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Randomized control trials

Effectiveness of nutritional treatment and synbiotic use on gastrointestinal symptoms reduction in HIV-infected patients: Randomized clinical trial

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SUMMARY

Background & aims: Gastrointestinal symptoms are among the most frequent reported complaints by people living with HIV and AIDS (PLWHA). Treatments that aim to attenuate these symptoms are important to avoid low adherence to antiretroviral therapy and to improve the quality of life. This study aimed to evaluate the effectiveness of nutritional treatment and synbiotic use in PLWHA on reducing gastrointestinal symptoms.

Methods: A randomized clinical trial nested to an outpatient cohort was conducted to evaluate the effectiveness of two treatments for gastrointestinal symptoms reduction in adult patients with antiretroviral therapy presenting at least one gastrointestinal symptom: 1) nutritional treatment + placebo (6 g maltodextrin) and 2) nutritional treatment + synbiotic (*Lactobacillus* and *Bifidobacterium* strains + 6 g fructooligosaccharides). Placebo and synbiotic were consumed twice a day during six months. The primary outcome variable was percentage reduction in the incidence of diarrhea, and secondary outcomes the decrease in the incidence of nausea and/or vomiting, dyspepsia, heartburn, constipation, flatulence, and the presence of three or more gastrointestinal symptoms.

Results: Out of 283 patients evaluated for eligibility, 64 met inclusion criteria to enter in this study with 1:1 allocation ratio. Both analyzed groups were homogeneous regarding sociodemographic, clinical and lifestyle variables at baseline. In the intergroup analysis, no difference was found between groups except for heartburn, which had a higher reduction in the placebo group (0.01). Regarding the intragroup analysis, in the placebo group a significant decrease in diarrhea ($p = 0.02$) and heartburn ($p < 0.01$) were observed while there was a significant reduction for nausea e/or vomit ($p = 0.01$), dyspepsia ($p = 0.10$), diarrhea ($p = 0.01$) and constipation ($p = 0.08$) in the synbiotic group.

Conclusions: Diarrhea decreased in both groups, but no statistical difference between treatments was observed. The use of synbiotic appeared to reduce a greater number of symptoms although there were no statistical differences in the intergroup analysis.

This clinical trial was registered at ClinicalTrials.gov (NCT02180035).

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1. Introduction

The gastrointestinal tract is affected by HIV-infection. The intestinal immune system is the primary target of the virus [1]. HIV-infection exerts an adverse impact on the gastrointestinal system, affecting its structure and function, favoring the disease progression through bacterial translocation and generalized immune system activation [2]. Progressive loss of TCD4+ cells leads to gastrointestinal enteropathy characterized by epithelial degeneration, impairment of intestinal microvilli, and inflammation, causing discomfort, diarrhea, abdominal distention and nutritional deficiencies [3].

The intestinal tract is one of the most affected sites by the HIV-infection [4]. Before antiretroviral treatment (ART), the presence of gastrointestinal symptoms was strongly associated with the occurrence of opportunistic diseases. With the depletion of defense cells in the organism owing to the viral load increase, the HIV-infected individual becomes vulnerable to opportunistic infections caused by various pathogens, leading mostly to diarrhea [5,6].

Despite the improvement in immune function with ART use [7], adverse effects as gastrointestinal intolerance symptoms like diarrhea and nausea can occur, constituting an important factor in treatment discontinuation and poor medication adherence [8,9]. Nevertheless, the etiology of gastrointestinal symptoms in people living with HIV/AIDS (PLWHA), particularly diarrhea, may involve both factors related to ART as the HIV-infection itself [9].

Probiotics, prebiotics, and synbiotics have nutritional functions, metabolic and physiologic effects that are beneficial to health. In PLWHA, probiotics, prebiotics, and synbiotics have shown positive effects in the gut physiology, intestinal barrier integrity and improvement in the immune function, and they can be recommended as adjuvant therapy in these patients' treatment [10–12]. The use of probiotics can bring benefits on the incidence of gastrointestinal symptoms [13], while prebiotics plays a significant role in the intestinal flora, modulating and improving its composition [14].

In an extensive literature search, the use of synbiotic in HIV-infected adult patients was identified only in two studies that investigated its effect on function and integrity of gastrointestinal mucosa [10] and bacterial translocation [11]. Studies evaluating the effect of nutritional treatment and synbiotic use on gastrointestinal symptoms in PLWHA with or without ART were not found. This study assessed the effect of synbiotic supplementation combined with nutritional treatment in PLWHA on ART in reducing gastrointestinal symptoms: diarrhea, nausea and/or vomit, dyspepsia, heartburn, constipation, and flatulence, considering the assumption of the coadministration of probiotic and prebiotic potentiating action in the treatment of gastrointestinal disorders.

2. Materials and methods

This research is a double-blind randomized clinical trial nested to a larger research project called PRECOR, conducted at the Outpatient Clinic of Infectious and Parasitic Diseases (OCIPD) from Hospital das Clinicas, Federal University of Goias, Brazil. The OCIPD is one of the specialized care centers for people living with HIV/AIDS, the second Goias State's outpatient clinic with the greater flux of PLWHA. The Hospital das Clinicas of Federal University of Goias Ethics Committee approved this clinical trial, named PRECOR-NUT (protocol number 163/2009). All patients who agreed to participate signed an informed consent.

All patients receiving routine health care at OCIPD between March 2010 and July 2011 were invited to participate in PRECOR study. Adult patients in ART for at least 30 days were referred to a nutrition consultation and asked to participate in PRECOR-NUT, totalizing 176 patients. Inclusion criteria for this study was incidence of at least one gastrointestinal symptom among diarrhea, nausea and/or vomit, dyspepsia, heartburn, constipation and flatulence at the initial evaluation by the nutritionist. Pregnant and lactating women and patients with an opportunistic disease diagnosed in less than two months or more with no clinical resolution during the time of the recruitment period were excluded from the study sample. The flow diagram of patients' recruitment, entry and follow-up is shown in Fig. 1. The average interval between baseline and end of follow-up was 30 weeks.

The research coordinator generated the randomization sequence after signature of the consent form. Each patient received a random number used for simple allocation in three groups at 2:1:1 ratio. In this study, only the latter two groups were evaluated: 1) nutritional treatment + placebo and 2) nutritional treatment + synbiotic. The patients and health care professionals involved in the research were unaware of which group receives placebo or synbiotic. Synbiotic and placebo sachets were monthly distributed to the participants after the nutrition consultation. The sachets were identical, differentiating only by a serial number printed on the side of the package to maintain the blinding of the study.

The placebo group received sachets with 6 g of maltodextrin. The synbiotic group received 6 g of synbiotic containing fructooligosaccharides, *Lactobacillus paracasei* (LPC-37), *Lactobacillus rhamnosus* (HN001), *Lactobacillus acidophilus* (NCFM) *e Bifidobacterium lactis* (HN019) at a concentration of 10^6–10^9 CFU per strain (LACTOFOS©). Both groups were instructed to consume two sachets/day, one by morning and other before sleep, diluted in 100 ml of room temperature water.

A company provided synbiotic and placebo in sponsorship character according to pre-established ethical principles. This company has the product registration and follows strict development criteria according to the Brazilian National Agency of Sanitary Vigilance recommendations.

Nutritional counseling for healthy eating, individual counseling for any pre-existing medical condition such as diabetes, hypertension or dyslipidemias and for the presence of gastrointestinal symptoms composed the nutritional treatment applied to both groups. Additionally, a personalized eating plan was calculated in agreement with nutrient requirements, clinical and socioeconomic conditions. The nutritional counseling was based on the Brazilian Clinical Manual in Assistance to Adults Infected with HIV [15] and the Dietary Guidelines for the Brazilian Population [16].

The research team was previously trained for nutritional treatment's effectuation and implantation in agreement with the research protocol in order to standardize all executed procedures.

The primary outcome of this study was the intergroup percentage reduction in the incidence of diarrhea between baseline and the end of follow-up. Secondary outcomes were the intergroup percentage reduction in the incidence of other gastrointestinal symptoms (nausea and/or vomiting, dyspepsia, heartburn, constipation, flatulence, and the presence of three or more gastrointestinal symptoms).

The sample size was determined considering expected success rate of 5% for the standard treatment and 30% for the synbiotic treatment with 10% alpha and 80% power, resulting in 25.5 patients in each group [17]. Another calculation was performed considering the same parameters above with a 5% alpha, resulting in 32 patients in each arm of the study [17]. The choice of an alpha of 10% was due to the intervention's characteristics, which has low cost and has a small probability of adverse effects. In such cases, a weighing between statistical significance and clinical relevance is taken into account.

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