Clinical Trial Protocol
Iranian Registry of Clinical Trials
10 Jul 2023

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
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, BAAAB, 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
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The end of University Street., Arak
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3818649433
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Email
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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
City
Arak
Province
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
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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

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

Person responsible for scientific 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
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Person responsible for updating data

Contact
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Elahe Sarlak
Position
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Latest degree
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Other areas of specialty/work
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Email
sarlakelahe41@gmail.com
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**