

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Oral health in people in need in long-term care

Trial Acronym

MundPflege

URL of the trial

[---]*

Brief Summary in Lay Language

Developments in oral care and dentistry have enabled more and more older people to keep their own teeth longer. This positive development, however, is offset when the need for long-term care arises and they are less able to look after themselves. Poor dental hygiene leads to a decline in oral health, an increased risk of tooth loss, a deterioration of nutritional status and the development of systemic diseases. Quality of life thus also depends on oral health. For good oral health, proper dental care with personalized oral care guidance is important - in the domestic setting as well as in care homes.

The aim is to maintain and optimize the oral health of those in need of care at home and thereby contribute to the best possible quality of life.

Potential study participants are people who are insured by the participating health insurance funds, whose primary place of residence is in Bremen or Lower Saxony, who are in need of long-term care in accordance with Book XI of the German Social Code, and who do not live in a care home. The study evaluates the utilization of dental services as well the participants' oral health status after being given individual oral care guidance in the domestic setting.

Brief Summary in Scientific Language

Recent studies show that people in need of long-term care use dental services much less frequently than non-care dependents. At the same time there is evidence of an increased need for support for daily oral care, also among care dependents in the lower care categories.

The Oral Health Care Project (MundPflege / Oral Care) is testing a new form of care for non-residential care dependents with the aim of enhancing dental care in this group of people. Improving their oral hygiene should lead to an improved oral health-related quality of life - determined among other things by freedom from pain, the ability to adequately chew and swallow food and to speak - and, hence, social participation.

This new form of health care is provided by registered dentists and qualified dental assistants. An essential feature of this scheme is the low-threshold, outreach approach. Long-term care dependents are contacted by their insurance

funds and informed about the scheme. Dental appointments are even made for them. After a dental examination and an individual risk analysis in the context of the scheme, patients and their informal caregivers are given individual coaching on oral care by specially trained dental assistants. In this way, care dependents can be visited and looked after in their home environment.

Potential study participants are people who are insured by the participating health insurance funds, whose primary place of residence is in Bremen or Lower Saxony, who are in need of long-term care in accordance with Book XI of the German Social Code, and who do not live in a care home. The study evaluates the utilization of dental services as well the participants' oral health status after being given individual oral care guidance in the domestic setting.

The evaluation of this new form of health care is based on a two-arm randomized controlled trial (RCT). In addition, a routine analysis of the health fund data is carried out linking the primary patient data of the RCT to the available routine data. In addition, a health economic evaluation and a potential analysis are carried out.

If the evaluation is successful, the goal is to take this new health care form on board as an element of standard care and thus to contribute to the improvement of care standards pursuant to § 22a SGB V of the Federal Joint Committee (G-BA).

Organizational Data

- DRKS-ID: **DRKS00013517**
- Date of Registration in DRKS: **2018/06/11**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **MundPflege , Ethikkommission der Universität Bremen
Bibliothekstr. 1
28359 Bremen**

Secondary IDs

Health condition or Problem studied

- ICD10: **K00-K14 - Diseases of oral cavity, salivary glands and jaws**

Interventions/Observational Groups

- Arm 1: **Intervention group: t0: Examination of oral health status and training of the people in need of care to oral care. t1: Application of Oral Health Assessment Tool, Oral Health Impact Profile and Parodontaler Screening Index; data analysis Betriebskrankenkassen.**

- Arm 2: **Control group: t1: Application of Oral Health Assessment Tool, Oral Health Impact Profile and Peridontaler Screening Index; data analysis Betriebskrankenkassen**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **investigator/therapist**
- Control: **Control group receives no treatment**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Assesment-Tool for an oral health survey (Oral Health Assessment Tool (OHAT)). Starts from November 2018.

Secondary Outcome

Questionnaire: Oral Health Impact Profile (OHIP) and examination to periodontosis by Periodontal Screening Index (PSI). Starts from November 2018.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **in der eigenen Häuslichkeit , Bremen und Niedersachsen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/04/30**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Monocenter trial**



Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2018/04/30**

Target Sample Size: **1000**

Monocenter/Multicenter trial: **Monocenter trial**

■ National/International: **National**

Inclusion Criteria

■ Gender: **Both, male and female**

■ Minimum Age: **18 Years**

■ Maximum Age: **no maximum age**

Additional Inclusion Criteria

long-term care in accordance with book XI of the German Social Code

Exclusion criteria

/

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

DRKS-ID: **DRKS00013517**

Date of Registration in DRKS: **2018/06/11**

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Klinischer Studien**

German Clinical
Trials Register

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*
