

Effectiveness of the implementation project 'Don't forget the mouth!' - maintaining and improving oral health and general health of community dwelling elderly persons suffering from dementia.

Published: 08-12-2016

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The aim of this study is to evaluate the process of the implementation project *Don*t forget the mouth!*

| | |
|------------------------------|---------------------|
| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Other condition |
| Study type | Interventional |

Summary

ID

NL-OMON45997

Source

ToetsingOnline

Brief title

The implementation project *Don*t forget the mouth!*

Condition

- Other condition
- Dementia and amnestic conditions

Synonym

cognitive impairment, Dementia, general health, general healthiness, healthiness of the mouth, oral health

Health condition

oral health and general health

Research involving

Human

Sponsors and support

Primary sponsor: Academic Centre for Dentistry Amsterdam (ACTA)

Source(s) of monetary or material Support: Ministerie van OC&W, ZonMw, Achmea Zorgverzekeringen, Achmea Zorgverzekeringen and Koninklijke Nederlandse Maatschappij tot Bevordering der Tandheelkunde (KNMT) , Koninklijke Nederlandse Maatschappij tot Bevordering der Tandheelkunde (KNMT)

Intervention

Keyword: dementia, education, elderly persons, oral health

Outcome measures

Primary outcome

The main study parameter is the quality of implementation of the implementation project *Don't forget the mouth!.*

Secondary outcome

Secondary outcome measures are oral hygiene, oral health status, oral health related quality of life, and general health and care dependency.

Study description

Background summary

Worldwide, there are 46.8 million people suffering from dementia, and this number continues to rise. It is very important for elderly persons suffering from dementia to have good oral health, since good oral health decreases the risks of pneumonia, improves regulation of diabetes mellitus, decreases the risks of heart and cardiovascular diseases and prevents malnutrition. The oral health of fragile elderly is poor; both the community dwelling and institutionalized. The demand for (professional) oral health care increases,

but the current health care system is not prepared for this growing demand. The implementation project *'Don't forget the mouth!'* sets out to support multidisciplinary collaborations and to improve education, with the aim to maintain and improve the oral health and general health of community dwelling elderly persons suffering from dementia.

Study objective

The aim of this study is to evaluate the process of the implementation project *'Don't forget the mouth!'*.

Study design

The project is set up as a process evaluation and a prospective longitudinal single-blind multicenter study, and takes place in at least 11 towns.

Intervention

The implementation project *'Don't forget the mouth!'*. The implementation project supports multidisciplinary collaborations and improved education focused on maintaining and improving oral health and general health, to healthcare professionals and caregivers of community dwelling elderly persons suffering from dementia. With regard to the participants, the intervention will be compared to oral health care as usual.

Study burden and risks

There are no risks for the healthcare professionals involved with participating in the study.

For the population community dwelling elderly persons suffering from dementia the Non Investigated Medical Products (NIMPs) for gathering information about the dental plaque (DP) and dental prosthetic plaque (DPP) are dental probes, dental mirrors, and DPP disclosing solutions (0.05% methylene blue), which are used within their indication and not in combination with other products. The risks of using the medical instruments are comparable with normal dental care interactions outside the study, and therefore the risks are negligible and acceptable.

There is awareness regarding possible agitation of the participant because of the dementia, and precautions have been taken. The burden of the DP and DPP measurements is reduced to minimal. The intervention can lead to improved oral health care and could be applied indefinitely. The control group will get access to the same education and multidisciplinary collaborations of the implementation project *'Don't forget the mouth!'* at the end of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Participant is 65 years or older, has at baseline a score from 18 through 24 on the Mini Mental State Examination, is registered with the home care organization that participates in the research, and is registered with a general health practice.;In order to be eligible to participate in this research, the general health practice, the dental practice and the home care organization are willing to include oral health care for elderly persons in the care program.

Exclusion criteria

Participant lives in a care facility, or is terminally ill, or has no natural nor artificial dentition, or has a MMSE score lower than 18 at baseline, or has no physician. Additionally: participant

of the control group is registered as a patient of a physician and/or dentist of the intervention group. ;A general health practice, dental practice and/or home care organization will be excluded from participation if: the physician has a temporary position, duration less than 1 year; the dental practice is poorly accessible; and the home care organization has no clients above the age of 65 years.

Study design

Design

| | |
|---------------------|---------------------------------|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |

Primary purpose: Health services research

Recruitment

| | |
|---------------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 18-02-2017 |
| Enrollment: | 176 |
| Type: | Actual |

Ethics review

| | |
|--------------------|--------------------|
| Approved WMO | |
| Date: | 08-12-2016 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO | |
| Date: | 15-02-2017 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO | |
| Date: | 22-01-2018 |

Application type: Amendment
Review commission: METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

| Register | ID |
|----------|----------------|
| CCMO | NL57460.029.16 |