

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The Effect of a Nurse-Led Educational Intervention on Health Literacy of Patients Who are Medically Diagnosed With Heart Failure

Protocol summary

Study aim

To examine the effectiveness of an intervention program in enhancing heart failure-specific health literacy among patients with heart failure.

Design

A quasi-experimental design was employed to achieve the aforementioned objectives. 64 subjects will be assigned to join the study group. The rest will be in the control group. The total sample size would be 128 subjects.

Settings and conduct

A 128 heart failure patients, who were visiting outpatient clinic in 3 major teaching hospitals at Maysan City. Study subjects were recruited when they were seeking the follow-up of their health problems and prescriptions refilling. The simple randomization procedure would involve throwing a dice (eg, below & equal to 3 = control, over 3 = treatment). No allocation concealment will be carried out.

Participants/Inclusion and exclusion criteria

Inclusion: *Consent & compliance with all aspects of the study protocol, methods, providing data during follow-up phase.*Contact male & female patients, who are 18-70 years old at the time of data collection phase
Exclusion:*Involvement with any other ongoing studies.
*Medically diagnosed with psycho-mental diseases
*Morbidly ill subjects, whereas their physical & mental capacity are impaired

Intervention groups

Intervention group: The starting point of the intervention phase will start by asking the subjects to respond to "Heart Failure Specific Health Literacy scale" (Linköping University, 2016). This mandatory step will help in categorizing the subjects according to their health literacy level. Intervention group subjects will be armed with orally & in a written form of simple, yet specific instructions to enable them managing their health literacy. The intervention group will be contacted after 14 days to see the influence of the given instruction on

their health literacy level status.

Main outcome variables

Improvement of health literacy level

General information

Reason for update

Acronym

Improving health literacy trial (IHLT)

IRCT registration information

IRCT registration number: **IRCT20220924056029N1**

Registration date: **2023-01-15, 1401/10/25**

Registration timing: **retrospective**

Last update: **2023-01-15, 1401/10/25**

Update count: **0**

Registration date

2023-01-15, 1401/10/25

Registrant information

Name

Sarah Hassan

Name of organization / entity

University of Baghdad college of Nursing

Country

Iraq

Phone

+964 781 216 2020

Email address

sarra.falaah1102b@conursing.uobaghdad.edu.iq

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-09, 1400/12/18

Expected recruitment end date

2022-11-17, 1401/08/26

Actual recruitment start date

2022-07-31, 1401/05/09
Actual recruitment end date
2022-11-17, 1401/08/26
Trial completion date
2022-11-17, 1401/08/26

Scientific title
The Effect of a Nurse-Led Educational Intervention on Health Literacy of Patients Who are Medically Diagnosed With Heart Failure

Public title
Intervention program for patient with Heart Failure Specific Health Literacy

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Consent & compliance with all aspects of the study protocol, methods, providing data during follow-up phase
Contact male & female patients, who are 18-70 years old at the time of data collection phase

Exclusion criteria:
Involvement with any other ongoing studies. Medically diagnosed with psycho-mental diseases Morbidly ill subjects, whereas their physical & mental capacity are impaired

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **128**
Actual sample size reached: **128**

Randomization (investigator's opinion)
Not randomized

Randomization description
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
2022-07-29, 1401/05/07

Ethics committee reference number
2395

Health conditions studied

1

Description of health condition studied
Heart Failure Specific Health Literacy

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Improvement of Health literacy level

Timepoint
Subjects response to the educational intervention will be within two weeks of the first meeting to examine the effectiveness of the intervention on health literacy level

Method of measurement
Self-report of health literacy level after being exposed to the intervention program

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The starting point of the intervention phase will start by asking the subjects to respond to Heart failure specific health literacy scale (linkopingsUniversity,2016). This mandatory step will help in categorizing the subjects according to their smoking trigger. Intervention group subjects will be armed with orally & in a written form of simple, yet specific instructions to enable them managing their dominant smoking trigger. The intervention group will be contacted after 14 days to see the influence of the given instruction on their smoking status.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center

The outpatient clinic of the AL Sadar Teaching Hospital , Maysan Center for Heart Disease and Surger

Full name of responsible person

Sarah F.Hassan

Street address

Bab AL-Muadum

City

Baghdad

Postal code

10001

Phone**Email**

Sarra.Falaah1102b@conursing.uobaghdad.edu.iq

Full name of responsible person

Sarah F.Hassan

Position

PH.Dc

Latest degree

Master

Other areas of specialty/work

Nursing

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Phone

0098478012162020

Email

Sarra.Falaah1102b@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 Huda Baqer, PhD. Dean

Street address

Bab AL-Muadum

City

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Postal code

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Phone

+964 1 521 1494

Email

s.al-fayyadh@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 trial 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**

Other

Person responsible for general inquiries

Contact

Name of organization / entity

University of Baghdad, College of Nursing

Person responsible for scientific inquiries

Contact

Name of organization / entity

University of Baghdad, College of Nursing

Full name of responsible person

Sadeq AL-Fayyadh

Position

Faculty member-An Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursing

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Person responsible for updating data

Contact

Name of organization / entity

University of Baghdad, College of Nursing

Full name of responsible person

Sarah F.Hassan

Position

PH.Dc

Latest degree

Master

Other areas of specialty/work

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009847812162020

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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

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

The researcher is acknowledging the scientific community to have verifiable findings of the study. 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

God willing, once finishing the process of data collection, analysis and successfully publishing the manuscript, all the related files will become available for 6 months after publications

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 and acknowledging his contribution.

From where data/document is obtainable

The author's professional e-mail that will be available with the published manuscript can be used to contact the author. e-Mail: s.al-fayyadh@conursing.uobaghdad.edu.iq

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

N/A

Comments

Profound appreciations are due to the IRCT members for their genuine efforts in helping researchers fulfilling their academic endeavors