CALL FOR INVESTIGATOR-INITIATED RESEARCH PROTOCOL FOR SMALL EXTRAMURAL GRANTS

24.02.202 No.: ICMR/BMI/EPMS/CallforProposal/2023

SLNO	PRIMARY INVESTIGATOR	DEPARTMENT
1	DR SREEJITH M	ENDOCRINOLOGY
2	DR KALYANI PILLAI	PEDIATRICS
3	DR PARVATHI MOHAN	PEDIATRICS
4	DR V SREERAJ	HEMATOLOGY
5	DR FEBIN ANTONY	RADIOTHERAPY
6	DR SUSEELA K V	MICROBIOLOGY
7	DR SRUTHI M V	COMMUNITY MEDICINE
8	DR SANDRA JOBIN	COMMUNITY MEDICINE
9	DR STEFFI FRANCIS	COMMUNITY MEDICINE

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Note: *Copy of application will be available only with the Primary Investigator.*

Sandra

Paper (missing)

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edical Research (ICMR)

of Health Research

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ed Research Proposals

Date of submission: 13-Mar-2024 02:33:45 PM

-2024-01-03946, **Version Id:** F1,

Title: SKILLS-FOCUSSED NUTRITION EDUCATION INTERVENTIONS FOR SCHOOL GOING ADOLESCENTS IN THRISSUR DISTRICT, KERALA -- AN RESEARCH

Details of Principle Investigator (PI)

BLOCK LETTERS),	DR SANDRA PAULSON,
Email, Contact No., Gender, DOB, Date of	Assistant Professor, sandrajobin28@gmail.com,9495579656, Female, 06-09-1988, 01-01-2055
Employment	Permanent
	Amala Institute of Medical Sciences , Private academic institutions with valid UGC/AICTE/PCI or NMC approved Medical colleges ,

Proposal Details PART-A

currently under regular employment in Medical Research Institutes, Universities, Colleges, Research & Development laboratories, and semi-government organizations, and	Yes
tvement	Call for Investigator-Initiated Research Proposals for small extramural grants - 2024

up to 250 words): A structured summary should contain the following subheadings: Rationale/ gaps in existing knowledge, Novelty, Objectives, Methods, and Expected outcome.

When the adolescents are equipped with the practical skills and included in the decision process of food selection in the family, they tend to make more choices. Methods - By introducing a behavior change communication session based on their food choices and targeting their value negotiation process the eating behaviors we aspire to make enable them to make informed food choices. Objective - 1. To compare dietary intake of school going children using 24 hour recall method and food frequency questionnaire using interview method and food diaries in village and town area schools before and after intervention. aims at implementing strategies to inculcate practical cognitive culinary skills to the adolescents so as to enable them to prepare healthy meals for and their families. Novelty - It will be tailored and context specific for each school based on their dietary intake data collected. Expected Outcome -On with Dieticians to suggest tailor made interventions for them with an eye on continuing sustainable healthy eating patterns throughout their growing into adulthood.

Area/Priority Area diseases	Reproductive, Maternal and Child Health, Nutrition / Adolescent health
keywords (i.e. keywords separated by comma which best describe your provided.	Skills, nutrition, dietary intake, Intervention, education, adolescents, Kerala
Abbreviations Only standard abbreviations should be used in the text. List abbreviations maximum of ten may be given as a list.	Govt - Government , CBSE - Central Board of Secondary Education , hr - hour

atement (up to 500 words): State the currently available information to present the problem adequately.

ıtered as God s own country, with highest health indices and literacy rate, is unambiguously placed at the highest epidemiologic transitions zone which had ətic effects on the morbidity and mortality tables of the state. The rampant urbanization and modernization which had infiltrated even to the grass root e state, irrespective of the region and economic strata, influenced lifestyle of the population making the state fertile for non-Communicable diseases to e mortality and morbidity due to lifestyle diseases soon began to surpass those due to communicable diseases RCH issues combined. The available studies ıce of these diseases indicate high trends of NCD placing the state in the top spot of prevalence chart. The study conducted by Achutha Menon Centre for ence Studies in 2017 was a shocking revelation into precarious the position of the state with findings pointing that one in five of the population being ı one in three being hypertensive. This along with the poor control rates and high out of pocket expenditure for the management of this diseases made ·ub of Non-Communicable Diseases in the country. The unhealthy dietary practices and lack of physical exercise in all sections of the population irrespective ınd economic status has contributed to the rise in lifestyle diseases with the statistics pointing that 52% of the total death in the age productive age group ı and 70 being due to one or other cause of NCD. Of 217 students in the age group of 15-17 years studied in a rural school in Thiruvananthapuram district ı found in 2.8% of students, 45.6% falls under normal category and the rest 51.6% were in the underweight category. The prevalence of hypertension and ension in males are 8.4% and 30.8% respectively, whereas none of the females are hypertensive and 18.2% are in pre hypertensive group. The food choice ms include biological determinants, economic elements, structural determinants and social characteristics. The individual's personal system based on these ncluding a value negotiation process and a set of strategies will finally lead to food choices. The biological mechanisms that regulate food choice do not ence against the current food supply system that provides low-cost palatable energy dense foods with high reward potential and limited nutritional value. ndustry is to be blamed for creating sweet, salty and high fat foods with the intent of capitalizing on innate biological predispositions. On top of that, limited ı of nutritious foods in schools and food outlets just add fuel to the fire. Even where healthy food is available and affordable, adolescent choices can be ıenced by commercial influences. These include advertising and marketing factors (e.g., clarity of labelling, supermarket placement, and social media ıs well as convenience.

ı of **the study (up to 250 words)** Mention how the research question addresses the critical barrier(s) in scientific knowledge, technical capability, and/or programmatic/ clinical/lab practice ance to local, national and international context with relevant bibliography.

ıce provides an excellent opportunity to correct nutritional deficiencies that may have occurred in early life and to catch-up on growth, and to establish good ehaviors that will in the help in combating both undernutrition and overnutrition and thereby pave way for a healthier Kerala and healthier India. When the ıı are equipped with the practical skills and included in the decision process of food selection in the family, they tend to make more responsible choices. By ıg a behaviour change communication session based on their food choices and targeting their value negotiation process involving the eating behaviors we make enable them to make informed food choices. Our research aims at implementing strategies to inculcate practical cognitive culinary skills to the ıı so as to enable them to prepare healthy meals for themselves and their families. It will be tailored and context specific for each school based on their ıse data collected. The skills focussed education interventions targeting the adolescents will include meal planning, reading food labels, role of food lists in ood procurement and making informed food selection

sis/ **Research question (up to 100 words) :** Will the strategy of nutrition skills educational intervention among school going adolescents of Thrissur district ther diet quality

Methodology

Include objective-wise work plan under the following sub-headings:

Study Objective No. 1

Study Objective : To determine the physical and physiological status using anthropometry, physical activity and sleep pattern, blood pressure measu hemoglobin level and random blood glucose

Study Design : School based cross sectional design

Study Area : Government, Government Aided and CBSE upper primary and high schools in Thrissur district

Sample Size : Multistage random sampling would be used for this study. In the first stage, the list of Government upper primary and high schools, Governmen upper primary and high schools and CBSE upper primary and high schools in rural as well as urban area would be prepared. From this list, 2 schools in village a 2 schools in town area from each Govt, Govt Aided and CBSE schools category would be selected randomly by lottery method. From each selected scho students would be selected. So a total of 600 students from each area would be selected. In the second stage, from each standard (8,9,10,11,12) one division w randomly selected and from each division 20 students would be included in the study such that 10 would be girls and 10 would be boys. So the total sam would be 1200 students.

Project Implementation Plan : After obtaining Institutional Research and Ethics Committee clearance , the permission from Heads of the institutions will be Following which consent from parents and assent from children will be sought through PTA meetings and social media messaging apps.

Design of Statistical analysis : Categorical variables will be analyzed and expressed in percentage and frequency . Continuous variables will be expressed i and standard deviation .Association will be checked using Chi square where needed. Correlation will be checked for continuous variables where suitable.

Study Objective No. 2

Study Objective : To compare dietary intake of school going children using 3-day 24 hr recall method and food frequency questionnaire using interview meth food diaries in village and town area schools before and after intervention

Study Design : School based cross sectional study design

Study Area : community

Sample Size : Multistage random sampling would be used for this study. In the first stage, the list of Government upper primary and high schools, Governmen upper primary and high schools and CBSE upper primary and high schools in rural as well as urban area would be prepared. From this list, 2 schools in village a 2 schools in town area from each Govt, Govt Aided and CBSE schools category would be selected randomly by lottery method. From each selected scho students would be selected. So a total of 600 students from each area would be selected. In the second stage, from each standard (8,9,10,11,12) one division wo randomly selected and from each division 20 students would be included in the study such that 10 would be girls and 10 would be boys. So the total samp would be 1200 students.

Project Implementation Plan : After getting permission from Heads of the Institution , sensitization of the study is done to the teachers as well as parents th meetings and messaging apps. Importance of the study and its relevance in todays world is emphasized. Through PTA meetings it shall be conveyed also. W consent taken from parents by sending the forms through students school diary. Ensuring it is signed and duly returned the next day. School going children st in 5th,6th, 7th,8th,9th 10th standard in Government ,Government Aided and CBSE schools in Thrissur district . A printed booklet will be handed over to the st after taking down their first 24 hour recall method and food frequency by a trained interviewer so as to complete their second and third 24 hour dietary recall.

Design of Statistical analysis : Data coded and entered into excel worksheet and analysis will be performed using SPSS 23. Result on continuous measureme presented on mean /- SD and result on categorical measurements presented in number (%). Significance assessed at 5% level. Normality of data tested using S wilk test. If normal, correlation between nutrient deficiency and variables analyzed by Pearson correlation coefficient , if not normal Spearman rank correlation. T of malnutrition was analyzed by linear and logistic regression.

Study Objective No. 3

Study Objective : To implement a behavioral change communication session based on the Skills-focussed nutrition education interventions among the school adolescents of Thrissur district

Study Design : Quasi experimental study

Study Area : Government upper primary and high schools, Government Aided upper primary and high schools and CBSE upper primary and high schools in Th district

Sample Size : Twelve schools selected as per the above objectives will be chosen for conducting health communication on the skills- focused nutrition edu session.

Methodology

Include objective-wise work plan under the following sub-headings:

mplementation Plan : Two sessions will be conducted in each of the selected schools. Pre and post test scores will be analyzed to check for the effectiveness on communication session. Periodic reminders, pamphlets will be circulated in regular intervals so as to reinforce the message. After a gap of two months, 24 hour dietary recall as well as food frequency questionnaire will be employed to check for the effectiveness of the intervention.

pressure measu

Statistical analysis : Paired t test scores will be analyzed to check for the difference in the knowledge , attitude and practice of the adolescents.

Outcome/ Deliverables aligned with research question (up to 100 words): Improved diet quality of adolescents in line with reduced consumption of processed foods after the behavioral change communication session.

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The next steps following the end of the project(up to 100 words): Presentation in conference proceedings to bring about radical changes in the school policy as well as inclusion of nutrition education in academic curriculum.

Will the study is going to generate new intellectual property: yes

Timeline with achievable targets Download

itutions will be

Proposal Details (PART-B)

Primary work done by the PI including the source of funding (up to 250 words): nil

be expressed i
suitable.

Past experience of the research team (Highlight only salient points (along with 5 relevant publications) that provides confidence to reviewers that team can implement the project with

interview meth

incipal investigator Dr Sandra Paulson has conducted research among adolescents namely : 1) Thilak SA , Sandra Paulson , Sarada A.K . Academic stress gh School Students in Thalassery educational block , Kerala : A cross sectional study .National Journal of Research in Community Medicine , Vol 6 Supp Issue 1 2. George J, Paulson S. Recent Status of Covid-19 Pandemic: A Perspective to Global and Indian Scenario . RDMMR-V15 Internet. 2021 Nov. 23 cited 2023 [cited Available from: https://stm.bookpi.org/RDMMR-V15/article/view/5006 PI - Dr SRUTHI MV - 1) Sunil V, Valsan SM. A study on risk factors of abortion in a ge hospital in Thrissur District, Kerala. Int J ReprodContraceptObstetGynecol 20209:4118-22. 14. Kumar SS, Kamaladevi LV, Valsan SM. Utilization of diabetic fo screening among diabetic patients at a tertiary care hospital in Kerala, India. Int J Community Med Public Health 20218:4938-43 15. Teenu S R, Sruthi M V, Mohammed Rafi The Role of Health Education on Larval Indices and Fever Cases from Rural Area of Thrissure District, Kerala: A Quasi Randamized Control Medicine And Health Research Journal, Vol. 2 No. 2 (2022), 28 March 2022 , Page 87-91https://cmhrj.com/index.php/cmhrj/article/view/38 16. Nithya M , C R Saju, Mohammed Rafi. A Study on Mosquito Density and Trend of Larval Indices from a Hospital Campus of Rural Area, Thrissur District Kerala. Journal of Multidisciplinary research and analysis 202205(7): 1620- 1625. 17. Jose NK, Sruthi MV, Rachel J, Jerome K, Vaz C, Saju CR. Barriers and of noncommunicable disease (NCD) prevention in Kerala: A qualitative study. J Family Med Prim Care. 2022 Jun11(6):3109-3114. doi: 10.4103/jfmpc147121. Epub 2022 Jun 30. PMID: 36119306 PMCID: PMC9480671. DR CR SAJU - He He associated with different projects in various capacities a)

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Officer - AMALA-UNICEF Project on "Facts for Life", b) Research associate-"Evaluation of Pulse Polio Program" conducted by IndiaCLEN. c) "Evaluation of Family Health Awareness Campaign" conducted by IndiaCLEN. d) Project coordinator-WHO project on Hospital Waste Management at the Maternal and Child Health, Govt. Medical College Calicut. e) UNICEF project on timely achievement of targets related to MDGs and f) UNICEF Project on awareness among adolescence. Publications 1. A study on the awareness and practice of medical education technologies among medical college teachers. ncent, VM Joshy International Journal of Research in Medical Sciences 8 (1), 330 2. Assessing risk factors of Non-Communicable Diseases using STEPS rural area of Thrissur District, Kerala. Saju CR, Catherin Nisha, Jerry Rachel, Kerline Jerome, Subin Koshy, Vidhu J, International Journal of Medical Science Research 2(40, 241 3. A study on selected behavioral factors of mothers influencing acute diarrhoea in under-five children in a rural part of Kerala, India. S

ell as parents th
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dietary recall.

Saju CJ Navya, VM Joshy, MP Jini, MV Radhamani International Journal of Community Medicine and Public Health 3 (8), 2211 4. An assessment of the tatus of underfive children in a rural area of Thrissur district, Kerala, India. R Priyanka, V Vincent, MP Jini, CR Saju Int J Community Med Public Health 3 (12), 5. Nutritional status and cognitive impairment in elderly population in a rural area of Thrissur district, Kerala. R Ramachandran, JM Mundodan, CR Saju, VM Community Med Public Health 5 (3), 1218-1223

Institutional Support/ Facilities: Institutional Research Committee , Institutional Ethics Committee , Several interdepartmental projects have been carried out

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tested using S
k correlation. T

Laboratory facilities (in-vitro/ in-silico) Institutional resources such as instruments/ equipment and other physical resources available for use in the project proposed animal house etc. EL ACCREDITED LABORATORY PRESENT

Conflict of Interest declaration (if any) The authors declare no conflicts of interests.

Duration (in Months) 24 Months

ong the school

Investigator Details

Name	Institute	Designation	Email	Contact No.	Role in Proposal
gh schools in Th SANDRA PAULSON	Amala Institute of Medical Sciences	Assistant Professor	sandrajobin28@gmail.com	9495579656	PI
d nutrition educ Sruthi M V	Amala Institute of Medical Sciences	Associate Professor	sruhar086@gmail.com	9495966828	Co-PI

Investigator Details

#	Name	Institute	Designation	Email	Contact No.	Role in Proposa
3	Prof Saju Cherumadathil	Amala Institute of Medical Sciences	Professor	drsajucr@gmail.com	9495315986	Co-PI

Documents consideration

#	Document Name	Is Applicable?	Uploaded Document
1	Declaration & Attestation Form(duly signed by Head of Department/ Director)	Yes	View
2	Additional supplementary information including figures tables flow diagrams etc can be shared as PDF	Yes	View

Proposed Budget Details

Institute	Budget Year	Manpower Budget (Rs.)	Contingency	Consumables	Equipment	Travel	Overhead	Total
Amala Institute of Medical Sciences	1	3172000.00	0	61645.00	1399.00	72000.00	0	33070
Amala Institute of Medical Sciences	2	3474000.00	467000.00	53745.00	0	132000.00	0	41267
Total in (Rs.):		**6646000**	**467000**	**115390**	**1399**	**204000**	**0**	**7,433,**

Budget Breakup Details (Staff/Manpower)

#	Budget Year	Institute	Designation	No. of Person(nos)	Require Month(nos)	Cost Per Person(Rs.)	Overhead(Rs.)	Co
1	**Year: 1**	Amala Institute of Medical Sciences	Project Technical Support - I	1	2	18,000	0.00	36
Justification : DATA ENTRY OPERATOR								
2	**Year: 1**	Amala Institute of Medical Sciences	Project Nurse - II	1	5	20,000	0.00	100
Justification : BLOOD SAMPLE COLLECTION								
3	**Year: 1**	Amala Institute of Medical Sciences	Project Research Scientist - II (Medical)	1	12	80,000	0.00	960
Justification : CO PRINCIPAI INVESTIGATOR								
4	**Year: 1**	Amala Institute of Medical Sciences	Project Research Scientist - II (Medical)	1	12	80,000	0.00	960,
Justification : PRINCIPAL INVESTIGATOR								
5	**Year: 1**	Amala Institute of Medical Sciences	Project Research Scientist - III (Medical)	1	12	93,000	0.00	1,116,
Justification : SUPERVISING AND EXPERT OPINION								
6	**Year: 2**	Amala Institute of Medical Sciences	Project Technical Support - I	1	2	18,000	0.00	36,0
Justification : DATA ENTRY OPERATOR								

Total Cost (Rs.) including overhead **6,646,0**

Budget Breakup Details (Staff/Manpower)

Role in Proposa							
	Amala Institute of Medical Sciences	Project Reseach Scientist - II (Non Medical)	1	6	67,000	0.00	402,000.00
Co-PI	DIETICIAN - PLANNING AND DELIVERING BCC SESSIONS						
	Amala Institute of Medical Sciences	Project Research Scientist - II (Medical)	1	12	80,000	0.00	960,000.00
	CO PRINCIPAL INVESTIGATOR						
	Amala Institute of Medical Sciences	Project Research Scientist - III (Medical)	1	12	93,000	0.00	1,116,000.00
	SUPERVISING AND EXPERT OPINION						
	Amala Institute of Medical Sciences	Project Research Scientist - II (Medical)	1	12	80,000	0.00	960,000.00
Total	PRINCIPAL INVESTIGATOR						
							6,646,000.00

Contingency budget breakup details

Budget Year	Institute	Overhead Charges (Rs.)	Total Cost(Rs.)
1	Amala Institute of Medical Sciences	0.00	167,000.00

Item Name :miscellaneous

Conference presentation

2	Amala Institute of Medical Sciences	0.00	300,000.00

Item Name :Article publishing charges

For publishing the research in a peer-reviewed journal with high impact factor

467,000.00

Consumables Budget Breakup Details

Budget Year	Institute	Consumables Name	Overhead	Total Cost(Rs.)
1	Amala Institute of Medical Sciences	refreshments	0.00	5,000.00

Sensitization and training of staff involved regarding research purpose along with

1	Amala Institute of Medical Sciences	dry cotton, wet cotton , 2 cc syringe , wound plaster , EDTA tube , Clot tube	0.00	7,900.00

for blood sample collection Hb and RBS

1	Amala Institute of Medical Sciences	printer black ink	0.00	745.00

for printing questionnaire

115,390.00

Consumables Budget Breakup Details

4	**Year: 1**	Amala Institute of Medical Sciences	1) printed consent papers , sociodemographic data , 3 day 24 hour dietary recall booklet with food frequency questionnaire	0.00

Justification : for data collection

5	**Year: 2**	Amala Institute of Medical Sciences	refreshments	0.00

Justification : sensitization and training of staff involved regarding research purpose

6	**Year: 2**	Amala Institute of Medical Sciences	printed sociodemographic data , 3 day 24 hour dietary recall booklet with food frequency questionnaire, post test and pre test questionnaire	0.00

Justification : for data collection

7	**Year: 2**	Amala Institute of Medical Sciences	printer black ink	0.00

Justification : for printing data collection tool and pre test and post test questionnaire

Total Cost (Rs.) 11

ng overhead

Equipment Budget Breakup Details

#	Budget Year	Institute	Equipment Name	Equipment Model	Equipment Manufacturer	Equipment Type
1	**Year: 1**	Amala Institute of Medical Sciences	small adult blood pressure cuffs		MEDTECH	Domestic

Justification :for taking automatic digital BP

Mode of Proposed disposal : For further use again

Total (Rs.):

Travel Justification

	Year	Amount(Rs.)
1	**Year: 1**	72000.00

Justification :travelling to the twelve schools for permission and consent , collecting data prior to intervention - total of 24 visits to school in first year

2	**Year: 2**	60000.00

Justification :for meetings related to project, travelling to ICMR

3	Year: 2	72000.00

Justification :Health education sessions and collecting data after intervention,- total of 24 visits to schools

Total: **204,000.00**

Short resume PI/Co-PI

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
Prof Saju Cherumadathil	1962-10-23	Epidemiology, Tuberculosis, Adult vaccination	0	nil	Fellowship program in medical education	Co-PI

Short resume PI/Co-PI

Maximum of 10 primary research publications related to the proposal

details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.
on the Knowledge and Attitude Regarding Internet Blue Whale ng Adolescent School Children in a Private School in a Rural Area of dia. VTKD Menon, H Kumar, CR Saju, V Joshi Call for Editorial ders 1 (2), 67	nil	co author	nil
status and cognitive impairment in elderly population in a rural district, Kerala. R Ramachandran, JM Mundodan, CR Saju, VM mmunity Med Public Health 5 (3), 1218-1223	4.52	co author	nil
factors of Non-Communicable Diseases using STEPS Survey in a Thrissur District, Kerala. Saju CR, Catherin Nisha, Jerry Rachel, Subin Koshy, Vidhu J, International Journal of Medical Science Research 2(40, 241	5.565	co author	nil

Experience as Investigator

Project	Role	Funding Agency	Amount of Funding	Reference of main publications
on timely achievement of targets DGs	PI	UNICEF	193000.00	Capacity building of timely achievement of Millenium Developmental Goals in India
Project on HIV/AIDS Awareness among	PI	UNICEF	251500.00	HIV/AIDS Awareness of college students in Kerala, South India
UNICEF Project on "Facts for Life",	PI	UNICEF	1197000.00	NIL

Ongoing research projects (funded by ICMR)

Title	Grant Amount	Start Date	End Date

PI/Co-PI	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
	1986-11-04	maternal health	0	nil	nil	Co-PI

Maximum of 10 primary research publications related to the proposal

details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.
Sruthi MV, Rachel J, Jerome K, Vaz C, Saju CR. Barriers and facilitators of communicable disease (NCD) prevention in Kerala: A qualitative study. J Family Care. 2022 Jun11(6):3109-3114. doi: 10.4103/jfmpc.jfmpc147121. Epub 30. PMID: 36119306 PMCID: PMC9480671.	1.4	first	nil
Vidas , K S Premlal , Sruthi M V, A Study on Dental Caries and Risk Factors Communicable Diseases among Undergraduate Medical Students of District, Kerala , Indian Journal of Public Health Research Development: o. 8 (2020)	1.0	corresponding author	nil

Experience as Investigator

Role in Proposal	e project	Role	Funding Agency	Amount of Funding	Reference of main publications
Co-PI					

Ongoing research projects (funded by ICMR)

Title	Grant Amount	Start Date	End Date

Short resume PI/Co-PI

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role i Propo
Dr SANDRA PAULSON	1988-09-06	nutrition , adolescence	0	nil	nil	PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization products where cited.
1) Thilak SA , Sandra Paulson , Sarada A.K . Academic stress among High School Students in Thalassery educational block , Kerala : A cross sectional study .National Journal of Research in Community Medicine , Vol 6 Supp Issue 1 , July 2017	2.12	co author	nil

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date

Declaration

I hereby declare that the entries in this form and the additional particulars, if any, furnished herewith are true to the best of my knowledge and belief. I understa in the event of my information being found false or incorrect at any stage, my project/proposal shall be liable to cancellation / termination without notice or ar compensation in lieu thereof.

I hereby certify that the research proposal I have submitted to ICMR, New Delhi, for potential funding is entirely my original idea and has not been copied or re from any other source. Furthermore, I confirm that this proposal has undergone scrutiny using a standard plagiarism detection tool, verifying its originality and confirming that its contents have not been directly taken from any other sources. Additionally, I declare that there have been no established or pending plagiari charges against me in the last five years.
In the event that the funding agency identifies any form of plagiarism or inconsistencies in the aforementioned proposal, I acknowledge and agree to comply w actions deemed necessary by ICMR. I take full responsibility for any such discrepancies and will adhere to the consequences as required.

SKILLS-FOCUSSED NUTRITION EDUCATION INTERVENTIONS FOR SCHOOL GOING ADOLESCENTS IN THRISSUR DISTRICT, KERALA– AN IMPLEMENTATION RESEARCH

Kerala considered as God's own country, with highest health indices and literacy rate, is unambiguously placed at the highest epidemiologic transitions zone which had exerted drastic effects on the morbidity and mortality tables of the state. The rampant urbanization and modernization which had infiltrated even to the grass root levels of the state, irrespective of the region and economic strata, influenced lifestyle of the population making the state fertile for non-Communicable diseases to flourish. The mortality and morbidity due to lifestyle diseases soon began to surpass those due to communicable diseases & RCH issues combined.

The available studies on prevalence of these diseases indicate high trends of NCD placing the state in the top spot of prevalence chart. The study conducted by Achutha Menon Centre for Health Science Studies in 2017 was a shocking revelation into precarious the position of the state with findings pointing that one in five of the population being diabetic and one in three being hypertensive. This along with the poor control rates and high out of pocket expenditure for the management of this diseases made Kerala the hub of Non-Communicable Diseases in the country. The unhealthy dietary practices and lack of physical exercise in all sections of the population irrespective of the age and economic status has contributed to the rise in lifestyle diseases with the statistics pointing that 52% of the total death in the age productive age group between 30 and 70 being due to one or other cause of NCD.Of 217 students in the age group of 15-17 years studied in a rural school in Thiruvananthapuram district obesity was found in 2.8% of students, 45.6% falls under normal category and the rest 51.6% were in the underweight category. The prevalence of hypertension and pre hypertension in males are 8.4% and 30.8% respectively, whereas none of the females are hypertensive and 18.2% are in pre hypertensive group.

The food choice determinants include biological determinants, economic elements, structural determinants and social characteristics. The individual's personal system based on these influences including a value negotiation process and a set of strategies will finally lead to food choices. The biological mechanisms that regulate food choice do not stand a chance against the current food supply system that provides low-cost palatable energy dense foods with high reward potential and limited nutritional value. The food industry is to be blamed for

creating sweet, salty and high fat foods with the intent of capitalizing on innate biological predispositions. On top of that, limited availability of nutritious foods in schools and food outlets just add fuel to the fire.Even where healthy food is available and affordable, adolescent choices can be heavily influenced by commercial influences. These include advertising and marketing factors (e.g., clarity of labelling, supermarket placement, and social media influences) as well as convenience.

Rationale

Adolescence provides an excellent opportunity to correct nutritional deficiencies that may have occurred in early life and to catch-up on growth, and to establish good dietary behaviours that will in the help in combating both undernutrition and overnutrition and thereby pave way for a healthier Kerala and healthier India. When the adolescents are equipped with the practical skills and included in the decision process of food selection in the family, they tend to make more responsible choices. By introducing a behaviour change communication session based on their food choices and targeting their value negotiation process involving the eating behaviours we aspire to make enable them to make informed food choices. Our research aims at implementing strategies to inculcate practical cognitive culinary skills to the adolescents so as to enable them to prepare healthy meals for themselves and their families. It will be tailored and context specific for each school based on their dietary intake data collected. The skills focussed education interventions targeting the adolescents will include meal planning, reading food labels, role of food lists in guiding food procurement and making informed food selection

Aim

To implement a strategy to impart a Skills-focussed nutrition education interventions for school going adolescents in Thrissur district, Kerala

Objectives

1. To compare dietary intake of school going children using 3-day 24 hr recall method and food frequency questionnaire using interview method and food diaries in village and town area schools before and after intervention
2. To implement a behavioural change communication session based on the Skills focussed nutrition education interventions among the school going adolescents of Thrissur district

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udy **design-** Quasi experimental study design

udy **Setting –** Government upper primary and high schools, Government Aided upper imary and high schools and CBSE upper primary and high schools inrural as well as urban eas.

udy **Population**: The study population include school going adolescents from classes 8^{th}, , 10^{th}, 11^{th} and 12^{th} standard.

ampling Technique:

Iultistage random sampling would be used for this study. In the first stage, the list of overnment upper primary and high schools, Government Aided upper primary and high hools and CBSE upper primary and high schools in rural as well as urban areawould be epared. From this list, 2schools in village area and 2 schools in town area from each Govt, ovt Aided and CBSE schoolscategory would be selected randomly by lottery method. From ch selected school, 100 students would be selected. So a total of 600 students from each ea would be selected.In the second stage, from each standard (8,9,10,11,12) one division ould be randomly selected and from each division 20 students would be included in the udy such that 10 would be girls and 10 would be boys.So the total sample size would be 200 students.

nclusion criteria

chool going children studying in.8^{th},9^{th},10^{th},11^{th} and 12^{th}standard

xclusion criteria

hose children who do not consent.

tudy tool

1) Dietary evaluation by Three-day 24 hr recall method and food frequency questionnaire,
2) Sociodemographic data
3) BMI,BP,Haemoglobin status, RBS

Data Analysis

Data would be entered in Microsoft excel. Data will be analysed using SPSS version 23. Descriptive analysis like mean, standard deviation, median and proportions will be used. Appropriate statistical measures would be used for analysis.

Ethical clearance: Institutional Research Committee and Ethical committee clearance would be obtained. Informed consent from parents and will be taken from each subject. Detailed subject information would be provided to the subjects to read before taking consent. There are no risks involved in the study. Confidentiality of the subjects would be maintained.

Implementation strategy: a) Baseline dietary data collection

From each school, selected number of adolescents would be asked to about their 24-hr dietary recall of two weekdays by interview method and a weekend day by questionnaire method. The portion sizes will be given as references. Food frequency questionnaire will also be employed to collect data so as to tailor make the suggestions

b) Health Education

We are planning to conduct Behaviour change communication sessions in all Government, Aided and CBSE schools in Thrissur districts. These sessions include meal planning, reading food labels, role of food lists in guiding food procurement and making informed food selection. The awareness classes would be held by expert faculty from Community medicine and Nutrition department.

c) After intervention dietary data collection

From each school, selected number of adolescents would be asked to about their 24-hr dietary recall of two weekdays by interview method and a weekend day by questionnaire method. Food frequency questionnaire will also be employed to collect data so as to tailor make the suggestions and these data will be compared with the baseline data to evaluate the effectiveness of the intervention.

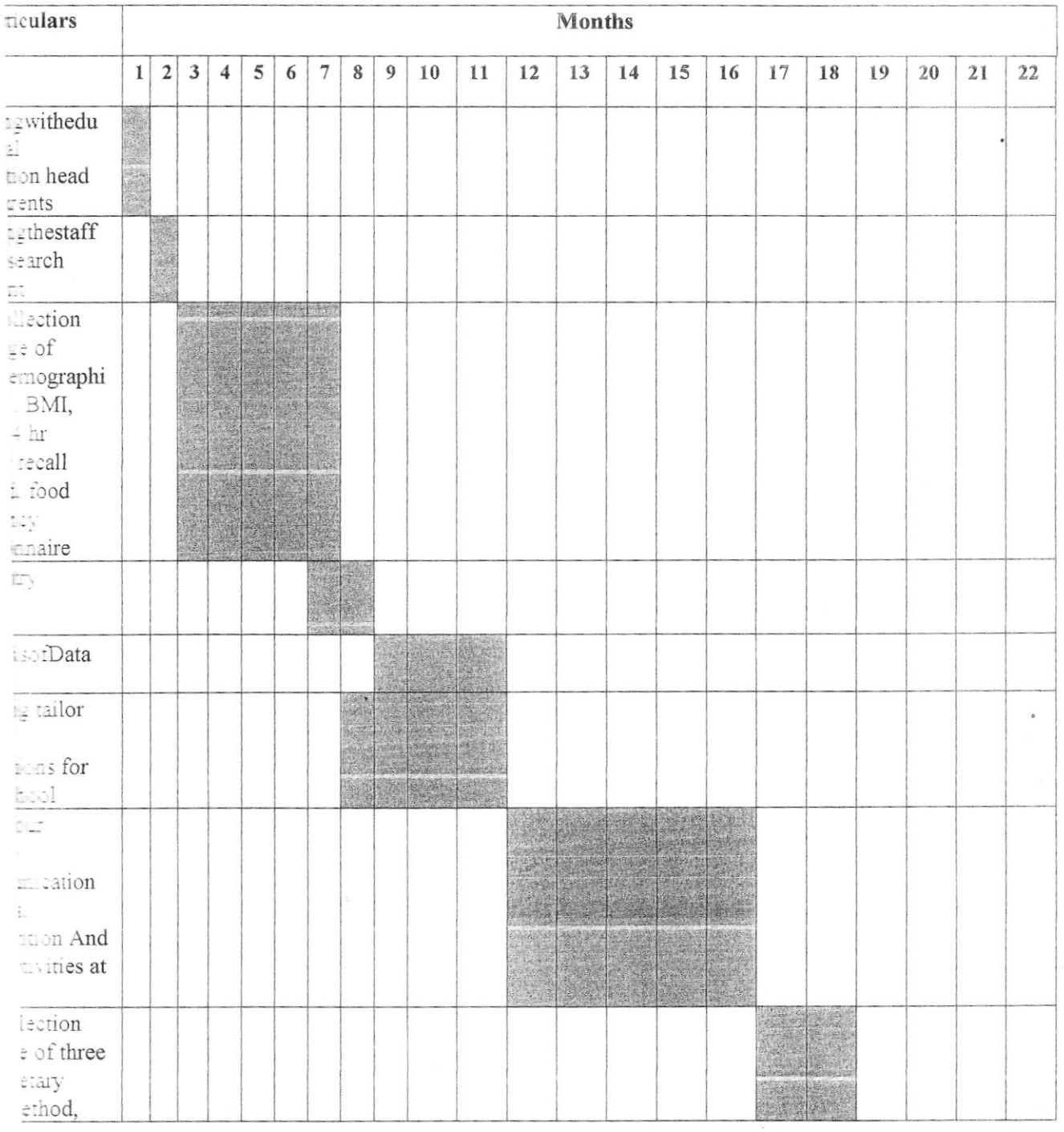
Expected Outcome

Highly processed foods are bad for people and the planet: reducing consumption will be beneficial for both human and planetary health. Advocacy for healthy adolescent nutrition needs to address commercial, structural, and ecological drivers of food choice, and use the agency of young people to bring about transformative change.

uture Plans

e hope these steps will help pave for a effective school canteen policy with emphasis on ealthy food and nutrition literacy will be integrated into the academic curriculum of Indian udents throughout.

Gnatt Chart



	food frequency questionnaire																			
7	Interim reportwriting																			
8	Conferencepresentationand Publication with final report																			

Budget

Sl. No.	Particulars	Quantity	Rate per unit	Per year	Total	Justif
1.	Human Resource*	1 Project Research Scientist II (Medical)	Rs. 80,000	Full Time	80000 X24= **Rs.1,920,000**	For guidanc conduction of achieving objectives,da monitoring th for an
		1 Project Research Scientist II (Non-medical)	Rs. 67,000	Full Time	67,000 X 24= **Rs 1,608,000**	
		1 Project Research Scientist 1 (Medical)	Rs 67,000/ head	1 year	**67,000 X 12= Rs 80,4000**	For Training
		1 Project Technical Support – 1I				For taking bloo laborator
		2 Project Technical Support – 1I 2 Dietician	Rs 30,000/head	1 years	**60,000 X 12= 7,20,000**	For counsellin serv
		1 Project Technical Support – I	Rs 18,000	2 years	**18,000 X 24= Rs 4,32,000**	Data
2.	Dietary data questionnaires Consumables (recurring expenses)	Printout of questionnaires and food diary	Rs 100/	Initial 2 year	**100 x 4800= Rs 480,000**	
3.	IEC and conventional health education materials & organizing interactive activity in schools	12 schools	Rs.2000	3 months	**Rs.36000**	For dissem information, a drug a
4.	Travel Grant	Field Work	Rs. 3000	3 months	**3000 X 20 visits = 60,000**	School Visits

Annexure-V

ICMR-Call for Application: ICMR/BMI/EPMS/Call for Proposal/2023

e of the project: Skills Focussed Nutrition Education Interventions for school going Adolescents in Thrissur district - An Implementation Research

e of the PI: Dr Sandra Paulson

e of the Institute: Amala Institute of Medical Sciences, Thrissur, Kerala

Declaration & Attestation

ereby certify that:

We have read the terms and conditions for ICMR Research Grant. All necessary Institutional facilities will be provided if the research project is approved for financial assistance.

The equipment(s) that is being requested as part of this project is/are not available in the Institute/Department /or these are available and are being used at full capacity (Strike off the inappropriate one)

The equipment(s) requested as part of this project have not been purchased earlier from the funds provided by ICMR for previous project(s) in the Institute.

Justif

No utilization certificate (UC)/ statement of expenditure (SoE) final report is pending for earlier ICMR project(s) under the PI and the final report(s) for earlier projects have been submitted.

For guidanc conduction of achieving objectives,da monitoring tha for an

The project has not been submitted to any funding agency or institution other than the ICMR.

The PI does not have more than 5 (five) ICMR projects at present as a Principal Investigator.

We understand that ICMR shall only fund for the project positions, as enumerated in the criteria for engagement of Non-Institutional Project Human Resource Positions, purely on temporary contractual basis. ICMR has apprised us of this rule and we have carefully noted it.

For Training

The PI and Co-investigator(s) hereby submit the ICMR Declaration of Interest form in prescribed format.

The name of the Statutory Audit Authority of our Institute is as follows:

For taking bloc laboratory

_____

[Please attach a copy of the resolution if a private firm is engaged]

For counselling servi

Registration/Unique ID no. assigned by NITI Ayog, GoI (on DARPAN Portal) (applicable only for NGOs): NA

Data

CV of the investigator and Co-Investigators is/are attached in prescribed format.

	Name	Signature	Date
Principal Investigator	Dr Sandra Paulson		09/03/2024
Co-Investigator(s)	Dr SRUTHI-MV		09/03/2024
Head of the Department	Dr C.R.SAJU		9/3/2024

re of the Head of the Institution with seal

Julious Arakkal CMI
Director

AMALA INSTITUTE OF MEDICAL SCIENCES THRISSUR

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School Visits

Indian Council of Medical Research (ICMR)

Deptartment of Health Research

(Ministry of Health and Family Welfare)

Investigator-Initiated Research Proposals

Date of submission: 14-Mar-2024 02:01:35 PM

Proposal Id: IIRPSG-2024-01-05012, **Version Id:** F1,
Proposal Title: Single fraction versus multi fraction hemostatic radiotherapy in pelvic malignancies – a randomized controlled trial

Personal details of Principle Investigator (PI)

Name of PI (IN BLOCK LETTERS), Designation, Email, Contact No., Gender, DOB, Date of Superannuation	DR FEBIN ANTONY, Assistant Professor, febinanthony@gmail.com,9496347880, Male, 07-04-1990, 23-07-2051
Nature of Employment	Permanent
Institute	Amala Institute of Medical Sciences , Private academic institutions with valid UGC/AICTE/PCI or NMC approved Medical colleges , UNDERPROCESS

Proposal Details PART-A

Are you currently under regular employment in Medical Institutes, Research Institutes, Universities, Colleges, recognized Research & Development laboratories, Government and semi-government organizations, and NGOs?	Yes
Advertisement	Call for Investigator-Initiated Research Proposals for small extramural grants - 2024

Summary (up to 250 words): A structured summary should contain the following subheadings: Rationale/ gaps in existing knowledge, Novelty, Objectives, Methods, and Expected outcome.

Rationale: Literature is scant regarding the exact dose and fractionation of radiotherapy (RT) needed for hemostasis in pelvic malignancies. Thus single institution study is designed to compare the outcomes and toxicity profile of two different hypo fractionated RT regimens. Novelty: This is the first phase III randomized study in the field of hemostatic RT. This trial has the potential to reduce the cost of hemostatic RT. Objectives: Primary objective is to determine if single fraction RT regimen is non inferior to multi fraction RT regimen for achieving hemostasis in pelvic malignancies. Secondary objective is to compare the acute toxicities in the two arms. Methodology: Eligible patients are 18-80 years of age with a WHO performance score of 0-3, diagnosed with metastatic anorectal or utero-cervical carcinoma with grade 2 (CTCAE v5.0) rectal or vaginal bleeding and or≥ grade 1(CTCAE 5.0) anemia. Patients will be randomly assigned (1:1) to receive 8Gy in single fraction RT or 20Gy in five fractions RT. Patients who received 8Gy in single fraction will be reassessed after 10 days and if any episode of bleeding, they will receive one more fraction of RT (8Gy). Acute toxicities are recorded as per RTOG scoring criteria. Bleeding response (BR) is assessed at 1 month from the initiation of RT and is classified to complete, partial, no response based on quantity of bleeding and hemoglobin levels. Expected outcome: BR in single fraction RT arm to be non-inferior to multi-fraction RT arm with a comparable/favorable acute toxicity profile.

Priority Area/Priority Area diseases	Non-Communicable Diseases / Cancer – breast, cervix, oral
Keywords Six keywords separated by comma which best	Bleeding, anemia, uterocervical carcinoma, anorectal carcinoma, radiotherapy,

..ur project may be provided. hemostasis.

..ations Only standard abbreviations should be used ... List of abbreviations maximum of ten may be given

BR Bleeding response CRU Clinical Research Unit CTCAE Common Terminology Criteria for Adverse Events CTRI Clinical Trials Registry India EQD2 Equivalent total doses in 2-Gy fractions IEC Independent Ethics Committee IRB Institution Review Board NABH National Accreditation Board for Hospitals Healthcare Providers NABL National Accreditation Board for Testing and Calibration Laboratories PI Principal Investigator RT Radiotherapy RTOG Radiation Therapy Oncology Group WHO World Health Organization

..n Statement (up to 500 words): State the currently available information to present the problem adequately.

..r vaginal bleeding associated with locally advanced or metastatic cancer is an oncological emergency treated with RT. Published ..focusing on RT dose and fractionation for hemostasis are rare. Though different fractionation regimens (8Gy in single fraction, .. five fractions, 30Gy in ten fractions) have been tested, till date there are no phase 3 studies comparing the efficacy of these. If ..es of single fraction RT in terms of hemostasis and toxicity profile are non-inferior to multi-fractionated regimens, this can be ..ented as the standard of care, which helps in reducing the number of RT related hospital visits and thus limit the financial toxicity for ..y and health system. This project aims to determine whether RT with 8Gy in single fraction is non inferior to 20Gy in five fractions ..eving hemostasis in these patients with a comparable/favorable acute toxicity profile.

..ale of the study (up to 250 words) Mention how the research question addresses the critical barrier(s) in scientific knowledge, technical capability, ..ogrammatic/ clinical/lab practice and its relevance to local, national and international context with relevant bibliography.

..is is a phase III randomized clinical trial, the results of this research project can address the unanswered question of exact dose and ..ation that provides hemostasis in bleeding pelvic malignancies. Technical capability: This single institution phase 3 clinical trial is ..onducted in a well reputed private medical college with a 50 years of experience in the field of Oncology particularly in Radiation ..gy. The entire clinical trial team is well experienced and have already completed and published their research works in reputed ..s. Moreover, the institution research and ethics board make sure that entire patient procedure including the randomization and ..on of funds are done in the highest ethical standards. The ethics committee has a separate adverse event monitoring committee, ..nsure the safety of participants and monitor any adverse event. We also have a clinical. research unit (CRU) with an expert bio-..cian and health analyst, a team that helps in assessing and comparing the data. Relevance to local, national and international context ..elevant bibliography: About 6-14% of patients with advanced cancers can develop tumor bleeding(1). Tumor angiogenesis, local ..essel infiltration, or tumor regression as a result of anti-neoplastic therapy can result in tumor bleeding (2). Palliative RT for ..ng hemostasis is required when the conservative measures fail(3).Radiation causes increase in release of von Willebrand factor ..n turn leads to enhanced platelet adhesion to the extracellular matrix of endothelial cells. It also causes vascular fibrosis and tumour ..ion, thereby achieving haemostasis (4,5). Different hypo fractionated palliative RT dose schedules were described in literature, ..includes 30Gy in 10 fractions,20Gy in 5 fractions or 5-10Gy in single fraction (6). There is scarcity of evidence in the optimal ..e radiation regimen for haemostatic RT for pelvic malignancies. There are no randomised trials which have compared the efficacy of ..ent fractionation schedules. Moreover, if a single fraction regimen could achieve an optimal haemostasis with acceptable toxicity, it ..e a cost-effective regimen both for the patient, family and the health care system. Being a tertiary cancer centre, our institution on an ..ge sees approximately 3000 newly diagnosed cancer cases per annum. Based on the above-mentioned studies, approximately 10% ..of the patients will require haemostatic RT. At our institution, single fraction RT costs around Rs. 9,000/- and 5 fraction RT costs ..Rs. 28,000/-. If 300 patients receive 5 fraction RT for haemostasis, then the cost will be around Rs. 84,00,000/-. However, if these ..atients receive single fraction RT, then the cost will be around Rs. 27,00,000/-. A noticeable difference of Rs. 57,00,000/- is observed .. comparing the cost of above fractionations. Moreover, a single visit to hospital by a patient family can result in approximately Rs. ..- (travel expenditure and loss of daily wages), which can be around Rs. 15,000/- if the same patient family attends hospital for 5 days .. Therefore, if single fraction RT has comparable outcomes with multi fraction RT, this can also translate into better health economics.

..othesis/ Research question (up to 100 words) : Single fraction radiotherapy has comparable results in terms of bleeding response ..toxicities to multi-fraction radiotherapy in patients with pelvic malignancies.

Methodology

Include objective-wise work plan under the following sub-headings:

Study Objective No. 1

Objective : Primary objective: To compare the efficacy of single fraction radiotherapy (RT) to multi fraction RT by comparing the ng response (BR) between two arms at one month after the intervention. Secondary objective: To compare the acute toxicities en two arms using RTOG scoring criteria.

Design : Non-inferiority open labelled randomized controlled trial.

Area : Single institution (Hospital), Amala Institute of Medical Sciences, Thrissur, Kerala.

le Size : In this study, we consider a 60% partial or complete response in the single fraction arm and an 80% partial or complete nse in the multiple fraction arm as clinically significant. Therefore, when we calculate sample size using n.for.2p from the epiDisplay age of R software with alpha as 0.05 and power of 80%, we get a value of 91 patients per arm accounting to a total of 182 patients.

ct Implementation Plan : The project will be ongoing for 3 years. The first 3-6 months will be utilized for setting up the team, getting egistration (CTRI), laying down the working SOPs, procuring relevant regulatory approvals (IRB/IEC), and training the team. The next 6-nths will be utilized for patient recruitment and data collection. The last 6 months will be utilized for data analysis.

gn of Statistical analysis : Demographic and baseline variables will be analyzed using descriptive statistics. Continuous variables will ssessed for normality and summarized as mean (±SD). Bleeding response comparing both the two different arms will be assessed by hi-squared test. Toxicity comparison will be compared between the 2 groups using non-parametric test Wilcoxon test.

ected outcome/ Deliverables aligned with research question (up to 100 words): Bleeding response in single fraction radiotherapy to be non-inferior to multi-fraction radiotherapy arm with a comparable/favorable acute toxicity profile. Thus, it can be considered as ew standard of care in radiotherapy for hemostasis.

ediate next steps following the end of the project(up to 100 words): The results of the research will be presented in a national and rnational conference and eventually be published as an original article in an international peer reviewed journal.

ether the study is going to generate new intellectual property: Apart from shortening the radiotherapy treatment duration to one this study won't generate any new intellectual property.

nelines with achievable targets Download

Proposal Details (PART-B)

eliminary work done by the PI including the source of funding (up to 250 words): Research team did a retrospective study among e patients who had received multi fraction radiotherapy for hemostasis and had observed a near complete to complete response in ajority of the patients. Our team also did a retrospective pilot study on the efficacy of single fraction radiotherapy in patients with poor

ce status and near complete or partial response was observed. Being a tertiary care hospital with a dedicated oncology and are wing, our previous data showed that we will get enough number of patients that meet the the inclusion criteria of the trial. ch team also did a cost comparison among the two different treatment regimens based on time-drive activity-based costing and the noticeable difference of Rs. 57,00,000/-, benefit that can happen to the health care system if treating approximately 300 th single fraction RT.

experience of the research team (Highlight only salient points (along with 5 relevant publications) that provides confidence to reviewers that team ent the project with quality.) **:** PI of the research project has got additional training in research activities (participated in 5th Tata statistics and clinical research methodology course) and has successfully completed and published the previous works in the ervical cancer, rectal cancer and hemostatic radiotherapy. PI has completed an international fellowship and had completed a

ive research work, preclinical research work at Canada which was presented in International conference and published. The co- have a good track record of research activities and one of the co-PIs is a PI of an ICMR project. Antony F, Dubey A, Skrabek P, Lambert P, Bybel B, Ahmed N. Hypofractionated Radiotherapy for Hematologic Malignancies during the COVID-19 Pandemic and Curr Oncol. 2024 Jan 1031(1):383-393. Antony F, Chalissery JR, Varghese KM, Gopu GP, Boban M. Relationship of irradiated bone olume and neutropenia in patients undergoing concurrent chemoradiation therapy for cervical cancer. J Cancer Res Ther. 2022 18(6):1498-1503. Febin Antony, Anuraag Shrivastav, Arbind Dubey, Nawaid Usmani, Aldrich Ong, Rashmi Koul, Harvey Quon, Sivananthan, William Hunter, Don Yee, Lindsay Rowe, Brita Danielson, Andrew Plesniarski, Ruey-Chyi Su, Julian O. Kim Abstract ffect of mTOR activity in peripheral blood mononuclear cells with metformin in high-risk prostate cancer patients receiving external diotherapy and androgen deprivation therapy. Cancer Res 1 April 2023 83 (7Supplement): 4858. Antony, F Chalissery, Jomon Gilvaz, Sareena1. Radiotherapy for successful symptom control in recurrent refractory endometriosis: A case report. Journal of Research and Therapeutics. April 30, 2023.

onal **Support/ Facilities:** Institution is a 1000 bedded NABH accredited hospital and a medical college. Cancer care was initiated in and is one among the best cancer hospitals of the state. For RT treatment, we have the state of art facilities (linear accelerator). We ve an NABL accredited biochemistry and hematology laboratory. CRU of the hospital helps in the smooth running of the trial and IRB monitors the ethical part of the trial. Statistical support will be provided by the Centre for Research Promotion.

Investigator Details

ne	Institute	Designation	Email	Contact No.	Role in Proposal
FEBIN ANTONY	Amala Institute of Medical Sciences	Assistant Professor	febinanthony@gmail.com	9496347880	PI
Rajkrishna B	Amala Institute of Medical Sciences	Assistant Professor	rajkb111@yahoo.co.in	9626947477	Co-PI
JAMUNA ANGEL OY	Amala Institute of Medical Sciences	Tutor	jamunajoy88@gmail.com	7736307467	Co-PI
Sunu Lazar Cyriac	Amala Institute of Medical Sciences	Associate Professor	drsunucyriac@gmail.com	9567602426	Co-PI
Mathew Varghese	Amala Institute of Medical Sciences	Associate Professor	drmathew@hotmail.com	7736134763	Co-PI
s Donna Liza hampan	Amala Institute of Medical Sciences	SCIENTIST-II	donna.thampan@gmail.com	9895787853	Co-PI
Dr JOMON RAPHAEL CHALISSERY	Amala Institute of Medical Sciences	Professor	joeraphael@gmail.com	9544316325	Co-PI
Prof V RAMAN KUTTY	Amala Cancer Research Centre	Professor	kuttyr@gmail.com	9847060199	Co-PI

Documents consideration

Document Name	Is Applicable?	Uploaded Document	Remarks
Additional supplementary information including figures tables flow diagrams etc can be shared as PDF	Yes	View	1 CONSORT flow diagram 2 grades of bleeding 3 grades of anemia 4 bleeding response 5 references
Declaration & Attestation Form(duly signed by Head of Department/ Director)	Yes	View	declaration and attestation form

Budget Breakup Details (Staff/Manpower)

dget ar	Institute	Designation	No. of Person(nos)	Require Month(nos)	Cost Per Person(Rs.)	Overhead(Rs.)	Total Cost(Rs.)
ear: 1	Amala Institute of Medical Sciences	Project Research Scientist - I (Medical)	1	12	77,720	27,979.00	932,640.00
on :For research							
ear: 1	Amala Institute of Medical Sciences	Project Nurse - II	1	12	23,200	8,352.00	278,400.00
ation :Data collection							
ear:	Amala Institute of Medical Sciences	Project Research Scientist - I (Medical)	1	12	77,720	27,979.00	932,640.00
ation :For research							
ear:	Amala Institute of Medical Sciences	Project Nurse - II	1	12	23,200	8,352.00	278,400.00
ation :Data collection							
st (Rs.) overhead							2,494,742.00

Contingency budget breakup details

udget Year	Institute	Overhead Charges (Rs.)	Total Cost(Rs.)
ear: 1	Amala Institute of Medical Sciences	750.00	25,000.00
gency Name :Contingency			
ation :Any treatment related extra cost			
Year: 1	Amala Institute of Medical Sciences	50,790.00	1,693,000.00
gency Name :Radiation treatment cost			

cation :Out of 91 patients enrolled in year 1, 45 patients will be into Arm A (single fraction RT) costing Rs. 9000/- and 46 patients in 5 fraction RT) costing Rs. 28000/- (45 x 9000 and 46 x 28000)

ar: 1	Amala Institute of Medical Sciences	1,980.00	66,000.00

ncy Name :Blood test

tion :Approximately Rs. 750/- per patient for testing Hemoglobin levels twice (Rs. 750 x 91 patients enrolled in year 1)

ear: 2	Amala Institute of Medical Sciences	750.00	25,000.00

ncy Name :Contingency

tion :Any treatment related extra cost

ear: 2	Amala Institute of Medical Sciences	1,500.00	50,000.00

ncy Name :Publication charges

tion :To publish the article into an International peer reviewed journal

ear: 2	Amala Institute of Medical Sciences	1,500.00	50,000.00

ncy Name :Article processing fee and conducting seminars

tion :To submit the article into an International peer reviewed journal

ear: 2	Amala Institute of Medical Sciences	50,220.00	1,674,000.00

ncy Name :Radiation treatment cost

tion :Out of 91 patients enrolled in year 2, 46 patients will be into Arm A (single fraction RT) costing Rs. 9000/- and 45 patients in fraction RT) costing Rs. 28000/- (46 x 9000 and 45 x 28000)

ear: 2	Amala Institute of Medical Sciences	1,980.00	66,000.00

ncy Name :Blood tests

tion :Approximately Rs. 750/- per patient for testing Hemoglobin levels twice (Rs. 750 x 91 patients enrolled in year 2)

3,758,470.00

Cost (Rs.)

Overhead

Consumables Budget Breakup Details

Budget Year	Institute	Consumables Name	Overhead	Total Cost(Rs.)
Year: 1	Amala Institute of Medical Sciences	Office stationery	750.00	25,000.00
Justification : For data collection				
Year: 2	Amala Institute of Medical Sciences	Office stationery	750.00	25,000.00
Justification : For data collection				
Total (Rs.)				51,500.00
Overhead				

Equipment Budget Breakup Details

Budget Year	Institute	Equipment Name	Equipment Model	Equipment Manufacturer	Equipment Type	Total Cost(Rs.)
Year: 1	Amala Institute of Medical Sciences	Printer			Domestic	15,000.00
Justification :For research						
Proposed disposal :Labelled and retained by institution						
Year: 1	Amala Institute of Medical Sciences	Laptop/Desktop			Domestic	75,000.00
Justification :For research						
Proposed disposal :Labelled and retained by institution						
					Total (Rs.):	90,000.00

Travel Justification

Year	Amount(Rs.)
Year: 1	40000.00
Justification :Attending seminar for interim data presentation	
Year: 2	40000.00
Justification :Attending seminar for final data presentation	
	80,000.00

Short resume PI/Co-PI

DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
1953-12-21	Research Methodology, Health Policy and Public Health Ethics, Data Analysis and Statistics, Epidemiology	55	45	NIL	Co-PI

Maximum of 10 primary research publications related to the proposal

...n details ...e	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.

Experience as Investigator

...e project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

...	Title	Grant Amount	Start Date	End Date

...	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
...ON ...EL ...SERY	1975-03-31	Head and neck malignancies, CNS, gynaecological malignancies	6	2	Faculty training Fellowship in Radiation Oncology at Washington University	Co-PI

Maximum of 10 primary research publications related to the proposal

...on details ...style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.

Experience as Investigator

...the project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

...id	Title	Grant Amount	Start Date	End Date

...e of ...-PI	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
...tthew	1976-	Gynaecological malignancies,	6	2	NIL	Co-PI

03-15 brachytherapy

Maximum of 10 primary research publications related to the proposal

details	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.

Experience as Investigator

project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

	Title	Grant Amount	Start Date	End Date

	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
B	1985-03-02	Haematological, rectal, breast malignancies	3	2	NIL	Co-PI

Maximum of 10 primary research publications related to the proposal

details	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.

Experience as Investigator

project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

	Title	Grant Amount	Start Date	End Date

	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
	1982-03-16	Data analysis, epidemiology	0	0	NIL	Co-PI

Maximum of 10 primary research publications related to the proposal

on details style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.

Experience as Investigator

...oject	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

	Title	Grant Amount	Start Date	End Date

	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
...ed	1976-06-10	Bone Marrow Transplantation, Gynaecological malignancies	25	9	Fellowship in Bone marrow transplantation	Co-PI

Maximum of 10 primary research publications related to the proposal

...details ...e	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.

Experience as Investigator

...e project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

...C	Title	Grant Amount	Start Date	End Date
...2023-0001870	An open-labelled multi-centric non-inferiority randomized controlled trial to compare sublingual Buprenorphine versus oral Tramadol for cancer pain	11900000.00	2024-01-12	2026-01-11
...ICR/11/Budget/2022	Hospital Based Cancer Registry in India	1500000.00	2022-01-04	2027-03-31

...ect ...e	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
...ARUNA ...ELLOY	1988-11-02	Gynaecological brachytherapy and head and neck cançers	0	0	NIL	Co-PI

Maximum of 10 primary research publications related to the proposal

...details ...e	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.

Experience as Investigator

			Funding	Amount of	Reference of main

Project	Role	Agency	Funding	publications
OF ONCOLOGICAL OUTCOMES IN LOCALLY ADVANCED RECTAL CARCINOMA RECEIVING NEOADJUVANT CHEMORADIATION THERAPY AND ADJUVANT HERAPY	Co-PI	NIL	0.00	NIL

Ongoing research projects (funded by ICMR)

Title	Grant Amount	Start Date	End Date

DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
1990-04-07	Rectal, Gynaecological and Hepatobiliary malignancies	5	3	Fellowship in Advanced Radiation Oncology	PI

Maximum of 10 primary research publications related to the proposal

details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.
Dubey A, Skrabek P, et al. Hypofractionated Radiotherapy for Malignancies during the COVID-19 Pandemic and Beyond. Curr 31(1):383-393. Published 2024 Jan 10. 390/curroncol31010025	2.6	First author	NIL

Experience as Investigator

e project	Role	Funding Agency	Amount of Funding	Reference of main publications
E OF ONCOLOGICAL OUTCOMES IN LOCALLY ADVANCED RECTAL CARCINOMA TS RECEIVING NEOADJUVANT CHEMORADIATION THERAPY AND ADJUVANT T-ERAPY	PI	NIL	0.00	NIL

Ongoing research projects (funded by ICMR)

Title	Grant Amount	Start Date	End Date

Declaration

...e that the entries in this form and the additional particulars, if any, furnished herewith are true to the best of my knowledge ...derstand that in the event of my information being found false or incorrect at any stage, my project/proposal shall be liable to ...termination without notice or any compensation in lieu thereof.

... that the research proposal I have submitted to ICMR, New Delhi, for potential funding is entirely my original idea and has not ... replicated from any other source. Furthermore, I confirm that this proposal has undergone scrutiny using a standard ...ection tool, verifying its originality and confirming that its contents have not been directly taken from any other sources. ... declare that there have been no established or pending plagiarism charges against me in the last five years. ...at the funding agency identifies any form of plagiarism or inconsistencies in the aforementioned proposal, I acknowledge and ...ply with any actions deemed necessary by ICMR. I take full responsibility for any such discrepancies and will adhere to the ... as required.

Annexure-V

Call for Application: Intermediate Extramural Grants 2023

Project: Utilization of Digital Technologies for Non Communicable Diseases Risk Factor Control among Young Adults - a Multi-Centric Study

The PI: Dr C R Saju

The Institute: Amala Institute of Medical Sciences, Thrissur, Kerala

Declaration & Attestation

We certify that:

We have read the terms and conditions for ICMR Research Grant. All necessary Institutional facilities will beprovided if the research project is approved for financial assistance.

The equipment(s) that is being requested as part of this project is/are not available in the Institute/Department
or these are available and are being used at full capacity (Strike off the inappropriate one)

The equipment(s) requested as part of this project have not been purchased earlier from the funds provided byICMR for previous project(s) in the Institute.

No utilization certificate (UC)/ statement of expenditure (SoE) final report is pending for earlier ICMRproject(s) under the PI and the final report(s) for earlier projects have been submitted.

The project has not been submitted to any funding agency or institution other than the ICMR.

The PI does not have more than 5 (five) ICMR projects at present as a Principal Investigator.

We understand that ICMR shall only fund for the project positions, as enumerated in the criteria for engagement of Non-Institutional Project Human Resource Positions, purely on temporary contractual basis. ICMR has apprised us of this rule and we have carefully noted it.

The PI and Co-investigator(s) hereby submit the ICMR Declaration of Interest form in prescribed format.

The name of the Statutory Audit Authority of our Institute is as follows:

_____

[Please attach a copy of the resolution if a private firm is engaged]

Registration/Unique ID no. assigned by NITI Ayog, GoI (on DARPAN Portal) (applicable only for NGOs):

……

CV of the investigator and Co-Investigators is/are attached in prescribed format.

	Name	Signature	Date
i)	Principal Investigator Dr C R Saju		
ii)	Co-Investigator(s) Dr Priya Chandran		20.3.24.
	Dr Sruthi C M		20/03/24
	Dr Sachin Chandramohan		20.3.24
	Dr Steffi Francis		
	Dr Fathimathul Salma O		
iii)	Head of the Department Dr C R Saju		

Dr. C.R. SAJU. MD
Professor of Community Medicine
Amala Institute of Medical Sciences
Thrissur-680555,Kerala

Signature of the Head of the Institution with seal

Date: 21/03/24

Fr. Julious Arakkal CMI
Director

AMALA INSTITUTE OF MEDICAL SCIENCES

ICMR

Department of Health Research

(Ministry of Health and Family Welfare)

Investigator-Initiated Research Proposals

Proposal in Draft Stage

Proposal Id: Not Generated Yet

Proposal Title: STUDY ON EPIDEMIOLOGY, ANTIMICROBIAL RESISTANCE AND MOLECULAR CHARACTERISATION INCLUDING SEQUENCING WITH DETECTION OF MACROLIDE RESISTANCE GENES OF CAMPYLOBACTER SPECIES

Personal details of Principle Investigator (PI)

Name of PI (IN BLOCK LETTERS), Designation, Email, Contact No., Gender, DOB, Date of Superannuation	DR SUSEELA KUNDOLY VELAYUDHAN, Professor, suseelasubru@yahoo.com,9847985710, Female, 19-02-1961, 18-02-2031
Nature of Employment	Permanent
Institute	Amala Institute of Medical Sciences , Private academic institutions with valid UGC/AICTE/PCI or NMC approved Medical colleges , YES (01-Jan-1970)

Proposal Details PART-A

Are you currently under regular employment in Medical Institutes, Research Institutes, Universities, Colleges, recognized Research & Development laboratories, Government and semi-government organizations, and NGOs?	Yes

Problem Statement (up to 500 words): Campylobacter is one of common causes of diarrheal illness worldwide. In India, diarrhea is the third common cause of mortality, with a mortality rate of 13%, and is responsible for the death of nearly 300,000 under 5 years' children every year. Campylobacter infections are generally mild, but can be fatal among very young children, elderly, and immunosuppressed individuals. Today, it is estimated that Campylobacter, particularly C.jejuni, provokes 30% of all GBS. Approximately 1 in every 1000 people infected with Campylobacter will develop GBS. It occurs 1 to 3 weeks after infection with Campylobacter. About 20% of patients with GBS have a complicated clinical course requiring prolonged intensive care. Despite the advances in the critical care management of GBS, it has mortality between 3% and 7%. Campylobacter can also cause invasive disease as septicemia. This bacterial infection can lead to intestinal perforation particularly with pre existing chronic bowel disease. Campylobacter is a slender, curved/spiral, "S"-shaped motile gram-negative, nonspore-forming microaerophilic organism with polar flagella. Ingestion of contaminated food and water remains the primary mode of transmission. Despite the public health problems posed by this organism, the routine isolation and identification of this are often missed due to the inappropriate diagnostic modalities. As Gram staining of stool samples is not routinely performed because of lack of expertise in identifying the organism in Gram staining and non availability of phase contrast microscope make the screening by microscopy cumbersome. Non availability of CO2 incubator, as it is expensive, results in the under reporting or nil reporting of campylobacter. Identification of this microorganism is a routine task for the clinical microbiologist, but correct differentiation to the species level is markedly hampered by the low biochemical reactiveness of it. As it is fastidious organism the samples should be reached to the lab without delay. Only appropriately equipped laboratories can handle this organism. Transportation should be suitable and prompt and it invites concern because of the need of man power to transport the samples from periphery to equipped labs. Correct identification of Campylobacter sp. from human samples is required for epidemiological study. Several immunological and molecular techniques are commercially available for the detection and identification of Campylobacter. These techniques offer rapid, accurate and more sensitive results compared to the traditional methods. But these methods demand more advanced instruments as well as specially trained individuals. To create awareness it needs prompt study of the exact burden of the disease. As it is a zoonotic infection the foods involved in the transmission should be studied to break the chain of infection. No collaborative studies had been conducted on this matter yet. WHO is promoting the integrated surveillance of antimicrobial resistance of pathogens in the food chain, collecting samples from humans, food and animals and analysing data across the sectors. Lack of knowledge on antimicrobial resistance in human, animal and environmental isolates is an obstacle to determine the link connecting all these.

Rationale of the study (up to 250 words) ... clinical/lab practice and its relevance to local, national and international context with relevant bibliography.

The high incidence of Campylobacter diarrhea, its duration and complications, make it highly important from a socio-economic perspective. In developing countries, Campylobacter infections in children under the age of two years are frequent, and may result in death. Antibiotic resistance in the most common species, Campylobacter jejuni (C. jejuni), is a challenge in the control of Campylobacter infections. A methodological effort with proper laboratory infrastructure is required for public awareness, diagnosis and disease control. A systematic approach including proper monitoring of the disease burden, source attribution, risk assessment and management, surveillance of antimicrobial resistance, and assessment of possible control measures is required. The outbreaks are commonly associated with water and food cross-contamination with animal shedding. The species of Campylobacter and sources of food chain contaminations should also be taken into account while developing disease control strategies. Numerous complications like GBS, reactive arthritis, myocarditis and pericarditis are reported associated with Campylobacter infection. A more severe autoimmune response and greater axonal damage are observed in C. jejuni-associated GBS. Antibiotics such as macrolides and fluoroquinolones can shorten the duration of invasive illness and complications if given early. There are some studies on Campylobacter prevalence among animals and poultry from Kerala. Study on epidemiology of campylobacteriosis in human is not available in the state. Even though a few cases of this infection are reported in this population the exact burden of the disease is not known. As the early and prompt diagnosis of this condition helps in prevention of complications, we propose the screening of all acute diarrheal infections by phase contrast microscopy to initiate antimicrobial therapy followed by confirmation with culture and study of antimicrobial susceptibility and molecular characterization. The isolates of Campylobacter will be subjected to sequencing to establish the strains and genes involved in macrolides resistance. The establishment for the proper and early diagnosis of campylobacteriosis will help to reduce the complications in this population. The transmission of C.jejuni may be prevented by improving sanitation, well-cooked poultry and other meat products, disinfection of water, and public health warnings about hazards of raw milk consumption. Breaking the chain of food contamination and disease by public awareness will definitely lower the burden of morbidity and economic loss in the state and thereby in nation in future. This study is formulated in collaboration with the Department of Veterinary Public health, College of Veterinary and Animal Sciences, Mannuthy, Thrissur, Kerala so that the samples from the animals will be procured and subjected to isolation, molecular testing for species identification and study of macrolides resistance

Hypothesis/ Research question (up to 100 words) : 1. Campylobacter infection is a significant cause of infective diarrhea in the study population 2. Animals are reservoirs and C. jejuni is the major species involved 3. Antimicrobial resistance is present and is mediated by particular gene 4. There is risk of contamination of soil and water in the geographical area selected for the study

Methodology

Include objective-wise work plan under the following sub-headings:

5

Study Objective No. 1

Study Objective : 1. To isolate Campylobacter species, molecular confirmation. 2. To detect the antibiogram, genes involved in antibiotic resistance 3. To identify the source and reservoir

Study Design : Descriptive study

Study Area : Department of Microbiology, Amala Institute of Medical Sciences, Thrissur, Kerala, India Dept of Veterinary Public health, College of Veterinary and Animal Sciences, Mannuthy, Thrissur, Kerala, India

Sample Size : Sample size: Stool N Z2 1-α PQ d2 p prevalence of (6%) qp-1 95% drelative precision (20% of 5.7 1.2) αsignificance level 5% 1.96 Minimum sample size n 1504 Meat and environmental samples N Z2 1-α PQ d2 p prevalence of (30%) qp-1 95% drelative precision (20% of 30 6) αsignificance level 5% 1.96 Minimum sample size n 224

Project Implementation Plan : Study procedure Stool samples from all infective diarrhea patients admitted in the hospitals will be collected. A macroscopic examination will be done to assess the consistency, presence of mucus, pus or blood. Samples will be screened by phase contrast microscopy to see the presence of bacteria with morphology suggestive of Campylobacter. All the samples will be processed for direct culture on Modified charcoal cefoperazone deoxycholate (mCCD) agar and enrichment in Blood-Free Campylobacter broth (CCD broth) and incubated under microaerophilic conditions at 42OC for 48 h. Colonies on mCCDA plates with characteristic greyish, flat, spreading type, shiny, mucoid and moistened surface having a tendency to spread, with or without metallic sheen will be subjected to Gram staining, catalase, oxidase and hippurate hydrolysis tests. Isolates will be confirmed by multiplex polymerase chain reaction and detection of 16S rRNA gene specific for Campylobacter genus and virulence gene cadF. It will be followed by species identification by using the primers C. jejuni specific mapA gene (589 bp) and C. coli specific ceuE gene (462 bp). The identified isolates will be subjected to antibiotic susceptibility testing using discs against azithromycin, amoxicillin–clavulanic acid and ciprofloxacin. Following the antibiotic susceptibility study gene sequencing will be done for strain identification as well as antibiotic resistance genes for macrolides. The samples from animals and birds like cattle meat and broiler chicken meat and environmental samples from soil and water from the area near to cattle and chicken farm will be collected and processed. Meat soil and drinking water samples will be inoculated to enrichment in mCCD (modified Charcoal Cefoperazone Deoxycholate) broth supplemented with CCDA selective supplement. Incubation will done under microaerophilic conditions at 42°C for 48 h followed by selective plating onto mCCDA supplemented with CAT selective supplement, Campylobacter supplement V and Polymyxin Bselective supplement (FD 003). It will be then incubated under microaerophilic conditions. All the positive Campylobacter isolates will be studied as above. Study tools Phase contrast microscope Carbon dioxide incubator Campy medium Stains for Gram staining Chemicals for catalase, oxidase and hippurate hydrolysis testing Antibiotic susceptibility disc for testing BSL class 2A cabinet Primers for molecular identification Gel doc PCR machine Study period 3 years

Methodology

Include objective-wise work plan under the following sub-headings:

Expected outcome/ Deliverables aligned with research question (up to 100 words): The reported cases of campylobacteriosis in this population are representing the tip of ice-berg and actual incidence of this disease will be revealed. The major species involved and the gene responsible for drug resistance will be known. Awareness will be created among the physicians so that more testing to detect this organism can be initiated. The level of environmental contamination by this organism will be revealed

Immediate next steps following the end of the project(up to 100 words): Routine screening of all diarrheal stool samples will be conducted. The sample collection for culture, molecular identification and antibiotic susceptibility testing for this organism will be extended to the health care settings in periphery. The importance of prevention of environmental contamination will be propagated to all stake holders. All steps for creating awareness for proper and optimum use of antibiotics in the patients will be initiated. The study on more cost effective methods for isolation of the organism will be started.

Whether the study is going to generate new intellectual property: On knowing the role of campylobacter in diarrheal illness in the study population and the presence of anti microbial resistance, the following concerns will arise a) the factor leading to development of resistance in this organism b) the role of injudicious use of antibiotics in animal husbandry c) the different methods to control the environmental contamination by this organism. As campylobacter can remain in the gut of animals and birds as a colonized flora, on administering different antibiotics for different purposes to these reservoirs, there is chance of development of anti microbial resistance in this bacteria and replace the susceptible strains. These strains in environment can spread through animal manure leading to outbreaks via food contamination.

Timelines with achievable targets Download

Proposal Details (PART-B)

Investigator Details

#	Name	Institute	Designation	Email	Contact No.	Role in Proposal
1	Dr Suseela Kundoly Velayudhan	Amala Institute of Medical Sciences	Professor	suseelasubru@yahoo.com	9847985710	PI
2	DEBEEDA BOBY	College of Veterinary and Animal Sciences, Mannuthy	Assistant Professor	drdeepaboby@gmail.com	7559007690	Co-PI

Role in

Documents consideration

#	Document Name	Is Applicable?	Uploaded Document	Remarks
1	Declaration & Attestation Form(duly signed by Head of Department/ Director)	Yes	View	Uploading declaration and resolution
2	Additional supplementary information including figures tables flow diagrams etc can be shared as PDF	Yes	View	nil

Proposed Budget Details

Institute	Budget Year	Manpower Budget (Rs.)	Contingency	Consumables	Equipment	Travel	Overhead	Total(Rs)
Amala Institute of Medical Sciences	1	1162200.00	10000.00	607500.00	1781027.66	82500.00	300	3643527.66
College of Veterinary and Animal Sciences, Mannuthy	1	0	0	0	0	0	0	0
Amala Institute of Medical Sciences	2	1394640.00	130000.00	607500.00	0	82500.00	3900	2218540
College of Veterinary and Animal Sciences, Mannuthy	2	0	0	0	0	0	0	0

Institute	Budget Year	Manpower Budget (Rs.)	Contingency	Consumables	Equipment	Travel	Overhead	Total(Rs)
Amala Institute of Medical Sciences	3	1000200.00	130000.00	1000000.00	0	120000.00	3900	2254100

Budget Breakup Details (Staff/Manpower)

#	Budget Year	Institute	Designation	No. of Person(nos)	Require Month(nos)	Cost Per Person(Rs.)	Overhead(Rs.)	Total Cost(Rs.)
1	Year: 1	Amala Institute of Medical Sciences	Project Technical Support - I	1	10	23,400	0.00	234,000.00

Justification :sample collection, transportation, in the laboratory- sample sorting, technical works as smear preparation, culture , preparation for antimicrobial susceptibility testing

2	Year: 1	Amala Institute of Medical Sciences	Project Research Scientist - III (Non Medical)	1	10	92,820	0.00	928,200.0

Justification :for data collection, in the laboratory – to do microscopy, identification, molecular characterisation,

3	Year: 2	Amala Institute of Medical Sciences	Project Technical Support - I	1	12	23,400	0.00	280,800

Total Cost (Rs.) 3,557,04(

including overhead

Justification :sample collection, transportation, in the laboratory- sample sorting, technical works as smear preparation, culture , preparation for antimicrobial susceptibility testing

4	Year: 2	Amala Institute of Medical Sciences	Project Research Scientist - III (Non Medical)	1	12	92,820	0.00	1,113,840.00

Justification :for data collection, in the laboratory – to do microscopy, identification, molecular characterisation

5	Year: 3	Amala Institute of Medical Sciences	Project Technical Support - I	1	4	18,000	0.00	72,000.00

Justification :data sorting

6	Year: 3	Amala Institute of Medical	Project Research Scientist - III (Non	1	10	92,820	0.00	928,200.00

Contingency budget breakup details

#	Budget Year	Institute	Overhead Charges (Rs.)	Total Cost(Rs.)
1	Year: 1	Amala Institute of Medical Sciences	300.00	10,000.00

Contingency Name :Questionnaire has to be printed in outside press

Justification :Questionnaire has to be printed in outside press

2	Year: 2	Amala Institute of Medical Sciences	3,900.00	130,000.00

Total Cost (Rs.) including overhead **278,100.00**

Contingency Name : Preparing software for data management or Apps for data entry -40,000/- Computer utilities, charges for analysis of data - 40,000/- Publication charges: 50,000/-

Justification : Computer utilities, charges for analysis of data ,IT professionals should be engaged, Involvement of statistician and Publication charges

3	**Year: 3**	Amala Institute of Medical Sciences		3,900.00	130,000.00

Contingency Name : Preparing software for data management or Apps for data entry -40,000/- Computer utilities, charges for analysis of data - 40,000/- Publication charges: 50,000/-

Consumables Budget Breakup Details

#	Budget Year	Institute	Consumables Name	Overhead	Total Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences	Stool sample containers– 10,000/- Glass slides – 2500/-, Cover slips – 70,000/- Staining reagents- 2,500/-, Campy Culture medias - 1,50,000/- , Disposable Petri dishes- 20,000/-, Antibiotic discs- 7,500/-, DNA extraction Kit – 25,000/-, Primers both genus and species – 3,20,000/-	0.00	607,500.00
	Justification : Requirements to process and analyze the samples during 1year				
2	**Year: 2**	Amala Institute of Medical Sciences	Stool sample containers– 10,000/- Glass slides – 2500/-, Cover slips – 70,000/- Staining reagents- 2,500/-, Campy Culture medias - 1,50,000/- , Disposable Petri dishes- 20,000/-, Antibiotic discs- 7,500/-, DNA extraction Kit – 25,000/-, Primers both genus and species – 3,20,000/-	0.00	607,500.0
	Justification : Requirements to process and analyze the samples during 2nd year				
					2,215,000

Total Cost (Rs.)
including overhead

#	Year	Amount(Rs.)
1	Year: 1	82500.00

Justification : Transportation of samples Meetings with collaborating institution

2	Year: 2	82500.00

Justification : Transportation of samples Meeting with collaborating institution

3	Year: 3	120000.00

Justification : Meeting with collaborating institution: Paper Presentation

Total:	285,000.00

Short resume PI/Co-PI

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
Dr DEEPA JOLLY	1972-04-09	15 years	8	5	NIL	Co-PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.
Deepa, J., Sunil, B., Latha, C., Vrinda, K. M., Mini, M. and Aravindakshan, T. V. 2022. Prevalence of Campylobacter spp. in marine fishes, crustaceans and molluscs in Kozhikode district, Kerala. J. Vet. Anim. Sci. 53(1): 32-38	0.81	First	Nil
Pravitha,C.P., Jolly Deepa, Latha,C., Sunil,B. and Ambily,R. 2022. Occurrence of Campylobacter spp. in organised layer farms and associated environmental samples of Central Kerala. J. Vet. Anim. Sci. 53(4): 682-687	0.81	coauthor	Nil
Deepa Jolly. B. Sunil, C. Latha, K. Vrinda Menon., Mini M. and Aravindalshan T. V. 2021. Antibacterial effect of aqueous cold leaf extract of Eichhorniacrassipes on Campylobacter jejuni NCTC 11168. The Pharma Innovation 10(5): 1338-1343,	2.38	First	nil

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal

Indian Council of Medical Research (ICMR)

Deptartment of Health Research

(Ministry of Health and Family Welfare)

Investigator-Initiated Research Proposals

Proposal in Draft Stage

Proposal Id: Not Generated Yet
Proposal Title: STUDY ON EPIDEMIOLOGY, ANTIMICROBIAL RESISTANCE AND MOLECULAR CHARACTERISATION INCLUDING SEQUENCING WITH DETECTION OF MACROLIDE RESISTANCE GENES OF CAMPYLOBACTER SPECIES

Personal details of Principle Investigator (PI)

Name of PI (IN BLOCK LETTERS), Designation, Email, Contact No., Gender, DOB, Date of Superannuation	DR SUSEELA KUNDOLY VELAYUDHAN, Professor, suseelasubru@yahoo.com,9847985710, Female, 19-02-1961, 18-02-2031
Nature of Employment	Permanent
Institute	Amala Institute of Medical Sciences , Private academic institutions with valid UGC/AICTE/PCI or NMC approved Medical colleges , YES (01-Jan-1970)

Proposal Details PART-A

Are you currently under regular employment in Medical Institutes, Research Institutes, Universities, Colleges, recognized Research & Development laboratories, Government and semi-govern[illegible] organizations, and NGOs?	Yes

Annexure-V

Ref. ICMR-Call for Application: 2024(88)

Title of the project: STUDY ON EPIDEMIOLOGY, ANTIMICROBIAL RESISTANCE AND MOLECULAR CHARACTERISATION INCLUDING SEQUENCING WITH DETECTION OF MACROLIDE RESISTANCE GENES OF CAMPYLOBACTER SPECIES

Name of the PI: Dr Suseela Kundoly Velayudhan

Name of the Institute: Amala Institute of Medical Science,

AmalaCancer Hospital Society, Amalanagar, Thrissur - 680 555,

Kerala

Declaration & Attestation

We hereby certify that:

i. We have read the terms and conditions for ICMR Research Grant. All necessary Institutional facilities will be provided if the research project is approved for financial assistance.

ii. The equipment(s) that is being requested as part of this project is/are not available in the Institute/Department
   a. /or ~~these are available and are being used at full capacity~~ (Strike off the inappropriate one)

iii. The equipment(s) requested as part of this project have not been purchased earlier from the funds provided by ICMR for previous project(s) in the Institute.

iv. No utilization certificate (UC)/ statement of expenditure (SoE) final report is pending for earlier ICMR project(s) under the PI and the final report(s) for earlier projects have been submitted.

v. The project has not been submitted to any funding agency or institution other than the ICMR.

vi. The PI does not have more than 5 (five) ICMR projects at present as a Principal Investigator.

vii. We understand that ICMR shall only fund for the project positions, as enumerated in the criteria for engagement of Non-Institutional Project Human Resource Positions, purely on temporary contractual basis. ICMR has apprised us of this rule and we have carefully noted it.

viii. The PI and Co-investigator(s) hereby submit the ICMR Declaration of Interest form in prescribed format.

ix. The name of the Statutory Audit Authority of our Institute is as follows: M/s. p V Chacko & Co, Chartered Accountant (Firm registration No.0005435), Palackal Court, M.G.Road, Cochin, Kerala

x. Registration/Unique ID no. assigned by NITI Ayog, GoI (on DARPAN Portal) (applicable only for NGOs): KL/2016/0108115

xi. CV of the investigator and Co-Investigators is/are attached in prescribed format.

	Name	Signature	Date
a)	Principal Investigator Dr Suseela Kundoly Velayudhan		24/02/2024
b)	Co-Investigator(s) Dr Iswarya Babu P		24/02/2024
	Dr Deepa Jolly		24/02/2024
c)	Head of the Department Dr Reena John		24/02/2024

ignature of the Head of the Institution with seal

ate: 24/2/2024

Dr. Sreeraj

Signed copy (missing)

A

n Council of Medical Research (ICMR)

Deptartment of Health Research

(Ministry of Health and Family Welfare)

Investigator-Initiated Research Proposals

Proposal in Draft Stage

Proposal Id: Not Generated Yet
Proposal Title: Feasibility of high fibre diet intervention in newly diagnosed multiple myeloma patietns and its effect on gut microbiome and myeloma control

Personal details of Principle Investigator (PI)

Name of PI (IN BLOCK LETTERS), Designation, Email, Contact No., Gender, DOB, Date of Superannuation	DR SREERAJ V, Assistant Professor, sreerajfleming@gmail.com,8826752985, Other, 28-01-1984, 31-01-2046
Nature of Employment	Permanent
Institute	Amala Cancer Research Centre, Private academic institutions with valid UGC/AICTE/PCI or NMC approved Medical colleges , UNDERPROCESS

Proposal Details PART-A

Are you currently under regular employment in Medical Institutes, Research Institutes, Universities, Colleges, recognized Research & Development laboratories, Government and semi-government organizations, and NGOs?	Yes
Advertisement	Call for Investigator-Initiated Research Proposals for small extramural grants - 2024

, ... the following subheadings. Rationale/ gaps in existing kn... ..dge, Novelty, Objectives, Methods, and Expected outcome.

... microbiome and role of dietary fibre in modification of gut microbiome have a role in cancer prevention,contro.Recommended dietary allowance o fibre is 30 to 40 gram per day.But average dietary fibre consumption is very low .Indian patients are keen on dietary modifications to be followed once diagnosed witl major illness like cancer because of the influence of ayurveda. Multiple myeloma(MM) is a common cancer in india. The incidence of cosntipation in MM is 23%.Afte MM diagnosis the fibre intake reduces for varying reason contributing to constipation. Recently Urvi sha etal showed high fibre plant based diet has better diseas control in MM patient in maintence chemotherapy. Novelty :No indian study perfomed high fibre diet intervention in induction therapy in MM or any active cancer.I feasible need randomised control trial to assess impact. Additional role of dietary intervention will be of great impact. Objective:Our study proposes for a feasibilt study of high fibre diet during intial induction treatment of multiple myeloma and look in the tolerability,safety,quality of life with high fibre dietary interventior (40gram/day) during induction chemotherapy to MM and exploratory outcome is to look in to the gut microbiome change and correlation with diease response Outcome:Tolerability and feasibility of high fibre diet,Change in gut microbiome and SCFA from baseline,correlation between SCFA change,Gut microbiome chang and disease response.

Priority Area/Priority Area diseases	Non-Communicable Diseases / NCD risk factors – diet,activity, alcohol, tobacco etc
Keywords Six keywords separated by comma which best describe your project may be provided.	Multiple myeloma,High fibre diet,Gut microbiome,Short chain fatty acids,butyrate,remission
Abbrevations Only standard abbreviations should be used in the text. List of abbreviations maximum of ten may be given as a list.	MM-Multiple myeloma RDA-Recommended dietary allowance SCFA-Short chain fatty acids VLD Bortezomib,Lenalidomide,Dexamethasone Dsat-45-45 item diet satisfaction quetionnaire GSRS Gastro intestinal symptoms rating scale CTCAE-Common terminology criteria for adverse event EORTC QLQ 30-European organisation for research and treatment of cancer quality of lif quetionnaire 30 PRO-Patient reported outcome

Problem Statement (up to 500 words): State

Indian patients are keen on dietary advise while diagnosed with maj

gut fibre.Recommended dietary allowance per day for dietary fibre is 40gram per day.But aver

fibre intake substantially reduces.Rice consuming ethnic group and women have lower average daily fibre intake. The

and its role in cancer control and prevention is well evident.Fibre in the diet influences the gut microb ne. Gut microbiome produces sho

fermentation of fibre in the gut. There is evidence that stool butyric acid (type of short chain fatty acid) produced by firmicutes actinobacteria,bacteriodeted and

fusobacteria orders have dierect immunomodulatory role and implicated in cancer prevention and control. There is recent study by Urvi sha et all and Pianko et al

showed butyrate producing gut microbiome have role in disease response in patients with multiple myeloma.The abundance of butyrate producers were correlated

with high fibre dietary intake. Multiple myeloma (MM) is a common cancer in india treated intially with immunomodulatory drugs like lenalidomide,proteosome

inhibitor like bortezomib with less impact on satiety and hunger making dietary intervention feasible in this group. The major problem with treatment is drug induced

contipation accounting to 25% of patients getting treatment. Average fibre intake of newly diagnosed MM patient is low due to various causes.Fibre rich diet will be

useful in relieving constipation. There are no indian studies looking in to role of dietary intervention as an additional treatment to chemotherapy in newly diagnosed

MM.Becuase the fibre rich diet is useful in chemotherapy related constipation,its role in gut microbiome change and associated disease control need furthe

exploration.Once feasible high fibre intervention should be tested in phase 3 randomised trial for confirmation of its additional role in cancer control.

Rationale of the study (up to 250 words) Mention how the research question addresses the critical barrier(s) in scientific knowledge, technical capability, and/or programmatic/ clinical/lab practic

and its relevance to local, national and international context with relevant bibliography.

Our research look in the role of fibre in change in gut microbiome and its role in disease control. We dont have indian data regarding the base line gut microbiome

profile in any cancer incluing MM. We also doesnt know about the levels of major short chain fatty acids produced by the gut microbiome. Although RDA for fibre i

indian recommendation is 40gram per day average indian diet is very low in fibre content.We need to know the feasibilty of high fibre diet (40gram /day) by modifyin

diet menu -Including nuts,pulses,legumes in diet in these patient. The tolerability,acceptability , complications of intervention need patient reported outcon

mesurements through various standardised questionaires. If high fibre diet is feasible and there is a correlation in change in gut microbiome to high fibre diet a

correlation with disease control , this will be a first study in the to look in to fibre intervention in active cancer control in MM which should pave way for phas

randomised control trial of fibre dietary intervention. Bibliography: 1.RDA for Indian -Reviewd 2024 .ICMR.NIN 2.Fibre content in indian diet,Singh.A,Asian journa

pharmaceutical and clinical research,Vol 8,no 3,May 2015,pp 58-61 3.Sun.J,Butyrate as promising therapeutic target in cancer,from pathogeneis to clinic,review,I

Oncol,2024 Feb 29,64(4)44 4.Pianko MJ,Minimal residual disease negativity in multiple myeloma is associated with intestinal microbiota composition,Blood adv.2

july 9,3(13)2040-4 5.Shah U,Sustained minimal disease negativity in multiple myeloma is associated with stool butyrate and healthier plant based diet,Clin Ca

Res.2022 Dec 1,28.(23),5149-55

Hypothesis/ Research question (up to 100 words) : Hypothesis: High fibre diet is toelrable,feasible and improve outcome in new MM patient taking ind

chemotherapy. Primary Objective:Establish the feasibility,tolerabiliy of high fibre diet in MM Secondary Objective: 1).To assess gut microbiome changes from b

after intervention. 2).To assess the changes in stool and serum SCFA from baseline after diet intervention 3).To assess the association between stool micr

changes with changes in SCFA and response in MM Design:Feasibilty study Intervention: Dietary menu suggestions based on legumes,pulses,nuts meeting prot

energy requirement with daily average fibre intake of 40gram per day during 4 months of VLD chemotherapy induction for newly diagnosed MM

Methodology

Include objective-wise work plan under the following sub-headings:

Study Objective No. 1

Study Objective : 1.To establish feasibility and tolerability of high fibre diet (40gram per day) in multile myeloma patients 2.To assess changes in Gut microbiome from baseline after introduction of high fibre diet to butyrate producing stool microbiome in MM patients recieving induction chemotherapy and correlate with disease response

Study Design : Feasibility /Phase I study

Study Area : Tertiary cancer hospital

Sample Size : 40 number.Sample size arrived from observationl studies.We feels sample size is adequate for feasible studies based on one observational studies 1)Sha U,Clin Cancer Research,2022.Deember.5149-55

Project Implementation Plan : We will recruit 1 patient per week for 18 months to aquire sample size.Inclusion criteria is all newly diagnosed MM patients less thar 60 years of age.Exclusion criteria is patients with contra indication for fibre,patients with renal failure.Once recruited participant will be teached for 40 gram fibre pe day .Diet diary maintence will be daily basis.Participants baseline stool sample will be freezed in -80degree for gut microbiome.Stool and serum sapmle will be processed for SCFA by Liquid chromatography/mass spectroscopy.Participants will be weekly reviewed by study dietician for veryfying diet diary,estimating previous week average daily fibre intake, participants will be asked to answer patient related outcome questionnaire GSRS,EORTC QoQ 30 weekly and Dsat45 Questionniare monthly.Advese events will be noted as per CTCAE adverse event grading on a weekly basis.Intercurrent antibiotics use will be noted on weekly review.Patients wil recive VLD chemotherapy induction for 4 month. At the end of 4 months MM disease response testing will be done.Along with that stool sample will be taken anc freezed for Gut microbiome.Stool and serum sample will be processed for SCFA estimation

Design of Statistical analysis : Feasibility outcome will be summarised descriptively using standard statistical techniques including means,median,ranges fo continous variables,frequncy and percentage for categorical measurements.Gut microbiome is assessed as relative abundance of each species.The levels and relative abundance will be summarised non parametrically using medins,interquartile ranges,compared with baseline using wilcoxon signed rank test.SCFA levels and changes will be summarised using means and standrad deviation,compared with baseline by paired t test.The association between gut microbiome changes and SCFA levels and changes will be explored using spearman correlation coeeficient.A two tailed p value less than 0.05 will be taken as statistical significance.SPSS version 29 will be used.The association between Microbiome levels and changes and disease response using spearman's correlation coefficient

Expected outcome/ Deliverables aligned with assessed by 1)Percentage of days of diet recommendations followed. 2)Percentage 3)Percentage of patients with tolerability based on DSat-45 quetionnaire monthly. 4)Average daily fibre intake microbiome alpha deveristy from baseline. 2)Percentage of patients with relative abundance of butyrate producers at 4 months intervention serum/stool SCFA after 4 months of intervention Exploratory outcome: 1)Correlation between disease response to changes in SCFA levels and Changes in Gut microbiome after 4 months of induction

Immediate next steps following the end of the project(up to 100 words): Once feasible and found to have correlation with MM outcome will proceed with phase II/Phase III randomised contro trial to estblish treatment effect

Whether the study is going to generate new intellectual property: No

Download

Timelines with achievable targets

Proposal Details (PART-B)

Preliminary work done by the PI including the source of funding (up to 250 words): No

Skill and experience of the research team (Highlight only salient points (along with 5 relevant publications) that provides confidence to reviewers that team can implement the project with quality.) : Co PI Dr.Sunu Cyric heads the clinical research unit funded by BIRAC conducting phase 4 clinical trials. Co PI Dr.Manu Aryan heads the translational immunology lab in cancer research with interest in stem cell biology,cancer immunology,GI cancer and editor in various journals.He heads the gut microbiome lab in our centre.

Institutional Support/ Facilities: We have BIRAC funded clinical research unit which conduct phase IV clinical trials and other trials in our institute.Co PI Dr.Sunu heads the CRU. We have gut microbiome research lab in our centre.Dr.Manu Aryan heads the gut microbiome lab

Laboratory facilities (in-vitro/ in-silico) Institutional resources such as instruments/ equipment and other physical resources available for use in the project proposed animal house etc. Our centre have Gut microbiome centre with Oxford nanopore facilty Our biochemistry department will be able to process stool and serum sample for SCF testing We will partner with neibhouring Kerala Veteniary science university (Within 20 km) for Liquid chromatography and mass spectroscopy We have -80 degr freezer for sample storgae

Conflict of Interest declaration (if any) nil

18 Months

Duration (in Months)

Investigator Details

#	Name	Institute	Designation	Email	Contact No.	Role in Proposal
1	Dr sreeraj v	Amala Cancer Research Centre	Assistant Professor	sreerajfleming@gmail.com	8826752985	PI
2	Dr Sunu Lazar Cyriac	Amala Institute of Medical Sciences	Associate Professor	drsunucyriac@gmail.com	9567602426	Co-PI
3	Dr Manu Kanjoormana Aryan	Amala Cancer Research Centre	Assistant Professor	manu.aryan@amalaims.org	7356410639	Co-PI
4	Dr Reena K Chittilappilly	Amala Institute of Medical Sciences	Manager	reenadiet@gmail.com	9633681802	Co-PI
5	Dr Sreejith J Kishore	Amala Institute of Medical Sciences	Assistant Professor	sjkofficial89@gmail.com	9447308523	Co-PI

Documents consideration

#	Document Name	Is Applicable?	Uploaded Document	Remarks
1	Declaration & Attestation Form(duly signed by Head of Department/ Director)	Yes	View	Certicate issued by director,amala cancer hospital society
2	Additional supplementary information including figures tables flow diagrams etc can be shared as PDF	Yes	View	PDF showing table of sequence of events of study particpants with time point

Institute	Budget Year	Manpower Budget (Rs.)	Contingency	Consu...				
Amala Cancer Research Centre	1	0	0	0	0	0	0	0
Amala Institute of Medical Sciences	1	1497120.00	445000.00	35000.00	109200.00	40000.00	0	2126320
Amala Cancer Research Centre	2	0	0	0	0	0	0	0
Amala Institute of Medical Sciences	2	1120480.00	655000.00	35000.00	0	40000.00	0	1850480
Total in (Rs.):		**2617600**	**1100000**	**70000**	**109200**	**80000**	**0**	**3,976,800.**

Budget Breakup Details (Staff/Manpower)

#	Budget Year	Institute	Designation	No. of Person(nos)	Require Month(nos)	Cost Per Person(Rs.)	Overhead(Rs.)	Cos
1	**Year: 1**	Amala Institute of Medical Sciences	Data Entry Operator	1	12	29,200	0.00	350,

2,61

Justification :for data collection

Total Cost (Rs.)

including overhead

Total(Rs)

Budget Breakup Details (Staff/Manpower)

2	**Year: 1**	Amala Institute of Medical Sciences	Project Technical Support - III	1	12	32,480	0.00	389,760.00

Justification :for performing microbiome and SCFA at lab with transportation

3	**Year: 1**	Amala Institute of Medical Sciences	Senior Project Assistant	1	12	30,600	0.00	367,200.00

Justification : For project management and team cordination

4	**Year: 1**	Amala Institute of Medical Sciences	Project Technical Support - III	1	12	32,480	0.00	389,760.00

Justification :for preparation of diet menu,follow up, counselling,Monitoring

5	**Year: 2**	Amala Institute of Medical Sciences	Data Entry Operator	1	8	29,200	0.00	233,600.00

Justification :for data collection

6	**Year: 2**	Amala Institute of Medical Sciences	Project Technical Support - III	1	8	32,480	0.00	259,840.00

Justification :for performing microbiome and SCFA at lab with transportation

7	**Year: 2**	Amala Institute of Medical Sciences	Senior Project Assistant	1	12	30,600	0.00	367,200.00

Justification : For project management and team cordination

Total Cost (Rs.) **2,617,600.00**

including overhead

Budget Breakup Details (Staff/Manpowe

8	**Year: 2**	Amala Institute of Medical Sciences	Project Technical Support - III	1	8	32,480	0.00	259,840.00

Justification :for preparation of diet menu,follow up, counselling,Monitoring

2,617,600.00

Total Cost (Rs.)
including overhead

Contingency budget breakup details

#	Budget Year	Institute	Overhead Charges (Rs.)	Total Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences	0.00	320,000.00

Contingency Name : Stool Microbiome

Justification : Stool microbiome testing at base line and end of 4 months for 20 patients in first year

2	**Year: 1**	Amala Institute of Medical Sciences	0.00	25,000.0

Contingency Name :contigency fund

Justification :contigency fund for first year

3	**Year: 1**	Amala Institute of Medical Sciences	0.00	100,000

Contingency Name : Printing questionnaire

1,100,00(

Total Cost (Rs.)
including overhead

budget breakup details

Justification :4 quetioonaire per patient per week for 20 patients

4	**Year: 2**	Amala Institute of Medical Sciences	0.00	320,000.00

Contingency Name : Stool microbiome testing

Justification :stool microbiome testing at baseline and end of 4 months for 20 patients

5	**Year: 2**	Amala Institute of Medical Sciences	0.00	50,000.00

Contingency Name : Publishing fees

Justification : Article publishing fees

6	**Year: 2**	Amala Institute of Medical Sciences	0.00	100,000.00

Contingency Name : Article processing fees

Justification : Article processing fees

7	**Year: 2**	Amala Institute of Medical Sciences	0.00	25,000.00

Contingency Name :contigency fund for second year

Justification :contigency fund for second year

8	**Year: 2**	Amala Institute of Medical Sciences	0.00	160,000.00

Total Cost (Rs.)
including overhead

1,100,000.00

Contingency budget breakup details

Contingency Name : Stool and serum SCFA mesurement

Justification : Per person 4 times testing of SCFA serum and stool based on liquid chromatography/mass spectroscopy.approximately 20 patient recruitemnt in second year

Total Cost (Rs.) **1,100,000.00**

including overhead

Consumables Budget Breakup Details

#	Budget Year	Institute	Consumables Name	Overhead	Total Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences	Dry ice for transportation	0.00	10,000.00
Justification : dry ice for sample transportation					
2	**Year: 1**	Amala Institute of Medical Sciences	office stationary	0.00	25,000.00
Justification : office stationary					
3	**Year: 2**	Amala Institute of Medical Sciences	Dry ice for sample transportation	0.00	10,000.00
Justification : dry ice purchase					
4	**Year: 2**	Amala Institute of Medical Sciences	office stationary	0.00	25,000.00
Justification : office stationary					

Total Cost (Rs.) **70,000.00**

including overhead

Equipment Budget Breakup Details

#	Budget Year	Institute	Equipment Name	Equipment Model	Equipment Manufacturer	Equipment Type	Total Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences	Printer			Domestic	15,000.00

Justification :for office purpose

Mode of Proposed disposal : As per electronic waste disposal policy of hospital

2	**Year: 1**	Amala Institute of Medical Sciences	Laptop/Desktop		Dell	Domestic	75,000.00

Justification : For Data collection

Mode of Proposed disposal : As per electronic waste disposal policy of hospital

3	**Year: 1**	Amala Institute of Medical Sciences	Deep frezer stool sample container			Domestic	16,000.00

Justification :100 rupees per unit x 160 units

Mode of Proposed disposal :as per hospital waste disposal policy

4	**Year: 1**	Amala Institute of Medical Sciences	Blood and stool sample container for SCFA estimation	Serum sample container for		Domestic	3,200.00

Justification :20 rs per vial x 160 sample

Total (Rs.): 109,200.00

Mode of Proposed disposal :as per hospital waste disposal policy

Total (Rs.): **109,200.00**

Travel Justification

#	Year	Amount(Rs.)
1	**Year: 1**	40000.00

Justification :1000 rs per travel for 2 times for each patient ,for 20 participants

2	**Year: 2**	40000.00

Justification :1000 rs per travel for 2 times for each study participant ,20 participants in second year

Total: **80,000.00**

Short resume PI/Co-PI

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
Dr Sreejith J Kishore	1989-06-09	biochemistry	0	0	society of clinical biochemitry	Co-PI

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications
Randomised control trial of effectiveness of pain control with sublingual buprenorphine versus oral tramadol	PI	icmr	11600000.00	Ongoing

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date

Name of PI/Co-Pi	**DOB**	**Domain Expertise**	**Number of articles in Pub Med (Past 10 years)**	**h-index**	**Fellow of Academics**	**Role in Proposal**
Dr Manu Kanjoormana Aryan	1980-12-11	cancer immunology,cancer stem cells	13	24	Indian association of cancer research,American association of cancer research,European association of cancer research	Co-PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization products where cited.

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
Dr Sunu Lazar Cyriac	1976-06-10	cell therapy,stem cell transplantation, leukemia	13	9	ASCO,ESMO, ASH	Co-PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.

Short resume PI/Co-PI

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications
Effect of VCNO on inhibition of inflammatory bowel disease in mice	PI	Target institute of medical education and research	1000000.00	Prabha.S,Virgin coconut alleviate dextran sulphate induced inflammatory bowel disease and modulate inflammation and immune response in mice,J Am Nutr Asso,2023,Oct 31,1-11,
study the role of APT2 mediated SCRIB depalmytyloation on regulating self renewal ability ,tumorigenicty ,therapy resistance in breast cancer	PI	DST-SERB	2900000.00	Ongoing

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date

Name of PI/Co-Pi	**DOB**	**Domain Expertise**	**Number of articles in Pub Med (Past 10 years)**	**h-index**	**Fellow of Academics**	**Role in Proposal**
Dr sreeraj v	1984-01-28	Hematology,Acute leukemia,Myeloma	0	0	Member of Indian society of hematology and blood transfusion	PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date

Declaration

☑ I hereby declare that the entries in this form and the additional particulars, if any, furnished herewith are true to the best of my knowledge and belief. I understand that in the event of my information being found false or incorrect at any stage, my project/proposal shall be liable to cancellation / termination without notice or any compensation in lieu thereof.

☑ I hereby certify that the research proposal I have submitted to ICMR, New Delhi, for potential funding is entirely my original idea and has not been copied or replicated from any other source. Furthermore, I confirm that this proposal has undergone scrutiny using a standard plagiarism detection tool, verifying its originality and confirming that its contents have not been directly taken from any other sources. Additionally, I declare that there have been no established or pending plagiarism charges against me in the last five years.
In the event that the funding agency identifies any form of plagiarism or inconsistencies in the aforementioned proposal, I acknowledge and agree to comply with any actions deemed necessary by ICMR. I take full responsibility for any such discrepancies and will adhere to the consequences as required.

Annexure V

Ref. ICMR-Call for Application: CALL FOR INVESTIGATOR-INITIATED RESEARCH PROTOCOL FOR SMALL EXTRAMURAL GRANTS

Title of the project: FEASIBILITY OF HIGH FIBRE DIETARY INTERVENTION IN NEWLY DIAGNOSED MULTIPLE MYELOMA PATIENTS AND ITS EFFECT ON GUT MICROBIOME AND DISEASE REMISSION

Name of the PI: DR. SREERAJ V

Name of the Institute: AMALA INSTITUTE OF MEDICAL SCIENCES, THRISSUR

Declaration & Attestation

We hereby certify that:

i. We have read the terms and conditions for ICMR Research Grant. All necessary Institutional facilities will be provided if the research project is approved for financial assistance.

ii. The equipment(s) that is being requested as part of this project is/are not available in the Institute/Department/ or these are available and are being used at full capacity (Strike off the appropriate one)

iii. The equipment(s) requested as part of this project have not been purchased earlier from the funds provided by ICMR for the previous project(s) in the Institute.

iv. No utilization certificate (UC)/ statement of expenditure (SoE) final report is pending for earlier ICMR project(s) under the PI and the final report(s) for earlier projects have been submitted.

v. The project has not been submitted to any funding agency or institution other than the ICMR.

vi. The PI does not have more than 5 (five) ICMR projects at present as a Principal Investigator.

vii. We understand that ICMR shall only fund for the project positions, as enumerated in the criteria for engagement of Non-Institutional Project Human Resource Positions, purely on temporary contractual basis. ICMR has appraised us of this rule and we have carefully noted it.

viii. The PI and Co-investigator(s) hereby submit the ICMR Declaration of Interest form in prescribed format.

ix. The name of the Statutory Audit Authority of our Institute is as follows:
P V CHACKO & CO, CHARTERED ACCOUNTANTS, PALACKAL COURT, M.G. ROAD, EKM, PIN 682035

x. Registration/Unique ID no. assigned by NITI Ayog, GoI (on DARPAN Portal) (applicable only for NGOs): KL/2018/0193553 - AMALA CANCER HOSPITAL SOCIETY

xi. CV of the investigator and Co-Investigators is/are attached in prescribed format.

	Name		Signature	Date
a)	Principal Investigator	Dr. SREERAJ V		11/3/24
b)	Co-Investigator(s)	Dr. SUNU CYRIAC		12/MAR/2024
c)	Head of the Department	Dr. ANIL JOSE		12/03/2024

Signature of the Head of the Institution with seal

Date: 13-03-2024

Fr. Julious Arakkal CMI
Director

AMALA INSTITUTE OF MEDICAL SCIENCES THRISSUR

E-mail: amalamch@amalaims.org
Web : www.amalaims.org

Phone : +91 487 2304000
FAX : +91 487 2307020

AMALA CANCER HOSPITAL SOCIETY

(Registered as a Society by Sl. No. 51/1978)
Amala Cancer Hospital Complex
Amalanagar, Thrissur - 680 555, Kerala

No. ACHS/ADM(a)/391/2024

21.02.2024

COPY OF RESOLUTION FOR REAPPOINTMENT OF THE STATUTORY AUDITORS

This is to certify that the following resolution is passed at the Administrative Committee of the Society Held on 21.02.2024 and has been duly recorded in the minute book of the Society.

"Resolved that the Auditors M/s. P V Chacko & Co, Chartered Accountants (Firm registration No.000543S), Palackal Court, M.G.Road, Cochin, Kerala is reappointed as the Statutory Auditors of Amala Cancer Hospital Society for the next financial year."

Fr. Julious Arakkal J. CMI

Director

A

Indian Council of Medical Research (ICMR)

Deptartment of Health Research

(Ministry of Health and Family Welfare)

Investigator-Initiated Research Proposals

Date of submission: 07-Mar-2024 11:19:59 PM

Proposal Id: IIRPSG-2024-01-02276, **Version Id:** F1,
Proposal Title: A Comprehensive Approach to Detect and Combat Substance Abuse among School Going Children in Thrissur District, Kerala.

Personal details of Principle Investigator (PI)

Name of PI (IN BLOCK LETTERS), Designation, Email, Contact No., Gender, DOB, Date of Superannuation	DR SRUTHI M V, Associate Professor, sruhar086@gmail.com,9495966828, Female, 04-11-1986, 09-12-2057
Nature of Employment	Permanent
Institute	Amala Institute of Medical Sciences , Private academic institutions with valid UGC/AICTE/PCI or NMC approved Medical colleges , YES (01-Jan-1970)

Proposal Details PART-A

Are you currently under regular employment in Medical Institutes, Research Institutes, Universities, Colleges, recognized Research & Development laboratories, Government and semi-government organizations, and NGOs?	Yes
Advertisement	Call for Investigator-Initiated Research P...

Summary (up to 250 words): A structured summary should contain the following subheadings: Rationale/ gaps in existing knowledge, Novelty, Objectives, Methods, and Expected outcome.

Drug abuse is a complex phenomenon, which has various social, cultural, biological, geographical, historical and economic impact on human life. Today, there is no part of the world that is free from the curse of drug trafficking and drug addiction. Millions of drug addicts, all over the world, are leading miserable lives, between life and death. There are paucity in research on early screening of drug usage among adolescents. Most of the previous research were looking on self-reported usage of substance abuse, where most of the data would be under reporting. Increasing the awareness on substance abuse were the only means to tackle this problem in younger generation. A comprehensive approach which include preventive, promotive, curative and rehabilitative service is novel approach in order to compact against this drug menace. The target population in this comprehensive approach is not only the school going adolescents but it include their parents, and school teachers. The laboratory detection of drug among adolescents is also another novel method which can be incorporated in school screening programme that can tackle the substance abuse. Hence this proposal is undertaken with a goal to make Thrissur district in Kerala drug free by adopting this comprehensive strategy. We expect through this comprehensive approach would help us to identify the real problem of drug abuse among adolescents. With the help of teachers and parents we can save the future generation from restrain from drugs.

Priority Area/Priority Area diseases	Reproductive, Maternal and Child Health, Nutrition / Adolescent health
Keywords Six keywords separated by comma which best describe your project may be provided.	Drugabuse, Adolescent, Kerala, , Anti-drug Task force
Abbrevations Only standard abbreviations should be used in the text. List of abbreviations maximum of ten may be given as a list.	WHO- World Health Organization , DAST- A- Drug Abuse Screening Test - Adolescent version. UNODC - United nations office on drugs and crime

Problem Statement (up to 500 words): State tl irrently available information to present the problem adequately.

Drugs and substance abuse has become a worldwide public health crisis. The abuse of drug is an international problem, which affects almost every country in the world. The World Health Organization defines drug as any substance which introduced into the living organism, can modify one or more of its functions. Drug use is defined as consumption of drug that does not negatively impact health. Drug consumption becomes abusive at the appearance of dependence, which is defined as the set of physiological, behavioural and cognitive manifestations in which the use of a drug is a priority for the individual. (1) The WHO's ICD defined substance abuse as a blanket term to include 10 separate classes of drugs, including alcohol, caffeine, cannabis, hallucinogens, inhalants, opioids, sedatives, hypnotics, and anxiolytics, stimulants, tobacco, and other substances.(2) it include both licit and illicit drugs. The licit drugs are those drugs which are within the law or anything that is legal. Eg: Tobacco, alcohol, caffeine and prescription medication. The illicit drugs are those drugs that are illegal or forbidden. Eg cannabis, heroin, opioids, cocaine, ecstasy. Drug addiction causes immense human distress and the illegal production and distribution of drugs have spawned crime and violence worldwide. According to world Drug Report 2022 by UNODC in 2022 about 284 million people aged 18-64 years are using illicit drugs. The usage of drugs showed an increasing trend of 26% over the past decade, with more users belonging to younger generate. Globally 8.7 million death is caused by tobacco use, 2.4 million deaths were due to alcohol use and 0.5 million deaths were due to illicit drug use. The Cannabis remains the world's most used drug. An estimated 209 million people used cannabis, 61 million people used opioids. Opioids remain the most lethal group of drugs, accounting for two thirds of deaths related directly to drugs, mostly due to over dosage. An estimated 21.5 million people used cocaine opioids, sedatives, and tranquilizers. (3) India too is caught in this vicious circle of drug abuse, and the number of drug addicts are increasing day by day. Tobacco use is a major preventable cause of premature death and disease worldwide. Nearly 1.35 million people die in India every year due to tobacco use.(4) . According to NFHS 5(2019-21) 38% of men were using any kind of tobacco Prevalence of alcohol consumption among men in India is 29.2%.(5). Cannabis, heroin, and Indian-produced pharmaceutical drugs are the most frequently abused drugs in India. A survey done in India by UNDOC showed that 36% were using heroin, 22% were using cannabis, 29% were using other opiates.(6) According to national crime record bureau report, Punjab ranks first in reporting maximum number of cases of drug trafficking .India witness 10 suicides every day related to drug abuse and one of them is from Punjab. The states of Maharastra, Madhya Pradesh, Tamil Nadu, and Kerala are at the top of the table of drug related suicide. (7)

Rationale of the study (up to 250 words) Mention how the research question addresses the critical barrier(s) in scientific knowledge, technical capability, and/or programmatic/ clinical/lab practice and its relevance to local, national and international context with relevant bibliography.

Drug abuse is a complex phenomenon, which has various social, cultural, biological, geographical, historical and economic aspects. The disintegration of the old joint family system, absence of parental love and care in modern families where both parents are working, decline of old religious and moral values etc lead to a rise in the number of drug addicts who take drugs to escape hard realities of life. The processes of industrialization, urbanization and migration have led to loosening of the traditional methods of social control rendering an individual vulnerable to the stresses and strains of modern life. Drug abuse has led to a detrimental impact on the society. It has led to increase in the crime rate. Drugs remove inhibition and impair judgment egging one on to commit offences. Incidence of eve- teasing, group clashes, assault and impulsive murders increase with drug abuse. Apart from affecting the financial stability, addiction increases conflicts and causes untold emotional pain for every member of the family. A comprehensive approach which include the screening of school children for detecting symptoms or behavioural problems of drug abuse along with laboratory confirmation is a novel method for early detection of drug users among children. Substance abuse is often considered as a sensitive, stigmatized, shameful and even illegal act, hence self-reporting may cause subject bias 12. Numerous studies have shown that self-reported information about substance use cause underreporting in comparison with biological tests(13,14) Laboratory diagnosis of drug abuse gains importance in this present scenario. Since many drugs are lipid soluble, they must undergo metabolism in the liver to render them water soluble which then allows them to be eliminated in urine. Blood and breath reflect moment-to-moment serum levels of an ingested substance, and offer the earliest and shortest windows of detection for substances 15. Urine offers a somewhat longer window of detection for substances, usually varying from one day after consumption to several weeks. Urine tests are highly accurate for cannabinoids and cocaine, the two most frequently abused drugs. There are two types of urine drug screens. The first, called the immunoassay, is cost-effective and gives results fairly quickly. If first test comes back positive, a follow-up test known as gas chromatography/mass spectrometry (GC/MS) is done for confirmation. The target population for comprehensive approach against drugs are school going children, school teachers and caregivers/parents of school going children. Hence in order to save our future generation this project is aiming to adopt a comprehensive strategy to detect and combat the drug abuse among school going children in Thrissur district, Kerala. Our ultimate goal is to achieve drug free status among our school going children in Thrissur district, Kerala

Hypothesis/ Research question (up to 100 words) : Will comprehensive strategy can detect and combat against drug abuse among school going children in Thrissur district and can achieve a drug free district status in Kerala

Methodology

Include objective-wise work plan under the following sub-headings:

Study Objective No. 1

Study Objective : 1. To screen school going children symptomatically for drug abuse using DAST- A questionnaire. 2. To screen school going children for detecting presence of illicit drugs in urine using urine immunoassay method 3. To form Anti-drug task forces in each schools for identification of drug addicts and for creating awareness.

Study Design : Quasi –Experimental study design

Study Area : School based study

Sample Size : The sample size was calculated using the formulae Z (1-α/2)2 p q / d2 The parameter used for calculation is 'p', the prevalence of self-reported narcotics use among youth in Central Kerala as 2.98% .(15) Sample size was calculated p2.98% q100-p 97.02 d relative Precision, taken as 20% of the prevalence Sample size 3258 Taiking 10% as non response rate, calculated sample size – 3583 Sampling Technique: Multistage random sampling would be used for this study. In the first stage, the list of Government upper primary and high schools, Government Aided upper primary and high schools and CBSE upper primary and high schools in Thrissur district would be prepared. From this list, 6 school from each category would be selected randomly by lottery method. From each selected school, 200 students would be selected. In the second stage, from each standard (5,6,7,8,9,10) one division would be randomly selected and from each division 35 students would be included in the study.

Methodology

Include objective-wise work plan under the following sub-headings:

Project Implementation Plan : Implementation strategy a) Screening strategy From each school, selected number of adolescent would be screened symptomatically for assessing the drug usage. Drug abuse screening test – Adolescent version(DAST- A) self-administered questionnaire is used for screening drug abuse among study population. It contain 20 questions on potential involvement of adolescent with drugs in past 12 months, not including alcoholic beverages. The score above 6 is considered as substance use problem. The school children urine would be collected obeying the testing procedure with help of a laboratory technician for detecting the presence of drugs. The urine drug screening test would be done using immunoassay method. Once we detect drug abuse among adolescent children either by symptomatic screening or by laboratory method, the referral service to higher centres would be provided for de-addiction. b) Health Education In order to prevent further drug abuse among school children , we are planning to conduct awareness sessions in all government, aided and CBSE schools in Thrissur districts. Awareness sessions include various health related effects, social issues concerned with drug abuse, initial symptoms or signs of drug addicts for early detection. The awareness classes would be held by expert faculty from community medicine and psychiatry department. The separate sessions would be there for parents, teachers and for students. c) Other activity In order to make students understand about the ill effects of drug abuse, along with awareness sessions we are planning to do flash mob, skits , short films mime containing the message of not taking drugs. d) Interactive activity in school We would arrange various competitions like poster competition, essay competition for school children at school level in order to reinforce our message of no drug use. e) Teachers training programme- District Level Arrange one week teachers training programme at district level involving 2 high school 2 Upper primary teachers from each selected schools. The training programme would discuss about various issues, methods of drug abuse prevalent in schools and also give training on how to detect drug addicts at early stage by faculty from Psychiatry department. f) Formation of Anti Drug Task Force at each school We are planning to built an anti drug task force with headmaster as chairperson, 4 teacher from same school who had undergone training at district level, 4 school children (4 girls 4 boys) and child psychologist either posted in the school (if not posted from our institution psychologist would be a member) and one member from PTA Association. The aim of this task force is to identify early, those students who are drug addicts and to report them to psychiatrist or child psychologist for de-addiction and to prevent further use of same drugs among their peer groups..

Design of Statistical analysis : Data would be entered in Microsoft excel. Data will be analysed using SPSS version 23. Descriptive analysis like mean, standard deviation, median and proportions will be used. Appropriate statistical measures would be used for analysis

Expected outcome/ Deliverables aligned with research question (up to 100 words): The comprehensive strategy involving school children, their parents and teachers for early detection of drug users with laboratory confirmation would identify the real problem of drug abuse among school children.The preventive measures including health awareness sessions, and other school level competitions would change the adolescent behaviour on drug use and would help to groom younger generation free of drugs. The formation of Anti-drug task force in each school would continue the drug free status by early detection by trained teachers and routine surveillance of drug use among their peer group by volunteered children itself

...ing the end of the project(up to 100 words): Screening for drug usage among school children by their teachers and random testing of urine for detection of dr...need to be implemented in every schools Kerala in order to tackle drug menace. The formation of Anti-drug Task force in every schools in Kerala also would help in preventing, promoting and rehabilitative services in maintaining drug free status throughout the year.

Whether the study is going to generate new intellectual property: yes

Timelines with achievable targets Download

Proposal Details (PART-B)

Preliminary work done by the PI including the source of funding (up to 250 words): Nil

Skill and experience of the research team (Highlight only salient points (along with 5 relevant publications) that provides confidence to reviewers that team can implement the project with quality.) **:** yes 14. Kumar SS, Kamaladevi LV, Valsan SM. Utilization of diabetic retinopathy screening among diabetic patients at a tertiary care hospital in Kerala, India. Int J Community Med Public Health 20218:4938-43 15. Teenu S R, Sruthi M V, C R Saju, M Mohammed Rafi The Role of Health Education on Larval Indices and Fever Cases from Rural Area of Thrissure District, Kerala: A Quasi Randamized Control Study. Clinical Medicine And Health Research Journal, Vol. 2 No. 2 (2022), 28 March 2022 , Page 87-91https://cmhrj.com/index.php/cmhrj/article/view/38 16. Nithya M C, Sruthi M V, C R Saju, Mohammed Rafi. A Study on Mosquito Density and Trend of Larval Indices from a Hospital Campus of Rural Area, Thrissur District Kerala. International Journal of Multidisciplinary research and analysis 202205(7): 1620-1625. 17. Jose NK, Sruthi MV, Rachel J, Jerome K, Vaz C, Saju CR. Barriers and facilitators of noncommunicable disease (NCD) prevention in Kerala: A qualitative study. J Family Med Prim Care. 2022 Jun11(6):3109-3114. doi: 10.4103/jfmpc.jfmpc147121. Epub 2022 Jun 30. PMID: 36119306 PMCID: PMC9480671. 18. Paul AS, Saju CR, Sruthi MV, Varghese TC, Jini MP (2023) A Study On Sexual And Reproductive Health Communication Between Adolescents And Parents Among High School Students In Thrissur District, Kerala. J Comm Med And Pub Health Rep 4(03): Https://Doi.Org/1

Institutional Support/ Facilities: Coordination between clinical departments especially with Department of Psychiatry

Laboratory facilities (in-vitro/ in-silico) Institutional resources such as instruments/ equipment and other physical resources available for use in the project proposed animal house etc.
Nil

Conflict of Interest declaration (if any) NIL

Duration (in Months) 24 Months

Investigator Details

#	Name	Institute	Designation	Email	Contact No.	Role in Proposal
1	**Dr Sruthi M V**	**Amala Institute of Medical Sciences**	**Associate Professor**	**sruhar086@gmail.com**	**9495966828**	**PI**
2	Dr Steffi Francis Maliakel	Amala Institute of Medical Sciences	Assistant Professor	steffimaliakel@gmail.com	9539116548	Co-PI
3	Dr SANDRA PAULSON	Amala Institute of Medical Sciences	Assistant Professor	sandrajobin28@gmail.com	9495579656	Co-PI

Documents consideration

#	Document Name	Is Applicable?	Uploaded Document	Remarks
1	Declaration & Attestation Form(duly signed by Head of Department/ Director)	Yes	View	nil
2	Additional supplementary information including figures tables flow diagrams etc can be shared as PDF	Yes	View	DAST A 10 item screening tool used among adolescent for screening drug abuse.

Proposed Budget Details

Institute	Budget Year	Manpower Budget (Rs.)	Contingency	Consumables	Equipment	Travel	Overhead	Total(Rs)
Amala Institute of Medical Sciences	1	3418400.00	5000.00	113000.00	3583000.00	120000.00	0	7239400

Proposed Budget Details

Institute	Budget Year	Manpower Budget (Rs.)	Contingency	Consumables	Equipment	Travel	Overhead	Total(Rs)
Amala Institute of Medical Sciences	2	2354400.00	190000.00	0	0	60000.00	0	2604400
Total in (Rs.):		**5772800**	**195000**	**113000**	**3583000**	**180000**	**0**	**9,843,800.00**

Budget Breakup Details (Staff/Manpower)

#	Budget Year	Institute	Designation	No. of Person(nos)	Require Month(nos)	Cost Per Person(Rs.)	Overhead(Rs.)	Total Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences	Data Entry Operator	1	12	29,200	0.00	350,400.00
Justification :data entry								
2	**Year: 1**	Amala Institute of Medical Sciences	Project Technical Support - II	2	12	20,000	0.00	480,000.00
Justification : For counselling and rehabilitative services								
3	**Year: 1**	Amala Institute of Medical Sciences	Project Research Scientist - I (Medical)	1	12	67,000	0.00	804,000.00

Total Cost (Rs.)
including overhead

5,772,800.00

Budget Breakup Details (Staff/Manpower)

Justification :For Training school teachers on early identification of drug users among school children

4	**Year: 1**	Amala Institute of Medical Sciences	Project Technical Support - II	1	1	20,000	0.00	20,000.00

Justification :For Collecting urine sample and laboratory analysis

5	**Year: 1**	Amala Institute of Medical Sciences	Project Reseach Scientist - II (Non Medical)	1	12	67,000	0.00	804,000.00

Justification :For monitoring the field activities and for supervision

6	**Year: 1**	Amala Institute of Medical Sciences	Project Research Scientist - II (Medical)	1	12	80,000	0.00	960,000.00

Justification :For guidance and smooth conduction of project and for achieving the study objectives, data collection, monitoring the activities and for analysis.

7	**Year: 2**	Amala Institute of Medical Sciences	Data Entry Operator	1	12	29,200	0.00	350,400.00

Justification :data entry

8	**Year: 2**	Amala Institute of Medical Sciences	Project Technical Support - II	1	12	20,000	0.00	240,000.00

Total Cost (Rs.) **5,772,800.00**

including overhead

...mple and laboratory analysis

9	**Year: 2**	Amala Institute of Medical Sciences	Project Reseach Scientist - II (Non Medical)	1	12	67,000	0.00	804,000.00

Justification : For monitoring the field activities and for supervision

10	**Year: 2**	Amala Institute of Medical Sciences	Project Research Scientist - II (Medical)	1	12	80,000	0.00	960,000.00

Justification : For guidance and smooth conduction of project and for achieving the study objectives, data collection, monitoring the activities and for analysis.

Total Cost (Rs.)
including overhead

5,772,800.00

Contingency budget breakup details

#	Budget Year	Institute	Overhead Charges (Rs.)	Total Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences		

Contingency Name : Sensitization and training of PI and (along with tea) — 0.00 — 5,000.00

Justification : For explaining the purpose and scope of research

2	**Year: 2**	Amala Institute of Medical Sciences		

Total Cost (Rs.)
including overhead — 0.00 — 160,000.00

195,000.00

Contingency budget breakup details

Contingency Name : Conference Presentation

Justification :for presenting the impact of our project

3	**Year: 2**	Amala Institute of Medical Sciences	0.00	30,000.00

Contingency Name : Article Publishing Charges

Justification : For publishing the research in a peer-reviewed journal with high impact factor

Total Cost (Rs.) **195,000.00**
including overhead

Consumables Budget Breakup Details

#	Budget Year	Institute	Consumables Name	Overhead	Total Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences	IEC and conventional health education materials organizing interactive activity in schools. Rs 2000 per school. Total 18 schools would be there	0.00	36,000.00

Justification : For dissemination of information, awareness on drug abuse

2	**Year: 1**	Amala Institute of Medical Sciences	Translation of questionnaire	0.00	5,000.00

Justification : for screening drug abuse among school children using screening questionnaire tool

Total Cost (Rs.) **113,000.00**
including overhead

Consumables Budget Breakup Details

3	**Year: 1**	Amala Institute of Medical Sciences	72 Training Modules for training teachers. Rs 1000 per module	0.00	72,000.00

Justification : For dissemination of knowledge and skill on early detection of drug addicts among school children

Total Cost (Rs.)
including overhead **113,000.00**

Equipment Budget Breakup Details

#	Budget Year	Institute	Equipment Name	Equipment Model	Equipment Manufacturer	Equipment Type	Total Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences	Urine Drug Screening Kit	5 panel rapid drug test		Domestic	3,583,000.00

Justification : Laboratory confirmation of drug use

Mode of Proposed disposal :biomedical waste

Total (Rs.): 3,583,000.00

Travel Justification

#	Year	Amount(Rs.)
1	**Year: 1**	60000.00

Justification :school visits and surveys and other interventions

Total: **180,000.00**

2	**Year: 1**	60000.00
Justification : Visiting ICMR Hqrs for meetings and discussion		
3	**Year: 2**	60000.00
Justification :school visits for implementation of our goal		
Total:		**180,000.00**

Short resume PI/Co-PI

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
Dr Sruthi M V	1986-04-11	Public Health, Maternal and Child Health	1	2	nil	PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.
Paul AS, Saju CR, Sruthi MV, Varghese TC, Jini MP (2023) A Study on Sexual and Reproductive Health Communication Between Adolescents and Parents Among High School Studentsin Thrissur District, Kerala. J Comm Med and Pub Health Rep 4(03): https://doi.org/10.38207/JCMPHR/2022/JUN04030257	4.52	co author	nil

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date

Declaration

I hereby declare that the entries in this form and the additional particulars, if any, furnished herewith are true to the best of my knowledge and belief. I understand that in the event of my information being found false or incorrect at any stage, my project/proposal shall be liable to cancellation / termination without notice or any compensation in lieu thereof.

I hereby certify that the research proposal I have submitted to ICMR, New Delhi, for potential funding is entirely my original idea and has not been copied or replicated from any other source. Furthermore, I confirm that this proposal has undergone scrutiny using a standard plagiarism detection tool, verifying its originality and confirming that its contents have not been directly taken from any other sources. Additionally, I declare that there have been no established or pending plagiarism charges against me in the last five years.
In the event that the funding agency identifies any form of plagiarism or inconsistencies in the aforementioned proposal, I acknowledge and agree to comply with any actions deemed necessary by ICMR. I take full responsibility for any such discrepancies and will adhere to the consequences as required.

Printed on: Thu Mar 07 2024 at 11:20:08 PM

ICMR Proposal

Type of **research – Developmental Research**

A Comprehensive Approach to Detect and Combat Substance Abuse among School Going Children in Thrissur District, Kerala.

Summary

Drug abuse is a complex phenomenon, which has various social, cultural, biological, geographical, historical and economic impact on human life. Today, there is no part of the world that is free from the curse of drug trafficking and drug addiction. Millions of drug addicts, all over the world, are leading miserable lives, between life and death. There are paucity in research on early screening of drug usage among adolescents. Most of the previous research were looking on self-reported usage of substance abuse, where most of the data would be under reporting. Increasing the awareness on substance abuse were the only means to tackle this problem in younger generation. A comprehensive approach which include preventive, promotive, curative and rehabilitative service is novel approach in order to compact against this drug menace. The target population in this comprehensive approach is not only the school going adolescents but it include their parents, and school teachers. The laboratory detection of drug among adolescents is also another novel method which can be incorporated in school screening programme that can tackle the substance abuse. Hence this proposal is undertaken with a goal to make Thrissur district in Kerala drug free by adopting this comprehensive strategy. We expect through this comprehensive approach would help us to identify the real problem of drug abuse among adolescents. With the help of teachers and parents we can save the future generation from restrain from drugs.

Key Words : Drug abuse, Adolescent children, Kerala, Anti-drug Task force, Urine drug screening

Problem statement

Drugs and substance abuse has become a worldwide public health crisis. The abuse of drug is an international problem, which affects almost every country in the world. The World Health Organization defines drug as any substance which introduced into the living organism, can modify one or more of its functions. Drug use is defined as consumption of drug that does not negatively impact health. Drug consumption becomes abusive at the appearance of dependence, which is defined as the set of physiological, behavioural and cognitive manifestations in which the use of a drug is a priority for the individual. [(1)]The WHO's ICD defined substance abuse as a blanket term to include 10 separate classes of drugs, including alcohol, caffeine, cannabis, hallucinogens, inhalants, opioids, sedatives, hypnotics, and anxiolytics, stimulants, tobacco, and other substances[(2)] it include both licit and illicit drugs. The licit drugs are those drugs which are within the law or anything that is legal. Eg: Tobacco, alcohol, caffeine and prescription medication. The illicit drugs are those drugs that are illegal or forbidden. Eg cannabis, heroin, opioids, cocaine, ecstasy.

Drug addiction causes immense human distress and the illegal production and distribution of drugs have spawned crime and violence worldwide. According to world Drug Report 2022 by UNODC in 2022 about 284 million people aged 18-64 years are using illicit drugs. The usage of drugs showed an increasing trend of 26% over the past decade, with

more users belonging to younger generate. Globally 8.7 million death is caused by tobacco use, 2.4 million deaths were due to alcohol use and 0.5 million deaths were due to illicit drug use. The Cannabis remains the world's most used drug. An estimated 209 million people used cannabis, 61 million people used opioids. Opioids remain the most lethal group of drugs, accounting for two thirds of deaths related directly to drugs, mostly due to over dosage. An estimated 21.5 million people used cocaine opioids, sedatives, and tranquilizers. (3)

India too is caught in this vicious circle of drug abuse, and the number of drug addicts are increasing day by day. Tobacco use is a major preventable cause of premature death and disease worldwide. Nearly 1.35 million people die in India every year due to tobacco use.(4). According to NFHS 5(2019-21) 38% of men were using any kind of tobacco Prevalence of alcohol consumption among men in India is 29.2%.[5]. Cannabis, heroin, and Indian-produced pharmaceutical drugs are the most frequently abused drugs in India. A survey done in India by UNDOC showed that 36% were using heroin, 22% were using cannabis, 29% were using other opiates.[6]According to national crime record bureau report, Punjab ranks first in reporting maximum number of cases of drug trafficking .India witness 10 suicides every day related to drug abuse and one of them is from Punjab. The states of Maharastra, Madhya Pradesh, Tamil Nadu, and Kerala are at the top of the table of drug related suicide. [7]

Kerala considered as God's own country, with highest health indices and literacy rate, the narcotic drugs and psychotropic substances are fast taking hold across the state. According to Ministry of social justice department three cities in Kerala - Ernakulum, Kozhikode and Trivandrum were selected as vulnerable cities among 127 identified hot spots, for acute prevalence of drug dependency among adolescents and young children.According to Narcotic Drugs and Psychotropic Substances Act, there were 26,629 cases in 2022, which is almost 300 per cent more than the cases reported in 2016.[8]

Rationale

Drug abuse is a complex phenomenon, which has various social, cultural, biological, geographical, historical and economic aspects. The disintegration of the old joint family system, absence of parental love and care in modern families where both parents are working, decline of old religious and moral values etc lead to a rise in the number of drug addicts who take drugs to escape hard realities of life. The processes of industrialization, urbanization and migration have led to loosening of the traditional methods of social control rendering an individual vulnerable to the stresses and strains of modern life. Drug abuse has led to a detrimental impact on the society. It has led to increase in the crime rate. Drugs remove inhibition and impair judgment egging one on to commit offences. Incidence of eve- teasing, group clashes, assault and impulsive murders increase with drug abuse. Apart from affecting the financial stability, addiction increases conflicts and causes untold emotional pain for every member of the family. A comprehensive approach which include the screening of school children for detecting symptoms or behavioural problems of drug abuse along with laboratory confirmation is a novel method for early detection of drug users among children. Substance abuse is often considered as a sensitive, stigmatized, shameful and even illegal act, hence self-reporting may cause subject bias [12]. Numerous studies have shown that self-reported information about substance use cause underreporting in comparison with biological tests(13,14) Laboratory diagnosis of drug abuse gains importance in this present scenario. Since many drugs are lipid soluble, they must undergo metabolism in the liver to render them water soluble which then allows them to be eliminated in urine. Blood and breath reflect moment-to-moment serum levels of an ingested substance, and offer the earliest and shortest windows of detection for substances [15]. Urine offers a somewhat longer window of

detection for substances, usually varying from one day after consumption to several weeks. Urine tests are highly accurate for cannabinoids and cocaine, the two most frequently abused drugs. There are two types of urine drug screens. The first, called the immunoassay, is cost-effective and gives results fairly quickly. If first test comes back positive, a follow-up test known as gas chromatography/mass spectrometry (GC/MS) is done for confirmation. The target population for comprehensive approach against drugs are school going children, school teachers and caregivers/parents of school going children. Hence in order to save our future generation this project is aiming to adopt a comprehensive strategy to detect and combat the drug abuse among school going children in Thrissur district, Kerala. Our ultimate goal is to achieve drug free status among our school going children in Thrissur district, Kerala

Research question

Will comprehensive strategy can detect and combat against drug abuse among school going children in Thrissurdistict and can achieve a drug free district status in Kerala?

Aim

To adopt a comprehensive strategy to detect and combat substance abuse among school going children in Thrissur district, Kerala

Objectives

1. To screen school going children symptomatically for drug abuse using DAST- A questionnaire.
2. To screen school going children for detecting presence of illicit drugs in urine using urine immunoassay method
3. To form Anti-drug task forces in each schools for identification of drug addicts and for creating awareness.

Methodology

Study design- Quasi –Experimental study design

Study Setting – The present study would be conducted in upper primary and high schools of Thrissur district.

Study Population: The study population include school going adolescents their parents/ caregivers and school teachers

Sample size:The sample size was calculated using the formulae $Z_{(1-\alpha/2)}^2 \, p \, q \, / \, d^2$

The parameter used for calculation is 'p', the prevalence of self-reported narcotics use among youth in Central Kerala as 2.98% .[15]
Sample size was calculated
p=2.98%
q=100-p= 97.02
d= relative Precision, taken as 20% of the prevalence;
Sample size = 3258
Taiking 10% as non response rate, **calculated sample size –3583**

Sampling Technique:

Multistage random sampling would be used for this study. In the first stage, the list of Government upper primary and high schools, Government Aided upper primary and high schools and CBSE upper primary and high schools in Thrissur district would be prepared. From this list, 6 school from each category would be selected randomly by lottery method. From each selected school, 200 students would be selected. In the second stage, from each standard (5,6,7,8,9,10) one division would be randomly selected and from each division 35 students would be included in the study.

Inclusion criteria

School going children studying in 5^{th},6^{th}, 7^{th},8^{th},9^{th}&10^{th} standard

Exclusion criteria

Those children who are absent on day of study

Data Analysis

Data would be entered in Microsoft excel. Data will be analysed using SPSS version 23. Descriptive analysis like mean, standard deviation, median and proportions will be used. Appropriate statistical measures would be used for analysis.

Ethical clearance: Institutional Research Committee and Ethical committee clearance would be obtained. Informed consent from parents and will be taken from each subject. Detailed subject information would be provided to the subjects to read before taking consent. There are no risks involved in the study. Confidentiality of the subjects would be maintained.

Implementation strategy

a)Screening strategy

From each school, selected number of adolescent would be screened symptomatically for assessing the drug usage. Drug abuse screening test – Adolescent version(DAST- A) self-administered questionnaire is used for screening drug abuse among study population. It contain 20 questions on potential involvement of adolescent with drugs in past 12 months, not including alcoholic beverages. The score above 6 is considered as substance use problem. The school children urine would be collected obeying the testing procedure with help of a laboratory technician for detecting the presence of drugs. The urine drug screening test would be done using immunoassay method. Once we detect drug abuse among adolescent children either by symptomatic screening or by laboratory method, the referral service to higher centreswould be provided for de-addiction.

b)Health Education

In order to prevent further drug abuse among school children , we are planning to conduct awareness sessions in all government, aided and CBSE schools in Thrissur districts. Awareness sessions include various health related effects, social issues concerned with drug abuse, initial symptoms or signs of drug addicts for early detection. The awareness classes would be held by expert faculty from community medicine and psychiatry department. The separate sessions would be there for parents, teachers and for students.

c) Other activity

In order to make students understand about the ill effects of drug abuse, along with awareness sessions we are planning to do flash mob, skits , short films & mime containing the message of not taking drugs.

d) Interactive activity in school

We would arrange various competitions like poster competition, essay competition for school children at school level in order to reinforce our message of no drug use.

e) Teachers training programme- District Level

Arrange one week teachers training programme at district level involving 2 high school & 2 Upper primary teachers from each selected schools. The training programme would discuss about various issues, methods of drug abuse prevalent in schools and also give training on how to detect drug addicts at early stage by faculty from Psychiatry department.

f) Formation of Anti Drug Task Force at each school

We are planning to built an anti drug task force with headmaster as chairperson, 4 teacher from same school who had undergone training at district level, 4 school children (4 girls & 4 boys) and child psychologist either posted in the school (if not posted from our institution psychologist would be a member) and one member from PTA Association. The aim of this task force is to identify early, those students who are drug addicts and to report them to psychiatrist or child psychologist for de-addiction and to prevent further use of same drugs among their peer groups..

Expected Outcome

The comprehensive strategy involving school children, their parents and teachers for early detection of drug users with laboratory confirmation would identify the real problem of drug abuse among school children.The preventive measures including health awareness sessions, and other school level competitions would change the adolescent behaviour on drug use and would help to groom younger generation free of drugs. The formation of Anti-drug task force in each school would continue the drug free status by early detection by trained teachers and routine surveillance of drug use among their peer group by volunteered children itself. Thus this comprehensive strategy include preventive, promotive, curative and rehabilitative services for combating drug abuse among school children

Future Plans

Screening for drug usage among school children by their teachers and random testing of urine for detection of drug need to be implemented in every schools Kerala in order to tackle drug menace. The formation of Anti-drug Task force in every schools in Kerala also would help in preventing, promoting and rehabilitative services in maintaining drug free status throughout the year.

References

1. WHO : Substance Abuse;www.who.int/topics/substance_abuse/en/
2. American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing.
3. World Drug Report 2022. United Nations Office on Drugs and Crime 2022. https://www.unodc.org/unodc/en/data-and-analysis/world-drug-report-2022.html.
4. Tobacco in India- World Health Orgaization. https://www.who.int/india/health-topics/tobacco#:~:text=Tobacco%20use%20is%20a%20major,1.35%20million%20deaths%20every%20year.
5. NFHS 5
6. Global adult Tobacco survey : India https://ntcp.mohfw.gov.in/assets/document/surveys-reports-publications/Global-Adult-Tobacco-Survey-Second-Round-India-2016-2017.pdf
7. National Survey on Extent, Pattern and Trends of Drug Abuse in India Indiawww.unodc.org/pdf/india/presentations/india_national_survey_2004.pdf
8. Nationl crime record bureau, 2016 ncrb.gov.in/StatPublications/CII/CII2015/FILES/CrimeInIndia2015.pdf
9. **https://www.thecitizen.in/in-depth/why-are-keralas-teenagers-turning-to-drug-abuse-894367**

10. Basurto FZ, Montes JMG, Cubos PF, Santed FS, Ríos FL, Moreno AM. Validity of the self-report on drug use by university students: correspondence between self-reported use and use detected in urine. Psicothema. 2009;21(2):213–9.

13. Rashidian H, Hadji M, Marzban M, Gholipour M, Rahimi-Movaghar A, Kamangar F, et al. Sensitivity of self-reported opioid use in case-control studies: healthy individuals versus hospitalized patients. PLoS One.2017;12(8):e0183017. https://doi.org/10.1371/journal.pone.0183017.

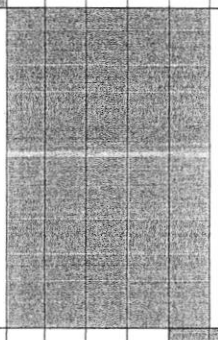
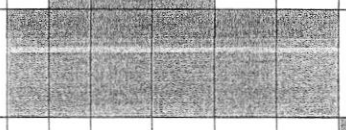
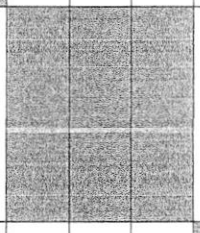
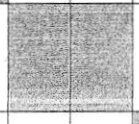
14. Yacoubian GS, VanderWall KL, Johnson RJ, Urbach BJ, Peters RJ. Comparing the validity of self-reported recent drug use between adult and juvenile arrestees. J Psychoactive Drugs. 2003;35(2):279–84. https://doi.org/10.1080/02791072.2003.10400010.

15. American Society for Addiction Medicine. *Drug Testing: A White Paper of the American Society of Addiction Medicine (ASAM)* Chevy Chase, MD: 2013. [Google Scholar]

16. Raphael L, Raveendran R, Sajna MV. Prevalence and determinants of substance abuse among youth in Central Kerala, India. Int J Community Med Public Health 2017;4:747-51

Gnatt Chart

Particulars	Months																				
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22

1	Meetingwitheducational institution head and Parents	
2	Trainingthestaff andResearch assistant	
3	Datacollection on usage of drugs among school children and collecting of urine sample and analysis of urine sample in laboratory	
4	Dataentry	
5	AnalysisofData	
6	Training of Teachers at district level	
7	Health Awareness sessions, Competition And other activities at school	
8	Formation of Anti-drug task force in schools	
7	Interim reportwriting	
8	ConferencepresentationandPublication with final report	

Budget

Sl. No.	Particulars	Quantity	Rate per unit	Per year	Total	Justification
	Human Resource*	1 Project Research Scientist II (Medical)	Rs. 80,000	Full Time	80000 X24= **Rs.1,920,000**	For guidance and smooth conduction of project and for achieving the study objectives, datacollection, monitoring the activities and for analysis.
		1 Project Research Scientist II (Non medical)	Rs. 67,000	Full Time	67,000 X 24= **Rs1,608,000**	
		1 Project Technical Support – 1I	Rs 18,000	2years	**Rs 4,32,000**	For Collecting urine sample and laboratory analysis
		1 Project Research Scientist 1 (Medical) 1 Psychiatrist	Rs 67,000/ head	1 year	**67,000 X 12= Rs 80,4000**	For Training school teachers on early identification of drug users among school children
		2 Project Technical Support – 1I 2Psychologist	Rs 30,000/head	1 years	**60,000 X 12= 7,20,000**	For counselling and rehabilitative services
		1 Project Technical Support – I	Rs 18,000	2 year	**18,000 X 24= Rs 4,32,000**	Data entry
	Laboratory Equipment (recurring expenses)	Urine drug screening – 3583 school children	Rs 1000/	Initial 2 year	**1000 x 3583= Rs 35, 83,000**	Laboratory confirmation of drug use
	District Level training for teachers	72 Training Module and Refreshments	Rs 1000	6 months	**72 x 1000= Rs 72,000**	For dissemination of knowledge and skill on early detection of drug addicts among school children
	IEC and conventional health education materials & organizing interactive activity in schools	18 schools	Rs.2000	3 months	**Rs.36000**	For dissemination of information, awareness on drug abuse
	Travel Grant	Field Work	Rs. 3000	3	**3000 X 20 visits =**	School Visits for surveys

				months	**60,000**	
		Visiting ICMR Hqrs	Rs 60,000		**Rs 60,000**	for meetings related to pr
6.	Sensitization and training of PI and (along with tea)	1	Rs. 5000	NA	**Rs.5000**	For explaining the purpc and scope of research
7.	Translation of questionnaire	1		NA	**Rs 5000**	For printing questionnaire local language
8.	Article Publishing Charges	NA	NA	NA	**Rs.30,0000**	For publishing the researcl a peer-reviewed journal w high impact factor
9.	5% Miscellaneous (conference Presentation)				**Rs 1, 67000**	
10.	**Grant Total**				**Rs 98,74,000**	

Consolidated Total Budget Required for completion of Project – Rs 98,74,000(Ninety eight lakh seventy four thousand only)

Annexure-V

Ref. ICMR-Call for Application: Small Extramural Grants Dec. 2023

Title of the project: A Comprehensive Approach to detect and combat Substance abuse among school going children in Thrissur district, Kerala

Name of the PI: Dr Sruthi M V

Name of the Institute: Amala Institute of Medical Sciences, Thrissur, Kerala

Declaration & Attestation

We hereby certify that:

i. We have read the terms and conditions for ICMR Research Grant. All necessary Institutional facilities will be provided if the research project is approved for financial assistance.

ii. The equipment(s) that is being requested as part of this project is/are not available in the Institute/Department /or these are available and are being used at full capacity (Strike off the inappropriate one)

iii. The equipment(s) requested as part of this project have not been purchased earlier from the funds provided by ICMR for previous project(s) in the Institute.

iv. No utilization certificate (UC)/ statement of expenditure (SoE) final report is pending for earlier ICMR project(s) under the PI and the final report(s) for earlier projects have been submitted.

v. The project has not been submitted to any funding agency or institution other than the ICMR.

vi. The PI does not have more than 5 (five) ICMR projects at present as a Principal Investigator.

vii. We understand that ICMR shall only fund for the project positions, as enumerated in the criteria for engagement of Non-Institutional Project Human Resource Positions, purely on temporary contractual basis. ICMR has apprised us of this rule and we have carefully noted it.

viii. The PI and Co-investigator(s) hereby submit the ICMR Declaration of Interest form in prescribed format.

ix. The name of the Statutory Audit Authority of our Institute is as follows:

_____

[Please attach a copy of the resolution if a private firm is engaged]

x. Registration/Unique ID no. assigned by NITI Ayog, GoI (on DARPAN Portal) (applicable only for NGOs)

.....

xi. CV of the investigator and Co-Investigators is/are attached in prescribed format.

	Name	Signature	Date
a) Principal Investigator	Dr Sruthi MV		01/03/24
b) Co-Investigator(s)	Dr Sandra Paulson		02/03/24
	Dr Stetfi Francis		01/03/24
c) Head of the Department	Dr C R Saju		01/03/24

Signature of the Head of the Institution with seal

Date: 01-03-2024

Fr. Julious Arakkal CMI
Director

AMALA INSTITUTE OF MEDICAL SCIENCES

Dr. Sreejith M

ı Council of Medical Research (ICMR)

Deptartment of Health Research

(Ministry of Health and Family Welfare)

Investigator-Initiated Research Proposals

Proposal in Draft Stage

Proposal Id: Not Generated Yet

Proposal Title: A cross sectional study to establish the normative data for trimester specific reference ranges for thyroid function tests in pregnant women from Kerala.

Personal details of Principle Investigator (PI)

Name of PI (IN BLOCK LETTERS), Designation, Email, Contact No., Gender, DOB, Date of Superannuation	DR SREEJITH M, Assistant Professor, drsreejitm@gmail.com,9971315039, Male, 05-11-1985, 05-11-2045
Nature of Employment	Permanent
Institute	Amala Institute of Medical Sciences , Private academic institutions with valid UGC/AICTE/PCI or NMC approved Medical colleges , YES (01-Jan-1970)

Proposal Details PART-A

Are you currently under regular employment in Medical Institutes, Research Institutes, Universities, Colleges, recognized Research & Development laboratories, Government and semi-government organizations, and NGOs?	Yes

Summary (up to 250 words): A ...
a.Rationale/Gaps in existing knowledge:Current guidelines on the ...
population-based trimester-specific reference ranges for TFT.This is an important aspect of clinical endocrinology, as ...
decision-making and institution of therapy. Studies done in western countries cannot be extrapolated to our population because the parameters are impacted by ...
method of assay and population specific factors like ethnicity,BMI and iodine intake.Also the studies done in different parts of India have shown varying results.Also
there is only a single study published from South India in this regard till date with no data from Kerala so far.b.Objectives: To establish a normative data for trimester
specific reference ranges for thyroid function tests(TFTs) in euthyroid pregnant women from Kerala d.Methods i.Study design-Cross sectional study ii.Study setting-The
study will be conducted in the outpatient setting in the antenatal clinic of the Obstetrics and Gynecology department and department of Endocrinology of a tertiary
care centre in Central Kerala. iii.Duration-3 years iv.Population-Pregnant women attending the antenatal clinic aged between 18-40 years with no previous history of
thyroid dysfunction who are Anti TPO negative with no goitre/thyroid nodules on clinical examination v.Sample size-Total of 300 pregnant women(100 from each
trimester). e.Expected outcome-To generate normative data for trimester specific reference ranges for TFT in pregnant women from Kerala so that it can be used for
clinical decision making in our population and this data can be used to generate a reference range for the Indian population

Priority Area/Priority Area diseases	Reproductive, Maternal and Child Health, Nutrition / Others
Keywords Six keywords separated by comma which best describe your project may be provided.	Pregnancy,thyroid function test,trimester specific,reference range
Abbrevations Only standard abbreviations should be used in the text. List of abbreviations maximum of ten may be given as a list.	TFT-Thyroid function tests TBG-Thyroid binding globulin HCG-Human Chorionic Gonadotropir ATA-American Thyroid Association BMI-Body mass index TPO-Thyroid Peroxidase

t hypothyroidism is associated with adverse maternal and fetal outcomes.Physiological changes associated with pregnancy such as increased serum thyroid ...ding globulin (TBG), increased human chorionic gonadotropin (hCG), and increased renal iodine clearance alter thyroid function in pregnancy.Hence, nonpregnant cut offs may not reflect the state of thyroid function during pregnancy appropriately(1).Apart from these, the transfer of iodine/thyroid hormone to fetus and increased activity of placental deiodinase activity also modulate maternal thyroid hormone status.So the cut offs used in the non pregnant population cannot be used to guide treatment of hypothyroidism in pregnant women.Hence, there is a need to establish trimester specific reference range for thyroid function tests(TFT) during pregnancy.In India we do not have population specific reference ranges for TFT in the pregnant population.We currently follow the American Thyroid Assiciation(ATA) guidelines for the treatment of thyroid disorders in pregnancy.But the international guidelines such as those of the American Thyroid Association and Endocrine Society have suggested that population specific trimester specific normative data for pregnancy need to be generated to interpret TFTs in pregnancy. Data from the western population cannot be extrapolated to the Indian population due to differences in method of assay as well as population-specific factors such as ethnicity, body mass index (BMI), and iodine intake(2).The analysis of the Indian data so far reveal a high heterogeneity between the various data sets,thereby underlining the need for further data generation from all parts of the country which will help create a pan India reference range.This can be used for appropriate clinical decision making throughout the country.Also there is only a single study from south India in this regard with no data from Kerala so far.

Rationale of the study (up to 250 words) Mention how the research question addresses the critical barrier(s) in scientific knowledge, technical capability, and/or programmatic/ clinical/lab practice and its relevance to local, national and international context with relevant bibliography.

Current guidelines on the management of thyroid disorders during pregnancy strongly recommend the establishment of population-based trimester-specific reference ranges for TFT. This is an important aspect of clinical endocrinology, as the reference range directly impacts clinical decision-making and institution of therapy. Population-based reference ranges are expected to be calculated based on data of healthy pregnant women, with no personal or family history of thyroid dysfunction, no visible or palpable goiter, with optimal iodine intake and negative thyroid peroxidase antibody status(3). In accordance with the International Federation of Clinical Chemistry, reference intervals should extend from the 2.5th to 97.5th percentile(4). Most of the studies done previously from our country used ELISA technique to measure TFT.ELISA is not used widely nowadays and hence the relevance of these data in modern times is debatable.A comparison of the previous studies show that some are cross-sectional whereas others are longitudinal.Some studies rely on dietary history whereas others measure urinary iodide concentration to assess iodine insufficiency.Ultrasound of the thyroid and Anti TPO antibodies have been done by some authors only.Some studies have not measured Free T3 and Free T4 values(5-11).Thus the analysis of the Indian data so far reveal a high heterogeneity between the various data sets,thereby underlining the need for further data generation from all parts of the country which will help create a pan India reference range.This can be used for appropriate clinical decision making throughout the country.Also there is only a single study from south India in this regard with no data from Kerala so far.Hence there is a pressing need to generate normative data for TFT in the pregnant women from various parts of India,especially from Kerala.

Hypothesis/ Research question (up to 100 words) : To establish the normative data for trimester specific reference ranges of thyroid function tests in pregnant women from Kerala

Include objective-wise work plan under the following sub-headings:

Study Objective No. 1

Study Objective : To establish the normative data for trimester specific reference ranges of thyroid function tests in pregnant women from Kerala

Study Design : Cross sectional study

Study Area : Hospital based study

Sample Size : Since we do not propose to explore any specific hypothesis,sample size consideration is mainly limited to ensuring sufficient numbers to establish the countours of the distribution in this population.For this purpose we propose to adapt a stratified sampling approach with each stratum being sampled separately to ensure adequate numbers to establish the parameters of the distribution.The three strata we will sample are women from the 1st,2nd and 3rd trimesters of pregnancy.We propose to recruit as many patients as possible who are attending the antenatal clinic of the Obstetric OPD,after exclusion of ineligible subjects with an aim of recruiting atleast 100 in each stratum so that the total sample size becomes 300 .

Project Implementation Plan : Pregnant women visiting the Obstetrics OPD will be invited to join the study.Eligible subjects fulfilling the inclusion criteria will be asked to sign the consent form and be a part of the study.The inclusion criteria will be 1.Age between 18-40 years 2.Singleton,intrauterine pregnancy 3.Consuming iodised salt Screening will be done by the PI and those who meet the exclusion criteria will be excluded.The exclusion criteria will be 1 .History of hyperemesis gravidarum 2.Past history of thyroidal illness 3.Family history of thyroid illness, 4.Presence of goitre/thyroid nodules on clinical examination 5.Anti TPO antibody positivity(Titre more than 34mIu/ml) 6. Overt hypothyroidism defined as TSH more than 10uIu/ml with or without low free T4 7.Overt hyperthyroidism defined as TSH less than 0.01uIu/ml with or without high FT4 . Serum samples for thyroid function tests will be collected between 8 am and 10 am after participants have fasted for 8-10 hours.The collected samples will be transported to the central laboratory by the Project Nurse.Serum levels of Total T3(TT3),total T4(TT4),free T3(FT3),free T4(FT4),Anti TPO Antibody will be analysed in the central laboratory by chemiluminescence assay using the Beckman Coulter Unicel Dxl 600 Immunoassay system

Design of Statistical analysis : In each stratum we will estimate the mean,median,standard deviation and percentiles of the the distribution.These will be presented graphically.Analysis will be done using the Jamovi software.The reference range for thyroid function tests will extend from the 2.5th to the 97.5th percentile.

Expected outcome/ Deliverables aligned with research question (up to 100 words): To generate normative data for trimester specific reference ranges for TFT pregnant women from Kerala so that it can be used for clinical decision making in our population and to use this data to generate a reference range for the Indi population.

next steps following the end of the pro[illegible](up to 100 words): We will treat pregnant women with thyroid function abnormalities on the basis of normative data derived from our research and also publish our data so that it can be followed by other doctors in our state.

Whether the study is going to generate new intellectual property: No

Timelines with achievable targets Download

Proposal Details (PART-B)

Preliminary work done by the PI including the source of funding (up to 250 words): Nil

Skill and experience of the research team (Highlight only salient points (along with 5 relevant publications) that provides confidence to reviewers that team can implement the project with quality.) **:** The PI already has already done 2 studies during residency at AIIMS New Delhi and has 2 publications in indexed journals.The co PI has 14 publications in indexed journals. 1.Ganie MA, Chakraborty S, Sehgal A, M Sreejith , Kandasamy D, Jana M, Rashid A. Bone Mineral Density is Unaltered in Women with Polycystic Ovary Syndrome Horm Metab Res. 2018 Oct 50(10):754-760. 2.M Sreejith.Mohd Ashraf Ganie,Ravinder Goswami, Nikhil Tandon, Randeep Guleria, Devasenathipathy Kandasamy. Prevalence of Sleep-Related Disordered Breathing among Acromegaly Patients and its Correlation to Cephalometric Parameters An Indian Perspective. Ann Natl Acad Med Sci (India) 202056(01): 09-14. 3.B.Thomas, A.Thomas, A.Mhaskar. Review of Maternal mortality in a Tertiary Care Hospital of India over Ten years . International Journal of Gynaecology and Obstetrics India 2006:9(5):19-21 4.Kundoly V Suseela ,VasanthyJayaraj, Thomas Betsy , FareenaJabeen, Mohan Ramya. Incidence of group B streptococci colonization during the third trimester of pregnancy in two tertiary care centers in central part of Kerala. International Journal of Contemperory Medical research 2016 3 (2) : 568-570. 5.Mereena George, Betsy Thomas, V.K Sreenivasan. Incidence of Hyperbilirubinemia in Neonates of Parturients undergoing augmentation of labour with Oxytocin : A Prospective Cohort Study . Indian J Obstet Gynecol . 2019 7(4Part-II): 579-593.

Institutional Support/ Facilities: The centre is a teaching institute with high volume antenatal clinic and has NABL accredited lab with autoanalysers to measure thyroid function tests.Samples will be collected in the OPD by the project assistant who will be a qualified nurse/lab technician and transported to the laboratory and analysed immediately.Data entry will be done by a data entry operator.

Laboratory facilities (in-vitro/ in-silico) Institutional resources such as instruments/ equipment and other physical resources available for use in the project proposed animal house etc.
The centre has an NABL accredited lab with autoanalyser to measure thyroid function tests.

Conflict of Interest declaration (if any) Nil

Duration (in Months) 36 Months

Investigator Details

#	Name	Institute	Designation	Email	Contact No.	Role in Proposal
1	**Dr SREEJITH M**	**Amala Institute of Medical Sciences**	**Assistant Professor**	**drsreejitm@gmail.com**	**9971315039**	**PI**
2	Prof Betsy Thomas	Amala Institute of Medical Sciences	Professor	betsythomas53@gmail.com	8921046272	Co-PI

Documents consideration

#	Document Name	Is Applicable?	Uploaded Document	Remarks
1	Declaration & Attestation Form(duly signed by Head of Department/ Director)	Yes	View	Declaration form signed by the head of institution
2	Additional supplementary information including figures tables flow diagrams etc can be shared as PDF	Yes	View	Auditor details

Proposed Budget Details

Institute	Budget Year	Manpower Budget (Rs.)	Contingency	Consumables	Equipment	Travel	Overhead	Total(Rs)
Amala Institute of Medical Sciences	1	475200.00	25000.00	375000.00	30000.00	25000.00	11250	941450
Amala Institute of Medical Sciences	2	782400.00	25000.00	250000.00	0	0	7500	1064900
Amala Institute of Medical Sciences	3	782400.00	25000.00	125000.00	0	50000.00	3750	986150

Proposed Budget Details

Institute	Budget Year	Manpower Budget (Rs.)	Contingency	Consumables	Equipment	Travel	Overhead	Total(Rs)
Total in (Rs.):		**2040000**	**75000**	**750000**	**30000**	**75000**	**22500**	**2,992,500.00**

Budget Breakup Details (Staff/Manpower)

#	Budget Year	Institute	Designation	No. of Person(nos)	Require Month(nos)	Cost Per Person(Rs.)	Overhead(Rs.)	Total Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences	Project Nurse - I	2	12	19,800	0.00	475,200.00
Justification : To recruit patients,take consent and to draw blood sample								
2	**Year: 2**	Amala Institute of Medical Sciences	Data Entry Operator	1	12	29,200	0.00	350,400.00
Justification : For data entry								
3	**Year: 2**	Amala Institute of Medical Sciences	Project Nurse - I	2	12	18,000	0.00	432,000.00
Justification : To recruit patients,take consent and to draw blood sample								
4	**Year: 3**	Amala Institute of Medical Sciences	Project Nurse - I	2	12	18,000	0.00	432,000.00
Total Cost (Rs.) including overhead								**2,040,000.00**

Justification : To recruit patients,take consent and to d) blood sample

5	**Year: 3**	Amala Institute of Medical Sciences	Data Entry Operator	1	12	29,200	0.00	350,400.00

Justification : For data entry

Total Cost (Rs.) **2,040,000.00**
including overhead

Contingency budget breakup details

#	Budget Year	Institute	Overhead Charges (Rs.)	Total Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences	0.00	25,000.00

Contingency Name : Printing of questionnaire,Computer utilities,Acquisition of documents in relation to the research

Justification : Printing of questionnaire,Computer utilities,Acquisition of documents in relation to research

2	**Year: 2**	Amala Institute of Medical Sciences	0.00	25,000.00

Contingency Name : Printing of questionnaire,Computer utilities

Justification : Printing of questionnaire,Computer utilities

3	**Year: 3**	Amala Institute of Medical Sciences	0.00	25,000.00

Total Cost (Rs.) **75,000.00**
including overhead

Budget Breakup Details (Staff/Manpower)

Contingency budget breakup details

Contingency Name :Computer utilities,charges for analysis of data,expenses for preparation of final report

Justification :Computer utilities,charges for analysis of data,expenses for preparation of final report

Total Cost (Rs.) **75,000.00**
including overhead

Consumables Budget Breakup Details

#	Budget Year	Institute	Consumables Name	Overhead	Total Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences	Hormone assay kits,syringes,needles	11,250.00	375,000.00
Justification : Hormone assay kits,syringes,needles					
2	**Year: 2**	Amala Institute of Medical Sciences	Hormone assay kits,syringes,needles	7,500.00	250,000.00
Justification : For purchasing hormone assay kits,syringes,needles					
3	**Year: 3**	Amala Institute of Medical Sciences	Hormone assay kits,syringes,needles	3,750.00	125,000.00
Justification : To purchase hormone assay kits,syringes,needles					

Total Cost (Rs.) 772,500.00
including overhead

#	Budget Year	Institute	Equipment Name	Equipment Model	Equipment Manufacturer	Equipment Type	Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences	Laptop			Domestic	30,000.00

Justification :Laptop for data entry and other project related activities

Mode of Proposed disposal :To be retained by the institute or given to ICMR as per the discretion of ICMR

Total (Rs.): 30,000.00

Travel Justification

#	Year	Amount(Rs.)
1	**Year: 1**	25000.00

Justification :Attending a training course related to the project(for project nurses)

2	**Year: 3**	50000.00

Justification :To attend conference to present the research work

Total:	**75,000.00**

Short resume PI/Co-PI

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal

Preethy Thomas	1974-10-18	Obstetrics and Gynecology	4	3	Fellow of Royal College of Obstetricians and Gynecologists,United Kingdom	Co-PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date
IIRPIG-2023-0000653	Development,Implementation and Evaluation of protocolized Cardio-obsteric care in improving maternal cardiac,obstetric and fetal outcomes of pregnant women with heart diseases in India.	960000.00	2024-05-01	2028-04-30

Name of PI/Co-Pi	**DOB**	**Domain Expertise**	**Number of articles in Pub Med (Past 10 years)**	**h-index**	**Fellow of Academics**	**Role in Proposal**
Dr SREEJITH M	1985-11-05	Endocrinology	2	1	Fellowship in Paediatric Endocrinology,Royal Hospital for Children,Glagow,UK	PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date

Declaration

☐ I hereby declare that the entries in this form and the additional particulars, if any, furnished herewith are true to the best of my knowledge and belief. I understand that in the event of my information being found false or incorrect at any stage, my project/proposal shall be liable to cancellation / termination without notice or any compensation in lieu thereof.

☐ I hereby certify that the research proposal I have submitted to ICMR, New Delhi, for potential funding is entirely my original idea and has not been copied or replicated from any other source. Furthermore, I confirm that this proposal has undergone scrutiny using a standard plagiarism detection tool, verifying its originality and confirming that its contents have not been directly taken from any other sources. Additionally, I declare that there have been no established or pending plagiarism charges against me in the last five years.
In the event that the funding agency identifies any form of plagiarism or inconsistencies in the aforementioned proposal, I acknowledge and agree to comply with any actions deemed necessary by ICMR. I take full responsibility for any such discrepancies and will adhere to the consequences as required.

rinted on: Mon Mar 11 2024 at 8:40:13 PM

DOB	Domain Expertise	Med (Past 10 years)	index	Fellow of Academics	Role in Proposal

Annexure V

Ref. ICMR-Call for Application: CALL FOR INVESTIGATOR-INITIATED RESEARCHPROTOCOL FOR SMALL EXTRAMURAL GRANTS

Title of the project: A CROSS-SECTIONAL STUDY TO ESTABLISH THE NORMATIVE DATAFOR TRIMESTER SPECIFIC REFERENCE RANGE OF THYROID FUNCTION TEST IN PREGNANT WOMEN FROM KERALA

Name of the PI: DR. SREEJITH M

Name of the Institute: AMALA INSTITUTE OF MEDICAL SCIENCES, THRISSUR

Declaration & Attestation

We hereby certify that:

i. We have read the terms and conditions for ICMR Research Grant. All necessary Institutional facilities will be provided if the research project is approved for financial assistance.

ii. The equipment(s) that is being requested as part of this project is/are not available in the Institute/Department/or these are available and are being used at full capacity (Strike off the appropriate one)

iii. The equipment(s) requested as part of this project have not been purchased earlier from the funds provided by ICMR for the previous project(s) in the Institute.

iv. No utilization certificate (UC)/ statement of expenditure (SoE) final report is pending for earlier ICMR project(s) under the PI and the final report(s) for earlier projects have been submitted.

v. The project has not been submitted to any funding agency or institution other than the ICMR.

vi. The PI does not have more than 5 (five) ICMR projects at present as a Principal Investigator.

vii. We understand that ICMR shall only fund for the project positions, as enumerated in the criteria for engagement of Non-Institutional Project Human Resource Positions, purely on temporary contractual basis. ICMR has appraised us of this rule and we have carefully noted it.

viii. The PI and Co-investigator(s) hereby submit the ICMR Declaration of Interest form in prescribed format.

ix. The name of the Statutory Audit Authority of our Institute is as follows:
P V CHACKO & CO, CHARTERED ACCOUNTANTS, PALACKAL COURT, M.G. ROAD, EKM, PIN 682035

x. Registration/Unique ID no. assigned by NITI Ayog,GoI (on DARPAN Portal) (applicable only for NGOs): NA

xi. CV of the investigator and Co-Investigators is/are attached in prescribed format.

	Name	Signature	Date
a)	Principal Investigator DR. SREEJITH. N		9/3/24.
b)	Co-Investigator(s) DR. BETSY THOMAS		9/3/24
c)	Head of the Department DR. SREEJITH. N		9/3/24.

Signature of the Head of the Institution with seal

Fr. Julious Arakkal CMI

AMALA INSTITUTE OF MEDICAL SCIENCES

Dr. Kalyani Pillai

edical Research (ICMR)

of Health Research

lth and Family Welfare)

:ed Research Proposals

12-Mar-2024 12:17:27 PM

Proposal Id: IIRPSG-2024-01-02907, **Version Id:** F1,
Proposal Title: Developing a prediction equation for estimating height using segmental length for use to monitor growth and nutrition in Indian children with physical disabilities

Personal details of Principle Investigator (PI)

Name of PI (IN BLOCK LETTERS), Designation, Email, Contact No., Gender, DOB, Date of Superannuation	DR KALYANI PILLAI, Professor, pillaiskpillai@yahoo.co.in,9447834079, Female, 24-03-1966, 31-03-2036
Nature of Employment	Permanent
Institute	Amala Institute of Medical Sciences , Private academic institutions with valid UGC/AICTE/PCI or NMC approved Medical colleges ,

Proposal Details PART-A

Are you currently under regular employment in Medical Institutes, Research Institutes, Universities, Colleges, Recognized Research & Development laboratories, Government and semi-government organizations, and NGOs?	Yes
Advertisement	Call for Investigator-Initiated Research Proposals for small extramural grants - 2024

Summary (up to 250 words): A structured summary should contain the following subheadings: Rationale/ gaps in existing knowledge, Novelty, Objectives, Methods, and Expected outcome

Rationale: Height is essential for assessing growth and nutrition in children. In physically disabled children direct height measurement is very difficult. The purpose of this study was to develop a valid and reliable method for estimating height by deriving an equation using segmental length, in non-disabled, healthy Indian children and thus monitor growth and nutrition in disabled children. Novelty: There is no study from India to assess height in disabled children using predictive equations. The goal was to cover a larger age group range than those previously published and to be simple enough for daily clinical use in disabled Indian children. Objective: We aim to develop prediction equations to calculate estimated height using segmental length measurement for use in Indian children with disabilities. Methodology: A cross-sectional study that collects data from healthy children from 2 to 18 years of age in the community. They will be divided into 4 groups of both sexes based on age groups (2-5 years, 6-10 years, 11-14 years, 15-18 years). The Height, UA (Upper Arm length), KH (Knee Heel length), and T (Tibial length) measurements will be taken using portable anthropometric measurement tools by a trained team. Expected outcome: We propose to develop several prediction algorithms and test the algorithm in a test sample that is naive to the algorithms. The performance of different algorithms will be assessed, and the best one chosen for recommendation. The development of anthropometric protocols, that emerged from such research, would benefit the follow-up of children with severe psychomotor disabilities

Priority Area/Priority Area diseases	Reproductive, Maternal and Child Health, Nutrition / Childhood Malnutrition, Breastfeeding and complementary Feeding
Keywords Six keywords separated by comma which best describe your project may be provided.	*Segmental length, height, height prediction, disability, children, India*
Abbreviations Only standard abbreviations should be used in the text. List of abbreviations maximum of ten may be given as a list.	WHO World Health Organization BMI body mass index CP cerebral palsy UA upper arm length KH knee heel length T tibial length

Problem Statement (up to 500 words): State the currently available information to present the problem adequately.

Anthropometric measurements provide simple, non-invasive methods to assess the nutritional status of children Monitoring linear growth and nutritional status is critical for diagnosis of malnutrition in children. Even though there are certain challenges such as ethnic variation, assessment in normal children is generally straightforward using standardized growth charts. For children with cerebral palsy (CP) and similar neurodevelopmental disabilities and children with physical disabilities who are more likely to be malnourished compared to normal children, assessing their growth and nutritional status is challenging. There are no growth curves made specially for them and it is difficult to collect anthropometric data in such children. Given the importance of accuracy in height measures to evaluate growth and nutritional status in children, it is crucial to carry out research to establish an equation to predict height for use in children with physical disabilities in whom both growth and nutritional status are likely to be affected. The development of anthropometric protocols, that emerged from such research, would benefit the follow-up of children with severe psychomotor disabilities and facilitate the accurate assessment of nutritional status in field studies.

Rationale of the study (up to 250 words) Mention how the research question addresses the critical barrier(s) in scientific knowledge, technical capability, and/or programmatic/ clinical/lab practice and its relevance to local, national and international context with relevant bibliography.

According to the State of the Education Report for India 2019 by UNESCO, India is home to 8 million children with disabilities. (1) In the 2011 census, around 7.62 percent of India's total population with a disability was children. (2) The World Health Organization's (WHO) growth curves provide health professionals with a valuable tool for monitoring the growth of children and adolescents. However, these charts for weight, length, height, and body mass index (BMI) according to gender and age were created based on healthy subjects. (3) As such, they do not include children with physical disabilities both psychomotor and orthopedic, in which measuring recumbent length and height is unreliable if a child has contracture, high tone, scoliosis, or poor cooperation interfering with the optimal positioning. ICMR has in December 2023, called for expression of interest for applications to participate in data collection for a multi-growth reference research initiative to generate growth references for Indian children with no constraints to growth. This is the ideal time to think about the disadvantaged population of children, those with disabilities. In children with motor limitations, as in the case of cerebral palsy (CP), height measurement is currently performed by segmental measurements, as proposed by Stevenson in 1995. (4) According to the author, height can be estimated by using the equations he proposes with each measured segment: upper arm length (UA), knee heel length (KH), and tibial length (T). These equations are available for Caucasians, Latin Americans, Africans, Australians, and certain Asian populations. (5,6,7,8,9,10) No such equation has been derived for our Indian population by Indian researchers. (11) A systematic review by Lamounier JA et al (3) highlights the limitations of various studies. Most studies lack age group stratification. Of the measurement techniques employed, only some of the studies did use a suitable instrument. Because these were all cross-sectional studies, there was no follow-up of the populations studied. In addition, the samples evaluated in these studies were mostly small. However, there are not many articles on the topic addressed in the review of literature. Thus, given the importance of the accuracy of height measurements to assess child health, further research is needed to establish height predictive equations from segmental length. The estimated stature may be plotted on standard growth charts to monitor growth and nutritional status in Indian children with disabilities. This may help in the early pickup of malnutrition in this traditionally disadvantaged population of children

Hypothesis/ Research question (up to 100 words) : Using a normative sample of non-disabled healthy Indian children to derive predictive equations, can segmental length be used to estimate height in physically disabled Indian children to monitor growth and nutritional status

Methodology

Include objective-wise work plan under the following sub-headings:

Study Objective No. 1

Study **Objective :** 1) To determine the anthropometric measurements (height and segmental length) in a normative sample of non-disabled healthy Indian children. 2) To develop and assess the performance of prediction algorithms for estimating height using different segmental lengths. 3) To recommend the best one as a height-predictive equation using segmental length.

Study **Design :** cross-sectional study

Study **Area :** The community and schools in a panchayath in a semi-urban district in a state in South India, India

Sample **Size :** Subjects will be enrolled by consecutive sampling The study involves children aged 2-18 years. They will be divided into 4 groups (2-5 years, 6-10 years, 11-14 years, 15-18 years) respectively. The predictors involved in the study are age, gender, Height, UA (Upper Arm length), KH (Knee Heel length), and T (Tibial length). Considering that there are 5 predictors, we propose to take 20 children per predictor accounting for a total of 100 children per stratum, (i.e., 400 children in the training set) to develop the prediction algorithm. Further, we will recruit an additional 25 children in each stratum, a total of 125 children, to be included in the test set to validate the algorithm developed. The total sample size, therefore, will be 500, with 125 children in each of the 4 age groups selected

Project **Implementation Plan :** Healthy children from 2 to 18 years of age and both sexes coming to the outpatient clinic on a routine visit or from school visits in the panchayath will be included in the study. Children with an amputated limb(s), inability to move, and chronic disease that could affect or have affected their growth, or were unable to cooperate for measurements will be excluded. Anthropometric measurements of interest -Height and UA, KH, and T as segmental length measurements will be taken during a routine outpatient clinic visit or school visit. Study tools used are portable anthropometric measurement tools include Portable Stadiometer Shor knee height measuring caliper Harpenden Anthropometer to measure standing height and arm length flexible steel tapes. The same team of trained health workers will perform the measurements during the course of the study. To assess repeatability, all the measurements will be done in triplicate on a subset of subjects by the same examiner, and with repeated measurements separated by equal time to lessen recall bias. All unilateral measurements will be taken on the left side of the body. All measurements will be recorded to the nearest 0.01 cm. Informed consent will be obtained from parents, and assent will be given by children where possible. Operational definitions for various anthropometric measurements will be defined using standard references. (12)

Design of **Statistical analysis :** The study aims to develop a prediction algorithm for estimating height using segmental length. In our exercise, we propose to develop several prediction algorithms in an adequate sample with a minimum sample size of 20 for each predictor variable and test the algorithm in a test sample that is naive to the algorithms. Then the performance of different algorithms will be assessed using statistical principles of error reduction, and the best one chosen for recommendation.

Expected **outcome/ Deliverables aligned with research question (up to 100 words):** a) To develop several prediction algorithms using different segmental lengths for different age groups and both sexes to predict estimated height. b) The performance of different algorithms will be assessed, and the best one chosen for recommendation. The development of anthropometric protocols, that emerged from such research, would benefit the follow-up of the growth and nutritional status of children with severe psychomotor disabilities.

Immediate **next steps following the end of the project(up to 100 words):** Clinical application of segmental lengths to populations in whom it is difficult to measure anthropometric data. Specialized growth charts have been developed for many other conditions, including Down syndrome,18 Prader-Willi syndrome, Turner syndrome, De Lange syndrome, and even meningomyelocele. There is a great need for diagnosis-specific reference data. Future research may lead to a specialized growth chart for CP.

Whether the study is going to generate new intellectual property: We will be developing several prediction algorithms for estimated height using 3 segme measures in 4 age groups in both sexes for an Indian population. The performance of different algorithms will be assessed, and the best one chose recommendation in each age group. No such equation has been derived for our Indian population by Indian researchers.

Timelines with achievable targets Download

Proposal Details (PART-B)

Preliminary work done by the PI including the source of funding (up to 250 words): Preliminary review of literature and sourcing of equipment needed done

Skill and experience of the research team (Highlight only salient points (along with 5 relevant publications) that provides confidence to reviewers that team can implement the project v quality.) : • PRINCIPAL INVESTIGATOR Dr Kalyani Pillai MD(Paediatrics) , Professor Department of Pediatrics Amala Institute Of Medical Sciences, Thrissur Kerala Ema pillaiskpillaiyahoo.co.in • ACADEMIC QUALIFICATION EDUCATIONAL QUALIFICATIONS Degree College University Year of passing MBBS Seth G S Medical CollegeKE Hospital,Mumbai Mumbai University 1987 M D Paediatrics Seth G S Medical CollegeKEM Hospital, Mumbai Mumbai University 1992 TEACHING EXPERIENCE (Post M University College Date Manipal University K M C Manipal 17.02.1993 to 10.07.1994 Calicut University and KUHS Amala Institute of Medical Sciences, Thriss 02.06.2003 date I am at present working as Professor, Department of Pediatrics, Amala Institute of Medical Sciences, Thrissur, Kerala.I am a permanent employee of th institution. LIST OF PROJECTS IN LAST 3 YEARS 1) 2021 A study on the metabolic derangements after using 0.9 %normal saline as maintenance IV fluid in childre attending tertiary care centre in Kerala 2) 2022-A study on anemia as a risk factor for acute lower respiratory tract infections in children aged 3 months to 5 years age attending a tertiary care centre in Kerala 3) 2023 -A study on the seroprevalence of Hepatitis A virus antibody and its determinants in pediatric age group in tertiary care centre in Kerala AWARDS 1 State IAP President's Special Award – at State Pedicon 2006 for Organizing Secretary 2nd Annual State IAP Kerala Adolescer Chapter Meet 2006 2 Best paper (Poster) award at State Neonatology conference conducted by NNF Kerala branch, Feb. 2007 3 Best paper(poster) award in teachin staff category at South Zone Pediatric conference in October 2008 4 Best paper (free paper) State IAP conference November 2010 5 Best paper 2 nd Prize for (fre paper) State IAP conference November 2012 6 "Manampurath Oommen John Memorial Award" for the best original research paper published in 2019 member c Indian Academy of Pediatrics ,Kerala State 7 Best Guide for MD/DNB thesis for oral presentation year 2023 by IJP KC Choudary foundation at AIIMS New Delh Examiner for MBBS MD Paediatrics at Kerala University of Health Sciences, Rajiv Gandhi University, MGR University Tamil Nadu, MAHE University, Yenapoya Universit Jipmer. Publications – 17 publications in indexed National International Journals. LAST 10 RECENT PUBLICATIONS orcid id: 0000-0002-3310-5912 Sl. No. Title Yea Citation URL Category 1 Kidney Injury Molecule-1 as a Urinary Biomarker for Aminoglycoside Induced Acute Kidney Injury, among Non-Critically Ill Children 202: Online George, M., Pillai, K. Suseela, K.V. Kidney Injury Molecule-1 as a Urinary Biomarker for Aminoglycoside Induced Acute Kidney Injury, among Non-Critically Il Children. Indian J Pediatr (2023). https://doi.org/10.1007/s12098-023-04987-x https://rdcu.be/dtPrl Scientific letter in PubMed Indexed Journal 2 Non-invasive assessment of volume status of children with edema due to steroid sensitive nephrotic syndrome using urinary indices and inferior venacava ultrasonography. 202: Kalyani Pillai, Jalaludeen J, Vadakoot Krishnan Parvathy. Asian J Med Sci . 2023 Jan 1.14(1):217-21. DOI:10.3126/ajms.v14i1.4858 https://www.nepjol.info/index.php/AJMS/article/view/48586 Original research article in DOAJ/Scopus indexed journal 3 Effect of Second-hand smoke exposure or Pulmonary Function Test and predictors of abnormal PFT, in children attending a tertiary care center in a semiurban area in South India", 2022 Kalyani Pillai , Mohamed Rabeeh International Journal of Science Engineering Development Research (www.ijsdr.org), ISSN:2455-2631, Vol.7, Issue 9, page no.100 - 104, September-2022 http://doi.one/10.1729/Journal.31832 Original research article in DOAJ indexed journal 4 Serum zinc levels and predictors of severity of acute lower respiratory tract infections in children under five years of age 2021 Shisira Philip1, Jessie Jose2, Kalyani Pillai3, Vadakkoottu Krishnan Parvathy4 Sri Lanka Journal of Child Health, 2021 50(4):630-636 htpp://doi.org//10.4038/sljch.v504.9852 Original research article in Scopus indexed journal 5 Non-operatively corrected congenital knee dislocation: A rare disorder 2020 Dr. Tharun C Vasrghese, Dr. Kalyani Pillai and Dr. S Ramaraj, IJOS 2020 6(4): 668-669 © 2020 IJOS https://doi.org/10.22271/ortho.2020.v6.i4j.2400 Case Report in Indexed Journal 6 Diagnosis And Assessment Of Severity of Paediatric Pneumonia Using The Respiratory Index Of Severity (Risc) Scoring System 2021 Kalyani Pillai, Edwin Ros Sartho, Lekshmi T P, Parvathy V K Diagnosis And Assessment of Severity of Paediatric Pneumonia Using The Respiratory Index Of Severity (Risc) Scoring System.Indian Pediatr.2021 Nov1558(11):1052-1053 PMID:34837366 https://pubmed.ncbi.nlm.nih.gov/34837366/ Original research article in PubMed Indexed Journal 7 "Use of online survey tools to conduct online medical examination during lockdown time" 2020 Varghese T.C., Pillai K., Ramaraj S., Use of online survey tools to conduct online medical examination during lockdown time. Int.J.Med.Sci.Educ 20207(4):18-22 www.ijmse.com Original research article in PubMed Indexed Journal 8 Platelet Indices as an Acute Phase Reactant 2019 Pillai K, Premarajan S,Parvathy VK. Platelet Indices as an Acute Phase Reactant. J Pediatr Crit Care 20196(2): 15-17. https://www.researchgate.net/publication/332920090JOURNALOFPEDIATRICCRITICALCARE Original research article in PubMed Indexed Journal 9 Asthma inchildren with Atopic Dermatitis 2010 Kalyani Pillai ,Sandhya Acharya, Indian Journal Of Pediatric Dermatology 2010 vol12 no 1 :6-9 http://www.ijpd.in/ Original research article in PubMed Indexed Journal 10 Kasabach merritt syndrome: Management with interferon 2010 Acharya S, Pillai K, Francis A, Criton S, Parvathi V K, Indian Journal of Dermatology 2010:55(3):281-3 http://www.e-ijd.org/text.asp2 010/55/3/281/70705 Case Report in PubMed Indexed Journal COPRINCIPAL INVESTIGATOR Dr V Ramankutty MD(Paed),Mphil MPH Research Director Amala Centre for Research Promotion and Amala Cancer Research Centre Society , Thrissur Kerala 680555 Email: rdamalacrcs.org Over 60 peer reviewed publications •

Institutional Support/ Facilities: Amala Institute of Medical Sciences is a tertiary care medical college with 100 seats for MBBS, 45 postgraduate seats for broad specialties, and super specialty DM, DNB, and MCh courses. Amala Cancer Research Centre Society is in the same campus and has been recognized by the Department of Scientific and Industrial Research (DSIR). The institute has state-of-the-art infrastructure and well-equipped laboratories. There is an Amala Centre for Research Promotion at the institute that will help us in designing the study and data analysis. We are looking at a collaboration with the Amala Centre for Research Promotion and Department of Community Medicine which will help us in training health workers, data collection, securing permissions in school and community, and data analysis

Laboratory facilities (in-vitro/ in-silico) Institutional resources such as instruments/ equipment and other physical resources available for use in the project proposed animal house etc.
not applicable

Conflict of Interest declaration (if any) nil

Duration (in Months) 33 Months

Investigator Details

#	Name	Institute	Designation	Email	Contact No.	Role in Proposal
1	Dr KALYANI PILLAI	Amala Institute of Medical Sciences	Professor	pillaiskpillai@yahoo.co.in	9447834079	PI

Investigator Details

	Institute	Designation	Email	Contact No.	Role in Proposal
[redacted] Cherumadathil	Amala Institute of Medical Sciences	Professor	drsajucr@gmail.com	9495315986	[redacted]
[redacted] RAMAN KUTTY	Amala Cancer Research Centre	Professor	kuttyr@gmail.com	9847060199	[redacted]

Documents consideration

Document Name	Is Applicable?	Uploaded Document	Remarks
[redacted] supplementary information including figures tables flow diagrams [redacted] be shared as PDF	Yes	View	equipment that needs to be imported for the study
[redacted] Declaration & Attestation Form(duly signed by Head of Department/ [redacted]	Yes	View	declaration form

Proposed Budget Details

[redacted]	Budget Year	Manpower Budget (Rs.)	Contingency	Consumables	Equipment	Travel	Overhead	Total(Rs)
[redacted] Cancer Research Centre	1	0	0	0	0	0	0	0
[redacted] Institute of [redacted] Sciences	1	69600.00	25000.00	55500.00	1247700.00	174000.00	6	1571806
[redacted] Cancer Research Centre	2	0	0	0	0	0	0	0
[redacted] Institute of [redacted] Sciences	2	734400.00	25000.00	25000.00	0	0	3	784403
[redacted] Cancer Research Centre	3	0	0	0	0	0	0	0
[redacted] Institute of [redacted] Sciences	3	1667040.00	150000.00	0	0	0	0	1817040
[redacted] in (Rs.):		**2471040**	**200000**	**80500**	**1247700**	**174000**	**9**	**4,173,249.00**

Budget Breakup Details (Staff/Manpower)

#	Budget Year	Institute	Designation	No. of Person(nos)	Require Month(nos)	Cost Per Person(Rs.)	Overhead(Rs.)	Total Cost(Rs.)
[redacted]	**Year: 1**	Amala Institute of Medical Sciences	Project Nurse - II	3	1	23,200	3.00	69,600.00
Justification : For data collection								
[redacted]	**Year: 2**	Amala Institute of Medical Sciences	Senior Project Assistant	2	12	30,600	0.00	734,400.00
Justification : For project management and team coordination								
[redacted]	**Year: 3**	Amala Institute of Medical Sciences	Project Reseach Scientist - II (Non Medical)	1	12	77,720	0.00	932,640.00
Justification : For research								

Total Cost (Rs.)
[redacted] cluding overhead

2,471,043.00

Budget Breakup Details (Staff/Manpower)

4	**Year: 3**	Amala Institute of Medical Sciences	Senior Project Assistant	2	12	30,600	0.00	734,40

Justification :For project management and team coordination

Total Cost (Rs.) **2,471,043**
including overhead

Contingency budget breakup details

#	Budget Year	Institute	Overhead Charges (Rs.)	Total Cost(R
1	**Year: 1**	Amala Institute of Medical Sciences	0.00	25,000.(

Contingency Name :initial costs

Justification :initial costs

2	**Year: 2**	Amala Institute of Medical Sciences	0.00	25,000.0

Contingency Name :contingency for research

Justification :for research

3	**Year: 3**	Amala Institute of Medical Sciences	0.00	150,000.00

Contingency Name :for publication and seminar

Justification :to disperse knowledge regarding the study

Total Cost (Rs.) **200,000.00**
including overhead

Consumables Budget Breakup Details

#	Budget Year	Institute	Consumables Name	Overhead	Total Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences	1 Office Stationery 25000.00 25000.00 50000.00 2 Course material for training 3000.00 3000.00 3 Refreshments for training 2500.00 2500.00 4 Refreshments for participants 500 x 50 25000.00	3.00	55,500.00

Justification : necessary material for data entry,data collection and training

2	**Year: 2**	Amala Institute of Medical Sciences	office stationary	3.00	25,000.00

Justification : for data

Total Cost (Rs.) **80,506.00**
including overhead

Equipment Budget Breakup Details

#	Budget Year	Institute	Equipment Name	Equipment Model	Equipment Manufacturer	Equipment Type	Total Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences	International shipping cost			Domestic	199,200.00

Justification :shipping costs of equipment, For research, accounting for fluctuations in dollar rates

Total (Rs.): **1,247,700.00**

Equipment Budget Breakup Details

)0.00 ...e of **Proposed disposal** :no disposal

Year: 1	Amala Institute of Medical Sciences	Steel tape		Domestic	1,500.00

...tification :for research ,500 Rs each for 3 tapes

00 ...se of **Proposed disposal** :reusable in clinics

Year: 1	Amala Institute of Medical Sciences	Harpenden portable anthropometer for height, UL length	(Holtain Model 601)	Domestic	870,000.00

...tification :3 numbers required for carrying out research , accounting for fluctuations in dollar rates

...se of **Proposed disposal** :can be used in disabled children for anthropometry

Year: 1	Amala Institute of Medical Sciences	Shor knee height calliper		Imported	87,000.00

...tification :3 numbers for research , accounting for fluctuations in dollar rates

...se of **Proposed disposal** :can be used in disabled children for anthropometry

Year: 1	Amala Institute of Medical Sciences	Printer		Domestic	15,000.00

...tification :for data entry statistics ,research

...se of **Proposed disposal** :not required

Year: 1	Amala Institute of Medical Sciences	Laptop / Desktop		Domestic	75,000.00

...tification :for data entry statistics ,research

...se of **Proposed disposal** :not required

Total (Rs.): **1,247,700.00**

Travel Justification

...ear	Amount(Rs.)
Year: 1	174000.00

...tification :SL. NO PURPOSE RATE/trip Trips per month No. of months No. of people ALLOWANCE JUSTIFICATION 1 Transport of team to field ? 1,000.00 12.00 12.00 ...00.00 6 up and down taxi trip per month, each ?1000 per trip x 12 months 2 Transport allowance for trainers ? 6,000.00 5.00 30000.00

...tal: **174,000.00**

Short resume PI/Co-PI

...me of Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal

Short resume PI/Co-PI

Prof Saju Cherumadathil	1962-10-23	Community medicine epidemiology	1	6	a) Nodal Officer - AMALA-UNICEF Project on "Facts for Life", b) Research associate-"Evaluation of Pulse Polio Program" conducted by IndiaCLEN. c) Investigator-"Evaluation of Family Health Awareness Campaign" conducted by IndiaCLEN. d) Project coordinator-WHO project on Hospital Waste Management at the Institute of Maternal and Child Health, Govt. Medical College Calicut. e) UNICEF project on timely achievement of targets related to MDGs and f) UNICEF Project on HIV/AIDS Awareness among adolescence.	Co-

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization c products where cited.
Breast Feeding Practices Among Post Natal Mothers In A Tertiary Care Hospital In Thrissur District, Kerala, India. MV Sruthi, CR Saju, N Catherin, MP Jini, VK Parvathy European Journal of Biomedical 3 (6), 473-477	NA	SECOND	NA
The style of mothering and its determinants: a study among mothers of lower primary school children. M Hasin, CR Saju, JM Mundodan, MP Jini International Journal of Community Medicine and Public Health 6 (2), 808	NA	SECOND	NA
Assessment and comparison of hygiene practices on complementary feeds among mothers in the urban and rural area in Thrissur district, Kerala. BS Kuruvilla, CR Saju, JM Mundodan, MP Jini Indian Journal of Forensic and Community Medicine 6 (2), 66-69	NA	SECOND	NA
A Comparative Study on Complementary Feeding Practices among Mothers in Urban and Rural Areas in Trichur District, Kerala. BS Kuruvilla, CR Saju, JM Mundodan National Journal of Community Medicine 11 (07), 294-298	NA	SECOND	NA
Utility of Broca's index in assessing body mass: analysis of anthropometric measures from a cross sectional study. JM Mundodan, CR Saju, VM Joshy National Journal of Community Medicine 10 (11), 600-604	NA	SECOND	NA
An assessment of the nutritional status of underfive children in a rural area of Thrissur district, Kerala, India. R Priyanka, V Vincent, MP Jini, CR Saju Int J Community Med Public Health 3 (12), 3479-3486	NA	AUTHOR	NA
Assessing risk factors of Non-Communicable Diseases using STEPS Survey in a rural area of Thrissur District, Kerala Saju CR, Catherin Nisha, Jerry Rachel, Kerline Jerome, Subin Koshy, Vidhu J, International Journal of Medical Science and Current Research 2(40, 241	NA	FIRST	NA

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposa

Short resume PI/Co-PI

RAMAN	1953-12-21	Epidemiologist, Modernising Government Programme (MGP-a Govt of Kerala initiative): 2004	33	NA	Member, Technical Advisory Committee, Health Technology Assessment India (HTAIn), Department of Health Research, Government of India (continuing) Member, Steering Committee of SHARE- South Asian Hub for Advocacy, Research and Education in Mental Health, a US National Institutes of Health initiative for supporting community mental health research in India, Pakistan, Bangladesh, Sri Lanka, Nepal and Afghanistan Chairman, Technology Development and Adaptation Program, Kerala State Council for Science, Technology and Environment, Government of Kerala Member, Committee for evaluation of proposals for conducting seminars, symposia and workshops, Kerala State Council for Science, Technology and Environment Member, Governing Board, Institute of Health Systems, Hyderabad Chairman, Health Action by People, an NGO working in community based health research in Kerala Member, IDPAD (Indo-Dutch Programme for Alternatives in Development) MEMBERSHIP IN PROFESSIONAL BODIES Member, International Epidemiological Association Fellow, International Academy of Cardiovascular Sciences	Co-PI

Maximum of 10 primary research publications related to the proposal

details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.
gren, K Theo, S Rangarajan et al (including VR Kutty). Psychosocial factors esity in 17 high-, middle-, and low-income countries: The Prospective Epidemiological (PURE) study. International Journal of Obesity 8:1217-23	NA	AUTHOR	NA
mar A Kasar, Raghavan Nair Suresh Kumar, Vellappillil Raman Kutty. growth following congenital heart surgery in economically vileged children. Heart Asia 2011:3,1:135-139	NA	AUTHOR	NA
Sensarma, Subhasis Bhandari, and V Raman Kutty. Immunisation status predictors among children of HIV-infected people in Kolkata. Health and Care in the Community 201220,6:645-652	NA	AUTHOR	NA
ghese, V Raman Kutty and Mala Ramanathan. The interactions of ethical and moral values of immediate stakeholders of immunization services in an states: a qualitative study. BMJ Open 20133: e001905. doi:10.1136/ -2012-001905	NA	SECOND	NA
a P, Bhandari S and Kutty VR. Barriers to immunization among children fected mothers in Kolkota, India: a qualitative study. Asia Pac J Public May 201527,2:1362-71	NA	AUTHOR	NA
akshmi,Sanjeev Nair, Biju Soman,Rani Alex, K Vijayakumar, V R Kutty. al and neonatal outcomes of gestational diabetes: a retrospective cohort from Southern India. Journal of Family Medicine and Primary Care 395-8	NA	AUTHOR	NA
TR, Sarma PS, Kutty VR. Utilization of maternal health care services in nflict Nepal. International Journal of Women's Health 2015 7:783-90	NA	AUTHOR	NA
asssery Sankar, V Raman Kutty, T N Anand. Measuring childhood socio- position in health research: development and validation of childhood economic position questionnaire using mixed method approach. Health on Perspectives 2019 9 (1): 40-49	NA	SECOND	NA

Experience as Investigator

the project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

	Title	Grant Amount	Start Date	End Date

Short resume PI/Co-PI

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Propos
Dr KALYANI PILLAI	1966-03-24	paediatrics	10	*nil*	*nil*	PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.
Diagnosis And Assessment Of Severity of Paediatric Pneumonia Using The Respiratory Index Of Severity (Risc) Scoring System 2021 Kalyani Pillai, Edwin Ros Sartho, Lekshmi T P, Parvathy V K Diagnosis And Assessment of Severity of Paediatric Pneumonia Using The Respiratory Index Of Severity (Risc) Scoring System.Indian Pediatr.2021 Nov1558(11):1052-1053 PMID:34837366 https://pubmed.ncbi.nlm.nih.gov/34837366/ Original research article in PubMed Indexed Journal	2.3	FIRST	NA
Serum zinc levels and predictors of severity of acute lower respiratory tract infections in children under five years of age 2021 Shisira Philip1, Jessie Jose2, Kalyani Pillai3, Vadakkoottu Krishnan Parvathy4 Sri Lanka Journal of Child Health, 2021 50(4):630-636 htpp://doi.org//10.4038/sljch.v504.9852 Original research article in Scopus indexed journal	0.132	AUTHOR	NA
Kalyani Pillai , Mohamed Rabeeh International Journal of Science Engineering Development Research (www.ijsdr.org), ISSN:2455-2631, Vol.7, Issue 9, page no.100 - 104, September-2022	NA	FIRST	NA
Kalyani Pillai, Jalaludeen J, Vadakoot Krishnan Parvathy. Asian J Med Sci . 2023 Jan 1.14(1):217-21.	NA	FIRST	NA
George, M., Pillai, K. Suseela, K.V. Kidney Injury Molecule-1 as a Urinary Biomarker for Aminoglycoside Induced Acute Kidney Injury, among Non-Critically Ill Children. Indian J Pediatr (2023).	4.3	CORRESPONDING	NA

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date

Declaration

I hereby declare that the entries in this form and the additional particulars, if any, furnished herewith are true to the best of my knowledge and belief. I understand that in the event of my information being found false or incorrect at any stage, my project/proposal shall be liable to cancellation / termination without notice or any compensation in lieu thereof.

I hereby certify that the research proposal I have submitted to ICMR, New Delhi, for potential funding is entirely my original idea and has not been copied or replicated from any other source. Furthermore, I confirm that this proposal has undergone scrutiny using a standard plagiarism detection tool, verifying its originality and confirming that its contents have not been directly taken from any other sources. Additionally, I declare that there have been no established or pending plagiarism charges against me in the last five years.
In the event that the funding agency identifies any form of plagiarism or inconsistencies in the aforementioned proposal, I acknowledge and agree to comply with any actions deemed necessary by ICMR. I take full responsibility for any such discrepancies and will adhere to the consequences as required.

Short resume PI/Co-PI

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Propos
Dr KALYANI PILLAI	1966-03-24	paediatrics	10	nil	nil	PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.
Diagnosis And Assessment Of Severity of Paediatric Pneumonia Using The Respiratory Index Of Severity (Risc) Scoring System 2021 Kalyani Pillai, Edwin Ros Sartho, Lekshmi T P, Parvathy V K Diagnosis And Assessment of Severity of Paediatric Pneumonia Using The Respiratory Index Of Severity (Risc) Scoring System.Indian Pediatr.2021 Nov1558(11):1052-1053 PMID:34837366 https://pubmed.ncbi.nlm.nih.gov/34837366/ Original research article in PubMed Indexed Journal	2.3	FIRST	NA
Serum zinc levels and predictors of severity of acute lower respiratory tract infections in children under five years of age 2021 Shisira Philip1, Jessie Jose2, Kalyani Pillai3, Vadakkoottu Krishnan Parvathy4 Sri Lanka Journal of Child Health, 2021 50(4):630-636 htpp://doi.org//10.4038/sljch.v504.9852 Original research article in Scopus indexed journal	0.132	AUTHOR	NA
Kalyani Pillai , Mohamed Rabeeh International Journal of Science Engineering Development Research (www.ijsdr.org), ISSN:2455-2631, Vol.7, Issue 9, page no.100 - 104, September-2022	NA	FIRST	NA
Kalyani Pillai, Jalaludeen J, Vadakoot Krishnan Parvathy. Asian J Med Sci . 2023 Jan 1.14(1):217-21.	NA	FIRST	NA
George, M., Pillai, K. Suseela, K.V. Kidney Injury Molecule-1 as a Urinary Biomarker for Aminoglycoside Induced Acute Kidney Injury, among Non-Critically Ill Children. Indian J Pediatr (2023).	4.3	CORRESPONDING	NA

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date

Declaration

I hereby declare that the entries in this form and the additional particulars, if any, furnished herewith are true to the best of my knowledge and belief. I understand that in the event of my information being found false or incorrect at any stage, my project/proposal shall be liable to cancellation / termination without notice or any compensation in lieu thereof.

I hereby certify that the research proposal I have submitted to ICMR, New Delhi, for potential funding is entirely my original idea and has not been copied or replicated from any other source. Furthermore, I confirm that this proposal has undergone scrutiny using a standard plagiarism detection tool, verifying its originality and confirming that its contents have not been directly taken from any other sources. Additionally, I declare that there have been no established or pending plagiarism charges against me in the last five years.
In the event that the funding agency identifies any form of plagiarism or inconsistencies in the aforementioned proposal, I acknowledge and agree to comply with any actions deemed necessary by ICMR. I take full responsibility for any such discrepancies and will adhere to the consequences as required.

ICMR CONCEPT PROPOSAL PART A

1 Title:

Developing a prediction equation for estimating height using segmental length for useto monitor growth and nutrition in Indian children with physical disabilities

2 Summary:

Rationale: Height is essential for assessing growth and nutrition in children. In physically disabled children direct height measurement is very difficult. The purpose of this study was to develop a valid and reliable method for estimating height by deriving an equation using segmental length, in non-disabled, healthy Indian children and thus monitor growth and nutrition in disabled children.
Novelty: There is no study from India to assess height in disabled children using predictive equations. The goal was to cover a larger age group range than those previously published and to be simple enough for daily clinical use in disabled Indian children.
Objective: We aim to develop prediction equations to calculate estimated height using segmental length measurement for use in Indian children with disabilities.
Methodology: Across-sectional study that collects data from healthy children from 2 to 18 years of age in the community. They will be divided into 4 groupsof both sexes based on age groups (2-5 years, 6-10 years, 11-14 years, 15-18 years). The Height, UA (Upper Arm length), KH (Knee Heel length), and T (Tibial length) measurements will be taken using portable anthropometric measurement tools by a trained team.
Expected outcome:We propose to develop several prediction algorithms and test the algorithm in a test sample that isnaive to the algorithms. The performance of different algorithms will be assessed,andthebestonechosenforrecommendation. The development of anthropometric protocols, that emerged from such research, would benefit the follow-up of children with severe psychomotor disabilities

3 Priority area:

Reproductive, Maternal and child health,Nutrition
Childhood malnutrition*

4Keywords:

Segmental length, height, height prediction, disability, children, India

5Abbreviations:

WHO World Health Organization
BMI body mass index
CP cerebral palsy
UA upper arm length
KH knee heel length
T tibial length

6 Problem Statement:

Anthropometric measurements provide simple, non-invasive methods to assess the nutritional status of childrenMonitoring linear growth and nutritional status is critical

for diagnosis of malnutrition in children. Even though there are certain challengessuch as ethnic variation, assessment in normal childrenis generally straightforward using standardized growth charts. For children with cerebral palsy (CP) and similar neurodevelopmental disabilities and children with physical disabilities who are more likely to be malnourished compared to normal children, assessing their growth and nutritional status is challenging. There are no growth curves made specially for them and it is difficult to collect anthropometric data in such children.Given the importance of accuracy in height measures to evaluate growth and nutritional status in children, it is crucial to carry out research to establish an equation to predict height for use in children with physical disabilities in whom both growth and nutritional status are likely to be affected. The development of anthropometric protocols, that emerged from such research, would benefit the follow-up of children with severe psychomotor disabilitiesandfacilitate the accurate assessment of nutritional status in field studies.

7 Rationale of the study:

According to the State of the Education Report for India 2019 by UNESCO, India is home to 8 million children with disabilities.(1)In the 2011 census, around 7.62 percent of India's total population with a disability was children. (2)
The World Health Organization's (WHO) growth curves provide health professionals with a valuable tool for monitoring the growth of children and adolescents.However, these charts for weight, length, height, and body mass index (BMI) according to gender and age were created based on healthy subjects. (3) As such, they do not include children with physical disabilities both psychomotor and orthopedic, in which measuring recumbent length and height is unreliable if a child has contracture, high tone, scoliosis, or poor cooperation interfering with the optimal positioning.ICMR has in December 2023, called for expression of interest for applications to participate in data collection for a multi-growth reference research initiative to generate growth references for Indian children with no constraints to growth. This is the ideal time to think about the disadvantaged population of children, those with disabilities. In children with motor limitations, as in the case of cerebral palsy (CP), height measurement is currently performed by segmental measurements, as proposed by Stevenson in 1995. (4) According to the author, height can be estimated by using the equations he proposes with each measured segment: upper arm length (UA), knee heel length (KH), and tibial length (T). These equations are availablefor Caucasians, Latin Americans, Africans, Australians, and certain Asian populations.(4,5,6,7,8,9,10)No such equation has been derived for our Indian population by Indian researchers. (11)A systematic review byLamounier JA et al (3) highlights the limitations of various studies.Most studies lack age group stratification.Of themeasurement techniques employed, only some of the studies diduse a suitable instrument. Because these were all cross-sectional studies, there was no follow-up of the populations studied. In addition, the samples evaluated in these studies were mostly small. However, there are not many articles on the topic addressed in the review of literature. Thus, given the importance of the accuracy of height measurements to assess child health, further research is needed to establish height predictive equations from segmental length.The estimated stature may be plotted on standard growth charts to monitor growth and nutritional status in Indian children with disabilities. This may help in the early pickup of malnutrition in this traditionally disadvantaged population of children

8 Hypothesis/Research Question:

Using a normative sample of non-disabled healthy Indian childrento derive prediction equations,can segmental length be usedto estimate heightin physically disabled Indian childrento monitor growth and nutritional status?

9 Study Objectives:

1) To determine the anthropometric measurements (height and segmental length) in a normative sample of non-disabled healthy Indian children.
2) To developand assessthe performance of prediction algorithmsfor estimating height using different segmental lengths.
3) To recommend the best one as a height-predictive equation using segmental length.

10Methodology:

a)Study design:cross-sectional study

b)Study area: The community and schools in a panchayathin a semi-urban district in a state in South India, India

c) **Study samplingand sample size:**

Subjects will be enrolled by consecutive sampling

The study involves children aged 2-18 years. They will be divided into 4 groups (2-5 years, 6-10 years, 11-14 years, 15-18 years) respectively.
The predictors involved in the study are age, gender, Height,UA (Upper Arm length), KH (Knee Heel length), and T (Tibial length).
Consideringthatthereare5predictors,weproposetotake20childrenperpredictoraccounting for a total of 100 children per stratum, (i.e., 400 children in the training set) todevelop the prediction algorithm. Further, we will recruit an additional 25 children in eachstratum, a total of 125 children, to be included in the test set to validate the algorithm
developed.Thetotalsamplesize,therefore,willbe500,with125childrenineachofthe4 age groups selected

d)Project implementation:

Healthy childrenfrom 2 to 18 years of age and both sexescoming to the outpatient clinic on a routine visit or from school visits in the panchayath will be included in the study.

Children with an amputated limb(s), inability to move, and chronic disease that could affect or have affected their growth,who were unable to cooperate for measurements will be excluded.
Anthropometric measurements of interest -Height and UA,KH, and T as segmental lengthmeasurements will be taken during a routine outpatient clinic visit or school visit.Study tools used are portable anthropometric measurement tools include

Portable Stadiometer
Shor knee height measuring caliper
Harpenden Anthropometer to measure standing height and arm length
flexible steel tapes.

The same team of trained health workers will perform the measurements during the course of the study. To assess repeatability, all the measurements will be done in

triplicate on a subset of subjects by the same examiner, and with repeated measurements separated by equal time to lessen recall bias. All unilateral measurements will be taken on the left side of the body. All measurements will be recorded to the nearest 0.01 cm.
Informed consent will be obtained from parents, and assent will be given by children where possible.
Operational definitions for various anthropometric measurements will be defined using standard references. (12)

e)Statistical Analysis

The study aims to develop a prediction algorithm for estimating height using segmental length. In our exercise,we propose to develop several prediction algorithms in an adequate sample with a minimumsample size of 20 for each predictor variable and test the algorithm in a test sample that isnaive to the algorithms. Then the performance of different algorithms will be assessed usingstatisticalprinciplesoferrorreduction,andthebestonechosenforrecommendation.

11 Expected outcomes:

a) To develop several prediction algorithms using different segmental lengths for different age groups and both sexes to predict estimated height.
b) The performance of different algorithms will be assessed,andthebestonechosenforrecommendation.
The development of anthropometric protocols, that emerged from such research, would benefit the follow-upof the growth and nutritional status of children with severe psychomotor disabilities.

12 Immediate next steps following the end of the project

Clinical application of segmental lengths to populations in whom it is difficult to measureanthropometric data. Specialized growth charts have been developed for many other conditions, including Down syndrome,18 Prader-Willi syndrome,Turner syndrome, De Lange syndrome, and even meningomyelocele. There is a great needfor diagnosis-specific reference data.Future research may lead to a specialized growth chart for CP.

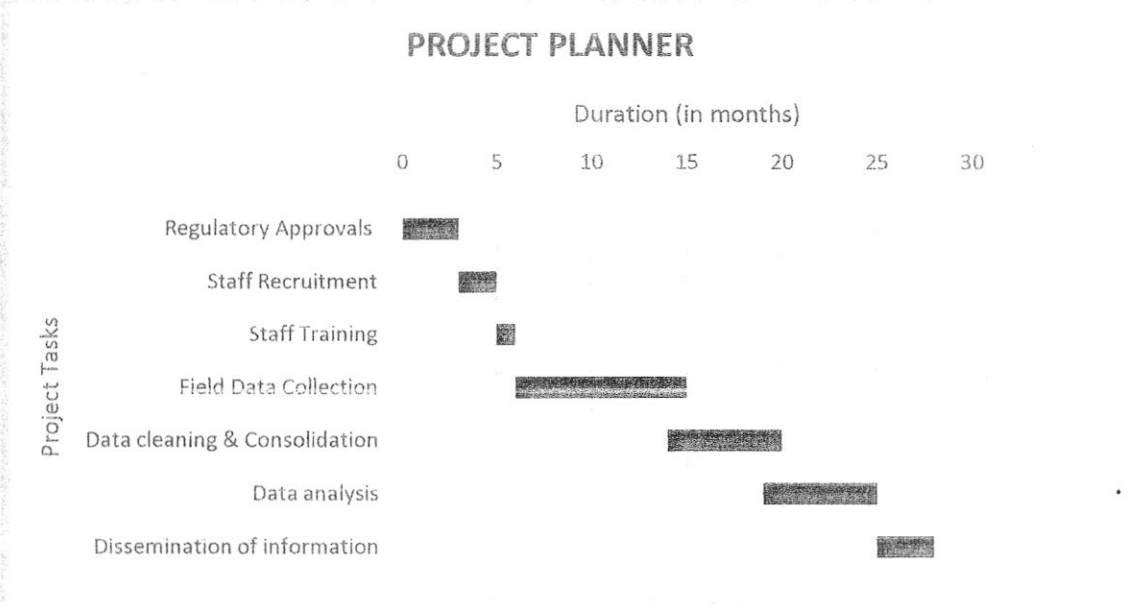
13 Whether the study is going to generate new intellectual property

We will be developing several prediction algorithms for estimated height using 3 segmental measures in 4 age groups in both sexes for an Indian population. The performance of different algorithms will be assessed,andthebestonechosenforrecommendation in each age group.No such equation has been derived for our Indian population by Indian researchers.

14 Timelines with achievable targets

Project Tasks	Duration (start)	Time required (in months)
Regulatory Approvals	0	3
Staff Recruitment	3	2

Staff Training	5	1
Field Data Collection	6	9
Data cleaning & Consolidation	14	6
Data analysis	19	6
Dissemination of information	25	3



According to this plan, the project will take 2+ years (2 years + 4 months).

15 References

1)https://www.unesco.org/en/articles/n-nose-state-education-report-india-2019-children-disabilitieshttp://
2)www.ccdisabilities.nic.in/resources/disability-india
3) Lamounier JA, Marteletto NM, Calixto CA, Andrade MR, Tibúrcio JD. Stature estimate of children with cerebral palsy through segmental measures: a systematic review. Rev paulpediatr. 2020 jan 13;38:e2018185. Doi: 10.1590/1984-0462/2020/38/2018185. PMID: 31939510; PMCID: PMC6958543
4) Stevenson RD. Use of segmental measures to estimate stature in children with cerebral palsy. Arch PediatrAdolesc Med. 1995 Jun;149(6):658-62. doi: 10.1001/archpedi.1995.02170190068012. PMID: 7767422.

5)Ruiz Brünner MM, Butler C, Cuestas E. Development of regression equations for estimating height and weight using body segments in Argentine children. Nutrition. 2019 Jan;57:122-126. doi: 10.1016/j.nut.2018.05.012. Epub 2018 Jun 19. PMID: 30153574.
6)Amezquita G MV, Hodgson B MI. Estimación de la tallaen la evaluaciónnutricional de niños con parálisis cerebral [Alternatives to estimate stature during nutritional assessment of children with cerebral palsy]. Rev Chil Pediatr. 2014 Feb;85(1):22-30. Spanish. doi: 10.4067/S0370-41062014000100003. PMID: 25079180.
7)Chumlea WC, Guo SS, Steinbaugh ML. Prediction of stature from knee height for black and white adults and children with application to mobility-impaired or handicapped persons. J Am Diet Assoc. 1994 Dec; 94(12):1385–1388. 1391. quiz 1389–1390. [PubMed: 7963188]
8)Gauld LM, Kappers J, Carlin JB, Robertson CF. Height prediction from ulna length. Dev Med Child Neurol. 2004 Jul; 46(7):475–480. [PubMed: 15230461]
9)Kihara K, Kawasaki Y, Yagi M, Takada S. Relationship between stature and tibial length for children with moderate-to-severe cerebral palsy. Brain Dev. 2015;37:853-7. https://doi.org/10.1016/j.braindev.2015.01.007
10)Rumapea F, Fadlyana E, Dhamayanti M, Tarigan R, Rahmayani R, Rusmil K. Height Prediction Using the Knee Height Measurement Among Indonesian Children. Food Nutr Bull. 2021 Jun;42(2):247-258. doi: 10.1177/03795721211002067. Epub 2021 Mar 24. PMID: 33759603.
11)Yousafzai AK, Filteau SM, Wirz SL, Cole TJ. Comparison of armspan, arm length and tibia length as predictors of actual height of disabled and nondisabled children in Dharavi, Mumbai, India. Eur J Clin Nutr. 2003 Oct;57(10):1230-4. doi:10.1038/sj.ejcn.1601705. PMID: 14506482.
12)Haapala H, Peterson MD, Daunter A, Hurvitz EA. Agreement Between Actual Height and Estimated Height Using Segmental Limb Lengths for Individuals with Cerebral Palsy. Am J Phys Med Rehabil. 2015 Jul;94(7):539-46. doi: 10.1097/PHM.0000000000000205. PMID: 25299521; PMCID: PMC4866590

Annexure-V

ICMR-Call for Application: INVESTIGATOR INITIATED RESEARCH PROPOSAL FOR SMALL EXTRAMURAL 2024 (SE)

Title of the project: DEVELOPING A PREDICTION EQUATION FOR ESTIMATING HEIGHT USING SEGMENTAL LENGTH.

Name of the PI: DR KALYANI PILLAI

Name of the Institute: AMALA INSTITUTE OF MEDICAL SCIENCES

Declaration & Attestation

I hereby certify that:

i. We have read the terms and conditions for ICMR Research Grant. All necessary Institutional facilities will be provided if the research project is approved for financial assistance.

ii. The equipment(s) that is being requested as part of this project is/are not available in the Institute/Department /or these are available and are being used at full capacity (Strike off the inappropriate one)

iii. The equipment(s) requested as part of this project have not been purchased earlier from the funds provided by ICMR for previous project(s) in the Institute.

iv. No utilization certificate (UC)/ statement of expenditure (SoE) final report is pending for earlier ICMR project(s) under the PI and the final report(s) for earlier projects have been submitted.

v. The project has not been submitted to any funding agency or institution other than the ICMR.

vi. The PI does not have more than 5 (five) ICMR projects at present as a Principal Investigator.

vii. We understand that ICMR shall only fund for the project positions, as enumerated in the criteria for engagement of Non-Institutional Project Human Resource Positions, purely on temporary contractual basis. ICMR has apprised us of this rule and we have carefully noted it.

viii. The PI and Co-investigator(s) hereby submit the ICMR Declaration of Interest form in prescribed format.

ix. The name of the Statutory Audit Authority of our Institute is as follows:

_____

[Please attach a copy of the resolution if a private firm is engaged]

x. Registration/Unique ID no. assigned by NITI Ayog, GoI (on DARPAN Portal) (applicable only for NGOs): .....

xi. CV of the investigator and Co-Investigators is/are attached in prescribed format.

	Name	Signature	Date
a)	Principal Investigator DR KALYANI PILLAI	Kalyani Pillai	9/3/24
b)	Co-Investigator(s) DR RAMANKUTTY & DR CRSAJU		9/3/24
c)	Head of the Department DR RAMARAJ	9/3/24	

Signature of the Head of the Institution with seal

Date: 9/3/24

Fr. Julious Arakkal CMI
Director

AMALA INSTITUTE OF MEDICAL SCIENCES

Indian Council of Medical Research (ICMR)

Deptartment of Health Research

(Ministry of Health and Family Welfare)

Investigator-Initiated Research Proposals

Proposal in Draft Stage

Proposal Id: Not Generated Yet

Proposal Title: Control of Dengue viral disease through community participation and source reduction activities in an urban area of Thrissur District– A Pilot Project.

Personal details of Principle Investigator (PI)

Name of PI (IN BLOCK LETTERS), Designation, Email, Contact No., Gender, DOB, Date of Superannuation	DR STEFFI FRANCIS MALIAKEL, Assistant Professor, steffimaliakel@gmail.com,9539116548, Female, 28-10-1991, 28-10-2061
Nature of Employment	Permanent
Institute	Amala Institute of Medical Sciences , Private academic institutions with valid UGC/AICTE/PCI or NMC approved Medical colleges ,

Proposal Details PART-A

Are you currently under regular employment in Medical Institutes, Research Institutes, Universities, Colleges, Recognized Research & Development laboratories, Government and semi-government organizations, and NGOs?	Yes
Advertisement	Call for Investigator-Initiated Research Proposals for small extramural grants - 2024

Summary (up to 250 words): A structured summary should contain the following subheadings: Rationale/ gaps in existing knowledge, Novelty, Objectives, Methods, and Expected outcome.

Dengue is a fast emerging pandemic prone viral disease in many parts of the world.1 Of the 3.5 billion people around the world living in dengue endemic countries and at risk of contracting dengue fever, 1.3 billion live in dengue endemic areas in 10 countries of the SEA Region.2 The number of dengue cases reported to WHO in South East Asian(SEA) region has increased by 46% (from 451,442 to 658,301) from 2015 to 2019.2 The current situation of the high burden of dengue cases in the SEA region is coupled with the absence of effective treatment and lack of comprehensive sustainable vector control. 2 Kerala is the southernmost state of India with favorable temperature for Aedes mosquito. Vector control measures are the most important intervention for controlling the outbreak of dengue viral disease. Novelty - Objectives- Methods- Expected outcome-

Priority Area/Priority Area diseases	Communicable Diseases (bacterial,viral, fungal, parasitic) / Vector borne diseases (other than malaria)
Keywords Six keywords separated by comma which best describe your project may be provided.	Dengue, vector control, multi - sectoral, stakeholder involvement, community participation
Abbreviations Only standard abbreviations should be used in the text. List of abbreviations maximum of ten may be given as a list.	ASHA - Accredited social health activist AWW - anganwadi workers ICDS - Integrated Child Development Scheme BI - Breteau Index

Problem Statement (up to 500 words): State the currently available information to present the problem adequately.

Dengue is a fast emerging pandemic prone viral disease in many parts of the world.1Dengue virus is the most geographically widespread Arbovirus and is a major public health threat in the tropics and subtropics. Of the 3.5 billion people around the world living in dengue endemic countries and at risk of contracting dengue fever, 1.3 billion live in dengue endemic areas in 10 countries of the SEA Region.2 The number of dengue cases reported to WHO in South East Asian(SEA) region has increased by 46% (from 451,442 to 658,301) from 2015 to 2019.2 The current situation of the high burden of dengue cases in the SEA region is coupled with the absence of effective treatment, and lack of comprehensive sustainable vector control. 2

Rationale of the study (up to 250 words) Mention how the research question addresses the critical barrier(s) in scientific knowledge, technical capacity, and/or [illegible] relevance to local, national and international context with relevant bibliography.

Anti-larval operations causing the reduction or permanent elimination of mosquito breeding places or sites are defined as source reduction methods. [illegible] primarily aims to prevent development of aquatic stages of mosquito larvae by reducing breeding source.(3) These methods are environment friendly, [illegible] the long run with minimum maintenance and surveillance. On the other hand use of insecticides are becoming difficult due to development of [illegible] insecticides. The source reduction activities are further classified into elimination or reduction of breeding sites primarily involving engineering methods like filling, drainage, drains and by drainage in irrigation schemes. The environmental manipulations include changing the salt content of water, silting, flooding, [illegible] levels etc. which are relatively difficult to implement. Throwing of disposable/used tea cups, glasses, buckets, tyres, utensils is a very common habit in the community particularly in residential urban settlements, irrespective of slums or organized localities. During monsoon and peri - monsoon months these small temporary water containers become enormous potential breeding sources for both Anopheles and Aedes vector mosquitoes. Open tanks, overhead and underground tanks, disused wells in urban, peri-urban or semi-urban locality are also potential breeding source. Shortage of potable water to slums dwellers forced to store water in containers. Construction sites has high breeding potentials. Labourers engaged in construction activities were often from malaria and dengue endemic areas, might [illegible] potentials in construction sites with asymptomatic carriers of malaria parasites caused severe malaria outbreaks in New Delhi.(3) Concrete roof and terrace without proper drainage may lead to water collections, during monsoon months forming breeding sites. The above described breeding sources in urban, semi or peri urban areas are therefore considered for comprehensive source reduction by involving communities, residential welfare associations, various religious groups, organizations, schools, hospitals, gram panchayats, office building, local PWD or CPWD, Railways and municipal bodies/corporations.

Hypothesis/ Research question (up to 100 words) : Will Community participation, field workers training and involvement of multiple stakeholders for planning and implementation of source reduction activities reduce the Dengue disease burden in an urban area of Thrissur District.

Methodology

Include objective-wise work plan under the following sub-headings:

Study Objective No. 1

Study Objective : To assess the baseline knowledge, attitude and practice regarding Dengue disease and its vector source reduction activities.

Study Design : Cross sectional

Study Area : Community

Sample Size : The selected corporation consists of 55 divisions. Each division contain 250-300 households. 10% houses of each division will be surveyed of field workers. i.e. 30 houses per division Sample size will be 30 x 55 i.e 1650 Sampling Technique - systematic random sampling - every 10th house will / one house in each lane

Project Implementation Plan : 1. Constitution of a District Coordination Committee to coordinate source reduction activities. 2. Organization of Dis workshop for obtaining suggestions from different authorities regarding the implementation plan. 3. Conduction of baseline survey to assess the knowe practice pertaining to Dengue vector control. District Coordination Committee– It will comprise of members from district vector control unit, Corporatio Supervisor, representative from Collector's office, Ward Counsellors, District Malaria Officer, Junior Administrative medical officers, ASHA mentor, Anganwadi ICDS Supervisor, NGOs (eg.Kuriakose Elias Sevice society), Youth groups co- ordinator (eg. NSS co-ordinator), Community Medicine faculty and an Entomol Executive body: Principal investigator NVBDCP program officer Public health expert Entomologist CDPO District Program manager District Corporation supervisor. A pre- test survey will be conducted with the help of field workers to assess the awareness level of the population, larval indices and acute febrile cases. Vector breeding sources detected will be removed. iii. Preparatory activities: There are total of 290 field workers (ASHA and Anganwadi teachers) and a mir of 50 other volunteers will be identified from the community and youth groups. TOTs will be conducted for them to train them for required field work. Incentiv be provided for the survey conducted. -Resource materials and teaching modules for the workshops will be prepared. -Development of GIS enabled applicatic recording field level data. -Health education videos and reels to be circulated via social media.

Design of Statistical analysis : Descriptive statistics. prevalence will be assessed in percentages

Study Objective No. 2

Study Objective : 2. To improve awareness regarding dengue and vector control methods among the stakeholders and implement source reduction with communi participation

Study Design : Quasi experimental

Study Area : Community

Sample Size : Field workers and volunteers from the study area.The field workers consist of ASHA(155) workers and Anganawadi workers(135). along with them volunteers will be involved (50 - 100) total - 350 to 400

Project Implementation Plan : Awareness generation- a. Conduction of Training of trainers (TOT) sessions for volunteers and field workers. b. Awareness campaigns and risk communication for general population using various modalities of communications like social media platforms and mass media c. Behavioral change in the community towards adopting good vector control practices. II. Training of trainers: Workshops will be conducted for the volunteers and field workers in batches of 30- 40. They will be equipped with knowledge of dengue, vector transmitting it and techniques of vector control. Source reduction methods and field survey techniques will be taught. They have to conduct health awareness sessions in their locality for which honorarium will be given. Training on data collection and entry will be conducted by the IT experts. III. Organization of heath awareness sessions at community level: The community awareness sessions will be organized and co-ordinated by the trained leaders themselves with technical and financial support from the project team. They will be paid a honorarium for the same. IV. Conduction of weekly source reduction drives : it will be done in all areas under the supervision of field supervisors.

Design of Statistical analysis : Intervention stage - no statistical analysis involved

Study Objective No. 3

Study Objective : To assess the outcome of source reduction activities and community participation in reducing the vector burden and dengue disease burden

Study Design : Cross- sectional

Study Area : Community

Sample Size : 10% of total population - 30 houses in each division -Sampling - systematic random sampling

Project Implementation Plan : Post – intervention survey: After conduction of health awareness sessions and source reduction in all the areas post test survey will be conducted. The district co-ordination committee meetings will be held at least once in 3 months and executive body meeting at least once a month to assess and guide the progress of the activities. Best block/ division to achieve good source reduction will be identified and felicitated in the District committee meetings. Multi - sectoral involvement will be given prime importance

Methodology

Include objective-wise work plan under the following sub-headings:

Statistical analysis : Descriptive statistics, pre and post intervention differences will be checked using paired T test and Wilcoxans signed rank test, tests for association (chi square)

Expected outcome/ Deliverables aligned with research question (up to 100 words): 1. Increased field awareness - regarding Dengue, its transmission and prevention. Importance of source reduction. 2. Reduction in the Larval Indices (Breteau Index and House Index) 3. Reduction in the Dengue outbreaks

Immediate next steps following the end of the project(up to 100 words): Ensure continuity and sustainability of the activities. Scaling up the activities to other areas.

Whether the study is going to generate new intellectual property: Yes.

Timelines with achievable targets Download

Proposal Details (PART-B)

Preliminary work done by the PI including the source of funding (up to 250 words): A small scale project was rolled out within the campus premises when the Breteau Index(BI) was found to be above 100. All sections of workers from the cleaning department till the doctors and management were given health education and involved in source reduction activities. Weekly source reduction drives were conducted under the leadership of the entomologist, involving the gardening, security and cleaning department. This multi - departmental involvement led to reduction of BI to less than 5. Campus was declared to be aedes mosquito free campus.

Skill and experience of the research team (Highlight only salient points (along with 5 relevant publications) that provides confidence to reviewers that team can implement the project with Research team consists of well experienced and dedicated members. Team includes an entomologist who has conducted similar projects successfully.

Institutional Support/ Facilities: The Institution supports and promotes research. There is a Reasearch unit dedicated to helping and guiding faculties in research.

Laboratory facilities (in-vitro/ in-silico) Institutional resources such as instruments/ equipment and other physical resources available for use in the project proposed animal house etc. The institution has a well established entomology lab that can support the implementation of the said project.

Conflict of Interest declaration (if any) Nil

Duration (in Months) 24 Months

Investigator Details

Name	Institute	Designation	Email	Contact No.	Role in Proposal
Dr Steffi Francis Maliakel	Amala Institute of Medical Sciences	Assistant Professor	steffimaliakel@gmail.com	9539116548	PI
Mr Mohamed Rafi M	Amala Institute of Medical Sciences	Entomologist	mohamedrafi920@gmail.com	9747913254	Co-PI
Dr Sruthi M V	Amala Institute of Medical Sciences	Associate Professor	sruhar086@gmail.com	9495966828	Co-PI
Prof Saju Cherumadathil	Amala Institute of Medical Sciences	Professor	drsajucr@gmail.com	9495315986	Co-PI

Documents consideration

#	Document Name	Is Applicable?	Uploaded Document	Remarks
1	Declaration & Attestation Form(duly signed by Head of Department/ Director)	Yes	View	Declaration
2	Additional supplementary information including figures tables flow diagrams etc can be shared as PDF	Yes	View	declaration

Proposed Budget Details

Institute	Budget Year	Manpower Budget (Rs.)	Contingency	Consumables	Equipment	Travel	Overhead	Total(
Amala Institute of Medical Sciences	1	2801000.00	25000.00	8985000.00	76000.00	500000.00	0	123870
Amala Institute of Medical Sciences	2	0	0	0	0	0	0	0
Total in (Rs.):		**2801000**	**25000**	**8985000**	**76000**	**500000**	**0**	**12,387,0**

Budget Breakup Details (Staff/Manpower)

#	Budget Year	Institute	Designation	No. of Person(nos)	Require Month(nos)	Cost Per Person(Rs.)	Overhead(Rs.)	T Cost(
1	**Year: 1**	Amala Institute of Medical Sciences	Senior Project Assistant	1	3	30,600	0.00	91,800.
Justification : For data analysis and writing the report								
2	**Year: 1**	Amala Institute of Medical Sciences	Office Helper	1	12	26,800	0.00	321,600.0
Justification : For office documentation, communication and administrative activities								
3	**Year: 1**	Amala Institute of Medical Sciences	Data Entry Operator	1	12	29,200	0.00	350,400.00
Justification : For field survey data entry and management								
4	**Year: 1**	Amala Institute of Medical Sciences	Project Technical Support - I	1	12	18,900	0.00	226,800.00
Justification : For field support and co-ordination								
5	**Year: 1**	Amala Institute of Medical Sciences	Project Technical Support - I	2	6	18,000	0.00	216,000.00
Justification : to assist the entomologist and in field work								
6	**Year: 1**	Amala Institute of Medical Sciences	Project Research Scientist - I (Medical)	1	8	67,000	0.00	536,000.00
Justification : for preparation of Training modules, overall co-ordination with the district health officers, liason officer, Resource person for TOTs, supervision of field activities								
7	**Year: 1**	Amala Institute of Medical Sciences	Project Research Scientist - I (Non Medical)	3	6	58,800	0.00	1,058,400.00
Justification : For the initial formation of District Co-ordination Cell, conduction of meetings, setting the protocols, involvement of multiple sectors, volunteers recruitment, TOTs								

Total Cost (Rs.)
including overhead

2,801,000.00

Contingency budget breakup details

#	Budget Year	Institute	Overhead Charges (Rs.)	Total Cost(Rs.)
1	**Year: 1**	Amala Institute of Medical Sciences	0.00	25,000.00

Total Cost (Rs.)
including overhead

25,000.00

Contingency budget breakup details

Total(Rs.)

Name :Development of GIS enabled software - 15,000 Printing of questionnaires/ forms - 10,000

for smooth and effective roll out of the project and publishing the findings

12387000

Cost (Rs.) 25,000.00

0

Consumables Budget Breakup Details

2,387,000.00

Budget Year	Institute	Consumables Name	Overhead	Total Cost(Rs.)
Year: 1	Amala Institute of Medical Sciences	Training of ASHA Workers Anganawadi workers a) Training Module - Rs. 50,000 b) Refreshments - Rs. 10,000 c) TA/DA for field workers Rs 1,00,000 Organizing Community Awareness sessions to entire population at Thrissur Corporation Thrissur corporation – 55divisions 1 Division- 7000 Population (14 sessions(500 each) for covering 7000 population) Rs 10,000/ session x 14 x 55 will be Rs 77,00,000 Incentives to ASHA and anganwadi workers - Rs 50/house covered (including pre and post survey)- 50 x 300 houses x 55 divisions - Rs. 8,25,000 Organizing a district level workshop - Rs. 3,00,000	0.00	8,985,000.00

Total Cost(Rs.)

91,800.00

Justification : consumables, refreshments and other expenses of conducting district level workshop , incentives for ASHA/ AWW/Volunteers

500.

Cost (Rs.) 8,985,000.00

overhead

Equipment Budget Breakup Details

.00

Budget Year	Institute	Equipment Name	Equipment Model	Equipment Manufacturer	Equipment Type	Total Cost(Rs.)
Year: 1	Amala Institute of Medical Sciences	Tablet			Domestic	13,000.00

Justification :For data collection and GIS mapping of cases and vector breeding sites by needy ASHA/ AWW worker/volunteer

Mode of **Proposed disposal** :it will be returned to ICMR upon completion of project

Year: 1	Amala Institute of Medical Sciences	Laptop			Domestic	50,000.00

Justification :For GIS software development, data entry and other technical purposes

Mode of **Proposed disposal** :will be returned back to ICMR

Year: 1	Amala Institute of Medical Sciences	Tablet			Domestic	13,000.00

Justification :For data collection and GIS mapping of cases and vector breeding sites by needy ASHA/ AWW worker/volunteer

Mode of **Proposed disposal** :it will be returned to ICMR upon completion of project

Total (Rs.): **76,000.00**

Travel Justification

Year	Amount(Rs.)
Year: 1	500000.00

Justification :For coordinating District Committee meetings, Field survey, organising field level workshop

Total: **500,000.00**

Short resume PI/Co-PI

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role i Propo
Prof Saju Cherumadathil	1962-10-23	Epidemiology, Public health	2	2	nil	Co-PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization products where cited.
Soorya S, Menon VTK, Saju CR, Rafi M, Joshy V M. The knowledge, attitude and practices on mosquito borne diseases among people in a rural area in Thrissur. J Commun Dis 2020 52(4):66-69.	0	co-author	nil
Vaz C, Harikumar A, Mundodan JM, Rafi M, Saju CR. Mosquito density in rural Kerala: a study on the trend of Aedes larval indices over monsoon in a rural area of Thrissur district, India. Int J Community Med Public Health 20196:1-5	4.52	co-author	nil
VT Krishnadas Menon, Jerry Rachel, CR Saju, M Mohamed Rafi, Vidhu M Joshy. A study on mosquito density in rural Kerala before and after floods. International Journal of Community Medicine And Public Health 2019 6 (2), 659-663.	4.52	co-author	nil

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications
UNICEF project on timely achievement of targets related to MDGs	Co-PI	Unicef	193000.00	nil
UNICEF Project on HIV/AIDS Awareness among adolescence.	Co-PI	Unicef	251500.00	nil
UNICEF Project on "Facts for Life",	Co-PI	Unicef	1197000.00	nil

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date

Short resume PI/Co-PI

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
Dr Sruthi M V	1986-11-04	Epidemiology, Public health	1	2	nil	Co-PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.
The Role of Health Education on Larval Indices and Fever Cases from Rural Area of Thrissure District, Kerala: A Quasi Randamized Control Study. SR Teenu, MV Sruthi, CR Saju, MM Rafi Clinical Medicine And Health Research Journal 2 (2), 87-91	4.58	co-author	nil

Short resume PI/Co-PI

Experience as Investigator

[illegible]	Role	Funding Agency	Amount of Funding	Reference of main publications
[illegible] Barriers and [illegible] of Non-communicable disease [illegible] prevention in Kerala	Co-PI	financially supported by Achutha Menon Centre for Health science studies Trivandrum.	50000.00	Jose NK, Sruthi MV, Rachel J, Jerome K, Vaz C, Saju CR. Barriers and facilitators of noncommunicable disease (NCD) prevention in Kerala: A qualitative study. J Family Med Prim Care. 2022 Jun11(6):3109-3114. doi: 10.4103/jfmpc.jfmpc147121. Epub 2022 Jun 30. PMID: 36119306 PMCID: PMC9480671.

Ongoing research projects (funded by ICMR)

[illegible]	Title	Grant Amount	Start Date	End Date

[illegible] of PI/Co-PI	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
[illegible] Francis Maliakel	1991-10-28	Epidemiology, Public health	1	1	nil	PI

Maximum of 10 primary research publications related to the proposal

[illegible] details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ protocol document or patent/commercialization of products where cited.
[illegible]y, S., Maliakel, S. F. (2021). A comparative study on the health [illegible] and substance abuse among the tobacco farmers and non-tobacco farmers in hassan district, Karnataka. Indian Journal of Occupational [illegible] Environmental Medicine, 25(1), 33-38.	0.9	corresponding author	nil

Experience as Investigator

[illegible] of the project	Role	Funding Agency	Amount of Funding	Reference of main publications
[illegible] detection of oral cancer – detection of oral premalignant lesions.	Co-PI	Karnataka State Anti-tobacco cell	50000.00	Indian Journal of Cancer 58(Suppl 1):p S45-S70, December 2021.
[illegible]ence of Iodine deficinecy disorders [illegible]-12 years school children in Hassan	Co-PI	NIDCCP	100000.00	nil
[illegible] of Tobacco farming on health [illegible] livelihood of tobacco farmers	Co-PI	Karnataka State Anti-tobacco cell	50000.00	Indian journal of occupational and environmental medicine,2021, 25(1), 33–38. https://doi.org/10.4103/ijoem.IJOEM4120

Ongoing research projects (funded by ICMR)

[illegible]	Title	Grant Amount	Start Date	End Date

Name of PI/Co-Pi	DOB	Domain Expertise	Number of articles in Pub Med (Past 10 years)	h-index	Fellow of Academics	Role in Proposal
[illegible]ammed Rafi M	1971-05-24	Entomologist	0	2	entomologist	Co-PI

Short resume PI/Co-PI

Maximum of 10 primary research publications related to the proposal

Publication details in AMA style	Impact factor of journal	Author type (first, corresponding, coauthor)	Name of policy/programme/ pro document or patent/commerciali products where cited.
Mosquito density in rural Kerala: a study on the trend of Aedes larval indices over monsoon in a rural area of Thrissur district, India. C Vaz, A Harikumar, JM Mundodan, M Rafi, CR Saju	0	co-author	nil
A Study on Larval Indices of Aedes and Risk for Dengue Outbreak in a Rural Area of Thrissur District, Kerala. AS Paul, J Vincent, CR Saju, MM Rafi Journal of Communicable Diseases (EISSN: 2581-351X P-ISSN: 0019-5138) 52	0	co-author	nil
Kerline P Jerome, Jenyz M Mundodan, Mohammed Rafi and C R Saju. Impending Dengue outbreak: an assessment on mosquito density, diversity and awareness. International Journal of mosquito research. 2019 6(6):22-25.	5.29	co-author	nil
Anna SP, Vincent J, Saju CR, Rafi MM. A Study on larval indices of dengue and risk of Dengue outbreak in a rural area of Thrissur district, Kerala. J Commun Dis. 2020 52(1):1-6.	0	co-author	nil
Vaz C, Harikumar A, Mundodan JM, Rafi M, Saju CR. Mosquito density in rural Kerala: a study on the trend of Aedes larval indices over monsoon in a rural area of Thrissur district, India. Int J Community Med Public Health 20196:1-5	4.52	co-author	nil
VT Krishnadas Menon, Jerry Rachel, CR Saju, M Mohamed Rafi, Vidhu M Joshy. A study on mosquito density in rural Kerala before and after floods. International Journal of Community Medicine And Public Health 2019 6 (2), 659-663.	4.52	co-author	nil
Rafi M., M., Vincent, J., C. R., S., Johny V., F. (2023). Trend of mosquito larval indices over a year in a rural area of Thrissur district, Kerala. International Journal Of Community Medicine And Public Health, 10(5), 1856–1860. https://doi.org/10.18203/2394-6040.ijcmph20231286	4.52	First	nil

Experience as Investigator

Title of the project	Role	Funding Agency	Amount of Funding	Reference of main publications

Ongoing research projects (funded by ICMR)

Project Id	Title	Grant Amount	Start Date	End Date

Declaration

☑ Please check the checkbox I hereby declare that the entries in this form and the additional particulars, if any, furnished herewith are true to the best of my knowledge and belief. I understand that in the event of my information being found false or incorrect at any stage, my project/proposal shall be liable to cancellation / termination without notice or any compensation in lieu thereof.

☑ I hereby certify that the research proposal I have submitted to ICMR, New Delhi, for potential funding is entirely my original idea and has not been copied or replicated from any other source. Furthermore, I confirm that this proposal has undergone scrutiny using a standard plagiarism detection tool, verifying its originality and confirming that its contents have not been directly taken from any other sources. Additionally, I declare that there have been no established or pending plagiarism charges against me in the last five years.
In the event that the funding agency identifies any form of plagiarism or inconsistencies in the aforementioned proposal, I acknowledge and agree to comply with any actions deemed necessary by ICMR. I take full responsibility for any such discrepancies and will adhere to the consequences as required.

ıted on: Thu Mar 14 2024 at 2:51:38 PM

Annexure-V

ICMR-Call for Application: ICMR/BMI/EPMS/Call for Proposal/2023

Title of the project: Control of Dengue viral disease through community participation and source reduction activities in an urban area of Thrissur District

Name of the PI: Dr Malliakel Steffi Francis

Name of the Institute: Amala Institute of Medical Sciences, Thrissur.

Declaration & Attestation

I hereby certify that:

- We have read the terms and conditions for ICMR Research Grant. All necessary Institutional facilities will be provided if the research project is approved for financial assistance.
- The equipment(s) that is being requested as part of this project is/are not available in the Institute/Department or these are available and are being used at full capacity (Strike off the inappropriate one).
- The equipment(s) requested as part of this project have not been purchased earlier from the funds provided by ICMR for previous project(s) in the Institute.
- No utilization certificate (UC)/ statement of expenditure (SoE) final report is pending for earlier ICMR project(s) under the PI and the final report(s) for earlier projects have been submitted.
- The project has not been submitted to any funding agency or institution other than the ICMR.
- The PI does not have more than 5 (five) ICMR projects at present as a Principal Investigator.
- We understand that ICMR shall only fund for the project positions, as enumerated in the criteria for engagement of Non-Institutional Project Human Resource Positions, purely on temporary contractual basis. ICMR has apprised us of this rule and we have carefully noted it.
- The PI and Co-investigator(s) hereby submit the ICMR Declaration of Interest form in prescribed format.
- The name of the Statutory Audit Authority of our Institute is as follows:

  ____

  [Please attach a copy of the resolution if a private firm is engaged]
- Registration/Unique ID no. assigned by NITI Ayog, GoI (on DARPAN Portal) (applicable only for NGOs) N-A
- CV of the investigator and Co-Investigators is/are attached in prescribed format.

Name		Signature	Date
Principal Investigator	Dr Malliakel Steffi Francis	[signature]	9/3/2024
Co-Investigator(s)	Dr. SRUTHI MV	[signature]	09/03/24
Head of the Department	Dr. C.R. SAJU	[signature]	09/03/24

Dr Mohd Rafi [signature]

[signature]

Head of the Institution with seal

Fr. Julious Arakkal CMI

Director

9/3/2024

AMALA INSTITUTE OF MEDICAL SCIENCES THRISSUR

Annexure-V

Ref. ICMR-Call for Application: Intermediate Extramural Grants 2023

Title of the project: Sarcopenia Reduction Strategies for Fall Risk Mitigation in Elderly – a Multicentric Quasi Experimental Study Comparing Community and Hospital Based Approaches in Kerala

Name of the PI: Dr Maliakel Steffi Francis

Name of the Institute: Amala Institute of Medical Sciences, Thrissur, Kerala

Declaration & Attestation

We hereby certify that:

i. We have read the terms and conditions for ICMR Research Grant. All necessary Institutional facilities will beprovided if the research project is approved for financial assistance.

ii. The equipment(s) that is being requested as part of this project is/are not available in the Institute/Department
/or these are available and are being used at full capacity (Strike off the inappropriate one)

iii. The equipment(s) requested as part of this project have not been purchased earlier from the funds provided byICMR for previous project(s) in the Institute.

iv. No utilization certificate (UC)/ statement of expenditure (SoE) final report is pending for earlier ICMRproject(s) under the PI and the final report(s) for earlier projects have been submitted.

v. The project has not been submitted to any funding agency or institution other than the ICMR.

vi. *The PI does not have more than 5 (five) ICMR projects at present as a Principal Investigator.*

vii. We understand that ICMR shall only fund for the project positions, as enumerated in the criteria for engagement of Non-Institutional Project Human Resource Positions, purely on temporary contractual basis. ICMR has apprised us of this rule and we have carefully noted it.

viii. The PI and Co-investigator(s) hereby submit the ICMR Declaration of Interest form in prescribed format.

ix. The name of the Statutory Audit Authority of our Institute is as follows:

_____

[Please attach a copy of the resolution if a private firm is engaged]

x. Registration/Unique ID no. assigned by NITI Ayog, GoI (on DARPAN Portal) (applicable only for NGOs):

.....

xi. CV of the investigator and Co-Investigators is/are attached in prescribed format.

	Name	Signature	Date
a)	Principal Investigator Dr Steffi Francis		20.03.24
b)	Co-Investigator(s) Dr Sruthi C M		20.03.24
	Dr Sachin Chandramohan		20.03.24
	Dr Noufal S		19.03.24
	Dr Betsy A Jose		20.03.24
	Dr Nithin C M		20.03.24
	Dr C R Saju		20.03.24
	Dr Christy Maria		20.03.24
	Dr Roshni S S		20.03.24.

c) Head of the Department Dr C R Saju

Signature of the Head of the Institution with seal

Date: 21/03/24

Fr. Julious Arakkal CMI
Director

AMALA INSTITUTE OF MEDICAL SCIENCES
AMALA NAGAR, THRISSUR-680 555
PRINCIPAL
DR. BETSY THOMAS
MD, FRCOG, DNB, MICOG