Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effectiveness of a health education program based on E-Learning versus leaflets in promoting oral hygiene practice of school children.

Protocol summary

Study aim
The study aimed to compare between the traditional educational leaflets and E-applications in improving oral health knowledge, oral hygiene and gingival health in schoolchildren of Damascus city, Syria.

Design
Two arm parallel group, clustered randomized controlled trial

Settings and conduct
The trial was conducted at two public primary schools of Damascus city, Syria. Schools were randomly allocated into two clusters: Children in Leaflet cluster received oral health education through leaflets, and children in E-learning cluster received oral health education through an E-learning program. A trained investigator clinically examined all children in their classroom. This was performed without informing children about oral examination and intervention dates. Dental Plaque was assessed using Plaque Index (PI) for Silness and Löe. Gingival health was assessed using Gingival Index (GI) for Löe and Silness. After collecting the baseline data, oral health educational tools were provided to subjects in which leaflets were given to children in Leaflet cluster, whilst children in E-learning cluster were provided with CDs which contained instructions on how to access the website via the link www.oralhealthforchildren.com. The level of oral health knowledge, plaque accumulation and gingival status were also re-evaluated after a period of six weeks and also after twelve weeks by the same investigator.

Participants/Inclusion and exclusion criteria
All healthy children aged 10-11 year old from the selected schools were included in the study. Children receiving dental health education through another source and/or physically or mentally compromised children were excluded from the study.

Intervention groups
Intervention group 1: Leaflets, Intervention group 2: E-learning program.

Main outcome variables
Change in oral health knowledge

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180214038729N1**
Registration date: **2018-03-21, 1397/01/01**
Registration timing: **retrospective**

Last update: **2018-03-21, 1397/01/01**
Update count: **0**

Registration date
2018-03-21, 1397/01/01

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2016-01-24, 1394/11/04
Expected recruitment end date
2016-01-24, 1394/11/04
Actual recruitment start date
2016-01-25, 1394/11/05
Actual recruitment end date

2016-01-25, 1394/11/05

Trial completion date

empty

Scientific title

The effectiveness of a health education program based on E-Learning versus leaflets in promoting oral hygiene practice of school children.

Public title

E-Learning for improving oral health of children.

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

All healthy children who accepted to take part in this study Children who did not receive any previous dental educational program Children who had internet access connection and ability to browse and use the internet

Exclusion criteria:

children outside the age range of the study children currently under the regular care of an oral health care provider children who have access to oral health education through a different and separate source than our intervention children with acute dental issues (e.g.: dental abscess) mentally or physically compromised children children whose parents did not provide consent for participation in our study

Age

From **10 years** old to **11 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **220**

Actual sample size reached: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using coin-tossing. The unit of randomization was the school. Allocation is not concealed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ministry of Education

Street address

Al-Mazraa, Al-Shahbandar Square, Ministry of Education, Damascus, Syria

City

Damascus

Postal code

Not applicable

Approval date

2016-01-11, 1394/10/21

Ethics committee reference number

252

Health conditions studied

1

Description of health condition studied

Dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

2

Description of health condition studied

Oral hygiene

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Gingivitis

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

4

Description of health condition studied

Level of oral health knowledge

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Change in oral health knowledge level

Timepoint

Oral health knowledge level was assessed at baseline, 6 and at 12 weeks of oral health education.

Method of measurement

Oral health knowledge level was assessed using a questionnaire designed specifically for the study

Secondary outcomes

1

Description
Change in plaque accumulation
Timepoint
Dental Plaque was assessed at baseline, 6 and at 12 weeks of oral health education.
Method of measurement
Plaque accumulation was assessed using Plaque Index (PI) for Silness and Löe.

2

Description
Change in gingival health.
Timepoint
Gingival health was assessed at baseline, 6 and at 12 weeks of oral health education.
Method of measurement
Gingival health was assessed using Gingival Index (GI) for Löe and Silness.

Intervention groups

1

Description
Intervention group 1: Leaflet group: A colorful and attractive leaflet in the form of a short story named “Adnan likes the dentist” was designed by a graphic designer. The leaflets were designed with particular emphasis on creating interest amongst the children. These educational papers included information related to proper brushing technique and frequency; introduced the regular use of dental floss; emphasized regular dental visits as well as provided basic demonstration of dental plaque and the implications of not removing it. The leaflets also contained nutritional guidelines in regards to minimizing caries risk, and finally the role of fluoride in caries control.
Category
Prevention

2

Description
Intervention group 2: E-learning group: An E-learning program was designed by an expert in artificial intelligence. The program was full of colorful images, videos, interactive quizzes and age-related developmental tasks in the quest to deliver the information in an interactive, entertaining and simple manner. The E-learning program included the same information of the leaflet; only the way in which the content is conveyed to the children was different.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Al Beirouni school
Full name of responsible person
Rana Kabtoul
Street address
West Tejara, Al Beirouni school, Damascus, Syria
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Postal code
Not applicable
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amal-omry88@hotmal.com

2

Recruitment center
Name of recruitment center
Mary Alajami school
Full name of responsible person
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George Khouri square, Mary Alajami school, kassaa, Damascus, Syria
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Not applicable
Phone
+963 11 446 2868
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berna.kabalan.ed@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Damascus University/ Faculty of Dentistry
Full name of responsible person
Prof. Mohammad Salem Rekab
Street address
Mazzah Highway, Faculty of Dentistry, Damascus, Syria
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Not applicable
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+963 11 212 1635
Fax
+963 11 212 4757
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dean.dent@damasuniv.edu.sy
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Damascus University/ Faculty of Dentistry
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Damascus University
Full name of responsible person
Susan Bardaweel
Position
Master student
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position
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Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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Latest degree
Medical doctor
Other areas of specialty/work
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Damascus
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Damascus
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Study Protocol, Statistical Analysis, Clinical Study Report, Leaflets used in the study, Oral Health Questionnaire
When the data will become available and for how long
Immediately following publication. Ending 5 years following publication
To whom data/document is available

Researchers who provide a methodologically sound proposal

Under which criteria data/document could be used

Data could be used for academic research only, and could not be available for third party without agreement of the authors. Also, available data will be written in Arabic language and its use should be either in Arabic or in an English translation after verifying the translation with the author, exception of the Leaflets and Oral Health Questionnaire because there is an English versions.

From where data/document is obtainable

Directly from the author at susan.bardaweel@hotmail.co.uk

What processes are involved for a request to access data/document

The author will respond to the applicant within one week of receiving his/her request by e-mail, but final data providing will be within three months.

Comments

We do not have postal code in Syria. I do not have professional email address