# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Effect of Immersive Virtual Reality During Arteriovenous Fistula Puncture on Pain Intensity among Children Undergoing Hemodialysis in El Beheira Governorate

## Protocol summary

**Study aim**

Evaluate the effect of immersive virtual reality on pain intensity at arteriovenous fistula puncture site among children undergoing hemodialysis in El Behira Governorate

**Design**

Quasi-experimental design (one group pre-posttest) (virtual reality experience controlled/compared versus traditional care on the same group)

**Settings and conduct**

It will be conducted at eight governmental hemodialysis units of the general hospitals affiliated to the Ministry of health in eight administrative districts of El Beheira Governorate – Egypt.

**Participants/Inclusion and exclusion criteria**

- Children aged 7-18 years. - Both sexes. - Receiving hemodialysis therapy for more than 6 months through an arteriovenous fistula (AVF). - Not receiving any other pharmacological and/or non-pharmacological interventions for pain. - Not suffering from any other source of pain rather than the AVF. - Not suffering from any visual, auditory, or cognitive impairments. - Didn't use the VR headset before.

**Intervention groups**

All children receiving hemodialysis through an arteriovenous fistula in the selected study settings. - Before the procedure, children will choose either to watch a 3D animated cartoon movie or to play a simple 3D game. - The baseline data will be recorded before the procedure. - children will start to watch the cartoon movies or games for about 10 minutes before the procedure and continue watching till the end via a mobile smartphone placed inside the VR headset. - post-test values will be recorded.

**Main outcome variables**

Pain intensity will be assessed through: - The subjective pain through a self-reported numerical rating scale of pain severity. - The physiological indicators of pain: heart rate, respiratory rate, blood pressure, and oxygen saturation - Behavioral indicators of pain through direct observation of the children's pain behavior and distress during AVF puncture procedure.

## General information

**Reason for update**

**Acronym**

Virtual Reality-AVF puncture

**IRCT registration information**

IRCT registration number: **IRCT20210612051555N3**
Registration date: **2021-12-22, 1400/10/01**
Registration timing: **prospective**

Last update: **2021-12-22, 1400/10/01**
Update count: **0**

**Registration date**

2021-12-22, 1400/10/01

**Registrant information**

**Name**

Samiha Hamdi

**Name of organization / entity**

Dmanhour University, Faculty of Nursing

**Country**

Egypt

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-02-01, 1400/11/12

**Expected recruitment end date**
2022-03-01, 1400/12/10
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Effect of Immersive Virtual Reality During Arteriovenous Fistula Puncture on Pain Intensity among Children Undergoing Hemodialysis in El Beheira Governorate

**Public title**
Effect of Immersive Virtual Reality During Arteriovenous Fistula Puncture on Pain Intensity among Children Undergoing Hemodialysis in El Beheira Governorate
**Purpose**
Health service research
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Children aged between 7 and 18 years. Both sexes. Receiving hemodialysis therapy for more than 6 months through an arteriovenous fistula (AVF). Not receiving any other pharmacological and/or non-pharmacological interventions for pain management. Not suffering from any other source of pain rather than the AVF Not suffering from any visual, auditory, or cognitive impairments.- Didn’t use the Virtual Reality headset before.
**Exclusion criteria:**
**Age**
From **7 years** old to **18 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **50**
More than 1 sample in each individual
Number of samples in each individual: **3**
Pain intensity will be measured using pain rating scale and physiological parameters before and after the arteriovenous fistula puncture procedure. The behavioral pain response will be observed during the AVF procedure using a specified Likert scale
**Randomization (investigator's opinion)**
N/A
**Randomization description**
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Single
**Other design features**
All the available children who meet the inclusion criteria will be included in the study as the target population is small, thus there is no randomization.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethic's committee of the Faculty of Nursing-Damanhour University
**Street address**
Damanhour, Elbehira, Governorate, Egypt
**City**
Damahour
**Postal code**
22511
**Approval date**
2021-12-15, 1400/09/24
**Ethics committee reference number**
09-12-05-2021 EC

## Health conditions studied

### 1

**Description of health condition studied**
hemodialysis arteriovenous fistula puncture procedure
**ICD-10 code**
I95.3
**ICD-10 code description**
Hypotension of hemodialysis

## Primary outcomes

### 1

**Description**
pain intensity
**Timepoint**
before and immediately after intervention
**Method of measurement**
subjective numerical pain scale

### 2

**Description**
physiological indicators of pain
**Timepoint**
before and immediately after intervention
**Method of measurement**
physiological measurement of heart rate, blood pressure, respiratory rate, blood pressure and oxygen saturation

### 3

**Description**
Objective assessment of the behavioral pain response during the procedure

**Timepoint**
During arteriovenous puncture procedure of routine care and virtual reality intervention
**Method of measurement**
Procedural Behavior Rating Scale

**4**

**Description**
Assess children’s degree of immersion in the VR experience.
**Timepoint**
After the arteriovenous puncture procedure using VR headset for pain reduction
**Method of measurement**
The Gold-Rizzo Immersion and Presence (GRIP) Inventory

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: - Before the procedure, the researchers will explain the numerical pain rating scale to the children. The physiologic parameters and behavioral pain responses will be assessed as baseline data - During the AVF puncture, the researchers will observe the behavioral pain responses of the children.- Just after the procedure, the researchers will re-assess the physiologic parameters and the self-reported pain intensity as pre-test or control reference values. Second Day (Implementing the VR intervention):- Before the procedure, children will be informed about the VR headset and how to use it and choose either to watch a 3D animated cartoon movie or to play a simple 3D game. - The baseline data will be recorded before the procedure. -The VR headset will be placed on the child’s head. it consisted of special eyeglasses and headphones generating a 3D visual environment in a high definition (HD) quality video and audio to ensure complete immersion.- The children will start to watch the cartoon movies or games for about 10 minutes before the procedure and continue watching till the end via a mobile smart phone placed inside the VR headset. -Each child will be observed during the procedure to assess the behavioral pain responses. After the procedure, the physiologic parameters and self-reported pain intensity will be measured as post-test values.- At the end, the children will be asked about their opinion regarding the VR experience
**Category**
Rehabilitation

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Governmental hemodialysis units affiliated to general hospitals in El Behira governorate
**Full name of responsible person**
Ebtsam Salah Yonis Mahrous
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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Ebeed.saleh@yahoo.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Damanhour University- Faculty of Nursing
**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**
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Damanhour University- Faculty of Nursing
**Full name of responsible person**
Samiha Hamdi Sayed Ramadan
**Position**

Assistant professor

**Latest degree**
Ph.D.

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Public Health/Community Medicine

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**
Published research report that contains all the findings of the study

**When the data will become available and for how long**
within one year and will be available long life

**To whom data/document is available**
for public

**Under which criteria data/document could be used**
for scientific use and public education

**From where data/document is obtainable**
none

**What processes are involved for a request to access data/document**
none

**Comments**
none