

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 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

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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		Blinding (investigator's opinion) Not blinded	
Public title The effect of Guided Imagery on Nausea and Vomiting and Quality of Life in Cancer Chemotherapy		Blinding description Placebo Not used	
Purpose Supportive		Assignment Parallel	
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		Other design features	
Age From 18 years old to 65 years old		Secondary Ids empty	
Gender Both		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	
Phase N/A		Approval date 2020-11-22, 1399/09/02	
Groups that have been masked <i>No information</i>		Ethics committee reference number IR.BMSU.REC.1399.462	
Sample size Target sample size: 70		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	
Randomization (investigator's opinion) Randomized		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	
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.		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

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Sheikh Baha'i Street , Mulla Sadra Street,

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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

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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

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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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Position

MS in Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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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