Adapting an Evidence-Based Program that Improves Oral Hygiene and Health for Assisted Living Residents with Dementia

NCT number NCT03892200
Document Date 07/23/2024

Adapting an Evidence-Based Program that Improves Oral Hygiene and Health for Assisted Living Residents with Dementia

Protocol

Version 6.0_23 July 2024

PROTOCOL CHANGE LOG:

Date (to HSS)	Version #	Affected Section(s)	Exact Revision Made	Date Modification was Approved by Executive Committee	Date Modification Became Effective
15 Jun 2021	1	N/A	Initial Version	N/A	N/A
18 Jun 2021	2	4.1 4.3	Randomization will occur at the AL community-level. The project coordinator will work with the NC DHHS Special Care Dentistry Program partners to identify the AL communities that (a) have not been trained in MCWB, (b) were trained within the last year, and (c) were trained longer than one year ago. A total of 48 AL communities (that are licensed to provide care for at least 50 residents and have not been trained in MCWB in the last year) will be recruited across the state, eight from each of the two largest regions (Regions 4 and 5), and four from each of the other eight regions. The project coordinator will recruit them within region, with a preference given to those that have never been trained. After confirming eligibility and willingness to participate, the analyst will randomly assign the community to treatment	23 June 2021	23 June 2021

Date (to HSS)	Version #	Affected Section(s)	Exact Revision Made	Date Modification was Approved by Executive Committee	Date Modification Became Effective
			or control one-to-one within regions.		
18 Jun 2021	2	6.2.2	The oral hygiene status of ~~15~~ up to 20 residents in each … site … will be obtained at baseline, four, and eight months.	23 June 2021	23 June 2021
22 Nov 2021	3	4.2	AL community does not have at least ~~20~~ 10 residents with dementia (i.e., translating roughly to having 50 beds or more, given that on average, 42% of residents have moderate or severe dementia, and taking into account actual census which is lower than licensed beds)	01 December 2021	06 December 2021
22 Nov 2021	3	9.2	The estimate of statistical power is based on Aim 2 where the outcome is change in oral hygiene measured by the PI-LTC and GI-LTC at four months. Based on our completed pragmatic trial in NHs, 24-month treatment effects between MCWB and control sites suggested that our planned sample of ~ ~~288~~ 230 residents (i.e., enrolling an average of 15 per home and allowing for a 20% attrition rate) should provide more than 80%	01 December 2021	06 December 2021

Date (to HSS)	Version #	Affected Section(s)	Exact Revision Made	Date Modification was Approved by Executive Committee	Date Modification Became Effective
			power using two-sided p≤0.05 significance tests even if the treatment effect was as much as ~~25~~ 24% less in AL compared with NHs which we consider a conservative estimate.		
15 August 2022 (submitted to HSS by AOR)	4	Precis and 3	Added "up to" when referring to number of potential respondents in the sample size and population (in the Precis) and in Section 3, reflecting reduced resident census and staffing shortages that affect anticipated sample size (e.g., will include up to 720 residents with dementia …)	Consistent with approval 01 December 2021	06 December 2021
15 August 2022 (submitted to HSS by AOR)	4	3	Clarified the situation regarding blinding	Not applicable (updated to harmonize with MOP)	Not applicable
15 August 2022 (submitted to HSS by AOR)	4	4.3 5.2 6.2 10.2	Added two adverse events to the list of those queried on a regular basis: any new or worsening symptoms or disease, emergency department visit without hospitalization	28 April 2022	28 April 2022
15 August 2022 (submitted	4	5.2.2	For completeness, added material that control communities will continue standard care and may	Not applicable (updated to harmonize with MOP)	Not applicable

Date (to HSS)	Version #	Affected Section(s)	Exact Revision Made	Date Modification was Approved by Executive Committee	Date Modification Became Effective
to HSS by AOR)			receive the training at the end of the project.		
15 August 2022 (submitted to HSS by AOR)	4	5.2.1 10.2	For completeness, elaborated the section related to assent: Able residents will be asked to provide assent. In all cases, residents must assent to the oral hygiene assessment; if they refuse, the assessment will not be conducted. Residents will be asked to give assent at each study visit; if a resident chooses to give assent (or not give assent) at one visit, study staff will continue to ask for their assent at subsequent visits.	Not applicable (updated to harmonize with MOP)	Not applicable
15 August 2022 (submitted to HSS by AOR)	4	5.2.4	Clarified procedures if there is an excessive delay between baseline visits and training, or between baseline and follow-up, including that if the intervention community has a delay, study staff will replicate that timeline and delay as best as they are able in the control community in the same region.	Not applicable (updated to harmonize with MOP)	Not applicable
15 August 2022 (submitted to HSS by AOR)	4	6.3.1	For clarity and completeness, slightly modified wording of general AE and SAE reporting procedures	Not applicable (updated to harmonize with MOP)	Not applicable

Date (to HSS)	Version #	Affected Section(s)	Exact Revision Made	Date Modification was Approved by Executive Committee	Date Modification Became Effective
15 August 2022 (submitted to HSS by AOR)	4	4.3 5.2.1 5.2.2	Allow that all eligible residents will be recruited (i.e., not limiting the number to 20): All residents who fit these criteria will be eligible and allowed to join the study/All residents who meet the eligibility criteria will be eligible and allowed to join the study/All enrolled residents.	15 September 2022	15 September 2022
1 March 2023 (submitted to HSS by AOR)	5	Precis 3.0 4.3 5.2.1 5.2.2 5.2.4 10.2	Revised the data collection follow up period to be completed "up to" the 8-month mark (only to be ended earlier than the 8-month follow-up point when necessary for project timeline adherence). This allows for more data to be collected for the primary outcome of change – oral hygiene at the 4-month follow up.	16 November 2022	16 November 2022 (IRB approval)
1 March 2023 (submitted to HSS by AOR)	5	4.3 5.2.1 5.2.3 6.2 10.2	Moved the details of weekly adverse event collection from the Study Enrollment Procedures section (4.3) to the Adverse Event section (6.3) for simplicity and consistency: "…weekly contact with the AL health care supervisor, to collect adverse events and	16 November 2022	16 November 2022 (IRB approval)

Date (to HSS)	Version #	Affected Section(s)	Exact Revision Made	Date Modification was Approved by Executive Committee	Date Modification Became Effective
			incidence of pneumonia…"		
1 March 2023 (submitted to HSS by AOR)	5	6.3	Revised the definition of adverse events, so that adverse events collected include: infectious diseases such as coronavirus (COVID), flu, pneumonia, urinary tract infections (UTIs), and diarrhea. As per DSMB decision on 11/08/2022, adverse events will not include non-infectious medical occurrences such as cancer/decline, general decline, and falls.	16 November 2022	8 February 2023 (IRB approval)
1 March 2023 (submitted to HSS by AOR)	5	8.2	Replaced paragraph describing statistical power. Updates to the statistical power have been reflected responsive of protocol changes made (regarding number of enrolled residents and follow up period of enrolled residents).	16 November 2022	16 November 2022 (IRB approval)
1 March 2023 (submitted to HSS by AOR)	5	Appendices	Updated consent forms to reflect currently approved IRB consents.	16 November 2022	5 December 2022
July 2024	6	Precis 5.1 9.1	Added Dental Hygienist self-efficacy form to lists (Aim 3 only) and updated usage (at MCWB training, not baseline)	Consistent with Aim 3 description in protocol	11 May 2023 (IRB approval)

Date (to HSS)	Version #	Affected Section(s)	Exact Revision Made	Date Modification was Approved by Executive Committee	Date Modification Became Effective
July 2024	6	4.3 5.2.1 10.2 Appendix A	Clarified Dental Hygienist consent procedure (embedded consent consistent with staff form on which DH form was based)	Consistent with Aim 3 description in protocol	11 May 2023 (IRB approval)
July 2024	6	5.1 5.2.3	Indicated discontinuation of daily mouth care checklist. Low participation and poor feedback from Aim 2 led us to discontinue form for Aim 3.	28 February 2024 (IRB submission)	7 March 2024 (IRB approval)
July 2024	6	Precis 3 5.2.2 8.2.2	Updated AL community recruitment to reflect that geographic coverage for Aim 3 will not be statewide.	26 October 2023 (DSMB Meeting) 28 February 2024 (IRB submission)	7 March 2024 (IRB approval)
July 2024	6	Precis 3 4.3 8.2.1	Updated sample size change. Aim 2 up to 360 residents, Aim 3 up to 200 residents. Based on analysis of Aim 2 data.	26 October 2023 (DSMB Meeting) 28 February 2024 (IRB submission)	~~7 March 2024 (IRB approval)~~*Submission in error based on DSMB meeting discussion. Formal DSMB approval not received.*
July 2024	6	4.3 5.2.1 10.2	Added use of email during Resident/LAR recruitment	28 February 2024 (IRB submission)	7 March 2024 (IRB approval)
July 2024	6	4.3	Added payment of AL administrators for staff time associated with recruitment	04 April 2024 (IRB submission)	9 April 2024 (IRB Approval)
July 2024	6	Precis 3 4.3 5.2.2 8.2.1	Increased the number of AL communities recruited from 24 to up to 28	27 June 2024 (Email from NIA project officer)	1 July 2024 (IRB Approval)

Date (to HSS)	Version #	Affected Section(s)	Exact Revision Made	Date Modification was Approved by Executive Committee	Date Modification Became Effective
		8.2.2		28 June 2024 (IRB submission)	
July 2024	6	Precis 3 4.3 8.2.1	Adjusted Aim 3 resident recruitment (from 360 to up to 233)	27 June 2024 (Email from NIA project officer) 28 June 2024 (IRB submission)	1 July 2024 (IRB Approval)
July 2024	6	Precis 3 4.3 5.1 5.2.2 5.2.4 8.4.1	Omitted 8-month follow up for residents and dental hygienists in Aim 3	27 June 2024 (Email from NIA project officer) 28 June 2024 (IRB submission)	1 July 2024 (IRB Approval)
July 2024	6	4.3 5.2.2 8.2.2	Allowed that communities with as few as 13 residents (formerly at least 50) may be contacted for recruitment while still striving to assure at least 10 residents meet eligibility criteria	8 July 2024 Email from PI and IRB Submission	23 July 2024 (IRB Approval)

ADAPTING AN EVIDENCE-BASED PROGRAM THAT IMPROVES ORAL HYGIENE AND HEALTH FOR ASSISTED LIVING RESIDENTS WITH DEMENTIA

Principal Investigator:

Sheryl Zimmerman, PhD
University Kenan Distinguished Professor
Co-Director, Program on Aging, Disability, and Long-Term Care
Cecil G. Sheps Center for Health Services Research
Director of Aging Research, School of Social Work
The University of North Carolina at Chapel Hill

Supported by:

The National Institute on Aging
5R01AG061966

Study Intervention Provided by:

N/A

Sponsor of IND/IDE:

N/A

Version 6.0
July 23, 2024

TABLE OF CONTENTS

Page

PROTOCOL CHANGE LOG: ..... **i**

TABLE OF CONTENTS ..... **i**

PRÉCIS ..... **iv**

Study Title iv

Specific Aims iv

Design and Outcomes v

Interventions and Duration v

Sample Size and Population vi

STUDY TEAM ROSTER **1**

Principal Investigator: ..... Sheryl Zimmerman, PhD 1

Co-Investigators: ..... Philip Sloane, MD, MPH 1

Co-Investigators: ..... Jennifer Leeman, PhD 1

Co-Investigators: ..... Jane Weintraub, DDS 1

Co-Investigators: ..... Sally Stearns, PhD 2

Co-Investigators: ..... John Preisser, PhD 2

PARTICIPATING STUDY SITES **2**

1 Study objectives **3**

1.1 Primary Objective 3

1.2 Secondary Objectives 3

2 BACKGROUND AND RATIONALE **3**

2.1 Background on Condition, Disease, or Other Primary Study Focus 3

2.2 Study Rationale 3

3 STUDY DESIGN 3

4 SELECTION AND ENROLLMENT OF PARTICIPANTS 4

4.1 Inclusion Criteria 4

4.2 Exclusion Criteria 5

4.3 Study Enrollment Procedures 5

5 STUDY PROCEDURES 7

5.1 Schedule of Evaluations 8

5.2 Description of Evaluations 9

5.2.1 Screening Evaluation 9

5.2.2 Enrollment, Baseline, and/or Randomization 10

5.2.3 Follow-up Visits 12

5.2.4 Completion/Final Evaluation (8 months) 13

6 SAFETY ASSESSMENTS 13

6.1 Specification of Safety Parameters 13

6.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters 13

6.3 Adverse Events, Serious Adverse Events, and Unanticipated Problems 14

6.3.1 Reporting Procedures 15

6.3.2 Follow-up for Adverse Events 16

6.4 Safety Monitoring 16

7 INTERVENTION DISCONTINUATION 17

8 STATISTICAL CONSIDERATIONS 17

8.1 General Design Issues 17

8.2 Sample Size and Randomization 18

8.2.1 Sample Size 18

8.2.2 Randomization 19

8.3 Interim analyses and Stopping Rules 19

8.4 Outcomes 20

8.4.1 Primary outcomes 20

8.4.2 Secondary outcomes 20

8.5 Data Analyses 21

9 DATA COLLECTION AND QUALITY ASSURANCE 22

9.1 Data Collection Forms 22

9.2 Data Management 22
9.3 Quality Assurance 23
9.3.1 Training 23
9.3.2 Quality Control Committee 23
9.3.3 Metrics 23
9.3.4 Protocol Deviations 23
9.3.5 Monitoring 23

10 PARTICIPANT RIGHTS AND CONFIDENTIALITY 23

10.1 Institutional Review Board (IRB) Review 23
10.2 Informed Consent Forms 24
10.3 Participant Confidentiality 24
10.4 Study Discontinuation 24

11 ETHICAL CONSIDERATIONS 25

12 COMMITTEES 25

13 PUBLICATION OF RESEARCH FINDINGS 25

14 REFERENCES 25

15 Appendix A – Consent Forms 25

PRÉCIS

Study Title

Adapting an Evidence-Based Program that Improves Oral Hygiene and Health for Assisted Living Residents with Dementia

Specific Aims

Aim 1. Refine Mouth Care Without a Battle (MCWB) for implementation in assisted living (AL) communities.

a. Identify stakeholder perspectives. Interview (1) the administrator, health care supervisor, and a personal care aide (PCA) from 20 AL communities across North Carolina (NC) who have already been trained in MCWB by community-based public health dental hygienists from the DHHS Special Care Dentistry Program; (2) the dental hygienists who provided that training; and (3) within each community up to two able residents with dementia who received tooth brushing in accordance with MCWB techniques, and two family members of residents with dementia who received tooth brushing in accordance with MCWB techniques, to learn attitudes regarding MCWB as developed for nursing homes, the extent to which care has changed, and recommended modifications to MCWB for AL.
b. Create a one-hour MCWB training video (web and DVD format) targeted to AL. Modifications include videorecording AL staff providing mouth care to residents with dementia, and interviews with residents and families; AL administrators, supervisors and PCAs; and dental hygienists.

Aim 2. Evaluate research efficacy of the MCWB program in a nested cohort cluster randomized trial of 24 ALs, with training and support provided by an experienced research dental hygienist.

a. Evaluate MCWB in terms of (1) the reach of the intervention; (2) effects on mediators/targets of change at the organizational and individual level; (3) outcomes (oral hygiene, pneumonia, hospitalizations); (4) associations between change at the organizational and individual level and outcomes, and also associations with characteristics of the AL community and staff; and (5) attitudes, barriers, and facilitators.
b. Develop a coaching manual for community hygienists to provide training and support to AL staff, reflecting lessons-learned from analyses.

Aim 3. Evaluate real-world efficacy of the MCWB program using a second nested cohort cluster randomized trial of up to 28 ALs, transferring responsibility for training and support to community public health dental hygienists, thereby testing efficacy of a nationally generalizable model.

a. Assess dental hygienists' (up to N=24) self-efficacy to provide training and support at MCWB training and 4 months.
b. Evaluate MCWB as per Aim 2a, including examining associations with characteristics of the hygienists.

c. Compare implementation and effectiveness outcomes between research and real-world efficacy.
d. Refine the coaching manual for community dental hygienists to provide training and coaching, reflecting lessons-learned from analyses.

By the conclusion of this project, MCWB will be ready for definitive evaluation in a larger pragmatic trial of AL residents with dementia and the staff who provide their care.

Design and Outcomes

The nested cohort cluster randomized trials in Aims 2 and 3 will each recruit up to 24 assisted living (AL) communities (increased to up to 28 AL communities for Aim 3) across 10 statewide regions. Note that for Aim 3, the intervention will be delivered by dental hygienists employed by the State of North Carolina Department of Health and Human Services (NC DHHS) on a voluntary basis; depending on the counties to which they are assigned, geographic coverage may not be statewide. Within each region, one-half of AL communities will be randomized to treatment (MCWB) and one-half to control.

The primary outcomes pertain to the change in oral hygiene, as measured by the Plaque Index for Long-Term Care (PI-LTC), the Long-Term Care Gingival Index (GI-LTC), and the Denture Plaque Index (DPI). Secondary outcomes include pneumonia and hospitalizations.

Interventions and Duration

Description of intervention: MCWB highlights that mouth care is infection control (e.g., can reduce pneumonia); includes techniques and products to clean and protect the teeth, tongue, gums, and dentures (e.g., the jiggle-sweep approach to remove plaque; use of an interdental brush instead of floss); care provision in special situations (e.g., broken teeth); and a toolkit of dementia-sensitive approaches for people who are resistant (e.g., refuse to open the mouth). MCWB also includes information about potential dental emergencies and issues that merit assessment, which the care provider is advised to immediately convey to supervisory staff.

In Aim 2, a research dental hygienist will train AL staff on MCWB and provide ongoing support; in Aim 3, this responsibility will be transferred to community public health dental hygienists working with the North Carolina Department of Health and Human Services (NC DHHS) Oral Health Section.

Duration of intervention: For Aim 2, AL communities will be followed for up to 8 months (only to be ended earlier than the 8-month follow-up point when necessary for project timeline adherence), with at least a 4 month follow-up period. For Aim 3, all AL communities will be followed for only 4 months in order to maintain project timelines and accommodate data collection in additional communities.

Sample Size and Population

The project will include up to 593 AL residents with dementia (up to 360 for Aim 2, up to 233 for Aim 3), 348 AL staff, and 24 dental hygienists from up to 52 NC AL communities.

STUDY TEAM ROSTER

Principal Investigator: Sheryl Zimmerman, PhD

725 Martin Luther King Jr. Blvd.
Chapel Hill, NC 27599
(919) 966-7111
Sheryl_Zimmerman@unc.edu
Main responsibilities/Key roles: Will be responsible for overall administration of the study, including modifying MCWB for AL and the conduct of the research efficacy and real-world efficacy trials. Oversight includes research protocol development and implementation; measurement development; assisted living partnerships; subject recruitment and engagement; research staff supervision; training activities; data analysis; and manuscript and product development and dissemination.

Co-Investigators: Philip Sloane, MD, MPH

725 Martin Luther King Jr. Blvd.
Chapel Hill, NC 27599
(919) 966-4439
philip_sloane@med.unc.edu
Main responsibilities/Key roles: Will provide medical and dementia care expertise on the project, and will be involved in modifying MCWB for AL. He will provide consultation to the dental hygienists doing the training as the coaching program is being developed, and he will be closely involved in the development of the related manual, especially for matters related to behavioral expressions of persons with dementia.

Co-Investigators: Jennifer Leeman, PhD

Carrington Hall, S. Columbia Street
Chapel Hill, NC 27599
(919) 966-3648
jleeman@email.unc.edu
Main responsibilities/Key roles: Will be involved in measurement development and data collection and analysis related to implementation, as well as in assuring that the modifications made to MCWB will be optimal for AL.

Co-Investigators: Jane Weintraub, DDS

385 S Columbia Street
Chapel Hill, NC 27599
(919) 537-3240

jane_weintraub@unc.edu
Main responsibilities/Key roles: Will oversee the quality of the oral hygiene data; initiate dental referrals for AL residents with immediate care needs; and participate in analysis, interpretation, and dissemination of results.

Co-Investigators: **Sally Stearns, PhD**

McGavran-Greenberg Hall, 135 Dauer Drive
Chapel Hill, NC 27599
(919) 843-2590
sally_stearns@unc.edu
Main responsibilities/Key roles: Will inform measurement development and data collection and analysis related to cost, and will oversee analysis determining effect size estimates for the subsequent pragmatic trial.

Co-Investigators: **John Preisser, PhD**

McGavran-Greenberg Hall, 135 Dauer Drive
Chapel Hill, NC 27599
(919) 966-7265
jpreisse@bios.unc.edu
Main responsibilities/Key roles: Will provide analytic consultation to the study analyst, provide guidance in project design and sampling, oversee analytic model creation and interpretation, and participate in manuscript preparation.

PARTICIPATING STUDY SITES

N/A; not a multi-site study

1 STUDY OBJECTIVES

1.1 Primary Objective

The primary objective is to improve oral hygiene in older adults with dementia who reside in assisted living communities; it is hypothesized that MCWB will result in improved oral hygiene.

1.2 Secondary Objectives

The secondary objective is to reduce pneumonia and hospitalizations by improving oral hygiene in older adults with dementia who reside in assisted living communities; it is hypothesized that MCWB will result in a lower incidence of pneumonia and hospitalizations.

2 BACKGROUND AND RATIONALE

2.1 Background on Condition, Disease, or Other Primary Study Focus

Many people with dementia resist mouth care – almost 90% in nursing homes, in fact. As a result, only 16% have their teeth brushed regularly, putting them at risk for aspiration pneumonia when they inhale bacteria from their teeth, tongue, and gums. Overall, persons with dementia have more oral mucosal lesions, plaque, coronal and root caries, and decayed tooth roots than those without dementia, and the situation is worse as dementia progresses.

In 2013, Drs. Zimmerman and Sloane developed one of the two existing dementia-focused mouth care programs for nursing homes -- Mouth Care Without a Battle (MCWB) -- which already has become a standard of nursing home care. MCWB changes caregivers' attitudes and behavior, improves oral health, and in a cluster randomized trial, MCWB provided by nursing assistants reduced pneumonia incidence by 32 percent (Zimmerman et al., 2020).

2.2 Study Rationale

The next step is to extend MCWB to AL, the primary long-term residential care provider for persons with dementia. There are 30,200 AL communities across the country; 90% of their 835,200 residents have cognitive impairment and 42% have moderate or severe dementia (and on average, five untreated oral health conditions), meaning MCWB has the potential to improve the health and quality of life of more than 350,000 AL residents with dementia annually.

3 STUDY DESIGN

The nested cohort cluster randomized trials will recruit up to 24 AL communities across 10 statewide regions for Aim 2 and up to 28 AL communities for Aim 3 (total up to N=52). Note that for Aim 3, the intervention will be delivered by dental hygienists employed by the State of North Carolina Department of Health and Human Services (NC DHHS) on a voluntary basis; depending on the counties to which they are assigned, geographic coverage may not be statewide. Within each region, one-half of AL communities will be randomized to treatment (MCWB) and one-half to control. The

primary outcomes are change in oral hygiene, as measured by the Plaque Index for Long-Term Care (PI-LTC), the Long-Term Care Gingival Index (GI-LTC) and the Denture Plaque Index (DPI). Secondary outcomes include pneumonia and hospitalizations.

The project will include up to 593 residents with dementia (up to 360 for Aim 2, up to 233 for Aim 3), 348 AL staff, and 24 dental hygienists from up to 52 NC AL communities. The duration of the study is up to eight months (for Aim 2, only to be ended earlier than the 8-month follow-up point when necessary for project timeline adherence; for Aim 3, all AL communities will be followed for only 4 months in order to maintain project timelines and accommodate data collection in additional AL communities.

Description of intervention: MCWB highlights that mouth care is infection control (e.g., can reduce pneumonia); includes techniques and products to clean and protect the teeth, tongue, gums, and dentures (e.g., the jiggle-sweep approach to remove plaque; use of an interdental brush instead of floss); care provision in special situations (e.g., broken teeth); and a toolkit of dementia-sensitive approaches for people who are resistant (e.g., refuse to open the mouth). MCWB also includes information about potential dental emergencies and issues that merit assessment, which the care provider is advised to immediately convey to supervisory staff.

Administration of intervention: AL staff will be trained on the principles of MCWB. They will use these techniques for eight months with the residents in the AL community. During Aim 2, a research dental hygienist will provide the training and coaching. During Aim 3, community public health dental hygienists will provide the training and coaching.

Blinding and unblinding (masking and unmasking)
AL communities in both arms will be blinded to the study hypotheses, as will the data collectors during the recruitment of AL communities and families.
The data collectors are likely to become unblinded after recruitment has been completed due to the logistics of scheduling training sessions and differing data collection procedures for on-site visits in intervention versus control arms.
The project manager will be unblinded.
The Principal Investigator will be blinded.
During the safety meetings, the DSMB and NIA representative(s) will review the study data, blinded and unblinded, to make informed decisions about the continuation of the study.

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria

AL Communities

- Licensed as an Adult Care Home in NC (the AL category used in NC)
- Staff in the AL community have not been trained in MCWB

AL Staff

- Age 18 years or older
- Employed in a participating AL community

Residents

- Age 18 years or older
- Has a diagnosis of dementia
- Lives in a participating AL community

Public health dental hygienists

- Age 18 years or older
- Employed by NC DHHS

4.2 Exclusion Criteria

AL Communities

- Administrator reports that the AL community will be closing in the next year
- AL community does not have at least 10 residents with dementia (i.e., translating roughly to having 50 beds or more, given that on average, 42% of residents have moderate or severe dementia, and taking into account actual census which is lower than licensed beds). NOTE: In AL communities that are exclusively memory care, the percent of residents with moderate or severe dementia will be 100%, therefore allowing that some communities may have markedly fewer than 50 beds.
- Does not agree for staff to attend training, provide mouth care in accordance with MCWB, and/or keep logs regarding mouth care provision

AL Staff

- Not able to read and speak English fluently
- Does not provide direct care to AL residents

Residents

- On hospice or tube-feeding (and does not eat or drink), meaning if the resident is on a feeding tube and does not eat or drink, he/she is ineligible.
- Expected to die or be discharged in next six months
- Does not have teeth and/or have and use a denture
- Requires antibiotic prophylaxis prior to oral care assessment

Public health dental hygienists

- Not able to read or speak English fluently

4.3 Study Enrollment Procedures

AL Communities: A total of up to 52 AL communities will be recruited across the state. The research team will work in collaboration with the NC DHHS Oral Health Section to identify the AL communities that have been trained in MCWB. Using IRB approved procedures, an introductory letter will be mailed to the AL administrator describing the effort and inviting them to contact the research team if they do not want to learn more about the project. If they do not contact the research team, the letter will be followed by a telephone call from the principal investigator or project coordinator. All contact with the AL communities will be tracked and maintained recruitment databases. The number, proportion, and representativeness of the AL administrators willing to participate when solicited by the principal investigator/project coordinator will be obtained, as will the characteristics of participating and non-participating communities (i.e., location/region, size, for-profit status,

ownership, affiliation with another level of care, presence of a dementia special care unit, resident case-mix, and physician and nurse staffing). The AL communities will be offered $300 to compensate them for administrative staff time spent preparing lists of eligible residents and other tasks related to study participation.

Randomization will occur at the AL community-level. The project coordinator will work with the NC DHHS Special Care Dentistry Program partners to identify the AL communities that (a) have not been trained in MCWB, (b) were trained within the last year, and (c) were trained longer than one year ago. A total of up to 52 AL communities (that are licensed to provide care for approximately 50 or more residents and have not been trained in MCWB in the last year) will be recruited across the state; Aim 3 will allow that communities with as few as 13 residents may be contacted for recruitment while still striving to assure at least 10 residents meet eligibility criteria. For Aim 2, the AL communities will include eight from each of the two largest regions (Regions 4 and 5), and four from each of the other eight regions. The project coordinator will recruit them within region, with a preference given to those that have never been trained. After confirming eligibility and willingness to participate, the analyst will randomly assign the community to treatment or control one-to-one within regions. Note that for Aim 3, the intervention will be delivered by dental hygienists employed by the State of North Carolina Department of Health and Human Services (NC DHHS) on a voluntary basis; depending on the counties to which they are assigned, geographic coverage may not be statewide. Within each region, one-half of AL communities will be randomized to treatment (MCWB) and one-half to control.

AL Staff: All PCAs who work on the first and second shifts (when mouth care is typically provided) will be visited on-site and asked to consent to a questionnaire related to the provision of mouth care (i.e., a measure of self-efficacy) at baseline, four, and up to eight months (only to be ended earlier than the 8-month follow-up point when necessary for project timeline adherence). Staff will be given the option to refuse participation without penalty from their employer. In addition, the administrator will be interviewed on-site or by telephone at baseline, four and eight months to learn about mouth care practices and policies in effect. Informed consent is not required for the practices and policies interview.

Residents: The project will include up to 593 residents with dementia (up to 360 for Aim 2, up to 233 for Aim 3). A HIPAA waiver will allow the Health Care Supervisor/Liaison within each AL community to provide a list of residents who (1) have dementia; (2) are not on hospice or tube-feeding; (3) are not expected to die or be discharged in the next six months; (4) have teeth and/or have and use a denture; and (5) do not require antibiotic prophylaxis prior to oral care assessment. All residents who fit these criteria will be eligible and allowed to join the study. Family members who are legally authorized representatives will be sent an introductory letter describing the project and inviting them to contact the research team if they do not want to learn more about it. The letter will be followed by a telephone call from the research staff, who will discuss all components of informed consent and confirm eligibility. Participation includes (1) an oral hygiene examination of the resident up to three times; (2) a telephone interview with the family member regarding resident characteristics (e.g., cognitive and functional status); (3) weekly contact with the AL health care supervisor, to collect adverse events and instances of pneumonia, (4) observations of

mouth care. If unable to reach the family/LAR by phone, the research assistant may also contact them by email.

Public Health Dental Hygienists: A list of public health dental hygienists currently employed will be provided by NC DHHS Oral Health Section. Before the public health dental hygienists are trained to provide training and coaching, their own self-efficacy to provide training and mouth care will be assessed; this same assessment will be conducted at four months (after coaching is completed); consent will be obtained. Descriptive data obtained for public health dental hygienists will include age, years in practice, dementia-related experience, experience in nursing homes and AL, and training received after licensure. Consistent with the staff self-efficacy questionnaires, research staff will meet with DHHS Dental Hygienists and present the questionnaire that includes an embedded consent form and allow them time to read the consent form and choose to participate or decline participation without penalty.

5 STUDY PROCEDURES

5.1 Schedule of Evaluations

Assessment	*Screening*	*Baseline*	*Month 4 (Aims 2 and 3) and Month 8 (Aim 2 only)*	*Weekly*	*Ongoing*
Informed Consent Form – Residents	**X**				
Informed Consent Form - Staff	**X**				
Self-efficacy Questionnaire – Public Health Dental Hygienists (Aim 3 only)*	**X**		**X**		
Baseline interview about resident		**X**			
Post-training staff evaluation questionnaire (WEVAL)		**X**			
Salaries		**X**			
Assisted living characteristics		**X**	**X**		
Oral hygiene assessments		**X**	**X**		
Staff mouth care questionnaire (self-efficacy)		**X**	**X**		
Observation of mouth care			**X**		
Follow-up staff program evaluation questionnaire (WAFU)			**X**		
Adverse events and pneumonia				**X**	
Training log (intervention sites only)		**X**			
Training support log (intervention sites only)					**X**
Daily mouth care checklist (intervention sites only)**					**X**

* Delivered at initial training of DHHS Dental Hygienists, Aim 3 only

** Discontinued after low participation and poor feedback from Aim 2, Aim 2 only

5.2 Description of Evaluations

5.2.1 Screening Evaluation

Consenting Procedure

Residents: All residents who meet the eligibility criteria will be eligible and allowed to join the study. The name, address, and telephone number of their legally authorized representative (LAR) will be obtained from the AL community. The LAR recruitment letter and the resident/LAR consent form will be mailed to this individual. Three business days after the letter is mailed, the research assistant will call the LAR to explain the study, answer questions, solicit consent, and encourage prompt return of the form. The LAR calling script will guide this call. Consent includes (1) an oral hygiene examination of the resident up to three times; (2) a telephone interview with the family member regarding resident characteristics (e.g., cognitive and functional status); (3) weekly contact with the AL health care supervisor, to collect adverse events and instances of pneumonia, (4) observations of mouth care. If unable to reach the family/LAR by phone, the research assistant may also contact them by email.

Able residents will be asked to provide assent. In all cases, residents must assent to the oral hygiene assessment; if they refuse, the assessment will not be conducted. Residents will be asked to give assent at each study visit; if a resident chooses to give assent (or not give assent) at one visit, study staff will continue to ask for their assent at subsequent visits.

A signed HIPAA authorization will be obtained for all participating residents in the study. The project coordinator/research assistant will explain to the family member that the Health Care Supervisor will be interviewed weekly to check for pneumonia cases and adverse events. It will also be explained that the HIPAA authorization will not stop unless the family member stops it in writing.

Staff: PCAs who work on the first and second shifts (when mouth care is typically provided) will be visited on-site and asked to consent to a questionnaire related to the provision of mouth care (i.e., a measure of self-efficacy) at baseline, four, and up to eight months. Research staff will meet with PCAs and present the questionnaire that includes an embedded consent form and allow them time to read the consent form and choose to participate or decline participation without penalty.

Dental hygienists: Public Health Dental Hygienists who deliver the training intervention in Aim 3 will be asked to consent to a questionnaire related to the provision of training (i.e. a measure of self-efficacy) before and after receipt of research training on how to deliver MCWB training to the AL staff. Consistent with the staff self-efficacy questionnaires, research staff will meet with DHHS Dental Hygienists and present the questionnaire that includes an embedded consent form and allow them time to read the consent form and choose to participate or decline participation without penalty.

Screening

Residents: Additional screening will be completed during the recruitment call to the family member/LAR. The project coordinator/research assistant will confirm that the resident meets all the eligibility criteria for participation. The resident subject tracking form will be completed for all residents/LARs who are approached for participation. All recruitment efforts will be documented on the resident tracking form; specifically, all

enrollments, refusals, and ineligibles (including the reasons for refusals and ineligibles) will be documented for each approached resident.

Staff: Staff members will be screened for eligibility during the enrollment and consent process.

Dental hygienists: Dental hygienists will be screened for eligibility during the enrollment and consent process.

5.2.2 Enrollment, Baseline, and/or Randomization

Enrollment

This study uses a single informed consent form. Date of enrollment is considered the date the participant completes the baseline assessment.

Baseline Assessments

- Assisted living characteristics, policies, practices interview: Information will be obtained from administrators regarding leadership endorsement and policy/procedure change (e.g., provision of training for new hires, retraining for ongoing staff, strategies for accountability, use of performance evaluations, highlighting mouth care in marketing materials). AL location, size, ownership, chain affiliation, affiliation with a nursing home or hospital, percent occupancy, private pay rate, staff type and ratio, presence of a special care unit, on-site dental or dental hygiene care, percent residents with dementia, and percent Medicaid residents will be obtained.
- Baseline interview about resident: Family members will complete a brief interview about the resident at baseline. Resident age, gender, race, and ethnicity will be obtained. Function will be measured with the Minimum Data Set Activities of Daily Living scale (MDS-ADL) scale, which assess assistance in seven activities; it evidences good reliability (kappa .87-.94) and discriminant validity. Severity of dementia will be measured with the Minimum Data Set Cognition Scale (MDS-COGS), a nine-item measure that indicates no, mild, moderate, or severe cognitive impairment. It has been used in nursing homes and validated for use by AL staff, and demonstrates good specificity (84%-97%) and sensitivity (49%-67%) depending on the cut point. Family involvement will be determined based on the number of days in which family visited, discussed the resident's care, and participated in a service plan meeting.
- Staff mouth care baseline questionnaire: The Self-Efficacy for Providing Mouth Care questionnaire will be administered to all PCAs on the first and second shift at baseline. The self-efficacy measure has 11 items, scored 1 (strongly disagree) to 4 (strongly agree). Sample items include "I am familiar with the practical procedures to do this job" and "I know ways to successfully provide mouth care to residents who hit or scream", both of which evidenced significant improvement in our prior work.
- Oral hygiene assessments: The oral hygiene status of all enrolled residents in each site will be obtained at baseline, four, and up to eight months (only to be ended earlier than the 8-month follow-up point when necessary for project timeline adherence). Dentate/edentulous status, presence of dentures, and presence/absence of each tooth will be documented, and three measures will be used to assess oral hygiene, the Plaque Index for Long-Term Care (PI-LTC),

Gingival Index for Long-Term Care (GI-LTC), and Denture Plaque Index (DPI). The PI-LTC is a modification of the Simplified Oral Hygiene Index (OHI-S). To assess debris/plaque, six teeth are selected (one from each sextant), and each is rated based on the proportion of the tooth surface covered with plaque or debris. There are directions regarding which tooth to assess, and substitution rules if teeth are missing. The sum of the tooth scores is divided by the number of segments scored. The GI-LTC is a simplification of the Gingival Index (GI). The GI is a measure of inflammation and gingivitis around six specific teeth (one in each sextant) that assesses the gingiva around the tooth's four surfaces: mesial, distal, buccal and lingual. A score is assigned to each surface. The mean of the four scores obtained around each tooth yields the GI for that tooth. To derive the final score, the GI scores are summed and divided by the number of teeth examined. The GI-LTC is also by recording the worst score (0-3) in each sextant using the same scoring criteria. The DPI is scored for individuals with full dentures by assigning a score to each of eight quadrants, four on the facial surface and four on the basal (tissue contact) surface for each maxillary and mandibular denture.

- Post-training staff evaluation questionnaire (WEVAL): This 22-item Likert measure assesses utilization (e.g., "you used similar materials in the past with little success"), resources (e.g., "you have enough staff to implement the procedures"), training (e.g., "you would attend follow-up training"), and support (e.g., "your director would support and encourage use"). The WEVAL will be administered immediately after training.
- Salaries: Average hourly salaries of full-time PCAs and health care supervisor will be obtained from the administrator at baseline.

Randomization

Randomization will occur at the AL community-level. The project coordinator will work with the NC DHHS Special Care Dentistry Program partners to identify the AL communities that (a) have not been trained in MCWB, (b) were trained within the last year, and (c) were trained longer than one year ago. For Aim 2, a total of 24 AL communities (that are licensed to provide care for approximately 50 or more residents and have not been trained in MCWB in the last year) will be recruited across the state, eight from each of the two largest regions (Regions 4 and 5), and four from each of the other eight regions. For Aim 3, the intervention will be delivered by dental hygienists employed by the State of North Carolina Department of Health and Human Services (NC DHHS) on a voluntary basis; depending on the counties to which they are assigned, geographic coverage may not be statewide. For this aim, up to 28 ALs will be recruited and it will be allowed that communities with as few as 13 residents will be contacted for recruitment while still striving to assure at least 10 residents meet eligibility criteria. The project coordinator will recruit them within region, with a preference given to those that have never been trained. After confirming eligibility and willingness to participate, the analyst will randomly assign the community to treatment or control one-to-one within regions.

Communities that are randomized to the control arm will continue their standard oral hygiene procedures. They will not be asked to change current practice. At the end of the study intervention (up to 8-months for Aim 2, 4 months for Aim 3), they will be given MCWB training materials (including video and Toolkit). Control communities

will also have the option of receiving training from the DHHS dental hygienist team if they so choose.

5.2.3 Follow-up Visits

- Four months:
  - Assisted living policies, practices interview: Information will be obtained from administrators regarding leadership endorsement and policy/procedure change (e.g., provision of training for new hires, retraining for ongoing staff, strategies for accountability, use of performance evaluations, highlighting mouth care in marketing materials).
  - Staff mouth care follow-up questionnaire: The Self-Efficacy for Providing Mouth Care measure will be administered to all PCAs on the first and second shift in control and treatment communities. In the treatment sites, the measure will include a retrospective pre-test that asks respondents to reflect on their initial self-efficacy after having learned what they might not have known that they did not know previously. This technique is useful to learn reflections about the perceived effectiveness of a program. The self-efficacy measure has 11 items, scored 1 (strongly disagree) to 4 (strongly agree). Sample items include "I am familiar with the practical procedures to do this job" and "I know ways to successfully provide mouth care to residents who hit or scream", both of which evidenced significant improvement in our prior work.
  - Oral hygiene assessment: See description in baseline assessment section.
  - Observation of mouth care: At four months an estimate of the amount of time spent providing mouth care will be based on observations conducted by the research assistant of mouth care provided to participating residents.
  - Follow-up program evaluation questionnaire (WAFU): The WAFU is a 14-item Likert measure with subscales related to training satisfaction (e.g., "do you expect to use these materials") and implementation barriers. Eight barriers are provided, related to resources (e.g., "lack of time") and procedures (e.g., "doesn't fit my style"); other barriers are queried.
- Weekly:
  - Adverse Events and Pneumonia: Adverse events and pneumonia cases will be collected weekly. The Health Care Supervisor will be contacted about adverse events and positive pneumonia cases diagnosed in the past week.
- Implementation (Initial and Ongoing):
  - Training Log: The number of staff on the first and second shift who watched the training video and attended the in-service will be recorded.
  - Training Support Log: The number of PCAs on the first and second shift who participated in coaching and telephone support will be recorded by the dental hygienist.
  - Daily Mouth Care Checklist: The resident-specific checklist will indicate, by day, whether mouth care was initiated and provided, including notes related to implementation (e.g., successful strategies to provide care, which

can be shared with weekend and other staff; or, if mouth care did not occur, the reason why. Note that this form was in use for Aim 2 only. During Aim 2, very few ALs completed this form and feedback indicated it was a barrier to program participation so it was discontinued in advance of Aim 3.

5.2.4 Completion/Final Evaluation (8 months, Aim 2 only)

- Assisted living policies, practices interview: See description in four-month follow-up visit
- Staff mouth care follow-up questionnaire: See description in four-month follow-up visit
- Oral hygiene assessments: See description in baseline assessment section
- Observation of mouth care: See description in four-month follow-up visit
- Follow-up program evaluation questionnaire (WAFU): See description in four-month follow-up visit

If for some reason there is an excessive delay between baseline visits and the in-service training for intervention communities, 4-month visit and 8-month visits will be scheduled according to the in-service training date, rather than the date of Baseline data collection. Although these delays are not expected, they may be unavoidable due to COVID-19 outbreaks and community procedures, and other unexpected events. In the case that an intervention community has a delay between baseline visit and in-service training, study staff will replicate that timeline and delay as best as they are able to the control community in the same region. This same procedure will hold true for delays that may occur between the 4-month and 8-month visits.

6 SAFETY ASSESSMENTS

Safety data will only be collected for enrolled resident participants in the study.

6.1 Specification of Safety Parameters

Potential Risks:

The potential risks to study participants include:

- Emotional discomfort caused by study questions (AL staff and dental hygienists)
- Swallowing problems caused by using foaming toothpaste to brush teeth (which is not advised in MCWB) or if a loose tooth becomes dislodged and swallowed during tooth brushing (about which information is provided in MCWB; AL residents)
- Persistent bleeding or pain following oral hygiene assessment or daily mouth care (assessment conducted by professional dental hygienists; AL residents)
- Allergic reaction to mouth care products (e.g., rash due to allergy to mint flavoring, about which information is provided in MCWB; AL residents)
- Emotional or economic (employment-related) harm due to breach of confidentiality of data (for which precautions are in place; AL staff and dental hygienists)

6.2 Methods and Timing for Assessing, Recording, and Analyzing Safety Parameters

In terms of potential risks, having mouth care provided regularly is a standard activity of daily living that does not pose risk, unless, for example, the individual has swallowing

problems and foaming toothpaste is used to brush the teeth (which is not advised in MCWB), or a loose tooth becomes dislodged and swallowed during tooth brushing (which is discussed in MCWB).

For AL staff and dental hygienists, providing information about resident and organizational characteristics and attitudes and behaviors related to mouth care is not expected to pose risk, although it is possible that participants may become distressed if the questions raise sensitive issues or if they are concerned others may learn of less than favorable attitudes or behaviors.

In order to facilitate the reporting of potential adverse events (AEs) to study staff, the following procedures will be in place:

- AL staff will be provided research staff contact information, including study phone and e-mail addresses. AL staff will be encouraged to contact research staff in the event of potentially adverse events of participating residents.
- Throughout the intervention, the health care supervisor will be contacted weekly about potential adverse events. If the event occurred, the health care supervisor will be asked to describe the event in detail.
- Participating staff members will be given the contact information of the PI and UNC IRB if they have any questions or concerns about study participation.

6.3 Adverse Events, Serious Adverse Events, and Unanticipated Problems

Adverse Event (AE): Unfavorable and unintended medical occurrence regardless of whether it is considered related to the study, including infectious diseases such as coronavirus (COVID), flu, pneumonia, urinary tract infections (UTIs), and diarrhea. As per DSMB decision on 11/08/2022, adverse events will not include non-infectious medical occurrences such as cancer/decline, general decline, and falls.

Serious Adverse Event (SAE): Any AE that:

- Results in death
- Is life threatening, or places the participant at immediate risk of death from the event as it occurred
- Requires or prolongs hospitalization
- Causes persistent or significant disability or incapacity

Unanticipated problem (UP): A risk to subjects or others that includes, 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 (in this protocol, “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.

Data on AEs, SAEs, and UPs will be collected on an ongoing basis from study start to study completion.

6.3.1 Reporting Procedures

General AE Procedures. After receiving confirmation that a potential AE occurred using the Weekly Adverse Event Reporting Form (see DSMP Appendix A), study staff will ask the AL community to complete the Adverse Event Reporting Form (DSMP Appendix B). After the Appendix B Adverse Event Reporting Form has been received from the AL community, the project coordinator will report all potential AEs to the PI and Safety Officer immediately. The Safety Officer will determine the severity and the relatedness of the AE, and will confer with the DSMB as needed. If the AE is serious and/or unexpected, possibly related to study participation, and suggests increased risk for participants, the procedures outlined below will also be followed.

AE reports will collected by the project coordinator, summarized, and de-identified. A summary report of all AEs to date will be sent to the PI, DSMB, and NIA program officer for both Aims 2 and 3 at mid-intervention (Aim 2); post-intervention (completion of Aim 2); mid-intervention (Aim 3); and post-intervention (completion of Aim 3).
As per UNC IRB guidelines, all AEs will be reported to the UNC IRB during the yearly study review process.

Serious AE Procedures. The project coordinator will report all SAEs to the PI immediately using the Adverse Event Reporting Form (see DSMP Appendix B), after having gathered all necessary details. For all deaths and for any SAE related or possibly related to study participation, the PI will send this report and any additional information, including corrective actions already taken, within 24 hours of study team awareness of the event (defined by date Adverse Event Reporting Form [DSMP Appendix B] is received by study sites), to the DSMB chair, UNC IRB, and NIA program officer. The PI will follow any additional course of action recommended by the UNC IRB, NIA, and/or DSMB.

Unexpected AEs/UPs with Increased Risk. All AEs deemed (1) unexpected (the nature or severity of the event is not consistent with information about the intervention in the protocol or consent form); (2) possibly or probably related to study participation; and that (3) suggest increased risk for study participants, will be reported to the UNC IRB, NIA project officer, and the DSMB chair within 48 hours of study team awareness of the event, using each organizations' respective reporting formats. In these reports, the PI will identify any corrective action planned or already undertaken. The PI will follow any additional course of action recommended by the UNC IRB, NIA, and/or DSMB.

Severity of Event

This study uses the following AE grading scale:

- Mild: An experience that is transient and requires no special treatment or intervention. The experience does not generally interfere with usual daily activities. In this study, an example includes mild emotional distress that persists after an interview has been completed.

- Moderate: An experience that is alleviated with simple therapeutic treatments. The experience impacts usual daily activities. In this study, an example includes physical distress caused by swallowing toothpaste.

- Severe: An experience that requires therapeutic intervention. The experience interrupts usual daily activities. In this study, an example includes swallowing a tooth and requiring treatment if it becomes lodged in the throat. If any hospitalization (or prolongation of hospitalization) is required for treatment, it becomes an SAE.

Relationship To Study Intervention

This study uses the following AE attribution scale:

- Not related: The AE is clearly not related to the study procedures (i.e., another cause of the event is most plausible and/or a clinically plausible temporal sequence is inconsistent with the onset of the event).

- Possibly related: An event that follows a reasonable temporal sequence from the initiation of study procedures, but that could readily have been produced by a number of other factors.

- Related: The AE is clearly related to the study procedures.

This study uses the following AE expectedness scale:

- Unexpected: The nature or severity of the event is not consistent with information about the intervention in the protocol or consent form.

- Expected: The event is known to be associated with the intervention under study (There are no expected AEs or SAEs given the study team's experience fielding two previous studies of the mouth care program.)

6.3.2 Follow-up for Adverse Events

An interim project analysis will be conducted to evaluate the safety of the intervention after the first cluster randomized trial (Aim 2) is completed. One of the tasks of the Data Safety Monitoring Board (DSMB) will be to review preliminary data and make a recommendation regarding whether or not the study should continue.

6.4 Safety Monitoring

The Data and Safety Monitoring Board (DSMB) will act in an advisory capacity to the National Institute of Aging (NIA) Director to monitor participant safety, data quality and evaluate the progress of the study. The DSMB will be led by the Committee Chair, who will submit a report after each DSMB meeting that summarizes the state of the study and any recommendations. DSMB reports will be submitted to the UNC IRB and NIA staff.

The DSMB responsibilities are to:

- review the research protocol, informed consent documents and plans for data safety and monitoring;
- advise the NIA on the readiness of the study staff to initiate recruitment;
- evaluate the progress of the trial, including periodic assessments of data quality

and timeliness, recruitment, accrual and retention, participant risk versus benefit, performance of the trial sites, and other factors that can affect study outcomes;
- consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial;
- review study performance, make recommendations and assist in the resolution of problems reported by the Principal Investigator;
- protect the safety of the study participants;
- report to NIA on the safety and progress of the trial;
- make recommendations to the NIA, the Principal Investigator, and, if required, to the Food and Drug Administration (FDA) concerning continuation, termination or other modifications of the trial based on the observed beneficial or adverse effects of the treatment under study;
- if appropriate, review interim analyses in accordance with stopping rules, which are clearly defined in advance of data analysis and have the approval of the DSMB;
- ensure the confidentiality of the study data and the results of monitoring; and,
- assist the NIA by commenting on any problems with study conduct, enrollment, sample size and/or data collection.

The DSMB will discharge itself from its duties when the last participant completes the study.

7 INTERVENTION DISCONTINUATION

The following are the reasons for discontinuing the study early:

- The occurrence of a serious adverse event, possibly or definitely related to the study protocol, occurring in any participant. In this study, it would include serious physical distress causing death or hospitalization.
- Adverse events, possibly or definitely related to the study protocol, occurring in three or more participants. In this study, this would include participants who withdrew from the study due to new physical symptoms possibly related to allergic reactions. Cases will be examined carefully by the PI and DSMB to determine if the cases warrant study discontinuation.

Interim analyses will occur at the end of Aim 2. Summary data related to the above bullets will be made available to the DSMB at least 2 weeks before meeting, or within 24 hours of becoming known to the study team in the case of a serious adverse event (e.g., hospitalization or death) or 48 hours in the case of an unexpected and related adverse event our unanticipated problem (UP) with increased risk.

8 STATISTICAL CONSIDERATIONS

8.1 General Design Issues

The evaluation of research efficacy (Aim 2) addresses (1) the reach of the intervention; (2) effects on mediators/targets of change at the organizational and individual level; (3) outcomes (oral hygiene, pneumonia, hospitalizations); (4) associations between change at the organizational and individual level and outcomes, and also associations with characteristics of the AL community and staff; and (5) attitudes, barriers, and facilitators. Analyses will be cross-sectional at each time point and longitudinal to assess change. Analyses for Aim 3 will be based on a priori specified statistical models developed in Aim 2

with the key difference being this aim is assessing real-world efficacy in a new sample. Results across the two aims and samples will be comparable by using in Aim 3 the identical set of resident- and AL-level fixed effects and random effects identified in Aim 2.

8.2 Sample Size and Randomization

8.2.1 Sample Size

Original Estimate

The original estimate of statistical power is based on Aim 2 where the outcome is change in oral hygiene at four months; it was based on enrolling 360 residents (15 per community) in 24 communities (12 intervention and 12 control) and allowing for a 20% attrition rate; N=288. At the time, we allowed for the chance that effect sizes in assisted living would be considerably less than observed in our nursing home study (Weintraub et. al. 2018) because residents in the former are generally healthier, and so we planned for the conservatively high sample size of 288 based on enrollment of 360 participants.

Allowing for a conservative treatment effect <25% lower than found in our previous research (a mean difference ≥ 0.374), power would equal approximately 68%, assuming N=170 divided among 20 AL communities with the number of clusters in the intervention group = 9 (K1) and the number of clusters in the control group =11 (K2), an intraclass correlation coefficient (ICC) of .09 (based on previous work), a coefficient of variation (COV) among cluster sizes of 0.30, a between-subject SD of 0.76, and an alpha value of .05 for a two-sided test. These values reflect the assumptions in the original power analysis for the Plaque Index for Long-Term Care and scenarios that achieve 80% power by altering assumptions regarding effect size and ICC.

Revised Estimate (for Aim 3 based on Aim 2)

The Aim 2 trial was completed with 200 enrolled participants in 24 communities. However, one AL community withdrew prior to the four- month visit, and another could not be scheduled for the four- month data collection due to repeated cancellations responsive to COVID outbreaks. Thus, the Aim 2 trial had 117 participants from 22 communities having both baseline and four- month outcome data, which corresponds to an average of 5.3 residents per community.

Informed by data from the completed Aim 2 trial, power analyses were re-calculated to determine power to detect between-group differences in mean four-month change in the oral health outcomes (plaque index and gingival index) in the Aim 3 trial. In most scenarios, power to detect anticipated mean differences in change scores between treatment groups is at least 80% (Table 8.2.1).

Table 8.2.1. Power of the Aim 3 CRT to detect standardized effect size (Cohen's d) of change in Oral Hygiene score from baseline to four-months assuming unequal cluster sizes with Coefficient of Variation of 0.43, intraclass correlation of 0.10 and an average cluster size in the analysis dataset of 5									
No. of clusters	Average Cluster size	Total Sample Size	Target Enrollment		d=0.6	d=0.65, GI-LTC in Aim 2	d=0.7	d=0.75 PI-LTC in Aim 2	d=0.80
			60% evaluable	70% evaluable					
20	5	100	167	143	65	72	78	83	88
22	5	110	183	157	70	76	82	87	91
24	5	120	200	171	74	80	86	90	93
26	5	130	217	186	77	84	89	92	95
28	5	140	233	200	81	86	91	94	96
30	5	150	250	214	83	89	93	96	97

We aim to enroll 233 participants in Aim 3. Based on data from Aim 2, a small percentage of these (less than 5%) will be edentulous at baseline or become edentulous prior to month 4 and not contribute to the Primary analysis of PI-LTC and GI-LTC. Table 8.1.2 shows that 80% power to detect an effect size of Cohen's d = 0.6 is attainable if we enroll a total of 28 clusters to achieve a total sample size for analysis of 140 residents. Depending upon the percentage of participants with evaluable data (i.e., with teeth and an oral exam at both baseline and four month follow-up), we would need to enroll 233 residents assuming 40% are non-evaluable.

8.2.2 Randomization

Randomization will occur at the AL community-level. The project coordinator will work with the NC DHHS Special Care Dentistry Program partners to identify the AL communities that (a) have not been trained in MCWB, (b) were trained within the last year, and (c) were trained longer than one year ago. For Aim 2, a total of 24 AL communities (that are licensed to provide care for approximately 50 or more residents and have not been trained in MCWB in the last year) will be recruited across the state, eight from each of the two largest regions (Regions 4 and 5), and four from each of the other eight regions. For Aim 3, the intervention will be delivered by dental hygienists employed by the State of North Carolina Department of Health and Human Services (NC DHHS) on a voluntary basis; depending on the counties to which they are assigned, geographic coverage may not be statewide. For this aim, up to 28 ALs will be recruited and it will be allowed that communities with as few as 13 residents will be contacted for recruitment while still striving to assure at least 10 residents meet eligibility criteria. The project coordinator will recruit them within region, with a preference given to those that have never been trained. After confirming eligibility and willingness to participate, the analyst will randomly assign the community to treatment or control one-to-one within regions.

8.3 Interim analyses and Stopping Rules

The following are the reasons for discontinuing the study early:

- The occurrence of a serious adverse event, possibly or definitely related to the

study protocol, occurring in any participant. In this study, it would include serious physical distress causing death or hospitalization.

- Adverse events, possibly or definitely related to the study protocol, occurring in three or more participants. In this study, this would include participants who withdrew from the study due to new physical symptoms possibly related to allergic reactions. Cases will be examined carefully by the PI and DSMB to determine if the cases warrant study discontinuation.

Interim analyses will occur at the end of Aim 2. Summary data related to the above bullets will be made available to the DSMB at least 2 weeks before meeting, or within 24 hours of becoming known to the study team in the case of a serious adverse event (e.g., hospitalization or death) or 48 hours in the case of an unexpected and related adverse event our unanticipated problem (UP) with increased risk.

8.4 Outcomes

8.4.1 Primary outcomes

The primary comparisons are the differences between intervention and control treatment conditions in mean oral hygiene scores, as measured by the Plaque Index for Long-Term Care (PI-LTC), Long-Term Care Gingival Index (GI-LTC), and Denture Plaque Index (DPI) at four months adjusting for baseline scores. The three outcomes are collected at baseline, four months (Aims 2 and 3), and eight months (Aim 2 only); additional comparisons between treatment arms will be conducted at eight months, adjusting for baseline scores, to assess maintenance effects of the intervention. Descriptive statistics will include the calculation of mean outcome scores at each of the three time points for control and intervention conditions. Preliminary effectiveness analysis for the oral hygiene outcomes will compare MCWB sites to control sites for their change from baseline score through calculation of difference-in-differences based on mean summary scores at four and eight months to ascertain whether hygiene improves from baseline to follow-up. Resident and AL characteristics will be summarized for the two treatment arms using means for continuous variables and frequencies for categorical variables. Sensitivity analysis of primary models (described next) will include characteristics that are shown to be imbalanced despite randomization; in the case of continuous covariates, a criterion that differences between treatment arms exceed 10% relative to the control condition will be applied.

For each outcome, a repeated measures linear mixed effects model for the joint analyses of the mean outcome at 4 months and 8 months follow-up will follow an analysis of covariance approach with the baseline score of oral hygiene as a covariate decomposed into individual and cluster level components (Klar and Darlington, 2004). The mixed effects model will include random effects for AL sites, residents and residual error as well as fixed effects: an indicator for intervention/control status of the AL community (to test the intervention effect at 4 months), an indicator for eight months (time), and an interaction of intervention status and time allowing assessment of a maintenance effect at 8 months. Due to the moderately small number of clusters (24), Kenward-Roger degrees of freedom correction will be used in all linear mixed effects models.

8.4.2 Secondary outcomes

Secondary outcomes include pneumonia and hospitalizations. The secondary outcomes of pneumonia and hospitalization will be examined with generalized linear models for cluster-aggregated count data with a log link function, offsets for resident-days of follow-up and

corrections for likely overdispersed counts (i.e., negative binomial models); we expect these analyses to be preliminary given the limited number of events over four and eight months. Analyses will determine effect size and the necessary sample to detect change in pneumonia incidence in AL residents for the subsequent pragmatic trial.

8.5 Data Analyses

For quantitative data, univariate statistics will be obtained for all variables, overall and by setting and staff characteristics, including frequencies, proportions, and 95% confidence intervals. Reach will be assessed with bivariate tests (i.e., X^2-based tests, t-tests) to detect differences between participating and non-participating AL sites and AL staff and residents to inform representativeness. Fidelity will be examined overall and across sites, to determine and describe variability. To assess the effect of MCWB on organizational targets of change, change in the number of mouth care policies/practices will be determined, overall and in comparison to control sites (to detect a Hawthorne effect). To assess the effect of MCWB on the individual-level target of change (e.g., self-efficacy), a simplified linear mixed model will compare change in intervention versus control at four months; the model will include a variable for intervention/control allocation, baseline self-efficacy, and random effects for sites. A second model will assess eight-month change relative to four-month data (as will also be done for organizational practices). For adoption, implementation, and maintenance of behavior change, the amount of care provision will be examined through four and eight months, exploring drift over time. Cost analyses will calculate a "cost per patient per unit of improvement in oral hygiene" but will not include other outcomes, such as reduction in pneumonia. These data will be useful in planning cost-effectiveness analyses for the subsequent pragmatic trial.

For associations between implementation and effectiveness in the twelve MCWB sites, we will examine bivariate relationships between implementation measures (including the mediators of organizational- and individual-level change) and oral hygiene outcomes with graphical displays and summary measures of association; power is limited for more sophisticated analyses due to sample size. Graphs will identify monotonic associations between implementation success and change in oral hygiene. We will analyze staff data both individually and aggregated at the site level. We will use evidence gathered from the analyses above to guide our inquiries, noting the outcomes that did/did not experience change. For example, suppose (a) the MCWB arm is not significantly associated with reductions to residents' PI-LTC scores but reveals a trend in the expected direction, and (b) the amount of organizational change or change in self-efficacy varies significantly by AL site and is correlated with change in PI-LTC. Our goal will be to determine whether effect in the targets of change (mediators) explain intervention effectiveness and, if not, whether lack of effectiveness is systematic or isolated. In the latter case, we will identify outlying sites that have poor implementation and also anomalous ALs that exhibit good implementation but poor effectiveness. Analyses will examine a variety of implementation variables although our primary focus will be on the mediators/targets of change, and developing (if possible) an aggregated summary score of overall implementation success from the individual implementation measures across the RE-AIM domains. Overall, such information has potential to guide selection and emphasis of materials to include in the coaching manual to maximize implementation and outcomes.

For attitudes, barriers and facilitators, we will analyze AIM, IAM, FIM, WEVAL and WAFU scores similarly as with the staff self-efficacy and oral hygiene outcomes. If barriers remain (e.g., low scores in the measures), the research team will use this information to inform content of the dental hygienist coaching manual for Aim 3.

For Aim 3, analyses will compare all results obtained under Aim 2 analyses with those for Aim 3 analyses. Comparisons will be largely descriptive in nature and will comprise comparison of models and their derived parameter estimates across the two samples. We also may consider the combined samples as a meta-analysis of two studies, with data at the individual level; outcomes could be combined and modeled as a function of three "treatments" (combining the control conditions).

9 DATA COLLECTION AND QUALITY ASSURANCE

9.1 Data Collection Forms

The following outlines the research team member(s) who will be collecting data from each participant group.

Data Collection Form	Research Team Member(s)
Data obtained from residents	
Oral hygiene assessments	Dental hygienist
Data obtained from LAR	
Baseline interview about resident	Research assistant
Data obtained from staff members	
Staff mouth care baseline questionnaire	Research assistant
Post-training staff evaluation questionnaire (WEVAL)	Dental hygienist
Staff mouth care follow-up questionnaire	Research assistant
Observation of mouth care	Research assistant
Follow-up staff program evaluation questionnaire (WAFU)	Project coordinator/research assistant
Data obtained from Administrators	
Assisted living characteristics, polices, practices interview	Project coordinator/Research assistant
Salaries	Project coordinator/Research assistant
Data obtained from Health Care Supervisors	
Adverse Events and Pneumonia	Project coordinator/Research assistant
Data obtained from training and AL records	
Training log	Dental hygienist
Training support log	Dental hygienist
Daily mouth care checklist	Dental hygienist
Data obtained from Public Health Dental Hygienists	
Dental Hygienist Self-efficacy Questionnaire	Project coordinator/Research assistant

9.2 Data Management

The study's data management process will comprise four distinct yet interrelated tasks:

1. development and organization all data sources (interviews, questionnaires, assessments);
2. development and organization of all data files;
3. identification, classification, and correction of all data anomalies (i.e., cleaning); and
4. development and organization of cleaned data in preparation for analysis.

Three members of the study team will be assigned data management tasks and will comprise the data management team. The project coordinator will have primary responsibility for completing tasks 1 and 2. The data analyst will have primary responsibility for completing tasks 3 and 4. The PI will have oversight of all data management tasks. All three team members will share responsibility for communicating with the broader study team members regarding data management processes.

The data management team will give specific attention to the identification of potential adverse events among study participants. The data management team will develop a specific reporting mechanism and form to track all such events and will communicate with the broader study team regarding any outcomes as necessary. The study team will work collaboratively to prevent and mitigate any such events.

9.3 Quality Assurance

9.3.1 Training

All staff will be highly experienced in their job responsibilities and receive project-specific training from the PI, dementia care specialist, dental specialist, project coordinator, biostatistician, and/or others as necessary.

9.3.2 Quality Control Committee

N/A

9.3.3 Metrics

Data will be double entered; data cleaning will include logic checks and examination for outliers.

9.3.4 Protocol Deviations

Protocol deviations will be monitored using the Protocol Deviations Log.

9.3.5 Monitoring

All research procedures will be detailed in a written protocol. Only experienced data collectors will be employed; they will be trained in the importance of protecting confidentiality and will complete NIH Human Subjects Ethics Training. They will track completion of all forms, including consent forms, and the project coordinator will review the tracking database on a weekly basis to assure that forms are completed in a timely manner. Further, the project coordinator will confer with the dental hygienist regularly to assure compliance to the intervention protocol. If compliance is poor, remedies will be enacted (e.g., additional training or replacement of data collectors, more intense training provided by the clinical specialists). All matters will be reported to the PI and their remedy undertaken with her guidance.

10 PARTICIPANT RIGHTS AND CONFIDENTIALITY

10.1 Institutional Review Board (IRB) Review

All procedures will be reviewed by the UNC IRB. The protocol and informed consent documents will be reviewed prior to the initiation of the study. Any subsequent modifications will be reviewed and approved by the IRB. Refer to **Appendix A** for the approved informed consent documents.

10.2 Informed Consent Forms

Residents: The LAR recruitment letter and the resident/LAR consent form will be mailed to this individual. Three business days after the letter is mailed, the research assistant will call the LAR to explain the study, answer questions, solicit consent, and encourage prompt return of the form. The LAR calling script will guide this call. Consent includes (1) an oral hygiene examination of the resident up to three times; (2) a telephone interview with the family member regarding resident characteristics (e.g., cognitive and functional status); (3) weekly contact with the AL health care supervisor, to collect adverse events and incidence of pneumonia, (4) observations of mouth care. If unable to reach the family/LAR by phone, the research assistant may also contact them by email.

Able residents will be asked to provide assent. In all cases, residents must assent to the oral hygiene assessment; if they refuse, the assessment will not be conducted. Residents will be asked to give assent at each study visit; if a resident chooses to give assent (or not give assent) at one visit, study staff will continue to ask for their assent at subsequent visits.

A signed HIPAA authorization will be obtained for all participating residents in the study. The project coordinator/research assistant will explain to the family member that the Health Care Supervisor will be interviewed weekly to check for any pneumonia cases or adverse events. It will also be explained that the HIPAA authorization will not stop unless they stop it in writing.

The resident subject tracking form will be completed for all residents/LARs who are approached for participation. All recruitment efforts will be documented on the resident tracking form; specifically, all enrollments, refusals, and ineligibles (including the reasons for refusals and ineligibles), will be documented for each approached resident.

Staff: Research staff will meet with PCAs and present the questionnaire that includes an embedded consent form and allow them time to read the consent form and choose to participate or decline participation without penalty.

Dental hygienists: Consistent with the staff self-efficacy questionnaires, research staff will meet with DHHS Dental Hygienists and present the questionnaire that includes an embedded consent form and allow them time to read the consent form and choose to participate or decline participation without penalty.

10.3 Participant Confidentiality

To maintain confidentiality during recruitment, subjects will be approached in private in the place of their choosing. Mailings will be done in an unmarked envelope that does not allude to the nature of the contact. For any refusals, documents will be shredded immediately. All other documents will be safely stored in locked cabinets.

Nothing on the interview forms will enable a person to identify a participant. All data will be summarized in reports, presentations, or publications. It will not be possible to identify an individual participant from data summaries.

10.4 Study Discontinuation

The study may be discontinued at any time by the IRB, the NIA, or other government agencies as part of their duties to ensure that research participants are protected.

11 ETHICAL CONSIDERATIONS

This study was reviewed in accordance with federal regulations governing human subjects research, including those found at 45 CFR 46 (Common Rule), 45 CFR 164 (HIPAA), 21 CFR 50 & 56 (FDA), and 40 CFR 26 (EPA).

12 COMMITTEES

None

13 PUBLICATION OF RESEARCH FINDINGS

Findings from this trial that are shared in publications or presentations will be of data vetted past the DSMB.

14 REFERENCES

Klar N, Darlington G. Methods of Modelling Change in Cluster Randomization Trials. Statist Med 2004;23:2341-2357.

Zimmerman S, Sloane PD, Ward K, Wretman CJ, Stearns SC, Poole P, Preisser JS. Effectiveness of a Mouth Care Program Provided by Nursing Home Staff vs Standard Care on Reducing Pneumonia Incidence: A Cluster Randomized Trial. JAMA Netw Open. 2020 Jun 1;3(6):e204321. doi: 10.1001/jamanetworkopen.2020.4321. PMID: 32558913; PMCID: PMC7305523.

15 APPENDIX A – CONSENT FORMS

16 UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Adult Participants *–Legally Authorized Representative*

Consent Form Version Date: June 28, 2024
IRB Study # 18-2795
Title of Study: Oral hygiene in assisted living
Principal Investigator: Sheryl Zimmerman
Principal Investigator Department: Cecil G. Sheps Center for Health Services Research
Principal Investigator Phone number: (919) 962-6417
Principal Investigator Email Address: sheryl_zimmerman@unc.edu
Funding Source and/or Sponsor: NIH National Institute on Aging (NIA)

Study Contact Telephone Number: (919) 843-7811
Study Contact Email: LSampson@email.unc.edu

What are some general things you should know about research studies?
Your family member is being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Your family member may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your/your family member's relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If your family member is a patient with an illness, your family member does not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to learn about and improve care and outcomes in assisted living communities. Your family member is being asked to participate in this research study because he/she lives in a participating assisted living community.

Are there any reasons your family member should not be in this study?
Your family member should not be in this study if he/she is younger than 18 years of age, has no teeth or denture, is on hospice or tube-feeding, expected to discharge in the next six months, does not have a diagnosis of dementia, or requires prophylactic antibiotics prior to dental examinations.

How many people will take part in this study?
There will be approximately 720 people in this research study.

How long will your family member's part in this study last?
Your family member's participation will last up to four months.

What will happen if your family member take part in the study?
If your family member takes part in this study, he/she will first receive an oral hygiene screening by a dental hygienist to assess his/her oral health. This person will examine your family member's teeth and gums, and record information about how clean and healthy they are. This examination will last about 20 minutes. Your family member will receive a follow-up oral hygiene screening after beginning the study.

You will also be interviewed about your family member's current cognitive and functional status and your participation in the community. The research team will also contact the Health Care Supervisor regarding whether your family member had pneumonia or experienced an adverse event during the study event (death, hospitalization, experienced a life-threatening event or a new disability, had swallowing problems related to mouth care or allergic reactions to mouth care products).

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. The benefits to your family member from being in this study may be the identification of serious oral conditions for which he/she need treatment. Although unlikely, if such a condition is found, the dentist or hygienist will advise the assisted living staff.

What are the possible risks or discomforts involved from being in this study?
The oral hygiene screening may be uncomfortable, but the discomfort is expected to be minor and brief. In addition, there may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your family member's participation.

How will information about your family member be protected?
Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your family member's information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA or NIH) for purposes such as quality control or safety.

Your family member's name will not be connected to the results of the oral hygiene screening. Instead, a number will be used. The data will be secured in a password-protected file and not shared with anyone outside the research team, unless you request otherwise.

What is a Certificate of Confidentiality?
This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen if your family member is injured by this research?
All research involves a chance that something bad might happen. This may include the risk of personal injury. In spite of all safety measures, your family member might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your family member's insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay your family member for any such reactions or injuries, or for the related medical care. You do not give up any of your family member's legal rights by signing this form.

What if you want to stop before your family member's part in the study is complete? You can withdraw your family member from this study at any time, without penalty. The investigators also have the right to stop your family member's participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will your family member receive anything for being in this study?
Your family member will not receive anything for taking part in this study.

Will it cost your family member anything to be in this study?
It will not cost your family member anything to be in this study.

Who is sponsoring this study?
This research is funded by the National Institute on Aging. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if you have questions about your family member's rights as a research participant? All research on human volunteers is reviewed by a committee that works to protect your family member's rights and welfare. If you have questions or concerns about your family member's rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Unencrypted Messaging
The study team may want to message you by email about reminders and notifications about the study, however you may say "no" to receiving these messages and still participate in this study. If you say "yes", messages may contain personal information about you and may be sent or received by the study team's personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team.

If, at any point, you wish to stop receiving unprotected communication from the study team, please notify the study team. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving un-encrypted (un-protected) communication, you will no longer receive un-encrypted messages specific to this study.

Participant's Agreement:

☐ Check here to allow study staff to be able to email you if necessary.

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Legally Authorized Representative Date

_____

Printed Name of Legally Authorized Representative

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent

Staff Consent: Baseline (Control)

This questionnaire is part of a research study and is designed to help us learn about how mouth care is thought about and provided in this assisted living community. There are no right or wrong answers – we are only interested in your thoughts and opinions about providing mouth care.

Completing this questionnaire is voluntary and should take about 10 minutes. You will not receive anything for completing this questionnaire.

The risks involved in completing this questionnaire are minimal. Your responses are confidential and you are not asked to provide your name. The responses we receive from everyone will be combined together, with no way to identify you individually.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information or documents that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

If you have any questions about the research study or questionnaire items, you may contact the Principal Investigator for this project, Sheryl Zimmerman at (919) 966-7173.

If you have any questions about your rights as research participant, you may also contact the Institutional Review Board at the University of North Carolina at Chapel Hill at (919) 966-3113.

This research study was reviewed and approved by the Institutional Review Board at the University of North Carolina at Chapel Hill #18-2795.

By completing this form you agree to participate in the study.

Staff Consent: Follow-Up (Control)

This questionnaire is part of a research study and is designed to help us learn about how mouth care is thought about and provided in this assisted living community. There are no right or wrong answers – we are only interested in your thoughts and opinions about providing mouth care.

Completing this questionnaire is voluntary and should take about 10 minutes. You will not receive anything for completing this questionnaire.

The risks involved in completing this questionnaire are minimal. Your responses are confidential and you are not asked to provide your name. The responses we receive from everyone will be combined together, with no way to identify you individually.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information or documents that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

If you have any questions about the research study or questionnaire items, you may contact the Principal Investigator for this project, Sheryl Zimmerman at (919) 966-7173.

If you have any questions about your rights as research participant, you may also contact the Institutional Review Board at the University of North Carolina at Chapel Hill at (919) 966-3113.

This research study was reviewed and approved by the Institutional Review Board at the University of North Carolina at Chapel Hill #18-2795.

By completing this form you agree to participate in the study.

Staff Consent: Baseline (Intervention)

This questionnaire is part of a research study and is designed to help us learn about how mouth care is thought about and provided in this assisted living community. There are no right or wrong answers – we are only interested in your thoughts and opinions about providing mouth care.

Completing this questionnaire is voluntary and should take about 10 minutes. You will not receive anything for completing this questionnaire.

The risks involved in completing this questionnaire are minimal. Your responses are confidential and you are not asked to provide your name. The responses we receive from everyone will be combined together, with no way to identify you individually.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information or documents that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

If you have any questions about the research study or questionnaire, you may contact the Principal Investigator for this project, Sheryl Zimmerman at (919) 966-7173.

If you have any questions about your rights as research participant, you may also contact the Institutional Review Board at the University of North Carolina at Chapel Hill at (919) 966-3113.

This research study was reviewed and approved by the Institutional Review Board at the University of North Carolina at Chapel Hill #18-2795.

By completing this form you agree to participate in the study.

Staff Consent: Follow-Up (Intervention)

Your assisted living community has partnered with researchers from the University of North Carolina at Chapel Hill on a program to train and support staff to provide better mouth care. This questionnaire is part of a research study designed to understand how you feel about mouth care at your community now and also how you felt about mouth care before you were trained.

There are no right or wrong answers – we are only interested in your thoughts and opinions about providing mouth care.

Completing this questionnaire is voluntary and should take about 10 minutes. You will not receive anything for completing this questionnaire.

The risks involved in completing this questionnaire are minimal. Your responses are confidential and you are not asked to provide your name. The responses we receive from everyone will be combined together, with no way to identify you individually.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information or documents that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

If you have any questions about the research study or questionnaire items, you may contact the Principal Investigator for this project, Sheryl Zimmerman at (919) 843-7811.

If you have any questions about your rights as research participant, you may also contact the Institutional Review Board at the University of North Carolina at Chapel Hill at (919) 966-3113.

This research study was reviewed and approved by the Institutional Review Board at the University of North Carolina at Chapel Hill, #18-2795.

By completing this form you agree to participate in the study.

Dental Hygienist Mouth Care Questionnaire

This questionnaire is part of a research study designed to understand how mouth care training for assisted living staff is perceived and provided. There are no right or wrong answers; it asks your thoughts and opinions about providing mouth care training in assisted living.

Completing this questionnaire is voluntary and should take approximately 10 minutes. You will not receive anything for completing this questionnaire.

The risks involved in completing this questionnaire are minimal. Your responses are confidential; they will not be shared with your employer or any other people. Results will reflect only aggregate (group-level) information.

If you have any questions about the questionnaire or research study, you may contact the Principal Investigator for this project, Sheryl Zimmerman at (919) 966-7173.
If you have any questions about your rights as research participant, you may contact the Institutional Review Board at the University of North Carolina at Chapel Hill at (919) 966-3113.
This research study was reviewed and approved by the Institutional Review Board at the University of North Carolina at Chapel Hill #18-2795.

By completing this questionnaire you agree to participate in the study.