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Improving oral health of dependent elderly living in long-term care facilities in the Netherlands and Belgium

Submission date	Recruitment status	[_] Prospectively registered
30/03/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/11/2010	Oral Health	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.mondzorgonderzoek.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effectiveness of an oral hygiene based intervention to improve oral health of dependent elderly living in long-term care facilities in the Netherlands and Belgium: a cluster randomised controlled clinical trial

Acronym
ABRIM

Study objectives
Supervised implementation of the guideline "Oral health care in institutions providing long-term care to elderly people" is more effective than to non-supervised implementation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee of the Ghent University approved in June 2008 (ref: EC UZG 2008/440; B67020084505)
2. Ethics Committee of the Radboud Universtity of Nijmegen approved in November 2008 (ref: CMO NL2466.091.08)

Study design
Cluster randomised intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Oral health

Interventions

The intervention consisted of supervised implementation of the guideline and derived protocols. Supervision was conducted by an external implementation supervisor (researcher). In the intervention group the oral health care will be given after oral health training sessions to the nurses and nurse-aides.

The derived protocols contained all assignments and forms for implementing oral health care as inextricable part of the daily care of the residents. Six assignments and three forms were assigned to the managing director and two assignments and two forms were concerning the executive care providers.

The intervention includes:
1. Initiating an oral health care team by appointing an oral health care project leader, wards' organising oral health care providers, a nursing home physician, and optionally a speech therapist or an occupational therapist. All team members are employees of the institution.
2. A PowerPoint presentation (1.5 hours) on the guideline, the derived protocols, and the supervising process in each institution of the intervention group at the start of the study, addressing the managing director or his/her substitute, the institution's ward heads and the appointed oral health care project leader. This presentation will be provided by the external implementation supervisor.
3. One teaching and 1 practical education session (2 hours each) at the start of the study addressing all wards' organising oral health care providers. The education will be provided by an experienced dental hygienist. The education deals with common oral diseases in elderly people, oral health assessment and management, as well as oral hygiene care and products. The wards' organising oral health care providers will be trained additional skills facilitating to educate executive care providers at ward level.
4. One practical education session (1.5 hour) for all executive care providers, 1 month after the start of the study. The education sessions will be provided at ward level by the wards' organising oral health care provider using a PowerPoint presentation prepared by the external implementation supervisor. All instructions for oral health care (e.g. tooth brushing) will be taught and demonstrated on site with residents per ward.
5. Monitoring the supervised implementation of the guideline will be carried out by the external implementation supervisor by consultations with the wards' organising oral health care providers of each institution of the intervention group at 6 and 18 weeks after the start of the study. The consultations will be guided by 10 open questions concerning the progress of the supervised implementation process (content and questionnaires SWOT-analysis), the target group (involvement of all residents and the residents' reflections), and the organisational aspects (time spent, reflections of the oral health care team members).

Residents in the control group contain the same 'profile' as the residents in the intervention group. In the control group oral health care will be given as usual.

In both arms of the trial an a-select sample of 30 residents in each LTC will be followed for a period of 6 months after the baseline oral hygiene assessment.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

An important outcome variable of the intervention is the oral hygiene score of the residents, assessing scores of denture and dental plaque. Denture plaque will be scored using Methylene Blue® disclosing solution according to Augsburger and Elahi (score range = 0 to 4). Dental plaque will be scored using the validated plaque index described by Silness and Löe (score range = 0 to 3). The assessment will be performed at a subset of the 6 so-called 'Ramfjörd teeth'. In absence of one of these teeth, the corresponding distal neighbour tooth will be assessed. Examiners are dentists and master dental students practically educated and calibrated on the diagnostic criteria. Prior to the study, 16 residents will be examined for determining the intra- and inter-examiners reliability. Detailed information on reliability will be determined comparing each examiners score with the scores of a golden standard.

Measured in January - June 2009 and again in August 2008 - January 2010. Focus group interviews were done only in the intervention arm, over a period of 6 months after the initial oral health care training session. Semi-structured interviews have been done within 3 months after the intervention period of 6 months (January 2010 - March 2010).

Secondary outcome measures
The process evaluation involves assessing the extent to which the intervention program is performed according to protocols, the nature of the oral care recommendations made to the participants, compliance with these recommendations, care providers judgements about the intervention program and oral care recommendations. Data on these topics will be collected using focus-groups. Semi-structured interviews will be held with the participating care providers and nursing home physicians during the intervention period in order to record their experiences and opinions on the guideline "Oral health care in institutions providing long-term care to elderly people" and derived protocols.

Overall study start date
01/03/2009

Completion date
01/06/2010

Eligibility

Key inclusion criteria
Institutions of long-term care:
1. Providing long-term care to 120 to 150 residents
2. Having wards with mainly somatic and psycho-geriatric residents, with 20 residents minimally
3. Netherlands: moderately or highly care dependent; Belgium: also providing care for minor dependent residents
4. Residents aged 70 - 100 years, men and women

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
360 residents in each country

Key exclusion criteria
An institution will not be eligible for inclusion if any of the following exclusion criteria is applicable:
1. A guideline or protocol for oral health care is already in function
2. Extra education courses on oral health care for the executive care providers had been held during the last 24 months

Individuals:
1. Residents in coma
2. Terminally ill. Terminally ill is defined as death expected within six months.
3. In day-care or in short-term residency

Date of first enrolment
01/03/2009

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
Belgium

Netherlands

Study participating centre
Department of Oral Function and Prosthetic Dentistry
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Sponsor information

Organisation
De Open Ankh Foundation (Netherlands)

Sponsor details
Oude Tempellaan 1
Soesterberg
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Sponsor type
Research organisation

Website
http://www.openankh.nl/

Funder(s)

Funder type
Research organisation

Funder Name
De Opbouw Foundation (Netherlands)

Funder Name
De Open Ankh Foundation (Netherlands)

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/07/2010		Yes	No