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

rjalali@kums.ac.ir

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
Street address
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
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Street address
Vice Research and Technology Affair, No 2 Building, Shahid Beheshti Blvd,
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Web page address
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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
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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