EFFECT OF YOGA ON LIPID PROFILE AMONG DIABETIC AND PRE-DIABETIC POPULATION IN URBAN BANGALORE - ONE ARM PRE-POST DESIGN

DISSERTATIONSUBMITTED BY

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UNDER THE GUIDANCE OF SRI. PADMASRI GUDAPATI



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Padmasri Gudapati Assistant Professor S-VYASA University Bangalore **DECLARATION**

I, hereby declare that this study was conducted by me at Swami Vivekananda $Yog\bar{a}$

Anusandhana Samsthana (S-VYASA), Bangalore, under the guidance of Padmasri Gudapati,

M.Sc S-VYASA University Bangalore.

I also declare that the subject matter of my dissertation entitled "EFFECT OF YOGA ON LIPID

PROFILE AMONG DIABETIC AND PRE-DIABETIC POPULATION IN URBAN

BANGALORE(JIGANI) - ONE ARM PRE-POST DESIGN" has not previously formed the basis of

the award of any degree, diploma, associate-ship, fellowship or similar titles.

DATE:

PLACE: Bangalore

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STANDARD INTERNATIONAL TRANSLITERATION CODE USED TO TRANSLITERATE

SANSKRIT WORDS

$$pa = \Psi$$

au

sa

स

ABSTRACT

Introduction

Type 2 diabetes is a major health problem in many countries including India. Most of the studies have reported the effect of yoga on improving Quality of Life (QoL) in diabetic patients. This study investigated the impact of Yoga module prepared by AYUSH MANTRALAYAM on lipid profile in diabetic and pre diabetic patient.

Methods

This One Arm Pre Post study includes 33 participants of diabetic and pre diabetic in which male (n=18) female (n=15) which took part in yoga intervention for three months. Yoga Program included 1 Hour practice consisting of Breathing Exercises, Loosening practices, Suryanamaskara, Asanas and Pranayama. Biochemical parameters such as Cholesterol, triglycerides, High density lipoprotein (HDL), Low density Lipoprotein(LDL) were determined at begining and at the end of three months.

Result

Results showed that mean value of Cholesterol reduced from 175.24±56.70 to 168.15±50.43, Triglycerides reduced from 178.15±137.62 to 160.66±113.73, LDL reduced from 96.33±51.02 to 94.39±44.93. However the reductions in Cholesterol, Triglycerides and LDL are not statistically significant. High density lipoprotein's mean value decreased from 44.45±6.54 to 43.45±12.39.

Conclusion

From the statistical analysis of the results obtained in the present study we may say that three months of practice of yoga improves the Lipid levels however a higher sample size can conform a statistically significant improvement in Lipid profile.

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1 INTRODUCTION

1.1 OVERVIEW OF DIABETES AND PRE DIABETES

Diabetes is the very serious, chronic metabolic disease that prevent the body to utilise glucose completely or partially. It is characterised by raised glucose level in the body and alteration in the carbohydrate, protein and fat metabolism. This can be due to failure in the formation of insulin or liberation or action(B Shrilakshmi, 2014). Prediabetes is a condition in which patient's blood glucose levels are higher than normal but do not meet diagnostic criteria for type 2 diabetes mellitus (T2DM) (Utas& Warren, 2017). The American Diabetes Association (ADA) defines prediabetes as either fasting plasma glucose of 100 to 125 mg/dL, 2-hour plasma glucose of 140 to 199 mg/dL after a 75-g oral glucose tolerance test, or hemoglobin A1c (HbA1c) of 5.7 to 6.4% (American Diabetes Association, 2017).

Diabetes is caused either due to pancreas not producing enough insulin or the cells of the body not responding properly to the insulin produced. There are three main type of diabetes mellitus: Type 1 DM results from the pancreas failure to produce enough insulin also called as "insulin dependent diabetes mellitus" or "juvenile diabetes". The cause of type 1 DM is unknown but it is said that it is because of the autoimmunity or genetic predisposition. Type 2 DM begins with insulin resistance, it is a condition in which cells fails to respond to insulin properly. This form is also referred as "non-insulin-dependent diabetes mellitus" (NIDDM) or "adult-onset diabetes". The cause of type 2 DM is excessive body weight and lack of physical exercise. The Gestational diabetes is the third main form of diabetes which occurs when a pregnant women develop high blood glucose level without previous history of diabetes.

1.2 DIAGNOSIS CRITERIA

According to American Diabetes Association diabetes can be provisionally diagnosed with any of the three criteria listed below(American diabetes Association, 2017).

1.2.1 DIAGNOSIS CRITERIA FOR DIABETES

FPG \$126 mg/dL(7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 h.* "OR" 2-h PG \$200 mg/dL(11.1 mmol/L) during an OGTT. The test should be performed as

described by the WHO, using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.* "OR"

A1C \$6.5% (48 mmol/mol). The test should be performed in a laboratory using a method that

is NGSP certified and standardized to the DCCT assay.* "OR"

In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, a random plasma glucose \$200 mg/dL (11.1 mmol/L).

1.2.2 DIAGNOSIS CRITERIA OF PRE-DIABETES

Impaired Fasting Glucose (IFG), a category, when fasting plasma glucose is between 100 and 125mg/dl and in Impaired Glucose Tolerance (IGT) is when 2-hour sample results of the oral glucose tolerance test are between 140 and 199 mg/dl.

Categories of increased risk for diabetes (Pre-diabetes)*

FPG 100 mg/dL (5.6 mmol/L) to 125 mg/dL (6.9 mmol/L) (IFG). "OR"

2-h PG in the 75-g OGTT 140 mg/dL (7.8 mmol/L) to 199 mg/dL (11.0 mmol/L) (IGT) OR

A1C 5.72 - 6.4% (39247 mmol/mol)

1.3 PREVALANCE OF DIABETES

The prevalence of diabetes (DM) is constantly increasing worldwide at an alarming rate. Over the past decade, diabetes prevalence has risen faster in low and middle-income countries compare to high-income countries. Diabetes at least doubles a person's risk of death. There was an estimated 422 million adults living with diabetes in 2014(World Health Organization, 2016). The prevalence of diabetes in India was 60 million in 2011 that is projected to increase by 63%, reaching 98 million by 2030 (McDermott et al., 2014). 77.2 million people in India have pre-diabetes. Further compounding the problem, nearly 52% of Indians are not aware that they are suffering from high blood sugar and 44 laks Indians in their most productive years-aged 20-70 years are in this category.

1.4 COMPLICATIONS

Diabetes increases the risk of serious long-term complications. People with type 2 DM are more Prone to various forms of complications, which often lead to their premature death. Years of poorly controlled hyperglycemia may lead to multiple, primarily vascular complications that affect small vessels (microvascular), large vessels (macrovascular), or

^{*}In the absence of unequivocal hyperglycemia, results should be confirmed by repeat testing.

^{*}For all three tests, risk is continuous, extending below the lower limit of the range andbecoming disproportionately greater at the higher end of the range.

both (Manjunath, Vinutha, & Raghavendra, 2015). Complications of DM account for increased morbidity, disability and mortality and represent a threat for the economies of all countries, especially the developing ones(Papatheodorou, Papanas, Banach, Papazoglou, & Edmonds, 2016). Diabetes can lead to microvascular complications such as nephropathy, retinopathy, and neuropathy. Nephropathy, retinopathy and neuropathy are nothing but the problems related to Kidney, eyes and neurons respectively (Nguyen, Shaw, & Grant, 2012). Diabetes can cause mild to severe nerve damage that can cause tingling, pain, or weakness in the foot. Eye problem is the commonly known complication of the diabetes that can lead to blindness. There is a risk of blindness, but most people who have diabetes have nothing more than minor eye disorders. Some of the most common conditions are eye insight, glaucoma, cataracts and retinopathy. Another specific complication in Diabetes is diabetic cardiomyopathy which develops independently of coronary artery disease or hypertension and it also leads to increased morbidity and mortality (Jia, DeMarco, & Sowers, 2016). Diabetes also increases the risk of macrovascular complications such as Atherosclerosis and stroke. Atherosclerosis is more common in people with diabetes mellitus than in those without. And another complication of diabetes is Diabetic kidney disease (DKD), defined as a decline in renal filtration function and/or albuminuria, affects more than 50% of patients with diabetes (Khoury et al., 2013).

1.5 MANAGEMENT

Lifestyle modifications are the cornerstone of management of Diabetes Mellitus which include modification of diet, regular exercise, management of stress and a disciplined life. Several clinical trials established that lifestyle intervention prevents Type 2 Diabetes Mellitus in high risk individuals (Dunbar et al., 2010).

1.5.1 Management ByDietaryModificatons

The aim of dietary management is maintenance of ideal body weight and desirable lipid profile. Lower consumption of total and saturated fat and processed food, and higher consumption of fibers, whole grains, and vegetables have been shown to improve glycemic control in type 2 diabetes patient. A diet adequate in fiber-containing foods usually has fewer calories, fat, and refined sugar, and is also usually rich in micronutrients and non-nutritive ingredients that have additional health benefits. A fiber-rich meal is processed more slowly in the gastrointestinal tract, thus promoting satiety. These salubrious features of a high-fiber diet

promote the treatment and prevention of overweight, obesity, cardiovascular disease, and type 2 diabetes (Rizvi, 2009).

1.5.2 Physical Activity

The role of exercise for diabetes is pronounced since ages. In everyday life one should do some physical workout. And whatever exercises a person is doing should be according to the capabilities and disabilities of that person. According to the American diabetes association regular physical activity is a part of standard treatment for diabetes. The benefits which can be gained by the physical exercise are improved glycemic control, decreased insulin concentration, prevention of cardiovascular disease, reduction in bad cholesterol, enhancement of weight loss and weight maintenance. Yoga has also been proved to be beneficial for diabetic patients.

1.6 ROLE OF YOGA

Yoga has been studied for several decades for its role in the management of several chronic diseases including hypertension, asthma, obesity, neuromuscular diseases and psychiatric illnesses (Aljasir, Bryson, & Al-Shehri, 2010). It is widely recommended to do yoga to prevent type 2 diabetes as yoga ensure reducing risk factors for type 2 diabetes by promoting weight loss, help in improving glucose levels and reducing blood pressure and lipid levels (Yang et al., 2011). Several other studies have also been done which shows that yoga helps in controlling both the symptoms and the complications associated with diabetes mellitus type II (Malhotra et al., 2004; Sahay, 2007). With multiple co-lateral benefits, Yoga is safe and simple to learn which can be practiced by even ill, elderly or disabled individuals. Being safe, simple and economical therapy, it can be considered as beneficial for DM patients (Kohli & Kohli, 2012). Integrated approach of yoga therapy (IAYT), which includes practice of yoga postures (asana), regulated breathing (pranayama), cleansing techniques (kriya), meditation and lectures on yoga has shown to reduce medication scores, plasma glucose levels, HbA1C, and serum cholesterol levels in patients with T2 diabetes mellitus (DM) (Vinutha, Raghavendra, & Manjunath, 2015).

2 LITERATURE REVIEW

All the slokas related to swadhyaya from the following scriptures have been placed in the dissertation.

Scriptures
Patanjali Yoga Sutras
Hatha Yoga pradipika
Bhagavad Gita
Taittariyaupanishad
Chandogya Upanishad

And also the following scriptures are throughly checked. Upanishads are Katha, Kena, Ishavasya, Aittariya, Mandukya, Mundaka and Karika, Svetasvetara, Brhadaranyaka. But no reference to Swadhyaya was found.

2.1 ANCIENT LITERATURE REVIEW

2.1.1 Diabetes According To SushrutaSamhita

प्रमेहपुर्वपाणामाकतर्यत्र द्दयते। किञ्चिञ्चाण्यधिकं मुत्रं त प्रमेहिणामादिशेत। क्रस्तात्यध्दाति वा यस्मित पुर्वरुपाणि मानेव। प्रवुध्दमुत्रमत्यर्थं तं प्रमेहिणमादिशेत।

pramehapurvapaaNaamaakrataryatra ddashyate | ki~nchia~nchaaNyadhikaM mutraM ta pramehiNaamaadisheta | krtstaatyardhdaati vaa yasmita purvarupaaNi maaneva |

pravrudhdamutramatyarthaM taM pramehiNamaadisheta |

(Su . ni 6/25, 26)

In Ayurvedic texts prameha (diabetes) was defined as disease, which is to be characterized with excessive urination and turbidity. The word Prameha is a combination of "Pra" upasarga (Prefix) and "Meha" a Dhatu (root). Meha is derived from the root "Mehi - Sechane" meaning Watering. In reference to disease of human body, it may have meaning of passing urine. The meaning of "Pra" is excessive in both quantity and frequency. Therefore the word Prameha means "Passing of urine profusely both in quantity and frequency.

2.1.2 Concept of swadhyaya according to ancient text

2.1.2.1 According to Patanjali

तपः स्वध्यायेश्वरप्रणिधानानि क्रिया योगः।

tapaḥ svadhyāyeiśvarapraṇidhānāni kriyā yogaḥ l

PYS-2.1

Meaning:

Practice characterized by rigor and vigilance toward itself, without attachment to the outcome, is known as kriya yoga.

शौचसंतोषतपः स्वध्यायेश्वरप्रणिधानानि नियमाः।

śaucasantosatapah svadhyāyeiśvarapranidhānāni niyamāh

PYS-2.32

Meaning:

Cleanliness (shaucha), contentment (santosha), self-discipline (tapas), learning from yourself (svadhyaya) and accepting your fate (iishvara-pranidhana) automatically translate into the practice of respect (niyama).

स्वध्यायादु इष्टदेवतासम्प्रयोगः।

svadhyāyād iṣṭadevatāsamprayogaḥl

PYS-2.44

Meaning:

Self-study and reflection on yourself (svadhyaya) brings you into contact with the desired ideal.

2.1.2.2 According to Hatha Yoga

तपः संतोष आस्तिक्यं दानयीश्वरपुजनम्।

सिद्धान्त वाक्यश्रवणं हीमती चतपो हुतम्।

नियमाद्दा संप्रोक्ता योगस्त्र विशारदैः॥

Tapaḥ santoṣa āstikyam dānayīśvarapujanam

Siddhānta vākyaśravaṇam hrīmatī catapo hrutam

Niyamādaśa samproktā yogastra viśāradaiḥ||

HY-1.16.2

Meaning:

Penance(austerity), contentment, belief (faith) in the supreme(God), charity, worship of God, listening to the recitations of sacred scriptures, modesty, a discerning intellect, japa (mantra repetition), and sacrifice are the ten observations (niyamas).

Listening to the spiritual knowledge and what ancient sages found in their first hand experience helps develop our higher faculty of knowledge. It helps us understand the spirited path and the way in which the spirit unfolds.

It preserves mental and emotional energy and it keeps one's awareness in the realm of /spiritual vibrations and aspirations.

2.1.2.3 According to Bhagavad Geeta

अनुद्वेगकरं वाक्यं सत्यं प्रियहितं च यत्। स्वाध्यायाभ्यसनं चैव वाङ्मयं तप उच्यते॥ anudvegakaram vākyam satyam priyahitam ca yat| svādhyāyābhyasanam caiva vāmmayam tapa ucyate||

BG-17.15

Meaning:

Words which cause no annoyance to others and are truthful, agreeable and beneficial, as well

as the study of the vedas and others sastras and the practice of the chanting of the divine

name this is known as penance of the speech.

द्रव्ययज्ञास्तपोयज्ञा योगयज्ञास्तथापरे।

स्वाध्यायायज्ञानयग्यश्च यतयः संशितव्रताः॥

dravyayajñāstapoyajñā yogayajñāstathāpare

svādhyāyāyajñānayaġyaśca yatayaḥ samśitavratāḥ||

BG-4.28

Meaning:

Some perform sacrifice with material possessions; some other sacrifice in the name of

austerities; others sacrifice through the name of practice of yoga; while some striving souls,

observing austere vows, perform sacrifice in the shape of wisdom through the study of sacred

texts.

अभयं सत्वसंशादीर्ज्ञानयोगव्यवस्थितिःञ

दानंदयश्च यज्ञश्च स्वाध्यायस्तप आर्जवम् ॥

Abhayam satvasamśaddhīrjñānayogavyavasthitiah

Dānamdayaśca yajñaśca svādhyāyastapa ārjavam | | |

BG-16.1

Meaning:

Absolute fearlessness, perfect purity of mind, constant fixity in the yoga of meditation for the

sake of self realization, and even so, charity in its sattvik form, contol of the senses,

workship of God and other deties as well as ones elders including the performance of the

agnihotra (pouring oblations into the sacred fire) and others sacred duties, study and

teachings of the vedas and other sacred books as well as the chantings of Gods name and

glories, sufferings hardship for the discharge of ones sacred obligations and uprightness of

mind as well as the bodies and senses.

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2.1.2.4 According to Bhagvatham

कुते यद्ध्यायतो विष्णुंत्रेताया यजतो मखैः। द्वापरे परिचर्यायां कलो तध्दरिकीर्तनात्॥

Kute yaddhyāyato viṣṇumtretā yāmyajato makhaiḥ l Dvāpare paricaryāyām kalau tadhdarikīrtanāt l

Bhagvatham-12.3.52

Meaning:

Through the japa and keerthana of the divine name with faith and reverence(complete belief or respect), through the cultivation of association with saints and through the study of scriptures like the Bhagavad Gita, and Bhagavatham, everyone should strive his utmost to make this human life a sucess.

2.1.2.5 According to Upanishads

अथातःशौवउद्गीथस्तद्ध बको दाल्भ्यो ग्लावो वा मैत्रेयः स्वाध्यायमुद्धत्राज। athātaḥśauva udgīthastaddha bako dālbhyo glāvo vā maitreyaḥ svādhyāyamudvavrāja

Chan Upa-1.12.1

Meaning:

Therefore next begins the Udgitha seen in the dogs. Once Dalbhaya Baka, called also Maitreya Glava, went out (of the village) for the study of the Vedas.

तद्धैतद्ब्रहमा प्रजापतय उवाच प्रजापतिर्मनवे मनुः प्रजाभ्य आचार्यकुलाद्वेदमधीत्य यथाविधानं गुरोः कर्मातिशेषेणाभिसमावृत्य कुट्मबे श्चौ देशे स्वाध्यायमधीयानो धार्मिकान्विदधदात्मनि सर्वेन्द्रियाणि सम्प्रतिष्ठाप्याहि । सन्सर्वभूतान्यन्यत्र तीर्थेभ्यः स खल्वेवंवर्तयन्यावदायुषं ब्रह्मलोकमभिसम्पद्यते न च पुनरावर्तते न च पुनरावर्तते॥ $taddhaitadbrahm\bar{a}$ prajāpataya uvāca prajāpatirmanave manuḥ ācāryakulādvedamadhītya yathāvidhānam guroḥ karmātiśeṣeṇābhisamāvṛtya kuṭumbe śucau deśe svādhyāyamadhīyāno dhārmikānvidadhadātmani sarvendriyāṇi sampratisthāpyāhi sansarvabhūtānyanyatra tīrthebhyaḥ khalvevamvartayanyāvadāyuṣam brahmalokamabhisampadyate na ca punarāvartate na ca punarāvartate||

Chan Upa 8.15.1

Meaning:

Brahma expounded this to Prajapati, Prajapati to Manu and Manu to his descendants. He who has read the Veda according to the prescribed rule, in the time left over after performing his duties tothe teacher, he who after having come back from the teacher's house, settles down in his household, continues the study of the Veda in a clean place and has virtous sons and disciples, he who withdraws all his senses into the Atman, who practices non-injury to all beings except in places specially ordained, he who behaves thus throughout his life reaches the world of Brahman and does not return again – yea does not return again.

सोऽहं भगवो मन्त्रदेवास्मि नात्मविच्छुत ह्येव मे भगवद्दृ शेभ्यस्तरित शोकमात्मविदिति सोऽहंभगवःशोचामि तं मा भगवाञ्छोकस्य पारं तारयत्विति त होवाच यद्वै किञ्चैतदध्यगीष्ठा नामैवैतत्॥

soo'ham bhagavo mantradevāsmi nātmavicchruta hyeva me bhagavad dṛśebhyastarati śokamātmaviditi so'ham bhagavaḥśocāmi tam mā bhagavāṣchokasya pāram tārayatviti ta hovāca yadvai kiṣcaitadadhyagīṣṭhā nāmaivaitat||

Chan Upa-7.1.3

Meaning:

'Revered sir, however, i am only a knower of verbal texts, not a knower of Atman. Indeed i have heard from persons like your revered self that a knower of Atman goes beyond grief. Iam in such a state of grief. May your revered self take me across it.' 'Whatsoever you have studied here, really it is only a name.

ऋतं च स्वाध्यायप्रवचने च। सत्यंच स्वाध्यायप्रवचने च। तपश्व स्वाध्यायप्रवचने च। दमश्व स्वाध्यायप्रवचने च। रामश्व स्वाध्यायप्रवचने च। अग्तयश्व स्वाध्यायप्रवचने च। मानुषं च स्वाध्यायप्रवचने च। प्रजा च स्वाध्यायप्रवचने च। प्रजनश्व स्वाध्यायप्रवचने च। प्रजातिश्वस्वाध्यायप्रवचने च। सत्यमिति सत्यवचा रायीतरः। तप इति तपोनित्यः पौरुशिष्टिः।स्वाध्यायप्रवचने एवेति नाको मौद्गल्यः।तिद्धि तपस्तिद्धि तपः॥

ṛtaṁ ca svādhyāya pravacane cal satyaṁ ca svādhyāyapravacane cal tapaśva svādhyāyapravacane cal damaśva svādhyāyapravacane cal rāmaśva svādhyāyapravacane cal svādhyāyapravacane cal agtayaśva mānusaṁ svādhyāyapravacane svādhyāyapravacane cal cal prajā ca svādhyāyapravacane cal prajātiśva svādhyāyapravacane cal satyamiti satyavacā rāyītaraḥ tapa iti taponityaḥ pauruśiṣṭiḥ svādhyāyapravacane eveti nāko maudgalyaḥ l taddhi tapastaddhi tapaḥ l l

Meaning:

Righteousness and learning and teaching (are to be practised). Truth and learning and teaching (are to be practised). Austerity and learning and teaching (are to be resorted to). Control of the outer organs and learning and teaching (are to be practised).control of the inner organs and learning and teaching (are to be resorted to). The fires (are to be kept up), and learning and teaching (are to be followed).the Agni hotra is to be performed, and learning and teaching (are to be carried on). Guests (are to be adored), learning and teaching (are to be practised). Social good conduct (is to be adhered to), and learning and teaching (are to be practised). Progeny (is to be begotten), and learning and teaching (are to be carried on). A grandson (is to be raised), and learning and teaching (are to be practised). Truth (is the thing) – this is what Satyavaca, of the line of Rathitara, thinks. Austerity (is the thing) – this is what Taponitya, son of Purusisti, thinks. Learning and teaching alone (are the things) – this is what Naka, son of Mudgala, thinks. For that indeed is the austerity; for that indeed is the austerity.

वेदमनूच्याचायौऽन्तेवासिनमनुशास्ति। सत्यं वद। धर्मं चर। स्वाध्यायान्मा प्रमदः। आचायि प्रियं धनमाहृत्य प्रजातन्तुं मा व्यवच्छेत्सीः। सत्यान्न प्रमदितव्यम्। धर्मान्न प्रमदितव्यम्। कुशलान्न प्रमदितव्यम्। भूत्यै न प्रमदितव्यम्। स्वाध्यायप्रवचनाभ्यांन प्रमदितव्यम्॥

vedamanūcyācāyau'ntevāsinamanuśāsti| satyam vada| dharmam cara| svādhyāyānmā pramadaḥ| ācāyayi priyam dhanamāhutya prajātantum mā vyavacchetsīḥ| satyānna pramaditavyam| dharmānna pramaditavyam| kuśalānna pramaditavyam| bhūtyai na pramaditavyam| svādhyāyapravacanābhyām na pramaditavyam||

Taittiriya-1.11.1

Meaning:

Having taught the Vedas, the preceptor imparts this post-instruction to the students: 'Speak the truth. Practice righteousness. Make no mistake about study. Having offered the desirable wealth to the teacher, do not cut off the line of progeny. There should be no inadvertence about truth. There should be no deviation from righteous activity. There should be no mistake about protection of yourself. Do not be careless about learning and teaching.



2.2 SCIENTIFIC LITERTURE REVIEW

2.2.1 Yoga and Lipid Profile

S.N.	Author/Year of publication	Sample size	Design	Intervention	Assessment tool	Results	Conclusion
1	(Gordon et al., 2008)	N=231(77 in 3 groups)	randomized control study	Hatha yoga	Biochemical parameterswere determined at baseline and at two consecutive three monthly intervals.	This study showed decrease in concentrations of FBG and there was also a significant reduction in serum total cholesterol. The concentrations of VLDL differed significantly from baseline values. Lipid peroxidation significantly decreased.	conventional PT exercise may have therapeutic preventative and protective
2	(Singh, Kyizom, Singh, Tandon, & Madhu, 2008)	N=60, Yoga group(3 0), control group(3 0)	Two group pre-post study	Pranayama and yoga asana were given to Yoga group for 45days and Control group continued with medicines.	observation were assessed by Mercodia insulin ELISA kit before	The study showed a decrease in BMI,a significant decrease in blood sugar, serum insulin level and an improvement in lipid profiles was observed in group 1 while group 2 patients showed non-	asanas and pranayamas, significant reduction in the blood sugar and lipid levels was achieved in group 1 while group 2 although

						significant improvement in other parameters.	show significant change.
3	(Shantakumari , Sequeira, & El Deeb, 2013)	N=100, Experimental group(50), control group(50)	Randomized parallel study	Yoga and pranayama practices were given to Experimental Group for 3 months.The control group was prescribed oral hypoglycemic drugs only	Biochemical observation were assessed Before and after intervention.	The study group showed a decrease in total cholesterol, triglycerides and LDL, with an improvement in HDL.	The present study has shown an efficacy of improving the dyslipidemic state associated with diabetes.
4	(Siu, Yu, Benzie, & Woo, 2015)	N=182, Yoga(8 4), control(98)	randomized controlled, parallel stud y	Participants in the yoga group attended three yoga sessions weekly for 1 year.	Biochemical Observations were assessed for both the groups at the baseline and at the end of the Intervention.	A reduction of the number of diagnostic components for Metabolic syndrome was found to be associated with the yoga intervention. A trend towards a decrease in SBP was observed following yoga intervention.	These results suggest that yoga exercise improves the cardiovascular risk factors including central obesity and blood pressure in middle-aged and older adults with MetS. These findings support the complementary beneficial role of yoga in managing MetS.

5	(Nilakanthan, Metri, Raghuram, & Hongasandra, 2016)	Sample size 22.	A pilot study.	All the subjects underwent 6 months of yoga intervention, 1h daily for 4 days in a week.	cholesterol, triglycerides, HDL and LDL) and TSH	The results showed significant reduction in total cholesterol (p=0.006; – 8.99%), LDL (p=0.002; – 9.81%) and triglycerides (0.013; –7.6%), and there was a significant increase in HDL (p=0.02; +9.65%).	6 months practice of yoga may help in improving cholesterol level, serum TSH, may also help in reducing the thyroxine requirement in female patients suffering from hypothyroidism.
6	(Pal et al., 2011)	Yoga group(8 5) control group (85)	Two arm pre-post design.	Yoga group were given yogic practices for 35-45min/day, 5 days in a week for the period of 6 months.	Five millimetre of peripheral fasting blood was collected before and after the yoga intervention.	In the present study, BMI, fat, fat free mass, SBP, DBP, total cholesterol, HDL, LDL, triglycerides were changed significantly.	After yoga practices is beneficial for cardiac and hypertensive patient as it helps in reduction of SBp. DBP. Heart rate, body fat, total cholesterol, triglycerides, LDL.
7	(Rani & Sreekumaran, 2013)	N=73	Prospective study	Yoga practices. 90mintus daily for 3 months.	Biochemical estimation were done on 0 th day and 90 th day.	The results showed statistically singnificant decrease in glucose, HbA1c, lipids, cortisol, ferritin, MDA, and significant increase in catalase activity after yogic practices.	Yoga may improve risk profiles induced by stress in geriatric patients with type 2 diabetes and may have promise for the prevention or delay in diabetes complications.
8	(Nagarathna et al., 2012)	N=277, Yoga (141), control(136)	Two-armed intervention al randomized control	Yoga practices for YLSP and exercise were given for ELSP. For 9 months.	Blood samples were drawn from anantecubital vein in the fasting state.Biochemical measures included	HDL increased by 7 % in YLSP (P00.002) with significant difference between groups (P00.007). LDL reduced significantly in YLSP by 12.3 % (P<0.001),	After 9 months of intervention there was significant difference between groups (P<0.01) in HDL, LDL and medication requirement with higher

			study		blood glucose, HbA1c and lipid profile.	with difference between groups at P00.003. Triglycerides, total cholesterol and VLDL reduced significantly in both groups with non significant differences between groups and better effect sizes in yoga group.	effect sizes in YLSP group.
9	(Vaishali, Kumar, Adhikari, & UnniKrishnan, 2012)	N=60, yoga grpup(3 0), control group (30)	A Randomized Controlled study.	For yoga group Asanas and Pranayamas were practiced45–60 min daily for 6 days a week over 12 weeks.		Results of yoga group showed a significant improvement in HbA1c, Fasting glucose level, and serum lipid profile compared to Educational group.	13,
10	(Dash & Thakur, 2014)	N=60, yoga group(3 0) control group(3 0)	A Randomized Controlled study.	All the subjects with in the yoga group were taught Yoga asana and pranayama. The duration of practice was for 30 to 40 minutes from 7A.M. to 8A.M. for 40days.	investigation were	There were decreases in the values of Cholesterol (CHOL) from 177.07±9.92 mg/dl to 166.5±6.76mg/dl, and Triglyceride from 156±9.16 mg/dl to 149.9±6.63mg/dl. There were also decreases in Low Density Lipoprotein Cholesterol (LDL) from135.63±9.57 mg/dl to 132.67±8.32 mg/dl and Very Low Density Lipoprotein	of the results obtained in the present study and their comparison with other published reports, it may be concluded that yoga helps in decreasing blood sugar level and keep the diabetes in

11	(Agte & Tarwadi,	divided	A preliminary	The treatment subjects underwent			a simple and economical
	2004)	into treatme	Study	a special course given at the Art of	recorded before and after the	cholesterol, triglycerides, and oxidative stress,	therapy, might be considered as a benefi- cial
		nt		Living Foundation		measured as TBARS. The	adjuvant for patients with
		group(5 7) and		for 6 days. The patients were		fasting glucose was significantly lowered from	NIDDM
		non-		taught SKY as well		144 to 119 mg/dL ($t = 3.72$,	
		treatme		as pranayam,		P<0.001) after practice of	
		nt group(3		asanas, and meditation for 4		SKY for 4 months. Decreases in serum	
		group(3 0)		months.		cholesterol and triglycerides	
						were more prominent than	
						drops in fasting glucose	
						(respectively, $t = 6.64$ and 4.99, P<0.001)	
						,	

2.2.2 Yoga and HbA1c

S.N.	Author/Year of publication	Sample size	Design	Intervention	Assessment tool	Results	Conclusion
1	(S Mullur & Ames, 2016)	N=10, yoga group 5, control group 5	A randomized control study	10 minute seated yoga program for 3 months.	Biochemical observations(HbA1 c, CBG) and Physiological parameters(BP, weight, BMI) were assessed before and after the intervention.	There were no statistically significant changes in the haemoglobin A1C, systolic blood pressure, weight, or body mass index in either group.	This small pilot study reinforces the current medical evidence supporting the use of yoga, combined with standard care, to improve health outcomes in diabetes.
2	(Datey, Hankey, & Nagendra, 2017)	N=112, Rasahara and yoga Group 38, Yoga 37, Control group 37	3-arm controlled trial	Supplemented Ayurveda herbal juices and Yoga for 1 st group, Yoga for 2 nd Group, No intervention for 3 rd group for 3 months	FBS and PPBS levels were measured every 2 weeks; HbA1c and blood lipids were determined pre- and post-intervention.	Observed changes in HbA1c were: group 1, -0.044 ± 0.059 mg/dl; group 2, $+0.024 \pm 0.456$ mg/dl (not significant); and group 3, $+0.365 \pm 0.369$ mg/dl (p < 0.0001).	This study of Yoga for the treatment of diabetes shows that all male prisoners could benefit from the Yoga prison programs.
3	(Satish & Lakshmi, 2016)	N=91	One arm pre-post design	Yoga therapy sessions, which included 12 supervised sessions spread over a 3- month period.	The fasting and postprandial blood sugar, glycosylated hemoglobin (HBA1c), cognitive tasks, depression, cognitive failure,	There were no marked changes in the postprandial blood sugar and HBA1c.	Yoga practice enhances the subjective wellbeing, QOL, improves mood and concentration, and facilitates achievement of adequate glycemic control among Type II diabetic

4	(Youngwanic hsetha, Phumdoung, & Ingkathaworn wong, 2014)	N=170, yoga group (85), Control group (85)	A randomized controlled Study.	Yoga group were encouraged to follow mindfulness eating and yoga exercise at home 5 times a week for 8 weeks.	and diabetic-related quality of life (QOL) were measured. Fasting plasma glucose, 2-h postprandial blood glucose, and hemoglobin A1c were measured	The intervention group showed significantly reduced fasting plasma glucose, 2-h postprandial blood glucose, and glycosylated hemoglobin (HbA1c) in the intervention group (p<0.05).	patients. Mindfulness eating and yoga exercise had health benefits on glycemic control in pregnant women with GDM. It should be recommended in clinical and community health services.
5	(Skoro- Kondza, Tai, Gadelrab, Drincevic, & Greenhalgh, 2009)	N=59, Intervent ion group (29) and control group (30)	Exploratory randomised controlled trial	The intervention group were offered 12 weeks of a twice-weekly 90-minute yoga class; the control group was a waiting list for the yoga classes.	The primary outcome measure was HbA1c.measures were taken at baseline, immediately on completion of the yoga class. In addition, they monitored fingerprick blood glucose levels before and after each yoga class.	here was a small fall in HbA1c in the yoga group which was not statistically significant and which was not sustained six months later, and no significant change in other outcome measures.	This exploratory trial, which failed to demonstrate a significant impact of yoga in Type 2 diabetes, suggests that recent reports about the benefit of this intervention may have been premature.
6	(Nagothu, Rajagopalan, Indla, & Paluru, 2017)	N= 68, Yoga group(34), control group(34	A randomized controlled Study.	Yoga group were given Yogasana and pranayam for 6 months. No specific exercise	Glycosylated haemoglobin (HbA) concentration were measured using Bio-Rad	In test group six months practice of yogasanas and pranayama has also significantly brought down the high glycaemic values	These findings allow the study to conclude that regular practice of yogasanas and pranayama has a beneficial effect on

)	for control group.	Apparatus.	which were observed in the	cognitive performance in
				control group.	type 2 diabetic subjects by
					stabilizing blood glucose.

2.2.3 Yoga and FBS, PPBS

S.N.	Author/Year of publication	Sample size	Design	Intervention	Assessment tool	Results	Conclusion
1	(Sharma, Amin, & Prajapati, 2014)	N=30	Single arm Pre-Post design	Subjects were instructed to follow Yogic procedures including Āsanas, prāṇāyāma, and śuddhikriyas along with guḍūcīghana administration for 8 weeks.	FBS and PPBS levels were measured at every 2 weeks intervals.	The results are highly significant in terms of P value. 7.85% and 8.78% fall in FBS and PPBS levels, respectively, after the complete course of treatment.	The current study can provide a satisfactory and affordable approach in managing diabetes by building up a bridge between drug administration and Yoga therapy.
2	(Chimkode, Kumaran, Kanhere, & Shivanna, 2015)	N=60, Diabetic(30), Non- diabetic (30)	Prospective case control study	All the participants were given Yoga practice for 6 months	In all the participants fasting (FBS) and post-prandial blood sugar (PPBS) was estimated before, during (at three months) and after (six months) yoga training.	At the end of six months the reduction in mean values of FBS and PPBS was highly significant (p <0.001) in both the groups.	The results of the present study demonstrated that the yoga is effective in reducing the blood glucose levels in patients with T2DM.
3	(Angadi et	N=52	Pre-post	Yoga practice for 6	Fasting blood sugar	At the end of 6 months yoga	Adherence to yoga has an

	al., 2017)		experimenta l research design	months.	(FBS), and postprandial blood sugar (PPBS) levels, test using the oral glucose tolerance test method was conducted at baseline and the end of 1st, 3rd, and 6th month.	adherence was significantly negatively correlated with FBS and stress. Further there was a trend towards those who dropped out having higher FBS.	effect on the blood glucose parameters in diabetes.
4	(McDermott et al., 2014)	N=41, Yoga group (21), control group(20	A pilot randomized controlled trial	Yoga practices for yoga group for 8 weeks. Walking for control group for 30min, 6days a week for 8 weeks.	Observations were done at the baseline	blood glucose, postprandial	lifestyle intervention for decreasing weightrelated type 2 diabetes risk factors and potentially increasing

3 AIMS AND OBJECTIVES

3.1 AIM

The aim of the study is to study the effect of YOGA on LIPID PROFILE in Diabetic and Pre-diabetic in Urban area of Bangalore.

3.2 OBJECTIVES

The objectives of the study are to assess the effect of YOGA on LIPID PROFILE in Diabetic and Pre- diabetic people and to bring the awareness in people about lifestyle.

3.3 REASERCH QUESTION

Will YOGA change lipid profile in Diabetic and Pre-diabetic people?

3.4 RESEARCH HYPOTHESIS

There will be an effect of YOGA on LIPID PROFILE in Diabetic and Prediabetic people.

3.5 NULL HYPOTHESIS

There will be no effect of YOGA on LIPID PROFILE in Diabetic and Prediabetic people.

3.6 OPERATIONAL DEFINITIONS

3.6.1 Lipid profiles:

It is the pattern of lipids in the blood which usually includes the levels of total cholesterol, high-density lipoprotein (HDL) cholesterol, triglycerides and Lowdensity lipoprotein (LDL).

4 METHODS AND MATERIAL

4.1 SOURCE OF SUBJECTS

Subjects are taken from JIGINI, Anekal, BANGALORE.

4.2 SAMPLE SIZE

Sample size is calculated using the G-Power software using the variable of the previous study (Shantakumari et al., 2013). With effect size = 0.84, α value = 0.05 and keeping the confidence level at 0.95. Required sample size was 21 however a sample of size 40 people was taken for the study but because of drop-out total participants at the end of study were 33.

4.3 INCLUSION AND EXCLUSION CRITERIA

4.3.1 Inclusion criteria:

Persons age range from 20yrs to 70 years whose IDRS score is greater than 60 from both genders whoever has agreed for the study.

4.3.2 Exclusion criteria:

People who have undergone major surgery in the past, inability to exercise, any severe or unstable myocardial Ischaemia, congestive heart failure or other severe cardiac disease, severe hypertension who may be at risk when mildly increasing physical activity, those who are planning to move out of the area in the next three months, those who have documented cognitive impairment that would interfere with the ability to comprehend the informed consent and actively participate in the study, people with Tuberculosis, people with head injury, neurological or psychiatric disorder in the past.

4.4 DESIGN

One arm pre-post design

Г		3 month yoga practice 6days in a week		7
	PRE		POST	

4.5 ASSESSMENT TOOLS

4.5.1 Blood test:-

Blood sample is collected from the subjects after an over night fasting period of 8-12 hours, from the arm using a syringe. Blood sample is taken from the vein in the antecubital fossa. Further, the samples are sent for analysis of Lipid Profile in a NABL accredited lab.

4.5.2 Social demographic profile: -

Participants were asked for their age, sex, education level, income level, marital status, occupation and the information was noted on the data sheet.

4.6 INTERVENTION

Yoga Practice was given to the participants for 3 months, 6 days in a week for 1hour consist of asana, pranayama, meditation and relaxation techniques. The yoga practice module has been prepared by AYUSH MANTRALAYAM, INDIA.

4.7 PROCEDURE

For the purpose of testing the Standardised Yoga Module designed by AYUSH MANTRALAYAM for SDM, a 3months camp was organised in Jigani, Anekal, Bangalore. To spread the awareness of Diabetes and its precautions to prevent and to obtain subjects for the purpose of the study, announcements were made by means of banners, phone calls and by visiting homes in the nearby areas for 15days prior to the commencement of the camp. The first 2 days and the last 2 days were reserved for the assessment.

On the first day of assessment 40 participants were registered for the camp who met the condition of inclusion and exclusion criteria. These participants underwent blood test for assessment of biochemical parameters. After the first blood test the intervention started for 3 months and in the middle of the intervention 7 people dropped out due to various reasons(time clashes, migrated to other places) and only 33 participants successfully completed the intervention.

On the last 2 days of camp again blood test was conducted and data was recorded.

5 DATA ANALYSIS

Data was assessed using R studio. Shapiro Wilk's test was used to check normality of base line data. As the data from clinical parameters for the Cholesterol and LDL was normally distributed Welch two sample T-test was used to analyse the data, and the Triglycerides and HDL was not normally distributed. Wilcoxon's sign rank test was used for further analysis.

6 RESULTS

6.1 DEMOGRAPHIC DATA OF PARTICIPANTS

Yoga intervention started from 3^{rd} march till 5^{th} june 2017 for 1 hour a day. Among the sample size of 40, 33 were regular till the end of the yoga program for 90days with mean age of 44.69 ± 12.05 .

	CATEGORY	NO. OF PARTICIPANTS	PERCENTANGE	
	TOTAL	33	100%	
GENDER	MALE	18	55%	
	FEMALE	15	45%	
AGE	20-40	16	48%	
	41-70	17	52%	
HEALTH STATUS	DM	13	39%	
	PRE-DM	20	61%	

Table 1: Demographic data of participants.

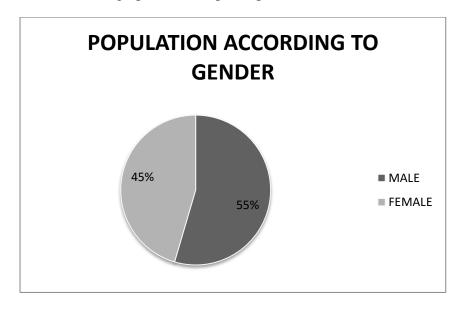


Figure 2: Population with respect to Gender.

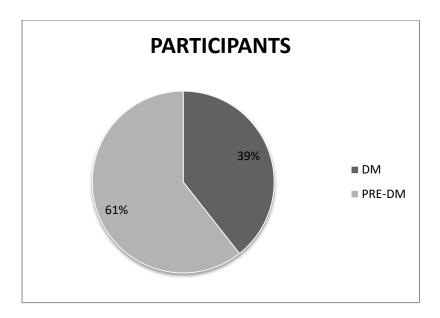


Figure 3: Health status of Participants.

6.2 CUMULATIVE RESULTS.

VARIABLES	PRE		POST		PRE-POST	
	MEAN	SD	MEAN	SD	%CHANGE	P-Value
TRIGLY	178.15	137.62	160.66	113.73	9.81%	0.2176
HDL	44.45	6.54	43.45	12.39	2.24%	0.0817
LDL	96.33	51.02	94.39	44.93	2.01%	0.8704
CHOL	175.24	56.70	168.15	50.43	4.04%	0.5933

SD: Standard deviation, %: Percentage change

Table 2: Results of intervention

6.3 RESULTS OF BIOCHEMICAL PARAMETERS

6.3.1 Result of Triglycerides

VARIABLE		MEAN	SD	% CHANGE	P-Value
TRIGYL	PRE	178.15	137.62	9.81%	P>0.05
	POST	160.66	113.73		

P value: 0.2176

Table 3: Results of triglycerides

Triglycerides showed no significant reduction (P>0.05) from 178.15 ± 137.62 to 160.66 ± 113.73 with 9.81% change.

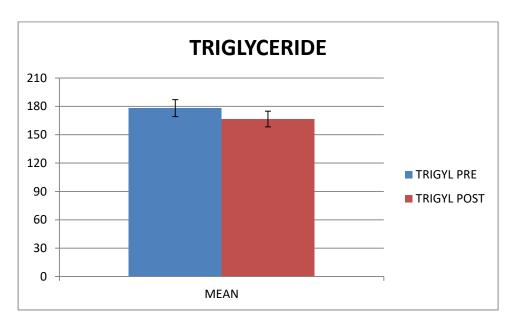


Figure 4: Results of Triglycerides

6.3.2 Results of HDL

VARIABLE		MEAN	SD	% CHANGE	P-Value
HDL	PRE	44.45	6.54	2.24%	P>0.05
	POST	43.45	12.39		

P Value: 0.0817

Table 4: Results of HDL

HDL showed no significant Increase(P>0.05) from 44.45 ± 6.54 to 43.45 ± 12.39 with 2.24% change.

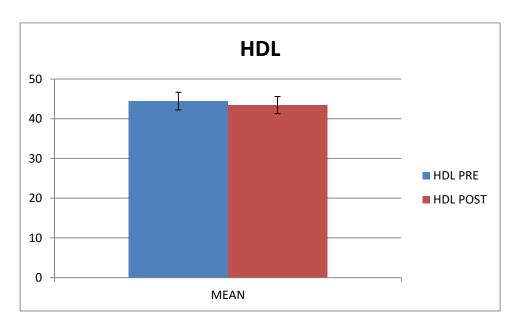


Figure 5 : Result of HDL

6.3.3 Result of LDL

VARIABLE		MEAN	SD	% CHANGE	P-Value
LDL	PRE	96.33	51.02	2.01%	P>0.05
	POST	94.39	44.93		

P value : 0.8704

Table 5 : Result of LDL

LDL showed no significant reduction (P>0.05) from 96.33 ± 51.02 to 94.39 ± 44.93 with 2.01% change.

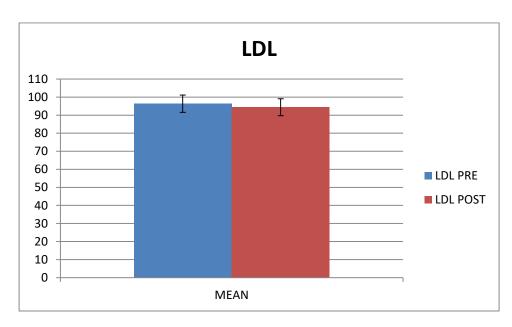


Figure 6 : Results of LDL

6.3.4 Result of Cholesterol

VARIABLE		MEAN	SD	% CHANGE	P-Value
CHOL	PRE	175.24	56.70	4.04%	P>0.05
	POST	168.15	50.43		

P value: 0.5933

Cholesterol showed no significant reduction (P>0.05) from 175.24 ± 56.70 to 168.15 ± 50.43 with 4.04% change.

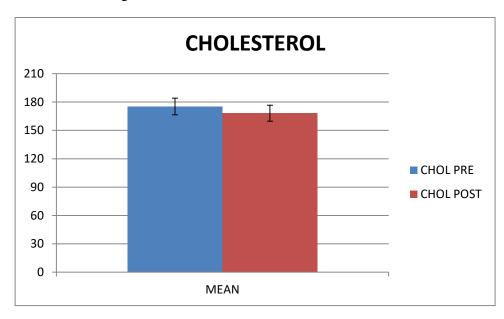


Figure 7 : results of Cholesterol

7 DISCUSSION

7.1 AIM:

This study was aimed to study the effect of Yoga on lipid profile in Diabetic and Pre-diabetic. At the end of the study it is observed that there is a reduction in Cholesterol, LDL, triglycerides though it was not statistically significant and there is no improvement in HDL.

7.2 PREVIOUS STUDY ON LIPID PROFILE IN DIABETIC PEOPLE

SL no.	Author	Subjects	Intervention	Mean and % change of	Mean and % change of		Mean and % change of
				TRIGLY	HDL	LDL	CHOL
1	(Rani & Sreekumaran	143	90days	Mean	Mean	Mean	Mean
	, 2013)			159.39±10.2	43.45±1.58	154.21±5.79	5.47±0.21 to
				8 to	to	to	4.17±0.14
				122.88±7.78	47.51±2.03	126.39±4.92	
				220/	0.20/	100/	23%
				23%	9.3%	18%	
2	(Singh et al., 2008)	60	45days	Mean	Mean	Mean	Mean
				162.93±79.2	36.23±8.05	118.90±41.7	185.60±45.8
				1 to	to	0 to	6 to
				137.37±58.7	39.23±6.23	104.30±40.2	169.37±37.1
				8		5	4
				15.68%	8.28%	12.27%	8.74%
				13.00%		12.27%	0.74%
3	(Nagarathna et al., 2012)	277	9 months	Mean	Mean	Mean	Mean
				174.10±81.2	44.75±13.82	91.16±33.10	182.86±39.5
				2 to	to	to	5 to
				147.28±49.1 4	47.88±11.80	79.89±30.20	162.20±36.7 4
				4.5.40	6.99%	12.36%	11.20
				15.40%			11.29%
4	(Vaishali et al., 2012)	60	12 weeks	Mean	Mean	Mean	Mean
				169.74±16.3	35.85±0.94	152.18±13.8	234.45±25.5
				9 to	to	0 to	5 to

					151.14±7.54	41.70±1.03	131.14±6.79	200.25±8.08
					10.95%	16.31%	13.82%	14.58%
5	(Dash Thakur,	&	60	40days	Mean	Mean	Mean	Mean
	2014)				156.10±9.16	42.47±6.08	135.63±9.57	177.07±9.92
					to	to	to	to
					149.90±6.63	48.93±4.02	132.67±8.32	166.5±6.76
					3.97%	15.21%	2.18%	5.96%

7.3 PRESENT STUDY RESULTS:

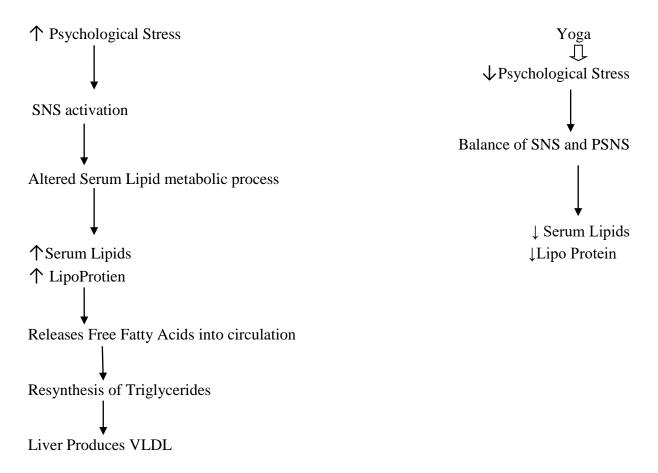
Results showed that there is a reduction in the Triglycerides from 178.15±137.62 to 160.66±113.73, Reduction in LDL from 96.33±51.02 to 94.39±44.93, Reduction in Cholesterol from 175.24±56.70 to 168.15±50.43. However the reductions are not statistically significant. High density lipoprotein's mean value has changed from 44.45±6.54 to 43.45±12.39 which shows that there is no improvement. The data of Cholesterol and LDL were normally distributed. Hence the data was analysed using parameteric test Welch two sample T-test to see within the group pre-post changes. The P value of Cholesterol is 0.5933 and of LDL is 0.8704. The data of HDL and Triglycerides were not normally distributed. Hence the data was analysed using Non-Parametric test Wilcoxon's signed rank test to see within group pre-post changes. The p value of HDL is 0.0817 and of Triglycerides is 0.2176.

7.4 MECHANISM

During the psychological stress the Sympathetic Nervous System gets activated leading to increase in production of serum lipid and lipoproteins by altering serum lipid metabolic processes. Adrenal gland induce lipolysis and release free fatty acids (FFA) into the circulation. FFA in turn serve as substrate for the re-synthesis of triglycerides and subsequently VLDL production by the liver.(Subramanian, Elango, Malligarjunan, Kochupillai, & Dayalan, 2012)

By doing a physical activity, it leads to lowered Plasma triglycerides concentration and ultimately increased plasma HDL cholesterol. The reduction in triglycerides and increased in HDL could be due to hydrolysis of TG-rich lipoproteins that simultaneously replace

intramuscular fat used during pranayama and yogic practices. This improvement could be due to increased hepatic lipase and lipoprotein lipase in cellular level, which effects the metabolism of triglycerides by adipose tissue.(Prasad et al., 2006)



9 APPRAISAL

9.1 STRENGTHS OF THE STUDY

Long term intervention and the yoga module of this study is not only limited to asanas, but also the different aspects of yogas such as Breathing practices, Pranayama, and relaxation techniques were included in the intervention.

9.2 LIMITATIONS OF THE STUDY

The limitations of the study are that many of those identified with diabetes could not take part in present study due to their time schedule, the lack of control group, the study has been covered only in one part of the town in Shivanagara(layout no:21) and Kuntlureddy layout(no:18) and regular monthly blood tests would have been encouraging to ensure good glycemic control and the subjects could access the changes themselves and motivate themselves to strongly adhere to yoga based life style change program. And there was no lectures on dietry control.

9.3 RECOMMENDATIONS

It is recommended to conduct a different study for diabetic and pre diabetic people and to have a control group.

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11 APPENDIX

11.1 CONSENT FORM





Informed Consent form for participants participating in Diabetes Control Movement Yoga Based Lifestyle program Multi Center- Matched Waitlist Control Trial

Name of Organization: Indian Yoga Association

Name of Principal Investigator: Dr. R Nagarathna

[Name of Organization]: : Indian Yoga Association

[Name of Sponsor]- AYUSH Through CCRYN

Name of Program Director:Dr HR Nagendra

Name of Program: Diabetes Control Movement Yoga Based Lifestyle program MultiCenter-Matched Waitlist Control Trial

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

There may be some words that you do not understand. Please ask us to stop as we go through the information and we will take time to explain. If you have questions later, you can ask them to the investigator.

Purpose of the research

Diabetes is disease affecting the overall health status of an individual. This disease can affect anyone but more susceptible population are people having obesity, high cholesterol, high blood pressure, and physical inactivity. Since Diabetes is a serious disease leading to many complications it is imperative to take measures to prevent and control it by various means including holistic ways of living.

Yoga is an age old Indian tradition which has helped to improve the overall health status of an individual. Yoga has also proven to be helpful in various diseases like diabetes, hence this study is being done to provide further evidence of its effectiveness in preventing and controlling diabetes.

Type of Research Intervention

This research will consist of answering certain questions, some physical measurements for all and if you are found within the inclusion criterion of the study a blood test would be performed. The aforementioned activities will be done before the intervention, and in case you are selected for further processes then these would be repeated after 3 months. Also, if you are selected to participate further in the research then you will be taught yoga in local camps for 9 days, and later you will have to do your home practice by yourself for 3 months. Moreover, there would be weekly yoga follow-ups by a trained yoga trainer for 3 months which you would be required to attend.

Participant selection

If you are between 20-70 years you would be requested to fill a screening and registration questionnaire and body vitals (Blood pressure, pulse rate, Waist circumference, hip circumference, bhramri time and respiratory rate) would be taken. If found within the inclusion criterion of the study a blood test(FBS,PPBS,HbA1c& Lipid Profile)would be performed and you would be selected for further part of the program.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. You may change your mind later and stop participating even if you had agreed earlier.

Information on the Trial

Diabetes is growing alarmingly in India, and according to International Diabetes Federation there are around 69.1 million cases in the year 2015. Studies done in the past have shown beneficial effect of yoga on people having diabetes, and this study would further strengthen the evidence.

This study is unique to measure the impact of yoga on diabetics and prediabetics on a large sample size spread all over the country. With the huge and diverse population sample, the study intends to capture any significant reduction in conversion of prediabetes to diabetes or any improvement in the diabetes status of people with diabetes.

Yoga is an age-old practice, which is being followed in India for hundreds of years. It includes physical exercises called Asana, breathing exercises called Pranayama and meditation called Dhyana. Along with these, the yoga module used in this research also includes relaxation, lecture sessions and counseling. It is absolutely safe if done according to the instructions given by the therapist. You may experience generalized body pain cramps or a catch in the first few days, which is normal and gets all right by itself.

Procedures and Protocol

Once your participation in the study is confirmed, body vitals (Blood pressure, pulse rate, Waist circumference, hip circumference, bhramri time and respiratory rate) and blood test(FBS,PPBS,HbA1c& Lipid Profile)would be done before and after 3 months intervention. To test the effect of yoga we will put participants of this research into two groups.

Participants in one group will be given the yoga practice and the other group will continue their routine activities. Later, after 3 months all the study participants would undergo physical examination and blood test as done before the start of the study.

If there is anything you are concerned about or that is bothering you about the research please talk to the trainer or investigator .

B. Description of the Process

During the research,

- During the first visit, we will give you informed consent form and explain about the study. Only after your confirmation to participate in the study we will ask you a few questions and take certain physical measurements. After selection for later stages of participation a blood test would be done.
- Later, you will be randomly allotted a group, either the one undergoing yoga training or the one pursuing only routine activities.
- If you get the yoga group you will have to attend yoga sessions in your locality for 9 days in the yoga camp followed by weekly classes for next 81 days (total 90 days intervention); conducted by a motivated local trainer who will be trained in imparting the yoga protocol.
- Irrespective of which group you belong to, after three months, you will undergo the the same physical measurements and blood tests which were previously done on you.

Duration

The research takes place over 3 months in total. If you get a chance to be included in the yoga group, you will have to attend yoga camp for 9 days taken by a trained yoga trainer and later do the daily yoga practices by yourself. However, there would be weekly yoga follow-ups taken by your yoga trainer. We would like to meet with you three months after the intervention and repeat the tests done earlier.

Side Effects

As already mentioned, yoga therapy will have no side effects. It can make you tired and it can cause some temporary soreness of the muscles of your body, cramps and muscle catch. It is

possible that it may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or any problems. Or we may stop one or more practices.

Benefits

If you participate in this research, yoga will be provided free of cost to you. There may not be any benefit to you, but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

Reimbursements

You will not be given any money or gifts to take part in this research.

Confidentiality

With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given toanyone except the people involved in the research and the research clinician.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential personal information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. Also, you may stop participating in the research at any time that you wish.

Whom to Contact

If you have any questions you may contact the following person:

Dolly Ravi Teja, mobile-9030430212, email id-dollyraviteja@gmail.com

This proposal has been reviewed and approved by Indian Yoga Association ethical committee. IRB is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact The technical coordinator, IRB- IYA, 68 Ashoka Road Delhi 110001 India.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participan	t
Signature of Participant	
Date	

Statement by the researcher/person taking consent

We have accurately read out the information sheet to the potential participant, and to the best of our ability made sure that the participant understands that the following will be done:

- 1. Baseline assessment.
- 2. Supervised intervention for three months.
- 3. Final assessment after three months.

We confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of our ability. We confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

consent		Signature		Researcher	/person	taking	the
Date	· · · · · · · · · · · · · · · · · · ·						
For study staff	f only:						
YVDM ID:							
Date of Intervi	ew:/						
Interview Time	e::_	a.m.	p.m. (che	ck a.m. or p.m.)			
Study ID:	 . [Ш					
	State	District	Village/To	wn SRL Co	ode		
11.2							

11.3 YOGA MODULE

Table: Module conducted for 100days one hour daily

S.NO	PRACTICE	ROUNDS	TIME DURATION
	Breathing practices		
	Hands stretch breathing	5	2min
1	Ankle stretch breathing	5	1min
1	Ankie stretch breating	5	1min
	Tiger breathing	5	1min
	Straight Leg raise breathing		
2	Surya Namaskara	6	6 min
3	Instant Relaxation technique(IRT)		3min
	Loosening Exercise		
	Jogging		1min
	Forward and Backward Bending	50	1min
	-	10	1min
4	Side Bending	10	
	Twisting	10 5	1min 1min
	Pavanamuktasana Kriya	3	1min
	Dhanurasana swing		
5	Quick relaxation technique(QRT)		4min

1min
1min
1min
1min
1min
1
1min
1min
7min
1min
1min
1min
1min
1min
10min
5 min

11.4 RAW DATA

PRE DATA

TRIGLY:Triglycerides,HDL: High-density lipoprotein , LDL: low-density lipoprotein,Chol: Total cholesterol.

NAME	AGE	GENDER	TRIGLY	HDL	LDL	CHOL
Sulochana	38	Female	291	39	161	258
Suresh	35	Male	183	45	119	201
Sukanya. S	50	Female	150	37	42	109
Adilakshmi	58	Female	646	35	118	241
Dakshayini	48	Female	203	53	166	260
Ravikumar GS	54	Male	116	49	35	107
Mary. J	35	Female	545	43	42	195
Saraswati	40	Female	414	38	21	142
Jayashree Paul	44	Female	115	58	118	199
Lakshmamma	45	Female	170	43	75	152
Nagesh	45	Male	191	47	55	140
Siddappa	54	Male	157	36	71	138
Rajesh n	39	Male	370	43	56	173
Neelamma	50	Female	174	36	98	169
Venkatalakshmamma	55	Female	221	49	251	344
Munirajappa	60	Male	138	38	57	123
Krishnappa	57	Male	53	40	56	107
Somashwarrao	56	Male	154	45	102	178
Gopalnayak	34	Male	68	45	139	198
Babu	38	Male	49	44	21	75
Sonika	26	Female	51	56	94	160
Shobha D	33	Female	75	49	95	159
Venugopal	70	Male	87	39	47	103
MangalaGowri	38	Female	150	42	103	175
Mahesh R.	33	Male	142	43	74	145
Mohan Krishna	29	Male	125	47	154	226
Raghu	39	Male	79	45	96	157
Sashikala	33	Female	128	57	91	174
Annojirao	36	Male	219	35	109	188
Marappa	45	Male	136	40	93	144
Pallavi S	25	Female	130	57	76	142
Lakshmanreddy	63	Male	234	46	167	251
Shrinivas Murthy	70	Male	233	48	177	250

POST DATA

TRIGLY:Triglycerides,HDL: High-density lipoprotein , LDL: low-density lipoprotein,Chol: Total cholesterol.

NAME	AGE	GENDER	TRIGLY	HDL	LDL	CHOL
Sulochana	38	Female	371	34	161	269
Suresh	35	Male	100	77	98	195
Sukanya. S	50	Female	154	40	54	125
Adilakshmi	58	Female	400	89	98	208

Dakshayini	48	Female	224	39	127	211
Ravikumar GS	54	Male	118	40	38	102
Mary. J	35	Female	400	29	38	169
Saraswati	40	Female	372	33	36	143
Jayashree Paul	44	Female	99	57	121	198
Lakshmamma	45	Female	106	38	85	144
Nagesh	45	Male	55	47	102	160
Siddappa	54	Male	118	34	91	149
Rajesh n	39	Male	400	30	85	170
Neelamma	50	Female	131	37	88	151
Venkatalakshmamma	55	Female	214	44	229	316
Munirajappa	60	Male	143	48	18	95
Krishnappa	57	Male	45	50	37	96
Somashwarrao	56	Male	236	43	94	184
Gopalnayak	34	Male	50	37	134	189
Babu	38	Male	55	47	59	117
Sonika	26	Female	78	37	86	139
Shobha D	33	Female	64	35	98	146
Venugopal	70	Male	76	35	44	94
MangalaGowri	38	Female	87	47	123	187
Mahesh R.	33	Male	210	39	64	145
Mohan krishna	29	Male	144	38	146	213
Raghu	39	Male	72	36	93	143
Sashikala	33	Female	96	46	99	164
Annojirao	36	Male	158	37	133	202
Marappa	45	Male	78	55	65	136
Pallavi S	25	Female	39	53	69	130
Lakshmanreddy	63	Male	269	38	142	234
Shrinivas Murthy	70	Male	140	45	160	233