

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of electronic education of clinical management of substance dependent pregnant women during labor and postpartum on knowledge and clinical skill performance of midwives

Protocol summary

Study aim

comparison the mean score of knowledge and clinical performance of midwives before, immediately and one month after the end of the e-education of clinical management of substance dependent pregnant women during labor and postpartum in intervention and control group

Design

Experimental parallel group randomized study with intervention and control group

Settings and conduct

Sampling from midwives working in delivery rooms and dividing them into control and intervention groups using permuted block randomization. First, knowledge and clinical performance assessment in control group, 3 weeks later, doing posttest and one month later doing retention test. Simultaneously with retention tests in control group, doing pretest in the intervention group. Then starting the e-learning education during 3 weeks via LMS. Doing posttest and retention test, immediately after intervention and one month after that

Participants/Inclusion and exclusion criteria

Inclusion criteria: BSc in midwifery, work in Maternity Hospitals, Researcher access to samples, complete informed consent form, Having Internet access, Have at least information for work with computer, No participation in training courses related with research title before. Exclusion criteria: Unwillingness to continue study, Participate in other classes related to research during the study, Failure to complete one content of e-learning

Intervention groups

Participation in 1 hour training session and nine 40 minute e-learning sessions for 3 weeks in intervention group. Answering to 15 to 20 multiple choice questions to better understand the content at the end of each training session. Doing pretest, posttest and retention test of

knowledge and clinical performance, Before, immediately after intervention and one month after

Main outcome variables

Improvement of knowledge and clinical performance in clinical management of substance-dependent pregnant women during labor and postpartum

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180928041164N1**

Registration date: **2018-11-13, 1397/08/22**

Registration timing: **prospective**

Last update: **2018-11-13, 1397/08/22**

Update count: **0**

Registration date

2018-11-13, 1397/08/22

Registrant information

Name

hasti heidarian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3271 8170

Email address

stud3240914115@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of electronic education of clinical management of substance dependent pregnant women during labor and postpartum on knowledge and clinical skill performance of midwives

Public title
Effect of electronic education of clinical management pregnant women during labor and postpartum on knowledge and clinical performance

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Having at least BSc degree in midwifery Employment in Governmental Maternity Hospitals Affiliated to Shiraz University of Medical Sciences in Shiraz. Researcher access to samples during the study period (For example, not having the intent of samples for unpaid or long-term leave). Satisfaction to participate in the study and complete the informed written consent form Having Internet access. Have at least information for working with the computer to enter LMS. Not participation in training courses associated with research title before starting the research.
Exclusion criteria:
Unwillingness to continue to participate in research Participate in other classes related to research title during the study period Failure to study at least one of the content of e-learning in this study

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Random units are midwives, and the method is based on permuted random allocation. Using random block method and block size 4, and using the Random Allocation software has been developed by M. Saghaei) With a block size of four and twenty- five blocks (A total of 100 samples) A random list is generated And based on that list, Quadrilateral Blocks Combined, ABBA, BAAB, BABA, ABAB, BBAA, AABB Are produced And based on the combination obtained from 25 blocks. Accordingly, midwives are assigned to the intervention and control group

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In this study, in order to prevent the information leakage from the intervention group to the control group and not to alter the results of the study, at first, the pre-test and post-test of knowledge and clinical skills will be done in the control group, one month after posttest, knowledge and clinical retention test will be done and simultaneously with retention test in the control group, the pre-test will be performed in the intervention group and will be subjected to e-learning. Immediately after completing e-learning and one month after that, a post-test and retention test of knowledge and clinical skills will be taken from the intervention group. At the end of the study, the educational content is also available to the control group. Additionally, midwives who have completed the course with completion of the pre-test and post-test, and have at least a retraining score, will be awarded a Continuous Medical Education (CME).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethic committee of Shiraz University of Medical Sciences

Street address

Flat 7, Shiraz University of Medical Sciences Building, Zand Blv.

City

Shiraz

Province

Fars

Postal code

7193613119

Approval date

2018-09-12, 1397/06/21

Ethics committee reference number

IR.SUMS.REC.1397.510

Health conditions studied

1

Description of health condition studied

Clinical management of substance dependent pregnant women during labor and postpartum

ICD-10 code

O99.3

ICD-10 code description

Mental disorders and diseases of the nervous system complicating pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Midwives Knowledge regarding Clinical management of substance dependent mothers during labor and post-partum period

Timepoint

Before the intervention, immediately after the end of the intervention

Method of measurement

A researcher-made questionnaire for measuring knowledge has 38 multiple choice questions

2

Description

Midwives clinical performance on Clinical management of substance dependent mothers during labor and post-partum period

Timepoint

Before the intervention, immediately after the end of the intervention

Method of measurement

Objective Structured Clinical Exam (OSCE), made up of 5 stations

Secondary outcomes

1

Description

Knowledge Retention regarding on Clinical management of substance dependent mothers during labor and post-partum period

Timepoint

One month after intervention

Method of measurement

Researcher made questionnaire for knowledge assessment with 38 multiple choice questions

2

Description

Clinical performance Retention regarding Clinical management of substance dependent mothers during labor and post-partum period

Timepoint

One month after intervention

Method of measurement

Researcher made questionnaire for knowledge assessment with 38 multiple choice questions

Intervention groups

1

Description

Intervention group: At first, a pre-test of knowledge and clinical performance will be performed from the intervention group, Then, the user code and password are provided for the samples to enter the Learning Management System (LMS). The intervention group will be trained for 3 weeks by 1 session of 1hour face to face and nine 40-minutes sessions of e-learning.

Category

Other

2

Description

Control group: In the control group, without any intervention, three timed knowledge questionnaire and clinical performance using OSCE will be done.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Delivery room of Hazrat Zeynab Hospital in Shiraz

Full name of responsible person

Hasti Heidarain

Street address

Defa moghadas Crossroad

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Province

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Phone

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Email

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2

Recruitment center

Name of recruitment center

Delivery room of Hafez Hospital in Shiraz

Full name of responsible person

Hasti Heidarain

Street address

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City

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Province

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34786-71946

Phone

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Email

hafezhospt@sums.ac.ir

3

Recruitment center

Name of recruitment center

Delivery room of Shoushtari Mother and Child
Hospital in Shiraz

Full name of responsible person

Hasti Heidarain

Street address

Nader ave

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4

Recruitment center

Name of recruitment center

Delivery room of Shahid Beheshti Hospital in Shiraz

Full name of responsible person

Hasti Heidarain

Street address

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7136816695

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shoushtari@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

Street address

Flat 7, research deputy, Shiraz University of Medical
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vcrdep@sums.ac.ir

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Hasti Heidarian

Position

Msc student in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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School of Nursing and Midwifery Shiraz, Namazi
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Phone

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hastiheidarian@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Roksana Janghorban

Position

Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hasti Heidarian
Position
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Latest degree
Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
there is not more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available