

Differential learning and oral hygiene

Submission date 30/05/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/05/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/03/2018	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Toothbrushing to remove dental biofilm (bacteria) is important to prevent oral diseases. Accurate brushing techniques are necessary to improve biofilm removal compared to habitual toothbrushing, but are difficult to adopt. This study aims to analyse the effect of differential learning on the adoption of a toothbrushing technique.

Who can participate?

Healthy children aged 6 to 9

What does the study involve?

Participants are randomly allocated to three groups. The intervention lasts for 15 days, and all children receive the same toothbrush and toothpaste during the whole study. In the control group, the children are asked to brush their teeth with their habitual brushing technique. In the second group, the brushing technique is instructed once a day by verbal instruction and demonstration models. In the third group, the brushing technique is instructed once a day according to the differential learning approach (one variation per day, 15 variations in total). Oral hygiene is assessed before the intervention and 21 days, 42 days and 63 day after the beginning of the intervention.

What are the possible benefits/risks of participating?

The participants might improve their personal oral hygiene. No side effects are expected.

Where is the study run from?

Department of Preventive Dentistry, Periodontology and Cariology, University Medical Center Göttingen (Germany)

When is study starting and how long is it expected to run for?

December 2015 to June 2016

Who is funding the study?

Department of Preventive Dentistry, Periodontology and Cariology, University Medical Center Göttingen (Germany)

Who is the main contact?
Prof. Dr Annette Wiegand

Contact information

Type(s)
Public

Contact name
Prof Annette Wiegand

Contact details
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37075

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13/1/16

Study information

Scientific Title
Effect of differential learning on the oral hygiene status of 6- to 9-year-old children

Study objectives
The null hypothesis is that there is no significant difference in the oral hygiene status (Quigley-Hein plaque-index and papilla bleeding index) of children brushing:
1. With the habitual technique
2. After instruction of a brushing technique
3. After instruction of a brushing technique with the differential learning approach
at 21, 42 and 63 days after the start of the study

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the University Medical Center Göttingen, 24/02/2016, No:13/1/16

Study design

Single-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Oral hygiene

Interventions

This single-center study is conducted by the Department of Preventive Dentistry, Periodontology and Cariology at the Primary School Drispensstedt, 32235 Hildesheim, Germany. Approximately fifty children are randomly allocated to three groups:

1. Control: No treatment, habitual toothbrushing with standardized toothbrush and toothpaste
2. Instruction of brushing technique: Toothbrushing technique is instructed, toothbrushing is performed with standardized toothbrush and toothpaste
3. Instruction of brushing technique and differential learning: Toothbrushing technique is instructed, toothbrushing is performed with standardized toothbrush and toothpaste while applying differential learning

Intervention Type

Behavioural

Primary outcome measure

1. Quigley-Hein plaque index at day 21, 42 and 63
2. Papilla bleeding index at day 21, 42 and 63

Secondary outcome measures

None

Overall study start date

01/12/2015

Completion date

10/06/2016

Eligibility

Key inclusion criteria

Healthy children aged 6 to 9 years

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

6 Years

Upper age limit

9 Years

Sex

Both

Target number of participants

50

Key exclusion criteria

Toothpaste allergy

Date of first enrolment

14/03/2016

Date of final enrolment

06/04/2016

Locations**Countries of recruitment**

Germany

Study participating centre

University of Göttingen (Germany)

Department of Preventive Dentistry, Periodontology and Cariology
37075

Sponsor information**Organisation**

University of Göttingen (Germany)

Sponsor details

Department of Preventive Dentistry, Periodontology and Cardiology
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37075

Sponsor type

University/education

ROR

<https://ror.org/01y9bpm73>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Medical Center Göttingen (Germany)

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2018		Yes	No