

# Theory based oral hygiene intervention in adolescents

<b>Submission date</b> 30/07/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/08/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/08/2015	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Background and study aims

This study investigates whether individually tailored education for adolescents on how to take care of their teeth improves their oral self-care.

Who can participate?

All 15-16 year old pupils attending one of the four public secondary schools participating in the study.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the intervention group receive oral self-care education provided by their school. Those in the control group carry on as usual. Three oral cleanliness assessments are then done for the control group (at the start of the study, and then 6 months and 12 months later) and four oral cleanliness assessments are completed by the intervention group (before the study begins, after the intervention, 6 months and then 12 months later)

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Four Lithuania secondary schools

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

December 2013 to September 2015

Who is funding the study?

Vilnius University (Lithuania)

Who is the main contact?

Dr Vilma Brukiene

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Vilma Brukiene

**Contact details**

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08217

## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

6B-12-352

## **Study information**

**Scientific Title**

Self-efficacy theory based oral hygiene intervention in adolescents: cluster randomized controlled trial. Focus on oral self care practice and skills

**Study objectives**

Multiple individualized instructions are superior to conventional dental instruction for improving both oral self-care skills and practice in adolescents

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Bioethics Committee of the Ministry of Health, Lithuania

**Study design**

Cluster randomized controlled trial

**Primary study design**

Interventional

**Secondary study design****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 self care

**Interventions**

All 15- to 16-years-old from four public secondary schools were invited to participate. 112 were randomly allocated in the intervention group and 94 to the control group. All interventions were implemented through a school-based environment and aimed to improve the oral hygiene skills and practice of the 15-16 years old children. Three oral cleanliness assessments were done for the control group (baseline, 6 and 12 months) and four oral cleanliness assessments were completed for the intervention group (baseline, after intervention, 6 and 12 months).

**Intervention Type**

Behavioural

**Primary outcome measure**

Oral self care skills

Three assessments for control group (baseline, 6 and 12 months)

Four assessments for intervention group (baseline, after intervention, 6 and 12 months)

**Secondary outcome measures**

Oral self care practice

Three assessments for control group (baseline, 6 and 12 months)

Four assessments for intervention group (baseline, after intervention, 6 and 12 months)

**Overall study start date**

05/12/2013

**Completion date**

14/09/2015

**Eligibility****Key inclusion criteria**

Healthy school-aged 15 -16 years old attending public schools

**Participant type(s)**

All

**Age group**

Child

**Lower age limit**

15 Years

**Upper age limit**

16 Years

**Sex**

Both

**Target number of participants**

254

**Key exclusion criteria**

Adolescents undergoing orthodontic treatment

**Date of first enrolment**

10/01/2014

**Date of final enrolment**

07/02/2014

**Locations****Countries of recruitment**

Lithuania

**Study participating centre**

Lithuania secondary schools

Vilnius District

Lithuania

21375

**Sponsor information****Organisation**

Institute of Odontology, Vilnius University

**Sponsor details**

Zalgirio 117,

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Lithuania

08217

**Sponsor type**

University/education

**ROR**

<https://ror.org/03nadee84>

## **Funder(s)**

**Funder type**

University/education

**Funder Name**

Vilnius University (Lithuania)

## **Results and Publications**

**Publication and dissemination plan**

**Intention to publish date**

02/11/2015

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Data sharing statement to be made available at a later date