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Study protocol for a randomised controlled trial of a care partner assisted intervention to improve oral health of individuals with mild dementia

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ABSTRACT

Introduction Individuals with mild dementia are at high risk of poor oral health outcomes. To address this issue, we describe an intervention to teach care partners skills to guide individuals with mild dementia in proper oral hygiene techniques and provide reminders to practice oral hygiene care. By providing support to perform these tasks successfully, we aim to delay oral health decline among this vulnerable population.

Methods and analysis This multisite study is a three-arm randomised controlled trial. The primary objective is to evaluate the efficacy of an intervention to improve oral hygiene outcomes by promoting positive oral hygiene behaviours and skills among individuals with mild dementia. Care partners' behaviour factors, such as oral care self-efficacy and implementation of the care plan, serve as mediators of the intervention. Participant–care partner dyads will be randomly assigned to either Treatment Group 1, Treatment Group 2 or the Control Group. All groups will receive an educational booklet. Treatment Group 1 and Treatment Group 2 will receive a smart electronic toothbrush. Treatment Group 2 (the intervention group) will also receive an oral hygiene care skill assessment, personalised oral hygiene instruction and treatment plan; and care partners will receive in-home and telephone coaching on behaviour change. Oral health outcomes will be compared across the three groups. The duration of the active intervention is 3 months, with an additional 3-month maintenance phase. Data collection will involve three home visits: baseline, 3 months and 6 months. The study enrollment started in November 2021, and the data collection will end in Spring 2024.

Ethics and dissemination The study has been approved by the Institutional Review Board of the NYU Grossman School of Medicine and Duke University, and is registered at Clinicaltrials.gov. A Data Safety Monitoring Board has been constituted. The study findings will be disseminated via peer-reviewed publications, conference presentations and social media.

Trial registration number NCT04390750.

Strengths and limitations of this study

⇒ One of the first behaviour interventions to work with informal care partners to improve oral health for community-dwelling older adults with mild dementia.
⇒ Focusing on individuals with mild dementia, this study aims to delay or prevent severe oral health problems, maintain oral function (eg, speaking, swallowing and chewing) and minimise oral discomfort as the dementia progresses.
⇒ While most interventions have relied on self-reported information on frequency and duration of toothbrushing, our study will use an objective measure of toothbrushing behaviour.
⇒ The dental hygienist cannot be blinded for oral health assessments.
⇒ This study will not directly generalise to individuals with mild dementia who do not have a care partner.

INTRODUCTION

Oral health problems accumulate over the life span, but occur with increased frequency in later life[1] and are associated with systemic diseases such as diabetes and cardiovascular diseases, functional impairment and mortality.[1–4] Oral health is integral to quality of life. Individuals with cognitive impairment are at higher risk of poor oral health and significantly worse oral health-related quality of life[5]; they have more oral plaque, more severe periodontal disease, more caries and fewer teeth than cognitively intact older individuals,[6 7] and are less likely to have regular dental visits.[8] These problems begin early and worsen in the long, insidious course of dementia.[9 10] Because the number of impacted individuals will increase exponentially due to the rapid expansion of the ageing population in the USA, interventions for improving oral health among people with mild dementia are imperative to address the health of this population.[11 12]

To address this gap, we are conducting a study of the impact of an intervention on oral health for individuals with mild dementia residing in the community and their care partners. The aim of the intervention is to delay or prevent oral health diseases and problems, maintain oral function and minimise oral discomfort. Those with mild dementia experience myriad symptoms such as alteration in memory, judgement and decision-making, and slowed task completion as well as disturbances in emotional regulation, social behaviour and motivation.[13] These symptoms may lead to individuals forgetting to brush or floss, using the wrong supplies for oral care such as lotion instead of toothpaste, or not following tasks to completion. We have developed this study with a control group and two treatment groups at different levels of intervention to inform about the level of intensity necessary to improve oral health in these groups.

Although persons with mild dementia have poorer oral hygiene than older adults who are cognitively intact, there is a lack of interventions for individuals with mild dementia residing in the community. There have been a few studies conducted in nursing homes that show with routine oral hygiene care provided by care staff, the oral health of persons with dementia improves notably in a short period.[14–16] However, many more individuals with early stage dementia live in the community than in nursing homes.[7] Thus, our intervention aims to improve oral health and reduce risk of oral health problems among people with mild dementia living in the community. Our intervention is based on evidence showing that inadequate oral hygiene practices are a major contributing factor for poor oral health.[17–19] Our previous study found that only 36% of individuals with cognitive impairment brushed their teeth two times a day, as compared with 72% of those with normal cognition and frequency of toothbrushing was associated with better oral health outcomes than among people with cognitive impairment,[8] a finding consistent with well-established evidence that regular and proper toothbrushing helps prevent plaque build-up.[17–19] Plaque control can lessen or prevent severe oral health conditions such as dental caries and periodontal disease. We propose that an intervention to improve the quality and frequency of toothbrushing for community-dwelling individuals with mild dementia would have similar positive results. To our knowledge, this will be among the first oral health intervention studies to be conducted among community-dwelling individuals with mild dementia.

Our rationale for addressing oral health problems early in cognitive impairment is that these individuals are still able to perform oral hygiene tasks with minimal assistance from an informal caregiver. Interventions for individuals with more advanced dementia would likely be more extensive and costly and require delivery of oral care by another as shown in nursing home studies.[14–16] In mild dementia, the individual can be an active partner in oral care. By intervening at this earlier point, we aim to establish behaviour changes to delay or prevent severe oral health problems, maintain oral function and minimise oral discomfort as the dementia progresses. Informal caregivers play a pivotal role in facilitating individuals with mild dementia to complete activities of daily living such as oral care.[20 21] Yet, oral hygiene tasks are often neglected by busy caregivers.[22] Structured assistance from caregivers has proven to be useful in studies of other intervention outcomes involving individuals with mild dementia.[23]

Thus, the care partner-assisted intervention is an ideal strategy for helping individuals with mild dementia maintain regular oral self-care. Our rationale is that individuals with mild dementia characteristically have trouble learning complex new tasks or performing multistep tasks, such as following a recipe or performing complex household chores; yet they retain procedural memory, the ability to remember how to perform simple well-learnt everyday tasks.[24] The basic steps and motions involved in toothbrushing use procedural memory.[25] Thus, individuals with mild dementia often can continue to perform routine hygiene tasks, often independently. In this intervention, care partners will learn to create routines and simplify oral care into discrete steps that will help lead the participant through the procedures of oral self-care. With cognitive impairment, the quality of performance on these tasks may decline. For example, most individuals with mild dementia may remember to brush their teeth if it has been a lifelong pattern of behaviour, but they may be less thorough in their toothbrushing. If regularly brushing their teeth has not been part of their routine, then they may now forget to brush their teeth at times. Thus, the care partner will learn how to guide the participant in proper brushing techniques and provide reminders to brush their teeth, thus enabling them to perform routine oral hygiene tasks successfully. With care partner support, we believe that maintaining or improving good oral hygiene is an obtainable goal for preserving oral health as long as possible for individuals with mild dementia and therefore is the focus of our intervention.

In summary, previous studies including those by our research group have provided evidence that oral health declines more rapidly in mild dementia than among those who are cognitively intact and this is an optimal stage for intervention. There is a lack of research on improving oral health among older adults with dementia other than a limited number of studies conducted in nursing homes with individuals with more advanced dementia. None has been conducted among community-dwelling older adults, with a focus on mild dementia. Care partners play an essential role in helping participants in daily activities. However, care partner assistance in oral hygiene is often overlooked. Thus, we will address this knowledge gap by introducing a rigorous and innovative care partner-assisted intervention and assess its effectiveness (eg, oral hygiene outcomes measured by plaque index and gingival index), and the mechanisms of change (mediators), in improving oral hygiene with mild dementia.

METHODS AND ANALYSIS

Open label, randomised, multisite trial to study oral health intervention in individuals with mild dementia (ie, participants) and their care partners at two sites in the USA: Duke University in Durham, North Carolina and New York University (NYU) in New York, New York. The total number of dyads will be 120 (60 dyads per site). The recruited dyads, each consisting of an individual with mild dementia and his/her care partner will be randomly assigned to one of three groups: Treatment Group 1, Treatment Group 2 and the Control Group. An equal targeted number of participants will be allocated across the three groups. The first 3 months will be the active treatment phase and the final 3 months will be the maintenance phase. Data from each dyad will be collected over a period of 6 months.

The flow chart of the trial is depicted by the schema diagram in figure 1.

Sample selection

At both sites, we will recruit from sources with large numbers of individuals diagnosed with mild dementia. At NYU, we will recruit participants from the NYU Alzheimer's Disease Research Center, which is a part of the Department of Neurology at NYU School of Medicine. The NYU site will also recruit from the Pearl I. Barlow Center for Memory Evaluation and Treatment at NYU Langone. At Duke University, we will recruit participants from the Duke Memory Disorders Clinic and local support groups for individuals with mild dementia. At the medical clinics and centres at both NYU and Duke, potential participants will be identified by the provider or from medical records. The study will be introduced in person by providers or study coordinators, or via a letter from the provider. To recruit from the support groups, members will be given a flyer describing the study and providing the contact information for the study coordinator to learn more information. Our plans to retain participants in this 6-month intervention include (1) ensuring that the individuals understand the purpose and benefit of the study, (2) being responsive to their inquiries and (3) sending visit confirmation letters and visit reminder phone calls.

Inclusion criteria

Participant eligibility is determined according to the following criteria:
1. The participant is 60 years or older.
2. The participant has been given a diagnosis of mild dementia within the past year. The following guidelines will be used to differentiate between a diagnosis of mild dementia versus moderate/severe dementia: (a) a diagnosis of dementia by a physician with dementia expertise, (b) from medical records, a recent Montreal Cognitive Assessment score >14 or a Mini-Mental Status Examination score >16 and (c) can follow 2–3-step commands.[26][27]
3. The participant has at least four natural teeth.
4. The participant is community dwelling.
5. The participant lives with an informal, unpaid, care partner who is 18 years or older and who is willing to participate in the study.
6. The participant is physically able to brush their own teeth.

Exclusion criteria

Any participant who meets any of the following criteria will be excluded from the study:
1. The participant is unable to have an oral health evaluation.
2. The participant is prescribed antibiotics to be taken prior to a regular dental visit.
3. In the opinion of the investigator, the participant has sensory or physical problems that prevent participation in the intervention.
4. In the opinion of the investigator, the participant has a terminal illness or behavioural or psychiatric disorder that would interfere with participation in the intervention.
5. The participant has a medical condition that places him/her at greater risk of infection from the manipulation of the gingivae to measure the gingival index. These conditions are serious congenital heart conditions, previous infective endocarditis, prosthetic cardiac valves and cardiac transplantation with cardiac valvopathy.
6. The participant has a medical condition that suppresses the immune system.
7. The participant has had a total joint replacement and has had an infection in the replaced joint.
8. The participant is at increased risk of bleeding due to bleeding disorder such as haemophilia or the use of antiplatelet therapy.

Randomisation

The study coordinators will be blinded during the phone screening interview and prior to the randomisation of study participants. The procedures for the study visits differ based on which study group a participant is assigned; thus, the research staff conducting the study visits are not blind to the participant's assigned group. The randomisation group determines which research staff members attend the home visits. Because the interventionist does not attend study visits for participants in the Control Group and Treatment Group 1, randomisation must be done prior to the first visit. The research staff consists of a study coordinator, a dental hygienist and an interventionist. Staff conducting the study visits with participants and care partners will be trained to adhere to study procedures and interventions appropriately based on the group assignment. The interventionist does not attend the visits for the Control Group and Treatment Group 1, reducing risk of spill-over through delivery of in-person coaching. In addition, the intervention will be conducted at each participant's home, so the chances of spill-over effect are small. Blinded randomisation assignments will be determined by a statistician at the beginning of the study using
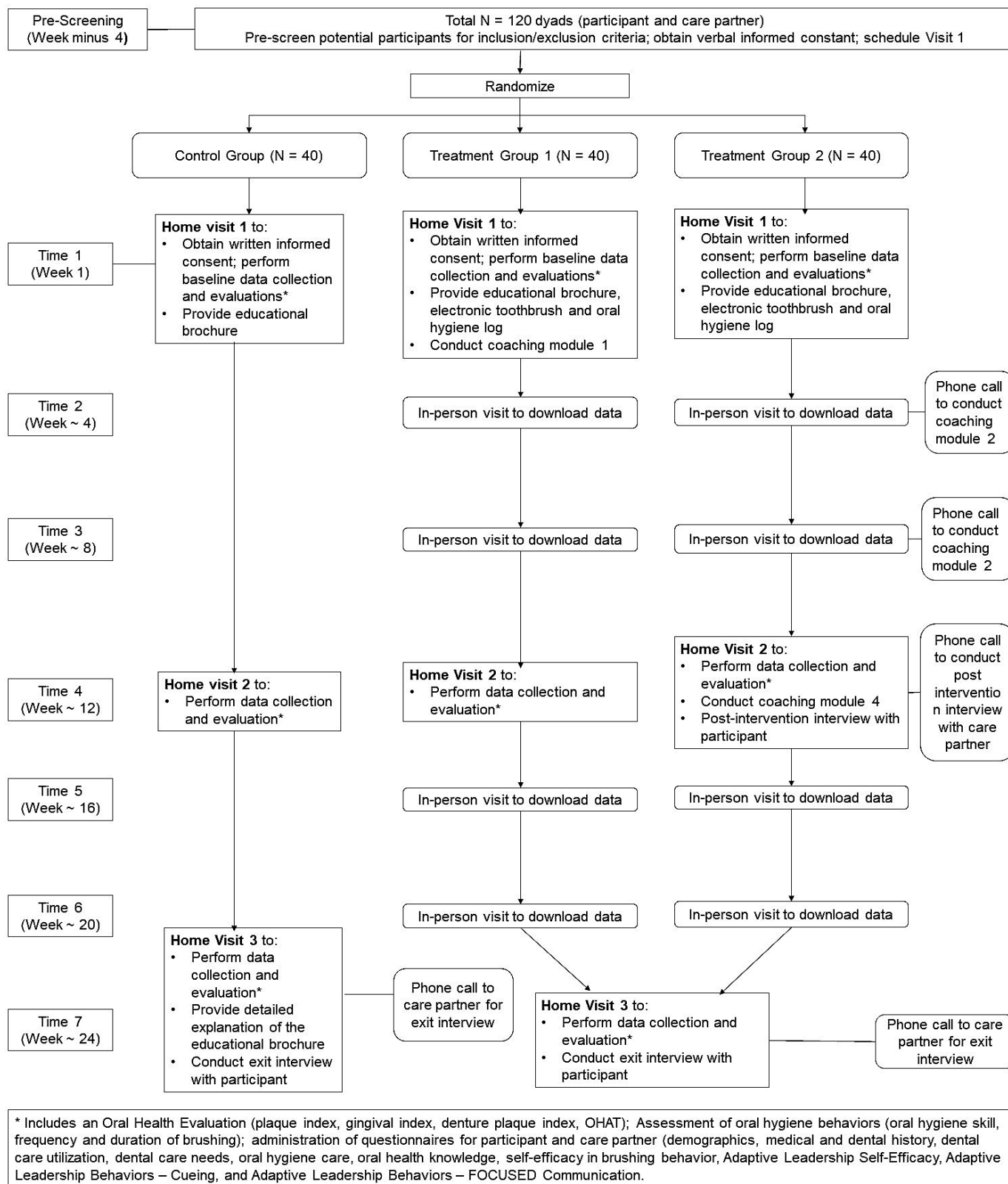
Figure 1 Flow chart for all three treatment groups.

a block random allocation algorithm generated a priori by the statistician assuring there will be equal allocation to arms by site. This is a three-group randomised trial using randomisation blocks by site to ensure balance within this potential confounder. Each randomisation block will be composed of two units, male and female in each treatment arm by site. Randomisation error will be minimised by ensuring that an equal number of all of the units are randomised to each group. As minorities are recruited, they will sequentially be assigned to each group. To assess

for randomisation balance, we will use χ^2 tests to examine if there are any statistically significant differences between race and site by the three groups.

Intervention or experimental manipulation

Intervention components for the three study groups are shown in table 1. A dental hygienist will perform the oral health evaluation. There is one dental hygienist in each site, and these dental hygienists will be calibrated. The control group will receive a standard educational booklet and a clinical oral health evaluation with no instruction on oral hygiene technique. The dental hygienist will observe the participant's normal toothbrushing technique, interdental cleaning procedures and the cleaning of dentures.

Treatment Group 1 will receive a standard educational booklet, clinical oral health evaluation and a smart electronic toothbrush with no instruction other than basic instruction on proper use of the smart electronic toothbrush. The dental hygienist will observe and record the participant's normal toothbrushing technique, interdental cleaning procedures and the cleaning of dentures.

Treatment Group 2 (intervention group) will receive a standard educational booklet, clinical oral health evaluation with tailored instruction on oral hygiene technique and care partner coaching (briefly detailed in table 1). The participant and care partner will receive training on how to complete a daily log in which they check off whether toothbrushing occurred and write-in the length in minutes.

The interventionist uses established, evidence-based behaviour change techniques in the coaching session (table 2).[28 29] The tailored instruction for participants and the coaching for care partners are inter-related and thus the hygienist and interventionist work together at points during the home visits. The participant and care partner will receive training on how to complete a daily log in which they check off whether toothbrushing occurred and write-in the length in minutes.

Sample size calculation

Since we will collect data from the predictors [X], mediators [M] and outcomes [Y] at all three time points (baseline, 3 months, 6 months), we will use generalised linear mixed models to account for longitudinal repeated measurements over time to produce sample based inferential effects, which is a group-specific averaged effect size slope over all three time points to estimate each pathway strength. For the power analyses, we proposed a small to medium effect size of 0.3 for our main outcome analyses without mediators. This was based on a combination of the effect size that is needed to detect what is reasonably thought to be a meaningful change and guidance from our pilot study. Thus, for the main effect we need a minimum of 107 subjects to reach 80% power at a significance level of 0.05. For the sequential mediation models, a sample of 120 provided at least 85% power at a significance level of 0.05. Thus, our target is a sample size of 120 individuals complete the intervention.

Measurements

Primary outcome measures at three data points (baseline, 3 months and 6 months)

Oral hygiene clinical outcomes are measured by Plaque Index using UNC Modified Green and Vermillion Oral Hygiene Index,[30] and Gingival Index using UNC Modified Loe and Silness Gingival Index.[31] Plaque will be measured as 0=No plaque, 1=Plaque covers <1/3 tooth, 2=Plaque covers >=1/3 but <2/3 tooth and 3=Plaque covers >=2/3 tooth. Gingival inflammation is classified as 0=Normal gingiva, 1=Mild inflammation, no bleeding on probing, 2=Moderate inflammation, bleeding on probing, 3=Severe inflammation, tendency to spontaneous bleeding.

Oral hygiene behavioural outcomes are measured by participants' frequency and duration of toothbrushing and interdental cleaning (eg, flossing and interdental brushing). Oral hygiene skills are assessed by a dental hygienist on participants' appropriateness, quality and duration of toothbrushing and flossing.

Key mediators for care partners at three data points (baseline, 3 months and 6 months)

Oral care self-efficacy is measured by care partner's confidence in own ability to do oral self-care, and his/her confidence in facilitating the participants to perform self-care. The team used a slightly modified version of the Geriatric Self-Efficacy Scale for Oral Health measure containing six items that assess oral hygiene behaviours.[32]

Adaptive leadership self-efficacy

The investigators adapted the Caregiver Confidence in Contributing to Self-Care to measure the care partners' confidence in facilitating the participant to perform oral self-care.[33 34]

Adaptive leadership behaviours-cueing

The investigators adapted the Caregiver Contribution to Self-Care Management scale to measure use of adaptive leadership cueing strategies by the care partner to facilitate the participant in performing oral self-care.[34]

Adaptive leadership behaviors-FOCUSED communication

The investigators adapted the Caregiver Contribution to Self-Care Management scale to measure use of adaptive leadership tailored communication strategies by the care partner to facilitate the participant in performing oral self-care.[34]

Key covariates

Participant's physical function is measured by Alzheimer's Disease Cooperative Studies Activities of Daily Living Instrument (ADCS ADL) at baseline. The ADCS ADL is administered to the care partner to rate the participant's functional ability on 27 daily activities during the previous 4 weeks.

The conceptual framework for Treatment Group 2 is depicted by the schema diagram in figure 2.

Table 1 Intervention activities for Control Group and Treatment Groups 1 and 2

No. of weeks from baseline visit	Control Group	Treatment Groups 1 & 2 intervention components	Additional components for Treatment Group 2 (also includes all items in Treatment Group 1)

Baseline	► Home visit.
	► Oral hygiene exam.
	► Complete questionnaires.
	► Educational booklet.
	► Provide sheet to monitor brushing frequency.
		► Home visit.
		► Oral hygiene exam.
		► Complete questionnaires.
		► Educational booklet.
		► Provide sheet to monitor brushing frequency/length.
		► Demonstration of safe use of electronic toothbrush.
			► Educational booklet with explanation and discussion.
			► Individualised instructions on oral hygiene techniques (demonstration/return demonstration).
			► Individualised care plan (eg, type of floss to use, ways to correct poor technique).
			► Plaque disclosing tablets for evaluating brushing technique with instruction and return-demonstration.
			► Coaching module 1, including:
			  – Session begins with care partner only.
			  – Assess challenges and motivation.
			  – Introduce cueing and reminding strategies and practice.
			  – Invite participant to join coaching session and assess challenges/motivation.
			  – Jointly (ie, participant, care partner, hygienist and interventionist) set S.M.A.R.T goals for manageable steps (eg, let toothbrush do the work, incremental goals for flossing and brushing to reach daily and three times a day, respectively).

Week 4	► No visit.	► Home visit to download data from toothbrush and collect sheet to monitor brushing frequency/length.	► By phone, Coaching Module 2 (begin with care partner only).
			  – Review care partner use of cueing and reminding strategies.
			  – Assess challenges and motivation.
			  – Assess progress on goals.
			  – Review and practice cueing strategies.
			  – Introduce FOCUSED communication strategies and practice a few selected by care partner.
			  – Invite participant to join phone-delivered coaching session and review his/her perceptions of progress.
			  – Jointly revise S.M.A.R.T goals to support progression.

Week 8	► No visit.	► Home visit to download data from toothbrush and collect sheet to monitor brushing frequency/length.	► By phone, Coaching Module 3 (begin with care partner only).
			  – Review care partner use of cueing, reminding, and FOCUSED communication strategies.
			  – Assess challenges and motivation.
			  – Assess progress on goals.
			  – Review cueing strategies.
			  – Review and practice FOCUSED communication.
			  – Invite participant to join coaching session and review his/her perceptions of progress.
			  – Jointly revise S.M.A.R.T goals to support progression.

Continued

Table 1 Continued

No. of weeks from baseline visit	Control Group	Treatment Groups 1 & 2 intervention components	Additional components for Treatment Group 2 (also includes all items in Treatment Group 1)
Week 12	▶ Home visit for final oral hygiene exam and questionnaires.	▶ Home visit for final oral hygiene exam, download data from toothbrush and collect sheet to monitor brushing frequency/length, complete questionnaires.	▶ Coaching Module 4 (session begins with care partner only). – Review care partner use of cueing, reminding and FOCUSED communication strategies. – Assess challenges and motivation. – Assess progress on goals. – Review and practice cueing strategies. – Review and practice FOCUSED communication. – Invite participant to join coaching session and review his/her perceptions of progress. – Revise S.M.A.R.T goals to sustain behaviour changes.

Safety and adverse events

All reported adverse events (AEs) will be related to the study procedures or the intervention as assessed by an appropriately trained investigator. The degree of certainty about causality will be graded using the categories 'Related' or 'Not Related'. The principal investigators will be responsible for determining whether an AE is expected or unexpected. An AE will be considered unexpected if the nature, severity or frequency of the event is not consistent with the risk information previously described for the study procedures. This study is considered to be at minimum risk. All AEs and serious AEs (SAEs) that are spontaneously reported to study personnel or elicited by them during subject interviews or contacts will be systematically assessed. The coordinator will maintain a tracking log of all AEs and SAEs. For all reportable AEs and all SAEs, details of the event will be collected and recorded. Information to be collected includes event description, time of onset, assessment of severity, relationship to study procedures (assessed only by those with the training and authority to make a diagnosis) and time of resolution/ stabilisation of the event. All reportable AEs and all SAEs will be followed to adequate resolution. Any medical or psychiatric condition that is present at the time that the participant is screened will be considered as baseline and not reported as an AE. Some participants' health conditions may decline during the study period. If the participant's condition deteriorates significantly during the study, it will be recoded as an AE.

Statistical analysis

A statistical analysis plan (SAP) will be prepared and finalised prior to the data analysis. This document will provide details regarding the definition of analysis variables and analysis methodology to address all study objectives. A data review will assess the accuracy and completeness of the study database and appropriateness of the planned statistical methods. The SAP will not be posted publicly or registered before the study begins.

We will conduct data analysis in the following steps:

1. Descriptive analysis on the sample characteristics, potential mediators and oral hygiene behavioural and clinical outcomes. For the categorical variables, we will present percentages. For continuous variables, we will present means (with range and SD).
2. We will conduct Analysis of Variance (ANOVA) and χ^2 analysis to compare group differences for the variables listed above. This will be based on two-tailed hypothesis testing. We will use p value and 95% CI for the statistical significance test. P value of 0.05 will be considered the level of significance.
3. We will use linear mixed models for repeated continuous outcomes (eg, plaque index, gingival index, oral hygiene skills and duration of toothbrushing from smart toothbrush for Treatment Groups 1 and 2) accounting for within-participant correlation over time.
4. We will use generalised linear mixed models for repeated ordinal variables (eg, self-reported duration of toothbrushing) accounting for within-participant correlation over time.
5. Key covariates will be specified in the SAP.
6. The tests for the underlying assumptions for the models will be specified in the SAP.

Analysis of endpoints
Analysis of primary endpoint

The first step will test whether the intervention is associated with differences across groups in the primary oral hygiene clinical outcomes. We will use linear mixed models for continuous outcomes (eg, plaque index and gingival index) accounting for within-participant correlation over time. In addition to group, all models will be adjusted for site and time point and the interaction between group and time point—to assess whether group difference varied over time—as fixed effects; we will include a random effect for participants to handle within-participant clustering. Significant interaction between group and time point (p<0.05) will provide statistical evidence for the efficacy of the intervention

Table 2 Definitions of behaviour change techniques with examples of how applied in the oral health study (italics in examples highlight behaviours specific to each definition)

| Behaviour change technique	Definition (from verbatim from open source)*	Example
1.1 Goal setting (behaviour)	Set or agree on a goal defined in terms of the behaviour to be achieved.	► Set *SMART behavioural goals specifically for the care partner to learn and practice cueing behaviours;* obtain verbal commitment and provide copy of goals in writing.
2.2 Problem solving	Analyse, prompt the person to analyse, factors influencing the behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators (includes 'Relapse Prevention' and 'Coping Planning').	► Prompt *care partner to engage in problem-solving* by identifying anticipated challenges that the PARTICIPANT will face in doing tailored oral care. ► Review the care partner's SMART behavioural goals and *engage care partner in problem-solving regarding challenges encountered in practicing cueing techniques*, providing feedback and additional instruction as needed.
1.5 Review behaviour goal(s)	Review behaviour goal(s) jointly with the person and consider modifying goal(s) or behaviour change strategy in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of (or in addition to) the first, or no change.	► *Review the care partner's SMART behavioural goals* and engage care partner in problem-solving regarding challenges encountered in practicing cueing techniques, providing feedback and additional instruction as needed. ► Engage the care partner and participant in *assessing successes in meeting oral care goal*.
1.8 Behavioural contract	Create a written specification of the behaviour to be performed, agreed on by the person and witnessed by another.	► *Set* SMART behavioural goals specifically for the care partner to learn and practice cueing behaviours; obtain verbal commitment and *provide copy of goals in writing*.
1.9 Commitment	Ask the person to affirm or reaffirm statements indicating commitment to change the behaviour.	► Set SMART behavioural goals specifically for the care partner to learn and practice cueing behaviours; *obtain verbal commitment* and provide copy of goals in writing.
2.2 Feedback on behaviour	Monitor and provide informative or evaluative feedback on performance of the behaviour (eg, form, frequency, duration, intensity).	► Prompt care partner to assess his/her usual cueing approaches with the PARTICIPANT and engage in problem-solving regarding their usefulness; *provide feedback on behaviour*. ► Review the care partner's SMART behavioural goals and engage care partner in problem-solving regarding challenges encountered in practicing cueing techniques, *providing feedback* and additional instruction as needed.
2.3 Self-monitoring of behaviour	Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy.	► *Provide log for daily tracking* of frequency and length of participant toothbrushing with instruction for completing it.
3.1 Social support (non-specific)	Advise on, arrange or provide social support (eg, from friends, relatives, colleagues, 'buddies' or staff) or *noncontingent praise* or reward for performance of the behaviour. It includes encouragement and counselling, but only when it is directed at the behaviour.	► *Prompt care partner to assess his/her own self-efficacy and motivation* to engage in planned behaviours.
4.1 Instruction on how to perform a behaviour	Advise or agree on how to perform the behaviour (includes 'Skills training').	► *Provide instruction* on cueing and reminding strategies relevant to oral care difficulties. ► Review the care partner's SMART behavioural goals and engage care partner in problem-solving regarding challenges encountered in practicing cueing techniques, providing feedback and *additional instruction as needed*.
6.1 Demonstration of the behaviour	Provide an observable sample of the performance of the behaviour, directly in person or indirectly for example, via film, pictures, for the person to aspire to or imitate (includes 'Modelling').	► Link *communication strategies specifically to oral hygiene care by role-playing identified PARTICIPANT behaviours (described in #1)* while the care partner practices using FOCUSED communication and cueing strategies.
7.1 Prompt/cues	Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance.	► Provide instruction on *cueing and reminding strategies relevant to oral care difficulties*.

Table 2 Continued

Behaviour change technique	Definition (from verbatim from open source)*	Example
8.1 Behavioural practice/ rehearsal	Prompt practice or rehearsal of the performance of the behaviour one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill.	▶ Link communication strategies specifically to oral hygiene care by role-playing identified PARTICIPANT behaviours *while the care partner practices* using FOCUSED communication and cueing strategies.
9.1 Credible source	Present verbal or visual communication from a credible source (eg, health professionals) in favour of or against the behaviour.	▶ Engage care partner and PARTICIPANT (*with hygienist present*) to revise SMART behaviour goals and/or develop new SMART goals for sustaining newly learnt behaviours for tailored oral self-care.

*Retrieved from Michie *et al*.[28]

in improving oral health outcomes in Treatment Group 2 as compared with Treatment Group 1 and the Control Group. The subsequent steps will test the strength of the indirect effect of the intervention on oral hygiene clinical outcomes through mediators such as care partner factors and oral hygiene behaviour outcomes. The following step will test if the indirect effects are stronger than the direct intervention effects in Treatment Group 2 compared with Treatment Group 1 and the Control Group. The final step will test whether the impact of the intervention on oral hygiene clinical outcomes is sequentially mediated first by care partner's factors and then by oral hygiene behavioural outcomes.

Analysis of secondary endpoint

The secondary endpoints are oral hygiene behavioural outcomes. We will test whether the intervention is associated with differences across groups in the oral hygiene behavioural outcomes. We will use linear mixed models for continuous and ordinal outcomes accounting for within-participant correlation over time. In addition to group, all models will be adjusted for site and time point and the interaction between group and time point—to assess whether group difference varied over time—as fixed effects—and include a random effect for participants to handle within-participant clustering. Significant interaction between group and time
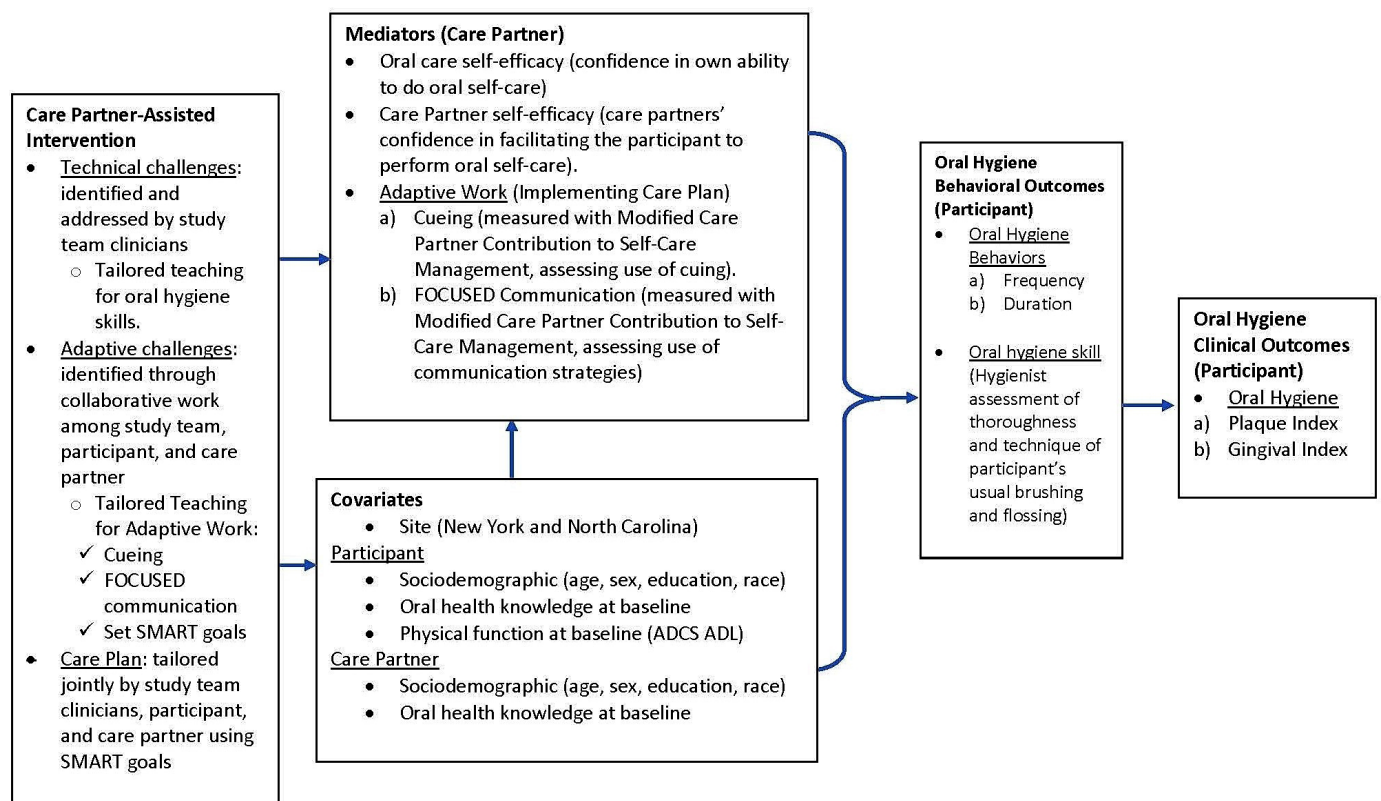
Figure 2 Conceptual framework for Treatment Group 2 (intervention group). ADCS ADL, Alzheimer's Disease Cooperative Studies Activities of Daily Living Instrument.

point (p<0.05) will provide statistical evidence for the efficacy of the intervention in improving oral health outcomes in Treatment Group 2 as compared with Treatment Group 1 and the Control Group. Similar to the approach taken with the primary endpoints, we will then test the strength of the indirect effects of intervention on oral hygiene behavioural outcomes through mediators.

Limitations

A potential limitation of this trial, which applies to most clinical trials, is generalisability. The trial was designed to maximise the chances of the results being as generalisable as possible, but it cannot be declared that our participants are representative of the entire population of the USA because some individuals without access to healthcare may be excluded. Second, our participants do have access to their regular healthcare professionals and dentists where they may receive additional information or guidance on oral hygiene care. Lastly, the dental hygienist cannot be blinded for oral health assessments.

Patient and public involvement

No formal patient advisory committee was set up. Participants and care partners provided input in the design of the intervention protocol. The intervention protocol was further refined after the intervention was pilot tested among participants and care partner. No participants were involved in the design of the study or in the decision of outcome measures. Neither will participants/care partners be involved in the recruitment of participants. We will assess the burden of the interventions on the participants/care partners by collecting information about AEs, satisfaction and time spent on the study. We will gather information about self-reported satisfaction of participants/care partners with the treatment through an interview at the end of intervention.

ETHICS AND DISSEMINATION

The trial will be carried out in accordance with International Council on Harmonisation Good Clinical Practice (ICH GCP) and the following: United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312 and/or 21 CFR Part 812). National Institutes of Health (NIH)-funded investigators and clinical trial site staff who are responsible for the conduct, management or oversight of NIH-funded clinical trials have completed Human Subjects Protection and ICH GCP Training. External monitoring for this study will be performed by the National Institute of Dental and Craniofacial Research (NIDCR) Clinical Research Operations and Management Support contractor. The monitor will evaluate study processes and documentation based on the International Council for Harmonisation (ICH), E6: Good Clinical Practice guidelines (GCP). The plan for external clinical site monitoring will be detailed in a Clinical Monitoring Plan developed by the NIDCR.

This study will be conducted in accordance with the following publication and data sharing policies and regulations: National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH funded research. This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. This trial is registered at ClinicalTrials.gov, and results information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data collected for this study will be analysed and stored at the NYU Data Coordinating Centre. After the study is completed, the de-identified, archived data will be stored in an approved data repository such as the Inter-University Consortium for Political and Social Research and will be available to eligible researchers. We plan to disseminate the study findings to study participants and to multiple local community organisations, including the Alzheimer's Association, the Duke Family Support Programme and the NYU Caregivers Programme.

Current trial status

The anticipated start date for this trial is November 2021 and the last participant is expected to reach the primary endpoint in Spring 2024.

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