2013). It is characterized by problems with cognition, memory deficits, difficulties in processing new information, impairment in executive function, errors in problem solving, poor decision making, etc (Spudich, 2013). This in turn leads to stress, anxiety, social isolation, difficulty coping, and may impact every day functioning such as adherence to medication and paying bills. (Tedaldi, Minniti, & Fischer, 2015). HAND is thought to result from structural damage in the fronto-striatial-thalamatory circuits in the brain, and hence there is no cure (Heaton et al., 2010) Strategies such as a switch to cART combinations with better central nervous system penetration have not been successful (Heaton et al., 2010; Monforte et al., 2004). With the addition of the cognitive decline of normal aging, HAND symptoms may become more apparent, further impairing the aging HIV-infected adult's ability to cope (Eaton, Craig, & Wallace, 2017; Hopcroft et al., 2013).

Psychosocial interventions have been studied in the general aging population with cognitive impairment and depression with the goal to decrease stress and depression and improve coping, daily functioning, and quality of life. Given success of these interventions in that setting, a similar approach might be useful to mitigate HAND's impact. However, research in this area is limited and most reports have studied only small cohorts, in diverse populations, and the optimal intervention type is unclear (Illa et al., 2014; Tedaldi, Minniti, & Fischer, 2015). Psychosocial factors (i.e., social networks, spirituality, mood) have been found to be significant predictors of the ability to cope with HAND when demographic variables (i.e., gender, age, educational level, and ethnicity) and neurocognitive variables (i.e., test scores) are controlled for (Cody et al., 2016). Cognitive remediation therapy training is developed to improve cognition in particular domains (like memory or speed or reasoning) or more globally (Cody, Fazeli, & Vance, 2015; Vance et al., 2010). The delivery of such training varies widely from person training with pen and paper or computer programs to group activities which may also be enhanced with exercise and nutritional advice. Cognitive remediation therapy has been found to decrease HAND-related stress and anxiety amongst middle-aged and older adults living with HIV (Cody, Fazeli, & Vance, 2015; Vance et al., 2010).

1.2 Selection of HAND Intervention Model

St. Michael's Hospital hosts a NeuroAIDS Research Program within their Neurobehavioural Research Unit. This program has been in operation for many years, and is the only site for gold standard neuropsychological HAND testing in Toronto, Ontario, Canada. People living with HIV who are concerned about thinking and memory problems are referred by their physician to this program for 3-4 hours of neurocognitive evaluation by a clinical neuropsychologist. As this is a research program, HAND-diagnosed participants are given the option of consenting to participate in further research.

The ideal HAND intervention model has yet to emerge. Brain training games have shown promise in people with HAND, especially in studies from Dr. David Vance at the University of Alabama at Birmingham. There are many options for psychosocial group therapy that have been tested in the general population with dementia and depression (e.g., Mindfulness-Based Stress Reduction (MBSR), Mindfulness-Based Cognitive Therapy (MBCT), and Dialectical Behavior Therapy (DBT)) (Gu, Strauss, Bond, & Cavanagh, 2015). These mindfulness interventions have demonstrated promising outcomes in reducing stress and anxiety, and improving coping. Although these strategies have not been fully tested in HAND, they could have similar benefit. To determine the components of the novel intervention in this trial, we interviewed six HAND researchers from the United States, Canada, Spain, and Australia. These conversations indicated that: a) initiating brain training software in a group setting would be a novel strategy that could improve uptake and use (PositScience by BrainHQ was the preferred software); and b) MBSR may be the most suitable group therapy to complement the brain training software (see more details below). The combination of brain training games and MBSR fits within the category of Cognitive Remediation Group Therapy (CRGT), according to these expert informants. Additionally, we held two focus groups in Toronto – one of community leaders who are aging with HIV (n=10) and one of service providers working in the field of HIV (predominantly social workers, n=8).These focus groups were held to ascertain the community's opinion on: a) the ideal brain training software out of a short list (i.e., PositScience by BrainHQ, Lumosity, or Elevate); b) the ideal group therapy (i.e., MBSR, MBCT, DBT); b) the logistics of the novel intervention arm (i.e., setting, time of day, length of each session); c) a study name brainstorm; and d) the questionnaires' language and ideal method of completion (i.e., in-person with a coordinator, online). Focus group attendees agreed with the expert informants that PositScience by BrainHQ was the most compelling option for a brain training game, based on personal use experience, existing literature, and the software's ability to be used on all devices (i.e., computer, tablet, phone). The focus groups also identified that weekday afternoons may be the ideal time, and that three hours per session (with a break each hour) is a suitable length. The method of administering the questionnaires (see section nine) and the study's title (IN HAND) were decided directly from the focus group feedback.

Brain training games from PositScience by BrainHQ have been associated with improved self-report in people with MND when focused on specific domains (such as executive functioning or speed-of-processing), however most work to date has provided this software to individuals in their homes with relatively low uptake. Uptake is especially low among those who have more severe cognitive impairment.

Mindfulness-Based Stress Reduction (MBSR) is currently being examined in people with MND in a trial at the University of California, San Francisco's Memory and Aging Center (Velcour, in communication). This study is showing some promising preliminary feasibility and acceptability. At this site, MBSR is delivered in a group therapy format for eight weekly 2-hour sessions. It is facilitated by regulated health professionals (i.e., social worker and a nurse) and includes meditation, deep breathing, yoga, and talk therapy activities.

Our study will blend brain training with MBSR in a group environment in an attempt to improve uptake of the PositScience activities and the emotional coping strategies that can emerge from MBSR. MBSR was selected instead of MBCT or DBT as: a) it can delivered in fewer sessions (the current guideline for DBT is a minimum 20 sessions); and b) MBSR is focused more on adaptive management as

opposed to the crisis-oriented behavior change that MBCT and DBT seek to impact. In the community and provider focus groups, MBSR was favored over the MBCT and DBT options. This combined focus on practical and emotional tools could show promise as a feasible, acceptable intervention model that can be tested in a larger trial.

1.3 Study Rationale

There is a need for effective HAND treatment, especially in older adults. A pilot trial is required before embarking on a full-scale study for the following reasons:

Complexity: HAND is a complex condition that has only begun to be addressed psychosocially in controlled settings. We have completed preliminary expert consultation to ensure that: (a) the design of the cognitive remediation group therapy (CRGT) aligns with interventions designed from this modality in other sites and contexts; (b) to determine how appropriate training will be provided to the facilitators of the pilot interventions; and (c) to review the measurement tools to ensure they are the best available for this pilot.

Determining Study Participants & Sample Size: Our entry criteria need to be tested in a pilot study to ensure feasibility and to determine sample size needed for a full-scale trial.

1.4 Potential Risks and Benefits to Human Participants

The proposed research requires participants to attend 10 consecutive weeks of group therapy sessions.

Risks

- Discomfort, anxiety, and/or unease arising from participants disclosing sensitive information about themselves to other participants in a group therapy setting.
- Legal risk regarding the standard limits of confidentiality (i.e., harm to self or other, neglect or abuse of a minor, abuse by a regulated health professional).

Benefits

- Potential to improve coping with HAND
- Potential for participants to make connections with one another for informal support following the therapy session
- Participants will contribute to a feasibility study that, if successful, would be the basis for a larger trial.

2. STUDY OBJECTIVES AND DESIGN

2.1 Overall Study Design

This is a pilot, parallel design, randomized, controlled trial (RCT) that will allocate a sample (n=16) of people (≥ 40 yrs old) aging with HIV who have been diagnosed with MND from St. Michael's Hospital (SMH) in Toronto to either ***arm 1:*** 10 weekly 3-hour sessions of CRGT; or ***arm 2:*** 10 weekly 3-hour sessions of HIV group therapy.

2.2 Primary Objectives

- Determine if a 10-session CRGT is feasible and acceptable to older adults with mild-to-moderate HAND.

Feasibility will be measured based on a sampling frame of approximately 100 people. The following targets (all based on a denominator of 100) would need to be met for a larger study to be considered feasible: ≥30% of those contacted agree to participate, ≥25% complete the Baseline Visit, ≥20% attend the first session, ≥16% complete the full series and complete the Follow-up Visit. Each participant must attend 80% (8/10) of the group sessions to be considered as completing the series. Similar targets have been set in other pilot studies of psychosocial interventions (Kazak et al., 2005; Ledderer et al., 2013). These targets are also set to ensure that the study feasibly lead to a larger trial, as support groups require a minimum four participants per session (Stewart, Usher, & Allenby, 2009). There is also a risk to intervention integrity and group cohesion if participants consistently miss multiple sessions, usually defined as more than two sessions in a time-limited program (Stewart, Usher, & Allenby, 2009).

For acceptability, the number of participants in the sampling frame will be reported. Those who consent to participate will be described (i.e., age, gender, ethnicity, length of time living with HIV, length of HAND diagnosis, length of time since last HAND follow-up at St. Michael's Hospital). For those who discontinue participation in the study, the research coordinator will follow-up by phone to ascertain the reason for attrition and this will be described, if the participant agrees. Participants will complete a standardized satisfaction scale (i.e., the Helping Characteristics of Self-Help and Support Groups Measure) that will be complemented by questions about session length, number of sessions, activities used, and evaluation of facilitators.

2.3 Secondary Objective

- Determine if a 10-session CRGT can be delivered with fidelity.

To measure fidelity, facilitators of both study arms will submit weekly session reports. These reports will include tick-box lists of the therapy components; use of an average 80% of components listed will be considered as good fidelity. These reports will also include open-ended questions about the sessions, including questions on group dynamics, challenges faced, and detail on activities used. Qualitative reports from each arm will be analyzed by coders familiar with the intervention models.

2.4 Exploratory Objectives

- To evaluate the change in stress, anxiety, and coping.
- Sustained use of brain training activities
- Change in use of mindfulness strategies

3. SELECTION AND ENROLLMENT OF PARTICIPANTS

3.1 Number of Participants

A total of 16 participants (8 in each study arm) will be enrolled.

3.2 Inclusion Criteria

1. Male or female; aged ≥ 40 years
2. Documented HAND diagnosis of Mild Neurocognitive Disorder (MND)
3. ≥ 5 years of HIV infection
4. Provided consent to St. Michael's Hospital to be contacted for future research studies
5. Can feasibly attend 10 weeks of group therapy in downtown Toronto

3.3 Exclusion Criteria

1. Diagnosis of another significant psychiatric diagnosis (i.e., schizophrenia, bipolar disorder, etc.) and/or past traumatic brain injury
2. Documented HAND diagnosis of asymptomatic neurocognitive impairment (ANI) or HIV-associated dementia (HAD)
3. Active intravenous or crystal meth drug use
4. Hospitalization within past 1 month
5. Inability to communicate in English
6. Inability to use a tablet

3.4 Concomitant Alcohol and "Street" Drug Use

Active intravenous drugs and/or crystal meth drug use will exclude potential participants from the study. Drug use will not be actively tested during the study period, however both arms will establish and maintain a 24-hour sobriety norm. Participants may be asked to leave a group session if their substance impairment is negatively effecting the group experience for other participants.

3.5 Recruitment and Enrollment Procedures

A list of participants who appear to meet entry criteria (based on their last clinic visit) will be provided to the research coordinator by the St. Michael's Hospital Neurobehavioral Research Unit. The research coordinator will sequentially contact participants by phone during a Screening Call, starting with those who accessed the clinic most recently. The study and entry criteria will be briefly described by phone and, if the prospective participant is interested, a Screening Visit will be scheduled between the potential participant and the research coordinator. The Screening Visit will involve the research coordinator meeting with the participant to discuss the study and review the informed consent form; if the participant does not consent, the visit will end. If the participant is interested but requests more time to look over the informed consent form with family, friends, or their family doctor, an alternative Screening Visit date can be scheduled. If the potential participant immediately consents to participate in the research study, the research coordinator will obtain the participant's preferred schedule to attend a 10-week group (i.e., afternoons, evenings), and will then discern the participant's access to a mobile device (i.e., smartphone or tablet). If a prospective participant does not have a mobile device that the PositScience software could be used on, a mobile device will be provided to the participant for the course of the study (returned at the follow-up visit). Participants will also be asked to self-report any changes that they have noticed in their cognition since their last clinic visit. The consent form will include a section allowing the research coordinator to conduct a chart review, to collect demographic information, health history and medication use to confirm eligibility. Once eligibility has been confirmed, participants will be contacted by the research coordinator to schedule a Baseline Visit. Baseline Visits will be held within the same week, to control for a potential time effect. At the conclusion of the Baseline Visit, the participant will be randomized into one of the two study arms. Participants will have a preliminary meeting with the therapy facilitators to acquaint themselves to the upcoming group prior to the first session. This meeting is described in a section 9.3.2.

3.6 Co-enrollment guidelines

Co-enrollment in another HAND or mindfulness treatment study is not permitted.

3.7 Sampling and Recruitment

There are approximately 100 people currently in the sampling frame (see Appendix V). This should provide an adequate frame to recruit participants (n = 16), especially as there is little other treatment

available for HAND in Toronto (or elsewhere). We will initiate the trial with a minimum of 75% participant enrolment (n = 12, with n = 6 in the Experimental arm and n = 6 in the Active Control arm) if required.

4. WITHDRAWAL OF PARTICIPANTS

4.1 Withdrawal criteria

Investigators may withdraw a participant from the study in the event that:

- a new health condition appears that is suspected to require care or medications prohibited by the protocol
- it is in the participant's best interest according to an Investigator's clinical judgment
- a participant misses two consecutive sessions
- a participant's substance use has become a hindrance to the experience of other participants

Participants may cancel their participation in the study at any time. When participants cancel, they will be asked if they consent to provide a reason for their withdrawal. Participants will not be replaced in this study once the group therapies commence, as replacement could negatively impact group dynamics.

4.2 Procedures for Discontinuation

If a participant withdraws or is removed from the study for any reason prior to the completion of the study, the reason will be recorded on the appropriate case report form (CRF).

5. RANDOMIZATION PROCEDURE

5.1 Randomization

Once enrollment is complete and all participants have consented to take part in the study and been screened for entry criteria, and attended the Screening Visit and Baseline Visit, the research coordinator will contact the CTN to request randomization assignments. Participants will be randomly assigned to one of the two study arms (Arm 1 = Experimental or Arm 2 = Active Control) using random numbers in blocks of size two. Randomization will be performed in a 1:1 fashion to allow for equal numbers of participants in both arms.

6. THERAPY OVERVIEW

6.1 Arm 1: Experimental Therapy

CRGT will be comprised of 10 weekly 3-hour sessions held at Toronto General Hospital and facilitated by an MBSR-certified social worker and a peer (i.e., person aging with HIV). The peer will lead facilitation of the brain training exercise, which will comprise 1/3 of each group session. The brain training exercise will be delivered on tablets using PositScience software by BrainHQ.This software will be downloaded to participants' mobile device (phone or tablet). If a participant does not have a mobile device, a tablet will be provided. This software tailors the participant experience based on deficit domains. Participants will work through activities and support one another through their various strengths and weaknesses. The MBSR-certified practitioner will lead facilitation of the MBSR

component, which will comprise the remaining 2/3 of each group session. MBSR involves various activities such as meditation, breathing exercises, etc. to achieve emotional regulation.

6.2 Arm 2: Active Control

The active control group will be comprised of 10 weekly 3-hour sessions of a *Living with HIV Support Group* held at the AIDS Committee of Toronto (ACT). This support group will be facilitated by a certified social worker and a peer (i.e., person aging with HIV). These groups use a model of mutual aid to encourage peer-based discussion on the effects of living with HIV. Topics are determined by the group; facilitators ensure that safety is maintained throughout and make connections between participants as appropriate. This model is the standard of group therapy for people with dementia (Toms, Clare, Nixon, & Quinn, 2015) and is also frequently used for people living with HIV community-based service organizations in Ontario.

7. RISKS AND PRECAUTIONS

7.1 Risk Management

There is potential for research participants/group members to expose sensitive information about the group and/or other group members. Research participants/group members will be asked during the consent process and throughout the group sessions to maintain the confidentiality of the group, however group members are not bound by professional obligations to maintain the confidentiality of the group. Facilitators are bound by professional obligations to maintain the confidentiality of the group. The potential exposure of sensitive information will be highlighted in the consent form, and research participants/group members will be advised to practice some caution before sharing personal and sensitive information. Participants will only be referred to by a first name, and will be offered the possibility of using a pseudonym in group.

Research participants/group members may also experience discomfort and/or unease with discussion topics that emerge in the group context. Throughout the group sessions, the co-facilitators will debrief with research participants/group members and offer them opportunities to discuss any discomfort one-on-one. Research participants/group members will also be provided with information related to other counselling and support services available to them.

In terms of legal risk, participants will be informed of the standard limits of confidentiality during the consent process (harm to self or other, neglect or abuse of a minor, abuse by a regulated health professional). Co-facilitators will follow all legal requirements, in adherence with the policies set out by the agencies participating in this project.

7.2 Mental Health Support

A list with crisis centres, counselling options, and emergency supports will be provided to participants. Participants will also be informed that they are welcome to avail themselves of free, confidential counselling at the AIDS Committee of Toronto (ACT) by a counsellor unrelated to the study team.

8. CLINICAL EVALUATIONS

8.1 Questionnaires

For all questionnaires, the coordinator will be provided with a script so that they do not bias the answers. Baseline, Follow-Up, and End of Study questionnaires (as identified in Table 1) will be completed on a tablet or computer, unless the participant prefers a paper version, with the research coordinator assisting the participant with understanding questions and selecting responses. The group

satisfaction questionnaire in sessions 5 & 10 will be completed on paper. This questionnaire will contain the scale identified in Table 1, and will be complemented by questions regarding satisfaction with session, length, content, and feedback on the facilitators.

The stress, anxiety, mindfulness, and coping questionnaires will be completed electronically on a tablet or computer by the participant with the research coordinator's assistance at baseline, post-therapy, and 3-month follow-up. These questionnaires can be completed on paper and entered into the database by the research coordinator if requested by the participants

The Helping Characteristics of Self-Help and Support Groups Measure will be completed on paper by participants in the fifth and in the final session of their group therapy.

- **Appendix I:**
  - HIV/AIDS Stress Scale (29 items, Likert, α = 0.76-0.85) (Packenham & Rinaldis, 2002).
- **Appendix II:**
  - Anxiety in Cognitive Impairment and Dementia (Gerolimatos et al., 2015)
- **Appendix III:**
  - Helping Characteristics of Self-Help and Support Groups Measure (20 items, Likert, α = 0.79-0.87)
- **Appendix IV:**
  - Five Facet Mindfulness Questionnaire – Short Form (FFMQ-SF) (24 items, Likert, α = 0.73-0.91)
- **Appendix V:**
  - Coping Self-Efficacy Scale of Health Problems (10 items, Likert, α = 0.779) (Gandoy-Crego et al., 2016)

9. STUDY PROCEDURES

9.1 Schedule of Events

Table 1: Schedule of Events

Study Period	**Screening Period**			**Study Period** (Facilitator meeting & 10 weekly, 3-hour sessions)			**Follow-up Period**	
Visit Name	Screening Call	Screening Visit	Baseline Visit	Facilitator meeting	Sessions 1-9	Sessions 5 & 10	Follow-up Visit	End of Study Visit (3 Month Follow-up)
Visit No.	-3	-2	-1	0	1,2,3,4,6,7,8,9	5 & 10	11	12
Week No.			-1	1-10			11	23
Day No.	-56 to -7 days		-7	1-70			77	167
Visit Window	+/- 7	+/- 7	+/- 7	+/- 7	+/- 0	+/- 0	+/- 7	+/- 7
Procedures:								
Written Informed Consent		X						
Entry Criteria Assessment	X	X						
Chart abstraction		X						

(demographics, medical history, medications)								
Randomization			X[2]					
Group Session (CRGT or Control)				X[3]	X	X		
Weekly Session Report[1]					X	X		
Helping Characteristics of Self-Help and Support Groups Measure Questionnaire						X		
HIV/AIDS Stress Scale			X				X	X
Anxiety in Cognitive Impairment and Dementia Scale			X				X	X
Coping Self-efficacy of Health Problems Scale			X				X	X
Five Facet Mindfulness Questionnaire – Short Form (FFMQ-SF)			X				X	X

[1] Completed by therapy facilitator
[2] To occur once all participants have been enrolled and eligibility confirmed
[3] Acquaintance with group only; no therapy will be administered during this session

9.2 Screening Period Procedures/Assessments

9.2.1 Screening Call [Visit no. -3]

The research coordinator will phone the participant to:

- Describe the study
- Review entry criteria
- Schedule a time to meet for the Screening Visit

It is expected that this call will be approximately twenty (20) minutes.

9.2.2 Screening Visit [Visit no. -2]

The following activities will occur at the Screening Visit:

- The Informed Consent Form will be reviewed with the participant
- The participant will be asked to sign the consent form

- The participant's availability to participate in a 10-session group will be ascertained (e.g., preference for afternoons, time of day)
- The participant's ability to access a mobile device (i.e., smartphone or tablet) will be determined

It is expected that this visit will be approximately thirty (30) minutes.

After the Screening Visit and if the participant has signed in the Informed Consent Form, the research coordinator will conduct a chart review to abstract demographics, medical history, and medications. This chart abstraction will confirm entry criteria.

9.2.3 Baseline Visit [Visit no. -1]

The following activities will occur at the Baseline Visit:

- The participant will be asked to complete the following study questionnaires:
    - HIV/AIDS Stress Scale
    - Anxiety in Cognitive Impairment and Dementia Scale
    - Coping Self-efficacy of Health Problems Scale
    - Five Facet Mindfulness Questionnaire – Short Form
    - Two brief questions on use of brain training activities

The Baseline Visit will take approximately thirty (30) minutes to complete.

9.3 Study Period Procedures/Assessments

9.3.1 Study Arms

Arm 1 (Experimental Therapy): CRGT will be facilitated by an MBSR-certified social worker and a peer (i.e., person aging with HIV). The peer will lead facilitation of the brain training exercise, which will comprise one-third of each group session. Brain training exercises will be delivered on tablets using PositScience software by BrainHQ. This software tailors participant experience based on deficit domains. Participants will work through activities and support one another through their strengths and weaknesses. The social worker will lead facilitation of the MBSR component, which will comprise the remaining time of each session. MBSR involves activities such as meditation and breathing exercises to achieve emotional regulation.

Arm 2 (Active Control): The active control group will be facilitated by a social worker and a peer. These groups use a model of mutual aid to encourage peer-based discussion on the effects of living with HIV. Topics are determined by the group; facilitators ensure that safety is maintained throughout and make connections between participants as appropriate.

9.3.2 Facilitator Meeting [Visit no. 0]

The Facilitator meeting in both study arms will include a preliminary meeting with the experimental therapy and active control facilitators to acquaint themselves to the upcoming group prior to the first session. This will take approximately 20 minutes and will take place at the therapy site (**arm 1 (Experimental):** Toronto General Hospital; **arm 2 (Active Control):** ACT).

9.3.3 Therapy Sessions 1, 2, 3, 4, 5, 6, 7, 8, 9 & 10 [Visit no. 1, 2, 3, 4, 5, 6, 7, 8, 9, & 10]

During these visits all participants will attend the three-hour sessions as described above during ten consecutive weeks.

After each visit, the therapy facilitator will complete a weekly session report.

At the conclusion of visits 5 & 10, the following activity will occur:

- Participants will be asked to complete the “Helping Characteristics of Self-Help and Support Groups Measures” questionnaire.

This questionnaire will take approximately ten minutes to complete.

9.4 Follow-up Period Procedures/Assessments

9.4.1 Follow-up Visit [Visit no. 11]

The participant will be asked to complete the following study questionnaires:

- HIV/AIDS Stress Scale
- Anxiety in Cognitive Impairment and Dementia Scale
- Coping Self-efficacy of Health Problems Scale
- Five Facet Mindfulness Questionnaire – Short Form
- Two brief questions on use of brain training activities

This visit will take approximately thirty (30) minutes to complete.

9.5 End of Study Visit [Visit no. 12]

The participant will be asked to complete the following study questionnaires:

- HIV/AIDS Stress Scale
- Anxiety in Cognitive Impairment and Dementia Scale
- Coping Self-efficacy of Health Problems Scale
- Five Facet Mindfulness Questionnaire – Short Form
- Two brief questions on use of brain training activities

This visit will take approximately thirty (30) minutes to complete.

9.6 Early Termination

If a participant cancels participation in the study, the research coordinator will attempt to follow-up with them to determine the reason for cancellation. These reasons will be described to inform the feasibility and acceptability outcomes.

10. STATISTICAL CONSIDERATIONS

10.1 General Study Design

This study is primarily focused on feasibility, acceptability, and intervention fidelity. Feasibility and acceptability will be analyzed using descriptive statistics (# of attendees, % satisfaction, etc.). Intervention fidelity will be analyzed qualitatively regarding how closely the facilitators adhered to their intervention model.

10.2 Sample Size Considerations/Justification

A sample size of 16 participants (8 in each study arm) has been selected as: (a) 8 participants has been found to be an ideal size for a 10-week group therapy intervention (Stewart, Usher, & Allenby, 2009; Erickson, 1982; Weis, 2003); and (b) this number will provide preliminary insight into the acceptability of novel CRGT arm, which will be important to consider before the larger RCT is initiated. This sample size has also been selected for feasibility: 16 qualifying participants can be feasibly enrolled in the pilot given the number of qualifying participants available for sampling from the patients tested for HAND at St. Michael's Hospital Neurobehavioral Research Centre (N=~100). It is expected that this sample can be enrolled in a 2-month period.

10.2.1 Efficacy: Intent-to-Treat

The intent-to-treat (ITT) data set will include data from all randomized participants. All data will be included and no participants excluded because of protocol deviations. The proportion of patients who consented to participate and who actually participated will be described against the total number of patients contacted.

10.3 Analysis of Demographic and Baseline Data

Demographics will be described, to provide characteristics (i.e., gender, age, ethnicity, sexual orientation) of participants in this pilot study.

10.4 Analysis of Primary Outcome Measures

Feasibility and acceptability results will be reported against the targets specified in Section 2.2 of this protocol.

10.5 Analysis of Secondary Outcome Measures

The sample size severely limits any statistical procedures for analyzing change in stress, anxiety, and coping. Depending on the nature of the results (and the true sample size), non-parametric tests or a power analysis may be appropriate.

10.6 Other Analytical Issues / Considerations

Loss to follow-up rates are important to consider for the feasibility of a larger trial. The research coordinator will attempt to contact a participant on three separate days to schedule follow-up visits. A participant will be welcome to attend the Follow-Up and End-of-Study visits within +/- 2 weeks of the actual visit date.

11. STUDY ETHICAL CONSIDERATIONS

11.1 Ethical Conduct of the study

This study will be conducted in accordance with the ICH GCP Guidelines, the Tri-Council Policy Statement Version 2 (TCPS2) and the principles in the Declaration of Helsinki.

11.2 Informed Consent

All participants will be given detailed oral and written information about the study. Consent forms describing in detail the study procedures and risks will be given to each participant and written documentation of informed consent is required prior to starting any study procedures. Participants

must sign an informed consent document that has been approved by a participating centre's REB/IRB prior to any procedures being done specifically for the trial. Each participant should have sufficient opportunity to discuss the study, have all of their questions addressed and consider the information in the consent process prior to agreeing to participate. Participants may withdraw consent at any time during the course of the study without prejudice. The informed consent form will be signed and dated by the participant and the study coordinator. The original signed informed consent form will be retained in the participant's study files and a copy will be provided to the participant.

The informed consent form must be signed before the participant undergoes any screening procedures that are performed solely for the purpose of determining eligibility for the study.

11.3 Confidentiality

All participant-related information including Case Report Forms, evaluation forms, reports, etc. will be kept strictly confidential. All records will be kept in a secure, locked location and only accessible to research staff. Participants will be identified only by means of a coded number specific to each participant . All computerized databases will identify participants by numeric codes only, and will be password protected.

Upon request, and in the presence of the investigator or his/her representative, participant records will be made available to the study sponsor, monitoring groups representative of the study sponsor, representatives of funding groups, and applicable regulatory agencies for the purpose of verification of clinical trial procedures and/or data, as is permissible by local regulations.

11.4 Institutional Review Board, Ethics Committee, or Research Ethics Board

A copy of the protocol (including protocol amendments), all versions of informed consent forms, other information to be completed by participants such as survey instruments or questionnaires, and any proposed advertising/ recruitment materials must be reviewed and approved by the REB/IRB of each participating centre prior to implementation of the trial. The site investigator will be responsible for obtaining REB/IRB approval of the annual Continuing Review throughout the duration of the study.

12. General Trial Conduct Considerations

12.1 Adherence to Protocol

12.1.1 Protocol Deviations

No deviations from this protocol will be permitted without the prior written approval of the Sponsor, except when the modification is needed to eliminate an immediate hazard or hazards to participants. Any deviations that may affect a participant's treatment or informed consent, especially those increasing potential risks, must receive prior approval from the REB unless performed to remove an immediate safety risk to the participants. In this case it will be reported to the REB and the Sponsor immediately thereafter. Any departures from the protocol must be documented.

12.2 Record Keeping

12.2.1 Data Collection

All data will be entered electronically into a password-protected study database that will be accessible by the study team and the CTN. All paper documents will be stored in a locked filing cabinet in the

office of Andrew Eaton at the AIDS Committee of Toronto (ACT) for a period of seven years, at which point they will be destroyed.

12.2.2 Data Corrections

Corrections of data entered on source documents must be made in the following manner:

- The original response crossed out and the new response indicated in blueink. The change will be initialed and dated by the person making the correction.

12.2.3 Source Documents

The Investigator must maintain adequate and accurate source documents upon which CRFs for each participant are based. They are to be separate and distinct from CRFs except for cases in which the Investigator has pre-determined that direct data entry into specified pages of the participant's CRF is appropriate. These records should include detailed notes on:

- Oral and written communication with participant regarding the study therapy (risks/benefits)
- Participation in trial and signed and dated informed consent forms
- Inclusion and exclusion criteria details
- Visit dates
- Reason for premature discontinuation (if applicable)
- Enrollment number
- Compliance/noncompliance protocol deviation information

12.2.4 Data Management

Instructions concerning the recording of study data on CRFs will be provided by the CTN Data Management Centre. Each study site is responsible for submitting the data in a timely fashion.

Detailed aspects of data handling will be described in the Data Management Plan.

12.2.5 Record Retention

The Investigator will maintain all study records according to the ICH-GCP and REB/IRB requirements. Records will be retained for 7 years. If the Investigator withdraws from the responsibility of keeping the study records, custody must be transferred to a person willing to accept the responsibility and the Sponsor notified. The Investigator should ensure that no destruction of medical records occurs without the written approval of the Sponsor.

13. Disclosure and publication Policy

We plan to publish three academic papers based off this study: a) pilot trial protocol; b) feasibility and acceptability results; and c) a CRGT intervention fidelity paper.

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APPENDICES

Appendix I - HIV/AIDS Stress Scale

Below is a list of problems that people living with HIV sometimes have. For each question, there are two examples to describe the problem. Your own examples may differ from the ones provided, so long as they seem to fit within the problem category. Please circle a number to the right of each question that best describes how troublesome that problem has been for you during the past month.

How much were you troubled by:	Not at all	A bit (once or twice in the past month)	Moderate (once or twice a week for the past month)	A lot (three to six times a week for the past month)	Extreme (daily)
1. **Distressing emotions related to HIV** (e.g., you feel angry or fearful; you feel anxious or depressed)	0	1	2	3	4
2. **Relationship difficulties related to HIV** (e.g., you have arguments with your support person about how to best care for your health; you have difficulty establishing a relationship)	0	1	2	3	4
3. **Grief/bereavement related to HIV** (e.g., you are concerned about your own losses such as loss of independence; you are grieving for the loss of a loved one from AIDS)	0	1	2	3	4
4. **Confidentiality/privacy concerns related to HIV** (e.g., you are concerned about your HIV status breached; you are reluctant to disclose your status to others)	0	1	2	3	4
5. **Sexual difficulties related to HIV** (e.g., you're finding it hard to maintain safe sex behaviours; you are sexually frustrated)	0	1	2	3	4
6. **Difficulties in coming to terms with your HIV status** (e.g., you can't accept that you have HIV; you refuse to even think about HIV)	0	1	2	3	4
7. **Concerns about death related to HIV** (e.g., you are preoccupied with dying; you don't think about the possibility that you may die from HIV)	0	1	2	3	4
8. **Isolation related to HIV** (e.g., you have less contact with others because of HIV; you don't get invited out much now that you have HIV)	0	1	2	3	4
9. **Suicidal thoughts/attempts related to HIV** (e.g., you have thoughts of ending your life; you have actually attempted to end your life)	0	1	2	3	4

10. **Increased drug/alcohol intake related to HIV** (e.g., you use drugs and/or alcohol more now; you are often high or drunk)	0	1	2	3	4
11. **Discrimination/stigma concerns related to HIV** (e.g., you are concerned that you will be discriminated against because of HIV; you feel as if you have not been treated with respect)	0	1	2	3	4
12. **Religious/existential difficulties related to HIV** (e.g., you are having difficulty searching for meaning in your life; you are struggling to make sense of the predicament you are in)	0	1	2	3	4
13. **Overly attentive to bodily functions or changes** (e.g., you are constantly checking for HIV-related symptoms; you are overly attentive to any new physical changes such as appearance of a rash)	0	1	2	3	4
14. **Difficulties in telling others of your HIV status** (e.g., you don't know who, how, or when to tell of your HIV status; you have only told one or two people)	0	1	2	3	4
15. **Boredom related to HIV** (e.g., you are unable to use your free time doing things you would normally enjoy; you often find yourself sitting about doing nothing)	0	1	2	3	4
16. **Difficulty dealing with HIV-related symptoms of illness** (e.g., you often have difficulty dealing with fatigue or nausea; you have pain and physical discomfort most of the time)	0	1	2	3	4
17. **Difficulty in enhancing your health** (e.g., your attempts to maintain adequate nutrition, or a positive mental attitude often are short-lived)	0	1	2	3	4
18. **Difficulty with health care system** (e.g., you have difficulties in getting access to health services such as dentists or home care)	0	1	2	3	4
19. **Difficulties with HIV treatment** (e.g., you have difficulties managing side effects from HIV treatments; you can't adhere to HIV treatment)	0	1	2	3	4
20. **Transport difficulties related to HIV** (e.g., you have difficulty getting appropriate transport to places; public transport is physically demanding)	0	1	2	3	4
21. **Financial difficulties related to HIV** (e.g., you are unable to pay debts; you have problems with superannuation payouts)	0	1	2	3	4
22. **Daily living difficulties related to HIV** (e.g., you can't always do the shopping or cleaning; you can't keep up with the basic day-to-day chores)	0	1	2	3	4

23. **Reducing risk of infection** (e.g., you are preoccupied with thoughts about transmitting HIV to others; you can concerned that some of your behaviours may put others at risk)	0	1	2	3	4
24. **Difficulty in accessing information related to HIV** (e.g., you have received conflicting information on HIV; you can't get adequate treatment information)	0	1	2	3	4
25. **Employment difficulties related to HIV** (e.g., you can't obtain/maintain employment because of illness; you are concerned about work-related stress)	0	1	2	3	4
26. **Legal problems related to HIV** (e.g., you are involved in a legal process; you don't know who to assign power of attorney to)	0	1	2	3	4
27. **Planning difficulties related to HIV** (e.g., uncertaint with your health makes career planning difficult; you don't know whether to start new projects)	0	1	2	3	4
28. **Difficulties with thinking processes related to HIV** (e.g., you forget things more than usual; you can't concentrate as well as usual)	0	1	2	3	4
29. **Dealing with declining health related to HIV** (e.g., you have difficulty in dealing with increasing physical restrictions due to declining health; you have difficulty dealing with the change from being well to having illness)	0	1	2	3	4

Appendix II - Anxiety in Cognitive Impairment and Dementia Scale

Please circle yes or no for the following questions, thinking about the past 24 hours. If you answer yes to the numbered questions, please answer the corresponding letter question below it.

In the past 24 hours:

1. Have you experienced worry? Yes No
   (e.g., about health, memory of cognitive functioning, friends and family, etc.)
   a. If so, did worrying bother you? Yes No
2. Have you experienced anxiety? Yes No
   (e.g., about health, memory of cognitive functioning, friends and family, etc.)
   a. If so, did the anxiety bother you? Yes No
3. Have you been startled? Yes No
   (e.g., sudden scare, no sense of time and place, etc.)
   a. If so, did the startle bother you? Yes No
4. Have you experienced insomnia? Yes No
   (e.g., sleeplessness, etc.)
   a. If so, did the insomnia bother you? Yes No
5. Have you experienced irritability? Yes No
   (e.g., low patience, expression of frustration, etc.)
   a. If so, did the irritability bother you? Yes No
6. Have you experienced muscle tension? Yes No
   a. If so, did the muscle tension bother you? Yes No
7. Have you experienced restlessness? Yes No
   (e.g., fidgeting, etc.)
   a. If so, did the fidgeting bother you? Yes No
8. Have you experienced fatigue? Yes No
   (e.g., overly tired, not as much energy as normal etc.)
   a. If so, did the fatigue bother you? Yes No
9. Have you experienced cardiovascular issues? Yes No
   (e.g., chest pain, etc.)
   a. If so, did the cardiovascular issues bother you? Yes No
10. Have you experienced respiratory issues? Yes No
    (e.g., shortness of breath, etc.)

a. If so, did the respiratory issues bother you? Yes No

11. Have you experienced gastrointestinal issues? Yes No
(e.g., diarrhea, excessive flatulence, etc.)

a. If so, did the gastrointestinal issues bother you? Yes No

12. Have you experienced other somatic issues? Yes No
(e.g., pain, depression, etc.)

a. If so, did the somatic issues bother you? Yes No

13. Have you experienced any avoidance behaviours? Yes No
(e.g., denial, not wanting to attend appointments, etc.)

a. If so, did the avoidance behaviour bother you? Yes No

Appendix III - Helping Characteristics of Self-Help and Support Groups Measure

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Factor 1: Instilling Hope and Sense of Control

1. Since I started coming to meetings, I have begun to have more faith in my ability to change myself.[a]
2. Since I started coming to meetings, I have begun to cope much better with my life.
3. The group helps me find new coping strategies.
4. The group has helped me learn ways of solving my problems.[b]
5. The group has helped me find ways of controlling myself.

Factor 2: Alternative to Loneliness and Professional Intervention

6. The group makes me feel I'm not alone with my difficulties.
7. The group takes me out of my loneliness.
8. A professional could never understand me the way group members can.
9. The group helps me evaluate my coping strategies.
10. The group makes me feel I can function as well as anyone else.
11. Other group members' knowledge and experience helps me as much as the help I could get from professionals.

Factor 3: Emotional Disclosure and Catharsis

12. I share my life experiences with other members of the group.
13. I share my troubles with other members of the group.
14. Members of the group disclose personal and intimate details of their lives.
15. The group helps me to release tension.

Factor 4: Members' Experiential Knowledge

16. I contribute my own knowledge and experience to the other members.
17. I help the members of the group a lot through my own knowledge and experience.
18. The knowledge and experience I acquired as a result of my situation contribute to the group at least the same as the knowledge of a professional.

Factor 5: Caring and Concern

19. When something bothers me, members of the group treat me kindly.
20. Group members care about each other.

Factor 6: Coping Methods ("tips")

21. I give group members "tips" on how to cope with daily situations.
22. The group offers me "tips" on how to cope with daily situations.

Note . a. The range for items 1 to 3, 5, 9, 16, 21, and 22 after reversing the scale is 1 = never to 5 = always.
b. The range for items 4, 6 to 8, 10 to 15, and 17 to 20 is 1 = certainly wrong to 6 = certainly right.

Appendix IV – Five Facet Mindfulness Questionnaire – Short Form (FFMQ-SF)

Below is a collection of statements about your everyday experience. Using the 1–5 scale below, please indicate, in the box to the right of each statement, how frequently or infrequently you have had each experience in the last month (or other agreed time period). Please answer according to what really reflects your experience rather than what you think your experience should be.

never or very rarely true	***not often true***	***sometimes true sometimes not true***	***often true***	***very often or always true***
1	***2***	***3***	***4***	***5***

1	I'm good at finding the words to describe my feelings	*DS*	
2	I can easily put my beliefs, opinions, and expectations into words	*DS*	
3	I watch my feelings without getting carried away by them	*NR*	
4	I tell myself that I shouldn't be feeling the way I'm feeling	*/NJ*	
5	it's hard for me to find the words to describe what I'm thinking	*/DS*	
6	I pay attention to physical experiences, such as the wind in my hair or sun on my face	*OB*	
7	I make judgments about whether my thoughts are good or bad.	*/NJ*	
8	I find it difficult to stay focused on what's happening in the present moment	*/AA*	
9	when I have distressing thoughts or images, I don't let myself be carried away by them	*NR*	
10	generally, I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing	*OB*	
11	when I feel something in my body, it's hard for me to find the right words to describe it	*/DS*	
12	it seems I am "running on automatic" without much awareness of what I'm doing	*/AA*	
13	when I have distressing thoughts or images, I feel calm soon after	*NR*	
14	I tell myself I shouldn't be thinking the way I'm thinking	*/NJ*	
15	I notice the smells and aromas of things	*OB*	
16	even when I'm feeling terribly upset, I can find a way to put it into words	*DS*	
17	I rush through activities without being really attentive to them	*/AA*	
18	usually when I have distressing thoughts or images I can just notice them without reacting	*NR*	

never or very rarely true 1	***not often true 2***	***sometimes true sometimes not true 3***	***often true 4***	***very often or always true 5***

19	I think some of my emotions are bad or inappropriate and I shouldn't feel them	*/NJ*	
20	I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow	*OB*	
21	when I have distressing thoughts or images, I just notice them and let them go	*NR*	
22	I do jobs or tasks automatically without being aware of what I'm doing	*/AA*	
23	I find myself doing things without paying attention	*/AA*	
24	I disapprove of myself when I have illogical ideas	*/NJ*	

correct scores for items preceded by a slash (/NJ, /AA, etc) by subtracting from 6

non react = ; observe = ; act aware = ; describe = ; non judge =