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The effect of a lifestyle modification adherence tool on risk factors in patients with chronic hypertension compared to usual management

Webber, Janine

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Appendix A

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Webber

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M080521**
PROJECT	The effect of a lifestyle modification adherence tool on risk factor reduction in patients with hypertension
INVESTIGATORS	Mrs J Webber
DEPARTMENT	Physiotherapy
DATE CONSIDERED	08.05.30
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 08.07.03 **CHAIRPERSON** .....
(Professor P E Cleaton Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Prof A Stewart

DECLARATION OF INVESTIGATOR(S) Janine Webber

To be completed in duplicate and ONE COPY returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Information Sheet

Dear Sir / Madam,

Hello! My name is Janine Webber and I am doing a study on adherence to lifestyle changes and treatment in patients with high blood pressure. Research is the process of testing, comparing and analyzing information (new and old) to learn the answer to a question. In this study we want to learn whether a specific diary will help you with high blood pressure to stick to their programmes and in turn lower blood pressure. The study may help to improve adherence to lifestyle programmes in turn lowering blood pressure and helping you get better.

I am asking you to take part in a research study. The study is an experiment and will take place for a period of nine months. This means that there will be three groups in the study – one group will get the usual treatment in the clinic (control group), one group will get a diary and a once a month telephone call as well as the usual treatment in the clinic (experimental group 1) and the third group will get the once a month telephone call only and the usual treatment in the clinic (experimental group 2). The 'usual treatment' consists of a check-up with the doctor, assessment from the dietician, an educational talk and 20min exercise class with the physiotherapists (each time you come to the doctor at the hypertension clinic) and receiving your medication.

If you decide to take part in the study, your blood pressure, waist and hip measurements, weight and height, exercise capacity, heart rate and glucose level will be taken at the beginning, at six months and at the end of the study (nine months). This will not take longer than 30 minutes each time. A pin prick on your finger will be needed to get a drop of blood for the glucose test and will be done three times during the study at the beginning, six months and nine months. The exercise capacity test will involve a six minute walking test where you will walk between the beacons (20m apart) for 6 minutes as fast as you can. If you get tired you will be allowed to stop.

A questionnaire will also be filled in at the beginning of the study and this will take 15 minutes to fill out. It will include questions concerning age, education as well as health and exercise questions.

After the measurements are taken in the beginning, you will be randomized to one of the three groups. Randomizing means you will be allocated to a group by chance without being purposefully placed in a group. If you are in the control group, you will be expected to attend the clinic as you normally do and you will receive 'usual treatment'. If you are in experiment group 1, you will receive 'usual treatment' as well as a diary that you will take home with you and use for the nine months of the study. If you are in experimental group 2, you will receive the 'usual treatment' as well as a once a month phone call for a period of nine months.

The study will take place in the Hypertension Clinic at Helen Joseph Hospital and you will not be expected to travel anywhere else for the study.

The benefit of taking part in the study is that you will have the opportunity to be part of an intervention that may be helpful in lowering blood pressure. You will be given information on the study while involved in the project and after the results are available.

Your participation is voluntary and refusal to participate in the study does not mean that your treatment at the clinic will be changed in any way.
Your personal information will be kept confidential but absolute confidentiality cannot be guaranteed. Personal information may be disclosed if required by law. Certain organizations may inspect and/or copy your research records for quality assurance and data analysis such as the Research Ethics Committee and the Medicines Control Council.

You may contact us for further information or to report any adverse events in connection with the study.

Contact details are as follows:

Janine Webber (Researcher)	(011) 489 0334/5/6	084 567 8020

If you have any complaints or problems please contact:

Professor Peter Cleaton-Jones (Chair of Ethics Committee)	(011) 717 2301

Consent Form

I, _____ (the subject) consent to participate in the study explained above. All my questions have been answered and I understand I am free to leave the study and my treatment will not be changed.

_____	_____	_____
Subject	Researcher Janine Webber	Witness

Month: Date: Monday Month: Date: Tuesday

	Activity Done ✓		Activity Done ✓
Exercise for the day:		**Exercise for the day:**	
♥ Take a 10 - 15 minute walk or		♥ Take a 10 -15 minute walk or	
♥ Do the exercises on page 3		♥ Do garden work / clean your house	
Food topic for the week: Enjoy a variety of foods		**Food topic for the week:** Enjoy a variety of foods	
♥ Eat more than one type of food		♥ Eat a different vegetable every day	
♥ Your supper should have meat, starch and a vegetable		♥ To get all your vitamins and nutrients, eat different foods	
Don't forget to take your medicine!		Don't forget to take your medicine!	
Tips for the day:		**Tips for the day:**	
♥ Another word for high blood pressure is hypertension		♥ Every part of your body needs blood (e.g. your brain, heart, kidneys and muscles too)	
♥ High blood pressure is dangerous if it is not treated		♥ Blood takes oxygen and food to all parts of the body	
♥ You can feel well and still have high blood pressure		♥ Your heart pumps the blood in tubes called blood vessels	
♥ You cannot tell if someone has high blood pressure by looking at the person		♥ Your heart pushes blood through these blood vessels with a pressure – this is called blood pressure	

Month: Date: Monday	Activity Done ✓	Month: Date: Tuesday	Activity Done ✓
Exercise for the day:		**Exercise for the day:**	
♥ Take a 20 – 30 minute walk or		♥ Take a 20 – 30 minute walk or	
♥ Do the exercises on page 3		♥ Do garden work / clean your house	
Food topic for the week: Eat dry beans, lentils and soya		**Food topic for the week:** Eat dry beans, lentils and soya	
♥ Beans, lentils and soya can replace meat		♥ Add lentils to your rice to help the stomach break down the food	
♥ Make a stew consisting of kidney beans and chunky vegetables with samp		♥ Legumes can cause bloating, begin eating them once a week first	
Don't forget to take your medicine!		Don't forget to take your medicine!	
Tips for the day:		**Tips for the day:**	

REMINDER: YOU WILL GET A PHONECALL TODAY FROM THE PHYSIOTHERAPIST!!!

♥ Every part of your body needs blood (e.g. your brain, heart, kidneys and muscles too)

♥ Blood takes oxygen and food to all parts of the body- Your heart pumps the blood in tubes called blood vessels

♥ Your heart pushes blood through these blood vessels with a pressure – this is called blood pressure

Month:	Date:	Thursday	Month:	Date:	Friday
	Activity Done ✓			Activity Done ✓	
Exercise for the day:			**Exercise for the day:**		
♥Take a 20 – 30 minute walk or			♥Take a 20 – 30 minute walk or		
♥Do the exercises on page 3			♥Do garden work / clean your house		
Food topic for the week: Use salt sparingly			**Food topic for the week:** Use salt sparingly		
♥Avoid salty snacks like crisps, salty biscuits and biltong			♥Do not add salt after cooking. Remove the salt shaker from the table		
♥Rather snack on a fruit, popcorn, dried fruit or nuts			♥Foods like sausages, salami, ham and KFC are high in salt		
Don't forget to take your medicine!			Don't forget to take your medicine!		
Tips for the day:			**Tips for the day:**		
♥There are some things that can give you high blood pressure. They are called risk factors.			♥Diabetes is also known as having 'sugar problems'		
♥Some risk factors include being overweight, eating very salty or fatty foods, drinking too much alcohol, smoking, diabetes (sugar problems), not exercising, older than 50 years, someone in your family has high			♥High blood pressure and diabetes are often found together		
			♥If you have high blood pressure, you must also check for diabetes		
			♥If you have diabetes you must see the dietician to help you find out what you must and must not eat.		

Data Collection Form

Section A

Age: _____

Sex: Male / Female

Race: White / Black / Indian/ Coloured / Asian

Educational level: Grade 7 Grade 8 – 10 Grade 11 – 12 Tertiary

Annual income per annum: R 120,000 or more

R 80,000 - < R 120,000

R 50,000 - < R 80,000

R 30,000 - < R 50,000

R 20,000 - < R 30,000

R 15,000 - < R 20,000

Less than R 15,000

Section B

1. Have you ever had any of the following?

Stroke	Yes / No
Heart problems	Yes / No
Eye problems	Yes / No
Diabetes	Yes / No
Renal problems	Yes / No
High cholesterol	Yes / No

2. Do you:

3.1 Smoke

If yes, how many cigarettes per day?

1-5 6-10 11-15 16-20 more than 20

3.2 Drink Alcohol

If yes, how much alcohol per day?

1-2 units 3-5 units more than 5 units

(Where 1 unit = 1 tin beer / 1 tot / 1 glass wine/cherry)

Section C

1. How many times per week do you exercise?

0 1 2 3 4 5 More than 5

2. How long do you exercise for per day?

Less than 10 minutes / 10 minutes / 15 minutes / 20 minutes / 30 minutes or more

3. What type of exercise do you do?

Walking Running House/garden work Weights Aerobics Class

Other: _____

Subject Name: _____ Subject No: _____

Circle appropriate: Baseline 6 Months 9 Months

Variable	Measurement
Weight	
Height	
Body Mass Index (BMI)	
Waist / Hip ratio	
Glucose level	
Lipids	
Blood Pressure before 6 minute walk test	
Heart Rate before 6 minute walk test	
Distance walked - 6 minute walk test	
Blood Pressure Post 6 minute walk test	
Heart Rate post 6 minute walk test	
Medication	

Guidelines for Exercise Test Administration

Table 4–1. Contraindications to Exercise Testing.

Absolute Contraindications

1. A recent significant change in the resting ECG suggesting infarction or other acute cardiac events
2. Recent complicated myocardial infarction
3. Unstable angina
4. Uncontrolled ventricular dysrhythmia
5. Uncontrolled atrial dysrhythmia that compromises cardiac function
6. Third-degree A-V block
7. Acute congestive heart failure
8. Severe aortic stenosis
9. Suspected or known dissecting aneurysm
10. Active or suspected myocarditis or pericarditis
11. Thrombophlebitis or intracardiac thrombi
12. Recent systemic or pulmonary embolus
13. Acute infection
14. Significant emotional distress (psychosis)

Relative Contraindications

1. Resting diastolic blood pressure > 120 mm Hg or resting systolic blood pressure > 200 mm Hg
2. Moderate valvular heart disease
3. Known electrolyte abnormalities (hypokalemia, hypomagnesemia)
4. Fixed-rate pacemaker (rarely used)
5. Frequent or complex ventricular ectopy
6. Ventricular aneurysm
7. Cardiomyopathy, including hypertrophic cardiomyopathy
8. Uncontrolled metabolic disease (e.g., diabetes, thyrotoxicosis, or myxedema)
9. Chronic infectious disease (e.g., mononucleosis, hepatitis, AIDS)
10. Neuromuscular, musculoskeletal, or rheumatoid disorders that are exacerbated by exercise
11. Advanced or complicated pregnancy

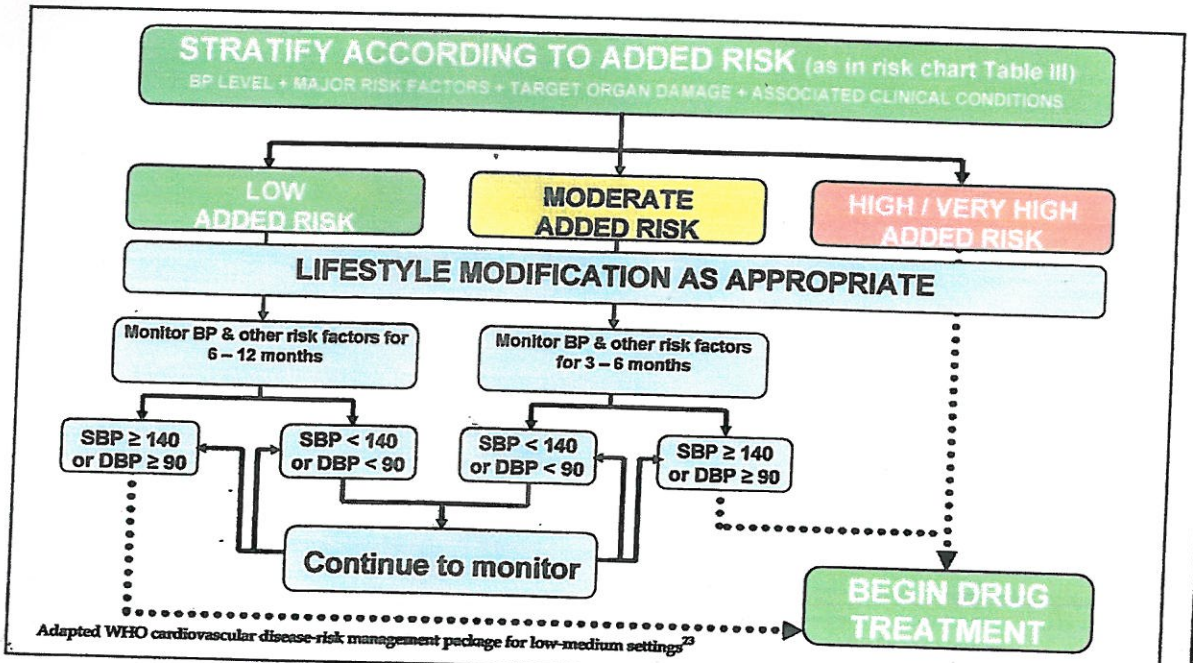


Fig. 1. Southern African hypertension management flow diagram based on added cardiovascular disease risk.

Table III. Stratification of risk to quantify prognosis*

Other risk factors and disease history	BP (mmHg)				
	Normal SBP 120 - 129 or DBP 80 - 84	High-normal SBP 130 - 139 or DBP 85 - 89	Stage 1 Mild hypertension SBP 140 - 159 or DBP 90 - 99	Stage 2 Moderate hypertension SBP 160 - 179 or DBP 100 - 109	Stage 3 Severe hypertension SBP > 180 or DBP > 110
No other major risk factors	Average risk	Average risk	Low added risk	Moderate added risk	High added risk
1 - 2 major risk factors	Low added risk	Low added risk	Moderate added risk	Moderate added risk	Very high added risk
≥ 3 major risk factors or target-organ damage or diabetes mellitus	Moderate added risk	High added risk	High added risk	High added risk	Very high added risk
Associated clinical conditions	High added risk	Very high added risk	Very high added risk	Very high added risk	Very high added risk

*Based on the European Society of Hypertension/European Society of Cardiology guidelines.[7]

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