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RESEARCH ARTICLE

Effect of yoga and music therapy with standard diabetes care in Type II Diabetes Mellitus- A randomized control Study

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Manuscript Info

Abstract

There is a clear need to study efficacy of alternative therapies like yoga and music therapy because of its holistic nature, cost effectiveness, self administered and free of side effects. The American Diabetes Association (ADA) Position Statement and other major guidelines recommend more clinical trials to improve evidence based practice of Yoga in Type II DM. This study aimed to evaluate effect of including yoga and music therapy intervention along with standard diabetes care over glycemic control, lipid profile, weight, BMI, anxiety, depression, exercise self efficacy and quality of life after 6 months program. A RCT study of parallel design comprising of Type II DM subjects above 20 years and diagnosed as per ADA criteria for at least a year and stabilized on OHA for minimum of 3 weeks with no prior exposure to yoga or music therapy or involved in a structured exercise program was conducted. Out of 902 subjects, 112 were recruited in yoga, 110 in music and 115 in control group while others were excluded. This is first study of its kind to have adhered to CONSORT and reports that Yoga shows beneficial effects of clinical importance in glycemic control, reducing anxiety and depression, reducing weight and BMI, and QOL. Interestingly, yoga improves exercise self efficacy by improving subjects' motivation to engage in exercise based programs. Music shows important benefits in reducing anxiety and depression which are important co-morbidities in diabetics. Yoga can be used as a cost effective adjuvant to standard care in Type II DM without side effects and self administered program which may show promising effects in prevention and management of Type II DM and can be launched as Community based strategy.

INTRODUCTION

Diabetes Mellitus (DM) is the biggest disorder in non-communicable diseases (NCD) group for Global Burden of Disease (GBD) 2010. Hypertension is most important risk factor for mortality due to Type II DM and dietary habits like tobacco, alcohol and low vegetable use adds to the risk factors and mortality.(Lozano et al., 2012) Expenditures for diabetes health care are too low as per the prevalence in developing nations like India which cannot sustain the actual expenditure. USA having lower diabetes population spent 45.2 billion USD in 1993.(Ramachandran et al., 2007) This is one of the reasons to explore effect of non pharmacologic approaches in

Type II DM. Abdominal adiposity is strongly and positively correlated with Diabetes in India and there is preferential abdominal adiposity in Indians irrespective of general adiposity. Lifestyle modifications and medications are mainstay of diabetes management. Exercise and diet restrictions are most important components of lifestyle modification. These life style changes pertaining to exercise behavior should look at subject's willingness to change, their present belief toward disease and psychosocial factors like anxiety and depression.(Bhutani and Bhutani, 2014)

Type II DM is directly associated with overweight and obesity. These subjects not only find exercises difficult but they also refrain from exercise based programs. Yoga is a vedic old, psychological, physical and spiritual exercise regimen that 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. Additionally yoga has been studied for controlling both the symptoms and the complications associated with Type II DM. These findings suggested that diabetics may benefit from yoga's ability to improve their glycemic control, stress and over all quality of life. The ancient Indian science of yoga is a holistic approach of life which includes primarily practicing exercises (*asanas)* and breathing practices (*pranayamas*). (Bhutani and Bhutani, 2014, Innes and Vincent, 2007)

Music has shown to be effective in reducing psychosocial morbidities like anxiety and depression in other disease populations but not in diabetes. However, stress, anxiety and depression show a considerable prevalence in diabetes and are directly correlated to disease condition of Type II DM which affects glycemic control and quality of life.(Bausewein et al., 2008) The present study tried to understand if music can reduce psychosocial morbidities like anxiety and depression in Type II DM which can affect glycemic control and other clinical parameters.

There is a clear need to study efficacy of alternative therapies like yoga and music therapy because of its holistic nature, cost effectiveness, self administered and free of side effects. The American Diabetes Association (ADA) Position Statement recommends that the use of adjuvant therapies be based on evidence from clinical research.(2013b)

Many previous experimental studies which have reported beneficial effects of yoga in Type II DM are limited by several issues like unclear methodology, interventions and program structure, Quasi experimental, lack of control group, confounding variables and smaller sample sizes. Some studies have even presented few data or too many confounders which make study difficult to generalize. This study aimed to evaluate effect of including yoga and music therapy intervention along with standard diabetes care over glycemic control, lipid profile, weight, BMI, anxiety, depression, exercise self efficacy and quality of life after 6 months program. It has been found that subjects show greater compliance to medications and lower compliance to exercise and lifestyle modifications. Further, increasing intensity of exercise leads to more dropouts from exercise based programs. This study further aimed to evaluate whether yoga practice helps to improve motivation and compliance to the exercise program by improving exercise self efficacy among the subjects.

Materials and Methods

Study design

Randomized Controlled trial (RCT) of parallel design comprising of three groups was conducted involving subjects with Type II DM from August 2011 to January 2014.

Based on effect size of 0.4 from a pilot study for primary outcome HbA1c, power at 80% and level of significance at .05, standard deviation of 2; sample size of 90 was required in three groups to know which is a better intervention. However, this was a 6 months follow-up study, we expected an attrition of 15%; therefore we decided to recruit 115 subjects in each group. We also kept the option of Intention to treat analysis if attrition was beyond 15%.

Study protocol was approved by Institutional Ethics Committee and then study was registered with Clinical Trials Registry-India- CTRI/2011/08/001954.

Subjects

Total of 902 subjects were identified out of which 565 were excluded due to several reasons mentioned in Figure 1. Interested subjects were invited to an assessment visit, at which the study was explained and informed consent was obtained. Subjects who met inclusion criteria were concealed allocated by another person, who was unaware of study, randomly by block randomization in three groups. There were 35 sequentially numbered opaque blocks used with 10 chits in each block for random allocation. Baseline physical examination was performed and laboratory tests were ordered. There were 112 subjects in yoga group, 110 in music group and 115 in control group at first stage. At the end of 6 months there were 96 subjects in yoga group, 92 in music group and 90 in control group. Reasons and stage of drop out has been shown in **Fig.1.**

Inclusion criteria comprised of Type 2 DM subjects over 20 years of age according to American Diabetes Association (ADA) criteria of diagnosis.(2013a) HbA1c range from 7%-9%, diagnosis of Type 2 DM for >1 Year, stabilized on Oral hypoglycemic agents(OHA) for atleast 3 weeks, no prior exposure to Yoga therapy and Music therapy as well as no involvement in structured exercise program self reported.

Exclusion criteria included subjects requiring insulin, subjects with HbA1c >9%, hypertension, unstable or under investigated coronary artery disease, cancer, severe osteoporosis or any other musculoskeletal disorder which may limit administration of yoga therapy, diagnosed cerebrovascular disease, subjects on antipsychotic drug like SSRI, aversion of music, already practicing yoga or music therapy.

Procedures

Demographic and baseline assessment was done on first day and intervention was started from the subsequent day. All subjects underwent clinical assessment by supervising physicians. All the subjects received standard care which included 150 minutes of physical activity per week with moderate intensity.(2014) Exercise prescription was done by a qualified physiotherapist.(2013b) Subjects in yoga group and music group were trained for two subsequent weeks after which they were asked to practice for 6 months along with their standard care. Subjects in control group were asked to adhere to standard care protocol only.

Adherence to program was ensured by asking all the subjects to maintain a daily log in a diary to keep a proper record of the activities and lapse. One of the subject parties were also asked to accompany subject during training and same will countersign once the subject finishes practice at home. All the subjects were called over telephone every week in order to know their compliance as well as their difficulty. Subject companion was also contacted at same time to countercheck. Subjects were asked to visit once a month after supervised training while practicing at home. All the groups were tested under similar laboratory conditions.

Yoga group (YG) was taught *pranayama* and *yoga-asana* by an instructor daily for initial two weeks and then they were called regularly at an interval of 1 month for supervision and compliance for 6 months. All subjects in yoga group were given a booklet with pictures of *Asanas* and self explanatory steps in English and Nepali to help subjects at home. At the end of 6 months all outcome measures were repeated. The whole yoga intervention consisted of following exercises:

Warm ups: (starting from the head, working towards the toes. 10 repetitions of each movement)
Neck rolls, Shoulder rotation, Arm rotation, Elbow movements, Wrist movements, Finger movements, Waist movements, Knee rotation, Ankle rotation, Toe movements.

Asanas
Standing
Surya Namaskar- Starting from 3 turns of each poses being maintained for ten seconds and adding each turns every week
Tad asana- starting from ¼ minute and adding ¼ minute every week
Trikonasana- starting from ¼ minute for each side, adding ¼ minute per week

Sitting
Vajrasana- starting from ¼ minute and adding ¼ minute every week
Padmasana- starting from ¼ minute and adding ¼ minute every week
Ardhamatsyendrasana- starting from ¼ minute for each side, adding ¼ minute per week

Paschimotasana- starting from ¼ minute for each side, adding ¼ minute per week

Prone
Bhujangasana- Starting from 3 turns to be maintained for ten seconds and adding one turn every week
Dhanurasana- Starting from 3 turns to be maintained for ten seconds and adding one turn every week
Supine
Halasana- Starting from 3 turns to be maintained for ten seconds and adding one turn every week
Naukasana- Starting from 3 turns to be maintained for ten seconds and adding one turn every week
Shavasana- starting from 2 minutes and adding a minute per week

Pranayama
Bhastrika- pranayama- starting from 3 min/day and adding 1 minute every month
Kapal-bhati- 10 min/day
Anulom-viloma- starting from 5 min/day and adding 1 minute every month
Bhramari- 5 times a day

Music group (MG) subjects got a collection of ten types of non-lyric Indian classical instrumental music. The collection was of 60-80 beats per minute, known to have relaxing effect. Personal preference of music has better effect on subject's responses to music therefore, subjects were asked to practice any one of music as per their choice. The subjects got supervised training for two weeks after which they were asked to practice for 6 months. Subjects were called every month for supervision and compliance. At the end of 6 months all outcome measures were repeated. There are certain factors which are important to consider while selecting music as intervention to promote relaxation. These factors are pitch and tempo, preference for music, sensitivity and type of music. In this study all possible factors were taken care of. Music group subjects listened to their selected music through head phones via a portable audio disc player for approximately 30 minutes in two sessions (morning and afternoon) on each day. Participants were given instructions which was adapted from a previously published literature.(Singh et al., 2009)

Outcome measures

Outcome measures were Glycated hemoglobin (HbA1c), Fasting Blood glucose level (FBS), Post prandial glucose level (PPBS), Body mass index (BMI), Lipid Profile, State trait anxiety inventory (STAI), Beck depression inventory (BDI), Diabetes- Quality of Life (D-QOL),(Nagpal et al., 2010) Exercise self efficacy,(Bandura, 2001) and Blood Pressure (BP).

Statistics
Data was analyzed by SPSS (version 22.0; SPSS inc. Chicago, Ill). Data analysis was blinded. First normal distribution of samples was plotted and verified by Smirnov-Kolmogorov test. All samples of variables under test was normally distributed and we decided to use ANOVA with repeated measures followed by post-Hoc analysis with Bonferroni's test, $p<0.05$ was considered to be statistically significant. ANOVA was used to analyze the changes in outcome variables from baseline to 6 months in a group and between the groups to know that which intervention caused greater change.

Results
Patients Characteristics
Out of 112 subjects in yoga group, 110 in music group and 115 in control group, there were 16 drop outs in yoga, 18 in music and 25 in control group. Therefore, 96, 92 and 90 subjects were analysed at the end of 6 months in yoga group, music group and control group consecutively. The flow of patients has been illustrated in **Figure 1**.
Baseline characteristics, demography and anthropometric measures of all three groups are shown in **Table 1**. In yoga group there were 36 males and 60 females, there were 51 males and 41 females in music group whereas 49 males and 41 females in control group. Mean age was 50.3, 50.4 and 49.4 in yoga, music and control group respectively. Socio economic status was determined as per Kuppuswamy scale which is a sum of scores summated for education, occupation and family income. This scoring system has been developed only for Indian population and is well accepted for determining socioeconomic status in India. (Sharma) Majority of subjects in all groups fall in to category of upper middle and upper class. Majority of subjects in all groups have no family history of diabetes while there is strong prevalence of tobacco use, smoking and alcohol consumption in subjects across all three groups. Mean height and weight of subjects were 160.4±6.9; 72.1±8.3 in yoga group, 158.4±5.2; 68.2±9.6 in music group and 158.2±6.1; 65.6±10.9 in control group respectively. BMI was 28.2±4.3 in yoga

subjects, 27.2±4.2 in music group subjects and 26.3±4.6 in control group subjects, mean of all three groups correspond to over weight category.

Mean SBP and DBP in Yoga group were 126.0±5.4, 82.1± 2.6 where as 126.1±5.4, 82.2±2.6 in music group and 129.0±5.4, 83.7±2.6 in control group. Mean of blood pressure of all three groups shows that subjects were in pre hypertensive group as per JNC VIII classification of hypertension.

Mean glycated haemoglobin was 8.6, 7.6 and 7.7 in yoga, music and control group respectively. FBS was 166.9±6.1 in yoga group, 157.3±4.7 in music group and 164.6±6.0 in control group where as PPBS were 214.1±7.6, 198.7±16.2, 194.9±6.5 respectively as fore mentioned groups. Total cholesterol was 182.5±29.6, 180.9±35.2, 172.6±34.1, triglyceride level was 208.1±6.0, 220.4±6.3, 226.2±6.1 and LDL was 136.9±10.4, 145.5±9.7, 145.1±9.4, where as HDL was 35.8±9.0, 35.1±9.6, 43.1±9.6 in Yoga, Music and Control group respectively. State anxiety, trait anxiety and total anxiety were 37.5±6.7, 32.4±6.5, 69.9±8.2 in yoga group, 35.4±8.3, 26.7±9.8, 62.1±12.6 in music group and 32.0±10.2, 24.7±8.2, 56.7±12.8 in control group as per the order mentioned. Level of depression measured by Beck Depression Inventory was 23.2±4.3 in yoga group, 23.7±3.6 in music group and 24.8±4.8 in control group. Self efficacy level of exercise was 31.1±9.9, 37.3±9.9, 35.2±9.6 in yoga, music and control group respectively. Quality of life was measured by D-QOL developed for diabetes subjects of Indian population specifically and mean of all three groups were 46.9±5.4, 50.2±9.1, 48.5±8.2.

Table 2 shows generic classification of scheduled drug intake by subjects across the groups which were fairly equivalent. Changes in yoga group, music group and control group from baseline to 3 months a nd 6 months have been shown with the help of mean and standard deviation, confidence interval, F value and p value in **Tables 3, 4 and 5** respectively.

Glycated haemoglobin changed from mean of 8.6 to 7.6 at the end of 6 months with p=0.000 in yoga group. In music group mean change was 7.6 to7.2 across 6 months with p = 0.016 and 7.7 to 7.1 in control group in 6 months with p= 0.000. FBS changed from 166.9±6.1 to 140±3.21 in yoga group with p=0.000, whereas same variable changed from 157.3±4.7 to 140.2±5.9 in music group with p=0.000 and from164.6±6.0 to 147.4±3.1 with p=0.000 in control group. There was a statistically significant change in PPBS which showed a change in mean from 214.1±7.6 to 173.3±5.9 in yoga group, 198.7±6.2 to 167.6±5.0 in music group and 194.9±6.5 to 164.1±5.1 in control group with p=0.000 across 6 months.

Evaluation of lipid profile also showed significant changes in mean values. TC changed from 182.5 to 160.3 in yoga group which was statistically significant with p=0.000 while this change was 180.9 to 155.2 with p=0.000 in music group and 172.6 to 160.0 with p=0.022 in control group over a period of 6 months. In yoga group TGs changed from 208.1 to 136.2 with p=0.000, in music group this change was 220.4 to 107.1 with p=0.000 and 226.2 to 127.8 in control group with p=0.000. LDL changed from 136.9 to 123.2 and 145.5 to 133.4 and 145.1 to 131.0 in yoga, music and control group respectively within 6 months. HDL also called as good cholesterol elevated in mean from 35.8 to 53.8 in yoga group, 35.1 to 40.9 in music group and 43.1 to 44.8 in control group with p=0.000 for yoga and music and p=0.224 for control group.

Anxiety evaluation had three components namely state anxiety, trait anxiety and total anxiety. SSAI changed from mean of 37.5 to 22.1, STAI changed from 32.4 to 26.6 and Total anxiety changed from 69.9 to 48.8 in control group with p=0.000 in yoga group. SSAI changed from 35.4 to 24.9 with p=0.000, STAI changed from 26.7 to 23.2 with p=0.056 and Total anxiety changed from 62.1 to 48.2 with p=0.000 in music group. In control group SSAI changed from 32.0 to 27.5, p=0.009 STAI changed from 24.7 to 21.7, p=0.008 and total anxiety from 56.7 to 49.2 with p=0.000. BDI showed a statistically significant change in all three groups with change in mean from 23.2 to 9.2 with p=0.000 in yoga group, 23.7 to 9.9 with p=0.000 in music group and 24.8 to 16.3 with p=0.000 in control group across 6 months of duration.

Self efficacy for change in exercise behaviour showed a statistically significant change from 31.1 to 65.8 with p= 0.000 in yoga group, 37.3 to 56.9 with p=0.000 in music group and 35.2 to 53.9 with p=0.000 in control group. Quality of life measured through DQOL showed mean changes from 46.9 to 84.7 with p=0.000 in yoga group, 50.2 to 54.4 with p=0.000 in music group and 48.5 to 58.0 with p=0.000 in control group. Changes in weight and BMI across yoga group was 72.1 to 60.8 and 28.2 to 23.7 with p=0.000 respectively. In music group weight and BMI changed from 68.2 to 64.0 with p=0.006, 27.2 to 25.6, p=0.018 respectively and control group changed from65.6 to 63.2 with p=0.208 and BMI from 26.3 to 25.3 at 6 months with p=0.270. Systolic and diastolic blood pressure changed from 126.0 to 121.6 and 82.1 to 80.5 in yoga group with p=0.000. Same variables changed

from126.1 to 121.7 and 82.2 to 80.5 in music group with p=0.000. Control group showed changes in SBP and DBP from 129.0 to 127.1 with p=0.037 and 83.7 to 82.0 with p=0.000 in 6 months. Changes within the group has been shown in Tables 3, 4 and 5 with their main effect (F value), confidence interval, mean changes and significance level (p<0.05).

Assessed for eligibility (n=902)

Excluded (n= 565)
Not meeting inclusion criteria (n=127)
Declined to participate (n=61)
Other reasons (n=40)

Randomized
(n= 337)

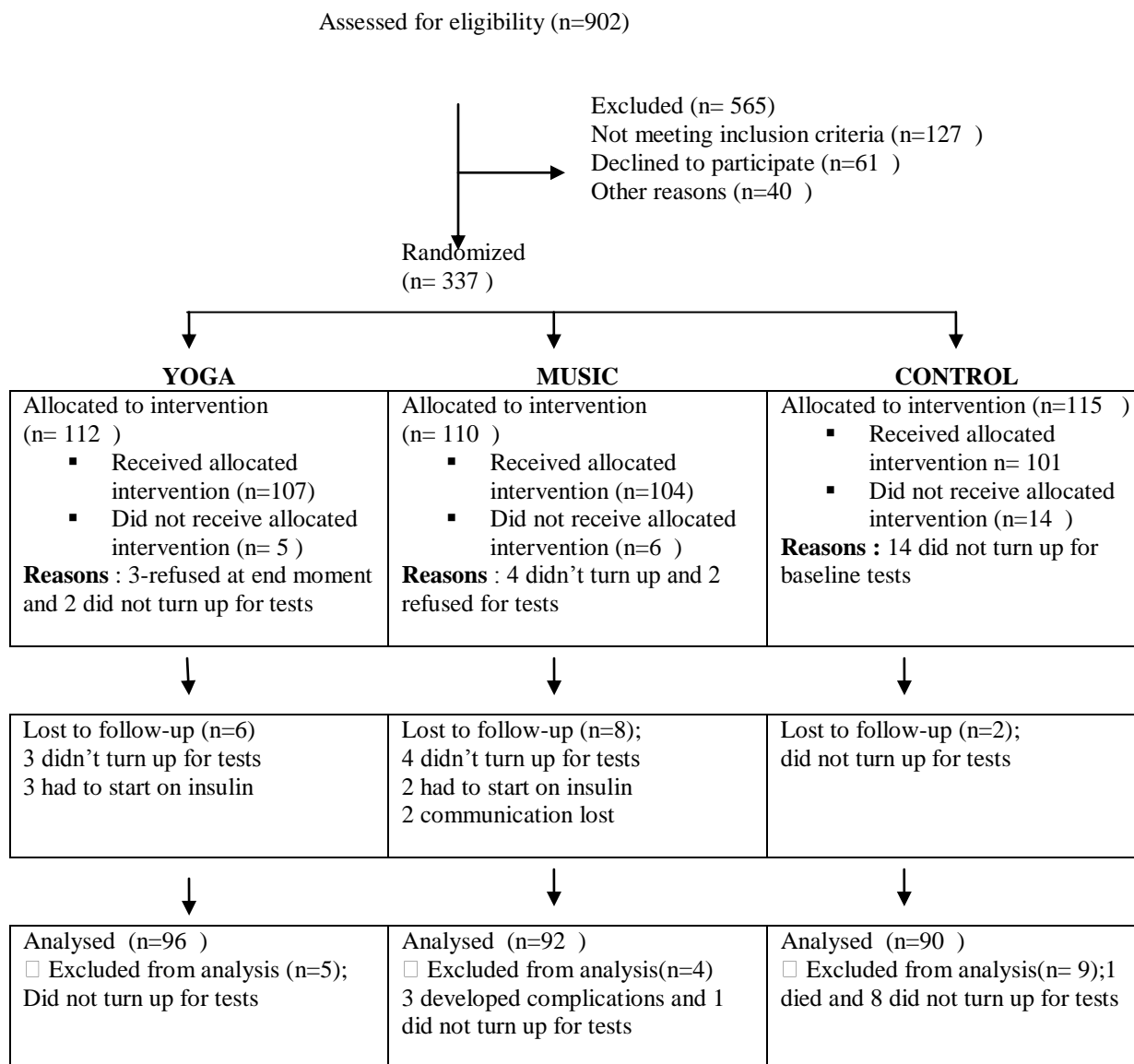| **YOGA**	**MUSIC**	**CONTROL**
Allocated to intervention (n= 112) • Received allocated intervention (n=107) • Did not receive allocated intervention (n= 5) **Reasons** : 3-refused at end moment and 2 did not turn up for tests	Allocated to intervention (n= 110) • Received allocated intervention (n=104) • Did not receive allocated intervention (n=6) **Reasons** : 4 didn't turn up and 2 refused for tests	Allocated to intervention (n=115) • Received allocated intervention n= 101 • Did not receive allocated intervention (n=14) **Reasons :** 14 did not turn up for baseline tests
Lost to follow-up (n=6) 3 didn't turn up for tests 3 had to start on insulin	Lost to follow-up (n=8); 4 didn't turn up for tests 2 had to start on insulin 2 communication lost	Lost to follow-up (n=2); did not turn up for tests
Analysed (n=96) ☐ Excluded from analysis (n=5); Did not turn up for tests	Analysed (n=92) ☐ Excluded from analysis(n=4) 3 developed complications and 1 did not turn up for tests	Analysed (n=90) ☐ Excluded from analysis(n= 9);1 died and 8 did not turn up for tests

Figure 1: CONSORT Flow diagram of subjects allocation, intervention, drop outs, follow-up and analysis.

Characteristics		**YOGA GROUP**	**MUSIC GROUP**	**CONTROL GROUP**
Gender	M:F	36:60	51:41	49:41
Age (years)	Mean ± S.D.	50.3±9.1	50.4±8.5	49.4±8.7
	Range (years)	23-73	23-70	29-72

Education	Middle school	11	00	00
	High school	10	00	08
	Intermediate	27	30	11
	Graduate /PG	32	31	37
	Professional	16	31	34
Occupation	Skilled worker	06	08	00
	Clerk, shop owner, farmer	30	23	32
	Semi professional	30	30	26
	Professional	30	31	32
Income (INR)	11817-15753	05	05	28
	15754-31506	30	36	27
	≥31507	61	51	35
Socio economic Status	Lower middle (11-15)	00	05	08
	Upper middle (16-25)	77	56	50
	Upper class (26-29)	19	31	32
Duration of diabetes (years)	1-2	33	39	36
	3-4	21	29	36
	5-6	30	24	18
	≥7	12	00	00
Family history of diabetes	Yes	28	25	16
	No	68	67	74
Tobacco use	Yes	53	58	77
	No	43	34	13
Smoking	Yes	63	71	89
	No	33	21	01
Alcohol	Yes	90	82	90
	No	06	10	00
Height	centimetres	160.4±6.9	158.4±5.2	158.2±6.1
Weight	kilograms	72.1±8.3	68.2±9.6	65.6±10.9
BMI	kg/m^2	28.2±4.3	27.2±4.2	26.3±4.6
SBP	mmhg	126.0±5.4	126.1±5.4	129.0±5.4
DBP	mmhg	82.1± 2.6	82.2±2.6	83.7±2.6
HbA1c	%	8.6±0.6	7.6±0.98	7.7±1.0
FBS	mg/dl	319.4±102.8	303.9±95.0	283.8±102.3
PPBS	mg/dl	434.1±108.2	411.5±107.4	386.6±84.5
TC	mg/dl	182.5±29.6	180.9±35.2	172.6±34.1
TGs	mg/dl	208.1±6.0	220.4±6.3	226.2±6.1
LDL	mg/dl	136.9±10.4	145.5±9.7	145.1±9.4
HDL	mg/dl	35.8±9.0	35.1±9.6	43.1±9.6
SSAI		37.5±6.7	35.4±8.3	32.0±10.2
STAI		32.4±6.5	26.7±9.8	24.7±8.2
Total Anxiety		69.9±8.2	62.1±12.6	56.7±12.8
BDI		23.2±4.3	23.7±3.6	24.8±4.8
Self efficacy		31.1±9.9	37.3±9.9	35.2±9.6
DQOL		46.9±5.4	50.2±9.1	48.5±8.2

Table 1: shows demographic, anthropometric measures and baseline characteristic of Yoga, Music and Control group.
 HbA1c= Glycated haemoglobin, FBS= Fasting blood sugar, PPBS=Post prandial blood sugar, TC= Total cholesterol, TGs= Triglycerides, LDL= Low density lipoproteins, HDL= High density lipoproteins, SSAI= Spielberger's State anxiety inventory, STAI= Spielberger's Trait anxiety inventory, Total Anxiety= Sum total of state and trait anxiety as mentioned by Spielberger. BDI= Beck depression inventory, DQOL= Diabetes quality of

life, Self efficacy= Exercise self efficacy scale, BMI=Body mass index, SBP=Systolic blood pressure, DBP=Diastolic blood pressure.

Type of Drugs	Yoga (n=96)	Music (n=92)	Control (n=90)
Metformin	90	89	87
Sulfonyl Ureas			
• Glimiperide	11	12	09
• Glibenclamide	10	11	13
alpha1glucosidase inhibitor			
• Acarbose	09	10	12
• Voglibose	22	19	20
GLP1 agonists			
• Sitagliptine	05	08	10
• Vildagliptine	07	08	11
Glitazones			
• Pioglitazone	07	06	11
Statins	45	42	43
Vitamin supplements	75	80	77

Table 2: shows general classes of Oral hypoglycaemic agents (OHA) and other drugs taken by subjects in all groups during study

Variables	Baseline	C.I.	6 Months	C.I.	F value	P value
HbA1c	8.6±0.6	8.5 8.7	7.6±0.6	7.5 7.7	51.221	.000
FBS	166.9±6.1	165.7 168.2	140.0±3.21	139.3 140.6	996.0	.000
PPBS	214.1±7.6	212.5 215.6	173.3±5.9	172.1 174.5	1039.1	.000
TC	182.5±29.6	176.5 188.5	160.3±21.6	155.9 164.7	19.1	.000
TGs	208.1±6.0	206.9 209.4	136.2±36.6	128.8 143.7	330.7	.000
LDL	136.9±10.4	134.8 139.0	123.2±9.7	121.2 125.1	44.5	.000
HDL	35.8±9.0	34.0 37.6	53.8±5.8	52.6 55.0	133.766	.000
SSAI	37.5±6.7	36.1 38.8	22.1±7.3	20.6 23.6	85.813	.000
STAI	32.4±6.5	31.1 33.7	26.6±6.7	25.2 28.0	18.786	.000
Total Anxiety	69.9±8.2	68.2 71.6	48.8±9.5	46.8 50.7	120.535	.000
BDI	23.2±4.3	22.3 24.0	9.2±1.6	8.8 9.5	533.888	.000
self efficacy	31.1±9.9	29.0 33.1	65.8±10.9	63.5 68.0	321.558	.000
DQOL	46.9±5.4	45.8 48.0	84.7±10.6	82.5 86.9	582.881	.000
Weight	72.1±8.3	70.5 73.8	60.8±9.6	58.8 62.7	38.962	.000
BMI	28.2±4.3	27.3 29.0	23.7±4.3	22.8 24.6	27.261	.000
SBP	126.0±5.4	124.8 127.10	121.6±2.5	121.1 122.9	25.517	.000

| DBP | 82.1± 2.6 | 81.6 82.7 | 80.5±1.1 | 80.2 80.7 | 21.010 | .000 |

Table 3: shows mean changes with standard deviation in Yoga group for variables tested at baseline, 3 moths and 6 months of intervention.
HbA1c= Glycated haemoglobin, FBS= Fasting blood sugar, PPBS=Post prandial blood sugar, TC= Total cholesterol, TGs= Triglycerides, LDL= Low density lipoproteins, HDL= High density lipoproteins, SSAI= Spielberger's State anxiety inventory, STAI= Spielberger's Trait anxiety inventory, Total Anxiety= Sum total of state and trait anxiety as mentioned by Spielberger. BDI= Beck depression inventory, DQOL= Diabetes quality of life, Self efficacy= Exercise self efficacy scale, BMI=Body mass index, SBP=Systolic blood pressure, DBP=Diastolic blood pressure. C.I.=Confidence Interval

Variables	Baseline	C.I.	6 Months	C.I.	F value	P value
HbA1c	7.6±0.98	7.48 7.89	7.2±0.9	7.0 7.4	4.195	.016
FBS	157.3±4.7	156.3 158.3	140.2±5.9	138.9 141.4	282.380	0.000
PPBS	198.7±16.2	195.4 201.1	167.6±5.0	166.5 168.6	321.504	0.000
TC	180.9±35.2	173.6 188.2	155.2±28.2	149.3 161.0	14.821	0.000
TGs	220.4±6.3	219.1 221.8	107.1±7.3	105.6 108.6	112.7	0.000
LDL	145.5±9.7	143.5 147.6	133.4±12.4	130.8 136.0	33.306	0.000
HDL	35.1±9.6	33.1 37.1	40.9±10.1	38.8 43.0	8.273	0.000
SSAI	35.4±8.3	33.7 37.1	24.9±8.7	93.1 26.8	33.495	.000
STAI	26.7±9.8	24.6 28.7	23.2±9.5	21.2 25.1	2.914	.056
Total Anxiety	62.1±12.6	59.5 64.8	48.2±13.2	45.4 50.9	25.171	0.000
BDI	23.7±3.6	23.0 24.5	9.9±1.3	9.6 10.2	629.042	0.000
self efficacy	37.3±9.9	35.2 39.4	56.9±10.9	54.7 59.2	133.523	0.000
DQOL	50.2±9.1	48.3 42.1	54.4±9.4	57.5 61.4	23.142	0.000
Weight	68.2±9.6	66.2 70.2	64.0±8.0	62.3 65.7	5.208	0.006
BMI	27.2±4.2	26.4 28.1	25.6±3.6	24.8 26.3	4.076	0.018
SBP	126.1±5.4	125.0 127.2	121.7±2.5	121.1 122.2	25.386	0.000
DBP	82.2±2.6	81.7 82.8	80.5±1.2	80.2 80.7	21.480	0.000

Table 4: shows mean changes with standard deviation in Music group for variables tested at baseline, 3 moths and 6 months of intervention.
HbA1c= Glycated haemoglobin, FBS= Fasting blood sugar, PPBS=Post prandial blood sugar, TC= Total cholesterol, TGs= Triglycerides, LDL= Low density lipoproteins, HDL= High density lipoproteins, SSAI= Spielberger's State anxiety inventory, STAI= Spielberger's Trait anxiety inventory, Total Anxiety= Sum total of state and trait anxiety as mentioned by Spielberger. BDI= Beck depression inventory, DQOL= Diabetes quality of life, Self efficacy= Exercise self efficacy scale, BMI=Body mass index, SBP=Systolic blood pressure, DBP=Diastolic blood pressure. C.I.=Confidence Interval

Variables	Baseline	C.I.	6 Months	C.I.	F value	P value
HbA1c	7.7±1.0	7.5 7.9	7.1±0.8	7.0 7.3	8.292	.000
FBS	164.6±6.0	163.4 165.9	147.4±3.1	146.8 148.1	171.884	.000
PPBS	194.9±6.5	193.5 196.3	164.1±5.1	163.0 165.1	359.547	.000
TC	172.6±34.1	165.4 179.7	160.0±29.9	153.7 166.3	3.881	.022
TGs	226.2±6.1	224.9 227.5	127.8±5.8	126.5 129.0	102.7	.000
LDL	145.1±9.4	143.1 147.1	131.0±12.4	128.4 133.5	45.73	.000
HDL	43.1±9.6	41.1 45.1	44.8±10.1	42.7 46.9	1.503	.224
SSAI	32.0±10.2	29.8 34.1	27.5±9.3	25.5 29.4	4.805	.009
STAI	24.7±8.2	23.0 26.4	21.7±5.2	20.6 22.8	4.863	.008
Total Anxiety	56.7±12.8	54.1 59.4	49.2±11.3	46.8 51.6	8.721	.000
BDI	24.8±4.8	23.8 25.8	16.3±2.2	15.8 16.8	122.131	.000
self efficacy	35.2±9.6	33.1 37.2	53.9±11.1	51.6 56.3	106.143	.000
DQOL	48.5±8.2	46.8 50.3	58.0±8.1	56.3 59.7	27.0	.000
Weight	65.6±10.9	63.3 67.9	63.2±9.2	61.3 65.2	1.578	.208
BMI	26.3±4.6	25.3 27.2	25.3±4.0	24.5 26.2	1.316	.270
SBP	129.0±5.4	127.8 130.1	127.1±3.9	126.3 128.0	3.350	.037
DBP	83.7±2.6	83.2 84.3	82.0±1.6	81.6 82.3	15.112	.000

Table 5: shows mean changes with standard deviation in Control group for variables tested at baseline, 3 moths and 6 months of intervention.
HbA1c= Glycated haemoglobin, FBS= Fasting blood sugar, PPBS=Post prandial blood sugar, TC= Total cholesterol, TGs= Triglycerides, LDL= Low density lipoproteins, HDL= High density lipoproteins, SSAI= Spielberger's State anxiety inventory, STAI= Spielberger's Trait anxiety inventory, Total Anxiety= Sum total of state and trait anxiety as mentioned by Spielberger. BDI= Beck depression inventory, DQOL= Diabetes quality of life, Self efficacy= Exercise self efficacy scale, BMI=Body mass index, SBP=Systolic blood pressure, DBP=Diastolic blood pressure. C.I.=Confidence Interval

Variables	YOGA GROUP				MUSIC GROUP				CONTROL GROUP				F	p
	M.D.	C.I.	S.E.	p	M.D.	C.I.	S.E.	p	M.D.	C.I.	S.E.	p		
HbA1c	0.98	0.56 1.3	0.1	.000	.42	0.04 0.84	.13	0.04	.59	0.16 1.0	0.13	.000	24.40	0.000
FBS	26.9	24.8 29.0	0.6	.000	17.1	14.9 19.2	0.6	.000	17	15.0 19.3	0.67	.000	464.7	0.000
PPBS	40.7	36.8 44.7	1.2	.000	31.1	27.1 35.1	1.2	.000	30	26.7 34.8	1.2	.000	343.9	0.000
TC	22.2	8.2 36.1	4.3	0.00	25.7	11.5 39.9	4.4	0.00	12	-1.8 26.9	4.48	0.183	9.940	0.000
TGs	71.8	65.6 78.0	1.9	0.00	113	106 119	1.9	0.00	98	92.0 104.8	1.99	0.000	11.56	0.000
LDL	13.7	8.9 18.4	1.4	.000	12.1	7.3 16.9	1.5	0.00	14	9.2 19.0	1.52	.000	48.39	0.000
HDL	17.9	-22.1 -13.8	1.2	.000	5.7	-9.9 -1.4	1.3	0.00	1.6	-5.9 2.6	1.34	.000	38.05	0.000
SSA I	15.3	11.2 19.5	1.3	.000	10.4	6.1 14.7	1.3	.000	4.5	0.18 8.8	1.3	0.031	27.15	0.000
STAI	5.7	2.1 9.4	1.1	.000	3.5	-.24 7.2	1.1	0.01	3.0	-.75 6.8	1.18	0.37	14.84	0.000
Total Anxiety	21.2	15.6 26.6	1.7	.000	13.9	8.3 19.5	1.7	.000	7.5	1.8 13.1	1.76	0.001	34.71	0.000
BDI	14.0	12.5 15.4	0.4	.000	13.7	12.3 15.2	0.4	.000	8.5	7.0 9.9	0.46	0.000	332.6	0.000
ESE	34.6	-39.0 -30.3	1.3	.000	19.6	-24 15.2	1.3	.000	18	-23.2 -14.2	1.39	0.000	151.4	0.000
DQOL	37.7	-41.8 -33.7	1.2	.000	9.2	-13 -5.0	1.2	.000	9.4	-13.6 -5.3	1.3	.000	186.7	0.000
Weight	11.3	7.0 15.7	1.3	.000	4.2	0.23 8.6	1.3	0.08	2.3	-2.0 6.8	1.93	1.0	11.86	0.000
BMI	4.4	2.4 6.3	0.6	.000	1.6	-.31 3.6	0.6	0.25	0.9	-1.0 2.9	0.62	1.0	8.515	0.000
SBP	4.3	2.1 6.4	0.6	.000	3.7	1.5 5.9	0.6	.000	1.8	-.41 4.0	0.69	0.321	27.66	0.000
DBP	1.6	.72 2.5	0.2	.000	1.3	.42 2.32	.29	.000	1.7	.78 2.7	.298	0.000	29.43	0.000

Table 6: shows comparison of changes across all groups in terms of mean difference (M.D.) with standard error (S.E.), C.I.=Confidence Interval and F value= Interaction effect computation of ANOVA across groups
HbA1c= Glycated haemoglobin, FBS= Fasting blood sugar, PPBS=Post prandial blood sugar, TC= Total cholesterol, TGs= Triglycerides, LDL= Low density lipoproteins, HDL= High density lipoproteins, SSAI= Spielberger's State anxiety inventory, STAI= Spielberger's Trait anxiety inventory, Total Anxiety= Sum total of state and trait anxiety as mentioned by Spielberger. BDI= Beck depression inventory, DQOL= Diabetes quality of life, Self efficacy= Exercise self efficacy scale, BMI=Body mass index, SBP=Systolic blood pressure, DBP=Diastolic blood pressure.

Discussion

Our study has shown different level of changes in means on comparison among three groups which is shown in **Table 6** with the interaction effect (F value). Glycated haemoglobin got reduced by 0.98 in yoga group, 0.42 in the music group and 0.59 in the control group at the end of six months. Life style modification programs do show

gradual change in HbA1c however, changes in yoga groups are higher than music and control group. A previous study has also shown similar result in HbA1c at the end of 9 months.(R. Nagarathna, 2012) Another study done by Balaji et al had shown a larger change in HbA1c where Type II DM subjects were classified as only on OHA and OHA with insulin compared to a control group.(Balaji et al., 2012)

FBS showed a mean change of 26.9 at the end of the six months in yoga group. However, this change was lesser in music group 17.1, and control group 17.2 at the end of 6 months. Changes in all the groups are statically as well as clinically significant. PPBS changed by 40.7 in yoga group, 31.1 in the music group and 30.8 in control group at 6 months respectively. Changes in yoga group were more but all the groups showed clinically significant changes at 6 months. These changes in all the groups can be attributed to the fact that standard care was common for all the groups which comprised of prescribed physical activity and dietary changes. However, yoga does also show added benefits in controlling blood glucose levels. Previous studies have shown similar results, however baseline values of subjects and duration of the yoga based intervention was different in all the studies.(Kyizom et al., 2010, Amita et al., 2009, Yang et al., 2011, R. Nagarathna, 2012)

Lipid profile showed a significant change in all the groups. TC reduced by 22.2, 25.7, and 12.5 in yoga, music and control group at 6 months respectively. TGs changed by 71.8 in yoga group, 113.3 in music group , 98.4 in control group at the end of 6 months. LDL reduced by 13.7 in yoga group , 12.1 in music group and 14.1 in control group whereas HDL raised by 17.9 in yoga group, 5.7 in music group and 1.6 in control group at the end of 6 months. There was a higher change in music group for TC and TGs at the end of 6 months These variations in changes cannot be commented with full evidence but a strict adherence to exercise program or diet restriction may influence the results. However, HDL also called as good cholesterol has raised more in yoga group as compared to other two groups. In previous studies by Nagrathna, Yang and Balaji have shown improvement of lipid profile through similar parameters in their study.(R. Nagarathna, 2012, Yang et al., 2011, Balaji P.A., 2011) There was a reduction in state anxiety by 15.3, 10.4 and 4.5 at the end of 6 months, whereas trait anxiety reduced by 5.7, 3.5 and 3.0 at 6 months with total reduction in anxiety by 21.2 in yoga group ,13.9 in music group and 7.5 in control group at the end of 6 months A previous study by Nidhi Gupta has also shown significant reduction in state and trait anxiety only in 10 days of yoga intervention.(Gupta et al., 2006) Interestingly, music group has also shown good reduction in anxiety more than control group which reinstate usefulness of the music in reducing anxiety. Though music has not been studied for the reducing anxiety in Type II DM, but its efficacy has been proved in reducing anxiety in COPD, Asthma, Heart disease, mechanically ventilated patients etc.(Kamioka et al., 2014, Singh et al., 2009)

Depression evaluated by BDI reduced by 14.0 in yoga group, 13.7 in music group and 8.5 in control group at the end of 6 months. In this study yoga shows promising effect on depression in Type II DM. Yoga has not been extensively studied for reducing depression in Type II DM but its efficacy in reducing depression has been studied in other populations. In recent past, studies have shown strong correlation between stress, anxiety, depression and pathophysiology of Type II DM,(McDermott et al., 2014) which are interrelated. Control of these psychosocial co morbidities may also show better glycemic control and lipid control in Type II DM subjects by heightening subjects' interest in engaging exercise activity, good dietary habits as well as life style changes. In this study Music has shown equivalent efficacy in reducing depression in Type II DM. Music has been studied to reduce depression in other populations but not in DM.(Maratos et al., 2008)

DQOL improved by 37.7, 9.2 and 9.4 in Yoga, Music and Control group respectively at the end of 6 months. Effect of Yoga on quality of life in diabetics has not been studied extensively however a study has shown positive effect of yoga on quality of life in diabetics with cardiac complication.(Jyotsna et al., 2014) In our study Yoga based program showed higher changes in DQOL which could not be marked in Music and Control group. This change is very important and requires lot of discussion. Yoga has greater potential in bringing change in outlook of diabetic subjects toward their life and it provides wholesome holistic benefits to subjects, which could not be achieved by exercises program or Music Therapy alone. This also redirects our attention to include yoga as an important tool in life style modification program/ standard care guidelines of Type II DM. This scale has been validated in Indian population in middle and higher income groups. Our base line data shows in Table I that most of our subjects belonged to this socio economic group. Further, higher socio economic groups are ready to accept Yoga as important life style program and Yoga may be launched as a community program to prevent and control diabetes.

Type II DM is directly related to overweight and obesity. In this study also subjects in all groups were overweight but not obese. Type II DM subjects have exhibited poor adherence to physical activity and exercises programs

and difficulty in initiating life style changes based on diet and exercise. In this study, ESE improved by 34.6 at 6 months in yoga group, 19.6 at 6 months in music group as well as 18.7 at 6 months in control group. Yoga is highly promising in improving motivation of diabetic subjects to change, come out of inertia of physical inactivity and adhere to active, exercise related program with other necessary life style modifications. A previous study by Yang has also reported similar change in exercise self efficacy of diabetic subjects after yoga intervention.(Yang et al., 2011) This was one of the important assumptions of our study which gets proved that Yoga is helpful in changing people positively toward exercise based program. Further, Yoga is an important tool which can be added to exercise programs to get increased benefits without increasing intensity of resistance and aerobic exercise programs frequently, which could be one of the reason for drop out of diabetic subjects from exercise based programs.

Our subjects were overweight in all groups with comparable mean height in all groups as shown in table 1. Weight reduced by 11.3 in yoga group, 4.2 in music group and 2.3 in control group at the end of 6 months. BMI reduced by 4.4 in yoga , 1.6 in music as well as 0.95 in control group at 6 months respectively. Our study shows Yoga is effective in reducing risk factors like weight and BMI more than music and control groups. It again shows better promising effect than general life style modification programs based on exercises and dietary restriction without yoga. Previous studies by Balaji and Yang have also reported reduction in weight and BMI after Yoga based programs.(Balaji P.A., 2011, Yang et al., 2011) There were significant changes in SBP and DBP by 4.3 and 1.6 in yoga group, 3.7 and 1.3 in Music group and 1.8 and 1.7 in Control Group at the end of 6 Months respectively. Our subjects were pre hypertensive and not hypertensive in all groups and they were not on any anti-hypertensive medications. This mean change is significant and yoga has good effect on modifying important risk factor of blood pressure. Music group also showed important benefit in reducing BP which can be attributed to its relaxing effect on body as reported in previous studies.

CONCLUSION AND LIMITATIONS

This study is first of its kind to be reported from Type II DM subjects where Yoga and Music therapy along with standard diabetes care showed beneficial outcomes on glycemic control, Lipid profile, weight and BMI, anxiety, depression, exercise self efficacy and Quality of life. However, yoga seems to be more promising than music therapy and standard care alone. Music has shown beneficial effects on psychosocial parameters like anxiety and depression which are important comorbidities in Type II DM. Standard care alone has also important benefits on health outcomes in Type II DM but lesser to yoga and music therapy as added intervention.

One of the major limitation of this study is subjects were trained under supervision for 2 weeks and they were asked to practice at their own homes for another 6 months, therefore, a comparison of supervised versus unsupervised training cannot be made.

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