Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Music Intervention Undergoing Dressing Changes: Its Effects on Children’s Pain and Anxiety

Protocol summary

Study aim
determine the effectiveness of music in reducing the pain and anxiety of thermally burned children during dressing changes
Design
A randomized control trial; of two parallel groups of children (control and study); was randomly selected total sample size of 80, with a blinded outcome assessment.
Settings and conduct
Specialized Burns Hospital in Baghdad city that provide a care for burns adults and pediatric patients, with a special room dressing for children. the both groups of the participant were blinded outcome assessment after exposure to music intervention.
Participants/Inclusion and exclusion criteria
children with school-age children both sex without hearing and cognitive impairment have burn surface area of less than 39% agree to participate
Intervention groups
children in the school-age group without previous burn injuries experience both sex have burn surface area of less than 39%
Main outcome variables
measuring children's responses during dressing changes in relation to pain and anxiety state

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231120060117N4**
Registration date: **2024-09-06, 1403/06/16**
Registration timing: **registered_while_recruiting**

Last update: **2024-09-06, 1403/06/16**
Update count: **0**
Registration date
2024-09-06, 1403/06/16

Registrant information
Name
Adraa Shawq
Name of organization / entity
University of Baghdad
Country
Iraq
Phone
+964 770 263 8811
Email address
adraa.hussein@conursing.uobaghdad.edu.iq

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-09-04, 1403/06/14
Expected recruitment end date
2024-12-04, 1403/09/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Music Intervention Undergoing Dressing Changes: Its Effects on Children’s Pain and Anxiety

Public title
Music Intervention for Reducing Children’s Pain and Anxiety During Dressing Changes
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
school-age children children with burn surface area were less than 39% accepted to participate in the study

Exclusion criteria:
children with hearing and cognitive impairments has a previous experience with burn injuries refuse to participate children with face burns

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Children are randomly divided into groups by using a simple random method, the researchers select a piece from a container with prepared papers containing the words control and intervene. Grouping the children will be done according to the paper selected.

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
Research Ethical Approval Committee at the College of Nursing

Street address
Bab AL-Muadum

City
Baghdad

Postal code
10001

Approval date
2024-06-25, 1403/04/05

Ethics committee reference number
280321PNS

Health conditions studied

1

Description of health condition studied
Daily dressing changes for burn injuries as a part of routine care, which is a painful procedure. Different degrees of pain intensity and anxiety are associated with individuals during dressing changes.

ICD-10 code
F41.9

ICD-10 code description
Anxiety disorder, unspecified

2

Description of health condition studied
Alternative methods for relieving pain and anxiety, which are based on psychological techniques without pharmacotherapy, can support analgesic action and achieve the desired goal of treatment

ICD-10 code
T25.0

ICD-10 code description
Burn of unspecified degree of ankle and foot

Primary outcomes

1

Description
decrease children's levels of pain after exposure to music listening

Timepoint
children who listen to music during daily dressing changes will measure their pain and anxiety every day for seven days

Method of measurement
objective pain scale for children, which was observed by the researchers after the dressing change, was used to assess their responses.

2

Description
decrease children's levels of anxiety levels before exposure to music listening

Timepoint
children who listen to music before and during daily dressing changes will measure their anxiety every day for seven days

Method of measurement
state anxiety trait inventory for children to describe their status before the procedure.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After identifying the children in the intervention group, they will listen to prepared music lists for 10 minutes before the dressing procedure. Then they have to describe their anxiety state according to the specific tool. the children were free to stay and listen to

music during the procedure. then after the dressing is finished their pain level will be measured.

Category

N/A

2

Description

Control group: After identifying the children in this group, they describe their anxiety state before the routine dressing procedure without music listening. then after the dressing is finished their pain level will be measured.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Specialized Burns Hospital

Full name of responsible person
Adraa Hussein Shawq

Street address
University of Baghdad

City
Baghdad

Postal code
00479

Phone
+964 770 263 8810

Email
adraa.hussein@conursing.uobaghdad.edu.iq

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
College of Nursing, University of Baghdad

Full name of responsible person
Professor Wissam Jabbar Qasim, PhD. Dean

Street address
Bab AL-Muadum

City
Baghdad

Postal code
10001

Phone
+964 781 427 5292

Email
adraa.hussein@conursing.uobaghdad.edu.iq

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
The author of the study is the funding source

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
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
College of Nursing, University of Baghdad

Full name of responsible person
Adraa Hussein Shawq

Position
associate professor

Latest degree
Ph.D.

Other areas of specialty/work
pediatric nursing

Street address
University of Baghdad

City
Baghdad

Province
Baghdad

Postal code
00479

Phone
+964 770 263 8810

Email
adraa.hussein@conursing.uobaghdad.edu.iq

Person responsible for scientific inquiries

Contact

Name of organization / entity
College of Nursing, University of Baghdad

Full name of responsible person
Adraa Hussein Shawq

Position
associate professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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College of Nursing, University of Baghdad

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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
Yes - There is 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
Yes - There is 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 researcher is acknowledging the scientific community to have verifiable findings of the study. The sharing plan includes making all the related data available through publishing the study report in peer-reviewed reputable journals.

When the data will become available and for how long
once the process of data collection, analysis, and analysis is complete successful publishing of the manuscript, all the related files will become available for 6 months after publication

To whom data/document is available
All the related files will be shared with any scientific interested parties.

Under which criteria data/document could be used
It may be used after seeking the author's permission.

From where data/document is obtainable
The author's professional e-mail will be available.

What processes are involved for a request to access data/document
N\A

Comments