

APPENDIX I (i)

Permission Letters to Enroll Students and Staff from Various Departments of Faculty Of Family And Community Sciences For Doctoral Research Purpose.



DEPARTMENT OF FOODS AND NUTRITION
FACULTY OF FAMILY & COMMUNITY SCIENCES
THE MAHARAJA SAYAJIRAO UNIVERSITY OF BARODA
VADODARA 390 002 – INDIA

To,

The Head
Department of Extension Education and Communication
Faculty of Family and Community Sciences
M.S. University of Baroda
Vadodara.

4th September, 2017


SUBJECT – TO COLLECT THE CURRENT LIST OF STAFF AND STUDENTS.


Dear Madam,


I the undersigned is involved in the doctoral research entitled “ Determining Biogenic Metabolites in Prebiotic Enriched Fermented Beverage as a Communicator between Gut and Brain ” under the guidance of Prof. Mini Sheth. The first phase of this study involves screening staff and students of all the departments of Faculty of Family and Community Sciences so as to determine their level of depression. I will be thankful to you if you please allow me to collect the current list of staff and students.

Thanking you.

Your's faithfully,


Shruti Dwivedi
Ph.D. Research scholar
(Department of Foods and Nutrition)


Prof Mini Sheth .


15.9.17
Pl. go ahead.

APPENDIX I (ii)



DEPARTMENT OF FOODS AND NUTRITION
FACULTY OF FAMILY & COMMUNITY SCIENCES
THE MAHARAJA SAYAJIRAO UNIVERSITY OF BARODA
VADODARA 390 002 – INDIA

To,

Professor Anjali Karolia
Director IFT
Faculty of Family and Community Sciences
M.S. University of Baroda
Vadodara.

19th September, 2018


Subject – Permission to collect list of staff and students of IFT and screen them for presence of mild to moderate depression.


Dear Madam,

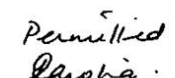
I the undersigned is involved in the doctoral research entitled “Determining Biogenic Metabolites in Prebiotic Enriched Fermented Beverage as a Communicator between Gut and Brain” under the guidance of Prof. Mini Sheth. The second phase of this study involves screening staff and students of all the departments of Faculty of Family and Community Sciences so as to determine their level of depression. I will be thankful to you if you please allow me to collect the current list of staff and students from IFT and screen them using Beck’s Depression Inventory after obtaining their consent.

Thanking you.

Your’s faithfully,


Shruti Dwivedi
Ph.D. Research scholar
(Department of Foods and Nutrition)


Prof. Mini Sheth
Research Supervisor


DEAN
Faculty of Family & Community Sciences
VADODARA

APPENDIX I (iii)



DEPARTMENT OF FOODS AND NUTRITION
FACULTY OF FAMILY & COMMUNITY SCIENCES
THE MAHARAJA SAYAJIRAO UNIVERSITY OF BARODA
VADODARA 390 002 – INDIA

To,

The Head
Department of Human Development and Family Studies
Faculty of Family and Community Sciences
M.S. University of Baroda
Vadodara.

4th September, 2017

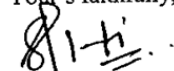
SUBJECT – TO COLLECT THE CURRENT LIST OF STAFF AND STUDENTS.

Dear Madam,

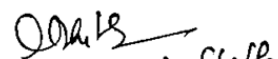
I the undersigned is involved in the doctoral research entitled “ Determining Biogenic Metabolites in Prebiotic Enriched Fermented Beverage as a Communicator between Gut and Brain ” under the guidance of Prof. Mini Sheth. The first phase of this study involves screening staff and students of all the departments of Faculty of Family and Community Sciences so as to determine their level of depression. I will be thankful to you if you please allow me to collect the current list of staff and students.

Thanking you.

Your's faithfully,



Shruti Dwivedi
Ph.D. Research scholar
(Department of Foods and Nutrition)


Prof. Mini Sheth

You may collect
the lists.
Administer to students
who consent
to participate.
(Sheth)
15/09/17

APPENDIX I (iv)



DEPARTMENT OF FOODS AND NUTRITION
FACULTY OF FAMILY & COMMUNITY SCIENCES
THE MAHARAJA SAYAJIRAO UNIVERSITY OF BARODA
VADODARA 390 002 – INDIA

To,

The Head
Department of Family and Community Resource Management
Faculty of Family and Community Sciences
M.S. University of Baroda
Vadodara.

4th September, 2017

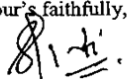
SUBJECT – TO COLLECT THE CURRENT LIST OF STAFF AND STUDENTS.

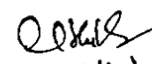
Dear Madam,

I the undersigned is involved in the doctoral research entitled “ Determining Biogenic Metabolites in Prebiotic Enriched Fermented Beverage as a Communicator between Gut and Brain ” under the guidance of Prof. Mini Sheth. The first phase of this study involves screening staff and students of all the departments of Faculty of Family and Community Sciences so as to determine their level of depression. I will be thankful to you if you please allow me to collect the current list of staff and students.

Thanking you.

Your's faithfully,


Shruti Dwivedi
Ph.D. Research scholar
(Department of Foods and Nutrition)


Prof. Mini Sheth.

Shruti bhai to pl provide the list.
mk 15/9/17


15/9/17
2:00 PM

APPENDIX I (v)

Permission Letter from Psychiatrist to Enroll Mild to Moderately Depressed Subjects for Participation in Food Intervention Trials as Part of Doctoral Research.

Department of Foods & Nutrition
Faculty of Family and Community Sciences
The Maharaja Sayajirao University Of Baroda



To,

Dr. Deepali Puneekar
MARG, Counseling center
Health Center
The Maharaja Sayajirao University of Baroda

SUBJECT- Permission to supplement mild to moderately depressed subjects with prebiotic and buttermilk as means to improve their depression status.

Dear Madam

I Shruti Dwivedi, working for doctoral dissertation in the Foods and Nutrition Department, Faculty of Family and Community Science M.S. University of Baroda, is conducting a research study on **"DETERMINING BIOGENIC METABOLITES IN PREBIOTIC ENRICHED FERMENTED BEVERAGE AS A COMMUNICATOR BETWEEN GUT MICROBIOTA AND BRAIN"**.

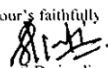
As a part of this study we will be screening subjects falling in the category of mild to moderate depression by Beck's Depression inventory. Researchers have shown that gut microbiota influences brain chemistry and behavior, and supplementing fermented beverage and prebiotics have shown to reduce stress, inducing relaxation and improving mental function. Fermentation amplify the specific nutrient or phytonutrients content of foods, the ultimate value of which is associated with mental health; furthermore fermented foods may also influence brain health via direct and indirect pathways (Selhub E. M. et al., 2014).

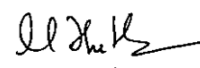
We understand that there is a standard protocol for the treatment of mild to moderately depressed individuals by psychiatrist. But as the researches have shown, college undergraduates who ate the most fermented foods, including sauerkraut and yogurt, were less likely to suffer from social anxiety, fear or depression. Prebiotic intake reduced the waking cortisol response and altered emotional bias in healthy volunteers (Kristin Schmidt et al., 2015).


We will be thankful if you kindly grant the permission to supplement mild to moderately depressed subjects with buttermilk and prebiotic and see the effect of intervention in reducing their depression status. Subjects will be informed about the study and their consent will be taken before the intervention trials.

Researcher will refer the subject to you if no effect of intervention is seen on their depression status.

Thanking you

Your's faithfully

Shruti Dwivedi
Research Scholar


Prof. Mini Sheth
(Research Guide)


(Deepali Puneekar)
(Not for medical purpose)

APPENDIX II

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 _____
 _____ Extre
 me depression

APPENDIX III (i)

SUBJECT CONSENT FORM

**DEPARTMENT OF FOODS AND NUTRITION
FACULTY OF FAMILY AND COMMUNITY SCIENCES
THE MAHARAJA SAYAJIRAO UNIVERSITY OF BARODA
VADODARA 390002 - INDIA**



INFORMED CONSENT FORM FOR SUBJECTS PARTICIPATING IN THE STUDY

I Shruti Dwivedi, PhD Research Scholar Department of Foods and Nutrition, Faculty of Family and Community Science M.S. University of Baroda, is planning to conduct a research study on **“DETERMINING BIOGENIC METABOLITES IN PREBIOTIC ENRICHED FERMENTED BEVERAGE AS A COMMUNICATOR BETWEEN GUT MICROBIOTA AND BRAIN”**

The gut-brain axis (GBA) consists of bidirectional communication between the central and the enteric nervous system, linking emotional and cognitive centers of the brain with peripheral intestinal functions. Researchers have shown that gut microbiota influences brain chemistry and behavior.

The first phase of this study involves screening staff and students of all the departments of Faculty of Family and Community Sciences so as to determine their stress levels. You are required to fill in the questionnaire having questions related to occurrence of degree of stress in healthy human beings. This is purely on a voluntary basis and the information collected from you will be kept confidential and will be used for research purpose only. The results of the survey may be shared with you if required.

Prof. Mini Sheth
Research Study Supervisor

Ph- 9879359229

Shruti Dwivedi
PhD Research Scholar

Ph – 7088565757

SUBJECT CONSENT:

I have read the above information and also shared it with my family and with their due permission I give my consent to participate in the study. I understand the importance of this study and the information derived from me. I ensure to share correct information and sincerely be a part of this study.

Name:

Address:

Phone No.:

Date:

Signature of the participant

APPENDIX III (ii)

SUBJECT CONSENT FORM

DEPARTMENT OF FOODS AND NUTRITION
FACULTY OF FAMILY AND COMMUNITY SCIENCES
THE MAHARAJA SAYAJIRAO UNIVERSITY OF BARODA
VADODARA 390002 - INDIA



INFORMED CONSENT FORM FOR SUBJECTS PARTICIPATING IN THE STUDY

I Shruti Dwivedi, PhD Research Scholar, at the Department of Foods and Nutrition, The M.S. University of Baroda, is conducting a research study on **“DETERMINING BIOGENIC METABOLITES IN PREBIOTIC ENRICHED FERMENTED BEVERAGE AS A COMMUNICATOR BETWEEN GUT MICROBIOTA AND BRAIN”**.

Globally, more than 264 million people of all ages suffer from depression (WHO factsheet, 2020).

Looking at the rise in the trend of depression among youth there is an urgent need to address the problem by preserving and restoring mental health. One probable solution lies in the highly dynamic human gastrointestinal tract. Microbiotas play an important role in maintaining the functionality of the intestinal barrier which is critical for human mental health. Microbes are thought to communicate directly with the brain labelled as ‘Gut-Brain Axis’. Biohacking our mental health is possible via the modulation of gut floras to a positive balance. Prebiotics, probiotics, and fermented beverages open up new avenues for psychological therapies by altering the intestinal microbiota axis. This study involves five group:

Subjects may be intervened either with ambil 200 ml, liquid FOS 10 ml, tetrapacked buttermilk 200 ml or fresh buttermilk 200 ml for 45 days respectively. No intervention will be given to control group. Ambil is a fermented health drink and its consumption has got no ill effect on human health. FOS is considered safe for use at different level, by Food and Drug Administration (US FDA, 2000). The study will involve your participation with regards to following aspects.

- You can be the subject to any one of the intervention groups.
- To test your gut micro flora, we will require your stool sample.
- Your kind cooperation will be required in helping us to collect information on the anthropometric measurements, medical and diet history.
- Rating Beck’s Depression Inventory to measure characteristics, attitude and symptoms of depression.

Note: Information collected by you and test reports will be kept highly confidential. However, they will be shared with you in case you require. The safety of the beverage supplied to you has been well established. Possible adverse effects may include: flatulence, constipation and vomiting. In case, any adverse effect is felt by you in terms of excessive flatulence or any other discomfort, the supplement may be discontinued.

SUBJECT CONSENT: I have read the above information and also shared it with my family and with their due permission, I give my consent to participate in the study. I understand the importance of this study and the information derived from me. I ensure to share correct information during the study and shall regularly and sincerely be a part of this study.

Name:

Address:

Phone No.:

Signature of the participant

Contact: Shruti Dwivedi
7088565757

A. General Information

7) Religion: (A7) a) Hindu (A7 a) b) Muslim (A7 b) c) Christian (A7 c)

d) Others (A7 d)

8) Education: (A8) a) Elementary (A8 a) b) High school (A8 b) c) Diploma (A8 c)
 d) Graduate (A8 d) e) Higher studies (A8 e)

9) Family Type a) Nuclear (A9 a) b) Extended nuclear (A9 b) c) Joint (A9 c)

10) No. of Family members: a) Adults (A10 a) b) Children (A10 b)

11) Total family income: _____ (A 11)

12) Per capita income: _____ (A 12)

B. Personal Habits

	Habits	Daily (Ba)	Weekly (Bb)	Monthly (Bc)	Occasionally (Bd)	Never (Be)
1	Alcohol	(Ba1)	(Bb1)	(Bc1)	(Bd1)	(Be1)
2	Cigarette	(Ba2)	(Bb2)	(Bc2)	(Bd2)	(Be2)
3	Tobacco	(Ba3)	(Bb3)	(Bc3)	(Bd3)	(Be3)
4	Yoga	(Ba4)	(Bb4)	(Bc4)	(Bd4)	(Be4)
5	Breathing exercises	(Ba5)	(Bb5)	(Bc5)	(Bd5)	(Be5)

C. ANTHROPOMETRIC MEASUREMENTS:

C1) Height (cm): _____

C2) Weight (kg):

C3) BMI (kg/m²):

D. Medical history

Da) Endocrine/ Glandular disorders

i) Thyroid problem or goiter

ii) Diabetes

iii) Cushing's syndrome

Db) Dermatological or skin problems

i) Skin trouble or rash

ii) Changes in hair or nail

Dc) Respiratory / lungs

i) Tuberculosis/ pneumonia

ii) Blood in sputum

Dd) Cardiovascular

i) Hypertension

ii) Heart attacks, angina

iii) Blood clots

De) Abdominal

i) Jaundice

ii) Liver disease

iii) Black or bloody stools

iv) Colon cancer

Df) Urinary

i) Blood in urine

ii) Kidney stones

iii) Sexual dysfunction

Dg) Neurological

i) Temporary loss of vision, speech or strength

ii) Impaired memory or confusion

iii) Stroke

iv) Panic attacks

v) Epilepsy

Dh) For men

i) Prostate problem (Eh i)

Di) For women

- i) At what age did your menstrual periods begin? (Eii)
- ii) Do you face irregularity in menstrual periods? (Ei ii)

E. INQUIRY ABOUT DEFECATION

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

F (i) Medication

Diseases (F i)	Drugs (F ii)	Dossage (F iii)

F (ii) Prebiotic/probiotic Supplementation
G. 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							
Fermented Beverages							
Curd							
Lassi							
Buttermilk							
Others							

H. 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:_____)			

APPENDIX V

COMPLIANCE CALANDER

Name		COMPLIANCE CARD				
Subject Code						
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31	32	33	34	35
36	37	38	39	40	41	42
43	44	45	Please cross the day on which you consumed the product Please return the empty sachet, and unconsumed packets			

