

Appendices

Appendix I

QUESTIONNAIRE FOR SCREENING OF ADULT FEMALES- PHASE I

CODE NO: _____

DATE: _____

1. Name of the respondent:

2. Address:

3. Contact no: (M) _____ (C) _____

4. Age:

5. Menopausal status:

- a) Pre Menopause
- b) Pari Menopause
- c) Post Menopause
- d) Hysterectomy
- e) Pregnancy

6. Pregnancy (for premenopausal)

- a) Yes
- b) No

7. Anthropometric details:

Weight (kg)	
Height (cm)	
BMI (kg/m ²)	



Appendix II**QUESTIONNAIRE FOR DETAILED RISK FACTOR ANALYSIS OF ADULT FEMALES- PHASE I**

CODE NO: _____

DATE: _____

A. BACKGROUND INFORMATION

1. Name:
2. Age:
3. Address:
4. Contact no.: (M) (R)
5. Religion:
 - a) Hindu
 - b) Muslim
 - c) Sikh
 - d) Christian
 - e) Jain
 - f) Other
6. Educational level:
 - a) Illiterate
 - b) Primary
 - c) Secondary
 - d) Higher secondary
 - e) Graduate
 - f) Post graduate
 - g) Others
7. Marital status:
 - a) Unmarried
 - b) Married
 - c) Divorcee
 - d) Widow/widower
8. Occupation:
 - a) Unemployed
 - b) Unskilled labour
 - c) Housewife
 - d) Service
 - e) Business
 - f) Retired
9. Type of family:
 - a) Nuclear
 - b) Joint
 - c) Extended
11. No. of family members:
12. Total income:



B. REPRODUCTIVE HEALTH

1. At what age did you start menstruating?

2. Pregnancy related information:

No. of pregnancies	No. of children	No. of abortions	No. of still births	Age of first pregnancy

3. Do you still have menses?

a) Yes

b) No

4. If yes, are your menses:

a) Regular

b) Irregular

5. If no, when did you have your previous menses?

6. Menopausal symptoms:

Sr. No	Symptom	Severity				
		Not present	Mild	Moderate	Severe	Very Severe
	Vasomotor					
1	Hot Flashes					
2	Night Sweats					
	Somatic					
3	Headaches					
4	Muscle/ joint pains					
5	Numbness/ tingling in parts of body					
6	Feeling dizzy/ faint					
7	Pressure/ tightness in body/head					
8	Heart beating strongly					
9	Lack of energy/ feeling tired					
	Psychological					
10	Feeling tense/nervous					
11	Excitable					
12	Concentration					



	difficulties					
13	Depressed/unhappy					
14	Irritable					
15	Loss of interest in things					
16	Crying spells					
17	Difficulty in sleeping					
	Urogenital					
18	Dryness of vagina/ pain during sex					
19	Urine incontinence					
20	Pain during urination					
21	Any changes in voice					

7. Are you undergoing any hormonal replacement therapy?
a) Yes b) No
8. Menopausal state:
9. Have you undergone a PAP smear and mammography at any point of time?

	Yes/No	When
PAP Smear		
Mammography		

10. Are you aware of self breast examination?
a) Yes b) No
11. If yes, how often do you practice it?

C. FAMILY HISTORY

Type	Mother	Father	Sibling 1	Grand-parents
Obesity				
Diabetes				
Hypertension				
CHD				
Hyperlipidemia				
Stroke				
Hypo/ Hyperthyroidism				
Asthma				
Cancer				
Any other (Specify)				



D. MEDICAL HISTORY

1. Do you go for regular general health checkups?
a) Yes b) No
2. If yes, How often?
3. Is there any sudden weight gain/loss (>5 kg) at any point of your life?
a) Yes b) no
4. If yes specify the reason and age:

	Reason	Age
Weight Gain		
Weight loss		

5. Present medical problems

Sr. No	Medical problem	Yes/No
1	Obesity	
2	Diabetes	
3	Hypertension	
4	CHD	
5	Hyperlipidemia	
6	Stroke	
7	Hypo/Hyperthyroidism	
8	Asthama	
9	Cancer	
10	Gastritis	
11	Acidity	
12	Constipation	

6. Are you taking any medication presently?
a) Yes b) No
7. Any kind of nutritional supplements taken:
a) Yes b) No

If yes, specify:

Type of supplement	Dosage	Frequency



8. Any sign and symptoms seen:

- | | |
|--|---------------------------|
| a) Fatigue/ Tiredness/ Lack of energy to do work | e) Look pale |
| b) Headache | f) Cramps/Muscle Weakness |
| c) Loss of appetite | g) Numbness |
| d) Breathlessness | h) Any other |

E. LIFE STYLE HISTORY

General habits:

Sr. No.	Type	Currently (Frequency)	Past (Frequency)
1	Tobacco		
	Pan		
	Patiki		
	Gutka		
	Patti		
	Cheekni		
2	Smoking		
	Bidi		
	Cigarette		
3	Alcohol		

- Are you suffering from depression or anxiety?
 - Yes
 - No
- Sleeping pattern
 - Peaceful
 - Disturbed
- Average hours of sleep:
- Do you take packed lunch at the office?
 - Yes
 - No

F. DIETARY HISTORY

- What type of diet do you take?
 - Vegetarian
 - Non vegetarian
 - Ovo-lactarian



2. Type of cooking oil purchased:
3. Quantity of cooking oil used per month/ per year:
4. Do you use the same type of oil for the whole year?
 - a) Yes
 - b) No
5. If no, duration of changing:
6. How do you use the oil which remains after deep frying?
 - a) Again use it for deep frying some other day
 - b) Use it in preparing vegetables
 - c) Discard it
7. Which milk do you generally use?
 - a) Cow
 - b) Buffalo
 - d) Packed (specify)
 - e) Other
8. Quantity of salt purchased in a month:
9. Quantity of sugar purchased per month:
10. Do you use RO or any other water purifying system at your home?
 - a) Yes
 - b) No

If yes since when you are using it?

G. ANTHROPOMETRIC MEASUREMENTS

1. Weight (kg): _____
2. Height (cm): _____
3. Waist Circumference (cms): _____
4. Hip circumference (cms): _____

H. BIOPHYSICAL MEASUREMENTS

1. Body Fat %: _____
2. Blood Pressure: Systolic BP (mm of Hg): _____
3. Diastolic BP (mm of Hg): _____



I. 24 HOUR DIETARY RECALL (ONE DAY)

Meal time	Name of the foodstuff	Ingredients	Raw weight (g)	Cooked volume (ml)
Morning				
Mid morning				
Lunch				
Evening tea				
Dinner				



J. FOOD FREQUENCY QUESTIONNAIRE

Food item	Daily	3times a week	Weekly	Monthly	Never	Amount
Vitamin B12 and folic acid rich food						
Green Leafy Vegetables						
Legumes						
Nuts						
Egg						
Fish						
Mutton						
Chicken						
Liver						
Kidney						
Trans fat rich food						
Samosa						
Pakodas/Bhajiya						
Biscuits						
Cake/ Pastry						
Milk based sweets						
Fried sweets						
Chips						
Sev/Namkeen						
Popcorn						
Puff						
Maggie						
Khari/Nankhatai						
French Fries						
Burger/vada pav						
Pizza						



K. INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE (2002)

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

_____ **days per week**

☐

No vigorous physical activities



Skip to question 3

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐

Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

_____ **days per week**

☐

No moderate physical activities



Skip to question 5



4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**
_____ **minutes per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

☐ No walking → **Skip to question 7**

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**
_____ **minutes per day**

☐ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hours per day**
_____ **minutes per day**

☐ Don't know/Not sure



Appendix III**QUESTIONNAIRE FOR SUPPLEMENTATION PHASE**

(Overweight/ obese subjects)

CODE:_____

DATE:_____

1. Name of the respondent:

2. Address:

3. Contact no: (M)

(C)

4. Age:

5. Menopausal status:

a) Pre Menopause

c) Post Menopause

b) Pari Menopause

d) Hysterectomy

6. Pregnancy

7. Anthropometric, Biophysical and Biochemical profile:

Weight (kg)	
Height (cm)	
BMI (kg/m ²)	
SBP (mmHg)	
DBP (mmHg)	
FBS (mg/dl)	

8. Brief medical and life style history:

Disease	Presence
Diabetes	
Hypertension	
CHD	
Cancer	
Others(specify)	
Life Style Factors	



Habit of Smoking (Present)	
Habit of Tobacco chewing (Present)	
Vigorous Physical Activities like heavy lifting, aerobics, digging, running etc.	
Thyroid disorder	
Any allergy to flaxseeds	

9. Food frequency for omega-3 rich foods

Food items	Daily	2-3 times in a week	4-5 times in a week	Once a week	Rarely	Never
Flaxseeds						
Flaxseeds oil						
Olive oil						
Soya bean						
Cod liver oil						
Walnut						
Fishes						



Appendix IV

CONSENT FORM FOR CROSS SECTIONAL STUDY ON ADULT FEMALES- PHASE I

Study Title: Cardio-metabolic profile of adult female subjects (30-60 y) of Vadodara

Guide

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Purpose of the study

With the changing sedentary lifestyle prevalence of risk of developing non communicable diseases like diabetes, cardiovascular diseases, cancer is increasing. Overweight, obesity, hypertension, tobacco chewing, alcohol intake, less physical activity, low intake of fruit and vegetables are major risk factors of developing these diseases. In the recent years the prevalence of overweight, obesity and hypertension is on a rise among women and is a cause of concern. Menopausal status can also affect development of such diseases. Therefore the present study will provide insight of the major causes lying behind development of non-communicable diseases in women between 30-60y of Vadodara.

Protocol of the study

Data regarding general information, family history, medical history, life style pattern, diet pattern, 24 hour diet recall and food frequency will be collected through a pre tested semi structured questionnaire. Anthropometric measurements will be taken using standard instruments and protocol. Automatic blood pressure measurement instrument will be used to measure BP and body fat analyser to obtain body fat percent. Blood (10ml) will be drawn once in fasting state i.e. after a fast for more than 8-10 hours. Following biochemical estimations will be done:



- CBC
- Ferritin
- Fasting blood glucose
- Insulin
- Glycated Hb
- Lipid Profile
- Hs CRP
- Vitamin B12
- Folic Acid
- Thyroid profile
- Liver profile
- Kidney profile

Costs

The tests, procedures, visits and cost of fruit, that are a part of this study will cost only your time and travel. There is no financial compensation for your participation in this research, but all the costs incurred on fruit and blood tests will be borne by the researcher.

Possible benefits and risks

The study will help to increase the scientific knowledge to assess the impact of phytochemical and antioxidant rich apple in the management of non-communicable diseases. Only disposable needles and syringes will be used for drawing blood, which will be done by a trained and authorized technician.

Confidentiality

Your identity in this study will be treated as confidential. The results of the study, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you.

Right to Withdraw

Your decision to join in this study is voluntary. You may quit at any time, for any reason, without notice. We hope you will take part for the entire time of the study because we need all of the information to draw correct conclusions.

Your joining is important to the success of this study. Unless many volunteers like you agree to join, this study will not be possible. In order for this study to be valid, you



should not join other health studies where you would be assigned to receive a medication, special test, or special treatment.

Availability of results and consultation

A copy of the report will be provided to you for your future use. If any abnormality seen in the biochemical profile you would be advised to contact your doctor, with reports provided to you.

Voluntary Consent

If you have any questions about any part of the study or your rights as a volunteer, the person in-charge for collection of information will be on hand to answer them before you sign this consent form. Also, if you have any questions about your rights as a participant in this study, please call the investigators listed at the beginning of this form. Before you sign this form, please ask any questions on any part of this study that is unclear to you.

Investigator's Statement

I have provided an explanation of the above research program, the purpose of the study and the possible benefits and risks. The participant was given an opportunity to discuss these procedures and to ask any additional questions.

Signature of Investigator with date

Participant statement

I, _____, certify that I have read, or had read to me, and that I understand the description of the study "Cardio-metabolic profile of adult female subjects (30-60 y) of Vadodara" By signing this form I am attesting that I have read and understood the information above.

I have had a chance to ask questions about the study. I understand that I may ask further questions at any time. I have been explained to my satisfaction the purpose of this study and I am also aware of my right to opt out of the study any time.

Participant name and signature

Date:



Appendix V**CONSENT FORM FOR SUPPLEMENTATION OF FLAXSEEDS- PHASE III**

Study title: Metabolic and inflammatory response to supplementation of whole roasted flaxseeds in pre-menopausal overweight/obese female subjects

Guide

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Purpose of the study

As the prevalence of overweight and obesity is increasing in India, people are more prone to the co morbidities associated with it. thus, the study is planned in a way to provide the cumulative beneficial effects of flax seeds which are rich in omega 3 fatty acids, fibres and lignans and have shown hypoglycemic, hypolipidemic, cardio-protective and weight reduction properties which could help to prevent the development of associated health risks.

Protocol for the study

If you decide to join in this supplementation trial, according to random placement you will be asked to either consume flaxseeds on daily basis (5g or 10g) or will be placed in control group where you have maintain your usual lifestyle. Your body measurements, body fat and blood pressure will be taken twice (at the beginning and after 8 weeks). A trained laboratory technician will draw your blood (10ml) to estimate your FBS, Insulin, hematological profile, lipid profile, Hs-CRP, liver function test, kidney function test and thyroid function test at baseline. Another blood sample will be drawn to estimate the effect of flaxseed consumption (in supplementation group) and no consumption (in control group) on your biochemical profile after 8 weeks.



Cost

This study requires only your time and co-operation. All the costs incurred on flaxseeds and blood tests will be borne by the researchers and there is no financial compensation for your participation in this research.

Possible benefits and risks

The study will help to increase the scientific knowledge to assess the impact of flaxseeds in the management of non-communicable diseases. The risk of participation in the study is minimal as only disposable needles and syringes will be used for drawing blood, which will be done by a trained and authorized technician. Allergy from flaxseeds is rare. 5-10g of flaxseeds has not shown any side effects in human studies. Still if you feel any kind of side effects due to ingestion of the flaxseeds you can immediately stop the consumption and inform the researcher about the side effects.

Confidentiality

Your identity in this study will be treated as confidential. The results of the study, including laboratory or any other data, may be published for scientific purposes but will not give your name or include any identifiable references to you.

Right to withdraw

Your decision to join in this study is voluntary. You may quit at any time, for any reason, without notice. We hope you will take part for the entire time of the study because we need all of the information to draw correct conclusions.

Your joining is important to the success of this study. Unless many volunteers like you agree to join, this study will not be possible. In order for this study to be valid, you should not join other health studies where you would be assigned to receive a medication, special test, or special treatment.

Voluntary consent

If you have any questions about any part of the study or your rights as a volunteer, the person in-charge for collection of information will be on hand to answer them before you sign this consent form. Also, if you have any questions about your rights as a participant in this study, please call the investigators listed at the beginning of this form. Before you sign this form, please ask any questions on any part of this study that is unclear to you.



Availability of results and consultation

A copy of the report will be provided to you for your future use. If any abnormality seen in the biochemical profile you would be advised to contact your doctor, with reports provided to you. If you have any questions about any part of the study or your rights as a volunteer, the person in-charge for collection of information will be on hand to answer them before you sign this consent form. Also, if you have any questions about your rights as a participant in this study, please call the investigators listed at the beginning of this form. Before you sign this form, please ask any questions on any part of this study that is unclear to you.

Investigator's statement

I have provided an explanation of the above research program, the purpose of the study and the possible benefits and risks. The participant was given an opportunity to discuss these procedures and to ask any additional questions.

Signature of Investigator with date

Participant statement

I, certify that I have read, or had read to me, and that I understand the description of the study. By signing this form I am attesting that I have read and understood the information above. I give my consent to be included as a subject in the study being carried out by Prof. Uma Iyer and Pooja Gaur in the M. S. University to investigate "Metabolic and inflammatory response to supplementation of whole roasted flaxseeds in pre-menopausal overweight/obese female subjects" I understand that the study requires the participants to consume the flaxseeds daily or not to consume flaxseeds for a period of 8 weeks depending upon the group and to undergo blood test to measure various parameters twice for which, the participants would be required to provide 10ml blood sample.

I have had a chance to ask questions about the study. I understand that I may ask further questions at any time. I have been explained to my satisfaction the purpose of this clinical trial and I am also aware of my right to opt out of the study any time.

Participant name and signature

Date:



Appendix VI

COMPLIANCE FORM FOR FLAXSEED SUPPLEMENTATION

NAME: _____

CODE NO.: _____

Please tick the box after consuming daily dose of flaxseed. If not consumed on a particular day, mark it cross (×)

September, 2013

M	T	W	T	F	S	S
						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						

October, 2013

M	T	W	T	F	S	S
	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			

