Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Effect of Supportive Educational Intervention through virtual social networks on the sleep of cancer patients

Protocol summary

Study aim
The effect of supportive-educational intervention through virtual networks on sleep of cancer patients
Design
Randomized clinical trial with control group, randomization by blocking method and block selection based on random number table
Settings and conduct
The participants were recruited from Ayatollah Khansari Hospital. The intervention group received supportive training messages on sleep through a virtual social network. The messages, including explanations about insomnia management, sleep quality, and strategies to improve sleep quality were sent to the intervention group in two to three text messages with related pictures and videos every day for one month. The control group received routine care. Immediately and one month after the intervention, participants were asked to complete the questionnaires again.
Participants/Inclusion and exclusion criteria
Inclusion criteria:Age range between 25-65 years, diagnosis of Gastrointestinal cancer, undergoing chemotherapy, cancer awareness, reading and writing ability, absence of mental illnesses and underlying diseases causing sleep disorder, no drug addiction and getting a higher than average score in the Pittsburgh Sleep Quality Questionnaire and one of the two questionnaires of Insomnia Intensity Index and Epworth sleepiness Scale. Exclusion criteria: Unwillingness to participate in the study
Intervention groups
The intervention group received supportive training messages on sleep through a virtual social network. The messages were sent to the intervention group in two to three text messages with related pictures and audio and video files every day for one month. To ensure that educational content was understood, the participants were asked two to three questions at the end of each week. The participants' questions were also answered.
The control group received routine care.
Main outcome variables
Sleep quality; Insomnia; Sleepiness

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220528055007N1**
Registration date: **2022-08-31, 1401/06/09**
Registration timing: **retrospective**

Last update: **2022-08-31, 1401/06/09**
Update count: **0**
Registration date
2022-08-31, 1401/06/09

Registrant information
Name
Elahe Sarlak
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 66 4333 5104
Email address
sarlakelahe41@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-08-01, 1398/05/10
Expected recruitment end date
2019-10-02, 1398/07/10
Actual recruitment start date
2019-08-16, 1398/05/25
Actual recruitment end date

2019-11-18, 1398/08/27

Trial completion date

2020-01-25, 1398/11/05

Scientific title

Effect of Supportive Educational Intervention through virtual social networks on the sleep of cancer patients

Public title

Effect of education and virtual support on sleep in cancer

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The age range between 25-65 years Definitive diagnosis of GIC (esophagus, stomach, liver, pancreas, and colorectal) Chemotherapy treatment Cancer awareness Smartphone availability Reading and writing ability Absence of mental illnesses and underlying diseases causing sleep No drug addiction Getting a higher than average score in the Pittsburgh Sleep Quality Questionnaire and one of the two questionnaires of Insomnia Severity Index and Epworth Sleepiness Scale

Exclusion criteria:

Unwillingness to participate in the study

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Formulas for determining the sample size are a minimum criterion, and the number of samples in each group can be increased depending on the project feasibility without imposing more cost on the study. Thus, in this study, we decided to add seven samples in each group to the specified minimum number of samples, which is not a problem in terms of methodology. Sampling was performed when patients were referred to the hospital for chemotherapy. Then the samples were randomly divided into two groups of 40 with random allocation in the intervention (A) and control (B) groups. First, the Quadruple blocks were defined as follows: ABAB, BBAA, BABA, BAAB, AABB, ABBA, etc., and were placed in an envelope and numbered, and the blocks were determined using a table of random numbers, and the individuals in terms of A and B They were divided into intervention and control groups. Patient A was in the supportive educational intervention group through Soroush virtual social network and patient B was in the control group.

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

Ethics committee of Arak University of Medical Sciences

Street address

Basij Sq, Payambar Azam University Complex, Arak University of Medical Sciences, Blue Wing, Third Floor, School of Nursing, Arak, Iran Country: Iran

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2019-07-28, 1398/05/06

Ethics committee reference number

IR.ARAKMU.REC.1398.116

Health conditions studied

1

Description of health condition studied

Insomnia

ICD-10 code

G47.0

ICD-10 code description

Disorders of initiating and maintaining sleep [insomnias]

2

Description of health condition studied

Sleepiness

ICD-10 code

G47.2

ICD-10 code description

Delayed sleep phase syndrome .Irregular sleep-wake pattern

3

Description of health condition studied

Sleep quality

ICD-10 code

G47.2

ICD-10 code description

Delayed sleep phase syndrome. Irregular sleep-wake

pattern

Primary outcomes

1

Description
Sleep quality score in the Pittsburgh Sleep Quality Questionnaire
Timepoint
At the beginning of the study (before the intervention) and immediately and one month after the supportive educational intervention
Method of measurement
Pittsburgh Sleep Quality Index questionnaire

2

Description
Insomnia severity score in Insomnia severity questionnaire
Timepoint
At the beginning of the study (before the intervention) and immediately and one month after the supportive educational intervention
Method of measurement
Insomnia Severity Index Questionnaire

3

Description
Sleepiness score in the sleepiness Questionnaire
Timepoint
At the beginning of the study (before the intervention) and immediately and one month after the supportive educational intervention
Method of measurement
Eoworth sleepiness Scale Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the intervention group were contacted through a virtual social network allowing users to send and receive texts, photos, videos, and audio. The intervention group received supportive training messages on sleep in addition to routine care. The content of the messages was developed as a protocol based on the latest investigations and textbooks on cancer nursing and supportive care and was approved by the oncology department. The messages, including explanations about insomnia management, sleep quality, and strategies to improve sleep quality (sleep health, nutritional advice, place and time of sleep, relaxation techniques, and stress and anxiety management), were sent to the intervention group in two to three text messages with related pictures and audio and video files (8 am to 8 pm) every day for one month. The participants were asked to send the message "the message was read" to the researcher. If the message were not read for more than 24 hours, a reminder message would be sent. To ensure that educational content was understood, the participants were asked two to three questions at the end of each week to obtain feedback. The participants' questions were also answered. After finishing the intervention, the participants were asked to review the sent messages and report their sleep quality for one month. To support the participants, they were constantly monitored and encouraged to perform training.
Category
Other

2

Description
Control group: The control group received routine care.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Khansari Hospital in Arak
Full name of responsible person
Dr. Jamshid Ansari
Street address
The end of University Street., Arak
City
Arak
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Markazi
Postal code
3818649433
Phone
+98 86 3367 5007
Email
jamshidsa@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Alireza Kamali
Street address
Deputy of research and technology., Payambar Azam University Complex., Arak University of Medical Sciences., Arak Town
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Province

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3848176341

Phone
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Email
alikamaliir@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Elahe Sarlak

Position
nurse

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
School of Nursing., Third Floor., Blue Wing., Arak University of Medical Sciences., Payambar Azam University Complex., Basij sq., Arak Town

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Elahe Sarlak

Position
nurse

Latest degree
Master

Other areas of specialty/work
Nursery

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sarlakelahe41@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Elahe Sarlak

Position
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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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can potentially be shared after unidentifiable individuals and also information about the main implications.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Researchers working in academic institutions can submit requests for unidentified personal data or other documents.

From where data/document is obtainable

To receive the data, send an email to the responsible author, Dr. Nazi Nejat. N.nejat@arakmu.ac.ir

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

After receiving the email, the data will be sent within one working week.

Comments