

Theory based oral hygiene intervention in adolescents

Submission date 30/07/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/08/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/08/2015	Condition category 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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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,

Vilnius

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