Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 " (linkopings 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 litrecy 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

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
Baghdad

Postal code
10001

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

Full name of responsible person
Sarah F.Hassan

Position
PH.Dc

Latest degree
Master

Other areas of specialty/work
Nursing

Street address
Bab AL-Muadum

City
Baghdad

Province
Baghdad

Postal code
10001

Phone
0098478012162020

Email
Sarra.Falaah1102b@conursing.uobaghdad.edu.iq

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

Street address
Baghdad

City
Baghdad

Province
Baghdad

Postal code
10001

Phone
+964 1 521 1494

Email
s.al-fayyadh@conursing.uobaghdad.edu.iq

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
Nursing

Street address

Bab AL-Muadum
City
Baghdad
Province
Baghdad
Postal code
10001
Phone
009847812162020
Email
Sarra.Falaah1102b@conursing.uobaghdad.edu.iq

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