# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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

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1-km Raiwind road

**City**
Lahore

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54000

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+92 334 4342501

**Email**
ijaz.rahmannn@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
The University of Lahore
**Full name of responsible person**
Dr. Saqib Naeem Siddique
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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

**Contact**
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Assistant Professor
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**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**
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The University of Lahore
**Full name of responsible person**
Uswa Qaiser
**Position**
Demonstrator
**Latest degree**
Bachelor
**Other areas of specialty/work**
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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 ahred.

**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**