Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of nano-curcumin supplementation on the severity of behavioral symptoms in children with autism spectrum disorder: A randomized controlled clinical trial.

Protocol summary

Study aim

Determine the effect of nano- curcumin supplementation on the severity of behavioral symptoms in children aged 6-12 years with autism spectrum disorder in the Kermanshah city.

Design

A controlled, parallel-group, double- blind, randomized phase 3 clinical trial on 54 patients. Participants will be allocated into two groups of intervention and placebo using a stratified block randomization method via the randomization. com website.

Settings and conduct

Anthropometric and behavioral indicators will be assessed using questionnaires at baseline and week 12 in autism schools and psychiatric office. patients will be randomized 1:1 receive either two 40 mg nano-curcumin capsules or two placebos daily for 12 weeks while maintaining their usual diet.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Confirmed diagnosis of autism spectrum disorder, age 6–12 years, and stable severity of behavioral symptoms during the three months prior to study entry. Exclusion criteria: Comorbid neurodevelopmental disorders; metabolic, gastrointestinal, or hepatic diseases; history of allergy to turmeric; concurrent use of supplements affecting behavioral symptoms; and inability of parents to cooperate during the study stages.

Intervention groups

The intervention aims to evaluate the impact of nano-curcumin supplementation on the severity of behavioral symptoms in autistic children.Participants divided into two groups that receiving nano-curcumin and placebo for 12 weeks. outcomes will evaluate by relevant questionnaires.

Main outcome variables

Primary outcomes will include changes in behavioral symptom severity and childre s dietary intake. Secondary outcomes will involve social and communicative function, repetitive and stereotyped behaviors, irritability, challenging behaviors, and sleep quality.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181111041611N10**
Registration date: **2026-10-17, 1405/07/25**
Registration timing: **prospective**

Last update: **2026-10-17, 1405/07/25**
Update count: **0**

Registration date

2026-10-17, 1405/07/25

Registrant information

Name

Mehnoosh Samadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3710 2009

Email address

mehnoosh_samadi@yahoo.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-27, 1405/09/06

Expected recruitment end date

2027-11-27, 1406/09/06

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of nano-curcumin supplementation on the severity of behavioral symptoms in children with autism spectrum disorder: A randomized controlled clinical trial.

Public title
The effect of nano-curcumin supplementation on the severity of behavioral symptoms in children with autism spectrum disorder: A randomized controlled clinical trial.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of autism spectrum disorder by a psychiatrist based on DSM-5 criteria Age 6–12 years Stability of behavioral symptom severity over the past three months based on medical records Ability to take oral supplements Written informed consent from parents or legal guardian
Exclusion criteria:
Presence of co-occurring neurodevelopmental disorders, such as uncontrolled epilepsy or other neurological disorders affecting the assessment of study outcomes. Having chronic metabolic, hepatic, or gastrointestinal diseases that could affect the safety of nano-curcumin supplement consumption or the study results. History of hypersensitivity or adverse reaction to curcumin or other ingredients in the supplement being used. Concomitant use of supplements or medications affecting behavioral symptoms or containing curcumin within the past three months. Inability of parents to cooperate in carrying out the study procedures and completing the required assessments.
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
Stratified block randomization will be performed to assign participants to the intervention and placebo using the website www.randomization.com. Stratification will be based on age categories (6-8 years and 9-12 years) to ensure age balance between groups. within each stratum, patients will be randomly allocated to either group in a 1:1 ratio using a block size of 4. To ensure allocation concealment, the randomization sequence will be generated by an independent researcher outside of the study team and placed in sequentially Numbered, Opaque, Sealed Envelopes, which will be opened only after participant enrollment and signed informed consent.
Blinding (investigator's opinion)
Double blinded
Blinding description
This will be a double-blind study. Participants/parents, outcome assessors, and data analysts will be blinded to group allocation.Nano-curcumin and placebo capsules will be identical in color, shape, size, weight, odor, taste, and packaging. Packaging and coding will be performed by the pharmaceutical company or a third party outside the research team. The codes are kept by an independent person until data analysis is completed.
Placebo
Used
Assignment
Parallel
Other design features
The study presents no noteworthy unique characteristics.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences
Street address
Building No. 2, Research Council of Kermanshah University of Medical Sciences (KUMS), Shahid Beheshti Boulevard, Kermanshah, Iran.
City
Kermanshah
Province
Kermanshah
Postal code
6719851351
Approval date
2026-06-06, 1405/03/16
Ethics committee reference number
IR.KUMS.REC.1405.117

Health conditions studied

1

Description of health condition studied
Autism
ICD-10 code
F84.0

ICD-10 code description
Autistic disorder

Primary outcomes

1

Description
Change in the severity of behavioral symptoms in children with autism (Aberrant Behavior Checklist total score) from baseline to the end of the study.
Timepoint
Baseline,1month later, and end of study
Method of measurement
Aberrant Behavior Checklist (ABC) questionnaire; ADOS-2 for baseline assessment if needed.

Secondary outcomes

1

Description
• Social and communication functioning
Timepoint
Baseline, 1month later, and end of study
Method of measurement
SRS-2 questionnaire

2

Description
Repetitive and stereotypical behaviors
Timepoint
Baseline, 1month later, and end of study
Method of measurement
ABC(Aberrant Behavior Checklist) and SRS-2(Social Responsiveness Scale) repetitive behavior subscale

3

Description
Irritability and challenging behaviors
Timepoint
Baseline, 1month later, and end of study
Method of measurement
ABC (Aberrant Behavior Checklist) subscale

4

Description
Children's sleep quality
Timepoint
Baseline, 1month later, and end of study
Method of measurement
Children's Sleep Habits Questionnaire (CSHQ)

5

Description
Hyperactivity
Timepoint
Baseline, 1month later, and end of study
Method of measurement
CBCL (Child Behavior Checklist) subscale

6

Description
food intake
Timepoint
Baseline, 1month later, and end of study
Method of measurement
3-Day stimated food record

7

Description
Hieght
Timepoint
Baseline, 1month later, and end of study
Method of measurement
Non-stretch tape measure

8

Description
wieght
Timepoint
Baseline, 1month later, and end of study
Method of measurement
Digital scale

Intervention groups

1

Description
Intervention group: Oral nano-curcumin capsule 40 mg (Sina Curcumin, Exir Nano Sina, Iran), one capsule twice daily (every 12 hours) for 12 weeks. Each capsule contains 40 mg nano-curcumin; total daily dose is 80 mg.
Category
Treatment - Other

2

Description
Control group: Control/placebo group: Identical placebo capsule in packaging, color, shape, size, weight, odor, and taste, one capsule twice daily for 12 weeks. Placebo is provided by the same manufacturer.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
psychiatrist s clinic
Full name of responsible person
Dr mehnoosh samadi
Street address

Kermanshah, Isar square, next to farabi hospital, faculty of food science and food industries

City
kermanshah

Province
Kermanshah

Postal code
6719851552

Phone
+98 912 601 6296

Fax
+98 83 3710 2002

Email
mehnoosh_samadi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr mehnoosh samadi

Street address
Kermanshah, Isar square, next to Farabi hospital, faculty of food science and food industries

City
Kermanshah

Province
Kermanshah

Postal code
6719851552

Phone
+98 912 601 6296

Fax
+98 83 3710 2002

Email
mehnoosh_samadi@yahoo.com

Web page address

Grant name
Kermanshah university of medical science

Grant code / Reference number
50006699

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
Dr mehnoosh samadi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Kermanshah, Isar square, next to Farabi hospital, faculty of food science and food industry

City
Kermanshah

Province
Kermanshah

Postal code
6719851552

Phone
+98 912 601 6296

Fax
+98 83 3710 2002

Email
mehnoosh_samadi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr mehnoosh samadi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

Street address
Kermanshah, Isar square, next to farabi hospital, faculty of food science and food industries

City
Kermanshah

Province
Kermanshah

Postal code
6719851552

Phone
+98 912 601 6296

Fax
+98 83 3710 2002

Email
mehnoosh_samadi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Sahar aziz
Position
Graduate student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Sanandaj, Zagros street
City
Sanandaj
Province
Kurdistan
Postal code
6617788135
Phone
+98 87 3372 4050
Email
sahar.aziz92@gmail.com

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
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
This study protocol will be written and published in the form of an article. The clinical result of the study will be published in the form of an article.
When the data will become available and for how long
9 months after the end of the study.
To whom data/document is available
The information will be made available to the public.
Under which criteria data/document could be used
To use the findings in the clinic or to write other articles, including review articles. In the case of original articles, researchers will be allowed to do so.
From where data/document is obtainable
Update information via email to the person in charge.
What processes are involved for a request to access data/document
After receiving the request from the person in charge of updating, the study will be provided to the researcher in consultation with the scientific officer.
Comments