PREVALENCE AND CORRELATES OF COMPLEMENATRY AND ALTERNATIVE MEDICINE USE BY DIABETIC PATIENTS IN KOLLAM DISTRICT, KERALA

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DECLARATION

I hereby declare that this dissertation titled **"Prevalence and Correlates of Complementary and Alternative Medicine use by Diabetes patients in Kollam district, Kerala"** is the bonafide record of my original field research. It has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

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CERTIFICATE

Certified that the dissertation on **"Prevalence and Correlates of Complementary and Alternative Medicine use by Diabetes patients in Kollam district, Kerala"** is a record of the research work undertaken by Mr. Vishnu Nataraj in partial fulfilment of the requirements for the award of the degree of "Master of Public Health" under my guidance and supervision.

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Abstract

Background: The Indian state of Kerala has the highest proportion of type 2 diabetes in rural areas. Data on complementary and alternative system of medicine (CAM) use by diabetes patients in the state are limited. The objectives of this study were to find out the proportion of self reported diabetes patients using exclusive CAM and its correlates

Method: In a community based cross sectional study 400 self reported diabetes patients (mean age 59 years, men 54.5%) were selected using a multi-stage cluster sampling technique. Information on socio-demographic characteristics, use of different systems of medicine, expense for treatment, co-morbidity, diet and exercise was collected using a pre-tested structured interview schedule. Multivariate logistic regression analysis was done to find the correlates of exclusive CAM use.

Results: Exclusive CAM treatment was reported by 9% (Men 11%, women 7%), exclusive modern medicine by 61% (men 62%, women 60%) and combined treatment by 30% (men 27%, women 33%). Patients without any co-morbidity were four times [Odds Ratio (OR) 4.19, 95% CI, 1.14-12.42], patients who were employed were three times (OR 2.84, CI 1.28-6.27) and those who reported regular exercise were three times (OR 2.60, CI 1.24-5.45) more likely to use exclusive CAM compared to those who used exclusive modern medicine. Expense for medicines was not significantly different ($p>0.05$) for CAM compared to modern medicine both in government and private sector.

Conclusion: Less than 10% of self reported diabetes patients used CAM in this study. Patients with any co-morbidity were less likely to use CAM indicating that CAM use was limited to milder cases of diabetes.

CHAPTER1

INTRODUCTION

The increasing incidence of chronic diseases such as diabetes mellitus (DM) along with other chronic diseases, their serious complications and incurable nature may force people to use Complimentary and Alternative Medicine (CAM) either alone or in combination with modern medicines. Kerala state in India reported the highest prevalence of type 2 diabetes in rural areas (20.6%) (Thankappan *et al,* 2010).

The terms 'Complementary and Alternative Medicine' (CAM) are used interchangeably with traditional medicine in some foreign countries. They refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the health care system. It includes professionally regulated and unregulated practices, for example: ayurveda, yoga and naturopathy, unani, siddha, homeopathy, acupuncture, osteopathy, reiki, aromatherapy, faith healing, (Warren *et al.* 2013). Complementary medicine is one that is used along with conventional system of mediicne, but the alternative medicine is used as an alternate to conventional system of medicine (Kumar *et al,* 2006). Developed countries such as United States of America (USA) reported use of at least one CAM therapy among health plan members who had health related behavior problem (Gray *et al,* 2002).CAM use was also reported among pediatric patients with type 1 diabetes in Germany (18.4%) and USA (36.4%). Most of them used vitamins, minerals, herbal therapies and dietary supplements

(Lemay et al, 2011). Most patients in USA used CAM as a complementary one with modern medicine (Egede *et al,* 2002). Research from Australia also reported CAM use including yoga, prayer, meditation and tai chi (Warren *et al, 2013*). Various indicators of CAM use include strong cultural beliefs, chronic diseases, and advertisements in news papers. Prevalence of CAM use was reported by 22.1% among Indian emigrants for treatment of diabetes (Singh *et al,* 2004). In Nigeria most chronic diseases were described on a cultural and spiritual way and this caused about 46% of the people to use CAM. Around 80-90% of health care was provided through CAM in Africa (Obgera *et al,* 2010). Severity and failure of the conventional system of medicine caused people of Uganda to use traditional medicines more, where there was a need for cooperation between the traditional healers and practitioners of conventional medicine as many patients were following the traditional system of medicine (Hjelm and Atwine, *2011*). Most Chinese patients first consulted with the conventional medicine practitioners and after that around 42% of them consulted traditional Chinese herbalists. (Lee *et al,* 2004). Among hyperglycemia patients in Srilanka76% reported the use of CAM to reduce hyperglycemia (Medagama *et al,* 2014).

Evidence from a large meta analysis reported that glycosylated hemoglobin & fasting blood glucose (FBG) level could be reduced by using chromium (Nahas and Moher, 2009). In Allahabad (India), 30% of users adopted CAM without any conventional treatment and among them only 42.2% got some relief. Diet control and exercise, along with CAM were reported to provide maximum degree of satisfaction (61.9%) among users. The researcher suggested the need for community based studies to find the pattern of CAM use among patients who are not attending the clinics run by the conventional system of medicine. All

therapies under CAM should be tested for dosage, contaminants, and bioavailability and cost effectiveness before introducing them into the healthcare system. (Kumar *et al,* 2006). Around 64% used CAM for treatment of hypertension in Chandigarh, among which ayurveda was mostly used (Shafiq *et al* 2003). Results of a study in Mumbai showed that 34.4% of the patients were using CAM. The author suggested eliciting the use of CAM at least among chronic patients considering the possibility of modern drug interaction with CAM. Studies showed that a large proportion of people including those who are affected with diabetes are using CAM along with modern medicines, so history of use of CAM should be checked considering the safety and appropriate use as only very few patients discussed CAM therapies with their treating physicians (Bhalerao *et al,* 2013). A randomized controlled pilot study in Bangalore confirmed yoga related intervention for decreasing weight related type 2 diabetes risk factors and better mental health. The patients who participated in yoga intervention had a great reduction in weight and waist circumference than control participants (McDermott *et al,* 2014). A review article that focused mainly on herbal drugs and preparations used in the treatment of chronic diseases including diabetes, listed the details regarding the medicinal plants that are being used for herbal treatment for diseases including diabetes. The common name, botanical name, parts of the plant used, family and therapeutic uses were discussed. But the paper lacked information regarding the chemical constituents having potent therapeutic activity. The paper also reported that herbal drugs had some therapeutic activity and that was proved in animal models and further research was suggested including clinical trials (Umashankar and Shruti, 2011). A hospital based qualitative study conducted among 50 urban residents of Kerala showed that about 20% of the patients used ayurvedic medicine for the management of the disease, along with phytotherapy and food

control as adjuncts. Easy availability and low cost motivated them to select phytotherapy. Culture, place, kin, family and social support were found to be associated with these types of therapies (Chacko, 2003).

Rationale of the study

Many patients especially those patients who are affected with chronic diseases such as diabetes are depending upon traditional, complementary and alternative medicines either alone or in combination with conventional medicines because of its perceived safety, efficacy and low cost. The modalities of such therapies are different in different parts of the world. But there is a lack of comprehensive research studies in determining the prevalence, correlates and satisfaction of patients who are using Traditional, Complementary and Alternative medicines. Also studies are lacking in Kerala except one which was based on culture and therapy of the people alone. As Kerala is a state having the highest prevalence of 20.6 percent of diabetes in rural areas and 16.3 percent in urban areas with limited access to anti diabetes medicines from the public sector it is important to study the use of complementary and alternative medicines for the treatment of diabetes. Most of the studies in India and foreign countries were modern medicine hospital based which were not representative of the diabetes population in the community. So there is a need for a comprehensive community based study to determine the prevalence, correlates and satisfaction of patients who are using Traditional, Complementary and Alternative medicine either alone or in combination with Conventional system of medicines. It is also required to understand the satisfaction levels of diabetes patients who use these medications.

Objectives

1. To study the proportion of self reported Diabetes patients using Alternative and Complementary medicines
2. To find the proportion of people who are taking modern medicine along with Complementary and Alternative Medicines
3. To study the various socio economic factors associated with the use of Complementary and Alternative Medicines
4. To study the cost of medicines for CAM and modern medicine

Chapter 2

Literature review

According to World Health Organization (WHO), 90 percent of the world's population is using traditional medicines for their primary health needs mainly in the form of herbal medicines (Rizvi and Mishra 2013) and in India which is marked as one of the world's 12 biodiversity countries, called as 'the botanical garden of the world' ranks top in the use of herbal or traditional medicines as part of their indigenous systems (for example: Ayurveda) with the perspectives of safety, efficacy and quality (Umashankar and Shruti, 2011)

- **Traditional medicines (TM)-** 'Traditional medicines is the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences and indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness'.
- **Complementary and Alternative medicine (CAM) -** The terms 'complementary and alternative medicine' are used interchangeably with traditional medicine in some countries. They refer to a broad set of health care practices that are not part of that country's own tradition and are not integrated into the dominant health care system'. It includes professionally regulated and unregulated practices: Chinese medicine, acu-puncture, naturopathy, homeopathy, chiropractic, osteopathy, Reiki, aromatherapy, faith healing and meditation (Warren *et a*, 2013).

- **Herbal Medicines**- 'Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products, that contain active ingredient parts of plants, or other plant materials, or combinations'.
- **Herbs:** They are crude plant material such as leaves, flowers, fruit, seed, stems, wood, bark, roots, rhizomes or other plant parts, which may be entire, fragmented or powdered.
- **Herbal materials:** 'in addition to herbs, fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs are used as herbal materials. In some countries, these materials may be processed by various local procedures, such as steaming, roasting, or stir-baking with honey, alcoholic beverages or other materials'.
- **Herbal preparations:** 'They are finished herbal products and may include comminuted or powdered herbal materials, or extracts, tinctures and fatty oils of herbal materials. They are produced by extraction, fractionation, purification, concentration, or other physical or biological processes. They also include preparations made by steeping or heating herbal materials in alcoholic beverages and/or honey, or in other materials'.
- **Finished herbal products:** 'These are herbal preparations made from one or more herbs. If more than one herb is used, the term mixture herbal product is used. Finished herbal products and mixture of herbal products may contain excipient in addition to the active ingredients. However, finished products or mixture products to which chemically defined active substances have been added, including

synthetic compounds and/or isolated constituents from herbal materials, are not considered to be herbal'(Burten *et al*,2013).

According to the World Health organization (WHO), traditional medicine is an important medicine in most part of the world, as it has been used for a longtime for the management and prevention of diseases especially chronic diseases. Therefore the WHO had developed and launched a traditional medicine strategy after the World Health Assembly resolution on traditional medicine. The strategy aims to support member States in developing proactive policies and implementing action plans that will strengthen the role traditional medicine plays in keeping populations healthy. To achieve its strategic goal of health for all WHO had paid great attention in the development of traditional medicine by starting various collaborating centers in various countries, so as to make full use of the scientific expertise, and for the development of traditional medicines in such countries and throughout the world.

The aims of the strategy are

1. harnessing the potential contribution of traditional Medicine (TM) to health, wellness and people centered health care.
2. promoting the safe and effective use of traditional medicine by regulating, researching and integrating TM products, practitioners and practice into health systems, appropriately.

The strategy also aims to support the member states in developing policies and action plans in Traditional medicines for the health of the populations.

The main aims are the following:

1. To integrate and frame policies with Traditional medicines at the national level.
2. Promote safety, efficacy, quality and access to poor
3. Promote rational use (therapeutically active) - by appropriate practitioners and consumers.

WHO identified various challenges to the member states for which they can frame national policies of their own as per the situations of the particular country:

1. A knowledge based active management of T & CM(Traditional and complementary medicine)
2. By proper quality assurance, safety and proper use of T & CM can be strengthened through implementation of regulations.
3. T&CM can be incorporated into the health service delivery under universal health coverage and ensure user friendly choices regarding treatment.

The 67th world health assembly recommended adoption of various resolutions indicating the need and importance of complementary and traditional medicines that are increasing at a large scale both globally and nationally. The availability of such medicines to any particular part of the world is to be integrated with the health service delivery. It also motivated the member states to frame policies regarding the strategies of WHO on complementary and traditional medicines (Burten *et al*,2013).

The American diabetes Association defines 'Diabetes mellitus as a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. The chronic hyperglycemia of diabetes is associated with long-term damage,

dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels'(American Diabetes Association, 2014).

2.1. Traditional, Complementary and Alternative Medicine use at the Global level

A study in the United States reported the prevalence and pattern of complementary and alternative medicine (CAM) usage in people with and without diabetes and the various factors associated with CAM use. In this study, definition of CAM was "approaches to health care that are different from those typically practiced by medical doctors in the U.S." It included acupuncture, nutritional advice or lifestyle diets, massage therapy, herbal remedies, biofeedback, meditation, and imagery or relaxation techniques. It was found that the prevalence of CAM usage among people with diabetes was 1.6 times more than people without diabetes. CAM treatments used by the diabetic patients included nutritional, diet and life style modification, spiritual healing, herbal medicines, massage, and meditation. They also found that people older than 65 years of age and with at least high school education were using CAM more than others. Comparison on independent predictors of diabetes with that of the general population was done. Most people used CAM in addition to the conventional methods of treatment. The study was conducted in households and 1996 MEPS (Medical expenditure panel Survey) data were used for it. The researchers studied certain other chronic diseases and compared it with diabetes on the basis of CAM use. They also did not consider those patients who had obtained CAM without consultation with a CAM practitioner. It was found that individuals used CAM mostly as a complementary therapy than as an alternative one. It was also found that 57% of the patients discussed CAM treatment with their regular

physician. The researcher suggested further research to find out efficacy and the quality of life of patients who were are using CAM. Data from the household and medical conditions of 1996 MEPS was combined to determine the prevalence and pattern of use of alternative medicines in Diabetes patients. The household part of survey of MEPS included the U.S civilian, non institutionalized population, with oversampling of Hispanics and blacks drawn from National Health Survey Sample. Chronic patients were studied to find out the estimates of CAM use and this was then compared with the CAM usage of patients with other chronic diseases. Cost involved in the treatment of CAM in diabetic patients were also studied and compared with the cost of CAM in non diabetic patients (Egede *et al*, 2002).

A study was conducted in Minnesota to find out the Complementary and Alternative Medicine (CAM) use among health plan members. The objective was to investigate the prevalence, utilization of conventional medicine among CAM users and satisfaction related to the use of CAM. 42% of the study population used at least one of the listed 16 CAM therapies. Relaxation techniques (18%), massage (12%), and herbal medicine (10%) were the commonly used alternative therapies. 46% of CAM use was found in females which was higher than males. Perceived improvement in health status motivated the use of CAM. CAM users were following a healthy lifestyle. 42% of the CAM users were satisfied with their health plan. One of the limitations in the study was that the status of preventive services among CAM users was higher than non CAM users. Only one question was used to assess the perceived efficacy of treatment. Stratified sampling was done to draw study participants who were 40 years of age or above. 3000 members were there in study sample having no chronic conditions, 2500 with chronic diseases and 2500 with four chronic diseases. Surveys

were conducted by mailing to 5107 members and 4404 responses were obtained. For members who did not respond to postal questionnaire, telephoning was used (Gray *et al,* 2002).

A self reported questionnaire based study was conducted in the Children's diabetic hospital of Alberta and it was found that the use of CAM in pediatric diabetes patients ranged between 11-68%. Vitamins, minerals, herbal therapies and dietary supplements were mostly used. Poor communication of traditional practitioners, belief of low side effects etc were the motivating factors that made them to select CAM and most of them never reported this to their conventional caregiver. Reports related to the use of CAM in Type 1 diabetes patients were very low (Lemay *et al,* 2011).

One study conducted in Australia revealed how the severity of diseases like Diabetes and CVD affected people who were out of 'control' and the use of CAM among those people to gain 'control' over the disease . CAM was defined as products (example: vitamins, minerals, herbs), practitioners (example: of naturopathy, chiropractic, massage therapy, acupuncture and so on) and practices that were believed to provide relief to the participants (example: yoga, prayer, meditation, Tai Chi). The'CAMELET'(Complementary and Alternative Medicine, Economics, Lifestyle and Other Therapeutic approaches for chronic conditions) study focused on how people with diabetes and CVD used CAM as a treatment for gaining 'control' over the health. The word 'control' means a person who cannot 'control' the desires and practice, (example: eating) cannot adhere to the dietary patterns. Here diabetes was considered as a disease because of loss of 'control'. Australians (from 2004 to 2006) spent

between $AU2–4 billion annually for treatment with CAM which included medications and products for chronic conditions.Nearly 80% of the people consulted herbalist or similar consultations. In depth interviews were used among 69 patients who had Diabetes or CVD or both. The study was multi disciplinary and multi method study which used the word 'CAMELOT' focused on care-seeking, self-management and use of CAM. Lay models of disease, therapeutic relationship between CAM and disease and patients reasons for using CAM were studied. Opportunistic sampling was used for getting patients for the study. Those people who were diagnosed the disease at least one year before the study and were using CAM were included in the study. Two main recruitment strategies were used for the study. For the first one, two researchers attended community support meetings (Diabetes Australia-Victoria and Heart Support Australia during 2009, where they described the purpose and invited interested members to participate in the study. Information regarding the project was disseminated via professional (CAM and integrative medicine) and consumer health-related organization via newsletters and emails, notice boards, local newspaper articles and at conferences. Out of 38 women and 31 men interviewed, 19 (28%) had been diagnosed with diabetes, 14 (20%) with CVD and 36 (52%) with both conditions. The majority (40) was aged over 65 years, and was noted as low income by the govt. of Australia. Fifteen participants did not disclose their income. Most responded positively and others were ambivalent regarding CAM use. Inability to recruit people with negative experiences was the limitation of the study. Semi-structured in depth interviews were conducted at the locations preferred by the participants (home was the preferred location by most of the people). Revision of the interview guide was done based upon the themes raised by the participants. Questions were included on reasons for the choice and frequency of use of different CAM

therapies, experience on the therapeutic activity, perceptions regarding the causation of diabetes and CVD, onset and treatment of the disease, facilitators and barriers of self-management of the disease, adherence to behavioral, medical or CAM prescriptions and socio-economic factors regarding the management of health. Grounded theory informed data collection and analysis. A theory of control was not generated but brought new insights into the CAM users perceptions regarding control over chronic diseases and how CAM helped them in achieving this state (Warren *et al*, 2013).

A study was conducted in the Indian community of Chatsworth in South Africa to determine the prevalence and utilization patterns of Complementary and Alternative medicine (CAM), attitudes regarding the use of CAM and the communication of the patients to their primary care doctors regarding the use of CAM. The author had listed seven categories of CAM developed by the American National Institute of Health's Office of Alternative Medicine. Prevalence of CAM usage was found to be 38.5%. 22.1% of Diabetes mellitus patients were using CAM. Natural herbal medicines were most commonly used accounting for about 48.1%. Spiritual healing was used by 42.8%. Positive outcomes regarding the use of CAM were noted by 79%. Those who had failed to inform their doctor regarding CAM were found to be 54% citing the reason that it was not necessary to inform them about CAM use. The author reported that the prevalence of use of CAM was similar to other parts of the world (USA-40% and European countries 20-50%). The indicators of CAM use were noted as strong cultural beliefs for chronic illnesses like Diabetic Mellitus, Hypertension, coronary artery disease. The researcher suggested need for integration between conventional medicine

with CAM along with increasing the communication between health care providers and patients regarding CAM use (Singh *et al*, 2004).

A cross sectional study in Nigeria was conducted to evaluate the pattern of use of CAM in diabetes participants and to find out the various determinants of the usage of CAM. The study was conducted among 263 patients and found that the prevalence of CAM usage was 46%. The male to female ratio was 2:1. About 80-90% of health care was provided through traditional medicines in Africa. Most chronic diseases were described on a cultural and spiritual basis in Africa, which motivated the use of CAM among people. CAM was defined as proprietary drugs like herbal products, vitamins and minerals. Biodata, duration of DM, type and pattern of CAM utilization and adherence to prescribed medications were documented. CAM usage was considered as important in the management of DM among patients and they used mostly biological therapies. In addition to CAM usage, adherence to prescribed medications was high. However this study did not evaluate the influence of CAM on glycemia. The study design was cross sectional with a sample of 263 patients, irrespective of the type of Diabetes. The study setting was the Diabetes Clinic of the Lagos State University Teaching Hospital, lkeja and the General Hospital Gbagada in Lagos State of Nigeria. Open ended structured questionnaire based on previous studies and informal interviews were used as the study instrument. Information collected included - biodata, anthropometric measurement, duration of DM and type of glucose lowering agents used. CAM in the questionnaires were listed as - local herbs, garlic, ginger, aloe vera, vitamins and bitter leaf. Patients who used at least one of the above agents more than once were selected for the study. Glycosylated hemoglobin values (HbA1c) <7% was considered as optimum

glycaemic control. Reasons for the use of CAM were included in the study. Information from the medical records was used to get patterns about the usage of glucose lowering agents used by the participants. Six doctors and clinical assistants handled the questionnaire. Patients who had taken CAM at least for one year was included in the study. Glycosylated hemoglobin values were also taken into account (Ogbera *et al*, 2010).

A study was conducted in Uganda to investigate the health care seeking behavior among patients with Diabetes mellitus including the use of Complementary and Alternative medicine (CAM) and to study the role of gender in health care seeking behavior. As the country of Uganda was having 560000 registered Diabetes patients and the number of people having Diabetes was increasing many of them were unaware of the treatment and was using different types of medications for the management of the disease. Health services were provided by both public and private sectors. Patients mainly seek treatment from professionals like doctors and nurses for their health care needs. High rate of follow up and utility of cost free public services were mostly seen among females. Due to the severity of the disease those who felt like the failure of the conventional system of medicine mainly used services from traditional and folk healers including CAM. Vaginal itching, dizziness, dry tongue, general weakness, fall down and collapse, abdominal muscle pain, were some of the reasons mentioned by the females for seeking CAM treatment. Joint pain, abdominal muscle pain, sexual dysfunction etc were reasons for seeking health care among males. Hyperglycemia, failed healthcare and complications with Diabetes Mellitus forced people irrespective of gender to seek services from traditional healers. Participants' perspective was mainly focused in this study. As it was a qualitative study the inability to generalize data and

lack of empirical testing of the model described by Helman were the limitations of the study. The author suggested the need for cooperation between the traditional healers and practitioners of conventional medicine as many patients were following the traditional system of medicine. The need for developing the role of nurses in assessing data and planning care for the health care needs was specially mentioned (Hjelm and Atwine, 2011).

A hospital based cross sectional study was conducted in Beirut in Lebanon to determine the prevalence and correlates of type 2 Diabetes mellitus. As per the US National Center, the CAM therapies were divided into four categories such as Mind body systems, Manipulative and body based practices, Energy medicine and biologically based practices. In this study, biologically based practices such as naturally occurring substances like herbs, dietary supplements, multivitamin and mineral supplements and prayers were studied. Those persons who used CAM at least once after the diagnosis of Diabetes Mellitus were included in the study. In the background the researcher reported that because of the difficulty in following the therapeutic regimens and changing lifestyle patterns patients were depending on CAM. The prevalence of CAM was found to be 38%. The percentage of patients who had told to their physician about CAM use was only 7%. About 5% of the patients were using CAM alternatively. Suggestions were made by the researcher to advice the patients regarding CAM use as most of them were using folk remedies and herbalist treatments without consultations. The author suggested interventions from practicing doctors, nurses, pharmacists and dieticians to enhance their knowledge related to CAM and to give proper information on the safe use of CAM therapies to patients. Further study on a national basis was recommended (Naja *et al*, 2014).

A cross sectional study conducted in Singapore found that one year prevalence of CAM use was 22.7%.The eligible subjects in this study were selected at two medical centers (Singapore Health Services Polyclinics)providing public sector primary out-patient care in Singapore over a one week period in January 2003. Eligible patients were Singaporean citizens or permanent residents, adults above 21 years of age, who were treated in the past year for one or more of 12 chronic conditions: asthma, chronic obstructive pulmonary disease (COPD), diabetes mellitus, hypertension, dyslipidaemia, coronary artery disease, cardiac failure, cardiac arrhythmias, stroke, arthritis, gout and other musculoskeletal conditions, such as chronic backache. Most Chinese patients first consulted with the conventional medicine practitioners and after that around 42% of them consulted traditional Chinese herbalists. The reasons for the patients' preferences to CAM were not fully understood, but discussed.CAM use in Chines patients was more prevalent (Chinese -77%, Malay -14%, Indian- 8%) because of traditional systems and beliefs associated with the 'chronic disease triad' (of arthritis, musculoskeletal disorders and stroke), satisfaction with care and cultural beliefs. CAM use was not associated with the quality of doctor–patient interaction. Those people who were using CAM for the past 12 months were selected for the study. Systematic sampling procedure was used to select every third patient. Out of 1670 eligible subjects, 539 were sampled, and 488 completed the interview. No statistically significant differences were seen in demographic and clinical characteristics in participating and non participating patients. A questionnaire with a glossary of terms was used to identify the type of CAM. Dietary therapy included any specific food, extracts and supplements used for the therapy of diabetes excluding those suggested by allopathic doctors (for example: vitamins and Supplements).

Mental well being was assessed using Epidemiological Research Survey questionnaire. Patient satisfaction with care, patient's specific self-care behaviors, patient's social network and support, Family influence on the patient's usage of CAM etc were studied based on questionnaire (Lee *et al*, 2004).

A cross sectional study was conducted in a teaching hospital in Peradiniya (Sri lanka) among 254 Type 2 Diabetes patients attending the clinic regarding CAM use and hyperglycemia. The main objective of the study was to evaluate the practice of Complementary and alternative Medicine among Diabetic patients in Srilanka and to find out the risk of hypoglycemia among CAM users, who also used allopathic system of medicine. 76% reported the use of CAM to reduce hyperglycemia in which most were females and the incidence of hypoglycemia was found to be 21% in CAM users and 16% in non CAM users. Symptoms like hunger, sweating, palpitations, lightheadedness, confusion, loss of consciousness and seizures were used to calculate the presence of hypoglycemia. Measurement of hypoglycemia based on symptoms score rather than biochemical measurements and small sample size were identified as the limitations of the study by the researcher. The presence of co morbidity was also checked and was found to be diagnosed in 162 participants. Bitter gourd (*Momordica charantia*) was the most commonly used CAM (50.8%) and the least used was fenugreek (2%).Among hypoglycemic patients in CAM users most of them used Crepe ginger. The researcher suggested further research on Crepe ginger about its therapeutic activity (Medagama *et al*,2014).

A Meta analysis was conducted to find out the evidence supporting complementary and Alternative medicine use in terms of glycaemic control among Type 2 Diabetes Mellitus patients. Glycosylated hemoglobin & fasting blood glucose (FBG) level could be reduced by using chromium which was found. Glycosylated hemoglobin was found reduced by Gymnema sylvestre in two small open label trials. FBG improved with cinnamon but effect was not found in glycosylated hemoglobin. Bitter melon and fiber were found to be having less effect. Effect of Green tea, Fenugreek on FBG levels was found in one clinical trial. Vanadium was found to reduce FBG. Better glycaemic control was achieved with Chromium and Gymnema sylvestre. The researcher suggested the need for more research on cinnamon and bitter melon since evidences were lacking on microvascular and macrovascular clinical outcomes on complementary and alternative medicines (Nahas and Moher, 2009).

A randomized controlled study was conducted to study the effects of honey in Diabetes therapy. However the researcher suggested further studies to get accurate results (Erejuwa, 2014).

2.2. Traditional, Complementary and Alternative Medicine use at the national level

In India more than 65 million people are affected with Diabetes (International Diabetes Federation Atlas, 2013). A cross sectional study in Allahabad was conducted in Swaroop Rani Endocrine Clinic, with a sample size of 464 participants, with an anticipated proportion of 70% CAM users. Higher levels of education, socio-economic status, low cost, easy availability, free from adverse effects, beliefs etc were the reasons for CAM use. Friends and neighbors were the main source of information about CAM and most of the patients were using naturopathy. About 30% of users adopted CAM without conventional treatment for the first time. Only 42.2% of users got some relief. The common relief found in diabetic patients was lowering of blood sugar. Significant positive correlates for CAM use were higher levels of education and socio-economic status. Diet control and exercise, along with CAM were reported to provide maximum degree of satisfaction (61.9%) among users. About 53.6% of people who used naturopathy found no relief. High prevalence of CAM use was reported even after higher levels of disappointment after use, believing that it will provide relief in future. The researcher suggested the need for community based studies to find the pattern of CAM use among patients who are not attending the clinics run by the conventional system of medicine. All therapies under CAM should be tested for dosage, contaminants, and bioavailability and cost effectiveness before introducing them into the healthcare system. During the study period a total of 6094 patients attended the outpatient clinic. Informed consent of the patients was obtained. Those participants who were not willing to give consent were excluded from the study and were replaced by new ones. A semi structured interview schedule was used to assess their knowledge, attitude and practices relating to CAM and

information on age, socioeconomic status, religion, family history of disease, source of knowledge, reasons of using CAM, methods of use, and perceived relief etc (Kumar *et al*, 2006).

A six month study was conducted in Post Graduate Institute of Medical Education and Research (PGIMER), Chandigargh regarding the use of CAM among hypertensive patients. It was found that 63.9% used CAM and among it, Ayurveda was used by most of the patients. Fear of adverse reactions was the reason for most of the patients to choose CAM. Dissatisfaction was higher in about half of the patients who used CAM. Around 5.4% of them informed the conventional caregiver about CAM (Shafiq *et al*, 2003).

A study was conducted among 4664 patients to assess the extent of use of CAM and satisfaction related to four chronic diseases such as Epilepsy, HIV, Rheumatoid Arthritis and Diabetes Mellitus in a tertiary care teaching hospital of conventional medicine in Mumbai, India. Data showed that 34.4% of the patients were using CAM. 63.2% Diabetes patients, 42.7% Rheumatoid Arthritis, 26.2% HIV, and 7.7% of epilepsy patients were using CAM. 57.1% of the CAM users were using Ayurveda, which was the most preferred modalities in CAM. 44% of Diabetes patients were found using home remedies mostly. Females were using CAM more than males for the treatment of Rheumatoid Arthritis (82%) and HIV (63%). Satisfaction with CAM use was highest in patients with HIV (69.4%) and lowest among Rheumatoid arthritis patients. Physicians awareness about CAM was highest (100%) in Rheumatoid Arthritis patient and lowest among the Diabetes Mellitus patients (29%). 59.9% patients refused to participate in the study citing the reason that their physician will

know about this, as the study setting was a modern medicine hospital based one. The author suggested eliciting the use of CAM at least among chronic patients considering the possibility of allopathic drug interaction with CAM (Bhalerao *et al,* 2013).

A 1:1 randomized controlled pilot study was conducted in Bangalore in order to study the feasibility and efficacy of yoga on diabetes risk factors among people with high risk of Diabetes. Forty one participants were randomized to yoga or walking control using computer generated random numbers. Those patients who were having a highest elevated fasting glucose level were selected for the study. Yoga classes or a complete monitored walking of three to six days in a week for eight weeks were done in the participants of the study. BMI, waist circumference, fasting blood glucose, postprandial blood glucose, insulin and its resistance, blood pressure, cholesterol, psychological well-being such as changes in depression, anxiety, perceived stress were the primary outcomes of the study.

It was found that there were no significant differences in the fasting blood glucose level, postprandial blood glucose, insulin resistance, but significant reductions were found in systolic blood pressure, total cholesterol, anxiety, depression, perceived stress in both yoga participants and walking control during the study. It was found that those patients who participated in yoga intervention had a great reduction in weight and waist circumference than the walking control participants. Therefore the study confirmed that yoga related intervention was effective in decreasing weight related type 2 diabetes (McDermott *et al,* 2014).

In a review article that focused mainly on herbal drugs and preparations used in the treatment of chronic diseases, the benefit of anti pyretic, anti ulcer, anti diabetic and anti cancerous drugs were described. As India is considered as the botanical garden of the world and out of the 2500 species of herbal plants (as listed by WHO), around 150 of them are being used commercially for the treatment of diseases. In the paper Umashankar et al listed the details regarding the medicinal plants that are being used for herbal treatment for diseases including Diabetes. The Common name, Botanical name, parts of the plant used, family and therapeutic uses were discussed. But the paper lacked information regarding the chemical constituents having potent therapeutic activity. The paper indicated that most of the plants were used in traditional Indian systems of medicine like Ayurveda in India. The paper also reported that herbal drugs had some therapeutic activity and that was proved in animal models and further research was suggested including clinical trials (Uma shankar and Shruti, 2011).

2.3. Traditional, Complementary and Alternative Medicine use at the state level (Kerala)

Within India, Kerala state was having the highest prevalence of 20.6% of Diabetes in rural areas (Thankappan *et al*, 2010). A study was conducted in Kerala about the complementary strategies used in the management of Diabetes Mellitus. The study was conducted among 50 urban residents aged 42 to 72 years old. The remedies which most of the patients used were related to their culture and environment available to them, in the context of Kerala. Ethnographic methods were used in this qualitative study. In depth interviews were conducted. Analysis of phytotherapy was done and the study listed 24 plants that were used for the treatment of Diabetes. Many of the participants used phytotherapy, food as adjuncts

and 20% of the patients used ayurvedic medicine for the management of the disease. Some of them used the word 'sugar' for Diabetes. Easy availability and low cost motivated them to select phytotherapy. Culture, place, kin, family and social support were found to be associated with these types of therapies. Qualitative methods such as participant observation and in-depth personal interviews were conducted at three hospitals of Cochin and Thrissur. The researcher studied the treatments used, patients' preferences and sources of information of these therapies. Semi-structured interviews were conducted in Malayalam for about 25-30 minutes to collect relevant information. Basic demographic information, questions about specific medical conditions that included age at which diabetes was detected, latest fasting/ postprandrial blood glucose levels from capillary tests, family history of diabetes and hypertension etc were collected. Height and weight were obtained from the patients' medical charts. Open-ended questions on self-reported care-seeking behaviors and the knowledge and use of conventional and complementary treatments for Type 2 diabetes were collected (Chacko, 2003).

Chapter 3

Methodology

3.1 Study design

Cross- sectional study design

3.2 Subject selection

Self reported diabetes patients were selected using multistage cluster sampling technique

3.3. Study setting

This was a community based study which was carried out in rural areas of Kollam district in Kerala. Kollam district had 11 block panchayaths, out of which two block panchayaths were randomly selected for the study

3.4. Study population

The study was conducted among diabetic patients aged 18 years or more residing in rural areas of Kollam district of Kerala. Patients who were not willing, could not respond to the study due to some disabilities and who did not understand or speak Malayalam were excluded from the study

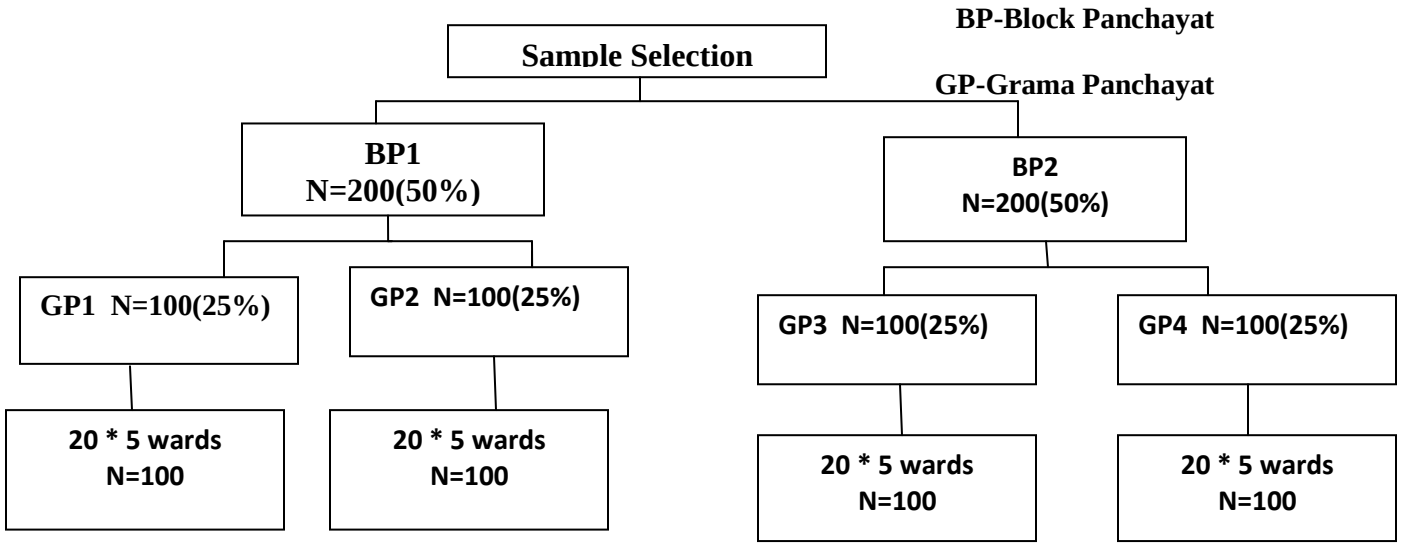
3.5 Sample size estimation

The sample size for the study was estimated using the following formula: $(1.96)^2*p*q/d^2$ where 1.96 is the value for 95% Confidence Interval, p the anticipated prevalence of the use of complementary and alternative medicine which was taken as 20 percent from a previous study in Kerala (Chacko 2003), q was equal to 1-p which was 1-0.2=0.8. 'd', the half width of the confidence interval taken as 0.05. Using this formula the sample size estimated was 246.With a design effect of 1.5 the final sample size was 369 (246*1.5), which was rounded of to 400.

3.6 Sample Selection procedure

Patients were selected using a multi stage cluster sampling technique. There were eleven community development blocks (CDB) in Kollam district out of which two community development blocks were randomly selected. From each of these CDB two Panchayaths each were selected randomly. From each of these selected panchayaths, five wards were randomly selected. Therefore the total number of wards were 20. From each of these selected wards, 20 self reported diabetic patients were selected for the study making a total sample size of 400(20*20). Ward was a cluster in this study. An interview schedule was developed and used to collect information from all the selected participants. Sample s selection process is given in Figure 1.

Figure1 Sample selection process



3.7. Data Collection techniques

Data were collected using a pre tested structured Interview schedule

3.7.1. Interview schedule

Interview schedule included questions on socio-demographic characteristics, history of disease and treatment, questions related to CAM use, factors associated with CAM use including cost of CAM and satisfaction with CAM use (See Anexures 1)

3.8 Study period

The study was conducted between June 16, 2015 to September 20, 2015

3.9 Variables used in the study

3.9.1 Dependent variables

Exclusive CAM use was the main outcome of the present study

3.9.2 Independent variables

3.9.2.1 Socio-demographic and economic variables

Age, sex, marital status, education, employment and occupation, total number of members in the household and household's average monthly expenditure were included as socio-demographic and economic variables.

3.9.2.2 History of disease and treatment

History of diabetes confirmed by a health care provider, treatment for diabetes, specific diet for control of diabetes and regular exercise for control of diabetes were included.

3.9.2.3 Questions related to CAM use

Any morbidity, distance to nearest health facility from home and system of medicine used for the treatment of diabetes were collected.

3.9.2.4 Factors associated with CAM use

Friends, relatives and neighbours working in CAM, reason for selection of CAM medications, consulted a doctor for CAM, frequency of visits to CAM practitioner, frequency of CAM use, supply of CAM, side effects from CAM , recommend CAM for someone were collected to see if any of this factors were associated with CAM use.

3.9.2.5 Expenses for Medicines

Details of the cost of medicines for both CAM and modern medicine were collected.

3.9.2.6 Satisfaction with CAM use

Satisfaction of CAM use was assessed by asking a question on whether the patients were satisfied with the CAM use.

3.10 Ethical considerations

The study received ethical clearance from the institutional ethics committee of Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum. Prior to the study informed written consent was obtained from each patient without any compulsion. Only those who consented without any compulsion were included in the study. Patient could withdraw from the study at any time if they wanted to do so. Privacy and confidentiality were

ensured during and after the study. There was no adverse event during the study. The principal investigator was responsible for maintaining the confidentiality of the data. The information obtained was exclusively for research purpose. The data were accessible only to the primary investigator and the guide. The data collected were stored in the computer after entry with pass word encryption of the file. The hard copy of the filled interview schedule and consent forms were strictly confined to the personal locker of the principal investigator in sealed covers. After three years of preservation in safe, the whole hard copy data will be destroyed as per ICMR guidelines

3.11 Data Analysis

The data entry was done using Microsoft excel software 2007 version and then imported into SPSS version 17. All statistical analysis was done with SPSS version 17. Data cleaning was done prior to analysis. Coding and recoding of the data were done prior to analysis. Descriptive data and frequency were obtained for all the data included in the study. Bivariate analysis was done using Chi-square test for categorical data. Multiple logistic regression analysis was done to find out the correlates of exclusive CAM use. Median expense for medicine was compared between CAM and modern medicine both in government and private sector using Mann Whitney test. A p value of <0.05 was used as cut off for statistical significance.

Chapter 4

RESULTS

The findings of the study are presented in this section. In the first section, general description of the study population is presented. History of diabetes and treatment pattern of diabetes is presented next. Details of CAM use are presented next. Cost of medicine (both modern medicine and CAM) and satisfaction with CAM use is described. Both bivariate and multivariate analysis results are presented for exclusive modern medicine users and exclusive CAM users. The same details for the combination users are also presented as Annexure 2.

3.1 Sample characteristics

A detailed depiction of the study has been given in this section. The study population characteristics are discussed under the following heads: background characteristics, history of disease and treatment, presence of co-morbidity and accessibility to nearest health facility.

3.1.1. Background characteristics

Socio-demographic and economic characteristics of the study sample are presented in Table 1. Mean age was 59 years (range:29 – 87), SD±10.4. Among the employed persons, 10.6% were government employees, 47.9% were private employees and the remaining were self employed, retired or pensioners. On an average there were four members in the household. The monthly median expenditure of the household was rupees 10,000/-.

Table 1. Socio-demographic and economic characteristics

Variables	N=400	%
Age (Years)		
<55	145	36.3
55-65	153	38.3
>65	102	25.4
Sex	218	54.5
Men	182	45.5
Women		
Marital status		
Married	334	83.5
Others*	66	16.5
Education		
< Higher secondary	275	68.7
>=Higher secondary	125	31.3
Employment		
Employed	142	35.5
Unemployed	258	64.5
Average monthly expenditure		
<10,000	140	35.0
>=10,000	260	65.0

*includes single, widows, divorced and separated

3.1.2. History of disease and treatment

Average duration of diabetes was 8 years (SD:7, range <one month to 44 years). When asked about the last visit to the physician or clinic, 48.3% reported within one month, 33% one to six months, 9.3% six months to one year and 9.6% more than one year. More than half of the sample (59.3%) sought treatment for diabetes from private hospital. To the question regarding the reason for using the system, multiple answers were given; easy to access, 43.1%, better treatment, 24.8%, better facilities, 32.6%, low cost, 32.0% and 4.8%

other reasons such as long waiting time, facility not available in the hospital, availability of doctors in the hospital etc.

Table 2 History of disease and treatment

	N=400	%
Last visit to your physician or clinic		
Within one month	193	48.3
Within 1-6 months	132	33.0
Within 6 months to one year	37	9.3
More than one year	35	8.7
Cannot say	3	0.7
Treatment sought last time		
Government	163	40.7
Private	237	59.3
Reason for selecting the above system		
Easy to access	9	2.2
Better treatment	98	24.5
Better facilities	1	0.3
Low cost	128	32.0
Others	19	4.0
Time of last blood sugar check		
Within the last two weeks	200	50.0
One moth	123	30.7
Within 1-6 month	64	16.0
6 month to one year	2	0.5
More than one year	8	2.0
Cannot say	3	0.8

Majority of them (87.3%) diagnosed diabetes during medical consultation for other disease, 11% diagnosed during regular check up and 1.7% in other occasions. Around 85% were following specific diet pattern and 32.8% did exercise regularly for the control of diabetes.

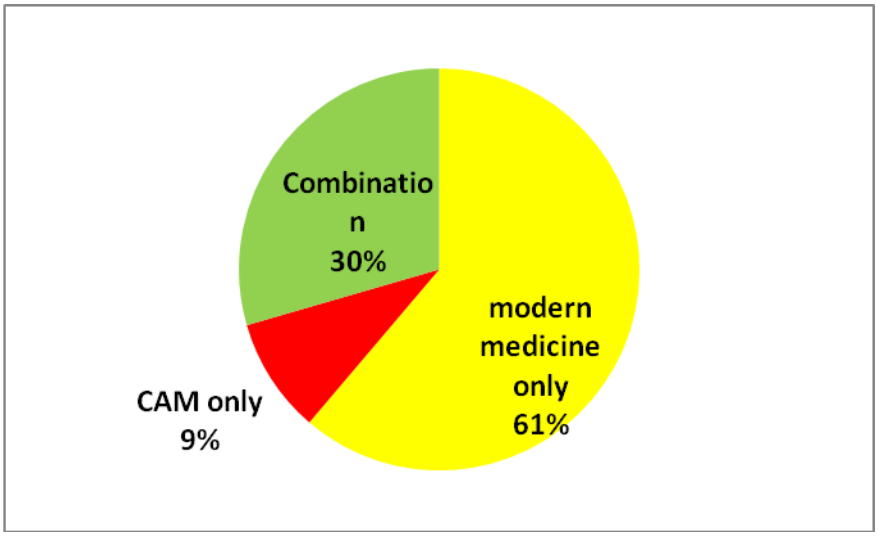
3.1.3. Presence of Co-morbidity

We collected details of other co-morbidity present at the time of the survey; 32.3% reported heart or circulatory disease, 55.5% reported elevated cholesterol, 6.8% kidney disorders, 10.5% neurological problem, 35.8% high blood pressure, 65.3% vision impairment, 47.0% sexual dysfunction, 1.5% liver disease and 4.0% other diseases such as asthma, hernia, hyper thyroidism, prostrate problem etc.

3.1.4. Accessibility to nearest health facility

Average distance to nearest health facility was reported as 2.4 km for modern medicine, 1.9km for ayurveda and 2.1km for homeopathy. For the treatment of diabetes 61.3% usually used modern medicine only (men 62.4%, women 59.9%), 9.3% CAM use only (men 11.0%, women 7.1%) and 29.5% combination of both (men 26.6%, women 33.0%) (see Figure 1).

Figure 2. System of medicine used for treatment of diabetes (N=400)



Among the CAM users, 26.5% reported use of ayurveda, 3.2% homeopathy, 7.1% yoga, 63.2% herbal medicine and 2.6% other use such as sugar therapy. Some of them used more than one type of treatment. Therefore percentages do not add to 100.

3.2. CAM users

Among CAM users, 18.1% had their relatives, friends or neighbors working in CAM (16.2% for CAM only users and 18.2% for combination users). The reason for selection of CAM medication for the treatment of diabetes reported were: ease of availability (9.1%), low cost (1.3%), free from adverse effects (20.6%), modern medicine treatment was not working (37.4%), modern medicine treatment too toxic or too mutilating (12.9%), control of treatment and faith in your hands (1.3%), user friendly (23.5%) and 7.7% reported other reasons such as it was better treatment than modern medicine, it decreases blood sugar etc. 39.4% consulted a doctor for getting CAM treatment. Among those who consulted, 39.3% consulted only once.

More than half of the CAM users (57.4%) used it daily, 8.4% weekly, 31.6% occasionally and 2.6% only once previously. The main source of getting CAM was CAM practitioners (45.8%), followed by friends and relatives (7.2%) and the remaining 47% other sources. Thirteen of the CAM user (8.4%) reported that they experienced some side effects from CAM. More than half (51.6%) recommended CAM for someone with diabetes.

3.3. Satisfaction with the use of CAM

Around 87% reported some reduction in symptoms of diabetes after the use of CAM and 71% were satisfied with the use of CAM for the treatment of diabetes.

3.4. Expenses for medicine

The mean expense for modern medicine was Rs 319 in government hospitals and 371 in private hospitals. Expense for CAM medicine was 302 in government and 367 in private sector.

The median expense for modern medicine was almost similar in government (237 rupees) and private sector (252 rupees). For CAM also the median expense was similar in government (150 rupees) and private sector (187 rupees). The median expense for CAM in government sector was similar to the median expense in the government sector for modern medicine ($p>0.05$). Similarly the median expense for CAM in private sector was similar to the median expense for modern medicine in the private sector ($p>0.05$).

Table 3. Expenses for modern medicine and CAM in the last month

Type of hospital	**Modern medicine only (N=168)**			**CAM only (N=37)**		
	Range	**Mean expense in Rs**	**Median expense in Rs**	**Range**	**Mean expense in Rs**	**Median expense in Rs**
Government	16-826	318.95	237.00	30-1000	302.00	150.00
Private	21-3000	371.11	252.00	60-2000	366.71	187.00

3.5. Socio-demographic and economic correlates of exclusive CAM users

For detailed bivariate and multivariate analysis we considered exclusive modern medicine and exclusive CAM users by excluding the combination users. The details of bivariate analysis of all the study participants by system of medicine use are presented in Annexure 2.

Association of socio-demographic and economic characteristics with exclusive CAM use is presented in Table 4.

Table 4. Socio-demographic and economic factors associated with exclusive CAM use: Results of bivariate Analysis (N=282)

Variables	System of Medicine			P value
	Modern medicine only	CAM use only	Total N=282	
Age				0.981
<55	84(86.6)	13(13.4)	97(100.0)	
55-65	91(86.7)	14(13.3)	105(100.0)	
>65	70(87.5)	10(12.5)	80(100.0)	
Sex				0.374
Men	136(85.0)	24(15.0)	160(100.0)	
Women	109(89.3)	13(10.7)	122(100.0)	
Marital status				0.636
Married	206(87.3)	30(12.7)	236(100.0)	
Others	39(84.8)	7(15.2)	46(100.0)	
Education				0.091
< Higher secondary	169(89.4)	20(10.6)	189(100.0)	
>=Higher secondary	76(81.7)	17(18.3)	93(100.0)	
Employment				0.003
Employed	76(78.4)	21(21.6)	97(100.0)	
Unemployed	169(91.4)	16(8.6)	185(100.0)	
Monthly average expenditure				0.715
<10,000	90(88.2)	12(11.8)	102(100.0)	
>=10,000	155(86.1)	25(13.9)	180(100.0)	

Type of hospital				
Government	96(86.5)	15(13.5)	111(100.0)	0.859
Private	149(87.1)	22(12.9)	171(100.0)	

Other correlates of behavioral modification such as diet control and physical activity, presence of other diseases with exclusive CAM use is presented in Table 5.

Patients who were doing regular exercise to control diabetes, those who did not have elevated cholesterol and those who did not have any other co-morbidity were more likely use CAM compared to their counterparts.

Table 5. Other correlates of using exclusive CAM

Variables	System of Medicine		Total	P value
	Modern medicine Only	CAM use Only		
Following specific diet for the control of diabetes				
No	37(86.0)	6(14.0)	43(100.0)	0.809
Yes	208(87.0)	31(13.0)	239(100.0)	
Regular exercise for control of diabetes				
No	179(91.3)	17(8.7)	196(100.0)	0.002
Yes	66(76.7)	20(23.3)	86(100.0)	
Disease Present				
Having Heart of circulatory disease				
No	171(87.2)	25(12.8)	196(100.0)	0.848
Yes	74(86.0)	12(14.0)	86(100.0)	
Elevated Cholesterol				
No	98(77.8)	28(22.2)	126(100.0)	<0.001
Yes	147(94.2)	9(5.8)	156(100.0)	
Kidney Disorder				
No	223(85.8)	37(14.2)	260(100.0)	0.091
Yes	22(100.0)	0(0.0)	22(100.0)	
Neurological problems				
No	223(87.5)	32(12.5)	255(100.0)	
Yes	22(81.5)	5(18.5)	27(100.0)	0.372
High BP				
No	145(84.8)	26(15.2)	171(100.01)	0.212
Yes	100(90.1)	11(9.9)	111(100.0)	
Vision impairment				
No	76(82.6)	16(17.4)	92(100.0)	0.187
Yes	169(88.9)	21(11.1)	190(100.0)	
Sexual dysfunction				
No	129(85.4)	22(14.6)	151(100.0)	0.483
Yes	116(88.5)	15(11.5)	131(100.0)	
Liver Disease				
No	241(86.7)	37(13.3)	278(100.0)	1.000
Yes	4(100.0)	0(0.0)	4(100.0)	
Others				
No	233(86.9)	35(13.1)	268(100.0)	1.000
Yes	12(85.7)	2(14.3)	14(100.0)	
Any morbidity				
No	14(66.7)	7(33.3)	21(100.0)	0.011
Yes	231(88.5)	30(11.5)	261(100.0)	

Logistic regression analysis was performed using CAM use as outcome variable. The variables found significantly associated with CAM use in the bivariate analysis were put as independent variables in multivariate analysis. The age adjusted logistic regression analysis results were presented in Table 6

Table 6 Results of age adjusted multiple logistic regression analysis of correlates of exclusive CAM use

Variable	%	OR (95% CI)
Any co-morbidity		
Yes	11.5	Reference
No	33.3	4.19(1.14-12.42)
Doing regular exercise for control of DM		
No	8.7	Reference
Yes	23.3	2.60(1.24-5.45)
Employed		
No	8.6	Reference
Yes	21.6	2.84(1.28-6.27)

CAM use was higher among those having any co-morbidity (OR 4.19, 95% CI 1.14-12.42), p=0.010, employed (OR 2.84, CI 1.28-6.27), p=0.011 those doing regular exercise for control of diabetes (OR 2.60, CI 1.24-5.45), p=0.011.

Chapter 5

DISCUSSION

In this study, we tried to find out the proportion of self reported diabetes patients who were using complementary or alternative medicines (CAM) for diabetes treatment either alone or in combination with conventional system of medicine, the various factors that were associated with the use of CAM and the cost of medicines for the treatment with CAM and modern medicine.

Proportion of patients who reported using exclusive CAM for diabetes was 9.3%, where as people who used CAM along with the conventional system of medicine was 29.5% and people who used modern system of medicine exclusively were 61.2%. Since studies on exclusive CAM use are limited, it is not easy to compare our results with previous studies. Combined use of CAM with modern medicine is what is practiced in many developed countries. The previous study from Kerala (Chacko, 2003) reported a prevalence of 20% which was lower than what we found. The higher use of CAM in our study could be due to non availability of free and regular diabetes medication from the public health system in Kerala. There could be other reasons such as poor adherence to modern medicine in Kerala. One of the previous studies in Kerala on adherence to diabetes medication reported that only one fourth of the patients were regularly adherent (Sankar *et al*, 2013). The remaining majority were non adherent due to non availability, cost, and side effects of medication. Patients were complementing CAM with modern medicines probably due to the cultural practices, lack of perceived side effects and acceptability of CAM in Kerala.

The use of CAM in our study (39%) was lower than that reported among diabetes patients in Mumbai (63%) (Bhalerao *et al*,2013). Use of CAM was reported to range from 25% to 85% among Turkey diabetes patients (Inanc *et al*,2007, Tan *et al*, 2004, Yeh *et al*, 2002). Higher CAM use was reported among diabetes patients in Bahrain (63%) (Khalaf *et al*, 2010), in Mexico (62%) (Argaez-Lopez *et al*,2003), Taiwan (61%) (Chang *et al*, 2011) and Palestinian (52%) (Ali-Shtayeh *et al*, 2012) and lower prevalence of CAM use in Jordan (16.6%) (Wazaifi *et al*, 2011), 17% in UK (Leese *et al*, 1997) and 25% in Canada (Ryan *et al*, 2001). The present study reported that 39% consulted CAM use with a doctor which was similar to that reported earlier (Barrett and Naja *et al*, 2014).

One of the major factors associated with exclusive CAM use in our study was the absence of any co-morbidity. Patients without any co-morbidity were four times more likely to use exclusive CAM compared to patients with some co-morbidity indicating that exclusive CAM was preferred by milder or early cases of diabetics. There is a possibility that these patients may be afraid of the side effects of modern medicine and a perception of comparatively safer feeling towards CAM. This also shows that as the disease progresses or with development of any other co-morbidity, they are likely to use modern medicine.

Another major factor associated with exclusive CAM use was the practice of regular exercise for the control of diabetes. Regular exercise is a life style modification. Those who are likely to involve in life style modification would like to control disease without strong medications such as modern medicine. Many people in Kerala are afraid of the side effects of modern medicine resulting in either shifting to alternative medicine or combining modern

medicine with alternative medicine. Therefore they are likely to use what they perceive as a comparatively safer medicine such as CAM to control diabetes.

The third major factor was employment. Unlike to what was reported earlier (Naja *et al*, 2014), our finding showed that patients who were employed were three time more likely to use exclusive CAM compared to those who were unemployed.

Our findings on the expenses for medicine was in the expected line that the median expenses for CAM in both government and private sector was significantly less than that of modern medicine. However, the CAM was mainly used for milder cases of diabetes which could be one of the reasons for the lower expenditure. When co-morbidities were present, more and more people used modern medicine probably because the patients thought that modern medicine would be more effective than CAM when co-morbidities are present or when the disease is more advanced.

As per the reported monthly expenditure for modern medicine, the annual expenses for medicine for one patient was estimated to be rupees 2844 (237 * 12) in the public sector and in the private sector rupees 3024 (252 * 12). The combined expenses would be around Rs 3000 per month. As per the Census 2011 data Kerala had 23.38 million individuals in the age group of 20 years and above. Among them, at least 20% are likely to have diabetes (4.7 million) (Thankappan *et al* 2010). The total expenses for drug will be Rs.1410 crore. The total government health expenditure for Kerala in the year 2009-2010 was Rs 3600 crores (Government of Kerala, 2015). If all the diabetes patients are given free medicines,

government will have to spend 39.2 % of state's total health expenditure for treating the diabetes patients alone.

Strengths of the study

A community based study representing self reported diabetes patients in rural Kollam and the entire data was collected by a single Primary Investigator

Limitations of the study

All treatments were self reported and not validated with any prescriptions. Exclusive CAM use was reported by 9% and the findings cannot be generalized to all diabetes patients.

Conclusion

Exclusive CAM treatment was reported by 9%, exclusive modern medicine by 61% and combined treatment by 30%. Patients with any co-morbidity were less likely to use CAM. Patients who were employed and those who reported regular exercise were more likely to use exclusive CAM .Cost of medicines was not significantly different for CAM compared to modern medicine both in government and private sector. Out of expenses for medicine alone for the patient accounted for nearly 40 % of the total Government expenses for one year in Kerala. It is therefore important to prevent or delay the onset of diabetes in Kerala by implementing effective programs on enhancing physical activity and promoting healthy eating behavior among the entire population.

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ANNEXURE 1

Prevalence and correlates of Complementary and Alternative Medicine Use by Diabetes Patients in Kollam district, Kerala

Interview schedule

1. **Questions 1 to 9 : Socio- Demographic data**
2. **Questions 10 to 20 :History of the disease and treatment**
3. **Questions 21 to 24 : Related to CAM use**
4. **Questions 25- 32: Factors associated with CAM use**
5. **Questions 33 & 34: Cost of treatment**
6. **Questions 35 & 36: Satisfaction with CAM use**

Identification code:	Serial number:	Date: ---/---/2015

Questions 1 to 9: Socio- Demographic Information

1. Age (in completed years):---------
2. Sex 1. ☐ Male
   2. ☐ Female
3. Marital status : 1. ☐ Married
   2. ☐ Single
   3. ☐ Widow/widower
   4. ☐ Divorced
   5. ☐ Others (Specify):------
4. Education: 1. ☐ Illiterate
   2. ☐ Primary (up to class4)

3. ☐ Secondary (5 to 10)

4. ☐ Higher secondary/ equivalent (10+2)

5. ☐ Graduate

6. ☐ Postgraduate

7. ☐ Others (specify) ----------

5. Are you employed?

1 ☐ Yes

0 ☐ No

(If yes go to question number 6, otherwise skip to question number 7)

6. Profession/Occupation:

1. ☐ Clerical

2. ☐ Manual laborers/ unskilled workers

3. ☐ Professionals

4. ☐ Home maker

5. ☐ Self employed

6. ☐ Retired/pensioned

7. ☐ Others (specify---)

7. Total number of members in the household ----------

8. What is your household's average monthly expenditure ----------

9. Material used in the flooring of the house?

1. ☐ Mud

2. ☐ Red oxide

3. ☐ Cement

4. ☐ Tiles

5. ☐ Granite

6. ☐ Marble

7. ☐ Any other (specify):----------

Questions 10-20: History of the disease and treatment

10. When were you told by a health care provider that you have diabetes?

Years --- Months -----

11. When did you last visit your physician/ clinic?

1. ☐ Within one month

2. ☐ Within 1-6 months

3. ☐ Within 6 months to 1 year

4. ☐ More than I year

5. ☐ Cannot say

12. Where did you seek treatment for diabetes in the last time?

1. ☐ Government including ESI and cooperative sector

2. ☐ Private

13. Why did you use the above sector?

1. ☐ Easy to access

2. ☐ Better treatment

3. ☐ Better facilities

4. ☐ Low cost

5. ☐ Others (specify) --------

14. Which system of medicine do you use usually?

Sl.No.	System of medicine used usually	Reason for use
1	Allopathic	1. ☐ Ease of availability 2. ☐ Low cost 3. ☐ Free from adverse effects 4. ☐ Other treatments is not working 5. ☐ Conventional treatment is too toxic or dangerous 6. ☐ User friendly 7. ☐ Others (specify) ----------
2	Ayurveda	
3	Homeopathy	
4	Unani	
5	Siddha	
6	Yoga and naturopathy	
7	Acupuncture	
8	Herbal medicine	
9	Reiki	
10	Others (specify):----------	

15. If you are a person following allopathic system of medicine, what is the type of medication used?

1. ☐ Oral hypoglycemic tablets
2. ☐ Injection (Insulin)
3. ☐ Insulin pumps
4. ☐ Others (specify) ----------

16. When were you diagnosed to have diabetes for the first time? -------

1. ☐ During regular check up
2. ☐ During medical consultation for any other disease/ surgery
3. ☐ Others (specify) ----------

17. How long ago you started treatment for diabetes?

---------Years --- Months

18. When did you check your blood sugar last?

1. ☐ Within the last two weeks
2. ☐ 1 month
3. ☐ Within 1-6 months
4. ☐ 6 months to 1 year
5. ☐ More than one year ago
6. ☐ Cannot say

19. Do you follow any specific diet for the control of diabetes?

1 ☐ Yes

0 ☐ No

20. Do you do any regular exercise for the control of Diabetes?

1 ☐ Yes

0 ☐ No

Questions 21 to 24 related to CAM use

21. Do you currently have any of the following conditions?

Sl. No	Name of the disease	Disease present	Disease not present	Treatment : Yes/ No	Type of treatment	CAM treatment: Yes/ No
1	Heart or					

	circulatory diseases					
2	Elevated cholesterol					
3	Kidney disorders					
4	Neurological problem					
5	Diabetic foot					
6	High blood pressure					
7	Vision impairment					
8	Sexual dysfunction					
9	Liver disease					
10	Others (specify----)					

22. How much is the distance to your nearest health facility from your home?

Sl. No	Name of the system of medicine	Distance(in kms)	Don't know
1	Allopathy		
2	Ayurveda		
3	Homeopathy		
4	Others (specify)---------		

23. Which system of medicine do you usually use for treatment for diabetes?

1. ☐ Allopathic only
2. ☐ CAM only
3. ☐ Combination of the above

(If option 1 is selected then go to question no. 33, skip all other questions)

24. If you use CAM, what among the following do you use?

1. ☐ Ayurveda
2. ☐ Homeopathy
3. ☐ Unani
4. ☐ Siddha
5. ☐ Yoga and naturopathy
6. ☐ Acupuncture
7. ☐ Herbal medicines
8. ☐ Reiki
9. ☐ Others (specify):----------
10. ☐ Combination of the above system of medicine (Specify):----------

Questions 25- 32: Factors associated with CAM use

25. Do you have any of your relatives, friends, and neighbors working in CAM?

1 ☐ Yes

0 ☐ No

26. What is the reason for selection of CAM medications for the treatment of diabetes?

1. ☐ Ease of availability
2. ☐ Low cost

3. ☐ Free from adverse effects

4. ☐ Allopathic treatment is not working

5. ☐ Allopathic treatment is too toxic or too mutilating

6. ☐ Take control of your treatment and your faith in your own hands

7. ☐ Allopathic treatment is too mechanistic/technological and lacks human touch

8. ☐ User friendly

9. ☐ Others (specify) ----------

27. Did you consult a doctor for getting CAM treatment?

1 ☐ Yes

0 ☐ No

28. If yes, how frequently have you visited CAM practitioner since you were diagnosed to have diabetes?

1. ☐ Once

2. ☐ Several times

29. How frequently have you been using CAM medications for diabetes?

1. ☐ Daily

2. ☐ Weekly

3. ☐ Occasionally

4. ☐ Only once previously

30. How do you get your supply of CAM?

1. ☐ From friends

2. ☐ From relatives

3. ☐ From CAM practitioners

4. ☐ From the market

5. ☐ Others (specify) ----------

31. Have you experienced any side effects from CAM?

1. ☐ Yes (specify) ---------

0. ☐ No

32. Would you recommend CAM for someone with diabetes?

1 ☐ Yes

0 ☐ No

Questions 33 & 34: Cost of treatment

33. What was the cost of allopathic medicines in the last month?

Sl. No.	Name of medicine	Dose	Frequency	Rate	Total
1					
2					
3					
4					
5					

34. What was the cost of CAM in the last month?

Sl. No.	System of medicine	Name of medicine	Dose	Frequency	Rate	Total
1						
2						
3						
4						
5						

Questions 35 & 36: Satisfaction with CAM use

35. Did you notice any reduction in symptoms of diabetes after taking CAM?

1 ☐ Yes

0 ☐ No

36. Are you satisfied with the use of CAM for the treatment of diabetes?

1 ☐ Yes

0 ☐ No

Prevalence and correlates of complementary and alternative medicine use by diabetes patients in Kollam district,Kerala

Submitted by-Vishnu Nataraj, E.code-6650, dated 22/04/2015

Achutha Menon Centre for Health Science Studies

Sree Chitra Tirunal Institute for Medical Sciences and Technology

Thiruvananthapuram-11

Informed Consent form

ID Number: | | |

Good morning/ Good afternoon/good evening. I am Vishnu Nataraj, a student of Masters of Public Health (MPH) at Achutha Menon Centre for Health Science Studies, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram. As a part of the course requirement, I am conducting a study to find out the '**Prevalence and correlates of complementary and alternative medicine use by diabetes patients in Kollam district, Kerala'.** For this, I would like to conduct an interview for about 30 minutes.

I am assuring that all the information that you will be sharing with me will be kept highly confidential and only used for research and academic purpose only. You may not be getting any direct benefits by participating in this study, but the information you share will be useful for making health policy in future. Your participation in this study is purely voluntary. You may choose not to answer any question and you have the right to withdraw your participation at any time during the interview without any explanation, without fear of harm or penalty. Your co-operation will add greatly to scientific knowledge and benefit to the society.

For any clarification regarding the study, you can contact me directly (Ph: 9809962004, vishnu@sctimst.ac.in,vishnukailas7@gmail.com). In case you wish to seek any further clarification regarding this study, you can contact the member secretary of the Institute Ethics Committee of SCTIMST, Dr. Mala Ramanathan (Ph: 0471-25224234, email: mala@sctimst.ac.in).

Place: Name and Signature of the interviewer:

Date:

ID Number: | | |

Consent form

I have read the details in the information sheet. The purpose of the study and my involvement in the study has been explained to me. By signing on this consent form, I indicate that, I am willing to participate in the study and I understand what will be expected from me. I know that I can withdraw my participation at any time during the interview without any explanation. I have also been informed who should be contacted for further clarifications.

I, ---------- agree to participate in the study.

Place:

Date: Signature of the participant:

Signature of the interviewer:

Name of the interviewer:

Thank you

ANNEXURE 2

Bivariate analysis of CAM use

Table 1. Bivariate analysis results of socio-demographic and economic factors with CAM use

Variables	System of Medicine		Total	P value
	Allopathy	CAM use		
Age				
<55	84(57.9)	61(42.1)	145(100.0)	0.200
55-65	91(59.5)	62(40.5)	153(100.0)	
>65	70(68.6)	32(31.4)	102(100.0)	
Sex				
Men	136(62.4)	82(37.6)	218(100.0)	0.342
Women	109(59.9)	73(40.1)	182(100.0)	
Marital status				
Married	206(61.7)	128(38.3)	334(100.0)	0.782
Others	39(59.1)	27(40.9)	66(100.0)	
Education				
<Higher secondary	169(61.5)	106(38.5)	175(100.0)	0.912
Higher secondary and above	76(60.8)	49(39.2)	125(100.0)	
Employment				
Employed	76(53.5)	66(46.5)	142(100.0)	0.024
Unemployed	169(65.5)	89(34.5)	258(100.0)	
Monthly average expenditure				
<10,000	90(64.3)	50(35.7)	140(100.0)	0.210
>=10,000	155(59.6)	105(40.4)	260(100.0)	

Type of hospital				
Government	96(58.9)	67(41.1)	163(100.0)	0.465
Private	149(62.9)	88(37.1)	237(100.0)	

Other correlates of behavioral modification such as diet control and physical activity, presence of other diseases with CAM use was presented in Table 4

Table 2. Other correlates of using CAM

Variables	System of Medicine		Total	P value
	Allopathy	CAM use		
Regular exercise for control of diabetes				
No	179(66.5)	90(33.5)	131(100.0)	0.002
Yes	66(50.4)	65(49.6)	269(100.0)	
Following specific diet for the control of diabetes				
No	37(62.7)	22(37.3)	59(100.0)	0.885
Yes	208(61.0)	133(39.0)	341(100.0)	
Disease Present				
Having Heart of circulatory disease				
No	171(63.1)	100(36.9)	271(100.0)	0.275
Yes	74(57.4)	55(42.6)	129(100.0)	
Elevated Cholesterol				
No	98(55.1)	80(44.9)	178(100.0)	0.024
Yes	147(66.2)	75(33.8)	222(100.0)	
Kidney Disorder				
No	223(59.8)	150(40.2)	373(100.0)	0.027
Yes	22(81.5)	5(18.5)	27(100.0)	
Neurological problems				
No	223(62.3)	135(37.7)	358(100.0)	0.242
Yes	22(52.4)	20(47.6)	42(100.0)	
Diabetic foot				
No	62(61.4)	39(38.6)	101(100.0)	1.000

	Yes	183(61.2)	116(38.8)	299(100.0)	
High BP					
	No	145(56.4)	112(43.6)	257(100.0)	0.010
	Yes	100(69.9)	43(30.1)	143(100.0)	
Vision impairment					
	No	76(54.7)	63(45.3)	139(100.0)	0.053
	Yes	169(64.8)	92(35.2)	261(100.0)	
Sexual dysfunction					
	No	129(60.8)	83(39.2)	212(100.0)	0.918
	Yes	116(61.7)	72(38.3)	188(100.0)	
Liver Disease					
	No	241(61.2)	153(38.8)	394(100.0)	1.000
	Yes	4(66.7)	2(33.3)	6(100.0)	
Others					
	No	233(60.7)	151(39.3)	384(100.0)	0.303
	Yes	12(75.0)	4(25.0)	16(100.0)	
Any morbidity					
	No	14(42.4)	19(57.6)	33(100.0)	
	Yes	231(62.9)	136(37.1)	367(100.0)	0.025