

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

Effect of Iranian massage on the physical symptoms of post intensive care syndrome (PICS) in patients discharged from the respiratory intensive care unit

Protocol summary

Study aim

Effect of Iranian massage on the physical symptoms of post intensive care syndrome(PICS) in patients discharged from the respiratory intensive care unit

Design

Clinical trial with control group, single blind, randomized, on 74 patients. For randomization, Ede method with SPSS software will be used.

Settings and conduct

The place of the intervention (Iranian Delak massage) will be the respiratory department of Imam Khomeini, Sina and Shariati hospitals. One-way blinding will be applied to the statistical analyst.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. age between 18 and 65 years 2 .has been admitted for at least one week in intensive respiratory care unit and has received common treatment for intensive care units. 3. Intubation during ICU stay. 4.during the ICU stay , diagnosing one types of respiratory diseases such as COPD , corona ,ARDS ,pneumonia ,cystic fibrosis and asthma by the practitioner. 5. show at least two signs of physical symptoms of post intensive care syndrome (pain ,muscle weakness ,impairment in daily activities ,dyspnea).
Exclusion criteria: 1. Suffering from an underlying disease of the neuromuscular system (neurological symptoms in the limbs, suffering from diabetic neuropathy and a history of lumbar and cervical disc herniation) 2. Epilepsy 3. Pregnancy 4. Suffering from hemophilia 5. History of diagnosed psychological diseases

Intervention groups

The intervention in the Iranian Dalk massage test group is of the talent Dalk type, which takes place in four consecutive sessions daily for thirty minutes each time. In the control group, routine ward care will be performed.

Main outcome variables

Pain, muscle weakness, ability to perform daily activities independently, shortness of breath

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191027045257N2**

Registration date: **2022-10-08, 1401/07/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-08, 1401/07/16**

Update count: **0**

Registration date

2022-10-08, 1401/07/16

Registrant information

Name

Pegah Matourypour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4126

Email address

matourypour@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of Iranian massage on the physical symptoms of post intensive care syndrome (PICS) in patients discharged from the respiratory intensive care unit

Public title
The effect of massage on physical symptoms after discharge from the intensive care unit

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
1. Age between 18 to 65 years 2. Has been hospitalized in the respiratory intensive care unit for at least one week and has received the usual treatments in the intensive care unit. 3. Intubation of the patient during ICU hospitalization 4. The diagnosis of one of the types of respiratory diseases such as COPD, improved covid19 patients, ARDS, pneumonia, cystic fibrosis and asthma is made by the treating physician. 5. Show at least two signs of the physical symptoms of the post intensive care syndrome (pain, muscle weakness, disturbance in daily activities of life, dyspnea)
Exclusion criteria:
1. Underlying disease of the musculoskeletal system (neurological symptoms in the limbs, diabetic neuropathy and a history of hernia and lumbar and cervical disc) Epilepsy pregnancy hemophilia History of diagnosed mental illness

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
The present study will be a two-group randomized clinical trial in which the effect of Iranian Dalk massage on the physical symptoms of the post intensive care syndrome will be investigated. 74 patients who were admitted to the respiratory intensive care unit (37 in the control group, 37 in the intervention group) and were transferred to the respiratory ward, who had at least two signs of physical symptoms of the post intensive care syndrome and based on Inclusion criteria will be included in the study. Random allocation will be done, by writing "control group" and "Intervention Group" on cards and we request patients who has inclusion criteria to pick one card from dish to know in which group should go (cards do not replace in dish).

Blinding (investigator's opinion)

Single blinded

Blinding description
By coding the intervention and control group

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in the Research Institute of the Faculty of Nursing and Midwifery and the Faculty o

Street address

Tohid sq, Dr Mirkhani st

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2022-01-13, 1400/10/23

Ethics committee reference number

IR.TUMS.FNM.REC.1400.180

Health conditions studied

1

Description of health condition studied

respiratory diseases

ICD-10 code

R06. 03

ICD-10 code description

R06. 03

Primary outcomes

1

Description

Pain, muscle weakness, ability to perform activity of daily living

Timepoint

Before the intervention, immediately after the intervention and one month after the intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

Dyspnea

Timepoint

Before the intervention, immediately after the intervention, one month after the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Doing Iranian Dalk massage for 30 minutes for four consecutive days , in addition to the routine care of the ward.

Category

Prevention

2

Description

Control group: They will receive the usual care of the ward.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

Seyyed Ali menshadi

Street address

Dr Gharib st, Keshavarz Blvd, Tehran town

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Web page address

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2

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Ahmadreza jamshidi

Street address

Shariati Hospital, Jalal Al Ahmad Street, North Kargar St., Tehran town

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Web page address

<http://shariati.tums.ac.ir/>

3

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Mohammad taleb pour

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Sina hospital, Imam Khomeini St., Hassan Abad Square, Tehran town

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<https://sinahospital.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Deputy of research and technology, Tehran University of Medical Sciences

Street address

6th floor of Research and Technology Vice-Chancellor., Central Organization of the University, corner of Quds St,Keshavarz Blvd. Tehran Town

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vcr@tums.ac.ir

Web page address

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
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Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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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