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PARTICIPANT INFORMATION AND CONSENT FORM

Study 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 Number:	CTNPT 029
Principal Investigator:	Mr. Andrew D. Eaton, MSW, RSW, PhD Student Factor-Inwentash Faculty of Social Work, University of Toronto Group Programming Coordinator, AIDS Committee of Toronto (ACT) 416-340-8484 ext. 283 (Monday to Friday 9am-5pm)
St. Michael's Hospital Investigator:	Dr. Sean B. Rourke, MD, PhD, FCAHS Clinical Neuropsychologist, St. Michael's Hospital Scientist, Li Ka Shing Knowledge Institute Professor of Psychiatry, University of Toronto 416-878-2779 (Monday to Friday 9am-5pm)
Co-Investigator(s):	Dr. Sharon L. Walmsley, Toronto General Research Institute (TGRI) University, Health Network (UHN) Dr. Shelley L. Craig, Factor-Inwentash Faculty of Social Work, University of Toronto Dr. Barbara A. Fallon, Factor-Inwentash Faculty of Social Work, University of Toronto
Study Sponsor:	University Health Network (UHN)
Study Funder:	CIHR Canadian HIV Trials Network (CTN)
Study Coordinator:	Mr. Galo F. Ginocchio, AIDS Committee of Toronto (ACT) 416-340-8484 ext. 295 (Monday to Wednesday 9am-5pm)
24-HOUR CONTACT:	(416) 864-5431 (Hospital Locating)

INTRODUCTION

You are being asked to take part in a research study involving group therapy because you are living with HIV-Associated Neurological Disorder (HAND), more specifically, Mild Neurocognitive Disorder (MND).

Before deciding to take part in this study, it is important that you read and understand the following explanation about the study and its risks and benefits. Participation is voluntary. Please ask the study investigator or study staff to explain any words you don't understand. If you have any questions please ask a study investigator or study staff for more information. If you wish to take part in this study, you will be asked to sign this form.

If the study doctor is also your treating doctor, this will be discussed with you.

Please take time to read the following information carefully and if you wish discuss it with your family, friends, and doctor before you decide.

BACKGROUND

Approximately half of the aging HIV-positive population will be affected by HAND. People with HAND can experience memory impairment and issues with processing new information, problem solving and decision making. With the development, access to, and early initiation of modern antiretroviral therapy (ART), HAND is less severe and less common than it once was. However, people who were treated with old therapies, ones that were less effective and with higher rates of toxicity compared to current regimens, or who experienced AIDS defining illnesses, may be affected by HAND more frequently and more severely.

In the general aging population cognitive behaviour therapy (CBT) has been shown to decrease stress and depression and improve coping and quality of life. This type of therapy typically involves meeting with a trained therapist either individually or as a group to learn new skills and techniques to help overcome thinking, reasoning and memory problems. These types of therapies can vary widely they have not been fully tested in people aging with HAND.

In this study we will explore the use of cognitive behaviour therapies remediation group therapy (CRGT) in aging HIV-positive adults affected by Mild Neurocognitive Disorder. This type of therapy is intended to help improve memory, attention, organizational skills and will involve the use of electronic brain-training games in a group setting. This will be combined with Mindfulness-Based Stress Reduction (MBSR) involving meditation, breathing exercises. In the general aging population MBSR has been shown to be helpful in reducing stress, anxiety and depression.

PURPOSE OF THE STUDY

The purpose of this research study is to determine if it is possible to conduct cognitive remediation group therapy (CRGT) in older HIV-positive adults living with mild-to-moderate HAND and if this type of therapy is acceptable. Researchers will compare this experimental group therapy to the standard of care group therapy that is available to persons living with HIV. As part of the study researchers will also evaluate if there are any changes in your stress, anxiety, and coping from the beginning to the end of the research study.

If you agree to take part in this study you will be one of approximately 16 participants recruited from St. Michael's Hospital.

WHO CAN TAKE PART IN THE STUDY

You may be able to participate in this study if:

- You are aged 40 or older
- You have received a documented HAND diagnosis of MND
- You have been living with HIV for 5 or more years
- You provided consent to St. Michael's Hospital to be contacted for future research studies
- You are available to attend 10 weeks of group therapy in downtown Toronto

You will not be eligible to participate in this study if:

- You have been diagnosed with another significant psychiatric condition (i.e. schizophrenia, bipolar disorder, etc.) and/or past traumatic brain injury
- You have a documented HAND diagnosis of asymptomatic neurocognitive impairment (ANI) or HIV-associated dementia (HAD)
- You have active intravenous or crystal meth drug use
- You have been hospitalized within the past month
- You are unable to communicate in English
- You are unable to use a tablet
- You are currently participating in another HAND, or mindfulness treatment study

DESIGN OF THE STUDY

If you are eligible to take part in this study you will be randomized, which means you will be selected by chance (like a flip of a coin) to one of two therapy groups described below. The randomization for this study is in a 1:1 ratio, which means you will have an equal chance of being in either group. There will be approximately 8 participants in each group.

Participants in each group will be asked to attend 10 weekly 3-hour group therapy sessions:

Group A: (Experimental Cognitive remediation group therapy)

If you are assigned to Group A your group therapy sessions will be led by a Mindfulness-Based Stress Reduction (MBSR)-certified social worker and a peer (person aging with HIV) at Toronto General Hospital. For about one hour you will complete brain training exercises on a tablet using PositScience software by BrainHQ. Study participants will support each other working through these activities. For about two hours you will take part in mindfulness-based stress reduction activities such as meditation and breathing exercises. This type of therapy is research and is not the standard of care for persons living with HIV-Associated Neurological Disorder (HAND).

Group B: (Active Control-Living with HIV Support Group Therapy)

If you are assigned to Group B your therapy sessions will be led by a certified social worker at the AIDS Committee of Toronto (ACT). This group involves peer-based discussion on the effects of living with HIV, with topics determined by the group in the meeting. This is the standard care therapy for persons living with HIV.

DURATION OF THE STUDY

The total length of your participation in the study will be about 6 months. There will be a screening period (to confirm your eligibility to take part in this study) which may last 1 to 2 weeks. Once you are confirmed to be eligible to take part in this study you will attend a baseline visit to complete a study questionnaire. After all the participants in the study have been enrolled you will be randomized to one of the two therapy groups and you will be asked to meet with the group

facilitator and then attend 10 therapy sessions once a week for 10 weeks. At the end of the therapy sessions you will visit the study center for follow-up at about one week after the therapy sessions end and again about 3 months later.

STUDY PROCEDURES

Screening Visit (30 minutes)
Once you have agreed to take part in the study and signed the informed consent form study staff will ask you about:

- Your demographic information, medical history and alcohol/drug use
- Any changes in your cognition (memory, problem solving, coping) since your last clinic visit
- Your preferred schedule to attend a 10-week group therapy program
- Your access to a mobile device (i.e., smartphone, tablet) for the purpose of using brain training games from PositScience by BrainHQ.

After the screening visit study staff will access your patient chart at St. Michaels Hospital to collect information about your medical history, medications and clinic visits to see if you meet the specific requirements to be in the study. Your demographics (age, ethnicity, gender etc) will also be collected from your patient chart.

If you meet the study entry criteria you will be asked to visit the study center for a baseline visit.

Baseline Visit (40 minutes)
At this visit you will be asked to complete a study questionnaire that asks about your emotions and thoughts surrounding living with HIV and HAND. This survey will be completed on a computer but if you prefer you can complete it on paper. Study staff will be available to help you with any questions you do not understand.

Group Assignment (Randomization)
Once all the study participants have been enrolled in the study you will be randomly assigned to one of the two therapy groups:

Group A: Experimental Cognitive Remediation Group Therapy **or**
Group B: Active Control-Living with HIV Support Group Therapy (standard of care group therapy)

Facilitator Meeting (20 minutes)
After you have been assigned to a group you will be asked to meet with your group facilitator before the therapy sessions begins. The facilitator will give you more information on what to expect at the therapy sessions.

Therapy Sessions (Visit 1-10, 3 hours each)
You will be asked to attend 10 group therapy sessions for 10 weeks in a row. Each session will last about 3 hours. This is a total of 30 hours of group therapy.

Visit 5 and 10 Questionnaires (10 minutes each)
At the end of therapy sessions 5 and 10 you will also be asked to complete a questionnaire about your satisfaction with the session's length, content and facilitators. This will be completed on paper.

Follow-up Visit (40 minutes)
You will be asked to visit the study center 1-2 weeks after the group therapy sessions have ended. At this visit you will be asked to complete a study questionnaire that asks about your emotions and thoughts surrounding living with HIV and HAND. This is the same questionnaire that you completed at the baseline visit. This survey will be completed on a computer but if you prefer you can complete it on paper. Study staff will be available to help explain any questions you do not understand. This visit will take about 40 minutes to complete.

End of Study Visit (40 minutes)
You will be asked to visit the study center about 3 months after the follow-up visit. At this visit you will be asked to complete a study questionnaire that asks about your emotions and thoughts surrounding living with HIV and HAND. This is the same questionnaire that you completed at the baseline and follow-up visits. This survey will be completed on a computer but if you prefer you can complete it on paper. Study staff will be available to help explain any questions you do not understand.

After this, you will have finished all of the study visits and your participation in the study will be completed.

POTENTIAL HARMS AND DISCOMFORTS

We do not think you will be harmed in any way during this study, but there is a chance that you could find some parts of the study uncomfortable.

- You may feel anxious, upset or sad when answering questions or completing questionnaires. You are not required to answer any questions that make you feel uncomfortable.
- During the group therapy you will be asked some personal questions about your experiences with HIV and HAND. We need to ask these questions for the study to understand the impact of the program, and what could be done better in the future. This may make you experience discomfort, anxiety, and/or unease from disclosing sensitive information about yourself to other participants during the group therapy.

If you have any concerns about your feelings during the study please contact the study team and they can direct you to the appropriate support service. You can also follow-up with your social worker or other health care professional.

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 therapy 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. Research participants/group members will be advised to practice some caution before sharing personal and sensitive information. All participants will only be referred to by a first name, and will be offered the possibility of using a pseudonym (false name) in the group.

POTENTIAL BENEFITS

We do not know whether being in this study will benefit you. It is possible that you may learn new skills that may help you cope with HAND but this is not certain.

This is a “pilot study” which is done to test the study plan and to find out whether enough participants will join a larger study and accept the study procedures. The results may be used as a guide for larger studies, although there is no guarantee that they will be conducted. Knowledge gained from pilot studies may be used to develop future studies that may benefit others.

ALTERNATIVES TO PARTICIPATION

You do not have to join this study to receive services related to HAND. If you decide not to take part in this study you will still be able to receive any standard of care treatment you are already receiving, or are due to receive.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may withdraw from this study at any time without giving reasons. Your decision will not affect your or your family’s ability to receive medical care at St. Michael’s Hospital or any of the other study sites, and you will not lose any benefits to which you are otherwise entitled.

The study investigator may also stop your participation in the study without your consent if it is in your best interest or if you do not follow the requirements of the study. If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision.

The data you provide up to the point of withdrawal may still be used in the analysis. No further information will be collected from you.

NEW INFORMATION

If any new information becomes available during the study that could affect your willingness to continue to participate, it will be supplied to you.

COSTS TO PARTICIPATION AND COMPENSATION

There will be no cost to you for taking part in this study. You will not be paid for your participation in this study. However, you will be provided with a maximum of $300 in compensation for your time and travel. Compensation will be provided according to the following schedule:

- $20 for attending the Screening Visit
- $20 for attending the Baseline Visit
- $20 for attending the Facilitator Meeting
- $20 for attending each therapy session (10 sessions x $20 = $200)
- $20 for completing the Follow-up Visit
- $20 for completing the End of Study Visit

RIGHTS AS A PARTICIPANT

If you are harmed as a result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

PROTECTING YOUR HEALTH INFORMATION: PRIVACY AND CONFIDENTIALITY

If you agree to join this study, the study investigator and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your

- Name and age
- Address
- Hospital ID,
- Date of birth,
- New or Existing medical records, including types, dates and results of medical tests or procedures

All persons involved in the study, including the study investigators, coordinators, nurses and delegates (hereby referred to as "study personnel"), are committed to respecting your privacy. No other persons will have access to your personal health information or identifying information without your consent, unless required by law. The study personnel and the study sponsor will make every effort to keep your personal health information private and confidential in accordance with all applicable privacy legislations, including the Personal Health Information Protection Act (PHIPA) of Ontario.

The following groups or people may come to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- University Health Network (the study sponsor) or its representative
- Representatives of St Michaels Hospital and University Health Network Research Ethics Boards

Any personal identifying information (such as your name) will be "de-identified" by replacing your personal identifying information with a "study number". This number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will be available to St. Michael's Hospital investigator Dr. Sean Rourke and the study staff. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your coded study data will be sent to and accessed by study personnel at the AIDS Committee of Toronto (ACT), University Health Network (UHN), and the CIHR Canadian HIV Trials Network (CTN). This data will not include your name or address, date of birth or any information that directly identifies you. To protect your privacy, data will be password protected and access to study data will be limited to authorized persons and transmission of the data will be encrypted.

The data collected for this study will not be part of your medical record, however your participation in this study may be recorded in your medical record. You have the right to review your personal data and request changes if not correct. However, access to your study data during the study may be limited if it weakens the integrity of the study.

All study data will be kept in a locked and secure area by the study investigator. Electronic files will be stored securely on the hospital network. Study data will be kept for 7 years after the end of the study at which time paper study documents will be shredded and electronic data will be destroyed.

STUDY REGISTRATION AND RESULTS

A description of this clinical trial will be available on http://www.hivnet.ubc.ca/clinical-trials/ctnpt-029/, as required. This website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

The study results may be published in medical literature or presented at conferences, seminars or other public forums, but you will not be identified by name or any other identifying information.

COMMUNICATION WITH YOUR FAMILY DOCTOR OR SPECIALIST

If you consent, we will be informing your primary treating doctor and/or specialist of your study participation. We will send your primary physician and/or specialist a letter which will include a brief summary of the study so they can provide proper medical care.

RESEARCH ETHICS BOARD CONTACT

If you have questions regarding your rights as a research participant, you may contact the Director, Sharon Freitag, Research Ethics, St. Michael's Hospital, at 416-864-6060 ext. 2385 during business hours.

This research project and information and consent form have been reviewed and approved by the Research Ethics Board (REB) at St. Michael's Hospital. The REB is a group of scientists, medical staff, individuals from other backgrounds (including law and ethics), as well as members from the community. The committee is established by the hospital to review studies for their scientific and ethical merit. The Board pays special attention to the potential harms and benefits involved in participation to the research participant, as well as the potential benefit to society. This group is also required to do periodic review on ongoing research studies. As part of this review, someone may contact you from the REB to discuss your experience in the research study.

STUDY CONTACTS AND EMERGENCY CONTACT

If you have any questions about this study at any time, or if you experience a research-related injury, you should contact:

Principal Investigator:	Mr. Andrew Eaton 416-340-8484 ext. 283 / aeaton@actoronto.org
St. Michael's Principal Investigator:	Dr. Sean Rourke 416-878-2779 / sean.rourke@utoronto.ca
Research Coordinator:	Mr. Galo Ginocchio 416-340-8484, ext. 295 / gginocchio@actoronto.org

STATEMENT OF CONSENT

Study 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

This research study has been explained to me, and my questions have been answered to my satisfaction. I have been informed of the alternatives to participation in this study. I have the right not to participate and the right to withdraw without affecting the quality of medical care at St. Michael's Hospital for me and for other members of my family. As well, the potential harms and benefits (if any) of participating in this research study have been explained to me.

I have been told that I have not waived my legal rights nor released the study investigators, study sponsor, or involved institutions from their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that records relating to me and my care will be kept confidential and that no information will be disclosed without my permission unless required by law. I have been given sufficient time to read the above information.

Consent to notify primary care physician (s) or specialist(s) of your participation in this study This is not a consent to release medical information.

Initial: _____ Yes, I want the study investigator to advise my primary care physician(s) or specialist(s) of my participation in this study.

Initial: _____ No, I do not want the study investigator to advise my primary care physician(s) or specialist(s) of my participation in this study.

Consent to participate in the study
I hereby consent to participate in this study. I have been told I will be given a copy of this signed consent form.

Participant's Name (Print)	Participant's Signature	Date [MM/DD/YYYY]

I have explained the study to the above-named participant. I have explained the nature and purpose, the potential benefits, and possible risks associated with participation in this research study. I have answered all questions that have been raised about the study.

Name and Position of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date [MM/DD/YYYY]

APPENDIX A (Study Visit Schedule)

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	+/- 0	+/- 0	+/- 7	+/- 7
Procedures:								
Written Informed Consent		X						
Entry Criteria Assessment	X	X						
Chart abstraction (demographics, medical history, medications)		X						
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		
Stress, Anxiety, Coping and Mindfulness Questionnaires[4]			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
[4] 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 (FFMQ-SF)