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Oral health care intervention for elderly patients with dementia

Submission date
08/06/2020

Recruitment status
No longer recruiting

Registration date
06/07/2020

Overall study status
Completed

Last Edited
01/11/2022

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format.

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 measure
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

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

Overall study start date
01/01/2018

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

Age group
Senior

Sex
Both

Target number of participants
200

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
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80145

Sponsor information

Organisation
National Health Research Institutes

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Sponsor type
Government

Website
http://english.nhri.org.tw/NHRI_WEB/nhriw001Action.do

ROR
https://ror.org/02r6fpx29

Funder(s)

Funder type
Government

Funder Name
National Health Research Institutes (Taiwan)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Additional documents are not available now.

Intention to publish date
31/12/2022

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