INTRODUCTION

Earlier in India where under-nutrition was a biggest challenge today it is facing a dual burden of Malnutrition on extreme edges. Where undernutrion is on one edge, Obesity is the other extreme edge impacting drastically the "Weight of Nation", associated comorbidities and the healthcare cost !!! (WHO, 2017; Karla & Unnikrishnan, 2012). At simplest level we all know that, obesity is a mismatch between the energy intake and expenditure but it's not as simple as it seems. Unfortunately, if we look at the data over last 3 decades we have seen increase in obesity prevalence and current scenario has forced healthcare professionals to declare obesity as a "Disease". In last two decades there have been various terminologies coined for the word "Obesity" based on its exploding prevalence rates and associated co-morbidities. To name a few, it has been termed as "New World Syndrome" (Mohan et.al., 2012), "Globesity" (WHO, 2001) and "Diabesity" (Ethan, 1973). Now it's time to consider newer approaches to evaluate, diagnose and to combat this epidemic of obesity.

Recently, in 2017 according to a new position statement released by the American Association of Clinical Endocrinologists (AACE, 2017) and the American College of Endocrinology (ACE, 2017) Obesity has bagged one more diagnostic term named "ABCD – Adiposity – Based Chronic Disease"**.** Since BMI being a one dimensional approach and unable to differentiate between fat and muscles, authors find BMI a bit vague as a sole diagnostic tool and have emphasized more on "complications-centric" three pronged approach that considers assessment of excess body fat in terms of amount, distribution and its physiologic impact on health (Kedist, 2017). In 2004, Portugal was the only country in entire Europe that officially recognized Obesity as "Disease" (The Lancet Editorial, 2017). Later it was followed by Scottish Intercollegiate guidelines network in 2010. Moving forward, American Medical Association in 2013 and Canadian Medical Association in 2015 official recognized Obesity as a Disease.

Obesity has reached epidemic proportions globally. More than 1 billion adults are overweight, at least 300 million of whom are clinically obese. According to the Centers for Disease Control and Prevention, obesity affects more than one-third (36.5%) of U.S. adults (https://www.cdc.gov/obesity/data/adult.html); that number is more than double what it was in 1990 (<15%) (https://www.hsph.harvard.edu/nutritionsource/an-epidemic-of-obesity/).

Obesity and overweight pose a major risk of chronic diseases, including type-2 diabetes, cardiovascular disease, hypertension, and stroke. The key causes are an increased consumption of energy-dense foods high in saturated fats and sugars (Unnikrishnan et.al., 2012).

Obesity is also rising rapidly in India and can be seen as the first wave of a defined cluster of non-communicable diseases called "New World Syndrome," creating an enormous socioeconomic and public health burden in poorer countries (Unnikrishnan et.al., 2012; Ramachandran et.al., 2010). Given the rapid rise of obesity rates in India, it is important to know the "weight of the nation." The long-term consequences and the cost burden of obesity on the health care system are enormous. Obesity is a major driver for the widely prevalent metabolic syndrome and type-2 diabetes mellitus (T2DM) (Pednekar, 2008).

Prevalence varies within the country because of differences in the lifestyle, mainly in the dietary patterns, and physical activity. In addition to this urbanization and industrialization are the main culprits for the increase in the prevalence of obesity. Unhealthy processed foods are now easily accessible due to India's integration in global food market (Gulati & Misra, 2017). Obese individuals exhibit unique features like excess body fat, abdominal adiposity, increased subcutaneous and intra-abdominal fat, and deposition of fat in ectopic sites (such as liver, muscle and others).

Apart from Dietary factors, consuming alcohol also affects components of energy-balance equation. Results of several review literatures on alcohol and obesity demonstrates that heavy drinking is a major risk factor for obesity as compared with light to moderate intake. According to Traversy & Chaputt (2015) there are several potential mechanisms that influence weight gain on alcohol consumption like amounts of alcohol enhance energy intake due to the caloric content of the alcohol as well as its appetite-enhancing effects. Experimental evidence from several metabolic studies showed a suppression of lipid oxidation by alcohol and thus the enhancement of a positive fat balance (Sutter, 2005). The non-oxidized fat is preferentially deposited in the abdominal area. Also, studies conducted by Röjdmark et al. (2008) and Raben et al. (2013) demonstrate that alcohol intake influences number of hormones linked to satiety. Alcohol may influence energy intake by inhibiting the effects of Leptin, or glucagon-like peptide-1 (GLP-1). To date, the evidence suggests that alcohol does not appear to increase appetite through the action of peptide YY (PYY),

Ghrelin, Gastric inhibitory peptide (GIP), or Cholecystokinin (CCK) (Calissendorff et al., 2006; Manabe et al., 2013; Traversy & Chaputt, 2015). There are several associations between alcohol and obesity and these are heavily influenced by lifestyle, genetic and social factors (Bates et al., 2009; Dennis et al., 2009). The relationships between obesity and alcohol consumption differ between men and women. Presently, it can be said that alcohol calories count in combination with a high-fat diet in overweight and obese subjects (Schutze et al., 2009).

The World Health Organization statistics (2013) has described depression as "the number one cause of disability in the United States and the third largest, behind heart disease and stroke, in Europe" (World Health Statistics, 2013). Dr. Michael Craig Miller, an assistant professor of psychiatry at Harvard Medical School explains that depression and obesity feed each other. "Obesity affects parts of the brain that regulate your mood. When you're depressed, low energy and motivation can translate into less activity and exercise, this may result in weight gain" (Miller, 2013).

There is a need to explore the role of unconventional factors in etiology of obesity. Recently, the role of Gut – Brain Axis is being explored widely to unwind the underlying molecular mechanisms that control centers of hunger-satiety via biochemical signaling. The relationship between gut flora and humans is not merely commensal (a non-harmful coexistence), but rather a mutualistic relationship (Sherwood, et.al. 2013). It's well known that gut microbiota plays a major role in the development of food absorption and low grade inflammation, two key processes in obesity and diabetes. Animal and human data have suggested that the composition of the gut microflora may be an important mediator of the risk of obesity and diabetes (Delzenne & Cani, 2011). Human gut microorganisms benefit the host by collecting the energy from the fermentation of undigested carbohydrates and the subsequent absorption of short-chain fatty acids (SCFAs), acetate, butyrate, and propionate (Quigley, 2013; Clarke et al., 2014).

Prebiotics are fermented dietary fibers have been shown to impact the host by specifically stimulating changes in the composition and/or activity of bacteria in the colon, and thus improving the hosts' health. These have been shown to mostly target *Bifidobacteria* and *Lactobacilli* (Macfarlane, Macfarlane & Cummings, 2006; Gibson et al., 2004).

Recently, with the aim to clarify the prebiotic concept, Bindels et al. (2015), proposed to define prebiotic as "a non-digestible compound that, through its metabolism by microorganisms in the gut, modulates composition and/or activity of the gut microbiota, thus conferring a beneficial physiological effect on the host" (Bindels et al., 2015).

The mechanisms through prebiotics exert their benefits are:

1) Selective stimulation of the growth and/or activity of intestinal bacteria associated with health, mainly Lactobacilli and Bifidobacteria (Carlos Gomez Fallego & Seppo Salminen, 2015)
2) Production of short chain fatty acids (SCFAs), particularly butyrate, which have antimicrobial activity by reduction of intestinal pH and other immunological and physiological activities (Bindels et al., 2015).

Oligofructose is a potential prebiotic candidate that enhances satiety and has positive organoleptic properties that would foster incorporation into a variety of foods (Claire et al., 2016; Van Hoffen et al., 2008; Cani et al., 2006; Daddaoua, 2006; Delzenne et al., 2001). The mechanisms by which oligofructose enhances satiety may involve fermentation by select bacterial strains and increased production of short-chain fatty acids in the gut lumen (Claire et al., 2016; Parnell & Reimer, 2013; Pylkas, Juneja & Slavin, 2005). The effectiveness and mechanisms by which oligofructose may act to promote weight loss in humans warrant further investigation.

The gut communicates with areas in the hypothalamus that control energy balance via glucagon like peptide-1 (GLP-1), gastric inhibitory peptide (GIP) and peptide YY (PYY) considered as satietogenic peptides (Mekkes et al., 2013). Few human studies have indicated reduced plasma concentrations of GLP-1, GIP and PYY in obesity (Lean & Malkova, 2016). This impaired secretion may promote the development of obesity or hinder weight loss or both. Of the gut satiety hormones, those that are responsive to diet composition, including GLP-1, GIP and PYY are promising targets for weight management through diet modification. FOS has been extensively studied as a prebiotic and there is ample evidence in human subjects, including infants, as well as in animal and in vitro studies that, prebiotics significantly increase the proportion of fecal *Bifidobacteria* and sometimes *Lactobacillus* even at fairly low levels of consumption (5–8 g per day) (ILSI Europe, 2011), however its potential to enhance satiety has to be further validated.

Glucagon-like peptide 1 (GLP-1) has numerous antiobesity and antidiabetic actions, including inhibition of food intake, delayed gastric emptying, weight loss, stimulation of insulin secretion, and induction of b cell proliferation. Conversely, Ghrelin stimulates food intake and weight gain as well as promotes adiposity (Perry & Wang, 2012; Wren et al., 2001; Tschop et al., 2000). Of the gut satiety hormones, those are responsive to diet composition, including GLP-1, GIP, PYY, and Ghrelin (Neary et al., 2003), are promising targets for weight management through diet modification. Interest in oligofructose supplementation for weight management stems from rat studies that report reductions in energy intake, increased plasma GLP-1 and PYY concentrations, and decreased Ghrelin (Delzenne et al., 2011; Cani et al., 2004). Collective results from studies reveal the effects of Leptin, indicating that Leptin may be a naturally occurring insulin sensitizer. The widely reported hyperleptinemia in obese subjects lends facile support to this study because obesity is associated with insulin resistance. Previous studies documented marked variability in plasma Leptin levels among persons of comparable adiposity (Lean & Malkova, 2016; Askari et al., 2010).

Because Leptin exerts potent insulin-sensitizing effects in rodents we hypothesized that the variations in fasting Leptin levels in persons of similar body mass index (BMI) reflect differences in insulin sensitivity (Grudell & Camilleri, 2007) and humans (Batterham et al., 2002; Chaudhri, 2007; Drucker et al., 2006). Studies show that fasting Leptin levels are correlated directly with adiposity and fasting insulin levels and inversely with insulin sensitivity. Fasting Leptin status remains a strong predictor of insulin sensitivity.

Human trials specifically evaluating oligofructose supplementation for weight loss and glucose response are lacking. Several results support the relevance of prebiotic fermentation in appetite management in healthy and obese humans (Cani et al., 2006; Whelan et al., 2006; Parnell et al., 2009; Genta et al., 2009).

To date, few data are available that concomitantly describe the influence of prebiotics on appetite sensation, gut peptide secretion and metabolism in humans. Interestingly, one study reports that prebiotic (oligofructose) consumption (20 g/d) significantly elevated plasma GLP-1 after a mixed meal (Piche & Varannes et al., 2003). On the other hand, a decrease in Ghrelin and an elevation in serum PYY were observed with prebiotic supplementation in obese individuals (Parnell & Reimer, 2009).

Also, Obesity is also clearly linked to disturbances in energy intake; therefore, the identification of novel foods that promote satiety or dilute energy density provide a possible first line of defense in managing obesity and its associated comorbidities (Amar et al., 2008). Human trials specifically evaluating oligofructose supplementation for weight loss and understanding the interactions amongst the gut microbiota and gut incretins altogether are lacking and no study has been conducted in Indian setup.

Hence, the present study entitled "Acceptability Trials of Fructooligosaccharide (FOS) Added Popular Indian Recipes and Impact Evaluation of FOS Intervention in Modulating Gut Microflora, Gut Satietogenic Hormones and Anthropometric Indices of Young Obese Bank Employees of Urban Vadodara: A FAT – FIT Study" was undertaken in 4 phases with following objectives

OBJECTIVES

PHASE I – Snap-shoting the presence of obesity in young banks employees of Urban Vadodara

- Screening the subjects from various banks of Vadodara city for their Anthropometric measurements, body composition analysis, random blood sugar and blood pressure.
- To classify the bank employees under various categories of BMI (non-obese and obese) based on the screening data.
- Determining prevalence of obesity by classifying subjects in different grades of BMI

PHASE II– Comparison Between Parameters of Non-obese and Obese bank employees with regards to:

- Socio Economic Status (SES), Anthropometric measurements, Family medical history, personal medical history, defecation profile, personal habits, addiction profile, physical activity pattern, hunger and satiety scale, depression scores and dietary intakes of Non obese and Obese subjects
- To assess obesity status of the subjects through anthropometric measurements and body composition analysis.
- To study Gut microflora of non-obese and obese subjects with regards to
  (a) *Bifidobacterium* (b) *Lactobacillus* (c) *Clostridium* (d) *Bacteriodes*

- ✪ To determine the baseline levels of 6 Gut Satietogenic Hormones
  - Gut Incretin : GLP-1 and GIP
  - Gut Hormones : PYY, Ghrelin, Leptin and Insulin

PHASE III– To study Impact of FOS Intervention for 90 days in Obese Subjects: A Randomized Control Trial

To Study how efficiently FOS supplementation in obese subjects for period of 90 days can bring change or Modulate in terms of :

- ✪ Anthropometric
- ✪ Biophysical measurements
- ✪ Defecation Profile
- ✪ Gut Microflora : Bifidobacteria, Lactobacillus, Clostridium, Bacteriodes
- ✪ Gut Satietogenic Hormones : GLP-1, GIP, PYY, Ghrelin, Leptin and Insulin post Intervention

PHASE IV– Acceptability Trials of FOS added popular Indian Recipes

- ✪ Addition of FOS in the base material of popular Indian Recipes at varying levels along-with different cooking methods like

  - *Dudhi Muthiya* - Steamed
  - *Vegetable Chilla* - Shallowfried
  - *Handwa* - Baked
  - *Veg. Patti Samosas* - Deep Fried

- ✪ Conducting the organoleptic evaluation of the developed products using 9 point Hedonic scale.
- ✪ To establish the most acceptable level of FOS addition using various cooking methods

REVIEW OF LITERATURE

Chapter will focus on the available literature under following heads:

- Obesity – A Global Epidemic / A Global Public Health Issue
- Global Scenario
- Indian perspective
- Obesity is now recognized as "Disease": ABCD - A new diagnostic term
- Obesity – A state of Low Grade Inflammation
- Determinants of Obesity : Direct and Indirect
- Gut Brain Axis – Underlying Molecular Mechanisms
- Role of Gut Satietogenic Hormones in regulation of body weight
- Gut Incretin's – Newer approach in management of Obesity
- Gut microflora and obesity – An Inner rain forest
- Factors influencing Gut Microbiota and Health
- Role of Probiotics and Prebiotics in Obesity
- Fructooligosaccharide (FOS) as a potential prebiotic

METHODS AND MATERIAL

The present study was undertaken in four phases

METHODOLOGY:

This section outlines the experimental design and discusses the methods and materials used to fulfill previously mentioned objectives of the study.

ETHICS COMMITTEE APPROVAL:

Approval to undertake the study was obtained from the Institutional ethics committee of The M.S. University of Baroda. Written informed consent was obtained from each one of the subjects who participated in this study.

SAMPLE SIZE CALCULATION:

For Screening, Sample size was calculated using formula for finite population (<50,000) as the population of bank employees working in private banks is limited to 1500 employees in Vadodara city. The sample size estimates for screening of bank employees was calculated

to minimum 428 subjects and were based upon two sided confidence level of 95%, confidence interval of 4 and a power of 90% (David Freedman, 1997).

For clinical trial, the sample size was calculated using the software developed by Dr. David with support from the MGH Mallinckrodt General Clinical Research Center,Havard. The sample size was based on power calculations that used weight loss as the primary outcome. With an estimated weight loss of 1.0 kg and an SD of 1.0 kg based on 0.9 power to detect a significant difference (P=0.01, 2 sided), a minimum of 64 subjects were needed. We made an effort to collect data for more than 64 subjects. Total 150 subjects willingly participated in study (75 in each group – placebo and experimental).

For biochemical parameters like gut incretins, with an estimated mean difference of 0.25 pg/ml and an SD of 0.25 pg.ml based on 0.9 power to detect a significant difference (P=0.05, 2 sided), a minimum of total 46 subjects (23 in each arm) were needed in both arms and data was collected for total 80 subjects (40 subjects in each arm)

SELECTION OF BANKS FOR SCREENING:

List of private banks was taken from the website of Indian Banks Association (www.iba.org.in /viewmembanks.asp?id=3). Eighteen out of listed 24 private banks exist in Vadodara city. Six banks (A total of 20 different branches) in different areas of Vadodara city were conveniently selected based on the permission obtained from the administration department to organize the health screening camp. People in the eligible age group were briefed on the objective and benefits of the study, and were motivated to participate by providing an informed consent. Proper record of the eligible members who refused to participate in the study was maintained.

A total of six hundred and fifty (650) bank employees irrespective of age and gender were screened for their anthropometric measurements, Body fat percentage, Blood pressure and random blood sugar in sub-samples. In the present study, all anthropometric measurements were made using the guidelines adopted at the NIH sponsored Arlie Conference (Lohman et al 1988)

SELECTION OF THE SUBJECTS:

Out of 650 subjects screened, 150 Non-obese (BMI 18.5–22.9 kg/m2) and 150 obese subjects (BMI 25-30 kg/m2) between the ages of 25 – 35 year and middle income group were voluntarily recruited from the private banks of urban Vadodara. All subjects had a stable body weight for ≥ 3mo before the study. Subjects who had clinically significant cardiovascular abnormalities, liver or pancreatic disease, diabetes, major gastrointestinal surgeries, were pregnant or lactating, exhibited alcohol or drug dependence, were on drugs influencing appetite, were following a diet or exercise regimen designed for weight loss, or chronically used antacids or bulk laxatives were excluded from study. All subjects completed a health and lifestyle questionnaire to determine eligibility. Subjects were encouraged to maintain their regular lifestyle, and not to consciously try to gain or lose weight throughout the study. Approval to undertake the study was obtained from the institutional ethics committee of The M.S. University of Baroda. Written informed consent was obtained from each one of the subjects who participated in this study.

INCLUSION CRITERIA FOR SELECTION OF THE SUBJECTS:

- Non – Obese : BMI between 18.5 – 22.9 kg/m2
- Obese : BMI between 25-30kg/m2
- Age 25 - 35 years old
- Middle income group

EXCLUSION CRITERIA FOR SELECTION OF THE BANK EMPLOYEES:

Subjects with following confirmed disorders were excluded:

- Hypertension, Diabetes mellitus, Cardiovascular Disorder, Thyroid Hormone Disorder, Valve Replacement Surgery, Gastric surgery or Perforation, Renal Disorder, Locomotor Disorder, Cancer / AIDS, Psychological disorder, Heavy Physical Activity

STUDY DESIGN - DOUBLE BLIND RANDOMIZED CONTROLLED TRIAL

Method for Randomization

Obese subjects (n=150) were randomly assigned to groups that received either intervention of 20g FOS/d (FOS-P powder; provided by Meiji Co., Ltd, Tokyo, Japan) or an equicaloric amount of 10g comparator agent Maltodextrin for 90 days. The study participants were enrolled by the investigators and they were randomly allocated using computer generated sequence. The method of allocation concealment was centralized and the allocation sequence was done by the employee of department, not involved in the study. In this study the participant, investigator and outcome assessor were blinded.

Trial Monitoring Plan and compliance check

The FOS group received two 10 g packets/d, providing 20 Kcal/packet, and placebo group received 5 g packets/day, providing 20 Kcal/packet that were to be taken before meals. Both the FOS and placebo were provided to the subjects in identical opaque packages. Sachets were given on weekly basis and total 14 sachets were provided to one subject in one week. Subjects were instructed to return all packets to assess compliance. A compliance card was also provided to all subjects and they were asked to tick (√) in the card on daily basis after consuming 2 sachets and the investigator visited once a week for checking the compliance and collection of empty sachets. At the end of 3 months all the ticks (√) were counted and compliance was calculated.

Study food: FOS is ―Generally Recognized as Safe. FOS, ingested at up to 20g/day in adults, appears to be safe and well tolerated. Maltodextrin was selected as the placebo because it has a similar taste and appearance.

ANTHROPOMETRIC MEASUREMENTS

Anthropometry is the measurement of body dimensions to characterize skeletal and tissue development, and effect relationship between nutrient and level of well-being of the body is assessed. In the present study, all anthropometric measurements were made using the guidelines adopted at the NIH sponsored Arlie Conference (Lohman et al 1988)

Weight : A digital platform weighing scale to the nearest 100gm was used to measure weight. The subject was weighed in standard office clothing, bare feet and without leaning against or holding anything. Scale was „zeroed" before taking any weight, and was calibrated using standard weights after every third subject. Calibration values were maintained (Robinson et al., 1988).

Height : It is a linear measurement made up of the sum of four components i.e. legs, pelvis, spine and skull. Stedometer was used to measure the height of the subjects. Height was recorded to the nearest 0.1 cm after the subject inhaled fully and maintained the erect position without altering the load on the heels. In this position, a mark was made on the wall and height was recorded with a measuring tape. Two consecutive reading were taken (Jellife, 1966).

Waist Circumference: Circumference of the waist is an important indicator of the risk of CVD when calculated with hip circumference to give waist-hip ratio (WHR) the subject was made to stand erect with the abdomen relaxed and the arms at the sides. The circumference was recorded using the Flexi tape at the narrowest part of the abdomen between the ribs and iliac crest. This was done with measurer facing the subject and identifying the natural waist (i.e. the point of narrowing). The measurement was taken to the nearest 0.1 cm at the end of a normal expiration, without the tape compressing the skin (Walker et al., 1996).

Hip Circumference: was measured at the point yielding the maximum circumference over the buttocks. The Flexi tape was placed around the buttocks in a horizontal plane at this level without compression the skin. The measurement was noted to the nearest 0.1 cm.

COMPUTED ANTHROPOMETRIC INDICES

Body Mass Index (BMI): A relatively new classification of BMI has been recommended by WHO for the Asians. Under this, a BMI of more than 25 kg/m^2 is considered obese for Asian Indians in contrast to 30 for other population (WHO 2004; North American association for the study of obesity, 2001; JAPI, 2009; WHO, 2000)

Waist- Hip Ratio (WHR): This ratio gives an idea of central adiposity. High WHR often indicates an atherogenic lipid profile that tremendously enhances the cardiovascular risk (Suk et al., 2003). Males with WHR of ≥ 0.9 and Females with WHR of ≥ 0.85 were taken as cut-offs for central obesity (WHO, 2008)

BIOPHYSICAL INVESTIGATIONS

Blood Pressure: Blood pressure measurements were taken after the subject was made to sit down quietly for at least 5 minutes. The bare arm of the subject was supported and position at heart level. In position blood pressure was measured using digital blood pressure monitor UA-767PC (Saitama, Japan) on the right arm.

On each occasion two or more readings were averaged. Classification given by American Heart Association, 2011 in publication named "Understanding blood pressure readings" was used. Desired Systolic BP was 90 -119 mmHg and Diastolic BP was 60 – 79 mmHg.

Body composition analysis: Digital body fat monitor (Omron healthcare co. ltd Japan; model no. HBF – 306 –C1; SN: 2010100047 IUF) was used to measure body fat percentage, basal metabolic rate and body mass index. It also displayed graphical interpretation of body types like lean, lean normal, muscular, latent obesity and obese.

ADMINISTRATION OF INTERVIEWER BASED QUESTIONNAIRES

The socio economic status : General information with regards to age sex, religion, educational level, marital status, income etc was collected from the subjects using the Kuppuswamy's socioeconomic status scale (2012).

Defecation profile: Information was collected using Bristol stool chart and defecation scores given by Tokunaga *et al*., Effects of FOS Intake on the intestinal microflora and defecation in healthy volunteers (Bifidus, 1993) regarding the various aspects like frequency, quantity, odour, colour, hardness, and feeling after defecation.

General Physical Activity Questionnaire (GPAQ 2 – WHO, 2007) - A checklist containing various types of activities along with the time spent to perform each activity was used to assess the activity pattern of the subjects. Physical activity level (PAL) was used as a composite index of physical activity patterns and was calculated as, 24 hour energy expenditure/ Basal Metabolic Rate. Subjects who scored <1.4 PAL, were sedentary active. 1.55-1.60 PAL was considered as moderately active and >1.6 PAL as heavily active.

Hunger and satiety scale : A score card was used to rate the degree of hunger and satiety, before and after meals developed by Lisa Burgoon MS, RD, LD, sports nutritionist, sports-well centre, McKinley health centre, university of Illinois at Urbana – champain, 1998. Scores are from 1 – 10, where 1 stands for severe starvation and 10 stands for extreme fullness to level of bursting and pain.

Depression status: Data on their psychological background was obtained using Becks Depression Inventory (BDI) which was included in the questionnaire. The subjects were classified as mild, moderate and severely depressed based on the BDI scores **(**Beck et al., 1961).

Dietary Recall Nutrient Calculations: Nutrients like carbohydrates, protein, fat, vitamin and minerals were calculated for each product using "Diet Soft" Software for nutrient calculation (Kaur, 2018).

DETERMINATION OF GUT MICROFLORA:

Gut microflora was determined by using pour plate method with respect to species of *Bifidobacterium, Lactobacillus, Bacteroides,* and *Clostridium* from the stool samples of the subjects. All glass wares were sterilized in hot air oven at 160^0C for 2 hours. Stool samples were collected in sterile container directly placed in a ―Genbag Anaer®‖ device (Biomerieux, Marcy Etolle, France) – This helps the sample to remain in an anaerobic environment until it is processed at the laboratory. All samples were collected fresh and processed immediately within 4 hours of collection. One gram of stool sample was added in stomacher bag. To this 99ml of peptone water (0.1% w/v peptone and 0.005% w/v of NaCl) was added. Homogenization was done using a stomacher blender (bag mixer 400 vw) at 200

rpm for 1 minute. Ten-fold serial dilution was performed from 10-2 to 10-12 as per WHO & FAO (1979). 100 µl of the faecal homogenate was plated in the Petri plates of selective Media. Anaerobic Jars were used for the Petri plates of obligate anaerobes like *Bifidobacterium, Clostridium, and Bacteroides.* Gas pack was opened up and kept in the Anaerobic Jars. The Plates of *Lactobacillus* were kept in the desiccators. All plates were kept for incubation at 37^0 C for 48 – 72 hours. The colonies were counted using a digital colony counter and data was recorded by converting them to the log 10 counts

Media Used :

- ***Lactobacillus*** **-** Hi Media MRS Agar M 641 (67.15 g in 1000 ml distilled water).
- ***Bifidobacterium*** – Hi Media *Bifidobacterium* Agar M 1396 (49.3 g in 1000 ml distilled water).
- ***Clostridium*** – Hi Media Anaerobic Agar M 228 (58 g in 1000 ml distilled water).
- ***Bacteriodes*** – Hi Media Anaerobic Basal Agar M 1635 (45.9 g in 1000 ml distilled water).

BIOCHEMICAL PARAMETERS

Estimation of Random blood sugar: This test was performed using Digital Aqua check glucometer. The finger was first wiped with the cotton swab dipped in alcohol. The first drop of blood was discarded and the second drop of blood was placed on the strip attached to glucometer. The results were automatically displayed on the screen and recorded.

Estimation of Gut Satietogenic Hormones :

Gut Incretins' and hormones was analyzed using Milliplex map human gut hormone panel kit (#HGT68K) of Millipore Merck company.

Principle: MILLIPLEX™ MAP is based on the LUMINEX® xMAP® technology. Luminex® uses proprietary techniques to internally color-code microspheres with two fluorescent dyes. Through precise concentrations of these dyes, 100 distinctly colored bead sets can be created, each of which is coated with a specific capture antibody. After an analyte from a test sample is captured by the bead, a biotinylated detection antibody is introduced. The reaction mixture is then incubated with Streptavidin-PE conjugate, the reporter molecule, to complete the reaction on the surface of each microsphere. The microspheres are

allowed to pass rapidly through a laser which excites the internal dyes marking the microsphere set. A second laser excites PE, the fluorescent dye on the reporter molecule. Finally, high-speed digital-signal processors identify each individual microsphere and quantify the result of its bioassay based on fluorescent reporter signals.

Blood sampling

At overnight fasting state, a cannula was inserted into the antecubital vein for blood draw in a cooled EDTA-treated tube containing DPPIV inhibitor (10 ug/mL blood; Millipore Merck). Tube was inverted several times to mix. Within 30 min, the blood was centrifuged at 1000 rpm for 10 min at 4ºC. Plasma was removed and 2 aliquotes of samples were stored at -80ºC. All samples were stored in polypropylene tubes.

Plasma analysis

Plasma was analyzed for GIP (glucose-dependent insulinotropic polypeptide) and GLP-1 (active). Frozen plasma samples were thawed completely and mixed well by vortexing. Plasma samples were centrifuged prior to use in the assay to remove particulate. A maximum of 25 µL per well of plasma was used. GIP and GLP-1 concentrations were quantified with the use of a Human Gut Hormone Panel Kit (Millipore Merck). According to the manufacturer, the assay sensitivities (minimum detectable concentration, pg/ml) for GIP is 0.2 pg/ml and 5.2 pg/ml for GLP-1. The intra-assay variation (% CV) is <11% and the inter-assay variation (% CV) is <19% (Millipore). Accuracy for GIP is 89% and for GLP-1 is 83%.

Cross-Reactivity

According to the manufacturer, the antibody pairs in the panel are specific only to the desired analyte and exhibit no or negligible cross-reactivity with other analytes in the panel.

METHODOLOGY FOR ACCEPTABILITY TRIAL OF FOS ADDED PROFUCTS:

The possibilities of incorporating FOS in the popular Indian foods were studied by the method of addition. The products included *Dudhi muthiya, Veg.Chilla, Handwa and Veg. Samosa* which were incorporated with various levels of FOS and studied for their physical and organoleptic characteristics.

All the products standardization was carried out using the standard recipes of Pasricha and Rebello (1995).

Development of FOS added popular Indian products at various levels.

Organoleptic evaluation of the standard and FOS incorporated products was conducted by 25 semi trained judges, after

- Screening of panelists (Ranganna,1995)
- Training of the selected panel members and
- Development of score cards for the sensory evaluation of the products

Tools for Organoleptic evaluation of the products:

- Numerical Scoring test
- Nine point Hedonic Scale

STATISTICAL ANALYSIS

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS 21.0v) software. Results were expressed as mean values ±SD. ANOVA was performed to determine the significant differences in the mean scores. Percent increase and decrease was also determined by calculations to compare. Frequency and percentages were calculated for background information. Student "t" test of unequal variance was used to observe the difference that exists between the values. The significance levels were set at 5% by two sided tests. Student "t" test was performed for the comparison between control and experimental group. Paired "t" test was performed to observe the effect of FOS supplementation. Pearson's correlation was used to determine the relevant association between the parameters.

RESULTS

The results of the study are presented in the following sections:

PHASE I– SNAP-SHOTING THE PRESENCE OF OBESITY IN BANK EMPLOYEES OF URBAN VADODARA (N=650)

Screening of bank employees revealed that total 650 people participated in camp. Out of 650 employees, 74.77 % were males and 25.23 % were females. Age wise distribution of employees ranging from 20 – 60 years revealed that 42% of obese employees belonged to age range of 25 – 30 years followed by 27% in age range of 31 – 35 years. According to BMI classification, 33% of employees were in normal range of BMI (18.5 – 22.9). Moving forward with categories of Overweight and Obesity, 34% of employees belonged to Grade I obesity (BMI 25 - 30) followed by 20% overweight employees and 7% with Grade II Obesity.

Anthropometric profile of Screened employees

Assessment of anthropometric measurements revealed that the average height and weight (Mean ± SD) for males was 170.2 ± 6.16 cm; 70.62 ± 12.18 kg and for females was 156.44 ± 6.67 cm; 58.21 ± 12.20 kg respectively. Prevalence of Abdominal obesity according to waist circumference (WC) measurements was observed in 43.69% of total employees and Central obesity according to Waist Hip Ratio (WHR) was present in 56.31% of subjects.

Biophysical and Biochemical profile of Screened employees

Biophysical profile revealed that 58.31% of employees had excess of body fat (>25%), followed by 31.38% in acceptable range of body fat percentage. Surprisingly only 6.92% of employees had body fat in fitness level category (14-17%) and merely 3.38% of employees had body fat of 6 – 13% which is similar to athletes.

With respect to Basal Metabolic Rate (BMR), the results revealed a very sedentary lifestyle of bank employees with mean values of 1607.03 ± 219.39 for males and 1309.32 ± 208.90 Kcals for females.

Measurement of Blood Pressure revealed that 30.92% of employees had normal blood pressure. However, majority of the employees 48% were in pre-hypertension stage followed by 16.31% employees in Stage I and 4.77% in stage II of Hypertension.
Random blood sugars were in normal range of all the bank employees with mean values of 100.36 ± 36 mg%.

Association of Body fat % with Anthropometric and Blood pressure profile

Significant association ($p<0.001$) was observed between Body fat percentage and Abdominal obesity (χ^2 =197.81), Central obesity (χ^2 =73.77) , Hypertension (χ^2 =11.11) and Basal Metabolic Rate (χ^2 =58.63).

The odds of having excess body fat in people with abdominal obesity is 19.87 times higher (CI 95%, 11.87 – 33.54) and with central obesity is 4.14 times higher (CI 95%, 2.93 – 5.85) as compared to people with normal waist line and Risk Ratio of developing excess body fat is two and half times (2.54) in employees with abdominal obesity and 1.05 times in people with central obesity.

Significant association ($p<0.001$) was also observed between elevated blood pressure values and various computed parameters like obesity grade I - BMI 25 – 30 kg/m^2 (χ^2 =21.32) , WC (χ^2 =11.12)and WHR (χ^2 =16.62). The odds of developing hypertension in employees with obesity grade-I is 2.25 times, with abdominal obesity is 1.79 times and with central obesity is 1.97 times higher as compared to subjects without any associated derangements.

PHASE II – COMPARISON BETWEEN PARAMETERS OF NON-OBESE (N=150) AND OBESE BANK (N=150) EMPLOYEES

Baseline Characteristics

Background information of selected 300 employees according to inclusion and exclusion criteria divided equally in two arms (non-obese-150 and obese-150) depicted higher percentage of males (non-obese 33.67% and obese 44%) as compared to female employees (non-obese 16.33% and obese 6%). Socio economic data revealed that majority of the subjects surveyed were 95% Hindus (non-obese 48.33% and obese 46.67%). However, most

of the employees resided in nuclear type family (non-obese 34.33% and obese 37%) as compared to joint family (non-obese 15.67% and obese 13%). All employees were literate and 93.33% possessed graduate degree and above (non-obese 46% and obese 47.33). Most of them financially belonged to middle class (93.33%) with 68% of employees had income of > 28114 and 32% with income <28114.

Anthropometric, Biophysical and Physical activity profile

Anthropometric data analysis comparing two groups (non-obese and obese) revealed that no significant difference was observed in values of mean height (cm) in both groups. However, significant difference ($p<0.001$) was observed in rest all other anthropometric parameters like weight (non-obese - 57.57±7.37 kg and obese 79.06±8.57 kg), BMI (non-obese – 21.03±1.29 kg/m^2 and obese 27.64±1.48 kg/m^2), WC (non-obese – 78.08±7.98 cm and obese 95.59±7.62 cm), hip circumference (HC) (non-obese – 90.11±5.21 cm and obese 102.73±6.10 cm) and WHR (non-obese – 0.86±0.10 and obese 0.93±0.05). Biophysical data analysis also revealed highly significant difference ($p<0.001$) in body fat percentage (non-obese – 24.49±4.44 % and obese 31.31±4.66 %), basal metabolic rate (BMR) (non-obese – 1355.46±162.65 kcals and obese 1739.79±213.33 kcals), systolic blood pressure values (non-obese – 122.73±13.35 mmHg and obese 127.63±8.90 mmHg) and diastolic blood pressure values (non-obese – 76.3±10.13 mmHg and obese 80.45±7.34 mmHg).

Abdominal obesity was present in 5.67 % of non-obese and 40 % of obese employees and this association between obesity and waist circumference data was highly significant at $p<0.001$ ($\chi^2 = 142.5^{***}$). According to WHR data 13.67% of non-obese and 41.33 % of obese employees were at risk of developing non communicable diseases in future. Fitness association analysis according to body fat percentage was found to be highly significant ($\chi^2 = 171.18^{***}$) and data depicts barely 5.67% of non-obese population to be fit and none in the obese group. Employees falling in the acceptable level of fitness were found to be 36% in non-obese arm and only 2.33% in obese arm. Surprisingly 8.33% of employees with normal BMI range and weight had excess of accumulated body fat percentage similar to 47.67 % of obese employees.

Almost equal percentage of bank employees were found in sedentary group (non-obese 24.33% and obese 23.33%) and moderate to heavy activity group (non-obese 25.66% and obese 26.66%)

Family History and Personal Medical History

Data on family medical history of bank employees revealed that 26.33 % of obese employees had strong family history of obesity (34.33%), hypertension (41.67%), diabetes mellitus (28.67%) and CVD's (18.67%) as compared to 7.33% of non-obese employees. Almost equal percentage of non-obese (15%) and obese (12.67%) had moderate family medical history. However, 27.67% of non-obese employees had mild family medical history and 11% of obese employees with mild family medical history already headed towards weight gain.

Personal medical history of bank employees revealed that majority of them had dental problems (non-obese 37.33% and obese 27.66%), flatulence (non-obese 16.66% and obese 22.66%) and constipation (non-obese 14% and obese 19.66%). Uniquely, locomotor disorders were more prevalent in obese (non-obese 7% and obese 23.33%) followed by acidity and heartburn (non-obese 9% and obese 13%) this association of obesity and medical history was also highly significant ($p<0.001$) ($\chi^2 =67.6$)

Addiction Patterns and Depression profile

Personal habit profile of bank employees revealed highest consumption of Aerated drinks (Non-obese – 45.33% and Obese 43.67%), followed by Tea (Non-obese – 16.67% and Obese 34.33%) and alcohol (Non-obese – 16.33% and Obese 29.67%). Also as compared to Non-obese almost double percentage of Obese employees consumed Cigarette (Non-obese – 7% and Obese – 14.67%), Coffee (Non-obese 6.33% and Obese 12%) and Chewing Tobacco products (Non-obese 3% and Obese 5%). Strong significant association ($p<0.001$) was observed of BMI with varying degree of addiction ($\chi^2 =24.46$)

Defecation profile

Defecation profile data as reported according to employees' perception revealed 19.67% of obese and 14% of non-obese employees to be constipated. More percentage of obese individuals reported small quantity of stool (13.33%), hard stools (20.33%), dark colored stools (46.67%), strong odor (13.33%) and bad feeling after defecation (9.33%). On the contrary higher percentage of non-obese individuals reported large quantity of stool

(41.67%), medium to soft stools (44.33%), normal colored stools (39.33%), weak odor (47%) and good feeling after defecation (45.67%)

Dietary Intake Profile

Dietary recall data (24 hours) for 3 consecutive days revealed significant difference in the macro nutrient intake of non-obese and obese employees. Total calories consumed by obese employees (both genders) was way far in excess ($p<0.001$) then RDA (2722 ± 582 kcals) as compared to non-obese employees (2004 ± 738 kcals). Protein intake was significantly ($p<0.001$) high in obese males (83.36 ± 25.41 g) as compared to non-obese males (60.51 ±20.06 g). However, obese females consumed slight higher amount of protein but this difference was not significant. Fat intake amount differed significantly ($p<0.001$) with higher intake consumed by obese (96.78 ± 42.40 g) as compared to non-obese (71.87 ± 32.26 g). Similar trend of higher intake was found for carbohydrates (obese - 373.59 ± 86.89 g and non-obese – 276.14 ± 125.15 g)

With respect to fiber intake, no significant difference was observed in insoluble dietary fiber intake by non-obese and obese employees. Intake of soluble (5.10 ± 1.66 g), crude (8.94 ± 2.55 g) and total dietary fiber (19.73 ± 7.47 g) was significantly higher in obese employees as compared to non-obese. The reason for this contradiction could be simply higher intakes of overall food consumption by obese employees.

Hunger and Satiety Pattern

The inversely related score (1 -10) based approach was used for measuring hunger and satiety, where lesser score depicts severe starvation and higher value depicts extreme fulness. Data depicts no significant difference between hunger scores of employees in both groups during all meal times. On the contrary, significant difference was observed in the satiety scores during meal time of lunch (non-obese - 6.31 ± 0.70 and obese - 6.81 ± 0.93), evening (non-obese – 5.63 ± 1.03 and obese – 6.02 ± 0.66) and dinner (non-obese – 6.64 ± 0.80 and obese – 7.21 ± 1.03). Probably obese individuals consumed excess amount of food to fullness and hence reported higher scores for delayed satiety.

Gut Microbial Profile

Significant difference in the mean log values (CFU/g) of stool sample for *Bifidobacteria, Clostridium and Bacteroides* was observed between non-obese and obese employees. However, no significant difference was observed in the counts of *Lactobacillus* (non-obese – 11.84 ± 1.54 and obese – 11.99 ± 1.61). Colonization of gut in obese employees was dominated by pathogenic *Clostridium* (12.33 ± 1.15) as compared to non-obese (11.82 ± 1.54). The gut microbial profile of non-obese employees depicted predominance by *Bifidobacterium* (non-obese – 12.63 ± 1.68 and obese 12.09 ± 1.12), and *Bacteroides* (non-obese – 12.85 ± 1.44 and obese 11.80 ±1.55).

Biochemical Profile : Gut Incretins and Hormones

Using Luminex X MAP technology, Hormones were analyzed in fasting plasma samples. The mean values of Gut satietogenic hormones GLP-1 (20.78 pg/ml), GIP (12.12 pg/ml), and PYY (70.21 pg/ml) were significantly higher in non-obese employees as compared to obese (7.68, 5.04, 41.31 pg/ml respectively) justifying their role in weight and appetite regulation. Plasma insulin values were in normal range in both groups (non-obese - 214.30 pg/ml and obese – 584.51 pg/ml). Leptin being directly proportional to fat, it was three times higher in obese employees as compared to non-obese (non-obese – 4039.5 pg/ml and obese – 12191.79 pg/ml). Similarly, ghrelin which is an anorexogenic hormone was significantly higher in non-obese (258.91pg/ml) as compared to obese (113.56 pg/ml) employees justifying skipping of breakfast by obese employees in morning time.

Correlation of weight with various parameters of non-obese and obese

A positive significant ($p<0.001$) correlation of weight was observed with body fat ($r=0.459$), systolic blood pressure ($r=0.421$), diastolic blood pressure ($r=0.365$), defecation frequency ($r=0.241$), alcohol intake ($r=0.283$), tea consumption ($r=0.452$), degree of personal habits – severe addiction ($r=0.435$), total satiety scores ($r=0.418$), energy intake ($r=0.340$), protein ($r=0.463$), fat ($r=0.263$), Leptin ($r=0.667$) and Insulin ($r=0.539$)

Significant ($p<0.001$) negative correlation of weight was observed with defecation odor ($r=0.249$), feeling after defecation ($r=0.337$), physical activity ($r=0.205$), total hunger scores ($r=0.307$), hunger scores at dinner time ($r=0.330$), depression ($r=0.233$), insoluble dietary fiber ($r=0.257$), soluble dietary fiber ($r=0.545$), total dietary fiber ($r=0.282$), high fiber fruits

(r=0.391), moderate fiber fruits (r=0.222), *Bacteroides* (r=0.258), GLP-1 (r=0.717), GIP (r=0.610), PYY (r=0.763) and ghrelin (r=0.700)

Regression Analysis for Strongest Predictor of Obesity in Young Bank Employees of Urban Vadodara

Step-wise regression model summary for strongest predictor of obesity in all young bank employees turned out to be Gut hormone PYY, followed by soluble dietary fiber, alcohol intake, frequent tea consumption, fat intake, *Bacteroides* counts, Gut hormone Ghrelin and *Clostridium* counts

PHASE III – IMPACT EVALUATION OF FOS INTERVENTION FOR 90 DAYS IN OBESE BANK EMPLOYEES: A RANDOMIZED CONTROL TRIAL (N=150)

Obese employees were equally divided into two intervention arms: placebo arm – N=75 and experimental arm – N=75. There were 5 dropouts from placebo arm and 3 from experimental arm. Results were collected for 70 placebo and 72 experimental group obese subjects.

Effect of FOS Supplementation on Anthropometric and Biophysical Parameters of Obese Bank Employees

Significant reduction ($p<0.001$) in Mean ± SD values was observed in most of the anthropometric parameters of Experimental group Obese employees as compared to Placebo group. Weight reduced by 2.52 kg (3.25%), BMI values dropped by 3.25%, WC reduced by 2.31% and WHR by 1.07%. However no significant difference was observed in Hip Circumference.

FOS supplementation also helped reduce Body Fat by 3.39% and Systolic Blood pressure values by 1.51%. No significant change was observed in the BMR and Diastolic Blood pressure values.

Effect of FOS Supplementation on Dietary Parameters, Hunger and Satiety Scores of Obese Bank Employees

Significant reduction was observed in most of the dietary parameters of Experimental group like Energy (8.84%), Carbohydrate (8.67%), Fat (10.78%), soluble dietary fiber (10.82%) and Total dietary fiber (10.17%) as compared to Placebo group. However, no significant difference was observed in Protein, Insoluble fiber and Crude fiber of both groups.

Hunger pangs significantly ($p<0.001$) reduced in Experimental group during meal time of Lunch (14.76%) and Dinner (3.83%) as compared to Placebo group. Simultaneously, Experimental group achieved early satiety significantly ($p<0.001$) during meal time of Lunch (10.22%) and Dinner (12.58%).

Effect of FOS supplementation on Defecation Profile and Depression Scores of Obese Bank Employees

Post FOS consumption for 90 days significant improvement in overall defection profile was observed in Experimental group. Reduction in Constipation was reported in 14% of obese employees. Frequency of passing partial stool twice increased in 15% of them and improved by clearing bowels completely. Quantity of stool (bulk) increased in 8%, hardness reduced in 17%, foulness in stool odor reduced in 8% and 17% of obese employees felt much better after defecation with FOS intervention.

Improvement was also observed in the Depression scores obtained by Becks Depression Inventory. Significant reduction ($p<0.001$) in scores (4.40%) was observed in Experimental group as compared to Placebo arm.

Effect of FOS supplementation on Gut Incretin's and Hormones of Obese Bank Employees

After FOS intervention in Experimental group, Significant increase was observed in Gut Incretin's, GLP-1 (3.34%, $p<0.01$) and GIP (0.77%, $p<0.05$). Other hormones like PYY increased significantly ($p<0.001$) by 3.11% along-with increase in Ghrelin secretion (14.77%).

Reduction was observed in hormone Leptin by 5.87% and Insulin by 6.23%, which was also highly significant ($p<0.001$)

Effect of FOS supplementation on Gut Microflora of Obese Bank Employees

FOS intervention significantly improved the Gut microbial profile of experimental group obese employees. Gut health improved with significant increase in colonization of gut with *Lactobacilllus* by 22.64% and *Bifidobacterium* by 7.99%. However, counts of pathogenic bacteria, *Clostridium* reduced significantly by 4.49% and No significant change was observed in *Bacteroides* counts in experimental group.

Correlation of Fasting Gut Hormones with Various Parameters of Obese Bank Employees

GLP-1

Positively correlated ($p<0.001$) with depression scores ($r=0.203$), soluble dietary fiber ($r=0.21$), PYY ($r=0.709$), Ghrelin ($r=0.315$) and *Bifidobacterium* ($r=0.359$) and

Negatively correlated ($p<0.001$) with weight ($r=0.546$), body fat ($r=0.204$), Leptin ($r=0.441$), Insulin ($r=0.258$)

GIP

Positively correlated with dinner satiety scores ($r=0.225$) and

Negatively correlated with weight ($r=0.178$), body fat ($r=0.289$), systolic blood pressure ($r=0.220$)

PYY

Positively correlated with Ghrelin ($r=0.332$), GLP-1 ($r=0.709$) and *Bifidobacterium* ($r=0.344$) and

Negatively correlated with weight ($r=0.498$), body fat ($r=0.333$), diastolic blood pressure ($r=0.266$), energy intake ($r=0.249$), Leptin ($r=0.495$)

Ghrelin

Positively correlated with GLP-1 ($r=0.315$) and PYY ($r=0.332$) and

Negatively with weight ($r=0.302$), body fat ($r=0.358$), lunch satiety scores ($r=0.203$), soluble dietary fiber ($r=0.201$), total dietary fiber ($r=0.204$) and Leptin ($r=4.00$)

Leptin

Positively correlated with weight (r=0.351), body fat (0.778), lunch satiety scores (r=0.225), energy intake (r=0.220) and fat (r=0.310) and

Negatively correlated with ghrelin (r=4.00), GLP-1 (r=0.441), PYY (r=0.495), *Bifidobacterium* (r=0.291)

Insulin

Positively did not correlate with any parameter

Negatively correlated with GLP-1 (r=0.258) and no significant positive correlation were observed

Regression Analysis for Strongest Predictor of Obesity in Obese Bank Employees

Step-wise regression model summary for strongest predictor of obesity in obese bank employees turned out to be GLP-1, followed by hunger scores, total dietary fiber, depression scores, fat, energy and carbohydrate intake.

PHASE IV– ACCEPTABILITY TRIALS OF FOS ADDED POPULAR INDIAN RECIPES

FOS was added to *Dudhi-Muthiya* (steamed), *Veg. chilla* (shallow fried), *Handwa* (baked) and Veg. *Patti-samosa* (deep fried) at 10, 15 and 20 gm to these recipes and then were compared with standard product. The results of the acceptability trials revealed that as the level of addition of FOS increased from 10g to 20 g per serving, there was a significant improvement in attributes of taste by 16.6% ($p < 0.001$) and after-taste by 15% ($p < 0.01$) of *Dudhi-muthiya*. Analysis of variance (ANOVA) revealed similar significant improvements in *Veg. chilla* with respect to mouth-feel -11.2% ($p<0.01$), texture - 6.47% ($p<0.05$), taste - 18.5% ($p<0.001$), after-taste - 16% ($p<0.001$) and overall acceptability–13% ($p < 0.001$) at 20 gm per serving FOS addition. Also improvement in sensory attributes of *Handwa* was also observed with regards to mouth feel ($p<0.01$), taste ($p<0.01$), after-taste ($p<0.05$) and overall acceptability ($p<0.05$).

On the contrary, *Veg. Patti-samosa* was the only product which was not at all accepted even at minimum addition of 10 g /serving as after FOS addition it became soggy and difficult to deep fry due to oozing of liquid. Significant reduction ($p<0.05$) in scores of color and appearance was observed as it got too dark while frying and had burnt appearance.

CONCLUSION AND RECOMMENDATIONS

In current scenario, where obesity and stressful lifestyle are feeding each other, FOS proved to be a promising supplement from clinical and public health perspective in 90 days intervention period. From clinical perspective FOS helped improve overall health by firstly reducing constipation and normalizing bowel movements. Secondly, It helped achieve weight loss by 3.25% (i.e. 2.52kg in 90 days) without any changes in lifestyle, modulated gut flora by colonizing it with gut friendly bacteria's like *Lactobacillus, Bifidobacterium* and reducing counts of *Clostridium* and finally, sensitizing secretion of gut hormones GLP-1, GIP and PYY that influence signaling pathways of appetite regulation in brain.

Further to recommend, studies with FOS intervention should be conducted to assess the long term effect on weight-loss, plateau effect and especially on post weight maintenance. With respect to gut microflora, strain specific studies would provide deeper insights especially for opportunistic and pathogenic bacteria's like *Bacteroides* and *Clostridium* respectively.

REFERENCES

Ait-Aissa, A. & Aider, M. (2014). Lactulose: production and use in functional food, medical and pharmaceutical applications. Practical and critical review. *Int J Food Sci Technol*. https://doi.org/10.1111/ijfs.12465

Assudani, A. & Sheth, M. (2015). Newer strategy to combat obesity amongst the bank employees of urban Vadodara – Insights into its mechanism. *World Journal of Pharmacy and Pharmaceutical Sciences*, 4 (2), 658-672.

Assudani, A., Sheth, M., & Jain, N. (2013). Feasibility and Acceptability of Adding Fructooligosaccharide at Varying Levels in *Dudhi muthiya* and *Vegetable chilla*. *Inventi Impact: Nutraceuticals*, 4, 1-6.

Assudani, A., Sheth, M., & Jain, N. (2014). Indirect determinant's of obesity in bank employees of urban Vadodara – A cross sectional study. *International Journal of Applied Biology and Pharmaceutical Technology*, 5 (3), 5-12.

Becky, McCall (2016). Adiposity-Based Chronic Disease: A New Name for Obesity? – *Medscape*, 29.

Bindels, L.B., Delzenne, N.M., Cani, P.D., & Walter, J. (2015). Towards a more comprehensive concept for prebiotics. *Nat Rev .Gastroenterol Hepatol*, 12, 303-310.

Clarke, G. (2014). "Minireview: Gut microbiota: the neglected endocrine organ". *Mol Endocrinol.* 28 (8), 1221–38. doi:10.1210/me.2014-1108.

Gomez, G. & Salminen (2016). Novel Probiotics and Prebiotics: How Can They Help in Human Gut Microbiota Dysbiosis? *Appl Food Biotechnol*, 3 (2).

Gulati, S. & Misra, A. (2017). Abdominal obesity and type 2 diabetes in Asian Indians: dietary strategies including edible oils, cooking practices and sugar intake. *Eur J Clin Nutr,*71(7), 850-857. doi: 10.1038/ejcn.2017.92.

Jain, N., Sheth, M., & Assudani, A. (2013). Sensory Attributes of Indian Fried Foods Incorporated with Different levels of Fructooligosaccharides. *International Journal of Applied Biology and Pharmaceutical Technology*, 4 (3), 255-259.

Jeffrey, I., Mechanick, D.L. Hurley, & Timothy G.W. (2017). Adiposity-based chronic disease as a new diagnostic term: the American association of clinical endocrinologists and american college of endocrinology position statement. ABCDs of Obesity. *Endocr Pract*, 23(3), 373.

Kalra, S. & Unnikrishnan, A.G. (2012). Obesity in India: The weight of the nation. *J Med Nutr Nutraceut*, 1:37-41.

Kedist, T. (2017). ABCD: Obesity Has A New Name, But Will It Stop The Epidemic? American Council on Health Science. Retrieved from: https://www.acsh.org/ news/ 2017/01/20/abcd-obesity-has-new-name-will-it-stop-epidemic-10751

Lean, M.E.J. & Malkova, D. (2016). Altered gut and adipose tissue hormones in overweight and obese individuals: cause or consequence? *International Journal of Obesity*, 40, 622–632. doi:10.1038/ijo.2015.220

Maukonen, J. & Saarela, M. (2015). Human gut microbiota: does diet matter? *Proc Nutr Soc.* 74, 23–36.

Miller, M.C. (2013). Depression and obesity: Confirming the link. Havard Health Letter, *Havard Health Publishing Medical School*. Retrieved from: https://www.health. harvard.edu/mind-and-mood/depression-and-obesity-confirming-the-link

Mohan, R.N., Kumar, K., & Jamil, K. (2012) New World Syndrome (Obesity) in South India, 1, 567 doi:10.4172/scientificreports.567

Parnell, J. A. & Reimer, R. A. (2013). Weight loss during oligofructose supplementation is associated with decreased ghrelin and increased peptide YY in overweight and obese adults. *Am J Clin Nutr.* 89(6). doi:10.3945/ajcn.2009.27465.

Quigley, E.M. (2013). "Gut bacteria in health and disease". *Gastroenterol Hepatol*, 9, 560–9.

Sherwood, L., Willey, J., & Woolverton, C. (2013). Prescott's Microbiology (9th ed.). New York: McGraw Hill. pp. 713–721. ISBN 978-0-07-340240-6. OCLC 886600661

Sheth, M., Assudani, A., & Jain, N. (2013). FOS Intake: A Successful Alternative for managing obesity and constipation. Sixth International Conference on "Fermented Foods Health Status and Social Well-being" organized by Swedish South Asian Network on Fermented Foods, LUND University and Anand Agricultural University, Anand, 6 – 7 December, 2013 at AAU, Anand.

The Lancet Editorial (2017). Should we officially recognise obesity as a disease? http://dx.doi.org/10.1016/S2213-8587(17)30191-2. Retrieved from: www.thelancet. com/diabetes-endocrinology.

Traversy, G. & Chaputt, M. E. J. (2015). Alcohol Consumption and Obesity: An Update. *Curr Obes Rep* 4, 122–130. doi: 10.1007/s13679-014-0129-4

WHO (2017). The double burden of malnutrition. Policy brief. United Nations decade of action on nutrition 2016-2025. WHO/NMH/NHD/17.3.

World Health Statistics (2013). WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland.