Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effects of resilience intervention on adolescent labourers’spiritual well_being

Protocol summary

Study aim

assessment the effects of resilience intervention on adolescent labourers’spiritual well_being

Design

In this single-blinded randomized study, first a pilot study will be conducted with a sample of 40 individuals (20 individuals in each group) to determine the sample size of the study.

Settings and conduct

The samples will be divided into the study groups blindly. This is a single-blinded study in which, the participated are blinded. To control the distracting variables, interventions are conducted at a single center, and adolescents from different centers are referred to this center to receive the Penn intervention sessions

Participants/Inclusion and exclusion criteria

Willing to participate in the study Having a minimum of 15 and maximum of 17 years of age Being covered by work center and centers affiliated with the Iran’s Welfare Organization Having no background of participation in the courses or studies related to the resiliency or spiritual wellbeing

Intervention groups

The study include the control and intervention groups. Routine interventions used in the centers will be provided for the control group, and the Penn Resilience Program (PRP), developed by the University of Minnesota, will be implemented for the intervention group to promote resilience at the school age. In fact, the PRP is a group-based cognitive-behavioral intervention for promoting resilience based on concepts such as social and emotional learning, cognitive-behavioral approaches, positive psychology, and subjective wellbeing. The intervention includes 24 sessions (two one-hour sessions in a week).

Main outcome variables

The results can be useful in the development of empowerment programs to promote the spiritual wellbeing of adolescents. Identifying the challenges of implementing resilience interventions for youth workers, and using this knowledge in formulating the future plans for resilience promotion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180409039252N1**
Registration date: **2018-10-10, 1397/07/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-10, 1397/07/18**
Update count: **0**

Registration date

2018-10-10, 1397/07/18

Registrant information

Name

Katayoon Faraji

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of resilience intervention on adolescent labourers'spiritual well_being

Public title

Investigating the effects of resilience intervention on adolescent labourers'spiritual well_being

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Willing to participate in the study Having a minimum of 15 and maximum of 17 years of age Being covered by work center (Child Work Unit) and centers affiliated with the Iran's Welfare Organization Having no background of participation in the courses or studies related to the resiliency or spiritual wellbeing. Considering the self-reporting method of the questionnaire, literacy level of more than primary school is important for participation in the Persian language classes.

Exclusion criteria:

Being absent for more than two sessions of the intervention in the intervention group Not willing to continue with the study in both groups

Age

From **15 years** old to **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

After making an integrated list of 15-17 years old youth workers and obtaining consent from them and their legal guardians, they would randomly be divided into two intervention and control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single-blinded intervention, the participants would not be aware of the sample allocation into the study groups. Also, the sessions will take place before the start of intervention with the presence of all participants and their legal guardians. Based on the integrated list, the adolescents, their parents or their legal guardians will be informed about the study objective and intervention method in a simple language, and their questions will be answered. The researchers' phone number and access information will also be given to them and their consent to participate in the study will be obtained. In the next step, according to the ethical consideration guideline regarding vulnerable groups in Iran prepared by the Ethical National Committee in Biomedical Research that states informed consent must be obtain from 15 years old participants and above as well as their legal guardian, the written consent form would be explained to the parents and the adolescents in a simple and understandable language. Then, an informed consent will be obtained from the parents and adolescents who are willing to participate in the study. In relation to the illiterate parents, the consent form will be read for them by an individual from the relevant organization. The ethical considerations such as confidentiality, giving information and result to parents or adolescents if they requested and the right to stay in or leave the study.

Placebo

Not used

Assignment

Other

Other design features

The adolescents whose consents had been taken are divided into intervention and control groups by random allocation method, as the random allocation method is used to control the intervention and distracting variables. Meanwhile, the routine interventions would be conducted for the control group. To control the intervention variables, the intervention will be conducted in a center and the participants from other centers will come for the PENN intervention sessions by cars provided by the research group. Before each session, the parents will be informed about the hours, and transportation of their children via phone. Adolescents in the intervention group will be asked not to share their training, experience and information with other classmates (via phone, etc). Additionally, the adolescents in the control group will be promised to do assured that, they will receive the PEN intervention after the end of study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

School of Nursing Midwifery, Tehran University of Medical Sciences Nosrat st. Tohid sq

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2017-08-30, 1396/06/08

Ethics committee reference number

IR.TUMS.FNM.REC.1396.3297

Health conditions studied

1

Description of health condition studied
spiritual well-being
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The score of spiritual well-being on SHALOM (Spiritual Health And Life-Orientation Measure) questionnaire
Timepoint
before intervention, at the end of intervention, eight weeks of the end of intervention
Method of measurement
SHALOM (Spiritual Health And Life-Orientation Measure) spiritual well-being validated questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: In this study, resilience-enhancing intervention, based on the Penn Resiliency Program developed by the University of Minnesota, will be implemented. This program is specific for promoting the resilience of school-age students, which has been implemented and evaluated for 25 years. The core of the Penn Resiliency Program is the Elise's ABC model. In fact, Penn program is a group-based cognitive-behavioral intervention to improve resilience. The modules of this intervention have been designed for the instructors, and the teacher-student relationship is in the heart of this intervention. The theories that this program is based on are developed from concepts such as social and emotional learning, cognitive-behavioral approaches, positivist psychology, and subjective development. The intervention will be implemented according to the schedule, including 24 one-hourly sessions (two sessions in a week), which will be held as group training, question and answer, pamphlet, and educational content. If needed, some meetings will be organized for questions and answers. Each subject is taught in two sessions that include: Session1: Relationship between thoughts and feelingsThe first half of the Session 1 is devoted to introducing the students to the program, establishing sense of cohesion, and group allocation. The cognitive component of this session is based on the Elise' ABC model. Involuntary thoughts are introduced as "conversations inside the heads", or "self-talk", and students are encouraged to describe recent events or difficulties, and to recall what they have "said to themselves". The final part of session 1 focuses on the relationship between thoughts and feelings. Students, with the aid of 3-frame cartoons, generate the involuntary thoughts that lead to the sense of specific emotional outcomes with respect to difficulties. Session 2: Thinking styles/methodsThe focus of this session is on the explanatory methods, particularly the stable-unstable aspect of thought. Optimism and pessimism, referred to as "thinking styles" in Penn resilience intervention, are presented to the students through a series of short and joyful plays in the group. The students practice how to identifying stable thoughts in similar plays. The final activity for the session requires the students to generate alternatives for the initial thoughts, and explain thinking styles in the plays. Session 3: Challenging the beliefs: Alternatives and evidence After Sessions 1 and 2, the students are able to identify their pessimistic involuntary thoughts and understand that we often uncritically accept these thoughts as accurate thoughts. They also practice how to generate optimistic alternatives. In the session 3, the students consolidate the skill of generating alternatives and learn how to evaluate the accuracy of their own initial involuntary beliefs and thoughts. The group leader reads a story for the students that explains the process of generating alternatives and evaluating evidence as a detective. The story is about two fictional characters, for example; Sherlock Holmes and Merlock Worms. Merlock Worms is a bad detective because he only comes up with one suspect (i.e. endorses his initial involuntary thoughts and fails to generate alternatives) and overlooks evidence which is vital to the case (i.e., fails to evaluate the thought). Sherlock Holmes, however, is a good detective because he draws up a list of suspects (generates desired beliefs) and looks for clues to narrow down the list (evaluates evidence). The skill of evaluating evidence is practiced in the 'File Game' activity. The students receive a confidential portfolio about a fictional child, which contains letters, report cards, diary entries, and gifts, etc. The child's involuntary thoughts will be presented to the students, and their task is to use the information in the portfolio to evaluate the accuracy of the thoughts. Session 4: Evaluating the thoughts and putting them in perspective The sessions 1 to 3 focus on the caustic causes of beliefs about the past events. In Session 4, the focus will shift to thoughts about the negative events at present. The skills of generating alternatives and evaluating vital evidence will become practical. The notion of events with be conveyed to the students with a modern modified view of the classical story of Chicken Little and the Acorn. Chicken Little is compared with Merlock Worms; both believe in the first thought that popped into their heads without generating alternatives and looking for clues. The students differentiate the "worst case", "best case", and "most likely" scenarios for consequences of the difficulties (In another words, they generate alternatives). The students have now learned three essential cognitive skills; generating alternatives, producing counter-evidence, and putting them in perspective. However, these skills will only counter pessimism successfully if they could match the automaticity of negative thoughts. The final

activity for the session would be the "On time Resilience: The Hot Seat", that the students are required to use these skills in real time. Session 5: Discussion on Contradictions and Review of Sessions 1 to 4: Parental conflict is an established risk factor for child and adolescent depression. Because of this, the fifth session is clearly devoted to the application of cognitive skills (developed at sessions one to four) for the wrong proportion of marital conflicts (for example, it is my fault that they are arguing with each other) and disastrous thoughts about the outcomes (for example: They divorce and I will never see my dad again). Session 6: Assertiveness and negotiation In the session 6, the first module will be the interpersonal problem-solving. This module aims to apply the basic cognitive skills learned in the first half of the program to the interpersonal domain, determine interaction style, and promote social skills, and social problem-solving. Comic plays are used to illustrate the three interaction styles; aggression, passivity, and assertiveness. The students spend most of the session practicing assertiveness and role-playing the use of negotiation skills when assertiveness fails to bring about the desired goal. Session 7: Coping StrategiesSession 5 focuses on cognitive strategies to more accurately attribute the causes of parental fighting and to effectively put in perspective thoughts about the consequence of family conflict. Session 7 teaches students the behaviorally oriented techniques to help them cope in stressful situations, like when their parents are arguing. The group leader teaches the students the skills of controlled breathing and muscle relaxation and guides them through practicing each of them. In addition, the group leader helps the students formulate a positive visual image (e.g., their next birthday party), which they can recall the time they begin to feel angry or anxious. Session 8: Grading the duties and social skills training The first half of this session is devoted to procrastination. Many cases of procrastination are a consequence of all-or-none-thinking. The idealistic children believe that; "My social studies paper has to obtain the top score". They tend to convert the task of writing the paper into a seemingly insolvable problem. The behavioral consequence of such thoughts is avoidance, or procrastination. This component of the program aims to apply the cognitive skills learned in the first 4 weeks of the program to negative thoughts about projects and daily tasks. The second half of session 8 continues the progressive application of the basic cognitive skills to the interpersonal domain. In Session 8 the focus is on involuntary thoughts when meeting new people and making new friends. Session 9: Decision making and review of sessions 6 to 8 Indecisiveness is common in children who are experiencing symptoms of depression. The frequency of similar thoughts leads them to procrastination, which can make decision making difficult for children and adolescents at-risk of depression. In Session 9 the group leader shows students how to use a four-cell technique for decision-making, so that, they could generate the positive and negative aspects for two options available to them. In the final section of the session, this technique is applied to examples from the students' lives.Session 10: Social problem-solving Children at risk of depression and conduct disorder have a selective tendency towards hostile signs and ambiguous behavior of others (Dodge, 1986; Dodge & Frame, 1982). Resistance is taught to students during this course, which is showed by the initial causal attribution and making of several appropriate alternatives. They are taught to gather evidence, put it in perspective, and determine what their goal is in the situation. They use the technique of four-cell, positive-negative aspects to choose a course of action and approve their decision, and even if their behavior doesn't satisfy their goal, they modify their behavior and try again. The final part of this session is spent on practicing their social problem-solving skills with several scenarios offered by the group leader. Sessions 11 and 12: The social problem-solving skill is consolidated in session 11, which provides a forum for the students to apply the five-step technique to difficult interpersonal situations in their own lives. In the session 12, the whole program is reviewed and a celebration will be held for the students. The importance of attending the booster sessions is discussed.

Category

Behavior

2

Description

Control group: For the control group, the routine interventions are performed by the centers they are covered by.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

State Welfare Organization of IRAN

Full name of responsible person

Anoshiravan Mohseni Bandpey

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Katayoon Faraji
Position
Pediatric nurse
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Bachelor
Other areas of specialty/work
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Person responsible for updating data

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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
The data of the participants in the study will not be published due to the research ethics and vulnerability of the samples.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The data of the participants in the study will not be published due to the research ethics and vulnerability of the samples.
When the data will become available and for how long
One year after the publication, access to the data will be possible.
To whom data/document is available
Researchers working in academic and scientific institutes, and independent researchers will have access to the documents.
Under which criteria data/document could be used
be researcher
From where data/document is obtainable
To receive the documents after contacting the research team, whose contact information is included in the publication of the results, the applicant will be given access after the approval of the research team.
What processes are involved for a request to access data/document
After submitting the application for the documents to the research group, the request is reviewed by the research team and will be answered within two weeks.
Comments