

APPENDICES

APPENDIX –I

WRITTEN INFORMED CONSENT FORM

Subject Information Sheet and Consent Form

You are being asked to take part in a research study. Before you decide, if you want to take part, it is important for you to understand why the research is being done, how your information will be used, what the study will involve and the possible benefits and discomforts. Please take time to read the following information carefully.

Information about this study is made available on public websites. These sites include, but are not limited to, www.clinicaltrials.gov which is a registry and a results database of clinical studies conducted in the United States and around the world.

About The Study

Gut flora (microorganisms established in large intestine) consists of microorganisms that live in the digestive tracts of humans. The human body, consisting of about 10 trillion cells and carries about ten times as many microorganisms in the intestines. Researchers have proved that different people have different establishment of gut flora. Researchers suggest that the relationship between gut flora and humans is a non-harmful co-existence, but rather a mutual relationship.

The microorganisms perform a host of useful functions, such as fermenting unused energy substrates, training the immune system, preventing growth of harmful pathogenic bacteria, regulating the development of the gut, producing vitamins for the host (such as biotin and vitamin K), and producing hormones to direct the host to store fats. Diet may affect human health, partly by modulating the gut microbiota composition. Gut incretins are the various regulatory peptides secreted from cells that line the lumen of the gut. They regulate food intake and insulin sensitivity. The presence of endotoxins in the blood, which is derived from gram-negative rod-shaped bacteria, is called endotoxemia, which may have a role in the causation of various non-communicable diseases.

Little information is available about the composition and colonization of gut flora and its association with gut incretins of the adult population with normal BMI. Hence, we are conducting a situational analysis of the adult population with normal BMI for determining the composition of gut flora and establish an association between gut flora with diet, lifestyle and gut incretins

As a part of this study you will have to:

- 1) Provide data to fill up the questionnaire regarding socioeconomic status, eating pattern, satiety level, depression levels and dietary intake.
- 2) Anthropometric measurements and blood pressure measurements.
- 3) Donate blood sample of 5 ml for biochemical analysis.
- 4) A stool sample for microbiological analysis.

DO I HAVE TO TAKE PART?

It is up to you to decide whether you would like to participate in the study or not. Even if you decide not to participate in the study, you will not be disadvantaged in any way. If you do decide to take part you will be given this informed consent form to sign. If you decide to take part you are still free to withdraw at any time.

Likewise, while we are conducting the study, we may decide that continuing participation in the study is no longer in your best interest and you will be withdrawn. When you stop taking part in the study, you must go through study withdrawal procedures that we consider necessary for your safety.

The reasons for study termination include, but are not limited to, safety reasons, non cooperation in providing proper information to us. If you withdraw from the study, you will be asked to provide a reason why you have chosen to withdraw and if you have/had any problems or discomfort during the study.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you are found to be eligible and decide to take part in the study, you need to provide information about the questionnaire, and also provide us stool sample and 5ml of blood sample. This is one time effort from your side.

VISIT 1 (Screening) : For Normal BMI subjects : (Around June –July 2012)

Once you have given your consent to take part in this study, you will be assessed at Visit 1 to confirm that you are eligible to take part. This screening process will involve:

- Filling up of Questionnaire which includes your personal, medical, physical activity, satiety levels, depression levels and dietary recall history. If you are unable to fill up the questionnaire due to reading, writing, or language problems we will read the questions out loud explaining it in your local language word for word and will record your answers.
- Taking you Anthropometric measurements, including height, weight, waist and hip circumference and body fat measurements.
- Measurement of your resting Blood pressure and Random Blood sugar.

VISIT 2 (Sample Collection): For Normal BMI Subjects (Around end of July 2012)

- Once you are eligible to take part in our study, we will come to collect your blood sample (5 ml) and stool sample. Blood sample will be used to study the Gut hormones and LPS and Stool samples will be used to study the Gut Flora.
- This would be the last step of Participation.

WHAT IS THE COST OF TAKING PART?

There is no cost involved for participating in this study. You will also receive copy of the reports, if you need them.

HOW WILL MY PERSONAL DATA BE USED?

By signing this form you consent to us collecting and using personal data about you for the study. This includes: your date of birth, your sex, your ethnic origin and personal data on your physical or mental health or condition. Your consent to use of Study Data does not have a specific expiration date, but you may withdraw your consent at any time by notifying us. Please note, the results of the study may be published in medical literature, but you will not be identified.

You have the right to request information about the data held by us and sponsoring institute. You also have the right to request that any inaccuracies in such data can be corrected.

By signing this form, I consent to the use of Study Data as described in this form.

WHOM SHOULD I CONTACT IF I NEED MORE INFORMATION OR HELP?

In case if you have questions about the study, please contact:

Dr. Mini Sheth

Ms. Aparna Assudani

Mb: 09879359229

Mb: 9879228428

CONSENT FORM

PORTOCOL NUMBER (# IECHR/2012/13 ; # CTRI/2018/03/012514)

Subjects Name: _____

Date of Birth / Age: _____

1. I confirm that I have read and understood this information sheet for the above study and have /had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.
3. I understand that the sponsor, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.
4. 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).
5. I understand the study will involve one time collection of data in terms of following:
 - The filling up of questionnaire regarding socioeconomic status, my health behavior, eating pattern, satiety level, depression levels and dietary intake.
 - Anthropometric measurements and blood pressure measurements
 - A blood sample of 5 ml for biochemical analysis.
 - A fecal sample for microbiological analysis.
6. I understand that I will be informed of the results of the test (even if they are abnormal) when they are ready. In addition I understand the information obtained from me be kept strictly confidential

I agree, to participate voluntarily in the community health study conducted by The Dept. of Foods & Nutrition, Faculty of Family and Community Nutrition, The Maharaja Sayajirao University of Baroda.

Thanking You.

Date:

Name &Signature of the subject:

APPENDIX –II

QUESTIONNAIRE

**CONFIDENTIAL
(FOR RESEARCH
USE ONLY)**

DATE OF SURVEY

CODE :

| |
|--|
| |
| |

SERIAL NO.

A . GENERAL INFORMATION:

A1 Name: _____

A2 Address: _____

A3 Contact No.

H) _____ (0) _____ (M) _____

Email : _____

A4 Date of Birth : _____

A5 Age (years) : _____

A6 Sex :

| | | |
|------|--------|--|
| A6 1 | Male | |
| A6 2 | Female | |

A7 Religion :

| | | |
|------|-----------|--|
| A7 1 | Hindu | |
| A7 2 | Muslim | |
| A7 3 | Sikh | |
| A7 4 | Christian | |
| A7 5 | Others | |

A8: Type of Family :

| | | |
|------|------------------|--|
| A8 1 | Joint | |
| A8 2 | Nuclear | |
| A8 3 | Extended nuclear | |

A9 : Number of Family Members :

| | | |
|------|----------|--|
| A9 1 | Adults | |
| A9 2 | Children | |

APPENDIX III

A 10 : Socio Economic Status :

| A10 A : Education of the Head (Main earning Member) | | Score | Tick(√) |
|---|--------------|----------------------------|----------------|
| 1. Profession or Honours | | 7 | |
| 2. Graduate or post graduate | | 6 | |
| 3. Intermediate or post high school diploma | | 5 | |
| 4. High school certificate | | 4 | |
| 5. Middle school certificate | | 3 | |
| 6. Primary school certificate | | 2 | |
| 7. Illiterate | | 1 | |
| A 10 B : Occupation of the Head (Main earning Member) | | Score | Tick(√) |
| 1. Profession | | 10 | |
| 2. Semi-Profession | | 6 | |
| 3. Clerical, Shop-owner, Farmer | | 5 | |
| 4. Skilled worker | | 4 | |
| 5. Semi-skilled worker | | 3 | |
| 6. Unskilled worker | | 2 | |
| 7. Unemployed | | 1 | |
| A10 C: Family income per month in Rs (2010) | | Score | Tick(√) |
| 1. > 28114 | | 12 | |
| 2. 14050 – 23113 | | 10 | |
| 3. 10533 – 14049 | | 6 | |
| 4. 7016 – 10532 | | 4 | |
| 5. 4204 – 7015 | | 3 | |
| 6. 1407 – 4203 | | 2 | |
| 7. < 1406 | | 1 | |
| Total Score | | | |
| Scores | Codes | Socioeconomic class | Tick(√) |
| 26-29 | A10CI | Upper (I) | |
| 16-25 | A10CII | Upper Middle (II) | |
| 11-15 | A10CIII | Lower middle (III) | |
| 5-10 | A10CIV | Upper lower (IV) | |
| <5 | A10CV | Lower (V) | |

B. ANTHROPOMETRIC MEASUREMENTS:

B1) Height (cm): _____

B2) Weight (kg): _____

B3) BMI (kg/m²): _____

B4) Abdominal Obesity - Waist Circumference (cm): _____

B5) Hip Circumference (cm): _____

B6) WHR: _____

B7) Body Fat (%) : _____

B8) BMR : _____

C. FAMILY HISTORY

| Members Of Family | Obesity | Hypertension | Diabetes mellitus | Coronary Heart Disease |
|------------------------|---------|--------------|-------------------|------------------------|
| | C1 | C2 | C3 | C4 |
| Both Parents | | | | |
| Single Parent (F / M) | | | | |
| Brother | | | | |
| Sister | | | | |
| Grand parents | | | | |
| Other Relation | | | | |
| Total Score | | | | |

SCORE FOR EACH CATEGORY :**Strong Family History : 6 – 4****Moderate Family History : 3 – 5****Mild Family History : 0 – 2****D6 a : INQUIRY ABOUT DEFECACTION**

| CODE | DEFECACTION | CONDITIONS SCORE | | | | | |
|-------|-------------------|------------------|---------|----------|------|-------|-----------|
| D6a | Constipation | Yes (1) | No (0) | | | | |
| D6a 1 | Frequency (times) | 1 | | 2 | | 3 | >3 |
| D6a 2 | Quantity of Stool | Small (1) | | Middle | | | Large (3) |
| D6a 3 | Hardness of stool | Very | Hard(2) | Medium | Soft | Muddy | Watery |
| D6a 4 | Color of Stool | Blackish | | Middle | | | Yellowish |
| D6a 5 | Odor of Stool | Strong | | Medium | | | Weak (3) |
| D6a 6 | Feeling after | Bad (1) | | Fine (2) | | | Very fine |
| D6a 7 | Regular use of | Yes(1) | No (0) | | | | |

DEFECATION SCORE CUTOFFS:

Constipated : < 07
Normal Defecation: 08 – 13
Watery Stools: > 14

SCORE CUTOFFS FOR DEGREE OF CONSTIPATION:

Severe Constipation : 1 – 2
Moderate Constipation: 3 – 5
Mild Constipation : 6 – 7

D6 b. INQUIRY ABOUT FLATULENCE :

| CODE | FLATULENCE | CONDITIONS SCORE | | | | | |
|-------|--------------------|------------------|--|--------|--|---|------------|
| D6b | Flatulence | No (0) | | | | | Yes (1) |
| D6b 1 | Frequency (times / | 1 | | 2 | | 3 | >3 |
| D6b 2 | Odor of Flatulence | Weak (1) | | Medium | | | Strong (3) |
| D6b 3 | Regular Use of any | No (0) | | | | | Yes(1) |

SCORE CUTOFFS FOR DEGREE OF FLATULENCE:

Mild Flatulence : 0 – 1
Moderate Flatulence: 3 – 2
Severe Flatulence: 8 – 4

D. SUBJECT'S MEDICAL HISTORY

| Disorder | Code | Yes -1 No - 0 | Diagnosed in year | Duration (yrs) | Medication name | Dosage and frequency | Frequency of disorder |
|-------------------|------------------|--|----------------------|-------------------|--------------------|----------------------------|--------------------------|
| | | | | | | | |
| Obesity | D1 | | | | | | |
| Hypertension | D2 | | | | | | |
| Diabetes | D3 | | | | | | |
| CHD | D4 | | | | | | |
| Valve replacement | D4a | | | | | | |
| Renal disorder | D5 | | | | | | |
| Frequency of UTI | D5a | | | | | | |
| ARF | D5b | | | | | | |
| Gi disorders | D6 | | | | | | |
| Constipation | D6a | Refer detailed information on defecation | | | | | |
| Use of laxatives | D6a ₁ | | | | | | |
| Flatulence | D6b | Refer detailed information on flatulence | | | | | |
| Diarrhoea | D6c | | | | | | |

| Disorder | Code | Yes -1 No - 0 | Diagnosed in year | Duration (yrs) | Medication name | Dosage and frequency | Frequency of disorder |
|--------------------------|------|------------------------|----------------------|-------------------|--------------------|----------------------------|--------------------------|
| Abdominal pain | D6d | | | | | | |
| Heart burn/ acidity | D6e | | | | | | |
| Gi ulcers | D6f | | | | | | |
| Gi surgery | D6g | | | | | | |
| Dental problems | D7 | | | | | | |
| Bad breath | D7a | | | | | | |
| Dry mouth | D7b | | | | | | |
| Cavities | D7c | | | | | | |
| Bleeding/swollen gums | D7d | | | | | | |
| Locomotor disorders | D8 | | | | | | |
| Knee joint pain | D8a | | | | | | |
| Swollen feet | D8b | | | | | | |
| Back pain | D8c | | | | | | |
| Osteoporosis | D8d | | | | | | |
| Osteoarthritis | D8e | | | | | | |
| Thyroid | D9 | | | | | | |
| Hyper | D9a | | | | | | |
| Hypo | D9b | | | | | | |
| Skin disorder | D10 | | | | | | |
| Cancer | D11 | | | | | | |
| Auto immune disorder | D12 | | | | | | |

E. PERSONAL HABITS

| Addiction | Co de | Daily | Wee kly | Fort night | Mont hly | Quater ly | Yea rly | Occassio nally | Never |
|--------------------|----------|-------|------------|---------------|-------------|--------------|------------|-------------------|-------|
| | | 7 | 6 | 5 | 4 | 3 | 2 | 1 | 0 |
| Alcohol | E1 | | | | | | | | |
| Cigarette/Bidi | E2 | | | | | | | | |
| Tobacco Powder | E3 | | | | | | | | |
| Tobacco Paste | E4 | | | | | | | | |
| Snuff | E5 | | | | | | | | |
| Tea (> 4Cups/Day) | E6 | | | | | | | | |
| Coffee (>4 | E7 | | | | | | | | |
| Aerated drinks | E8 | | | | | | | | |
| TOTAL SCORE | | | | | | | | | |

SCORE CUTOFFS FOR DEGREE OF HABITUATION

| | |
|------------------------|---------|
| Mild Habituation : | < 4 |
| Moderate Habituation : | 5 – 10 |
| Severe Habituation: | 11 – 24 |
| Extreme Habituation : | > 25 |

APPENDIX IV

F. PHYSICAL ACTIVITY PATTERN (GPAQ VERSION 2 :WHO 2007)

| Physical Activity | | | |
|---|---|---|--------------|
| <p>Next I am going to ask you about the time you spend doing different types of physical activity in a typical week. Please answer these questions even if you do not consider yourself to be a physically active person.</p> <p>Think first about the time you spend doing work. Think of work as the things that you have to do such as paid or unpaid work, study/training, household chores, harvesting food/crops, fishing or hunting for food, seeking employment. <i>[Insert other examples if needed]</i>. In answering the following questions 'vigorous-intensity activities' are activities that require hard physical effort and cause large increases in breathing or heart rate, 'moderate-intensity activities' are activities that require moderate physical effort and cause small increases in breathing or heart rate.</p> | | | |
| Questions | Response | | Code |
| Activity at work | | | |
| 1 | Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate like <i>[carrying or lifting heavy loads, digging or construction work]</i> for at least 10 minutes continuously? <i>[INSERT EXAMPLES] (USE SHOWCARD)</i> | Yes 1 No 2 <i>If No, go to P 4</i> | P1 |
| 2 | In a typical week, on how many days do you do vigorous-intensity activities as part of your work? | Number of days <input type="text"/> | P2 |
| 3 | How much time do you spend doing vigorous-intensity activities at work on a typical day? | Hours : minutes <input type="text"/> : <input type="text"/> hrs mins | P3 (a-b) |
| 4 | Does your work involve moderate-intensity activity that causes small increases in breathing or heart rate such as brisk walking <i>[or carrying light loads]</i> for at least 10 minutes continuously? <i>[INSERT EXAMPLES] (USE SHOWCARD)</i> | Yes 1 No 2 <i>If No, go to P 7</i> | P4 |
| 5 | In a typical week, on how many days do you do moderate-intensity activities as part of your work? | Number of days <input type="text"/> | P5 |
| 6 | How much time do you spend doing moderate-intensity | | P6 |
| Travel to and from places | | | |
| <p>The next questions exclude the physical activities at work that you have already mentioned.</p> <p>Now I would like to ask you about the usual way you travel to and from places. For example to work, for shopping, to market, to place of worship. <i>[insert other examples if needed]</i></p> | | | |
| 7 | Do you walk or use a bicycle (<i>pedal cycle</i>) for at least 10 minutes continuously to get to and from places? | Yes 1 No 2 <i>If No, go to P 10</i> | P7 |
| 8 | In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places? | Number of days <input type="text"/> | P8 |
| 9 | How much time do you spend walking or bicycling for travel on a typical day? | Hours : minutes <input type="text"/> : <input type="text"/> hrs mins | P9 (a-b) |
| Recreational activities | | | |
| <p>The next questions exclude the work and transport activities that you have already mentioned.</p> <p>Now I would like to ask you about sports, fitness and recreational activities (leisure), <i>[insert relevant terms]</i>.</p> | | | |
| 10 | Do you do any vigorous-intensity sports, fitness or recreational (<i>leisure</i>) activities that cause large increases in breathing or heart rate like <i>[running or football]</i> for at least 10 minutes continuously? <i>[INSERT EXAMPLES] (USE SHOWCARD)</i> | Yes 1 No 2 <i>If No, go to P 13</i> | P10 |
| 11 | In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational (<i>leisure</i>) activities? | Number of days <input type="text"/> | P11 |
| 12 | How much time do you spend doing vigorous-intensity sports, fitness or recreational activities on a typical day? | Hours : minutes <input type="text"/> : <input type="text"/> hrs mins | P12 (a-b) |

| Physical Activity (recreational activities) contd. | | | |
|--|---|--|--------------|
| Questions | | Response | Code |
| 13 | Do you do any moderate-intensity sports, fitness or recreational (<i>leisure</i>) activities that causes a small increase in breathing or heart rate such as brisk walking, (cycling, swimming, volleyball) for at least 10 minutes continuously? [INSERT EXAMPLES] (USE SHOWCARD) | Yes 1 No 2 If No, go to P16 | P13 |
| 14 | In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational (<i>leisure</i>) activities? | Number of days <input type="text"/> | P14 |
| 15 | How much time do you spend doing moderate-intensity sports, fitness or recreational (<i>leisure</i>) activities on a typical day? | Hours : minutes <input type="text"/> : <input type="text"/> hrs mins | P15 (a-b) |
| Sedentary behaviour | | | |
| The following question is about sitting or reclining at work, at home, getting to and from places, or with friends including time spent [sitting at a desk, sitting with friends, travelling in car, bus, train, reading, playing cards or watching television], but do not include time spent sleeping. [INSERT EXAMPLES] (USE SHOWCARD) | | | |
| 16 | How much time do you usually spend sitting or reclining on a typical day? | Hours : minutes <input type="text"/> : <input type="text"/> hrs min s | P16 (a-b) |

G. HUNGER AND SATIETY SCALE (ZERO DAY)

| Sr. No | MEAL TIME | HUNGER | SATIETY |
|--------|-------------|--------|---------|
| 1 | BREAKFAST | | |
| 2 | LUNCH | | |
| 3 | EVENING | | |
| 4 | DINNER | | |
| | TOTAL SCORE | | |
| | MEAN SCORE | | |

SCORE CARD FOR APPETITE – SATIETY SCALE

| Scale | Score |
|--|-------|
| Famished, starving | 1 |
| Headache, weak, cranky, low energy | 2 |
| Want to eat now, stomach growls and feels empty | 3 |
| Hungry - but could wait to eat, starting to feel empty but not there yet | 4 |
| Not hungry, not full | 5 |
| Feeling satisfied, stomach feels full and comfortable | 6 |
| Feeling full, definitely don't need more food | 7 |
| Uncomfortably full | 8 |
| Stuffed, very uncomfortable | 9 |
| Bursting, painfully full | 10 |

Source : Developed by Lisa Burgoon MS, RD, LD, Sports Nutritionist, Sportwell Center, McKinley Health Center, University of Illinois at Urbana – Champaign, 1998 .

APPENDIX - V

H. BECK'S DEPRESSION INVENTORY

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.
 4 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.
4 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.
5 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.
2 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.

TOTAL SCORE:**I. FOOD FREQUENCY**

| Food items | Daily | 2-3 week | Once week | Fort-nightly | Monthly | Rarely | Never |
|----------------------------|-------|----------|-----------|--------------|---------|--------|-------|
| Total dietary fiber | | | | | | | |
| Cereals | | | | | | | |
| Bajra | | | | | | | |
| Jowar | | | | | | | |
| Maize, dry | | | | | | | |
| Ragi | | | | | | | |
| Rice | | | | | | | |
| Wheat | | | | | | | |
| Pulses and legumes | | | | | | | |
| Dals, dehusked | | | | | | | |
| Dals with husk | | | | | | | |
| Legumes | | | | | | | |
| Vegetables | | | | | | | |
| Green leafy | | | | | | | |
| Roots and tubers | | | | | | | |
| Other vegetables | | | | | | | |

| Food items | Daily | 2-3 week | Once week | Fort-nightly | Monthly | Rarely | Never |
|---|-------|----------|-----------|--------------|---------|--------|-------|
| Nuts and oil seeds | | | | | | | |
| Nuts (dry fruits) | | | | | | | |
| Oil seeds (peanut, til seeds etc) | | | | | | | |
| Condiments and spices | | | | | | | |
| Aniseed (sauf) | | | | | | | |
| Cardamom (elaichi) | | | | | | | |
| Fenugreek | | | | | | | |
| Garlic | | | | | | | |
| Ginger | | | | | | | |
| Onion | | | | | | | |
| Fruits consumed: days per week _____ | | | | | | | |
| High fiber (g%) : > 5 | | | | | | | |
| Sapota | | | | | | | |
| Custard apple | | | | | | | |
| Amla | | | | | | | |
| Dates , dry | | | | | | | |
| Dates, fresh | | | | | | | |
| Fig | | | | | | | |
| Guava | | | | | | | |
| Moderate fiber (g%): 4.99 – 2.0 | | | | | | | |
| Sweetlime | | | | | | | |
| Mango | | | | | | | |
| Pineapple | | | | | | | |
| Plum | | | | | | | |
| Pomogranate | | | | | | | |
| Strawberry | | | | | | | |
| Papaya | | | | | | | |
| Zizyphus | | | | | | | |
| Apple | | | | | | | |
| Jack fruit | | | | | | | |
| Jambu | | | | | | | |
| Pear | | | | | | | |
| Low fiber (g%): 1.99 – 0.5 | | | | | | | |
| Banana | | | | | | | |
| Cherry | | | | | | | |
| Grapes, green | | | | | | | |
| Musk melon | | | | | | | |
| Water melon | | | | | | | |
| Orange | | | | | | | |
| Peach | | | | | | | |

APPENDIX - VI

J. DIETARY PATTERN (24 hr Dietary Recall Method)

| Meal and Time | Foods taken | Ingredients | Amount |
|---------------------------------------|---|-------------|--------|
| STANDARD MEASURES: | 1 CUP (KATORI) = 200 ml 1 TEA CUP =150 ml 1 GLASS =200 ml | | |
| EARLY MORNING: (Time:_____) | | | |
| BREAKFAST: (Time:_____) | | | |
| MID MORNING: (Time:_____) | | | |
| LUNCH: (Time:_____) | | | |
| EVENING : (Time:_____) | | | |
| DINNER: (Time:_____) | | | |

L. BIOCHEMICAL DATA

| Parameters | Values |
|------------------------------|--------|
| Blood Glucose Random (mg/dl) | |
| GLP-1 (Active) pg/ml | |
| GIP (Total) | |
| Insulin | |
| Leptin | |
| Grehlin (active) | |
| PP | |
| PYY (Total) | |
| LPS EU/ml | |

M. MICROBIAL ANALYSIS

| Parameters | Values |
|-----------------------------|--------|
| Faecal Lactobacilli Count | |
| Faecal Bifidobacteria Count | |
| Faecal Clostridium Count | |
| Faecal Bacteriodes Count | |
| Short Chain Fatty Acid | |
| Acetate | |
| Butyrate | |
| Propionate | |
| Isobutyrate | |

F. STRATEGIES ADOPTED TO MANAGE OBESITY

| STRATEGY | CODE | YES (1) / NO (0) | DURATION (Yrs) | Score |
|-------------------------------------|------|------------------|----------------|-------|
| DIET Therapy | F1 | | | |
| Controlling Carbohydrates | F1a | | | |
| Only Sugar | F1b | | | |
| Controlling over all fat | F1c | | | |
| Controlling only ghee and butter | F1d | | | |
| Controlled outside food (junk food) | F1e | | | |
| Increased Physical Activity | F2 | | | |
| Joined any Weight loss Institute | F3 | | | |
| Pharmacotherapy (also refer D1) | F4 | | | |

IMPACT ANALYSIS QUESTIONNAIRE**I. GENERAL**

Name: _____ Code no. _____

No. Of Days Supplementation:
_____**II. ANTHROPOMETRY**

| Parameters | Baseline value | Post value |
|--------------------------|----------------|------------|
| Weight (kg) | | |
| Height (cm) | | |
| BMI | | |
| Waist circumference (cm) | | |
| Hip circumference (cm) | | |
| WHR | | |
| % Body Fat | | |

III. BIOPHYSICAL DATA

| Blood Pressure | Baseline value | Post value |
|---------------------------------|----------------|------------|
| Systolic Blood Pressure (mmHg) | | |
| Diastolic Blood Pressure (mmHg) | | |

IV. BIOCHEMICAL PARAMETERS

| Parameters | Baseline value | Post value |
|---------------|----------------|------------|
| GLP-1 pg/ml | | |
| GIP pg/ml | | |
| PYY pg/ml | | |
| Leptin pg/ml | | |
| Ghrelin pg/ml | | |
| Insulin pg/ml | | |

V. MICROBIAL COUNTS

| Parameters | Baseline value | Post value |
|-----------------------------|----------------|------------|
| Faecal Lactobacilli Count | | |
| Faecal Bifidobacteria Count | | |
| Faecal Clostridium Count | | |
| Faecal Bacteriodes Count | | |
| Short Chain Fatty Acid | | |

VI. COMPLIANCE

a) Full b) Partial (>60 days) c) Less (<60 days)

- Remarks of the compliance:

- Consumption pattern: a) Substituted b)
Additional

a) Breakfast b) Mid Morning c) Lunch d) Mid Afternoon e) Dinner

Remarks of the subjects for the acceptability of prebiotic added food consumption:

APPENDIX – VII [A]

SENSITIVITY THRESHOLD TEST

Name: _____

Date: _____

You are provided with a series of containers having solutions with increasing concentration of one of the taste qualities (sweet, salty and sour). Please identify the taste in each set and score them according to the concentration. The samples are not allowed to be retested.

| Sample Code | Set-1 | Set-II | Set III | Total Score |
|--------------------|-------|--------|---------|-------------|
| A | | | | |
| B | | | | |
| C | | | | |
| D | | | | |
| E | | | | |
| Mean Scores | | | | |

Scale:

While awarding the intensity scores, take the following basis into account;

- 0 - None or taste of pure water
- 1 - Different from water but taste quality not identifiable
- 2 - Weak taste
- 3 - Medium
- 4 - Strong
- 5 - Very strong

Signature of Judge

APPENDIX – VII [B]

THRESHOLD TEST

B) Procedure for Preparation of Solution Required for Threshold Test

| Sr. No. | Molarity | Salty | Sweet | Molarity | Sour | Bitter |
|---------|----------|---|---|----------|---|---|
| | | Stock solution 5.845 g of NaCl/L | Stock solution 34.23 g of sucrose / L | | Stock solution 21.015 g of citric acid/L | 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 VIII

Sensory Acceptability Score Card

HEDONIC RATING SCALE

Panel Member's Name : _____ **Contact No.** _____

Test these samples and check how much you like or dislike one. Use appropriate scale to show your attitude by assigning points that best describe your feeling about the sample. An honest feeling of your expression will help to get unbiased data.

PRODUCT NAME : _____ **DATE:** _____

| Code | Colour / Appearance | Mouth feel | Texture | Taste | After Taste | Overall Acceptance |
|------|------------------------|---------------|---------|-------|----------------|-----------------------|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| | | | |
|-----------------------------------|---------------|----------------------------|---------------|
| Scale | Score: | Scale: | Score: |
| Liked Extremely: | 9 | Disliked Slightly: | 4 |
| Liked Very much: | 8 | Disliked Moderately | 3 |
| Liked Moderately: | 7 | Disliked very Much | 2 |
| Like Slightly: | 6 | Disliked Extremely | 1 |
| Neither liked nor dislike: | 5 | | |

REMARKS :-

Signature of Judge:
