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A randomized controlled trial of culturally adapted motivational interviewing for Hispanic heavy drinkers: Theory of adaptation and study protocol

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ABSTRACT

Background: The NIH Strategic Plan prioritizes health disparities research for socially disadvantaged Hispanics, to reduce the disproportionate burden of alcohol-related negative consequences compared to other racial/ethnic groups. Cultural adaptation of evidence-based treatments, such as motivational interviewing (MI), can improve access and response to alcohol treatment. However, the lack of rigorous clinical trials designed to test the efficacy and theoretical underpinnings of cultural adaptation has made proof of concept difficult.
Objective: The CAMI2 (Culturally Adapted Motivational Interviewing) study design and its theoretical model, is described to illustrate how MI adapted to social and cultural factors (CAMI) can be discriminated against non-adapted MI.
Methods and design: CAMI2, a large, 12 month randomized prospective trial, examines the efficacy of CAMI and MI among heavy drinking Hispanics recruited from the community ($n = 257$). Outcomes are reductions in heavy drinking days (Time Line Follow-Back) and negative consequences of drinking among Hispanics (Drinkers Inventory of Consequences). A second aim examines perceived acculturation stress as a moderator of treatment outcomes in the CAMI condition.
Summary: The CAMI2 study design protocol is presented and the theory of adaptation is presented. Findings from the trial described may yield important recommendations on the science of cultural adaptation and improve MI dissemination to Hispanics with alcohol risk.

1. Introduction

In the United States, Hispanics experience greater alcohol-related health disparities compared to other social groups [1]. Although the total volume of drinking (e.g., number of drinks/month) on average is not higher among Hispanics compared to other racial/ethnic groups [2–4], there is a greater burden of negative health and social effects of drinking [5–9]. Hispanics are less likely to receive treatment for substance-use problems than non-Hispanics [10,11] irrespective of health insurance or level of alcohol severity [12,13]. Once in treatment, Hispanics demonstrate lower completion rates compared to non-Hispanic Whites [14]. Providing linguistically and culturally tailored evidence-based treatments (EBTs) can increase engagement in care by increasing its availability and relevance to the target population [15,16].

Motivational Interviewing (MI) is a collaborative counseling style designed to elicit and reinforce participant motivation to change [17–22]. Meta-analyses have established its efficacy [23–26], and although effect sizes vary by the primary outcome of interest [22,27,28], effects of MI on alcohol consumption and related harms have the strongest evidence base [21,29]. MI causal theory posits that therapist MI-consistent behaviors, such as the use of open questions[1] and complex reflections, and high MI spirit (the demonstration of accurate empathy and high working collaboration), will increase client change talk (statements

[1] Open questions invite longer answers (e.g., What brings you here today?). Simple reflections are statements that repeat/rephrase what person has said "You've missed work because of your drinking". Complex reflections are statements that add something to what the client has said "You are tired of the consequences of drinking". Change talk are statements that favor change (e.g., "I want to stop drinking"), and sustain talk are arguments for not changing (e.g., "I just love to drink"; [20]).

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favoring behavior change) and decrease sustain talk (statements against behavior change) [20,30–33], which then predicts decreased drinking or drug use.

Although cultural adaptation of EBTs like MI is important to reduce disparities in health and health care, few tests of adaptation efficacy exist. These interventions must meet the rigorous criteria of an EBT while simultaneously integrating relevant cultural and social elements [34]. Stated differently, successful adaptations must retain the key active ingredients of the original treatment while judiciously adapting what is necessary [35]. Despite these challenges, emerging results have supported cultural adaptation in addictions treatment [36,37]. For example, Project CAMI1 (Culturally Adapted Motivational Interviewing), the foundation for the current study, reported that those who received a culturally adapted version of MI reported greater reductions in alcohol-related consequences than those who did not [37]. However, the question of *how* treatment adaptation works has remained largely unaddressed.

2. Methods

The current study describes the protocol for Project CAMI2, which compares a single session of CAMI to a single session of MI delivered to Hispanic heavy drinkers. The CAMI2 study protocol is approved by the Institutional Review Board at Northeastern University, Boston, MA. All study data reported is based on the CAMI2 study.

2.1. Study aims

The overall study goal is to report the protocol of a clinical trial and the underlying theory of its experimental condition. Study aims of the RCT are to: 1) Examine the efficacy of the CAMI intervention on drinking outcomes (heavy drinking and negative alcohol-related consequences) compared to non-adapted MI, at 3, 6 and 12 month follow ups, controlling for baseline levels of drinking. A related study aim is to explore perceived acculturation stress as a moderator of alcohol treatment outcomes for Hispanics.

3. Theoretical rationale

3.1. The central causal theory of motivational interviewing

Motivational Interviewing is a directive, person-centered communication style to strengthen intrinsic motivation by eliciting and exploring thoughts about change in a collaborative atmosphere [20]. MI was originally developed for treating addictions and the most consistent evidence for MI efficacy has been with drug use and hazardous drinking [23,25,26]. The refinement of the MI approach was driven by clinical intuition and empirical observation [39]. There are four underlying therapeutic processes: **E**ngaging with the client, **F**ocusing on a goal with the client, therapist **E**voking the client's thoughts/feelings about change, and strengthening commitment to change during the **P**lanning process [20]. MI causal theory posits two key pathways to behavior change [31,32]: 1. The relational hypothesis posits that a non-judgmental and open therapeutic milieu (e.g., therapeutic empathy) creates a safe atmosphere that encourages clients to verbalize complex thoughts about making a change, and 2. The technical hypothesis posits that therapist MI-consistent behaviors (e.g., open questions, complex reflections) strengthen client motivation to change. Increased MI relational and technical elements are hypothesized to increase client change talk (i.e., statements of perceived ability, desire, need, reason, and commitment to make change) and decrease client sustain talk (e.g., statements of reasons to not change) [40]. Thus, client change-talk has been viewed as a main MI causal mechanism.

3.2. Mediating processes for both MI and CAMI

Theory-based mediators are discussed herein to explain how they relate to MI causal theory, based on the underlying theory of the experimental condition (see Fig. 1) (investigation of these mediators are not conducted as part of the primary RCT).

3.2.1. Client change talk

Although early process research on MI documented that increased change talk predicted treatment outcomes [32], a more clinically nuanced picture has evolved, documenting that the relationship between client statements about making a change (change talk) and behavioral outcomes is variable [41,42]. For example, in some studies only certain *types* of change talk, such as commitment language (e.g., "I will make a change" [43]), or the *strength* of commitment statements, predicted subsequent decreases in drug and alcohol use [32,44]. One study that delivered MI to non-treatment seeking, young male heavy drinkers ($n = 174$), found that the strength of change talk statements mediated the relationship between MI-consistent therapist behaviors and client drinking outcomes *only* when therapists had more MI experience, suggesting that MI theory may not be operative under all therapeutic conditions [45]. Another study compared two versions of MI (with and without feedback) to a control condition with college students and demonstrated that student change talk predicted outcome (decreased heavy drinking) *only* when MI was provided with feedback [46]. These findings suggests that the relationship between change talk and outcomes may be moderated by other clinical factors, such as how the intervention was delivered [42,44], or under-researched MI mediators, such as self-exploration.

3.2.2. Self-exploration

The MI emphasis on evocation (i.e., therapist eliciting client thoughts and feelings about change), distinguishes MI from other therapeutic approaches [20]. It is hypothesized that client self-exploration is an important part of the MI evoking process, as clients try to understand his/her beliefs, values, motives, and actions, in the presence of a therapist who attempts to facilitate the process [47]. In MI, self-exploration is defined as the exploration of "personally relevant material" (e.g., disclosure of material that might make the client feel more vulnerable) [48]. Self-exploration thus reflects *emotional* processes underlying attitudes towards change that may facilitate new learning, as illustrated in a qualitative analysis of MI [49]. Preliminary data support self-exploration as a potential mediator of MI effects. In a study delivering MI to 14–18 year olds recruited from a Level 1 Trauma Center, self-exploration was associated with an empathic counseling style [50]. A second study that combined data from two clinical trials with college students, including a more ethnically diverse sample (51% African-American), reported that high therapist MI spirit was positively associated with increased client self-exploration, which predicted decreased alcohol use at later time points.

3.3. Theoretical development of the Social Context Theory of cultural adaptation

Development of the Social Context Theory in CAMI1 and its refinement in CAMI2 followed empirically-based recommendations for adaptation [51,52]. First, adaptation should preserve and not dilute active ingredients in the original treatment [35]. Project CAMI1, the pilot study that initially compared CAMI to MI, documented that MI key ingredients (e.g., collaboration with therapist) were preserved in the CAMI adaptation [37,53]. Second, unique risk factors predicting the health behavior of concern in the population of interest, were identified [51]. Consistent with recommendations by experts in medicine [54,55] and in ethnic minority psychology [53,56], CAMI formative work assumed that risky health behaviors like heavy drinking were equally influenced by social and cultural