Research article

A "food for special medical purposes" for the treatment of intestinal insufficiency/deficiency

Mediterranean Journal of Nutrition and Metabolism
1–9

DOI: 10.1177/1973798X241297425
journals.sagepub.com/home/mnm

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Abstract

Background: Insufficient absorption of nutrients from food can be caused by impaired digestion, absorption or transport of nutrients, and can affect macronutrients, micronutrients, or both.

Objective: The aim of this multicentric retrospective observational study is to confirm the efficacy of a formula (Bariatrifast, BIOITALIA S.r.l., Italy), supplementing vitamins and minerals, in patients with intestinal insufficiency from multiple different aetiologies, excluding bariatric surgery.

Methods: A total of 78 patients were enrolled, assessing anthropometrics, blood pressure, and blood tests at baseline, 2, 4 and 6 months. Bariatrifast was the only supplement assumed. Mean age and BMI were 55.7 years and 23.4 kg/m^2.

Results: The study shows preliminary results of 20.6% and 52.9% of patients completing 6 and 4-month follow-up: increase of red blood cells and haemoglobin; a trend to increase over time for ferritin and iron; stable leukocytes, platelets and folate; a modest downward trend of transferrin; Vitamin-D improved remarkably then stabilized; mean values of heart rate and systolic-diastolic blood pressure remained stable. No undesirable effects were reported.

Conclusions: In conclusion preliminary results suggest that using Bariatrifast in patients with intestinal insufficiency can improve the haematological panel, increasing Vitamins B12 and D, iron and ferritin, therefore confirming the efficacy of this special medical purpose food in intestinal insufficiency.

Keywords

food for special medical purposes, micronutrient supplementation, intestinal malabsorption syndrome, nutrition

Received: 19 August 2024; accepted: 8 October 2024

Background and introduction

Intestinal Insufficiency or Deficiency (II/ID) is defined as an impaired bowel absorption of nutrients not requiring intravenous supplementation (IVS).[1,2]

Impaired intestinal functions requiring IVS can be transient or permanent, the latter condition is defined as chronic Intestinal Failure (IF).

Multiple causes could be responsible of the reduced absorption at different levels for macronutrients, micronutrients, water or a combination of those. Nutrient absorption requires three steps starting with luminal and brush border digestion, subsequent mucosal absorption and finally the transport through circulation.[3,4]

Commonly, maldigestions is also known and referred to as malabsorption, although it is mostly due to an impairment of the luminal phase, being both interdependent.

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Starting from the mouth the **(digestive) luminal phase** requires the secretion and proper function of liver, pancreas, stomach, and intestines enzymes to aid hydrolysis and digestion (breakdown of food to bolus), solubilization or emulsification (to reduce into macronutrients and molecules), linkage and transportation along intestinal tracts to allow the following phases.

The second (**absorptive**) **mucosal phase** requires the integrity of the intestinal brush border for absorption from the lumen through systemic circulation to allow the third and final **transportation phase**.

Each phase can be affected with one or multiple defects at any point, causing malabsorption of various micro and macronutrients or fluids and electrolytes, or any combination of them. Anatomical or pathophysiological impairment, or also a functional defect and dysmotility can lead to the disruption of this complex and interdependent system.[2]

As showed in Figure 1 the major acquired causes of malabsorption or intestinal insufficiency can be divided in four different domains, each can affect the three steps of nutrient uptake in the body: transportation, mucosal or luminal phases. Summarising, multiple different reason can reduce the area of absorption in the intestine.

Clinical reasons can be considered infections or neoplasia, inducing dysmotility or obstruction or requiring medications or chemo or radiotherapies altering the enterocytes' function or integrity and the bowel motility. Notably, some cause can overlap more than one dimension: intestinal fistulas and lymphatic obstruction can be considered between anatomical and pathophysiological reasons of malabsorption for the excessive loss of fluids and nutrients outside the bowel. Moreover, the bowel can be too short or the motility can be dysfunctional; the integrity of the enterocyte function and brush border enzymes and transporters is required along different intestine sites. The site interested can be variable, therefore it could affect one or multiple different nutrients.

Table 1 shows the most common sites of absorption or the organs required to be functional for specific nutrient uptake, by producing a specific enzyme or factor required to digest or absorb a specific nutrient.

To name an example, the absorption of the B12 vitamin requires the functionality of multiple sites: the gastric acid induces the Vit.B12 degradation, while intrinsic factor (IF) produced by specific gastric cells binds the vitamin and allows its uptake in the ileum.[5] At the same time hematological parameter can be affected by multiple nutrients, vit. B12, folic acid and iron, involving more than one intestinal site as already discussed.

Multiple nutritional approaches could be considered for the nutritional management of intestinal failure or insufficiency[6] before home parenteral nutrition is required.

The process of intestinal adaptation can gradually bring to a partial recovery or total resolution of the pathological condition, while medical intestinal rehabilitation may require surgical, pharmacological and/or nutritional therapy to treat the deficiency that can be a short-term (<1 year) or long-lasting condition.[7]

Patients with intestinal insufficiency could require multiple nutrient supplementations, being difficult to achieve all targets with specific or single products.

Aim

The aim of this study is to demonstrate the efficacy of a "Food for Special Medical Purposes" (FSMP), commercially distributed in Italy with the name "Bariatrifast" and commonly used for bariatric and metabolic surgery, in the treatment of Intestinal Insufficiency or Deficiency due to a wide range of aetiological causes other than bariatric surgery.

Materials and methods

This is a multicentric retrospective observational study with 8 nutrition centres participating all over Italy: Bologna, Bari, Brindisi, Cagliari, Faenza, Matera, Roma, Siena, Torino.

Patients

The inclusion criteria to be enrolled in the study was any diagnosis of intestinal malabsorption/ intestinal insufficiency other than bariatric surgery; the latter was considered an exclusion; the infusion of any intravenous fluid or nutrient was an exclusion criteria for the enrolment in the study. The other inclusion criteria were the prescription of Bariatrifast as the only supplement included in their medical therapy. A total of 78 subjects were enrolled until December 2023, 40 were female and 38 males with a mean age of 56 years and a mean BMI of 23.4 Kg/m^2. Within 78 patients only 2 subjects had a BMI below 18.5 Kg/m2 (both 18.4 Kg/m2), but considering subjects with a BMI below 20 kg/m2 the number raised to 15 (19% of the sample). Subjects with a BMI within the range of obesity were below 1% of the sample: among the 6 subjects the highest BMI was 38.9 Kg/m2 (class II obesity). Considering the weight range our sample included patients starting from 40 Kg to 103 Kg of body weight.

The main causes of intestinal insufficiency were surgical resection, 46% underwent gastric resection and about 10% other bowel tract resection (see Table 2 for specific sites of resections), while 15% were diagnosed with celiac disease, about 14% with inflammatory bowel disease, and 14% had diarrhoea mainly caused by small intestinal bacterial overgrowth (SIBO). Table 2 shows the detailed list of aetiological causes of subjects' intestinal insufficiency. Bariatrifast posology was one tablet/day and the composition of the 1.3 g tablet is showed in Table 3. All those patients taking other nutritional supplements, as different mono or multivitamin, trace elements (e.g., iron, zinc …),

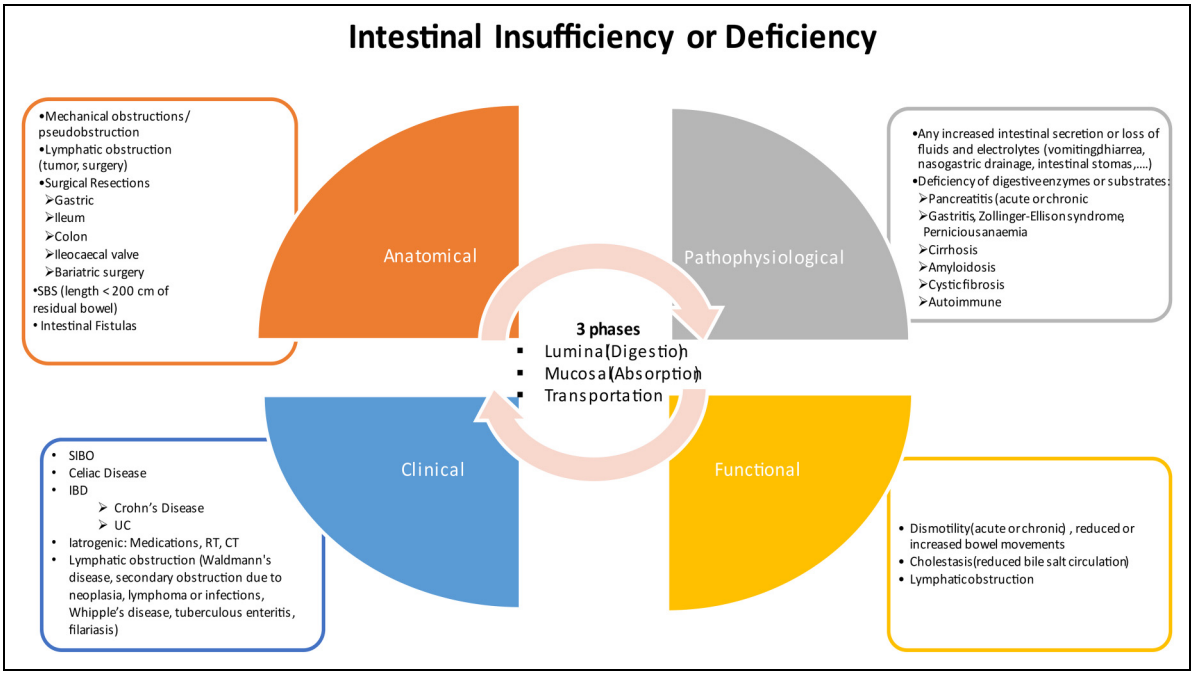

Figure 1. Main acquired causes of malabsorption. Listed are the main common causes of intestinal insufficiency or deficiency, divided by four domains that can be affected by impaired digestion, absorption, or transportation of nutrients, the three intestinal phases described for macro and micronutrients uptake. Legend: CT chemotherapy, CIPO chronic intestinal pseudo-obstruction, IBD inflammatory bowel disease, RT radiation therapy, SBS short bowel syndrome, SIBO small intestinal bacterial overgrowth, UC ulcerative colitis.

Table 1. Intestinal sites involved in specific nutrient absorption.

Intestinal site	Nutrients affected
Stomach	Intrinsic Factor (IF), Alcohol
Duodenum	Magnesium, Folic Acid, Calcium, Iron
Jejunum	Most macro and micro nutrients, Sugars, Calcium, Zinc
Ileum	Fluids, Electrolytes, vitamins, proteins and fats
Distal Ileum	Bile acids, Vit. B12- IF, Sodium, Water
Colon	Fluids, Electrolytes, Short chain fatty acids
Liver	Fats
Pancreas	Fats and Proteins

This table shows the main site or organ required to absorb specific macro or micronutrients. The site listed can be the actual intestinal part required for the absorption, otherwise it can be the site producing a specific enzyme or factor needed for the proper absorption in another intestinal site, as in the case of liver or pancreas.

Table 2. Causes of Malabsorption in study subjects (n and %).

	n	%
Gastric resection	36	46
Celiac disease	12	15
Crohn disease	5	6.4
Ileo-colic Crohn disease	5	6.4
Terminal ileum disease	1	1.2
Ileum resection	3	3.8
Partial ileum resection	1	1.5
Colectomy	1	1.5
Hemicolectomy	2	2.5
Small intestinal bacterial overgrowth (SIBO)	9	11.5
Diarrhea of unknown origin	2	2.5
Intestinal amyloidosis	1	1.5

and all the patients with any acute or chronic disease other than intestinal insufficiency were excluded. All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki, Finland, and its later amendments, revised by the 29th World Medical Assembly in Tokyo in 1975. We did not apply to the ethics committee for this study because we classified our protocol in the categories of "negligible risk research" (research in which there is no foreseeable risk of harm or discomfort). Furthermore, for the purpose of the study, the used formulation (Bariatrifast) is not experimental but is already register and included as "food for special medical purposes" in the register of the Italian Minister of Health (code number 942820515) and therefore already has all the authorizations to be prescribed to patients intestinal insufficiency from multiple different aetiologies, excluding bariatric surgery.

The Bariatrifast supplement was kindly provided free of charge to all trial participants by Bioitalia srl, which had no role in designing the trial, or in patient enrollment in the different participating sites, or in processing any trial-related data.

Table 3. Bariatrifast composition.

Mean value	Each tablet (1.3 G)	RDA (%) M/F
Energy	19 kj (5 kcal)	/
Magnesium (mg)	56.3	23.4
Iron (mg)	**65**	**650/360**
Zinc (mg)	10	83/111
Copper (mg)	1	111
Selenium (μg)	55	100
C Vitamin (mg)	120	114/141
E Vitamin(mg)	100	769/833
Thiamine (mg)	10	833/909
Riboflavin (mg)	1.3	81/100
B6 Vitamin (mg)	1.5	115
Pantothenic Acid (mg)	10	200
Niacin (mg)	10	55
A Vitamin (μg)	1200	171/200
Folic Acid (μg)	**400**	**100**
Biotin (μg)	50	166
B12 Vitamin (μg)	**500**	**20833**
Cholecalciferol – D Vitamin (μg)	**175**	**1166**
K Vitamin (μg)	150	107

Complete composition of the FSMP "Bariatrifast" for each tablet of 1.3 gr (measure units are next to each single element). RDA column shows the % of each element for the adult population, if different by sex numbers are showed as male/female otherwise as single %. Highlighted in bold type are those nutrients measured in the study or those mainly involved in the haematological panel analysed.

Informed written consent was obtained from each participant after being informed about the purpose and nature of the study.

Anthropometric and biochemical measurements

At baseline (T1), a physician collected clinical history and medication list. A physical exam was performed before enrolment.

Anthropometrics included height without shoes with shoulders, heels, and hips in contact with the wall, measured to the nearest 0.1 cm using a Harpenden stadiometer, and body weight measured with light clothing to the nearest 0.1 kg using an electronic scale; BMI was calculated in kg/m2 as body weight in kilogram divided by the height in square meter.

Blood pressure in mmHg and heart rate per minute were measured with a digital sphygmomanometer after participants had been sitting quietly for at least 15 min, with their right arm supported at the level of the heart and feet resting flat on the floor.

Blood samples were obtained at every timepoint after 12 h overnight fasting and tested using standardized methods in the Hospital's Laboratory, including the following haematological and biochemical parameters: complete blood count, glucose, ferritin, transferrin, iron, vitamin D, vitamin B12 and folate.

Clinical and biochemical data were collected at baseline as T1 and every 2 months, excluding height, for a period of 6 months following timeline in T2-T3-T4. Data included clinical history, medications, anthropometrics, and biochemical analysis. Those patients without complete data collected were excluded from the study.

Table 4. Study subjects' characteristics.

Sample	(n)	78
Gender	M (n)	38
	F (n)	40
Age (years)	mean (SD)	55.7 (16.8)
Height (cm)	mean (SD)	170 (10)
Weight (Kg)	mean (SD)	64.5 (14.1)
BMI (Kg/m^2)	mean (SD)	23.4 (4.6)

Statistical analysis

This was a "real word" observational study, mirroring the current clinical practice. The non- parametric data were described as frequencies. The parametric data were described as mean and standard deviation (SD) or as geometric mean/median and minimum and maximum value, depending on whether the variables had a normal (skewness +1/+1) or non-normal distribution. For normally-distributed variables, the mean of differences baseline-last available value (four or six months of observation) was calculated and the 95% confidence interval (IC 95%) of the mean was estimated, assuming that the ICs outside the zero value suggest a statistically significant ($P < 0.05$) difference.

Results

Data presented refers to T2 −2 months- (63 ± 12 days) available for all subjects, T3- 4 months- (123 ± 15 days) for 41 subjects (52.6%), and T4- 6 months- (187 ± 21 days) available for 16 subjects (20.6%).

Anagraphic and anthropometrics

Table 4 summarize the main demographic and anthropometric characteristics describing the sample of 78 subjects with the distribution by gender, age, BMI. All subjects enrolled were caucasian, half of the sample was composed by men and the rest by women, with a median age of 56 years old and a BMI falling into the normal weight category 23.4 ± 4.6 Kg/m^2. At the end of the 6 months follow up there was a minimal trend of weight gain (mean from 64.8 Kg to 68.2 Kg) without statistical significance, while blood pressure and heart rate remained stable along the study.

Causes of subjects' intestinal insufficiency

Table 2 lists the specific causes leading to subjects' intestinal insufficiency with frequency and its proportion (%)

Table 5. Biochemical measurements from baseline (T1) to 6-month follow-up (T4).

		T1	T2	T3	T4	Mean difference T4 vs T1
	n	78	78	41	16	
Red blood cell ($n\times10^3/mm^3$)	*Mean ± (standard deviation)*	4310 ± (703)	4509 ± (789)	4821 ± (589)	5109 ± (614)	364 (IC 95%: −211/+517)
Haemoglobin (g/dL)	*Mean ± (standard deviation)*	11.6 ± (1.4)	12.1± (1.3)	12.4 ± (1.1)	12.2 ± (1.2)	0.9 (IC 95%: +0.6/+1.2)
White blood cell ($n\times mm^3$)	*Mean ± (standard deviation)*	6203 ± (1761)	6237 ± (2353)	6419± (2377)	5757± (1464)	18 (IC 95%: +17.6/+18.4)
Platelet ($n\times10^3/mm^3$)	*Mean ± (standard deviation)*	231 ± (62)	235 ± (58)	238± (61)	231± (66)	6 (IC 95%: −5.5/+17.5)
Ferritin (ng/mL)	*Mean*	21.1	27.6	30.4	30.2± ()	
	min-max	4–907	7–410	10–110	16–62	
Ferritin skewness		6.4	3.7	2.3	2.1	
Transferrin (mg/dL)	*Mean ± (standard deviation)*	247± (61)	248± (51)	236± (40)	225± (39)	−1.9 (IC 95%: −14.8/+11.21)
Iron (mcg/dL)	*mean*	41.0	51.8	58.8	61.4	
	min-max	5.0–166.0	17.0–150.0	16.0–155.0	28.0–137.0	
Iron skewness		1.5	1.4	1.4	2	
D-Vitamin (ng/mL)	*Mean ± (standard deviation)*	17.8 ± (7.5)	26.6 ± (8.6)	30.9 ± (7.7)	28 ± (2.7)	12.5 (IC 95%: +10.3/+14.7)
B12- Vitamin (pg/mL)	*Mean ± (standard deviation)*	252 ± (128)	295± (167)	329 ± (130)	378 ± (98)	51.2 (IC 95%: +12.9/+89.5)
Folate (ng/mL)	*Mean*	6.4	6.7	6.8	6.9	
	min-max	1.0–20.0	2.0–40.0	2.1–21.2	3.2–9.8	

Legend: T1 is baseline, T2 is after 2 months, T3 is at 4-month follow-up, T4 is after 6 months.

of occurrence in the study sample. In summary, the main causes were surgical resections in 56% of the sample, being 82% of it represented by gastric resection, while inflammatory bowel disease and celiac disease were diagnosed in about 15% of the sample, the rest was SIBO (11.5%) and other causes of diarrhoea of unknown origin (2.5%) for the inclusion.

Biochemical analysis

Table 5 reports all the measured parameters in the study listed by the follow-up period (T1 at baseline, T2 is after 2 months, T3 is at 4-month follow-up, T4 is after 6 months).

Red blood cell significantly increased in the mean number with a linear positive correlation between the number of RBC and the length of Bariatrifast administration (Figure 2). The level of haemoglobin showed a similar but less marked increase (Figure 3), while the number of white blood cell and platelets remained stable along the time. There was a marked skewness to the right for the ferritin values with the geometric mean increasing along the follow up, while transferrin level showed a negligible trend to reduction. Iron level appeared not normally distributed at baseline (right skewness); the geometric mean increased from 41.0 mcg/mL at baseline to 62 mcg/mL at last control.

Both vitamin B12 (cobalamin) and vitamin D (25-hydroxyvitamin D) serum levels showed a significative increase. Folate levels showed also an increase but was not normally distributed.

No adverse events were reported during the follow up.

Discussion

Our study shows how a special formula supplementing multiple vitamin and mineral is effective in improving the nutritional status of subject with intestinal insufficiency from different aetiologies.

Bariatrifast is classified as a "Food for special medical purposes" (FSMP) and is commonly used as multivitamin and mineral supplement in subjects undergoing bariatric surgery.[8] The absorption of nutrients can occur in different bowel tracts requiring multiple phases that can be affected at any level, causing malabsorption of various vitamins or minerals, or any combination of them.[3] Our aim was to demonstrate the efficacy of this FSMP extending the target from bariatric surgery to other aetiologies of nutrient malabsorption and intestinal insufficiency.

Our study recorded a slight increase in body weight (data not showed, from 64.8 KG to 68.2 Kg at the 6 month follow up) with an improvement in nutritional status without significant change in hearth rate and blood pressure.

Anemia is often found in chronic diseases due to a complex process, including cellular immunity mechanisms and pro-inflammatory cytokines, in addiction to the micronutrient malabsorption considered in our cohort. Anemia can include a decrease in hemoglobin, haematocrit and red blood cell counts.[9,10]

In our study the mean red blood cell count increased significantly together with haemoglobin level, while white blood cell and platelet count remained stable. Ferritin values also showed a trend to increase along the follow-up period, while transferrin only showed slight trend to reduction. Iron levels raised during the study with a constant and significant increase along the follow up period. Our study is consistent with results reported in bariatric surgery patients,[8] while they did not show any trend in ferritin level during the study period.

The prevalence of vitamin deficiency in patients with intestinal insufficiency, including inflammatory bowel disease (IBD), celiac disease (CD), short bowel syndrome is higher than that in the general population.[5,11]

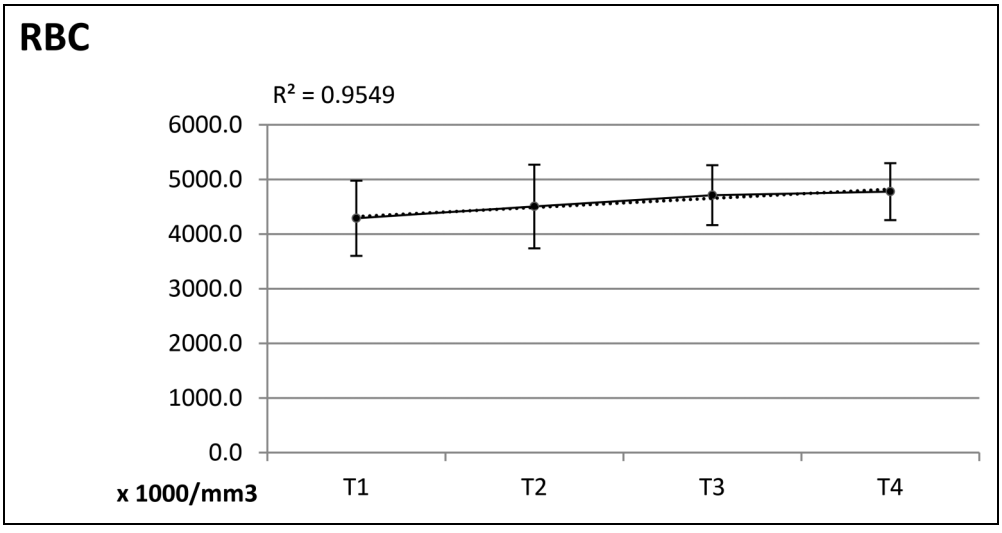

Figure 2. Regression line for Red Blood Cell (RBC) mean number during the follow-up.

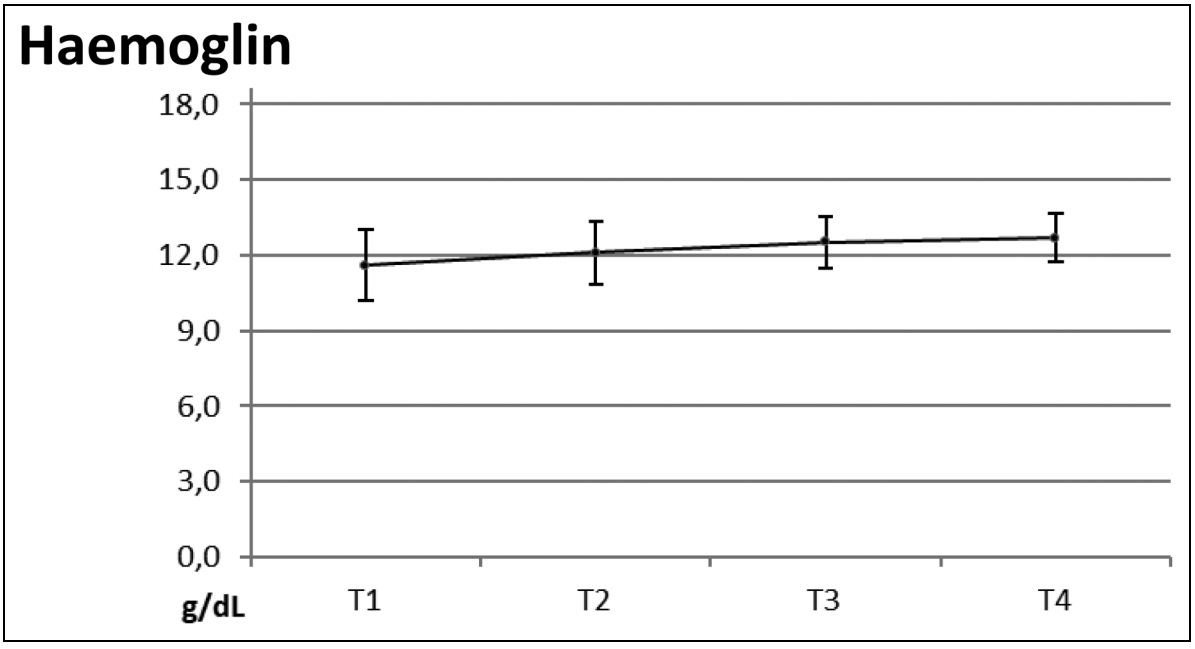

Figure 3. Haemoglin mean value ± standard deviation.

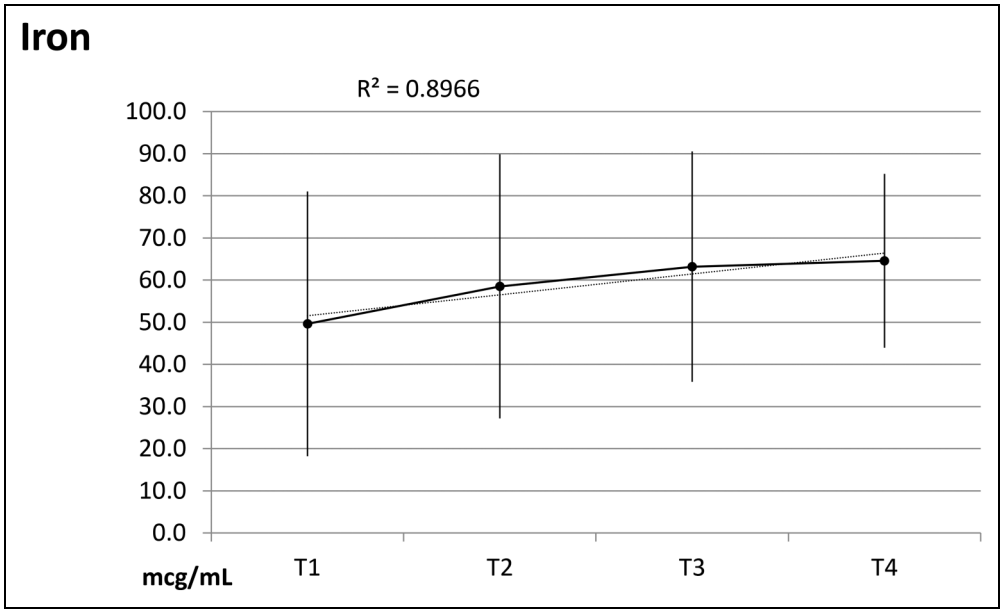

Figure 4. Iron mean value ± standard deviation, dottet is the regression line.

Even under a gluten free diet patient suffering from celiac disease often show multiple vitamin and mineral deficiencies.[12] In our study supplementing Bariatrifast brought to a significative increase in the serum level of both vitamin B12 (cobalamin) and vitamin D (25-hydroxyvitamin D), and also folate levels increased with a stable trend.

No side effects or adverse events were reported during the follow-up of our subjects.

Limitations of our study is the retrospective design and the number of patients with multiple aetiology of intestinal insufficiency. The sample size covers a wide spectrum of different causes for intestinal insufficiency and does not allow to collect enough data for each single aetiology to further discuss the results. Moreover, data are still under collection as only 56% of the sample has completed the 4-month follow-up, although preliminary data are in line

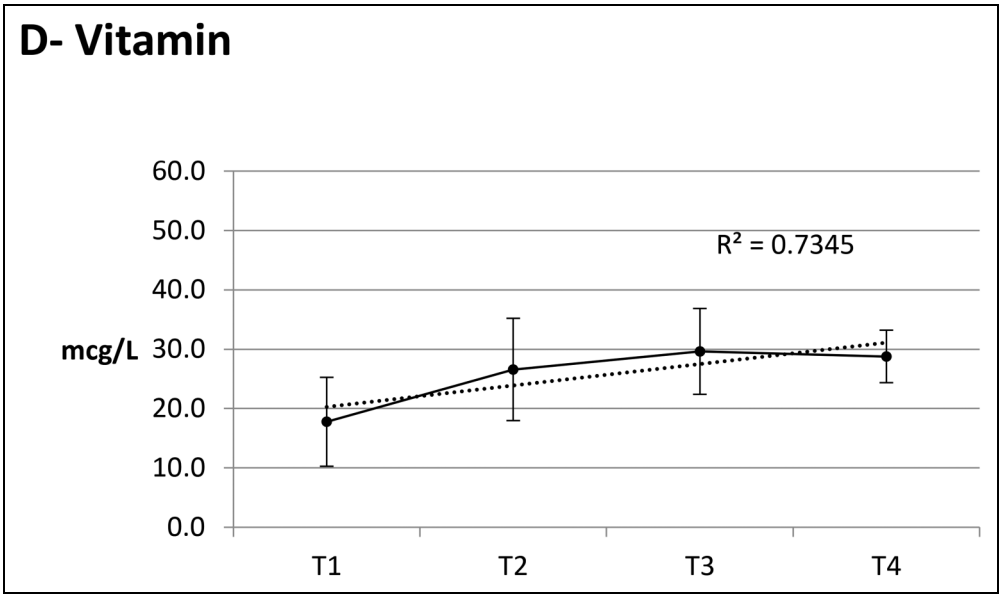

Figure 5. Vitamin D mean value ± standard deviation, dottet is the regression line.

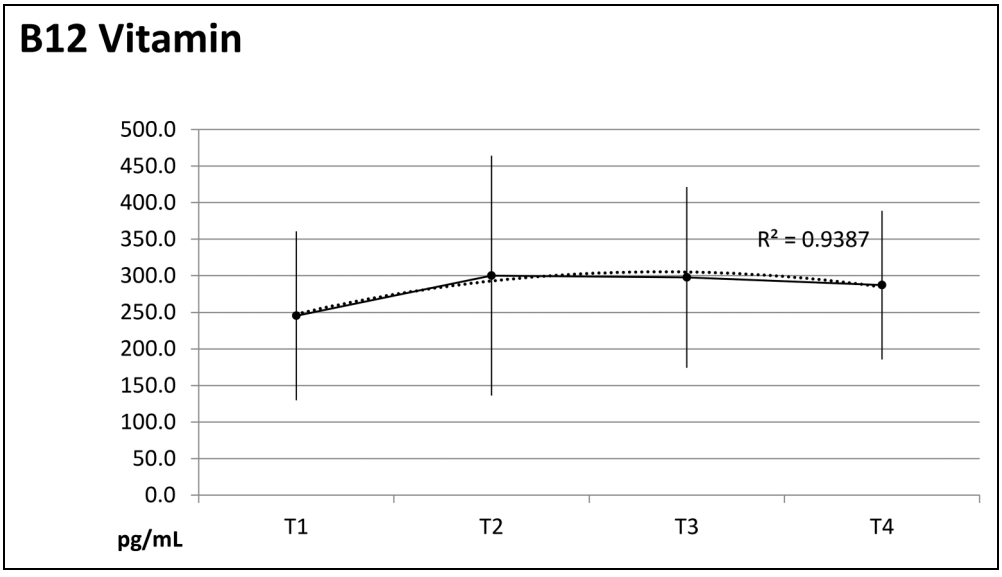

Figure 6. B12 Vitamin mean value ± standard deviation, dottet is the regression line.

with the results showed. Another limitation is that we do not analyse blood samples measuring every single component of the Bariatrifast formula, mostly our focus was on the heamatological panel and the vitamin D measurements together with clinical data collection at each visit. Other nutritional deficiencies might be developed and not recognized for elements not measured here, although a panel of detailed tests would require a more extensive study. Moreover, being multicentric the samples have been analysed in different laboratories, adding a risk of bias or measurement error in the study.

To date, in our knowledge this is the first study analysing a specific oral formula administered to patients with intestinal insufficiency or deficiency by multiple aetiological causes. This FSMP could be used as a tool for the nutritional management of these patients before the need for home parenteral nutrition or before the use of single nutrient invasive supplementation (subcutaneous or endovenous); as well as delaying the need for a pharmacological approach.[13] Our findings should be confirmed by larger randomized trials with larger sample size and longer follow-up, possibly with a differential analysis for each particular aetiology of intestinal insufficiency.

Conclusion

In conclusion, our study testing Bariatrifast, BIOITALIA S.r.l. as multivitamin and mineral formula in patients with intestinal insufficiency from different aetiologies other than bariatric surgery shows how patients followed up to 6 months improved haematological parameters and increased serum levels of Vitamin-D and vitamin B12. Also, a slight increase in body weight was registered without any side effects reported during the follow-up period. Therefore, supplementing this special medical purpose formula to patients with intestinal insufficiency from many different aetiological causes is safe and can contribute to an improvement of their nutritional status.

Acknowledgements

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Statements and declarations

Author contributions

CE wrote the manuscript, CMG coordinated the multicentric group and revised manuscript MB, CMG, AF, PB, PS, RF, VM, BC, LG, GI collected the data each one in their centers, revised manuscript.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: "The authors report no funding for this project". The food for special medical purpose (Bariatrifast) is registered in the register of the Italian Minister of Health (code number 942820515). The Bariatrifast supplement was kindly provided free of charge to all trial participants by Bioitalia srl, which had no role in designing the trial, or in patient enrollment in the different participating sites, or in processing any trial-related data.

Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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