

Oral health care intervention for elderly patients with dementia

Submission date 08/06/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/07/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/11/2022	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Oral care training for the elderly can help to reduce the rapid deterioration of oral diseases and the incidence of aspiration pneumonia, and further improve their health and quality of life. There is also an association between poor oral health status and cognitive impairment. This study aims to develop and apply a new method of basic oral hygiene care for the elderly with dementia, and evaluate the effectiveness of the intervention.

Who can participate?

Elderly with mild dementia who have at least four pairs of functional teeth

What does the study involve?

Participants will be randomly assigned to the experimental group or the control group. A one-on-one oral health education teaching activity will be conducted with experimental group members and their primary caregivers by a well-trained dental hygienist, including oral hygiene skill, chewing and swallowing practices, safe eating methods, dietary options, methods to reduce the risk of coughing, and oral function rehabilitation training. The participants will be encouraged to do it themselves at home at least once a day. Researchers will call experimental group participants twice a month by phone to check if they have problems with daily oral care. For those participants in the control group, participants are given a leaflet to read which includes general information about oral health. Before and after 3 and 6 months a questionnaire will be used to collect data on oral health care behaviours, oral hygiene, oral hygiene, and body mass index (BMI).

What are the possible benefits and risks of participating?

Participants may benefit from an improvement to their oral health, oral function, and quality of life. Risks of participating in the study are low, participants may feel uncomfortable during the oral examination.

Where is the study run from?

Kaohsiung Medical University Hospital and Kaohsiung Municipal Ta-Tung Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
January 2018 to June 2021

Who is funding the study?
National Health Research Institutes (Taiwan)

Who is the main contact?
Prof. Hsiao-Ling Huang
hhuang@kmu.edu.tw

Contact information

Type(s)
Scientific

Contact name
Prof Hsiao-Ling Huang

ORCID ID
<https://orcid.org/0000-0002-1180-9011>

Contact details
No.100
Shin-Chuan 1st Road
Sanmin Dist.
Kaohsiung City
Taiwan
80708
+886 (0)7 3121101 ext. 2159
hhuang@kmu.edu.tw

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NHRI-107AI-PHCO-03181808

Study information

Scientific Title
Follow-up study of oral health care and oral function intervention for elderly patients with dementia: a randomized controlled trial

Study objectives

The basic oral health care and oral function intervention is an effective method for elderly patients with dementia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/05/2018, Institutional review board of Kaohsiung Medical University Chung-Ho Memorial Hospital (No. 100, Tzyou 1st Road, Kaohsiung 807, Taiwan; +886 (0)7 3121101 ext. 6646; irb-training@kmuh.org.tw), ref: KMUHIRB-SV(I)-20180015

Study design

Randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Oral health of elderly patients with mild dementia (Clinical Dementia Rating=1.0)

Interventions

In this study, the elderly with mild dementia will be recruited in the Kaohsiung Medical University Hospital and Kaohsiung Municipal Ta-Tung Hospital. The physicians of Neurology Dementia outpatient clinic will recommend 200 suitable participants to the study. Participants will be randomly assigned using paper bags to the experimental group (EG) and control group (CG); each group has 100 participants.

A 30 minutes face-to-face teaching activity for EG participants and their caregivers was implemented by a well-trained dental hygienist. It concluded oral function promotion exercise and oral care methods, using a leaflet and dental models as teaching aids. Dental hygienist shared experiences with the participants and their caregivers, and consult immediately to improve the learning effect. The intervention aims to let the participants have sufficient oral care abilities at home, eat safely and effectively, reduce chewing and swallowing problems, obtain adequate nutrition, reduce the incidence of choking. In order to overcome the situation that many participants do not live with their children, or do not have a daily primary caregiver, special aids are designed. They were given to the participants to use at home, including: refrigerator magnets (remind to do oral function promotion exercise), stickers for bathroom mirror (reminder for oral cleaning), and "oral care logbook", provide participants to record their daily oral care activities. Moreover, the EG participants received one reminder phone call every 2 weeks from researcher.

For those participants in the CG, participants are given a leaflet to read which includes general information about oral health.

Pre-test for two groups will be done before. There are post-tests after 3 months and 6 months. A structured questionnaire will be used to collect data on oral health care behaviors, plaque

index (PI), Winkel tongue coating index (WTCI), repetitive saliva swallowing test (RSST), measurement of the oral diadochokinetic (DDK), and body mass index (BMI). T-tests, Chi-square test, Fisher's exact test, and logistic regression will be used for analysis.

Intervention Type

Behavioural

Primary outcome(s)

1. Oral hygiene measured using the Plaque Index (PI) and Winkel tongue coating index (WTCI) at pre-test and after 3 and 6 months
2. Oral function measured using the repetitive saliva swallowing test (RSST), oral diadochokinesis (DDK), perceived xerostomia and dysphagia scales at pre-test and after 3 and 6 months
3. Physical status measured using the Body Mass Index (BMI) at pre-test and after 3 and 6 months

Key secondary outcome(s)

Oral health care behaviors measured using questionnaire at pre-test and after 3 and 6 months

Completion date

30/06/2021

Eligibility

Key inclusion criteria

1. Aged over 65 years
2. Diagnosis of mild dementia (Clinical Dementia Rating=1.0)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Total final enrolment

136

Key exclusion criteria

1. Patients with post-stroke dementia
2. Smokers or betel quid chewers, or both users who have quit less than 6 months
3. Conditions that cause patients can not receive examination or intervention (such as blind, deaf)
4. Patients who have fewer than 4 pairs of functional teeth

Date of first enrolment

14/06/2018

Date of final enrolment

30/06/2020

Locations

Countries of recruitment

Taiwan

Study participating centre

Kaohsiung Medical University Chung-Ho Memorial Hospital

No.100, Tzyou 1st Rd, Sanmin Dist.

Kaohsiung City

Taiwan

80756

Study participating centre

Kaohsiung Municipal Ta-Tung Hospital

No.68, Jhonghua 3rd Rd, Cianjin District

Kaohsiung City

Taiwan

80145

Sponsor information

Organisation

National Health Research Institutes

ROR

<https://ror.org/02r6fpx29>

Funder(s)

Funder type

Government

Funder Name

National Health Research Institutes (Taiwan)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/09/2022	01/11/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes