

APPENDIX I

INFORMED CONSENT

Dear Sir/Mam,
Greetings of the Day!!!

I, Kankona Dey, doctoral student working in the **Department of Foods and Nutrition, Faculty of Family and Community Sciences, The M. S. University of Baroda**. I am conducting my doctoral research study under the guidance of **Prof. Mini Sheth** entitled “**Screening for the presence of constipation among the staff of The Maharaja Sayajirao University of Baroda.**”.

Information about the Study

Chronic constipation is infrequent bowel movements or difficult passage of stools that persists for several weeks or longer. Constipation is generally described as having fewer than three bowel movements a week. Though occasional constipation is very common, some people experience chronic constipation that can interfere with their ability to go about their daily tasks, reducing their productivity and quality of life.

The study is divided into two phases. Kindly give your consent for participation. Your participation is essential for the success of the study. Please indicate your willingness to participate by putting \surd mark in the boxes below.

For Phase 1, You will be required to fill up the questionnaire regarding socioeconomic status, behaviour, eating pattern, stool pattern, personal and family medical history and dietary intake in a google form after giving your consent to be a part of this study.

For Phase 2, the confirmed constipated subjects will be requested to participate in the clinical trials which will involve intake of small sized Prebiotic (Galactooligosaccharide/GOS) enriched gummies for a period of one month. The healthy dietary fibre enriched gummies are developed by substituting refined sugar with GOS, has already been tested for their safety and sensory tests.

Regular intake of prebiotics has been proven to colonize the beneficial microflora and even improve the gut brain axis and reduce the colonization of enteric pathogens which are known to produce harmful toxins. Food colours and flavours has been added to the gummies in permitted amounts (by FSSAI) to increase the acceptability of the gummies by the subjects.

The expected outcome of Phase 2 of the study includes improvement in the colonisation of beneficial bacteria in the gut as well as improvement in the constipation profile.

Abiding by the laws of research ethics, I declare that your answers will be treated with absolute confidentiality only for my research study. The data obtained will not be shared with any third party. If you have any questions or want to receive more detailed information about the survey, please contact me. I understand your time is precious; It will take 15-20 minutes to complete the survey.

Please help us circulate the survey link with faculty/staff of your respective Department.

Sincerely,

Kankona Dey

Ms Kankona Dey
Ph.D. Research Scholar
Ph: 7044187477

Through:

Mini Sheth

Prof. Mini Sheth
Research Study Supervisor
Ph: 09879359229

I have understood and accepted the terms and conditions.

Signature:

Date:

PERSONAL INFORMATION: Tick wherever applicable.

1. Name: _____
2. Faculty: _____
3. Phone number: _____
4. Age: 20-34 35-49 50-62. >63
5. Gender: _____

For females only:

6. Last menstrual cycle: _____
7. Pregnancy: Y/N
8. Menstrual disturbance: Y/N. , Since when
9. Menopause: Y/N, Since when

GENERAL INFORMATION

10. Marital status: _____
11. Type of Family: _____
12. Education: _____
13. Occupation: _____
14. Weight (kg): _____
15. Height (inches/m/cm): _____
16. Family monthly income: $\geq 123,322$ 61,663-123,321 46129-61,662. 30,831-46,128. 18,497-30,830
(Please tick the right option)

Questions on head of the Family:

17. Are you the head of the family? Yes /No. (Tick the correct option)
18. If no, what is the highest education qualification of The head of the family? _____
19. What is the Occupation of The head of the family _____
(Mention Unemployed/UE if not working)

20. MEDICAL HISTORY:

DISORDER	YES (0) NO (1)	Duration >1 year (2) 1-2 years (3) 2-3 years (4) >3 years (5)	Medication Yes (0)/No (1)	If yes, homeopathy/ allopathy/ ayurveda
OBESITY (BMI > 30)				
HYPERTENSION (Blood pressure > 130/90)				

DIABETES (DM) (Fasting blood sugar level >110mg/dal Post prandial blood sugar level >140mg/dl HbA1c >6.5) Type 1 Type 2				
Coronary heart Disease				
Renal disorder (Kidney Problems)				
DENTAL PROBLEMS Bad Breath Dry Mouth Cavities				
LOCOMOTOR DISORDERS Knee joint pain Swollen feet Back pain Osteoporosis Osteoarthritis				
THYROID Hyperthyroidism Hypothyroidism				
Anemia				
SKIN DISORDER				
CANCER				
History of Psychiatric illness				
Insomnia				

21. Family History for Constipation

SI No.	Members Of Family	Constipation (Or mention NA)	If yes, Since when	If yes, Medications, if any	If yes, Specific food/ treatment	If yes, Which ones?
		Yes (0) No (1)	<1 year (2) 1-2 years (3) 2-3 years (4) >3 years (5)	Yes (0) No (1)	Yes (0) No (1)	Food (1) Ayurveda(2) Medicine (3)
C1	Father					
C2	Mother					
C3	Brother					
C4	Sister					
C5	Grand father					
C6	Grand mother					

22. Personal Habits

Addiction	Daily	Weekly	Occasionally	Never
Alcohol				
Cigarette/Bidi				
Tobacco Powder /paste/ snuff				
Tea (> 4 cups/day)				
Coffee (>4 Cups/Day)				
Carbonated/cold drinks (cola/Lima etc)				

23. Physical activity pattern:

Addiction	Daily	Weekly	Occasionally	Never
Cycling (>30 mins)				
Jogging/ Running (>30 mins)				
Brisk Walking (>30 mins)				
Yoga (>30 mins)				
Gym(>30 mins)				
Zumba/ Dance (>30 mins)				

How many hours are you sitting in a day?

- a) 8 hours. B) 8-10 hours. C) >12 hours d) <8 hours

24. Gastrointestinal Function

A. Are you currently facing any gastrointestinal function?

Sl No.	Members Of Family	Constipation	If yes, Since when	If yes, Medications, if any	If yes, Specific food/ treatment	If yes, Which ones?
		Yes (0) No (1)	<1 year (2) 1-2 years (3) 2-3 years (4) >3 years (5)	Yes (0) No (1)	Yes (0) No (1)	Food (1) Ayurveda(2) Medicine (3)
C1	Acidity					
C2	Diarrhea					
C3	Constipation					
C4	Heartburn					
C5	Reflux					
C6	IBS/IBD					

25. Perception & Attitude towards Constipation

- A) Do you consider Constipation as a "social taboo" (Note: Social taboo refers to something which you don't want to discuss with your family/ friends)? Yes/No
- B) Do you consider Constipation as a minor health issue? Yes/No
- C) Do you/ Will you feel shy to seek medical help for constipation? Yes/No
- D) On an average, how many months will you wait before seeking medical help, if you have constipation/ irregular stool pattern?
 1. Immediately 2. 1-2 weeks 3. 15days-1month 4. >2months
- E) If you have constipation, what will you do first?
 1. Treat with Home remedies 2. Seek medical help 3. Self medication
- F) Please rate your Gastrointestinal function (any problem with your stomach and intestines) on a scale of 5, since last 6 months
 Best 1 2. 3. 4 5 Worst.

Mention the reason for your rating: _____ (If you rate between 3-5)

26. Defecation Profile (For the last 6 months)

	DEFECATION	OPTIONS			
A	Stool Frequency (times / day)	1	2	3	>3
B	Stool Frequency (times / week)	Daily	Alternate day	3times/week	<3 times/week
C	Quantity of Stool	Less than Normal		Normal	
D	Color of Stool	Blackish		Brownish	Yellowish
E	Odor (Smell) of Stool	Strong	Medium	Weak	No smell
F	Daily use of defecation Laxatives	Yes	No	Often (1-2 times/week)	Sometimes (once in 14 days/ month)

G. Do you experience loose stools after having laxatives?

1. Yes 2. Sometimes 3. Rare 4. Never

H. If options 1 &2, how many times/week?

1. Once. 2. More than Once

I. Do you check your faeces during or after bowel passage?

1. Yes 2. Sometimes 3. No

Please Note: If you haven't checked recently, Kindly check this week and indicate

J. This is a Bristol Stool Chart.

Please indicate your willingness to participate by putting \surd mark in the boxes (P.T.O).

28. Dietary History & Chrono nutrition Profile- since last 6 months

A. What is the Type of diet consumed? (Please tick the correct answer)

1. Vegetarian 2. Non vegetarian. 3. Ovo vegetarian. 4. Lacto ovo vegetarian 5. Vegan. 6. Jain

B. Do you skip any meals? If yes & sometimes & often, which meal?

	Yes/no	If yes, How many times/week
Breakfast		
Lunch		
Snacks (Mid-morning/ Evening)		
Dinner		

C. Do you eat out (Restaurant Intake)? If yes & sometimes & often, which meal?

	Yes/no	If yes, How many times/week
Breakfast		
Lunch		
Snacks (Mid-morning/ Evening)		
Dinner		

D. What is the amount of chewing per one bite (times)

1. >20 times 2. 10-20 times 3. <10 times 4. Unknown

E. Do you wake up at night to eat?

1. Yes 2. Sometimes 3. Rare 4. Never

F. Are you taking any supplements? (Last 6 months)

1. No 2. Calcium 3. Iron 4. Multivitamins 5. Fiber

G. Which is your largest meal of the day?

1. Breakfast 2. Lunch 3. Snacks 4. Dinner

H. What is your drinking water intake for the day? (Last 6 months)

1. < 1 litre 2. 1-2 litre 3. >2 litre

I. The following questions are designed to assess your chrono nutrition profile (Please mention the timing of your eating and sleeping).

	On Free Day	On a working Day	On a weekend
What Time do you Wake up			
What is the first meal timings			
What is the last meal timings			
When do you go to bed to sleep at night?			

J. Have you found any triggering food (s) which might lead to constipation?

1. Yes 2. No

K. If yes, tick the name of foods you think may act as a trigger for constipation

1. Milk and Milk products 2. Cereals 2. Pulses 3. Sweets 4. Tea/Coffee
5. Others, please specify _____

L. Do you Follow any home remedies to cure/treat your constipation status (anytime)?

1. Yes 2. No

M. If yes, what do you follow? _____

29. Food Frequency

A. How often do you consume the following food items:

		Daily	2-3 times/ week	Weekly once	Fortnightly	Once a month	Never
A	Fruits (>100g) (Any fruit/ Seasonal)						
B	Milk & Milk Products (>200ml)						
C	Whole pulse/ Chilke wali dal (30g=1 standard katori)						
D	Split Pulse/ Without chilka dal (30g=1 standard katori)						
E	Green leafy vegetable (100g of Palak/ Methi/Amaranth etc = 1/2 standard katori of vegetable)						
F	Vegetables like bottle gourd/ ridge gourd/ snake gourd/ ash gourd/ parwal/ Bittergourd (200g vegetable=1 standard katori)						
G	Other vegetables like onions, French beans, carrots etc						
H	Sweeteners (Honey/ Jaggery)						
I	Artificial Sweeteners (Please mention the name_____)						
J	Non vegetarian foods						

	(1 egg/1pc Fish/ 1pc chicken/1 pc mutton)						
K	Processed foods Chips/French fries Biscuits/Cookies Burgers/Pizza Ready to eat items						

L. What is your sugar intake/ day? (Note: 1 tsp= 5g)

	I don't take	<1 tsp	1-2 tsp	2-4 tsp	>4 tsp
Salt					
Sugar					

APPENDIX II

THRESHOLD TEST

(ii) Procedure for preparation of solution required for threshold test

Solution No.	Molarity	Salty (Stock solution 5.845 g of sodium chloride/L)	Sweet (Stock solution 34.23 g of sucrose/L)	Molarity	Sour (Stock solution 21.015 g of citric acid/L)	Bitter (Stock solution 19.41 g of caffeine/L)
		ml of stock solution to be diluted to 1 L	ml of stock solution to be diluted to 1 L		ml of stock solution to be diluted to 1 L	ml of stock solution to be diluted to 1 L
1	0.0002	2	2	0.0005	0.5	0.5
2	0.0004	4	4	0.0001	1	1
3-	0.0008/	8	8	0.0002	2	2
4	0.0016	16	16	0.0004	4	4
5/	0.0032'	32	32	0.0006	6	6
6	0.0064	64	64	0.0008	8	8
7-	0.0128	128	128	0.0010	10	10
8	0.0256.	256	256	0.0012	12	12
9'	0.0512	2.994 g/L	17.526 g/L	0.0014	14	14
10	0.1024	5.988 g/L	35.052 g/L	0.0016	16	16
11'	0.2048	11.976 g/L	70.103 g/L	0.0032	32	32
12	0.4096	23.953 g/L	140.206 g/L	0.0064	64	64

Source : Jellinek, G. (1964). J. Nutri. Diet. 1:219

APPENDIX III

THRESHOLD TEST**Sensitivity- Threshold Test**

Name: _____

Date: _____

You are provided with a series of containers having solutions with increasing concentrations of the one of the 3 taste qualities (sweet, salty, sour). Please start with Sample No. 1 and continue with Samples No. 2, No. 3, *Re-tasting of already tested solutions is not allowed.

Please describes the taste or give intensity scores using the following intensity scale:

0 = None or pure water taste
not identifiable

? = Different from water, but taste quality

X = Threshold very weak (Taste identifiable)

1 = Weak taste

2 = Medium

3 = Strong

4. Very strong

5- Extremely strong

Intensity Score

Sample No	Description of Taste and Feeling Factors (Sweet)	Sample No	Description of Taste and Feeling Factors (Salty)	Sample No	Description of Taste and Feeling Factors (Sour)
A		A		A	
B		B		B	
C		C		C	
D		D		D	
E		E		E	

Signature of Judge _____

=====

APPENDIX IV

INFORMED CONSENT FORM

INFORMATION ABOUT THE PRODUCT

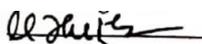
I, Kankona Dey, pursuing my PhD from the Department of Foods and Nutrition, Faculty of Family and Community Sciences, The M. S. University of Baroda, am conducting a research study on the “feasibility of prebiotic rich gummies and its sensory evaluation and its acceptability”.

GOS or galactooligosaccharide is a prebiotic majorly present in mammalian milk. Prebiotics are proven to reduce the colonization of enteric pathogens which are known to produce harmful toxins by triggering the mutation of the colonocytes. These toxins are also believed to produce anti-inflammatory markers and hence trigger co-morbidities like diabetes, obesity, hypertension, etc. Regular intake of prebiotics has been proven to colonize the beneficial microflora and even improve the gut brain axis. The gummies presented will be having varying proportions of GOS, from 60%-100% replacing the sugar content either partially or wholly. Food colours and flavours has been added to the standard gummies in permitted amounts to increase the liking of the consumers and its acceptability.

For training purpose, you are requested to taste one gummy a day for the next consecutive 7 days from the packet provided. You are also requested to fill up the google form which will be sent to you via whatsapp. The forms have to be filled each day you taste the gummy for its quality parameters.

This product is safe to consume and does not pose any harm or after effects. GOS also has established safety levels in many recent research studies and its consumption is safe.

Thus, I would request you to: Taste the given products and give feedback for its quality parameters.



Prof. Mini Sheth
Research Study Supervisor
Ph: 09879359229



Ms Kankona Dey
PhD Research Scholar
Ph: 07044187477

SUBJECT CONSENT FORM

Name: Age: Sex:

Phone number:

Email Id:

I confirm that I have read and understood the above information and have/had the opportunity to ask questions.

I understand that my participation in this study is voluntary and I am free to reject being a part of this study, without giving a reason.

I understand that the ethics committee and the regulatory authorities will not need my permission to look at my health records and my identity will not be revealed in any information released to third parties or published.

I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

I understand the study will involve multiple times of collection of data, in terms of tasting the product and give marks for its quality.

I understand that the medical expenses will not be borne by the research investigators from any allergic reactions arising due to consumption of the gummies, unless proven.

I agree to consume the GOS Gummies as offered.

I voluntarily agree to participate in the community health study conducted by the Department of Foods and Nutrition, Faculty of Family and Community Sciences, The MS University of Baroda.

Date:

Signature of the Participant

APPENDIX V

COMPOSITE SCORE CARD FOR PRODUCT EVALUATION

Name:

Date:

Contact Number:

Taste the given products and check the level of acceptability by assigning scores that best describe how you feel about the sample. Use appropriate scale (1-10) for rating where 10 being the most acceptable and 1 being least acceptable. An honest expression will help to get unbiased data.

Sl.No	Parameters	Maximum Score	Products															
			1				2				3				4			
			A	B	C	D	A	B	C	D	A	B	C	D	A	B	C	D
1	Color/ Appearance	10																
2	Mouth feel	10																
3	Texture	10																
4	Overall taste	10																
5	Flavour	10																
6	After taste	10																
7	Chew ability	10																
8	Overall acceptability	10																
	TOTAL SCORE	80																

Remarks, If any:

Signature of the Judge:

APPENDIX VI

DIFFERENCE TEST

- You are given a reference sample (A) and other test samples to be compared with reference individually.
- Rate Direction of difference in each sample according to the following scale

Scale: Direction of difference:

1.	Equal
2.	Superior
3.	Inferior

Attribute	Sample Code		
	B	C	D
Overall Acceptability			

Comments:

Name:

Signature:

APPENDIX VII**INFORMED CONSENT FORM**

INFORMATION ABOUT THE STUDY

I, Kankona Dey, pursuing my Ph.D. from the Department of Foods and Nutrition, Faculty of Family and Community Sciences, The M. S. University of Baroda, am conducting a research study on the “**Presence of Functional Constipation in the teaching Staff of The M. S. University of Baroda and Impact Evaluation of Supplementation of Galactooligosachharides (GOS) added Gummies on their Constipation Profile and gut health- Double Blind Randomised Control clinical trial**”. The study has been registered with CTRI (Clinical Trial Registry of India) ICMR. The registration number for this trial is CTRI/2021/10/037474.

With reference to your consent given for participating in the clinical trial of my study on constipation, I would like to request you to accept intake of 4 gummies per day for a period of 30 days. As a part of the double blind clinical trial, you will be given either GOS or standard gummies.

The standard gummies are made with sugar, while the experimental gummies are made with 100% GOS, which is a prebiotic and likely to improve the defecation profile and gut health by improving the colonisation of beneficial bacteria in terms of *Lactobacillus* and *Bifidobacteria* and reducing the colonisation of pathogenic bacteria in terms of *Clostridium*. It is also likely to bring about an improvement in the depression status and overall quality of life.

The product does not pose any harm or after effects. The ingredients used for the production of gummies (agar, GOS, citric acid, natural colours and flavours) bear FSSAI license number and thus are safe to consume daily. GOS has also established its safety levels in many research studies and its consumption is safe. The results of the study will be informed to the subjects upon completion.

Thus I would request you to kindly sign the informed consent form attached for enrolment in the study.



Prof. Mini Sheth
Research Study Supervisor
Ph: 09879359229



Ms Kankona Dey
PhD Research Scholar
Ph: 07044187477

SUBJECT CONSENT FORM

Name: _____ Age: _____ Sex: _____

Phone number: _____

Email Id: _____

I confirm that I have read and understood the above information and have/had the opportunity to ask questions.

I understand that my participation in this study is voluntary and I am free to reject being a part of this study, without giving a reason.

I understand that the ethics committee and the regulatory authorities will not need my permission to look at my health records and my identity will not be revealed in any information released to third parties or published. My responses will not be shared with anyone, friends or relatives.

I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

I understand the study will involve multiple times of collection of data.

I understand that the medical expenses will be borne by the research investigators from any allergic reactions arising due to consumption of the gummies, if proven.

I understand the study will involve:

- Filling up of questionnaires regarding defecation profile, dietary intake, depression status and quality of life on Day 0 and Day 30.
- Collection of fecal sample for microbiological analysis in terms of RTPCR and chemical analysis in terms of Short chain fatty acids (Propionic acid, acetic acid and butyric acid) on Day 0 and Day 30.

I agree to consume the standard or GOS gummies as offered.

I voluntarily agree to participate in the research study conducted by the Department of Foods and Nutrition, Faculty of Family and Community Sciences, The MS University of Baroda.

Date: _____

Signature of the Participant

APPENDIX VIII

Name:

Date:

24 HOUR DIETARY RECALL**DAY 1**

Meal	Item	Amount
Morning		
Mid-morning		
Lunch		
evening		
Dinner		

Please mention above all that you eat on this day.

Name:

Date:

24 HOUR DIETARY RECALL

DAY 2

Meal	Item	Amount
morning		
Mid-morning		
Lunch		
evening		
Dinner		

Please mention above all that you eat on this day.

Name:

Date:

24 HOUR DIETARY RECALL

DAY 3

Meal	Item	Amount
morning		
Mid-morning		
Lunch		
evening		
Dinner		

Please mention above all that you eat on this day.

APPENDIX IX

COMPLIANCE SHEET OF GUMMIES CONSUMPTION

Name: _____

Code: _____

Date of Enrolment: _____

Contact: _____

Please check the box after having 4 gummies/day. If you were not able to consume, please put against the particular day. Mention in Remarks for bloating, gas or any other issue faced for the day.

Week 1 –

M	T	W	T	F	S	S

Remarks: _____

Week 2 –

M	T	W	T	F	S	S

Remarks: _____

Week 3 –

M	T	W	T	F	S	S

Remarks: _____

Week 4 –

M	T	W	T	F	S	S

Remarks: _____

Week 5 – (Mark the 3 days)

M	T	W	T	F	S	S

Remarks: _____

Comments: _____

Signature: _____

APPENDIX X

Defecation Profile (For the last 1 month)

Name: _____

Code: _____

Date of Enrolment: _____

Contact: _____

	DEFECATION	OPTIONS			
		1	2	3	>3
A	Stool Frequency (times / day)	1	2	3	>3
B	Stool Frequency (times / week)	Daily	Alternate day	3times/week	<3 times/week

C. This is a Bristol Stool Chart.

Please indicate your willingness to participate by putting \checkmark mark in the boxes below.

Bristol Stool Chart

Type 1		Separate hard lumps, like nuts (hard to pass)
Type 2		Sausage-shaped but lumpy
Type 3		Like a sausage but with cracks on the surface
Type 4		Like a sausage or snake, smooth and soft
Type 5		Soft blobs with clear-cut edges
Type 6		Fluffy pieces with ragged edges, a mushy stool
Type 7		Watery, no solid pieces. Entirely Liquid

Type 1
Type 2
Type 3
Type 4
Type 5
Type 6
Type 7

Specific Criteria for Constipation (For the last 1 month) (Rome IV criteria)

Questions Regarding Facing obstruction or difficulty during passing stools) Indicate with the number given beside the option

		Always (2)/ Sometimes (1)/ Never (0)	If yes & Sometimes, how many times
A	Do you experience a sensation of Incomplete bowel movement or passing of stools?		
B	Do you need to apply Straining while passing stools?		
C	Do you experience excessive Gas/ Flatulence?		
D	Frequency of manual manoeuvres to facilitate defecations		
E	Sensation of anorectal obstruction(blockage in intestine)		
F	Do you experience abdominal pain every time during passing of stools?		

APPENDIX XI

Beck's Depression Inventory

This depression inventory can be self-scored. The scoring scale is at the end of the questionnaire.

1.
 - 0 I do not feel sad.
 - 1 I feel sad
 - 2 I am sad all the time and I can't snap out of it.
 - 3 I am so sad and unhappy that I can't stand it.
2.
 - 0 I am not particularly discouraged about the future.
 - 1 I feel discouraged about the future.
 - 2 I feel I have nothing to look forward to.
 - 3 I feel the future is hopeless and that things cannot improve.
3.
 - 0 I do not feel like a failure.
 - 1 I feel I have failed more than the average person.
 - 2 As I look back on my life, all I can see is a lot of failures.
 - 3 I feel I am a complete failure as a person.
4.
 - 0 I get as much satisfaction out of things as I used to.
 - 1 I don't enjoy things the way I used to.
 - 2 I don't get real satisfaction out of anything anymore.
 - 3 I am dissatisfied or bored with everything.
5.
 - 0 I don't feel particularly guilty
 - 1 I feel guilty a good part of the time.
 - 2 I feel quite guilty most of the time.
 - 3 I feel guilty all of the time.
6.
 - 0 I don't feel I am being punished.
 - 1 I feel I may be punished.
 - 2 I expect to be punished.
 - 3 I feel I am being punished.
7.
 - 0 I don't feel disappointed in myself.
 - 1 I am disappointed in myself.
 - 2 I am disgusted with myself.
 - 3 I hate myself.
8.
 - 0 I don't feel I am any worse than anybody else.
 - 1 I am critical of myself for my weaknesses or mistakes.
 - 2 I blame myself all the time for my faults.
 - 3 I blame myself for everything bad that happens.
9.
 - 0 I don't have any thoughts of killing myself.
 - 1 I have thoughts of killing myself, but I would not carry them out.
 - 2 I would like to kill myself.
 - 3 I would kill myself if I had the chance.
10.
 - 0 I don't cry any more than usual.
 - 1 I cry more now than I used to.
 - 2 I cry all the time now.
 - 3 I used to be able to cry, but now I can't cry even though I want to.

11.
 0 I am no more irritated by things than I ever was.
 1 I am slightly more irritated now than usual.
 2 I am quite annoyed or irritated a good deal of the time.
 3 I feel irritated all the time.
12.
 0 I have not lost interest in other people.
 1 I am less interested in other people than I used to be.
 2 I have lost most of my interest in other people.
 3 I have lost all of my interest in other people.
13.
 0 I make decisions about as well as I ever could.
 1 I put off making decisions more than I used to.
 2 I have greater difficulty in making decisions more than I used to.
 3 I can't make decisions at all anymore.
14.
 0 I don't feel that I look any worse than I used to.
 1 I am worried that I am looking old or unattractive.
 2 I feel there are permanent changes in my appearance that make me look unattractive
 3 I believe that I look ugly.
15.
 0 I can work about as well as before.
 1 It takes an extra effort to get started at doing something.
 2 I have to push myself very hard to do anything.
 3 I can't do any work at all.
16.
 0 I can sleep as well as usual.
 1 I don't sleep as well as I used to.
 2 I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
 3 I wake up several hours earlier than I used to and cannot get back to sleep.
17.
 0 I don't get more tired than usual.
 1 I get tired more easily than I used to.
 2 I get tired from doing almost anything.
 3 I am too tired to do anything.
18.
 0 My appetite is no worse than usual.
 1 My appetite is not as good as it used to be.
 2 My appetite is much worse now.
 3 I have no appetite at all anymore.
19.
 0 I haven't lost much weight, if any, lately.
 1 I have lost more than five pounds.
 2 I have lost more than ten pounds.
 3 I have lost more than fifteen pounds.

- 20.
- 0 I am no more worried about my health than usual.
 - 1 I am worried about physical problems like aches, pains, upset stomach, or constipation.
 - 2 I am very worried about physical problems and it's hard to think of much else.
 - 3 I am so worried about my physical problems that I cannot think of anything else.
- 21.
- 0 I have not noticed any recent change in my interest in sex.
 - 1 I am less interested in sex than I used to be.
 - 2 I have almost no interest in sex.
 - 3 I have lost interest in sex completely.

INTERPRETING THE BECK DEPRESSION INVENTORY

Now that you have completed the questionnaire, add up the score for each of the twenty-one questions by counting the number to the right of each question you marked. The highest possible total for the whole test would be sixty-three. This would mean you circled number three on all twenty-one questions. Since the lowest possible score for each question is zero, the lowest possible score for the test would be zero. This would mean you circles zero on each question. You can evaluate your depression according to the Table below.

Total Score _____ Levels of Depression

1-10 _____	These ups and downs are considered normal
11-16 _____	Mild mood disturbance
17-20 _____	Borderline clinical depression
21-30 _____	Moderate depression
31-40 _____	Severe depression
over 40 _____	Extreme depression

PAC-QOL©

PATIENT ASSESSMENT OF CONSTIPATION

The following questions are designed to measure the impact constipation has had on your daily life over the past 2 weeks. For each question, please check one box.

The following questions ask about your symptoms related to constipation. During the past 2 weeks, to what extent or <u>intensity</u> have you...	Not at all 1	A little bit 2	Moderately 3	Quite a bit 4	Extremely 5
1. felt bloated to the point of bursting?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. felt heavy because of your constipation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The next few questions ask about how constipation affects your <u>daily life</u> . During the past 2 weeks, how much of the time have you...	None of the time 1	A little of the time 2	Some of the time 3	Most of the time 4	All of the time 5
3. felt any physical discomfort?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. felt the need to have a bowel movement but not been able to?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. been embarrassed to be with other people?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. been eating less and less because of not being able to have bowel movements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The next questions ask about your <u>feelings</u> related to constipation. During the past 2 weeks, to what extent or intensity have you...	Not at all 0	A little bit 1	Moderately 2	Quite a bit 3	Extremely 4
19. been worried about not knowing when you are going to be able to have a bowel movement?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. been worried about not being able to have a bowel movement?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. been more and more bothered by not being able to have a bowel movement?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The next questions ask about your <u>life with constipation</u> . During the past 2 weeks, how much of the time have you...	None of the time 1	A little of the time 2	Some of the time 3	Most of the time 4	All of the time 5
22. been worried that your condition will get worse?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. felt that your body was not working properly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. had fewer bowel movements than you would like?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The next questions ask about your <u>degree of satisfaction</u> related to constipation. During the past 2 weeks, to what extent or intensity have you been...	Not at all 0	A little bit 1	Moderately 2	Quite a bit 3	Extremely 4

25. satisfied with how often you have a bowel movement?	<input type="checkbox"/>				
26. satisfied with the regularity of your bowel movements?	<input type="checkbox"/>				
27. satisfied with the time it takes for food to pass through the intestines?	<input type="checkbox"/>				
28. satisfied with your treatment?	<input type="checkbox"/>				

REVISION 3/23/04



APPENDIX XIII

Clinical Trial Details (PDF Generation Date :- Fri, 10 Mar 2023 11:41:48 GMT)

CTRI Number	CTRI/2021/10/037474 [Registered on: 22/10/2021] - Trial Registered Prospectively		
Last Modified On	07/02/2023		
Post Graduate Thesis	Yes		
Type of Trial	Interventional		
Type of Study	Other (Specify) [Prebiotics]		
Study Design	Randomized, Parallel Group, Placebo Controlled Trial		
Public Title of Study	Clinical trial to study the effects of Galactooligosachharides (GOS) added gummies in the Teaching Staff with Functional Constipation		
Scientific Title of Study	Presence of Functional Constipation in the Teaching Staff of The M. S. University of Baroda and Impact Evaluation of Supplementation of Galactooligosachharides (GOS) added Gummies on their Constipation Profile and Gut Health		
Secondary IDs if Any	Secondary ID	Identifier	
	NIL	NIL	
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator		
	Name	Ms Kankona Dey	
	Designation	Research Scholar	
	Affiliation	The Maharaja Sayajirao University of Baroda	
	Address	A 503, Satva Prime, Chhani, Vadodara Vadodara GUJARAT 391740 India	
	Phone	7044187477	
	Fax		
	Email	deykankona@gmail.com	
	Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
		Name	Prof Mini Sheth
Designation		Professor	
Affiliation		The Maharaja Sayajirao University of Baroda	
Address		Department of Foods and Nutrition Faculty of Family and Community Sciences The Maharaja Sayajirao University Pratapgunj Vadodara 390002 Vadodara GUJARAT 390002 India	
Phone		8780680784	
Fax			
Email		mini.sheth-fn@msubaroda.ac.in	
Details Contact Person (Public Query)	Details Contact Person (Public Query)		
	Name	Ms Kankona Dey	
	Designation	Research Scholar	
	Affiliation	The Maharaja Sayajirao University of Baroda	
	Address	Department of Foods and Nutrition Faculty of Family and Community Sciences The Maharaja Sayajirao University Pratapgunj Vadodara 390002 Vadodara GUJARAT 390002	



	India		
Phone	7044187477		
Fax			
Email	deykankona@gmail.com		
Source of Monetary or Material Support	Source of Monetary or Material Support		
	> SHODH-ScHeme Of Developing High quality research		
Primary Sponsor	Primary Sponsor Details		
Name	SHODHScHeme Of Developing High quality research		
Address	SHODH-ScHeme Of Developing High quality research Knowledge Consortium of Gujarat Prajna Puram Campus, Opp. PRL, Between Govt. Girls Polytechnic and L.D College of Engineering, Navrangpura, Ahmedabad, Gujarat, India		
Type of Sponsor	Government funding agency		
Details of Secondary Sponsor	Name	Address	
	NIL	NIL	
Countries of Recruitment	List of Countries		
	India		
Sites of Study	Name of Principal Investigator	Name of Site	Site Address
	Kankona Dey	The Maharaja Sayajirao University of Baroda	Department of Foods and Nutrition Faculty of Family and Community Sciences, The Maharaja Sayajirao University of Baroda Pratapgunj, Vadodara 390002 Vadodara GUJARAT
			7044187477 deykankona@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval
	Institutional Ethics Committee for Human Research (IECHR)	Approved	03/09/2021
			Is Independent Ethics Committee?
			No
Regulatory Clearance Status from DCGI	Status	Date	
	Not Applicable	No Date Specified	
Health Condition / Problems Studied	Health Type	Condition	
	Patients	Other specified diseases of the digestive system	
Intervention / Comparator Agent	Type	Name	Details
	Intervention	Galactooligosachharide	Galactooligosachharide 10 g OD for 30 days
	Comparator Agent	Standard sugar gummies	Standard sugar gummies 10g OD for 30 days
Inclusion Criteria	Inclusion Criteria		
	Age From	25.00 Year(s)	
	Age To	60.00 Year(s)	
	Gender	Both	
	Details	Duration: Symptoms >6 months (As per Rome IV Criteria) Age group: 25-60 years Fecal Calprotectin levels >50 microgram 	



Exclusion Criteria					
Exclusion Criteria	<p>Details</p> <p>(1) prior intestinal resection; (2) patient history of GI diseases like hiatal hernia, gastroesophageal reflux disease (GERD), fissures and hemorrhoids; (3) antibiotic use within the last 12 weeks prior to enrollment; (4) regular use of NSAIDs (Eg: aspirin) (5) excessive alcohol intake (more than two drinks for men and one drink for women daily); (6) presence of chronic metabolic disease such as symptomatic cardiovascular disease, uncontrolled diabetes, current active treatment of cancer; (7) consumption of probiotics, prebiotics, or synbiotics on a regular basis (8) 60 years (9) Pregnant women</p>				
Method of Generating Random Sequence	Computer generated randomization				
Method of Concealment	An Open list of random numbers				
Blinding/Masking	Participant and Investigator Blinded				
Primary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>1. Extent of presence of constipation 2. Intake of GOS added gummies will Improve the constipation profile of the subjects</td> <td>1. Baseline 2. Baseline and 4 weeks</td> </tr> </tbody> </table>	Outcome	Timepoints	1. Extent of presence of constipation 2. Intake of GOS added gummies will Improve the constipation profile of the subjects	1. Baseline 2. Baseline and 4 weeks
Outcome	Timepoints				
1. Extent of presence of constipation 2. Intake of GOS added gummies will Improve the constipation profile of the subjects	1. Baseline 2. Baseline and 4 weeks				
Secondary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>1. Relief from depression 2. Feasibility & Acceptability of GOS gummies as a supplement 3. Improving Chrono nutrition Profile & Quality of Life 4. Improving the colonization of probiotics (Bifidobacteria and Lactobacillus) and reduction in the colonization of E.coli in the gut)</td> <td>1. Relief from depression- 30 days 2. Feasibility & Acceptability of GOS gummies as a supplement- 15 days 3. Improving Quality of Life- 30 days 4. Improving the colonization of probiotics (Bifidobacteria and Lactobacillus) and reduction in the colonization of E.coli in the gut)- 30 days</td> </tr> </tbody> </table>	Outcome	Timepoints	1. Relief from depression 2. Feasibility & Acceptability of GOS gummies as a supplement 3. Improving Chrono nutrition Profile & Quality of Life 4. Improving the colonization of probiotics (Bifidobacteria and Lactobacillus) and reduction in the colonization of E.coli in the gut)	1. Relief from depression- 30 days 2. Feasibility & Acceptability of GOS gummies as a supplement- 15 days 3. Improving Quality of Life- 30 days 4. Improving the colonization of probiotics (Bifidobacteria and Lactobacillus) and reduction in the colonization of E.coli in the gut)- 30 days
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Target Sample Size	<p>Total Sample Size=50 Sample Size from India=50 Final Enrollment numbers achieved (Total)=35 Final Enrollment numbers achieved (India)=35</p>				
Phase of Trial	Phase 3				
Date of First Enrollment (India)	01/12/2021				
Date of First Enrollment (Global)	No Date Specified				
Estimated Duration of Trial	<p>Years=0 Months=0 Days=30</p>				
Recruitment Status of Trial (Global)	Not Applicable				
Recruitment Status of Trial (India)	Completed				
Publication Details	Preparing manuscript				
Brief Summary					



This study is a ^{double blind} randomized clinical trial, comparing the efficacy of Galactooligosachharide (GOS) gummies daily for 30 days in 35 patients with functional constipation among the teaching staff of The Maharaja Sayajirao University of Baroda. The primary outcome measures was to assess relief from Constipation in the subjects after 30 days trial. The secondary outcomes was to assess relief from depression, improved quality of life and improved gut colonization after 30 days feeding trial.