

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The Effects of Color Therapy on patient's anxiety under chemotherapy in oncology unit:A Randomized Clinical Trial study

Protocol summary

Study aim

Determining the effect of color therapy on the anxiety of chemotherapy patients referred to the oncology department

Design

A clinical trial with two control and intervention groups, with parallel groups, one blind strain, randomization using a random number table, with a number of 189 samples.

Settings and conduct

In this study, 189 patients referred for chemotherapy to the chemotherapy department of Bistoon Hospital are studied. Both intervention and control groups are given the Beck questionnaire to measure anxiety, and after filling it and using a table of random numbers, randomization is done and for blinding, the study subjects are blinded from the corridor inside the room. and the intervention group was transferred to a private room with a blue color spectrum and the control group was transferred to a normal room with the normal color spectrum of the hospital and they stayed in that environment for twenty minutes. Then again, the anxiety level of people in both groups is measured by Beck's questionnaire.

Participants/Inclusion and exclusion criteria

Conducting at least one chemotherapy session and being hospitalized for more than 6 hours for chemotherapy and willingness to participate in the study are the entry criteria and unwillingness to participate in the study or not completing the questionnaire completely are the criteria for excluding people from the research.

Intervention groups

Both the intervention and control groups will be given the Beck questionnaire to measure anxiety and after filling it, the intervention group will be transferred to a private room with a blue color spectrum, and the control group will be transferred to a normal room with the usual color spectrum of the hospital and spend twenty minutes in that environment. As. Then again, the anxiety level of

people in both groups is measured by the Beck questionnaire.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130603013568N8**

Registration date: **2023-04-24, 1402/02/04**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-24, 1402/02/04**

Update count: **0**

Registration date

2023-04-24, 1402/02/04

Registrant information

Name

Rostam Jalali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3724 6613

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-11, 1401/09/20

Expected recruitment end date

2023-06-10, 1402/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Color Therapy on patient's anxiety under chemotherapy in oncology unit:A Randomized Clinical Trial study

Public title

Effects of Color Therapy on patient's anxiety under chemotherapy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Do at least one chemotherapy session Hospitalization for more than 6 hours for chemotherapy Willingness to participate in the study

Exclusion criteria:

Unwillingness to participate in the study Failure to fully complete the questionnaire

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **189**

Randomization (investigator's opinion)

Randomized

Randomization description

It will be simple randomization with random assignment to intervention and control groups and using a table of random numbers from top to bottom. First, the patients in the study are placed in the waiting room and are registered by the researcher, then the researcher moves from top to bottom by using the table of random numbers and in order to allocation Concealmen the numbers are written on a card and the cards are placed in the letter envelopes in order. In order to preserve the random sequence, the pass number is done in the same order on the outer surface of the envelopes. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration of the participants, the order of entry of qualified participants into the study, one of the envelopes will be opened in order and the assigned group will participate. Each sample will be assigned a number. The study subjects are divided into two groups of 95 people (total study 189 people) A and B, the even numbers of group A, which is the intervention group, and the odd numbers of group B, which is the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, blinding is done in a one-way blind method, in such a way that after registering and assigning an

envelope to them, in order to determine the intervention or control group, according to the number in the envelope, the subjects left the waiting room. He/She passed through the rooms and if the number inside the envelope seen by the researcher is an even number, the person in question will go to the intervention room, and if the number is odd, the sample will go to the control room.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

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Shahid Beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2023-02-28, 1401/12/09

Ethics committee reference number

IR.KUMS.REC.1401.553

Health conditions studied**1****Description of health condition studied**

Anxiety

ICD-10 code

F43

ICD-10 code description

Reaction to severe stress, and adjustment disorders

Primary outcomes**1****Description**

Anxiety

Timepoint

Before and after intervention

Method of measurement

Beck's Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group: First, they fill out the Beck questionnaire, then they are transferred to one of the two private rooms of the ward through a corridor that is not clear inside the rooms, these rooms are blue in color with blue light, blue bedspread, blue pillowcase and blue blanket. , the curtain around the bed is blue, the lacquer is blue, and the flowers are blue, and they stay in this room for 20 minutes, and then Beck's questionnaire is given to them and the level of anxiety is measured.

Category

Behavior

2

Description

Control group:First, they fill out the Beck questionnaire, then they are transferred to one of the common rooms of the ward through a corridor that is not clear inside the rooms, which are white with the usual color range of the ward, and have moonlight, white bedding, The white pillowcase and blanket, the curtain around the bed is green, the lacquer is green, and they stay in this room for 20 minutes, and then Beck's questionnaire is given to them and the level of anxiety is measured.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Bistoon hospital

Full name of responsible person

Shahin Panahi

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126 Alley,Hashem Azadi Street,Amjadian Blv.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farid Najafi

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Vice Research and Technology Affair, No 2 Building,
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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Rostam Jalali

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

For keeping anonymous

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available