INTRODUCTION

CHAPTER 1

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Functional constipation (FC) is a significant clinical and public health issue. The Gut Health Survey conducted by Abbott India (2018) sheds light on the predicament of these "silent sufferers," as well as the causes and implications of chronic constipation. Thirteen percent of adult Indians reported experiencing severe constipation, according to the research. The survey also indicated that despite the fact that 88% of respondents with the disease are concerned about it, few are willing to discuss it with close friends or family members since it is regarded as a social taboo. According to the findings of the study, 49% of respondents were reluctant to seek medical assistance for an issue. In reality, respondents admit delaying medical treatment by an average of four months. Thirty three percent who experienced constipation do nothing, while 48% seek home remedies to relieve it.

Hard stools or scybala (hard, inspissated stool), unsuccessful calls (wanting to but unable to), cylindrical and cracked or cylindrical and thick stools, frequency of bowel movements less than three times per week, and straining for more than 25% of the time are all considered to be objective and subjective indicators of constipation (Hyams et al, 2002). Constipation has a multifaceted pathogenesis, with particular emphasis on genetic predisposition, socioeconomic level, poor fibre intake, inadequate fluid intake, immobility, disruption of the hormone balance, drug side effects, or body structure (Rajindrajith and Devanarayana, 2011). Constipation is not just a problem for the elderly; it may also affect people in their middle years and young adults. Sedentary behaviour and physical inactivity are two main risk factors for constipation. Most of the studies have been conducted on the free living population. However, there is a need to explore the presence of FC on the sedentary population who are actively mentally engaged especially in the middle aged University teaching staff.

Chronic idiopathic constipation can be treated with lifestyle modifications such a high-fiber diet and exercise, CBT, biofeedback therapies, and, in some cases, surgery. In addition to being easily accessible over-the-counter, medications such bulking fibers, laxatives (osmotic & stimulants), and stool softeners are frequently used to treat symptoms (Lu & Mousa, 2018).

However, due to side effects such as stomach bloating, diarrhea, dehydration, and abnormal electrolytes, a large number of people either do not respond at all or cease taking these treatments. Additionally, there is no evidence that these treatments can change or affect how a disease develops naturally (Hayat et al, 2017).

An important requirement to consider when examining the eating habits and sleep schedule of constipation sufferers is their chrononutrition profile (Duboc et al, 2020). Chrononutrition is the study of how a person's diet corresponds to their circadian rhythm, which includes their internal metabolism, including digestion and absorption, among others. It aligns with the principle of eating at the same times every day as your body. When dietary patterns are abnormal, the diet's macronutrients, for example, may not be processed properly, which can result in weight gain and other metabolic issues. The chrono nutrition profile consists mostly of six questions, including the size of the largest meal consumed and the frequency and timing of meals, which have a significant impact on the circadian clock and circadian rhythm and ultimately lead to poor metabolism (Bjelajac & Đerčan,2019). This significant study is the first to establish an association between constipation and chrononutrition.

Consumption of sugary confectioneries is on the rise, which could be considered a public health risk. Food additives, sugar, and glucose syrup supplemented at a high level (above 50%) are examples of ingredients that could be harmful to human health (Garcia, 2000). Garcia (2000), also estimates that around half of the market is made up of the confectionery category, which includes gummies, nougat, and hard and soft sweets. Therefore there is a need to develop non sugary sweets that may add as a healthy alternative that may act as a treatment for FC. The present study of replacing sugar with GOS in the gummies is also a pioneering work. The objective of the study was to create healthy vegan gummies with prebiotic properties using Galactooligosaccharide (GOS). Hence in this study we also aimed to prove whether gummies with 100% GOS can improve the gut health of sedentary adults suffering from functional constipation.

Prebiotics can also be explored as an alternative for treating functional constipation. Prebiotics have been proved beneficial for reducing bloating, abdominal pain, constipation and abdominal cramps (Mezzasalma et al. 2016). These are naturally occurring, undigested dietary components that promote the growth of beneficial gut bacteria reducing the colonization of pathogenic bacteria. Fructooligosaccharide (FOS), inulin are the most popular prebiotics

studied in research on the effects of prebiotics on several pathologies including irritable bowel syndrome, bowel diseases etc (Moayyedi et al, 2010).

Galactooligosaccharide (GOS) is a relatively less explored prebiotic which also lowers blood cholesterol, enhances mineral absorption, and treats several acute and chronic illnesses (Gosling et al, 2010). Galactooligosaccharide is a naturally occurring prebiotic present in human milk. *Bifidobacteria bifidum* and *Lactobacillus rhamnosus* are the most researched probiotic strains that have shown to increase in great numbers upon consumption of GOS (Arnold et al, 2021; Bakker et al, 2005; Fischer and Kleinschmidt, 2015) while inhibiting the growth of harmful and pathogenic bacteria (Torres et al, 2010; Moreno & Sanz, 2014). Studies on hypertensive subjects also shown improved colonisation in beneficial bacteria using RTPCR (Sheth et al, 2015). Gut health has shown to be improved in studies conducted on obesity, diabetes, hypertension (Sheth et al, 2019; Sheth et al, 2016). However, limited studies using GOS have been undertaken to assess the growth of beneficial and pathogenic microbes in subjects suffering from FC.

Short chain fatty acids (SCFA) assist large intestine to operate normally and fight infections by functioning in the lumen and on the colonic muscles and blood vessels. This is achieved through their metabolism by colonocytes (Cani PD et al 2005; Cicek et al 2009). Literature review showed that SCFA and gut health of participants with pre-hypertension and diabetes were improved by daily consumption of 10g of FOS (Sheth et al, 2016; Sheth et al, 2015). The improvement in SCFA profile is however, relatively less explored with the consumption of GOS.

FC is a very common functional gastrointestinal condition that could have a major impact on both the quality of life and the depression status (Wald A et al, 2007). Research studies have shown a significant positive association between mental health and gut health (Jalanka et al, 2018). A study conducted by Dwivedi and Sheth (2019) revealed that depression status can be significantly improved by regular consumption of prebiotics such as FOS. A study conducted by showed a significant improvement in quality of life of life upon regular consumption of FOS (Sheth and Assudani, 2014). However the role of GOS on these parameters needs to be explored.

Thus the present study entitled **"Presence of Functional Constipation in the Teaching staff of The M.S. University of Baroda and Impact Evaluation of Supplementation of**

Galactooligosaccharide (GOS) added gummies on their Gut Health and Constipation Profile – A Randomized Double Blind Placebo Control Trial" was undertaken in the following three phases:

Phase 1 Screening and identification of functional constipation in University teaching staff

Phase II Development, acceptability trials and shelf life studies of Galactooligosaccharide (GOS) added gummies

Phase III Impact evaluation of supplementing GOS gummies to subjects suffering from FC on their constipation profile, gut microflora, SCFA profile, depression status and quality of life