Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Designing a training program for mindful participation of parents in self-care performance of children with autism spectrum disorder aged 6-12 years based on the Canadian Model of Occupational Performance-Engagement and investigating its effectiveness on children's performance and parents' satisfaction in performing self-care skills

Protocol summary

Study aim
Designing a training program for mindful participation of parents in self-care performance of children with ASD based on the CMOP-E model and investigating its effectiveness on children's performance and parents' satisfaction in performing self-care skills

Design
Randomized, superiority, exploratory, parallel group trial. randomization.com is used for randomization.

Settings and conduct
Comprehensive Autism Center of Tabriz University of Medical Sciences and the National Autism Association in Tehran, Iran. The outcome assessor will be blinded.

Participants/Inclusion and exclusion criteria
Children: ASD diagnosis at Level 1 or 2 Received rehabilitation services for at least 6 months in the past 2 years Identified at least 3 priorities in COPM related to self-care Ages 6 to 12 years Parents: Proficient in reading and writing DASS score < 13 Standard score < 110 in two MIPQ subscales Willingness and commitment to fully participate in the research Exclusion Criteria: Participation in another mindfulness study Concurrent participation in psychological counseling sessions Responsibilities for the care of a disabled person other than a child with ASD Lack of consent to continue participating in the study

Intervention groups
The intervention involves a 9-week program led by an MBSR-trained researcher, integrating general and personalized mindfulness techniques. Participants, randomly assigned to the Mindful Participation Educational Program or control group, receive tailored interventions alongside conventional occupational therapy. The control group specifically receives conventional occupational therapy for self-care.

Main outcome variables
Child's self-care performance; Parent's satisfaction with child's self-care performance; Parental function in rehabilitation; child's adjustment; parent's self-efficacy; Mindful parenting; Parenting stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180521039770N2**
Registration date: **2024-01-02, 1402/10/12**
Registration timing: **prospective**

Last update: **2024-01-02, 1402/10/12**
Update count: **0**

Registration date
2024-01-02, 1402/10/12

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-03, 1403/01/15
Expected recruitment end date
2024-05-21, 1403/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Designing a training program for mindful participation of parents in self-care performance of children with autism spectrum disorder aged 6-12 years based on the Canadian Model of Occupational Performance-Engagement and investigating its effectiveness on children's performance and parents' satisfaction in performing self-care skills

Public title
Mindful Participation: A Program to Support Children with Autism in Self-Care performance
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A confirmed diagnosis of Autism Spectrum Disorder (ASD) at Level 1 or 2 by a child psychiatrist subspecialist, determined through a semi-structured clinical interview aligned with the diagnostic criteria outlined in the 5th edition of the Diagnostic and Statistical Manual of Psychiatric Disorders. The child must have received continuous rehabilitation services for a minimum of six consecutive months over the past two years. This requirement is essential for accurately assessing parental involvement in the rehabilitation process and is a prerequisite for completing the FFQR questionnaire. Participants must have a minimum of three priorities identified in the Canadian Occupational Performance Measure (COPM) that are directly related to the child's self-care occupations. The child must be between the ages of 6 and 12 years. Parents must possess the ability to read and write. Parents must obtain a score lower than 13 on the Depression Anxiety Stress Scale (DASS), indicating an absence of very severe, severe, and moderate depression. Specifically, scores in the range of 0-9 indicate no depression, 10-13 mild depression, 14-20 moderate depression, 21-27 severe depression, and scores above 28 represent very severe depression. Parents must score lower than 110 in two specific subscales of the Mindfulness in Parenting Questionnaire (MIPQ), indicating a level of moderate to low mindfulness in parenting. Standard scores within the range of 90 to 110 are considered indicative of moderate mindful parenting, with higher scores representing elevated levels of mindfulness in parenting practices. The family must demonstrate a genuine willingness and commitment to actively engage in and fully participate in the research process.
Exclusion criteria:
Parents currently engaged in another study involving mindfulness practices will be excluded. Parents concurrently involved in psychological counseling sessions during the study period will be excluded. Exclusion applies to parents caring for a disabled person other than a child with Autism Spectrum Disorder (ASD), including children with other disorders or other family members. Participants who choose not to provide consent to continue their participation in the study will be excluded.
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
Method of Randomization: The method employed for randomization is a block randomization approach. This entails organizing participants into blocks, each containing an equal number of individuals, to ensure balanced allocation between the two study groups. Unit of Randomization: Individual participants are the primary unit of randomization in this study. Randomization Strata in Stratified Randomization: No stratified randomization is utilized in this study. Participants are randomized without stratification. Tools Used in Randomization: The randomization process is facilitated using the randomization.com website, a validated online tool. This website ensures a precise and unbiased allocation of participants to either the intervention or control group. Building the Random Sequence: The random sequence is generated through the randomization.com website, ensuring the creation of a unique and unpredictable sequence of assignments for participant allocation. Allocation Concealment: Allocation concealment is implemented to maintain the integrity of the randomization process. Sealed envelopes containing the group assignments are utilized, ensuring that the random allocation remains undisclosed until the time of participant enrollment. Independent Randomization: Randomization is performed by an individual independent of the therapeutic interventions and evaluations. This impartial approach minimizes the potential for bias in the allocation process.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants: Owing to the didactic nature of the intervention, participants are exposed to the educational component in their respective environments through the providing companies. Acknowledging the inherent difficulty in blinding participants due to the educational context, this intentional approach aligns with the

intervention's nature. This consideration is explicitly outlined in the study design. While participant blinding is challenging, the study makes concerted efforts to ensure impartiality in outcome evaluation and data collection, thereby mitigating potential biases. Principal Investigator (Provider of the Studied Intervention): The principal investigator, as the provider of the studied intervention, maintains awareness of the study groups. This transparency is a conscious aspect of the study design, recognizing the pivotal role of the principal investigator in the intervention's administration. Occupational Therapist - Common Occupational Therapy Interventions: The occupational therapist responsible for the common occupational therapy interventions remains intentionally blinded to the study groups. This deliberate blinding strategy is employed to uphold consistency in the delivery of interventions across both groups. Data Collectors: Individuals tasked with data collection during the trial diligently adhere to protocols to maintain objectivity. While participant blinding may not be practically achievable, data collectors ensure their assessments are impartial and comparable across the studied groups. Outcome Evaluators: Professionals conducting outcome evaluations are adept at comparing participants across interventions, fostering an unbiased interpretation of results. This approach is designed to uphold the scientific rigor and credibility of the study's outcome assessments. Authors of the Article: Authors of the paper, while not directly involved in the day-to-day operations of the trial, adhere to established research reporting standards. They employ anonymized data to ensure objectivity in reporting, contributing to the transparency and scholarly integrity of the study findings.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Highway, next to Milad Tower, Iran University of Medical Sciences, Central Headquarters Building, Research and Technology Vice-Chancellor

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-10-04, 1402/07/12

Ethics committee reference number

IR.IUMS.REC.1402.588

Health conditions studied

1

Description of health condition studied

Autism Spectrum Disorder (ASD)

ICD-10 code

Childhood

ICD-10 code description

autistic psychopathy

Primary outcomes

1

Description

Child's self-care performance: In this study, "self-care performance" refers to the scores obtained by participants in the self-care performance section of the COPM.

Timepoint

Assessment points are scheduled before the intervention, at 2 months, and at 4 months after the start of the intervention.

Method of measurement

The Canadian Occupational Performance Measure (COPM) is a reference-oriented measurement scale assessing self-perception in self-care, productivity, recreation, and work performance. Utilizing a semi-structured interview, individuals, including parents for children with ASD, identify goals and rate performance and satisfaction on a ten-point scale. The semi-structured interview is employed to evaluate self-care performance in children with ASD.

2

Description

Parent's satisfaction with the child's self-care performance: In this study, "Parent's satisfaction with the child's self-care performance" refers to the scores obtained by participants in the satisfaction section of the COPM related to self-care performance.

Timepoint

Assessment points are scheduled before the intervention, at 2 months, and at 4 months after the start of the intervention.

Method of measurement

The Canadian Occupational Performance Measure (COPM) is a reference-oriented measurement scale assessing self-perception in self-care, productivity, recreation, and work performance. Utilizing a semi-structured interview, individuals, including parents for children with ASD, identify goals and rate performance and satisfaction on a ten-point scale. The semi-structured interview is employed to evaluate self-care performance in children with ASD.

Secondary outcomes

1

Description

Family Functioning in Rehabilitation: In this study, "Family Functioning in Rehabilitation" pertains to the overall score parents receive in the Family Functioning Questionnaire in Rehabilitation (FFQR). This score comprises the total scores from four subscales: engagement in rehabilitation, social participation, behavior and attitude, and awareness.

Timepoint

Assessment points are scheduled before the intervention, at 2 months, and at 4 months after the start of the intervention.

Method of measurement

Family Functioning Questionnaire in Rehabilitation (FFQR):The FFQR is a questionnaire specifically crafted to assess family functioning in the context of rehabilitation. Comprising 48 items, it gauges four dimensions: awareness, attitude and behavior, social participation, and engagement in rehabilitation. Parents of children with special needs complete the questionnaire, providing responses on a five-point Likert scale ranging from 1 ("strongly disagree") to 5 ("strongly agree") for each question.

2

Description

Child's adjustment: In this study, "child's adjustment" refers to the scores obtained by children in the child adjustment section of the Child Adjustment and Parent Efficacy Scale-Developmental Disability (CAPES-DD).

Timepoint

Assessment points are scheduled before the intervention, at 2 months, and at 4 months after the start of the intervention.

Method of measurement

Child Adjustment and Parent Efficacy Scale-Developmental Disability (CAPES-DD):The CAPES-DD is a parent-response questionnaire designed to assess both child behavior and parent self-efficacy in managing those behaviors. Comprising 24 items, child adjustment-related items range from 0 ("not at all") to 3 ("very much"), while parent self-efficacy items range from 1 ("I'm sure I can't manage the situation") to 10 ("I'm sure I can manage the situation"). Elevated scores in child-related items indicate increased emotional or behavioral challenges, whereas higher scores in parent-related items signify heightened levels of parental self-efficacy.

3

Description

Parent's self-efficacy:In this research, the term "Parent's self-efficacy" denotes the scores obtained by parents from the self-efficacy section of the Child Adjustment and Parent Efficacy Scale-Developmental Disability (CAPES-DD) scale.

Timepoint

Assessment points are scheduled before the intervention, at 2 months, and at 4 months after the start of the intervention.

Method of measurement

Child Adjustment and Parent Efficacy Scale-Developmental Disability (CAPES-DD):The CAPES-DD is a parent-response questionnaire designed to assess both child behavior and parent self-efficacy in managing those behaviors. Comprising 24 items, child adjustment-related items range from 0 ("not at all") to 3 ("very much"), while parent self-efficacy items range from 1 ("I'm sure I can't manage the situation") to 10 ("I'm sure I can manage the situation"). Elevated scores in child-related items indicate increased emotional or behavioral challenges, whereas higher scores in parent-related items signify heightened levels of parental self-efficacy.

4

Description

Mindful parenting: In this research, "Mindful parenting" refers to the scores obtained by parents from the scales of Mindful discipline and Being in the moment with the child in the Mindfulness in Parenting Questionnaire (MIPQ).

Timepoint

Assessment points are scheduled before the intervention, at 2 months, and at 4 months after the start of the intervention.

Method of measurement

Mindfulness In Parenting Questionnaire (MIPQ):The MIPQ, consisting of 28 items, assesses two factors: "Mindful discipline" and "Being in the moment with the child." The "Being in the moment with the child" factor, encompassing questions 1 to 13, gauges parenting awareness and mindfulness-based parenting. Questions 14 to 28, related to the "Mindful discipline" factor, measure parents' acceptance and empathic understanding of the child. Applicable for children and adolescents aged 2 to 16 years, the questionnaire employs a four-point Likert scale (1 rarely to 4 always). Parents reflect on their interactions with their child in the past two weeks, with standard scores falling between 90 and 110 indicating a moderate level of mindful parenting, while higher scores signify elevated mindfulness in parenting practices.

5

Description

Parenting stress: In this research, "Parenting stress" will be assessed using the Parenting Stress Index-Short Form (PSI-SF).

Timepoint

Assessment points are scheduled before the intervention, at 2 months, and at 4 months after the start of the intervention.

Method of measurement

Parenting Stress Index-Short Form:The Parenting Stress Index-Short Form (PSI-SF) comprises 36 items designed to evaluate parental stress. Respondents rate items on a 5-point Likert scale, ranging from 1 (strongly agree) to 5 (strongly disagree). The scale encompasses three sub-scales: Parental Distress, Dysfunctional Parent-Child

Interaction, and Difficult Child. The total stress score results from summing the sub-scale scores. Scores ranging from 86-90 indicate borderline stress, 91-98 signify high parental stress, and 99 and above suggest extremely high parental stress.

Intervention groups

1

Description

Intervention group: In this research, the investigator, having completed the mindfulness training course on the Palouse Mindfulness platform in its original English content, has obtained permission from the course designer, Dave Potter, to translate and re-record all the material, including the intervention manual, videos, podcasts, and textual content, into Farsi. The mindfulness training, based on the Mindfulness-Based Stress Reduction Program (MBSR), will be delivered by the researcher.An occupational therapist with a minimum of 2 years of clinical experience will be selected as an interviewer using the Canadian Occupational Performance Measure (COPM), and this selection will be carried out in a blinded manner. The general mindfulness component involves teaching 10 mindfulness techniques in group sessions lasting 2 hours each week for 8 weeks, with one session per week. These sessions include video and podcast presentations, researcher-led lectures, and participant discussions and Q&A sessions. Participants are required to practice each week's techniques for half an hour a day, six days a week at home.Personalized mindfulness, integrated into daily activities, will be practiced by parents for 15 minutes a day, six days a week. The intervention spans 9 weeks, including an introductory week about mindfulness and its significance in rehabilitation.The mindful Participation Educational Program, uniquely tailored for each parent to enhance their child's self-care performance, will be provided to the intervention group. Motivational interviewing, open questioning, and encouraging reflection will be integral components of each group session. These strategies, facilitated by the researcher's occupational therapist, aim to prepare parents for active participation in the intervention sessions. Intervention group will also receive conventional occupational therapy, with therapists trained to address occupational performance issues identified through the COPM for each child and parent.

Category

Rehabilitation

2

Description

Control group: The control group will receive conventional occupational therapy, with occupational therapist trained to address occupational performance issues identified through the COPM for each child and parent.This group will receive the Mindful participation training package after the study concludes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Autism Center of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Babak Kashefimehr

Street address

Golshahr Block, Imam Khomeini Clinic, 1st Floor, Autism Comprehensive Cer, Tabriz University of Medical Sciencesent

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East Azarbaijan

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Phone

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Email

autismcenter@tbzmed.ac.ir

Web page address

https://autismcenter.tbzmed.ac.ir/

2

Recruitment center

Name of recruitment center

انجمن اتیسم ایران- موسسه خیریه توانبخشی پزشکی آرمان شایان ایرانیان

Full name of responsible person

Dr. Mehdi Alizadeh zarei

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second square of Sadeghieh, Ayatollah Kashani St., Behnam St., in front of Tarbiat Bostan, Arman Shayan Medical Rehabilitation Charity

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Reza Falak

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Shafagh Saei

Position
Occupational therapy PhD candidate

Latest degree
Master

Other areas of specialty/work
Occupational Therapy

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Position
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
Occupational therapy PhD candidate

Latest degree
Master

Other areas of specialty/work
Occupational Therapy

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https://scholar.google.com/citations?user=Cytb0zoAAAAJ&hl=en&oi=ao

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Title of Data/Document: Raw Deidentified Individual Participant Data (IPD) Details: All data is shared after individuals are de-identified.

When the data will become available and for how long
The deidentified individual participant data (IPD) will become available starting 3 months after publication. The data will remain accessible for a period of two years from the start date.

To whom data/document is available
The deidentified individual participant data (IPD) and accompanying documents will be made available to researchers affiliated with academic institutions, including faculty, students, and researchers. Access is also extended to professionals and therapists working in relevant businesses, fostering inclusivity in data utilization.

Under which criteria data/document could be used
Access Criteria: Access to deidentified individual participant data (IPD) and related documents will be granted for the purpose of further analyses relevant to the scope of this study. Researchers intending to access the data should submit a formal request, outlining the specific analyses they plan to conduct. The mechanism for access will involve submitting requests through a designated online platform or contacting the principal investigator directly. Review Process: Requests for access will be reviewed by the principal investigator to ensure alignment with the intended analyses and compliance with ethical standards. Priority will be given to research proposals that contribute meaningfully to the understanding of the studied interventions and outcomes.

From where data/document is obtainable
The preferred way of communication is via email. Please send your access requests to [sh.saie@yahoo.com]. Contact Information: Email: [sh.saie@yahoo.com] Telephone: [00989146735546] Contact Person: [Shafagh Saei]

What processes are involved for a request to access data/document
Data Access Process: Submission of Access Request: Applicants are required to submit a formal access request via email to [sh.saie@yahoo.com]. The request should include the applicant's name, affiliation, purpose for data use, and specific data/documents requested. Initial Review: Upon receiving the request, an initial review will be conducted to ensure it aligns with the stated purpose and ethical considerations. Applicants will be notified within 4-7 days regarding the acceptance of their request for further processing. Data Sharing Agreement: If the request is accepted, applicants will be provided with a Data Sharing Agreement outlining terms and conditions. The agreement must be reviewed, signed, and returned within 3-5 days. Access to Data/Documents: Once the signed agreement is received, access credentials and instructions for downloading data/documents will be provided. Access will be granted for a specified period as outlined in the agreement. Support and Queries: Throughout the process, applicants can contact [Shafagh Saei] for any clarifications or support needed. Queries related to the data or access process will be addressed within 3 working days. Estimated Timeline: Initial Review: 4-7 days Data Sharing Agreement: 3-5 days Access Granted: 7 days after receiving the signed agreement

Comments
It's important to note that the provided timeline is an estimate, and actual duration may vary based on the volume and complexity of requests, as well as the internal processes of our team.