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Protocol for a pilot randomised controlled trial evaluating feasibility and acceptability of cognitive remediation group therapy compared with mutual aid group therapy for people ageing with HIV-associated neurocognitive disorder (HAND) in Toronto, Canada

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ABSTRACT

Introduction HIV-associated neurocognitive disorder (HAND) may affect 30%–50% of people ageing with HIV. HAND may increase stress and anxiety, and impede coping. Psychosocial group therapy may ameliorate HAND's symptoms, yet the ideal intervention is unclear. This protocol outlines a pilot randomised controlled trial (RCT)—designed using community-based participatory research—to pilot cognitive remediation group therapy (CRGT) against an active comparator.

Methods and analysis This is a pilot, parallel design, two-arm RCT that will recruit participants diagnosed with the mild neurocognitive disorder form of HAND from a neurobehavioural research unit at a tertiary care hospital in Toronto, Canada. Eligibility criteria include age ≥40 years, known HIV status for 5+ years, English fluency, able to consent and able to attend 8 weeks of group therapy. Eligible participants will be randomised to one of two treatment arms, each consisting of eight-session group interventions delivered once weekly at 3 hours per session. Arm 1 (novel) is CRGT, combining mindfulness-based stress reduction with brain training activities. Arm 2 (active control) is mutual aid group therapy. The primary outcomes are feasibility, measured by proportions of recruitment and completion, and acceptability, determined by a satisfaction questionnaire. The secondary outcome is intervention fidelity, where content analysis will be used to assess facilitator session reports. A between-group analysis will be conducted on exploratory outcomes of stress, anxiety, coping and use of intervention activities that will be collected at three time points.

Ethics and dissemination Ethical approval was obtained from the Research Ethics Boards of St. Michael's Hospital and the University of Toronto. Findings will be disseminated through peer-reviewed publications, conference presentations and community reporting. This study could provide insight into design (eg, recruitment, measures) and intervention considerations (eg, structure, content) for a larger trial to lessen the burden of cognitive decline among people ageing with HIV.

Trial registration number NCT03483740; Pre-results

Strengths and limitations of this study

- Patient and public involvement was prioritised in this protocol as people ageing with HIV co-designed the study, will deliver the interventions and will be involved in analysis and dissemination of results.
- There are a lack of proven interventions to address the stress and anxiety caused by HIV-associated neurocognitive disorder.
- Interventions for complex comorbidities need to be pilot tested to ensure feasibility and acceptability before conducting a large-scale trial.
- This protocol's active design permits comparison between two distinct interventions, as evaluations of psychosocial trials are often limited by inactive controls.
- The key limitations of this protocol are a small target sample, lack of participant blinding, a single recruiting site, restriction to anglophones, lack of long-term follow-up, potential confounders (eg, stage of HIV, concurrent comorbidities, depression), requirement to know how to use a tablet and the internet for brain training activities, and the ability to commit to 8 weekly 3-hour group therapy sessions.

INTRODUCTION

Background and rationale

Cognitive impairment is a significant comorbidity for people ageing with HIV; 30%–50% may be affected to some degree

by HIV-associated neurocognitive disorder (HAND).[1–3] HAND is thought to result from structural damage to fronto-striatal-thalamatory circuits in the brain (neural pathways that mediate cognitive, motor and behavioural functions); hence, there is no cure.[3–8] HAND is diagnosed in three categories of graded severity based on the Frascati criteria determined by the CNS HIV Antiretroviral Therapy Effects Research (CHARTER) cohort study of people ageing with HIV and neurological challenges.[3 4] The Frascati categories (with estimated prevalence from CHARTER in parentheses) are (1) asymptomatic neurocognitive impairment (ANI: 33%); (2) mild neurocognitive disorder (MND: 12%–20%); and (c) HIV-associated dementia (HAD: <2%–3%).[4] These categorisations are determined by neuropsychological testing of the degree of abnormality in cognitive domains (eg, speed-of-processing, executive functioning) and by level of impairment to activities of daily living.[4 5] Without effective HIV medication, people living with HIV may rapidly progress through these stages, demonstrated by high rates of the most severe form (HAD) prior to the introduction of successful combination antiretroviral therapy (cART) regimens.[2–5] HAND may be a result of uncontrolled HIV replication in the brain.[4–7] The development and widespread use of modern cART, and the trend towards earlier treatment initiation, has reduced HAND's severity and its consequences; however, it remains a significantly debilitating issue.[3 9 10] It is seen more commonly and is of particular concern, in AIDS survivors—people ageing with HIV who were treated with incompletely suppressive antiretroviral regimens and with medications that had higher rates of mitochondrial toxicity, often late in disease such as after an AIDS defining illness or when the immune system was very weak.[6–8] The shift in prevalence from severe to moderate HAND, and the higher risk among AIDS survivors, may suggest that uncontrolled replication of HIV in the brain is causative, and that there is less opportunity for replication when effective treatment is initiated early.[5]

HAND symptoms include memory deficits, problem-solving errors, difficulties in processing new information, executive function impairment and poor decision-making.[3–8] This, in turn, leads to stress, anxiety, social isolation, difficult coping and impacts daily activities (eg, medication adherence).[11–13] HAND differs from Alzheimer's disease and other cognitive impairments in numerous clinical areas.[7] Perhaps the most distinguishing characteristic is that people living with HIV are at similar risk of mild HAND in their 40s and 50s as the general population is at risk of mild dementia in their geriatric years.[10 11] With cognitive decline from normal ageing and other syndemic factors (eg, intersecting HIV and ageing comorbidities), HAND symptoms are amplified and further impair the ageing HIV-infected adult's ability to cope.[13] With the earlier age of impairment and syndemic factors associated with HIV, HAND may be a condition in need of specific psychosocial intervention distinct from what is currently being tested in geriatric adults with dementia.[12 14] Yet despite exploratory research on the unique challenges of HAND and a stated community need,[11 12 15–17] HAND intervention research in the era of modern cART is limited and the optimal intervention is unclear.[13 14]

Psychosocial factors (ie, social networks, mood) have predicted the ability to cope with HAND symptoms among people with varying levels of cognitive impairment and among diverse demographics (ie, gender, age, education and ethnicity),[18] so interventions that improve psychosocial factors may enhance coping with HAND symptoms. Mindfulness-based stress reduction (MBSR) group therapy has decreased stress and anxiety, and improved coping for people with dementia.[19] Computerised brain training activities (BTAs) have had similar benefit in middle-aged and older adults with HAND, but participants have requested emotional support (such as MBSR) to complement BTA.[20] In the general population with dementia, a systematic review synthesis found that these group-based, multicomponent strategies improve global cognitive functioning and activities of daily living to a greater extent than a single-component therapy.[21] Similar evidence for people living with HIV is still emerging; however, a recent scoping review found that combination approaches (ie, mindfulness, cognitive training techniques and group therapy) to psychosocial interventions may have better health outcomes for people living with HIV than a single technique approach.[22] People with the emotional stability and practical coping strategies can more successfully adapt to the challenges of ageing, such as cognitive decline.[23–25] Combination approaches that facilitate emotional well-being (ie, MBSR) and practical tasks to improve coping with cognitive impairments (ie, BTA) may therefore be better suited to ameliorating the effects of HAND for people ageing with HIV than a single therapy approach.

Using community-based participatory research to engage people ageing with HIV and HAND researchers, this study will pilot cognitive remediation group therapy (CRGT)—combining MBSR and BTA—in a pilot randomised controlled trial (RCT) of feasibility and acceptability. CRGT will be against an active control—mutual aid group therapy— chosen as an established intervention in both the HIV[26] and dementia[27] fields that mimics the form (ie, support group) of CRGT while controlling for the inherent benefit (ie, social connection) of group therapy.[28]

Objectives

The primary objective of this pilot RCT is to test CRGT for a sample of people ageing with HIV who have been diagnosed with mild-to-moderate HAND (ie, MND), and to compare feasibility and acceptability outcomes against an active control of mutual aid group therapy. The secondary objective is to assess implementation fidelity of both trial arms. Exploratory objectives are to compare stress, anxiety, coping and use of mindfulness and brain training activities.

Trial design

This is a pilot, parallel group design RCT that will recruit people ageing with HIV (≥40 years old) who have been diagnosed with MND-HAND since 1 January 2016 from a neurobehavioural research unit in Toronto, Canada. The trial uses a refinement framework to assess, in a preliminary sense, whether therapy of this nature is feasible and acceptable to this population.[29] The recruited sample (target n=12–16) will be randomised to either 8 weekly 3-hour sessions of CRGT or 8 weekly 3-hour sessions of mutual aid group therapy.

METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

Study setting

Participants will be recruited from St. Michael's Hospital's Neurobehavioral Research Unit, a clinic dedicated to HAND assessment in downtown Toronto, Canada. This clinic uses Frascati criteria[3] to assess cognitive impairment via neuropsychological testing conducted by two psychologists. The intervention arms will be at community-based organisations in downtown Toronto, Canada. The novel CRGT arm will be at the Centre for Mindfulness Studies, a facility that owns the necessary equipment for MBSR (eg, yoga mats). The control mutual aid arm will be at the AIDS Committee of Toronto (ACT), who have been offering mutual aid groups for people living with HIV for over 20 years.

Patient and public involvement

Community-based participatory research (CBPR) and implementation science guided an approach to engage people ageing with HIV and affected by HAND, alongside service providers and HAND researchers, as the protocol was being developed. First, an exploratory CBPR study surveyed (n=108) and interviewed (n=20) people ageing with HIV in Ontario; approximately one-eighth of participants had been diagnosed with HAND and the entirety of the sample self-identified recently reduced function and ability in more than one cognitive domain (eg, memory, speed-of-processing).[12] The purpose of this initial study was to determine the direction for psychosocial interventions in HIV and cognition, with a focus on social work due to the profession's history of effective engagement with people living with HIV.[23 30] The initial study also sought to understand the impacts of peer service provision and peer research from people affected by HAND themselves.[31 32] The results of this study suggested that a cognitive remediation intervention, combining emotional and practical coping skills training in a group setting, may help people living with HAND manage their symptoms and improve their well-being.[12]

Second, the first author conducted key informant interviews with six HAND researchers from Canada, the USA, Spain and Australia. These interviews discussed work-in-progress and design considerations for intervention research, an example of which is BTA. BTA, comprised of online and offline games and activities targeted for cognition, shows promise in helping people with cognitive impairment improve their function at specific tasks and activities (eg, remembering sequences, responding quickly) through repeated practise.[20] BTA has been predominantly administered as an individual activity, such as software installed on a person's home computer with clinic follow-up on progress. This may contribute to relatively low uptake of BTA as a promising intervention technique.[33]

Third, the first and sixth authors held two focus groups in downtown Toronto: one with people ageing with HIV and concerned about HAND (n=10) and one of social workers in the HIV field (n=8). These consultations were conducted to finalise trial components, including intervention selection, appropriate questionnaires and a sensitive method of data collection. These activities supported CBPR's aim of co-constructing new interventions with people most affected by the issue under study,[34] and implementation science's recommendation of preliminary consultation to improve the potential for scale-up should the study determine promising results.[35]

Eligibility criteria

Inclusion criteria: People who (1) are aged ≥40 years; (2) have a documented HAND diagnosis of MND; (3) were diagnosed with HIV ≥5 years ago; (4) provided consent to St. Michael's Hospital to be contacted for future research studies; and (5) could feasibly attend 8 weeks of group therapy in downtown Toronto. *Exclusion criteria:* Participants who (1) have a documented HAND diagnosis of ANI or HAD; (2) have been hospitalised in the past month; (3) are unable to communicate in English; (4) are unable to use a tablet for BTA; or (5) are assessed by the research coordinator to be disruptive to a group therapy setting (eg, due to discriminatory remarks). *Justification:* MND is chosen instead of ANI or HAD due to the potential for unacceptably high false-positive error rates in ANI[36] and the potential null effect from psychosocial interventions for people with HAD.[14] As the two arms will address HAND and not HIV, a limit of ≥5 years since HIV diagnosis is set to mitigate the risk that some participants may want to discuss issues associated with a recent HIV diagnosis instead of issues associated with HAND. Forty years of age is chosen as the lower limit as it is approximately 1 SD below the mean of MND diagnosis in the CHARTER cohort[3 4] and at the recruiting clinic. Therefore, 40 years of age may be an appropriate lower limit for a study of this nature so that participants can still bond over the shared experience of ageing with HIV while being inclusive of the age range of people most likely to be diagnosed with HAND. Other criteria were set in accordance with the study's context. For example, recent hospitalisation could suggest poor health and could bar participation in an 8-week group. There are no eligibility criteria for viral load, other comorbidities, and alcohol and substance use.

Interventions

Both interventions consist of nine, 3-hour weekly sessions (an orientation session and eight group sessions) and will be at community-based organisations in downtown Toronto, Canada.

Cognitive remediation group therapy (novel arm)

CRGT is a blend of two emerging interventions—MBSR and BTAs—that will be combined for the first time for people with HAND in this study. MBSR will comprise two-thirds of each weekly session and will be facilitated by a physician and a social worker using the MBSR manual that includes meditation, body scans, deep breathing and other exercises to relieve stress and regulate emotions.[37] BTA will comprise the remaining one-third of each group session and will be facilitated by a peer ageing with HIV. Participants will have access to Samsung tablets and a 1-year license to BrainHQ training by PositScience. BrainHQ tailors training (ie, games) to participant's deficit domains (eg, speed-of-processing, memory) via a screening exercise and then offers activities of increasing difficulty. If people practise for a minimum of 3 hours per week for 8 weeks, they may self-report a positive change in coping.[33] As this may be the first time BTA is offered in a group setting, the peer facilitator will use a participatory approach by soliciting participants' input on how to structure sessions (eg, individual practice, group discussion on training progress and challenges, or some combination).

Mutual aid group therapy (control arm)

Mutual aid groups consist of facilitated discussion of challenges and coping strategies associated with an illness or issue.[28] Mutual aid groups may be the most recognisable form of group therapy, as Alcoholics Anonymous has popularised the model.[38] These groups use the principle that people can help one another overcome their health and social challenges when trained facilitators—often social workers—help the group maintain respect, stay on topic and explicate connection and shared experience between participants.[39] For this study, mutual aid will be facilitated by a social worker and a peer ageing with HIV. Refer to supplementary file 1 for the facilitators' manual of this model.

Discontinuation criteria

Participants may cancel their participation at any time. Intervention arms will be discontinued if, due to cancellations, the total number of participants registered to an arm is three or less.

Protocol adherence strategies

The study sponsor has access to the participant database and will monitor the timeline of protocol procedures. Facilitators of each intervention arm will submit weekly session reports that will be checked to ensure that interventions are progressing as designed.

Concomitant care and interventions

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

Outcomes

Outcomes and measures are listed in table 1. As a pilot study, feasibility and acceptability are primary outcomes to assess whether a larger trial could further test group therapy for people with HAND. Intervention fidelity (ie, how closely the facilitators adhere to each arm's therapy model) is a secondary outcome to assess whether the interventions are delivered as planned. Exploratory outcomes of stress, anxiety, coping and use of brain training and mindfulness activities will also be assessed.

Participant timeline

The study started on 6 August 2018 and is expected to end by 31 December 2019. Refer to table 2 for the schedule of events. The timeline consists of three distinct periods: (1) screening, where eligibility will be confirmed, the research coordinator will obtain consent and participants will complete baseline questionnaires; (2) study, where intervention arms will be administered; (3) and follow-up, where participants complete questionnaires at the interventions' conclusion and a 3-month follow-up.

Sample size

A sample size of 12–16 participants (6–8 in each study arm) has been selected as (1) 6–8 participants have been found to be an ideal size for 8 weeks of group therapy[40]; and (2) this number can provide preliminary insight into the feasibility and acceptability of the novel CRGT arm before initiating a larger study. Further, 12–16 participants are 30% to 40% of the sampling frame (n=40). So, if this pilot's results prove promising, scale-up to a larger study with similar recruitment proportions would feasibly require a sample of 90–120 from approximately 300 potential participants.

Recruitment

A clinical psychologist from the recruiting site will attempt to contact all participants in the sampling frame (n=40) at their last known phone number and email. Three distinct contact attempts will be made for each individual. This contact will briefly explain the study and determine whether a participant elects to meet with the study coordinator to confirm eligibility and review the consent form.

METHODS: ASSIGNMENT OF INTERVENTIONS

Allocation

Concealed allocation will be used for this study. The first author will provide the study sponsor with unique identifiers of each enrolled participant. The sponsor will then randomise participants in a 1:1 fashion using blocks of size two to either the novel or control arm. Individual allocation results will then be communicated to each participant.

Table 1 Outcomes and measures

Outcomes	Measures	Description
Feasibility	Participant recruitment and retention	Proportion of eligible participants who agree to participate, complete the pretest, attend the first group session, complete the full group series and complete the study
	Chart abstraction of participant demographics	The sampling frame's demographics (ie, age, gender, ethnicity, length of time living with HIV, length of HAND diagnosis) will be described in terms of those who agree and decline to participate
Acceptability	Helping characteristics of self-help and support groups measure[51]	22-item Likert measure where higher scores indicate greater group satisfaction, administered in sessions four and eight of each arm
	Reasons for withdrawal (if applicable)	If participants withdraw from the study, they will be asked if they consent to having the reason for withdrawal described
Intervention fidelity	Facilitators' session reports	Facilitators will submit weekly session reports that will include checklists of therapy components and open-ended questions about group activities, dynamics and challenges
Stress	HIV/AIDS Stress Scale[52]	29-item Likert measure where higher scores indicate greater HIV-related stress
Anxiety	Anxiety in Cognitive Impairment and Dementia Scale[53]	26-item dyadic measure where higher scores indicate greater cognition-related anxiety
Coping	Coping Self-Efficacy Scale of Health Problems[54]	10-item Likert measure where higher scores indicate greater coping with health problems
Use of mindfulness strategies	Five Facet Mindfulness Questionnaire—Short Form[55]	24-item Likert measure where higher scores indicate greater use of mindfulness strategies
Use of brain training activities	Novel arm—PositScience progress reports Control arm—self-report	The brain training software provided to participants in the novel arm tracks their activity. For the control arm, participants will self-report use of brain training activities

Blinding

Facilitators of the study arms will be blind to outcome assessments; otherwise, this study is not blinded. Blinding participants to psychosocial trials is difficult, as participants are actively involved in their therapy.[41] Blinding of this nature often requires deception, which raises ethical concerns.[42] The limitations to this approach and mitigating strategies will be discussed in the results paper.

METHODS: DATA COLLECTION, MANAGEMENT AND ANALYSIS

Data collection methods

Demographics will be abstracted from participant charts at the recruiting site. A research coordinator will collect self-reported data for exploratory outcomes from participants at three times (baseline, postintervention and 3-month follow-up). Further, the coordinator will collect acceptability data via a questionnaire at the midpoint and endpoint of the interventions. Group facilitators will write structured session reports to be submitted weekly following each group session. Refer to supplementary file 2 for consent and data collection forms.

Participant retention plans

To promote participant retention in group sessions, the study coordinator will send weekly reminders to participants. To promote completion of questionnaires, three distinct contact attempts will be made to schedule study visits. If a participant withdraws from the study, the coordinator will ask for permission to report the reason for withdrawal.

Data management

All data collected will be labelled with a unique identifier for each participant. The study coordinator will enter data into REDCap (Research Electronic Data Capture), a browser-based database; these data will be verified by the principal investigator.

Analysis

The stakeholders (people ageing with HIV, service providers and researchers) who provided initial consultation to study design will reconvene to collectively analyse the de-identified results, to inform the design of a larger study of group therapy for people ageing with HIV who are experiencing cognitive challenges. For intervention fidelity, content analysis will be performed by two independent coders familiar with the models of group therapy.[43] With a small target sample, analysis of the exploratory outcomes will be limited. With a Kenward-Roger adjustment for small sample size (ie, scaling F by factor λ and determining denominator df m for an approximate expectation and variance of a $F_{l,m}$ distribution)[44] to the covariance matrix, a between-group treatment effect may

Table 2 Schedule of events

Visit details	Screening period			Study period			Follow-up period	
Visit name	Screening call	Screening visit	Baseline visit	Orientation	Sessions 1–7	Sessions 4 and 8	Follow-up visit	End of study visit
Visit No.	–3	–2	–1	0	1, 2, 3, 4, 6, 7	4 and 8	9	10
Week No.			–1	0–8			9	21
Day No.	–56 to –7 days		–7	0–56			63	153
Day window	+/–7	+/–7	+/–7	+/–7	+/–0	+/–0	+/–7	+/–7
Procedures								
Informed consent		X						
Entry criteria assessment	X	X						
Chart abstraction (demographics)		X						
Randomisation			X*					
Group sessions				X†	X	X		
Facilitator session reports					X	X		
Helping characteristics of self-help and support groups measure						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			X				X	X

*To occur once all participants have been enrolled and eligibility confirmed.
†Acquaintance with group only; no therapy will be administered during this session.

be detected while minimising false-positive error risk in these exploratory outcomes.[45]

SAFETY CONSIDERATIONS

Group therapy poses risk of psychological and social distress when participants feel uncomfortable discussing sensitive concerns and when they believe their confidentiality may be jeopardised. To mitigate these potential risks, the nature of a group setting and the limits of confidentiality will be discussed with participants at the consent stage. Facilitators will also meet with participants individually in an orientation meeting prior to the group's commencement to discuss norms and guidelines for group behaviour. Additionally, participants may withdraw their participation at any time, without any impact on their current standard of care. Further services and resources will be provided to participants who withdraw. Conducting the intervention arms at community-based sites that currently offer other types of support services to people living with HIV (such as counselling) may provide an opportunity for participants to access additional supports if necessary.

ETHICS AND DISSEMINATION

The study sponsor will monitor the trial and audit the data at their discretion. Consent forms and data will be stored separately on secure, encrypted servers for 7 years following study completion. The study protocol and

consent form have been approved by the Research Ethics Boards of St. Michael's Hospital (No. 17-334) and the University of Toronto (No. 35860). The trial was registered on clinicaltrials.gov (No. NCT03483740) before recruitment commenced. Protocol amendments, if applicable, will be communicated to the study sponsor, ethics boards and registry prior to implementation. Outputs from this study will include journal publications, conference presentations and community reporting. Outputs will not identify participants.

DISCUSSION

This pilot RCT may provide preliminary insight into how the novel CRGT as a combination intervention (ie, MBSR, BTA and group therapy) compares with the mutual aid standard of group therapy that comprises the active control. The community-based approach may also provide insight into how patient and public involvement can inform the design and analysis of psychosocial intervention trials,[46] with implications for other social researchers seeking to design rigorous and community-informed intervention studies of a similar nature.

CRGT may offer participants practical and emotional coping strategies alongside the inherent social connection benefit that participants can receive from the mutual aid control. This will build on existing research showing that combination approaches are preferable to people living with HIV[22] and people with dementia,[19] while addressing the gap in psychosocial interventions for people with HAND. This refinement pilot trial will provide insight into the feasibility and acceptability of CRGT and a study of this nature, to inform the development of a larger study. A pilot is needed, given HAND's complexity and the lack of existing interventions for this condition, to preliminarily assess these interventions before a larger trial is designed. Based on other psychosocial intervention pilot trials,[47 48] a sample of 12–16 completing the study with positive acceptability results and strong intervention fidelity could potentially justify upscaling this pilot into a full-scale trial.

There has been little research conducted that provides people living with HAND the opportunity to interact with one another in a confidential group setting. It is possible that this group experience could be helpful for people living with HAND, as exploratory research has identified a dual stigma associated with the condition.[11 17] The dual stigma is people feel that they cannot speak about HAND to their HIV-positive community due to dementia stigma, nor could they discuss it with HIV-negative friends and service providers who are familiar with cognitive impairment due to HIV stigma. Such community-building and shared support around the stress and uncertainty of ageing with HIV may ameliorate the damaging effects of stigma.[49 50]

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Contributors ADE conceived and developed the protocol, and drafted the manuscript. SLW provided expertise with trial design. SLC provided expertise with intervention design. SBR and TS provided expertise in HIV-associated neurocognitive disorder. JWM and BAF contributed to protocol refinement. All authors edited and approved the final version of the manuscript.

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