Chapter 1

1. INTRODUCTION

1.1 Burden of Diabetes

The world is experiencing 30% increase in mortality due to non-communicable diseases (NCD), from 2,65,60,300 deaths in 1990 to 3,45,39,000 in 2010. Diabetes Mellitus (DM) is the biggest disorder in this group for Global Burden of Disease (GBD) 2010, which has taken a heavy toll of 12,81,300 deaths in 2010, 92.7% to rise over 6,65,000 deaths in 1990. Systemic complications of DM have also shown steep rise like Chronic Kidney Disease (CKD) has caused 91,900 mortality in 1990 as compared to 1,78,300 in 2010 with 94.1% rise in a span of decade. Diabetes has ranked 15th in global list of causes of death in 1990 has jumped many steps to position itself to 9th in 2010. In South Asia Diabetes is 10th important cause of death in the list. According to GBD, prevalence of DM was 22,75,88000 in 2010. Hypertension is most important risk factor for mortality due to Type II DM in 2010 followed by High Body Mass Index (BMI), high fasting blood sugar (FBS) and high total cholesterol. Dietary habits like tobacco, alcohol and low vegetable use adds to the risk factors and mortality.(1) Global health expenditure on diabetes is predicted to be 490 billion USD in 2030 as compared to 375 billion USD in 2010. One study which understated prevalence of diabetes in India to be 20 million estimated 90,200 million INR (2.2 billion USD) for diabetes health care which is too low as per the prevalence as a developing nation like India which cannot sustain the actual expenditure. USA having lower diabetes population spent 45.2 billion USD in 1993.(2) This projection clearly shows inability of developing nations like India in diabetes health care. Metabolic syndrome comprises of hyperglycemia,
dyslipidemia, insulin resistance, hypertension and upper body adiposity causes even high risk for diabetes complications and cardiovascular diseases (CVD). Countries with highest diabetes prevalence are India, China and USA where India has achieved dubious title of ‘Diabetes Capital of World’.

1.2 Diabetes in India
Patterns of DM are different in developed nations and developing nations like India. Age range of 45-64 yrs comprises maximum diabetics in Indian population as compared to ≥ 65 yrs in USA. It implies that productive population of India is falling prey to DM and this trend is increasing in urban India. Prevalence of DM has been found lower in low economic group as compared to high income group (12.6% v/s 24.6% in ≥ 40 yrs of age) and this is directly related to physical activity where job nature of lower socio-economic class involves moderate to strenuous physical activity at work place. Abdominal adiposity is strongly and positively correlated with Diabetes in India.(3) An important fact emerged out that despite having lower BMI; low socio-economic status group had a waist to hip ratio (WHR) comparable to high income group. This implies that there is preferential abdominal adiposity in Indians irrespective of general adiposity. Mohan et al also found a lower prevalence of diabetes in low income group as compared to high income group in South India.(4-5)

1.3 Yoga and Music in Type II DM
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 behaviour should also look at subject’s willingness to change, their present belief toward disease and psychosocial factors like anxiety and depression.(6)
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. Exercise is primary therapeutic option for diabetes management. Exercise improves the condition of a diabetic patient. Exercise also includes yoga practices which have a role to play in the prevention of type 2 diabetes.(7) The ancient Indian science of yoga is a holistic approach of life which includes changes in mental attitude, diet, by practicing asanas, breathing practices (pranayamas), and meditation. 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.(8-9)

Music has been used for centuries to promote relaxation and reduce anxiety and pain. Music therapy can be defined as a non-pharmacologic intervention that has been shown to be effective in promoting relaxation and reducing anxiety in patients. Music is an important non pharmacologic approach which has been researched extensively in recent time. Its effectiveness has already been proved in cardiac disorders, respiratory disorders like asthma and COPD and mechanically ventilated subjects.(10-14) Music is known for its relaxing effect. Music has relaxing effect on central nervous system and thereby causes overall relaxation. Induction of relaxation is sufficient to cause reductions in anxiety, dyspnea and sympathetic parameters. Sympathetic arousal is physiologic manifestation of anxiety and hence reduction in anxiety could lead to reduction in these measures. There is a plethora of
studies indicating possible effect of music in allaying, anxiety, dyspnea and physiologic measures like blood pressure. (15-16) Music has shown to be effective in psychosocial factors related to diabetes like anxiety, depression, quality of life and sympathetic arousal but there is lack of literature related to direct effect of music therapy over glycemic control. The present literature paves a way to understand if music can reduce psychosocial morbidity in diabetes then this reduction affects glycemic control and other clinical parameters or not.

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. (17-18) The present study tried to understand if music can reduce psychosocial morbidities like anxiety and depression in Type II DM which can indirectly affect glycemic control and other clinical parameters.

1.4 Need of the Study

There are several hypotheses for the biological mechanisms that link the benefits of yoga to diabetes management. One hypothesis points at the role of stress and relaxation, while others suggest endocrinal modulation and improvements in oxidative stress through neuroendocrinal mechanism. These hypotheses, however, have a limited generalizability as the studies they refer to have small sample sizes, different types of outcome and methodological issues. These limitations should be taken into consideration before evidence based conclusions can be drawn. (19-20) 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. (21-22) The American Diabetes Association (ADA) Position Statement
recommends that the use of adjuvant therapies be based on evidence from clinical research.\textsuperscript{(23)}

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.\textsuperscript{(24)}

### 1.5 Objectives of the Study

This study aims to evaluate effect of yoga and music therapy intervention along with standard diabetes care over glycemic control, lipid profile, anxiety, depression, weight, BMI, exercise self efficacy and quality of life after 3 and 6 months program.

Presently there is no comprehensive evidence in the existing literature that compares and addresses the effectiveness of yoga and music therapy practice in Type II Diabetes Mellitus management. There is paucity of literature evidence from randomized blinded trials with adequate sample. However our literature search could not retrieve any study from North East/Sikkim population about these interventions in Type II DM. This study will provide better insight about these non pharmacologic, life style modification approaches for Type II DM and will help practitioners to practice evidence based yoga and music therapy interventions in diabetes management.
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 a lifestyle modification program. This will be first study to evaluate whether yoga practice and music therapy help to improve motivation and compliance to the program. (25)

This study will help to understand whether inclusion of yoga and music therapy is helpful to control glucose level to acceptable level so that frequent increase in exercise intensity will not be done and subjects’ compliance to exercise program will be maintained.

This study also tends to find out association between psychosocial parameters and disease course. This will help to understand whether yoga and music therapy can help in controlling psychosocial parameters like anxiety and depression and thereby controlling disease condition in terms of glycemic control and cardiac parameters.