

# Supervised versus non-supervised implementation of an oral health care guideline in (residential) care homes: A cluster randomized controlled clinical trial.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON29576

### Source

NTR

### Brief title

Implementatation of an Oral Hygiene protocol in care homes

### Health condition

Oral health care, Oral hygiene, Oral health, Care Homes, nursing homes, oral health guideline, older people.

## Sponsors and support

**Primary sponsor:** Birkhoven Zorggoed, Radboud University Nijmegen Medical Centre

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## Intervention

## Outcome measures

### Primary outcome

Primary outcome variable is the oral hygiene level of the participating residents.

### Secondary outcome

To determine the stimulating or inhibiting factors of the implementation project and the nurses' and nurse aides' compliance and perceived barriers, a process evaluation is carried out.

## Study description

### Background summary

Background:

The increase of the proportion of elderly people has implications for health care services. Advances in oral health care and treatment have resulted in a reduced number of edentulous individuals. An increasing number of dentate elderly people have tooth wear, periodontal disease, oral implants, and sophisticated restorations and prostheses. Hence, they are in need of both preventive and curative oral health care continuously. Weakened oral health due to neglect of self care and professional care and due to reduced oral health care utilization is already present when elderly people are still community-dwelling. At the moment of (residential) care home admittance, many elderly people are in need of oral health care urgently. The key factor in realizing and maintaining good oral health is daily oral hygiene care. For proper daily oral hygiene care, many residents are dependent on nurses and nurse aides. In 2007, the Dutch guideline "Oral health care in (residential) care homes for elderly people" was developed. Previous implementation research studies have revealed that implementation of a guideline is very complicated. The overall aim of this study is to compare a supervised versus a non-supervised implementation of the guideline in The Netherlands and Flanders (Belgium).

Methods/Design:

The study is a cluster randomized intervention trial with an institution as unit of randomization. A random sample of 12 (residential) care homes accommodating somatic as well as psycho-geriatric residents in The Netherlands as well as in Flanders (Belgium) are randomly allocated to an intervention or control group. Representative samples of 30 residents in each of the 24 (residential) care homes are monitored during a 6-months period. The intervention consists of supervised implementation of the guideline and a daily oral

health care protocol. Primary outcome variable is the oral hygiene level of the participating residents. To determine the stimulating or inhibiting factors of the implementation project and the nurses' and nurse aides' compliance and perceived barriers, a process evaluation is carried out.

## Discussion:

The method of cluster randomization may result in a random effect and cluster selection bias, which has to be taken into account when analyzing and interpreting the results.

## Study objective

The scientific hypothesis of the present study is that supervised implementation of the guideline "Oral health care in (residential) care homes for elderly people" is more effective in improving oral health and oral health care of the residents when compared to non-supervised implementation.

## Study design

At baseline and at 6 months, an oral examination of the random sample of 30 residents is carried out by a team of trained external examiners.

At baseline, a questionnaire on personal and medical details of every resident of the random sample is completed. Furthermore, at baseline and at 6 months a questionnaire addressing the nurses and nurse aides is completed. Finally, at the end of the study, a process evaluation is conducted in the institutions of the intervention group to acquire insight in the stimulating and inhibiting factors of the implementation process.

## Intervention

The intervention consists of supervised implementation of the guideline "Oral health care in (residential) care homes for elderly people" and the daily oral health care protocol derived from the guideline. In each institution of the intervention group, every ward head appoints a nurse who will act as ward oral health care organizer (WOO). The managing director, physician(s), ward heads, WOO's, nurses, nurse aides, and a sample of 30 residents are involved in the study. The implementation of the guideline is supervised by a dental hygienist and includes:

1. A 1.5-hour informative oral presentation on the guideline, the daily oral health care protocol, and the supervised implementation project before the start of the study, introduced by the dental hygienist and one of the investigators and addressing the managing director, the institution study supervisor, the ward heads, and the WOO's. Important objective of the

informative oral presentation is to lay a strong institutional foundation of the implementation project and the study;

2. A 2-hour lecture and in total 3 hours of practical education for the WOO's. The education, presented by the dental hygienist, regards the theoretical and practical essentials of the guideline. The WOO's are practically educated in skills facilitating them to practically educate and encourage the nurses and nurse aides of their wards;

3. A 1.5-hour theoretical and executive education session at each ward, presented by the WOO, for all ward nurses and nurse aides. This education session is scheduled after the baseline data collection. A summary of the guideline is presented and all executive actions, such as tooth brushing, are taught and demonstrated with ward residents on site. As from the education session, the WOO will encourage and assist the nurses and nurse aides regularly in the daily delivery of oral health care;

4. Providing oral health care materials and products for each resident by the dental hygienist;

5. Monitoring visits of the dental hygienist and an investigator every 6 weeks, meeting the institution study supervisor and WOO's for listing and resolving implementation and study problems.

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

To participate in the study, a resident should:

1. Supply a written informed consent, undersigned by himself or his legal representative;
2. Have teeth and/or partial or complete dentures;
3. Have the cognitive and physical condition required for undergoing an oral examination;
4. Be residing in the institution during the entire 6-months period presumably.

## Exclusion criteria

Residents are excluded when in day-care, in short-term residency, in coma, in palliative care or terminally ill, using a denture adhesive, expressing verbal or physical resistiveness before or during an oral examination.

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2009
Enrollment:	360
Type:	Actual

## Ethics review

Positive opinion	
Date:	13-08-2010
Application type:	First submission

## 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
NTR-new	NL2359
NTR-old	NTR2466
CCMO	NL24666.091.08
ISRCTN	ISRCTN86156614

## Study results

### Summary results

Study protocol: BMC Oral Health 2010, 10:17.