

INPLASY PROTOCOL

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None declared.

Exclusion Diets in Functional Dyspepsia

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Review question / Objective: To analyze the impact and efficiency of certain exclusion diets undertaken by patients suffering from functional dyspepsia.

Condition being studied: Functional dyspepsia (FD) is defined, according to the Rome IV criteria, as any combination of the following symptoms: postprandial fullness, early satiety, epigastric pain, and epigastric burning that are severe enough to interfere with the usual activities, occurring at least 3 days per week over the last 3 months with an onset of at least 6 months before the presentation. It represents a common disorder of the gut-brain interaction with a prevalence of 3% in the general population and certain risk factors including smoking, non-steroidal anti-inflammatory drugs, *Helicobacter pylori* infection, acute gastroenteritis, female sex, psychological comorbidity, and psychological stress being identified. Additionally, micro-inflammation, gastrointestinal infections, alterations in the gastrointestinal microbiota, and hypersensitivity to certain nutrients have all been incriminated in the intricate pathogenesis of FD. Besides the conventional pharmacological therapy focused on the eradication of the *Helicobacter pylori* infection, the management of the disease includes lifestyle and dietary changes.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 May 2022 and was last updated on 04 May 2022 (registration number INPLASY202250026).

INTRODUCTION

Review question / Objective: To analyze the impact and efficiency of certain exclusion

diets undertaken by patients suffering from functional dyspepsia.

Rationale: Functional dyspepsia represents a common disorder of the brain-gut

interaction with multiple risk factors identified and intricate pathogenesis. Apart from the classic pharmacological therapies consisting of antacids, proton pump inhibitors, prokinetics, neuromodulators, and antibiotics against *Helicobacter pylori*, nutrition plays an important role in the disease's management. With symptomatology strongly impacting patients' quality of life, dietary recommendations are of utmost importance. With research conducted in this domain establishing a correlation between functional dyspepsia and food intolerances, many patients are prone to adopting certain exclusion diets, leading to weight loss, restrictive eating behavior, and an unbalanced nutritional state. Thus, our aim was to analyze and assess the correlation between symptomatology triggered by functional dyspepsia and several exclusion diets.

Condition being studied: Functional dyspepsia (FD) is defined, according to the Rome IV criteria, as any combination of the following symptoms: postprandial fullness, early satiety, epigastric pain, and epigastric burning that are severe enough to interfere with the usual activities, occurring at least 3 days per week over the last 3 months with an onset of at least 6 months before the presentation. It represents a common disorder of the gut-brain interaction with a prevalence of 3% in the general population and certain risk factors including smoking, non-steroidal anti-inflammatory drugs, *Helicobacter pylori* infection, acute gastroenteritis, female sex, psychological comorbidity, and psychological stress being identified. Additionally, micro-inflammation, gastrointestinal infections, alterations in the gastrointestinal microbiota, and hypersensitivity to certain nutrients have all been incriminated in the intricate pathogenesis of FD. Besides the conventional pharmacological therapy focused on the eradication of the *Helicobacter pylori* infection, the management of the disease includes lifestyle and dietary changes.

METHODS

Search strategy: The electronic databases PubMed, EMBASE, and Cochrane Library were searched without any restrictions from their inception until March 1st, 2022, to identify potential observational and interventional studies. The following search string was entered for PubMed (“Functional Dyspepsia” [Mesh]) OR (“Dyspepsia” [All Fields]) AND (“Diet” [Mesh]) OR (“Nutrition” [All Fields]) OR (“fermentable oligosaccharides, disaccharides, monosaccharides, and polyols” [Mesh]) OR (“FODMAP” [All Fields]) OR (“Gluten” [Mesh]) OR (“Lactose” [All Fields])).

Participant or population: Various clinical settings.

Intervention: Exclusion diets.

Comparator: Controls, with the exception of one before-after type of study with no control group.

Study designs to be included: Observational and interventional studies.

Eligibility criteria: The original articles were included in the systematic review and qualitative assessment if they satisfied the following criteria: (1) Observational or interventional study, population/hospital/primary care-based; (2) FD was confirmed by Rome II, III, or IV criteria; (3) FD diagnosis based on the criteria established in each study; (4) Studies on humans solely. The exclusion criteria were represented by: (1) Studies published in languages other than English (2) Case reports, letters, reviews, short surveys, practice guidelines, press articles, conference abstracts/papers; (3) Abstracts published without full-text or with the paper unavailable; (4) Pediatric studies.

Information sources: The electronic databases PubMed, EMBASE, and Cochrane Library were searched without any restrictions from their inception to March 1st, 2022, in order to identify potential observational and interventional

studies analyzing the impact of certain exclusion diets in alleviating the symptomatology of patients with FD. Moreover, we performed a manual search for missed relevant publications by analyzing the references of the already-included studies.

Main outcome(s): The principal outcome was represented by an improvement in patients' symptomatology after following certain exclusion diets.

Quality assessment / Risk of bias analysis: Two investigators (V.D.B. and S.L.P.) used the National Heart, Lung and Blood Institute (NHLBI) and Newcastle-Ottawa Scale (NOS) to assess the quality of the included studies. Controlled intervention studies and before-and-after studies with no control group were analyzed using the NHLBI tools accordingly. The quality of case-control and cross-sectional studies was assessed using the NOS for this type of study design. Regarding the NHLBI quality assessment tools, the evaluation criteria were answered either by "Yes", "No", "CD" (cannot determine), or "NR" (not reported) upon completion of the evaluation. For the NOS, studies were evaluated based on the number of stars they obtained, as well as the selection, comparability, the assessment of the outcome, and statistical methods used in the study. Any discrepancies regarding the quality assessment between the two evaluators were further solved by discussion. The quality of the included studies did not affect their eligibility in the systematic review.

Strategy of data synthesis: We conducted a qualitative synthesis of all included studies.

Subgroup analysis: Subgroup analysis was conducted in accordance with the available data from the extracted data from the included studies, such as additional diagnoses, symptomatology, and sex.

Sensitivity analysis: No sensitivity analysis was conducted in our systematic review.

Language: Studies included had to be published in English.

Country(ies) involved: Romania and Italy.

Keywords: FODMAPs; diet; functional dyspepsia; functional gastrointestinal disorders; disorders of the brain-gut interaction.

Dissemination plans: Publication in a peer-reviewed journal.

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