

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Beheira 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

Samaha Hamdi

Name of organization / entity

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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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Full name of responsible person

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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

Name of organization / entity

Damanhour University- Faculty of Nursing

Full name of responsible person

Samiha Hamdi Sayed Ramadan

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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