

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of Happiness Educational Program of Fordyce on the sense of coherence and psychological well-being of adolescents who have a parent with cancer

Protocol summary

Study aim

Determining the effect of Happiness Educational Program of Fordyce on the sense of coherence and psychological well-being of adolescents who have a parent with cancer

Design

Field trial with a control group, with parallel groups, randomized, 92 people

Settings and conduct

Approval of the research plan in the university ethics committee. Selection of research units if they have a child in the research age group in the morning and evening shifts in the oncology ward of Shahid Rajaei Hospital. Obtain informed consent. Completion of the demographic checklist, Antonovsky's Sense of Coherence Questionnaire-13 and the Ryff's scale of Psychological well-being-18 at the beginning. For the intervention group, the number of sessions will be 6 sessions of 60 minutes and one day a week for 6 weeks. At the end of the research intervention, the Antonovsky's Sense of Coherence Questionnaire-13 and the Ryff's scale of Psychological well-being-18 are completed by both intervention and control groups. The place of training will be a room to protect the privacy of teenagers in Shahid Rajaei Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Consent to participate in the study and sign the informed consent form by the parent and adolescent 2. At least six months have passed since the definitive diagnosis of parent cancer by an oncologist. Criteria for non-inclusion: 1. Lack of adolescent awareness of parental cancer 2. History of participation in similar training courses in the last six months

Intervention groups

The number of sessions in the intervention group will be 6 sessions of 60 minutes and one day a week for 6 weeks. The interventions will be performed in groups and in groups of 5 to 10 people. Control group: Non-

intervention: This training group will not be given.

Main outcome variables

Sense of Coherence and Psychological well-being

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210331050795N1**

Registration date: **2021-06-21, 1400/03/31**

Registration timing: **prospective**

Last update: **2021-06-21, 1400/03/31**

Update count: **0**

Registration date

2021-06-21, 1400/03/31

Registrant information

Name

Raziye Forutan nasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3322 2524

Email address

razie2624@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Happiness Educational Program of Fordyce on the sense of coherence and psychological well-being of adolescents who have a parent with cancer

Public title

The effect of Happiness Educational Program of Fordyce on the sense of coherence and psychological well-being of adolescents who have a parent with cancer

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Consent to participate in the study and sign the informed consent form by the parent and adolescent One of the parents has cancer At least six months have passed since the definitive diagnosis of parental cancer by an oncologist Simultaneously obtaining a score of 52 or less in the Antonovsky's Sense of Coherence Questionnaire-13 and Ryff's scale of Psychological well-being-18

Exclusion criteria:

Lack of adolescent awareness of parental cancer Simultaneous infection of a teenager or a first-degree member of his family with other incurable diseases Simultaneous infection of a teenager or a first-degree member of his family with mental illness Both parents have cancer History of participating in similar training courses in the last six months

AgeFrom **13 years** old to **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **92****Randomization (investigator's opinion)**

Randomized

Randomization description

The random assignment of a block will be such that first by multiplying the number of groups studied (two groups) by 2, the number of samples of each block is calculated equal to 4, then by factorial calculation, the number of samples of each block ($4! = 4 \times 3 \times 2 \times 1 = 24$), the number of blocks resulting from all states of arrangement of individuals, 24 calculated blocks and blocks involving the possible arrangement of individuals considering A (gray manikin) for the intervention group and B (white manikin) for the control group will be. Then, since the number of people in each block is 4 people and the estimated sample size is 92 people, so by matching 18 random numbers produced by Sample Randomizer software with the number of the above cases, how to arrange 92 people research sample and assign each

number from 1 to 92 to one of the specific intervention or control groups and a block random allocation list will be compiled. Eligible research samples, based on the time priority of the referral, will be assigned a code to each of them, by matching that number with the block random allocation list, the adolescents participating in the research will be assigned to one of the intervention or control groups. This process will continue until the estimated sample size is completed.

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 Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2021-06-02, 1400/03/12

Ethics committee reference number

IR.YUMS.REC.1400.050

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

Cancer

ICD-10 code

C80.0

ICD-10 code description

Malignant neoplasm, without specification of site

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

Sense of Coherence

Timepoint

Adolescents' sense of Coherence at the beginning of the study (before the intervention) and immediately after the start of the study

Method of measurement

Antonovsky's Sense of Coherence Questionnaire-13

2

Description

Psychological well-being

Timepoint

Adolescents' psychological well-being at the beginning of the study (before the intervention) and immediately after the start of the study

Method of measurement

Ryff's scale of Psychological well-being-18

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The number of sessions in the intervention group will be 6 sessions of 60 minutes and one day a week for 6 weeks. The interventions will be performed in groups and in groups of 5 to 10 people. The Fordyce Happiness training program will be implemented by the researcher using the methods of lectures, group discussions, questions and answers, and thoughts. The following will be briefly mentioned in 6 sessions: Session 1: Defining happiness, its necessity and importance, Session 2: Training to spend more time in communities and group activities, Session 3: Principles of better planning and organization, Session Fourth: Teaching the principles of positive and optimistic thinking, Session 5: Teaching the principles of cultivating social and extroverted personality and Session 6: Teaching the principles of sincere communication as the most important source of happiness.

Category

Lifestyle

2

Description

Control group: Non-intervention: This training group will not be given.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital

Full name of responsible person

Razieh Forutannasab

Street address

Shahid Rajaei Hospital, facing the governor's office, Imam Hossein Square, Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Hossein Mari Oryad

Street address

Yasuj University of Medical Sciences, Shahid Motahari Blvd., Yasuj, Kohgiluyeh and Boyer-Ahmad, Islamic Republic of Iran

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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

Yasouj 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

razie2624@gmail.com

Contact

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Razieh Forutannasab

Position

Master Student of Pediatric Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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