

APPENDICES

APPENDIX 1

Volunteer consent form for “Prevalence of Non Alcoholic Fatty Liver Disease (NAFLD) in Association with Cardio Metabolic Risk Factors in Type 2 Diabetic Patients.”

Study Title

Prevalence of Non Alcoholic Fatty Liver Disease (NAFLD) in Association with Cardio Metabolic Risk Factors in Type 2 Diabetic Patients.

Principal Investigator

Prof. Uma Iyer
Head, Department of Foods & Nutrition
Faculty of Family & Community Sciences
M S University of Baroda, Vadodara
(M) 9824056921

Person in-charge for data collection

Ms. Kuhu Roy
Doctoral Fellow, Department of Foods & Nutrition
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(M) 9898468153

Purpose of the study

Diabetes mellitus is a major non-communicable chronic diseases and non alcoholic fatty liver disease (NAFLD) is a common condition, which is still under-recognised and under-diagnosed in India. It is a multifactorial disease that is caused by a complex interplay of genetics, diet, and lifestyle. It is emerging as another major lifestyle disease. NAFLD is strongly associated with obesity, type-2 diabetes mellitus and hyperlipidema. It has been reported that fatty liver influences the severity of hepatic insulin resistance in type-2 diabetes mellitus. The hepatic fat content predicts the amount of daily insulin needed to maintain adequate glycemic control. NAFLD is a common chronic condition of which diabetic fatty liver accounts for a large proportion. Your participation in the study will help you to know about your liver.

Protocol for the study

If you decide to join in this part of the study, you will be asked to provide information regarding medical and family history of lifestyle diseases, details of the diet and physical activity patterns with the help of a questionnaire. Your body measurements will also be taken to assess your nutritional status. A trained laboratory technician will draw your blood (10ml) to estimate your liver function test, kidney function test, haemoglobin, lipid profile and hs-crp. If you will be willing to undergo sonography, an abdominal ultrasound will be performed on you to determine the presence of fat in the liver, by an experienced radiologist. The ultrasound will be painless.

Costs

The tests, procedures and visits that are a part of this study and will cost only your time and travel. 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 predictor variables that lead to non alcoholic fatty liver disease and may help in early diagnosis and treatment for NAFLD in the diabetic patients. The risk of participation in the study is minimal as it is a cross sectional study. If you are diagnosed with a fatty liver, follow up sessions will be conducted and you will be asked to consult your physician.

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. If a fatty liver is detected during the study period, you will be told about it and the information will be given to your doctor.

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 in entire study because we need all of the information to draw correct conclusions. If you decide to leave the study, it will not affect your regular medical care. 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 or any complaints 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. 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, including possible alternatives, 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 and I give my consent to participate in this research study. I understand that I may quit the study at any time. I have had a chance to ask questions about the study. I understand that I may ask further questions at any time.

Participant name and signature: _____

Date:

Code No. _____

Date _____

APPENDIX 2

Questionnaire for “Prevalence of Non Alcoholic Fatty Liver Disease (NAFLD) in Association with Cardio Metabolic Risk Factors in Type 2 Diabetic Patients.”

Name:

Address:

Age:

Contact No.

Gender:

Family History

Type	Mother	Father	Siblings	Grandparents
Obesity				
Diabetes				
Hypertension				
CHD/Stroke				
Cancer				
Other				

Present medical problems:

Health Problem	Date of diagnosis	Treatment (Medicine)	Dosage and frequency
Diabetes Mellitus			
Other (specify)			

Consumption of health supplements (specify):

Tobacco/ cigarette smoking: Yes / No

ANTHROPOMETRY

- Weight:
- Height:
- BMI:
- WC:
- HC:
- WHR:
- WSR:
- AVI:

BIOPHYSICAL MEASUREMENTS

- Systolic BP (mmHg):
- Diastolic BP (mmHg):

DIETARY PATTERNS

- Type of diet: Vegetarian / Ovo-vegetarian / Non-vegetarian
- Cooking oil:
- Consumption of same type of oil throughout the year? Yes / No
- If yes, duration of changing:
- Salt brand and monthly consumption:
- Sugar monthly consumption:
- Frequency of consumption of outside food:

24 HOUR DIETARY RECALL

Meal time	Name of the foodstuff	Ingredients	Raw weight (g)	Cooked volume (ml)
Breakfast and mid morning snack				
Lunch				
Evening tea				
Dinner				

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

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

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

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

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 3

QUALITY OF LIFE ASSESSMENT OF TYPE 2 DIABETES SUBJECTS
WITH NON-ALCOHOLIC FATTY LIVER DISEASE

Broad Areas	A	F	O	S	N
Role Limitation Due To Physical Health					
1 How often do you miss work because of your diabetes?					
2 A person with diabetes has the requirement of adhering to a schedule for eating and taking regular medication. How often does this affect your work?					
3 How often does diabetes affect your efficiency at work?					
4 How often do you find diabetes limiting your social life?					
5 To what extent do you avoid travelling because of your diabetes?					
6 Compared to others of your age are your social activities limited because of your diabetes?					
Physical Endurance (last three months)					
7 How often has your overall health problems limited the kind of vigorous activities you can do like lifting heavy bags/objects, running, skipping, jumping.					
8 How often has your overall health problems limited the kind of moderate activities you can do like moving a table, carrying groceries or utensils.					
9 How often has your overall health problems limited you from walking uphill or climbing 1-2 floors.					
10 How often has your overall health problems limited you from walking 1-2 km at a stretch.					
11 How often has your overall health problems limited you from bending, squatting, or turning.					
12 How often has your overall health problems limited you from eating, dressing, bathing, or using the toilet.					
Symptom Botherness					
13 How many times in the past three months have you had thirst/dry mouth?					
14 How many times in the past three months have you felt excessive hunger?					
15 How many times in the past three months have you had frequent urination related to diabetes management?					

(C) General Health

Questions	P	F	G	VG	E
16 In general would you say your health is					
	Not at all	A little	Moderate	Very much	Extremely well
17 How well are you able to concentrate in everything like working, driving, reading etc?					
	Always	Frequently	Often	Sometimes	Never
18 How many times in the past three months have you had fatigue/ felt very tired?					

(D)Treatment Satisfaction

Questions	Very dissatisfied	Moderately dissatisfied	Neither dissatisfied or satisfied	Moderately Satisfied	Very satisfied
19 How satisfied are you with your current diabetes treatment?					
20 How satisfied are you with amount of time it takes to manage your diabetes?					
21 How satisfied are you with the amount of time you spend getting regular checkups (once in 3 months)?					
22 A person with diabetes needs to exercise for 35-45 min, 4 times a week. Keeping this in mind how satisfied are you with the time you spend exercising?					

(F) Financial Worries

Questions	Very expensive	Little expensive	Reasonable	Not at all expensive
23 What do you think about the cost involved in your management of diabetes?				

Questions	A lot	Highly	Little	Very little	Not at all
24 To what extent has your priority of expenditure shifted towards diabetes management?					
25 To what extent has your family budget got affected by the expenses related to the management of diabetes?					
26 To what extent has your diabetes limited your expenditure on other aspects of life?					

(G) Emotional/Mental Health

Questions	Very dissatisfied	Moderately dissatisfied	Neither dissatisfied or satisfied	Moderately Satisfied	Very satisfied
27 How satisfied are you with yourself?					
28 How satisfied are you with your personal relationships					
29 How satisfied are you with the emotional support you get from your friends and family?					

Questions	Always	Frequently	Often	Sometimes	Never
30 How often are you discouraged by your health problems?					

Questions	Not at all	A little	Moderate	Very much	Extremely well
31 All people want to fulfill certain roles and lead their lives in a purposeful manner. To what extent do you feel that you have been able to lead your life in the same way?					

(H) Diet Satisfaction

Questions	Always	Frequently	Often	Sometimes	Never
32 How often do you feel because of your diabetes a restriction in choosing your food when eating out?					
33 How often do you eat the food items that you shouldn't, in order to hide the fact that you are having diabetes.					
	No choice	Very little	Little	Enough	A lot
34 As you have diabetes, how much choice do you feel you have in eating your meals or snacks away from home e.g. if you go in a party and there is a buffet where there are also a lot of fried snacks and desserts would you be able to make enough choice?					

APPENDIX 4

BOOKLET ON MANAGEMENT OF NON-ALCOHOLIC FATTY LIVER DISEASE IN TYPE 2 DIABETES (ENGLISH VERSION)

**Lifestyle Management of
Type II Diabetes Mellitus
and
Non Alcoholic Fatty Liver Disease**



Developed by: Kuhu Roy and Uma Iyer
Department of Foods And Nutrition,
Faculty of Family and Community Sciences,
The Maharaja Sayajirao University of Baroda
Baroda - 390002

What is Diabetes Mellitus?

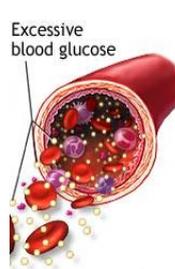
It is a condition where your body is not able to make enough insulin or where the insulin is not being used properly, leading to a rise in the blood glucose

↓

Insulin enables your body to get energy from glucose - the sugar broken down from the foods you eat

↓

An imbalance between insulin and blood glucose levels can result in high glucose (hyperglycemia) or low blood glucose (hypoglycemia) levels in your blood.



Excessive
blood glucose

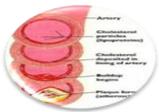
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Types Of Diabetes Mellitus

		
<p>Type 1 diabetes</p> <p>Insulin deficiency</p>	<p>Type 2 diabetes</p> <p>Non Utilization Of Insulin</p>	<p>Gestational diabetes mellitus</p> <p>Elevated blood sugar during pregnancy</p>

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Who All Are At Risk of Having Type II Diabetes Mellitus ?

 <p>Family history of diabetes</p>	 <p>Body Mass Index ≥ 23</p>	 <p>Elevated blood pressure</p>	 <p>Waist measurement >90 cms (in men) & >80 cms (in women)</p>
 <p>Inactive lifestyle</p>	 <p>High Intake Of Fat</p>	 <p>Low Intake Of Fruits, Vegetables</p>	 <p>Heart disease</p>

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Signs and symptoms, How to confirm Diabetes ?

Increased thirst (polydipsia)

Increased urination (polyuria)

Hunger (polyphagia)

Tiredness and weight loss

Pain and numbness in hands or feet

Blurred vision

	Glucose in mg/dl
Fasting Blood Sugar	≥126
Post Prandial Blood Sugar (after meal)	≥200

FBS

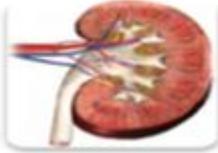
Normal	Borderline	Confirmed Diabetes
100	125	>126

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What are the possible complications that a diabetic patient can have?



Eyes (optic)



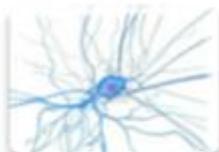
Kidneys (renal)



Heart (cardiovascular) and blood vessels



Liver (hepatic)



Nerves (neuropathic)

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Know Your ABCs Of Diabetes

A

A1C levels

B

Blood pressure

C

Cholesterol levels

	Good	Fair	Poor
HbA1c (%)	<6.0	<7.0	>7.0
Blood pressure (mm Hg)	<120/80	<130/85	>130/85
Total cholesterol (mg/dl)	<180	<200	>200
LDL (bad) cholesterol (mg/dl)	<100	<130	>130
Plasma triglyceride (mg/dl)	<150	<180	>180
HDL (good) cholesterol (mg/dl)	>45	>40	<40

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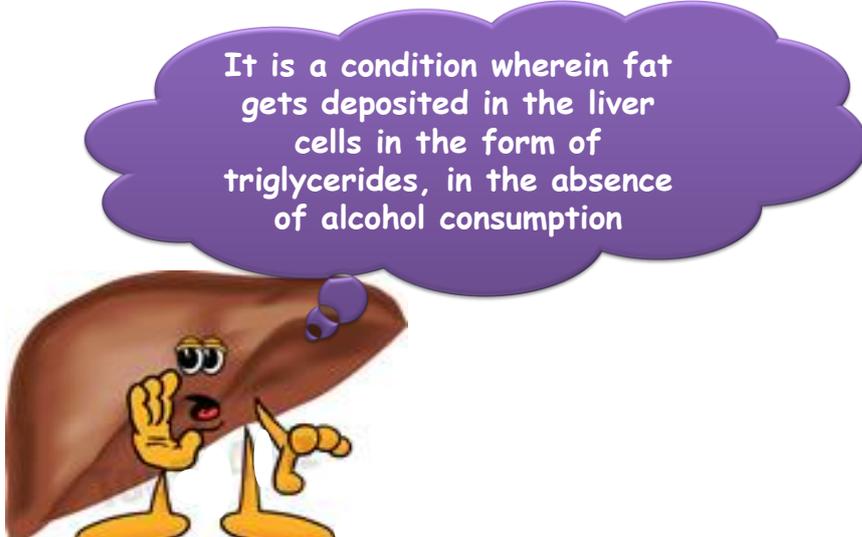
Glycated Hemoglobin (HbA1c)

It tells you about your blood sugar trends in the past three months

- >8 Action Suggested
- 7-8 Good
- 6-7 Goal
- <6 Excellent

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What is Non-Alcoholic Fatty Liver Disease ?



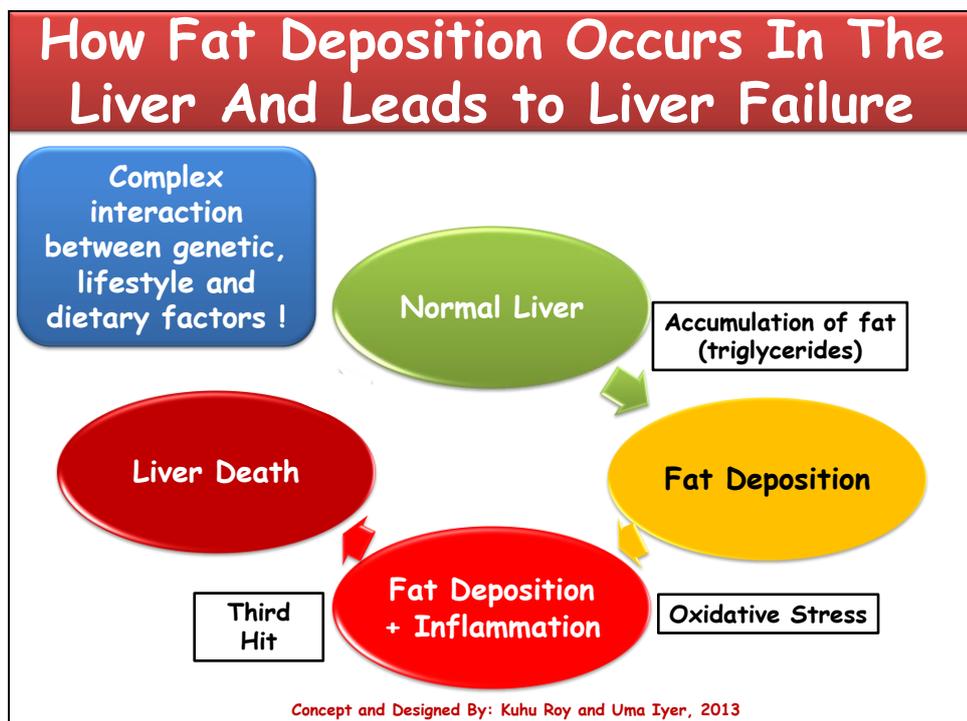
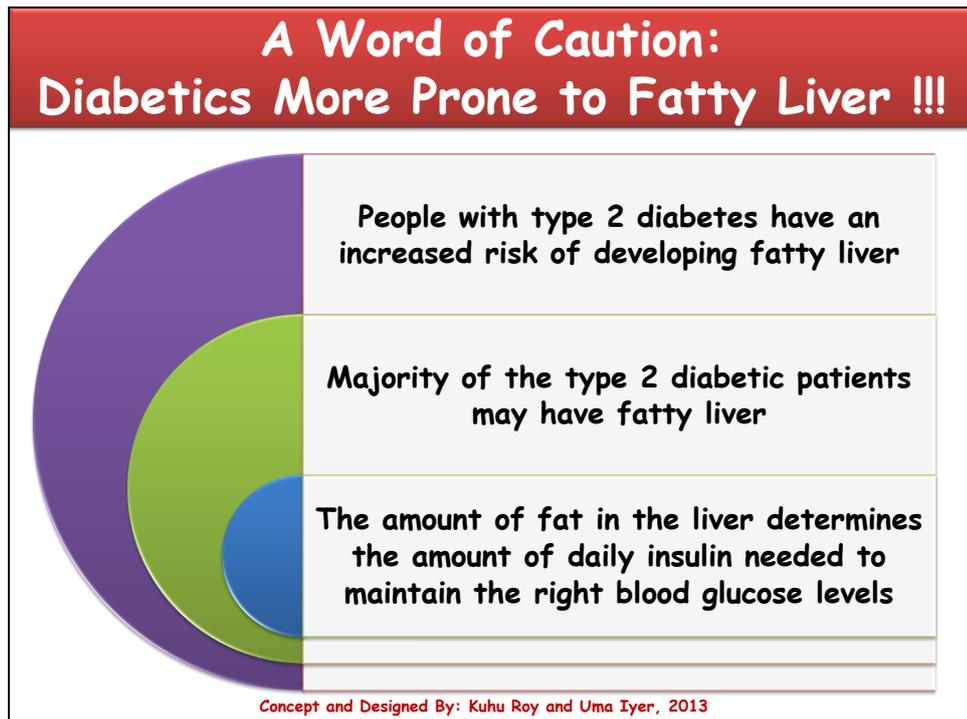
It is a condition wherein fat gets deposited in the liver cells in the form of triglycerides, in the absence of alcohol consumption

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You Are At Risk Of Having A Fatty Liver If...

Health	Nutrition	Medicines
BMI >23	Lack of energy and protein in the diet	Glucocorticoids
Diabetes Mellitus	Rapid Weight Loss	Oestrogens
BP >120/80 mm Hg	Stomach and intestine surgery	Cancer treatment drugs
Triglycerides >150 mg/dl	Food intake through tubes	Blood thinning drugs

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Indicators Of Fatty Liver and Diagnosis

Ultrasound of Liver (For confirmation of fatty liver)

Elevated storage form of Iron (ferritin)

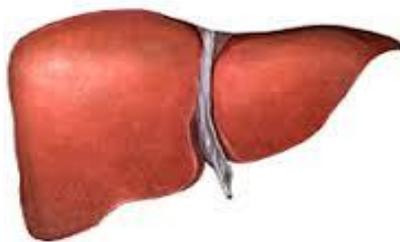
Elevated liver enzymes (AST:ALT ratio <1, GGT >35 U/L)

BMI >23, BP >120/80 mm Hg, disturbed lipid profile, Type II diabetes

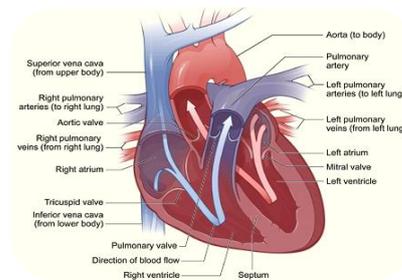
Usually No Symptoms !

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Why is treatment for fatty Liver necessary ?



To prevent development of liver related complications



To reduce the risk of heart and blood vessels disease

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What Should I Do If I Am Diagnosed With Fatty Liver?



Weight Control
Physical Activity
Healthy Diet



Cholesterol and
Triglyceride
Lowering
Medicines



Medicines to
increase the
utilization of
Insulin



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Points To Be Kept In Mind



Maintain a healthy weight or a BMI of less than 23



WC not to exceed 35" in men and 31" in women



Make half the plate fruits & vegetables



Switch to fat free or low fat milk

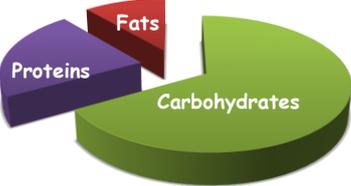
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	Reduce salt intake (less than 5 grams/day, if high BP patient, less than 3 grams/day)
	Drink water instead of other beverages
	Regular physical activity for at least 30 minutes on most days of the week
	Avoid smoking and use of tobacco in any form

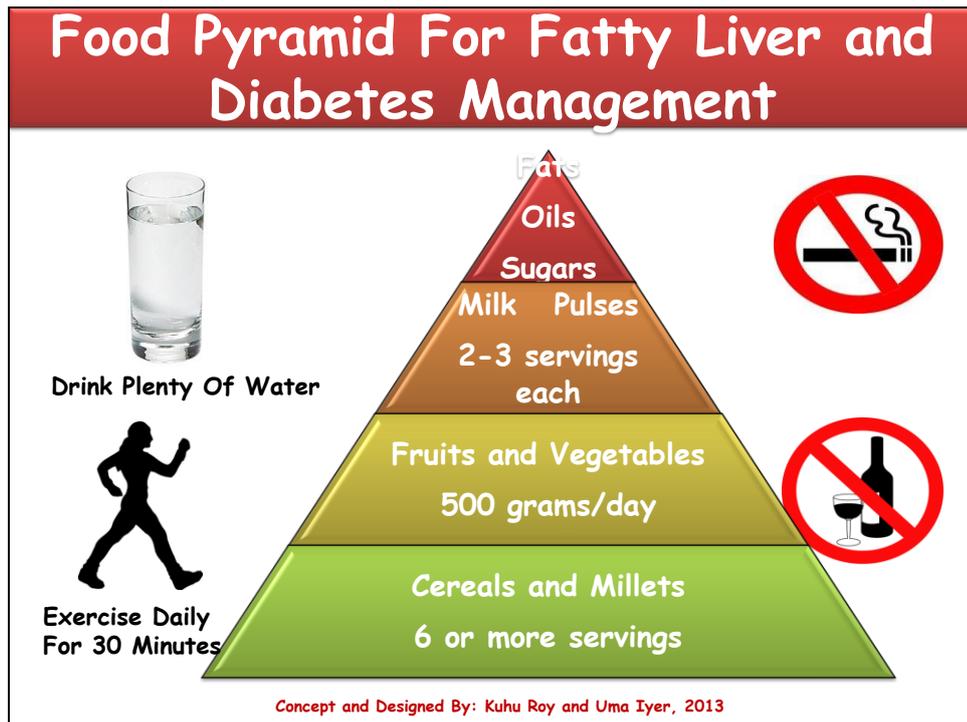
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Dietary Management Of Diabetes Mellitus And Non Alcoholic Fatty Liver Disease

		
Carbohydrates	Protein	Fats
55-60% of total calories	15-20% of total calories	20-25% of total calories



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Simple Sugars and Artificial Sweeteners

In Moderation

Use of artificial sweeteners in limited quantity is acceptable

Limit consumption of foods with maida and suji cooked with vanaspati and added sugar, honey and jaggery

Choose breakfast cereal that contain no or less added sugars

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Dietary Fibre



- Consume high fiber foods such as legumes, whole-grain products, fruits and vegetables
- Choose whole fruits more often than fruit juice
- Start the day with a whole grain breakfast cereal. Top it with fruit for even more fibre
- 30-40 g/day preferably from natural sources



Sources of Fibre

Barley, nuts, seeds, beans, lentils, peas, apple wheat bran, vegetables, whole grains

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Whole Grains

Replace maida, suji with whole wheat flour, multigrain flour
 Consume at least half of all grains as whole grains, pulses

Grain Products To Avoid

Maida/Suji

White bread

Noodles

Biscuits / Bakery goods

Grain Products to choose

Whole wheat flour

Whole grain / multigrain bread

Oatmeal

Ground flaxseed

Brown rice

Barley

Pulses

Concept and Designed By: Kuhu Roy and Uma Iyer, 2013

Proteins and Dairy Products



- Protein 1 g/kg body weight.
- Incorporate legumes, soyabean that are an excellent source of soluble fibre, plant sterols.
- Choose a mix of cereals, millets, pulses
- Sprout legumes
- If meat is consumed, extra lean meat should be the choice. Eat fatty fish twice at least per week if religion permits



- Increase intake of fat-free or low-fat milk and milk products
- Use low fat milk when preparing desserts

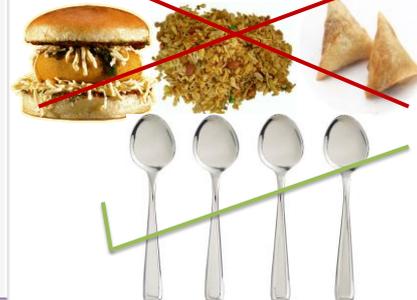
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Fats and Oils

Type of fat	Recommendation
Total fat	Less than 20-25% of total daily calories
Saturated fat	Less than 7% of total daily calories
Trans fat	Less than 1% of total daily calories
Cholesterol	Less than 200 mg/d for adults with high levels of LDL -C or those who are taking cholesterol-lowering medicines

Healthy Practices

- Cook with minimum oil.
- Avoid foods high in trans-fats.
- Avoid re-use of cooking oils.
- Avoid ghee, butter, whole milk & cream in food preparation.
- Cooking oil: 0.5 kg/month/person



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Oil Blends



Cooking Oil Combinations
Groundnut/Seasame/Rice bran + Mustard
Groundnut/Seasame/Rice bran + Canola
Groundnut/Seasame/Rice bran + Soyabean
Palmolein + Soyabean
Safflower/ Sunflower + Palmolein + Mustard
Sunflower / Safflower + Palmolein / Olive
Safflower / Sunflower + Groundnut /Seasame/ Rice bran



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Tips For Healthy Eating

Avoid	<ul style="list-style-type: none"> • Sugar items
Use Sparingly	<ul style="list-style-type: none"> • Fermented foods, Ragi, Rice, refine flours, fats
Use Moderately	<ul style="list-style-type: none"> • Snacks with cereal-pulse, cereal-pulse-veg. Minimum processing and having less fat
Use Liberally	<ul style="list-style-type: none"> • Whole grains, Cereal-Pulse, Cereal-Pulse-Veg, Fruits and Vegetables

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Calorie Intake Based On Weight



Category	Calorie Requirement
Overweight	20 kcal/kg/day
Ideal weight	30 kcal/kg/day
Underweight	40 kcal/day

Calorie Intake Based On Activity



Lifestyle	Daily calorie requirement
Sedentary	20-25 Kcal/kg of IBW
Moderately active	26-30 Kcal/kg of IBW
Strenuous	31-35 Kcal/kg of IBW

Ideal body weight (%)

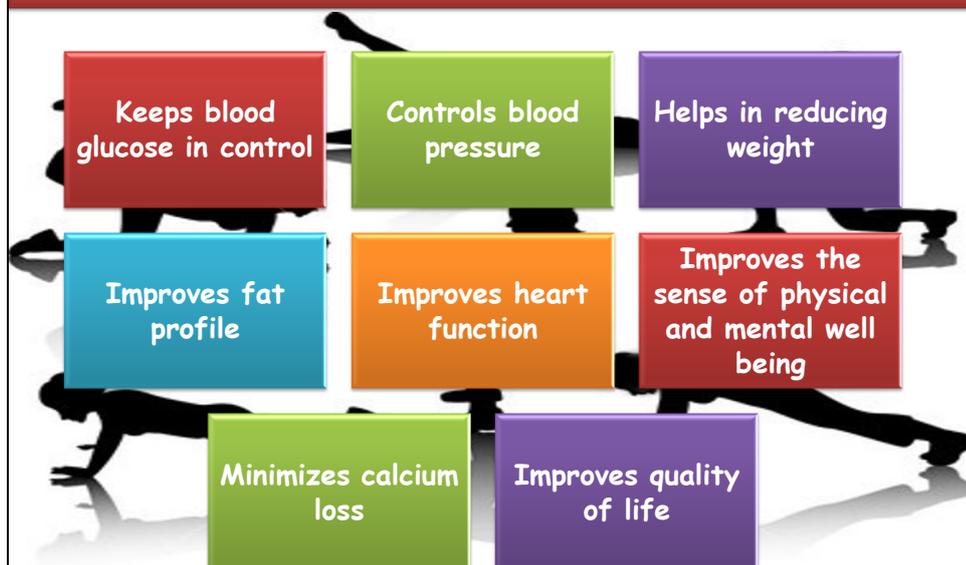
>80- <100

<120

>120

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Physical Exercise Helps You As It...



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Things You Need To Keep In Mind For The Correct Way of Exercise

- 1 • Feet should be inspected daily (before and after exercise) for cuts, blisters and infections
- 2 • Exercise should be avoided in extreme hot and cold weather conditions
- 3 • The exercise program should start slowly, build up gradually
- 4 • Include exercises that you are familiar with
- 5 • Always carry quick acting carbohydrate to be used in the event of hypoglycemia

Concept and Designed By: Kuhu Roy and Uma Iyer, 2013

APPENDIX 5

Volunteer consent form for “Role of Interpersonal Counselling in The Management of Non Alcoholic Fatty Liver Disease in Type 2 Diabetic Patients.”

Principal Investigator

Prof. Uma Iyer
Head, Department of Foods & Nutrition
Faculty of Family & Community Sciences
M S University of Baroda, Vadodara
(M) 9824056921

Person in-charge for data collection

Ms. Kuhu Roy
Doctoral Fellow, Department of Foods & Nutrition
Faculty of Family & Community Sciences
M S University of Baroda, Vadodara
(M) 9898468153

Purpose of the study

Non alcoholic fatty liver disease (NAFLD) is a common condition, which is still under-recognised and under-diagnosed in India. It is a multifactorial disease that is caused by a complex interplay of genetics, diet, and lifestyle. It is emerging as another major lifestyle disease. NAFLD is strongly associated with obesity, type-2 diabetes mellitus and hyperlipidemia. It has been reported that fatty liver influences the severity of hepatic insulin resistance in type-2 diabetes mellitus. The hepatic fat content predicts the amount of daily insulin needed to maintain adequate glycemic control. NAFLD is a common chronic condition of which diabetic fatty liver accounts for a large proportion. Lifestyle modification can be used as a strategy to manage NAFLD along with T2DM.

Protocol For The Study

If you decide to join this study, you will be allocated in either of the two groups; one that will receive nutrition counselling for four months and the other group that will remain just on the consultation of physician. You will be asked to provide information regarding medical and family history of lifestyle diseases, details of the diet and physical activity patterns with the help of a questionnaire. Your body measurements will also be taken to assess your nutritional status. A trained laboratory technician will draw your blood (10ml) to estimate your liver function test, kidney function test, haemoglobin, lipid profile and hs-crp. If you will be willing to undergo sonography again, the changes that occur in the liver during the four months period can be observed. The ultrasound will be painless. The sonography reports along with the blood parameters reports will be provided to you.

Costs

The tests, procedures and visits 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 blood tests and ultrasound will be borne by the researcher.

Possible benefits and risks

The study will help to increase the scientific knowledge to assess the impact of lifestyle modification in the management of non alcoholic fatty liver disease. Follow up sessions will be conducted and you will be asked to consult a physician.

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. If a fatty liver is detected during the study period, you will be told about it and the information will be given to your doctor.

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. If you decide to leave the study, it will not affect your regular medical care. 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.

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If you have any questions/complaints about any part of the study or your rights as a volunteer, the person in-charge for collection of information will be hands on to answer it. 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, including possible alternatives, 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 and I give my consent to participate in this research study. I understand that I may quit the study at any time. I have had a chance to ask questions about the study. I understand that I may ask further questions at any time.

Participant name and signature: _____

Date:

APPENDIX 6

KNOWLEDGE ATTITUDE AND PRACTICES (KAP) OF TYPE 2 DIABETES PATIENTS WITH NON-ALCOHOLIC FATTY LIVER DISEASE (NAFLD)

Name:

Age:

Gender:

1. What is diabetes?
 - a. Elevation of blood glucose
 - b. Non-utilisation of insulin
 - c. Inadequate production of insulin
 - d. Do not know
2. What are the risk factors for diabetes ?

<ol style="list-style-type: none"> a. Family history of diabetes b. Excess body weight c. Hypertension d. Heart disease e. Sedentary lifestyle f. High intake of fats 	<ol style="list-style-type: none"> g. High intake of sugars h. Low intake of fruits and vegetables i. Stress j. Do not know k. Excess waist circumference
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3. What are the symptoms of diabetes?

<ol style="list-style-type: none"> a. Increased thirst b. Increased urination c. Excess hunger d. Unexplained weightloss e. Blurred vision 	<ol style="list-style-type: none"> f. Fatigue g. Pain and numbness in hand and feet h. Delayed wound healing i. Do not know
---	---
4. How can diabetes be diagnosed?
 - a. Oral glucose tolerance test
 - b. Fasting blood sugar test
 - c. HbA1c test
 - d. Urine sugar test
 - e. Do not know
5. Diabetes affects which organs?
 - a. Eye
 - b. Kidney
 - c. Nerves
 - d. Feet
 - e. Heart
 - f. Liver
 - g. Do not know
6. Which points are to be kept in mind for diabetes management?
 - a. Timely medication
 - b. Balanced diet
 - c. Physical activity
 - d. Regular blood test
 - e. Do not know

7. Have you ever heard about non-alcoholic fatty liver disease (NAFLD) ?
 - a. Yes
 - b. No
8. If yes, then what is NAFLD ?
 - a. Accumulation of fat in the liver
 - b. Do not know
9. What are the risk factors for NAFLD?
 - a. Obesity
 - b. Insulin resistance/T2DM
 - c. Hypertension
 - d. Altered lipid profile
 - e. Surgery
 - f. Ingestion of hepatotoxic drugs
 - g. Do not know
10. How does diabetes predispose you to NAFLD?
 - a. Fatty liver influences the severity of hepatic IR in T2DM
 - b. The hepatic fat content predicts the amount of daily insulin required to maintain adequate glycemic control
 - c. Do not know
11. How does NAFLD occur and progress?
 - a. Diet rich in sugars
 - b. Diet rich in fats
 - c. Insulin resistance
 - d. Do not know
12. What are the symptoms of NAFLD?
 - a. Asymptomatic
 - b. Fatigue
 - c. Abdominal discomfort
 - d. Do not know
13. How is NAFLD diagnosed?
 - a. Ultrasound
 - b. Liver function test
 - c. Both of the above
 - d. Lipid profile
 - e. Do not know
14. Why is treatment of NAFLD necessary?
 - a. To prevent liver complications
 - b. To prevent heart disease
 - c. To prevent diabetes complications
 - d. Do not know
15. How can NAFLD be treated?
 - a. Weight control
 - b. Balanced diet
 - c. Metformin/ Insulin sensitizing drugs
 - d. Fat lowering drugs
 - e. Physical activity
 - f. Do not know

**ATTITUDE AND PRACTICE TOWARDS HEALTH RELATED BEHAVIOUR
AMONG TYPE 2 DIABETES PATIENTS WITH NON-ALCOHOLIC FATTY
LIVER DISEASE PATIENTS**

16. Are you happy with your current exercise regime?
 - a. Yes
 - b. No
17. What dietary restrictions do you keep in mind while eating?
 - a. Avoid sweets
 - b. Avoid sweet fruits
 - c. Avoid fatty and oily food
18. Do you miss taking your medicine?
 - a. Yes
 - b. No
19. How often do you visit the diabetologist (PRE)? Henceforth, how often will you visit the diabetologist (POST)?
 - a. Once in 3 months
 - b. Once in 6 months
 - c. Once in a year
 - d. Once in 2 years
 - e. Never
20. How often do you get FBS checked (PRE)? Henceforth, how often will you get FBS checked (POST)?
 - a. Weekly
 - b. Fortnightly
 - c. Once a month
 - d. Once in 2 months
 - e. Once in 3 months
 - f. Never
21. How often do you get HbA1c checked (PRE)? Henceforth, how often will you get HbA1c checked (POST)?
 - a. Once in 3 months
 - b. Once in 6 months
 - c. Once in a year
 - d. Once in 2 years
 - e. Never
22. How often do you get your BP checked (PRE)? Henceforth, how often will you get your BP checked (POST)?
 - a. Weekly
 - b. Fortnightly
 - c. Once a month
 - d. Once in 2 months
 - e. Once in 3 months
 - f. Never
23. How often do you get lipid profile checked (PRE)? Henceforth, how often will you get lipid profile checked (POST)?
 - a. Once in 6 months
 - b. Once in a year
 - c. Once in 2 years
 - d. Never

24. How often do you get your kidney profile checked (PRE)? Henceforth, how often will you get your kidney profile checked (POST)?
- Once in 6 months
 - Once in a year
 - Once in 2 years
 - Never
25. How often do you go for eye examination (PRE) ? Henceforth, how often will you go for eye examination (POST)?
- Once in 6 months
 - Once in a year
 - Once in 2 years
 - Never
26. Have you ever gone for a liver ultrasound, other than the study protocol (PRE) ? Henceforth will you go for a liver ultrasound (POST) ?
- Yes
 - No

APPENDIX 7

Code No. _____

Date _____

Role of Interpersonal Counselling (IPC) in The Management of Non Alcoholic Fatty Liver Disease (NAFLD) in Type 2 Diabetic Patients

Address:

Name:

Contact No.

Age:

Gender:

Family History

Type	Mother	Father	Siblings	Grandparents
Obesity				
Diabetes				
Hypertension				
CHD/Stroke				
Cancer				
Other				

Present medical problems:

Health Problem	Date of diagnosis	Treatment (Medicine)	Dosage and frequency
Diabetes Mellitus			
Other (specify)			

Consumption of health supplements (specify):

Tobacco/ cigarette smoking: Yes / No

ANTHROPOMETRY

- Weight:
- Height:
- BMI:
- WC:
- HC:
- WHR:
- WSR:
- AVI:

BIOPHYSICAL MEASUREMENTS

- Systolic BP (mmHg):
- Diastolic BP (mmHg):

DIETARY PATTERNS

- Type of diet: Vegetarian / Ovo-vegetarian / Non-vegetarian
- Cooking oil:
- Consumption of same type of oil throughout the year? Yes / No
- If yes, duration of changing:
- Salt brand and monthly consumption:
- Sugar monthly consumption:

24 HOUR DIETARY RECALL

Meal time	Name of the foodstuff	Ingredients	Raw weight (g)	Cooked volume (ml)
Breakfast and mid morning snack				
Lunch				
Evening tea				
Dinner				

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

5. 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**

6. 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

7. 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**

8. 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

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**

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

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

Don't know/Not sure

9. 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 8

Volunteer Consent Form For “Impact Of *Tinospora Cordifolia* Supplementation In The Management Of Diabetic Dyslipidemia”

Purpose of the study: Incorporation of herbal medicines can be an important strategy, to be used as a combination therapy for the management of the medical problems. There is a lot of scope and hope in this traditional medicinal plant- *Tinospora cordifolia*. It is widely used in ayurvedic system of medicine for its medicinal properties. Due to its deep rooted qualities, its demand has been increasing tremendously. Although, its importance and immense medicinal potential is well known, still it remains underutilised in the management of dyslipidemia especially in type 2 diabetic subjects. Being an easily available and economical ayurvedic resource, it can be utilised by the community for the control and management of various diseases and disorders.

Study Design and protocol: Information regarding medical and family history of lifestyle diseases, details of the diet and physical activity patterns will be assessed with the help of a questionnaire. Your body measurements will also be taken twice (at the beginning and the end of the study) to assess your nutritional status. A trained laboratory technician will draw your blood (10ml) to estimate your liver function test, kidney function test, haemoglobin, lipid profile and hs-crp. Another blood sample will be drawn to estimate the effect of *Tinospora cordifolia* supplementation on your biochemical profile after 2 months of supplementation.

If you decide to join this study, you will be randomly allocated in either of the two groups;

Group A: You will be asked to consume 500mg Guduchi capsules, Himalaya Herbal Health Care product, for a period of 60 days along with your other fat lowering drugs.

Group B: You will be asked to only continue your regime of fat lowering drugs.

Costs: The tests, procedures, visits and cost of the capsules, 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.

Possible benefits and risks: The study will help to increase the scientific knowledge to assess the impact of *Tinospora cordifolia* in the management of non-communicable diseases, especially diabetic dyslipidemia. The risk of participation in the study is minimal as the supplemented product is ayurvedic in nature. If at all, any side effects are reported, the subject will be asked to discontinue with the consumption of the capsules.

Participation in this research does not provide any direct benefit to you. However, the results from this study may confirm that there is a potential for *Tinospora cordifolia* supplementation in the management of diabetic dyslipidemia. The individual findings (changes in the lipid and glycemic profile after the supplementation) will be conveyed to you and the blood estimations reports will be provided to you.

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. Also, if you have any questions or complaints 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, including possible alternatives, 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 and I give my consent to participate in this research study that is being carried out by Prof (Dr.) Uma Iyer and Ms. Kuhu Roy in the M. S. University to investigate the benefits of *Tinospora Cordifolia* supplementation in the management of diabetic dyslipidemia. I understand that I may or may not get to eat *Tinospora cordifolia* (Guduchi capsules, 500mg) on a daily basis as a part of the study for a period of 60 days. The period of consumption of *Tinospora cordifolia* will be preceded and followed by a blood test to measure various parameters for which, I will be required to provide 10ml blood sample. 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. I understand that I may quit the study at any time. I have had a chance to ask questions about the study. I understand that I may ask further questions at any time.

Participant Signature with date _____

APPENDIX 9

QUESTIONNAIRE FOR IMPACT OF TINOSPORA CORDIFOLIA SUPPLEMENTATION IN THE MANAGEMENT OF DIABETIC DYSLIPIDEMIA

Background Information

Name:

Age:

Gender: M / F

Address:

Contact number:

Medical Profile

Duration of diabetes:

Secondary ailments:

Drug profile:

Supplements consumed:

Addictions:

Family history of NCDs:

Anthropometric profile

Weight:

Height:

Waist circumference:

Hip circumference:

SBP:

DBP:

Food patterns

Food choice: Vegetarian / Ovo-vegetarian / Non-vegetarian

Type of oil consumed:

24 HOUR DIETARY RECALL

Meal time	Name of the foodstuff	Ingredients	Raw weight (g)	Cooked volume (ml)
Breakfast and mid morning snack				
Lunch				
Evening tea				
Dinner				

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

9. 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**
10. 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

11. 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**
12. 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

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

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

Don't know/Not sure

11. 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