Annexures II- Patient Information sheet

Influence of *Bacopa monnieri (L.)* Wettst on telomerase activity, telomere length and aging-related changes and cognitive functions with relation to prakriti (Constitution) of healthy adults.

INFORMATION SHEET

I am Dr. HLNR.Pradeep, attached to the Department of Basic principles, Ayurveda Anatomy and Physiology, Faculty of Indigenous Medicine. My current designation is Lecturer (Probationary). I would like to invite you to take part in the research study on Bacopa monnieri (L.) Wettst Conducted by Professor. Dilshani Dissanayake, Professor. P. K. Perera, Professor Nilakshi Samaranayake, Professor. PR.Waratenne and myself at Neuroscience research Centre, Department of Physiology, Faculty of Medicine, University of Colombo, Sri Lanka and Clinical Trial Unit, Faculty of Indigenous Medicine, University of Colombo, Sri Lanka

1. Purpose of the study

The purpose of this research is Influence of *Bacopa monnieri* (L.) Wettst on telomerase activity, telomere length and aging- related changes and cognitive functions with relation to prakriti (Constitution) of healthy adults.

2. Voluntary participation

Your participation in this study is voluntary. You are free to not participate at all or to withdraw from the study at any time despite consenting to take part earlier. There will be no loss of medical care or any other available treatment for your illness or condition to which you are otherwise entitled. If you decide not to participate or withdraw from the study you may do so at any time.

3. Duration, procedures of the study and participant's responsibilities

This study will be conducted over a period of 90 days. If you volunteer to participate in this study, we will ask you to do the following:

You will be provided with either **(a)7 packets to prepare decoction at home or (b) 7 decoction sachets to prepare decoction at home** for 45 days.

If you are selected to **prepare decoction**

a) You will need to prepare the decoction by adding the content of the packet into a earthen pot or stainless steel vessel with 1920 ml (8 patha) water and heat in mild fire and reduce to 240 ml (1 patha). Then consume half the volume (120 ml) before breakfast and the other half (120 ml) before dinner, around 6 am in the morning and 6 pm in the evening.

(A measuring cup will be provided to measure water and prepared decoction)

If you are selected to **decoction sachets**

b) You will need to prepare the decoction by adding the content of the sachet into 240 ml of hot water and dissolve and consume half the volume (120 ml) before breakfast

and the other half (120 ml) before dinner, around 6 am in the morning and 6 pm in the evening.

(A measuring cup will be provided to measure water and prepared decoction)

The decoction should be drunk continuously for 45 days. After the treatment you have to visit Clinical trial Unit, Faculty of Indigenous Medicine, University of Colombo, Sri Lanka at monthly intervals for 2 months to assess your disease condition further.

You will be asked to come on Day 1, 45th and 90th to the Clinical trial Unit, Faculty of Indigenous Medicine, University of Colombo, Sri Lanka to assess your health conditions and improvement. On these days a questionnaire will be administered to you by the investigators to collect data on your views regarding these dosage form.

Blood samples from the participants will be taken for the analysis by a qualified Phlebotomist (Nurse/MLT) before Drug administration (on the initial day), after 45 days of BMFD dosage form or placebo administration and 45 days after the completion of BMFD placebo administration (the 90th day).

We will give you a booklet named as “Diary”. You have to mention your daily changes related to the study protocol in the booklet. Detailed information will give at the 1st visit (day 1) to fill the diary properly.

Nerve conduction Test (NCT)

What are the risks and potential complications of a nerve conduction test?

The risks and potential complications of NCT testing are very low. There is a small risk of disruption if you have a pacemaker or a cardiac defibrillator. However, according to some studies, disruption is rare, so this should not keep you from having the test.

It is important to let your doctor know if you have a pacemaker or a cardiac defibrillator.

In rare cases, there is also a risk of:

- Infection
- Bleeding
- Bruising
- Nerve injury

How do I prepare for a nerve conduction test?

First, tell your doctor about all medications, herbal supplements, and over-the-counter drugs that you are taking, including aspirin or nonsteroidal anti-inflammatory drugs.

Questions to ask your doctor

Some questions you may want to ask your doctor before the test include:

- Why do I need a nerve conduction test?
- What can I expect during the test?
- Will it be painful for me?
- What information will you get from a nerve conduction test?
- How many nerves do you need to test?
- How long will the test take?
- Will I need someone to drive me to the appointment?
- Will I be given any sedatives during the test?
- When can I expect the results?
- What other tests or procedures might I need?

On the day of the test

You can prepare for the test by following these steps:

Take a bath or shower that morning to remove any lotions or oils from your skin. Wear comfortable, loose-fitting clothes.

Do not use oils, lotions, moisturizers, or hair products.

Bring a list of your medications and take them as usual unless instructed otherwise. Remove all jewelry.

Tell the doctor if you are taking blood thinners or have a pacemaker.

During the test

- You will have to change into a gown.
- You will sit or lie down for the test.
- Your neurologist will locate the nerve.
- They will attach the electrodes to the skin over the nerves.
- Signals are transmitted.
- The speed and distance of the electric impulses are measured.
- Your neurologist will repeat this process for each nerve tested.
- You may experience minor discomfort during the procedure.

After the test

Your doctor will give you orders regarding what activities to resume and when to return to work. However, in most cases, you can resume your activities the same day.

EEG (Electroencephalogram)

What is an EEG?

An EEG tracks and records brain wave patterns. Small flat metal discs called electrodes are attached to your scalp with wires. The electrodes analyse the electrical impulses in your brain and send signals to a computer that records the results.

Are there risks associated with an EEG?

EEG is usually painless and very safe. If an EEG does not produce any abnormalities, stimuli such as strobe lights, or rapid breathing may be added to help induce any abnormalities.

Before the test, you should take the following steps:

Ask your doctor if you should stop taking any medications before the test. You should also make a list of your medications and give it to the technician performing the EEG.

Wash your hair the night before the EEG. Don’t put any products like sprays or gels on the day of the test.

Avoid eating or drinking anything containing caffeine for at least 8 hours before the test. Your doctor may ask you to sleep as little as possible the night before the test if you have to sleep during the EEG. You may also be given a sedative to help you relax and sleep before the test begins. In some cases, you may need to be given a sedative during the procedure. If so, your doctor will ask you to bring someone who can drive you home afterward.

What to expect during an EEG

- Specialized technicians administer EEGs at hospitals, doctor's offices, and laboratories. The test usually takes roughly 30 to 60 minutes Trusted Source to complete and involves the following steps:
- You'll lie down on your back in a reclining chair or on a bed.
- A technician will measure your head and mark where to place the electrodes. These spots are scrubbed with a special cream that helps the electrodes get a high-quality reading.
- The technician will put a sticky gel adhesive on 16 to 25 electrodes and attach them to spots on your scalp.
- Once the test begins, the electrodes send electrical impulse data from your brain to the recording machine.
- This machine converts the electrical impulses into visual patterns that appear on a screen. A computer saves these patterns.
- The technician may instruct you to do certain things while the test is in progress. They may ask you to lie still, close your eyes, breathe deeply, or look at stimuli (such as a flashing light or a picture).
- During the test, very little electricity passes between the electrodes and your skin, so you'll feel very little to no discomfort.

After the procedure

- After the test is complete, the technician will remove the electrodes from your scalp.
- You can continue with your regular routine.
- However, if you were given a sedative, the medication will remain in your system for a little while. This means that you may need to have someone with you to take you home after the test. You'll need to rest and avoid driving until the medication wears off.

4. Potential benefits

Participation in this study may benefit you by your contribution to a new anti-aging therapy gaining access to scientifically proved treatment which is being used in Ayurveda; you will

be playing an active role in your own health care and helping others by contributing to this medical research.

5. Risks, hazards and discomforts

As blood will be drawn, there will be physical discomfort to the participants.

6. Reimbursements

You will not be paid for your participation in this research since funds have not been allocated for this purpose in the grant, but the transport and the treatment costs will be borne by the investigator.

7. Confidentiality

Confidentiality of all records is guaranteed and no information by which you can be identified will be released or published. These data will never be used in such a way that you could be identified in any way in any public presentation or publication without your express permission.

8. Termination of study participation

You may stop participating in this study at any time (with no penalty or effect on medical care or loss of benefits). Please notify the investigator as soon as you decide to withdraw your consent.

9. Clarifications

If you have questions about any of the tests / procedures or information please feel free to ask any of the persons listed below.

1.Dr. HLNR.Pradeep-94-71-1723286

2.Professor. Dilshani Dissanayake -+94-71-8232420

3. Professor. P. K. Perera-+94-71-6419072

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"Our study has received ethical clearance from the Ethics Review Committee (ERC), ensuring that all protocols and procedures comply with ethical standards. This approval highlights our commitment to maintaining the highest ethical principles in research, safeguarding participant rights, and adhering to regulatory requirements." – Faculty of Indigenous Medicine, University of Colombo, Sri Lanka