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Theory based oral hygiene intervention in adolescents

Submission date	Recruitment status	[ ] Prospectively registered
30/07/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/08/2015	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/08/2015	Oral Health	[ ] 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
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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Cluster randomized controlled trial

Study type(s)
Prevention

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(s)
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)

Key secondary outcome(s)
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)

Completion date
14/09/2015

Eligibility

Key inclusion criteria
Healthy school-aged 15 -16 years old attending public schools

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Child

Lower age limit
15 Years

Upper age limit
16 Years

Sex
All

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

ROR
https://ror.org/03nadee84

Funder(s)

Funder type
University/education

Funder Name
Vilnius University (Lithuania)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date