

Section / Item	Item No.	Description	Location in Manuscript (Section/Page)
Title & Abstract	1a	Identification as a randomised trial.	Title
	1b	Structured summary of trial design, methods, results, and conclusions.	Abstract
Open Science	2	Trial registry name and identifying number (with URL).	Ethical Considerations (IRCT)
	3	Where the protocol and statistical analysis plan can be accessed.	Availability of Data and Materials
	4	Where and how participant data and statistical code can be accessed.	Availability of Data and Materials
Funding & COI	5a	Sources of funding and role of funders.	Funding Section
	5b	Financial or non-financial conflicts of interest of authors.	Conflicts of Interest Section
Introduction	6	Scientific background and explanation of rationale.	Introduction
	7	Specific objectives regarding both benefits and harms.	End of Introduction
Methods	8	Patient or public involvement in the design and conduct.	Not reported.

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	9	Trial design (e.g., parallel, allocation ratio) and framework.	Study Design (Parallel, 1:1 ratio)
	10	Important changes to methods after trial commencement.	None reported.
	11	Settings and locations where the data were collected.	Study Design (Urmia, Iran)
Eligibility	12a	Eligibility criteria for participants.	Participants Section
	12b	Eligibility criteria for centers and those performing interventions.	Study Design (Specialized clinic)
Interventions	13	Details of interventions and comparator to allow replication.	Interventions Section
Outcomes	14	Pre-specified primary and secondary outcomes and timing.	Outcome Measures
	15	How harms were defined and assessed.	Outcome Measures / Adverse Events
Sample Size	16a	How sample size was determined and assumptions.	Sample Size Calculation
	16b	Interim analyses and stopping guidelines.	Not applicable.

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Randomization	17a	Method used to generate the random allocation sequence.	Randomization (Variable block size)
	17b	Type of randomization and details of any restriction.	Randomization (Block randomization)
	18	Mechanism used to implement the allocation (concealment).	Randomization (Opaque sealed envelopes)
	19	Who generated the sequence and enrolled/assigned participants.	Randomization (Independent researcher)
Blinding	20a	Who was blinded after assignment to interventions.	Randomization (Double-blind)
	20b	Description of the similarity of interventions for blinding.	Randomization (Identical appearance)
Statistical Methods	21a	Statistical methods used to compare groups for outcomes.	Statistical Analysis
	21b	Definition of the population analyzed in each group.	Participant Flow / Results
	21c	How missing data were addressed.	Results (No loss to follow-up)

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	21d	Methods for additional analyses (subgroup/sensitivity).	Statistical Analysis
Results	22a	Number of participants assigned and analyzed.	Participant Flow / Results
	22b	Losses and exclusions after randomization and reasons.	Participant Flow (None)
	23a	Dates defining the periods of recruitment and follow-up.	Study Design (Year 2023)
	23b	Why the trial ended or was stopped early.	Not applicable.
Intervention Delivery	24a	Fidelity: how the intervention was actually delivered.	Follow-Up Section
	24b	Concomitant care and interventions that were permitted.	Interventions (Rescue medication)
Baseline Data	25	A table showing baseline demographic and clinical features.	Table 1
Outcomes & Harms	26	For each outcome, results for each group and effect size.	Results / Tables 2, 3, 4
	27	All important harms or unintended effects in each group.	Adverse Events / Table 5

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	28	Any other analyses performed (subgroup/post hoc).	None reported.
Discussion	29	Interpretation consistent with results (balance of benefits/harms).	Discussion
	30	Trial limitations (potential bias, imprecision, generalizability).	Discussion (Limitations)