

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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 Loe. Gingival health was assessed using Gingival Index (GI) for Loe 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

Susan Bardaweel

Name of organization / entity

Damascus University

Country

Syrian Arab Republic

Phone

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Email address

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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 Loe.

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 Loe 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 Tejera, Al Beirouni school, Damascus, Syria

City

Damascus

Postal code

Not applicable

Phone

+963 11 446 0085

Email

amal-omry88@hotmail.com

2

Recruitment center

Name of recruitment center

Mary Alajami school

Full name of responsible person

Berna Kabalan

Street address

George Khouri square, Mary Alajami school, kassaa, Damascus, Syria

City

Damascus

Postal code

Not applicable

Phone

+963 11 446 2868

Email

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

City

Damascus

Postal code

Not applicable

Phone

+963 11 212 1635

Fax

+963 11 212 4757

Email

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
Dentistry

Street address
Antara Alabsi street, East Tejara, Ninth floor,
Apartment 2, Damascus, Syria

City
Damascus

Province
Damascus

Postal code
Not applicable

Phone
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Email
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Damascus University

Full name of responsible person
Susan Bardaweel

Position
Master student

Latest degree
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Person responsible for updating data

Contact

Name of organization / entity
Damascus University

Full name of responsible person
Susan Bardaweel

Position
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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