Title: Good Oral Health - A Bi-level Intervention to Improve Older Adult Oral Health

Trial Number: 14-188-6

Date: January 18, 2021

Contents

Protocol with statistical analysis

Consent forms: Campaign Committee Consent, Motivational Interviewing followed by Campaign Condition and Campaign followed by Motivational Interviewing Condition

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Good Oral Health: A Bi-level Intervention to Improve Older Adult Oral Health

NIDCR Protocol Number: 14-046-E

NIDCR Grant Number: DE024168

Principal Investigators: Susan Reisine and Jean Schensul

NIDCR Program Official: Melissa Riddle, Ph.D.

NIDCR Medical Monitor: Kevin D. McBryde, MD

Draft: 1.6

January 3, 2019

STATEMENT OF COMPLIANCE

The study will be conducted in accordance with the International Conference on Harmonisation guidelines for Good Clinical Practice (ICH E6), the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and the NIDCR Clinical Terms of Award. All personnel involved in the conduct of this study have completed human subjects protection training.

SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

Principal Investigators:

Signed: _____ Date: _____

Name: Susan Reisine

Title: Professor Emeritus, University of Connecticut

Signed: _____ Date: _____

Name: Jean Schensul

Title: Senior Scientist, Institute for Community Research

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LIST OF ABBREVIATIONS

ADL	Activity of Daily Living
AE / SAE	Adverse Event / Serious Adverse Event
AMI	Adapted Motivational Interviewing
CA	Campaign
CDC	Centers for Disease Control and Prevention
CES-D	Center for Epidemiologic Studies - Depression Scale
DAS	Dental Anxiety Scale
FAQs	Frequently Asked Questions
GEE	General Estimating Equations
GI	Gingival Index
GLMM	General Linear Mixed Model
GOH	Good Oral Health
GOHAI	General Oral Health Assessment Inventory
ICF	Informed Consent Form
ICR	Institute for Community Research
IM	Integrated Model of Behavioral Prediction
IRB	Institutional Review Board
MFFD	Modified Fractional Factorial Design
NIDCR	National Institute of Dental and Craniofacial Research, NIH
NIH	National Institutes of Health
OCTOM	Office of Clinical Trials Operations and Management, NIDCR, NIH
OH	Oral Health
OHRQoL	Oral Health Related Quality of Life
OHRSA	Oral Health Research Strategic Alliance
OHRP	Office for Human Research Protections
PHI	Protected Health Information
PI	Principal Investigator
PM	Practice to Mastery
PMS	Practice to Mastery Score
Pro-GOH	Project Good Oral Health
QDS	Questionnaire Development System
SDM	University of Connecticut School of Dental Medicine

SOP	Standard Operating Procedure
SPSS	Statistical Package for the Social Sciences
TPB	Theory of Planned Behavior
TRA	Theory of Reasoned Action
UCHC	University of Connecticut Health Center
UPIRSO	Unanticipated Problem Involving Risk to Subjects or Others
US	United States
WHO	World Health Organization

PROTOCOL SUMMARY

Title: Good Oral Health: A Bi-level Intervention to improve older adult oral health

Précis: This study will test an intervention designed to change oral health norms and reduce disparities in oral health among vulnerable adults residing in publicly funded senior housing in Central Connecticut. The intervention model is based on Fishbein's modified theory of reasoned action operationalized through Adapted Motivational Interviewing and Practice-to-Mastery (AMI-PM). The intervention includes two components: 1) a face to face administration of the AMI-PM, a participatory counseling model, and 2) a targeted building-level campaign (CA) consisting of up to three half-day oral health events with skills development through practice to mastery (PM) to parallel the individual intervention (CA+PM), all based on the study's conceptual model. The study uses a modified fractional factorial design to evaluate the face to face and campaign components separately and in different additive sequences. Six buildings will be paired in three dyads. The buildings in each dyad will be randomized to either having the AMI-PM intervention first followed by CA+PM or to having the CA+PM first followed by AMI-PM. Sixty residents will be recruited in each building for a total of 360 participants. There will be four assessments:

1) T0 will include a survey, oral hygiene skills assessment and clinical assessment of the Gingival Index and Plaque Score. The survey will provide data on the conceptual domains that are the target of the tailored intervention;

2) T1 will follow the AMI-PM or CA+PM (depending on condition) and will include the survey, oral hygiene skills assessment and clinical assessment of the Gingival Index and Plaque Score. This assessment will occur 1-3 months after the AMI-PM or CA+PM;

3) T2 will follow the AMI-PM or CA+PM and will include the survey, oral hygiene skills assessment and clinical assessment of the Gingival Index and Plaque Score. This assessment will occur 1-3 months after the AMI-PM or CA+PM.

4) T3 will include oral hygiene skills assessment and clinical assessment of the Gingival Index and Plaque Score. This will

occur 16-18 months after study entry. We will use general linear mixed models (GLMM) or general estimating equations (GEE), respectively, to fit a model with intervention and period effects using the MIXED procedure in SAS®.

Objectives:

Primary Objectives:

1. To assess the separate and combined effectiveness of two components of a cognitive/behavioral intervention that together improve oral hygiene behaviors and oral hygiene status;

2. To assess whether differential sequenced combinations of these components has a differential effect on behavioral and clinical outcomes;

3. To investigate the mediation effects of cognitive/behavioral factors in changing clinical outcomes.

Primary Outcome Measures: Plaque Scores and Gingival Index

Secondary Outcome Measure: Oral Health Related Quality of Life

Population:

Sample size: 360

Gender: Males and Females

Age: Children and adults aged 18-61 with disabilities and those aged 62 and older who meet income guidelines and may have chronic health conditions with quotas of 52 people 62> and 8 people <61 in cycles II and III established by NIDCR in October, 2016

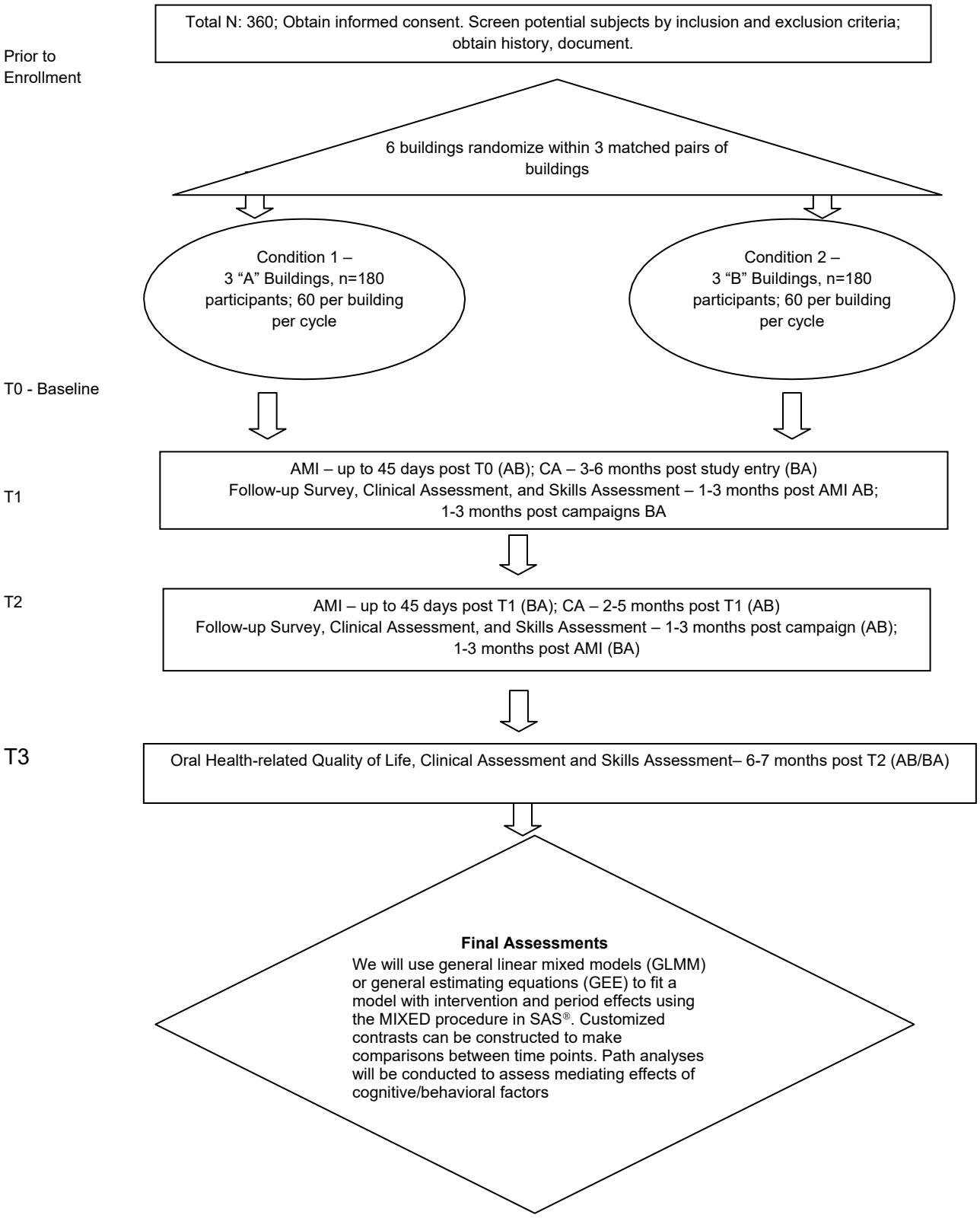
Demographic group: Vulnerable adults or children; we will recruit from low income senior housing in Central Connecticut. Residents must meet income guidelines and be over the age of 62 or be disabled adults or children.

General health status: The participants are independent living older adults residing in low income senior housing. Residents include vulnerable adults over age 21 and individuals meeting the NIH definition of children ages 18-21.

Geographic location: Central Connecticut

Phase:	not applicable
Number of Sites:	6 recruitment sites (housing for seniors and disabled individuals); The University of Connecticut School of Dental Medicine and the Institute for Community Research are coordinating sites.
Description of Intervention:	The intervention includes two components: 1) a face to face administration of the AMI-PM, a participatory counseling model, and 2) a targeted building-level campaign consisting of up to three half-day oral health events, all based on the study's conceptual model.
Study Duration:	60 months
Subject Participation Duration:	16-18 months
Estimated Time to Complete Enrollment:	approximately 36 months

SCHEMATIC OF STUDY DESIGN:



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2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

Older adults have a high prevalence of preventable and treatable oral health problems, and oral health disparities among impoverished older adults and adults with disabilities from all racial/ethnic backgrounds are striking, particularly with respect to African Americans and Latinos (Griffin, Jones, Brunson, Griffin, Bailey, 2012). Oral health is recognized as related to general health; thus, improving oral health can achieve improved overall health, which is critically important for racial/ethnic minority populations who also suffer from disproportionate rates of cardiovascular disease and diabetes. The development of a low cost intervention, conducted in locations where older and disabled adults live, that can develop potentially sustainable normative support for oral health, hygiene and change specific oral health practices (brushing, flossing, cleaning mouth and tongue, etc.) can reduce short and longer term psychosocial and economic costs associated with chronic illness and disability. Reducing persistent oral health disparities among vulnerable low income older adults and adults with disabilities is a central objective in Healthy People 2020 (*healthypeople.gov/2020/about/default.aspx*) and is a priority of state health departments and Area Agencies on Aging. Limited knowledge of oral health in general and related prevention and treatment alternatives, cultural differences in language and perception of oral health problems, and structural barriers to care such as insurance gaps, limited personal mobility and transportation, and inadequate culturally relevant public health education combine to increase oral health disparities in vulnerable populations. In 2009, NIH held its first conference to address ways of crafting and evaluating cognitive and behavioral interventions to address these issues. The conference specifically emphasized the importance of theoretical framing and tailored interventions to meet individual participant needs.

To address oral health disparities among older adults, a partnership of the University of Connecticut School of Dental Medicine, the Institute for community Research and the North Central Area Agency on Aging developed and received funding for two studies led by investigators Reisine and Schensul. Together, these projects developed the capacity, materials, design and infrastructure for the expansion of the pilot, entitled "*Good Oral Health – A Bi-level Approach to Improve Older Adult Oral Health*"

*Building Collaborative Research Infrastructure to Reduce Oral Health Disparities among Low Income Older Adults (*1 RC4 DE021324) built associations with 15 low income senior housing buildings in Meriden (3), Hartford (8) and New Britain (4) through contacts with management and building committees and presentations. Overall building demographics were: 64% - Private; 36% -Public; 52% - Hispanic, 29% - African-American/Caribbean, 19% - Non-Hispanic White. The project also allowed us to

develop health education materials, together with building residents based on the notion of FAQs. The final FAQs were formatted into a booklet for use in the pilot study.

Our successful pilot intervention *Changing Oral Health Norms and Hygiene Practices among Vulnerable Older Adults* supported by NIDCR #R34 DE022271 (2011-2013) was based on Fishbein's modified theory of reasoned action called Integrated Model (IM) of Behavioral Prediction (Fishbein, 2008) operationalized through Adapted Motivational Interviewing (AMI) and Bandura's notions of self-efficacy and skills reinforcement operationalized through Practice-to-Mastery or PM (Liska, 1984; Connor, 2010). The pilot study was conducted in a single building of approximately 200 apartments in the Greater Hartford Area. It included two components offered sequentially, a face to face intervention (the AMI) with practice of oral hygiene skills to mastery (PM), and two campaign fairs promoted by a small committee of building residents. Post intervention, participants (n=30) demonstrated a significant improvement in the Plaque Scores from a mean score at baseline of 84% (sd=11.8%) to 58% (sd=31.2%) at follow-up ($p<0.001$) and the Gingival Index from a mean baseline score of 1.2 (sd=0.56) to a mean follow-up score of 0.54 (sd=0.47), $p<0.001$. Differences in P-M skills scores from pre to post instruction in brushing and flossing, part of the AMI-PM session showed significant improvement. Brushing scores increased from 1.9 (fair/poor) prior to the AMI-PM session to 2.9 (good/excellent; $p<0.001$) after and flossing skills improved from 1.7 to 2.7 ($p<0.001$). In the intervention group, we found significant mean decreases (improvements) from pre to post in several important cognitive domains including perceived risk of oral disease which decreased from a mean of 2.5 to 2.0 (sd=.70 for both, p=.04) self-management worries which decreased from a mean of 1.36 (sd=.66) to 0.57 (sd=.97); p=.002) and self-management fears which decreased from a mean of 2.2 (sd=.81) to 1.53 (sd=.97; p=.001). In contrast, non-AMI respondents showed mean increases (deterioration) from pre to post in all three domains.

The pilot intervention evaluated the outcomes of both intervention components together. The proposed study uses a modified fractional factorial design (MFFD), a design approach developed to maximize capacity and cost effectiveness of testing intervention designs with multiple components which are found to be effective, but in which the interactivity of the components to produce positive outcomes is not well understood (Chakraborty, Collins, Strecher, Murphy, 2009; Collins, 2013; Nair, Strecher, Fagerlin, Ubel, Resnicow, Murphy, et al. 2008; Collins, Dziak, Li, 2009; Collins, Murphy, Nair, Strecher, 2005). Thus, the study is designed to evaluate the face to face and campaign components against each other, and in different additive sequences to determine which component has better short term outcomes, and whether sequencing components makes a difference in the final outcome.

2.2 Rationale

A search of the literature on disparities in geriatric oral health, state reports and local agency agendas point to significant gaps and needs to be addressed in this study. There are great disparities in oral health of older adults and those with disabilities including the high prevalence of decay, periodontal disease, edentulism, unmet

treatment needs and impaired quality of life associated with oral health conditions among older adults (Anders & Davis, 2010; Appollonio, Carabellese, Frattola, Trabucchi, 1997; Jensen, Saunders, Thierer, Friedman, 2008; Petersen, Yamamoto, 2005; Ritchie, Joshipura, Silliman, Miller, Douglas, 2005; Slade, Spencer, Locker, Hunt, Strauss, Beck, 1996) and adults with disabilities (Anders & Davis, 2010). Further there are significant disparities in burden of oral disease, oral health care, and oral health related quality of life by race/ethnicity, social class, and medical, functional and psychological comorbidities (Appollonio, Carabellese, Frattola, Trabucchi, 1997; Jensen, Saunders, Thierer, Friedman, 2008; Petersen, Yamamoto, 2005; Ritchie, Joshipura, Silliman, Miller, Douglas, 2005; Slade, Spencer, Locker, Hunt, Strauss, Beck, 1996; Ahluwalia &, Sadowsky, 2003; Ahluwalia, 2004, Lamster & Northridge, 2008; Petersen, 1990). Oral health is reciprocally related to systemic health (Kandelman, Petersen, Ueda, 2008) and systemic health conditions and physiological declines associated with aging can, in turn, have deleterious effects on oral health. Improving oral health in vulnerable older adults should have a significant impact on the reduction of disparities in other systemic health conditions. Oral health disparities affect ethnic and ethnic and racial minorities and low income populations and have a greater effect on quality of life among older African Americans compared to Whites on every dimension, but particularly in psychological discomfort, pain and functional limitations (Ahluwalia &, Sadowsky, 2003; Locker & Slade, 1994; Makhija, Gilbert, Boykin, Litaker, Allman, Baker, et al. 2006; Sheiham, Steele, Marcenes, Lowe, Finch, Bates, et al., 2001; Gerdin, Einarson, Jonsson, Aronsson, Johansson, 2005). Improving oral health related quality of life should be an important objective of oral health interventions.

There are studies that show that significant reductions in plaque and gingivitis can be achieved with manual tooth brushing (van der Weijden & Hioe, 2005; Robinson, Deacon, Deery, Heanue, Walmsley, Worthington, et al., 2005 Robinson, Deacon, Deery, Heanue, Walmsley, Worthington, et al., 2005 Jönsson, Ohrn, Lindberg, Oscarson, 2010;Jönsson, Lindberg, Oscarson, Öhrn; 2006) and one study demonstrates the importance of motivational interviewing in achieving these outcomes. These studies also provide the basis for estimating effect sizes for the current intervention. However other research indicates that both brushing and knowledge are not sufficient to result in long term improvements in oral hygiene. Without good behavioral self-management, the effects of clinical interventions are not persistent (Korber, 2006; Ajzen, 1980) and require cognitive-behavioral understanding and knowledge, daily attention to oral hygiene, and a pro-oral health environment.

Fishbein's integrated model of behavioral prediction, the IM is built on extensive empirical evidence supporting its ability to explain and predict health behaviors. The utility of the IM model in guiding prevention programming is supported by a substantial body of literature on factors contributing to improved oral health and prevention of periodontal disease of older adults above and beyond knowledge. These include oral health knowledge, locus of control, self-efficacy, social norms, intentionality of action and behavioral practice with a trusted role model. To it we have added an additional measure missing in the literature, on fears and concerns about oral health and hygiene

self-management. Understanding the contribution of oral health fears to oral hygiene is important in ensuring prevention-oriented oral health self-management. To address this gap, we have developed a new measure of oral health fears through formative research in the study population.

In addition, the IM model emphasizes the importance of social norms which are widely recognized to influence individual behavior (Cialdini & Trost, 1998). There is no research on social norms related to oral health, especially among older adults. Analysis of survey data on social supports for oral health information seeking and the results of analysis of the domain content/delivery of the AMI point to lack of social support for obtaining oral hygiene information.

Combined with Bandura's notions of self-efficacy and skills practice (Tedesco, Keffer, Fleck-Kandath, 1991; Bandura, 1989) and the additional conceptual domains identified above, the MI offer a cognitive behavioral approach to understanding and operationalizing an intervention to improve oral health self-management behaviors. In this study, it will be operationalized at the individual level through Adapted Motivational Interviewing (AMI), a scripted, standardized and measurable motivational interviewing approach and Practice-to-Mastery (PM) and at the group level through participant-driven campaigns (CA) with MI driven messages based on domains in the theoretical model (figure 1) and opportunities for Practice-to-Mastery (PM) embedded the campaigns.

Recognizing that individual level interventions have limited capacity to sustain change, many researchers propose multi-component, multi-level intervention approaches in producing both better immediate outcomes, and higher potential for sustainability (Schensul & Trickett, 2009; Trickett, 2009; DiClemente, Salazar, Crosby, 2007; Manhart, Holmes, 2005; Sallis, Cervero, Ascher, Henderson, Kraft, Kerr, 2006; van Empelen, Kok, van Kesteren, van den Borne, Bos, Schaalma, 2003; Trickett, Beehler, Deutsch, Green, Hawe, McLeroy, et al., 2011; Albarracin, Rothman, Di Clemente, del Rio, 2010; Albarracin, Tannenbaum, Glasman, Rothman, 2010; Latkin, Weeks, Glasman, Galletly, Albarracin, 2010; Schensul, Radda, Coman, Vazquez, 2009; Schensul, Trickett, 2009). Patrick, et al.(2006) are among those who argue for the need for multilevel approaches to improve oral health, particularly among ethnic minorities. A multilevel approach that supports and reinforces the same predictors and oral health practices both publicly, through resident led activities, and in individually through a tailored intervention should maximize outcome effects in a residential social environment and pave the way for future sustainability.

The pilot study on which the current protocol is based was structured as a bi-level intervention, delivered at the individual and at the "building" level. The pilot intervention was delivered as a "package" without differentiating the contributions of each component to the outcomes. Further, the pilot study did not allow us to assess whether the order of administration of the main components (individual versus group/community) made a difference in outcome. The study sample was too small to explore fully the

interaction of cognitive and behavioral domains in contributing to clinical outcomes. The design of the proposed expansion study will allow us to address these limitations.

2.3 Potential Risks and Benefits

2.3.1 Potential Risks

Risks to respondents from participation in this study are minimal. General risks might include: a) discomfort in presenting/discussing oral health conditions and behaviors; b) negative responses to oral health peer advocate committee members by building residents; c) possible loss of confidentiality if Campaign Committee members reveal any personal communications between themselves and residents related to opinions or questions related to oral health. These events have not occurred in previous studies. Risks associated with the oral health screening include some discomfort from the assessment. If a participant experiences sensitivity to the gum region, the topical anesthetic benzocaine 20% will be applied with a cotton swab to the cheek and gum side of the gum tissue prior to the screening exam. In the event that a dental condition discovered during the screening exam requires emergent/urgent evaluation or care, the participant will be notified immediately of the findings and will be referred immediately for treatment.

2.3.2 Potential Benefits

Individual participants may benefit from the clinical evaluation, and referral for further evaluation or treatment for dental, periodontal and soft tissue problems. The subjects will be notified of the findings of the oral health screening during the AMI-PM intervention, and any concerns or obstacles to improved oral health self-management will be addressed; thus participants may be able to improve their own self-care and prevent or reduce plaque accumulation and gum inflammation. Building residents will have the opportunity to reinforce their knowledge and oral health management behaviors in three campaigns (fairs) where they can obtain expert consultation for specific queries. Residents have the opportunity to play a leadership role in their building.

3 OBJECTIVES

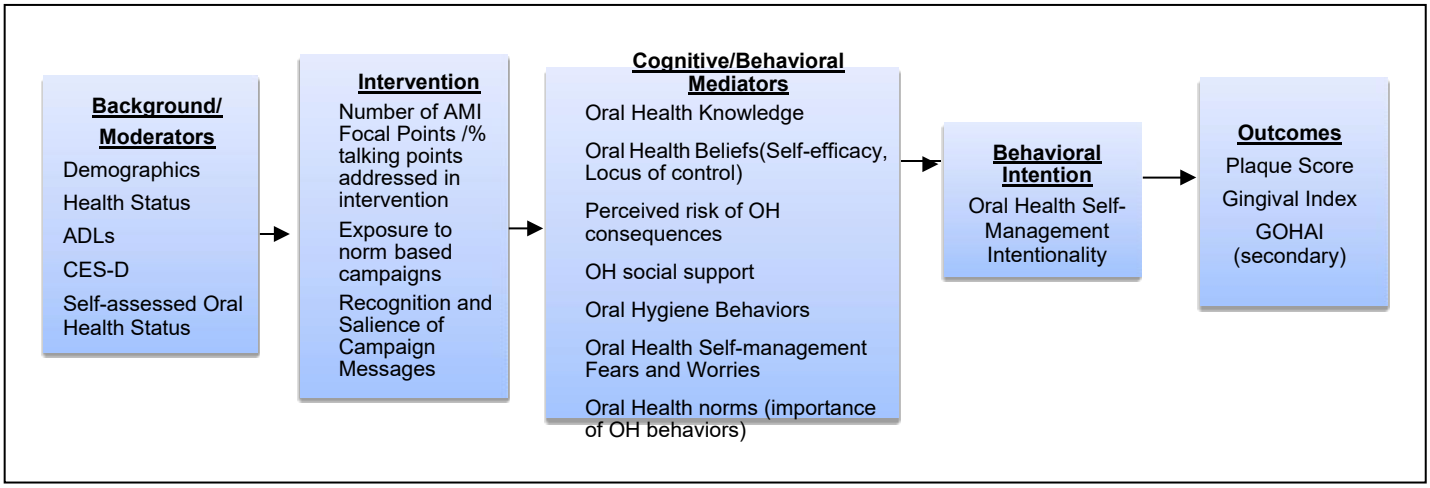
3.1 Study Objectives

1. To assess the separate and combined effectiveness of two components of a cognitive/behavioral intervention that, together, improve oral hygiene behaviors and oral hygiene status.

2. To assess whether differential sequenced combinations of these components has a differential effect on behavioral and clinical outcomes..

3. To investigate the mediation effects of cognitive/behavioral factors in changing clinical outcomes. The following figure presents the conceptual model with moderators, intervention variables, mediators and outcome variables.

Figure 1. Conceptual Model



3.2 Study Outcome Measures

3.2.1 Primary

The primary outcome measure is the clinical assessment of oral hygiene status:

Plaque Score: We will use a plaque scoring scheme developed by O'Leary (O'Leary, Drake, Naylor, 1972). This index consists of dichotomous presence or absence scores for plaque on each tooth surface. The supragingival bacterial plaque will be assessed with the use of erythrosine disclosing solution in six surfaces of each tooth. The non-toxic vegetable-based solution will be applied to the teeth by the examining hygienist. The number of surfaces stained red will be calculated over the total number of surfaces and the plaque score will be expressed as a percentage of surfaces with plaque as a

ratio. We used this measure in the pilot study and demonstrated significant reductions in plaque after the intervention.

Gingival Index: The Gingival Index (GI) (Loe & Silness, 1963) will be used to assess the gingival status related to six surfaces of each tooth. Each surface is scored for gingival inflammation: 0=no visual signs of inflammation; 1=slight change in color and texture of the gingiva but no bleeding; 2=visual sign of inflammation and bleeding upon swiping; 3=overt inflammation and spontaneous bleeding. The index is calculated by summing each surface GI and dividing by the total number of surfaces (mean value). Individual scores are summed to obtain a mean. Again, we used this measure in the pilot study and demonstrated significant reductions in the Gingival Index after the intervention.

3.2.2 Secondary

Oral Health Related Quality of Life (OHRQoL): We will use the General (Geriatric) Oral Health Assessment Inventory (GOHAI), a commonly used 12-item measure initially developed for older adults that has been used with low income populations (Atchison & Dolan, 1990). The GOHAI was translated into Spanish and back translated for the pilot study and was found to be acceptable across the racial/ethnic spectrum.

The GOHAI will be administered as part of the survey at T0 through T3. Research staff will be trained in administering the GOHAI as part of the general training in administering the survey. An objective of the study is to assess how the interventions and sequencing of the interventions affect OHRQOL and whether mediators differentially affect OHRQOL outcomes. Our primary outcomes are plaque scores and gingival index, but we expect that the interventions will have beneficial effects on OHRQOL as participants gain confidence and improve their oral health skills and experience better oral hygiene leading to better oral health. As Broder and others state, measures of OHRQOL are “congruent with patient-centered care… can help identify participant strengths and weakness…more accurately reflects risks and benefits of the intervention… and helps in defining clinically meaningful change”.

The mean score at baseline for the intervention group was 30.7 (sd=10.3), which indicates relatively poor OHRQOL as compared to other studies. The mean score at follow-up was 29.9 (sd=9.9) which was not a significant change. We would not anticipate significant changes in such a short period, but we could observe larger changes over a longer time period. Cronbach alpha was 0.76.

3.2.3 Mediators

Cognitive and Behavioral Mediators (Cronbach’s alphas based on pilot sample N=84)

Oral health knowledge: Oral health knowledge is a 7-item true/false test based on previously developed knowledge test used with low income older African Americans (Slaughter & Evans, 2007) (Alpha=.66).

Oral health beliefs/norms: The Dental Coping Beliefs Scale (Wolfe, Stewart, Maeder, Hartz, 1996; Wolfe, Stewart, Hartz, 1991; Wardh & Sorensen, 2005) is a 26-item scale consisting of four subscales, Oral Health Beliefs, Internal Locus of Control, External Locus of Control, and Self-Efficacy. The scales were adapted in the pilot study and used to measure oral health beliefs, locus of control, and self-efficacy, key domains in the study model (Alpha = .61).

Oral Health Norms: We will measure social norms with a scale that measures the perceived importance of oral hygiene behavior (Alpha =.68 with 1 item deleted).

Oral Health Social Support: These are two questions asking how building residents participants can obtain oral health information; and from how many others who regularly work in or visit the building participants can obtain oral health information (Likert scale: none,1-2, 3-4, 5 or more).

Perceived Oral Health Risks: This is a five-item scale that assesses perceived risk of oral heal problems, including getting cavities, toothaches, gum problems, oral cancer and oral health problems that would cause a visit to the hospital. Participants rate the likelihood of having these problems on a four-point Likert scale, 1 (very unlikely) to 4 (very likely). Chronbach Alpha = 0.83.

Oral hygiene behaviors: A measure consisting of questions that assess oral health self-management behavior including frequency and timing of brushing, flossing teeth, cleaning dentures (3 items, Alpha =.71).

Oral health self-management fears and worries: A scale was developed from formative data collected through our prior studies and evaluated during the pilot consisting of items identified by residents in focus group sessions related to worries and fears about conducting oral hygiene behaviors. Dental Worries Scale (23 items) Alpha=.90; Dental Fears (4 items) Alpha = .75.

Oral Health Self-Management Intentionality: Intention to perform the oral health self-management behaviors, a critical component of the IM model, will be assessed using the protocol described by Ajzen and Fishbein (1980) and Tedesco, et al. (1991) and adapted based on formative data. Participants will be asked to rate their intention to brush and floss daily using a five item four point Likert scale Alpha=.81.*3.2.4* Intervention Variables

Exposure to norms based campaign: *Dosage* will be assessed by: (a) reported attendance at each campaign activity (three), and (b) number of activities respondent participated in at each event (passport).

Number of focal points addressed in intervention: This is a count based on respondents' score below the cutoff points for main cognitive and behavioral domains measured and addressed in the intervention.

3.2.4 Moderator Variables

Demographic background information: Items include age, gender, building, length of time in building, length of time in U.S., marital status, race and ethnicity, current living arrangement, times moved in the past year, work status, religious engagement, income and income satisfaction, language use, telephone, transportation availability, home care and health insurance.

Health status: This will be measured by: (a) subjective health status, a single item, shown to be a valid measure of health status across ethnic groups, (b) an index assessing current health status based on self-report of diagnosis on 13 health problems common in older adults and used in earlier ICR studies, (c) a composite measure of physical health distress based on degree to which each problem prevents participation in normal daily activities.

Self-assessed Oral health status: measured with a five point Likert scale assessing subjective oral health status (Locker et al., 2000).

Activities of Daily Living: Activities of Daily Living (ADLs) a widely used measure of the functional status of an individual, It consists of 8 behaviors that indicate ability to take care of personal basic needs (Katz , 1983; Lawton & Brody, 1969)

CES-D. This is the 10-item short version of the CES-D Screening Instrument that measures depressive symptoms in community populations. The Spanish version of the 10-item CES-D has been validated for use with Puerto Rican older adults and has been used in several studies of older adults, including in public housing, in the study area (Radloff & Rae, 1979; Irwin, Artin, Oxman, 1999; Mahard, 1988; Robison, Gruman, Gaztambide, Blank, 2002; Robison, Schensul, Coman, Diefenbach, Radda, Gaztambide, et al., 2009; Diefenbach, Disch, Robison, Baez, Coman, 2009).

4 STUDY DESIGN

Overall Design: The study utilizes a modified fractional factorial design (MFFD) which compares the short term outcomes of the two intervention components: the tailored individual level brief intervention (AMI-PM) and the group level Campaign including embedded oral health skills development through practice-to-mastery (CA+PM). It also evaluates the effects of differential sequencing of these modes of delivery components in relation to short and longer term outcomes. Finally, it evaluates intervention mechanisms through mediational modeling of the cognitive and the behavioral components over time. The two intervention components are the individualized AMI-PM (Component A), and the group CA+PM (Component B). To evaluate sequencing we will randomize pairs of senior residences into two conditions: Condition 1 and Condition 2. Buildings in Condition 1 will initiate with Component A, followed by Component B. Buildings in Condition 2 will initiate with Component B, followed by Component A. This study design will allow us to compare the AMI-PM outcomes to CA+PM short term outcomes, and to determine which condition sequence (A+B or B+A) will produce the best clinical outcomes. Each of 3 cycles of Condition 1 (A+B) compared to Condition 2 (B+A) will take place over a 16-18 month period each in two matched buildings with an N of 60 per building (N per cycle of 120; total N for all three cycles approximately 360). We anticipate an attrition rate of approximately 25% and a final N of approximately 270 by the T3 measure, 135 in Condition 1 and 135 in Condition 2. Primary outcomes are improvements in gingival health and decreases in plaque scores.

A description of the study population: Participants will be recruited from low income senior housing in Central Connecticut. The population consists of independent living older adults many of whom have chronic health conditions. Residents also include adults less than 62 years of age residing in these buildings who are disabled. Residents must meet income guidelines and be over the age of 62 or be disabled children and adults between the ages of 18 and 61.

Methods for collecting data for assessment of study objectives: Data collection will consist of clinical assessment, and surveys evaluating changes in cognitive domains (See Section 16).

Clinical Assessments: Clinical assessments will be conducted to collect data on Plaque Scores and Gingival Index, described in Section 3.2.1. Trained and calibrated licensed hygienists will conduct the exams under the supervision of Dr. Lalla.

Referrals for Emergent Dental Needs: Emergent dental needs are not uncommon in this population; when found, they will be referred to the University of CT. School of Dental Medicine or to the nearest Community Health Center. Emergent dental needs include inability to eat due to tooth or mouth pain, visual swelling of the face or mouth, fever of >100.5 of probable dental origin, and oral lesion located in a high oral cancer risk area. Once participants have been treated for the emergent dental issue they will be offered the opportunity to continue with the study. Emergent needs will be ranked

using the system employed by the NHANES dental teams: Level 1 - participant should see a dentist immediately; Level 2 - participant should see a dentist within the next 2 weeks; Level 3 - participant should see a dentist at his/her earliest convenience; Level 4 – participant should continue with his/her regular routine. The form is included in the appendix.

Training and Calibration of clinical assessments (*Adapted from National Health and Nutrition Examination Survey Dental Examiners Procedures Manual*

Training is divided into three phases as follows:

1. The instructional phase in which examination team members are familiarized with research examination procedures and criteria for research assessments.
2. The standardization phase in which they are trained to use standard procedures and apply standard criteria for the oral health assessments.
3. The calibration phase in which the degree of correlation within and among the examiners and the standard examiner is measured.

Instruction

The instructional phase of the training sequence was conducted by Ruth Goldblatt DMD who served as the initial Clinical Director, and standardized examiner or gold standard, with experience as a researcher and examiner on the previous pilot study. Rajesh Lalla, DDS is the current Clinical Director and will conduct the instructional phase with any new dental hygienists who join the study. He has appropriate experience both as a researcher and clinician. Instructions are to be conducted in each type of oral health assessment (Gingival Index and Plaque Score). The trainer presents lectures on criteria for each of the oral health assessments to be used in the study. Lectures are accompanied by slides depicting a wide variety of possible observations and illustrating application of assessment criteria to those observations. The lecture-slide presentations on each assessment are followed by instructions on data recording for that assessment. Although the instructional phase consists primarily of lectures and slide presentations, some demonstrations of examination technique and equipment use are conducted. All phases of the training and calibration will be redone anytime there is a change in clinical examiners.

Standardization

The second phase of training is devoted to standardization. During this phase of training, the standard examiner reviews examination procedures and techniques and the criteria for each assessment, stressing the importance of consistency and uniformity among all examiners and the standard examiner in performing the examination and in applying the criteria to observations. Rationale for differences between a research examination and a diagnostic examination are discussed and professional ethics of

research examinations reviewed. A demonstration of the examination by the standard examiner and practice examinations by the examiners being trained is among the salient features of this phase. Standardization of all examiners will be achieved by examining 4 patients in the field replicating research subjects and conditions. Discussion will occur to aid standardization. The Clinical Director (standard examiner) will monitor and referee examinations and discussion of observations during these sessions.

Calibration

The reliability of the assessments is measured by determining the degree to which examiners can produce uniform and consistent results when performing independent replicate examinations without discussion. In this phase of training, the standard examiner and all examiners in training will each examine 4 patients who are similar in demographics to the study population. The standard examiner monitors the calibration session without discussing observations with any of the examiners.

Data from the calibration sessions are analyzed to measure correlation within and between each examiner and the standard examiner (e.g., Kappa and McNemar's Test). If correlations between each of the examiners and the standard examiner are not within acceptable ranges or some examiners are consistently higher or lower than the standard examiner (i.e., significant McNemar's test) additional training sessions will be scheduled.

Monitoring and Recalibration

Continual gathering of clean, reliable data in a consistent and uniform manner is one of the main objectives of the clinical control trial. Several quality control procedures will be carried out periodically to assure continuing quality of data gathered by the dental team throughout the duration of the study. As in the initial calibration, the standard examiner and all examiners will each examine 4 patients who are similar in demographics to the study population. Recalibration will occur prior to or at the beginning of each study cycle.

Expert Replication and Monitoring Field Operations

During the field operations, examiners and recorders should periodically review their training manuals to prevent deviation, or "drift" from the standards achieved during the training period. Particular attention should be devoted to uniform adherence to the criteria for making correct decisions about observations such as scoring of gingival indices and presence or absence of plaque. Strict compliance with infection control procedures is another important consideration for dental teams. In order to help the dental teams maintain their standards, the clinical director for the study will make periodic visits to field personnel to observe their performance and offer feedback on the results of their examinations. Field observations occur twice per assessor for each time

point. Observation and matched scoring for GI and Plaque Score occur once per assessor per time point. The standard examiner will choose one patient per each of the dental hygienists on whom the examination will be replicated. The replicated exam will be completed in paper format and compared to the one entered on the computer so as not to confound the data collection for the study. The purpose of these so called “expert replications” is to determine whether the examiners are maintaining the examination standards achieved during training, and to measure the degree of deviation, if any, from those standards. If correlation between the standard examiner and the field examiner is not within acceptable limits, retraining will be conducted.

Annual Retraining

The long duration of the study (5 years) requires the need for regularly scheduled retraining periods. In addition to the regularly scheduled recalibration sessions with the standard examiner, there will be an annual retraining session for each dental examiner, also conducted by the standard examiner.

Training and Calibration of Oral Hygiene Skills Assessment (Practice to Mastery and T0 – T3).

Training is divided into two phases as follows:

1. The instructional phase in which research interventionists and dental hygienists are familiarized with oral hygiene instruction and oral hygiene practice to mastery skill assessment scale.
2. The standardization phase in which the interventionists and dental hygienists are trained to use standard procedures and apply standard criteria for the oral hygiene skills assessment (and oral hygiene instruction for the interventionists).

Instruction

The instructional phase of the training sequence was conducted by Ruth Goldblatt DMD who served as the initial Clinical Director, and standardized examiner or gold standard, with experience as a researcher and examiner on the previous pilot study. Rajesh Lalla, DDS is the current Clinical Director and will conduct the instructional phase with any new intervention staff or dental hygienist who join the study. He has appropriate experience both as a researcher and clinician. Instructions will be given regarding the Oral Hygiene Skills Assessment Evaluation Form and each mastery level on the form. Demonstrations will be given using the tooth brushing models. Although the instructional phase consists primarily of lecture, slide presentations and video clips, some demonstrations of examination technique and models are conducted. All phases of the training and calibration will be redone anytime there is a change in field staff during the study.

Standardization

The second phase of training is devoted to standardization. During this phase of training, the standard examiner reviews oral hygiene instruction procedures and techniques used in oral hygiene education and the criteria for each assessment, stressing the importance of consistency and uniformity among all examiners and the standard examiner in performing the examination and in applying the criteria to observations. Rationale for differences between simple oral hygiene instruction and the practice to mastery evaluation are discussed and reviewed. A demonstration of the practice to mastery evaluation by the standard examiner and a rehearsal practice to mastery by the examiners being trained is among the salient features of this phase. Standardization of all examiners will be achieved by assessing the same 4 subjects in the field, replicating actual research conditions. Discussion will occur to aid standardization. The Clinical Director (standard examiner) will monitor and referee examinations and discussion of observations during these sessions.

Annual Retraining

The long duration of the study (5 years) requires the need for regularly scheduled retraining periods. There will be an annual retraining session for all study staff conducting the Oral Hygiene Skills Assessment, conducted by the Clinical Director.

In addition to the clinical and skills assessments, there will be annual retraining sessions for all study staff on the conduct of the survey and AMI process, conducted by the study PIs.

5 STUDY ENROLLMENT AND WITHDRAWAL

The Pro-GOH target population consists of residents living in buildings housing older adults and disabled adults in Central Connecticut, including the towns of Hartford, New Britain, and Meriden. Based on previous studies in these buildings, we anticipate that the population in the study buildings overall will consist of approximately 40% African American/Caribbean, 45% Latino (mainly Puerto Rican) and 10-15% other ethnic (Euro-American and Polish) residents. Approximately 13% will be under 62 years of age and will have some form of disability. All buildings are located in low income or working class neighborhoods that are medically and socially disadvantaged. Residents often lack access to regular health care and are at high risk for a variety of health and mental health problems.

We will select, match and work in three pairs of buildings of 100 – 250 apartments each. Six buildings have agreed to participate (See letters of support). Our goal in selection of buildings is to achieve a representative sample of residents that approximate the ethnic/racial balance identified above. One building in each pair will be randomly assigned to each condition.

5.1 Subject Inclusion Criteria

Inclusion criteria are:

a) Disabled children and adults aged 18 years and above, and adults 62 and above, including both male and female building residents, and minorities and non-minorities; restricted to 13.33% under the age of 62 in Cycles II and III by NIDCR as of Oct. 2017.

b) Permanent residence in sample buildings;

c) Independent of conservator;

d) Must be able to speak English or Spanish;

e) Judged competent to participate (based on ability to respond correctly to key questions about information covered during administration of informed consent.

f) Have two or more remaining natural teeth.

5.2 Subject Exclusion Criteria

Exclusion criteria are:

a) Considered by research staff to be cognitively unable to give informed consent;

b) Exhibition of continued disruptive behavior while participating in the project;

c) History of infective endocarditis, and/or prosthetic cardiac valve replacement in past 6 months, insertion of an arterial stent in past 6 weeks, myocardial infarction (heart attack) in past 6 weeks;

d) Under conservatorship;

e) Fewer than two natural teeth;

f) Currently on dialysis

5.3 Strategies for Recruitment and Retention

During the first five months of each full intervention cycle 120 residents will be enrolled into the study, 60 in each condition to which their building has been randomly assigned. Research team members will introduce the study in each of the buildings to tenants' associations and onsite managers, soliciting their support for the study. They will conduct 2 presentations 2 weeks apart to inform residents of the study, recruit and enroll potential participants, and within 2 – 3 days schedule appointments to conduct baseline surveys and clinical assessments. Participants will be recruited, enrolled, consented and scheduled for surveys during the first five months regardless of sequence of intervention. Thus, the timing of all surveys and clinical assessments will be the same for both buildings. Research team members will establish a base in a central location in each of the buildings from which to continue recruiting, place informational posters in elevators and in other public locations, actively recruit through engaging people in public spaces, and organizing weekly activities such as bingo games through which recruitment and enrolment will occur. These strategies were very successful in the pilot study. At the same time, 5 - 10 resident volunteers will be invited to join a campaign committee to co-plan and facilitate three building-wide campaigns. Based on prior experience we estimate overall attrition to be approximately 25%.

Retention. Retention in the study will be accomplished:

a) Through continuous presence in the intervention buildings

b) Repeated contact through face to face communication and fliers with intervention participants throughout the delivery of each component,

c) Active telephone and mail reminders in advance of scheduled appointments for surveys, clinical assessments, individual AMI-PM session and campaigns.

We will retain people in the study who, for medical or travel reasons, missed no more than one intervention, one assessment time point, or one intervention and one assessment time point.

Based on prior studies in senior housing, these methods have demonstrated intervention acceptability and are expected to result in almost 100% retention among those residents who are not ill, have not passed away, and have not moved elsewhere.

5.4 Treatment Assignment Procedures

Study implementation will take place over a five year period with buildings in pairs of 2 (matched and randomized to condition 1 (AMI-PM followed by CA+PM) or condition 2 (CA+PM followed by AMI-PM).

See Appendix A for details.

5.4.1 Randomization Procedures

Buildings will be paired on the basis of their age, ethnicity and gender characteristics and randomized by a statistician. Individual participants will not be randomized.

5.5 Subject Withdrawal

All participants will be told during the consent process that 1) their participation is voluntary; 2) they are free to withdraw from the study at any time; 3) withdrawal from the study will not affect their opportunity to participate in other studies conducted by the research partners; 4) there will be no penalty or loss of benefits to which they would be entitled, and 5) their withdrawal from the study will not affect any present or future care received at the University of CT Health Center.

5.5.1 Reasons for Withdrawal

Reasons for withdrawal will be recorded in the participant tracking data base.

5.5.2 Handling of Subject Withdrawals or Subject Discontinuation of Study Intervention

The sample size was powered anticipating an attrition rate of 25% which greatly exceeds our experience in the pilot study which was 15%. We do not expect people to withdraw because of adverse effects of the interventions. Once we are certain at any point in time that a participant has withdrawn or has discontinued, we will retain the person in the study up to the point at which they have withdrawn. If they withdraw after T1, we will include them in the T1 comparison. If they withdraw after T2 and before T3, we will include them in the T2 analysis, but exclude them from the T3 sustainability of effect analysis.

5.6 Premature Termination or Suspension of Study

This study may be prematurely terminated if, in the opinion of the investigator, the sponsor, or the IRB there is sufficient reasonable cause. Written notification, documenting the reason for study termination, will be provided to the investigator and/or

sponsor by the terminating party. Circumstances that may warrant termination include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to subjects;
- Insufficient adherence to protocol requirements;
- Failure to obtain sufficient follow-up data to evaluate the effectiveness ofthe intervention.

Submission of 6-month NIDCR and Medical Monitor Oversight Reports, and monthly progress reports are submitted electronically through UConn Health to the NIDCR project officer monthly. No DSMB is required for this study.

If the study is prematurely terminated or suspended, the sponsor will promptly inform the investigators/institutions, and the regulatory authority(ies) of the termination or suspension and the reason(s) for the termination or suspension. The IRB will also be informed promptly and provided the reason(s) for the termination or suspension by the sponsor or by the investigator/institution, as specified by the applicable regulatory requirement(s).

6 STUDY INTERVENTION

Study Behavioral or Social Intervention(s) Description

Conceptual Framework

The conceptual framework for the study intervention based on an adaptation of Fishbein's MI model utilized in our pilot study is summarized in Figure 1. Moderators include: demographic variables, subjective health, activities of daily living (ADLs), symptoms of depression (CES-D), self-assessed oral health; Intervention variables are the following: cognitive behavioral mediators to be targeted by the intervention include oral health knowledge, oral health beliefs, oral health social support, self-reported oral hygiene behaviors; oral health self-management worries and fears, oral health norms and behavioral intentions. Primary outcome variables are the Plaque Score and Gingival Index. Oral Health Quality of Life is a secondary outcome.

Intervention Implementation

The intervention we are proposing is a tailored bi-level intervention with two components, an individual level component (component A) with tailored messages based on performance on clinical assessment results, ADLs and cognitive domains in the survey delivered through adapted motivational interviewing with practice to mastery (AMI-PM); and a building level campaign (component B) open to all building residents that includes building tailored messages based on cognitive domains and skills reinforcement through Practice to Mastery.

Tailored Individual Level Intervention through Adapted Motivational Interviewing: (Component A).

The individually tailored individual-level intervention is approximately 45 minutes, and will take place within 45 days of administration of the baseline survey and clinical assessment in Condition A buildings, and within 45 days of administration of the T1 survey and clinical assessment in Condition B buildings. Trained project staff will administer the intervention. Interventionists will make appointments with residents who have completed the baseline assessment, review assessment materials and construct the intervention checklist specific to that individual based on findings from the survey and the clinical assessment. They will conduct the intervention either in the privacy of the resident's apartment or in a private location within the building.

The AMI-PM approach will address ADL related problems, any cognitive domain for which the response is below a designated cutoff, the results of the clinical assessment and brushing and flossing skills. The clinical examination will produce information on gingivitis and locations demonstrating accumulation of plaque. The survey will produce information on ADLs and incorrect beliefs, gaps in knowledge, gaps in self-efficacy and limitations in intentions to practice and gaps in reported skills and specific oral hygiene

practices. These data will be amalgamated using standardized forms to summarize the participant's cognitive and behavioral status prior to the intervention. The summary will be used to conduct the intervention. The AMI intervention for each participant will consist of the following:

1. Identify the domains that score under the cutoff point and check them on the Focal Point form.

2. Start the AMI with a discussion with the participant of their own oral health, oral health problems, concerns and fears, practices and intentions, challenges in performing oral health hygiene.

3. Show the participant how their own concerns connect to their survey responses and domains requiring intervention. Based on the discussion, identify any other areas requiring intervention.

4. Address each of the focal points (domains scoring below the cutoff point on the survey results), the survey and scripted set of messages for each domain (see appendix B) The process calls for correcting misunderstandings, increasing knowledge and addressing barriers to intention (cognitive: knowledge, beliefs, attitudes, fears, worries, efficacy/locus of control, intention) and dealing with any ADL concerns.

5. Show participant results of their own clinical assessment illustrating plaque scores.

6. Demonstrate on mouth model and through videos correct brushing and flossing.

7. Observe participant brushing and flossing on mouth model and score ability on P – M form.

8. Review ADL needs, reported cognitive and behavioral domains, and behavioral skills and build a cognitive behavioral plan together, for participant's improvement of oral health.

9. Obtain signature from participant on plan, and make a copy for participant and copy for file.

10. Participant will be given oral hygiene starter kit (tooth brush, toothpaste, floss, floss holder, tongue cleaner, and denture brush and cup if needed), brushing and flossing handouts and denture care handout if needed.

Individuals who score below the cutoff point on each of the following domains in the survey (see appendix B) will require cognitive / behavioral intervention.

All AMIs will be recorded for process documentation purposes.

Domain	Items	Cut-off points
1a. ADLs	Need help with grooming, dressing, eating, brushing teeth/cleaning dentures.	Need help on any of these
2a. Oral health knowledge	7-item knowledge test	<5 correct
3a. Oral health self-efficacy	If you brush and floss correctly, you expect fewer dental problems; You believe that you know how mouth sores can be treated; If someone showed you how to clean your teeth, you would be able to practice better oral health care; If you knew the facts about dental disease, you would be able to practice better oral care; You believe you can remove most of plaque to help prevent cavities and gum disease;	Mean of items <3 (disagree and strongly disagree)
3b. Locus of control	You believe tooth loss is a normal part of growing old	If response to this item was agree or strongly agree)
4a. Oral Health Norms - Beliefs about Impor-tance of oral hygiene	**How important do you think the following behaviors are**: Visit the dentist once a year; Brush your teeth at least once a day; Brush with fluoride toothpaste; Floss or clean between teeth at least once a day; Check for sores in the mouth	1 or 2 on any item (Not at all important; not very important)
5a. Oral health Social Support	Local access to health/oral health information	If all sources are “0” (none)
6a. Oral hygiene behaviors	**How often do you:** Brush in a day	<2 times per day
7a. Perceived Oral Health Risks	**What are the chances that you will** Get cavities? Get a toothache? Have problems with your gums? Develop oral cancer? Have to go to the hospital for problems related to your teeth, gums or mouth?	Mean <3 (4 - very unlikely; 3 - unlikely; 2 - likely; 1 - very likely)
8a. Self-management worries	**How worried are you that**: You cannot clean your dentures properly; You can’t control your bad breath Medications you are taking may be affecting your teeth If you brush your teeth your gums might get irritated You don’t brush your teeth enough When you floss there is bleeding You don’t brush your teeth properly You are not using the correct toothbrush You don’t know how to clean your tongue You don’t know the best time to go to the dentist If you use mouthwash it might dry out your mouth Your mouth feels dry all the time If you take your dentures out you could lose them You might have to get dentures of false teeth made from dead men’s teeth so you keep your bad teeth If you go to the dentist you might get a mouth or tooth infection or cancer You can’t clean the teeth in the back of your mouth Your teeth may keep you from socializing Your bad teeth are keeping you from eating foods Your teeth get discolored When you try to brush you feel pain When you put your dentures in it hurts	Mean <3 for scale (4 = not at all; 3= not much)

9a. Self-management fears	**You are afraid:** That bleeding gums may be a serious problem; You cannot clean your dentures properly; Of losing your teeth; Of oral cancer: That problems with your teeth and gums might affect your general health	Mean < 3 (4= not at all; 3 = not much)
10a. Oral Health Self-Management Intentionality	**What is the possibility that:** You will brush your teeth at least twice a day? You will floss your teeth or clean between your teeth at least once a day? You will clean your mouth daily? You will check your mouth for loose teeth? You will visit the dentist in the next year for a check-up and screening for oral cancer?	Mean <1 (0= no possibility; 1= slight possibility)
11a. Dry mouth	Do you sip liquids to aid in swallowing dry foods?	Yes
12a. Diet	**How often do you:** Eat sweet snacks; Eat starchy snacks; Suck on hard candies; Drink/eat sweets after brushing at night; Drink fruit juice on an average day.	>2-3 times a day on any item.
Clinical Assessment	Plaque Score and Gingival Index	All participants

Practice to Mastery.

The following criteria are defined for practice to mastery scores during the intervention. AMI (and for mastery scores during T0, T1, T2 and T3 observation points*)[1]

Excellent (4): (P-M) Is able to easily use the appropriate oral hygiene aids and correctly mimic the instruction from the video/live demonstration without additional instruction.

(*T0-T3) Is able to easily use the appropriate oral hygiene aids.

Good (3): (P-M) Is able to use the appropriate oral hygiene aids and requires no more than two corrective instructions to correctly mimic the instruction from the video/live demonstration.

(*T0-T3) Is able to use the appropriate oral hygiene aids and would require no more than two corrective instructions.

Fair (2): (P-M) Has difficulty using the appropriate oral hygiene aids and requires three or more corrective instructions to correctly mimic the instruction from the video/live demonstration.

(*T0-T3) Has difficulty using the appropriate oral hygiene aids and would require three or more corrective instructions.

Poor (1): (P-M) Does not understand the concepts in the video clips. Uses the incorrect brushes to demonstrate on the models. Needs complete instruction or intervention to mimic the oral hygiene instruction from the video clip or live demonstration.

(T0-T3) Does not understand the concepts in correct oral hygiene. Uses incorrect brushes to demonstrate on the models.

[All] Prior to the Practice to Mastery skills assessment, ask if participant is using any modification or adaptive device to his/her toothbrush or denture brush, or using a floss handle in order to better clean their teeth/denture/partial. If yes, provide the participant with the appropriate adaptive device to use during the skills assessment. [For P-M only] If no, and you determine that the client has a physical disability and cannot manage the oral hygiene aids due to arthritis for example, then you may suggest the tubing to adapt their tooth/denture brush or floss holder.

Behavioral skills assessment form checklist

Skill	Mastery Level	Lacks manual dexterity due to physical disability (i.e. arthritis, stroke)*		Sensory impairment limiting or modifying oral hygiene instruction (i.e. visual or aural impairment)**	
	Code #	Code #	Comments	Code #	Comments
Tooth brushing					
Flossing					
Cleaning Dentures or Partials					

***Dexterity codes**: **4** = full dexterity; **3** = good dexterity-can manage well without any help; **2** = requires some help, having difficulty if not using any help; **1 =** having high level of difficulty in demonstrating skills.

****Sensory impairment (visual or aural) codes: 4** = no sensory problem apparent for either; 3 = some visual or aural impairment; request for repetition of instructions and vocabulary; some difficulty with print size (not related to literacy); **2** = has difficulty hearing and/or can't see instructions at all; **1** = cannot hear sufficiently to respond to a question properly (not a language problem), and/or cannot see enough to recognize the pattern of plaque on teeth (not a comprehension problem).

[1] We are measuring oral hygiene skills at T0 – T3, but do not intend to use the results as a mediating measure in accordance with an NIDCR approved request to remove the OH skills assessment as a mediating measure from the study. It was never used as an outcome, but only as a mediator.

Group Level Intervention through Oral Health Campaigns

The group level oral health campaign involves volunteer residents as partners in the development of the fairs designed to delivery oral hygiene self-management messages based on the cognitive domains, ADL related problems in brushing and flossing, and brushing and flossing skills, and offer an opportunity to practice brushing and flossing on a mouth model to mastery. To fulfill the requirements of the campaign component of the study (CA), up to three health fairs will be implemented over approximately a three month period. CA+PM procedures include the following:

Identification, Training and Preparation of Pro-GOH Campaign Volunteers. Throughout Condition 1 (AMI-PM+CA+PM) and in the first month of Condition 2 (CA+PM+ AMI-PM) the study team will recruit 5-10 building residents to facilitate the group intervention. The committee will include building residents as role models who are broadly representative of the composition of the building by age, ethnicity, gender, ability and language. All committees will have bilingual (English/Spanish) capacity. Once recruited, consented and enrolled, committee members will meet with study trainers for 2-hour sessions twice a week, for a minimum five to six week period, to learn how to implement pro-oral health campaigns, to plan for each fair and to work with study interventionists to develop campaign materials. The Pro-GOH campaign events follow primary communications principles:

a) Message redundancy: same message delivered through different materials (at least 4 different types of materials in English and Spanish),

b) Multiple channels (messages delivered through oral, visual, written and practice means)

c) Multiple exposures (each message will be presented at least twice during each event)

d) Interactivity of residents with each other and oral health study personnel through interactive message based games and activities, for learning reinforcement;

e) Delivery of messages through respected role models (building volunteers, testimonials and oral health experts).

After each campaign event, research staff and campaign volunteers will reflect on the experience and document the results. The specific roles and responsibilities of the volunteers, working with study staff, include: a) learning about oral health and good oral health hygiene; b) using the Oral Health script materials to prepare messages for their fairs, linked to the theoretical domains; c) raising and addressing any concerns they might have about oral health promotion; d) agreeing to participate in recruitment of residents to fairs events; e) developing the plan and schedule for the fairs , including eliciting the support of building management; f) organizing expert presentations on oral health; g) arranging oral health good practice testimonials; h) staffing oral health practice to mastery tables on brushing, flossing and cleaning dentures; i) organizing tables by conceptual domain to deliver messages related to that domain. Delivery may

be in different formats (games, contexts, quizzes, bingo etc.); j) helping to set up and deliver food and entertainment.

Pro-GOH Campaign Volunteer Training Program. The volunteer training modules are as follows: Module 1: building group identity and scope of work (committee roles and responsibilities, establishing ground rules and introduction to core theoretical concepts guiding the intervention); Module 2: Review of the components of the Pro-GOH Campaign, protecting and respecting study participants, effective communication; Module 3: oral health and oral health self-management (presentation by collaborating dentist), confirmation of campaign event schedule; Module 4: creation of a campaign plan (selecting messages for each domain 1 – 12); Module 5: development of campaign materials based on module 4; Module 6: preparation for campaign event. Two additional sessions will focus on finalizing campaign materials, and practicing testimonials and oral health skills demonstrations and instruction on P - M on mouth model.

Standardized components of the Campaign. The core components are developed and structured to standardize the pro-oral health campaign, ensure the inclusion of the theoretical principles, and prepare for fidelity of implementation.

- Campaign messages: One message per conceptual domain based on domain scripts.
- Campaign Background Materials: include AMI domain specific scripts; Domain maps with definitions of domains, fliers and brochures, posters, videos from official oral health sites (e.g. NIDCR).
- Campaign recruitment: Resident volunteers will recruit residents to the campaign events using a plan that they devise to market the events and reach all residents in the building. They will prepare and post recruitment materials.
- Pro-GOH Campaign Activity Guide and checklist.
- The Campaign Passport, a document given to each building resident who attends each fair. It will record their name, attendance, duration of stay, and stamped evidence of participation at each message station during the fair.

7 STUDY SCHEDULE

See Appendix A.

7.1 Screening

Building residents will be screened for the inclusion/exclusion criteria at the time of recruitment to the study. The IRB has approved a script to be used for screening purposes.

7.2 Enrollment/Baseline

Section 5, Appendices A and B and MOP.

7.3 Intermediate Visits

See above.

7.4 Final Study Visit

See above.

8 STUDY PROCEDURES/EVALUATIONS

8.1 Study Procedures/Evaluations

The study procedures (described in section 3) include clinical assessments to assess Plaque Score and Gingival Index; oral health skills assessment/Practice-to-Mastery assessment; a survey administered by a research assistant, and recording and hard copy and digital documentation of the AMI-PM to assess fidelity of the intervention.

Trained interventionists will administer the AMI-PM. One or more will be fluent in Spanish and will undergo extensive training to assure fidelity. All intervention sessions will be audio recorded, with participant's permission. Audio recordings and hard copy/digital documentation from 10% of the AMI-PM sessions will be reviewed to measure fidelity.

The interventionists will conduct the training sessions for the campaign committee and will work with participants on developing campaign messages, materials and activities that are consistent with the conceptual model. Examples of materials will be provided to committee members based on the pilot study.

Surveys will be administered by trained research assistants, some of whom may be social workers, graduate or health professional students. Several will be fluent in Spanish. They will be supervised by the survey coordinator and the survey coordinator will not be involved in the intervention.

Most of the measures we are using to assess the constructs in the conceptual model have been previously developed, standardized and utilized as noted in Section 3. The exceptions are the Oral Health Self-Management Fears and Worries scale, the Perceived Oral Health Risks Scale and the Oral Health Self-Management Intentionality, which have good internal reliability and face validity. This study will provide the opportunity to investigate discriminant validity. The oral health skills assessment/Practice to Mastery Score is part of the intervention to assess improvements in participants' oral hygiene skills on a typodont during the intervention[2].

The primary outcomes are the Gingival Index and Plaque Scores. These are valid and reliable measures of oral hygiene. A secondary outcome measure is the OHQOL (Oral Health Quality of Life Scale). This is also a well known and utilized validated scale widely used with both younger and older adults. The dental hygienists will conduct the majority of clinical assessments under the supervision of Dr. Lalla who may conduct some of the assessments. All assessors will be calibrated to assure inter-rate and intra-rater reliability.

[2] We continue to collect OH skills assessment data at four time points, but we do not plan to use the data to measure changes in this variable.

9 ASSESSMENT OF SAFETY

Participant safety is of paramount importance in conducting our research project. The tailored one-on-one and building interventions present minimal risk to the participants. The study assessments also present minimal risk to participants. Some participants may find some portions of the survey stressful and upsetting. Participants may skip sections that are stressful or discontinue the survey at any point. The dental exam may present a very minimal risk of infection. If an infection occurs, the dentist on the study team will prescribe an antibiotic at the expense of the study. If the participant finds the exam painful, topical anesthetic will be applied. The PIs and the dentist will oversee safety precautions during the study. Participants with emergent dental treatment needs discovered during the dental exam will be referred for immediate treatment. Participants will be advised of other treatment needs and will be provided with a referral if needed. As with all research projects, reporting of suspected abuse is mandatory and participants are informed of this at the time of informed consent.

9.1 Specification of Safety Parameters

9.1.1 Unanticipated Problems

Participation in this study meets minimal risk criteria consistent with 45 CFR 46. Thus, safety monitoring for this study will focus on unanticipated problems involving risks to subjects, including unanticipated problems that meet the definition of a serious adverse event.

The Office for Human Research Protections (OHRP) considers unanticipated problems involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

- related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Incidents or events that meet the OHRP criteria for unanticipated problems require the creation and completion of an unanticipated problem report form. PIs will complete the

following information when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the IRB:

- appropriate identifying information for the research protocol, including the title, investigators' names, and the IRB project number;
- a detailed description of the adverse event, incident, experience, or outcome;
- an explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an unanticipated problem;
- a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

To satisfy the requirement for prompt reporting, unanticipated problems will be reported using the following timeline:

- Unanticipated problems that are serious adverse events will be reported to the IRB and to NIDCR within 1 week of the investigator becoming aware of the event.
- Any other unanticipated problem will be reported to the IRB and to NIDCR within 2 weeks of the investigator becoming aware of the problem.
- All unanticipated problems should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the investigator.

All unanticipated problems will be reported to NIDCR's centralized reporting system via Rho Product Safety:

- Product Safety Fax Line (US): 1-888-746-3293
- Product Safety Hotline: 1-888-746-7231
- Product Safety Email: *rho_productsafety@rhoworld.com*

General questions about SAE reporting can be directed to the Rho Product Safety Help Line (available 8:00AM – 5:00PM Eastern Time):

9.1.2 Adverse Events

An adverse event is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's

participation in the research, whether or not considered related to the subject's participation in the research.

9.1.3 Serious Adverse Events

A serious adverse event (SAE) is one that meets one or more of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability or incapacity
- Results in a congenital anomaly or birth defect
- An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

9.2 Time Period and Frequency for Event Assessment and Follow-Up

Unanticipated problems will be recorded in the data collection system throughout the study.

The PI will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit.

Any AE meeting the specified Serious Adverse Event criteria will be submitted on an SAE form to NIDCR's centralized safety system via Rho Product Safety. This report may be sent by fax or email. Once submitted, Rho Product Safety will send a confirmation email to the investigator within 1 business day. The investigator should contact Rho Product Safety if this confirmation is not received. This process applies to both initial and follow-up SAE reports.

SAE Reporting Contact Information:

- Product Safety Fax Line (US): 1-888-746-3293
- Product Safety Hotline: 1-888-746-7231
- Product Safety Email: *rho_productsafety@rhoworld.com*

General questions about SAE reporting can be directed to the Rho Product Safety Help Line (available 8:00AM – 5:00PM Eastern Time):

The study clinician will complete a Serious Adverse Event Form and submit via fax or email within the following timelines:

- All deaths and immediately life-threatening events, whether related or unrelated, will be recorded on the Serious Adverse Event Form and submitted to Product Safety within 24 hours of site awareness.
- Serious adverse events other than death and immediately life-threatening events, regardless of relationship, will be reported by fax within 72 hours of site awareness.

All SAEs will be followed until resolution or stabilization.

9.3 Characteristics of an Adverse Event

9.3.1 Relationship to Study Intervention

To assess relationship of an event to study intervention, the following guidelines are used:

1. Related (Possible, Probable, Definite)
    a. The event is known to occur with the study intervention.
    b. There is a temporal relationship between the intervention and event onset.
    c. The event abates when the intervention is discontinued.
    d. The event reappears upon a re-challenge with the intervention.
2. Not Related (Unlikely, Not Related)
    a. There is no temporal relationship between the intervention and event onset.
    b. An alternate etiology has been established.

9.3.2 Expectedness of SAEs

The NIDCR Medical Monitor and the Study PIs will be responsible for determining whether an SAE is expected or unexpected. An adverse event will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the intervention.

9.3.3 Severity of Event

The following scale will be used to grade adverse events:

1. Mild: no intervention required; no impact on activities of daily living (ADL)
2. Moderate: minimal, local, or non-invasive intervention indicated; moderate impact on ADL
3. Severe: significant symptoms requiring invasive intervention; subject seeks medical attention, needs major assistance with ADL

9.4 Reporting Procedures

The UCHC IRB requires reporting of unexpected adverse events that may represent an unanticipated problem involving risks to subjects or others (UPIRSO). Such events are to be reported using the *Problem Report Form* available on the UCHC website. Upon review the Institutional Review Board (IRB) may require changes to informed consent forms and/or protocols or other actions such as increased monitoring. The IRB makes the final determination as to whether an internal adverse event constitutes an unanticipated problem and whether changes to the consent and/or protocol are required. For external events, the sponsor should indicate if they have deemed the event to be a UPIRSO, and if so the IRB is to be informed.

All investigators and study personnel must be familiar with the policy for reporting unanticipated problems, inclusive of unexpected adverse events that may be unanticipated problems, to the IRB. All policies are available on the UCHC website. Such events must be reported using the Problem Report Form within 5 working days (7 calendar days) of becoming aware of the event. See Section 9.3.

9.4.1 Unanticipated Problem Reporting to IRB and NIDCR

Reporting unanticipated problems to the IRB is discussed in Sections 9.1.1 and Section 4. As with reporting requirements for the IRB, the PI will record all reportable events with start dates occurring any time after informed consent is obtained until 7 (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization. These events will be reported in writing to NIDCR within 5 working days for serious adverse events and within one month for non-serious adverse events.

9.4.2 Serious Adverse Event Reporting to NIDCR

Any AE meeting the specified Serious Adverse Event criteria will be submitted on an SAE form to NIDCR's centralized safety reporting system via *rho_productsafety@rhoworld.com*. See section 9 of the MOP for SAE reporting requirements.

9.5 Halting Rules

Study halting may occur as required by the IRB or NIDCR. The study PIs may temporarily suspend enrollment pending review by these authorities if warranted based on the presence, type, or frequency of SAEs or other changes in the study protocol which may place participants in greater than anticipated risk.

10 STUDY OVERSIGHT

The Principal Investigators, Drs. Reisine and Schensul, PIs on the prior NIDCR funded studies, will be responsible for study oversight, including monitoring safety, ensuring that the study is conducted according to the protocol and ensuring data integrity. The PIs will review the data for safety concerns and data trends at regular intervals, and will promptly report to the IRB and NIDCR any Unanticipated Problem (UP), protocol deviation, or any other significant event that arises during the conduct of the study.

In addition to the PIs responsibility for oversight, study oversight will be under the direction of the NIDCR Medical Monitor. The PIs will submit a report every 6 months to the NIDCR Medical Monitor for review. This report will include data regarding enrollment and retention, unanticipated problems and protocol deviations, outcome measures, quality management findings and other relevant parameters. If necessary, additional steps may be taken to ensure data integrity and protocol compliance.

The field team will be directed by the intervention coordinator and the survey coordinator. Both will work closely with the data analyst who will be responsible for tracking field progress and reporting to the study team. The PIs will remain in close contact with the field administrative team.

It is our practice for the research team to meet weekly and this group functions as a steering committee. We discuss and monitor: the general design and conduct of the study: preparation of the essential study documents, including the protocol, protocol amendments, MOP and data collection forms; review of data collection practices and procedures; changes in study procedures as appropriate; allocation of resources based on priorities of competing study demands; review of study progress and implementation of necessary steps to ensure the achievement of study goals; review and implementation of recommendations from those responsible for safety monitoring. We submit a monthly report electronically to the NIDCR program officers to keep them advised of our progress.

11 CLINICAL SITE MONITORING

Clinical site monitoring will not be done for this study; however, the NIDCR reserves the right to conduct independent audits or clinical monitoring as necessary.

12 STATISTICAL CONSIDERATIONS

12.1 Study Hypotheses

1. The AMI-PM will produce better short term (T1) clinical outcomes than the Campaign (CA+PM) (AIM 1).

2. The CA+PM+AMI-PM will produce better mid-term (T2) and long-term (T3) clinical outcomes than the AMI-PM+CA+PM (AIM 2).

3. The AMI-PM will produce more change in mediating cognitive domains than the CA+PM.

4. Both AMI-PM+CA+PM and CA+PM+AMI-PM will result in no differences in change in mediating cognitive domains from T0 to T2.

5. The greater the dosage (proportion of total talking points recorded for all domains in a tailored AMI; and exposure to campaign activities and messages), the better the outcomes.

6. We will investigate an exploratory hypothesis examining the effects of the intervention and sequence on oral health quality of life (a secondary outcome), as well as on clinical outcomes.

12.2 Sample Size Considerations

Sample size calculations are based on the primary outcomes of continuous measures of the Gingival Index and Plaque Scores using estimates of effect and variation from the pilot grant. The MFFD design has two sequences, called A:B and B:A, and two periods (1 and 2). We will power on the first period, which is essentially a two-arm parallel design with randomization at the building level. The study design will recruit N=60/ building, with 3 buildings on sequence A:B (N=180) and three on sequence B:A (N=180).

Table Sample size for a two-group t-test, using a two-sided α=0.05

Outcome	Source	Mean difference	Std Dev	Effect Size	N per group	Power
Plaque Index	Pilot	0.25	0.34 (pilot)	0.74	123	99
Gingival Score	Pilot	0.66	0.60 (pilot)	1.1	123	99
Plaque Index	Pilot	0.25	0.47 (UCL)	0.53	123	98
Gingival Score	Pilot	0.66	0.81 (UCL)	0.82	123	99
Plaque Index	Pilot*.75	0.20	0.47 (UCL)	0.42	123	91
Gingival Score	Pilot*.75	0.50	0.81 (UCL)	0.62	123	99
UCL= Upper 95% CL of the pilot study SD						

Attrition: Longitudinal studies must account for attrition. If we assume a conservative 75% retention rate across the study that would leave us with approximately N=135 per intervention group, or N=45 per building.

Effects of intra-class correlation (ICC) within sites: The cluster design can sometimes impact the power of a study and our calculations consider this human phenomenon. To account for the cluster design, we calculated the effective sample size which is the sample size used for power calculations, according to Killip et al. With this design we expect to have 6 clusters of N=45 each finish the study, or 135 per sequence. Assuming an intracluster correlation coefficient (ICC) of 0.01 or 0.02, which are typical values for human subject studies, this gives effective sample sizes closer to 123. The strategy therefore is to accordingly adjust the sample sizes used in calculations. As a result, our sample size calculations are based on a maximum number of N=123 per intervention (not 135) after accounting for loss of power due to intra-class correlation. Using N=123 per group, our power ranged from 91 to 99 for different scenarios reflecting varied assumptions, as shown in the attached memo from September 5, 2016.

Calculation for Primary Outcomes: While the pilot data provide a good starting point for sample size estimation, we acknowledge that the study was small and the results provide only estimates. To be conservative regarding pilot results, we 1) decreased the observed effect size by 25% and 2) used the upper 95% CL of the standard deviation for calculations. Employing these two hedges gives protection and helps assure we will have sufficient power to detect similar (or smaller) effect sizes with 80% power. With N=135 per group our study still has more that 90% power to find detect the mean differences (MD) in the table below.

12.4 Final Analysis Plan

The usual inspection for outliers and influential data points will be conducted along with summary statistics and evaluations of distributions of the data. We have experience with the clinical outcome measures, which have approximately normal distributions. In the case of non-normal data, we will use standard transformations (e.g., log) or explore alternatives (e.g., non-parametric approaches or other distributions such as Poisson).

Period 1: parallel arm phase: Standard approaches for a parallel 2-arm randomized study will be conducted for the first period of the sequence, across all buildings. This analysis allows direct comparison of the AMI vs. the Campaign approach for clinical outcomes (Study Hypothesis #1).

Periods 1 and 2: assessing sequence of interventions: Study Hypothesis #2, which sequence gives better clinical outcomes, will be addressed using repeated measures models. Depending on whether the outcome is continuous or dichotomous, we use general linear mixed models (GLMM) or general estimating equations (GEE), respectively, to fit a model with intervention and period effects using the MIXED procedure in SAS®. Each set of measures from the same person (e.g., gingival outcomes) are treated as a correlated cluster of data. An AR-1 correlation structure is

likely to be appropriate. Customized contrasts can be constructed to make comparisons between time points. Time-varying covariates can be used in these models, and some missing data (under MAR or MCAR assumptions where applicable), is allowable.

Baseline & health status variables: As this study randomizes at the level of site and individuals are not randomized, we will likely stratify some results (or adjust in models) for demographics such as age, gender, marital status and individual characteristics such as health status, ADLs, depressive symptoms (CES-D) and oral health status (self-assessment). Any variable that shows potential for confounding or effect modification will be accounted for appropriately in all stages of the analysis.

Intervention variables: As all subjects are exposed to the same interventions, it is of interest to unpack the intervention into 1) dosage (percent of talking points covered for all focal points (domains) addressed in the intervention, and 2) exposure to focal point messages during campaigns. Study Hypothesis #5, regarding dosage of interventions, will be assessed by creating an ordinal scale that measures an individual's exposure to talking points through participation in the AMI and exposure to messages via campaigns, thus creating a measure of dosage. We will then assess if dosage predicts better outcomes. This can be done directly (e.g., compare mean gingival scores across dosage levels with ANOVA) or dosage can be used as a predictor variable in the statistical models and causal pathway analyses. Oral health skills/Practice-to-Mastery (a 4 point Likert scale) and focal points (count variable) can be analyzed using similar techniques and approaches.

MFFD layout: N at the beginning of study		
	Sequence	N
Building 1	A:B	60
Building 2	B:A	60
Building 3	A:B	60
Building 4	B:A	60
Building 5	A:B	60
Building 6	B:A	60

Secondary Outcome of General Oral Health Assessment Inventory (GOHAI): We will conduct a set of secondary analyses with GOHAI as a continuous outcome. It will also be incorporated into our statistical/mediator models as predictor to see if it acts as an effect modifier.

Cognitive Mediators: The following variables will be incorporated into the causal pathway analysis to address example hypotheses #3 and #4: knowledge, oral health beliefs/norms, social support, oral hygiene behaviors, fears/worries, practice to mastery, and behavioral intentions. We will use longitudinal mediation to compared the efficacy of AMI-PM+CA+PM *to* CA+PM+AMI-PM in terms of whether they differ significantly in the amount of change that they engender in the gingival index and plaque score, indirectly through the mediators measured in our model.

The classical Barron & Kenny (1986) mediation approach to longitudinal mediation would examine whether the intervention impacts the levels of our mediators, such as beliefs, at T1 (for example), which in turn affect clinical outcome measures resulting from participant behaviors as measured by the Gingival index and Plaque Scores at T2. Or, simply put, whether levels of self-efficacy at T1 are associated with the levels of gingival index scores at T2 indirectly through self-efficacy at T1 (and other mediators previously referenced). But, we are interested in examining whether there is a change in our mediators over time, and if so, whether this change significantly leads to a change in behaviors, as assessed by the Gingival Index and Plaque Scores. Recent methodological studies actually show that the analysis of change is more appropriately captured by specifying change (differences) in self-efficacy and our other mediators and behavioral outcomes between adjacent time points (i.e. T1-T0, and T2-T1) as latent difference scores, and explicitly modeling these change scores to represent dynamic change, i.e., the impact of change in the mediators on change in the behavioral outcomes.

Hypothesis #3 will be tested using latent change score analysis specifying AMI and Campaign as predictors of change in behavioral beliefs(ΔBB), OH social support (ΔSS), locus of control beliefs(ΔCB), self-efficacy(ΔSE), fears/worries (ΔF/W), social norms (ΔSN), and behavioral intentions (ΔBI) from baseline to first and second follow-up.

To test hypothesis #4, we will conduct dynamic mediation using latent change (difference) score (LCS) mediation analysis. The analyses will be conducted in Mplus 7 where change (difference) scores representing differences in each mediator and outcome variable from baseline to final follow up (i.e. T1-T0 (ΔT_{10}), and T2-T1(ΔT_{21}) will be generated. It is the difference scores of the mediators and outcome variables that are modeled. Generally speaking, causal paths specifying latent (true) change, represented by change in knowledge, oral health beliefs/norms, OH social support, oral hygiene behaviors, fears/worries, oral health practice to mastery skills, and behavioral intentions in going from T0 to T1, and T1 to T2 will be specified, to predict change in Gingival Index and Plaque Scores at T2 (i.e., ΔGingival $Index_{21}$, ΔPlaque $score_{21}$). For example, we will test whether change in fears/worries from T0 to T1 significantly predicts changes in Gingival Index and Plaque Scores at final follow-up,T2 (ΔGingival $Index_{21}$, ΔPlaque $scores_{21}$). To assess the impact of the change in self-efficacy (ΔSE), on changes in Gingival Index scores (ΔGingival Index), direct and indirect paths from change in self-efficacy from baseline to first follow up (ΔSE_{10}) that predict the change in Gingival Index at the final follow-up (ΔGingival $Index_{30}$) will be specified and tested. Select direct and indirect paths from change scores of the other mediator variables to change scores of behavioral outcomes will also be specified in a similar fashion, and all these relationships will be tested simultaneously.

Summary: Using a conservative set of assumptions and based on our own pilot data, we have demonstrated, using our pilot data estimates, that we will have sufficient power to detect significant changes, using a two-group t-test which makes minimal

assumptions about the data. It is worth noting that the proposed statistical models have greater power characteristics than the t-tests used to calculate power.

13 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

There are three sources of data for the study which include the survey, the clinical assessment of the Gingival Index and Plaque Scores, and campaign participation/dosage. The survey will be administered through the Questionnaire Development System (QDS) electronic data collection system installed on individual password-protected laptop computers, backed up on password-protected flash drives, and downloaded each day into a study designated directory and database on a password-protected computer by the study data manager. The data directories are backed-up automatically each day. Each interviewer will have her/his own designated laptop computer and flash drive. Interviewers will check each interview file for missing data and completeness before saving to the data directories.

Data from the clinical assessments will be recorded electronically (See Appendix B). The oral hygiene skills assessment will be conducted by research staff at the time of the clinical assessment and recorded on the data form for the clinical assessment though it will not be used for evaluation purposes. Data will be tracked in an ACCESS data file.

Individual Passports for each person attending each of the fairs in the campaign will include the person's name, time of arrival and time of leaving. The passport will collect information on what activities they participated in. The Passport will be stamped at each activity. Passports will be collected at the end of each fair during the building campaign and the number of activities and other data will be recorded in an ACCESS file as a measure of dosage of the intervention and linked to the individual's ID.

14 QUALITY CONTROL AND QUALITY ASSURANCE

Quality control and quality assurance begins with adequate training and calibration of the interventionists and assessors, both clinical examiners and interviewers. Quality assurance is further addressed by monitoring fidelity throughout the study. These issues are discussed above. Quality management efforts are outlined in this section and in the quality management plan.

Data collection and accurate documentation will be the responsibility of the study staff under the direction of the Intervention Director, the Survey Director and the data analyst and the supervision of the PIs. All source documents reports will be reviewed by the study team and data management staff, who will ensure that they are accurate and complete. The data analyst will maintain a tracking database to assure that all necessary documents are completed for each participant; follow-up surveys and clinical assessments are completed on time; and AMI sessions are completed on schedule. This electronic file will include participant names because it is used to track and follow participants. It is password protected, kept in a directory that is only accessible to study staff, and is only available to study staff and PIs. Additionally, each research record will have a checklist on the inside cover to assure that all necessary documents are completed for each participant; follow-up surveys and clinical assessments are completed on time; and AMI sessions are completed on schedule. The format for both files is shown in the appendix.

Survey data collection will be accomplished using the Questionnaire Development System (QDS) electronic data collection system installed on individual password-protected laptop computers, backed up on password-protected flash drives, and downloaded each day into a study designated directory and database on a password-protected computer by the study data manager. The data directories are backed-up automatically each day. Each interviewer will have her/his own designated laptop computer and flash drive. Interviewers will check each interview file for missing data and completeness before saving to the data directories.

Additional Quality Assurance Activities

Survey:

The Screener and Survey in QDS is designed with built in controls to minimize data entry errors. The data entry controls will be adjusted during the first few weeks of data collection based on the real needs from the field.

Participation process (from initial contact to completion of the study) will be documented in a tracking table in Access which allows multiple queries to check data status, potential errors and take action to make correction at the earliest stages

Multi-dimensional data collection forms (e.g. clinical assessment, intervention process etc.) will be entered into Access forms. Then they will be imported into either SPSS for

quick report. The collection of these data will be tracked in the participation process tracking table (Access).

Intervention

Face to face AMI: The first five audio recorded AMIs will be checked for consistency against hard copy (Focal Point record), hard copy plan and Access database digital fidelity forms. Thereafter 10% of all audio recorded AMIs will be reviewed and checked for fidelity by the study PIs. Areas of inconsistency or incompleteness will be addressed through review and retraining. After each AMI is completed, all participant responses will be entered into the Access database by the interventionists. The Intervention Coordinator will review each AMI record entered into the database to insure that all components of the AMI session have been completed and documented.

Campaign fairs: All recording forms (attendance, passport), will be collected, linked to enrolled participants, and checked for completeness. Observations will note instances of message delivery in general sessions, and participation at PM station. Campaign passport data will be recorded for dosage. Documentation will be reviewed after the first campaign, and gaps and missing data for participants noted and corrected.

Calibration of clinical assessment: Recalibration will take place and be recorded prior to or early during administration of T0 of each cycle (approximately once a year).

Random audits of participant research records will take place every six months to assure that all documents are filed properly in the research record. Ten records will be selected every six months for review. Corrective actions will be taken if problems are found. The IRB/Human Subjects Coordinator also will review all completed consent forms on a weekly basis to insure use of current IBR-approved forms that are properly signed and dated. Corrective actions will be taken if problems are found.

15 ETHICS/PROTECTION OF HUMAN SUBJECTS

15.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6; 62 Federal Regulations 25691 (1997).

15.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all subject materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any subject is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented in the study.

15.3 Informed Consent Process

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Extensive discussion of risks and possible benefits of study participation will be provided to subjects and their families, if applicable. A consent form describing in detail the study procedures and risks will be given to the subject. Consent forms will be IRB-approved, and the subject is required to read and review the document or have the document read to him or her. The investigator or designee will explain the research study to the subject and answer any questions that may arise. The subject will sign the informed consent document prior to any study-related assessments or procedures. Subjects will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. The rights and welfare of the subjects will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study. We also will repeat screening for the eligibility criteria.

All individuals will be consented by trained survey or clinical assessors in the study. Participants will be asked to respond to 5 key questions to evaluate whether they understand the purpose of the study, what activities their participation entails, risks that might be encountered, expected duration of participation, and whether participation is voluntary.

Two copies of the consent form will be signed and dated by participant and assessment administrator. One is kept in the participant's hard copy file, and scanned for electronic warehousing, and the second is given to the participant.

A record of consent administration by date will be kept in the participant's access form, data to be entered by the survey coordinator.

15.4 Exclusion of Women, Minorities, and Children (Special Populations)

Women and men and all ethnic and racial minorities will be included in the study. Children ages 18-21 are eligible for the study, but given the demographics of the residents of the building it will be unlikely that children will be in the study.

15.5 Subject Confidentiality

Participant confidentiality is strictly held in trust by the investigators, study staff, and the sponsor and its agents. This confidentiality is extended to cover testing of biological samples in addition to any study information relating to participants. Data will be collected for research purposes only.

The following procedures will be put in place to protect the confidentiality of data. To avoid loss of confidentiality, participants' names will not appear on any document associated with the project, except for informed consent, HIPAA forms and Campaign Passport. Unique ID numbers, not participants' names, will appear on all interview records used for computer data entry. Ethnographic observations, field notes and other project records will be kept in locked files and in password protected computer files at UCHC and ICR, to which only project staff will have access. No records will be kept at building sites at any time. Names and apartment numbers, which will be used for creating unique identifier lists and for follow-up, will be kept under lock and key at the ICR project office, under the direct supervision of the Project Coordinators, and used by the project director and field interviewers only. Digital audio-recordings will be uploaded daily to password protected computer files, and deleted after the interview has been checked for accuracy. All names will be converted to codes and all identifier information will be removed from the recording. Therefore, the participant's name will not be used anywhere in the recording.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. A subject's participation in this project will be kept confidential within the study team at UCHC and the Institute for Community Research. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the PIs and sponsor, and will be shared only in aggregated form. Study data will be presented in summary form. Participant names or other identifying information will never be included in project data to be presented to the public. Therefore, participants will not be identifiable in presentations or publications based on this research.

The study monitor or other authorized representatives of the sponsor, and the UCHC IRB and Human Subjects Protections Office may inspect all study documents and records required to be maintained by the investigator, including but not limited to,

medical records (office, clinic, or hospital) for the study participants. The clinical study site will permit access to such records.

Knowledge of elder, child or spousal abuse, or participant intent to harm self or someone else, or of certain communicable diseases learned during the course of the study, is required to be reported to State officials.

16 DATA HANDLING AND RECORD KEEPING

16.1 Data Management Responsibilities

The Public Health Researcher/Data Analyst is responsible for overseeing all data management operations, including data entry, data transfer to main SPSS file, clinical assessment data, intervention data, and data tracking file.

The Survey coordinator is responsible for entry of evaluation data into tracking file, data collection, survey data checking and transfer from field computers to main SPSS storage. The survey coordinator will enter all evaluation data records into main data tracking file.

The Intervention coordinator is responsible for coordination and entry of all intervention data into intervention data files (Excel or Access). The intervention coordinator will enter all intervention data records into main data tracking file.

Dental hygienists will enter all screening data into an Access data base, using participant ID numbers. Data will be amalgamated into main study data file by time point, by the Data Analyst or supervised staff.

Intervention and evaluation staff will be based at ICR. Oral health dentist and health educator () and clinical assessment personnel (dental hygienists) will be based at the SDM. Student survey intern personnel from the UCONN Sociology and Anthropology departments and School of Social Work will be placed as appropriate at either ICR or SDM but field coordinated through ICR under supervision of the survey coordinator. The study team will follow procedures for overall coordination established in the pilot study through weekly meetings, and electronic information sharing on a daily basis. Surveys collected on individually labeled project specific computers will be downloaded to the QDS warehouse on a weekly basis and stored in separate files by computer, condition and cycle along with fidelity and clinical assessment data. Copies of QDS data collected in the field, along with all clinical assessment data will be retained on flash drives linked to individualized study computers. Further all survey data collected through QDS will be retained in RTF files as backup on flash drives. They will be transferred weekly to file storage on the ICR password protected server. Flash drives will be kept by individual researchers in a secure place. All study computers will be returned to the ICR office daily in accordance with their schedule and kept in a locked office. Study participant files will be maintained at ICR and stored electronically in password protected files at ICR and SDM. Password protected files will be available only to study team field coordinators and PIs. All data, study results etc. will be shared by study partners (ICR and SDM) using protected means of transferring de-identified data files.

16.2 Data Capture Methods

Data will be collected in 4 ways:

a) Survey (cognitive and all reported health related behavior including ADLs, dry mouth);

b) Observation methods;

c) Clinical screening forms;

d) Electronic records of intervention administration.

16.3 Types of Data

Two classes of data will be collected in this study: a) evaluation data; b) intervention data.

The outcome evaluation data to be collected in this study are of two types: clinical assessments of gingiva and plaque; and survey assessing ADLs and cognitive domains. (As noted earlier we will continue to collect oral hygiene skills data, but will not be using the data for outcome analysis.)

The intervention process/fidelity data to be collected in this study will be collected during the face to face intervention (AMI-PM) and campaign (CA+PM) and include:

AMI-PM: record of main domains requiring attention in the intervention (Focal point record including domains to be addressed, whether they are or not, and whether the correct script is delivered for each point); P-M pre and post scores; and participant plan of action (copy to participant and for electronic file).

CA+PM: record of exposure to all campaigns through a “passport” recording presence, duration, and visits to stations during campaign, including participation in practice to mastery. Data will be collected from the passport and entered into the intervention data base as presence/absence for each “page” (station), date of fair, time of entry and exit.

16.4 Schedule and Content of Reports

The Access data tracking file will allow for weekly and monthly updates of intervention and evaluation progress. Reports on enrollment, evaluation (screening, skills assessment, clinical assessment and survey), and completion of intervention will be provided to the study team initially on a weekly or biweekly basis as needed.

16.5 Study Records Retention

For funded grants, documents must be maintained for 7 years after the grant is officially closed (1 year at the investigative centers and 6 at the federal records center).

16.6 Protocol Deviations

The tracking database will be reviewed with the Field Coordinator bimonthly to assure adherence with protocols. Protocol deviations will be reported to the IRB within the required timeframe. Protocol deviations will also be reported to the NIDCR program officer via NIDCR_reports@rhoworld.com, once monthly. Plans to prevent future deviations will be developed and implemented.

17 PUBLICATION POLICY

NIH Publication Policy

The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.

Specifics

1. The NIH Public Access Policy applies to all peer-reviewed articles that arise, in whole or in part, from direct costs 1 funded by NIH, or from NIH staff, that are accepted for publication on or after April 7, 2008.

2. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this Policy.

3. PubMed Central (PMC) is the NIH digital archive of full-text, peer-reviewed journal articles. Its content is publicly accessible and integrated with other databases (see: http://www.pubmedcentral.nih.gov/).

4. The final, peer-reviewed manuscript includes all graphics and supplemental materials that are associated with the article.

5. Beginning May 25, 2008, anyone submitting an application, proposal or progress report to the NIH must include the PMC or NIH Manuscript Submission reference number when citing applicable articles that arise from their NIH funded research. This policy includes applications submitted to the NIH for the May 25, 2008 due date and subsequent due dates.

Project GOH Publication Policy

Procedures for Approval of Manuscript/Paper/Presentation Project GOH

Acquiring Topic Approval

Any individual seeking to lead author a paper or presentation from this project, will need to submit a request for approval from the PIs. In this sheet, following information should be provided:

- Paper topic

- Study hypotheses and expected variables or concepts to be explored

- Date of submission to PIs
- Expected authors in expected authorship order (please see Authorship Guidelines below.)
- Expected Journal or Professional Conference to which you will submit

Paper proposals will be discussed during weekly meetings of the research team. After receiving an email from PIs approving the paper proposal, the authors will sign an agreement by which they agree to the roles and responsibilities and the authorship order. This will help prevent future conflicts and delineate the level of contribution each author would be required to make towards the scientific paper/monograph.

Authorship Guidelines

Authorship and Contributorship

According to the International Committee on Medical Journal Ethics (ICMJE), an author is defined as one who has made substantial contributions to the conception and development of a manuscript. The ICMJE guidelines state that “authorship credit should be based on all of the following: 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or advising it critically for important intellectual content; and 3) final approval of the version to be published”. All other contributors should be listed as acknowledgements.

This means that, while all project staff and investigators may be included as authors on any publications produced from this study, they will only be included as an author on any given publication or presentation if they meet guidelines for authors as defined by these ICMJE guidelines for authors. Otherwise, project investigators and staff, as defined above, will be listed as contributors to a given manuscript. HOWEVER, every effort will be made to involve all above listed investigators as authors on each paper produced from this project. It is the responsibility of the lead author on each given paper from this project to ensure such opportunities for involvement are given. A lead author must contact each project investigator to invite them to be an author on the paper and specify their expected role.

Authorship Order

LEAD/FIRST AUTHOR-- The lead or first author of a given paper or professional presentation will lead conceptualization and writing of a given manuscript or professional presentation. He or she will also decide authorship involvement and order. All of this will be subject to approval from the principal investigators, using the procedure outlined in the Procedures for Approval of Manuscript/Paper/ Presentation. It is the responsibility of the lead author to ensure that all listed authors on the paper or presentation contribute at the level submitted to and approved by the PI. Alteration of

authorship order subsequent to this approval will require re-approval by the PI serving as senior author on the paper.

SECOND AUTHOR-- The second author of a given paper or professional presentation will support the paper with co-conceptualization and extensive writing, such as taking a leadership role on writing a section of the paper or presentation. Given the nature of partnership between the university and ICR, the second author should be from one of these organizations. This approach will increase the collaboration, knowledge, and perspectives offered by the paper or presentation. For lead authors with less writing experience, inclusion of a more seasoned publication writer is recommended for second authors.

SENIOR (LAST) AUTHOR-- Senior authors of papers will be positioned as such due to their oversight of the paper/presentation as a whole and their ability to ensure that the paper/presentation fits within the overall study and the previous and ongoing papers and presentations developed from the initiative. As such, principal investigators are in the optimal position to serve as senior author on all papers and presentations produced from their respective studies.

Role of the lead author to Pursue the Paper/Presentation Once Approved: A lead author of an approved paper or presentation will have SIX MONTHS from the date of approval to submit the DRAFT paper or presentation for review. Should the paper or presentation not be completed within that SIX MONTHS time frame, rights to lead author this work are relinquished.

Obligations to Maintain Author Involvement on a Paper: In accordance with the guidelines of most journals, authors are required to share revisions and resubmissions with all authors at every resubmission. Nothing should be submitted to any journal or any conference without approval from all authors on the paper or presentation; unless they agree that you may submit it without their final approval. Each author must be provided with a final copy of any submitted manuscript, report or presentation for their records. The primary author must also provide each author with a full citation of presented or published work. Make sure to include PIs.

Changing Approved Paper Topic, including Hypotheses and Expected Variables to be Explored, Authors and Authorship Order, Journal or Conference for Submission: Any changes in information provided and approved via this topic approval process will require resubmission of the Topic Approval Form with specifications as to why these changes are needed. Authors may not alter this information without approval from the PI and the senior author. In such intentions, the lead author should discuss with other authors and send an email to the PIs and get feedback on the suggested change.

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SUPPLEMENTAL MATERIALS

These documents are relevant to the protocol, but they are not considered part of the protocol. They are stored and modified separately. As such, modifications to these documents do not require protocol amendments.

APPENDICES

APPENDIX A: SCHEDULE OF EVENTS

Building A – Tailored intervention first followed by campaign

Visit	Activity	Timing	Compensation
1. – T0	Survey – 1 hour	Entry to study	$15.00
2. – T0	Clinical assessment, skills assessment – 20 minutes	Entry to study	$15.00
3.	Tailored educational session 45 min – 1 hour	Up to 45 days post T0	None
4. – T1	Survey – 1 hour	1-3 months after educational session	$15.00
5. – T1	Clinical assessment, skills assessment – 20 minutes	1-3 months after educational session	$15.00
	3 Campaign Events/Oral health fairs – 2-3 hours each	2-5 months after T1	None
6. – T2	Survey– 1 hour	1-3 months after campaigns	$15.00
7. – T2	Clinical assessment, skills assessment – 20 minutes	1-3 months after campaigns	$15.00
8. – T3	Clinical assessment, skills assessment, GOHAI – 20 minutes	6-7 months after T2	$20.00

Building B – Campaigns first followed by tailored intervention first

Visit	Activity	Timing	Compensation
1. – T0	Survey – 1 hour	Entry to study	$15.00
2. – T0	Clinical assessment , skills assessment – 20 minutes	Entry to study	$15.00
	3 Campaign Events/Oral health fairs – 2-3 hours total	3-6 months after study entry	None
3. – T1	Survey– 1 hour	1- 3 months after campaigns completed	$15.00
4. – T1	Clinical assessment , skills assessment – 20 minutes	1- 3 months after campaigns completed	$15.00
5.	Tailored educational session 45 min. to 1 hour	Up to 45 days after T1	None
6. – T2	Survey– 1 hour	1-3 months after educational session	$15.00
7. – T2	Clinical assessment, skills assessment – 20 minutes	1-3 months after educational session	$15.00
8. – T3	Clinical assessment, skills assessment, GOHAI – 20 minutes	6-7 months after T2	$20.00

APPENDIX B: EXTERNAL APPENDIX TABLE OF CONTENTS

Study Eligibility Form – English

Study Eligibility Form – Spanish

Participant Enrollment Spreadsheet

Survey/AMI Telephone Reminder Script - English

Survey/AMI Telephone Reminder Script - Spanish

Survey/AMI Appointment Card – English

Survey/AMI Appointment Card – Spanish

Campaign Committee Recruitment Flyer – English

Campaign Committee Recruitment Flyer – Spanish

IV. INDIVIDUAL INTERVENTION (AMI-PM)

Section Cover Page

Focal Points Checklist – English

Focal Points Checklist – Spanish

Practice to Mastery Score Sheet – English

Practice to Mastery Score Sheet – Spanish

Practice to Mastery Training Guidelines

Individual Oral Health Plan – English

Individual Oral Health Plan – Spanish

Tooth Brushing (video)

Flossing (video)

Denture Care (video)

Brushing (brochure) - English

Brushing (brochure) - Spanish

Flossing (brochure) - English

Flossing (brochure) - Spanish

Denture Care (brochure) - English

Denture Care (brochure) - Spanish

Pre-Post Plaque Score Sheet - English

Pre-Post Plaque Score Sheet – Spanish

Oral Hygiene Skills Assessment Reference List

V. GROUP INTERVENTION (Campaign)

Section Cover Page

GOH Campaign Committee Training Curriculum

Training Session Agenda (example) – English

Training Session Agenda (example) – Spanish

Ground Rules – English

Ground Rules – Spanish

Components of the Campaign – English/Spanish

Good Oral Health “101” (PPT)

The Purpose and Role of the Campaign Committee/Components of the Campaign (PPT) – English

The Purpose and Role of the Campaign Committee/Components of the Campaign (PPT) – Spanish

GOH Committee Member Tasks – English/Spanish

Protecting and Respecting Participants in Research Studies – English

V. GROUP INTERVENTION (Campaign) (continued)

Protecting and Respecting Participants in Research Studies – Spanish

Campaign Committee Training-Keeping Our Mouths Clean and Healthy

Oral Health Fair Flyer/Poster – English

Oral Health Fair Flyer/Poster – Spanish

Event Program – English

Event Program – Spanish

Oral Health Message Poster – English

Oral Health Message Poster – Spanish

Oral Health Bingo (example) – English/Spanish

Test Your Oral Health Knowledge – English

Test Your Oral Health Knowledge – Spanish

What Is Your Recipe for Good Oral Health? – English

What Is Your Recipe for Good Oral Health? – Spanish

Oral Health Wheel of Fortune – English/Spanish

Oral Health Fair Passport – English

Oral Health Fair Passport – Spanish

Oral Health and Diabetes (PPT)

Campaign Committee Certificate of Completion

Campaign Committee Debriefing Interview Guide – English/Spanish

VI. EVALUATION

Section Cover Page

Survey – English

Survey – Spanish

Clinical Assessment Form

Oral Health Fair Evaluation Form – English

Oral Health Fair Evaluation Form – Spanish

Referral Letter – Dentist - English

Referral Letter – Dentist - Spanish

Referral Letter-Participant - English

Referral Letter-Participant – Spanish

Authorization for release of Information – English

Authorization for release of Information - Spanish

VII. DATA MANAGEMENT

Section Cover Page

Participant Data Sheet

Participant Record Checklist

Completed Survey/AMI Form

Basic Oral Health Information Card

Survey/AMI/Clinical Assessment Schedule Form

VIII. ORAL HEALTH RESEARCH STRATEGIC ALLIANCE (OHRSA) MEMBER LIST

The documents contained in this Appendix were developed for the pilot study, Changing Oral Health Norms and Hygiene Practices among Vulnerable Older Adults (NIDCR R34DE022271-1), and serve as examples and references. All materials will be revised as necessary to conform to the design, methodology and aims of the proposed study, and will be submitted for review and approval by the UCHC IRB prior to use.

IRB Review
IRB NUMBER: 14-188-6
IRB APPROVAL DATE: 01/17/2018
IRB EXPIRATION DATE: 01/16/2019

Principal Investigator (PI): Susan Reisine, Ph.D.

Back-up Principal Investigator: Jean Schensul, Ph.D.

PI Phone Number: 860 679 3823

Title of Research Study: GOH- Good Oral Health – A Bi-level Intervention to Improve Older Adult Oral Health

Expected Duration of Subject's Participation: Five months – including 6-8 two-hour training sessions, 4 two-hour sessions to create campaign materials, and 3 campaign events/oral health fairs.

Sponsor: National Institute of Dental and Craniofacial Research

IRB Number: 14-188-6

Name of Research Participant: _____

What Is The Purpose Of This Research Study?

This study is a collaboration between the University of Connecticut Dental School and the Institute for Community Research. The purpose is to improve the ways older adults and adults with disabilities care for their teeth and mouths.

Why Am I Invited To Participate?

You are invited to take part in this study because you are an older adult or a person with a disability living in senior housing.

How Many Other People Do You Think Will Participate?

We estimate that 5 - 10 people will enroll in the Good Oral Health (GOH) Campaign Committee at this building. In total we expect about 15-20 people to enroll in the study as members of the GOH Campaign Committees at other buildings. We expect that 60 people will enroll in the GOH intervention in this building and a total of 360 people from all the buildings in the study.

What Will I Be Asked to Do?

The specific role of the Campaign volunteers includes:

- learning about oral health and good oral health hygiene;
- raising and addressing any concerns you might have about oral health promotion;
- agreeing to recruit residents to campaign events
- organizing others' or presenting your own oral health testimonials;
- working with intervention staff on oral health campaign materials;
- staffing information tables and game and poster contest activities at the oral health fairs;

- helping to set up food and entertainment;

The training sessions include:

- Training for your roles as Committee members
- Explanations of the main ideas of the intervention
- Oral health and oral health self management behaviors, including demonstration and volunteer practice;
- Review of the components of the Pro-GOH campaign;
- Creation of a Campaign plan.

Additional sessions involve the creation of Pro-GOH campaign materials such as posters, flyers, and games in English and Spanish that will include Pro-GOH messages and images portraying oral health practices. Project staff will work with you to create these materials. You also will help organize and direct 3 campaign events/oral health fairs. After the oral health fairs are completed, we will ask you to take part in an interview about your experiences as a member of the Good Oral Health Campaign Committee in your building, which will take approximately 30-45 minutes and will be audio recorded, with your permission.

For How Long Will I be Expected to Participate?

Participation will last five months.

Is Participation Voluntary?

Participation in this study is voluntary. Before making a decision about whether to participate in this research study, please read this consent form carefully and discuss any questions you have with the researcher. You may also want to talk with family members or a friend before making a decision.

If you decide to participate in the study, you are free to withdraw from it at any time. If you decide not to participate or you withdraw from the study, your decision will not affect your present or future medical or dental care you receive at the University of Connecticut Health Center/John Dempsey Hospital and there will be no penalty or loss of benefits to which you are otherwise entitled.

What Are the Costs To Me For My Participation?

There will be no cost to you for participating in the research.

What Risks Are Involved If I Choose To Participate?

The possible risk is that your personal information may be seen or heard by people other than the researchers.

What Are the Benefits Of My Participation?

You will not benefit directly from the information we gather in the study other than learning information you did not know about taking care of your oral health. Your contribution may help other people to improve their oral health self-care in the future. There is also the possibility that no benefit will come from this study.

Will I Be Compensated For My Participation?

At the end of the campaign activities you will receive $100.00 for your participation on the Campaign Committee (attending more than half the sessions and helping with a minimum of one of the Campaign events). In addition, you will receive $10.00 upon completion of the interview that focuses on your experiences as a Campaign Committee member. Total compensation for all activities is $110.00.

I prefer not to receive compensation for this study. ____

If you receive over $600 from participating in research studies over the course of the calendar year that money must be reported to the IRS as income. Signing a W-9 may be required.

What Alternative Procedures or Treatments Are Available To Me?

You have the option not to participate in this study.

How Will My Personal Information Be Protected?

For you and other building residents who participate in the GOH Campaign Committee, the following procedures will be used to protect the confidentiality of your data that will be collected. All information related to your participation in this study will be kept in a research record. The study staff will keep all study records (including any codes to your data) locked in a secure location. All paper documents containing identifiable information (e.g., signed consent forms) will be kept in locked files that are separate from other study records. Research records will be labeled with a code and all contents of the research record will be labeled with only that code. A 6-digit code will be derived from your first and last initial and the month and day you were born. A master key that links names and codes will be maintained in a separate and secure location. All electronic files (e.g., computerized database, spreadsheet, etc.), including those containing identifiable information will be password protected. Any computer hosting such files will also have password protection to prevent access by un-authorized users. Data that will be shared with others will be coded as described above to help protect your identity. Only researchers officially appointed to work on this project, the sponsor and agencies or departments with responsibility for research compliance (e.g. FDA) will have access to your information while it is stored in an identifiable format.

We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee 100% confidentiality. You should know that the sponsor, NIDCR, the United States Department of Health and Human Services, the UCONN Health Center's Institutional Review Board and the Human Subjects Protection Office may inspect records to ensure that the study is being done correctly. Also, if during the course of this study we learn of elder, child or

spousal abuse, the intent to harm yourself or others, or of communicable diseases, we are required to report it to State officials.

At the conclusion of this study the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations. No individual persons will ever be named or referred to in these presentations of intervention results.

What If I Decide To Stop Participating on the Campaign Committee?

You are free to stop taking part in this study at any time. If you decide to stop taking part in the study, your relationship with your doctors, dentists or the University of Connecticut Health Center will not be affected. If you decide to withdraw we ask that you let us know by calling Dr. Susan Reisine at 860-679-3823 or by sending a written notice to Dr. Susan Reisine, 263 Farmington Ave., MC3910, Farmington, CT 06030.

Can Someone Make Me Stop Participating on the Campaign Committee?

We may ask you to stop participating in the committee if you miss more than half of the training sessions, do not attend any Campaign events, you exhibit continued disruptive behavior while participating in the study or if you move out of the building.

What If I Experience An Adverse (Bad) Event Related To My Participation?

If you have an adverse event you should tell the Principal Investigators as soon as possible. You may contact Dr. Susan Reisine at 860-679-3823 or by sending a written notice to her at The University of Connecticut School of Dental Medicine, 263 Farmington Ave., MC3910, Farmington, CT 06030, or you may contact Dr. Jean J. Schensul at 860-278-2044 ext. 227 or in writing at The Institute for Community Research, 2 Hartford Square West, Suite 100, Hartford, CT 06106.

The University of Connecticut Health Center (UCHC), the Institute for Community Research (ICR) and your building management do not provide insurance coverage to compensate for injuries incurred during this research. However, compensation may still be available. A claim may be filed against the State of Connecticut seeking compensation. For a description of this process contact a representative of the UCHC Institutional Review Board at 860-679-1019 or 860-679-4851.

The UCHC does not offer free care. However, treatment for a research related injury can be obtained at the UCHC for the usual fee.

What If I Have Questions?

The Principal Investigators and Co-Investigators are willing to answer any questions you have about the research, in English or Spanish. You are encouraged to ask questions before deciding whether to take part. You are also encouraged to ask questions during your study participation. If you have questions, complaints or concerns about the research, you should call the Principal

Investigators Dr. Susan Reisine at 860-679-3823 or Dr. Jean Schensul (who speaks Spanish) at ICR, 860-278-2044, ext 227; or by sending a written notice to Dr. Susan Reisine, 263 Farmington Ave., MC3910, Farmington, CT 06030 or Dr. Jean Schensul at ICR, 2 Hartford Square West, Hartford, CT 06106.

If you have questions about your rights as a research subject you may contact a coordinator at the University of Connecticut Health Center Institution Review Board (IRB) at 860-679-1019 or 860-679-4851. You may also call a coordinator at the IRB if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies.

Please do not call the IRB number for medical or dental related issues or to schedule or cancel an appointment.

Consent To Participation:

By signing this form you acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form.

By signing this form the individual obtaining consent is confirming that the above information has been explained to the subject and that a copy of this document, signed and dated by both the person giving consent and the person obtaining consent, along with a copy of the Research Participant Feedback Form, will be provided to the participant.

Role	Printed Name	Signature	Date	Time
Participant				
Person Obtaining Consent				

IRB Review
IRB NUMBER: 14-188-6
IRB APPROVAL DATE: 05/17/2018

Principal Investigator (PI): Susan Reisine, Ph.D.

Back-up Principal Investigator: Jean Schensul, Ph.D.

PI Phone Number: 860 679 3823

Title of Research Study: GOH- Good Oral Health – A Bi-level Intervention to Improve Older Adult Oral Health

Expected Duration of Subject's Participation: 8 visits – 3 surveys for about 1 hour each, 1 education session for about 1 hour; 4 dental exams and oral hygiene skills assessments for about 20 minutes each; and 3 campaign events (or oral health fairs) that last about 2 hours each over about 2 months. The study will last 16-18 months at your building.**

Sponsor/Funding Agency: National Institute of Dental and Craniofacial Research

IRB Number: 14-188-6

Name of Research Participant: _____

What Is The Purpose Of This Research Study?

This study is a collaboration between the University of Connecticut Dental School and the Institute for Community Research. The purpose is to improve the ways older adults and adults with disabilities care for their teeth and mouths.**

Why Am I Invited To Participate?

You are invited to take part in this study because you are an older adult or a person with a disability living in low income senior housing.

How Many Other People Do You Think Will Participate?

We estimate that 60 people will enroll for participation at this building. In total we expect about 360 people to enroll in the study including people at other residences.

How Long Will My Participation In This Study Last?

You will be asked to meet with research staff for up to eight visits. Three visits for the surveys and one visit for the educational session will last about an hour each. Four visits for the dental exam and oral hygiene skills assessment will last about 20 minutes each. There will be 3 campaign events or oral health fairs at the building which we ask that you attend and complete information about what activities you participated in. The following table shows how the visits will occur.

Visit	Activity	Timing	Compensation
1.-T0	Survey – 1 hour	Entry to study	$15.00
2.-T0	Dental exam and assessment	Entry to study	$15.00

	of oral hygiene skills on a mouth model – 20 minutes		
3.	Tailored educational session	Up to 45 days post-T0	None
4.-T1	Survey – 1 hour	1-3 months after educational session	$15.00
5.-T1	Dental exam and assessment of oral hygiene skills on a mouth model – 20 minutes	1-3 months after educational session	$15.00
	3 Campaign Events/Oral health fairs – 2-3 hours	2-5 months after educational session	None
6.-T2	Survey – 1 hour	1-3 months after campaigns	$15.00
7.-T2	Dental exam and assessment of oral hygiene skills on a mouth model – 20 minutes	1-3 months after campaigns	$15.00
8.-T3	Dental exam, brief survey and assessment of oral hygiene skills on a mouth model – 20 minutes	6-7 months after T2	$20.00

What Are the Costs To Me For Participating In This Study?

There will be no cost to you for participating in the research

What Will I Be Asked to Do?

The study will involve:

- completing questionnaires three times;
- having a dental hygienist examine your mouth four times;
- assessing your oral hygiene skills on a mouth model four times;
- meeting with a health educator for a one-on-one oral health educational session to discuss plans on how to take better care of your teeth and mouth and show you how to brush and floss your teeth;
- attending 3 campaign events (oral health fairs) that will take place in your building.
- A dentist from our study may conduct an additional dental exam.**

With your permission the educational session will be audio recorded to assure consistency across educators.

Procedure	**Mouth examination**
Procedure	A dental exam is a standard clinical procedure. This procedure will be done at your building at time that is convenient for you. We will assess the health of your gums and look for injuries in the mouth. A red dye will be applied to your teeth to see the amount of plaque on each tooth.
Risk - Infection	The potential risk for infection is minimal and is the same as brushing your teeth. If such an infection should occur, antibiotics will be

	prescribed without cost to you. The study will pay for the antibiotic.
Safeguard	Licensed dental hygienists will perform the clinical exams under the direction of the Clinical Director. Sterile procedures will be observed during examinations including use of new latex or plastic gloves, disposable instruments for the exams and sterile gauzes.
Cost to Participant	There will be no cost to you.
Procedure	**Mouth examination**
Risk - Pain	Individuals vary in their experience of pain during dental exams.
Safeguard	If you experience pain, we will numb your gums during the dental exam to minimize pain and discomfort. Topical anesthetic benzocaine 20% will be used. It will be applied with a Q-tip on the cheek and tongue side of the gum tissue prior to the examination if the area is sensitive.
Cost	No cost to participant
Procedure	**Questionnaire**
Risk - minimal	There are no physical risks associated with the questionnaire. You may feel uncomfortable answering some of the questions. Loss of privacy is possible if an unauthorized person would hear your responses
Safeguard	You may always choose not to answer a question that makes you feel uncomfortable. Questionnaires will be administered in a private area to protect privacy.
Cost to Participant	No Cost
Procedure	**Oral Hygiene Skills Assessment**
Risk - none	There are no risks associated with this assessment. You will be asked to show how you brush and floss on a mouth model.
Safeguard	None needed
Cost to Participant	No cost to participant
Procedure	**Individual level tailored intervention**
	An experienced health educator will meet with you to discuss how to take better care of your teeth and mouth. He or she will ask you about what prevents you from taking better care of your teeth and mouth and what helps you. The educator will help you to improve your own care of your mouth and gums based on your dental

	exam and survey responses. The educator will ask you to show that you understand clearly how to clean your teeth, gums and mouth. You and the educator will make a plan together to improve the way you take care of your teeth and mouth. The educator will show you how to brush and floss your teeth. Then, using a mouth model, you will practice the brushing and flossing as shown by the educator.
Risk - minimal	There are no physical risks associated with the intervention. You may feel uncomfortable answering some of the questions.
Safeguard	You can refuse to participate.
Cost to Participant	No Cost
Procedure	**Completing Passports at Oral Health Fairs**
Risk - minimal	There are no physical risks associated with completing the forms. You may feel uncomfortable answering some of the questions.
Safeguard	You can refuse to complete the forms or refuse to answer any of the questions on the forms
Cost to Participant	No cost**

Is There any Reason Why I May Not Be Eligible to Participate in this Study?

If you have ever had an infection in your heart, a heart valve replacement in the past 6 months, a stent (a small tube that keeps your arteries open) placed in your heart in the past 6 weeks, a heart attack (known as an MI) in the past 6 weeks, have fewer than two of your natural teeth, if you have a conservator (a guardian appointed by a judge to protect and manage your financial affairs and/or your daily life), or you are currently on dialysis (a medical process that takes over the role of your kidneys when they can no longer work properly; you have a tube or other form of access through your arm, leg, neck or abdomen) you are not eligible to participate.

Is Participation Voluntary?

Participation in this study is voluntary. Before making a decision about whether to participate in this research study, please read and listen to the reading of this consent form carefully and discuss any questions you have with the interviewer. You may also want to talk with family members or a friend before making a decision.

If you decide to participate in the study, you are free to withdraw from it at any time. If you decide not to participate or you withdraw from the study, your decision will not affect your present or future medical or dental care you receive at the University of Connecticut Health Center/John Dempsey Hospital or any future participation in the Institute for Community Research programs and services and there will be no penalty or loss of benefits to which you are otherwise entitled.**

What Are the Benefits Of Participating In This Study?

You may benefit from the dental exams. You will be provided with the results of the exams and you will be referred for dental care if we find a need for care. You will be responsible for paying for dental care. Other people who may have the same oral health problems may benefit in the future. We might find a better way to diagnose or treat oral health problems. There is also the possibility that no benefit will come from this study.

Will I Be Compensated For Participating In This Study?

You will receive $15 for each of four clinical exams, $15 for completing each of three surveys and $5 for completing one brief questionnaire for a total of $110.

I prefer not to receive compensation for this study. ____

If you receive over $600 from participating in research studies over the course of the calendar year that money must be reported to the IRS as income. Signing a W-9 may be required.

What Alternative Procedures or Treatments Are Available To Me?

You have the option not to participate in this study.

How Will My Personal Information Be Protected?

The following procedures will be used to protect the confidentiality of your data. The study staff will keep all study records (including any codes to your data) locked in a secure location. Research records or study records, where we keep individual research information, are both paper and electronic files. Research records will be labeled with a code and all contents of the research record will be labeled with only that code. A 6-digit code will be derived from your first and last initial and the month and day you were born. A master key that links names and codes will be maintained in a separate and secure location. All electronic files (e.g., database, spreadsheet, etc.), including those containing identifiable information, will be password protected. Any computer hosting such files will also have password protection to prevent access by un-authorized users. Data that will be shared with others will be coded as described above to help protect your identity.

We will do our best to protect the confidentiality of the information we gather from you but we cannot guarantee 100% confidentiality. You should know that the sponsor, NIDCR, the Department of Health and Human Services, the Health Center's Institutional Review Board and the Human Subjects Protection Office may inspect records. They may inspect records to ensure that the study is being done correctly. Also, if during the course of this study we learn of elder, child or spousal abuse, the intent to harm yourself or others or of communicable diseases we are required to report it to State officials.

At the conclusion of this study the researchers may publish their findings in journals or magazines. Information will be presented in summary format and you will never be identified in any publications or presentations.
All information related to your participation in this study will be kept in a research record, apart from your medical record. The research record and its contents will be labeled with a code and kept locked in file cabinet in the office of the principal investigator. Only researchers officially appointed to work on this

project, the sponsor and agencies or departments with responsibility for research compliance (e.g. FDA) will have access to your information while it is stored in an identifiable format.

Will I Find Out the Results Of This Research Study?

You will be provided with information if the results apply to you and the health of your teeth and mouth.

What If I Decide To Stop Participating In The Study?

You are free to stop taking part in this study at any time. If you decide to stop taking part in the study, your relationship with your doctors, dentists or the University of Connecticut Health Center will not be affected. If you decide to withdraw we ask that you let us know by calling Dr. Susan Reisine at 860 679 3823 or by sending a written notice to Dr. Susan Reisine, 263 Farmington Ave., MC3910, Farmington, CT 06030.

Can Someone Make Me Stop Participating in the Study?

We may ask you to stop participating if, during the study period, you have a heart valve or joint replacement, an infection in your heart, a stent (a small tube that keeps your arteries open) placed in your heart, a heart attack (known as an MI), have fewer than two of your natural teeth, if a conservator is appointed to you, or you are on dialysis. We also may ask you to stop participating if you no longer live in the building, you exhibit continued disruptive behavior while participating in the study or you become unable to complete the surveys.

What If I Experience An Adverse (Bad) Event Related To My Participation?

If you have an adverse event you should tell one of the Principal Investigators as soon as possible. You may contact Dr. Susan Reisine at 860-679-3823 or by sending a written notice to her at The University of Connecticut School of Dental Medicine, 263 Farmington Ave., MC3910, Farmington, CT 06030, or you may contact Dr. Jean J. Schensul (who speaks Spanish) at 860-278-2044 ext. 227 or in writing at The Institute for Community Research, 2 Hartford Square West, Suite 100, Hartford, CT 06106.

The University of Connecticut Health Center (UCHC), the Institute for Community Research (ICR) and your building management do not provide insurance coverage to compensate for injuries incurred during this research. However, compensation may still be available. A claim may be filed against the State of Connecticut seeking compensation. For a description of this process contact a representative of the UCHC Institutional Review Board at 860-679-1019 or 860-679-4851.

The UCHC does not offer free care. However, treatment for a research related injury can be obtained at the UCHC for the usual fee.

What if I Have Questions?

The Principal Investigators and Co-Investigators are willing to answer any questions you have about the research, in English or Spanish. You are encouraged to ask questions before deciding whether to take part. You are also encouraged to ask questions during your study participation. If you have questions, complaints or concerns about the research, you should call the Principal Investigators Dr. Susan Reisine at 860-679-3823 or Dr. Jean Schensul (who speaks Spanish) at ICR, 860-278-2044, ext 227; or by sending a

written notice to Dr. Susan Reisine, 263 Farmington Ave., MC3910, Farmington, CT 06030 or Dr. Jean Schensul at ICR, 2 Hartford Square West, Hartford, CT 06106.

If you have questions about your rights as a research subject you may contact a coordinator at the Institution Review Board at 860-679-1019 or 860-679-4851. You may also call a coordinator at the Institutional Review Board if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies.

Please do not call the IRB number for medical or dental related issues or to schedule or cancel an appointment.

Consent To Participation:

By signing this form you acknowledge that you have read, or have had read to you, this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form.

By signing this form the individual obtaining consent is confirming that the above information has been explained to the subject and that a copy of this document, signed and dated by both the person giving consent and the person obtaining consent, along with a copy of the Research Participant Feedback Form, will be provided to the participant.

Role	Printed Name	Signature	Date
Participant			
Person Obtaining Consent			

Principal Investigator (PI): Susan Reisine, Ph.D.

Back-up Principal Investigator: Jean Schensul, Ph.D.

PI Phone Number: 860 679 3823

Title of Research Study: GOH- Good Oral Health – A Bi-level Intervention to Improve Older Adult Oral Health

Expected Duration of Subject's Participation: 8 visits – 3 surveys for about 1 hour each; 1 education session for about 1 hour; 4 dental exams and oral hygiene skills assessments for about 20 minutes each; and 3 campaign events (or oral health fairs) that last about 2 hours each over about 2 months. The study will last 16-18 months at your building.**

Sponsor/Funding Agency: National Institute of Dental and Craniofacial Research

IRB Number: 14-188-6

Name of Research Participant: _____

What Is The Purpose Of This Research Study?

This study is a collaboration between the University of Connecticut Dental School and the Institute for Community Research. The purpose is to improve the ways older adults and adults with disabilities care for their teeth and mouths.**

Why Am I Invited To Participate?

You are invited to take part in this study because you are an older adult or a person with a disability living in low income senior housing.

How Many Other People Do You Think Will Participate?

We estimate that 60 people will enroll for participation at this building. In total we expect about 360 people to enroll in the study including people at other residences.

How Long Will My Participation In This Study Last?

You will be asked to meet with research staff for up to eight visits. Three visits for the surveys and one visit for the educational session will last about an hour each. Four visits for the dental exam and oral hygiene skills assessment will last about 20 minutes each. There will be 3 campaign events or oral health fairs at the building which we ask that you attend and complete information about what activities you participated in. The following table shows how the visits will occur.

Visit	Activity	Timing	Compensation
1.-T0	Survey – 1 hour	Entry to study	$15.00

2.-T0	Dental exam and assessment of oral hygiene skills on a mouth model – 20 minutes	Entry to study	$15.00
	3 Campaign Events/Oral health fairs – 2-3 hours	3-6 months after study entry	None
3.-T1	Survey– 1 hour	1-3 months after campaigns completed	$15.00
4.-T1	Dental exam and assessment of oral hygiene skills on a mouth model – 20 minutes	1-3 months after campaigns completed	$15.00
5.	Tailored educational session	Up to 45 days after T1	None
6.-T2	Survey – 1 hour	1-3 months after educational session	$15.00
7.-T2	Dental exam and assessment of oral hygiene skills on a mouth model – 20 minutes	1-3 months after educational session	$15.00
8.-T3	Dental exam, brief survey and assessment of oral hygiene skills on a mouth model – 20 minutes	6-7 months after T2	$20.00

What Are the Costs To Me For Participating In This Study?

There will be no cost to you for participating in the research

What Will I Be Asked to Do?

The study will involve:

- completing questionnaires three times;
- having a dental hygienist examine your mouth four times;
- assessing your oral hygiene skills on a mouth model four times;
- meeting with a health educator for a one-on-one oral health educational session to discuss plans on how to take better care of your teeth and mouth and show you how to brush and floss your teeth;
- attending the 3 campaign events (oral health fairs) that will take place in your building.
- A dentist from our study may conduct an additional dental exam.**

With your permission the educational session will be audio recorded to assure consistency across educators.

Procedure	**Mouth examination**
Procedure	A dental exam is a standard clinical procedure. This procedure will be done at your building at time that is convenient for you. We will assess the health of your gums and look for injuries in the mouth. A red dye will be applied to your teeth to see the amount of plaque on each tooth.

Risk - Infection	The potential risk for infection is minimal and is the same as brushing your teeth. If such an infection should occur, antibiotics will be prescribed without cost to you. The study will pay for the antibiotic.
Safeguard	Licensed dental hygienists will perform the clinical exams under the direction of the Clinical Director. Sterile procedures will be observed during examinations including use of new latex or plastic gloves, disposable instruments for the exams and sterile gauzes.
Cost to Participant	There will be no cost to you.
Procedure	**Mouth examination**
Risk - Pain	Individuals vary in their experience of pain during dental exams.
Safeguard	If you experience pain, we will numb your gums during the dental exam to minimize pain and discomfort. Topical anesthetic benzocaine 20% will be used. It will be applied with a Q-tip on the cheek and tongue side of the gum tissue prior to the examination if the area is sensitive.
Cost	No cost to participant
Procedure	**Questionnaire**
Risk - minimal	There are no physical risks associated with the questionnaire. You may feel uncomfortable answering some of the questions. Loss of privacy is possible if an unauthorized person would hear your responses
Safeguard	You may always choose not to answer a question that makes you feel uncomfortable. Questionnaires will be administered in a private area to protect privacy.
Cost to Participant	No Cost
Procedure	**Oral Hygiene Skills Assessment**
Risk - none	There are no risks associated with this assessment. You will be asked to show how you brush and floss on a mouth model.
Safeguard	None needed
Cost to Participant	No cost to participant
Procedure	**Individual level tailored intervention**
	An experienced health educator will meet with you to discuss how to take better care of your teeth and mouth. He or she will ask you about

	what prevents you from taking better care of your teeth and mouth and what helps you. The educator will help you to improve your own care of your mouth and gums based on your dental exam and survey responses. The educator will ask you to show that you understand clearly how to clean your teeth, gums and mouth. You and the educator will make a plan together to improve the way you take care of your teeth and mouth. . A health educator will show you how to brush and floss your teeth. Then, using a mouth model, you will practice the brushing and flossing as shown by the educator.
Risk - minimal	There are no physical risks associated with the intervention. You may feel uncomfortable answering some of the questions.
Safeguard	You can refuse to participate.
Cost to Participant	No Cost
Procedure	**Completing Passports at Oral Health Fairs**
Risk - minimal	There are no physical risks associated with completing the forms. You may feel uncomfortable answering some of the questions.
Safeguard	You can refuse to complete the forms or refuse to answer any of the questions on the forms
Cost to Participant	No cost**

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By signing this form the individual obtaining consent is confirming that the above information has been explained to the subject and that a copy of this document, signed and dated by both the person giving consent and the person obtaining consent, along with a copy of the Research Participant Feedback Form, will be provided to the participant.

Role	Printed Name	Signature	Date
Participant			
Person Obtaining Consent			