

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effectiveness of a voice care program versus no intervention in the reduction of voice handicap scores among primary school teachers in a Kota Bharu, Kelantan.

Protocol summary

Summary

Objectives: This study was aimed to determine the effectiveness of a voice care program among primary school teachers in a northeastern district in Malaysia. **Methodology:** This was a cluster randomized controlled trial that was conducted in eight randomly selected primary schools in Kota Bharu, Kelantan, Malaysia. The self-administered and validated Malay-Voice Handicap Index-10 (M-VHI-10) questionnaire was used to assess overall voice handicap scores pre and eight weeks post intervention. Teachers with a score of five or more (n=86) were randomized into intervention (n=41) and control groups (n=45) by schools. The intervention group received portable voice amplifiers and vocal hygiene instruction that was delivered by lectures and a booklet. The control group was not prescribed any intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081335655N1**
Registration date: **2017-10-03, 1396/07/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-03, 1396/07/11

Registrant information

Name

Esther Sundram

Name of organization / entity

Universiti Sains Malaysia

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Malaysia

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Recruitment status

Recruitment complete

Funding source

Universiti Sains Malaysia (Grant no: 304/PPSP/61313199)

Expected recruitment start date

2016-04-01, 1395/01/13

Expected recruitment end date

2016-06-30, 1395/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of a voice care program versus no intervention in the reduction of voice handicap scores among primary school teachers in a Kota Bharu, Kelantan.

Public title

The effectiveness of a voice care program among primary school teachers in a Kota Bharu, Kelantan.

Purpose

Other

Inclusion/Exclusion criteria

Inclusion Criterion: Primary school teachers with M-VHI-10 score of five and above
Exclusion criteria:
Teachers under Otorhinolaryngology (ORL) follow up;
Teachers who use voice amplifiers for teaching

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 85

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

cluster randomized controlled trial (cluster-RCT)

Secondary Ids

1

Registry name

Human Research Ethics Universiti Sains Malaysia

Secondary trial Id

USM/JEPeM/15040149

Registration date

2015-07-13, 1394/04/22

2

Registry name

Malaysian Ministry of Education

Secondary trial Id

KP(BPPDP)603/5/JLD.06(295)

Registration date

2015-08-12, 1394/05/21

Ethics committees

1

Ethics committee

Name of ethics committee

Human Research Ethics Committee, Universiti Sains Malaysia

Street address

Universiti Sains Malaysia

City

Kubang Kerian

Postal code

16150

Approval date

2015-07-13, 1394/04/22

Ethics committee reference number

USM/JEPeM/15040149

Health conditions studied

1

Description of health condition studied

Voice problems

ICD-10 code

R49

ICD-10 code description

Voice disturbances

Primary outcomes

1

Description

Malay Voice Handicap Index 10 (M-VHI-10) score

Timepoint

Pre and post intervention at 8 weeks

Method of measurement

Malay Voice Handicap Index 10 (M-VHI-10) questionnaire

Secondary outcomes

1

Description

Functional, Physical and Emotional Domain Scores

Timepoint

Pre and Post Functional, Physical and Emotional Domain Scores

Method of measurement

Malay Voice Handicap Index-10 Questionnaire

Intervention groups

1

Description

Control: Teachers with a score of five or more (n=86) were randomized into 2 groups by schools. The intervention group (n=45) comprised of four schools. This control group was not prescribed with any intervention.

Category

Other

2

Description

Intervention: Teachers with a score of five or more (n=86) were randomized into 2 groups by schools. The intervention group (n=41) comprised of four schools. This group received the voice care program: portable voice amplifiers and vocal hygiene instruction that was delivered by lectures and a booklet.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Primary Schools, Malaysian Ministry of Education

Full name of responsible person

Che Hanuni Bt Che Ali

Street address

Jabatan Pendidikan Negeri Kelantan, Bandar Baru
Tunjong,

City

Kota Bharu

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Universiti Sains Malaysia

Full name of responsible person

Nik Rosmawati Nik Husain

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Universiti Sains Malaysia

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Kubang Kerian

Grant name**Grant code / Reference number**

304/PPSP/61313199

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Universiti Sains Malaysia

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Position

Doctorate in Public Health

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty