Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

The effect of virtual education on self-efficacy and sense of coherence in health care carers in Khatam Alanbia Tehran hospital in 2018

Protocol summary

Study aim
The effect of virtual education on self-efficacy and sense of coherence in health care carers in Khatam Alanbia Tehran hospital in 2018

Design
Randomized clinical trial with control group, with parallel groups, one blinded.

Settings and conduct
The present study will be conducted at Khatam Al-Anbiya Hospital in Tehran and on the carers of cancer patients admitted. The data analyzer will not know how to allocate place in the control and intervention group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The willingness to participate in the study, having a age range of 17 to 70 years old Exclusion criteria: Unwillingness to continue cooperation in the study

Intervention groups
For samples of the intervention group, after installing the Soroush application on a mobile patient care , for one month and on a daily basis, all necessary education in the care of cancer patients in various fields of medicine, nutrition, Psychological needs, etc., and all necessary education in controlling, creating and strengthening the sense of coherence and self-efficacy are organized into categories, and the volume of the same content will be presented at the beginning of each day. Control samples will receive routine services without changing any routine conditions for caregivers.

Main outcome variables
Sense of coherence Self efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180828040891N2**
Registration date: **2018-09-30, 1397/07/08**
Registration timing: **retrospective**

Last update: **2018-09-30, 1397/07/08**
Update count: **0**

Registration date
2018-09-30, 1397/07/08

Registrant information

Name
neda fayazi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 4234 3395

Email address
n.fayazi@savehums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-01, 1397/05/10

Expected recruitment end date
2018-09-01, 1397/06/10

Actual recruitment start date
2018-08-01, 1397/05/10

Actual recruitment end date
2018-09-01, 1397/06/10

Trial completion date
2018-09-01, 1397/06/10

Scientific title
The effect of virtual education on self-efficacy and sense of coherence in health care carers in Khatam Alanbia Tehran hospital in 2018

Public title
Virtual education on self-efficacy and sense of coherence in caregivers of patients with cancer

Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
The willingness to collaborate in the study Having a range of 17 to 70 years old
Exclusion criteria:
Unwillingness to continue cooperation in the study
Age
From **17 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
The data analyzer will not know how to place the samples in the intervention and control group.
Placebo
Not used
Assignment
Parallel
Other design features
Samples were randomly assigned to two intervention and control groups using randomized block assignment.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Saveh University of Medical Sciences
Street address
Saveh University of Medical Sciences, Jomhouri Street.
City
Saveh
Province
Markazi
Postal code
3915953983
Approval date
2018-07-23, 1397/05/01
Ethics committee reference number
IR.SAVEHUMS.REC.1397.016

Health conditions studied

1

Description of health condition studied
Self efficacy
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Sense of coherence
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sense of coherence
Timepoint
Before the study and one month after the first day of intervention
Method of measurement
Antonovsky's Standard Questionnaire

2

Description
Self efficacy
Timepoint
Before the study and one month after the first day of intervention
Method of measurement
Bandura Standard Autoimmunity Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group": From the first day after installing Soroush's application on Mobile Caregivers of Cancer Patients, interventions, which include training on increasing the sense of coherence and self-efficacy of caregivers, are transmitted on a daily basis for one month by sending educational files Soroush's Patient Care Wear is done on the app.
Category
Lifestyle

2

Description
Control group: "Control group": Only received routine care and training, and no additional training or

intervention was provided.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam Alanbia Tehran hospital

Full name of responsible person
Homa Fayazi

Street address
Zafar street, Khatam Alanbia Tehran hospital

City
Tehran

Province
Tehran

Postal code
3915953983

Phone
+98 21 8670 5503

Email
nedafayazi10@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Saveh University of Medical Sciences

Full name of responsible person
Hamid Reza Baradaran

Street address
Saveh University of Medical Sciences, Jomhouri Street

City
Saveh

Province
Markazi

Postal code
3915953983

Phone
+98 86 4234 3395

Email
nedafayazi10@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Saveh 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
Saveh University of Medical Sciences

Full name of responsible person
Neda Fayazi

Position
Instructor, Member of faculty

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Jomhouri Street, Saveh University of Medical Sciences

City
Saveh

Province
Markazi

Postal code
3915953983

Phone
+98 86 4234 3395

Email
nedafayazi10@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Saveh University of Medical Sciences

Full name of responsible person
Neda Fayazi

Position
Instructor- member of faculty

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Saveh University of Medical Sciences, Jomhouri Street

City
Saveh

Province
Markazi

Postal code
3915953983

Phone
+98 86 4234 3395

Email
nedafayazi10@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Saveh University of Medical Sciences

Full name of responsible person
Neda Fayazi
Position
Instructor - member of Faculty
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Saveh University of Medical Sciences, Jomhouri Street
City
Saveh
Province
Markazi
Postal code
3915953983
Phone
+98 86 4234 3395
Email
nedafayazi10@yahoo.com

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
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Part of the data, such as information on the main outcome and the demographic information, can be shared after unidentifiable people.
When the data will become available and for how long
The start of the data access period is 12 months after the results are printed.
To whom data/document is available
For all researchers
Under which criteria data/document could be used
In order to utilize scientific purposes and mention the resources used
From where data/document is obtainable
Neda Fayazi nedafayazi10@yahoo.com
What processes are involved for a request to access data/document
After receiving the email from the requestor, the information will be sent within 4 to 5 business days.
Comments