



SCOPE OF INVESTIGATION

CHAPTER 3

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Based on the literature review, the following working hypotheses was formulated for 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**”

1. Null Hypothesis

There is no possibility of presence of functional constipation in the teaching staff of The M.S. University of Baroda.

1. Alternate Hypothesis

There is a possibility of presence of functional constipation in the teaching staff of The M.S. University of Baroda.

2. Null Hypothesis

It will not be possible to replace sugar with 100% GOS in gummies with acceptable sensory attributes, shelf quality and minimal loss of GOS after preparation.

2. Alternate Hypothesis

It will be feasible to develop 100% GOS gummies with acceptable sensory attributes, shelf quality and high recovery rates of GOS after preparation.

3. Null Hypothesis

Ten grams GOS supplementation (4 gummies) for 4 weeks will not improve the constipation profile, gut health with respect to higher colonisation of beneficial microflora (LAB and Bifidobacteria) and short chain fatty acid profile (acetic acid, propionic acid, butyric acid), quality of life and depression status in constipated subjects.

3. Alternate Hypothesis

Ten grams GOS supplementation (4 gummies) for 4 weeks will improve the constipation profile, gut health with respect to higher colonisation of beneficial microflora (LAB and

Bifidobacteria) and short chain fatty acid profile (acetic acid, propionic acid, butyric acid), depression status and quality of life in constipated subjects.

To authenticate the above mentioned hypothesis the present study was undertaken with the following objectives:

Phase I – Screening and identification of Functional Constipation in University teaching staff

- Snapshotting the presence of functional constipation among the teaching staff of The M.S. University of Baroda and collecting their data on baseline information in terms of their socio economic status, medical history, family history, physical activity and personal habits
- Assessment of the dietary practises, chrono nutrition profile and frequency of consumption of various fibrous and non-fibrous foods
- Identification and understanding the association and correlations of various factors with the presence of functional constipation in the teaching staff

Phase II Development of Galactooligosaccharide (GOS) added gummies and study their acceptability Trials and shelf life studies

- Development of standard gummies with varying levels of various ingredients (water, sugar, agar and citric acid)
- Substitution of sugar in the gummies with GOS varying levels (60%, 80%, 100%) and conducting their acceptability trials to obtain the most acceptable gummy
- Conducting physico chemical and recovery analyses of the 100% GOS added gummies
- Conducting shelf life studies of the 100% GOS added gummies at accelerated temperatures for a period of 6 months with respect to their microbial analysis and sensory evaluation

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

- Baseline information of subjects with FC was collected with respect to general information, constipation profile, gut microflora, SCFA profile, depression status and quality of life
- Analysing fecal samples of constipated subjects with respect to the relative quantification of gut microflora in terms of Bifidobacteria, Lactobacillus, Bacteroides, Clostridium and prominent phyla Firmicutes and Bacteroidetes and quantification of short chain fatty acid profile in terms of acetic acid, propionic acid and butyric acid
- Studying the effect of GOS gummy supplementation on the subjective assessment with respect to the constipation profile, depression status and quality of life before and after supplementation among the teaching staff
- Studying the prebiotic effect of GOS gummy supplementation on the objective assessment of gut health of constipated subjects with respect to the quantification of gut microflora (above mentioned parameters) and short chain fatty acid profile (above mentioned parameters) before and after supplementation among the teaching staff

