Original Article

Evaluating the effect of cow's milk fortified with albumin powder on malnutrition and anthropometric indices in primary-school children with mild-to-moderate underweight: A randomized double-blinded clinical trial

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Background: A proper diet plan is one of the necessary conditions for maintaining the children's health. The aim of this study was to evaluate the effect of consumption of pasteurized cow's milk fortified with albumin protein in primary-school children, in Yasuj, Iran. **Materials and Methods:** In this double-blind randomized clinical trial with 12 weeks of duration, 60 children aged 7–13 years, mild to moderate underweight (−1≥ weight-for-age *z*-score ≥−3), were randomly assigned to control and albumin groups. The albumin group and the control group received 200 cc of milk with 10 g of albumin powder and 200 cc of milk with 10 g of cornstarch powder, respectively. At the beginning and end of the study, food intake and anthropometric indices were measured. **Results:** After 12 weeks of intervention, none of the anthropometric indices (weight, weight-for-age *z*-score, body mass index (BMI), BMI-for-age *z*-score, and waist circumference) showed significant changes as compared to baseline in the control group, but weight-for-age *z*-score and BMI-for-age *z*-score showed significant increase as compared to baseline in the albumin group (before: −2.25 ± 0.40, after: −1.98 ± 0.35, $P = 0.001$ and before: −3.48 ± 0.86, after: −3.06 ± 0.71, $P = 0.009$, respectively). The comparison of the mean changes between the two groups showed significant difference regarding weight-for-age *z*-score (control group: −1.70 ± 0.31 in comparison with albumin group: −1.98 ± 0.35, $P = 0.002$), BMI (control group: 12.08 ± 1.96 in comparison with albumin group: 12.13 ± 1.49, $P = 0.03$), and BMI-for-age *z*-score (control group: −3.11 ± 0.91 in comparison with albumin group: −3.06 ± 0.71, $P = 0.02$). **Conclusion:** The consumption of albumin powder with milk can improve weight-for-age *z*-score and BMI-for-age *z*-score indices in children with mild-to-moderate underweight. Larger controlled interventional studies with longer duration are recommended.

Key words: Albumins, malnutrition, milk, primary-school children

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INTRODUCTION

Protein energy malnutrition (PEM) has been recognized as a major risk factor of global health, leading to remarkable deaths in children.[1] Pediatric malnutrition is described as an imbalance between nutrient body demand and food supply giving rise to energy, protein, and micronutrients deficiencies which may affect children growth, development, and incidence of chronic diseases.[2]

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Children are more likely to be malnourished due to their special nutritional requirements for their physical and mental growth and development.[3,4] Evidences suggest that malnutrition in the early years of life commonly leads to reduced body growth, mental disorders like mental retardation, lack of academic achievement, and reduced work efficiency.[5-7] Moreover, they may encounter physical and mental disorders in later life.[5-7] Therefore, an appropriate dietary plan is essential for maintaining children's health.[7,8] Primary school children are an important target group in terms of social, health and nutritional vulnerability, since they enter the new school environment, and this often causes alterations in some habits and methods of life, especially their dietary habits.[9-11]

PEM is the most common type of malnutrition among Iranian children,[12-14] and usually the median protein intake among Iranian children is less than recommended for their age group.[12-14] Previous studies have found insufficient food intake as the main reason for this finding.[12-14] Moreover, behavioral problems related to eating and lack of proper education of parents are the next influential factors in this deficiency.[12-14] Lack of adequate protein intake impairs height weight growth throughout affecting musculoskeletal growth. On the other hand, lack of protein intake by affecting the process of carbohydrate metabolism (glycogen storage of liver and muscle) leads to insufficient supply of substrate for the anabolic process participating in growth.[11,15,16] Low quality of protein intake is also determined as the main factor affecting the process of growth and repair.

Meats, eggs, dairy products, and legumes are the valuable food sources of protein with high biologic value, yet their consumption is less in the age group of children.[1,17,18] Issues such as family economy, individual taste, and increasing consumption of ready-to-eat foods are among the factors limiting the consumption of this valuable source of protein.[19-22]

For many years, various egg components including albumin have been available as ready-to-eat supplements for therapeutic purposes. Albumin is an egg white protein with very high nutritional value. According to some previous findings, the consumption of this protein can improve many indicators of malnutrition and therefore has been considered by researchers as a supplement of protein therapy.[19,21]

Given that children are more likely to be malnourished due to their special nutritional requirements for their physical and mental growth, finding a safe and workable nutritional solution to improve growth-related indicators seems necessary. Furthermore, because of positive effects of albumin protein have been shown in improving the malnutrition's indicators in some age groups and also lack of study on the age group of primary school children; we conducted this study with the aim at investigating the effect of consuming pasteurized cow's milk fortified with albumin protein in underweight 7–13 years-old primary school children in Yasuj, Iran.

METHODS

Study design and patients' characteristics

This is a randomized controlled, parallel, double-blind trial conducted on July 5, 2020 to November 10, 2020 and conformed to the Declaration of Helsinki Guidelines. The study protocol was reviewed and approved by the ethics committee of Shiraz University of Medical Sciences, Shiraz, Iran, (approval number.IR.SUMS.REC.1399.483), and enrolled in the Iranian Registry of Clinical Trials (IRCT20210109049971N1).

The inclusion criteria were as follows: Elementary students, with lack of underlying diseases affecting student development such as diabetes, hypothyroidism, liver and kidney problems, seizures, and mental retardation, do not take any dietary supplements or have a special diet 6 months before the study, mild to moderate underweight (as defined by the World Health Organization $-1 \geq z$-score≥ -3). Children who did not consume prescribed beverage, hospitalized during the intervention, and those who were lactose intolerant or had allergy to cow milk were excluded.

Sample size

The sample size of 60 was calculated according to weight for age in a previous similar study Graham *et al*.[23] with considering a type 1 error of 5%, power of 80%, and a drop-out rate of 10%.

Sampling

Participants aged 7–13 years old were selected by two-stage cluster sampling from the list of all primary schools in Yasuj, Iran. In this way, at first, the list of all primary schools in Yasuj was prepared and several schools were selected as the main cluster by simple random method. After coordination with the school principal, students were selected from each school. For all students whose parents had given their final consent, the anthropometric parameters (height and weight) were measured and entered into the Anthro WHO software to calculate the standard score (Z score). In a Z score system, weight-for-age is expressed as the number of standard deviations (SDs) or Z scores below or above the reference mean.[24] According to the definition of the World Health Organization, $-1 \geq$ weight-for-age z-score≥ -3 was considered as mild to moderate underweight.[25] This stage continued until the number of eligible children reached to 60.

Randomization

Participants were randomly allocated in a 1:1 ratio to the albumin and control groups. Randomization was conducted by the random allocation software[26] to allocate patients using blocked randomization with a fixed block size of two. The allocation was performed according to this order and continued until all participants are specified to an arm. Randomization was done by an investigator who had no clinical involvement in the trial. Furthermore, other procedures including enrollment, sequence generation, allocation concealment, and randomization process were all performed by the principal investigators.

Blinding

To blind patients to the samples, the interventions in the both groups were identical in appearance and color. The interventions were coded differently in each group to blind the investigator.

Intervention

Participants in the albumin group received 200cc cow's milk (3% fat, Pegah-e Fars Dairy Company, Iran) with 10 g albumin powder (Golpoodr Golestan Company, Iran) per day and in the control group received 200 cc cow's milk (3% fat, Pegah-e Fars Dairy Company, Iran) with 10 g cornstarch powder (Golpoodr Golestan Company, Iran) per day for 12 weeks. In this way, every 2 weeks, 14 packages 200 cc of cow's milk with 140 g of albumin powder in the albumin group and also, 14 packages 200 cc of cow's milk with 140 g of cornstarch powder in the control group were delivered to the children's parents and they were instructed to combine 10 g of albumin powder with 200 cc of lukewarm milk daily and be given with the child's usual breakfast in the albumin group and 10 g of cornstarch powder with 200 cc of lukewarm milk in the control group as the same.

Parents of children were asked to come every 2 weeks for delivery of interventions (cow's milk + albumin powder/ cow's milk + cornstarch powder) and adherence checklist. Adherence to the study was measured using a designed daily checklist. Parents determined daily consumption or nonconsumption of their children by marking this checklist. If participants consumed < 80% of the prescribed, subjects were excluded from the study analysis. Moreover, consuming the assigned intervention was reminded to the parents of the children by a text message every week and they were asked not to change their children's diet and normal physical activity and to refrain from taking any kind of food supplement during the study period.

Outcomes and measurements

Before the study, the demographic questionnaires were filled through face-to-face interview by the main investigator. To assess dietary intake and monitor dietary compliance, 3-day dietary recalls (including 2-week days and 1 weekend day) were collected from subjects at baseline and at the end of the study phase. Nutrient composition was determined by Nutritionist IV version 3.5.2 (Hearst Corp., San Bruno, CA). Height was measured using a wall-fixed tape to the nearest 0.1 cm. Before and after intervention, body weight was measured to the nearest 0.1 kg using (SECA) scale while participants were in light clothes. In addition, waist circumference was measured by a nonstretchable measure tape according to standard methods based on either bony landmarks (iliac crest, last rib, or midpoint) or external landmarks (minimal waist, largest abdominal circumference, umbilicus, 1 cm above umbilicus, or 1 inch above umbilicus).[27] Body composition indices including body fat percent, lean body mass percent, and present of total water were determined by BIA (Bodystat QuadScan 4000 device, England) at baseline and at the end of the study. Physical activity was measured using the Children's Physical Activity Questionnaire.[28]

Statistical methods

Statistical analysis of the data was performed using the SPSS software version 16 (IBM, Armonk, USA). Normality of data was assessed by Kolmogorove–Smirnov test. The Chi-square test was used for qualitative statistical data. Furthermore, to compare the changes between the start and end of the intervention in each group, paired *t*-test was used for the data with normal distribution and Wilcoxon signed-rank test was used for skewed data. Independent *t*-test was used to compare the two groups with normal distribution. The analysis of covariance was used to adjust energy and physical activity. Mann–Whitney test was used in the case of abnormal distribution. $P < 0.05$ was considered statistically significant.

RESULTS

Figure 1 shows the general study process. During the intervention phase of the study, three patients left the study due to different reasons. The mean ± SD of age of participant was 9.14 ± 2.11 and 9.87 ± 2.36 years in the control and albumin group, respectively. In our study, about 25% of the participants were boys. In the baseline, none of the measured parameters had a significant difference between the two groups.

The changes in the measured parameters are shown in Table 1. In the control group, none of the measured anthropometric indices including weight, body mass index (BMI), weight-for-age *Z*-Score, BMI-for-age *Z*-Score, and waist circumference (cm) could not show a significant change after 12 weeks of intervention compared to baseline ($P > 0.05$ for all cases). While in the albumin group, *z*-score weight for age (before:

Table 1: Effect of interventions on the levels of measured parameters in participants after 12 weeks

Valuables	Control group (*n*=29)			Albumin group (*n*=28)			*P***	*P****
	Before	After	*P**	Before	After	*P**		
Weight (kg)	21.88±4.32	22.10±5.69	0.83	20.46±4.15	21.22±4.54	0.11	0.27	0.38
BMI (kg/m²)	11.90±1.87	12.08±1.96	0.61	11.64±1.35	12.13±1.49	0.07	0.04	0.03
Weight-for-age *Z*-score	−1.77±0.27	−1.70±0.31	0.21	−2.25±0.40	−1.98±0.35	0.001	0.002	0.01
BMI-for-age *Z*-score	−3.22±0.77	−3.11±0.91	0.46	−3.48±0.86	−3.06±0.71	0.009	0.001	0.02
Waist circumference (cm)	52.86±3.14	52.75±4.55	0.63	51.23±3.77	52.45±4.21	0.38	0.32	0.45
Adipose tissue (%)	15.62±4.01	16.33±4.67	0.34	15.40±3.98	15.78±4.44	0.61	0.39	0.55
Lean tissue (%)	49.34±12.53	50.53±15.17	0.65	48.73±13.55	49.42±15.17	0.79	0.28	0.62
Total water (%)	64.45±16.78	63.59±15.23	0.77	64.35±16.91	64.71±16.36	0.90	0.76	0.9
Physical activity (MET/min/day)	31.65±7.88	29.86±9.35	0.43	35.17±8.45	33.28±7.89	0.39	0.14	0.19

*Paired *t*-test has been used for changes within groups; **Independent t-test was used to compare the mean of changes between the groups; ****P*-value was adjusted for energy and physical activity as confounders. Numbers are expressed as mean±SD. SD=Standard deviation; BMI=Body mass index

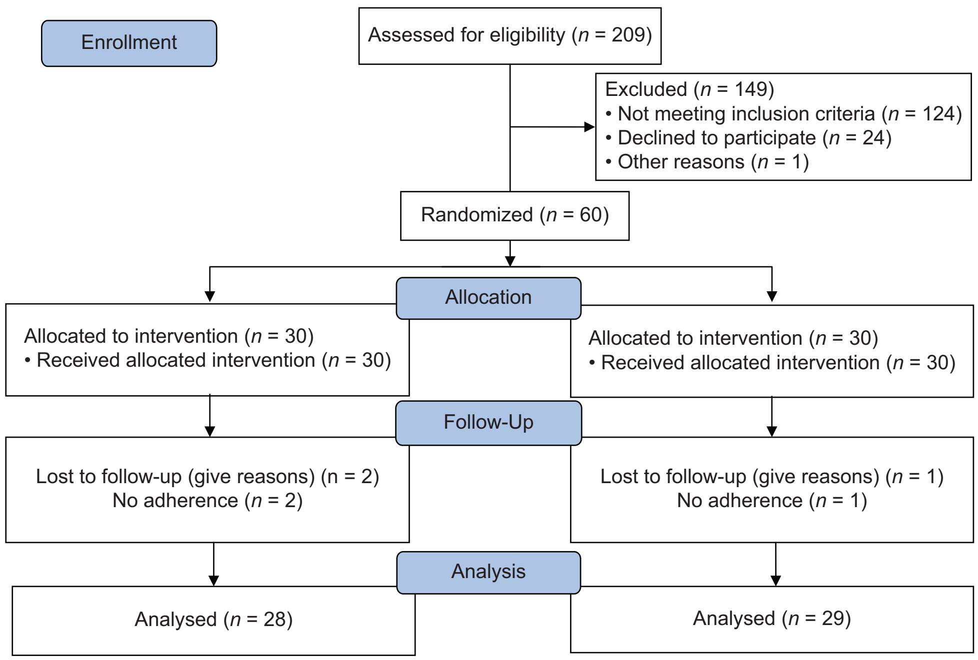

Figure 1: Flow diagram of the trial

−2.25 ± 0.40, after: −1.98 ± 0.35, *P* = 0.001) and *z*-score BMI for age (before: −3.48 ± 0.86, after: −3.06 ± 0.71, *P* = 0.009), were able to show a significant improvement compared to baseline. The changes were significant in comparison with the control group for BMI (control group: 12.08 ± 1.96 in comparison with albumin group: 12.13 ± 1.49, *P* = 0.03), weight-for-age *Z*-Score (control group: −1.70 ± 0.31 in comparison with albumin group: −1.98 ± 0.35, *P* = 0.002), [Figure 2a], and BMI-for-age *Z*-Score (control group: −3.11 ± 0.91 in comparison with albumin group: −3.06 ± 0.71, *P* = 0.02), [Figure 2b].

After 12 weeks' intervention, body composition (adipose tissue [%], lean tissue [%], and total water [%]) did not change significantly compared to baseline in any of the studied groups ($P > 0.05$ for all cases). Furthermore, the comparison of the mean changes of these indices between the study groups did not indicate any significant change ($P > 0.05$ for all cases). In term of physical activity, none of within and between the group changes was significant.

Table 2 shows the changes in food intake. In both groups, the amount of received energy showed a significant increase after the intervention, but after comparing the mean changes between the two groups, these changes were not significant ($P = 0.35$). Similarly, the amount of dietary fat intake in both groups showed a significant increase when compared to the baseline, while changes between the two groups could not show a significant difference ($P = 0.4$). The mean protein intake in both groups was significantly increased and this mean increase was significant in the albumin group compared to the control group ($P = 0.02$). In terms of carbohydrate and fiber, there was not seen a significant change between groups.

There was no change in the results after adjusting the effect of energy intake and physical activity.

Table 2: Effect of interventions on food intake in participants after 12 weeks

Valuables	Control group (*n*=29)			Albumin group (*n*=28)			*P***	*P****
	Before	After	*P**	Before	After	*P**		
Energy (kcal/kg)	81.38±113.29	96.98±107.11	0.04	88.62±108.93	105.32±122.99	0.03	0.17	0.35
Carbohydrate (g/day)	269.77±83.09	298.15±95.30	0.07	272.81±72.25	286.43±60.31	0.06	0.10	0.25
Protein (g/kg)	2.31±2.83	2.88±2.49	0.02	2.56±3.08	3.72±1.74	0.001	0.04	0.02
Fat (g/day)	64.99±5.65	73.17±7.36	0.03	64.80±6.31	70.78±11.19	0.001	0.10	0.4
Fiber (g/day)	5.66±2.61	5.81±3.03	0.23	4.92±3.88	5.26±2.43	0.03	0.52	0.8
Percentage calorie of carbohydrate out of total calorie	60.59±67.9	55.64±62.54	0.77	60.18±63.92	51.26±43.20	0.53	0.76	0.41
Percentage calorie of protein out of total calorie	11.37±10.01	11.91±9.31	0.83	11.57±11.31	14.15±5.65	0.27	0.27	0.11
Percentage calorie of fat out of total calorie	32.84±10.38	30.72±10.86	0.45	32.16±12.56	28.50±18.03	0.37	0.57	0.16

*Paired *t*-test has been used for changes within groups; **Independent t-test was used to compare the mean of changes between the groups; ****P*-value was adjusted for energy and physical activity as confounders. Numbers are expressed as mean±SD. SD=Standard deviation; BMI=Body mass index

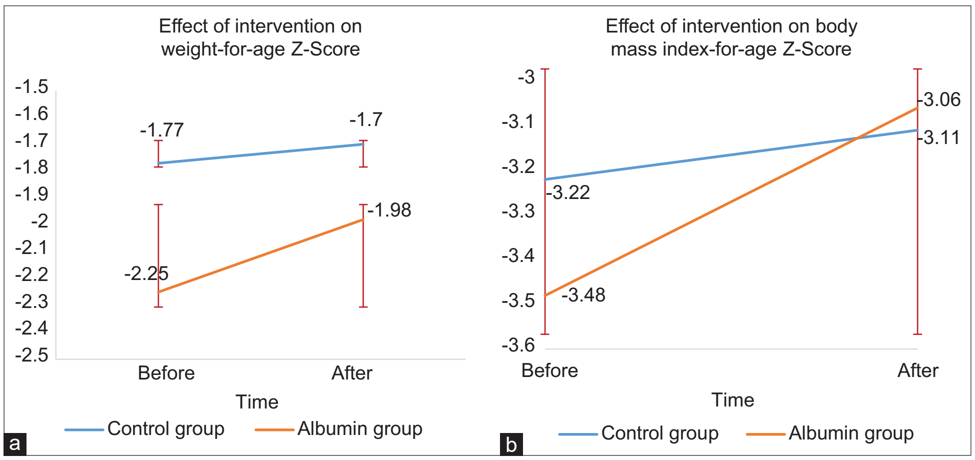

Figure 2: (a) Changes in weight-for-age *Z*-Score and (b) changes in body mass index-for-age *Z*-Score

DISCUSSION

To the best of the authors' knowledge, this is the first study that examined the effect of 12 weeks consumption of 200 cc cow's milk fortified with 10 g albumin powder on malnutrition indices in children with mild and moderate malnutrition. Our findings showed a significant improvement was seen in *Z*-score of weight-for-age, BMI, and *Z*-score of BMI-for-age after 12 weeks' intervention. The body mass composition of the participants did not change significantly neither in the group receiving albumin protein powder with milk nor in the group receiving cornstarch powder with milk.

In this study, consumption of cow's milk fortified with albumin powder for 12 weeks could not significantly change weight in participants. Contrary to our finding, the result of the school milk program on children's nutritional status in Malaysia showed a significant reduction in the prevalence of malnutrition and being underweight (6.8%–3.15% reduction);[29] however, it should be noted that this information was for a period of 2 years and it is possible to attribute this significant results to a longer study period. An interventional study examining the effect of school milk schemes on Chinese girls reported that milk consumption led to weight gain over 2 years.[30] Another interventional study of 92 Japanese children demonstrated an increase in weight among children who drank more milk over a 3-year period.[31] Again, in both previous studies, the longer duration of the intervention can be considered as a prominent point in these studies leading to significant weight gain. Berkey *et al.*[32] confirmed the positive relationship between milk consumption and weight gain, affirming that children who drink more than three glasses of milk per day have a higher BMI than children who drink 1–2 glasses or 0–0.5 glasses of milk per day. Drinking more milk by providing extra energy for underweight children can lead to more weight gain. The amount of milk intake in our study was not as much as mentioned by Berkey *et al*. Therefore, in addition to the short study time, the low amount of milk intake may be another reason for nonsignificant results in our study.

According to our findings, a significant improvement in *Z*-score of weight-for-age, *Z*-score of BMI-for-age, and BMI in the intervention group compared to the control group was observed. Although the 12-week intervention did not significantly alter weight directly, the weight-dependent indices improved significantly compared with the control group, which can be attributed to the albumin protein used in the study. However, measuring waist circumference did not show significant changes in this study, which short time of intervention may lead to this result.

None of the groups showed significant changes in body mass composition including adipose tissue, lean body mass, and total body water. The interpretation of this result is very difficult due to the lack of a similar study that measures the effect of albumin powder consumption on children's body mass composition. The lack of significance of changes in body mass composition in both groups, despite significant changes in some weight-dependent indicators, may be due to the fact that the overall impact on weight-dependent indicators changes was low. On the other hand, it should not be forgotten that the measurement of body mass composition with BIA can be affected by the measurement error or the required conditions that may lead to nonsignificant results.

After 12 weeks of intervention, calorie, fat, and protein intake increased significantly in both groups. However, the significant changes between groups were only observed in protein intake, which indicates the accuracy of the study design and acceptable adherence of participants.

Reporting no side effects by the participants is one of the noteworthy points of this study. In addition, this study is the first and only study to investigate the effect of consuming albumin powder with a beneficial food source such as milk on the anthropometric indices on underweight children, which could show the positive effect of this intervention in this important age group. One of the limitations of this study, in addition to the small sample size, is the short duration of the intervention. Furthermore, we did not measure and discuss the effects of our interventions on other nutrients intake. Due to the unclear effect of long-term use of albumin powder with rich and beneficial nutrients such as milk in underweight and malnutrition children, it is recommended to conduct a stronger controlled intervention study over a longer period of time.

CONCLUSION

According to the available results, it seems that the consumption of albumin powder with milk can improve some anthropometric indices in children with mild to moderate underweight without any side effects. Although body mass composition could not change significantly, it seems that better results could be achieved by prolonging the intervention time. It should be mentioned that although providing energy and protein intake are the main components of interventions to improve underweight status, micronutrients are of great significance in healthy growth and development, as well. Therefore, pure protein fortification may not substitute whole food consumption in growing children and all food groups should be consumed.

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Conflicts of interest

There are no conflicts of interest.

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