Interim Report:

Evaluating the impact of eliminating humoral imbalances with herbal medication

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Period of Study: May 2015 to September 2015.

Date of Report: November 2015 **Compiled by: Prof R. Bhikha and Dr J. P. Glynn**

Purpose of the study

The primary purpose of this pilot study consists of four parts: (a) to assess the benefit of herbal infusions on specific disorders linked to humoral imbalance; (b) to determine whether specific signs and symptoms/clinical features are associated with certain humoral imbalance; (c) to confirm that eliminating excess or abnormal humours underlying the disorder leads to clinical improvement; (d) to determine whether specific humoral imbalances are linked to specific temperaments. The secondary purpose is to detect any positive changes in certain biological parameters following herbal treatment.

Keywords: Herbal medicine – infusions - health & disease - humoral imbalance – temperament - disorders

Introduction

Herbal medicine has traditionally been adopted as a major form of treatment for illness conditions. It is now experiencing a major revival of interest in the light of greater understanding of our body's complex mechanisms and metabolism, in both health and disease. Together with the therapeutic benefits of a sound lifestyle, herbal remedies, or phytotherapy, make up a major form of Tibb treatment. Formulating individualized herbal infusions (or *teas)* as reliable and easy-to-use herbal remedies represent a step forward in the treatment of both acute and chronic disorders. In addition, if these infusions target specific humoral disharmonies linked to specific disorders, then substantial clinical benefit can be expected. This study was devised to test this hypothesis in the real world of South African clinics, in patients suffering from common chronic and recurring disorders.

*(More detailed information on Tibb theory and clinical practice is provided in **Appendix I**).(p6)*

Outline of Tibb medical theory and practice

Tibb (also known as *Unani-Tibb* or *Unani Medicine*) is a traditional healing paradigm, stretching back to the early pioneers Ibn Sina, Galen, and Hippocrates. These pioneers were instrumental in introducing the concepts of the four humours and temperament, which together remain major pillars of Tibb theory and practice. Health and disease reflect harmony or otherwise within these agencies, and healing is directed as restoring balance to the person's internal environment by calling on the power of physis, or our inner administrator and *inter alia*, our promoter of healing . Each

humour is made up of different qualities of heat, coldness, moistness and dryness, one of which is dominant, and the composition is unique for each of us. (*Additional information on humours is provided in **Appendix II**). (p7 to 9)*

Study design

The research protocol was drawn up in May 2015, and revised in July 2015. The researchers were qualified Tibb practitioners, registered with the Allied Health Professions Council of South Africa (AHPCSA). The study was conducted in the Saartjie Baartman and Langa Tibb Clinics, Cape Town.

Patient selection. A total number of 75 patients are being recruited for the study. All patients are administered the herbal infusion plus the eliminative medication: *Laxotab* and *Renotone*. When considered necessary, additional treatment in the form of cupping and/or medication is also prescribed. Twenty eight (28) patients, predominantly female (25 of 28) and aged between 22 and 70 years, were assessed for temperament and humoral imbalance. The purpose and practicalities of the study were explained to each individually, and verbal consent obtained.

Exclusion criteria. Potential candidates who were seriously ill, who were pregnant, or whose temperament could not be evaluated with confidence,

Temperamental selection. Patients falling into the four different dominant temperamental categories (sanguinous, phlegmatic, melancholic and bilious) were identified by random selection. The temperament (both dominant and subdominant) of each patient (sanguinous, phlegmatic, melancholic or bilious) was assessed by the established Tibb procedure.

Clinical condition. Patients were included into the study based upon the presenting signs and symptoms related to specific chronic or recurring clinical disorders with evident links to humoral imbalance or excess.

Study regimen. The herbal infusion, whether used for excess amounts or abnormal forms of the sanguinous, phlegmatic, melancholic or bilious humour, was based on the presenting symptoms and evident signs. Each infusion was directed at specific humours, based on Tibb's traditional experience. Each patient was requested to consume the specially prepared herbal infusion at specified times. The dosage range of ½ to 1 teaspoon, 2 – 3 times a day was determined according to the clinician's continued assessment, intuition and experience. The period of treatment ranged from 3 to 65 days. Patients with dominant *cold* qualities (i.e., those of a phlegmatic or and melancholic disposition) drank the teas while it was hot, whereas the patients with dominant *hot* qualities (i.e., sanguinous and bilious) drank the teas cold. Cupping and/or additional medication was given to patients requiring more assertive treatment according to the practitioner's clinical judgment.

*(The actual compositions of the four herbal concoctions are presented in **Appendix III**.)(p10)*

Elimination therapy. Together with the herbal infusions, *Laxotabs* and *Renotone* are prescribed for each patient, to encourage elimination via the bowel or kidney respectively.

Clinical assessment. Each patient was assessed at every clinical opportunity and consultation, or interview. The patient's blood pressure was measured in one selected patient at each visit. Blood total cholesterol levels were likewise measured at certain intervals.

Motivation. All follow-up treatment was provided at no cost to the patients, and no payment or reward was offered to participate in the study, or on termination.

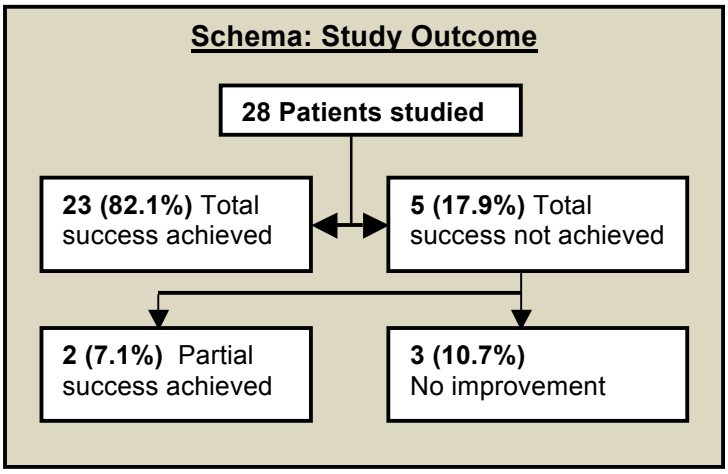
Results

Twenty eight (28) patients provided meaningful data from which relevant information was collectively correlated. *(Individual patient data is available on file, Ibn Sina Institute of Tibb, and available on request).*

Of the 28 patients treated, success was achieved in 23 (82.1%). Fifteen (65.2%) of these patients were only prescribed the herbal infusion and eliminatives, whereas in the balance of 8 (34.8%) patients herbal infusion together with medication and/or cupping was prescribed.

Of the five remaining patients, partial success was achieved in two (40.0%) of the patients, with no improvement in the three remaining patients. Of these partially successfully patients, the 50 year-old female reported some reduction of arthritis-related pain, but her insomnia persisted. In the other 40 year-old female patient, whilst there was some relief with the herbal infusion, additional medication without the herbal infusion was prescribed which successfully treated her condition. As the herbal infusion was stopped on her third consultation, this case study is reported as partially successful.

With respect to the three unsuccessful case studies, the reasons included: a) one patient (35 year-old male), wanted a more aggressive treatment; b) one patient (67 year-old female) was experiencing grieving; and c) no response from one patient (67 year female) due to suspected structural deformity.



Inspection of the signs and symptoms of each patient revealed a close correlation with their dominant temperament, and reflected the illness or disorder for which the patient initially presented. This observation was particularly evident in patients below the age of 40 years. This suggests that most ailments in this cohort of patients are associated with their temperament's dominant quality, whether heat or cold, moistness or dryness. The figures recorded for the link between the patients' signs and symptoms and dominant quality was 16 out of 28 (57.1%), with the remainder (12 out of 28) accounting for 42.8%. With respect to the presenting disorder in the younger section (i.e., 40 years of age or below), this figure rose to nine out of eleven, or 81.8.%, highlighting that most illness conditions in patients before 40 years of age are linked to the dominant quality associated with an individuals temperament. In comparison, in the older section of the patients, that is, in those above 40 years of age, the corresponding figure was 13 out of 17 (76.4%) had imbalance in the melancholic humour/qualities, highlighting that a large percentage of person's over the age of 40 will present with illness conditions linked to melancholic humour.

Regarding the patients' signs and symptoms, and their relationship to their perceived humoral imbalance, virtually every patient (26 out of 28, or 92.8%) had a positive linkage to specific excess or abnormal humours. The outlier patient could well reflect a qualitative imbalance from suspected over-indulgence in hot and spicy foods.

In one specific patient (No.16: A.E.) both blood pressure and total cholesterol were measured, before the study commencement, and after 25 days of herbal treatment and eliminative therapy. Blood pressure fell from 136/80 to 126/80 mm Hg, and total cholesterol from 6.77 to 5.87 mmol/L.

In another patient (No.24: G.) there was a significant reduction in the cholesterol level from 7.03 to 5.19 mmol/L after 33 days, indicative of the possible action on the melancholic infusion on cholesterol levels.
*(Patients' initial data is supplied in **Appendix** IV (p11) and the study's clinical results in **Appendix V**) (p12 to 13)*

Discussion

This pilot study assessed the clinical effect that herbal medicine in the form of aqueous infusion had on the clinical picture, mainly signs and symptoms, in patients at the two Tibb clinics in the Cape Town region. The study was conducted in the cold and wet season, when disorders related to the phlegmatic and melancholic humours are prevalent. The four herbal infusions were prepared from admixtures of a number of common and popular herbs, with each focused on any imbalance in one of the major humours. The study was designed to answer the question: What is the impact of these herbal infusions on the patients' signs and symptoms? Subsequent analysis revealed the strong connection between the patients' signs and symptoms and his or her dominant temperament. It also re-affirmed the link between the patients' clinical disorders and excessive or abnormal humoral imbalance. Some indication of the required duration of treatment by the herbal infusions was also obtained, although this must be more accurately quantified by larger, closer controlled studies in similar patients. Further clinical studies in summertime, when the cold and moist disorders typical of the winter months give way to more hot and dry qualitative imbalances.

Regarding the observed fall in patient's blood pressure and total cholesterol before and after the study - although this is an interesting observation which offers a degree of encouragement, the fall in these biometric parameters is as yet too tenuous to link to one or other part of treatment. The revised protocol applying to the end of study in May 2016 will include assessing the impact of the herbal infusions on blood pressure, and blood glucose and total cholesterol levels in patients presenting these conditions.

Conclusion

This pilot study, even with its undeniable limitations in terms of patient numbers, variable dosage time, range of disorders and limited quantitative data, provides enough data to justify extending the research to May 2016. This will provide additional and valuable data into the inter-relationships between signs and symptoms, humoral imbalances and patient temperament during treatment with herbal infusions.

Protocol revision

In the light of the encouraging clinical results emanating from this interim study, the research protocol is revised as follows:

1. The study is extended to include all seasons, rather than solely the cold winter period.
2. Additional and supplementary data on lifestyle factors practiced by the patients should be collected and recorded, especially in the light of the patients' temperamental status.
3. Additional biometric parameters should be measured, especially blood pressure and laboratory data such as blood cholesterol and glucose levels.

4. To carry out further dose-ranging and duration studies on the herbal infusion, and if necessary cupping and other medication. (*Revised protocol is provided* in ***Appendix VI****). (p14 to 19)*

Further reading

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Appendices

Appendix I: The Tibb medical philosophy

Appendix II: Humours, health and disease

Appendix III: Tibb herbal concoctions

Appendix IV: Participating patients / details

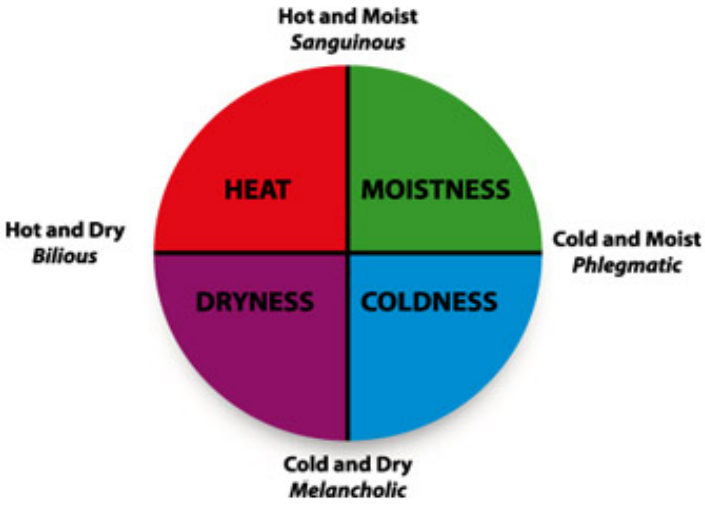
Appendix V: Clinical results

Appendix VI: Research protocol

Appendix I: The Tibb medical philosophy

Tibb philosophy is based on the temperamental and humoral theory. In order to maintain health each individual has their own unique humoral composition in relation to their unique temperamental combination. Associated with each of the humours are qualities of heat, coldness, moistness and dryness which results in every person having a unique humoral composition with an ideal combination of qualities with one quality being dominant. For example an individual with a sanguinous/phlegmatic temperament will have a dominant quality of moistness (see chart). Changes to this unique humoral composition, occurs from the influence of the Tibb lifestyle factors which include food and drink, environmental air and breathing, exercise and rest, sleep, emotions and eliminations of toxins – with the greatest influence being from food and drink. This change to the humoral composition will most likely occur from excess or abnormal states of their dominant humour. However, humoral changes can also occur from an increase into other humours. This change to the ideal humoral balance leads to pathological processes resulting in illness conditions.

Changes to this ideal humoral composition occurs from the qualitative effect of Lifestyle Factors which physis (the body's inherent wisdom) endeavours to restore homeostasis. Changes beyond the ability of physis to restore homeostasis results in pathological processes leading to signs and symptoms, associated with various illness conditions/systems of the body – all resulting from an excess/abnormal states of a particular humour.



Appendix II: Humours, health and disease

The following descriptions summarize the basic information on the four humours.

A. Sanguinous humour

- The sanguinous humour is produced mostly from Hot & Moist foods, the excess of which will result in an overabundance of the sanguinous humour.
- People with a sanguinous dominant/sub-dominant temperament are predisposed to illness conditions resulting from an excess of the sanguinous humour.
- Accumulation sites for sanguinous humour: heart, arteries, blood vessels, small capillaries, tissues and organs: liver and portal system, spleen and pancreas, the veins, uterus, kidneys, the skin, digestive system, respiratory and genitourinary mucosa.

Signs and symptoms:

- Nosebleeds, gingivitis, high blood pressure.
- Flushed complexion, angiomas, eczema, spider naevi.
- Fullness and heaviness of the body, behind the eyes, drowsy, sleepy , weak, heavy limbs.
- Sluggish, congested liver.
- Urinary tract infection, thick yellow urine.

B. Phlegmatic humour

- The phlegmatic humour is produced mostly from Cold & Moist foods, the excess of which will result in an overabundance of the Phlegmatic humour.
- People with Phlegmatic dominant/sub-dominant temperament are predisposed to illness conditions resulting from an excess of the Phlegmatic humour.
- Accumulation sites: stomach, upper respiratory tract. From the stomach the phlegmatic humour finds its way via the gastro pulmonary reflex, into the chest, lungs, throat, nose and sinuses. It presents as congestion making the head and brain feel stuffy. Phlegm congestion in the lungs and chest will cause congestion and stagnation in the lymphatic system. Excess Phlegmatic humour can affect any part of the body.

Signs and symptoms:

- Heaviness, lethargy, sleepiness, mental dullness, swollen, puffy eyelids, moistness, frontal headaches.
- Runny nose, congested nose, nasal discharges, post nasal drip, sinus congestion, productive cough (clear/ white), colds, flu, lung congestion, thick tongue, pale lips.
- Indigestion, weak digestion, sluggishness and drowsy ness after meals.
- Skin pale, white complexion, cold, clammy skin, weeping, oozing skin conditions, poor muscle tone.
- Swollen, tender glands; cellulite; congestion of lymph.
- Pale thick urine, leucorrhea, and amenorrhoea.
- Slow , deep , soft pulse.

C. Bilious humour

- The bilious humour is produced mostly from Hot & Dry foods, the excess of which will result in an overabundance of the Bilious humour.
- People with Bilious dominant/sub-dominant temperament are predisposed to illness conditions resulting from an excess of the Bilious humour.
- Accumulation site is the gall bladder from where it spills into the intestine in fat metabolism. The hot & dry qualities of the bilious humour results in the signs and symptoms below.

Signs and symptoms:

- Anger, impatient, irritability, forceful, agitated, stress, insomnia, restless.
- Migraines, unilateral headache, sore, red bloodshot eyes, itchy, jaundice (yellow), nosebleeds, dryness.
- Oral ulcerations, inflamed, yellow coat on tongue, bitter taste in the mouth, excessive thirst.
- Jaundice, fatty liver, hepatitis, hepatomegaly, gallstones, cholecystitis, constipation.
- Intolerant to greasy, fatty, fried foods. Stomach hyperacidity, acid reflux, gastric/duodenal ulcers, nausea, vomiting yellow/green bile, burning stools.
- Red sensitive skin, hives, rashes, yellow/ jaundiced.
- Inflammatory conditions.
- Burning urine, dark colour, rusty.
- Full rapid bounding pulse.

D. Melancholic Humour

- The melancholic humour is produced mostly from Cold & Dry foods, the excess of which will result in an overabundance of the Melancholic humour.
- People with Melancholic dominant/sub-dominant temperament are predisposed to illness conditions resulting from an excess of the Melancholic humour.
- Accumulation sites: builds up in the spleen and from there it spills over into the stomach and / or large intestine causing digestive complaints such as indigestion, flatulence, distention, bloating, colic and constipation. From the digestive tract it moves to other tissues and organs in the body.
- From the stomach, duodenum and small intestine, melancholic humour congests the gallbladder and hepatic portal system, and the liver moving into the chest, throat and upper stomach areas.
- From the colon, melancholic humour penetrates into the bones and joints of the sacrum, lower back and pelvic girdle, bringing degenerative arthritic changes to areas before affecting the entire or other areas of the musculoskeletal system.

Signs and symptoms:

- Nervousness, anxiety, moodiness, lonely, alienated, cynical, fearful.
- Spaciness, vertigo, light headedness, nervous exhaustion, insomnia, tinnitus.
- Constricted breathing, pain ,fullness.
- Hepatomegaly and splenomegaly, portal congestion.
- Irregular, nervous eating and food cravings, anorexia, poor appetite, stomach discomfort, flatulence, colic, intestinal obstruction, bloating, constipation.
- Poor blood circulation, cold hands and feet, clot forming, emboli, dark thick blood.
- Cold, dry rough skin, dark, cracked skin.

- Arthritis, rheumatism, neuromuscular complaints, stiffness, aching, sciatica, numbness in extremities, tremors, tics, cramps, spasms.
- Nervous sexual dysfunction.
- Irregular menses, dysmenorrhoea with painful spasms, food cravings, clotting thick flow, scanty, insufficient lactation.
- Thin clear urine.
- Weak pulse.

Appendix III: Tibb herbal infusions

The herbs listed were dried in controlled conditions, formulated into infusions, and supervised in their clinical use by members of the Tibb Institute.

.Concoctive for Sanguinous Humour	Concoctive for Bilious Humour
10g. Marshmallow (*Althea officinalis*)	10g. Chicory (*Cichorium intybus*)
10g. Burdock (*Artium lappa*)	10g. Fennel (*Foeniculum vulgare*)
10g. Bearberry (*Arctostaphylos uva- ursi*)	10g. Milk Thistle (*Silybum marianum*)
5g. Rooibos (*Aspalathus linearis*)	5g. Barberry (*Berberis vulgaris*)
5g. Borage (*Borago officinalis*)	5g. Wild mint (*Mentha Arvensis*)
5g. Chinese tea (*Camellia sinensis*)	5g. Himalayan rhubarb (*Rheumemodi*)
5g. Hawthorn *(Crataegus oxycantha*)	

Concoctive for Melancholic Humour	Concoctive for Phlegmatic Humour
15g. Yarrow (*Achillea millefolium*)	15g. Lavender (*Lavandula officinalis*)
15g. Agrimony (*Agrimonia eupatoria*)	15g. Basil (*Ocimum basilicum*)
10g. Dill seed (*Apium graveolens*)	15g. Fenugreek (*Trigonella foenum-graecum*)
10g. Barberry (*Berberis Vulgaris*)	5g. Caraway (*Carum Carvi*)
10g. Liquorice (*Glycyrrhiza glabra*)	5g. Cinnamon (*Cinnamomum cassia*)
5g. Senna (*Cassia angustifolia*)	5g. Ginger (*Zingiber officinale*)

Appendix IV: Patient details

No	Practitioner	Pat. initials	Gender/Age	Temperament	Imbalance
1	Y Abrahams	F.J.	Female 29 yrs	Sang. / Phleg.	Phlegmatic
2	B Mukarwego	M.D.	Male 58 yrs	Sang. / Phleg.	Bilious
3	Y Abrahams	R.B.	Female 28 yrs	Mel. / Phleg.	Melancholic
4	Y Abrahams	A.	Female 33 yrs	Phleg. / Sang.	Phlegmatic
5	R Salasa	R.A.	Female 65 yrs	Sang. / Phleg.	Phlegmatic
6	M Slarmie	S.C.	Female 66 yrs	Sang. / Phleg.	Melancholic
7	M Slarmie	A.A.	Female 57 yrs	Sang. / Phleg.	Phlegmatic
8	A Allie	A.X.	Female 44 yrs	Sang. / Phleg.	Melancholic
9	Y Abrahams	T.	Female 52 yrs	Sang. / Phleg.	Melancholic
10	J Suteka	F.	Female 60 yrs	Sang. / Bil.	Phlegmatic
11	F Osman	Z.P.	Female 36 yrs	Phleg. / Sang.	Phlegmatic
12	A Allie	X.	Female 36 yrs	Bil. / Sang.	Bilious
13	B Mukarwego	F.	Female 58 yrs	Sang. / Bil.	Bilious / Melancholic
14	F Osman	B.D.	Male 58 yrs	Sang. / Bil.	Bilious
15	R Hassen	S.C.	Female 70 yrs	Sang. / Phleg.	Melancholic
16	Y Abrahams	A.E.	Female 64 yrs	Mel. / Phleg.	Melancholic
17	B Mukarwego	G.P.	Female 37 yrs	Phleg. / Mel.	Phlegmatic
18	Y Abrahams	E.N.	Female 70 yrs	Phleg. / Mel.	Melancholic
19	F Osman	M.V.	Female 40 yrs	Sang. / Bil.	Melancholic
20	B Mukarwego	V.	Female 55 yrs	Sang. / Phleg.	Melancholic
21	B Mukarwego	D.	Female 22 yrs	Mel. / Bil.	Melancholic
22	A Allie	M.L.	Female 44 yrs	Sang. / Phleg.	Melancholic
23	B Mukarwego	H.T.	Female 35 yrs	Phleg. / Sang.	Phlegmatic
24	Y Abrahams	G.	Female 50 yrs	Sang. / Phleg.	Melancholic
25	A Allie	C.M.	Female 40 yrs	Bil. / Sang.	Bilious
26	R Salasa	L.N.	Male 35 yrs	Sang. / Phleg.	Melancholic
27	Y Abrahams	F.S.	Female 67 yrs	Sang. / Phleg.	Melancholic
28	B Mukarwego	W.D.	Female 67 yrs	Phleg. / Sang.	Melancholic

Code: Sang. = Sanguinous Phleg. = Phlegmatic Mel. = Melancholic Bil. = Bilious

Appendix V: Clinical results

No.	Patient initials	Treatment duration	Infusion & eliminative	Additional therapy	S & S / dominant temperament	S & S / humoral imbalance
1	F.J.	14 days	Yes	-	Yes	Yes
2	M.D.	6 days	Yes	-	No	No
3	R.B.	9 days	Yes	-	Yes	Yes
4	A.	3 days	Yes	-	Yes	Yes
5	R.A.	34 days	No	Meds	Yes	Yes
6	S.C.	65 days	No	Cupping + meds	No	Yes
7	A.A.	13 days	Yes	-	Yes	Yes
8	A.X.	18 days	Yes	-	No	Yes
9	T.	7 days	No	Cupping	No	Yes
10	F.	7 days	Yes	-	Yes	Yes
11	Z.P.	7 days	Yes	-	Yes	Yes
12	X.	11 days	No	Cupping + meds	Yes	Yes
13	F.	16 days	No	Cupping + meds	Yes	Yes
14	B.D.	8 days	No	Cupping	Yes	Yes
15	S.C.	12 days	Yes	-	No	Yes
16	A.E.	35 days	Yes	-	Yes	Yes
17	G.P.	6 days	Yes	-	Yes	Yes
18	E.N.	14 days	No	Cupping	Yes	Yes
19	M.V.	9 days	No	Cupping	No	Yes
20	V.	9 days	Yes	-	No	Yes
21	D.	7 days	Yes	-	Yes	Yes
22	M.L.	20 days	Yes	-	No	Yes
23	H.T.	10 days	Yes	-	Yes	Yes
24	G.	33 days	No	Cupping	No	Yes
25	C.M.	11 days	No	Meds	Yes	Yes
26	L.N.	6 days	No	Cupping	No	No
27	F.S.	8 days	No	Cupping	No	Yes
28	W.D.	9 days	No	Meds	No	Yes

Summary:

Patient No's. 1 to 23: Treatment was successful.

Patient No's. 24 and 25: Treatment was partially successful.

Patient No's. 26 to 28: Treatment was unsuccessful.

Appendix VI: Revised Research Protocol

Evaluating the impact of eliminating humoral imbalances with herbal treatment

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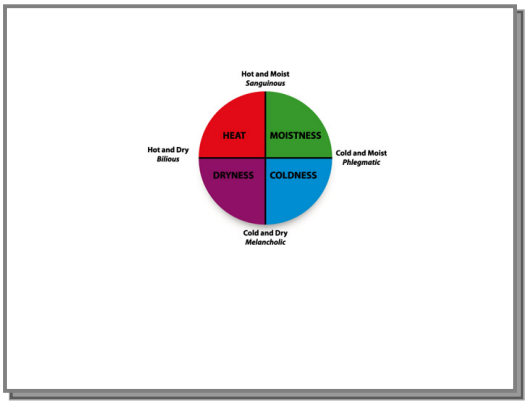
1. INTRODUCTION



The Ibn Sina Institute of Tibb intends conducting clinical research at the Tibb Medical Centre (Saartjie Baartman Centre) and the Tibb Medical Centre (Langa Clinic) in Cape Town during 2015. The researchers will be qualified Tibb Practitioners registered with the Allied Health Professions Council of South Africa (AHPCSA).

Tibb philosophy is based on the temperamental and humoral theory. In order to maintain health each individual has their own unique humoral composition in relation to their unique temperamental combination. Associated with each of the humours are qualities of heat, coldness, moistness and dryness which results in every person having a unique humoural composition with an ideal combination of qualities with one quality being dominant. For example an individual with a sanguinous/phlegmatic temperament will have a dominant quality of moistness (see chart). Changes to this unique humoural composition, occurs from the influence of the Tibb lifestyle factors which include food and drink, environmental air and breathing, exercise and rest, sleep, emotions and eliminations of toxins – with the greatest influence being from food and drink. This change to the humoural composition will most likely occur from excess or abnormal states of their dominant humour. However, humoural changes can also

occur from an increase into other humours. This change to the ideal humoural balance leads to pathological processes resulting in illness conditions.

Changes to this ideal humoral composition occurs from the qualitative effect of Lifestyle Factors which physis (the body's inherent wisdom) endeavors to restore homeostasis. Changes beyond the ability of physis to restore homeostasis results in pathological processes leading to signs and symptoms, associated with various illness conditions/systems of the body – all resulting from an excess/abnormal states of a particular humour.

The aim of the research is to assess the impact of eliminating the excess/abnormal humours associated with the different signs and symptoms/illness conditions. Listed below is a summary of the four different humours, the signs and symptoms associated with excess of each humour.

1.1 Sanguinous humour

- The sanguinous humour is produced mostly from Hot & Moist foods, the excess of which will result in an overabundance of the Sanguinous humour.
- People with Sanguinous dominant/sub-dominant temperament are predisposed to illness conditions resulting from an excess of the Sanguinous humour.
- Accumulation sites for sanguinous humour: heart, arteries, blood vessels, small capillaries, tissues and organs: liver and portal system, spleen and pancreas, the veins, uterus, kidneys, the skin, digestive system, respiratory and genitourinary mucosa.

1.1.1 Signs and symptoms:

- Nosebleeds, gingivitis, high blood pressure
- Flushed complexion, angiomas, eczema, spider neavi
- Fullness and heaviness of the body, behind the eyes, drowsy, sleepy, weak, heavy limbs.
- Sluggish, congested liver.
- Uti, thick yellow urine.

1.2 Phlegmatic humour

- The phlegmatic humour is produced mostly from Cold & Moist foods, the excess of which will result in an overabundance of the Phlegmatic humour.
- People with Phlegmatic dominant/sub-dominant temperament are predisposed to illness conditions resulting from an excess of the Phlegmatic humour.
- Accumulation sites: stomach, upper respiratory tract. From the stomach the phlegmatic humour finds its way via the gastro pulmonary reflex, into the chest, lungs, throat, nose and sinuses. It presents as congestion making the head and brain feel stuffy. Phlegm congestion in the lungs and chest will cause congestion and stagnation in the lymphatic system. Excess Phlegmatic humour can affect any part of the body.

1.2.1 Signs and symptoms:

- Heaviness, lethargy, sleepiness, mental dullness, swollen, puffy eyelids, moistness, frontal headaches.
- Runny nose, congested nose, nasal discharges, post nasal drip, sinus congestion, productive cough (clear/white), colds, flu, lung congestion, thick tongue, pale lips.
- Indigestion, weak digestion, sluggishness and drowsy ness after meals.
- Skin pale, white complexion, cold, clammy skin, weeping, oozing skin conditions, poor muscle tone.
- Swollen, tender glands, cellulite, congestion of lymph.
- Pale thick urine, leucorrhea, and amenorrhoea.
- Slow, deep, soft pulse.

1.3 Bilous humour

- The bilious humour is produced mostly from Hot & Dry foods, the excess of which will result in an overabundance of the Bilious humour.
- People with Bilious dominant/sub-dominant temperament are predisposed to illness conditions resulting from an excess of the Bilious humour.

- Accumulation site is the gall bladder from where it spills into the intestine in fat metabolism. The Hot & Dry qualities of the bilious humour results in the signs and symptoms below.

1.3.1 Signs and symptoms:

- Anger, impatient, irritability, forceful, agitated, stress, insomnia, restless.
- Migraines, unilateral headache, sore, red bloodshot eyes, itchy, jaundice (yellow), nosebleeds, dryness.
- Oral ulcerations, inflamed, yellow coat on tongue, bitter taste in the mouth, excessive thirst.
- Jaundice, fatty liver, hepatitis, hepatomegaly, gallstones, cholecystitis, constipation.
- Intolerant to greasy, fatty, fried foods. Stomach hyperacidity, acid reflux, gastric/duodenal ulcers, nausea, vomiting yellow/green bile, burning stools.
- Red sensitive skin, hives, rashes, yellow/jaundiced.
- Inflammatory conditions.
- Burning urine, dark colour, rusty.
- Full rapid bounding pulse.

1.4 Melancholic Humour

- The melancholic humour is produced mostly from Cold & Dry foods, the excess of which will result in an overabundance of the Melancholic humour.
- People with Melancholic dominant/sub-dominant temperament are predisposed to illness conditions resulting from an excess of the Melancholic humour.
- Accumulation sites: builds up in the spleen and from there it spills over into the stomach and/or large intestine causing digestive complaints such as indigestion, flatulence, distension, bloating, colic and constipation. From the digestive tract it moves to other tissues and organs in the body.
- From the stomach, duodenum and small intestine, melancholic humour congests the gallbladder and hepatic portal system, and the liver moving into the chest, throat and upper stomach areas.
- From the colon, melancholic humour penetrates into the bones and joints of the sacrum, lower back and pelvic girdle, bringing degenerative arthritic changes to areas before affecting the entire or other areas of the musculoskeletal system.

1.4.1 Signs and symptoms:

- Nervousness, anxiety, moodiness, lonely, alienated, cynical, fearful.
- Spaciness, vertigo, light headedness, nervous exhaustion, insomnia, tinnitus.
- Constricted breathing, pain, fullness.
- Hepatomegaly and splenomegaly, portal congestion.
- Irregular, nervous eating and food cravings, anorexia, poor appetite, stomach discomfort, flatulence, colic, intestinal obstruction, bloating, constipation.
- Poor blood circulation, cold hands and feet, clot forming, emboli, dark thick blood.
- Cold, dry rough skin, dark, cracked skin.
- Arthritis, rheumatism, neuromuscular complaints, stiffness, aching, sciatica, numbness in extremities, tremors, tics, cramps, spasms
- Nervous sexual dysfunction.
- Irregular menses, dysmenorrhoea with painful spasms, food cravings, clotting thick flow, scanty, insufficient lactation.
- Thin clear urine.
- Weak pulse.

2. HYPOTHESIS

Restoring homeostasis by eliminating the excess/abnormal humours will assist physis in reversing the pathological processes, at a cellular/sub-cellular level and in doing so will not only address the signs and symptoms, but also the cause/s of the various signs and symptoms/illness conditions – assisting physis in restoring homeostasis.

3. AIM OF THE RESEARCH

The aim of the research is to assess the impact of eliminating excess/abnormal humoural imbalances with herbal infusions.

4. SIGNIFICANCE OF THE STUDY

Targeting the elimination of excess/abnormal humours responsible for the pathological processes will assist physis in addressing the signs and symptoms of the illness conditions. This approach is in keeping with the Tibb philosophy of the maintenance/restoration of health where therapeutic intervention is aimed at addressing the causes and not the symptoms. The success of this study will be beneficial to Tibb Practitioners in treatment protocols that restore homeostasis by eliminating excess/abnormal humours which will most likely address signs and symptoms across various systems of the body associated with the excess/abnormal humour. This approach should improve the recovery time, and also have an impact on reducing treatment cost, with an improved quality of life.

5. RESEARCH OBJECTIVES

- Assess whether the presenting signs and symptoms/illness conditions is indicative of the excess humour in the patient;
- Assess whether the presenting signs and symptoms/illness conditions, corroborates with the dominant quality/ies of the dominant/sub-dominant temperament of the patient;
- Assess the value of herbal infusions in addressing/relieving the presenting signs and symptoms/illness conditions associated with the excess/abnormal humour;
- Assess whether the treatment with herbal infusion will have an impact in patients who are hypertensive, diabetics and those with high cholesterol; and
- To establish the duration, dosage of the different herbal infusions, in the treatment of the illness conditions associated with the different excess/abnormal humours.

6. RESEARCH QUESTIONS

- Are the presenting signs and symptoms/illness conditions indicative of an excess humour in the patient?
- Does the presenting signs and symptoms/illness conditions corroborate with the dominant quality/ies of the dominant/sub-dominant temperament of the patient?
- What is the impact of prescribing herbal infusions in addressing/relieving the presenting signs and symptoms/illness conditions associated with the excess/abnormal humour?
- What is the impact of the herbal infusion in patients who are hypertensive, diabetics and those with high cholesterol; and
- What is the duration, dosage of the different herbal infusions in the treatment of the illness conditions associated with the different excess/abnormal humours?

Note: The case study report must include a response on all of the above research questions.

7. RESEARCH METHODOLOGY

Clinical trial research will be conducted by trained and registered Tibb Practitioners within the Tibb Medical Centres on patients that are attending the Tibb clinics for consultations and their progress will be monitored over a period of twelve (12) months.

Most illness conditions, especially chronic conditions should manifest itself in individuals having similar qualities to the dominant/sub-dominant quality associated with the temperamental combinations – especially at the initial stages. Treatment in these patients will target the excess/abnormal humour and quality/ies, associated with the illness condition and/or the temperamental combination.

In patients with long standing chronic conditions that have deteriorated (i.e. rheumatoid arthritis that has deteriorated from the initial inflammation [Hot & Moist] to the nodular [Cold & Dry] stage), the appropriate excess/abnormal humour/quality will have to be identified and targeted.

The treatment protocol is based on the prescribing of herbal infusions aimed at the excess/abnormal humour.

7.1 Sampling

Random sampling will be used to identify patients that fall in the four different categories based on temperament, namely Sanguinous, Bilious, Melancholic and Phlegmatic. Random selection needs to ensure that patient's temperament is accurately evaluated, the clinical consultation, presenting signs and symptoms, and the humoral imbalance (excess/abnormal) is effectively identified.

7.2 Sample Size

A total number of 75 patients will be included in the study, with every patient being prescribed with the appropriate infusion and eliminatives (Laxotabs and Rentone). At the discretion of the practitioner additional medication and/or cupping can be included in the treatment protocol.

7.3 Exclusion Criteria

Certain patients will be excluded based on certain criteria, for example:

- Pregnant patients;
- Patients where clear temperament evaluations are impossible;
- Patient who are seriously ill as they should not be compromised.

7.5 Verification

In conditions where baseline blood samples are necessary, samples will be sent to Pathcare for blood testing on commencement of the research and again on completion of the research for scientific verification of the results.

8. PROTOCOLS TO BE USED

8.1 Protocol Sequence

- Recruiting patients into the study – this is done as per the inclusion criteria which requires a successful identification of the dominant/sub-dominant temperament of the patient. Once this is done, the patient can be informed of the research and enquire as to whether they would like to participate. Also informing them that they will not be charged for the follow up consultation/s – during the research.
- After complete history taking and having identified the excess/abnormal humour, quality/ies associated with the signs and symptoms/illness conditions the appropriate protocol will be prescribed – herbal infusion, Laxotabs, Renotone and if necessary additional medication and/or cupping.
- Lifestyle Factors needs to be evaluated so as to determine the possible cause/s of the imbalance humours/qualities.
- The period/duration of the signs and symptoms also needs to be recorded.
- After 3-5 days, the patient will be assessed – noting all the signs and symptoms and evaluating whether progress has been made or not.
- Patient must be re-evaluated after 3-7 days and if necessary a fourth/fifth visit 3-7days later.
- The research should be concluded after the fifth visit. However the research can be continued after consultation with the research supervisor.

8.2 Herbal Infusion

The herbal infusions to be used are the following:

Concoctive for Sanguinous humour	Concoctive for Bilious Humour	Concoctive for Melancholic Humour	Concoctive for Phlegmatic Humour
10g Althea officinalis 10g Artica lappa 10g Arctostaphylos uva- ursi 5g Aspalathus linearis 5g Borago officinalis 5g Camellia sinensis 5g Crataegus oxycantha	10g Cichorium intybus (Chicory) 10g Foeniculum vulgare (Fennel) 10g Silybum marianum (Milk Thistle) 5g Berberis vulgaris (Barberry) 5g Mentha Arvensis (Wild mint) 5g Rheumemodi (Himalayan rhubarb)	15g Achillea millefolium (Yarrow) 15g Agrimonia eupatoria (Agrimony) 10g Apium graveolens (Dill seed) 10g Berberis Vulgaris (Barberry) 10g Glycyrrhiza glabra (Liquorice) 5g Cassia angustifolia (Senna)	15g Lavandula officinalis (Lavender) 15g Ocimum basilicum (Basil) 15g Trigonella foenum-graecum (Fenugreek) 5g Carum Carvi (Caraway) 5g Cinnamomum cassia (Cinnamon) 5g Zingiber officinale (Ginger)

The infusions will be given in dosages of ½ to 1 teaspoon depending on the practitioner's clinical findings.

Melancholics and Phlegmatics patients will allow the tea to simmer for 15 minutes and then drink it.

Sanguinous and Bilious patients will allow the infusion to cool after boiling and then drink.

9.3 Patient Needs

Any patient needing a more aggressive treatment approach, depending on the practitioner's clinical findings, will be given extra herbal medication.

10. ETHICHAL CONSIDERATIONS

For this research to be conducted ethically, certain ethical considerations will be put in place, namely:

- Ensuring all participants have given informed consent to participate in the research – with the understanding that they can be excluded from the research at any time upon their request;
- Ensuring no harm comes to the patient by putting the patient health and wellbeing above the research being conducted, always ensuring that any treatment will be in the best interest of the patient;
- Ensuring only qualified and legally registered practitioners conduct the research; and
- Ensuring anonymity and confidentiality to the patients.

11. CONCLUSION

The research will commence on 10 May 2015 - end March 2016.

Date of preparation: 4th May 2015

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