

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The role of audiovisual aid in reduction of dental anxiety during tooth extraction: A randomized clinical trial

Protocol summary

Study aim

To evaluate the efficacy of audiovisual aid in reducing the level of dental anxiety in patients undergoing tooth extraction

Design

A randomized trial will be conducted where 162 patients will be randomly divided into two equal groups of 81 each, with help of random sequence generated using online tool.

Settings and conduct

University dental hospital, The university of Lahore. The person collecting the data will be blinded to the intervention given to the individuals.

Participants/Inclusion and exclusion criteria

Inclusion: Simple extraction procedure American society of anesthesiologist physical status class 1 & 2 Patient able to comprehend and follow the instructions
Exclusion: Surgical extractions More than two extractions to be performed Grade 2 or 3 mobility of the tooth
Patients who do not understand Urdu Patients who did not give consent

Intervention groups

1. Verbal instructions 2. Audiovisual aid

Main outcome variables

Dental anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221208056747N1**
Registration date: **2023-01-31, 1401/11/11**
Registration timing: **retrospective**

Last update: **2023-01-31, 1401/11/11**

Update count: **0**

Registration date

2023-01-31, 1401/11/11

Registrant information

Name

Palwasha Babar

Name of organization / entity

The university of Lahore

Country

Pakistan

Phone

+92 334 8740767

Email address

palwasha.babar@ucd.uol.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-20, 1401/09/29

Expected recruitment end date

2023-01-30, 1401/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The role of audiovisual aid in reduction of dental anxiety during tooth extraction: A randomized clinical trial

Public title

The role of audiovisual aid in reduction of dental anxiety

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Simple extraction procedure American society of anesthesiologist physical status class 1 & 2

Exclusion criteria:

Surgical extractions More than two extractions to be performed Grade 2 or 3 mobility of the tooth Patients who do not understand Urdu Patients who did not give consent

Age

From **17 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **162**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization technique will be followed and the 162 participants of the study will be randomly divided into two equal groups according to lottery method. 162 slips will be made, 81 for audiovisual aid and 81 for verbal instruction. A slip will be picked at random from the box to allocate the patient a group.

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

Institutional Review Board, The University of Lahore

Street address

1-km Raiwind road

City

Lahore

Postal code

54000

Approval date

2022-06-10, 1401/03/20

Ethics committee reference number

UCD/ERCA/12468

Health conditions studied

1

Description of health condition studied

Dental anxiety

ICD-10 code

F40.2

ICD-10 code description

Specific (isolated) phobias

Primary outcomes

1

Description

Dental anxiety

Timepoint

Before intervention and after intervention with tooth extraction

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Participants in this group will be verbally instructed about the steps involved in tooth extraction before the start of the procedure. Dental anxiety will be measured before and after the tooth extraction.

Category

Behavior

2

Description

Intervention group: Participants in this group will be informed using visual aid about the steps involved in tooth extraction before the start of the procedure . Dental anxiety will be measured before and after the tooth extraction.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

University dental hospital, The university of Lahore

Full name of responsible person

Ijaz ur Rehman

Street address

1-km Raiwind road

City

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54000

Phone

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Email

ijaz.rahmannn@gmail.com

Sponsors / Funding sources

ijaz.rahmannn@gmail.com

1

Sponsor

Name of organization / entity

The University of Lahore

Full name of responsible person

Dr. Saqib Naeem Siddique

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+92 331 7274267

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saqibns@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

The University of Lahore

Proportion provided by this source

100

Public or private sector

Private

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**

The university of Lahore

Full name of responsible person

Ijaz ur Rehman

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

Palwasha Babar

Position

Assistant Professor

Latest degree

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Person responsible for updating data

Contact**Name of organization / entity**

The University of Lahore

Full name of responsible person

Uswa Qaiser

Position

Demonstrator

Latest degree

Bachelor

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Dentistry

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data will be shared as published research article as "The role of audiovisual aid in reduction of dental anxiety during tooth extraction: A randomized clinical trial". The IPD measuring the primary outcome i.e. dental anxiety before and after the tooth extraction in both control and intervention group will be shared.

When the data will become available and for how long

The data will be available once the study is published. The article will be available online for 5 years or as per the journal policy.

To whom data/document is available

To fellow academic researchers and dentists.

Under which criteria data/document could be used

Data will be available for future research after approval by the principal investigator.

From where data/document is obtainable

Published journal

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

It will be as per the journal policy in which article is published.

Comments