1	Original Research Article		
2	Comparison and effectiveness of complementary and alternative		
3	medicine as against conventional medicine in the treatment and		
4	management of type 2 diabetes		
5	Abstract		
6 7 8	<b>Aim:</b> The main objective of the study was to compare, using laboratory data, the efficacy of herbal medicine against pharmaceutical drugs in treating and managing diabetes among type 2 diabetic patients.		
9 10 11 12	<b>Methodology:</b> Patients were included in the study from an Herbal Clinic and the Diabetic Clinic at the Georgetown Public Hospital after giving their consent and satisfying the inclusion criteria. Laboratory analysis was done and analyzed using SPSS version 17 with a p-value of 0.05 is being used to determine statistical significance.		
13 14 15 16 17	<b>Results:</b> Age, religion, ethnicity, education, marital status and monthly income were all found to have significant associations with the use of herbs. Persons using herbal medicine alone had normal HBA1C, FBS, and lipid profile. The most common herbs used were <i>Momordica charantia</i> and <i>Azadirachta indica</i> , which were used in combination or alone. Results showed a positive effect on coronary heart disease risk.		
18 19 20 21	<b>Conclusion:</b> The information generated from the study indicated that a significant number of diabetic patients using herbs alone had normal results. However, a more controlled study is required to validate these results.		
22	Key words: herbal medicine, complementary medicine, type 2 diabetes, alternative medicine		
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# 26 **1. INTRODUCTION**

Diabetes mellitus (DM) is a metabolic disorder that has become a significant and growing public health problem worldwide. Wanchai & Phrompayak conveyed World Health Organization (WHO) statistics of 1.5 million deaths due to diabetes in 2012 with 80% occurring in low and middle-income countries. Moreover, WHO had also reported that in 2014, 9% of adults aged 18 years and older had been diagnosed with DM. DM has been predicted to become the seventh leading cause of death by 2030 with the International Diabetes Federation envisaging a rise in prevalence of 642 million people by 2040 and a rise in the annual global healthcare spending on DM to \$US 802 billion<sup>[1]</sup>.

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35 DM treatment can be broadly divided into two approaches: conventional medicine and alternative medicine <sup>[1]</sup>. In diabetices patients, significant improvements can be achieved by treatment with 36 hypoglycemic or anti-hyperglycemic, insulin sensitizing, and insulin secretion enhancing drugs <sup>[2]</sup>. 37 38 However, although many drugs improve glycemic control, studies have shown that side effects are still 39 frequently reported when using these therapeutic regimes. Meta-analyses from different studies have 40 showed that intensive glycemic control using metformin, sulfonylurea, and thiazolidinediones increased 41 cardiovascular and mortality risk whilst long-term thiazolidinedione use increased the risk of fracture, 42 lower respiratory tract infection, and bladder cancer among those with diabetes. These reports have prompted the search for complementary and alternative medicine (CAM) for better management of 43 diabetes and its related complications <sup>[2, 3]</sup>. 44

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46 Wanchai & Phrompayak categorized CAM into two categories: natural products and practices of the body 47 and mind. Natural products include herbs, vitamins, minerals and probiotics. Practices of the body and mind include a diverse group of procedures or techniques administered or taught by a trained practitioner. 48 49 such as "yoga, chiropractic and osteopathic manipulation, meditation, massage, acupuncture, relaxation 50 techniques (i.e., breathing exercises, guided imagery, and progressive muscle relaxation), Taichi, Qigong, 51 healing touch, hypnotherapy and movement therapy". In addition, other complementary health 52 approaches that may not neatly fit into either of these two groups such as the practices of healers from the traditions of Ayurvedic medicine, Chinese medicine, homeopathy, and naturopathy <sup>[1]</sup>. Some studies on CAM use showed inconsistent results. Prevalence of CAM use ranges from 34-38% <sup>[4, 5, 6]</sup>. In studies related to CAM use by DM patients, the prevalence of CAM use varies from 17% to 80% <sup>[1, 7, 8,]</sup>. These 53 54 55 56 studies have also reported that the most commonly used CAM therapies in patients with diabetes should 57 be nutritional advice and lifestyle diets, herbal remedies, supplements, spiritual healing, and massage 58 therapy and meditation training.

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Thai diabetic patients relied mostly on a modified version of Taichi, Daode Xinxi technique were as nutritional supplements were common among T2D patients in Taiwan, China, whilst Iranians with DM used herbal remedies<sup>[1]</sup>. The possible reasons for these differences may be due to the differences in culture, socioeconomic status and geographic contexts.

Herbal remedies in particular are quite popular in the management of diabetes as from the patient perspective, it may be considered very acceptable to include plants as part of their medical intervention based on the recognition that herbal intervention is considered to be natural and have been part of culture and practices for many generations<sup>[9]</sup>.

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69 Guyana is a country steeped in culture and folklore due to its multiracial beginning. Consequently the use 70 of herbal remedies for ailments has been passed down from generation to generation and it is therefore 71 not surprising that with the upsurge of diabetes, Guyanese may take to herbs to combat this disease. This 72 study was done using laboratory studies, to compare the efficacy of herbal medicine used against 73 prescribed medicine among diabetic patients. It is stated that a high level of knowledge or awareness will 74 affect the outcome of the disease, regardless of race or the geographic location of the various sample 75 populations. Therefore, by providing knowledge on how effective herbal medicine is in managing diabetes 76 in Guyana, there can be better patient outcomes.

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Since most of the studies concerning herbal remedies affects and use were done in other countries, the results might not be applied for Guyanese patients appropriately due to differences in culture, behaviors, socioeconomics and other factors. Using herbs that have no proven clinical benefit to patients, may lead to delays in seeking appropriate treatment, leading to severe diabetes related complications and associated disability and mortality. The authors are conducting this research to determine factors associated with the use of herbal medicine and quality of life affects for Guyanese diabetic patients. The aim of this study was to compare, using laboratory analyses, the efficacy of herbal medicine used against prescribed medicine among diabetic patients in Guyana.

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# 88 **2. METHOD**

A total of sixty diabetic patients (diagnosed for at least six months) from both public medical clinics and a private herbal clinics were enrolled in the study. Patients attending medical clinic and using prescribed medication alone, for the past six months to manage their diabetes were enrolled. Patients attending herbal clinic using herbal medicine alone for the past six months to manage their diabetes. Healthy individuals from outpatient clinic were enrolled as controls.

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A semi-structured questionnaire was used to collect socioeconomic status of participants and other relevant data. Biochemistry and hematology reports of each participants were also collected for analyses.

97 The study was a prospective convenience based study with mixed method approach. Data was analyzed

98 using Statistical Package for Social Science (SPSS) version 20.0.

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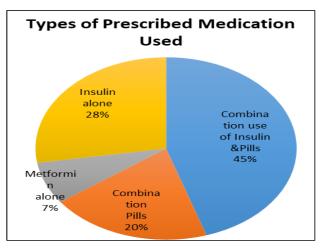
# 100 **3. RESULTS AND DISCUSSION**

### 101 **3.1 Socio-demographic status**

The study had a higher percentage of females than males ( $p \le 0.05$ ) and most participants were in the age group >60. Significantly higher percentage of participants was in East Indian ethnic group ( $p \le 0.05$ ). Almost 43.8% participants had secondary education and most (47.5%) were married. Majority of the participants were unemployed (42.5%) with most having annual income between 50, 000-100, 000 ( $p \le 0.05$ ). Significantly higher percentage of patients were  $\le 45$  years when diagnosed with Diabetes mellitus ( $p \le 0.05$ ) Figure 1.

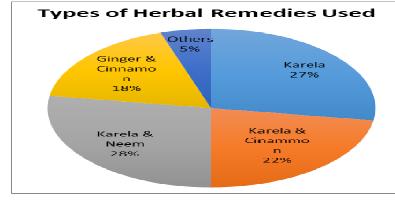
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## 109 Figure 1. Demonstrates types of prescribed medication used.



types of herbal medicine used by the participants.
Karela (27%) were used by majority of the participants
followed by Karela and Neem combination (28%),
followed by Karela and Cinnamon combination (22%).

Most participants (45%) used combination of insulin and OHA (either Metformin, Daonil or both) for control of DM. Figure 2 shows the different



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### Figure 2 Types of herbal remedies used by participants.

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## 127 **3.2 Laboratory analysis**

Table 1 shows laboratory values of study participants. Mean ± SD and 95% CI of lab values were recorded for the study participants. Mean BMI was 27.4±5.1 (95% CI 26.1-28.7) whereas higher mean HbA1c of 9.01±3.2 (95% CI 8.2-9.8). Mean FBS was also recorded to be high with 143.9±73.3 (95% CI 127.6-160.2).

Variable Mean ± SD 95% CI 27.4±5.1 26.1-28.7 BMI DM duration 0.32± HbA1c 9.01±3.2 8.2-9.8 Hb 13.2±1.4 12.9-13.6 WBC 7.2±2.2 67-7.6 Platelet 276.1±78.8 258.6-293.6 FBS 143.9±73.3 127.6-160.2 CHOL 193.4±42.7 183.9-202.9 ΤG 114.7±57.3 102.0-127.5 HDL 49.9±16.8 46.2-53.7 LDL 129.2±35.5 121.3-137.1 VLDL 21.9-27.8 24.8±13.4 CHD RISK 4.7±1.8 4.3-5.1 BUN 16.3±6.2 14.9-17.7 CREATININE 1.3±1.4 0.9-1.6 138.5±3.4 137.8-139.3 Na Κ 4.2±0.5 4.1-4.3 CI 102.6±3.1 101.9-103.3 GGT 29.3±39.7 20.4-38.1 AST 23.6±7.2 22.0-25.2 ALT 24.7±9.3 22.7-26.8 ALP 64.1-98.5 81.3±53.9 A/G/RATIO 1.2±0.5 1.1-1.4 GLOB 3.1-3.7 3.37±0.9 Uric Acid 4.34±1.7 3.8-4.9 Albumin 4.06±0.7 3.8-4.3 ΤP 7.58±1.1 7.2-7.9

133 Table 1. Showing laboratory values of study participants

Table 2 shows comparison of normal laboratory values of participants among the four groups using conventional medicine (CM), alternative medicine (AM), conventional and alternative medicine (CM+AM) and control. For HbA1c, significantly higher percentage (85.0%) of participants taking AM had normal value (p=0.000). For Hb normal value was reported among AM+CM group (p=0.01). Similarly significantly higher percentage of normal values were also observed among AM participants for FBS, AM, Cholesterol, TGL, HDL, LDL, VLDL and CHD.

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HbA1c	n (%)	p value
AM	17 (85.0)	-
AM+CM	0	
CM	2 (10.0)	
С	20	p=0.000
Hb		
AM	12 (60.0)	
AM+CM	17 (85.0%)	
CM	10 (50.0)	
С	20	p=0.01
WBC		
AM	20	
AM+CM	16 (80.0)	
СМ	18 (90.0)	
С	20	p=0.10
Platelets		
AM	20	
AM+CM	19 (95.0)	
CM	18 (90.0)	
С	20	p =0.53
FBS		
AM	17 (85.0)	
AM+CM	1 (5.0)	
CM	1 (5.0)	
С	20	p=0.00
CHOLEST		
AM	19 (95.0)	
AM+CM	8 (40.0)	
CM	8 (40.0)	
С	20	p=0.00
TGL		
AM	20	
AM+CM	10 (50.0)	
СМ	11 (55.0)	
С	20	p=0.00
HDL		
AM	20	
AM+CM	17 (85.0)	
СМ	16 (80.0)	
С	20	p=0.06
LDL		
AM	20	
AM+CM	15 (75.0)	

СМ	11 (55.0)	
C	20	p=0.002
VLDL		
AM	20	
AM+CM	19 (95.0)	
CM	19 (95.0)	
С	20	p=0.56
CHD		
AM	20	
AM+CM	12 (60.0)	
СМ	9 (45.0)	
С	20	p=0.00
BUN		
AM	17 (85.0)	
AM+CM	13 (65.0)	
CM	11 (55.0)	
С	20	p=0.004
CREATININE		
AM	18 (90.0)	
AM+CM	15 (75.0)	
СМ	11 (55.0)	
С	20	p=0.002
Na		
AM	19 (95.0)	
AM+CM	18 (90.0)	
СМ	19 (90.0)	
С	20	p=0.34
CHL		
AM	19 (95.0)	
AM+CM	17 (85.0)	
СМ	16 980.0)	
С	20	p=0.000
GGT		
AM	18 (90.0)	
AM+CM	1 (95.0)	
СМ	16 (80.0)	
С	20	p=0.000
AST		
AM	19 (95.0)	
AM+CM	18 (90.0)	
СМ	19 (95.0)	
С	20	p=0.000
ALT		
AM	20	
AM+CM	16 (80.0)	
СМ	19 (90.0)	
С	20	p=0.000
ALP		
AM	19 (95.0)	
AM+CM	19 (95.0)	
	10 (00.0)	

CM	18 (90.0)	
С	20	p=0.000

### 143 **Table 2 shows comparison of normal laboratory values of participants among the four groups**

144 The study was done to compare Hematology and Biochemistry values of diabetic patients using herbal 145 medicine and prescribed medicine, against Hematology and Biochemistry analyses of normal individuals. Graphical representation on frequency of the different types of prescribed medications used by 146 participants in the study indicated that combination use of Insulin and OHAs was the most popular 147 treatment choice. Martin claims that dissatisfaction with results from orthodox pharmaceuticals as main 148 reason among DM patients to use herbs <sup>[10]</sup>. Frequency of the different types of herbal medicines used by 149 the participants showed that majority used either Karela alone or combination of Karela and Neem. 150 151 Studies have reported several herbs to have lowering effects on HbA1C and FBG, including Fenugreek, Gymnema and Karela which was found to lower both HbA1C and FBG and Green tea and Cinnamon which was found to lower FBG but have no effect on HbA1C<sup>[3, 11, 12]</sup>. However even though these herbs 152 153 154 among others were reported by various studies, no study was found that did a comparison of their effectiveness against the effectiveness of prescribed medications. 155

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Gupta et al indicated that several of these herbs when used in concordance with prescribed medications 157 had better glucose lowering results than when either was used alone <sup>[13]</sup>; contrarily our results showed 158 that almost all the patients in the combination group had elevated HbA1C and FBG. Possible reason for 159 this could have been non-compliance to therapy as was reported by Shams et al who conducted a study 160 on predictors for non-adherence to therapy in T2DM patients and found that there was 73.7% non-161 compliance to therapy when drugs were being used with other modes of therapy <sup>[14]</sup>. It was reported that 162 most persons stopped therapy when they felt healthy. Non-adherence could also be the reason for the 163 drastically large number of persons with elevated HbA1C and FBG in the prescribed alone group. 164 165 According to WHO recommended glycemic levels are achieved by less than 50% of patients, which is usually associated with decreased adherence to long-term therapies<sup>[15]</sup>. 166

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Similarly studies have reported that some herbs used to treat diabetes may also have anti-lipid effects, namely Cinnamon, Karela, Fenugreek, Green Tea, Ginseng and Ginger <sup>[16, 17]</sup>. Even though there were significant number of persons with elevated LDL and TRIG values in the prescribed alone and combination groups, most had either low or normal CHOL values. All three groups had mostly normal HDL. However so, there were notable findings with regards to the CHD Risk. All patients in the HM group had normal CHD risk values whilst almost half in the PM group had elevated values. Only 5 out of 20 persons in the HM+PM group (half of that in the PM group) had elevated values, which can conclude that herbal remedies used did have a positive effect on CHD risk.

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Like cardiovascular disease, diabetes is a precursor for renal damage, also called Diabetic Nephropathy. 177 which usually occurs due to uncontrolled diabetes, and results in raised kidney function values <sup>[18]</sup>. From 178 179 our analysis considerable relationships were found with the Kidney Function Tests and herbal medicine 180 with BUN, CREAT and electrolytes (with the exception of Na) having highly significant p-values. There were very few persons (3) in the HM patient group with elevated BUN levels whilst there were 7 and 9 181 182 with high values in the HM+PM and PM patient groups respectively. Similar results were seen with 183 CREAT. As there is a link between uncontrolled glycaemia and raised BUN and CREAT, it can be reasoned that since the herbs were better at controlling glucose levels, they were indirectly responsible 184 for positively affecting BUN and CREAT levels. However, even when diabetes is controlled, the disease 185 can lead to chronic kidney disease and kidney failure with prolonged existence <sup>[18]</sup>. 186

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Although there may be relationships between elevated liver enzymes and diabetes, theses are multifactorial in origin and are mostly associated with features of metabolic syndrome rather than glycaemic control <sup>[19]</sup>. Results from our study indicate that all the tests in the Liver Function Panel (GGT, ALP, AST, ALT) had highly significant associations. However, most of the patients in all three groups had normal liver enzymes with very few being elevated; therefore these associations remain inconclusive, as many other factors have to be considered.

### 195 **4. CONCLUSION**

Elevated liver enzymes and diabetes are related and have mutifactoril origin. Results from our study indicated that all the tests in the Liver Function Panel (GGT, ALP, AST, ALT) had highly significant associations. However, most of the patients in all three groups had normal liver enzymes with very few being elevated; therefore these associations remain inconclusive, as many other factors have to be considered.

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#### 202 ETHICAL APPROVAL

Ethical approval was sought from the Institutional Review Board (IRB) before commencement of research. Informed consent was also obtained from the respondents before questionnaire was issued.

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