**A COMPARISON OF THE EFFECTIVENESS OF TWO HOMOEOPATHIC DOSAGE FORMS OF *MOMORDICA CHARANTIA* IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS IN PATIENTS ON METFORMIN**

By

Saiesh Govender

This mini-dissertation was submitted in partial compliance with the requirements for the Master's Degree in Technology: Homoeopathy, in the Faculty of Health Sciences at the Durban University of Technology.

I, Saiesh Govender, do hereby declare that this mini-dissertation represents my own work, both in concept and execution.

_____ _____

Signature of Student Date

APPROVED FOR FINAL SUBMISSION

_____ _____

Signature of Supervisor Date
Dr. M. Maharaj
M.Tech.Hom. (TN)

_____ _____

Signature of Co-supervisor Date
Dr. D.F. Naude
M.Tech.Hom. (TN)

***Dedicated to***

***my beloved mother,***

***Komathy***

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## ABSTRACT

### INTRODUCTION

It was reported by the International Diabetes Federation (IDF) Diabetes Atlas, in 2003, that a prevalence figure of 3.4% exists for the 24 million South Africans between the ages of 20 and 79, with an expected increase to 3.9% by 2025. Considering that patients with diabetes are at increased risk of cardiovascular disease, blindness, amputation and renal failure it is therefore not surprising that the costs associated with diabetes are estimated to increase worldwide. It is clear that according to the current trends in dietary and exercise practices, South Africa will be affected by the rise in obesity and subsequent diabetes mellitus. It is critical that a concerted effort involving all parties concerned be made to combat this rapidly increasing problem (Rheeder, 2006:20).

### AIM

The purpose of this double-blind, randomized clinical trial was to compare the effectiveness of *Momordica charantia* homoeopathic mother tincture as compared to *Momordica charantia* 6CH, in the treatment of type 2 diabetes mellitus in patients on Metformin.

### METHODOLOGY

Thirty patients were recruited and were selected for the study on the basis of inclusion and exclusion criteria. These participants were then randomly and equally divided into two groups. Each participant attended a total of four consultations with the researcher, over a two month period, at the Durban University of Technology (DUT) Homoeopathic Day Clinic.

At the commencement of the first consultation, each participant received the subject information letter (Appendix A) for perusal and the informed consent form (Appendix B) to sign. Following this, the researcher took a full, detailed

case history (Appendix F) and performed a physical examination (Appendix G) of each patient.

Participants were required to have a Glycosylated haemoglobin (HbA1C) test performed following the first and fourth consultations. Participants were also required to complete daily Log Sheets (comprising self administered fasting blood glucose readings using issued Bayer Ascensia Elite Glucometers) for the entire duration of the study (8 weeks).

SPSS version 18 was used to analyse the data. A *p* value $\leq$ 0.05 was considered as statistically significant. The time effect was assessed for intra-group comparison whereas the time x group treatment effect was assessed for inter-group comparison. Means were calculated for both fasting blood glucose and glycosylated haemoglobin for the two respective groups and tabulated in order to describe the data obtained (Descriptive statistics).

## RESULTS

Both groups reflected a statistically non significant decrease in fasting blood glucose levels with no significant differences between the two groups when comparing reduction in fasting blood glucose levels. Group 1 (*Momordica charantia* homoeopathic mother tincture) reflected a non significant increase in glycosylated haemoglobin (HbA1C) levels while Group 2 (*Momordica charantia* 6CH) reflected a statistically significant increase over time in HbA1C levels. There were no significant differences between the two groups when comparing reduction in HbA1C levels.

## CONCLUSION

Both homoeopathic preparations of *Momordica charantia* (mother tincture and 6CH) did not significantly reduce fasting blood glucose or glycosylated haemoglobin levels in patients with type 2 diabetes mellitus on Metformin. Although not statistically significant; a general reduction in fasting blood glucose levels evident in both groups' data does suggest a degree of clinical significance which warrants further investigation.

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## DEFINITION OF TERMS

**Centesimal potency**

The sequential addition of 1 part of the stock or of the previous potency to 99 parts of diluent. The number of these serial dilutions, performed with succussion, defines the centesimal potency. The potencies are designated by a number with the letter 'C' following it. Thus 6C represents a 1:99 dilution carried out serially 6 times, with succession at each stage (Swayne, 2000:36).

**Constitutional remedy**

A remedy of fundamental importance to the health of an individual during his entire lifetime. The constitutional remedy for a person is determined by the homoeopath who uncovers certain fundamental truths about the person and then repertorizes that symptomatology or examines the typology in order to uncover the patient's nature or constitution, and the corresponding constitutional remedy (Yasgur, 1998:56).

**Diabetes mellitus**

Is a chronic disease, which occurs when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces. This leads to an increased concentration of glucose in the blood (World Health Organisation, 2008:1).

**Homoeopathy**

Is a holistic therapeutic medical science based upon the teachings of Samuel Hahnemann, which treat illness and inherent constitutional problems by applying the 'like cures like' principle and using minute quantities of specially prepared plant, mineral or animal substances. *Simplex, simile, minimum* (single remedy, law of similars, minimum dose) are the three principles on which homoeopathy is based (Yasgur, 1998:112-113).

**LM potency**

Potencies based on a dilution factor of 1/50 000, as compared with 1/10 (decimal potency) and 1/100 (centesimal potency). The LM mother tincture is prepared from the C3 trituration of the source material dissolved in an ethanol and water mixture. From that point, successive potencies are prepared by serial dilutions of 1/50 000, with succussion (Swayne, 2000:127).

**Mother tincture**

It is the drug solution (alcoholic, hydroalcoholic, aqueous or glyceric) prepared in accordance with homoeopathic pharmacopoeial standards from the corresponding original succus or other soluble base constituent of the medicine. In preparing the homoeopathic mother tinctures (in significant contradistinction to either the phytotherapeutic or the allopathic mother tinctures), the quantity of original drug and the vehicle are proportioned, in such a way that it should represent one tenth (1/10) of the original drug (Gaier, 1991:354-355).

**Phytotherapy**

The term phytotherapy which is based upon herbal medicines was coined by Henri Leclerc, a French physician, and is the bridge between herbal folklore and allopathic medicine. Phytotherapy describes the efficacy and limitations of herbal medicines in the treatment of human diseases (Capasso *et al*., 2003:8).

**Potency**

The measure of the power of the medicine based on the degree to which it has been potentised, expressed in terms of the degree of dilution (Swayne, 2000:165-166).

**Proving**

The process of determining the medicinal properties of a substance; testing substances in material dose, mother tincture or potency, by administration to healthy volunteers, to elicit effects from which the therapeutic potential, or materia medica of the substance may be derived (Swayne, 2000:174).

**Sarcodes**

Are obtained from healthy endocrine or ductless glands or normal secretions (mostly hormones) of living human organs and lower animals (Banerjee, 2007:129).

**Simillimum**

A simillimum is the drug picture most like the clinical picture in the patient; the most accurate match between clinical characteristics of the patient and the materia medica (Swayne, 2000:194).

**Vital force**

That energy which maintains life in the individual. It is unique from person to person, each being endowed with his or her own quality of it. The vital force is a unique principle distinct from chemical or physical phenomenon (Yasgur, 1998:276-277).

# CHAPTER 1

# INTRODUCTION

## 1.1. INTRODUCTION

Diabetes mellitus is a chronic disease, which occurs when the pancreas does not produce enough insulin, or when the body cannot effectively use the insulin it produces. This leads to an increased concentration of glucose in the blood (World Health Organisation, 2008:1).

Ageing and westernization of developing countries have led to a dramatic increase in the worldwide prevalence of diabetes from 100 million in 1994 to an estimated 165 million in 2000 and 230 million in 2010. This increase is primarily due to an increase in type 2 diabetes, particularly in developing countries (Groop, 2002:1689). According to the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) (2011), the prevalence of type 2 diabetes in different South African population groups in urban areas is as follows:

- Mixed (Coloured) - 28.7%
- Indian - 13%
- African - 5.3-8%
- European - 3%

Diabetes affects the daily lives of not only those who have the disease, but also their friends and family. It affects what people with the disease can eat and drink, their lifestyle and many other areas of their lives. They may need to ensure that either they have quick access to food or they carry food with them at all times (Australian Institute of Health and Welfare, 2002:2).

Every chronic condition has the potential for psychological complications, and with the threat of amputation, kidney disease and retinopathy, diabetes is no exception. People with diabetes have a higher risk of developing anxiety and/or depression, along with other psychological difficulties (National Health Service, 2006:1).

The financial burden borne by people with diabetes and their families as a result of their disease depends on their economic status and the social insurance policies of their countries. Besides excess healthcare expenditure, diabetes also imposes large economic burdens in the form of lost productivity and foregone economic growth. The largest economic burden is the monetary value associated with disability and loss of life as a result of the disease itself and its related complications (World Diabetes Foundation, 2010:1). According to Brown (n.d.), figures for the costs of diabetes management in South Africa are unknown, but 2007 US statistics showed that the average medical expenses among people with diagnosed diabetes were 2.3 times higher than they would be in the absence of diabetes.

In the light of the personal, social, psychological and financial impact diabetes has on the human race, many efforts must be made to source a more efficient way to manage the disease. This study proposes to investigate two homoeopathic preparations to such an aim.

## 1.2. PURPOSE & OBJECTIVES OF THE STUDY

### 1.2.1. PURPOSE OF THE STUDY

The purpose of this double-blind, randomized clinical trial was to compare the effectiveness of *Momordica charantia* homoeopathic mother tincture as compared to *Momordica charantia* 6CH, in the treatment of type 2 diabetes mellitus in patients on Metformin.

### 1.2.2. 1ST OBJECTIVE

To determine the effect of *Momordica charantia* homoeopathic mother tincture on fasting blood glucose and glycosylated haemoglobin levels in type 2 diabetes mellitus patients on Metformin.

### 1.2.3. 2nd OBJECTIVE

To determine the effect of *Momordica charantia* 6CH on fasting blood glucose and glycosylated haemoglobin levels in type 2 diabetes mellitus patients on Metformin.

## 1.3. STATEMENT OF HYPOTHESES

### 1.3.1. THE FIRST HYPOTHESIS

It is hypothesised that *Momordica charantia* homoeopathic mother tincture will be effective in reducing the fasting blood glucose and glycosylated haemoglobin levels in type 2 diabetes mellitus patients on Metformin.

### 1.3.2. THE SECOND HYPOTHESIS

It is hypothesised that *Momordica charantia* 6CH will be effective in reducing the fasting blood glucose and glycosylated haemoglobin levels in type 2 diabetes mellitus patients on Metformin.

### 1.3.3. THE THIRD HYPOTHESIS

It is hypothesised that there will be no difference in effect between *Momordica charantia* homoeopathic mother tincture and *Momordica charantia* 6CH in reducing the fasting blood glucose and glycosylated haemoglobin levels in type 2 diabetes mellitus patients on Metformin.

# CHAPTER 2

# REVIEW OF THE RELATED LITERATURE

## 2.1. *MOMORDICA CHARANTIA*

### 2.1.1. DEFINITION

The Latin genus name, *Momordica*, means "to bite," and refers to the jagged edges of the leaves, which appear as if they have been bitten. *Charantia* the species' name, comes from Greek meaning beautiful flower (Jordan, 2008:1).

### 2.1.2. SOURCE

The *Momordica charantia* used to prepare the *Momordica charantia* homoeopathic mother tincture and *Momordica charantia* 6CH remedies were purchased from a vegetable market in Chatsworth, a suburb of Durban.

## 2.1.3. ORIGIN AND HABITAT

The original home of the species is not known, other than that it is a native of the tropics. Bitter melon grows in tropical areas, including parts of the Amazon, east Africa, Asia, and the Caribbean. It is widely grown in India and other parts of the Indian subcontinent (Kumar *et al.,* 2010:95).

## 2.1.4. DESCRIPTION

*Momordica charantia* (bitter melon) is a slender-stemmed tendril climber of the Cucurbitaceae family, the older stem is often flattened and fluted to six meters or longer. Leaves alternate, cut into 5-7 narrow-based lobes. The lobes are mostly blunt, but have small marginal points, up to about 12 cm long, very thin-textured, and characteristically pungent-aromatic. Flowers are yellow on short (female) or long (male) peduncles that are short-lived. Fruit narrowed to both ends, ribbed with prominent tubercles on the ribs, 8-15 cm long, orange when ripe and then becoming softly fleshy and opening to reveal pendulous seeds covered with red pulp (Ross, 1999:214).

## 2.1.5. CULTIVATION

According to Kumar *et al.* (2010:95), *Momordica charantia* is cultivated during the warm season by using 2-3 seeds in a pit. The pits are prepared at a distance of half a meter and provided with manure. Only one plant is retained and seedlings are watered once or twice a week. Plants begin to flower 30-35 days after sowing and the fruits are ready for harvesting 15-20 days after flowering.

The fruits were used in the preparation of the *Momordica charantia* homoeopathic mother tincture and *Momordica charantia* 6CH as described in 3.4.2. and 3.4.3. respectively.

### 2.1.6. TOXICOLOGY

*Momordica charantia* was shown to be safe (no signs of nephrotoxicity and hepatotoxicity and any adverse influence on the food intake, growth organ weights and haematological parameters) in experimental animals when ingested in low doses up to 2 months. Traditionally as well as in experiment, *Momordica charantia* has shown abortifacient activity (Grover and Yadav, 2004:128-129). Patients were excluded from participating in the study if they were pregnant or lactating.

## 2.2. DEFINITION OF DIABETES MELLITUS

The term diabetes mellitus describes a metabolic disorder of multiple aetiology characterized by chronic hyperglycaemia with disturbances of carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both. The effects of diabetes mellitus include long-term damage, dysfunction and failure of various organs. Diabetes mellitus may present with characteristic symptoms such as thirst, polyuria, blurring of vision, and weight loss. In its most severe forms, ketoacidosis or a non-ketotic hyperosmolar state may develop and lead to stupor, coma and, in the absence of effective treatment, death. Often symptoms are not severe, or may be absent, and consequently hyperglycaemia sufficient to cause pathological and functional changes may be present for a long time before the diagnosis is made (World Health Organisation, 1999:2).

The long-term effects of diabetes mellitus include progressive development of the specific complications of retinopathy with potential blindness, nephropathy that may lead to renal failure, and/or neuropathy with risk of foot ulcers, amputation, Charcot joints, and features of autonomic dysfunction, including sexual dysfunction. People with diabetes are at increased risk of cardiovascular, peripheral vascular and cerebrovascular disease. Several

pathogenetic processes are involved in the development of diabetes. These include processes which destroy the beta cells of the pancreas with consequent insulin deficiency, and others that result in resistance to insulin action. The abnormalities of carbohydrate, fat and protein metabolism are due to deficient action of insulin on target tissues resulting from insensitivity or lack of insulin (World Health Organisation, 1999:2-3).

## 2.3. INCIDENCE AND PREVALENCE

Ageing and westernization of developing countries have led to a dramatic increase in the worldwide prevalence of diabetes from 100 million in 1994 to an estimated 165 million in 2000 and 230 million in 2010. This increase is primarily due to an increase in type 2 diabetes, particularly in developing countries (Groop, 2002:1689).

At present, the total prevalence of diabetes varies between 0.8 per cent in Africa to 3.6 per cent in Europe and 5.3 per cent in Northern America. There are however, populations with a very high prevalence of diabetes. In India, the prevalence is about 13 per cent in the age group 30-64 years, in Micronesians on the Island of Nauru it is about 40 per cent in the same age-group while it approaches 50 per cent in the Pima Indians from Arizona (Groop, 2002:1689).

According to the Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA) (2011), the prevalence of type 2 diabetes in different South African population groups in urban areas is as follows:

- Mixed (Coloured) - 28.7%
- Indian - 13%
- African - 5.3-8%
- European - 3%

According to Statistics South Africa (2004:9), the percentage of the respective population groups in Kwa-Zulu Natal is as follows:

- African - 84.9%
- Indian - 8.5%
- European - 5.1%
- Coloured - 1.5%

According to the National Institute of Diabetes and Digestive and Kidney Diseases and the American Diabetes Association (2008), certain race groups tend to be more susceptible to developing type 2 diabetes mellitus. Several risk factors contribute to this pattern, including the following:

- *Genetic background*

  Certain racial groups tend to share a common genetic factor that may affect their insulin secretion and insulin resistance. For example, African-Americans and Asian-Americans may share a "thrifty gene" left over from their ancestors, which enabled them to survive during "feast and famine" cycles. However, with those cycles phasing out, that same gene may make a person more susceptible to developing type 2 diabetes.

- *Gestational diabetes*

  Women who develop gestational diabetes during pregnancy may have a 50 percent chance of developing type 2 diabetes within 20 years of the pregnancy. The prevalence of gestational diabetes is higher among certain groups.

- *Hyperinsulinemia and insulin resistance*

  Hyperinsulinemia, or higher than normal levels of fasting insulin, may lead to diabetes. Certain race groups tend to have higher insulin levels.

- *Obesity*

  Obesity is a major risk factor for type 2 diabetes. Obesity is more prevalent in certain races.

- *Physical inactivity*

  Lack of physical activity can lead to diabetes. Certain groups have higher levels of physical inactivity than others.

A prospective community study was undertaken to determine the incidence of type 2 diabetes and the risk factors associated with its development in a cohort of South African Indians who had been studied 10 years previously. This is a report on 563 subjects who participated both at baseline and at the 10-year follow-up study. In the baseline study, 2479 subjects (> 15 years) were studied; using 1985 World Health Organization criteria for glucose tolerance based on 75 g oral glucose tolerance tests (OGTT), the crude prevalence of diabetes mellitus (Diabetes) was 9.8% and of impaired glucose tolerance (IGT) 5.8% (age and sex-adjusted prevalence 13% and 6.9%, respectively). At the 10-year follow-up study, 563 of the subjects who could be traced consented to a repeat OGTT; of these, 91 (16.2%) were classified as Diabetes and 41 (7.3%) as IGT. Of the subjects who did not have diabetes at baseline (n = 517), 49 (9.5%) progressed to diabetes and 40 (7.7%) had IGT. The crude cumulative incidence of diabetes was 9.5% (rate of progression 0.95% per annum; incidence density 9.5/1000 person years) with an age and sex-adjusted cumulative incidence of 8.3% (rate of progression 0.95% per annum; incidence density 8.3/1000 person years). Examination of risk factors predictive of subsequent diabetes development was undertaken by analysis of baseline (year 0) variables in the 517 subjects who did not have diabetes at baseline. This long-term study has shown that in South African Indians there is a high incidence of type 2 diabetes, and in this population significant predictors include higher baseline blood glucose, body mass index (BMI) and obesity (Motala *et al*., 2003).

Diabetes can occur at any age. Type 2 diabetes mellitus is most common after middle age and occurs most often at 50-70 years of age. The peak incidence of type 1 diabetes mellitus is 10-12 years. Nevertheless, elderly people can have type 1 diabetes and a few children can present with type 2 diabetes (Watkins, 1996:3).

## 2.4. COMPARATIVE CLINICAL FEATURES OF TYPE 1 AND TYPE 2 DIABETES

According to Gazwa (n.d.), the two types of diabetes can be compared and contrasted according to their symptoms. Symptoms of type 1 diabetes are the result of high blood glucose levels whereas symptoms of type 2 diabetes are caused by the body's response to high blood glucose levels. Moreover, symptoms of type 1 diabetes usually develop quickly, over a few days to weeks, while in type 2 diabetes, symptoms often are not present in the early stages of this disease. Patients who have type 1 or type 2 diabetes may experience similar symptoms, such as increased urination, thirst, and weight loss. However, the two types of diabetes can differ in some symptoms. For example, type 1 diabetes symptoms include pain, vomiting, and rapid breathing. In contrast to type 1 diabetes, type 2 diabetes symptoms include slow healing of wounds and blurred vision.

According to Gazwa (n.d.), both types 1 and 2 diabetes have similar complications, such as diabetic nephropathy. Moreover, urinary tract infections in diabetes tend to be more severe and may result in kidney damage. Another complication is diabetic retinopathy. If bleeding and scarring have developed, retinal detachment may occur, causing blindness. Vascular changes in the iris may cause obstruction of the flow, which can cause glaucoma. Diabetics are also more likely than non-diabetics to

develop cataracts. In addition, the two types of diabetes can be contrasted in some complications. For example, type 1 diabetes can increase the risk of diabetic neuropathy while type 2 diabetes may increase the risk of heart disease. People with type 1 diabetes may develop temporary or permanent damage to nerve tissue. Neuropathy is more likely to develop if blood glucose is poorly controlled. In type 2 diabetes, complications include myocardial infarction, angina, hypertension, stroke, and atherosclerosis.

**Table 2.1. Comparative clinical features of Type 1 and Type 2 Diabetes**

| Table 2.1. | | |
|---|---|---|
| | **Type 1 Diabetes** | **Type 2 Diabetes** |
| **Age at onset** | < 40 years | > 50 years |
| **Duration of symptoms** | Weeks | Months to years |
| **Body weight** | Normal or low | Obese |
| **Ketonuria** | Yes | No |
| **Rapid death without treatment with insulin** | Yes | No |
| **Autoantibodies** | Yes | No |
| **Diabetic complications at diagnosis** | No | 25 % |
| **Family history of diabetes** | Uncommon | Yes |
| **Other autoimmune disease** | Yes | Uncommon |
| (Frier and Fisher, 2002:650) | | |

## 2.5. RISK FACTORS FOR TYPE 2 DIABETES

According to the Mayo Clinic (2010), researchers don't fully understand why some people develop type 2 diabetes and others don't. It's clear that certain factors increase the risk, however, including:

- *Weight*
  Being overweight (BMI $\geq$ 25) is a primary risk factor for type 2 diabetes. The more fatty tissue you have, the more resistant your cells become to insulin.
- *Fat distribution*
  If your body stores fat primarily in your abdomen, your risk of type 2 diabetes is greater than if your body stores fat elsewhere, such as your hips and thighs.
- *Inactivity*
  The less active you are, the greater your risk of type 2 diabetes. Physical activity helps you control your weight, uses up glucose as energy and makes your cells more sensitive to insulin.
- *Family history*
  The risk of type 2 diabetes increases if your parent or sibling has type 2 diabetes.
- *Race*
  Although it's unclear why, people of certain races - including blacks, Hispanics, American Indians and Asian-Americans - are more likely to develop type 2 diabetes than whites are.

- *Age*

  The risk of type 2 diabetes increases as you get older, especially after age 45. That's probably because people tend to exercise less, lose muscle mass and gain weight as they age. But type 2 diabetes is also increasing dramatically among children, adolescents and younger adults.

- *Prediabetes*

  Prediabetes is a condition in which your blood sugar level is higher than normal, but not high enough to be classified as type 2 diabetes. Left untreated, prediabetes often progresses to type 2 diabetes.

- *Gestational diabetes*

  If you developed gestational diabetes when you were pregnant, your risk of developing type 2 diabetes later increases. If you gave birth to a baby weighing more than 9 pounds (4.1 kilograms), you're also at risk of type 2 diabetes.

### 2.5.1. GENETICS OF TYPE 2 DIABETES

Type 2 diabetes (T2D) accounts for most individuals with non-autoimmune forms of diabetes. T2D is the quintessential multifactorial trait, where individual risk is defined by the complex interplay of genetic and environmental factors. The exponential increase in prevalence of T2D worldwide is well documented and the result of profound changes in patterns of individual environmental exposure (notably diet, exercise and other lifestyle changes that predispose to obesity). At the same time, evidence that T2D and related intermediate traits show appreciable heritability (gathered from twin, family and admixture studies) attests to the role played by genetic variation in modifying the individual response to these factors (Owen and McCarthy, 2007:239).

Despite the genetic predisposition in individuals with a family history of type 2 diabetes, Barnard (2007:8) states that abundant evidence shows that changes in diet and lifestyle can cut the odds that diabetes will occur. And when it does occur, diet can dramatically alter its course. The point is this: "Some genes are dictators and others are not. The genes for hair or eye colour, for example, really are dictators. If they call for you to have brown hair or blue eyes, you can't argue. But the genes for diabetes are more like committees. They don't give orders; they make suggestions. If our genes call for diabetes, we do not necessarily have to listen to them. We have more control than you might imagine."

## 2.6. PATHOGENESIS OF TYPE 2 DIABETES

The pathogenesis of type 2 diabetes is complex and involves the interaction of genetic and environmental factors. A number of environmental factors have been shown to play a critical role in the development of the disease, particularly excessive caloric intake leading to obesity and a sedentary lifestyle. The clinical presentation is also heterogeneous with a wide range in age of onset, severity of associated hyperglycaemia, and degree of obesity. From a pathophysiologic standpoint, persons with type 2 diabetes consistently demonstrate three cardinal abnormalities:
(1) resistance to the action of insulin in peripheral tissues, particularly muscle and fat but also liver; (2) defective insulin secretion, particularly in response to a glucose stimulus; and (3) increased glucose production by the liver (Buse *et al*., 2003:1429).

From a pathophysiologic standpoint, it is the inability of the pancreatic beta cells to adapt to the reductions in insulin sensitivity that occur over the lifetime of human subjects in response to puberty or pregnancy, a sedentary lifestyle, or overeating leading to weight gain that precipitates the onset of type 2 diabetes. An underlying genetic predisposition appears to be a critical

factor in determining the frequency with which this occurs (Buse *et al*., 2003:1429).

According to Steppel and Horton (2004:169), type 2 diabetes is the result of a progressive impairment of pancreatic beta-cell function in the setting of worsening insulin resistance. Studies in high-risk populations have demonstrated that during progression to diabetes, beta cells have declining function and lose the first phase of insulin secretion, resulting in less than adequate suppression of hepatic glucose production following meals. In addition, oscillations of insulin secretion become unmatched from their normal coupling with glucose. Several mechanisms are thought to be responsible for impaired beta-cell function, including glucose toxicity and lipotoxicity, and potentially contribute to beta-cell loss.

According to Tataranni (2002:27-28), circumstantial and experimental evidence indicate that weight gain causes hyperinsulinemia and insulin resistance. As long as insulin resistance and the resulting hyperglycemia persist, the pancreas is forced to constantly over-secrete insulin, a condition termed ‘allostatic load’. Obesity-induced insulin resistance may cause type 2 diabetes mellitus by increasing the allostatic load of the pancreas. One of the possible ways that an increased allostatic load can eventually lead to failure of the endocrine pancreas is through the direct detrimental effect of hyperglycemia on the beta cell, which is commonly referred to as glucotoxity. Fatati *et al.* (2009:111) state that obesity, meaning visceral adiposity, is the core problem in type 2 diabetes. In the abdominal adipose tissue, insulin resistance reduces the antipolytic effect of insulin, which in turn leads to reduced glucose uptake and increased free fatty acids (FFAs) and glycerol. Chronic exposure of beta cells to FFA levels causes detrimental consequences such as increased insulin secretion at low glucose concentrations, decreased proinsulin biosynthesis, depletion of insulin reserves and reduced response to concentrations of glucose stimulus.

## 2.7. DIAGNOSTIC CRITERIA

### Table 2.2. Diagnostic criteria for diabetes recommended by the World Health Organisation (WHO)

| **Table 2.2.** | |
|---|---|
| **Diabetes** | |
| Fasting plasma glucose | ≥ 7.0 mmol/L (126 mg/dl) |
| 2-h plasma glucose* | ≥ 11.1mmol/L (200mg/dl) |
| **Impaired Glucose Tolerance (IGT)** | |
| Fasting plasma glucose | < 7.0 mmol/L (126 mg/dl) |
| 2-h plasma glucose* | ≥ 7.8 mmol/L and <11.1 mmol/L (140 mg/dl and 200mg/dl) |
| **Impaired Fasting Glucose (IFG)** | |
| Fasting plasma glucose | 6.1 to 6.9 mmol/L (110 mg/dl to 125mg/dl) |
| 2-h plasma glucose* | < 7.8 mmol/L (140mg/dl) |
| * Venous plasma glucose 2-h after ingestion of 75g oral glucose load<br>* If 2-h plasma glucose is not measured, status is uncertain as diabetes or IGT cannot be excluded | |
| (World Health Organisation, 2006:3) | |

## 2.8. CLINICAL FEATURES OF DIABETES

- Thirst
- Dry mouth
- Polyuria
- Nocturia
- Weight loss
- Pruritus vulvae
- Balanitis
- Fatigue/tiredness
- Myopia (Watkins *et al.*, 2003:50).

Of Hippocrates' classic triad of diabetic symptoms - polyuria, polydipsia, and polyphagia - polyphagia is the most intriguing, for this symptom most likely reflects the intracellular (glucose deficiency) as opposed to extracellular (glucose excess) pathophysiology of diabetes. Hyperglycaemia does not, by itself, entirely define the risk for diabetes or its complications. Weight gain and insulin resistance, of which excessive calorie intake is the first clinical sign, are the keys to understanding type 2 diabetes (Fournier, 2000:603).

Patients with type 2 diabetes mellitus may present with symptomatic hyperglycemia but are often asymptomatic, and their condition is detected only on routine testing. In some patients, initial symptoms are those of diabetic complications, suggesting that the disease has been present for some time (Crandall, 2006:1277).

## 2.9. COMPLICATIONS OF DIABETES

According to Carter and Grant (2002:1755), diabetes mellitus is characterized by a range of complications related to the duration of the disease. These complications can be roughly divided into microvascular and macrovascular disorders. The microvascular complications are specific to diabetes while the macrovascular complications occur in the non-diabetic population also but appear at an earlier age and more frequently in people with diabetes. According to Panahloo and Yudkin (2002:1809), in type 2 diabetes up to 75 per cent of all deaths are attributed to macrovascular disease, yet the significance of this is often neglected.

### 2.9.1. MICROVASCULAR COMPLICATIONS

#### 2.9.1.1. RETINOPATHY

According to Carter and Grant (2002:1755), retinopathy occurs in over 90 percent of people with diabetes, given a sufficient duration of the disease. Approximately two per cent of people with diabetes will become legally blind as a result of diabetic retinopathy, and a larger number will have significantly impaired vision affecting their daily lives (MacKinnon and Forrester, 2002:1765).

The pathogenesis of diabetic retinopathy is not fully understood but essentially consists of a microangiopathy affecting both retinal and choroidal vessels. Degeneration of pericytes, the contractile supporting cells which encircle the capillary endothelial cells, is the earliest finding along with thickening of the basement membrane and the formation of microaneurysms (MacKinnon and Forrester, 2002:1766-1767).

### 2.9.1.2. NEPHROPATHY

Nephropathy occurs in less than 20 percent of people with type 2 diabetes (Carter and Grant, 2002:1755). According to Trevisan and Viberti (2002:1779), clinical diabetic nephropathy is defined by the presence of persistent proteinuria (urinary albumin excretion rate greater than 300 mg/day) in sterile urine of diabetic patients with concomitant retinopathy but without other renal disease or heart failure. Once manifest, diabetic nephropathy is characterized by a progressive decline in renal function, resulting in end-stage renal disease. Diabetic nephropathy is now the single most common cause of renal failure in the western world.

Diabetes duration and hypertension are related to the presence of proteinuria. The increase in blood pressure to a hypertensive level is an early feature and accelerates the progression of renal disease in type 2 diabetic patients. The Diabetes Control and Complication Trial (DCCT Study) and the United Kingdom Prospective Diabetes Study (UKPDS) have now precisely documented that the rate of development and progression of diabetic nephropathy is closely associated with glycaemic control both in type 1 and type 2 diabetic patients (Trevisan and Viberti, 2002:1781).

### 2.9.1.3. NEUROPATHY

Diabetic neuropathy is one of the most common complications of diabetes. Its clinical manifestation include; numbness in the feet which often results in ulceration and infection, neuropathic pain which can be severe and disabling, and autonomic neuropathy which can involve several systems. Neuropathy appears to be related to other microvascular complications; by the time a diabetic patient has severe neuropathy, retinopathy and albuminuria are also present (Tesfaye, 2002:1789).

According to Tesfaye (2002:1791-1792), we still do not have a comprehensive explanation for the pathogenesis of diabetic neuropathy, despite considerable research, although metabolic and vascular hypotheses have been proposed. Some of the proposed hypotheses of diabetic peripheral nerve damage include:

- Chronic hyperglycaemia
- Nerve microvascular dysfunction
- Protein kinase C hyperactivity
- Non-enzymatic glycation
- Increased free radical formation
- Abnormalities of nerve growth factors

## 2.9.2. MACROVASCULAR COMPLICATIONS

### 2.9.2.1. CORONARY ARTERY DISEASE

The presentation of cardiovascular disease in diabetes is similar to that in non-diabetic subjects, with angina, myocardial infarction and heart failure being the most prominent. Classical symptoms occur, although angina and myocardial infarction can be painless, possibly due to an autonomic neuropathy. Ischaemic events may present atypically, with sweating, malaise, dyspnoea and syncope, often confused with hypoglycaemia (Panahloo and Yudkin, 2002:1809).

An atherosclerotic plaque alone is not sufficient for the development of coronary heart disease, there being a need for superimposed inflammation, plaque rupture and thrombosis. The procoagulant changes in diabetes contribute to plaque thrombosis precipitating acute myocardial infarction (Panahloo and Yudkin, 2002:1814).

### 2.9.2.2. STROKE

According to Fowler (2008:80), diabetes is also a strong independent predictor of risk of stroke and cerebrovascular disease, as in coronary artery disease. Patients with type 2 diabetes have a much higher risk of stroke, with an increased risk of 150-400 per cent. Risk of stroke-related dementia and recurrence, as well as stroke-related mortality, is elevated in patients with diabetes.

### 2.9.2.3. PERIPHERAL VASCULAR DISEASE

Peripheral vascular disease (PVD) commonly referred to as Peripheral arterial disease (PAD), in diabetic patients, apart from its associated morbidity of intermittent claudication and possible amputation, also is a strong independent predictor for generalized vasculopathy and death. Coronary artery disease and stroke follow closely at the heels of PAD. Thus, PAD is a risk factor for cardiovascular death, and this risk increases with the severity of the claudication. Symptomatic peripheral vascular disease carries a 30 per cent risk of death within 5 years and almost 50 per cent within 10 years. Claudication, in turn, defines more aggressive diabetes mellitus and associated microangiopathy (Vinik and Flemmer, 2002:239).

According to Edmonds and Foster (2002:1821), major advances in the last decade have led to improved outcomes in ulcer management and reduced numbers of amputations. An important prelude to proper management of the diabetic foot is the correct diagnosis of its two main syndromes; the neuropathic foot, in which neuropathy predominates but the major arterial supply to the foot is intact, and the neuroischaemic foot, where both neuropathy and ischaemia resulting from a reduced arterial supply, contribute to the clinical presentation.

## 2.10. MANAGEMENT OF TYPE 2 DIABETES

### 2.10.1. LIFESTYLE INTERVENTION

According to SEMDSA (2010:508), weight loss is recommended for all overweight (BMI $\geq$ 25-29.9 kg/m$^2$) or obese (BMI $\geq$ 30 kg/m$^2$) individuals who have diabetes. Moderate weight loss of 5 per cent of body weight can produce significant health benefits, and may be a reasonable initial goal for most patients. For weight loss, either low-carbohydrate or low-fat calorie-restricted diets may be effective in the short term (up to one year). Regular physical activity helps to maintain weight loss and prevent weight gain.

#### 2.10.1.1. NUTRITION

According to the American Diabetes Association (2008:S64-S66), the following are some of the Nutritional Recommendations for the management of diabetes:

- A dietary pattern that includes carbohydrate from fruits, vegetables, whole grains, legumes, and low-fat milk is encouraged for good health. Monitoring carbohydrate, whether by carbohydrate counting, exchanges, or experienced-based estimation remains a key strategy in achieving glycemic control. People with diabetes are encouraged to consume a variety of fibre-containing foods.
- The primary goal with respect to dietary fat in individuals with diabetes is to limit saturated fatty acids, trans fatty acids, and cholesterol intakes so as to reduce risk for cardiovascular disease (CVD).
- For individuals with diabetes and normal renal function, there is insufficient evidence to suggest that usual protein intake should be modified.

In a study conducted by Barnand *et al.* (2006:1777), it was investigated whether a low-fat vegan diet (free of all animal products and added vegetable oils) improves glycaemic control and cardiovascular risk factors in individuals with diabetes. Individuals with type 2 diabetes (n = 99) were randomly assigned to a low-fat vegan diet (n = 49) or a diet following the American Diabetes Association (ADA) guidelines (n = 50). Participants were evaluated at baseline and 22 weeks. Forty-three per cent (21of 49) of the vegan group and 26 per cent (13 of 50) of the ADA group participants reduced diabetes medications. Including all participants, HbA1C decreased 0.96 percentage points in the vegan group and 0.56 percentage points in the ADA group. Excluding those who changed medications, HbA1C fell 1.23 points in the vegan group and 0.38 points in the ADA group. Body weight decreased 6.5 kg in vegan group and 3.1 kg in the ADA group. Body weight correlated with HbA1C change. Among those who did not change lipid-lowering medications, LDL cholesterol fell 21.2 per cent in the vegan group and 10.7 per cent in the ADA group. It was concluded that both a low-fat vegan diet and a diet based on ADA guidelines improved glycaemic and lipid control in type 2 diabetic patients, however these improvements were greater with a low-fat vegan diet.

### 2.10.1.2. EXERCISE

According to Buse *et al.* (2003:1459), there is a substantial body of literature supporting exercise as a modality of treatment in type 2 diabetes. Exercise is perhaps the single most important lifestyle intervention in diabetes as it is associated with improved glycaemic control, insulin sensitivity, cardiovascular fitness, and remodelling. Aerobic exercise and resistance (strength) training both have a positive impact on glucose control. Improvement in glycaemic control are generally apparent immediately, become maximal after a few weeks of consistent exercise, but may persist for only three to six days after

the cessation of training, hence the rationale for negotiating a minimum of three exercise sessions a week to maintain the benefit of the intervention.

In the large-scale Finnish Diabetes Prevention study of lifestyle intervention, 522 middle-aged obese subjects with impaired glucose tolerance were randomly assigned to receive either brief diet and exercise counselling (control group) or intensive personalized instruction on weight reduction and food intake and guidance on increasing physical activity (intervention group). After a mean follow-up of 3.2 years, a 58 per cent relative reduction in the incidence of diabetes mellitus was observed compared with the control group. The ability to stop the progression to diabetes was strongly correlated with the degree to which subjects were able to achieve one or more of the following goals: (a) weight loss of more than five per cent total body weight; (b) less than 30 per cent of energy intake from fat; (c) less than ten per cent of energy intake from saturated fat; (d) fibre intake of 15 g/1000 kcal or more; and (e) more than 150 minutes of exercise per week (American Association of Clinical Endocrinologists, 2007:14).

### 2.10.2. ORTHODOX PHARMACOLOGICAL INTERVENTION

According to Huddle (1999:152), oral hypoglycaemic agents are indicated in those patients with type 2 diabetes mellitus who have not attained adequate glycaemic control despite adhering to an effective programme of diet and exercise for four to six months, or who in those patients who are symptomatic from the outset.

There are three major groups of oral hypoglycaemic agents:

1. Biguanide (e.g. Metformin)

Metformin is the initial therapy of choice and should be initiated at the time of diagnosis in all patients (both overweight and of normal weight), unless specifically contraindicated (SEMDSA, 2010:509). Metformin acts by blocking glucose production in the liver (gluconeogenesis) and may also stimulate tissue uptake of glucose. It reduces insulin resistance but does not stimulate insulin secretion (Whittaker, 2010:20). Adverse effects of Metformin include abdominal pain, bloating, diarrhoea, anorexia and very rarely lactic acidosis (Whittaker, 2010:22). In the United Kingdom Prospective Diabetes Study (UKPDS) it was found that Metformin was responsible for a 42 per cent reduction in diabetes related death (Whittaker, 2010:22). Metformin reduces HbA1C by 1-2 per cent (SEMDSA, 2010:509).

2. Sulphonylureas (e.g. Glibenclamide)

Sulphonylureas are an option for first-line therapy when the HbA1C is above target and the patient is normal weight; or the patient is intolerant of Metformin; or when rapid control of hyperglycaemic symptoms is needed (SEMDSA, 2010:509). The major mode of action of Sulphonylureas relies on the ability of the pancreas to secrete insulin and they are therefore known as insulin “secretagogues” (Whittaker, 2010:22-24). Adverse effects of Sulphonylureas include hypoglycaemia and weight gain ( $\pm$ 2 kg) (SEMDSA, 2010:509). According to Whittaker (2010:20-24), Sulphonylureas have proven reduction of microvascular endpoints but unlike Metformin, they have not produced significant reductions in myocardial infarction, diabetes-related death and overall mortality. Sulphonylureas reduces HbA1C by 1-2 per cent (SEMDSA, 2010:509).

3. Thiazolidenediones (e.g. Rosiglitazone)

Thiazolidenediones are generic agents and are preferred because of cost-effectiveness (SEMDSA, 2010:509). Thiazolidenediones act by enhancing insulin action and promoting glucose utilisation in peripheral tissues and suppressing gluconeogenesis in the liver. They reduce insulin resistance but have no effect on insulin secretion (Whittaker, 2010:24). Adverse effects of Thiazolidenediones include unpredictable weight gain, development of peripheral oedema, mild anaemia and worsening heart failure (Whittaker, 2010:25). Potential beneficial effects of Thiazolidenediones include an improved cholesterol profile (Whittaker, 2010:24). Thiazolidendiones reduces HbA1C by 0.5-1.4 per cent (SEMDSA, 2010:510).

## 2.10.3. HOMOEOPATHIC TREATMENT

Homoeopathy is a holistic therapeutic medical science based upon the teachings of Samuel Hahnemann, which treat illness and inherent constitutional problems by applying the 'like cures like' principle and using minute quantities of specially prepared plant, mineral or animal substances. *Simplex, simile, minimum* (single remedy, law of similars, minimum dose) are the three principles on which homoeopathy is based (Yasgur, 1998:112-113).

*Similia similibus curantur* from the Latin, 'likes are cured by likes' is the homoeopathic formula expressing the law of similars (the doctrine that any drug which is capable of producing morbid symptoms in the healthy will remove similar symptoms occurring as an expression of disease) (Yasgur, 1998:234).

A simillimum is the drug picture most like the clinical picture in the patient; the most accurate match between clinical characteristics of the patient and the materia medica (Swayne, 2000:194).

According to Gray (2004:14), homoeopathic treatment can help improve the general health of a patient with diabetes. If a person with diabetes is in good health, his or her drug or insulin requirements will be steady and the blood glucose well controlled. If the general health is poor, it can be very difficult to achieve good control. This can be helped by administering a constitutional remedy based on the totality of the patient's symptoms and characteristics. The effect will be to improve the general sense of well-being, to improve diabetes control, and maybe to lower the drug or insulin requirements.

Vithoulkas (2002:258) states that type 2 diabetes is relatively easy to benefit and cure by homoeopathy if complications have not become too serious. Oral hypoglycaemic agents can simply be discontinued in most cases, diet controlled, and homoeopathic treatment pursued as usual.

Sarcodes, are obtained from healthy endocrine or ductless glands or normal secretions (mostly hormones) of living human organs and lower animals (Banerjee, 2007:129), such as Pancreatinum and Insulinum can be used in the treatment of type 2 diabetes. According to Seror (2005), Pancreatinum has been used with success in conditions due to disease or faulty action of the pancreas. According to Vermeulen (2000:1269-816), Insulinum can be used in the treatment of diabetes, restoring the lost ability to oxidise carbohydrates and again storing glycogen in the liver. If administered at suitable intervals in diabetes mellitus, the blood sugar is maintained at a normal level and the urine remains free of sugar.

The following are some of the commonly used Homoeopathic remedies for diabetes:

*Uranium nitricum*

According to Munta (2011), Laning states that no remedy gives such universally good results; it lessens the sugar and quantity of the urine; he recommended the 3X trituration. It is when the disease is due to assimilative

derangements that *Uranium nitricum* is the remedy, and symptoms such as defective digestion, languor, debility and much sugar in the urine, enormous appetite and thirst, yet the patient continues to emaciate.

*Syzygium jambolanum*

According to Munta (2011), this remedy is capable of diminishing the amount of sugar in the urine, especially when used in the tincture and lower triturations. According to Vermeulen (2000:1520), it is a most useful remedy in diabetes mellitus. No other remedy causes in so marked degree the dimunition and disappearance of sugar in the urine.

*Phosphoricum acidum*

According to Munta (2011), this remedy corresponds to diabetes of nervous origin. It suits cases due to grief and anxiety, those who are indifferent and apathetic, poor in mental and physical force. It is unquestionably curative of diabetes mellitus in the early stages, where there is great debility and bruised feeling in the muscles. There will be loss of appetite, sometimes unquenchable thirst and perhaps the patient will be troubled with boils. When patients pass large quantities of pale colorless urine or where there is much phosphatic deposit in the urine it is the remedy. According to Vermeulen (2000:1218), this remedy should be considered whenever the system has been exposed to the ravages of acute disease, excesses, grief, and loss of vital fluids.

*Plumbum metallicum*

According to Munta (2011), Hering considered Plumbum one of the most important remedies in diabetes mellitus. According to Vermeulen (2000:1269-1270), the diabetic symptoms of *Plumbum metallicum* are great hunger or complete loss of hunger, unquenchable thirst especially for cold water and scanty urine.

*Bryonia alba*

According to Munta (2011), no remedy has dryness of the lips as a symptom of hepatic disorder more marked than Bryonia, and this is often one of the first symptom of diabetes. There is a persistent bitter taste, the patient is languid, morose and dispirited, thirst may not be extreme nor the appetite voracious, the patient may lose strength through inability to eat.

In a study conducted by Patra (2005), 430 patients with type 2 diabetes mellitus were taken and split into two groups: Group 1 (215 patients – who were under proper diet and exercise) and Group 2 (215 patients – who were given a simillimum after a thorough case study). They were advised to discontinue allopathic medicines. In Group one, 65 patients were fully controlled by proper diet and exercise. In Group two, 170 patients responded to the homoeopathic medicine, while 45 patients developed complications and were referred for allopathic intervention.

Researchers at the University of Verona in Italy conducted a study comparing the effects of homoeopathic therapy with conventional drug therapy for diabetic neuropathy. Over a 12 month period, 32 patients treated with homoeopathy and 29 patients given conventional drug therapy were assessed for clinical symptoms and quality of life at baseline, 6 months and 12 months after beginning treatment. Improvement from baseline polyneuropathy symptoms was noted in both groups but only those treated homeopathically reached outcomes that were statistically significant. Both groups experienced improvements in blood pressure and body weight as well as levels of fasting blood glucose and glycosylated haemoglobin. In addition, only those in the homeopathy group noted an improvement in quality of life scores over the period of the study (Pomposelli *et al.*, 2009:17-25).

In a systematic review of randomized placebo-controlled studies regarding homoeopathic treatments in psychiatry conducted by Davidson *et al.* (2011:804), it was stated “Overall, we believe the findings offer sufficient

grounds to warrant further clinical trials and are compatible with the use of homoeopathy to treat certain conditions" thus encouraging the validity of using a randomized controlled trial (RCT) in homoeopathy, such as the one that was conducted in this study.

### 2.10.4. PHYTOTHERAPEUTIC TREATMENT

Plant derivatives with purported hypoglycaemic properties have been used in folk medicine and traditional healing systems around the world. Many modern pharmaceuticals used in conventional medicine today also have natural plant origins. Among them, metformin was derived from the flowering plant, *Galega officinalis* (French Lilac), which was a common traditional remedy for diabetes (Yeh *et al.*, 2003:1277,1280).

The following are some of the herbal remedies that have been proved in clinical trials to be effective in the management of diabetes:

*Momordica charatia*

According to Leung *et al.* (2009:1702), *Momordica charantia* (bitter melon) is a popular fruit used for the treatment of diabetes amongst the indigenous populations of Asia, South America and East Africa. The rationale for using *Momordica charantia* in mother tincture and homoeopathic dilution to treat type 2 diabetes mellitus despite it being unproved homoeopathically is that *Momordica charantia* is a common food in Indian cuisine and has been used extensively in folk medicine as a remedy for diabetes (Kumar *et al.,* 2010:95). Murray (1995:357-358) mentions that *Momordica charantia* is composed of several compounds with confirmed anti-diabetic properties. Charantin, extracted by alcohol, is a hypoglycaemic agent composed of mixed steroids that is more potent than the oral hypoglycaemic drug tolbutamide. *Momordica charantia* also contains an insulin-like polypeptide, polypeptide P, which lowers blood sugar levels when injected subcutaneously into type 1 diabetics.

Adverse effects of *Momordica charantia* include:

- Hypoglycaemic coma
- Favism (In individuals with glucose-6 phosphate defiency)
- Induction of abortions
- Abdominal discomfort
- Diarrhoea

(Leung *et al.*, 2009:1706).

The largest study, published in a 1999 issue of the Bangladesh Medical Research Council Bulletin, used an aqueous suspension of bitter melon vegetable pulp in 100 patients with type 2 diabetes mellitus. The authors evaluated the effect 1 hour after bitter melon was administered and then 2 hours after a 75 gram oral glucose tolerance test. The average blood glucose was 222mg/dl (12.33mmol/L), which was lower than the previous day's 2-hour value of 257mg/dl (14.28mmol/L) (Shane-McWhorter, 2005:2).

*Cinnamon*

A study conducted by Khan *et al.* (2003:3215) demonstrated that the intake of one gram, three grams, or six grams of cinnamon per day reduces serum glucose (18-29 per cent – after 40 days), triglyceride, LDL cholesterol, and total cholesterol in people with type 2 diabetes and suggest that the inclusion of cinnamon in the diet of people with type 2 diabetes will reduce risk factors associated with diabetes and cardiovascular disease.

*Gymnema sylvestre*

Two non-randomized controlled clinical trials involving groups of patients with type 1 diabetes and type 2 diabetes showed improved glycaemic control with chronic adjunctive use of Gymnema sylvestre (GS4) extract compared with those who received conventional treatment alone (Yeh *et al.*, 2003:1286).

*Panax ginseng*

The effects of Panax (Asian or Korean) ginseng, given in a dosage of 100 or 200 mg per day for eight weeks, were studied in 36 patients with newly diagnosed type 2 diabetes mellitus. The study showed improved fasting blood glucose levels. The 200-mg dose also resulted in improved HbA1C levels (Kiefer and Pantuso, 2003:1541). It is concluded by Vuksan and Sievenpiper (2005:149) that the best evidence for clinical efficacy in diabetes remains for ginseng.

## 2.11. OUTCOME MEASURES IN THE EVALUATION OF TREATMENT RESPONSES IN TYPE 2 DIABETES MELLITUS

### 2.11.1. FASTING BLOOD GLUCOSE

The fasting blood glucose test measures blood sugar levels and is used to diagnose diabetes. Relatively simple and inexpensive, the test exposes problems with insulin functioning (Close, 2008). The fasting blood glucose test provides a simple and reliable method of screening for diabetes and is performed at least eight hours after eating and drinking (Zimmet *et al*., 2002:1639). Prolonged fasting triggers a hormone called glucagon. It causes the liver to release glucose into the bloodstream. If a person doesn't have diabetes, his or her body reacts by producing insulin, which prevents hyperglycemia. However, if one's body cannot generate enough insulin or cannot appropriately respond to insulin, fasting blood sugar glucose levels will remain high (Close, 2008).

The properties of fasting plasma glucose (at a threshold of greater than or equal to 6.1 mmol/L) as a screening tool for diabetes has been reported in a only one exception, in each of these studies, the Oral glucose tolerance test was performed on the whole population, irrespective of an individual's fasting

glucose. From these data, the median sensitivity was 81 per cent, and the median specificity was 92 per cent (Zimmet *et al*., 2002:1639). Since the introduction of the new lower diagnostic threshold of 7.0 mmol/L for fasting plasma, it has been suggested that the Oral glucose tolerance test can be virtually dispensed with and the fasting blood glucose alone can be used to diagnose and exclude diabetes (Zimmet *et al*., 2002:1639). Fasting blood glucose was measured by the patient using a Glucometer (Bayer Ascensia Elite) which was provided to each patient for the duration of the trial. A Glucometer was used as opposed to utilising the services of a laboratory for obvious economical reasons as well as for the convenience of the patient. Blood glucose meters have often been used as part of screening programmes for diabetes (Zimmet *et al*., 2002:1639).

### 2.11.2. GLYCOSYLATED HAEMOGLOBIN (HbA1C)

The HbA1C test is an accurate reflection of the glucose control over the preceding two to three months – the average lifespan of the red blood cells – and should be measured every three months in patients with diabetes (Shah and Zinman, 2002: 1700). Test results indicate what percentage of haemoglobin proteins are "glycosylated" or have glucose stuck to them. The result is an average and a patient may have a "good" result even if they have had extreme high and low glucose levels, so regular self-monitoring is still important. The normal level for a person without diabetes is about 5%. The American College of Endocrinology and The International Diabetes Federation recommend levels under 6.5% for people with diabetes. The American Diabetes Association recommends levels under 7% for most people with diabetes (Woolley, 2011). The Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA, 2009:1) recommends levels under 7%.

Elevated HbA1C levels indicate poor glycaemic control and the need to adjust the patient's treatment regimen (Shah and Zinman, 2002: 1700). The

glycosylated haemoglobin test can be used for gauging the progression of chronic microvascular or macrovascular diabetic complications, with increasing HbA1C levels correlating with the increased risk of the above mentioned complications (Charles, 2002: 648). HbA1C is attractive as both a screening and diagnostic test because it is simple, requires no preparation and directly relates to treatment targets (Zimmet *et al*., 2002:1639). HbA1C was measured at baseline and after 41 days of treatment.

# CHAPTER 3

# METHODOLOGY AND MATERIALS

## 3.1. OBJECTIVE

The objective of this double-blind, randomized clinical trial was to determine the effect of *Momordica charantia* homoeopathic mother tincture and *Momordica charantia* 6CH on daily fasting blood glucose and glycosylated haemoglobin levels in type 2 diabetes mellitus patients on Metformin.

## 3.2. STUDY DESIGN

A sample group of 30 participants were voluntarily selected for the study on the basis of inclusion and exclusion criteria (as detailed in section 3.3.2.). These participants were then randomly divided into 2 groups (15 patients for each of the *Momordica charantia* homoeopathic mother tincture and *Momordica charantia* 6CH groups). Each participant had to attend a total of four consultations with the researcher, over a two month period, at the Durban University of Technology (DUT) Homoeopathic Day Clinic. Permission was granted by the Clinic Director, for the use of the facility over this period.

At the commencement of the first consultation, each participant received the subject information letter (Appendix A) for perusal and the informed consent form (Appendix B) to sign. Following this, the researcher took a full, detailed case history (Appendix F) and performed a physical examination (Appendix G) of each patient. At this point, if the patient met the inclusion criteria, then the patient qualified for the study.
Patients were required to fill in a Log Sheet (Fasting blood glucose readings) every day for a period of 56 days. Glycosylated haemoglobin (HbA1C) levels

were measured at consultation 1 (baseline) and consultation 4 (end of study).

The Homoeopathic Day Clinic laboratory technician dispensed medication to the respective groups according to the randomisation sheet drawn up by the research supervisor. This followed the second and third consultations for each participant.

The experimental medication was dispensed in liquid format (75ml) and comprised either the *Momordica charantia* homoeopathic mother tincture or the *Momordica charantia* 6CH. Each participant received 50 ml following the second consultation and 25 ml following the third consultation and was directed on how to take them.

Participants were asked to return for the second consultation 2 weeks following the first. If the participant's average fasting blood glucose level (Baseline after 2 weeks) was $\geq$ 7.0 mmol/L then the participant would be considered eligible to take part in the study and would then receive 50 ml of either the *Momordica charantia* homoeopathic mother tincture or the *Momordica charantia* 6CH.

The third consultation took place 6 weeks following the first, and the fourth consultation took place 8 weeks following the first consultation.

## 3.3. PARTICIPANTS

### 3.3.1. RECRUITMENT OF PARTICIPANTS

Participation in this study was on a voluntary basis. Participants were obtained by means of advertising, distribution of pamphlets, referrals as well as verbal communication. Advertisements were placed in the local tabloid.

The researcher recruited participants according to the selection criteria listed in 3.3.2.

Approximately 70 individuals, showing interest in the study, contacted the researcher and were subsequently screened via brief telephonic interview. 50 prospective participants were then invited to attend the first consultation with the researcher. Out of this number, 40 participants qualified for the study, based on the inclusion and exclusion criteria. Of these, 30 participants managed to complete the study. A small number of participants met the inclusion criteria at the start of the study but did not meet the inclusion criteria at the second consultation (i.e. their average fasting blood glucose level after 2 weeks was not $\geq$ 7.0 mmol/L and were thus excluded from the study). This was done to ensure that only patients' whose average fasting blood glucose levels were inadequately controlled (i.e. their average fasting blood glucose level was $\geq$ 7.0 mmol/L) despite being on Metformin, participated in the study. The participants were then randomly assigned to receive the *Momordica charantia* homoeopathic mother tincture (n = 15) or the *Momordica charantia* 6CH (n = 15), according to the randomisation chart, as administered by the Homoeopathic Day Clinic dispensing technician.

The Metformin each patient was on, was prescribed by their respective general practioner. All participants were informed to seek advice from their general practioner before commencing the trial. At no stage of the trial were patients required to discontinue taking their Metformin.

## 3.3.2. SELECTION CRITERIA

### 3.3.2.1. INCLUSION CRITERIA

- Participants had to be between 18 and 80 years of age.

- Participants who had been previously diagnosed with type 2 diabetes mellitus and were currently taking only Metformin (Glucophage®) for the treatment of their diabetes.
- Participants who had a stable fasting blood glucose of ≥ 7.0 mmol/L.
- Participants had to be willing not to change their lifestyle or dietary habits for the duration of the trial.

#### 3.3.2.2. EXCLUSION CRITERIA

➢ Participants who were:

- allergic to bitter melon or a member of the Curcurbitaceae (gourd or melon) plant families.
- pregnant or lactating during the study.
- diagnosed with glucose-6-phosphate deficiency.
- illiterate were excluded, as they were required to read, understand and complete the consent forms.
- unable to speak the English language were excluded, as the consultation for this research was facilitated in English.

## 3.4. TREATMENT

### 3.4.1. EXPERIMENTAL MEDICINES

The medicines utilised for the study were prepared at the Durban University of Technology Homoeopathic Day Clinic Dispensary. The medicines were in a liquid format and were dispensed in 50ml (second consultation) and 30ml (third consultation) amber glass bottles.

## 3.4.2. MANUFACTURE OF *MOMORDICA CHARANTIA* HOMOEOPATHIC MOTHER TINCTURE

The *Momordica charantia* homoeopathic mother tincture was produced in accordance with method 2a of the German Homoeopathic Pharmacopoeia (2005) and was dispensed in 43% alcohol base. In preparing the homoeopathic mother tinctures in significant contradistinction to phytotherapeutic mother tinctures, the quantity of original drug and the vehicle are proportioned, in such a way that it should represent one tenth (1/10) of the original drug (Gaier, 1991:354-355).

Mother tinctures according to Method 2a (Appendix H) (alcohol content approximately 43 per cent) are prepared by maceration and is described below:

The plants (*Momordica charantia)* were finely minced. A sample was used to determine loss on drying. To the minced plant material, not less than half the amount by mass of alcohol 86 per cent was added and then stored in a well-closed container at a temperature not exceeding 20 °C. The amount of alcohol 86 per cent required ($A_2$), for the plant material was calculated using the formula below. Then the amount of alcohol that had already been used was subtracted and the remaining amount was added to the mixture. The mixture was then left to stand for not less than 10 days at a temperature not exceeding 20 °C, and was swirled from time to time, before eventually being expressed and filtered.

$$A_2 = \frac{m \,.\, T}{100} \quad [kg]$$

$m$ = mass of plant material in kg

$T$ = loss on drying of the sample (in per cent)

Fresh *Momordica charantia* – 10g

Dried *Momordica charantia* – 0.988g

$A_2 = \frac{1.5 \times 90.12}{100}$ [kg]

= 1.3518kg

= 1351.8g

## 3.4.3. MANUFACTURE OF *MOMORDICA CHARANTIA* 6CH

*Momordica charantia* 6CH (liquid potency) was produced in accordance with method 5a (Appendix I) of the German Homoeopathic Pharmacopoeia (2005) and was dispensed in 43% alcohol base.

1 Part of the raw material (*Momordica charantia* homoeopathic mother tincture*)* was dissolved in 99 parts (= CH1) of the liquid vehicle and was succussed 10 times. The 2nd centesimal dilution (CH2) was made from 1 part CH1 and 99 parts of alcohol 43 per cent. Subsequent dilutions up to the 6CH potency required were produced accordingly.

Liquid preparations according to Method 5a are solutions produced from the raw material and a liquid vehicle. This required preparing the mother tincture according to Method 2a (Appendix I) as described in 3.4.2. The same batch used to make the *Momordica charantia* homoeopathic mother tincture was drawn from to make the *Momordica charantia* 6CH and was dispensed in the *Momordica charantia* homoeopathic mother tincture format.

## 3.4.4. INTERVENTION

The researcher took a full, detailed case history (Appendix F) and performed a performed a physical examination (Appendix G) of each participant.

Each participant was given 50ml following the second consultation and 25ml following the third consultation (75ml in total). Participants were directed to take 20 drops twice a day in a little water, approximately 30 minutes away from meals. The respective dose although administered orally with an active principle of 43% alcohol was considered safe since it was prepared in accordance with the German Homoeopathic Pharmacopoeia and was added to about a quarter glass of water thus further diluting the effects of the alcohol base. It was assumed that all participants took their medicine and administered it in the correct way, as directed.

## 3.5. OUTCOME MEASURES

Participants were required to have a Glycosylated haemoglobin (HbA1C) test performed following the first and fourth consultations. Participants were also required to daily fill in a Log Sheet (Glucometer readings - Fasting blood glucose levels) for the entire duration of the study (8 weeks).

### 3.5.1. FASTING BLOOD GLUCOSE

Fasting blood glucose was measured daily by the participants using a Glucometer (Bayer Ascensia Elite) which was provided to each participant for the duration of the study. Blood glucose meters have often been used as part of screening programmes for diabetes (Zimmet *et al*., 2002:1639). Participants were shown how to use the Glucometer correctly in consultation 1 and were thereafter asked to demonstrate how to use it. Participants also received instructions on how to perform a Blood Glucose Test (Appendix D). Participants recorded their blood glucose levels on a Log Sheet (Appendix E) on their own every morning before breakfast (Participants were advised not to have anything to eat or drink after supper the night before and in the morning before their blood glucose test was performed).

### 3.5.2. GLYCOSYLATED HAEMOGLOBIN (HbA1C)

Circulating glucose molecules are non-enzymatically and irreversibly bound to haemoglobin A molecules forming the electrophoretically fast haemoglobins A1a, A1b and A1c. For technical reasons, most clinical laboratories measure only A1c – the proportion of haemoglobin molecules which is glycosylated is a function of the plasma glucose concentration over time. Thus, the haemoglobin A1c is an accurate reflection of the glucose control over the preceding two to three months – the average lifespan of the red blood cells – and should be measured every three months in patients with diabetes. Elevated haemoglobin A1c indicate poor glycaemic control and the need to adjust the patient's treatment regimen (Shah and Zinman, 2002: 1700). The glycosylated haemoglobin test can be used for gauging the progression of chronic microvascular or macrovascular diabetic complications, with increasing HbA1C levels correlating with the increased risk of the above mentioned complications (Charles, 2002: 648). HbA1C is attractive as both a screening and diagnostic test because it is simple, requires no preparation and directly relates to treatment targets (Zimmet *et al*., 2002: 1639). HbA1C was measured at baseline and after 41 days of treatment.

## 3.6. STATISTICAL ANALYSIS

Only data collected from the Log Sheet (Appendix E) and the Lab results (Glycosylated haemoglobin levels) were used for analysis.

### 3.6.1. DATA ANALYSIS

Various Descriptive and Inferential statistical techniques were used. The Descriptive procedures used were various tables and graphs, and a few summary statistics including but not limited to means, proportions and

percentages. Inferential statistics included various hypothesis-testing techniques. Due to the size of the samples, namely 15 in each group, non-parametric tests were used. All tests set the type 1 error at 5%, or mentioned differently, $\alpha = 0.05$. If the *p* value reported was less than, or equal to 0.05 a significant result would be declared and the null hypothesis would be rejected.

#### 3.6.1.1. PROCEDURE 1 (Intra Tests for *Momordica charantia* homoeopathic mother tincture and *Momordica charantia* 6CH groups)

The time effect was assessed for intra-group comparison.

- **Hypothesis Testing**

The null hypothesis $H_0$, states that there is no significant difference between the four consultations being compared at the $\alpha = 0.05$ level of significance. The alternative hypothesis $H_1$, states that there is a significant difference between the four consultations being compared.

- **Decision rule**

At the $\alpha = 0.05$ level of significance, the null hypothesis is rejected if $p \leq \alpha$ where *p* is the observed significance level. Otherwise, the null hypothesis is accepted at the same level of significance.

### 3.6.1.2. PROCEDURE 2 (Inter Tests between both groups)

The time x group treatment effect was assessed for inter-group comparison.

- **Hypothesis Testing**

The null hypothesis $H_0$, states that there is no significant difference between the four consultations being compared at the $\alpha = 0.05$ level of significance. The alternative hypothesis $H_1$, states that there is a significant difference between the four consultations being compared.

- **Decision rule**

At the $\alpha = 0.05$ level of significance, the null hypothesis is rejected if $p \leq \alpha$ where $p$ is the observed significance level. Otherwise, the null hypothesis is accepted at the same level of significance.

### 3.6.1.3. PROCEDURE 3 (Descriptive statistics)

Means were calculated for both fasting blood glucose and glycosylated haemoglobin for the two respective groups and tabulated in order to describe the data obtained.

## 3.6.2. STATISTICAL PACKAGE

The statistical analysis of data entry was conducted using the Statistical Package for Social Sciences® (SPSS for Windows®, version 18 software suite).

## 3.7. ETHICS

The researcher explained the nature of the study to each participant who met the selection criteria. Each participant was given the subject information letter (Appendix A) for perusal, and all participants gave informed consent (Appendix B).

Participants were deliberately chosen to be on Metformin as it would be medically and ethically unsafe to discontinue their medication abruptly so that they could participate in this clinical trial. Each patient was made aware of the remedy contents if they inquired and thus made their own choice whether or not to participate.

The Durban University of Technology's Research Ethics Policy and Guidelines were used to ensure that ethical issues were identified and addressed in the most appropriate manner. Ethical approval was granted by the Faculty of Health Sciences Research Ethics Committee.

# CHAPTER 4

# RESULTS

## 4.1. INTRODUCTION

The following chapter encompasses both demographic and statistical data. The results of the study were obtained after statistically analysing Fasting blood glucose levels collected from Glucometer reading entries on a Log Sheet (Appendix E) and Glycosylated haemoglobin levels conducted by Flowpath Laboratory, using the SPSS for Windows®, statistical software suite (Version 18).

The statistically analysed data sought to determine the effectiveness of *Momordica charantia* homoeopathic mother tincture treatment over *Momordica charantia* 6CH treatment. Time effect was conducted for intra-group analyses, and inter-group comparisons were made using the Time x group treatment effect. The null and alternative hypotheses were either accepted or rejected based on the *p* value outcome of these tests. All tests set the type 1 error at $\alpha = 0.05$. If the *p* value reported was less than or equal to 0.05 a significant result would be declared and the null hypothesis would be rejected.

Pie charts were used to reflect demographics (gender and age).

## 4.2. KEY

Baseline (Fasting blood glucose): consultation two (week 2)
Baseline (Glycosylated haemoglobin): consultation one (week 1)
FU1: follow-up one / consultation two (week 2)

FU2: follow-up two / consultation three (week 6)
FU3: follow-up three / consultation four (week 8)

*p* value: observed significance level (*p* value $\leq$ 0.05)
* indicates a significant *p* value

$H_0$: The null hypothesis states that there is no statistical difference with regard to the variables in concern. This indicates that there was no statistically significant improvement of the condition, as the *p* value was greater than 0.05.

$H_1$: The alternative hypothesis states that there is a statistical difference with regard to the variables in concern. This indicates that there was a statistically significant improvement in the condition, as the *p* value was less than or equal to 0.05.

## 4.3. CRITERIA GOVERNING THE ADMISSIBILITY OF DATA

Data was only admissible if participants attended all consultations within the specified parameters of time, and met the inclusion criteria (Chapter 3) for the duration of the trial period.

The data obtained from the Log Sheet (Fasting blood glucose - Glucometer readings) and Flowpath Laboratory results (Glycosylated haemoglobin measurements) was admitted for data analysis.

The data obtained from the Log Sheet (Fasting blood glucose - Glucometer readings) and Flowpath Laboratory results (Glycosylated haemoglobin measurements) consisted of differences between “before treatment” and “after treatment” scores which were reflected in terms of one baseline reading and two follow up readings (FU2 and FU 3) (Glucometer readings),

and one baseline and one follow up reading (FU3) (Glycosylated haemoglobin). Significant improvement was considered if a significant reduction in fasting blood glucose levels and/or glycosylated haemoglobin (HbA1C) levels were noted.

## 4.4. DEMOGRAPHIC DATA OF THE SAMPLE

### 4.4.1. GENDER

There were 30 participants in the study, consisting of 6 males (20%) and 24 females (80%). See Figure 4.1. below

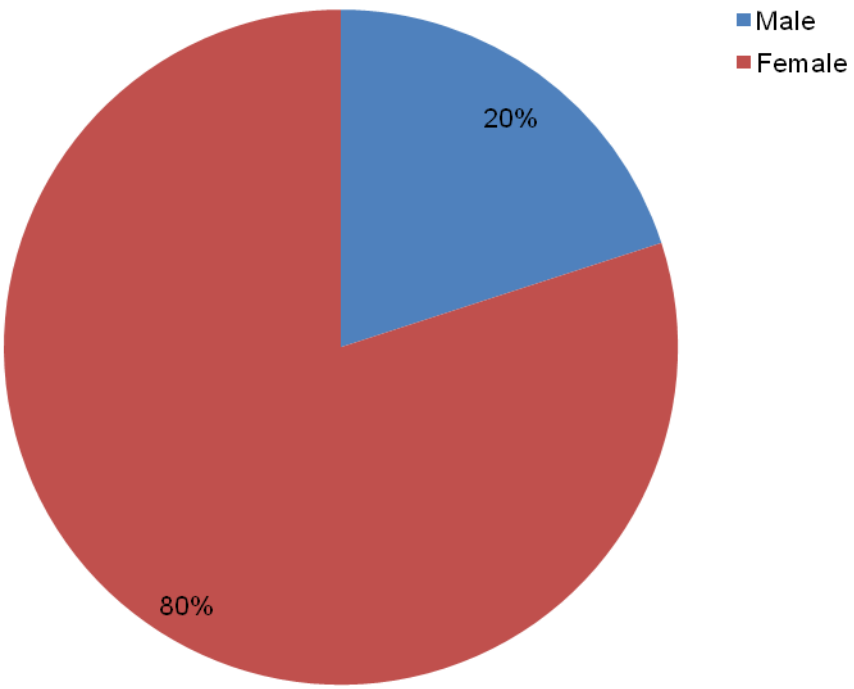



**Figure 4.1. Pie chart: Gender distribution of participants (%)**

## 4.4.2. AGE

The study consisted of participants between 18 and 80 years of age. There was 1 participant (3.33%) between the ages of 18 and 26 years, 2 participants (6.67%) between the ages of 27 and 35 years, 9 participants (30%) between the ages of 36 and 44 years, 11 participants (36.67%) between the ages of 45 and 53 years, 3 participants (10%) between the ages of 54 and 62 years, 3 participants (10%) between the ages of 63 and 71 years, and 1 participant (3.33%) between the ages of 72 and 80 years. See figure 4.2. below

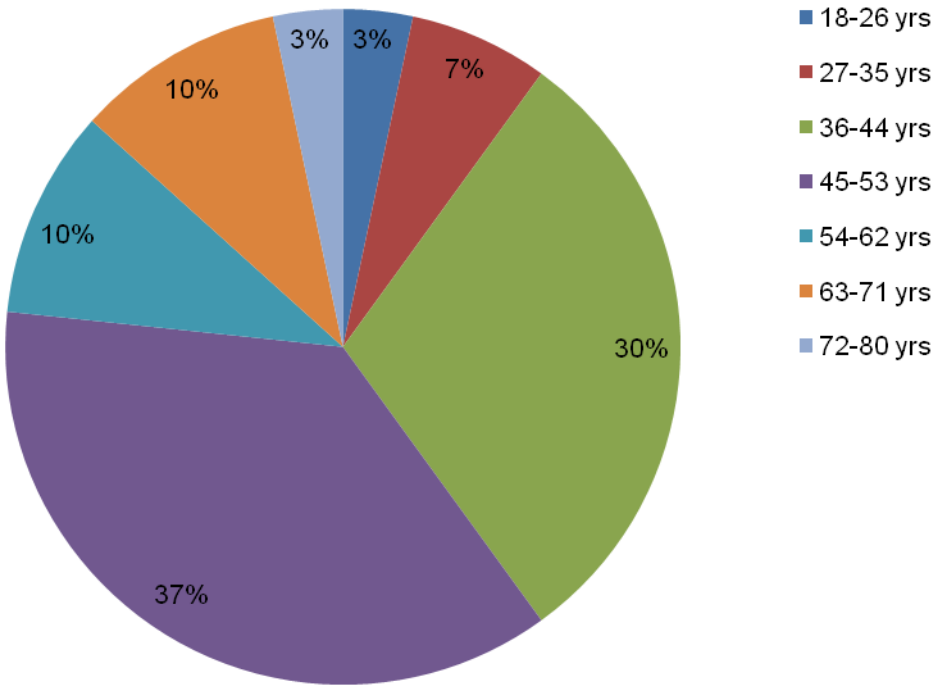



**Figure 4.2. Pie chart: Age distribution of participants (%)**

## 4.5. FASTING BLOOD GLUCOSE

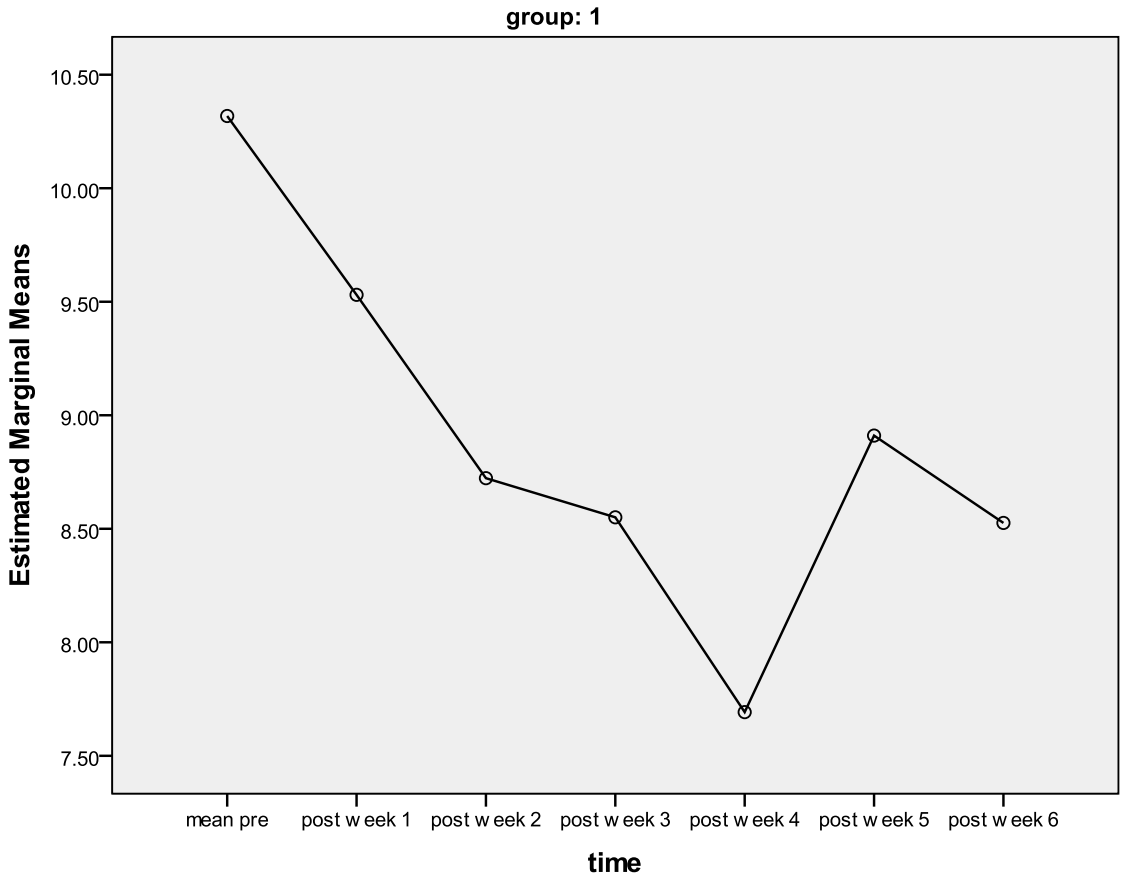
### 4.5.1. PROCEDURE 1 (INTRA-GROUP): TIME EFFECT FOR *MOMORDICA CHARANTIA* HOMOEOPATHIC MOTHER TINCTURE GROUP

**Table 4.1. FASTING BLOOD GLUCOSE: Comparison of reduction in fasting blood glucose levels**

| **GROUP** | ***p* value** |
|---|---|
| *MOMORDICA CHARANTIA* HOMOEOPATHIC MOTHER TINCTURE | 0.109 |

All tests were performed at α = 0.05 level of significance

As can be seen from table 4.1. there is no significant difference.




**<u>Figure 4.3.</u> Mean fasting blood glucose over time in treatment group 1 (*Momordica charantia* homoeopathic mother tincture)**

Figure 4.3. reveals that the mean fasting blood glucose level decreased non significantly over time.

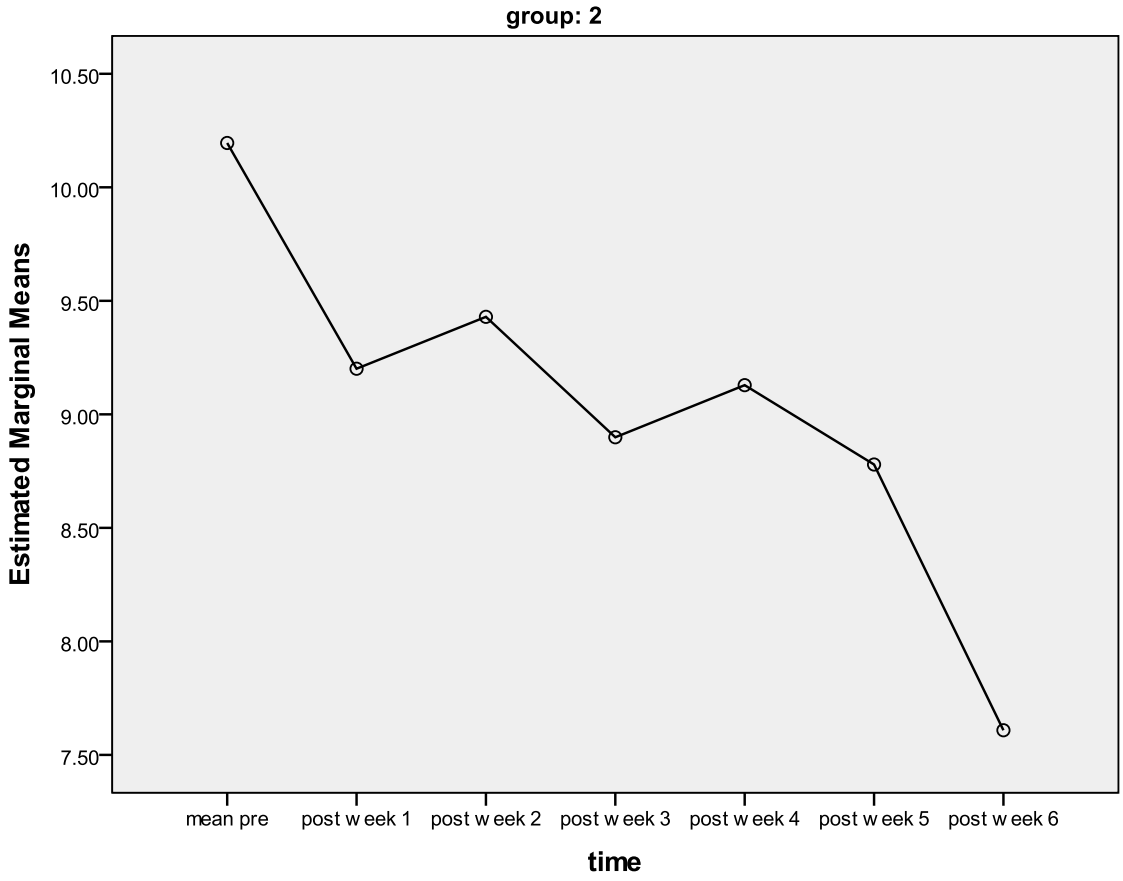
### 4.5.2. PROCEDURE 1 (INTRA-GROUP): TIME EFFECT FOR *MOMORDICA CHARANTIA* 6CH GROUP

**Table 4.2. FASTING BLOOD GLUCOSE: Comparison of reduction in fasting blood glucose levels**

| **GROUP** | ***p* value** |
|---|---|
| *MOMORDICA CHARANTIA* 6CH | 0.086 |

All tests were performed at α = 0.05 level of significance

As can be seen from table 4.2. there is no significant difference.




**<u>Figure 4.4.</u> Mean fasting blood glucose over time in treatment group 2 (*Momordica charantia* 6CH)**

Figure 4.4. reveals that the mean fasting blood glucose level decreased non significantly over time.

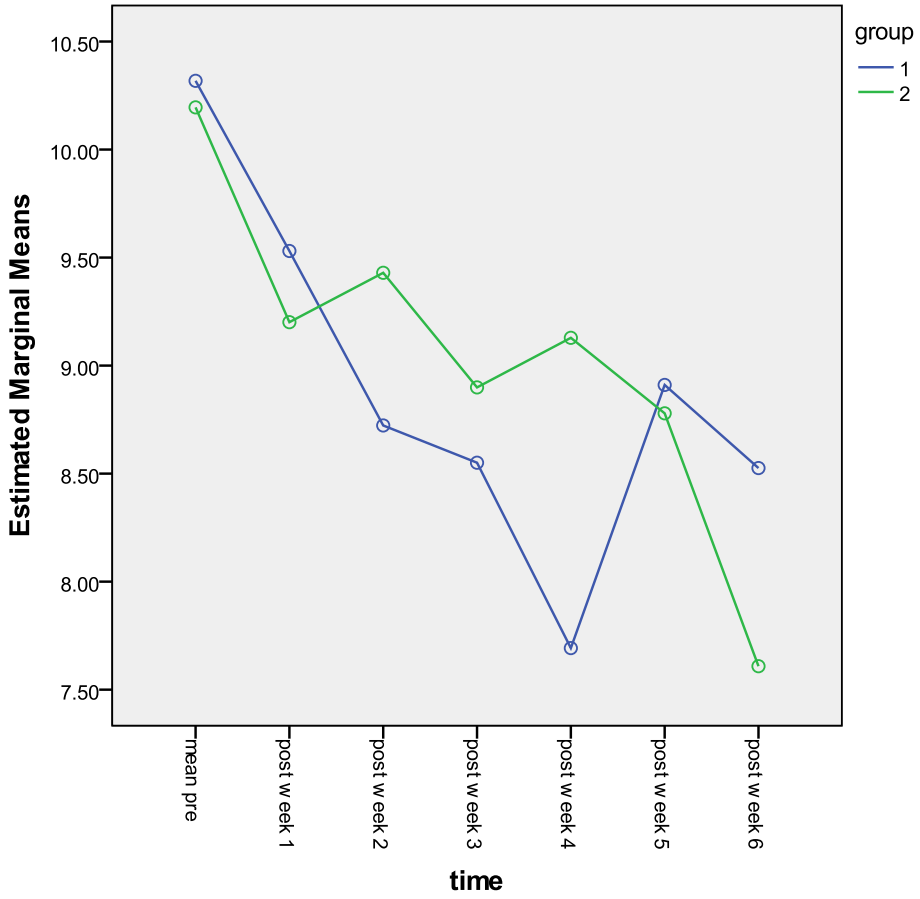
### 4.5.3. PROCEDURE 2 (INTER-GROUP): TIME X GROUP TREATMENT EFFECT

**Table 4.3. FASTING BLOOD GLUCOSE: Comparison of reduction in fasting blood glucose levels between both groups**

| | |
|---|---|
| ***p* value** | 0.226 |

All tests were performed at α = 0.05 level of significance

As can be seen from table 4.3. there are no significant differences between the two groups.




**<u>Figure 4.5.</u> Mean fasting blood glucose over time by treatment group**

Figure 4.5. reveals that the rate of decrease in fasting blood glucose was initially more pronounced in group 1 (*Momordica charantia* homoeopathic mother tincture) but group 2 (*Momordica charantia* 6CH) ended up with a lower mean fasting blood glucose value after 6 weeks than group 1; both groups experiencing a reduction in mean fasting blood glucose however not statistically significant.

## 4.5.4. PROCEDURE 3 (DESCRIPTIVE STATISITICS )

**Table 4.4. Comparison of mean fasting blood glucose levels**

| | **Baseline** | **FU2** | **FU3** |
|---|---|---|---|
| **Group 1 (*Momordica charantia* homoeopathic mother tincture)** | 10.32 | 8.62 | 8.72 |
| **Group 2 (*Momordica charantia* 6CH)** | 10.19 | 9.15 | 8.06 |

As can be seen from table 4.4. the groups were relatively similar at baseline, with both groups experiencing a reduction in their mean fasting blood glucose levels (not statistically significant) at FU2 and FU3 (end of the study).

## 4.6. GLYCOSYLATED HAEMOGLOBIN (HbA1C)

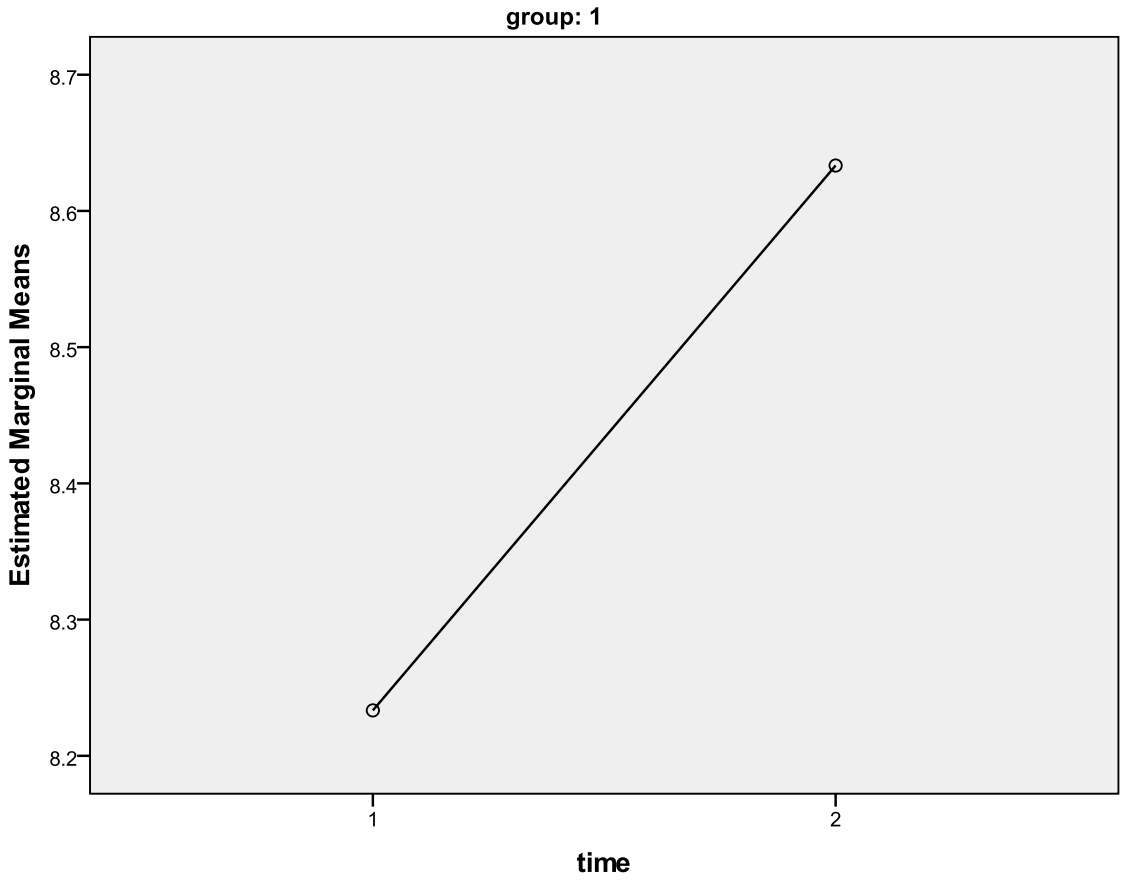
### 4.6.1. PROCEDURE 1 (INTRA-GROUP): TIME EFFECT FOR *MOMORDICA CHARANTIA* HOMOEOPATHIC MOTHER TINCTURE GROUP

**Table 4.5. HbA1C: Comparison of reduction in HbA1C levels**

| **GROUP** | ***p* value** |
|---|---|
| *MOMORDICA CHARANTIA* HOMOEOPATHIC MOTHER TINCTURE | 0.143 |

All tests were performed at α = 0.05 level of significance

As can be seen from table 4.5. there is no significant difference.




**<u>Figure 4.6.</u> Mean HbA1C over time in treatment group 1 (*Momordica charantia* homoeopathic mother tincture)**

Figure 4.6. reveals that there was a slight increase over time in HbA1C levels but the change was not statistically significant.

### 4.6.2. PROCEDURE 1 (INTRA-GROUP): TIME EFFECT FOR *MOMORDICA CHARANTIA* 6CH GROUP

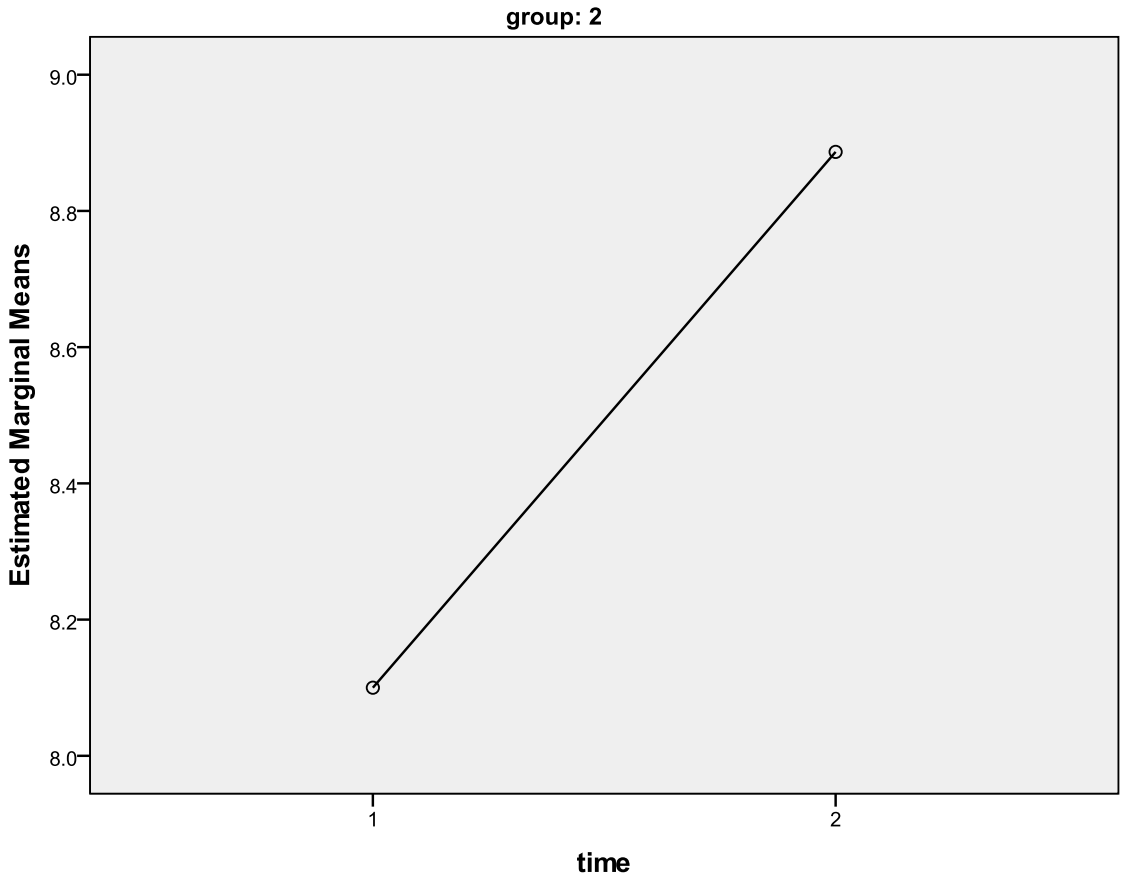
**Table 4.6. HbA1C: Comparison of reduction in HbA1C levels**

| **GROUP** | ***p* value** |
|---|---|
| *MOMORDICA CHARANTIA* 6CH | 0.013* |

All tests were performed at α = 0.05 level of significance

* indicates a significant *p* value

Table 4.6. reveals that there is a significant difference.




**<u>Figure 4.7.</u> Mean HbA1C over time in treatment group 2 (*Momordica charantia* 6CH)**

Figure 4.7. reveals that there was an increase over time in HbA1C levels which was statistically significant.

### 4.6.3. PROCEDURE 2 (INTER-GROUP): TIME X GROUP TREATMENT EFFECT

**Table 4.7. HbA1C: Comparison of reduction in HbA1C levels between both groups**

| | |
|---|---|
| ***p* value** | 0.314 |

All tests were performed at α = 0.05 level of significance

As can be seen from table 4.7. there are no significant differences between the two groups.

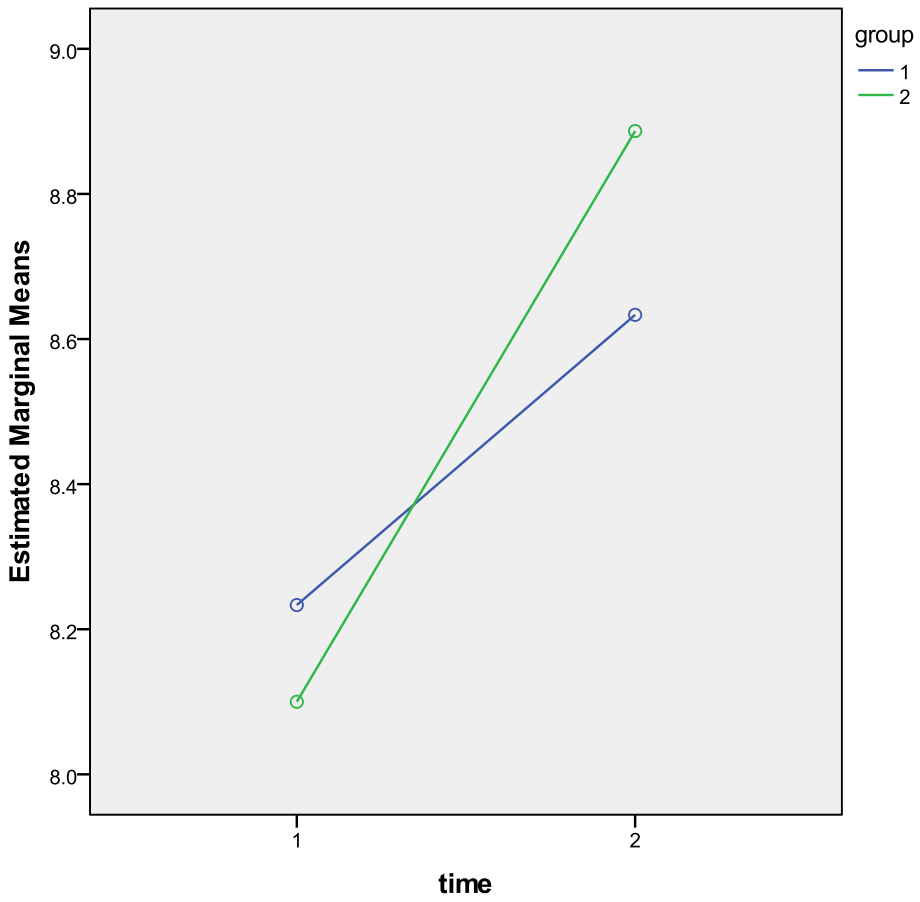



**Figure 4.8. Mean HbA1C over time by treatment group**

Figure 4.8. reveals that there was a non significant treatment effect between the two groups.

### 4.6.4. PROCEDURE 3 (DESCRIPTIVE STATISITICS )

**Table 4.8. Comparison of mean HbA1C levels**

| | **Baseline** | **FU3** |
|---|---|---|
| **Group 1 (*Momordica charantia* homoeopathic mother tincture)** | 8.23 | 8.63 |
| **Group 2 (*Momordica charantia* 6CH)** | 8.10 | 8.89 |

As can be seen from table 4.8. the two groups were relatively similar with respect to their mean HbA1C at baseline, with both groups experiencing an increase in their mean HbA1C during the study, the *Momordica charantia* 6CH group more so.

## 4.7. CONCLUSION

Fasting blood glucose decreased in both the *Momordica charantia* homoeopathic mother tincture and *Momordica charantia* 6CH groups over time (to a larger extent in the *Momordica charantia* 6CH group) however these reductions were not statistically significant, in contrast HbA1C readings increased in both groups (non statistically in the *Momordica charantia* homoeopathic mother tincture group and statistically in the *Momordica charantia* 6CH group); the limited statistical power of this study was not sufficient to confirm these trends though.

# CHAPTER 5

# DISCUSSION

The purpose of this double-blind, randomized clinical trial was to compare the effectiveness of *Momordica charantia* homoeopathic mother tincture as compared to *Momordica charantia* 6CH, in the treatment of type 2 diabetes mellitus patients on Metformin.

## 5.1. FASTING BLOOD GLUCOSE

The results of the intra-group analysis using Time Effect indicated that both Group 1 (*Momordica charantia* homoeopathic mother tincture) and Group 2 (*Momordica charantia* 6CH) reflected a non significant decrease in fasting blood glucose levels as seen in Table 4.1. and Table 4.2. respectively.

13/15 patients in the *Momordica charantia* homoeopathic mother tincture group experienced a reduction in their respective fasting blood glucose levels during the study. The mean fasting blood glucose in this group at baseline was 10.32 mmol/L, and at FU3 (the end of the study) 8.72 mmol/L (see Table 4.4.) this reduction although not statistically significant was notable.

The majority of patients (13/15) in the *Momordica charantia* 6CH group too experienced a reduction in their respective fasting blood glucose levels. The mean fasting blood glucose in this group at baseline was 10.19 mmol/L, and at FU3 (end of the study) 8.06 mmol/L (see Table 4.4.) although not a statistically significant reduction, this reduction is clinically significant the mean fasting blood glucose level decreasing steadily throughout the study (see Figure 4.4.).

The results of the inter-group analysis using Time X Group Treatment Effect indicated that there were no significant differences between the two groups when comparing reduction in fasting blood glucose levels as seen in Table 4.3.

## 5.2. GLYCOSYLATED HAEMOGLOBIN (HbA1C)

The results of the intra-group analysis using Time Effect indicated that Group 1 (*Momordica charantia* homoeopathic mother tincture) reflected a non significant increase in glycosylated haemoglobin (HbA1C) levels while Group 2 (*Momordica charantia* 6CH) reflected a statistically significant increase over time in HbA1C levels as seen in Table 4.5. and Table 4.6. respectively.

Mean HbA1C levels increased (non-significantly) over the six week period in the *Momordica charantia* homoeopathic mother tincture group. The mean HbA1C at baseline being 8.23% and at FU3 (end of the study) 8.63% (see Table 4.8.) with only 6/15 patients experiencing a reduction in their respective HbA1C levels.

The mean HbA1C levels increased significantly in the *Momordica charantia* 6CH group; the mean HbA1C at baseline being 8.10% and that at FU3 (end of the study) 8.89% (see Table 4.8.); with only 4/15 patients experiencing a decrease in their respective HbA1C levels.

The results of the inter-group analysis using Time X Group Treatment Effect indicated that there were no significant differences between the two groups when comparing reduction in HbA1C levels as seen in Table 4.7.

The respective increases in mean HbA1C experienced by both groups is clinically contradictory to that of the decrease in mean fasting blood glucose discussed in 5.1. and is elaborated on in 5.4.

## 5.3. DEMOGRAPHICS

There were thirty participants in this trial. Six participants were male and twenty four participants were female, with the majority of participants being between the ages of 45 and 53 years (37%). From this study it can be inferred that type 2 diabetes mellitus is more common in patients between 45 and 53 years of age. It has been considered however that statistically, a larger sample group would be required to re-affirm this statement. According to Watkins (1996:3), type 2 diabetes mellitus occurs most often at 50-70 years of age.

All the participants in this study were from the Indian population group. This study was conducted in Durban where there is a high concentration of Indians (Statistics South Africa, 2004:9), this contributed to the majority of patients in this study belonging to the Indian population group. This study was however open to participants of all race groups as long as the inclusion criteria was met. A long-term study undertaken to determine the incidence of type 2 diabetes and the risk factors associated with its development in a cohort of South African Indians has shown that in South African Indians there is a high incidence of type 2 diabetes as compared to other population groups, and in this population significant predictors include higher baseline blood glucose, body mass index (BMI) and obesity (Motala *et al*., 2003).

## 5.4. LIMITATIONS OF THE STUDY

### 5.4.1. PREMATURE RE-ASSESSMENT OF HbA1C

The fact that the HbA1C test was performed after two months (treatment commenced in the third week resulting in only six weeks of treatment) instead of three months could have affected the results of the study. The HbA1C test should be be measured every three months in patients with

diabetes mellitus (Shah and Zinman, 2002: 1700). Three months was the initial design of the study but due to the low compliance and the high dropout rate, eight weeks was eventually chosen as the duration of the study. It is highly likely that the early measuring of HbA1C contributed to the disparity between mean fasting blood glucose levels and mean HbA1C values recorded in this study.

### 5.4.2. MONITORING OF PATIENTS

There was an interval of four weeks between the second and third consultations; ideally this should have been a period of two weeks which would have allowed for closer monitoring of patients, ensuring better patient compliance and correct recording of daily fasting blood glucose levels.

### 5.4.3. POTENCY OF EXPERIMENTAL MEDICATION

The 6CH Potency was used in this study. Watson (1991:19) states that prescribing a low potency (6CH or 12CH) in repeated doses, varying the frequency to suit the individual, is particularly suited in cases where there is likelihood of the treatment being antidoted. According to De Schepper (2001:74), 6CH is a relatively low potency and can be used daily for chronic cases. However De Schepper (2001:100-101) mentions that LM potencies are quicker and deeper in action with less aggravations when compared to centesimal (CH) potencies. Long standing chronic diseases can be cured more quickly using this scale. The LM method hastens the process of cure by frequent repetition (De Schepper, 2001:100-101). LM potencies are recommended in chronic cases where the patient is taking regular allopathic medication and where the chance of antidoting is likely (De Schepper, 2001:102). In this study, the patients were taking chronic allopathic medication daily which may have altered the outcome of the study. Limiting

the study to the use of a 6CH potency possibly did not allow for the potential interference of the allopathic medication.

### 5.4.4. COMPLIANCE

Although participants were provided with clear instructions with respect to recording of fasting blood glucose, administration of medication and requested not to make changes to their lifestyle, diet and, quantity of exercise it was not possible to verify objectively whether each patient complied accordingly. This relates specifically to the measuring and recording of daily fasting blood glucose. In this study participants were each provided with a glucometer (Bayer Ascensia Elite) and were required to measure their blood glucose every morning before breakfast. The procedure entailed lancing of the fingertip and placing the required amount of blood onto a test strip which was inserted into the glucometer for analysis followed by correct recording of the reading on the log sheet. Although the correct procedure was clearly demonstrated at the first consultation process as with any self administered diagnostic test a margin for error does exist such as inadequate lancing and applying too little blood, it is also possible that participants may have forgotten to perform the test on occasion or performed the test after eating. It is possible that such errors in data collection may have contributed to the paradoxical relationship between mean fasting blood glucose levels and mean HbA1C levels noted in the study.

### 5.4.5. VARIATION IN EXTENT OF DISEASE

The degree and extent of diabetes in each patient varied depending on factors such as length of disease, control of disease thus far, use of Metformin, age, lifestyle etc. The glycosylated haemoglobin test can be used for gauging the progression of chronic microvascular or macrovascular diabetic complications, with increasing HbA1C levels correlating with the

increased risk of the above mentioned complications (Charles, 2002: 648). The Society for Endocrinology, Metabolism and Diabetes of South Africa (SEMDSA, 2009:1) recommends that HbA1C levels under 7% are desirable. Considering that patients that participated in this trial had HbA1C levels ranging from 5.3% to 12.4% it can be inferred that some patients were at a more advanced stage of the disease (type 2 diabetes mellitus) and thus may have responded better had this not been the case i.e. were experiencing a more moderate form of the disease. Ideally this variable should have been controlled either by stratified sampling or by limiting the extent or degree of existing disease in the inclusion/exclusion criteria. This variable particularly in light of the small sample size skewed the data due to the presence of statistical outliers.

### 5.4.6. LIMITATIONS TO NON-INDIVIDUALISED APPROACH

Type 2 diabetes mellitus is a chronic disease with advanced derangement of the vital force of the patient. To accommodate each patient's stage of disease in a chronic state, a deeper understanding of the entire disease process is required. So a comprehensive homoeopathic case taking process will reveal the deeper malady of the patient and thus a deeper acting remedy i.e. the patient's simillimum can be selected. This method will consider the patient's individual stage of disease as well as the sensitivity of the patient due to his disease stage. The sensitivity of the patient varies according to the patient's health, their reaction to external stimuli, the stage of disease and the use of allopathic medication, drugs and supplementation. Based on this sensitivity the posology is considered. So if a patient was hypersensitive as is in a chronic, advanced disease then the patient will require half a teaspoon of the LM potency with 2 succussions of the remedy in a 250ml bottle or 1 dry pellet of 6CH potency (De Schepper, 2001:73). Simillimum prescribing taking into consideration the sensitivity of the patient will be useful to achieve clear, positive results.

### 5.4.7. IMPLICATIONS OF SMALL SAMPLE SIZE

The implications of small sample size on factors such as statistical power, external validity, sampling error and likelihood of skewed data influencing results are well described in the literature. In this particular study the extent of the disease in patients was discussed as potentially negatively influencing the study by producing statistical outliers and skewed data; a larger sample may have resulted in more normally distributed data. Although a large sample is theoretically ideal the feasibility of such a study is questionable due to budgetary and time limitations and challenges to patient compliance and commitment. A larger sample is thus an ideal for such studies.

### 5.4.8. INFORMAL MATERIA MEDICA OF *MOMORDICA CHARANTIA*

No homoeopathic proving of *Momordica charantia* was done therefore it is difficult to explain the complete action of the remedy. According to Hahnemann (2001:144-145), “there is no other possible way to unerringly experience the peculiar actions of medicines upon the human condition – there is no single, surer, more natural arrangement for this intent than to administer each single medicine experimentally, in a moderate amount, to healthy persons in order to learn what alterations, symptoms and signs of its impinging action each medicine particularly brings forth in the condition of body and soul, that is, what disease elements each medicine is able to arouse.” A formal proving of the experimental medication will provide a deeper understanding of the therapeutic action and potential of *Momordica charantia* in addition provings using varying potencies may further guide the potency selection when using the substance clinically.

# CHAPTER 6

# CONCLUSION AND RECOMMENDATIONS

## 6.1. CONCLUSION

The aim of treating patients with type 2 diabetes mellitus is to reduce their fasting blood glucose and glycosylated haemoglobin levels so that it is as close to the recommended normal ranges as possible thus reducing the risk of both chronic microvascular and macrovascular diabetic complications (Charles, 2002: 648).

The purpose of this double-blind, randomized clinical trial was to compare the effectiveness of *Momordica charantia* homoeopathic mother tincture as compared to *Momordica charantia* 6CH, in the treatment of type 2 diabetes mellitus in patients on Metformin.

In light of the results and statistical analysis discussed in Chapter 5, hypotheses 1 and 2 were both rejected as neither intervention produced a statically significant reduction in fasting blood glucose or HbA1C levels. However hypothesis 3 was accepted there being no significant difference between the results obtained by the two respective interventions.

Despite the apparent negative outcome with respect to statistical analyses, there was an apparent clinically significant reduction in fasting blood glucose levels in both groups which justifies further investigation applying the following recommendations mentioned in 6.2.

## 6.2. RECOMMENDATIONS

The following recommendations are made for future research studies:

i. A study should be carried out over at least three months as it recommended that the HbA1C be measured every three months in patients with diabetes mellitus (Shah and Zinman, 2002: 1700).

ii. A larger sample size should be used to secure more reliable and statistical data in addition this would also ensure greater external validity.

iii. The follow-up consultations should be conducted every two weeks to ensure greater patient compliance.

iv. Closer monitoring of patients should be undertaken; telephonic contact should be made every week with each patient in order to ascertain compliance in terms of recording daily fasting blood glucose readings and taking the prescribed medication as well as to reiterate that he/she must not make any dietary or exercise changes during the duration of the trial.

v. Stratification of the patient sample with respect to stage, severity and duration of disease should be conducted in order to ensure a homogeneous group with respect to these variables.

vi. Greater flexibility with respect to potency selection and posology should be considered in future studies which would allow researchers to adapt the remedy potency according to each patient's individual sensitivity.

vii. Future research studies should ensure that all patients are taking the same dosage as well as formulation of Metformin.

viii. Future research studies could utilize a homoeopathic preparation of *Momordica charantia* in a full range of potencies including LM potencies which should be investigated thoroughly.

ix. A proving of *Momordica charantia* should be carried out in order to reveal the complete homoeopathic picture of the remedy.

x. A simillimum study should be carried out comparing the effectiveness of the homoeopathic simillimum and a homoeopathic preparation of *Momordica charantia* in the treatment of type 2 diabetes mellitus.

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# APPENDIX A

# INFORMATION LETTER

Title of Research Project
A comparison of the effectiveness of two homoeopathic dosage forms of *Momordica charantia* in the treatment of type 2 diabetes mellitus in patients on Metformin.

Name of Supervisor: Dr. M. Maharaj, M.Tech.Hom. (TN)

Name of Co-Supervisor: Dr. D.F. Naude, M.Tech.Hom. (TN)

Name of Research student: Saiesh Govender

Dear Patient

Thank you for considering to participate in this study. Students of Homoeopathy are required to complete a research project such as this as a partial fulfilment of their Master's Degree in Technology: Homoeopathy.

Aim of study
The aim of this study is to compare the effectiveness of *Momordica charantia* homoeopathic mother tincture as compared to *Momordica charantia* 6CH, as determined by daily fasting blood glucose and glycosylated haemoglobin levels in the treatment of type 2 diabetes mellitus in patients on Metformin.

Introduction
Diabetes mellitus is a disease in which there are above normal levels of glucose in the bloodstream. There are 2 main types of diabetes mellitus: type 1 and type 2. Type 1 diabetes usually occurs in young people. Type 2 diabetes is widely found in older people who are often overweight. It is more common than type 1 diabetes mellitus.

The demand for safe and effective treatment for this condition is quite evident and growing. There are no known "side-effects" with homoeopathic treatment however a slight homoeopathic aggravation may occur in some patients.

In order to ensure that this study complies with the scientific method, only certain persons may be accepted into this study.

Inclusion criteria
- have to enter the study voluntarily.
- have to be between 18 and 80 years of age.
- have been diagnosed with type 2 diabetes and are currently taking only Metformin (Glucophage®) for the treatment of their diabetes.
- have a stable fasting glucose of $\geq$ 7.0 mmol/L.
- have to be willing not to change your lifestyle or dietary habits for the duration of the trial.

Exclusion criteria
You will not be included in the study if you are pregnant, breastfeeding, allergic to bitter melon or a member of the gourd or melon plant families, or if you are diagnosed with glucose-6-phosphate defiency.

Duration of clinical trial
The duration of this study is 8 weeks, however you will be free to withdraw from this study, at any stage, and no explanation will be required.

After you have signed both the Information letter and Consent form, the following procedure, for each visit, will take place.

Procedure

Visit 1: (Day 1)
a) consultation with medical and personal history taking
b) general examination will be performed
c) patient will be shown how to use a Glucometer
d) blood will be drawn for the Glycosylated haemoglobin test

Visit 2: (Day 15)
a) general examination will be performed
b) treatment will be prescribed

Visit 3: (Day 42)
a) general examination will be performed
b) treatment will be prescribed

Visit 4: (Day 56)
a) general examination will be performed
b) analysis of one's average fasting blood glucose levels before and after treatment will be done
c) blood will be drawn for the Glycosylated haemoglobin test

Tests

1. Fasting blood glucose
   Patients will have to do a Fasting blood glucose test on their own, using a Bayer Ascensia Elite Glucometer provided, every morning for a period of 56 days (8 weeks). This test involves the pricking of one's fingers.

2. Glycosylated haemoglobin (HbA1C)
   This test requires 8 ml of blood to be drawn. 4 ml of blood will be drawn on Visit 1 (day 1) and 4 ml of blood will be drawn on Visit 4 , 41 days after the commencement of treatment, at Flowpath Clinical and Laboratory Practice.

Benefit of study

The direct benefit of this study is that the treatment may result in an improvement of your diabetes signs and symptoms. Your participation will increase our knowledge and understanding of the place and value of homoeopathy for type 2 diabetes mellitus treatment. There will be strict patient-practioner confidentiality. Your personal details will not be disclosed at any stage of the study. All data will only be accessible to the researcher and the supervisor concerned. A qualified homoeopath is supervising the treatment and the treatment is free of charge.

In case of any queries or problems arising during the research, please feel free to contact:

Saiesh Govender Cell: 083 787 7061

Dr. M. Maharaj Tel: (031) 373 2542 (Homoeopathic Day Clinic)

Thank you.

Kind regards

Saiesh Govender
(Final year Homoeopathic student)

.....

*Please complete, sign, detach and return to secretary.*

Patient Information
Full Name : _____
Date of Birth : _____
Age : _____
Sex : _____

I, _____ have read and understand the information letter and do hereby agree to abide by the delimitations and conditions set out in the above document.

Patient name : _____
Signature : _____

Witness name : _____

_____ _____
Saiesh Govender Date
(Final year Homoeopathic student)

## APPENDIX B

## INFORMED CONSENT FORM

**Title of Research Project:**
A comparison of the effectiveness of two homoeopathic dosage forms of *Momordica charantia* in the treatment of type 2 diabetes mellitus in patients on Metformin.

**Name of Supervisor:** Dr. M. Maharaj, M.Tech.Hom. (TN)

**Name of Co-Supervisor:** Dr. D.F. Naude, M.Tech.Hom. (TN)

**Name of Research Student:** Saiesh Govender

**Date:**

**Please circle the appropriate answer**

1. Have you read the information sheet? YES/NO
2. Have you had the opportunity to ask questions regarding the study? YES/NO
3. Have you received satisfactory answers to your questions? YES/NO
4. Have you had the opportunity to discuss the study? YES/NO
5. Have you received enough information about this study? YES/NO
6. Who have you spoken to? _____
7. Do you understand the implications of your involvement in this study? YES/NO
8. Do you understand that you are free to withdraw from this study?
   a) at any time,
   b) without having to give a reason for withdrawing, and
   c) without affecting your future health care.
   YES/NO
9. Do you agree to voluntarily participate in this study? YES/NO

**IF YOUR ANSWER IS 'NO' TO ANY OF THE ABOVE QUESTIONS, PLEASE ASK FOR FURTHER EXPLANATIONS BEFORE YOU PUT YOUR SIGNATURE.**

Patient Name: _____ Signature: _____
(in block letters)

Witness Name: _____ Signature: _____
(in block letters)

Research Student Name: _____ Signature: _____
(in block letters)

## APPENDIX C

## HOW TO TAKE YOUR HOMOEOPATHIC MEDICINES

1. Take your medicine at least ½ hour before a meal. Avoid mint before or after taking medication.

2. The medicine must be stored away from camphor (e.g. Vicks products), light, heat, and electromagnetic radiation (TV's, computers, cellphones, etc.).

3. Avoid the intake of stimulants such as coffee during your treatment.

4. Always take your medication as directed.

**For any queries regarding your medication, please feel free to contact:**

**Saiesh Govender** **Cell: 083 787 7061**

**Receptionist** **Tel: (031) 373 2041 (Homoeopathic Day Clinic)**

# APPENDIX D

# INSTRUCTIONS ON HOW TO PERFORM THE BLOOD GLUCOSE TEST

## Preparations for the Blood Glucose Test

1. Load the Lancing Device. (Place the Lancing Device on a clean surface while preparing for your Blood Glucose Test)
2. Wash your hands. Use warm soapy water. Rinse and dry thoroughly.
3. Remove foil packets from carton and tear off a single packet.
4. To open the Test Strip packet, carefully peel the foil until the Test Strip is completely exposed.
5. Remove the Test Strip from packet. Holding the round end, insert the Test Strip fully into the Meter. (Be sure to save the foil to use when disposing of the Test Strip). A beep sounds and a full display appears, followed by the Function Number (F#) and the previous test result. The previous test result begins flushing alternatively.

(Ascensia Elite User Guide, 2002:17-19)

## How to perform the Blood Glucose Test

1. Prick your finger with a lancet or Automatic Lancing Device and press the finger to form a small drop of blood.
2. Touch and hold the test end (tip) of the Test Strip to the drop of blood until the reaction chamber is completely filled and the meter beeps. You may now use a tissue or cotton ball for wiping the finger that was pricked.
3. After 29 seconds, your blood glucose result appears in the display. The test result remains in the display for 3 minutes. (You must record your Fasting blood glucose reading on the Log Sheet provided).

*CAUTION: Use a tissue to remove the Test Strip. Dispose of the used Test Strip and lancet carefully to prevent injury or contamination to others. Remember to use the empty foil packet to dispose of the Test Strip.*

(Ascensia Elite User Guide, 2002:20-21)

## APPENDIX E

## LOG SHEET (GLUCOMETER READINGS)

### Before Intervention

| *Day* | *Blood Glucose reading (mmol/L)* |
|---|---|
| 1 | |
| 2 | |
| 3 | |
| 4 | |
| 5 | |
| 6 | |
| 7 | |
| 8 | |
| 9 | |
| 10 | |
| 11 | |
| 12 | |
| 13 | |
| 14 | |

**After Intervention**

| *Day* | *Blood Glucose reading (mmol/L)* |
|---|---|
| 1 | |
| 2 | |
| 3 | |
| 4 | |
| 5 | |
| 6 | |
| 7 | |
| 8 | |
| 9 | |
| 10 | |
| 11 | |
| 12 | |
| 13 | |
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## APPENDIX F

## CASE HISTORY

| |
|---|
| **Date:** |
| |
| **Name:** |
| **Surname:** |
| **Age:** |
| **Gender:** |
| **Marital status:** |
| **Children:** |
| **Occupation:** |
| **Address:** |
| |
| |
| **Tel:** |
| |
| **Chief Complaint:** |
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| |
| **Past Medical History:** |
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| Surgical History: |
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| Allergies: |
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| |
| Vaccination History: |
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|---|
| Medication and Supplementation: |
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| |
| **Family History:** |
| Mother: |
| Father: |
| Siblings: |
| Grandparents: Mother's - mother: |
| - father: |
| Father's - mother: |
| - father: |
| |
| |
| **Nutritional History:** |
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| **Systems Review:** |
| General: |
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| |
| Skin: |
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| |
| Head, Eyes, Ears, Nose, Throat: |
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| |
| |
| Neck: |
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| |
| Breasts: |
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|---|
| Respiratory: |
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| |
| Cardiovascular: |
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| |
| Gastrointestinal: |
| |
| |
| Urinary: |
| |
| Genital: Male: |
| |
| |
| Female: - menarche: |
| - regularity: |
| - frequency: |
| - duration of periods: |
| - amount of bleeding: |
| - menopause: |
| |
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| Peripheral Vascular: |
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| |
| Musculoskeletal: |
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| |
| Neurologic: |
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| |
| Haematologic: |
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| Endocrine: |
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| Psychiatric: |
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## APPENDIX G

## PHYSICAL EXAMINATION

| |
|---|
| **Date:** |
| |
| **Name:** |
| **Surname:** |
| |
| **Vital Signs:** |
| Height: |
| Weight: |
| Blood pressure: |
| Pulse rate: |
| Respiratory rate: |
| Temperature: |
| |
| **General Examination:** |
| Cyanosis: |
| Anaemia: |
| Jaundice: |
| Clubbing: |
| Oedema: |
| Lymphadenopathy: |
| Dehydration: |
| Dyspnoea: |
| |
| **Eyes, Ears, Nose, Throat:** |
| |
| |
| **Respiratory Examination:** |
| |
| |
| **Cardiovascular Examination:** |
| |
| |
| **Abdominal Examination:** |
| |
| |
| **Musculoskeletal Examination:** |
| |
| |
| **Neurological Examination:** |
| |
| |

## APPENDIX H

## METHOD 2a (GERMAN HOMOEOPATHIC PHARMACOPOEIA)

## APPENDIX I

## METHOD 5a (GERMAN HOMOEOPATHIC PHARMACOPOEIA)

# APPENDIX J

# MEAN FASTING BLOOD GLUCOSE (FBG) LEVELS

| Patient no. | Group | FBG (Baseline) | FBG (FU 2) | FBG (FU 3) |
|---|---|---|---|---|
| 1 | 1 | 11.41 | 8.81 | 11.24 |
| 2 | 1 | 8.11 | 6.52 | 6.76 |
| 3 | 1 | 6.85 | 6.36 | 6.21 |
| 8 | 1 | 9.20 | 9.33 | 9.36 |
| 10 | 1 | 14.98 | 11.39 | 10.46 |
| 11 | 1 | 12.69 | 9.76 | 9.29 |
| 12 | 1 | 9.78 | 8.40 | 7.09 |
| 15 | 1 | 9.93 | 11.01 | 12.90 |
| 16 | 1 | 10.25 | 10.11 | 9.84 |
| 20 | 1 | 19.45 | 10.74 | 10.16 |
| 21 | 1 | 9.61 | 9.54 | 9.36 |
| 22 | 1 | 7.46 | 5.56 | 5.74 |
| 25 | 1 | 8.04 | 8.57 | 6.79 |
| 26 | 1 | 8.53 | 5.86 | 8.34 |
| 27 | 1 | 8.48 | 7.40 | 7.21 |
| | | | | |
| | *Mean Fasting Blood Glucose levels (Momordica charantia homoeopathic mother tincture group)* | *10.32 mmol/L* | *8.62 mmol/L* | *8.72 mmol/L* |
| | | | | |
| 4 | 2 | 14.02 | 11.58 | 11.69 |
| 5 | 2 | 8.31 | 7.21 | 8.36 |
| 6 | 2 | 10.52 | 8.81 | 9.24 |
| 7 | 2 | 11.26 | 14.12 | 10.61 |
| 9 | 2 | 8.27 | 7.58 | 7.88 |
| 13 | 2 | 9.82 | 7.73 | 4.61 |
| 14 | 2 | 10.61 | 8.71 | 7.49 |
| 17 | 2 | 8.74 | 8.88 | 9.03 |
| 18 | 2 | 7.16 | 11.99 | 5.66 |
| 19 | 2 | 7.89 | 4.07 | 7.31 |
| 23 | 2 | 16.47 | 15.16 | 11.49 |
| 24 | 2 | 8.03 | 7.72 | 5.82 |
| 28 | 2 | 7.71 | 7.54 | 5.91 |
| 29 | 2 | 8.64 | 7.31 | 6.79 |
| 30 | 2 | 15.46 | 8.88 | 9.05 |
| | | | | |
| | *Mean Fasting Blood Glucose levels (Momordica charantia 6CH group)* | *10.19 mmol/L* | *9.15 mmol/L* | *8.06 mmol/L* |

## APPENDIX K

## MEAN GLYCOSYLATED HAEMOGLOBIN (HbA1C) LEVELS

| Patient no. | Group | HbA1C (Baseline) | HbA1C (FU3) |
|---|---|---|---|
| 1 | 1 | 7.7 | 10.7 |
| 2 | 1 | 6.9 | 6.5 |
| 3 | 1 | 6 | 5.8 |
| 8 | 1 | 8.1 | 8.3 |
| 10 | 1 | 10.9 | 10.8 |
| 11 | 1 | 10.5 | 11.4 |
| 12 | 1 | 9.4 | 8.5 |
| 15 | 1 | 8.8 | 9.7 |
| 16 | 1 | 9.7 | 9 |
| 20 | 1 | 10.6 | 12.1 |
| 21 | 1 | 8.8 | 8.3 |
| 22 | 1 | 6.8 | 6.9 |
| 25 | 1 | 8 | 8.6 |
| 26 | 1 | 5.5 | 6.2 |
| 27 | 1 | 5.8 | 6.7 |
| | | | |
| | *Mean HbA1C levels (Momordica charantia homoeopathic mother tincture group)* | *8.23%* | *8.63%* |
| | | | |
| 4 | 2 | 11.6 | 11.1 |
| 5 | 2 | 7.5 | 8.9 |
| 6 | 2 | 6.7 | 8.5 |
| 7 | 2 | 8.7 | 8.9 |
| 9 | 2 | 8 | 7.6 |
| 13 | 2 | 5.7 | 6 |
| 14 | 2 | 6.3 | 6.4 |
| 17 | 2 | 9.9 | 11.3 |
| 18 | 2 | 6.2 | 6 |
| 19 | 2 | 9 | 11.5 |
| 23 | 2 | 10.9 | 11.5 |
| 24 | 2 | 6.2 | 6.8 |
| 28 | 2 | 5.3 | 8.2 |
| 29 | 2 | 7.1 | 6.8 |
| 30 | 2 | 12.4 | 13.8 |
| | | | |
| | *Mean HbA1C levels (Momordica charantia 6CH group)* | *8.10%* | *8.89%* |