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Evaluation Report: Pilot Research Project undertaken by Unani-Tibb Diploma Students* on the benefits of incorporating governing (lifestyle) factors into the treatment of patients with HIV and Aids in South African rural and urban clinical settings

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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 HIV and Aids patients, 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 HIV and Aids 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 the CD4 count and the reduction in orthodox medication ("drug sparing") that the intervention allows.

Methodology.

Seven student investigators, under appropriate supervision, treated a total of 72 HIV-positive patients 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, which remained unchanged 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 (CD4 counts; changes in body mass) and changes in signs and symptoms were also measured as the investigators' situation allowed.

Results.

In most of the parameters measured there was a positive improvement reported by the patients. Particularly positive were the gains in important quality of life issues such as sleeping quality, nervousness, perceived efficacy, social activities and personal energy levels. Those parameters in which "no change" were reported tended to be localised in two specific rural centres, perhaps reflecting interpretation problems by the investigators involved. Changes in body mass between the initial visit and the final follow-up varied widely, not only between investigator cohorts, but even within each cohort.

Overall, however, 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 positive trend upwards, suggesting that the governing (lifestyle) factors do have a positive effect on HIV and Aids.

Conclusion.

In spite of the acknowledged shortcomings of this initial study, further investigations in a greater number of patients, 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 HIV-positive patients' quality of life, and so delay the onset of Aids, 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 and hypertension.

The HIV and Aids epidemic in particular adversely affects the country at all levels - personal, familial, social, occupational and demographic. Although anti-retroviral drugs, when used in the proper context, are undoubtedly effective, they are beset by a number of problems, including cost, patient compliance, the development of resistance, and inconsistencies in the distribution chain.

For the South African scenario it may be opportune at the present time to evaluate the possibility of a more holistic approach to the management of people living with HIV and Aids. In effect, could conventional allopathic medical care, which deals mainly with the elimination or subjugation of the human immunodeficiency virus (HIV), be combined with Unani-Tibb, which concentrates on stimulating the patient's immune system and involving him or her to a greater extent in therapy, be a viable way of enhancing the value of treatment? The importance of non-pharmacological interventions, such as food quality, dietary supplementation, and physical exercise are being viewed as useful routes to improving clinical outcome and the quality of life in patients living with HIV and Aids.

This report analyses the overall outcome of applying Unani-Tibb principles to the treatment of HIV/Aids patients 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

The consequences of HIV infection are the most common causes of premature death in many sectors of our community, 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. Since the HIV and Aids pandemic began, total deaths from Aids-related diseases worldwide - such as tuberculosis, pneumonia and overwhelming infections - has reached 20 million. It is estimated that around 61 million people worldwide are HIV-positive at present².

In 2001, 3.4 million more people in Africa became HIV-positive, and 2.3 million people died from Aids linked diseases. 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 positive^{2,4}.

HIV and Aids is now the leading cause of mortality in the region, being responsible for 20% of all deaths⁵. This is twice the number from respiratory disorders, the second leading cause of death in Africa.

2.2. The extent of HIV and Aids in South Africa

In 2005, South Africa had around 5 million HIV-positive people, or 11%, out of the total population of 46 million³. This accounts for 13% of the world's total. †The disease has begun to impact on the life expectancy of our citizenry, which is now about 50 years, but decreasing steadily⁹.

The annual population growth rate is presently 0.8%, but Aids is likely to fall to around 0.4% by 2010. As a measure of the spreading disorder, something like 691,000 people were counselled for Aids in 2003/4, well up from around 413,000 in 2002/3. The increase in the number of "Aids orphans" is worrying, as there are now more than 1 million of these under the age of 18 years existing in South Africa¹⁰.

2.3. The challenge facing South Africa

There is considerable discussion on the role of anti-retroviral therapy in the South African context^{5,6}. Advocates of this treatment say that without it the number of deaths would be around 500,000; with anti-retroviral drugs the figure would be approximately 380,000. However this issue is conditional on the extent of the roll-out of antiretroviral drugs, which leads to projected figures of 290,000 (90% roll-out) or 450,000 (20% roll-out).

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.

The relatively slow roll-out of these drugs, together with major problems of compliance, tolerance and cost has encouraged the search for alternative and additional ways of dealing with people living with HIV and Aids which depend not so much on the elimination of the virus, but on strengthening the immune system of the affected individual, so delaying the onset of full blown Aids, and minimising its impact once it is established.

It is now well-accepted that an holistic approach to HIV infection and Aids management does work, and can offer a valuable partner, or even alternative, to antiretroviral chemotherapy. There is a place for other treatment modalities besides intensive anti-retroviral drug treatment¹².

The HIV and Aids awareness campaign emphasises that HIV infection can be effectively and affordably managed, and years can be added to a person's productive life. Also, voluntary counselling and testing can have a major beneficial influence on people's lifestyle and behaviour. People infected with the HIV can be channelled to wellness management and treatment programmes.

Another important aspect of this study is the potential for cost saving. If the onset of full-blown Aids can be delayed for even one year, this would result in a considerable saving in the direct treatment of the infection with anti-retroviral drugs, plus an indirect saving in the cost of treating the opportunistic infections which inevitably accompany it.

2.4. Alternative approaches to the treatment of HIV and Aids

There are a number of credible additional or alternative treatments for the treatment of people living with HIV and Aids. These vary greatly in accessibility and effectiveness. Although they do not claim to eliminate the HI virus, they can allow a person who is HIV-positive to take charge of his or her condition and have a happier, healthier life. Indeed, the Aids-related illnesses can, in most cases, be successfully managed and treated. Changes to a patient's lifestyle are now emerging as powerful therapeutic options.

Nutritional support. Malnutrition and dietary deficiencies undoubtedly play an important role in the deterioration of the immune system brought about by HI infection, and the ensuing complications such as pneumonia and opportunistic infections. Encouraging the patient to adopt an improved diet can increase the benefit brought about by conventional treatment.¹³

Complementary medicine. Most if not all 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 defense mechanisms⁷. One advantage of this type of treatment is that it can be combined with conventional medicine as integrative medicine.

Immune stimulants. There are a number of these, which to a greater or lesser extent bolster the patient's immune system, so delaying and lessening the impact of both the HIV and the subsequent opportunistic infective agents.

Herbal medication. There are numerous medications available in South Africa. These act to stimulate or boost the immune system, so allowing the person to resist the action of the offending virus, or the opportunistic infections which invariably follow.

Traditional medicine. This is broadly employed in South Africa, although evidence of long-term efficacy is more anecdotal than confirmed in reports.

Physical measures. Exercise, both aerobic and non-aerobic has proven benefits for the Aids patient. Breathing exercises also are particularly valuable.

Counselling. One important aspect of management is a real and pressing need for meaningful and appropriate support of the person living with HIV and Aids. 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.

2.5. Integrative medicine as a viable approach

In this model different systems are brought together in a controlled, organised manner, in order to emphasise health education and actively encourage self-help. In this "hybrid" model, 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 as 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 actions of the immune system, so works in partnership with conventional medicine, which focuses more on the perceived cause, the pathogenic retrovirus.

3. Outline of Unani-Tibb

Description. Unani-Tibb is a comprehensive healing system which has its roots in early Greek, Arabic and Western medicine⁷. 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 ailment⁷. 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 HIV and Aids is aimed at bolstering the patient's innate capacity for self-healing, by supporting the myriad of mechanisms, such as the immune system, which assist 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 to a greater or lesser extent in the diagnosis and subsequent therapy of the presenting ailment.

Temperament.

This concept defines the uniqueness of a person⁷. 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 disease⁷. 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 of diploma students, 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 living with HIV and Aids.

Study design. The research project on HIV and Aids was carried out by seven of the students, 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 investigator, both before introduction of Unani-Tibb lifestyle advice, and immediately afterwards. The clinical parameters (body mass, CD4 counts) were obtained from patients at the initial contact visit, and at two or more follow-ups.

Patient profile. Recruitment was conducted either at Day Clinics or Anti-retroviral Clinics in the area, or at local HIV and Aids counselling sessions. Admission criteria were that patients selected were proven HIV-positive, in a stable condition as a result of therapy with conventional or Unani-Tibb medication, and to be eliciting early symptoms of Aids.

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. Investigator and location details

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

4.3. Governing (lifestyle) factors selected for reinforcement

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 investigators 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 living with Aids 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.

	Diet	Breathing	Exercise	Emotion	Sleeping	Elimination	Other*
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
BM	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

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.

A quality of life study may include the patient's general health, the number and severity of the symptoms arising from their particular ailment, the degree of physical, emotional and cognitive functioning they are experiencing, their sexual behaviour, and their social well-being. Other studies focus on the negative effects of treatment, such as side effects and other toxicities, or place greater emphasis on the impact of treatment on the patient's psychological state, such as anxiety, depression and sleep disturbances.

Selection. The aspects of quality of life that were selected for this particular project were selected according to the profile of patients likely to be encountered, 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 student investigators. The main ones relevant to the project were changes in body mass and CD4 counts. Body mass changes are indicative of the status 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.

4.6. Medication used by patients

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 HIV infection and ensuing Aids. Most patients took a number of anti-retroviral drugs (ARVs) and vitamin supplements, or one or more immune system boosting herbal preparations.

(b) To deal with the co-existing disorders, especially infection. The majority of patients used one or more of a wide range of antibiotics and antifungal agents, especially fluconazole, or anti-microbial herbal preparations.

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

4.7. Analysis of data

The results obtained were recorded onto the appropriate pre-prepared documents by each investigator. The changes in Quality of Life for every patient within each criterion were arrived at by subtracting the final assessment quantum from the initial. They were recorded as: • Great improvement; • Significant improvement; - Noticeable improvement; NC No change; - Noticeable deterioration.

The changes in body mass and in CD4 counts for each patient were recorded at each visit, and presented in tabular form.

Findings

5.1. Quality of life parameters

The summary from each of the investigators is shown below:

Overall changes in the quality of life parameters

Global Quality of Life - -+ (6) : ± (1)

Current health status - -+ (7)

Personal energy level - + (5) : - ± (1) : †- (1)

Emotional or nervous state - -+++ (1) : ++ (1) : + (4) : ± (1)

Sleeping problems - ++ (2) : + (3) : ± (2)

Awareness of benefit - ++ (2) : + (3) : ± (2)

Social intercourse - ++ (2) : + (4) : ± (1)

Occupational competence - ++ (2) : + (4) : ± (1)

Personal satisfaction with treatment - ++ (1) : + (4) : ± (1)

Feeling of self esteem - + (7)

Affordability of Unani-Tibb therapy - ++ (1) : + (4) : ± (1) : - (1)

Value of Unani-Tibb therapy - ++ (1) : + (3) : ± (3)

Confidence about outcome - ++ (2) : + (5)

Understanding of the cause of the disorder - ++ (1) : + (6)

Feeling of control over the disorder - ++ (1) : + (6)

Recommendation to colleagues - + (6) : ± (1)

Key: +++ Great improvement; ++ Significant improvement; + Noticeable improvement; NC No change; - Noticeable deterioration

Unani-Tibb therapy achieved particularly 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 general 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 a more mixed response in a number of linked fields - the perceived value of Unani-Tibb therapy and its affordability. Most of the patients were personally satisfied with Unani-Tibb therapy, partly because it allowed them to continue their occupational activities and social life. At the same time, most of the patients reported improvements in their emotional state, increased energy levels and 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.

.2. Changes in body mass

The changes in body mass recorded for the patients between the first and the final visit are shown in the table below.

Investigator	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	0 to 1.8	-8 to 3	13 to 8	-25 to 18	1 to 9	-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 very wide variation in the changes in body mass recorded between the initial visit and the final follow-up. This variation is apparent both between different investigators, and also within most investigators' patient cohorts. There are several reasons for this variation, including:

- (a) the clinical condition of patients being enrolled varies markedly between the investigators, 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"). In spite of these reservations about the accuracy and relevance of these measurements, however, 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.

5.3. Changes in CD4 counts

As 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. As a result, not many investigators were able to record changes in CD4 counts between the initial visit and the final follow-up. In spite of this constraint, three of the seven investigators were able to record changes in CD4 counts:

Investigator	Patient No.	Improved	< 50 CD4/μl blood	> 50 CD4/μl blood
TQ	10	8	8	0
SO	9	8	2	6
SB	10	6	6	0

Although there is a distinct trend towards an increase in CD4 counts, with 21 of the 29 patients registering a modest, and one a substantial, increase, it is not possible to attribute this entirely to enhancement of 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) and therefore the overall increase in CD4 counts (although not significant) is indicative that the contribution of the governing (lifestyle) factors cannot be lightly dismissed. Clearly, other more strictly controlled and executed studies would be required to truly assess the role of governing (lifestyle) factor enhancement on the CD4 count and perhaps other haematological and metabolic markers.

6. Perceived deficiencies of the project

General. In retrospect there were certain drawbacks to the research projects which preclude more rigorous analysis and definite conclusions. The research was carried out by students who were not fully familiar with the process and requirements for carrying out clinical research. In addition, the design of the research project was too general in respect of the parameters that were required to be measured. This was identified when evaluating these research projects on HIV & Aids, as all of the students did not measure the same parameters such as CD4 count etc. Further research projects need to ensure that detailed protocols of parameters are included as well as appropriate training instruction.

Another drawback to the research project relates to the timescale employed. In retrospect 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.

Also, the study did not include a control group. Future studies should consider the inclusion of historical data of people with HIV and Aids, matched as closely as possible in terms of age, stage of the disease and therapy, who do not undergo enhancement of the governing (lifestyle) factors.

Quality of Life. There is no real previous experience of the investigators 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.

7. General conclusions

This preliminary investigation, in spite of its manifest drawbacks in design and execution, does reveal a consistent and definite trend to improvement in the majority of patients assessed in a number of important quality of life parameters. In addition the admittedly limited data on CD4 counts and changes in body mass suggest that application of the governing (lifestyle) factors has a positive effect.

The overall positive response strongly suggests that further, more extensive and better controlled studies along the same lines should be carried out, especially in the light of the serious management problems confronting our healthcare authorities in dealing with the HIV and Aids epidemic.

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 student investigator 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 recruitment, record keeping and reporting procedures.

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 student investigator.

Also, a record should be made which describes in detail which governing (lifestyle) factors were 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.

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.t

3. Study duration. Wherever possible this should be extended to four, or ideally six, months. This would allow for more confident assessment of any clinical improvement occurring in the patients.

4. 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. The Fundamentals of HIV/AIDS Education. Aids Unique. East London. 2003
3. Mail & Guardian. (Johannesburg). One in nine - it's official. 20 January, 2006. pS10
4. Medical Update (Vitamin Information Centre) (44) 2/2005
5. M & G (Johannesburg). Special issue: World Aids Day. 25/11/05 ñ 1/12/05
6. M & G. (Johannesburg). 2 January p27.
7. Tibb: Traditional Roots of Medicine in Modern Routes to Health. R. Bhikha and Muhammad A Haq. Mountain of Light. (SA). 2000
8. www.thebody.com/asp/mayjun04/exercise
9. www.sairr.org.za/wsc/pstory
10. www.avert.org/aidsorphans.htm
11. www.aids.org.za
12. www.writing.uct.ac.za/ELL319F/Sudents2001/Deborah
13. www.salialia.org.za/modules