CONSORT 2025 checklist of information to include when reporting a randomised trial*

Section / Topic	No	CONSORT 2025 checklist item description	Reported on page no.
Title and abstract			
Title and structured abstract	1a	Identification as a randomised trial Effect of Structured, Diet-Focused Educational Intervention on Knowledge, Attitude, and Practice Related to Vitamin D Among Medical Science Students: A Randomized Controlled Trial	Page 1
	1b	Structured summary of the trial design, methods, results, and conclusions **Introduction:** Vitamin D deficiency is a major public health problem worldwide, with a particularly high incidence among university students in the Middle East and Iran. Despite adequate general knowledge, there are still significant gaps in knowledge and practice in the field of vitamin D nutrition among medical science students. This study evaluated the effectiveness of a structured dietary education intervention on knowledge, attitudes, and practice (KAP) related to vitamin D in Northwestern Iran as part of a larger registry study that also assessed biochemical and academic outcomes (reported separately). **Methodology:** A parallel, double-blind, randomized controlled trial with pre- and post-intervention evaluation was conducted in 132 medical science students at Khoy University of Medical Sciences, West Azerbaijan, Iran, who were randomly assigned to an intervention (n = 66) or control (n = 66) group by stratified block randomization with secret allocation. Participants in the intervention group received four structured 60-minute sessions over four consecutive weeks that combined foundational content on vitamin D physiology and sun exposure with a primary focus on dietary sources and culinary strategies for increasing vitamin D intake. Vitamin D-related KAP was assessed at baseline and three months post-intervention using the validated D-KAP-38 questionnaire; no biochemical (serum 25-hydroxyvitamin D) or dietary intake measures were obtained. Analysis of covariance (ANCOVA) was used to compare post-intervention scores while controlling for baseline differences. **Results:**.At baseline, participants demonstrated relatively high general knowledge (86.16 ± 15.16%) but substantially lower nutritional knowledge (58.86 ± 22.26%) and practice scores (52.10 ± 7.89%). Following the intervention, the intervention group showed statistically significant improvements across all four D-KAP-38 subscales compared with controls: general knowledge (Δ = 9.02%, $p < 0.001$), nutritional knowledge (Δ = 17.88%, $p < 0.001$), attitude (Δ = 7.39%, $p < 0.001$), and practice (Δ = 7.84%, $p < 0.001$). ANCOVA confirmed significant between-group differences for all subscales (all $p < 0.001$, partial η^2 = 0.214–0.277; post-hoc power > 0.99 for all models). **Conclusion:** A four-session, diet-focused educational intervention significantly improved self-reported vitamin D-related knowledge, attitudes, and practice among medical science students in Northwestern Iran, with the greatest gain in nutritional knowledge—historically the weakest component of vitamin D literacy. Because outcomes reported here are knowledge- and self-report-based, they should be interpreted as evidence of improved KAP; whether these improvements are consistent with improved biochemical vitamin D status will be investigated in the companion report of the same study.	Page 1-2

Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration **Trial registration:** Iranian Registry of Clinical Trials (IRCT2026061206975N1), registered retroactively on August 6, 2026.	Page 2
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed The data from the current study are available from the corresponding author upon reasonable request.	
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed This information is available from the corresponding author upon reasonable request.	
Funding and conflicts of interest	5a	Sources of funding and other support (e.g., supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial This study was supported by grants from Khoy University of Medical Sciences to Dr. Jaleh Bagheri Hamzyan Olia (IR.KHOY.REC.1403.041), Khoy, IRAN.	
	5b	Financial and other conflicts of interest of the manuscript authors One of the authors, M. Karimi, was a co-developer of the D-KAP-38 questionnaire (Amiri et al., reference 26), the primary outcome measure used in this study; this prior involvement in instrument development is disclosed here for transparency and did not involve any financial interest. Beyond this, the authors declare no competing interests.	Page 22
Introduction			
Background and rationale	6	Scientific background and rationale Vitamin D deficiency is a major public health problem worldwide, with a particularly high incidence among university students in the Middle East and Iran. Despite adequate general knowledge, there are still significant gaps in knowledge and practice in the field of vitamin D nutrition among medical science students. This study evaluated the effectiveness of a structured dietary education intervention on knowledge, attitudes, and practice (KAP) related to vitamin D in Northwestern Iran as part of a larger registry study that also assessed biochemical and academic outcomes (reported separately).	Page 2-3
Objectives	7	Specific objectives related to benefits and harms Promoting healthy behaviors regarding the correct consumption of food sources rich in vitamin D and vitamin D supplementation. This study does not appear to have any particular harm to the target group.	Page 4
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial Participants from all academic years and fields of study at the Khoy Faculty of Medical Sciences - especially public health, operating room technology, nursing, and emergency medicine	Page 4
Trial design	9	Description of trial design including type of trial (e.g., parallel group, crossover), allocation ratio, and framework (e.g., superiority, equivalence, non-inferiority, exploratory) parallel-group, controlled trial of an educational intervention, with pre- and post-intervention evaluation	Page 4
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason No significant changes occurred in the trial after initiation.	

Trial setting	11	Settings (e.g., community, hospital) and locations (e.g., countries, sites) where the trial was conducted Khoy University of Medical Sciences, Khoy, Iran	Page 1
Eligibility criteria	12a	Eligibility criteria for participants The inclusion criteria were as follows: (1) at least one semester of enrollment as a student at the Khoy Faculty of Medical Sciences; (2) absence of chronic systemic diseases (e.g., renal failure, hepatic insufficiency, malabsorption syndromes, or immune-mediated disorders); (3) no use of vitamin D supplements within the preceding 3 months; (4) no current use of antioxidant agents or lipid-lowering medications; and (5) absence of pregnancy or lactation. The exclusion criteria were as follows: (1) unwillingness to continue with the study, (2) withdrawal from the study, (3) failure to attend required training sessions (intervention group: attendance < 75%), (4) failure to complete the planned T0 or T1 evaluations, and (5) initiation of a new vitamin D supplement regimen after enrollment, self-reported at the T1 assessment via a single yes/no screening question. because broader dietary or lifestyle changes could not be reliably or objectively measured during the follow-up period, only this specific, verifiable change was used as an exclusion criterion.	Page 5
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (e.g., surgeons, physiotherapists) Education should be provided by a specialized team that includes a health education and promotion specialist and a nutritionist and dietician.	Page 6
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (e.g., intervention manual) can be accessed Intervention details are listed in Table 1.	Page 7-10
Outcomes	14	Pre-specified primary and secondary outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome The primary outcomes of the study were changes in knowledge, attitudes, and behavior regarding vitamin D consumption.(table 3-4)	Page 13-15
Harms	15	How harms were defined and assessed (e.g., systematically, non-systematically) The harms considered in this study are low levels of knowledge, attitudes, and behavior regarding vitamin D consumption, that average scores of which were determined by completing a questionnaire.(table 4)	Page 14-15
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation The participants were randomly assigned to either the intervention or control groups by randomized, stratified block (block size = 12) randomization using the Web-Power statistical software (version 0.6, University of Missouri) (25). Randomization was performed by an investigator who was not involved in the data collection or delivery of the intervention, and allocation was concealed by sequentially numbered, sealed opaque envelopes after enrollment. The target sample size was calculated using the Web-Power software using the following parameters: two-tailed significance level of alpha = 0.05, statistical power $(1 - \beta) = 0.80$, and expected effect size (Cohen's d) = 0.35. The expected effect size of Cohen's d = 0.35 was based on a conservative estimate, as prior nutrition education intervention studies in medical science students have reported effect sizes ranging from moderate to large ($\eta^2 = 0.30–0.40$) for knowledge outcomes (22), with the assumption that a controlled design would yield a more conservative effect. These assumptions resulted in the minimum required sample of 54 participants in each group. Considering the expected attrition rate of approximately 20%, the final target was set at 66 participants in each group, resulting in a total sample of 132 participants (intervention group: n = 66; control group: n = 66).	Page 4-5
	16b	Explanation of any interim analyses and stopping guidelines There were no interim analyses or discontinuations in the study.	

Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used Randomization was performed by an investigator who was not involved in the data collection or delivery of the intervention.	Page 4
	17b	Type of randomisation and details of any restriction (e.g., stratification, blocking and block size) Individual random allocation to study groups was nevertheless performed, with concealed allocation and double blinding. The participants were randomly assigned to either the intervention or control groups by randomized, stratified block (block size = 12) randomization using Web-Power statistical software (version 0.6, University of Missouri). Randomization was performed by an investigator who was not involved in the data collection or delivery of the intervention, and allocation was concealed by sequentially numbered, sealed opaque envelopes after enrolment.	Page 4
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (e.g., central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned. Allocation was concealed by sequentially numbered, sealed opaque envelopes after enrolment.	Page 4
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence No	
Blinding	20a	Who was blinded after assignment to interventions (e.g., participants, care providers, outcome assessors, data analysts) Participants and outcome assessors blinded	Page 4
	20b	If blinded, how blinding was achieved and description of the similarity of interventions Double-blind design; participants and outcome assessors blinded; attention-matched control program; allocation codes held by statistician until analysis	Page 4
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms To evaluate the intervention's effectiveness, a paired t-test compared pre- and post-intervention scores within each group, and an independent t-test compared scores between groups at each time point. Analysis of covariance (ANCOVA) was performed to compare post-intervention scores between groups while controlling for baseline differences. Before ANCOVA, all relevant assumptions, including normality of residuals, homogeneity of variances, linearity, independence of covariate and treatment, and homogeneity of regression slopes, were tested and confirmed. The homogeneity of regression slopes assumption was met for all models (group × covariate interaction; exact interaction p-values for the four models are reported in Table 4 note). Partial eta squared (η^2) was reported as the effect size for all ANCOVA models and interpreted using Cohen's conventional benchmarks ($\eta^2 \approx 0.01$, small; ≈ 0.06, medium; ≥ 0.14, large). Post statistical power for each ANCOVA model was calculated from the observed partial η^2, the model degrees of freedom, and the total sample size (N = 132) using the noncentral F-distribution. A p-value < 0.05 was considered statistically significant for all analyses.	Page 10-11
	21b	Definition of who is included in each analysis (e.g., all randomised participants), and in which group Total sample size (N = 132) Intervention (n = 66) or control (n = 66) group	Page 11

	21c	How missing data were handled in the analysis We had no missing data.	Page 13-15
	21d	Methods for any additional analyses (e.g., subgroup and sensitivity analyses), distinguishing prespecified from post-hoc We had no additional analyses	
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome Intervention (n = 66) or control (n = 66) group	Page 13-15
	22b	For each group, losses and exclusions after randomisation, together with reasons We did not have any additions or deletions in the groups.	Page 11-15
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms Data were collected at two time points: at baseline (T0, before the intervention) and three months after the end of the training intervention (T1).	Page 5
	23b	If relevant, why the trial ended or was stopped The study was completed at the scheduled time and there were no unplanned or forced discontinuations.	
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (e.g., where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended [fidelity]) Randomization was performed by an investigator who was not involved in the data collection or delivery of the intervention. Double-blind design; participants and outcome assessors blinded; attention-matched control program; allocation codes held by statistician until analysis. Education should be provided by a specialized team that includes a health education and promotion specialist and a nutritionist and dietician. H.M. participated in the recruitment of participants, coordination of randomisation, data collection, and the administration of the questionnaire. M.K., a biostatistician who was previously involved in the development of the D-KAP-38 instrument (reference 26), contributed to the design of the study and the statistical analysis and interpretation of the data of the D-KAP-38. J.B.H.O. conceived and designed the study, obtained ethical approval and funding, and supervised all study phases. All authors contributed to drafting and critically revising the manuscript, read, and approved the final version for submission. Participants fulfilled their commitments and none dropped out of the study. We had no missing data.	Page 4 Page 6 Page 22 Page 13-15 Page 19-20
	24b	Concomitant care received during the trial for each group The details of the training for the intervention group are indicated in Table 1. To preserve blinding, the control group received an attention- matched program of four 60-minute sessions on general health education topics unrelated to vitamin D (e.g., general hygiene, sleep, and stress managment topics) delivered over the same four-week period by the same facilitators and in the same instructional format as the intervention program, but without any vitamin D- related content.	Page 7-10
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group Table 2	Page 12
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: ● the number of participants included in the analysis ● the number of participants with available data at the outcome time point ● result for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Page 11-15

		• for binary outcomes, presentation of both absolute and relative effect size Total sample size (N = 132) Intervention (n = 66) or control (n = 66) group	
Harms	27	All harms or unintended events in each group We had no harm or unwanted events in the groups.	
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post-hoc We didn't have any.	
Discussion			
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence All necessary items have been mentioned.	Page 16-20
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses All necessary items have been mentioned.	Page 19-20

*We strongly recommend reading this statement in conjunction with the CONSORT 2025 Explanation and Elaboration and/or the CONSORT 2025 Expanded Checklist for important clarifications on all the items. We also recommend reading relevant CONSORT extensions. See www.consort-spirit.org.

Citation: Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 Statement: updated guideline for reporting randomised trials. BMJ. 2025; 388:e081123. https://dx.doi.org/10.1136/bmj-2024-081123.