Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Studying the effect of mind-bending technique through virtual reality glasses on physiological indicators of patients undergoing extracorporeal lithotripsy using shockwaves.

Protocol summary

Study aim
Studying the effect of mind-distraction technique through virtual reality glasses on physiological indicators of patients undergoing extracorporeal shock wave lithotripsy

Design
The clinical trial is in the intervention and control group, which is determined by randomization by card and is performed on 99 patients.

Settings and conduct
The above project will be carried out in the Lithotripsy Department of Kowsar Hospital in Semnan to investigate the effect of virtual reality glasses on the physiological indicators of patients. This method will be carried out individually by researchers on the eligible intervention and control groups. In the intervention group, virtual reality glasses will be used for distraction. Blinding is not possible according to the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Minimum age 18 years، Communication skills and alertness، Complete customer satisfaction
Exclusion criteria: Having any type of high blood pressure and any type of diabetes، Types of mental illnesses، His unwillingness to continue cooperation

Intervention groups
The intervention group includes patients with kidney stones undergoing lithotripsy, who receive lithotripsy intervention using virtual reality glasses to distract the mind, and then measure blood pressure, heart rate, arterial oxygen saturation, and body temperature in four stages. The control group includes patients with kidney stones who are undergoing lithotripsy, for whom the intervention will be performed routinely and only their blood pressure, heart rate, arterial oxygen saturation, and body temperature will be measured and recorded in four stages. At the end, they will be provided with a pamphlet containing information about their disease as a token of their appreciation for the project.

Main outcome variables
blood pressure; pulse rate; Arterial blood oxygen saturation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250727066650N1**
Registration date: **2025-08-03, 1404/05/12**
Registration timing: **prospective**

Last update: **2025-08-03, 1404/05/12**
Update count: **0**

Registration date
2025-08-03, 1404/05/12

Registrant information

Name
SeyedMahyar Peyman

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-09-23, 1404/07/01

Expected recruitment end date
2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the effect of mind-bending technique through virtual reality glasses on physiological indicators of patients undergoing extracorporeal lithotripsy using shockwaves.

Public title
The effect of virtual reality glasses on vital signs of patients with stone disease.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Minimum age 18 years Diagnosis of upper or lower urinary tract stones by a doctor and performing at least one lithotripsy procedure Ability to communicate and be alert and aware of the disease Complete client satisfaction and willingness to participate in the research

Exclusion criteria:
Having any type of high blood pressure (systolic blood pressure above 140 and diastolic blood pressure above 80) and any type of diabetes (HbA1C above 6.5) Types of mental illnesses Having diseases that affect hemodynamic indicators, according to the doctor's opinion Death of the client His unwillingness to continue cooperation. The presence of chronic kidney stones affecting physiological indicators

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **99**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done randomly. Patients requiring extracorporeal lithotripsy at Kowsar Hospital who are eligible for inclusion in the study will be divided into two equal groups (50 people in each group) using sealed envelopes containing the letters (I) for intervention and (C) for control, after accepting and fully explaining the plan and obtaining informed consent. The envelope selection will be done by the patient before the intervention begins. Due to random sampling, the study subjects will have an equal chance of being selected into the two groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Semnan University of Medical Sciences

Street address
headquarters of Semnan University of Medical Sciences and Health Services-Basij Blvd

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semnan

Province
Semnan

Postal code
3514799442

Approval date
2025-07-12, 1404/04/21

Ethics committee reference number
IR.SEMUMS.REC.1404.106

Health conditions studied

1

Description of health condition studied
kidney stones

ICD-10 code
N20.0

ICD-10 code description
Calculus of kidney

Primary outcomes

1

Description
blood pressure

Timepoint
From fifteen minutes before the start of the intervention to fifteen minutes after the end of the intervention

Method of measurement
A dial pressure gauge will be used to measure this variable, and then it will be recorded by the researcher in a researcher-made physiological index recording table.

2

Description
Arterial blood oxygen saturation

Timepoint
From fifteen minutes before the start of the intervention to fifteen minutes after the end of the intervention

Method of measurement
To measure this variable, a finger pulse oximetry device will be used, and after the measurement, the physiological data will be recorded by the researcher in a researcher-made table.

3

Description
pulse rate
Timepoint
From fifteen minutes before the start of the intervention to fifteen minutes after the end of the intervention
Method of measurement
To measure this variable, a finger pulse oximetry device will be used, and after the measurement, the physiological data will be recorded by the researcher in a researcher-made table.

Secondary outcomes

1

Description
body temperature
Timepoint
From fifteen minutes before the start of the intervention to fifteen minutes after the end of the intervention.
Method of measurement
A laser thermometer will be used to measure this variable, and after the measurement, the physiological data will be recorded by the researcher in a researcher-made table.

Intervention groups

1

Description
Intervention group: After obtaining the ethics code and IRCT code, the researcher will refer to Kowsar Hospital in Semnan and take a sample from all patients who meet the conditions for inclusion in the study. Also, initially, an informed consent form is obtained from the patients, and then a demographic information questionnaire is presented to the patients and completed. Out of a total of 100 samples in the project, 50 people will be classified in this group. After sampling and the presence of patients in the intervention group, the method will be explained in detail to the patient by the researcher. The intervention includes performing lithotripsy (about thirty minutes to an hour, depending on the doctor's opinion) and using virtual reality glasses for patients from the beginning to the end of the process. In this intervention, virtual reality glasses will be placed over the patient's eyes, and clips of nature and relaxing landscapes will be used to distract and calm the patient And patients are asked to imagine themselves in the space related to the displayed scenes. It is obvious that during the intervention, the patient hears completely in order to establish compliance with the treatment and there is no need to stop the intervention when the doctor and technician give instructions. In this intervention, patients' physiological indicators such as blood pressure, heart rate, arterial oxygen saturation, and body temperature will be measured in four stages. The first stage is the measurement of physiological indicators 15 minutes before the start of the intervention, at which point the distraction technique has not yet been used. Then, the necessary coordination will be made with the relevant doctor and technician to start the therapeutic intervention and perform the thought diversion technique through virtual reality glasses. This technique will be used throughout the entire lithotripsy process. Also, to ensure that the clients adapt to the aforementioned device, virtual reality glasses will be provided to the patients in the intervention group ten minutes before the start of the intervention. After applying this technique, in addition to the first stage described above, the clients' physiological needs will be measured and recorded in three other stages (15 minutes after the start of the intervention, the end of the intervention, and 15 minutes after the end of the intervention). The intervention will be carried out individually in the lithotripsy ward of Kowsar Hospital, and the aforementioned forms will be completed by the researcher, and the intervention will be carried out from 8:00 AM to 12:00 PM, depending on the presence of the technician and the relevant doctor. A sphygmomanometer will be used to measure physiological indicators, and a finger pulse oximetry device available in the ward will be used to measure heart rate and oxygen saturation.
Category
Rehabilitation

2

Description
Control group: After obtaining the code of ethics, the researcher will refer to Kowsar Hospital in Semnan and take a sample from all patients who meet the conditions for inclusion in the study. Also, an informed consent form will be obtained from the patients first, and then a demographic information questionnaire will be presented to the patients and completed. The control group will receive routine lithotripsy care, and blood pressure, heart rate, arterial oxygen saturation, and temperature will be measured and recorded in four stages, just like the intervention group, to compare the two groups. At the end of the interventions, the control group will be provided with a pamphlet containing information about their disease so that they can benefit scientifically from the present project. The intervention will be carried out individually in the lithotripsy ward of Kowsar Hospital, and the aforementioned forms will be completed by the researcher, and the intervention will be carried out from 8:00 AM to 12:00 PM, depending on the presence of the technician and the relevant doctor. A sphygmomanometer will be used to measure physiological indicators, and a finger pulse oximetry device available in the ward will be used to measure heart rate and oxygen saturation.
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Semnan University of Medical Science, Kausar Hospital

Full name of responsible person
Seyedmahyar peyman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Semnan University of Medical Sciences

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
Semnan University of Medical Sciences

Full name of responsible person
SeyedMahyar Peyman

Position
Nursing student

Latest degree
A Level or less

Other areas of specialty/work
Nursery

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Position
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Latest degree
A Level or less

Other areas of specialty/work
Nursery

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Latest degree
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Fax

Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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