Bharath
INSTITUTE OF HIGHER EDUCATION AND RESEARCH
(Declared as Deemed-to-be University under section 3 of UGC Act, 1956)
(Vide Notification No. F.9-5/2000 - U.3, Ministry of Human Resource Development, Govt. of India, dated 4th July 2002)
Accredited by NAAC NATIONAL ASSESSMENT AND ACCREDITATION COUNCIL
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Chennai - 600 073. Tamil Nadu.

Ref. No.SMS-2015-O-03 Date: 17.08.2016

TO

Mr. R. Vijaykumar
Professor/Physiology
BIHER.

Thro: Concern Head of the Department

Greetings!!!

We are happy to announce that the Research Advisory Committee has approved your proposal for Seed Money Scheme-2015 which was presented by you. You are requested to complete the proposal and send the progress report to the Dean Research in the prescribed time period.

Title of the Project: Impact of Body Mass Index on Arterial Stiffness in Young Prehypertensives: A Cross Sectional Study

Seed Money Amount: Rs.1, 00,000/- (Rupees One Lakh Only)

Approved on: 10.08.2016

Payment details:

Voucher No.24 **Dated: 25.08.2016**

With Regards

Dean-Research

Bharath University

SELAIYUR, CHENNAI - 600 073, TAMIL NADU, INDIA.

CASH / PAYMENT VOUCHER

Date 25/08/2016

V.No. 24

Debit _____ Amount

Rs. 1,00,000/-

PAID TO Dr. R. Vijaya Kumar

RUPEES One lakh only

TOWARDS Seed Money Scheme-2015

BHARATH UNIVERSITY CHENNAI 600 073. INDIA.

Authorised by **Finance Manager** **Cashier/Accountant** **Payee's Signature**

PROPOSAL SUBMISSION

1. **Details of Principal Investigator**

Name	: Dr.R.Vijayakumar
Designation	: Professor
Highest Qualifications	: Ph.D.
Department	: Physiology
E-mail	: sivanviji@gmail.com
Contact no	: 9445383846
Date of Joining	: 2.1.2011

2. Details of Co-Principal Investigator

Name	: Dr. V. Deepika
Designation	: Associate Professor
Highest Qualifications	: Ph.D.
Department	: Physiology
E-mail	: deepy843@gmail.com
Contact No	: 9962279360
Date of Joining	: 27.07.2013

Technical details

1. Introduction:

With the rapid socioeconomic and nutritional transition in last few decades, obesity and hypertension have become the major cardiovascular (CV) risk factors. Even a mild elevation in blood pressure (BP) (115/75 mmHg) is associated with increased CV risk1. Therefore, in 2003, the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High BP introduced a new term "Prehypertension", a precursor stage of hypertension, defined as a condition where systolic blood pressure (SBP) ranges from 120 to 139 mmHg, and/or diastolic blood pressure (DBP) ranges from 80 to 89 mmHg2. Prehypertension has an increased risk of converting to full-blown hypertension, and increased risk of CV events 3, if left unaddressed. The incidence of prehypertension in India is increasing at an alarming rate, with the prevalence rate of 55% in South India4 and 32.2% in North India5, thus posing a potential health threat and economic burden to the modern society. With these perspectives in mind, targeting the vulnerable apparently healthy young individuals for earlier identification of prehypertension is justified and prudent. Obesity is defined as the overaccumulation of body fat and correlates to a risk of high blood pressure6 and persistent elevated BP is reported to be the major determinant of arterial stiffness progression and vascular damage7. Arterial stiffness is emerging as an interesting tissue biomarker for cardiovascular risk stratification8. It is also proved in animal model that arterial stiffening precedes systolic hypertension in diet-induced obesity9. Arterial compliance decreases with increase in adiposity10, but literature indicating the contribution of body mass index (BMI) to arterial stiffness in prehypertensive individuals is very meager and conflicting. The present study was undertaken to assess the nature and magnitude of arterial stiffness and the role of BMI as an independent contributor for arterial stiffness in prehypertensive individuals.

2. Review of status of Research and Development in the subject

Lurbe E, Torro I, Garcia-Vicent C, Alvarez J, Fernández-Fornoso JA, Redon J. Blood pressure and obesity exert independent influences on pulse wave velocity in youth. Hypertension. 2012; 60: 550-5.

Intrauterine fetal conditions can have lifelong cardiovascular effects. The impact of maternal diabetes mellitus on children's cardiovascular profile is not well established. The goal of this study was to explore the association between maternal diabetes mellitus and offspring's blood pressure (BP) ≤10 years of age. Generation XXI is a prospective birth cohort, which enrolled 8301 mother-offspring pairs, including 586 (7.1%) children of diabetic mothers. Cardiovascular disease often develops during childhood, but the determinants of vascular health and disease in young children remain unclear. The study aimed to investigate the association of obesity and hypertension, as well as physical

fitness with retinal microvascular health and large artery stiffness, in children. In this cross-sectional study.

2.1. International Status:

The study emphasizes the evaluation of arterial stiffness in individuals with higher BMI and prehypertension, in order to understand the magnitude of vascular damage occurred in the precursor stage itself. This will further help us to plan better interventional strategies at the earliest stage before any target organ damage is initiated.

2.2. National Status:

NIL

3. Progress/ achievement so far, if any

a). Reference papers was collected.
b). Literature survey was studied.
c). Materials and methods were designed.

4. Work plan

4.1 Methodology

Study design: This cross-sectional study was conducted in Sri Manakula Vinayagar Medical College and Hospital, Madagadipet, Puducherry, India as a part of the medical health check-up program. It was conducted for the students studying Bachelor of Medicine and Bachelor of Surgery (MBBS) course in the Medical College. The study was initiated after getting approval from the Institute Human Ethical Committee and informed consent was taken from the participants before the study.

Sample size and sampling: Considering the proportion 32.2%5 design effect-1, 95% CI and 10% of non-response, the sample size was calculated as 340 (calculated by Open Epi Software Version). The participants were selected by multistage sampling. From each year (strata), several subjects (clusters) were randomly selected and were enrolled.

Recruitment of subjects: Overall, 514 students of age group 18-25 yr were enrolled for the health check-up program during Jun 2016-Oct 2016. A detailed review of medical history through structured questionnaire and physical examination were performed to rule out any acute or chronic illness. All baseline characteristics and anthropometrics, height, weight, waist circumference (WC) and Hip circumference (HC) were acquired from all study participants. BMI was calculated using the formula: Weight in kg/ (Height)2 in meters. BP was measured in the right arm in the sitting position using a standard mercury sphygmomanometer after a 10-min rest period. Three measurements were taken at 5 min interval and the mean of three measurements was considered for analysis. Subjects with SBP greater than 130 mmHg and DBP greater than 90 mmHg, with any form of medical illness or

any drug treatment were excluded from the study. Based on exclusion criteria, 105 subjects were excluded and 62 subjects were unwilling to participate in the study after listening to the study protocol. Therefore, 347 subjects were enrolled.

Study groups

Based on the subjects BP recordings as per JNC-7 classification2 and BMI as per WHO recommendation on BMI for Asian population 11 they were classified into four groups as follows:

Group1: Normotensives with normal BMI (n=109): Healthy subjects having systolic BP 100–119 mm Hg, diastolic BP 60–79 mmHg, and BMI 18.5-22 kg/m2.

Group2: Normotensives with higher BMI (n=89): Healthy subjects having systolic BP 100–119 mm Hg, diastolic BP 60–79 mmHg, and BMI 23 kg/m2 or above.

Group3: Prehypertensive subjects with normal BMI (n=50): Healthy subjects having systolic BP 120–139 mmHg, diastolic BP 80–89 mmHg, and BMI 18.5-22.9 kg/m2.

Group 4: Prehypertensive subjects with higher BMI (n=99): Healthy subjects having systolic BP 120–139mmHg, diastolic BP 80–89 mmHg, and BMI 23 kg/m2 or above.

Principle and Calculation of arterial stiffness indices

Though various invasive and noninvasive techniques are available for the assessment of arterial stiffness, the simplest, validated, noninvasive technique that is independent of operator skill, widely used in clinical set up and which is gaining substantial interest in recent years is the pulse trace system, that records the digital volume pulse (DVP)12. This technique is based on measuring infrared light transmission through the finger (photoplethysmography) with wavelength of 940 nm. The main principle of this device is the conversion of pressure changes to voltage changes by means of the pressure transducer. It analyses two major measures of vascular function: stiffness index (SI) and reflection index (RI). Similar assessment of arterial stiffness was reported earlier13, 14. DVP contains two peaks: systolic peak and diastolic peak. The former peak is due to pulse wave transmitted from the left ventricle to the finger directly and the diastolic peak arises from pulse wave transmitted along the aorta to the small arteries in the lower part of the body, from where they are again reflected along the aorta as a reflected wave. This path length is directly proportional to the subject's height (h). Pulse transit time (PTT) is the time duration between systolic peak and diastolic peak. Magnitude of systolic and diastolic peak was also measured. Stiffness index and Reflective index were calculated 13 by the following formulas:

Stiffness index (SI) = Subject's height (h)/PTT.

Reflection index (RI) = Magnitude of diastolic peak (b)/ Magnitude of systolic peak (a) × 100

Protocol for arterial stiffness measurement

Subjects were requested to report to the Physiology lab and DVP was measured in a temperature-controlled room (22±2°C), in the right index finger for five min using the Digital Polyrite (RMS vital module LF201308, India). Pulse wave contour analysis was done using the Polyrite D software that gave the PTT, SI, and RI.

Body composition measurement

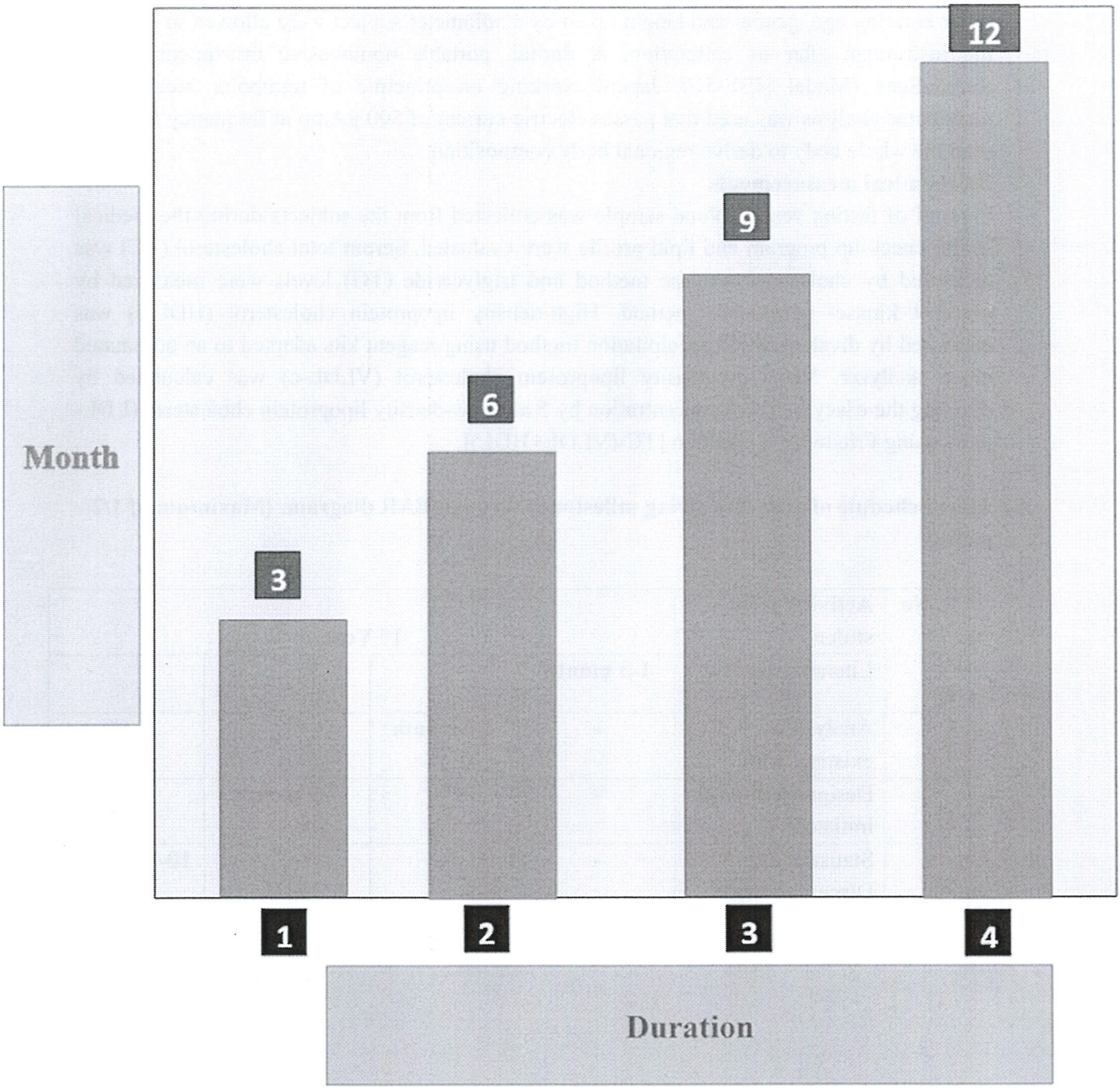
After entering age, gender and height taken by stadiometer subject were allowed to stand on the instrument after its calibration. A digital, portable noninvasive instrument Omron KaradaScan (Model HBF-510, Japan) working on principle of tetrapolar bioelectrical impedance analysis was used that passes electric current of 500 μAmp at frequency 5 kHz to scan the whole body to derive regional body composition.

Biochemical measurements

Five ml of fasting venous blood sample was collected from the subjects during the medical health check-up program and lipid profile were evaluated. Serum total cholesterol (TC) was measured by cholesterol oxidase method and triglyceride (TG) levels were measured by glycerol kinase- peroxidase method. High-density lipoprotein cholesterol (HDL-c) was measured by divalent cation precipitation method using reagent kits adapted to an automated blood analyzer. Very low-density lipoprotein cholesterol (VLDL-c) was calculated by dividing the triacylglycerol concentration by 5 and low-density lipoprotein cholesterol (LDL-c) by using Friedwald's equation [TC-(VLDL+HDL)].

4.2 Time Schedule of activities giving milestones through BAR diagram. (Maximum of 1/2 pages)

S. No	Activity/ mile stolen	1st Year			
1	Literature review	**1-3 month**			
2	Analysis of existing work	-	**4-6 month**		
3	Designing & work initiated	-	-	**7-9 month**	
4	Statistics & Discussion with results	-	-	-	**10-12 month**


Month
3
6
9
12
1
2
3
4
Duration

4.3 Expected outcome within the time period of See Money Scheme

The study emphasizes the evaluation of arterial stiffness in individuals with higher BMI and prehypertension, in order to understand the magnitude of vascular damage occurred in the precursor stage itself. This will further help us to plan better interventional strategies at the earliest stage before any target organ damage is initiated.

5. Suggested Plan of action stating the name of funding agency where the project will be communicated for financial support within the time period of project.

Nil

6. Bibliography: Nil

Nil

7. List of Projects submitted/implemented by the Investigators (Separate for Pi and Co-PI)

7.1 Details of Projects submitted to various funding agencies:

S.No	Title	Cost in Lakhs	Month of Submission	Role as PI/Co-PI	Agency	Status
1	NA	NA	NA	NA	NA	NA

7.2 Details of Projects under implementation

Sl. No.	Title	Cost in lakhs	Duration	Role as PI/ Co-PI	Agency
1	NA NA	NA	NA	NA	NA

7.3 Details of Projects completed during the last 5 years

Sl. No.	Title	Cost in lakhs	Duration	Role as PI/ Co-PI	Agency
1	NA	NA NA	NA	NA	NA

8. List of publications published by the Investigators, if any:

a) Principal Investigator

S. No	Author names	Title of paper	Name of Journal	Vol (Issue)	Page No.	Year
1.	Deepika.V1, **R.R.Vijaya Kumar2*,** S.Latha Vijaya Kumar3 And Dr.R.Srikumar4	Impact of body mass index on corrected QT Interval in prehypertensives	International Journal of Pharma and Bio Sciences	8(1): (B)	266 - 270	2017
2.	S Latha, **R Vijaya Kumar,** BR Senthil Kumar, G Bupesh, TSV Kumar	Acute and repeated oral toxicity of antidiabetic polyherbal formulation flax seed, Fenugreek and Jamun seeds in Wistar albino rat	Journal of Diabetes & Metabolism	7(3)	1-7	2016
3.	**Vijaya kumar R,** Kishor Kumar. C, Christy A, Sasikala C	Prevalence of Prehypertension among school students in Puducherry	Research Journal of Pharmaceutical, Biological and Chemical Sciences	6(1)	631-637	2015
4.	S Latha, **R Vijaya Kumar,** BR Senthil Kumar, G Bupesh, TSV Kumar	Acute and repeated oral toxicity of antidiabetic polyherbal formulation flax seed, Fenugreek and Jamun seeds in Wistar albino rat	Journal of Diabetes & Metabolism	7(3)	1-7	2016

b). Co-Principal Investigator

S. No	Author names	Title of paper	Name of Journal	Vol (Issue)	Page No.	Year
1.	**Deepika Veluswami,** B Ambigai Meena, S Latha, I Gayathri Fathima, K Soundariya, K	A study on prevalence of phenyl thiocarbamide (PTC) taste blindness among obese individuals	Journal of clinical and diagnostic research: JCDR	9(5)	**CC04**	2015

	Senthamil Selvi					
2.	SP Venkatesh, K Soundariya, V **Deepika**	A study on attitude of medical students towards learning of communication skills	J of Evolution of Med and Dent Sci	3(27)	7567-7573	2014
3.						

9. Budget

SI. No	Head	Amount (Rs.)
1	BP Apparatus, Stethoscopes, Body weight weighing machine, SPSS version 16 Chicago, IL, USA, ECG machine	45000
2	Consumables (gels bottles, cotton, sprit, testing charges, tools, etc.)	10000
3	Travel support for the purpose of research work.	10000
4	Contingency	25000
5	Others consumables	10000
	Total	**1,00,000**

*In case of any joint proposal for purchasing a same equipment, each of the associated PLs is also required to give separate budget (without any clubbing) to avoid any ambiguity, if all the associated projects are not awarded by committee.

10. Name of at least two subject experts from the Institute and one from the outside Institute with their contact details:

1. **Dr. R. Ravindran,** Professor in Physiology IBMS, Chennai **Mobile No**: 9444145990 **E-mail id:** ravindran89@gmail.com	2. **Dr. Vasuki,** Associate Professor in Physiology, Priyadharshini Dental College, Thiruvallur **Mobile No**: 9443793114 **E-mail id:** vasukiphysio@gmail.com

CERTIFICATE FROM THE INVESTIGATOR

Project Title: Impact of Body Mass Index on Arterial Stiffness in Young Prehypertensives: A Cross Sectional Study

It is certified that

1. I do hereby agree to submit a complete proposal for financial support to the external funding agency within the time period of SMS-2015.
2. I undertake that spare time on equipment procured in the project will be made available to other users.
3. I agree to submit a certificate from Institutional Biosafety Committee, if the project involves the utilization of genetically engineered organisms. I also declare that while conducting experiments, the Biosafety Guidelines of Department of Biotechnology, Department of Health Research, GOI would be followed in to.
4. I agree to submit ethical clearance certificate from the concerned ethical committee, if the project involves field trails/experiments/exchange of specimens, human & animal materials etc.
5. I agree to abide by the terms and conditions of SMS-2015, BIHER, and Chennai.

Name and signature of Principal Investigator

Name and signature of Co-Principal Investigator

Date: 19.07.2016
Place: Pondicherry

Forwarded by Head of the Department

Signature of the Head

DEAN
SRI LAKSHMI NARAYANA INSTITUTE OF MEDICAL SCIENCES
OSUDU, AGARAM VILLAGE,
KOODAPAKKAM POST,
PUDUCHERRY - 605 502

PROJECT EVALUATION FORMAT

Recommendation sheet

Name of the Principal Investigator	Dr.R.Vijayakumar
Name of the Co-Principal Investigator	Dr. V. Deepika
Name of the Department	Physiology
Title of project	Impact of Body Mass Index on Arterial Stiffness in Young Prehypertensives: A Cross Sectional Study
Recommendation of the evaluation committee (Recommended/Revision/Not Recommended)	Recommended
Financial allocation recommended	Rs. 1,00,000/-

SI. No.	Head	Amount
1	BP Apparatus, Stethoscopes, Body weight weighing machine, SPSS version 16 Chicago, IL, USA, ECG machine	45000
2	Consumables- Gel bottles, cotton, sprit, testing charges, tools, etc.	10000
3	Travel support for the purpose of research work.	10000
4	Contingency	25000
5	Others consumables	10000
	Total	**1,00,000**

Name and Signature of the Research Advisory Committee members with date

Internal Quality Assurance Cell ★ IQAC ★ SLIMS ★ Pondicherry-07

(Dr. P. Jayakumar)