ARIC Manuscript Proposal #H3579

PC Reviewed: 3/10/20 **Status: _____** **Priority: 2**
SC Reviewed: _____ **Status: _____** **Priority: ____**

1.a. Full Title: Development, assessment, and monitoring of audiologic treatment fidelity in the Aging, Cognition, and Health Evaluation in Elders (ACHIEVE) randomized controlled clinical trial

b. Abbreviated Title (Length 26 characters): Audiological Treatment Fidelity

2. Writing Group:

Writing group members: (Alphabetical)

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I, the first author, confirm that all the coauthors have given their approval for this manuscript proposal. MLA **[please confirm with your initials electronically or in writing]**

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3. Timeline: Manuscript submission 2-4 months following approval

4. Rationale:

Treatment fidelity, or the monitoring, assessment, and improvement of the reliability and validity of a study, is essential when testing complex behavioral interventions (Borelli, 2011). The goal of treatment fidelity is to increase confidence that the study findings are scientifically sound, and that changes in outcomes are a result of the tested intervention and not confounding factors (Robb, Burns, Docherty, & Haase, 2011). The concept of treatment fidelity has evolved to incorporate treatment integrity (an intervention is delivered as designed), treatment differentiation (critical components of comparison interventions are, indeed, different), treatment receipt (participants understand what to do with regard to the intervention), and treatment enactment (participants use the intervention) (Bellg et al., 2004; Robb et al., 2011). Failure to implement an appropriate treatment fidelity plan has important implications regardless of whether a tested treatment demonstrates efficacy or effectiveness.

Numerous strategies enhance treatment fidelity, such as training manuals, procedural checklists, and audio or video recordings of research appointments. Although utilization of treatment fidelity strategies is important in terms of assessing the efficacy of an intervention, publications describing the fidelity plans of clinical trials are lacking, likely due to (1) failure of researchers to implement treatment fidelity methods; (2) lack of reporting; and/or (3) editorial policies of academic journals (Borelli et al., 2005). In hearing loss treatment and aural rehabilitation, methods to implement and assess treatment fidelity are under-utilized and under-reported. This represents a critical gap in the field that has potential to impede advancements in audiologic treatment development, dissemination, and implementation.

The purpose of this paper is to describe the treatment fidelity strategies implemented in a multi-site randomized controlled trial (RCT), the Aging and Cognitive Health Evaluation in Elders (ACHIEVE) study (ClinicalTrials.gov Identifier: NCT02412254) (Deal et al., 2018). We modeled the ACHIEVE fidelity plan after the National Institutes of Health Behavioral Change Consortium (NIH BCC) Treatment Fidelity Workgroup's best practice guidelines for behavioral interventions (Bellg et al., 2004). Treatment fidelity is a key component of the overall quality control of the ACHIEVE RCT. The ACHIEVE RCT treatment fidelity plan can serve as a framework for the application of NIH BCC strategies, and thus enhance the reliability and validity of findings from future audiologic intervention studies.

5. Main Hypothesis/Study Questions:

The paper has the following aims:

1) To describe how best-practice hearing intervention treatment fidelity was implemented and is being monitored across four study sites in the Aging and Cognitive Health Evaluation in Elders randomized controlled clinical trial. The treatment fidelity plan is

based on a framework defined by the National Institutes of Health Behavior Change Consortium.

2) To describe the process of delivering the hearing intervention with regard to maintaining a high level of treatment fidelity. This will be largely based on descriptive feedback provided by audiologists at the 4 ACHIEVE study sites.
3) Note: Basic information about the ACHIEVE study will be included in this manuscript. However, the manuscript does not include a great deal of in-depth information about the intervention itself, outside the elements that relate to treatment fidelity. A thorough overview of the procedures and manualization of the hearing intervention, and results of the feasibility study is pending publication in Ear and Hearing (Sanchez, et al.).

6. Design and analysis (study design, inclusion/exclusion, outcome and other variables of interest with specific reference to the time of their collection, summary of data analysis, and any anticipated methodologic limitations or challenges if present).

This paper will be primarily descriptive. Authors Arnold, Chisolm, Haley and Sanchez will review the current Fidelity protocol to determine if the elements specified in the NIH Behavior Change Consortium (BCC) framework are included in the current Audiology Fidelity Plan for ACHIEVE. The BCC treatment fidelity recommendations address 5 areas related to the study of complex behavioral interventions: (1) study design, (2) training of providers, (3) delivery of treatment, (4) receipt of treatment, and (5) enactment of treatment skills. The paper will describe how the ACHIEVE study, particularly the hearing intervention, addresses each of these areas in terms of maximizing treatment fidelity. The various strategies and procedures used for study design, provider training, and treatment delivery, receipt, and enactment will be described. The assessment tool to be used is a 25-item checklist developed by the BCC that addresses recommendations from each of the 5 NIH BCC areas (attached to this proposal). Results will be reported in terms of reviewer checklist outcomes from each of the assessors. The discussion section will also include feedback from the audiologists working at each of the 4 ACHIEVE study sites with regard to the treatment fidelity process and lessons learned as they administered the hearing intervention.

Design: N/A

Participants: N/A

Inclusion/Exclusions: N/A

Outcome: N/A

Exposure: N/A

Analysis and potential challenges: We will examine inter-rater reliability based on the independent assessments of the current fidelity monitoring plan. We have included a non-audiologist expert (Dr. Bill Haley) as this will increase the validity of our ratings.

7.a. Will the data be used for non-ARIC analysis or by a for-profit organization in this manuscript? ____ Yes __X__ No

b. If Yes, is the author aware that the current derived consent file ICTDER05 must be used to exclude persons with a value RES_OTH and/or RES_DNA = "ARIC only" and/or "Not for Profit" ? ____ Yes ____ No

8.a. Will the DNA data be used in this manuscript? ____ Yes __X__ No

8.b. If yes, is the author aware that either DNA data distributed by the Coordinating Center must be used, or the current derived consent file ICTDER05 must be used to exclude those with value RES_DNA = "No use/storage DNA"? ____ Yes ____ No

9. The lead author of this manuscript proposal has reviewed the list of existing ARIC Study manuscript proposals and has found no overlap between this proposal and previously approved manuscript proposals either published or still in active status. ARIC Investigators have access to the publications lists under the Study Members Area of the web site at: http://www.cscc.unc.edu/aric/mantrack/maintain/search/dtSearch.html

X Yes _____ No

10. What are the most related manuscript proposals in ARIC (authors are encouraged to contact lead authors of these proposals for comments on the new proposal or collaboration)?

11.a. Is this manuscript proposal associated with any ARIC ancillary studies or use any ancillary study data? X Yes No

11.b. If yes, is the proposal

X A. primarily the result of an ancillary study (list number* 2016.03)

__ _ B. primarily based on ARIC data with ancillary data playing a minor role (usually control variables; list number(s)* __

*ancillary studies are listed by number https://sites.cscc.unc.edu/aric/approved-ancillary-studies

12a. Manuscript preparation is expected to be completed in one to three years. If a manuscript is not submitted for ARIC review at the end of the 3-years from the date of the approval, the manuscript proposal will expire.

12b. The NIH instituted a Public Access Policy in April, 2008 which ensures that the public has access to the published results of NIH funded research. It is **your responsibility to upload manuscripts to PubMed Central** whenever the journal does not and be in compliance with this

policy. Four files about the public access policy from http://publicaccess.nih.gov/ are posted in http://www.cscc.unc.edu/aric/index.php, under Publications, Policies & Forms. http://publicaccess.nih.gov/submit_process_journals.htm shows you which journals automatically upload articles to PubMed central.