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The effects of gluten-free diet versus hypocaloric diet among patients with fibromyalgia experiencing gluten sensitivity symptoms: Protocol for a pilot, open-label, randomized clinical trial

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ABSTRACT

Background: Fibromyalgia is a chronic musculoskeletal pain syndrome characterized by a broad spectrum of manifestations. Patients with fibromyalgia frequently suffer from manifestations similar to those experienced by patients with gluten-related disorders raising the possibility that some patients with fibromyalgia could suffer from underlying gluten sensitivity.
Objective: This study aims to assess whether avoiding gluten among patients with fibromyalgia and gluten sensitivity is beneficial.
Methods: Adult patients with fibromyalgia presenting gluten sensitivity symptoms are randomly allocated to receive gluten-free diet or hypocaloric diet for 24 weeks. The primary outcome measure is the mean change in the number of experienced gluten sensitivity symptoms. Secondary outcome measures include the mean changes in the body mass index, Revised Fibromyalgia Impact Questionnaire, Pittsburgh Sleep Quality Index, Brief Pain Inventory, Beck Depression Inventory—II, State-Trait Anxiety Inventory, Short-Form Health Survey and Patient Global Impression Scale of Severity. Other secondary outcome measures include the frequency of potential adverse events and the proportion of responders according to the Patient Global Impression Scale of Improvement.
Discussion: Previous studies assessing dietary interventions in fibromyalgia primarily evaluated their effects on the severity and impact of fibromyalgia symptoms and pain. The current study is the first to evaluate the effects of gluten-free diet on the gluten sensitivity symptoms experienced by patients with fibromyalgia. The results of this study will contribute to a better understanding of the potential role of gluten sensitivity in fibromyalgia.

Abbreviations: ACR, American College of Rheumatology; ANOVA, analysis of variance; BDI-II, Beck Depression Inventory—II; BPI, Brief Pain Inventory; FIQ-R, Revised Fibromyalgia Impact Questionnaire; GFD, gluten-free diet; GSQ, Gluten Sensitivity Questionnaire; IBS, irritable bowel syndrome; ITT, intention-to-treat; LOCF, last observation carried forward; NCGS, non-celiac gluten sensitivity; PGI-I, Patient Global Impression Scale of Improvement; PGI-S, Patient Global Impression Scale of Severity; PSQI, Pittsburgh Sleep Quality Index; SF-12, Short-Form Health Survey; STAI, State-Trait Anxiety Inventory.

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1. Introduction

Fibromyalgia syndrome, a chronic musculoskeletal pain disorder, is a relatively prevalent disorder affecting 2–5% of the general population [1]. It is characterized by widespread pain accompanied with a broad spectrum of symptoms and signs that include fatigue, stiffness, sleep disturbances and psychological disturbances.

Gastrointestinal manifestations, frequently reported by patients with fibromyalgia, were initially attributed to the common comorbidity of fibromyalgia and irritable bowel syndrome (IBS), which has been shown to range between 32% and 81% [2–4]. However, a considerable proportion of patients with fibromyalgia present non-specific gastrointestinal symptoms such as abdominal pain, dyspepsia, belching and bloating [5,6], which are not sufficient to establish a diagnosis of IBS, indicating the possible presence of other underlying factors.

Celiac disease and non-celiac gluten sensitivity (NCGS), which are classified under gluten-related disorders, share a wide array of gastrointestinal and extraintestinal manifestations such as diarrhea, abdominal pain, bloating, tiredness, fatigue, foggy mind, bone pain, headache, anemia, depression and anxiety [7–9]. In clinical practice, a considerable overlap in the symptomatologic spectrum of fibromyalgia and these gluten-related disorders can be noticed, whereby a remarkable similarity in gastrointestinal and extraintestinal manifestations was found between patients with fibromyalgia and patients with celiac disease or NCGS [10]. This symptomatologic overlap suggests a possible role of gluten sensitivity in at least a subgroup of patients with fibromyalgia who present gastrointestinal manifestations. This postulation can be supported by the increased susceptibility to multiple chemical sensitivity disorders [11] and hypersensitivity to food components [12,13] in fibromyalgia. Furthermore, NCGS has been linked to an underlying role in several disorders such as IBS and neuropsychiatric disorders [14,15], which indicates the possible presence of a broad range of disorders that could be affected by such sensitivity.

A considerable proportion of patients with fibromyalgia believe that dietary interventions are linked to a significant benefit and perceive symptomatic aggravation as being secondary to the intake of specific foods [16]. Thus, a general tendency exists toward adopting dietary interventions by up to 30% of patients with fibromyalgia [17]. Several attempts were undertaken to investigate the benefit of the commonly selected

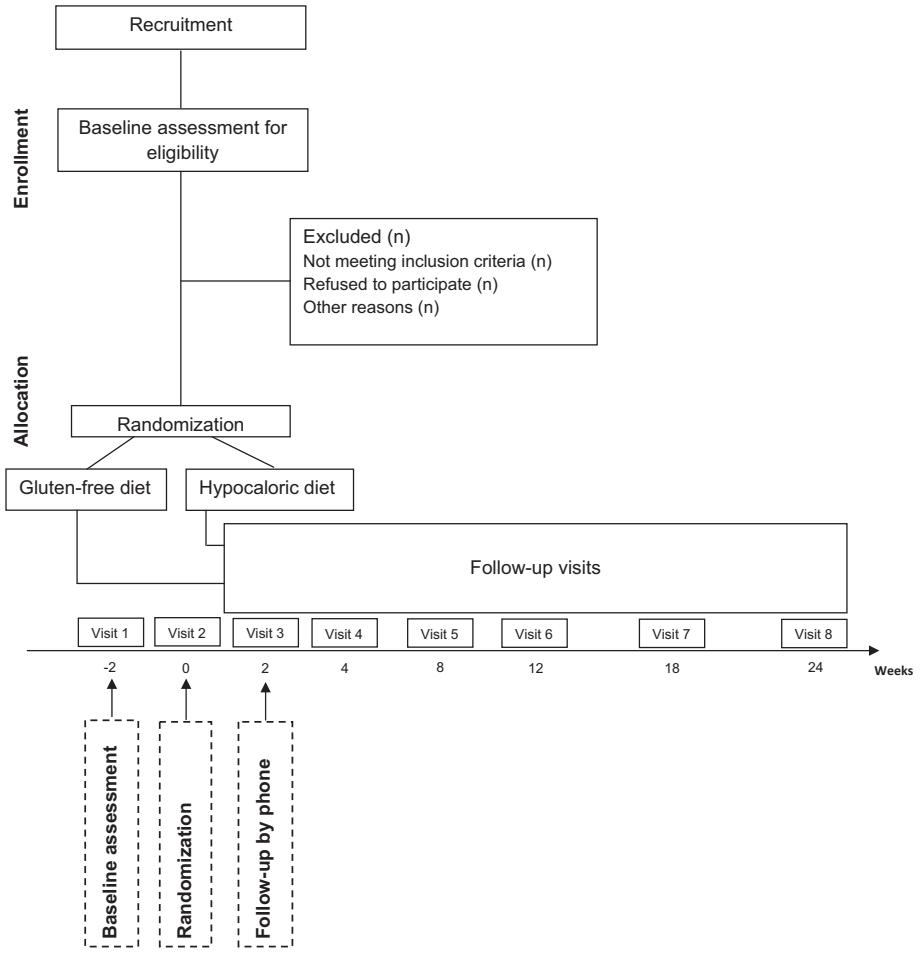

Fig. 1. Flow chart of the study.