



Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 10:55:59 GMT)

CTRI Number	CTRI/2011/12/002227 [Registered on: 14/12/2011] - Trial Registered Retrospectively	
Last Modified On	03/12/2013	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Yoga & Naturopathy Other (Specify) [Peer Support]	
Study Design	Randomized, Parallel Group, Multiple Arm Trial	
Public Title of Study	A trial to understand the effect of Yoga therapy and Peer support on women with Type II Diabetes Mellitus	
Scientific Title of Study	A randomised Control Trial on the effectiveness of Yoga therapy and Peer support on women with Type II Diabetes Mellitus	
Secondary IDs if Any	Secondary ID	Identifier
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Peers for Progress,N.Carolina and Amrita Institute of Medical Sciences			
Primary Sponsor	Primary Sponsor Details			
Name	Amrita Institute of medical sciences with monetary support from Peers for progressNCarolina			
Address	Amrita Institute of Medical sciences,Ponnekara P.O Ernakulam.Kerala			
Type of Sponsor	Research institution and hospital			
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
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Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institutional Ethics Committee, Amrita Institute of Medical Sciences, Cochin	Approved	29/08/2011	No
Regulatory Clearance Status from DCGI	Status	Date		
	Not Applicable	No Date Specified		
Health Condition / Problems Studied	Health Type	Condition		
	Patients	Type II Diabetes mellitus		
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Yoga	<ul style="list-style-type: none"> • Yoga therapy sessions for 60 min on two days a week • On the other days they will be asked to practice at home and to maintain a diary • 60 min session- 25 min-Surya namaskara-12 steps 5-7 min-Deep relaxation-Muscle relaxation technique 15 min Asanas Supine position-Pavanamuktasana Prone position-Bhujangasana,S 	



		halabhasana Sitting position-Ardhamatsyaendrasan a 15 min-2 types of pranayama-Nadi shudhi& Bhramari The duration of therapy is three months
Intervention	Peer Support	Peer Group: Peer mentors will be identified by health workers and three-four of them will be trained .The criteria for eligibility will be ? Having had type 2 Diabetes for at least one yr with a RBS 250 mg/dl in the last reading ? Judged by the investigation team to be generally adherent to treatment and behaviour change regime ? Capacity and commitment to undergo the training required ? Understanding of the importance of patients confidentiality ? Undertaking to liase with the concerned Dr if unanticipated problems arose during the course of their peer support activity • Peer Mentors Training: They will undergo training by the research team in two morning sessions. This will focus on basics of type 2 Diabetes and issues relating to working with groups and confidentiality • Peer support meetings: One Face to Face meeting with the patient in a week for about 45-60 min on assistance in applying disease management or prevention plans in daily life, providing emotional and social support and pro active flexible ongoing support.Each peer mentor will visit 10-12 women with Type II DM. This will be followed up by a telephone call. Peer review:A review of the activities will be undertaken once a month by the investigators The period of intervention is three months.
Comparator Agent	Control	This group will receive the general standard of care. They will continue their antidiabetes medication and will be followed up for a period of three months.

Inclusion Criteria

Inclusion Criteria	
Age From	30.00 Year(s)
Age To	65.00 Year(s)
Gender	Female
Details	Adult females between 30-65 yrs with a diagnosis of type 2 diabetes



	mellitus within the last 8 years. The diabetes must be uncontrolled with Hba1c equal to or more than 7% with normal cognitive function. 	
Exclusion Criteria	Exclusion Criteria	
	Details	Those already practicing Yoga, Meditation and those with known Diabetes Complications, pregnant & lactating women, any serious medical condition, on Homeo and Ayurvedic treatment and BMI>35.
Method of Generating Random Sequence	Computer generated randomization	
Method of Concealment	Centralized	
Blinding/Masking	Open Label	
Primary Outcome	Outcome	Timepoints
	Fasting Blood Sugar & Hba1c, Quality of Life measured by WHOQOLbref and Pharmacological adherence measured by Morisky scale.	3 months
Secondary Outcome	Outcome	Timepoints
	Body Mass Index, waist Hip ratio	3 months
Target Sample Size	Total Sample Size=120 Sample Size from India=120 Final Enrollment numbers achieved (Total)= Final Enrollment numbers achieved (India)=	
Phase of Trial	N/A	
Date of First Enrollment (India)	11/04/2012	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=1 Months=4 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Completed	
Publication Details	none	
Brief Summary	<p>Prevalence of Type 2 Diabetes has increased rapidly in the Asian Population. In India 30 million people are Diabetic which will rise to about 60 million by 2017 (Kutty & Raju, IJMR, 2010). As India experiences a rapid health transition, the mismatch between health care needs and resources is widened by an expanded list of health conditions that vie for attention from policy makers and public health action. The complexities are further compounded when policy has to prioritise on the basis of diseases burden, cost effectiveness and equity (Reddy, 2003).</p>	
	<p>The increasing rate of Diabetes in Asia is associated with a strong gene-environmental interaction which is propelled by lifestyle changes caused by modernisation. The overall prevalence rate of diabetes in urban and rural areas combined was estimated as 62.47 per thousand (Bela et al, 2004). There is evidence that the population of Kerala is also having a high prevalence of major risk factors for Chronic Non Communicable Disease (Thankappan et al, 2010). Estimates also show that Kerala may become the Diabetic Capital of India. The age standardized prevalence for Diabetes in Kerala works out to 14.9% in men and 13.2% in women (diabetoz.com-HAP study).</p>	
	<p>Diabetes mellitus has been described as the most complex and demanding of any chronic disease to manage. This is because it requires : modification of dietary practices, weight management,</p>	



exercise, monitoring of body fluids (blood,urine),footcare, use of drugs, learning new technical skills such as blood glucose monitoring. Health care systems need to be redesigned to deliver chronic care that is founded on existing primary care facilities, but supported by good referral systems.

Inaction will affect millions of lives-often the lives of those who have the least(Antonio et al,2011).To deal with the increasing morbidity and mortality it is important to develop and evaluate low cost interventions that build on available resources and can empower patients (Michele,2007).It is necessary to look at alternatives which are not resource intensive and which is nearer to the community that people live in. Yoga and Peer support are two such alternatives. Yoga holds promise as a therapeutic intervention and health promotion measure, though studies are not conclusive. Similarly Peer support is also considered a promising, potentially low cost, flexible means to supplement formal health care support. Peer support has been defined as the provision of support from an individual with experiential knowledge based on a sharing of similar life experiences or prevention plans in daily life.

The future offers challenges and opportunities to deal with the burden to the individual suffering from a chronic disease like Diabetes.

The null hypothesis is that Yoga and Peer support do not have any effect on women with Type II DM.The alternative hypothesis is that Yoga and Peer support are effective adjuncts to treatment.