Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Exploring the effects of Guided Imagery on Gastrointestinal complications and Quality of Life in Cancer patients undergoing Chemotherapy

Protocol summary

Study aim
Mental Health Interventions and Services will be studied on the side effects of Chemotherapy

Design
Control group clinical trial; With a randomized parallel group on 70 cancer patients

Settings and conduct
The field of study on cancer will be the research site of Baqiyatallah Hospital Participants will be divided into experimental and control groups The test group will be trained and given a guided audio file The nausea and vomiting questionnaire will be completed before and after chemotherapy Filling in the quality of life questionnaire pre-intervention and two months after the training will be done by two groups

Participants/Inclusion and exclusion criteria
Age above 18 and under 65 years; Minimum education level ; Willingness to participate in research ;nausea and vomiting experience in chemotherapy; not use nausea and vomiting medications other than routine And not using complementary medicines such as ginger; Failure to perform radiotherapy simultaneously with chemotherapy; No hearing disorders ; No history of gastrointestinal surgery; No history of gastrointestinal cancer; No history of mental disorder; No member in the health care team; Has not taken psychological skills training courses such as relaxation; And at least one course of chemotherapy is left after enrollment and is left at least one course of chemotherapy.

Intervention groups
The intervention group will be given a guided image during one hour of training and then during chemotherapy will hear the audio file guided by handsfree; to examine its effect on nausea and vomiting and quality of life ؛ in the control group to use handsfree only to prevent Listening to ambient noise will be done without listening to the audio file

Main outcome variables
frequency of Vomiting and Nausea, Quality of Life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200710048073N1**
Registration date: **2021-02-27, 1399/12/09**
Registration timing: **prospective**

Last update: **2021-02-27, 1399/12/09**
Update count: **0**

Registration date
2021-02-27, 1399/12/09

Registrant information

Name
Zahra Fereidouni Maman

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4442 9249

Email address
zfreidon50@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-28, 1399/12/10

Expected recruitment end date
2021-06-20, 1400/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Exploring the effects of Guided Imagery on Gastrointestinal complications and Quality of Life in Cancer patients undergoing Chemotherapy

Public title
The effect of Guided Imagery on Nausea and Vomiting and Quality of Life in Cancer Chemotherapy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age above 18 years and under 65 years Minimum Education Level Willingness to participate in research Nausea and Vomiting experience during the Chemotherapy At least one session of Chemotherapy is performed and at least one course of Chemotherapy has left after enrollment

Exclusion criteria:
Use of Nausea and Vomiting Medications other than routine and use of Complementary Medications such as Ginger Gastrointestinal Cancer Performing Radiotherapy simultaneously with Chemotherapy Hearing disorders History of Gastrointestinal Surgery Gastrointestinal Cancer History of mental disorder The participant is a member of the Healthcare team Have taken psychological skills training courses such as relaxation

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Considering that the research will be a clinical trial, it consists of two conditions; namely the intervention and random allocation. As a result, the sampling method is firstly based on the criteria of entering the target sampling method and then random allocation with quadruple blocks will be performed in two groups of intervention and control. The random characteristic method with quadratic blocks includes assignments of the intervention group A and to the observation group B. Six conditions of AABB، BBAA، ABAB، BABA، ABBA، BAAB, will be written separately and then will be thrown inside the container. One piece of paper will be randomly removed from the container, followed by writing down the condition. Then, the paper will be taken back into the container. Driven by the sample size, which is 70 patients, this operation will be repeated 15 times. Each time, the condition will be written in order. Each letter is allocated to a number from one to seventy. Each letter is placed in a matte envelope and numbers 1 to 70 are written on the envelope. Each time the disease is selected, one of these envelopes will be opened following the order written on the envelope and will be specified in the group in which the patient should be placed.

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 Baqiyatallah University

Street address
Baqiyatallah University of Medical Sciences, Sheikh Baha'i St., Mulla Sadra St., Vanak, Tehran

City
Tehran

Province
Tehran

Postal code
1435915371

Approval date
2020-11-22, 1399/09/02

Ethics committee reference number
IR.BMSU.REC.1399.462

Health conditions studied

1

Description of health condition studied
Chemotherapy-induced Nausea and Vomiting in Cancer

ICD-10 code
C00-D49

ICD-10 code description
Neoplasms of unspecified behavior

2

Description of health condition studied
Quality of Life in Cancer patients undergoing Chemotherapy

ICD-10 code
C00-D49

ICD-10 code description
Neoplasms of unspecified behavior

Primary outcomes

1

Description
Nausea and Vomiting

Timepoint

Pre-intervention، post-intervention and two months after the intervention

Method of measurement

Nausea and Vomiting Questionnaire (The Multinational Association of Supportive Care in Cancer

2

Description

Quality of Life

Timepoint

Pre-intervention and two months after the intervention

Method of measurement

Quality of Life Questionnaire - (European Organization for Research and Treatment of Cancer)

Secondary outcomes

1

Description

Nausea and Vomiting

Timepoint

Pre-intervention and after Chemotherapy and two months after the intervention

Method of measurement

Questionnaire Antiemesis Tool- The Multinational Association of Supportive Care in Cancer -

2

Description

Quality of Life

Timepoint

Pre-intervention and two months after the intervention

Method of measurement

Quality of Life Questionnaire - (European Organization for Research and Treatment of Cancer)

Intervention groups

1

Description

The intervention group will be given a Guided Imagery instruction by the researcher during one hour, then the audio file prepared by the researcher will be provided to the intervention group via WhatsApp to listen during Chemotherapy with handsfree. Approximate time to hear the audio file is about 20 minutes. Then people will be asked to listen to an audio file once a day for two months after this Chemotherapy.

Category

Rehabilitation

2

Description

The control group will be prevented from hearing environmental noise, by placing handsfree in their ears. On the other hand, they will not receive the audio file of the intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Zahra Fereidouni Maman

Street address

Sheikh Baha'i Street ، Mulla Sadra Street,

City

Tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 81261

Email

zfreidon50@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Alishiri Gholam Hossein

Street address

Sheikh Baha'i St., Mulla Sadra St., Vanak

City

Tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 8755 5250

Email

b.nehrir@bmsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Khamseh Feryal
Position
MS in Nursing
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Baqiyatallah University of Medical Sciences - Sheikh Baha'i St. - Mulla Sadra St. - Vanak
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 8755 5491
Fax
Email
khamseh_110@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Batool Nehrir
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Baqiyatallah University of Medical Sciences - Sheikh Baha'i St. - Mulla Sadra St. - Vanak
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 8755 5491
Email
rnehrir1739@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Zahra Fereidouni Maman
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
No. 18;Gulberg St., Park St, Hamila Blvd;Pounak
City
Tehran
Province
Tehran
Postal code
1469697413
Phone
+98 21 4442 9249
Email
zfreidon50@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available