Study title: **Functionally-tailored Oral Care Intervention for Community-dwelling Older Adults With Dementia and Their Caregivers**

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I. Purpose

The purpose of this project is to develop and validate an oral care intervention to support community-dwelling older adults with dementia and their family caregivers (FCG).

II. Research Team

Table 1 Providers and roles

III. Project Overview

Persons with dementia (PWD) gradually lose their ability to perform oral self-care, leading to poor oral hygiene. Poor oral hygiene increases the risk of dental caries, periodontal disease and other oral pathologies, and initiates a cascade of oral health decline among PWD, which in turn may accelerate cognitive decline. Importantly, these changes often begin before nursing home (NH) placement. Besides pain and discomfort, poor oral health can lead to agitation and delirium and increase caregiver (CG) stress. It can also affect quality of life, cause malnutrition, increase insulin resistance, and lead to aspiration pneumonia, cardiovascular complications, and other life-threatening conditions in these vulnerable individuals. Early intervention is essential to stop/slow down the oral health decline and its cognitive/systemic impacts in PWD.

Existing oral hygiene interventions have demonstrated efficacy in improving oral health, reducing aspiration pneumonia and even slowing down cognitive decline. However, these programs were designed for NH residents and are not tailored for the great majority of PWD who reside in the community. As such, they fail to account for the reciprocal physical and emotional relationship between the PWD and their family caregivers and its influence on oral care. Furthermore, although oral hygiene education is a standard component of dementia dental care, it is usually not tailored to each patient's level of oral self-care function. In response to these gaps, we propose a study to develop and evaluate a functionally-tailored oral hygiene intervention to improve oral health for community-dwelling PWD while reducing caregiver burdens and improving care partner relationships.

The study consists of two phases corresponding to two aims. For **Aim 1** we will develop a modularized, functionally-tailored oral care intervention based on literature review and CG interview input. We anticipate eight training modules that can be used alone or in varying combinations to provide functionally-appropriate oral care rehabilitation for PWD and need-based skills training to their family CGs. These will be adapted from Mouth Care Without a Battle, a validated oral hygiene intervention developed for NH residents with dementia. **Aim 2** will examine the efficacy and feasibility of the proposed intervention using a randomized controlled design among 40 PWD/CG pairs. After baseline assessment, a 4-week, dyadic, hands-on, functionally-tailored oral care intervention will be delivered to 20 PWD/CG dyads. Control group participants (n=20) will receive the oral hygiene education that is commonly provided to PWD during dental care. Data collection will occur at baseline, 4-weeks and 3 months. Differences between the control and intervention groups with regard to PWD outcomes (e.g., oral hygiene and behavior symptoms during oral care), caregiver outcomes (e.g., burden, self-efficacy) and the care partner relationship will be explored.

This protocol has been developed to guide the study of Aim I and the Aim II study.

IV. Eligibility, Enrollment, and Consent

Sources of Recruitment. Tentatively, the study participants will be recruited from the sites listed below. The site names and IDs are as follows:

Table 2 recruitment sites and ID

Recruitment site	Site ID
Phase I study	10
Dementia registry	20
UI Memory Care Clinic (Dr. Denburg)	30
UI Dental School	40
UI Geriatric Clinic (Dr. Wilbur/Larson)	50
Local Community (mass email)	60
UIHC list (TrinetX)	70
Mercy Caregiver Group	80
Huntington's Clinic	90
Mercy Center for Memory Health	11
Heritage Area Agency on Aging	12

Eligibility and Recruitment. 40 PWD/CG pairs will be recruited for the Aim 2 validation study. The eligibility criteria and recruitment strategies for both studies are the same. Recruitment letter will be mailed to the participants from site 10, 20, 40, 50 and 70. Approximately one week after mailing the letter, a member of the research team will contact the PWD or their legally authorized representatives (LARS). Recruitment material will also be distributed at site 30 and 50. A research team member will contact other participants from site 60 and 80 who expressed their interest to further explain the study and invite them to participate. All of the potential participants (PWD and FCG) will be screened according to the criteria below using *screening forms*.

The *participant screening and recruitment form* must be completed for ALL candidate participants who are approached for participation. All enrollments, refusals, withdrawn and excludes must be carefully documented for each approached PWD/CG and cross-checked among the recruitment sites.

PWD eligible for the study are those who meet the following criteria:

- 50 years of age or older 18 years or older with Huntington's Disease with a diagnosis of neurodegenerative disorder
- ≥1 natural teeth
- Not blind, deaf, or with severe physical disability (e.g., hemiplegia)
- English-speaking
- have a family CG who is age≥18, English-speaking, and willing to participate

PWD with the following condition will be excluded:

- Joint replacement with a history of prosthetic joint infection and/or that requires immediate dental referrals

- Oral health conditions (cancer, acute infection) that require an immediate dental referral
- Actively dying

The first seven conditions are included in the exclusionary criteria because the American Dental Association recommends antibiotic treatment prior to receiving dental care, which is not feasible in this study.

CG eligible for the study are those who meet the following criteria:

- Age≥18
- English-speaking

CG with the following conditions will be excluded:

- Cognitively impaired (based on 6-item cognitive screening tool);
- Blind, deaf, or severely disabled

Once eligibility is identified for both FCG and PWD, the research team member will ask if the dyad are self-responsible for consenting to research. If they are not, the research team member will ask for LAR contact information and proceed to contact the LAR, explain the study, and mail the informed consent to the LAR.

If dyad is self-responsible, prior to informed consent, the research assistant should evaluate the ability to provide informed consent of both PWD and FCG using *The Evaluation to Sign an Informed Consent*. If PWD, are deemed unable to consent, and have no designated LAR or POA , the research assistant should obtain written informed consent from the patient's next of kin in accordance with the UI IRB standard operating procedures for obtaining consent of human subjects with impairment in decision-making, specifically, in the order of spouse, adult child, siblings and relatives. Adequate time should be given for participants to process the information, and the research assistant should encourage participants to ask questions during the informed consent process.

Informed consent will be obtained from cognitively-intact caregivers using the protocol described above. If caregivers have legal guardians or power of attorney (POA), informed consent will be obtained from the responsible party. If the candidate caregivers are unable to consent and has no legal guardian or POA, the dyad will be excluded.

Either the self-responsible PWD, CG or his/her LAR will be asked to provide *written informed consent*

IV. Pilot study design

Pilot study: was conducted December 2020 to March 2021

V. Stratification and Randomization

After informed consent, PWD will be assessed using the Dental Activities Test (DAT). Based on the DAT score, PWD and their FCG will be classified into 4 levels. Each level contains 10 dyads of PWD and FCG. All participants will be assigned to the intervention until we

reach 20 dyads then we will resume a control group. Each group has 5 dyads of PWD and FCG.

Table 3 Group assignment criteria

	Independent (DAT=9, N=10)	Needs Supervision (DAT=6-8, N=10)	Needs Assistance (DAT=3-5, N=10)	Full Care (DAT=0-2, N=10)
Study group	5	5	5	5
Control group	5	5	5	5

VI. Oral Hygiene Intervention

Study group: a functionally-tailored oral care intervention will be provided to the dyads. The goal of the intervention is to improve oral hygiene for PWD while reducing the burden of the caregiver. Different modules will be combined to provide personalized oral care interventions for PWD and their FCGs based on their needs. The following table provides a general guide to develop an oral care intervention based on PWD's oral self-care function. Note that the intervention will need to be individualized based dyad's needs.

Table 4 Functionally Tailored Oral Care Interventions Corresponding to Dental Activities Test (DAT) Scores

	Independent (DAT Score 9)		**Needs Supervision (DAT Score 6-8)**		**Needs Assistance (DAT Score 3-5)**		**Full Care (DAT Score 0-2)**	
	PWD§	**Caregiver**	**PWD**	**Caregiver**	**PWD**	**Caregiver**	**PWD**	**Caregiver**
Goals of intervention	1. Regain/ Maintain function 2. Improve quality of self-care	1. Ensure quality of care	1. Maintain function 2. Improve quality of self-care	1. Ensure oral care quality 2. Provide assistance to facilitate oral self-care	1. Maintain function	1. Provide assistance to facilitate oral care 2. Provide oral care as needed 3. Ensure quality of care 4. Manage behavior symptoms	**N/A**	1. Provide oral care 2. Ensure quality of care 3. Manage disruptive behaviors 4. Identify PWD in pain or infection
Common intervention	1. Adapt environment for good care (module 7, as needed); 2. Oral hygiene products for special needs (module 8, as needed)							
Personalized Modules**	1, 2	1, 3	2	1, 3, 4	2	1 - 5	**N/A**	1 - 6

* ACLs-Allen Cognitive Levels; § PWD-Persons with dementia; ** Module 1-Oral disease and impacts; 2-Oral care techniques; 3-Quality improvement; 4-Cuing strategies; 5-working with behavior symptoms; 6-Recognizing oral pain/infection.

The intervention will consist of 4 sessions. The OCC will first assess dyad's oral care needs in the first visit and then develop the intervention protocol with Dr. Chen based on the guidance listed in table 3. The goals and intervention tasks of each visit are summarized in the following table.

Table 4. Tentative Intervention Sessions and Contents for the Control Group

Visit	Goal	Intervention
1	•Program overview •Dyad education •Goal identification •Need assessment	• Reviews intervention program • Deliver Module 1.1 and 3.1 to the dyad • Through dyad's demonstration, OCC assesses dyad's oral care skills (e.g., tooth brushing with disclosing solution and denture care, if applicable), preferences (e.g., floss vs. interdental brush), related challenges, and needs for adaptive oral hygiene products (specially-designed toothbrush, mouth prop) • Assesses need for environmental changes (e.g., lighting, contrast, set-up of oral care products) • Complete the rest of the items in the First visit assessment form
OCC develops functionally-tailored intervention plan to enhance what is currently working and compensate what needs to improve		
2	•Tooth brushing •Denture care (if applicable)	• Reviews intervention plan and materials • Works with dyads to develop mutually agreed upon oral care plan (e.g., when and how often to perform oral care, use of oral care products) Module 2.0 • Works with dyad to eliminate environmental obstacles Module 4.1 and other Modules and Scenarios as identified. • Reviews personalized oral hygiene products (e.g., special toothbrush, toothpaste, or mouth prop) with dyad. • Following the previously designed intervention plan, delivers hands-on, basic oral care (tooth brushing, denture care) and related skills training (e.g., cueing, quality improvement, behavior management as needed) via the trial & error strategy (tailor to dyad's needs and repeat until dyad demonstrates and fully learns the skills) • Delivers daily oral hygiene logs and instructions.
3	•Interdental brushing •Dry mouth care	• Review, discuss, and reinforce the basic skill set learned at the last visit. • Review and reinforcement daily oral hygiene log • Review oral care products required for interdental brushing, and dry mouth care. • Delivers training on cleaning between teeth, and dry mouth management. • Provide hand-on practice and real time feedback until dyads fully learn the skills.
4	•Advanced skills reinforcement •Program review, and wrap-up	• Reviews dyad's progress to date. • OCC assesses and gives feedback of a dyad's final demonstration of oral care skills with disclosing solution. • Review, discuss, and reinforce basic and advanced skill sets and tailor skills as needed. Discuss Modules that have not been reviewed, if necessary. • Trainer and dyad work together to develop maintenance plan (with the minimum goal of once-a-day oral care)

		• Distributes the educational packet and resources for future use.

Control group:

- Control group will have 3 visits: Initial visit, 4th week and F/U at 3 months. Control dyads will receive a 15-minute, home-based, untailored oral care training, using only Module 1 and Control Group OHI Module 2.7, in the first visit. After a demonstration, the OCC should allow participating dyads time to practice the oral care skills and provide real time feedback for the participants. After the demonstration, the1 Care recipient Feasibility Evaluation Questionnaire (if applicable) and the Caregiver Feasibility Evaluation questionnaire should be completed.

VII. Data Collection

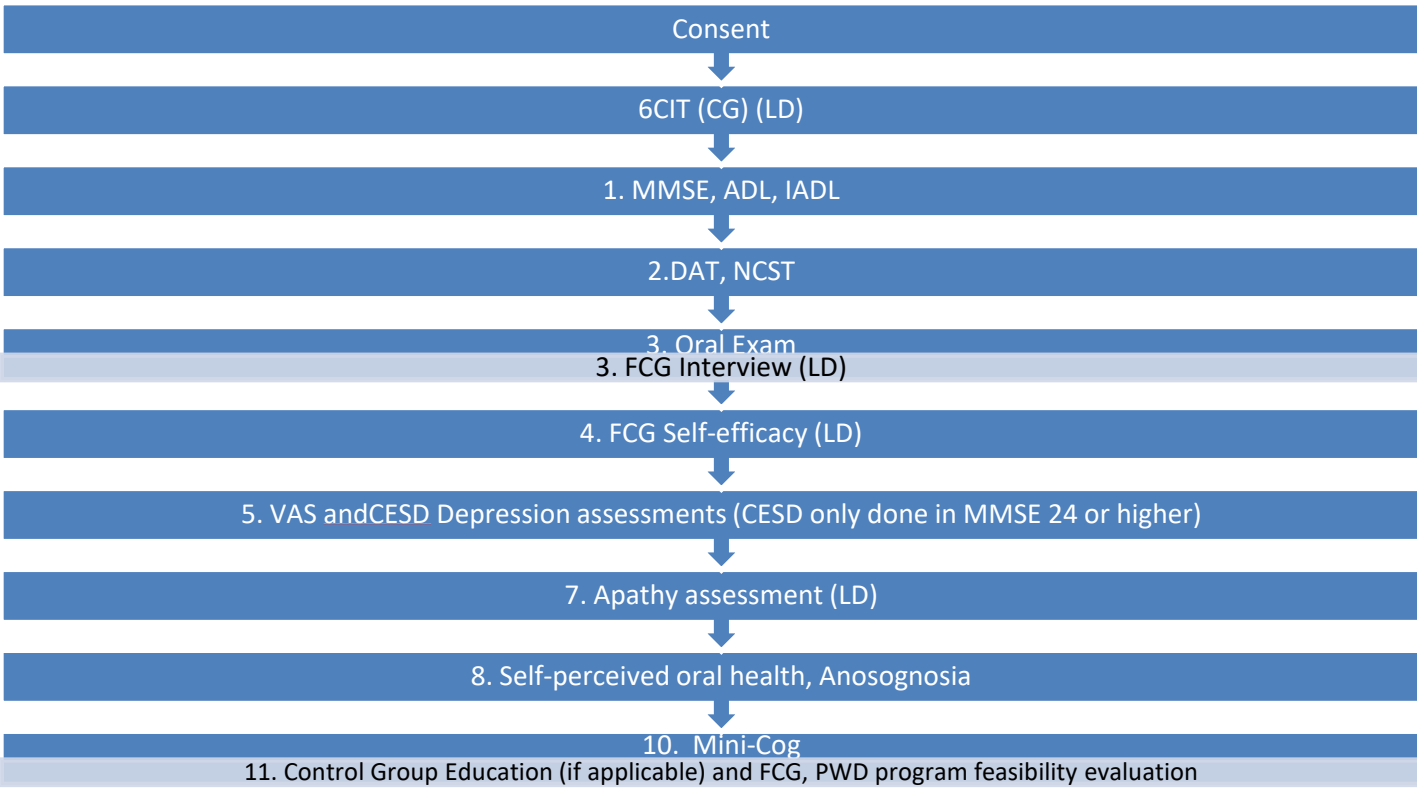
Validation study.

The oral care coach (OCC) and research assistant (RA) will visit participants. The following data (Table 5.) needs to be collected during the validation study. Some of the data will be collected multiple times. Specifically, to avoid overburden to the study participants, the study coordinator should arrange an appointment before the intervention to collect all the baseline data. All the interviews and assessments should be given in a relaxed, comfortable environment and format. Breaks should be given if participants become tired, anxious or frustrated.

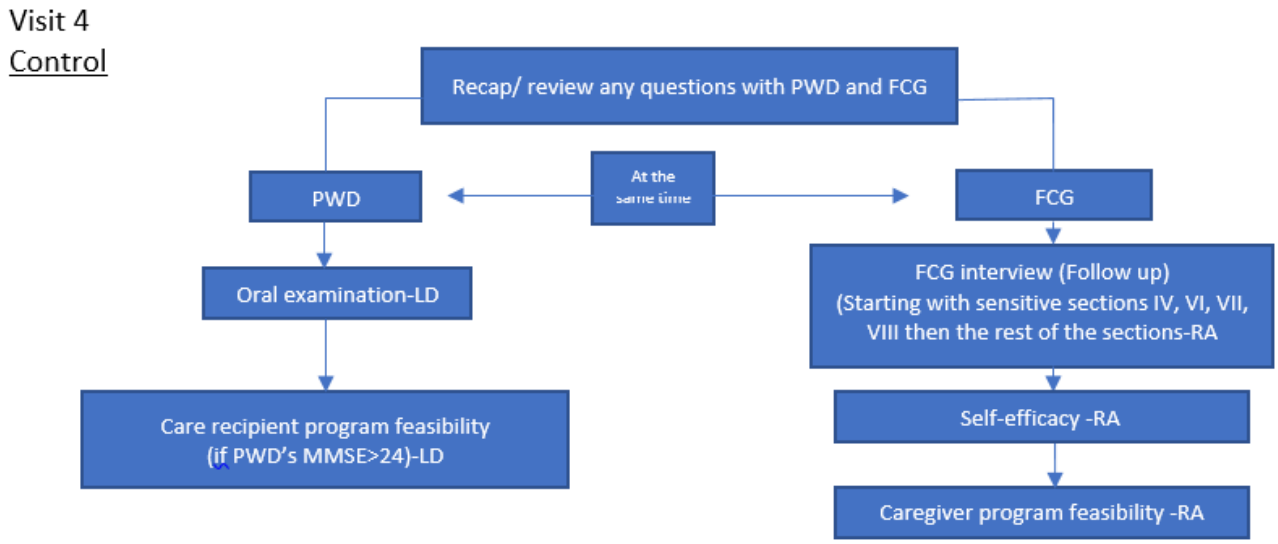
If a subject is identified as in need of immediate dental attention in the oral exam or during the intervention, the research assistant or OCC will document and communicate this need to the study coordinator. In accordance with approved IRB procedures and the data safety monitoring plan, the study coordinator will then send the consenting party a standardized notice recommending a follow-up examination. If needed, the identified issue will be reported to the IRB and the data safety monitoring committee.

The assessments should be given in the following order:

Visit 0

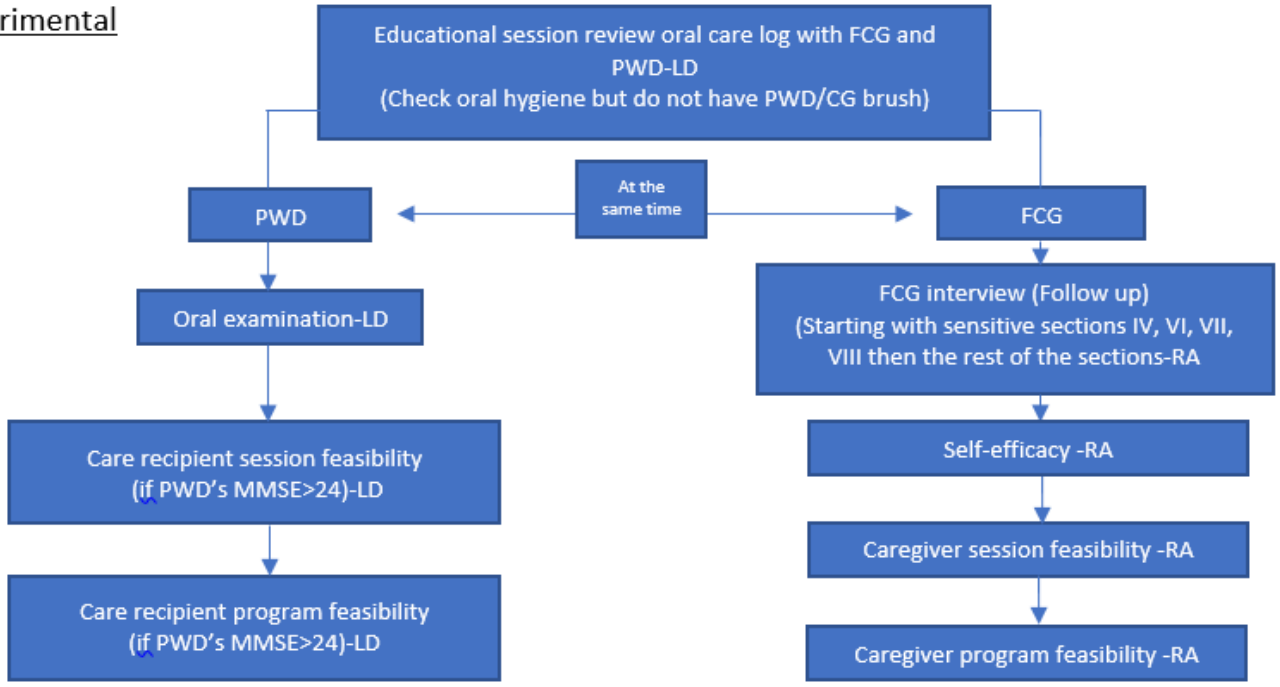


Visit 4



Visit 4

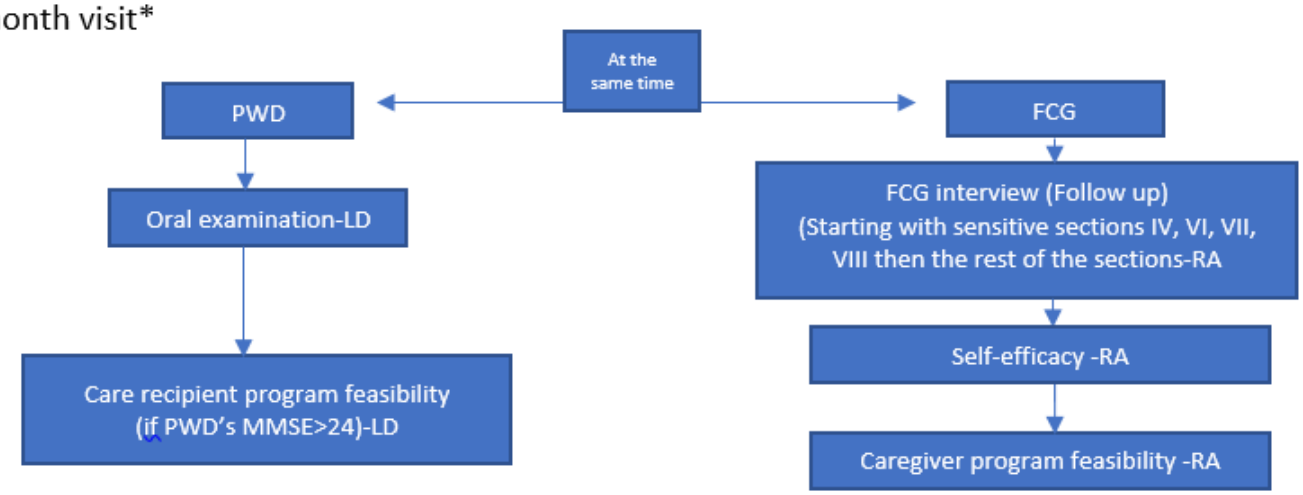
Experimental



Visit 3-month

Dyad dy

3-month visit*



*if experimental group, collect and review oral care log before starting

Table 5. Data to be collected in the validation study

Data	Measure/Tool	Subject	Time	Examiner
Oral self-care function	Dental Activities Test (DAT)	PWD	Baseline	RA
Cognition	• MMSE • New cognitive screening tool (NCST) • Mini-Cog	PWD	Baseline	RA
Daily function	ADL and IADL	FCG	Baseline	RA
Depression	• Visual analogue scale • CESD depression scale	PWD	Baseline	RA
Apathy	Dementia Apathy Interview and Rating	FCG	Baseline	RA
Anosognosia	• Anosognosia • Self-perceived oral health	PWD/FCG	Baseline	RA
Oral hygiene	• Plaque index • Gingival index	PWD	• Baseline • 4-week follow-up • 3-month follow-up	Dentist
• Sociodemographics • Medical history & medication • Dental care pattern	Caregiver Interview	FCG	Baseline	RA OCC
• Oral hygiene practice • Perceived oral hygiene and oral health • Behavior symptoms during oral care • Mouth Care Related Caregiver Burden • Dyadic relationship	Caregiver Interview	FCG	• Baseline • 4-week follow-up • 3-month follow-up	LD &RA
CG efficacy in providing oral care	Caregiver Self-efficacy Scale	FCG	• Baseline • 4-week follow-up • 3-month follow-up	RA
First visit assessment	First visit assessment form	PWD/FCG	1st visit	LD
Feasibility assessment (session)	• Care recipient Feasibility Evaluation Questionnaire • Caregiver Feasibility Evaluation Questionnaire	PWD/FCG	• Every session	LDRA
Trainer assessment	• Trainer evaluation questionnaire	Trainer	Every session	LD
Daily oral care practice	• Daily oral care log	PWD/FCG	• Every session • 3-month follow-up	LD

Feasibility assessment (program)	• Care recipient Program Feasibility Evaluation Questionnaire • Caregiver Feasibility Program Evaluation Questionnaire	PWD/FCG	• 4-week follow-up	RA
Implementation assessment	• Training log & trainer interview	Trainer	Every session	XC