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.
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, Elbeheira, Governorate, Egypt
City
Damanhour
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
- 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 smartphone 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.
- 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

Street address
Damanhour, Elbehira, Governorate, Egypt

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Damanhour

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+20 45 6511656

Email
nursing.of.damanhour@hotmail.com

Sponsors / Funding sources

1
Sponsor

Name of organization / entity
Damanhour University- Faculty of Nursing

Full name of responsible person
Ebid Abd Elaty Saleh

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Damanhour, Elbehira, Governorate, Egypt

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+20 45 3344206

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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
Name of organization / entity
Damanhour University- Faculty of Nursing

Full name of responsible person
Samiha Hamdi Sayed Ramadan

Position

Person responsible for scientific inquiries

Contact
Name of organization / entity
Damanhour University- Faculty of Nursing
Full name of responsible person
Rodaina Ahmed Mokbel
Position
Lecturer
Latest degree
Ph.D.
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

Contact
Name of organization / entity
Damanhour University- Faculty of Nursing
Full name of responsible person
Samiha Hamdi Sayed Ramadan
Position
Assistant professor

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