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Evaluation of the Impact of a Food Program on the Micronutrient Nutritional Status of Argentinean Lactating Mothers

--Manuscript Draft--

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Abstract:	This study was conducted to evaluate the impact of a food aid program (Plan Más Vida, PMV) on the micronutrient nutritional condition of lactating mothers one year after its implementation. The food program provided supplementary diets (wheat- and maize-fortified flour, rice or sugar and fortified soup) to low income families from the province of Buenos Aires, Argentina. A prospective, non-experimental study was carried out to evaluate the micronutrient nutritional status of lactating mothers (n=178 at baseline and n=151 after one year). Biochemical tests (hemoglobin, ferritin, zinc, vitamin A, folic acid), anthropometric assessments (weight and height) and dietary surveys (24 h-recall) were performed. We found no significant changes in anthropometric values one year after the intervention. The risk for vitamin A (retinol 20-30 µg/dl) and folate deficiency significantly decreased one year after PMV implementation (56.3% vs. 29.9% and 50.3% vs. 3.4%, respectively; p<0.001). Anemia was seen in 25.8% of lactating mothers at baseline, without statistically significant differences one year after (p=0.439). The nutritional data obtained after assessing the

	early impact of PMV actions may be useful to provincial health authorities to perform periodic evaluations in the future.

Cover Letter
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Instituto de Desarrollo e Investigaciones Pediátricas
Prof. Dr. Fernando E. Viteri

La Plata, August 21, 2012.

Managing Editor
Biological Trace Element Research

We are enclosing for your consideration the revised version of our manuscript "Evaluation of the Impact of a Food Program on the Micronutrient Nutritional Status of Argentinean Lactating Mothers".

All authors have read the revised version of the manuscript and have agreed to submit it in its current form for consideration for publication in the Journal.

Sincerely yours,

Horacio F. González, M.D., on behalf of all authors
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Dear Sirs:

Thank you for the comments to our paper "Evaluation of the Impact of a Food Program on the Micronutrient Nutritional Status of Argentinean Lactating Mothers". According to the reviewer´s suggestions, we have introduced the following changes, which have been read and approved by all authors:

Reviewer #1:

The authors should describe in more detail the program Plan Más Vida. On the website of the program is described that beneficiaries receive monthly a fixed amount of money, according to the number of children, for the purchase of food and that there is a daily delivery of milk to the beneficiaries. Both facts are not fully mentioned in the manuscript. Is this milk fortified with micronutrients?

The program Plan Más Vida has changed in the past few years. From 2003 to 2009 (our study period) it only delivered food items. From 2009 onwards, it is implemented differently: 1) the Ministry of Human Development deposits monthly a fixed amount of money according to the number of children; that money can only be used to buy food items. Beneficiaries also receive daily ½ a liter of iron-fortified milk per each child < 6 years.
This is the reason why new details are not included in the text given the changes in the program in the last years.
The food items included in the program during our intervention are described in Materials and Methods (page 4, lines 15-20).

Concerning the description of fortified products, the compound of iron and zinc utilized should be reported.

- The compunds have bee included (page 4, lines 15 and 18).

Table 3. It is necessary to include vitamin A intake and adequacy.

- The data have been included.

Are the folates intake underestimated? On the other hand, there is a wide dispersion of the folic acid intake values, at baseline and one year after surgery. What is the cause of this great dispersion of folic acid intake values?

- A comment has been included in the Discussion (page 10, lines 11-15).

Figure 1. Delete <mu>g/d

- The correction has been made and the figure has been replaced by another one, as suggested by Reviewer 2.

Abstract. Include more details about the program Plan Más Vida.

- Done (page 2, lines 3 and 4).

Reviewer #2: BTER-D-12-00109

Abstract

- **Rows 4-5: indicate what was evaluated. If not, the sentence is poorly written.**
- **Rows 8-9: indicate what changes were recorded.**
- **Row 10: change p=0.000 to p<0.001.**
- **The abstract needs revision by native speaker.**

- All suggestions have been answered accordingly.

Introduction

- **4th paragraph, rows 1-3: sentence needs rewriting. For example, change micro/macronutrient deficit/excess to double-burden of nutrition.**

- The sentence was rewritten (page 3, line 18).

Materials and Methods

Subjects

- **Indicate whether subjects provided a written consent and whether an ethics committee approved the study protocol prior to implementation.**

- The information has been included (page 5, lines 4-7).

Sample size

- Please provide the actual data of historical or reference prevalence of folate deficiency, anemia, etc. This is not mentioned anywhere in the manuscript.

- A reference has been included (≠17).

Assessments

- **Second sentence is unnecessary. Results should be provided in the results section.**

- The sentence has been eliminated.

Dietary survey

- **The nutritional intervention should probably be described before the description of the assessments.**

- The paragraph has been moved (page 4, lines 14-23).

- **The sentence regarding IRB approval should be included under the subjects sub-section. Information about subject consent is still needed.**

- The sentence has been included in the Subjects section and information about informed consent added (page 5, lines 4-7).

Statistical analysis

- Indicate whether the ferritin, folic acid, zinc and vitamin A concentrations actually had a log-normal distribution. Assuming this is not enough.

- The sentence has been rewritten (page 7, lines 4-6).

Results

- **Rewrite second sentence of first paragraph so that it does not seem as if the 8.6% increase was important.**

  - The sentence was rewritten.

- **Last paragraph: it had not been mentioned previously that milk was included in the food basket.**

  - The sentence has been eliminated

Discussion

- **Overall, this reviewer finds that the discussion needs major improvement, especially in the interpretation of how different data obtained might or might not explain observed results. At the moment the main (and very basic) results are compared to other studies, but no thorough discussion is provided. Also, little is mentioned regarding potential confounders.**

  - A paragraph with limitations of our study has been added (page 10, lines 24 and 25; page 11, lines 1 and 2).

- **Regarding folate: given that the intervention coincided with mandatory flour fortification with folic acid, authors need to provide a comment regarding how much of the observed decrease could be attributed to the intervention. Authors also need to bring together the results observed for adherence, intake and prevalence of deficiency. If adherence was high and the prevalence of deficiency dropped so markedly, why do subjects have low intakes at both periods?**

  - A comment has been included (page 10, lines 11-15).

- **Regarding zinc: how much of a factor is the low prevalence at baseline in not observing an effect of the intervention? How much can the data on intake explain the results?**

  - A comment in this regard has been included (page 9, lines 20 and 21).

- **Regarding iron: a 12-month intervention should be a long enough period to observe an effect of an intervention. Authors need to discuss relationship between observed anemia rates and observed iron deficiency prevalence.**
  - A comment has been included (page 9, line 26; page 10, lines 1 and 2).

Conclusions

- **Given the nature of the study design (pre-post evaluation with no control group) conclusions cannot be provided regarding the possible positive effect of the intervention on micronutrient deficiencies or its negative effect on obesity rates. Main findings and conclusions need to be put in perspective of overall context and also taking into account interpretation of all data as a whole.**

  - The conclusions have been rewritten.

Table 1
- **Statistical comparisons need to be included (test used, p-values, etc.)**

Table 2
- **Change p=0.000 to p< 0.001**

Table 3
- **Statistical comparisons need to be included (test used, p-values, etc.)**

Figure 1
- Display does not allow for reader to determine if curve shifts to the right. Probably better to include both distributions in a single plot that includes description of mean values (+/- SDs)

- The tests used and the p values have been included in all tables. The Figure has been replaced by another one.

Reviewer #3: Manuscript is interesting, but its English should be improved before critical evaluation.

The manuscript was revised by a native speaker.

Hoping that in its present form the manuscript will be suitable for publication,

Sincerely yours,

Horacio F. González, M.D., on behalf of all authors

Evaluation of the Impact of a Food Program on the Micronutrient Nutritional Status of Argentinean Lactating Mothers

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Short running head: Evaluation of a Nutritional Program in Argentinean Lactating Mothers

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Abstract This study was conducted to evaluate the impact of a food aid program (Plan Más Vida, PMV) on the micronutrient nutritional condition of lactating mothers one year after its implementation. The food program provided supplementary diets (wheat- and maize-fortified flour, rice or sugar and fortified soup) to low income families from the province of Buenos Aires, Argentina. A prospective, non-experimental study was carried out to evaluate the micronutrient nutritional status of lactating mothers (n=178 at baseline and n=151 after one year). Biochemical tests (hemoglobin, ferritin, zinc, vitamin A, folic acid), anthropometric assessments (weight and height) and dietary surveys (24 h-recall) were performed. We found no significant changes in anthropometric values one year after the intervention. The risk for vitamin A (retinol 20-30 µg/dl) and folate deficiency significantly decreased one year after PMV implementation (56.3% vs. 29.9% and 50.3% vs. 3.4%, respectively; $p<0.001$). Anemia was seen in 25.8% of lactating mothers at baseline, without statistically significant differences one year after ($p=0.439$). The nutritional data obtained after assessing the early impact of PMV actions may be useful to provincial health authorities to perform periodic evaluations in the future.

Key words Feeding Programs · Lactating Mothers · Anemia · Micronutrients · Nutritional Evaluation · Argentina

Introduction

The rapid changes in food habits and lifestyles that have occurred with industrialization, urbanization, economic development and market globalization over the past century have impacted markedly on the health and nutritional condition of populations, particularly in low income countries [1-3].

In developing countries, the prevalence of postpartum anemia is in the range of 50% and 80% and associated with an impaired quality of life, reduced cognitive abilities and emotional instability and depression, thus constituting a significant health problem in women of reproductive age [4].

Studies performed in lactating women in different countries have reported high prevalences of anemia and micronutrient deficiencies (vitamin A, zinc, folic acid) [5-8]. In this context, Latin America is no exception to this problem [9-11]. Nutritional interventions have shifted from the control of protein deficiency, to the concern of protein-energy deficiency, to the prevention and treatment of micronutrient deficiencies. Such change required different approaches to deliver the lacking nutrients and understand the optimal delivery systems [12].

One of the main characteristics of the epidemiological transition affecting developing countries is the double burden of nutrition due to changes in dietary habits, food availability, and lifestyle [13]. The coexistence of underweight and overweight is a challenge to public health programs, since strategies targeting undernutrition often contradict obesity prevention programs [13]. Therefore, these food programs, their beneficiaries, nutritional needs and the impact on obesity should be periodically evaluated [13, 14].

In 2004, the Ministry of Human Development of the province of Buenos Aires, Argentina, designed and implemented the *Plan Más Vida* (PMV) [15], an integral food aid program that provided diets considering the importance of adequate micronutrient supplementation, health controls and nutritional surveillance. The program was directed to low income and vulnerable

families from the province (children under the age of 6 years, pregnant and lactating mothers) and it included impact evaluations at different stages of implementation [15].

We conducted this study to evaluate the impact of PMV on the micronutrient nutritional condition of lactating mothers one year after implementation of the program.

Materials and Methods

A prospective, non-experimental, study with random sampling was carried out. We evaluated baseline data before the intervention and probabilistic samples by conglomerates in cross-sectional evaluations at baseline, 12 and 24-30 months, and 5 years after implementation of the program. In this study we present baseline and 12-month data. The external evaluation of the nutritional impact of PMV 1 year after its implementation was assigned to the Commission of Scientific Research of the Province of Buenos Aires (CICPBA), through the Institute of Development and Pediatric Research "Pr. Dr. Fernando E. Viteri" (IDIP).

The nutritional intervention consisted of the monthly supply of a basic food basket per household consisting of 1 kg fortified wheat flour (30 mg iron sulfate, 2200 µg folic acid, 6.3 mg thiamine, 1.3 mg riboflavin, 13 mg niacin per kilogram), 2 kg soy-enriched maize flour fortified with micronutrients (1500 µg RE vitamin A, 8 mg thiamine, 8 mg riboflavin, 100 mg niacin, 1000 µg folic acid, 40 mg iron, 30 mg zinc sulfate per kilogram), 1 kg sugar or 1 kg rice. Lactating mothers also received fortified soup powder to reconstitute in a cup, covering the estimated average daily requirements [16]: 9% energy, 18.4% calcium, 66.6% iron, 33.3% zinc, 20.7% vitamin A, 60% vitamin D, 16.6% vitamin C, 49% folic acid, 11.2% magnesium, 28,5% selenium, 50% thiamine, 43.6% riboflavin, 40% niacin, 45% vitamin B6, and 32% vitamin B12.

Subjects

Clinically healthy lactating mothers (age range, 15.1-47 years; *n*= 178 at baseline and 151 after 1-year program implementation) who were receiving the PMV and were willing to

participate in the study were evaluated. Exclusion criteria were the diagnosis of chronic, acute and/or infectious diseases at the beginning of the study, unwillingness to participate in the study and breastfeeding for more than 12 months.

The study protocol was approved by the Institutional Research Protocol Review Board of the Instituto de Desarrollo e Investigaciones Pediátricas "Prof. Dr. Fernando E. Viteri", La Plata´s Children Hospital. All subjects gave their written informed consent to participate in the study.

Sample selection

Sample selection at each study point was based on a previous food program census in the province that identified districts and neighborhoods receiving food programs, number of families in each block, and name of beneficiaries in each family. The conglomerate sample was designed using simple random sampling; we obtained 25 sample points (neighborhoods) from 11 municipalities of the province of Buenos Aires, representing 85% of the beneficiary population. These sample points were also used to evaluate the early impact of PMV actions. At each point, the systematic sampling of families and beneficiaries from each block was adjusted to the sample size assigned by neighborhood taking into account the relative population weight of each neighborhood, for the sake of beneficiary representativeness.

Sample size

To evaluate the impact of the intervention on lactating mothers, sample size based on historical or reference prevalences [17] of the parameters to be assessed – particularly prevalence of folate deficiency – and on values of the expected outcomes as a result of PMV actions, i.e., 15% decrease in such prevalence at 5 years (significance level of $\alpha = 0.05$ and a power of 80%). The minimal number to evaluate was therefore 150 lactating mothers in each period.

Assessments

Biochemical and anthropometric parameters were assessed and dietary surveys performed to all participating women.

Anthropometric assessments

Anthropometric parameters were obtained measuring weight and height during fieldwork with standard methods [18]. Height and weight data were used to calculate body mass index (BMI) dividing weight by height squared (Kg/m^2). Accordingly, women were classified in the following categories of nutritional status: underweight (BMI < 18.5 kg/m^2), normal weight (BMI ≥ 18.5 and ≤ 24.9 kg/m^2), overweight (BM ≥ 25.0 and ≤ 29.9 kg/m^2) and obese (BMI> 30 Kg/m^2) [19].

Biochemical assessments

Blood samples were taken after an 8 hour fast by venipuncture to determine hemoglobin (Hb) concentration using an automated hematology counter (PENTRA model 60, ABX Diagnostics, Montpellier, France). Ferritin and folic acid were determined by radioimmunoassay in an automated chemiluminescence system (Access-Beckman Coulter, Fullerton, US).

Zinc levels were assessed by flame atomic absorption spectrometry at 213.9 nm (Shimadzu AA6200). Levels of vitamin A were determined with reversed-phase high-performance liquid chromatography (HPLC).

Cut-off points for the parameters studied were as follows: anemia, Hb <12 g/dl [20]; iron deficiency, serum ferritin <12 ng/ml [18]; folate deficiency, plasma folates <3 ng/ml [21]; zinc deficiency, serum zinc <70 µg/dl [20]; vitamin A deficiency, serum retinol <20 µg/dl; risk of vitamin A deficiency, serum retinol 20-30 µg/dl [22].

Dietary survey

A 24 h-recall survey was made to each lactating mother to evaluate net macronutrient (g/day), micronutrient (mg/day or µg/day) and energy (Kcal/day) intake, and percent adequacy to

international recommendations [23]. Food supply, delivery and consumption were also surveyed.

Statistical analysis

Data were processed with SPSS 1.1 for Windows. Ferritin, folic acid, zinc and vitamin A concentration values were log-normally distributed in a Q-Q plot and expressed as geometric means (GM) (95% CI).

Hb results were expressed as means ± SD. Dietary intake results were expressed as medians and interquartile ranges. Mean baseline data and results one year after the intervention were compared using Student´s t-test (anthropometric variables and Hb), and Mann-Whitney test (ferritin, folate, zinc, vitamin A and dietary intake results). Prevalences of deficiencies at the same study points were compared using Chi-2. In all cases differences were statistically significant with $p < 0.05$.

Results

Table 1 shows the nutritional and anthropometric condition of participants at baseline and 1 year after PMV implementation. Differences in overweight/obesity were not statistically significant 1 year after PMV implementation.

Mean Hb levels decreased from 12.6 g/dl to 12.4 g/dl 1 year after the intervention (p= 0.014); however, values were within normal range. The prevalence of anemia was 25.8%, without statistically significant differences 1 year after PMV implementation (29.5%; p=0.439).

Table 2 shows the GM, confidence intervals and prevalences of deficiency of the micronutrients studied.

Concerning vitamin A risk of deficiency, values decreased after 1-year PMV implementation (Figure 1).

Results obtained with the 24 h-recall survey showed that the mean energy intake was not adequate either at baseline or 1 year after PMV implementation (Table 3). However, energy and micronutrient intake increased significantly 1 year after the program implementation ($p < 0.05$).

Discussion

Food aid programs are a public health action developed and regulated by governmental authorities to maintain and improve the nutritional health of the population, particularly that of vulnerable groups [13, 14]. Therefore, the periodic evaluation of food programs is necessary to improve, correct and redirect resources necessary to reinforce dietary approaches in deficient populations.

In our study, the prevalence of serum folate deficiency in lactating women decreased markedly from 50.3% to 3.4% one year after PMV implementation. It should be noted that although some of the products included in the program were fortified with folic acid, the implementation of the program was concomitant with the implementation of a regulation establishing the compulsory fortification of flour with iron and folic acid (Law 25.630) [24].

The 2005 National Nutritional and Health Survey (NNHS) evaluated the impact of fortified flour on women of reproductive age, reporting that mean serum folate levels in beneficiaries of food aid programs were higher than in people not receiving food assistance [25]. Such difference was statistically significant at national level and at the different Argentinean regions (north-east, north-west and Patagonia). On the other hand, mean serum folate levels were higher in women from households with unsatisfied basic needs (UBN) than in those without them (11.9 ng/ml vs 10.7 ng/ml, respectively). A study analyzing the NNHS results reported that food fortification with folic acid was associated with adequate intakes and serum folate levels in women, with a concomitant significant decrease in neural tube defects prevalence and mortality [26]. Similar results were found in Chilean [27], Canadian

and North-American women [28, 29]; recent estimations have demonstrated that additional intake of 100-150 µg/day folic acid in fortified food was effective in reducing neural tube malformations and in increasing serum folate concentrations.

Vitamin A deficiency is a public health nutritional concern because it affects 19 million pregnant and lactating women worldwide. Since this deficiency is primarily due to a chronic deficit of vitamin A in food, its fortification could be a useful preventive tool [30].

Our results showed a clear decrease in the risk of vitamin A deficiency 1 year after PMV implementation, similar to other findings evaluating the impact of food fortification with vitamin A. Huo et al. [31] evaluated poor rural adult women who received fortified flour for three years in China and found that vitamin A levels improved significantly from 12 to 36 month, as compared with baseline and control data [31]. Another study designed to determine the effect of a multiple-micronutrient-fortified beverage among adolescent girls from rural Bangladesh reported that the routine beverage ingestion increased retinol concentrations at 6 months (p=0.01) compared to the non-fortified beverage controls [32]. Similar results were described by Seal et al. with maize-fortified flour: the prevalence of vitamin A deficiency decreased in food aid-dependent lactating refugee adolescents from Zambia [33].

The correction from moderate to mild zinc deficiency in children, pregnant and lactating women is a particular concern for some authors [34, 35]. In our study, mean serum zinc values and the prevalence of its deficiency had no significant changes one year after PMV implementation. The increased percentage of adequacy during the intervention was not sufficient to produce an effect. However, several studies show that zinc-fortified flour decreased the prevalence of the deficiency in populations consuming adequate amounts of the fortified flour [31, 34, 36, 37].

Our results also showed that 1 out of 4 lactating women was anemic both at baseline and 1 year after program implementation. Probably, the iron ingested with the food provided by PMV was not enough to have a therapeutic effect. Although iron intake increased

significantly, it was below recommendations according to Dietary Reference Intakes (10 mg/day) [16], Therefore, therapeutic supplementation should be considered as an alternative strategy [7, 38]. Mitra and Khoury consider that in order to reduce the prevalence of anemia, preventive iron supplementation should be universal in low income postpartum women [11]; Cavalli-Sforza et al. [39] and consequently the WHO [40] are recommending iron-folate supplementation not only in the post-partum period but prior to and during pregnancy.

Regarding energy intake, it was similar to that reported by the 2005 NNHS (average 1776 Kcal in women of reproductive age). However, a considerable number of women could not reach an adequate intake, regardless of geographical location, socioeconomic condition, or age [25]. Calvo and Biglieri have reported that the decrease in the prevalence of folic acid deficiency associated with an adequate intake of fortified food [26]. The significant increase in the intake of folic acid reported in our study was not sufficient to explain the marked decrease in its prevalence. It should be noted that during the intervention, a national campaign of folic acid supplementation for pregnant women and women of reproductive age was implemented.

Different studies suggest that food aid programs are adequate to improve the nutritional condition of low-income populations; however, they may also contribute to overweight and obesity in women of reproductive age beneficiaries of such programs, reason why long-term evaluations should be considered [14, 41-44].

As expected, no significant changes were observed in the anthropometric nutritional status of lactating women because of the short intervention time. However, the high prevalence of overweight and obesity at baseline and the increasing trend 1 year after the intervention is a cause of concern.

One of the limitations of our study was related to the assessment of dietary intakes; although the 24-h recall method is not the most accurate one, it is appropriate for

epidemiological studies. Another limitation was concerned with the lack of pregestational data.

Conclusions

The early impact evaluation of PMV effects provided useful nutritional and behavioral data for future interventions and their evaluation. Also, the analysis and discussion of results can provide useful strategies aimed at enhancing the positive effects of the program, improving its implementation, and considering complementary actions.

The intervention was timely and concomitant with other strategies, such as flour fortification, which allowed to improve the nutritional condition of some micronutrients in lactating women. Our findings reinforce the need for the periodic evaluation of food programs in order to optimize the use of resources and to adapt them to new actors and scenarios. Further, these actions should complement other general policy actions involving programs to combat poverty.

Acknowledgments This study was funded by CICPBA and the Ministry of Human Development, Province of Buenos Aires. The authors are grateful to professionals from the Food Program Department of the Ministry of Human Development, Andrea Touza for logistics support, and Adriana Di Maggio for manuscript edition. Thanks are also due to Prof. Fernando Viteri for a critical review of the manuscript.

Disclosure statement The authors declare that they have no competing interests.

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Table 1 Anthropometric and nutritional condition of lactating mothers at baseline and 1 year after PMV implementation

	Baseline (n=178)	1 year after PMV implementation (n=151)
Underweight	7.3	6.0
Normal weight	55.6	48.3
Overweight	21.9	27.2
Obesity	15.2	18.5

Results are expressed as percentages. X_2test.

Table 2 Mean values and prevalence of micronutrient deficiency at baseline and 1 year after PMV implementation

	Baseline			1 year after PMV implementation			
	%	GM	CI	%	GM	CI	*p*
Ferritin (ng/ml)		17.7	15.6 - 20.0		19.6	17.1 - 22.0	0.188*
Prevalence of iron deficiency	28.7			23.9			0.308§
Folates (ng/ml)		2.96	2.75 - 3.18		8.12	7.51 – 8.77	<0.001*
Prevalence of folate deficiency	50.3			3.4			<.001§
Zinc (µg/dl)		84.8	82.1 - 87.6		85.5	82.8 - 88.3	0.044*
Prevalence of zinc deficiency	8.2			10.2			0.519§
Retinol (µg/dl)		27.9	26.8 - 98.1		32.9	30.1 - 36.0	<0.001*
Prevalence of vit A deficiency	7.9			13.6			0.088§
Prevalence of vit A risk of deficiency	56.3			29.9			<0.001*

*Mann-Whitney test. §X_2 test.

Table 3 Total micronutrient intake

	Baseline	1 year after PMV implementation
Energy (Kcal/day)	1423.6 ± 633.4	1924 ± 76.5*
Calcium (mg/day)	286.6 ± 259.9	371 ± 37.1*
Proteins (g/day)	51.2 ± 28.2	69.3 ± 35.5*
Iron (mg/day)	7.28 ± 3.4	9.65 ± 4.61*
Zinc (mg/day)	6.2 ± 3.7	7.61 ± 4.6*
Folates (µg/day)	78.6 ± 69	131.4 ± 15.4*
Vitamin A	356 ± 392	445.45 ±500*

Mann-Whitney test; *p<0.05.

Fig. 1 Distribution of Vitamin A levels before and after PVM implementation