

Appendix 1:

Informed Consent form

This Informed Consent Form is for patient who are having hypertension, and who we are inviting to participate in research on yoga and hypertension. The title of our research project is "Effect of yoga based lifestyle intervention on cardiovascular variables and psychological states in patients with essential hypertension: A controlled study"

Name of Principal Investigator: Kashinath G Metri

Name of Organization: S-VYASA University Bangalore

Name of Proposal and version: *"EFFECT OF YOGA BASED LIFESTYLE INTERVENTION ON CARDIOVASCULAR VARIABLES, PSYCHOPATHOLOGIES AND COGNITIVE FUNCTIONS IN HYPERTENSION PATIENTS"*.

Information Sheet

Introduction

I am Dr Kashinath, working for the S-VYASA Research Institute. We are doing research on Hypertension, which is very common in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.

Purpose of the research

Hypertension is one of the most common diseases in our country. In long run this disease leads to many complications of heart, brain and eyes and kidney. Nearly 1/3rd of world population is suffering from hypertension and in India 40.8% of urban and 17.9% of rural population are suffering with hypertension.. The reason we are doing this research is to find out if the yoga based life style intervention helps in hypertension management.

This research will involve practice of asanas (physical postures), pranayama, mediation, relaxation techniques, devotional sessions, and counselling sessions for two weeks.

Participant selection

We are inviting all individuals who are having hypertension attending Arogyadhama Sec B

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this centre will continue and nothing will change. If you choose not to participate in this research project, you will offer the treatment that is routinely offered in this centre for disease hypertension, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

The intervention we are testing in this research is called integrated approach of Yoga therapy (IAYT). It has been tested before with people having, diabetes, asthma hypertension etc. We now want to study its effect of heart and our nervous system. IAYT is developed by Yoga expert of S-VYASA University. Earlier studies no any adverse effect has seen during IAYT practice.

Procedures and Protocol

A. Unfamiliar Procedures

You will be undergoing two week of IAYT treatment. This means that you will be (explain the treatment). To confirm the cause of your swelling, a small sample of your skin will be taken. Before the practice you will be undergoing few investigations which will take hardly half an hour time and the same investigations will be carried out after 15 days of IAYT practice.

This investigation procedure will include assessment of your cardiac functioning by using non invasive technique called Finapres non invasive blood pressure monitoring system and you also will be asked to fill two questionnaires which assess your anxiety level and negative think pattern. This investigation will also carry mental arithmetic test in which you will be asked to subtract 2 digit number from one 4 digit number during your pre and post assessment.

B. Description of the Process

You will be staying the campus for two weeks and you will be given yoga therapy designed for hypertension. Your cardiac related non-invasive test will be done before and after your 15 days of IAYT.

Side Effects

There are no any unwanted effects. However, we will follow you closely and keep track of any unwanted effects or any problems. First aid will be provided by Arogyadhama S-VYASA Bangalore. **If required you will sent to higher center nearby, where you have to take care of hospital expenses there.**

Possible health problems during yoga practices:

Giddiness

Loss of balance

Note:As soon as you start feeling any of these symptoms please stop the practice and inform to the therapist.

Risks

In this research there is no possible greater risk. If, however, the IAYT is not working, we add Ayurveda and naturopathy also in along with IAYT. **This study is not covered under any insurance scheme.**

While the possibility of this happening is very low, u should still be aware of the possibility. We will try to decrease the chances of this event occurring, but if something unexpected happens, we will provide you with naturopathy and Ayurveda also.

Benefits

If you participate in this research, you will have the following benefits: You will be able learn the different yoga techniques. There may not be any benefit for you but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

Confidentiality

With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected. In future at any time if you wish to join this study you are welcome.

Alternatives to Participating

If you do not wish to take part in the research, you will be provided with the established standard treatment available at this centre.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact to **Dr Kashinath Metri**,

Mob: 90352576262,

Email: kgmhetre@gmail.com

This proposal has been reviewed and approved by [Institutional Ethical committee (IEC) of S-VYASA University, which is a committee whose task it is to make sure that research participants are protected from harm.

Example of question to elucidate understanding: Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. Cardiac assessments before intervention
2. About IAYT intervention
3. Confidentiality

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

**Appendix 2:
Hospital Anxiety and Depression Scale (HADS)**

Tick the box beside the reply that is closest to how you have been feeling in the past week.

Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			I feel as if I am slowed down:
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			I get a sort of frightened feeling like 'butterflies' in the stomach:
	0	Definitely as much		0	Not at all
	1	Not quite so much		1	Occasionally
	2	Only a little		2	Quite Often
	3	Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			I have lost interest in my appearance:
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			I feel restless as I have to be on the move:
	0	As much as I always could		3	Very much indeed
	1	Not quite so much now		2	Quite a lot
	2	Definitely not so much now		1	Not very much
	3	Not at all		0	Not at all
		Worrying thoughts go through my mind:			I look forward with enjoyment to things:
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			I get sudden feelings of panic:
	3	Not at all		3	Very often indeed

2	Not often	2	Quite often
1	Sometimes	1	Not very often
0	Most of the time	0	Not at all
I can sit at ease and feel relaxed:		I can enjoy a good book or radio or TV program:	
0	Definitely	0	Often
1	Usually	1	Sometimes
2	Not Often	2	Not often
3	Not at all	3	Very seldom

Please check you have answered all the questions

Scoring:

Total score: Depression (D) _____ Anxiety (A) _____

0-7 = Normal

8-10 = Borderline abnormal (borderline case)

11-21 = Abnormal (case)

Appendix 3: THE DIGIT MEMORY TEST

An assessment procedure for specialist teachers to investigate verbal memory difficulties in children's learning. Both parts are administered.

Digits forwards	
Start	Item A
Finish	Failure on both trials of a pair.
Directions	"Listen carefully as I say some numbers. When I finish, you say them."
Delivery	Digits should be given at the rate of one per second. Administer both trials of each item. Recite digits in an even monotone without any variation in pitch of voice.
Scoring	The individual's score is the total number of items correctly repeated forwards.

WORKED EXAMPLE

Item	First Trial	or X	Second Trial	or X
A	43		16	
B	792		847	
C	5941	X	7253	
D	93872	X	75396	X

In this example, the total correct is 5.

Digits Backwards

Directions Administer as above but say, “Repeat these numbers after me but this time I want you to say them backwards.” Give two practice trials of two digits first

– any two numbers. If the child gets them wrong - correct her or him. If the child repeats the digits *forwards*, give a reminder that they should be reversed.

Score As for digits forwards.

Final score Total number managed (ticks) backwards and forwards *added together*. Consult Table 1 for standard score. This can also be expressed as a Percentile equivalent: consult Table 2.

Comparison Most people can remember two more digits forwards than they can Backwards. If the gap is larger than three, or smaller than one, this may be Worthy of note.

DIGITS FORWARDS

Item	First trial	or X	Second trial	or X	Total
A	43		16		
B	792		847		
C	5941		7253		
D	93872		75396		
E	152649		216748		
F	3745261		4925316		
G	82973546		69174253		
H	246937185		37162594 8		
				Forwards score:	

**DIGITS
BACKWARDS**

Item	Trial one	or X	Trial two	or X	Total
A	83		29		
B	475		615		
C	2619		3852		
D	28736		59413		
E	624719		276391		
F	4183627		1586937		
G	52624197		94617385		
				Backwards score:	

**FINAL
SCORE:**

Total forwards and backwards:	
Standard score:	
Percentile equivalent:	