Pilot randomized controlled trial to determine the feasibility and acceptability of group therapy for people aging with HIV facing cognitive challenges

Andrew D. Eaton, Shelley L. Craig, Sean B. Rourke,
Barbara A. Fallon, John W. McCullagh, Sharon L. Walmsley

Contact: andrew.eaton@utoronto.ca

Regulatory: www.hivnet.ubc.ca/clinical-trials/ctnpt-029
https://clinicaltrials.gov/ct2/show/NCT03483740

Protocol: https://bmjopen.bmj.com/content/9/10/e033183

Results preprint: https://www.researchsquare.com/article/rs-21835/v1

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Background & Methods

- About 30-50% of people living with HIV may develop neurocognitive impairment; mostly, these impairments will be mild in nature
- A common cause of cognitive impairment in people living with HIV can be HIV-associated neurocognitive disorder (HAND)
- Cognitive impairments & symptoms attributable to HAND can be a significant source of stress and anxiety and can be difficult to cope with on a daily basis;
- Group therapy may be ideal to cope with these effects but it is untested in this population and the best form unknown
- Through extensive primary research & consultation, *cognitive remediation group therapy (CRGT)* combining mindfulness-based stress reduction (MBSR) and brain training activities (BTA) were tested against mutual aid group therapy in a pilot RCT of feasibility, acceptability, fidelity, and exploratory outcomes for people who had been diagnosed with mild forms of HAND

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Screening call

Inclusion:

1) Age 40+
2) ≥5 years living with HIV
3) MND diagnosis
4) Consented to future contact for research from St. Michael's Hospital
5) Can attend 10 weeks of group therapy in downtown Toronto

Exclusion:

1) Other significant psychiatric diagnosis
2) ANI / HAD diagnosis
3) Active intravenous drug / crystal meth use
4) Hospitalization within past 30 days
5) Inability to communicate in English
6) Cannot use a tablet

Screening Visit (informed consent, availability, mobile device access)

Chart Abstraction (demographics, medications, comorbidities from patient chart)

Baseline Visit (study questionnaire)

Randomization into:
Arm 1 (n = 8 in Experimental)
Or
Arm 2 (n = 8 in Active Control)

Facilitator Meeting & **Arm 1** = Experimental (8 consecutive weeks of novel cognitive remediation group therapy)

Facilitator meeting & **Arm 2** = Active Control (8 consecutive weeks of mutual aid group therapy)

Follow-up Visit (Post-assessment)

End of Study Visit (3 month follow-up)

Results

- *Feasibility:* Potential participants were identified from a database of PLWH who had been diagnosed with HAND and agreed to be contacted for future research. From April-September 2018, we attempted contact with 40 eligible participants of whom 15 replied, 12 recruited and 10 completed the study.
- *Acceptability:* At post-intervention, acceptability was 90% in the CRGT (novel) and 85% in the mutual aid (control) arm.
- *Fidelity*: Assessors confirmed intervention delivery with satisfactory fidelity, with no missing components or significant deviations.
- *Exploratory:* From pre-intervention to 3-month follow-up: anxiety decreased for all in the novel arm and half of the control; stress decreased and coping increased for half in both arms; & all participants increased and sustained BTA use and half with mindfulness activities.
- See results preprint for full details: https://www.researchsquare.com/article/rs-21835/v1

Discussion

- Group therapy may be feasible and acceptable to people aging with HIV with cognitive challenges.
- A complex intervention combining mindfulness and brain training activities may be preferential to the standard mutual aid type of group support but this needs to be confirmed in a larger study.
- Strengths of this pilot study include the participation of community in its design, and randomization including the use of an active comparator group (see bmjopen.bmj.com/content/9/10/e033183
- The small sample size limits outcome assessment and interpretation.
- A larger study would be compromised by limiting recruitment to a single site and/or requiring a formal diagnosis of mild-to-moderate HAND. A more streamlined approach to identifying cognitive symptoms and impairments that can occur in HIV (which may or may not be HAND) may more efficiently identify people with problems who may benefit
- As the role of therapy is to improve coping with symptoms, broadening these intervention techniques to people aging with HIV with cognitive challenges regardless of the exact diagnosis may enhance the success of a larger study.