Oral Health Education Interventions and Its Association with Behavioral Outcomes: A Clinical Trial

Date August 16 2017 (Approved by IRB)

1) Abstract of the study

Introduction: Older adults have been described as one of the most underserved and vulnerable groups, who are at the highest risk for coronal and root caries, especially because more elderly adults are retaining their teeth. The Northeast Philadelphia KleinLife site is an important destination for the region's Jewish population comprising of at least 6500 seniors, and assisting more than 4500 seniors through food security programs. Recently, Temple University Kornberg School of Dentistry (TUKSoD) purchased the dental center at the facility to expand the services provided to these underserved population and improve their oral health. The study aims to assess the efficacy of an oral health education group based activity versus an individual based oral health education activity in terms of changes in oral health related quality of life (OHRQoL), self-efficacy and oral health knowledge. **Methods:** A sample of 190 senior members will be invited to participate in the trial. Potential subjects will be obtained in person through the ongoing flow of patients at TUKSoD Clinic at Kleinlife and the dental school. Seniors who consent to participate in the study will be randomly allocated to one of the 3 groups (Control: subjects will continue receiving regular dental care at the clinic, Intervention 1: subjects will continue receiving regular dental care at the clinic and be invited to participate in 2 group based education sessions during a 12 month period, and Intervention 2: subjects will continue receiving regular dental care at the clinic and be invited to participate in an individual-based education and prevention activity over a 18 month period. Randomization will be determined according to a predetermined random sequence, and neither the patient nor the research staff will be aware of the randomization outcome until after the patient has agreed to participate. Subjects who consent to participate will be entered into a raffle to receive a $350-dollar visa gift card, if they complete the baseline and follow up assessments. The OHIP-14 will be used to assess OHRQoL, and self-efficacy scores will be the primary outcomes. Initially, we will assess the differences between the interventions and control using 2-sample *t*-tests. The main analysis will be based on linear mixed-effects models for repeated measures (using the OHIP 14 and self-efficacy scores as continuous outcome variables) to assess differences between intervention and control groups. Similar analyses will be conducted for secondary outcome measures Statistical significance will be set at $p < .05$.

2) Protocol Title

Oral Health Education Interventions and Its Association with Behavioral Outcomes: A Clinical Trial

3) Investigators

- Marisol Tellez, BDS, MPH, PhD, Associate Professor, Department of Pediatric Dentistry and Community Oral Health Sciences, Maurice H. Kornberg School of Dentistry

- Vinodh Bhoopathi, BDS,MPH, DScD, Assistant Professor, Department of Pediatric Dentistry and Community Oral Health Sciences, Maurice H. Kornberg School of Dentistry

- Sheryl Neckritz, Public Health Dental Hygienist, Department of Pediatric Dentistry and Community Oral Health Sciences, Maurice H. Kornberg School of Dentistry

4) Objectives

- **Primary Objective:**

The objective of this study is to test the efficacy of an oral health education group based activity versus an individual oral health education activity in terms of changes in oral health related quality of life (OHRQoL), self-efficacy and oral health knowledge.

- **Secondary Objective**

  The secondary objective of this study is:

a) To assess differences among intervention and control groups by senior's oral health knowledge.

- **Overall Hypotheses**

Ho: There are no significant differences in the selected behavioral outcome measures between the interventions, either group-based or individual based education and the control.

Ho: The two educational interventions are not equivalent in the selected behavioral outcome measures.

5) Rationale and Significance

Older adults or the elderly have been described as one of the most underserved and vulnerable groups. Many studies have shown that elderly adult population groups are at a higher risk for coronal and root caries, especially because more elderly adults are retaining their teeth. KleinLife is an important destination for the region's Jewish population. KleinLife comprises of at least 6500 seniors, and has assisted more than 4500 seniors through food security programs. The Northeast Philadelphia KleinLife site also has a dental center that provides routine care to the members who seek care. The Temple University Kornberg School of Dentistry (TUKSoD) recently purchased this dental center to expand the services provided to these underserved population and improve their oral health.

KleinLife is a vibrant community resource that provides social, educational and cultural programs, and vital health, wellness and social services to the multigenerational, ethnically diverse membership it serves. Individuals regularly come together to participate in enrichment offerings, receive vital services, enjoy each other's company, and connect to additional resources and support. KleinLife is an important destination for the region's Jewish population, both young and old. It serves as a lively home-away-from-home for seniors and a welcoming gathering place for Russian Jews. More than 7800 health care referrals to seniors and their families have been made through KleinLife.

TUKSoD and KleinLife's staff conducted a survey in December 2015 to develop a baseline needs assessment that would inform the development and implementation of a tailored oral health care model in this community. Two hundred oral health surveys were completed and from this initial survey, we learned that there were variations in knowledge, attitudes and practices related to oral hygiene among seniors and lack of understanding of key fundamental concepts in oral health education and oral health related quality of life.

Recent studies on this area have mainly focused on the effects of oral health educational interventions for caregivers at improving dental health among seniors but very few interventions report on the oral health-related knowledge and other important behavioral outcomes of seniors themselves. MacEntee et al in 2007 reported no significant changes to oral health of seniors with a pyramid-based educational intervention, however, in 2012, De Visschere et al reported a small, but statistically significant improvement in denture plaque following a 6-month supervised educational intervention.

A recent systematic review (Kay et al, 2016) showed that the motivational interviewing technique, which is based on the concept of autonomy support, has potential for helping patients with poor oral health. However, most of the studies appraised involved children and young adults or seniors with periodontal conditions and the outcomes examined were exclusively clinical. Relying on clinical indicators becomes problematic when evaluating the efficacy of educational interventions among adults as often times these populations are edentulous or partially dentulous and do not reveal the impact on additional behavioral and cognitive outcomes which in turn may affect the overall well-being of the individual. Moreover, although low parental self-efficacy has been associated with adverse dental outcomes among children, there has been little documented evidence of the role of self-efficacy in adult oral health outcomes. Even less has been reported on groups known to be at high risk of dental disease such as the elderly. There is a lack of information on how different types of oral health education activities may affect seniors oral health related quality of life and self-efficacy. These studies present a case for additional research on senior's self-efficacy, and oral health care knowledge, along with training interventions aimed at improving the poor oral health of the elderly.

The objective of this study is to test the efficacy of an oral health education group based activity versus an individual based oral health education activity in terms of changes in oral health related quality of life (OHRQoL), and self-efficacy among seniors at Kleinlife and at the Dental School.

6) Resources and Setting

All patients will be identified and evaluated at the dental clinic of the Temple University Kornberg School of Dentistry (TUKSoD) located in Kleinlife and at the Dental School. All participants will be provided with consent forms. All research staff has CITI training and will be required to read all the documentation related to the study and discuss any questions with the investigators before initiation of activities.

6) Prior Approvals

Not Applicable

7) Study Design

a) Recruitment Methods

Approximately 190 subjects, older than 55 years old will be recruited for the purpose of the study. There are no restrictions in terms of relative numbers of females and males. Potential subjects will be obtained in person through the ongoing flow of patients at TUKSoD Clinic at Kleinlife and at the Dental School. The research staff will also be available during regular operating hours to inform and recruit patients at the lobby at Kleinlife and at the Dental School. The consent form (See Appendix A) to participate in the study will be provided to the senior and if they decide to participate they will be entered into a raffle to receive a $350-dollar visa gift card, if they complete the baseline and follow up assessments. The information from the consent forms will only be used for the purpose of the raffle. This is required for compliance with Pennsylvania state laws. Information about the study will also be posted in a flyer (See Appendix B) in designated areas at Kleinlife and at the Dental School.

b) Inclusion and Exclusion Criteria

There are no restrictions on enrollment in terms of gender, economic status, race or ethnic group.

Inclusion criteria

Patients:

1) Must be 55 years old or older.
2) May be new, regular, emergency patients attending the TUKSoD clinic at Kleinlife or clinics at the Dental School or utilizing medical and social services at Kleinlife who have the intention to become patients of record at the dental clinic.

3) Must be able to speak and understand English.
4) Must be willing to provide consent to participate in the study for himself/herself.

Exclusion criteria:

Patients:

1) Subjects younger than 55 years old will be excluded from the study.
2) Subjects who do not provide consent for participation will be excluded from the study.
3) Subjects who do not speak and understand English.

c) Study Timelines

Table 1: Research Timelines

Approximate Months/ Year	Goals
March 2017	IRB submission
Summer-Fall 2017	Recruitment, implementation of educational interventions and baseline data collection
Spring Summer 2018	Follow up data collection
Fall 2018	Finalize manuscript for publication

d) Study Procedures and Data Analysis

Sample and Setting. All research procedures will be performed in the TUKSoD Clinic at Kleinlife and at the Dental School. Participation in the research is expected to take 1 hour regardless of study group. Seniors meeting the inclusion criteria will constitute the sample for the purpose of this study.

Sample Selection Procedures

All assessments will be conducted after informed consent has been obtained in person. Patients deemed ineligible or who do not wish to participate in the research will be referred for clinical services as appropriate. The decision to participate or not to participate in the research will have no effect on the dental treatment that the patient will receive. A sample of 190 seniors will be recruited from the TUKSoD Clinic at Kleinlife and at the Dental School for the purpose of this study.

Study Procedure

This will be a multi-center parallel group study with randomization to one of three arms as described below. The objective of this study is to test the efficacy of an oral health education group based activity versus an individual based oral health education activity in terms of changes in oral health related quality of life

(OHRQoL), and self-efficacy among seniors at Kleinlife and at the Dental School. A description of the activities to be conducted in the intervention and control groups is described below:

Seniors who consent to participate in the study will be randomly allocated to one of the 3 following groups. Randomization will be determined according to a predetermined random sequence, and neither the patient nor the research staff will be aware of the randomization outcome until after the patient has agreed to participation.

Control Group: (60 seniors).
Seniors who are randomly assigned to the control group will continue receiving regular dental care under the standard clinic operation. Subjects in this group will complete intake forms to assess main behavioral outcomes, at baseline and after 12 months. No other activities will be conducted in this group.

Intervention Group 1: (60 seniors).
Seniors who are randomly assigned to the intervention group 1 will continue receiving regular dental care under the standard clinic operation and will be invited to participate in 2 group based education activities over a 12 month period. The sessions will last for 1 hour each time and follow the guidelines established by the Oral Health America Curriculum. Baseline intake forms to assess changes in main behavioral outcomes will be administered before the first education session, after 6 months and after 12 months.

Intervention Group 2: (70 seniors (10 of these are calibration patients exclusively)).
Seniors who are randomly assigned to the intervention group 2 will continue receiving regular dental care under the standard clinic operation and will also be invited to participate in an individual-based education activity over a 12 month period. The clinic visits will last for 1 hour each time and follow the guidelines established by TUKSoD to provide oral hygiene instruction using a Motivational Interviewing approach. Tailored education will be based on review of health related information to be extracted from medical (systemic diseases), dental chart (oral hygiene behaviors) and patient interview at time of initial examination. Seniors in this group will also receive basic preventative care (dental cleanings, fluoride varnish application (high caries risk individuals only) or referral to a supervised brushing program with high concentration fluoride under the care of the dentist at Kleinlife if needed. All individual based preventative activities will be provided by a Public Health Hygienist, and 3 dental visits will be conducted for subjects in this group during the course of a 18 month period. Baseline intake forms to assess changes in main behavioral outcomes will be administered before the first home based education session, at each follow up visit and after 18 months.

Measurements:
The following instruments (Appendix C) will serve as outcome measures for this

study:

- Oral Health Related Quality of Life: The Short-Form Oral Health Impact Profile (OHIP-14; Slade, 1997) is a 14-item self-report measure that assesses individuals' perceptions of the social impact of oral conditions on their well-being. This scale evaluates the consequences of oral conditions across dimensions of functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. Items are rated on a 5-point Likert-type scale ranging from 0 (*never*) to 4 (*very often*), regarding how frequently impact has been experienced. The total score ranges from 0 to 56; higher OHIP-14 scores indicate greater impact, hence poorer oral-health-related quality of life. The OHIP-14 has been validated in two national surveys of populations in the UK and Australia (Kelly et al., 1998; Steele et al., 2004) and demonstrated good reliability, construct and discriminant validity, and internal consistency (Slade & Spencer, 1994; Slade, 1997).

- Self-efficacy will be assessed based on a modified version of an instrument developed by Finlayson and colleagues (Finlayson et al, 2007). It will be measured using a 6-item scale, asking participants to indicate how confident they feel about their ability to brush their teeth at night when they were: (1) under a lot of stress; (2) depressed; (3) anxious; (4) feeling that they were too busy; (5) tired or; (6) worried about other things in their life. The four response options range from 'very confident' to 'not at all confident'. The possible score range is 0 to 24, with high scores indicating high self-efficacy. Alpha was 0.91. Self-efficacy will be dichotomized based on a median split, with low self-efficacy pertaining to scores of 0 to 11 and high self-efficacy pertaining to scores of 12+.

- Oral Health Knowledge: A 15-item questionnaire with a three-point Likert Scale (yes, no, and don't know) will be used to assess the oral health information/knowledge of the seniors pre and post intervention. Its respective psychometric properties (validity and reliability) have already been reported (Khanagar et al, 2014).

- Demographic Factors Questionnaire will identify key demographic factors such as age, sex, race, ethnicity, education and income level of seniors.

Calibration:

For purposes of calibration and assuring treatment fidelity of the dental public health hygienist when delivering the MI oral health session (Intervention 2), 10 patients will be recruited and consented to receive this intervention only. The sessions with these patients will be audio recorded so that research staff can check treatment fidelity and provide feedback to the hygienist as appropriate before data collection starts. These 10 patients will not be part of the research study and will be offered a $30 dollar visa gift card for

completing baseline and follow up assessments during the calibration exercise that may require an estimated 3 hours during a 1 month period. These follow up sessions will be scheduled based on the patients and the hygienist's availability. The calibration group will also sign a HIPAA Authorization form. Please see Appendix D.

Data Management:

All demographic information and questionnaires will be administered in person. Data will be entered into an excel spreadsheet. Data will be downloaded to an IBM-compatible computer and stored on a password-protected account, and it will be exported to a computer data analysis program (SAS/SPSS). Data will be cleaned and checked for errors prior to the analysis; imputation procedures for handling missing data will be conducted depending on the number of cases with missing data. Participant names and corresponding identification numbers will be stored separately in a locked file cabinet or password-protected file.

Data Analysis:

Initial analyses will be conducted to determine normality of distributions of the continuous variables, and any necessary transformations will be conducted. Primary outcomes will be the OHIP 14 and the self-efficacy scores. All eligible patients will be randomly assigned to 1 of the 3 groups described above. Although randomization should provide relatively comparable groups, demographic variables that differ between groups and are correlated with the primary outcomes will be used as covariates. Preliminary analysis will include measures of central tendency and dispersion, as well as an examination of the bivariate relationships among the primary and secondary outcome variables, potential moderators, and demographic characteristics.

Differences between the groups on baseline demographic, and psychological measures will be examined using χ^2 (Pearson) or Student's *t*-tests, as appropriate. Moreover, differences on the variables listed above among completers and drop-outs will also be explored. Intention to treat (ITT) analyses will then be conducted.

OHIP 14 and self-efficacy scores will be the primary outcomes. Initially, we will assess the differences between the interventions and control using 2-sample *t*-tests. The main analysis will be based on linear mixed-effects models for repeated measures (using the OHIP 14 and self-efficacy scores as continuous outcome variables) to assess differences between intervention and control groups. Similar analyses will be conducted for secondary outcome measures Statistical significance will be set at $p < .05$.

e) Withdrawal of Subjects

Subjects may be withdrawn from the study because of failure to follow instructions of the research staff or if the principal investigator decides that the research study is no longer in the subject's best interest. Details are provided in the consent form.

f) Privacy & Confidentiality

As in any type of treatment or clinical research program, patients' confidentiality must be carefully guarded and respected. The study will use Protected Health Information (PHI) and a HIPAA Authorization form is being submitted with this application (see Appendix D).
There will be a separate file with identifiers in receipt of the principal investigator. All data with identifying information will be stored in locked files or encrypted, password-protected electronic data storage. Data being analyzed will be identified by subject codes (using the subject identification number) and identifying information will be removed. The identity of patients will not be revealed in the presentation or publication of any results from this project. All assistants and others working on the project will be educated about the importance of strictly respecting patients' rights to privacy and confidentiality and will have completed training concerning proper practice in accordance with HIPAA regulations.
Protected Health Information that will be collected includes the patient's name, date they were seen for the study, phone number, and age. In addition, dental record number, medical and dental chart information related to oral hygiene behaviors and systemic diseases will be accessed from the dental chart for those assigned to intervention group 2. Only those subjects assigned to intervention group 2 will be given the HIPAA Authorization form to sign. The electronic PHI data will be downloaded to a computer using encrypted, password- protected storage of electronic data. All participants will receive a unique random identification number, which will correspond to that person's data. Participant names and corresponding identification numbers will be stored separately in a locked file cabinet or encrypted, password-protected storage of electronic data.

8) Risks to Subjects

No risks are expected to the subjects. All clinical activities are part of regular dental treatment provided to patients in the normal course of dental treatment.

9) Potential Benefits to Subjects

Patients will be educated about oral health risky behaviors and oral hygiene techniques in this study. There are no other direct benefits to the subject from this study.

10) Costs to Subjects

Not Applicable

11) Informed Consent

See Consent Form (Appendix A and D) submitted with this protocol. Study will follow "HRP-802 INVESTIGATOR GUIDANCE: Informed Consent" to obtain informed consent.
Seniors who provide consent and complete entire participation in the study will be entered into a raffle to receive a $350-dollar gift card. This information has been included into the consent form.

12) Vulnerable Populations

The study involves does not involve a vulnerable population as defined by IRB regulations.

13) Compensation for Research-Related Injury

Not applicable

14) Economic Burden to Subjects

Not applicable

15) Drugs or Devices

Not applicable.

16) Multi-Site Human Research

Not applicable

17) Sharing of Results with Subjects

Results of the study can be provided to the participants, if requested. No other data will be shared with the subjects.

References

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Appendix (B)
Flyer

Interested in joining a research study?

If so, you may be eligible to participate in a research study investigating the efficacy of various oral health education strategies
For your participation, you will be entered in a contest to win a $350 gift card.
Seniors 55 years old and older may be eligible for participation

For more information, contact:
Marisol Tellez M PhD. - Principal Investigator
Maurice H. Kornberg School of Dentistry Temple University.
3223 N. Broad Street, Philadelphia, PA 19140
215.707.1773

Appendix C Measurement Instruments

(Demographics)

A1. What is the 5-digit ZIP code at your home address?
[__ ___ ___ ___ ___]

A2. What is your gender? [___]
1) __Male
2) __Female

A3. What is your age in years?
[_____]

A5. What is the highest grade of school that you completed?
[___]
1) __ less than high school (grades 0-8)

2) __ Some high school (grades 9-11)

3) __ High school graduate (grades 12 or GED)

4) __ Some college (include vocational, trade, or technical school after college, associate degree, No four-year degree)

5) __ College graduate (BS or other four year degree)

6) __ Post graduate or professional school after college

A6. What is your family's income level? [___]

1) __ Less than $19,999

2) __ $20,000 - $49,999

3) __ More than $50,000

A9. What race do you consider yourself to be? *(Place a check next to the correct answer)* [____]

1) __ White or Caucasian or European American

2) __ Black or African American

3) __ American Indian or Alaska Native

4) __ Asian

5) __ Native Hawaiian or Other Pacific Islander

6) __ Other (_____)

A10. Are you of Hispanic or Latino origin or descent? [____]

1) ___Yes

2) ___ No

Oral Health Self Efficacy Scale

Seniors oral health self-efficacy measure:

Oral Health Self-efficacy (OHSE) - Scale: 4=very confident, 1=not at all confident.

1. under a lot of stress
2. depressed
3. anxious
4. feeling like you do not have the time (too busy)
5. tired
6. worrying about other things in your life
7. bothered by your crying child
8. bothered because your child doesn't stay still when you want him or her to brush

9. told by your child that he/she does not feel like brushing right now

ORAL HEALTH IMPACT PROFILE SHORT VERSION OHIP-14*

Question

1. Have you had trouble *pronouncing any words* because of problems with limitation your teeth, mouth or dentures?

   0 1 2 3 4
   Never Hardly Ever Occasionally Fairly Often Very Often

2. Have you felt that your *seti.se of taste* has worsened because of problems with your teeth, mouth or dentures?

   0 1 2 3 4
   Never Hardly Ever Occasionally Fairly Often Very Often

3. Have you had *painful aching* in your mouth?

0 1 2 3 4
Never Hardly Ever Occasionally Fairly Often Very Often

4. Have you found it *uncomfortable to eat any foods* because of problems with your teeth, mouth or dentures?
   0 1 2 3 4
   Never Hardly Ever Occasionally Fairly Often Very Often

5. Have you been *self-conscious* because of your teeth, mouth or dentures?
   0 1 2 3 4
   Never Hardly Ever Occasionally Fairly Often Very Often

6. Have you *felt tense* because of problems with your teeth, mouth or dentures?
   0 1 2 3 4
   Never Hardly Ever Occasionally Fairly Often Very Often

7. Has your *diet been unsatisfactory* because of problems with your teeth, disability mouth or dentures?
   0 1 2 3 4
   Never Hardly Ever Occasionally Fairly Often Very Often

8. Have you had to *interrupt meals* because of problems with your teeth, mouth or dentures?
   0 1 2 3 4
   Never Hardly Ever Occasionally Fairly Often Very Often

9. Have you found it *difficult to relax* because of problems with your teeth, disability mouth or dentures?
   0 1 2 3 4
   Never Hardly Ever Occasionally Fairly Often Very Often

10. Have you been a bit *embarrassed because* of problems with your teeth, mouth or dentures?
    0 1 2 3 4
    Never Hardly Ever Occasionally Fairly Often Very Often

11. Have you been a bit *irritable with other people* because of problems with disability your teeth, mouth or dentures?
    0 1 2 3 4
    Never Hardly Ever Occasionally Fairly Often Very Often

12. Have you had *difficulty doing your usual jobs* because of problems with your teeth, mouth or dentures?

0	1	2	3	4
Never	Hardly Ever	Occasionally	Fairly Often	Very Often

13. Have you felt that life in general was *less satisfying* because of problems with your teeth, mouth or dentures?

0	1	2	3	4
Never	Hardly Ever	Occasionally	Fairly Often	Very Often

14. Have you been *totally unable to function* because of problems with your teeth, mouth or dentures?

0	1	2	3	4
Never	Hardly Ever	Occasionally	Fairly Often	Very Often

Seniors Oral Health Knowledge Assessment

Statements to be evaluated with a three-point Likert Scale (yes, no, and don't know)

1. "Health of mouth is directly related to body"
2. "You can chew just as well with denture tooth as with your natural teeth"
3. "When gums bleed during brushing, it is best to leave them alone"
4. "Older adults with dry mouth get more cavities"
5. "The most common cause of dry mouth is medication"
6. "Older adults with teeth need to use fluorides"
7. "Mouth rinsing is a good alternative to daily tooth brushing"
8. "People with no teeth need to be seen by a dentist"
9. "Dentures should be removed for few hours every day"
10. "Dentures those don't fit well can cause oral cancer"
11. "It is normal for residents to have pain and sores in their mouth"
12. "Residents who do not cooperate for daily mouth care are best left alone"

13. “Dental check-ups are as important as medical”
14. “Residents can lose their teeth if they remain dirty”
15. “As people get old they naturally lose their teeth”