Clinical Trial Details (PDF Generation Date :- Mon, 15 Nov 2021 13:26:11 GMT)

CTRI Number	CTRI/2018/04/013179 [Registered on: 11/04/2018] - **Trial Registered Prospectively**
Last Modified On	06/08/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Behavioral
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Intensive dietary counseling in non alcoholic fatty liver disease
Scientific Title of Study	Efficacy of intensive dietary counseling on metabolic, anthropometric and ultrasound parameters among adult Indian Non alcoholic fatty liver disease (NAFLD) patients: A Randomized control trial

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Piyush Ranjan
Designation	Associate Professor
Affiliation	AIIMS, New Delhi
Address	Department of Medicine All India Institute of Medical Sciences New Delhi South West DELHI 110029 India
Phone	9268714198
Fax	
Email	drpiyushaiims@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Piyush Ranjan
Designation	Associate Professor
Affiliation	AIIMS, New Delhi
Address	Department of Medicine All India Institute of Medical Sciences New Delhi South West DELHI 110029 India
Phone	9268714198
Fax	
Email	drpiyushaiims@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Piyush Ranjan
Designation	Associate Professor
Affiliation	AIIMS, New Delhi
Address	Department of Medicine All India Institute of Medical Sciences New Delhi South West DELHI 110029 India
Phone	9268714198

Fax	
Email	drpiyushaiims@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Facilities provided by AIIMS, New Delhi

Primary Sponsor

Primary Sponsor Details	
Name	NONE
Address	NA
Type of Sponsor	Other [NO FINANCIAL SUPPORT IS REQUIRED]

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Piyush Ranjan	All India Institute of medical sciences	Department of Medicine All India Institute of Medical Sciences New Delhi South West DELHI	9268714198 drpiyushaiims@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
INSTITUTE ETHICS COMMITTEE AIIMS NEW DELHI	Approved	25/08/2017	Yes

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Clinically stable patients with Non Alcoholic Fatty Liver Disease

Intervention / Comparator Agent

Type	Name	Details
Intervention	Intensive dietary counseling along with standard care	5 face to face and 4 telephonic dietary counseling sessions by a trained dietitian
Comparator Agent	Standard therapy	NAFLD patients receiving standard therapy

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	1. Patients diagnosed with NAFLD in the age group of 18- 60 years attending the OPD 2. Willing to give written consent for participation in the study 3. Patients with BMI between 25-29.9kg/m2

Exclusion Criteria

Exclusion Criteria	
Details	1. Alcohol intake >30gm/day in males or 20gm/day in females 2. Inability to attend follow-up session 3. Pregnant, lactating women or pregnancy anticipated during study 4. Diagnosed cases of Diabetes 5. Thyroid disease not controlled by medication

	6. Already participating in a formal weight loss program or on medication to promote weight loss 7. Significant changes in diet and exercise habits in previous 3 months resulting in weight loss >5% of body weight. 8. Known cases of endocrine disorders including Cushing's syndrome or history of long term steroid intake or any other secondary causes of fatty liver. 9. Known case of psychiatric illness

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
1) Change in CAP score in fibroscan after 6 months 2) Reduction of liver enzymes 3) Reduction in grade of steatosis through abdominal ultrasound 4) Reduction in 5% of the body weight among patients of NAFLD with normal liver enzymes and 10% of body weight among patients of NAFLD with raised liver enzymes 5) Reduction in waist circumference 6) Reduction in fat percentage through body composition analysis 7) Change in HOMA IR	3 and 6 months

Secondary Outcome

Outcome	Timepoints
none	none

Target Sample Size	**Total Sample Size=**140 **Sample Size from India=**140 **Final Enrollment numbers achieved (Total)=**140 **Final Enrollment numbers achieved (India)=**140
Phase of Trial	N/A
Date of First Enrollment (India)	01/05/2018
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**2 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	none
Brief Summary	NAFLD is a rapidly emerging chronic liver disorder that is set to become a critical global health problem. Diet is an important pathogenic factor in the progression of this disease (Eslamparast et al, 2015). Lifestyle management is the first line treatment of NAFLD. But, NAFLD

being an asymptomatic disease, adherence to treatment and lifestyle modification advice is poor. Despite the integral role of nutrition counseling in the holistic management of NAFLD, more than 50% of patients do not readily accept its importance nor do they follow the dietary advice (Yasutake et al, 2014). Weight reduction is typically recommended as an initial step in the management of NAFLD, but ef?cacy data are lacking (Promrat et al, 2010).Traditional dietary counseling methods have failed to bring about desired changes. Merely telling the patient about the potential disease progression, prescribing medications and suggesting lifestyle modification by the physician is not enough. Interventions should be aimed at modifying dietary behaviour to reduce the risk of disease progression. Dietary prescriptions need to be reinforced through multiple sessions to have positive patient outcomes (Schiller MR et al, 1998). The role of intensive nutrition counseling has been well documented in many diseases such as diabetes (Lazo et al, 2010), Cardiovascular disease (American Diabetes foundation, 2005) etc. An American pilot study in the year 2005 has also shown that intensive nutrition counselling can be beneficial in improving histology in NASH patients (Huang et al, 2005). Another Randomized controlled trial from Hong Kong has shown that community based lifestyle modification program is effective in reducing and normalizing liver fat in NAFLD patients (Sun Wong et al, 2013).

NAFLD patients should receive intensive counseling for adherence to a low carbohydrate and low saturated fat diet, avoidance of fructose-enriched soft drinks and increased consumption of fruits and vegetables (Bugianesi et al, 2005). Regular follow up with a dietitian should be an integral part of the treatment protocol. This will help the patients to overcome the barriers that come in the way of adherence to the prescribed diet. Periodic reinforcement of dietary advice, assistance in the form of ready to refer diet education material, easy to prepare healthy recipes, dietitian led support groups to increase motivation to follow the diet regime, are some ways to improve the dietary compliance in these patients.

Prior studies related to the effects of nutrition counseling on weight reduction in NAFLD have been uncontrolled, have used poorly de?ned patient populations, and non standardized weight loss interventions, and lacked a well-accepted primary outcome for NASH (Clark et al, 2006).

Also, the efficacy of dietary counseling in NAFLD has not been clearly defined in the Indian context, as there have been no randomized, controlled trials of intensive dietary therapy in outpatients with NAFLD. Rigorously conducted, randomized controlled trials are needed in this area.

Hence, this pilot study aims to compare the efficacy of intensive dietary counseling along with standard care versus standard care alone in improving the metabolic, ultrasound and anthropometric parameters in patients with NAFLD.

Hypothesis

Intensive dietary counseling along with standard care may be superior to standard care alone in improving metabolic, ultrasound and anthropometric parameters in patients with NAFLD.

Objectives

Primary objective

1. To design and develop an intensive dietary intervention program for adult NAFLD patients.

2. To assess the efficacy of intensive dietary counseling along with standard care in comparison to standard care alone in improving treatment outcomes in adults diagnosed with NAFLD.

Secondary objectives

1. To assess the anthropometric, biochemical, clinical and dietary profile of patients with NAFLD.