Efficacy of a multivitamin adherence program based on cognitive dissonance for bariatric patients: a randomized controlled trial

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ABSTRACT

Background and Objectives: Micronutrient deficiencies are common among bariatric patients; this study aimed to determine whether a cognitive dissonance-based virtual program improved adherence to multivitamin use in bariatric patients from northern Mexico. **Methods and Study Design:** A randomized controlled trial of the supplementation strategy was conducted over three months. The participants were randomized to an intervention or waitlisted control group and received two psycho-educative and four cognitive dissonance virtual sessions. Multiple linear regression was used to determine standardized estimates of associations between the intervention and dependent variables. Two path analyses were evaluated considering baseline and post-test measurements. **Results:** Intervention was associated with higher concentrations of Hb (β=0.758, p<0.001), vitamin D (β=0.577, p<0.001), iron (β=0.523, p<0.001), folate (β=0.494, p<0.01), calcium (β=0.452, p<0.01), higher adherence (β=0.467, p<0.001), and level of knowledge (β=0.298, p<0.05). **Conclusions:** The dissonance-based intervention potentiated the level of supplementation adherence. A higher level of adherence was reflected in micronutrient concentrations, thus providing confirmation of intervention. Thus, support is found for a multidisciplinary clinical practice that enhances nutrition status after bariatric surgery for obesity.

Key Words: bariatric surgery, cognitive dissonance, multivitamin adherence, self-care, self-efficacy

INTRODUCTION

Bariatric surgery (BS) has become the main treatment option for morbid obesity due to its effectiveness in reducing risk factors and mortality while optimizing anthropometric parameters and quality-of-life.[1] Even though it is a successful treatment, it is accompanied by important complications such as micronutrient deficiencies. These are attributed to reduced gastric storage capacity, digestion, and nutrient absorption caused by the surgical technique.[2]

Since 2013, the International Guidelines on Bariatric Clinical Practice specify that lifelong multivitamin supplementation needs to be prescribed in this population to prevent and treat possible deficiencies.[3] Post-BS micronutrient deficiencies have been reported globally with an incidence of 50% or more, especially in the first year of follow-up.[4] The main reported deficiencies are vitamin D (Vit-D) and calcium (with a prevalence of almost 100%) as well as folate (65%) and iron (62%).[5] These deficiencies are frequently accompanied by short- and

long-term health complications such as asthenia, adynamia, anemia, hyperparathyroidism, bone mass loss, and cognitive impairment.[6,7]

Even though multivitamin supplementation is fundamental to bariatric patient management, there adherence is relatively low (70%). Adherence involves decision-making, commitment, and consent about the prescribed treatment, and requires active collaboration between the health professional and the patient.[8] Low adherence in bariatric patients has been linked to factors such as limited education about the rationale and benefits of multivitamin supplementation with intervention focused on adherence to physical activity, diet and follow-up visits; multivitamin adherence is a secondary consideration.[9] Most studies assess adherence to supplementation through self-reporting and collect data through phone calls (59%), face-to-face interviews, or validated measurement instruments (23%); only a few perform confirmatory micronutrient measurements (18%) to objectively evaluate adherence.[10]

Multidisciplinary interventions can inform and motivate patients to minimize the nutritional risks of BS with post-surgical follow-up that acknowledges adherence to micronutrient supplementation as a management objective. An appreciation of the causal factors of nonadherence can aid in such management.[11] This study explores the potential for the modification of cognitive-behavioral factors found among morbidly obese people such as low self-efficacy and self-care deficit, which might compromise adherence.[12,13]

According to Bandura's Social Cognitive Theory, self-efficacy is defined as *the judgments that each individual makes about his or her abilities, on the basis of which he or she will organize and execute his or her actions in a way that allows him or her to achieve the desired performance*.[14] For its part, self-care is the conceptual axis in the theory of Dorothea Orem, who defines it as *the set of actions that mature (or in process) people carry out with the interest of staying alive and healthy, and continuing with personal development and well-being*.[15]

In this theory, the person exercises *self-care abilities by taking responsibility for his own care, seeking at all times to maintain and improve his state of well-being and quality of life*.[16] Previous studies have described how the level of self-efficacy can increase or reduce the motivation for self-care: Patients who have a high perceived self-efficacy have a greater capacity for self-care.[17,18] This encourages intervention based not only on psychoeducation, but strategies that modify the behavior such as those required for bariatric patients with respect to multivitamin supplementation that, in turn, inform the evaluation of the congruence between cognition and behavior. In this regard, the Theory of Cognitive Dissonance (TCD) proposed by Leon Festinger in 1957 *propounds* that cognitions (attitude, knowledge, values,

beliefs, and opinions) directly influence *behavioral decision*.[19] Festinger argued that *consonance* of the congruence or consistency between *cognitions* and *decision* allows the achievement of an *inner harmony* and life with *greater integrity*. *Inconsistency* between two or more cognitions is referred to as *cognitive dissonance* (CD) and is characterized by the presence of a *pressure* or *tension* with a *magnitude* and *resistance*. This motivates a person to want to decrease the dissonance through changes of perception, opinion, values, or behavior.

Festinger proposed two basic hypotheses: 1. That the existence of CD, being psychologically uncomfortable, motivates a person to reduce dissonance and achieve consonance. 2. That, when dissonance is present, situations and information will be actively avoided that are likely to increase the dissonance.[19] This theory has been demonstrably effective in several population studies of cognition and behavior including bariatric surgery; [20,21,22] virtual interventions based on this theory are also promising.[23,24]

Therefore, this theory is the fundamental basis for the development of this research that aims to determine the effectiveness of a virtual program based on TCD to improve adherence to multivitamins in post-bariatric surgery patients in Tijuana, Baja California, Mexico. The secondary objectives are to know the effect of the intervention on Hb values; serum concentrations of iron, Vit-D, calcium and folate; the level of adherence and knowledge; and to compare two models of adherence to the multivitamin one before and the other after the intervention. The proposed hypothesis is that participants exposed to the intervention based on Festinger's theory will change their attitude and behavior towards the multivitamin intake as a product of the CD.

MATERIALS AND METHODS

Study design and participants

A parallel randomized controlled trial (RCT) design was used.[25] Figure 1 depicts study methodology. The study was located in a private bariatric medical center in Tijuana, Mexico. The sample size was non-probabilistic. There were 54 patients who met the inclusion criteria and were invited by their treating surgeon to participate: Of these, 34 enrolled. They were Mexican men and women, Tijuana residents, and aged 18-65. The bariatric surgical technique employed was either sleeve gastrectomy (SG) or a Roux-en-Y gastric bypass (RYGB) at least six months prior to the study. Agreement to participate of eligible individuals was voluntary, and informed consent (IC) was signed. An assigned folio maintained patient privacy and confidentiality.

Participants were randomly assigned to an intervention group (IG) (n-17) or a wait-listed control group (CG) (n=17) by a research team member who had no direct contact with participants, but used an online statistical tool (GraphPad, QuickCalcs). All participants were dispensed two bottles of a micronutrients supplement for post-surgical bariatric patients (Advanced Multi EA®) with 90 chewable tablets; they were instructed to take two tablets a day for three months. The daily dose contained Vitamin A (as beta-carotene and retinyl palmitate) 3,000 mcg; Vitamin C (as sodium ascorbate and ascorbic acid): 90 mg; Vitamin D (as cholecalciferol): 75 mcg; Vitamin E (from d-alpha tocopheryl polyethylene glycol 1000 succinate, d-alpha tocopherol, and mixed tocopherols): 100.5 mg; Vitamin K (as phytonadione USP): 300 mcg; thiamin (as thiamin mononitrate): 36 mg; riboflavin (vitamin B2): 3.4 mg; niacin (as niacinamide): 20 mg; Vitamin B6 (as pyridoxine HCl): 4 mg; folate (as folic acid): 1,360 mcg DFE; vitamin B12 (as cyanocobalamin): 1,000 mcg; biotin: 600 mcg; pantothenic acid (as calcium D-pantothenate): 20 mg; calcium (as dicalcium phosphate): 170 mg; iron (as ferrous fumarate): 45 mg; phosphorous (as dicalcium phosphate): 130 mg; iodine (as potassium iodide): 150 mcg; magnesium (as magnesium hydrolyzed rice protein chelate): 50 mg; zinc (as zinc hydrolyzed rice protein chelate): 16 mg; selenium (as selenomethionine): 70 mcg; copper (as copper citrate): 2 mg; manganese (as manganese bisglycinate chelate): 2 mg; chromium (as chromium hydrolyzed rice protein chelate): 120 mcg; molybdenum (as sodium molybdate): 50 mcg; sodium: 10 mg; mixed tocopherols (including gamma, delta, and beta-tocopherols): 30 mg; coenzyme Q10 (as ubiquinone): 10 mg and boron (as boric acid): 2 mg. They were also given an information pamphlet about the importance of supplementation adherence, its indications, handling, and possible adverse effects.

This study protocol was approved by the Bioethics Committee of the Autonomous University of Baja California, Mexico (D240) on January 16, 2020. It was registered in ClinicalTrials.gov ID: NCT04612088[26] and has been presented the II Congreso Virtual Interdisciplinar Iberoamericano de Enfermería y Fisioterapia ISBN CD-ROM: 978-84-16679-16-4, Legal Deposit: M-19431-2021

Adherence level and micronutrient concentration were considered as the *primary outcome* to establish the effectiveness of the CD-based intervention and psychoeducation. Cognitive-behavioral changes such as level of knowledge, self-care capacity, and perception of overall self-efficacy were considered *secondary outcomes*.

Intervention was for three months (August to November 2020). All sessions were in virtual mode with a 90-minute duration at 15-day intervals. The IG received two psychoeducational

and four CD based sessions. The CG received two virtual psychoeducational sessions during the study: once when post-test measurements were obtained and then weeks 14 to 17. Table 1 shows the weekly sequence of study events by group and measurement. This allowed comparison of the effect of CD intervention in the IG to be compared with no CD intervention in the CG. Table 2 provides the session content by intervention.

Adherence

To measure the level of adherence, a questionnaire was used to evaluate therapeutic adherence according to Martín, Bayarre & Grau. The level of adherence was established from this score: "Total Adherents" those who had 38 to 48 points, "Partial Adherents" from 18 to 37 points, and "Non-Adherents" 0 and 17 points. The instrument showed good internal consistency in the sample (α 0.982, p<0.001); it accounted for 68.72% of accrued variance according to Martín, Bayarre & Grau.[27]

Self-care capacity

Self-care capacity was measured using the Appraisal of the Self-care Agency ASA-scale.[28] Each individual obtained a score between 24 and 96. It used three categories to evaluate the level of self-care capacity in the participating population: "Low" (<69 points), "Medium" (70 to 75 points), and "High" (> 76 points).[29] The self-care MI showed good internal consistency in this sample (α 0.864, p<0.001) and good validity as it explained 65.85% of the cumulative variance according to Manrique-Abril, Fernández, & Velandia.[30]

General self-efficacy

General self-efficacy was measured with Schwarzer's self-efficacy Test.[31] This test measures a person's perception of how well a person handles different stressful situations in his or her daily life. The questionnaire consists of 10 items with Likert-type answers where the person responds to each one according to what he/she perceives about his/her capacity at the moment of the test: incorrect (1 point), hardly true (2 points), somewhat true (3 points), or true (4 points). The minimum score was 10 points, and the maximum was 40 points. A higher score implied greater general self-efficacy. The cut-off point is 28 according to Blanco, Vázquez, Guisande, Sánchez & Otero.[32] The MI showed a good internal consistency in the sample (α 0.864, p<0.001) and a split-half reliability coefficient of 0.88 according to Sanjuán Suárez, Pérez García & Bermúdez Moreno.[33]

Level of knowledge

The Patient's knowledge test about their medication (PKMT) consists of 11 open items about the therapeutic objective, process of use, safety, and conservation.[34] The score is calculated according to each answer given by the patient and which must be recorded and evaluated by a pharmacist based on the degree of agreement between the information given by the patient and the reference information (medical prescription or failing that the summary of the characteristics of the drug). For the final computation of the PKMT, each question scores differently based on the dimension to which it belongs via the following formula:

$$CPM = \{[(1.2\sum P] /[(1.2x4) + (1.1x2) + (0.85x4) + (0.6)]\}$$

The scores obtained were categorized as: "doesn't know the medication": 0 to 0.59, "insufficient knowledge": from 0.60 to 1.26, "sufficient knowledge": from 1.27 to 1.60, and "optimal knowledge": from 1.61 to 2. According to Salmerón Rubio, García-Delgado, Ferreira, Santos & Martínez-Martínez, the factorial analysis showed a four-factor structure explaining 67% of the total variance and a Cronbach's alpha of 0.677.[35]

Biochemical measurement

Pre- and post-test blood sampling were performed before starting supplementation and three months later, respectively. Serum 25-hydroxyvitamin D and folate were measured by ELISA using AccuBind kits® in a Multiskan®; iron, phosphate and calcium concentrations by colorimetric spectrophotometry in a Wiener Lab bs-200®; and Hb by flow cytometry in a Mindray BS-3200®. Normal values were: folate >3 ng/mL, phosphate 2.5-5.6 mg/dL and calcium 8.5-10.5 mg/dL. Reference ranges for iron and Hb differed by sex: iron was 65-175 µg/dL for men and 50-170 µg/dL for women, and Hb was 13.8-18.5 g/dL for men and 11.7-16.3 g/dL for women. Vit-D was classified as very severe deficiency (<5 ng/mL), severe deficiency (5-10 ng/mL), deficiency (10-20 ng/mL), suboptimal (20-30 ng/dL), optimal (30-50 ng/mL), above normal (50-70 ng/mL), non-toxic overdose (70-150 ng/mL) and intoxication (>150 ng/mL).

Statistical analysis

Descriptive statistics were obtained for sociodemographic and study variables, and outcome variables were compared using Student's t-tests and Chi-squared (χ^2) tests. Two dichotomous variables were created for the analysis of the data: The first model included the variable "group" where 0 corresponds to the participants randomized to the CG and 1 to the participants randomized to the IG. In the second model the "intervention" variable was

included where “0” corresponds to participants who did not receive CD sessions and “1” to participants who did. Multiple linear regression was conducted using the group, intervention, self-efficacy and self-care as independent variables; the adherence, level of knowledge, and micronutrient concentrations as dependent variables used pre- and post-test data. Path analysis was used to analyze two models. Exploratory factor analysis and Cronbach's alpha were measured to determine the validity and reliability of the MI. The maximum-likelihood method was used to estimate the model parameters and values of χ^2, root-mean-square error of approximation (RMSEA), comparative fit index (CFI), and parsimonious normed fit index (PNFI); these were considered as model fit indicators. Data analysis was performed using the SPSS statistical software package (version 25, Chicago, IL, 2021) and IBM AMOS for SPSS (version 24.0, Meadville, PA, 2019).

RESULTS

Participant characteristics

Initially, 34 participants were randomized to either the IG or CG. However, one person assigned to the IG withdrew her consent due to an adverse event (nausea), and a CG participant changed her place of residence and was excluded from the study leaving 16 participants in each group. There were then 32 participants (28 women and 4 men) with a mean age of 39.2 ± 10.7 years. SG was the most prevalent bariatric procedure (84%); 59% underwent BS one to three years prior to the study, 25% between 6 months and one year prior, and 16% more than three years prior. (Table 3).

Comparison of MI (measurement instruments) and quantification of micronutrients pre- and post-test

The prevalence, means, and standard deviations of the results of the MI, micronutrients and Hb quantifications were obtained: These were grouped with respect to time (pre- and post-test) and group (IG and CG) and then compared by Student's t and χ^2 tests. The prevalence of micronutrient deficiencies and Hb were also determined. Prior to the intervention, 40.6% of the participants reported consuming some type of multivitamin supplement; however, when asked if the supplement they consumed was bariatric (high potency), only 2.77% (n=1) reported so; the rest consumed a protein supplement with added vitamins or a standard supplement.

Table 4 shows the results with respect to the level of adherence and knowledge. In the pre-test, no significant difference was found between groups with respect to adherence (p=0.193).

Most participants from the CG group were found in the "non-adherent" category; the majority of the IG were located in the "partial adherent" group. In the post-test, a significant increase in this variable was observed in both groups while the CG that only received psychoeducation was placed mostly in the category of "partial adherent." The group that received the CD sessions reached the category of "total adherent."

No significant difference was found between the groups (p=0.317) in the pre-test in terms of knowledge of multivitamins. Both were found in the category of "insufficient knowledge." In the post-test, both groups reached the category of "sufficient knowledge"; however, there was a significant difference between the number of participants from the CG and the IG with sufficient knowledge (p=0.008). The pre-test on knowledge about micronutrients (Table 5) showed that all participants had a high lack of knowledge regarding the process of use and safety of the supplement (items 2, 7, 8, and 9); the sub-scale on which they showed the greatest knowledge was the process of use (items 3 and 4).

Participants who did not consume a bariatric supplement reported that they were unaware of the recommended daily doses for people with bariatric surgery and thought that a standard supplement was adequate or sufficient to meet their requirements. Participants reported symptoms related to micronutrient deficiencies such as hair loss, palpitations, asthenia, adynamia, and anemia.

However, they did not perceive these symptoms as a lack or deficiency of micronutrients. They frequently mentioned that those were expected effects of the surgery and that “it was better to feel this way than to be obese” or that “some price had to be paid for losing weight”; these thoughts changed as the intervention progressed and their knowledge of the importance of adherence to BMVS (bariatric multivitamin supplementation) increased with thoughts such as “I had never felt as good after the surgery as now that I take vitamins”, “I feel more energetic”, and “I notice less hair loss”.

While the means of self-care capacity and pre-test self-efficacy level showed an adequate score in both groups, a significant difference was observed with respect to self-efficacy: The CG showed a higher mean (p=0.018), but both groups maintained a good self-efficacy score in the post-test. The IG increased enough not to find a significant difference between the two groups (Table 6).

Finally, no significant difference was found in micronutrient and Hb concentrations in the pre-test: Both groups had a similar prevalence of deficiencies (Table 7). In the post-test measurements, the IG showed concentrations within the normal range of micronutrients and Hb. One exception was Vit-D, which, while not deficient, was low in 31% of the participants.

Even though CG deficiencies improved, a significant difference was found between group means, and CG Vit-D deficiency prevalence increased.

Effect of the intervention, self-efficacy, and self-care on the level of adherence, knowledge, Hb, and micronutrients

The pre-test multiple linear regression analysis used the levels of adherence, knowledge, Hb, and micronutrients as dependent variables; the independent variables were the group, self-efficacy, and self-care. The results show that no statistically significant association was found between the variables (Table 8). A hypothetical pre-intervention model was proposed according to theory (model 1) or the path analysis corresponding to it (Figure 2). Exogenous variables were the group, self-care, and self-efficacy. Adherence, level of knowledge, micronutrient concentrations, and Hb were considered endogenous variables.

The level of adherence and knowledge were explained by self-efficacy, self-care, and group. A significant correlation was found between self-care and self-efficacy (r=0.584, p=0.005), however, there was a non-significant effect of the independent variables and a very low percentage of variance explained in all the dependent variables. In addition, the model showed poor goodness of fit according to the values of χ2, RMSEA, CFI, and PNFI.

The post-test multiple linear regression analysis shown in Table 9 used the levels of adherence, knowledge, concentrations of Hb, and micronutrients as dependent variables. Independent variables were intervention, self-efficacy, and self-care. It was found that 49.2% of the variance of the level of adherence was explained as well as 46.2% of the variance of the level of knowledge. The presence of the intervention was associated with higher concentrations of Hb (β=0.763, p<0.001), iron (β=0.507, p=0.003), Vit-D (β=0.552, p=0.001), folate (β=0.468, p=0.008), and calcium (β=0.484, p=0.006). On the other hand, an increase in the self-efficacy score was associated with higher levels of adherence (β=0.449, p=0.011) and knowledge (β=0.505, p=0.006).

Model 2 showed an adequate goodness of fit according to the values of χ^2, RMSEA, CFI, and PNFI (Figure 3) versus model 1. The intervention presented a positive effect on micronutrient concentrations, Hb, adherence and knowledge about the multivitamin. The level of Hb 0.758 (p<0.001), Vit-D 0.577 (p<0.001), iron 0.523 (p<0.001), folate 0.494 (p=0.002), calcium 0.452 (p=0.005), adherence 0.467 (p<0.001), and the level of knowledge 0.298 (p=0.030) increased with intervention. Self-efficacy showed a positive effect on adherence and knowledge: for each unit of increased self-efficacy, the level of adherence and knowledge increased 0.532 (p<0.001) and 0.346 (p<0.001), respectively.

Finally, a significant correlation between self-efficacy and self-care was found (r=0.631, *p*=0.003): An increase in one of these variables corresponds to an increase in the other. The percentage of variance explained in the level of adherence increased from 0.060 in model 1 to 0.501 in the post-intervention model. This indicates that even though self-efficacy and its relationship with self-care explain the level of adherence to the multivitamin, the intervention based on TCD potentiates the level of adherence and knowledge. The effectiveness of the intervention is reflected in the concentrations of biomarkers as objective indicators of the level of adherence to the bariatric supplement.

DISCUSSION

Intervention based on CD had a direct and positive effect on decision-making regarding consumption of the supplement: The dissonance sessions led the patients to adhere. This was consistent with Festinger's approach to the TCD, which states that *social support plays an important role in dissonance as opinions, and attitudes tend to be present in groups that are internally consistent*. This was proven in the IG because people who did not adhere to supplementation and who had an inclination to justify their behavior ended up adhering due to the dissonance generated during the group dynamics. The participants were those who, in a rationalized way, promoted adherence to the supplement among the other members of the group, thus leading them to feel an *internal pressure* caused by the *inconsistency* between what they promoted and their own behavior coupled with activities that promoted *social support* among the group where they shared strategies to be more self-effective and self-care.[36] Other studies have shown that self-efficacy and social support are fundamental for adherence in bariatrics. A high level of self-efficacy also requires this support for decision-making.[37]

We found that participants who showed a higher level of adherence achieved significantly higher concentrations of micronutrients and Hb. Previously, a clear relationship has been established between adherence to bariatric multivitamin supplementation, serum concentrations of micronutrients, and Hb. People who adhere properly have better concentrations of micronutrients than those with a lack of adherence even in pregnant women after bariatric surgery.[38,39] Unlike other interventions where the level of adherence is evaluated only through subjective variables, we found that the inclusion of biomarker quantification could objectively measure the level of adherence in bariatric patients. Such measurements proved to be decisive in demonstrating the effect of dissonance in the participants.

As observed, the intervention had a significant effect on the level of knowledge of the participants, which matches the results found by other authors regarding the effects of similar interventions.[40] One of the main objectives of the intervention was to transmit knowledge regarding relevant data with respect to the importance of adherence to the multivitamin supplement. This in turn can generate *internal pressure* in the participant, which is a determining factor for the adherence, acquisition, and retention of knowledge. Dissonance led to a positive change in behavior, which was reflected in increased levels of adherence and knowledge.

Self-efficacy and self-care were quite correlated similar to prior studies. These in turn influenced the level of adherence and knowledge in the study population. These data are similar to other authors.[41-43] However, patients had an adequate level of self-efficacy and self-care even before receiving the intervention; the main cause of the lack of adherence in the sample was that they did not consider the consumption of the supplement as something important to maintain their health: Most did not know the difference between a regular and a bariatric supplement and did not relate clinical symptoms to micronutrient deficiencies.

Furthermore, chronic patients who depend on their own care to improve, restore, or maintain their health can improve their self-care capacity through interventions based on psychoeducation. In addition, motivation plays a very important role in these patients because nursing interventions have shown that those who have a greater self-care capacity owe it to a motivation that drives them to have positive behaviors with respect to their health.44,45 Although no direct effect of self-care on the level of adherence or knowledge was found, its correlation with self-efficacy makes this variable fundamental for self-management of treatment.

One of the limitations of the study was the lack of data on pre-surgical micronutrient and hemoglobin quantifications of the participants as well as assessments of self-efficacy and self-care capacity. Therefore, it was not possible to compare the pre-surgical data with our data. A further significant factor was the smaller sample size. This does not represent the Mexican population as a whole due to its non-probabilistic nature.

Conclusion

Increasing adherence to micronutrient supplementation in post-bariatric surgery subjects improves their quality of life and reduces the prevalence of micronutrient deficiencies as well as the related costs likely incurred through possible complications in the short- and long-term. This is evidence for the need for clinical nutritional management of bariatric patients.

Interventions based on virtually provided CD have a positive effect on level of adherence to (and knowledge about) post-bariatric surgery multi-nutrient supplementation. Replication of this study in the private sector and public institutions is needed. Larger studies can further advance cognitive dissonance in nutrition counselling.

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AUTHOR DISCLOSURE

The authors declare that they have no conflict of interest.

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Table 1. Data collection and measurements in both groups

	Week 0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
1. Invitation	x																	
2. IC signature and Pre-Test MI in both IG & CG		x																
3. Brochure with information about micronutrients supplement to both IG & CG		x				x				x								
4. Pre-test Hb, iron, calcium, Vit-D, and folate in both IG &CG		x																
5. Psychoeducational sessions for IG & CG			x		x													
6. *CD sessions for IG*							x		x		x		x					
7. Post-test MI in both IG &CG														x				
8. Post-test quantification of Hb, iron, calcium, Vit-D, and folate levels both IG &CG														x				
9. *CD sessions* for CG															x	x	x	x

IC: Informed Consent; MI: Measuring Instrument; IG: Intervention Group; CG: Control Group; CD: Cognitive Dissonance.

Table 2. Session content

Session	Activity	Content
Psychoeducative		
1	Invitation to the program Audiovisual presentation	· Definition and classification of the BS. · Prevalence of micronutrient deficiency pre and post BS. · Micronutrient requirements in bariatric population.
2	Audiovisual presentation	· Importance of adherence to the BMVS. · Causes and effects on the body of non-adherence. · Difference between a standard and bariatric supplement.
CD based		
	Homework 1	· Make a list of diseases or symptoms that you have experienced after surgery to share in the next session.
1	Promoting adherence	· Identification of conditions associated with non-adherence "In my own body". · Group discussion of the signs or symptoms they had in common.
	Homework 2	· Draw a pyramid where you place 10 characteristics or positive abilities that a person has to meet their goals.
2	Self-efficacy pyramid	· Group and individual reflection on the goals achieved and those that remain to be met, motivating the participants to improve their perception of self-efficacy.
	Homework 3	· Plan the dynamics and select a health professional you want to represent, review the information contained in the brochure.
3	Role-Playing	· Participants assume the role of a health professional using a disguise that identifies them as such, in order to persuade their peers to adhere to the MVBS.
	Homework 4	· Perform an exercise of personal commitment at home, in front of the mirror remembering: What was the reason why I decided to have the operation? What did I commit myself to at that time? I am a person with characteristics that allow me to reach any goal, I have already identified them, I know what my strategies can be to achieve objectives, I can achieve what I propose! · Write what were the positive ideas or thoughts that passed through your mind to share in the next session
4	"From the wording"	· The participants write a formal letter where they express the importance of the consumption of a BMVS and its benefits as if it were going to be published in a journal.

BS: Bariatric Surgery, BMVS: Bariatric Multivitamin Supplement, CD: Cognitive Dissonance.

Table 3. Sociodemographic data

	CG	IG	Both Groups
Gender			
Male	18.75% (n=3)	18.75% (n=3)	18.75% (n=6)
Female	81.25% (n=13)	81.25% (n=13)	81.25% (n=26)
Age	35.75±10.07	42.68±10.63	39.21±10.78
Marital Status			
Single	43.75% (n=7)	25% (n=4)	34.375% (n=11)
Married	43.75% (n=7)	56.25% (n=9)	50% (n=16)
Divorced	0% (n=0)	18.75% (n=3)	9.375% (n=3)
Cohabitating	12.5% (n=2)	0% (n=0)	6.25% (n=2)
Education level			
Elementary	6.25% (n=1)	12.5% (n=2)	9.375% (n=3)
Middle	12.5% (n=2)	18.75% (n=3)	15.625% (n=5)
High school	25% (n=4)	18.75% (n=3)	21.875% (n=7)
Bachelor	50% (n=8)	43.75% (n=7)	46.875% (n=15)
Postgraduate	6.25% (n=1)	6.25% (n=1)	6.25% (n=2)
Surgery Technique			
Sleeve gastrectomy	93.75% (n=15)	75% (n=12)	84.375% (n=27)
Roux-Y Bypass	6.25% (n=1)	25% (n=4)	15.625% (n=5)
Time since surgery			
6 months to 1 year	31.25% (n=5)	18.75% (n=3)	25% (n=8)
1 to 3 years	62.5% (n=10)	56.25% (n=9)	59.375% (n=19)
Over 3 years	6.25% (n=1)	25% (n=4)	15.625% (n=5)

Table 4. Adherence and knowledge prevalence comparison between groups with respect to time

	Pre-test			Post-test		
	CG	IG	*p*	CG	IG	*p*
Adherence						
NA	8 (50%)	6 (37.5%)	0.193	0	0	0.013*
PA	6 (37.5%)	10 (62.5%)		12 (75%)	5 (31.25%)	
TA	2 (12.5%)	0		4 (25%)	11 (68.75%)	
Knowledge						
IK	15 (93.75%)	16 (100%)	0.317	7 (43.75%)	0	0.008*
SK	1 (6.25%)	0		9 (56.25%)	16 (100%)	
OK	0	0		0	0	

CG: Control Group; IG: Intervention Group; NA: Non-adherent; PA Partial adherent; TA: Total adherent; IK: Insufficient knowledge; SK: Sufficient knowledge; OK: Optimal knowledge.
*Indicates statistical significance ($p<0.05$).

Table 5. Knowledge items answers pre-test. (prevalence)

Item	Incorrect knowledge	Does not know	Insufficient knowledge	Sufficient knowledge
Therapeutic Objective				
1. Why do you need to take/use a bariatric multivitamin supplement?	0 (0%)	3 (9.4%)	25 (78.1%)†	0 (0%)
9. How do you know if the multivitamin is working?	0 (0%)	14 (43.8%)†	11 (34.4%)	7 (21.9%)
Process of use				
2. How much of the bariatric multivitamin should you take/use?	32 (100%)†	0 (0%)	0 (0%)	0 (0%)
3. How often do you have to take/use the bariatric multivitamin?	3 (9.4%)	6 (18.8%)	3 (9.4%)	20 (62.5%)†
4. For how long do you have to take/use this bariatric multivitamin?	4 (12.5%)	9 (28.1%)	3 (9.4%)	16 (50%)†
5. How should you take/use this bariatric multivitamin?	5 (15.6%)	18 (56.3%)†	5 (15.6%)	4 (12.5%)
Security				
6. What precautions should you take when taking/using this multivitamin?	2 (6.3%)	21 (65.6%)†	9 (28.1%)	0 (0%)
7. What adverse effects do you know about this multivitamin?	0 (0%)	30 (93.8%)†	2 (6.3%)	0 (0%)
8. What health problem or special situation should you not take/use this multivitamin for?	1 (3.1%)	28 (87.5%)†	3 (9.4%)	0 (0%)
10. What medications or foods should you avoid taking while using this multivitamin?	3 (9.4%)	24 (75%)†	4 (12.5%)	1 (3.1%)
Conservation				
11. How should you store your multivitamin?	1 (3.1%)	17 (53.1%)†	11 (34.4%)	3 (9.4%)

†Indicates the most frequent category.

Table 6. Measuring Instruments scores, Hb and micronutrients concentration.: pre-and post-test

	Pre-test			Post-test		
	CG	IG	*p*	CG	IG	*p*
Self-Efficacy Test score	35.9±1.3	30.5±1.7	0.018*	34.4±1.4	35.9±1	0.424
Self-Care test score	78.2±2	73±2.1	0.096	74.3±2.2	76.9±2	0.418
Hb (g/dL)	12.2±0.3	12.8±0.3	0.266	12.6±0.2	15±0.2	0.000*
Iron (µg/dL)	73.3±10.2	81.4±7.8	0.535	69.5±6.5	98.8±5.7	0.002*
Vit-D (ng/ml)	29.4±2.4	25.6±1.6	0.202	24.1±1.8	33.5±1.5	0.001*
Folate (ng/mL)	3.3±0.5	4.8±0.8	0.172	5.6±0.4	14.2±2.7	0.004*
Phosphate (mg/dL)	3.7±0.1	3.7±0	0.710	3.7±0.1	3.9±0.1	0.268
Calcium (mg/dL)	9.4±0	9.5±0	0.108	9.2±0	9.4±0	0.009*

CG: Control Group; IG: Intervention Group.
Data are mean±SD.
*Indicates statistical significance (p<0.05).

Table 7. Hb and micronutrients deficiency prevalences: pre-and post-test

	Pre-test		Post-test	
	CG	IG	CG	IG
Hb	6 (38%)	5 (31%)	1 (6%)	0 (0%)
Iron	4 (25%)	4 (25%)	2 (13%)	0 (0%)
Vit-D				
Suboptimal	7 (44%)	8 (50%)	6 (38%)	5 (31%)
Deficiency	2 (13%)	3 (19%)	6 (38%)	0 (0%)
Folate	8 (50%)	7 (44%)	2 (13%)	0 (0%)
Phosphate	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Calcium	0 (0%)	0 (0%)	0 (0%)	0 (0%)

CG: Control Group; IG: Intervention Group.

Table 8. Regression coefficients of adherence, level of knowledge and micronutrients concentration pre-test

	Group			Self-Efficacy			Self-Care		
	β^a	Adjusted R^2	*p*	β^a	Adjusted R^2	*p*	β^a	Adjusted R^2	*p*
Adherence test score	0.175	-0.063	0.399	0.047	-0.063	0.846	0.145	-0.063	0.531
Knowledge test score	-0.183	-0.056	0.377	-0.109	-0.056	0.652	0.140	-0.056	0.543
Hb (g/dL)	0.306	-0.004	0.134	0.253	-0.004	0.287	-0.005	-0.004	0.983
Iron (µg/dL)	0.160	0.021	0.420	0.362	0.021	0.127	-0.348	0.021	0.124
Vit-D (ng/mL)	-0.214	0.048	0.277	-0.219	0.048	0.343	0.362	0.048	0.105
Folate (ng/mL)	0.167	-0.003	0.406	-0.211	-0.003	0.374	0.109	-0.003	0.914
Phosphate (mg/dL)	0.007	-0.073	0.974	-0.046	-0.073	0.851	-0.143	-0.073	0.539
Calcium (mg/dL)	0.257	0.003	0.204	-0.159	0.003	0.500	0.112	0.003	0.616

Table 9. Regression coefficients of adherence, level of knowledge and micronutrients post-test

	Pre-test			Post-test		
	CG	IG	*p*	CG	IG	*p*
Self-Efficacy Test score	35.9±1.3	30.5±1.7	0.018*	34.4±1.4	35.9±1	0.424
Self-Care test score	78.2±2	73±2.1	0.096	74.3±2.2	76.9±2	0.418
Hb (g/dL)	12.2±0.3	12.8±0.3	0.266	12.6±0.2	15±0.2	0.000*
Iron (µg/dL)	73.3±10.2	81.4±7.8	0.535	69.5±6.5	98.8±5.7	0.002*
Vit-D (ng/ml)	29.4±2.4	25.6±1.6	0.202	24.1±1.8	33.5±1.5	0.001*
Folate (ng/mL)	3.3±0.5	4.8±0.8	0.172	5.6±0.4	14.2±2.7	0.004*
Phosphate (mg/dL)	3.7±0.1	3.7±0	0.710	3.7±0.1	3.9±0.1	0.268
Calcium (mg/dL)	9.4±0	9.5±0	0.108	9.2±0	9.4±0	0.009*

CG: Control Group; IG: Intervention Group; β^a: Standardized β.
*Indicates statistical significance (p<0.05).

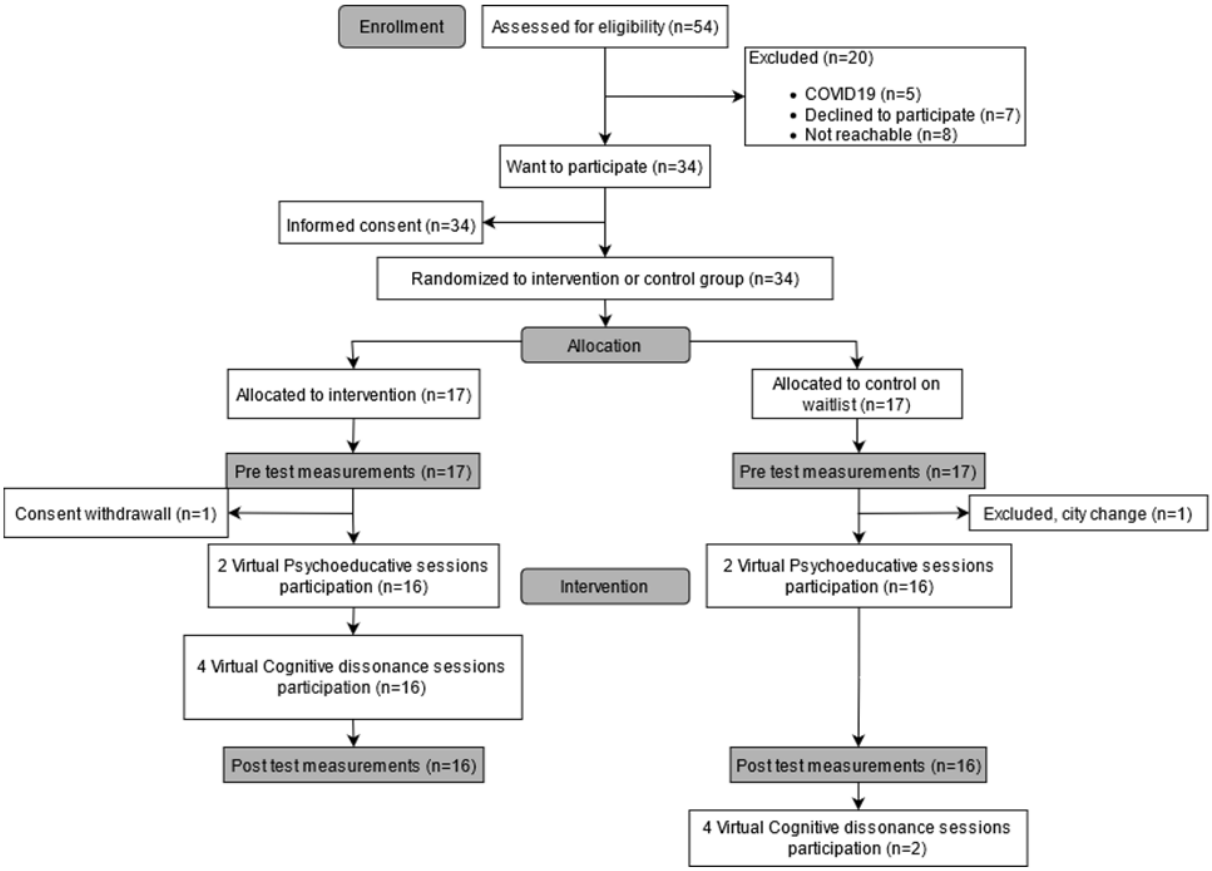

Figure 1. Study methodology.

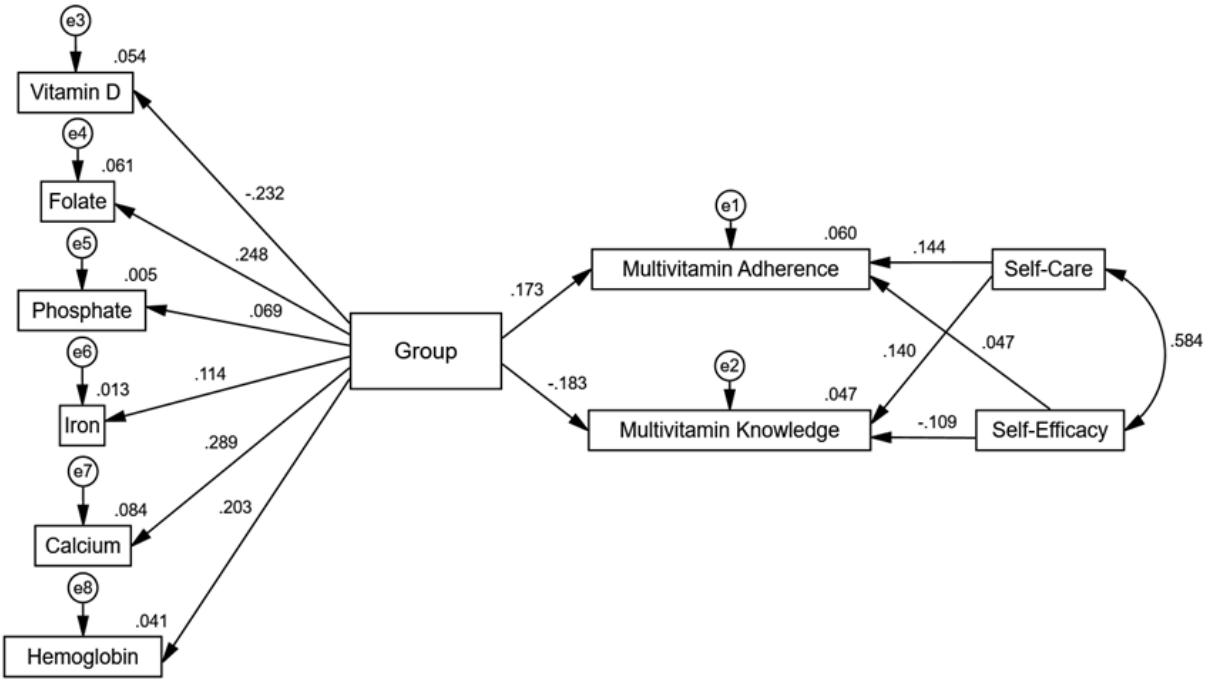

Figure 2. Model 1: Pre intervention model. Shapes are defined as follows: rectangles are measured variables and small ovals, measurement or prediction errors (e1, e2, e3, e4, e5, e6, e7, and e8). The values on the one-way arrows correspond to the standardized regression weights, and the double arrows indicate correlations. $\chi 2$=78.273, df=42, p=0.001; root mean square error of approximation= 0.167; comparative fit index= 0.230; parsimony normed fit index= 0.178.

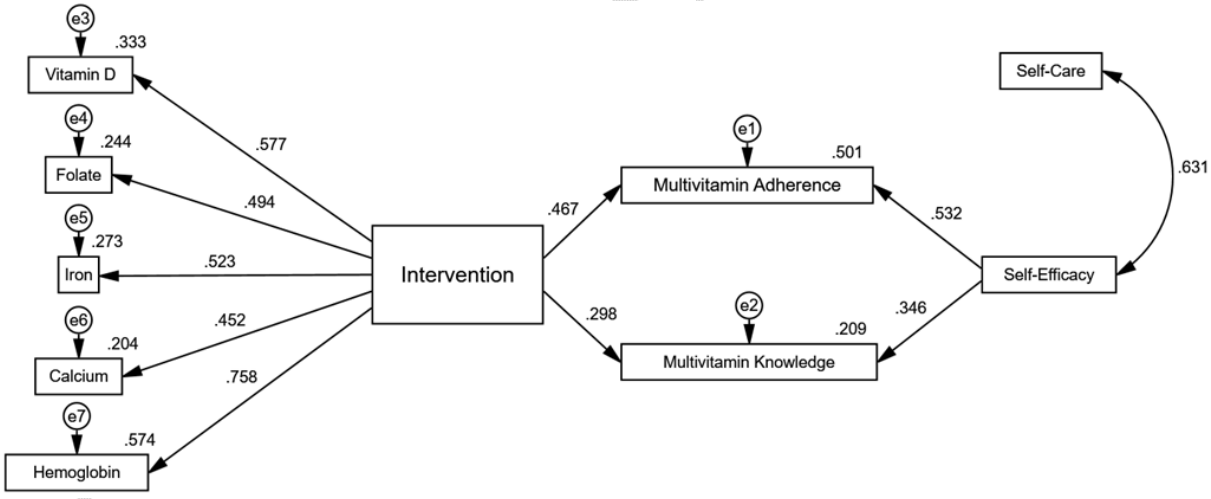

Figure 3. Model 2: Post intervention model based on Cognitive Dissonance Theory. Shapes are defined as follows: rectangles are measured variables and small ovals, measurement or prediction errors (e1, e2, e3, e4, e5, e6, and e7). The values on the one-way arrows correspond to the standardized regression weights, and the double arrows indicate correlations. $\chi 2$=29.149, df=35, p=0.746; root mean square error of approximation= 0.000; comparative fit index= 1; parsimony normed fit index= 0.617.