

**RESEARCH PROJECT CONDUCTED AT THE
UNIVERSITY OF WESTERN CAPE**

**ROLE OF LIFESTYLE
FACTORS IN THE
MANAGEMENT OF
PATIENTS WITH**

**HIV AND AIDS,
TYPE 2 DIABETES,
HYPERTENSION**



**UNIVERSITY of the
WESTERN CAPE**



TIBB
A SCIENCE OF MEDICINE
THE ART OF CARE

ROLE OF LIFESTYLE FACTORS IN THE MANAGEMENT OF PATIENTS WITH HIV AND AIDS, TYPE 2 DIABETES, AND HYPERTENSION

Principle Researcher: Dr R. Bhikha

Research Project leaders: Dr M. Haq, Dr J. Glynn, Dr F. Manxiwa

Co- Researchers:

[Hypertension] Norah N Jako, Noxolo Y Mpe, V S Makaluza, Nomzukilo P Mkiva, Nontutuzelo Ncobo.

[HIV and Aids] Vuyiswa P. Dyasi, Thozamile Qubuda, Nombuyiselo B. Jwambi, Siphokazi Buhlungu, Belelwa Magaqwa, Maurita Mogorosi, Summeiya Omar.

[Type 2 Diabetes] S Khan, G V Summerton, E N Mcetywa, T Sifamelo, N P Boo.

Prepared by: Dr Rashid Bhikha and Dr John P Glynn

March 2006

Keywords: Unani-Tibb ; research project ; multicentre ; chronic disorders ; HIV and Aids ; type 2 diabetes ; hypertension ; governing (lifestyle) factors ; quality of life ; clinical parameters

Table of Contents

Executive summary	3
1. Introduction	4
2. Background	6
2.1. General context	6
2.2. The treatment of chronic disorders in South Africa	7
HIV and Aids	7
Type 2 diabetes	7
Hypertension	8
2.3. The Unani-Tibb approach to the treatment of chronic disorders	10
2.4. Integrative medicine as a viable approach to chronic disorders	11
3. Outline of Unani-Tibb	12
4. Methodology	13
4.1. Background to the project	13
4.2. Researcher and location details	14
4.3. Governing (lifestyle) factors selected	15
4.4. Quality of life assessments	17
4.5. Clinical parameters	17
4.6. Concomitant medication	18
4.7. Analysis of the data	19
5. Results	20
5.1. Quality of life parameters	20
5.2. Changes in clinical parameters	22
HIV and Aids: Changes in body mass	22
HIV and Aids: Changes in CD4 counts	22
Type 2 diabetes: changes in blood glucose	23
Type 2 diabetes: changes in body mass	23
Hypertension: changes in blood pressure	24
Hypertension: changes in pulse rate	24
6. Deficiencies of the project	25
7. General conclusions	27
8. Suggestions for future research projects	28
References	28

Executive summary

Introduction. A mandatory requirement for the award of the UWC Diploma in Unani-Tibb is the satisfactory completion of a pilot research project evaluating the effectiveness of Unani-Tibb principles in health promotion and the treatment of disease. This report details the results obtained in patients with a chronic clinical disorder (HIV and Aids, type 2 diabetes, or hypertension) by enhancing the patients' governing (lifestyle) factors.

Aims & objectives. The primary objective ascertained whether the governing (lifestyle) factors, a central tenet of Unani-Tibb therapy, can have a positive influence on the clinical course of patients with one of the above disorders in a real-life clinical context, as reflected by changes in their quality of life indicators. The secondary objectives were to assess the clinical effect of the governing (lifestyle) factors in terms of changes in clinical parameters relevant to the disorder. The reduction in orthodox medication ('drug sparing') used in the management of their condition that the intervention allows was carried in some patients.

Methodology. Seventeen student investigators ('researchers'), under appropriate supervision, treated a total of 185 patients (HIV and Aids, 72; type 2 diabetes, 55; hypertension, 58) for 3 to 4 months according to Unani-Tibb's six governing (lifestyle) factors. All patients were considered stable, and receiving either conventional (allopathic) or Unani-Tibb medication throughout the study period. The study centres were located countrywide, and in both rural and urban settings. As the main clinical end-point, the quality of life index based on 15 subjective parameters obtained by face-to-face interview was adopted. Other clinical end-points which reflected clinical changes in patients with HIV and Aids (body mass; CD4 count), diabetes (random blood glucose; body mass), or hypertension (blood pressure; pulse rate) and changes in signs and symptoms were also measured as the researchers' situation allowed.

Results. In the *HIV and Aids* patients, positive improvements were noted in most quality of life parameters, especially sleeping quality, nervousness, perceived efficacy, social activities and personal energy levels. Changes in patients' body mass between the initial visit and the final follow-up varied widely, but overall there was a discernible trend towards an increase in body mass. The changes in CD4 counts in a limited number of patients were likewise mixed. There was a definite trend upwards, suggesting that the governing (lifestyle) factors do have a positive effect on HIV and Aids.

In the *diabetic* patients, quality of life assessments gave impressive responses in the patients' understanding of the disorder, feelings of self esteem, and consequently better personal control. In addition, there was a marked improvement in personal life and energy levels, feeling about their ailment. The global quality of life and current health status showed a noticeable improvement overall, especially for better sleeping patterns, emotional state, occupational and

social competence. Treatment was generally regarded as satisfactory, but not the cost and value of present therapy. Finally, patients tended to recommend this therapy to their friends. Clinically, there was a reduction in blood glucose levels during governing (lifestyle) factors application, with substantial variance between the patient cohorts. In some patients urinalysis was carried out, with marked improvement noted.

In the *hypertensive* patients, there was a positive improvement in most parameters. There were gains in quality of life issues, especially awareness of treatment benefit, understanding the disorder, and feeling of control. Also, there was a decrease in blood pressure for almost all patients, especially in those with very high blood pressure. Mean systolic blood pressure fell from 162 to 138 mm Hg, and for diastolic blood pressure from 99 to 88 mm Hg. The pulse rate/minute fell from a mean of 75 to 73. Overall, changes varied widely between initial visit and final follow-up, between and within patient cohorts.

Conclusion. In spite of the acknowledged shortcomings of this initial study, further investigations in a greater number of patients with chronic clinical disorders, with stricter and consistent methodological control, and for a longer intervention period are indicated.

Recommendation. The possibility, supported by this pilot research project, that serious and regulated lifestyle changes could improve both the quality of life of patients living with HIV and Aids, type 2 diabetes, and hypertension, and contribute to their clinical improvement, so leading to substantial savings in conventional therapeutic costs, should be explored further.

1. Introduction

As most people are well aware, South Africa is facing a healthcare crisis posed by a number of chronic clinical disorders which are having serious societal consequences. Amongst these are HIV and Aids, diabetes (especially the type 2, or non-insulin dependent, form) and hypertension.

Although the better part of resources is presently being directed at the HIV and Aids epidemic, the impact that diabetes and hypertension also exert should not be lost sight of. The clinical consequences of these common ailments if they are not properly managed are far reaching, expensive and adversely affect the sufferer on several levels – personal, familial, social, occupational and developmental.

Most people who develop diabetes and hypertension usually do so because of serious problems of lifestyle. These disorders can therefore aptly be termed “diseases of lifestyle”, and their management should focus on redressing the behaviour and environmental factors which lead inexorably to the disorder in the first place. HIV and Aids can also be regarded as a disease of lifestyle, albeit a much more complicated one. Also, the long term trajectory of the disease is largely determined by the affected person’s behaviour.

There is a vast array of conventional drugs and herbal medications for diabetics and hypertensive people which can reduce both abnormally high blood glucose and raised blood pressure respectively, and these are undoubtedly effective. Also, people living with HIV and Aids respond positively to ARV (anti-retroviral) drug therapy. However, all drugs employed are best used together with lifestyle changes to gain the optimum, desirable clinical effect.

Unfortunately many of the drugs recommended are beset by a number of problems. These include substantial costs, difficulty in maintaining patient compliance, the development of tolerance so that increasingly higher doses are needed, and (in the case of ARVs) microbial resistance.

For the South African healthcare scenario it is therefore opportune to evaluate the possibility of a more holistic approach to the management of people with these chronic diseases. In effect, could conventional allopathic medical care be combined with Unani-Tibb (which stimulates the patient's self-healing potential and involves him or her to a greater extent in therapy), as a viable way of enhancing the value of treatment? The importance of non-pharmacological interventions, such as better food selection, dietary supplementation, and physical exercise are being viewed as useful routes to improving clinical outcome and the quality of life in patients with chronic illnesses.

This report analyses the overall outcome of applying Unani-Tibb principles to the treatment of patients who are living with HIV and Aids, or who have type 2 diabetes or hypertension, by a number of healthcare practitioners, who as students are completing the pilot research project required by the Diploma Course in Unani-Tibb.

2. Background

2.1. General context

HIV and Aids. This disorder is the most common cause of premature death in South Africa, affecting young and old, male and female indiscriminately. The economically active sector of the population – especially those in the 20 to 30 year age bracket – is particularly badly affected¹.

Diabetes is a common cause of premature death in many sectors of our community, affecting young and old, male and female indiscriminately². The Type 2 form of diabetes, originally termed maturity onset diabetes, is becoming more prevalent, paralleling the increasing numbers of overweight and obese people.

Hypertension, or chronically raised blood pressure higher than the normal for a person of a particular age and gender, is not particularly dangerous in itself. However, if a person with high blood pressure is not treated properly, serious physical damage inevitably follows³. High blood pressure can inflict severe damage on a person's internal organs.

Consequences. If not treated properly, each of these disorders will have very serious, even fatal consequences. In the person suffering from HIV and Aids, opportunistic infections will inevitably follow the deterioration of the immune system, leading to tuberculosis, pneumonia, meningitis, thrush and many other conditions⁴. The person with diabetes will develop from eye problems, circulatory and kidney disorders, foot ulcers, and a whole range of other unpleasant symptoms⁵. The hypertensive patient often succumbs to a stroke (a 'brain attack'), or have a heart attack, or kidney failure. Problems in the legs' blood circulation may arise, making walking an ordeal. The eyes may be affected, leading to blurred vision. The lining of the person's blood vessels, especially in the heart, may be damaged, making it form blood clots or build up fatty deposits. This leads to angina and often a heart attack⁶.

Prevalence. Total deaths from Aids-related diseases worldwide have reached 20 million. It is estimated that around 61 million people worldwide are HIV-positive at present⁷. By the end of 2003, Sub-Saharan Africa had the highest prevalence rate of any part of the world, with something like 25 million people living with HIV. Overall, sub-Saharan Africa accounts for 75% of all people who are HIV positive⁸. HIV and Aids is now the leading cause of mortality in the region, being responsible for 20% of all deaths⁷. This is twice the number from respiratory disorders, the second leading cause of death in Africa. In 2005, South Africa had around 5 million HIV-positive people, or 11%, out of the total population of 46 million. This accounts for 13% of the world's total. It is estimated that 2000 people are infected with HIV every day in South Africa⁹. Aids has begun to impact on the life expectancy of our citizenry, which is now about 50 years, but decreasing steadily.

Worldwide, it is estimated that 1% of the population are affected by diabetes. Closer to home, more than 1.5 million South Africans suffer from it, and people of Indian and Malay origin are particularly susceptible. The majority of people with diabetes (around 85% to 90%) have the less serious form, Type 2².

Hypertension is a common disorder, affecting up to 25% of adults in South Africa. It is less prevalent in the rural communities, and more prevalent in the urban areas. It frequently occurs in people who are overweight or obese, coping poorly with stress, and who suffer from diabetes. As with other 'diseases of lifestyle', it is inexorably on the increase. A high-calorie, high-fat, high-salt fast food culture is undoubtedly contributing to this increase¹⁰.

2.2. The treatment of chronic disorders in South Africa

People suffering from clinical chronic disorders in South Africa, such as HIV and Aids, type 2 diabetes and hypertension, have recourse to a large number of conventional drugs obtainable through private and public medical institutions. In this situation South Africa is comparable to countries of the developed world, as transnational pharmaceutical companies distribute their range of drugs to all countries able to buy them, irrespective of developed, developing or emerging socio-political status. Generic companies, often locally based, are now assuming more and more of the mantle of production and distribution of the drugs used to treat people living with Aids.

(a) HIV and Aids is treated by drugs which:

- (a) Weaken the HI virus, by inhibiting the metabolic processes involved in its replication. Anti-retroviral drugs (ARVs) are generally combined as triple or quadruple therapy, are potent drugs when used this way, mainly to avoid the development of drug resistance by the virus.
- (b) Deal with the various symptoms from opportunistic disorders that result from HI infection, the so-called 'Aids indicator conditions'. These defining symptoms of HIV infection result from the opportunistic infections and cancers which appear later, such as tuberculosis, meningitis, pneumonia and Kaposi's sarcoma.

Currently, it is estimated that 500,000 people who are infected with the HI virus would benefit from antiretroviral therapy. Unfortunately, only around 40,000 are presently receiving them on a regular, controlled basis¹¹.

(b) Diabetes can be managed by a number of oral hypoglycaemic drugs. There are three groups of drugs:

- (a) One group stimulates the pancreas to make more insulin.
- (b) A second group makes the cells more sensitive to what little insulin there is already.
- (c) A third group slows down the digestion of carbohydrates in the gut, so that the glucose enters the bloodstream more slowly.

(c) Hypertension can be controlled, but not cured, by a wide range of drugs belonging to several different categories. These drugs are usually given in combinations of two or more types with different mechanism of action. The use of anti-hypertensive drugs is often complemented by advice on lifestyle, such as adopting measures for the patient to lose excess weight, cut down on alcohol and smoking, and taking more exercise.

The main groups of drugs are:

- (a) *The diuretics*. These agents initially encourage the loss of fluid and sodium from the body, leading to reduced cardiac output and so to a fall of blood pressure. In long-term therapy they act more like vasodilators.
- (b) *The vasodilators*. These widen the blood vessels, so reducing the resistance to blood flow in the peripheral circulation. This results in a fall in blood pressure.
- (c) *The sympatholytics*. These dampen down the activity of the peripheral, or autonomous, sympathetic nervous system, which leads to a reduced heart rate, cardiac output, and so a fall in blood pressure.

The increasing incidence of type 2 diabetes and most cases of hypertension reflects changes in lifestyle that have manifested over the last 20 years or so here and elsewhere, especially the trend to a sedentary way of life and the greater availability of high energy, relatively inexpensive and readily available “fast-food”.

Another factor is that people with Type 2 diabetes often have hypertension and high blood lipid levels, a phenomenon known collectively as the ‘metabolic syndrome’. These conditions themselves demand expensive intervention, including the use of conventional drugs, regular travel to the clinic, and frequent time off work.

Problems with conventional drug usage

The symptoms and longer-term consequences of poorly controlled chronic disorders are highly disruptive to a person’s personal, domestic and occupational life. Unfortunately, the widespread use of drugs brings with it a number of problems.

One is the cost of long term therapy. Even the use of well-established drugs comes with a substantial cost to the community; this cost is even greater when the newer agents are resorted to.

There are other problems. Side effects are the unavoidable companions of most if not all conventional drugs, manifesting as a wide range of subjective and objective problems. These side effects are a major contributor to poor compliance in the patient, and can lead to time consuming dosage adjustments and/or switching to possibly better tolerated drugs.

Understandably, therefore, there is considerable interest in the search for non-pharmaceutical approaches which provide satisfactory relief from the chronic disorders which are effective,

safe, cost-effective, generally available, and associated with good patient compliance. The need for a non-drug approach to therapy is all too evident.

Non-drug treatment of chronic disorders

On a more positive note, the person with Type 2 diabetes and hypertension can be controlled to a substantial degree by making conscious, long-term changes to his or her lifestyle. This has been demonstrated in numerous studies. Dietary changes alone, for example, can result in 50% improvement in Type 2 diabetic people, and moderate physical exercise can result in an impressive fall in raised blood pressure. The main options for the treatment of chronic disorders by non-pharmaceutical measures are given below.

Complementary medicine. Most of these healing paradigms stress the need to stimulate self-healing – “the doctor within”. Unani-Tibb, for example, provides a wide range of lifestyle changes and dietary interventions which are tailored for the individual person’s temperament, and are effective stimulators of the body’s self-regulatory mechanisms⁷. One advantage of this type of treatment is that it can be combined with conventional medicine as integrative medicine. The approach involves making changes to the patient’s lifestyle, and these are now emerging as powerful therapeutic options. Overall, they act by empowering a person to take charge of his or her condition. These involve reasonable modifications to the person’s diet and encouraging regular moderate physical exercise. Other options include stress alleviation, better sleeping and relaxation, and the systematic elimination of toxins from the body.

Nutritional approach. An imprudent diet over the longer term can encourage the development of both diabetes and high blood pressure. A regular intake of high fat, high sugar, high calorie food inevitably leads to obesity in the inactive person, and can encourage the onset of both type 2 diabetes and hypertension. Also a high salt, low fibre, food has been identified as the major culprit in the onset and development of hypertension. Encouraging the patient to adopt an improved diet can increase the benefit brought about by conventional treatment. By introducing a programme of healthy eating and meal planning the person’s chronic disorder can be improved markedly, leading to better control and less (or zero) need for conventional drugs.

Physical exercise. Controlled exercise, both aerobic and non-aerobic, has proven beneficial in people with certain chronic disorders, including diabetes and high blood pressure. Exercise has a two-fold benefit. Not only does it help to reduce excess body weight, which may be the underlying source of the disorder, but also helps in the transfer of glucose from the blood into the tissues, so leading to a fall in blood glucose levels. Numerous studies have shown that regular exercise helps to keep arteries elastic, even in older people, which in turn improves blood flow and lowers blood pressure. Sedentary people benefit particularly from light to moderate physical exercise.

Counselling. One important aspect of the management of chronic disorders is a real and pressing need for meaningful and appropriate support of the person affected. This not only involves day-to-day advice on the condition, but in empowering the person in his or her own treatment in order to maintain self-esteem and self-respect, so maintaining an optimum quality of life, and improving compliance with recommended therapy.

Herbal products. There are a number of herbal medications available in South Africa which are particularly valuable in reducing raised blood pressure and for the control of blood glucose in diabetic people.

2.3. The Unani-Tibb approach to the treatment of chronic disorders

Tibb generally regards the chronic disorders such as type 2 diabetes and hypertension not as diseases themselves, but as symptoms of an underlying *disharmony* within the body. That is, the homeostasis within the body has been disturbed. According to Tibb, both type 2 diabetes and hypertension are multifactorial disorders, with emotional, mental and even spiritual elements. In most cases of these disorders there is no one, single cause – there are several. In other words, these disorders are multi-factorial disorders. Moreover, the causes of type 2 diabetes and hypertension are in most cases associated with the poor management of the person's governing (lifestyle) factors. The Tibb approach, therefore, is to emphasise the role of these governing (lifestyle) factors, together with the administration of appropriate medication. HIV and Aids is relatively more complicated disorder, as there are strong overtones of the person's immune vulnerability, socio-economic factors, dietary considerations and cultural aspects. Once a person has contracted the virus, a host of factors come into play. Tibb adopts a two-pronged approach, dealing with both the acute and the chronic aspects of the disorder. In addition to treating these disorders with Unani-Tibb medication, supplementing with conventional treatment is the effective implementation of governing (lifestyle) factors to address the causes of the disorder. This is paralleled by a series of measures, which relate to (a) the person's clinical status, (b) the person's general behaviour, (c) the strengthening of the person's immune system, and (d) counselling of the person to enhance compliance to treatment and maintenance of quality of life.

More relevant to this report, however, is that Tibb, through its programme of governing (lifestyle) factor support, is well placed in providing a programme of activity which will both enhance the person's quality of life and encourage better compliance with recommended therapy.

2.4. Integrative medicine as a viable approach

In this healthcare model different systems are brought together in a controlled, organised manner, in order to emphasise health education and actively encourage self-help. Practitioners of conventional medicine and complementary medicine cooperate in actively encouraging the patient to strive for personal well-being, and to seek out – and redress – behaviour, dietary or environmental factors which may underlie a particular disease.

Integrative medicine does not just combine conventional and complementary medical practices, but sees the appropriate remedies given the patients situation and beliefs. It also involves the patient taking more responsibility for his or her healthcare; for example, by making realistic lifestyle changes in order to promote personal well-being.

Unani-Tibb combines well with conventional medicine in a realistic form of integrative therapy. It introduces holistic principles, is cost effective, is in line with the cultural practices of much of the patient population, and encourages patient empowerment. Importantly, Unani-Tibb enhances the person's capacity for self-healing by restoring internal harmony, so works well in partnership with conventional medicine, which focuses more on reducing blood pressure to a less threatening level.

3. Outline of Unani-Tibb

Description. Unani-Tibb is a comprehensive healing system which has its roots in early Greek, Arabic and Western medicine¹². It is a humanistic and holistic approach to health and illness, which recognises the physical, mental, emotional and spiritual contributions to health. The philosophy of Unani-Tibb is based upon concepts related to healthcare; the main ones from the perspective of this Report are physis, temperament and the governing (lifestyle) factors.

Physis is the body's innate drive and capacity to preserve health and where necessary self-heal any ailment¹². This concept is not unique to Unani-Tibb, but exists in a number of traditional and complementary health systems. In effect, treatment with Unani-Tibb in disorders such as hypertension is aimed at bolstering the patient's innate capacity for self-healing, by harmonising the myriad of cardiovascular mechanisms within the patient's body in counteracting the hostile outer environment and rectifying unwanted disturbances to inner harmony.

Closely allied to this concept is the encouragement of personal empowerment. By this is meant the assumption of responsibility for the therapy of the presenting ailment, and in adopting measures which will mitigate against the underlying causes initiated by an imprudent lifestyle.

Temperament. This concept defines the uniqueness of a person¹². It is a collective measure of a person's physical constitution and psychological profile, or personality. This concept has endured from its origin centuries ago, and is still applied, with suitable modifications in many medical and scientific spheres. Unani-Tibb applies this concept not only to the patient being

treated, but to the disorder affecting him or her, and even to the type of medication or activity recommended as therapy. Unani-Tibb affirms that each patient should be treated individually. *Governing (lifestyle) factors.* These are lifestyle and environmental factors which collectively influence a person's state of health and his or her progress towards disease¹². There are six main ones which have direct relevance to Unani-Tibb therapy – (1) atmospheric air and breathing; (2) the person's diet and eating practice; (3) bodily movement and rest; (4) sleep and wakefulness; (5) the emotional state; and (6) the toxin elimination processes. Each of these factors is involved to varying degrees in the Unani-Tibb health maintenance and therapeutic regimens.

Unani-Tibb therapy. Treatment of chronic ailments is carried out by way of four approaches:

- (1) Dietotherapy according to the patient's temperament and the nature of the ailment;
- (2) Pharmacotherapy, or treatment with one or more of a range of herbal products;
- (3) Regimental therapy, which include a number of therapeutic interventions, such as massage, cupping, purging and diuresis;
- (4) Advice and application of changes to the patients' governing (lifestyle) factors.

The pilot research project evaluated in this Report focuses on this latter approach.

4. Methodology

4.1. Background to the project

The Diploma in Unani-Tibb (Dip. UTM) is a 12-month elective programme which was introduced at the University of the Western Cape in 2003. Participants in the programme are qualified healthcare practitioners, and include orthodox (allopathic) doctors, homeopaths, and primary healthcare nurses.

Structure. The course is modular in format. It consists of six modules on the theory and philosophy of Unani-Tibb, followed by five modules on its practical application to a wide range of commonly encountered clinical situations. Of more relevance to this report, however, is that the twelfth, and final, module relates to a specific 'mini-research' project carried out by each participant.

Outcome. For the research project conducted by the 2005 intake, the students were asked to evaluate the effect of Unani-Tibb governing (lifestyle) factor enhancement in their practice, on a sample of between nine and twelve patients with a common chronic ailment, depending on the availability of these patients in their practice.

This Report focuses on the student investigations into patients diagnosed with HIV and Aids, diabetes or hypertension.

Study design. The research project on patients with HIV and Aids was conducted by seven students, diabetes and hypertension by five students each, and conducted over a period of at least three months. The quality of life assessments were conducted by direct face-to-face questioning by the researcher, both before introduction of Unani-Tibb lifestyle advice, and immediately afterwards. The clinical parameters relevant to the particular disorder under scrutiny were determined at the initial contact visit, and at the final follow-up contact.

Patient profile. Recruitment was conducted either at local Day Clinics or after referral to Unani-Tibb clinics. Admission criteria were that patients selected were unequivocally suffering from Aids related complaints, or were diabetic or hypertensive, and were in a stable condition as a result of therapy with conventional or Unani-Tibb medication.

Patient consent. Each patient enrolled into the study was informed of, and understood, the objectives, their involvement, and awareness of their possible discontinuation without prejudice. This agreement and consent by the patient was formalised by signature on an appropriate custom-drawn Consent Form.

4.2. Researcher and location details

The following table summarises the researchers, their location, the patients, and study duration.

HIV and Aids researchers

Investigator profile	Location	Patient No.	Duration (wks)
VPD ; PHC practitioner, practice nurse	Duncan Village, East London	12	10 - 12
TQ ; PHC nursing; B.Cur (nursing); M Phil(sociol.);Post-grad Dip. HIV/Aids managmt	Guguletho;, Western Cape	10	12
NBJ ; Specialist nurse midwifery, paediatrics	Guguletho Anti-retroviral Clinic, Western Cape	10	12
SB ; Prof. nurse; Dip. gen. nursing, clin. Nursing Sci, B Tech. Certs various	Langa Township, Western Cape	10	12
BM ; Reg. nurse; Dip.gen nursing, CH nursing Sci. B Tech., Certs. various	Langa Township, Western Cape	10	12
MM ; Prof. nurse; HND CH, midwifery, Certs. various , psychiat., overseas exp.	Macasar, Khayelitsha, Western Cape	12 (11)	Not stated
SO ; Gen pract (Wits.),overseas exp.	Muslim Aids Home, Mayfair, Johannesburg	9	10

Diabetes researchers

Investigator profile	Location	Patient No.	Duration (wks)
SK ; PHC nursing; Dips. gen. nursing, fam. plan.,	Duncan Village, East London	12 (10M;2F)	16
GVS ; PHC nursing; Dips. nurs. sci., midwif., psych., comm. nursing, integ. mangt. paed.	Duncan Village, East London	10 (6M;4F)	12
ENM ; B.A. nurs. admin., dip. nurs. sci. & art, comm.. nursing, midwifery, adv. dip. nurs.	Middeldrift, King Williams Town, Eastern Cape	12 (2M;10F)	12 (?)
TS ; Prof. nurse; dip. gen. nursing, midwifery, chief prof. nurse.	Stutterheim, Eastern Cape	11 (11F)	12 (?)
NPB ; Prof. nurse; dip. gen. nursing, midwifery, clin. nurs. sci.	Duncan Village, East London	10 (5M;5F)	9

Hypertension researchers

<i>Investigator profile</i>	<i>Location</i>	<i>Patient No.</i>	<i>Duration (wks)</i>
NNJ ; Prof. nurse; dipls. gen. nursing, midwifery, paed., surgery	Gateway Clinic, Frere Hosp., East London	12	9
VSM ; Prof. nurse; dipls. In gen. nursing, comm.. health, psychiat.; cert. PHC	Nkqubela Hosp., Mdantsa-ne , Buffalo City	12	12
NPM ; Prof. nurse; dipls. In gen. and comm. nursing 7 manag'mt; exp. PHC	Middledrift mobile clinic, Eastern Cape.	12	12
NN ; Prof. nurse; dipls. gen. nursing, midwifery, paed. exp. PHC	Qamata Clinic, Eastern Cape	10	12
NYM ; Prof. nurse; Dip. gen. nursing, midwifery, adv. comm.. nursing sci. & admin	Middledrift Health Care Clinic, Eastern Cape	12	9

2005 HIV and Aids Research Project / Diploma in Unani-Tibb Participants

V P Dyasi; Thozamile Qubuda; Nombuyiselo Beauty Jwambi; Siphokazi Buhlungu; Belelwa Magaqwa; Maurita Mogporos; Summeiya Omar

2005 Diabetes Research Project / Diploma in Unani-Tibb Participants

S Khan; G V Summerton; E N Mcetywa; T Sifamelo; N P Booii

2005 Hypertension Research Project / Diploma in Unani-Tibb Participants

Norah N Jako; V S Makaluza; Nomsukizo P Mkiva; Nontutuzelo Ncobo; Noxolo Y Mpe

4.3. Governing (lifestyle) factors selected

The investigators generally reinforced the six major governing (lifestyle) factors by direct face-to-face advice, by methods described during the Diploma Course. The table below indicates whether (yes) or not (*no*) each governing (lifestyle) factor was applied, and if yes, the extent to which it was carried out in each investigator's cohort of patients.

The governing (lifestyle) factors most emphasised were (a) changes to diet, and (b) regular physical exercise. This is in line with positive results reported in people with hypertension for nutrition⁴ and physical exercise⁸. In addition, breathing exercises were also recommended for

most of the patients, and advice on sleeping hygiene and emotional problems proffered as necessary.

HIV and Aids researchers

	<i>Diet</i>	<i>Breathing</i>	<i>Exercise</i>	<i>Emotion</i>	<i>Sleeping</i>	<i>Elimination</i>	<i>Other*</i>
VPD	Yes (all)	Yes (all)	Yes (11/12)	Yes (6/12)	No	No	No
TQ	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes
NBJ	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes
SB	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes (all)	No
BM	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes (all)	No
MM	Yes (all)	No	No	Yes (all)	Yes (all)	Yes (all)	No
SO	Yes (all)	No	Yes (all)	No	Yes (all)	Yes (all)	No

[*Other: cutting down on alcohol, smoking; improved hygiene; counselling]

Diabetes researchers

	<i>Diet</i>	<i>Breathing</i>	<i>Exercise</i>	<i>Emotion</i>	<i>Sleeping</i>	<i>Elimination</i>	<i>Other*</i>
SK	Yes	Yes	Yes	No	No	Yes	Yes
GVS	Yes	Yes	Yes	Yes	Yes	Yes	No
ENM	Yes	No	Yes	Yes	No	No	Yes
TS	Yes	No	Yes	Yes	No	Yes	Yes
NPB	Yes	Yes	Yes	Yes	Yes	Yes	Yes

[*Other: cutting down on alcohol, smoking; improved foot hygiene; counselling]

Hypertension researchers

	<i>Diet</i>	<i>Breathing</i>	<i>Exercise</i>	<i>Emotion</i>	<i>Sleeping</i>	<i>Elimination</i>	<i>Other*</i>
NNJ	Yes (all)	No	Yes (all)	No	No	No	Yes
VSM	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes
NPM	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes (all)	No	No
NN	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes (all)	Yes (all)	No
NYM	Yes (all)	Yes (10/12)	Yes (7/12)	Yes (1/12)	No	No	No

[*Other: wet cupping, cutting down on alcohol, smoking; improved hygiene; counselling]

4.4. Quality of life assessments

Definition. Although 'quality of life' is, like 'health' or 'well-being', a subjective, but ill-defined term, most people understand it intuitively to express a satisfaction with life as they presently experience it. Quality of life encompasses the physical, mental and spiritual dimensions of their existence.

This quality of life study included the patient's general health, the degree of physical, emotional and cognitive functioning they are experiencing, their sexual behaviour, their social well-being, and the psychological state, indicated by depression and sleep disturbances.

The quality of life indicators were selected according to the profile of patients likely to be encountered, and taking into consideration their educational background, conservative nature and language fluency. These were:

- ♦ Global quality of life
- ♦ Current health status
- ♦ Personal energy level
- ♦ Emotional or nervous state
- ♦ Sleeping problems
- ♦ Awareness of benefit
- ♦ Social intercourse
- ♦ Occupational competence
- ♦ Personal satisfaction with treatment
- ♦ Feeling of self esteem
- ♦ Affordability of Tibb therapy
- ♦ Value of Tibb therapy
- ♦ Confidence about outcome
- ♦ Understanding of the cause of the disorder
- ♦ Feeling of control over the disorder
- ♦ Recommendation to colleagues/ friends

4.5. Clinical parameters

The clinical parameters assessed were selected according to the capability of the laboratories and facilities available to the researchers. The main ones relevant to the projects were as follows:

(a) HIV and Aids. Changes in CD4 counts and body mass. The CD4 count is a useful indicator of the overall competence of the person's immune system. A level below 200 cells per mm³ suggests a dangerous vulnerability to opportunistic infections and cancers, whilst a count above 350 indicates a much smaller risk. Body mass changes are indicative of the patient's HIV and Aids status. A marked decline in body mass suggests rapid progress of the disease, deteriorating appetite, or the presence of oro-pharyngeal thrush. A marked increase in body mass suggests improvement in the condition, improving appetite, or resolution of the throat infection.

Blood pressure, blood sugar levels and the degree of oro-pharyngeal thrush infection were also measured by investigators who had access to the appropriate facilities in a number of patients. However, the relatively small number for which accurate, reliable data is available does not justify inclusion of these results in this evaluation.

(b) Diabetes. Changes in body mass and blood glucose levels. Body mass changes are important because the origin of the patient's diabetes may reside in excess body mass, so a marked decline in body mass suggests improvement in a major risk factor for type 2 diabetes. Blood sugar levels were also recorded before and after governing (lifestyle) factor intervention. The degree to which a trend to normoglycaemic levels is observed reflects the reduction in risk that hyperglycaemia poses.

Other clinical parameters measured were glucose levels in urine (by one investigator) and arterial blood pressure. ,

The drug sparing effect of governing (lifestyle) factor application was measured by comparing individual hypoglycaemic drug intake before and after three months therapy.

(c) Hypertension. Changes in blood pressure, pulse rate and body mass. Body mass changes were measured because of the proven link between excess body weight and raised blood pressure. A marked decline in body mass should contribute to a substantial fall in blood pressure. A fall in the pulse rate suggests a falling of in personal psychic tension, and a restoration of inner harmony.

Body mass readings were obtained from standard issue body mass scales, blood pressures were measured by standard issue mercury sphygmomanometer, and blood glucose derived from finger prick glucometer. A number of other clinical parameters were measured by some of the researchers who had access to the appropriate facilities, but the relative paucity of data precludes them from meaningful analysis.

4.6. Concomitant medication

Virtually every patient included in the research project was receiving either conventional drugs or herbal medication. There were several reasons for this intake of medication:

(a) To treat the target disorder. In the HIV and Aids group, most patients took a number of anti-retroviral drugs (ARVs) or Unani-Tibb medications and vitamin supplements, or immune system boosting preparations. In the diabetic group, the main oral hypoglycaemic drugs were metformin, gliclazide, glibenclamide, and insulin. In the hypertensive group, most patients took one of a number of conventional anti-hypertensive agents, especially diuretics, reserpine and ACE inhibitors. Many took Unani-Tibb medication, especially Pressure-Eeze, Coronary Care and Renotone.

(b) To deal with the co-existing disorders. In the HIV and Aids group, tuberculosis, arthritis and general aches and pains were treated routinely by standard therapy. In the diabetes group, other clinical disorders which are often associated with diabetes, specifically hypertension, as part of the metabolic syndrome. Hypertension was treated with diuretics and ACE inhibitors.

(c) To counteract everyday disorders, such as insomnia, headaches and arthritic pain. These included both conventional drugs (paracetamol; aspirin) and herbal medications.

As most researchers did not have regular access to records of each individual patient's drug consumption, it was not possible to determine accurately any drug-sparing effect the application of the governing (lifestyle) factors may have had, either in terms of actual daily dosage or specific drug usage.

4.7. Analysis of data

The results obtained were recorded onto the appropriate pre-prepared case history forms by each researcher. The changes in quality of life for every patient within each criterion were arrived at by subtracting the final assessment quantum from the initial. These changes were recorded as: great improvement (+++); substantial improvement (++); some improvement (+); no change noted (±); noticeable deterioration (-).

The changes in the clinical parameters (body mass, CD4 count, blood glucose, blood pressure, body mass and pulse rate) for each patient were recorded at each visit, and presented in tabular form.

5. Results

5.1. Quality of life parameters

The summary from each of the investigators is shown below:

Assessment	HIV & Aids	Diabetes	Hypertension
1. Global Quality of Life	+ (6) : ± (1)	+ (5)	+ (4) : ± (1)
2. Current health status	+ (7)	+ (5)	+ (5)
3. Personal energy level	+ (5) : ± (1) : - (1)	++ (1) + (4)	+ (5)
4. Emotional or nervous state	+++ (1) : ++ (1) : + (4) : ± (1)	+ (5)	+ (5)
5. Sleeping problems	++ (2) : + (3) : ± (2)	+ (5)	+ (5)
6. Awareness of benefit	++ (2) : + (3) : ± (2)	++ (1) : + (4)	++ (1) ; + (4)
7. Social intercourse	++ (2) : + (4) : ± (1)	+ (5)	+ (4) : ± (1)
8. Occupational competence	++ (2) : + (4) : ± (1)	+ (5)	+ (4) : ± (1)
9. Personal satisfaction with treatment	++ (1) : + (4) : ± (1)	++ (1) : + (4)	+ (4) : ± (1)
10. Feeling of self esteem	+ (7)	++ (1) : + (4)	+ (3) : ± (1) : - (1)
11. Affordability of Unani-Tibb therapy	++ (1) : + (4) : ± (1) : - (1)	+ (2) : ± (3)	+ (4) : ± (1)
12. Value of Unani-Tibb therapy	++ (1) : + (3) : ± (3)	+ (3) : ± (2)	+ (5)
13. Confidence about outcome	++ (2) : + (5)	++ (2) : + (2) : ± (1)	++ (1) : + (3) : ± (1)
14. Understanding the cause of the disorder	++ (1) : + (6)	++ (2) : + (2) : ± (1)	++ (1) : + (2) : ± (2)
15. Feeling of control over the disorder	++ (1) : + (6)	++ (2) : + (2) : ± (1)	++ (1) : + (3) : ± (1)
16. Recommendation to colleagues	+ (6) : ± (1)	+ (3) : ± (2)	+ (4) : ± (1)

[Key: +++ Great improvement; ++ substantial improvement; + some improvement; ± no change; - deterioration]

(a) HIV and Aids. Unani-Tibb lifestyle adjustments achieved impressive responses in the fields of general improvement to current health status, feelings of self-esteem, and the feeling of control over the condition. This improvement in mental and emotional health is a major achievement for patients who invariably suffer severe mental and emotional trauma as a consequence of HIV and Aids. The patients were also more confident about the outcome of the disorder and understanding more about it, which suggests a degree of success in educating the patients. There was, however, a more mixed response in a number of linked fields, such as the perceived value of Unani-Tibb therapy and its affordability.

Most patients were personally satisfied with Unani-Tibb therapy, partly because it allowed them to maintain their occupational activities and social life. At the same time, most of the

patients reported improvements in their emotional state, increased energy levels and (in some) better sleeping patterns. Overall, many patients were subjectively aware of the benefits that Unani-Tibb therapy can bring, and this was reflected in the global quality of life assessment and their positive inclination to recommend it to family and friends.

(b) Type 2 diabetes. Unani-Tibb therapy brought about impressive responses in the fields of understanding of diabetes by the patients, and consequently better control over it. This was reflected in better self-esteem. Furthermore, personal energy levels were improved, together with awareness of the benefit of governing (lifestyle) factor application. The patients claimed a more positive feeling about their condition and its outcome, with a better personal life reported. There was a noticeable improvement reported for the patients' global quality of life and current health status, with better sleeping patterns and emotional states noted. An improvement in the patients' occupational and social competence was also recorded.

Patients were generally satisfied with their treatment, although satisfaction with the cost and value of present therapy was not unequivocal. Finally, there was a distinct trend for patients to agree that they would recommend this form of therapy to their friends if approached.

(c) Hypertension. Unani-Tibb therapy achieved particularly impressive responses in the fields of general understanding of hypertension and its consequences if untreated, their degree of control of their condition, and their awareness of the benefit that effective management brings. The general improvement in these factors is a major achievement for patients who can be incapacitated through inadequate treatment, especially due to poor compliance. Most of the patients were personally satisfied with Unani-Tibb therapy, partly because it allowed them to continue their occupational activities and social life, and good returns were obtained on the perceived value of Unani-Tibb therapy and its affordability. At the same time, most of the patients reported improvements in their emotional state, increased energy levels and better sleeping patterns. The patients were inclined to be more confident about the outcome of the disorder, which suggests a degree of success in educating the patients. Overall, the benefit of Unani-Tibb therapy was reflected in the global quality of life assessment, and their positive inclination to recommend it to family and friends.

5.2. Changes in clinical parameters

(a) HIV and Aids patients

Changes in patients' body mass. The changes in body mass recorded for patients living with Aids between the first and the final visit are shown in the table below.

Researcher	VPD	TQ	NBJ	SB	BM	MM	SO
Patients*	10/12	10/10	10/10	10/10	10/10	11/11	9/9
Gain/loss body mass	▲	▼▼	▲▲	▼▼	▲▲	▲▲	▲▲
Change range (kg)	0 to 1.8	-8 to 3	13 to 8	-25 to 18	1 to 19	-0.5 to 5	-4 to 5

[* - number of pats. weighed / actual cohort number

▲ or ▼ - average body mass change less than 1 kg; ▲▲ or ▼▼ - average change greater than 1 kg]

There is evidently a wide variation in body mass between the initial visit and the final follow-up. This variation exists both between different investigators, and also within most investigators' patient cohorts. In spite of reservations about the accuracy and relevance of these measurements, there was a trend towards an increase in body mass in the majority of patients. As weight loss is one of the inexorable *sequelae* of HIV and Aids, this trend should be regarded in a favourable light.

Changes in CD4 counts. Three researchers were able to record changes in CD4 counts between the initial visit and the final follow-up. The results are given in the table below.

Researcher	No. of pats.	Improved	< 50 CD4/μl blood	> 50 CD4/μl blood
TQ	10	8	8	0
SO	9	8	2	6
SB	10	6	6	0

There is a firm trend towards an increase in CD4 counts, with 21 of the 29 patients registering a modest, and one a substantial, improvement. It is not possible to attribute this entirely to the patients' response to the governing (lifestyle) factors, as the patients were simultaneously taking anti-retroviral drugs and immune stimulants. However, bearing in mind that the patients recruited were stable on therapy (ARV or herbal medication), the overall increase in CD4 counts (although not significant) suggests a possible benefit from the governing (lifestyle) factors. Clearly, further strictly controlled and executed studies are required to assess the role of governing (lifestyle) factor enhancement on the CD4 count (and other haematological and metabolic markers).

(b) Diabetic patients

Blood glucose changes. The blood glucose levels recorded by each researcher for their cohort of patients is summarised in the table below.

Researcher	No. of pats.	Blood glucose levels (mmol/l)				% change
		Before	After	Difference	Range	
SK	12	9.21	5.82	3.39	13.1 to 4.4	36.8
GVS	10	9.41	8.47	0.94	12.0 to 6.0	10.0
ENM	12	14.8	5.1	9.7	20 to 4.0	65.5
TS	11	14.4	10.3	4.0	17.0 to 8.8	28.4
NPB	11	13.4	11.2	2.2	20 to 8.4	16.4
Combined	56	12.30	8.08	4.22	20+ to 4.0	34.3

Blood glucose levels vary widely both within and between patient cohorts. Overall, there is a consistent reduction in glucose levels, which suggests that the application of the governing (lifestyle) factors exerts a significant hypoglycaemic effect, other factors being equal. There are a number of discrepancies in the results, which may arise, *inter alia*, from differences in admission criteria applied by the various researchers. Further studies are indicated in order to resolve these differences in blood glucose changes.

Changes in patients' body mass. The changes in the patients' body mass after the governing (lifestyle) factor period of treatment are shown below.

Researcher	No. of Pats.	Before (kgs)	After (kgs)	Mass loss (kgs)	Change range (kgs)
SK	12	79.8	82.3	(-) 2.5	+6 to -6
GVS	10	76.1	74.9	1.2	+3 to -2.6
ENM	12	69.2	64.3	4.9	-4 to -17
TS	11	84.9	81.1	3.8	-2 to -15
NPB	11	75.7	75.1	0.6	+1 to -3
Combined*	56	77.1	75.5	1.6	+6 to -17

The variations in patients' weight before and after intervention vary widely between patients, as was the case with the blood glucose levels. Moreover, in one researcher's (SK) patient cohort there was a marked *increase* in body mass, in contradistinction to the patients examined by the other four researchers. Evidently, several factors are influencing the patients' body mass during the intervention period. It is not possible to identify the reason or reasons for this, so the discrepancy may reflect differences in either admission criteria for the study, or in weighing methodology, or in data recording. Again, further studies are indicated to resolve these discrepancies.

(c) Hypertensive patients

Blood pressure. The changes in blood pressure (mm Hg) recorded for the patients between the initial and the final visit are shown in the table below.

<i>Investigator</i>	<i>NNJ</i>	<i>VSM</i>	<i>NPM</i>	<i>NN</i>	<i>MYP</i>	<i>Mean</i>
Patients*	12	12	12	10	12	-
Initial mean systolic BP	181	155	164	158	153	162
Final mean systolic BP	131	149	142	131	139	138
Difference (mm Hg)	50	6	22	27	14	24
Initial mean diastolic BP	101	102	102	101	88	99
Final mean diastolic BP	90	91	88	97	77	88
Difference (mm Hg)	11	11	14	4	11	11

Changes in the pulse rate. The changes in the patients' pulse rate (beats per minute) recorded for the patients between the first and the final visit are shown in the table below.

<i>Researcher</i>	<i>NNJ</i>	<i>VSM</i>	<i>NPM</i>	<i>NN</i>	<i>MYP</i>	<i>Mean</i>
Patients*	12	12	12	10	12	-
Initial pulse rate (mean)	78	78	71	72	76	75
Final pulse rate (mean)	71	76	69	69	81	73
Difference (beats/min)	7	2	2	3	(-) 5	2

Changes in patients' body mass. The changes in body mass (kilograms) recorded for the patients between the first and the final visit are shown in the table below.

<i>Researcher</i>	<i>NNJ</i>	<i>VSM</i>	<i>NPM</i>	<i>NN</i>	<i>MYP</i>	<i>Mean</i>
Patients*	12	12	12	10	12	-
Mean loss of body mass	3.7 kg	1.1 kg	2.0 kg	3.74 kg	1.3 kg	2.3 kg
Change range (kg)	0 to 18	-2 to 5	13 to 8	-4 to 11	1 to 6	

[* - number of pats. weighed / actual cohort number]

A wide variation in body mass changes recorded between the initial visit and the final follow-up is evident. This variation is apparent both between different researchers, and also within most patient cohorts. There are several reasons for this variation, including the clinical condition of patients being enrolled. In spite of these reservations about the accuracy of these measurements, however, there was a trend towards a decrease in body mass in the majority of patients. As weight loss is an important component to the reduction in blood pressure in people who are overweight or obese, this trend should be regarded in a favourable light.

6. Deficiencies of the project

Conducting research in the working environment facing most researchers is fraught with many problems, a point not always appreciated by those unfamiliar with the situation. There are difficulties relating to authority, organization, access to information, cross-cultural communication, technical and administrative support, and of course finance. Even so, the data generated is invaluable, and should be conserved in a suitable data-base, accessible for future research activities. Identifying some of the drawbacks to the research project should assist in improving future research projects.

General. There are a number of drawbacks to the research project which preclude more rigorous analysis and definite conclusions. Amongst these are:

- ♦ Lack of previous experience of the researchers in conducting clinical studies. The research was carried out by people who were not fully familiar with the principles, processes and requirements for carrying out clinical research.
- ♦ Lack of a control group. The clinical outcome of a group of matched patients over the same period of time as that devoted to applying the governing (lifestyle) factors would be a valuable reference, so allowing the improvement due to intervention to be quantified.
- ♦ The lack of statistical analysis. Analysis from all pooled data cannot be done properly because of the variation in the quality or reproducibility of the data.
- ♦ Inter-centre variation. The differences in techniques adopted by the researchers for parameters such as blood pressure, blood glucose and body mass diminish the value of the data.

These concerns can be addressed by a session during the course devoted to the formal training of the researchers before the research project commences.

- ♦ Research project timescale. The three month intervention period is too short to pick up significant changes in certain clinical and biochemical parameters. Although this period may be long enough for changes to be confirmed in body mass and certain symptoms, it is not long enough to assess, say, the drug-sparing effects of the governing (lifestyle) factors, trends in CD4 counts, blood pressure variations and changes in biochemical parameters such as blood sugar and lipid profiles.

Quality of Life. There is no previous experience of the researchers with the quality of life assessment. There are marked variations between investigators in their competence with the quality of life instruments. Also, irrespective of which quality of life dimensions are selected for inclusion into a particular study, all ultimately depend on the subjective response to particular questions posed by the investigator, so problems of accurate communication arise. There is

also the “Hawthorne effect”, by which the patients are eager to please the investigators. This can create problems of understanding of specific terms, and this can be compounded by cultural factors. The lack of a control group accentuates this problem.

This problem can likewise be addressed by appropriate training prior to the search project.

Governing (lifestyle) factors. Future research projects should provide more information of which governing (lifestyle) factors were selected for reinforcement, and how this was achieved in practical terms. It would also be of interest to quantify the lifestyle changes, especially regarding the main ones, diet and exercise, and estimate the actual degree of commitment by the patient..

Clinical parameters. There were a number of discrepancies in certain clinical parameters. For example, in *body mass measurement* there was considerable variation which appears unlikely or excessive. There are several reasons for this variation, including: (a) the clinical condition of patients being enrolled varies markedly between the researchers, so marked weight fluctuations occur in the more affected patients; (b) The body mass readings were not made at the same time of the day, or patients were not wearing the same clothes, which could result in errors of 1 to 2 kg per patient, either up or down; (c) Non-standardised equipment, leading to innate inaccuracies and/or rounding-up or down (‘digit preference’).

Another example is *blood pressure measurement*. Perusal of the actual recorded data reveals a number of discrepancies which diminish the value of the data. There is substantial evidence of gross rounding up or down, digit preference, the appearance of physiologically unlikely values, and lack of care and calibration of the blood pressure measuring equipment.

Blood glucose measurement is another example. There are a number of concerns about these results, especially the extremely high levels reported for several patients. In fact, some figures reported were actually off scale, which raises concerns about the accuracy of the assay technique. Another is the very large difference, both actual and percentage, between before and after intervention.

Also, the *routine measurement of CD4 counts* is expensive, and requires competent laboratory facilities and staff, it is often beyond a clinic’s capacity, especially in the rural context. This means that not all researchers were able to have this measurement done, so losing the opportunity to provide valuable data. If this parameter is essential, then financial support needs to be obtained for future research projects.

7. General conclusions

This research project investigated the effect of governing (lifestyle) factor enhancement over a three month period on the quality of life and a number of clinical parameters in patients diagnosed with HIV and Aids, type 2 diabetes or hypertension.

The project, in spite of its manifest drawbacks in design and execution, indicates a consistent and definite trend to improvement in the majority of patients suffering from chronic disorders when they are encouraged to adopt a number of governing (lifestyle) factors. These improvements were observed in a number of parameters, including quality of life indicators, body mass, blood pressure and blood glucose levels.

The overall positive response suggests strongly that further, more extensive and better controlled studies along the same lines should be carried out, with closer control of methodology and data capture along similar lines should be performed, especially in the light of the serious management problems confronting our healthcare authorities in dealing with chronic ailments affecting people living with Aids, type 2 diabetes and hypertension.

8. Suggestions for further research

The experiences gained in this pilot research project point to a number of changes which can be incorporated into future research projects. From the researchers' perspective, a number of support training activities would enhance the value of the research data gathered, and so the credibility of the final results and conclusions.

1. *Clinical study principles and practice.* A training session should be devoted to the principles involved when conducting research, and how this translates into the real-life clinical context. Topics covered would include patient recruitment, administration (especially record keeping and reporting procedures) and communication channels.

2. *Methodology.* In addition to the detailed end-point measurements included in the protocol, instruction on how to obtain a number of relevant bio-data should also be offered. For example, if changes in body mass are an important criterion of treatment efficacy, then the proper process – equipment use, patient preparation, timing, recording, etc. – should be conveyed to the researcher.

3. *Governing (lifestyle) factors.* A record should be made which describes in detail which was employed, the actual advice given either orally or in writing, the extent of compliance with this advice, and the results of this advice in terms of behaviour modification.

4. *Comparator group.* Although the collective presentation of a number of case histories as in the research project evaluated here is of considerable value, the inclusion of comparative data

from a reference group of patients not treated with the governing (lifestyle) factors would add further value.

5. *Study duration*. Wherever possible this should be extended to four, or ideally six, months. This would allow for more confident assessment of, for example, changes in quality of life to emerge, and for any clinical improvement occurring in the patients become more evident.

6. *Patient follow-up*. Patients who show marked clinical improvement should be further investigated. The reasons for such improvement should be sought, whether these relate to, for instance, the patient's temperament, or the application of a specific governing (lifestyle) factor.

References

1. HIV and AIDS: Prevention, Care and Treatment. Khomanani. Jacana Media. 2004
2. Glynn JP. Diabetes and the drugs used to treat it. *Pharmacy Management*. Oct. 1998. 6-11
3. *ABC of Hypertension* (3rd Edition) BMJ Publishing Group. London, 1995. p37.
4. M & G (Johannesburg). Special issue: World Aids Day. 25/11/05 – 1/12/05
5. *ABC of Diabetes*. (3rd Edition). (1993). Ed. Watkins PJ. BMJ publishing. (London)
6. www.health24.com/medical/Condition_centres
7. www.thebody.com/asp/mayjun04/exercise
8. Mail & Guardian. (Johannesburg). One in nine – it's official. 20 January, 2006. pS10
9. www.health24.com/news/HV_AIDS
10. www.salia.org.za/modules
11. www.hst.org.za/healthstats/41/data
12. *Tibb: Traditional Roots of Medicine in Modern Routes to Health*. R. Bhikha and Muhammad A Haq. Mountain of Light. (SA). 2000



UNIVERSITY of the WESTERN CAPE
DEPARTMENT OF RESEARCH DEVELOPMENT

SR1

UWC RESEARCH PROJECT REGISTRATION AND ETHICS CLEARANCE APPLICATION FORM

This application will be considered by UWC Faculty Board Research and Ethics Committees, then by the UWC Senate Research Committee, which may also consult outsiders on ethics questions, or consult the UWC ethics subcommittees, before registration of the project and clearance of the ethics. No project should proceed before project registration and ethical clearance has been granted.

A. PARTICULARS OF INDIVIDUAL APPLICANT			
NAME: Rashid Ahmed Hassen Bhikha		TITLE: Dr	
DEPARTMENT: School of Natural Medicine Sciences		FACULTY: Faculty of Community & Health Sciences	
FIELD OF STUDY: Complementary Medicine			
ARE YOU:			
A member of UWC academic staff?	Yes	<input checked="" type="checkbox"/>	No <input type="checkbox"/>
A member of UWC support staff?	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
A registered UWC student?	Yes	<input type="checkbox"/>	No <input type="checkbox"/>
From outside UWC, wishing to research at or with UWC?	Yes	<input type="checkbox"/>	No <input type="checkbox"/>

B. PARTICULARS OF PROJECT	
PROJECT NUMBER: TO BE ALLOCATED BY SENATE RESEARCH COMMITTEE:	
EXPECTED COMPLETION DATE: November/December 2005	
PROJECT TITLE: To assess the integration of governing (lifestyle) factors into the treatment of patients suffering from chronic illness conditions.	
THREE KEY WORDS DESCRIBING PROJECT: Governing factors, chronic illnesses, integrative treatment.	
PURPOSE OF THE PROJECT: Departmental research	
M-DEGREE:	D-DEGREE:
POST GRADUATE RESEARCH: Diploma in Unani-Tibb	

C. PARTICULARS REGARDING PARTICULAR RESEARCHERS

TITLE:	FAMILY NAME:	INITIALS:
PRINCIPAL RESEARCHER: DR	BHIKHA	R.A.H.
OTHER RESEARCH PROJECT LEADERS: DR	HAQ	H.M.
DR	GLYNN	J.P.
DR	MANXIWA	F.

OTHER CO-RESEARCHERS:

- Booi, N.P.
- Buhlungu, Ziphokazi
- Dyasi, Vuyiswa Portia
- Galadla, W.Vusumzi
- Gcilishe, Lumka
- Jako, Norah Nomatshezi
- Jeneto, Nonceba Adelaide
- Jwambi, Nombuyiselo
- Kave, Lizeka Grace
- Khan, Sakina
- Lekhanya, Teboho E.M.
- Magaqa, Bulelwa
- Makaluza, Vuyelwa Sylvia
- Mcetywa, Elizabeth Nqweniswa
- Melapi, Tembisa
- Mgwayi, Mbulelo Jeremia
- Mkiva, Nomzukiso Primrose
- Mndi, Nolukhanyo Yolanda
- Mnisi, Jacob
- Mogorosi, Maurita
- Mokoena, Connie
- Mokoena, John Mvumbini
- Mpe, Noxolo Yvonne
- Mtala, Nosipho
- Mthembu, Nomachule Phillipa
- Mtshiselwa, M.Lulekwa
- Ncobo, Nontutuzelo
- Newman, Shiella
- Ngxoweni, P.M.
- Nkayi, Nonceba Catherine
- Omar, Summeiya
- Qubuda, Thozamile
- Raniga, Jaimini
- Sifanelo, Thobeka
- Summerton, Glenda

THESIS: STUDENT RESEARCHER:

THESIS: SUPERVISOR:

C. GENERAL INFORMATION

STUDY LEAVE TO BE TAKEN DURING PROECT (days): **N/A**

IS IT INTENDED THAT THE OUTCOME WILL BE SUBMITTED FOR PEER REVIEWED PUBLICATION?
YES X NO

COMMENTS: DEPARTMENTAL CHAIRPERSON:

SIGNATURE OF THESIS STUDENT RESEARCHER – WHERE APPROPRIATE:

DATE

SIGNATURE OF THESIS SUPERVISOR – WHERE APPROPRIATE:

DATE

SIGNATURE OF PRINCIPAL RESEARCHER – WHERE APROPRIATE:

DATE:

SIGNATURE OF DEPARTMENTAL CHAIRPERSON:

DATE:

NOTE: THESE SIGNATURES IMPLY AN UNDERTAKING *BY THE RESEARCHERS*, TO CONDUCT THE RESEARCH ETHICALLY, AND AN UNDERTAKING BY THE THESIS SUPERVISOR (WHERE APPROPRIATE), AND THE DEPARTMENTAL CHAIRPERSON, TO MAINTAIN A RESPONSIBLE OVERSIGHT OVER THE ETHICAL CONDUCT OF THE RESEARCH.

E. DESCRIPTION OF PROJECT AND RESEARCH ETHICS STATEMENT

Please type below, or attach a typed document, usually between 500 and 5000 words, setting out the purpose and process of the research. Please include a clear research ethics statement. The onus is on the applicant to persuade UWC that the research will be conducted ethically. This will normally require evidence of an up to date research ethics literature search in the particular discipline; evidence of what the world standard ethical practice is, in the particular discipline; an explanation of how the proposed research is to be conducted ethically; a detailed justification of any proposed departure from world standard ethical practice; and a clear undertaking to conduct the research ethically. It may be useful also to agree to conduct the research in line with the published ethical rules of a national or international disciplinary association. UWC reserves the right to stop or suspend any research undertaken by its staff or students, or by outsiders on its property or in association with it, if the research appears to be unethical.

SEE ATTACHED PROPOSAL

UNIVERSITY OF THE WESTERN CAPE
Faculty of Community and Health Sciences

School of Natural Medicine

ABSTRACT
RESEARCH PROJECT

Keywords:

Unani-Tibb, governing (lifestyle) factors, chronic illness management, integrative treatment, orthodox (conventional) treatment, quality of life.

1. Introduction

Over the past few years there has been a growing interest in integrative medicine. The basis of integrative medicine is incorporating elements of different systems for the benefit of the patient. The research project is the integration of Unani-Tibb with orthodox bio-medicine (conventional medicine). One of the greatest strengths of Unani-Tibb is the inclusion of the lifestyle (governing) factors in the treatment protocols of chronic illness conditions. Although orthodox bio-medicine recognizes the impact of these lifestyle factors, the effective implementation of these lifestyle factors is not appropriately included into the treatment protocol which is aimed primarily at the use of medication.

The research project is to evaluate a structured Unani-Tibb lifestyle programme (governing factors) that is to be included alongside orthodox treatment (with respect to medication) and to assess the benefits, if any, thereof.

The research project of the postgraduate Diploma is not only a measure of the student's understanding of the Unani-Tibb principles but also an important vehicle for conducting research in Unani-Tibb.

2. Aims and objectives of the study

This descriptive study will highlight any advantages (if any) of the integration of the governing (lifestyle) factors into the treatment of patients suffering from chronic illness conditions. These

patients will remain on their existing orthodox treatment whilst incorporating the Unani-Tibb lifestyle (governing) factors. The governing factors include: environmental air and breathing; food and drink, exercise, rest, emotional states and elimination.

Specific objectives are to:

- To assess any changes in quality of life before and after the incorporation of the governing factors into the treatment of the listed chronic illnesses.
- To assess whether the inclusion of the Unani-Tibb governing factors resulted in a reduction in the medication dosage required or the number of medications used for the chronic condition.

The following illness conditions are to be included in the research projects:

- Management and treatment of HIV/AIDS
- Hypertension;
- Diabetes Type II;
- Arthritis;
- Asthma;
- High cholesterol (hypercholesterolaemia);
- Anxiety, Depression and Stress Management;
- Tuberculosis.

3. Research methods and instruments

3.1 Study design

Descriptive study

3.2 Study sample

The research project is designed to evaluate ten (10) patients with one of the chronic conditions listed above. The patients must be stable on their existing orthodox bio-medical treatment before they are included in the study. Patients will be introduced to the governing factors and assessed over a period of 3-4 months.

3.3. Measurements

Before commencing on the introduction of the governing factors, the following forms must be filled in by each participant in the project:

- Temperamental Evaluation form
- Consent form
- Quality of Life (QoL) patient evaluation questionnaire

- First consultation (current treatment to be listed)
- Follow-up consultation

The number of contacts to be made with the patient, and over what period of time, should be at the discretion of the student as long as meaningful outcomes are achieved.

3.4. Timeframe for the study

The research project will take place over a **4 month** period.

4. Ethics statement

This proposed study will involve the active and willing involvement of all participants. It will be conducted according to accepted ethical practice. This includes:

- 4.1. A discussion with the patient on the value of the study
- 4.2. Informed consent by the patient after reasonable explanation of his or her involvement in the study.
- 4.3. An assurance to the patient of full confidentiality regarding his or her clinical condition and treatment and outcome information. The patient's name will not be included in the project text.
- 4.4. The option to the patient to withdraw from any stage of the study without explanation. All patients will be aware that they are free to discontinue their active involvement in this study, without prejudice.
- 4.5. There will be no physical involvement of the participants that expose them to physical or mental trauma. Clinical action if the patient is traumatised, either physically or emotionally will be detailed.

References

1. Ibn Sina Institute of Tibb. 2003. Diploma in Unani-Tibb (modules 1-11), Johannesburg, South Africa.
2. Jamia Hamdard. 1993. Al-Qanun Fi'l-Tibb. New Delhi.
3. O.C. Gruner. 1929. A Treatise on the Canon of Medicine of Avicenna. London.
4. R.Bhikha & M.A.Haq. 2000. Tibb – Traditional Roots of Medicine in Modern Routes to Health. South Africa.